AN APPROACH TO THE CONTROL

OF

TOXIC SUBSTANCES

November 12, 1973
HMC/OTS

PREFACE

This Report is an initial step toward development of a long-term strategy for controlling toxic substances. While a number of policy directions are suggested, further refinement of these approaches is clearly in order. Therefore, the Report will be revised periodically, and initially on a semi-annual basis.

The Report is directed primarily to chemical substances exhibiting adverse effects on man or the environment at relatively low concentration levels. At the same time it is recognized that almost any substance can be toxic if exposure levels are sufficiently high, and therefore it is not practical to specify which chemicals or chemical classes are or are not included. Additionally, the concern here is only for toxic effects resulting from sustained chemical or biological activity, and other hazardous effects, such as fire, explosions, and radioactivity, are not considered.

The EPA approach to controlling toxic substances must be carefully integrated with the myriad of related activities of other Federal and State agencies -- including regulatory, monitoring, and research activities. While better integration of all national efforts is a central concern, this Report does not present the activities of other interested organizations.

A principal purpose of this Report is to provide a broad perspective for the activities of the Office of Toxic Substances. Also, it should provide useful guidance in shaping the activities of a number of other EPA offices. However, the activities of these other offices are described in other Agency reports, and they are not set forth in this Report.

APPROACH TO CONTROL OF TOXIC SUBSTANCES

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I. GENERAL APPROACH

PROBLEM

More than 20,000 chemical substances are commercially produced and used in the United States, with 500 to 700 new substances entering commerce annually. They find a wide variety of uses as industrial chemicals, in consumer products, and in specialized uses such as drugs, food additives, and pesticides. In 1972, the value of the products of chemical manufacturers and processors exceeded $200 billion, which represents a sizeable portion of U.S. manufacturing activities.

The problems presented by the presence in the environment of some of these substances are all too well known (e.g. mercury, lead, asbestos). Other substances are believed to pose a latent health or environmental threat, while the risks associated with the vast majority of chemicals, acting individually or synergistically, are almost completely unknown. However, it seems clear that the problems associated with the presence of many chemical substances in the environment -- such as food and drinking water contamination, destruction of biota, and water and soil degradation -- will undoubtedly continue to grow in number, severity, and complexity in the years ahead.

Some of the hazards associated with chemical substances have been recognized and are controlled by the Government, e.g. pesticides and drugs. Other aspects of the toxic substances problem have only recently been identified, and appropriate regulatory measures do not yet exist. Still other pieces of the problem have yet to be identified. Many gaps remain in understanding why, how, and when a substance can have a negative impact on health or the environment, and how best to control or prevent such hazards.

Thus, the concern of EPA with toxic substances is twofold: identification and assessment of the risks associated with the manufacture, distribution, use, and disposal of chemicals which could adversely affect health and environmental quality; and practical steps, including regulatory actions as appropriate, to prevent or mitigate the problems posed by such chemicals.

GENERAL PROGRAM GOALS

-- Clarification of the risks to health and the environment associated with the manufacture, distribution, use, and disposal of new and existing chemical substances, with particular regard to chemical properties, production levels and trends, and exposure of the chemical to man and the environment;

-- More effective utilization of regulatory authorities and related tools available to the Agency to mitigate such risks, taking into account the economic and social impact of restrictions on toxic substances; and

-- Increasing the concern of and appropriate actions by the chemical and related industries to reduce risks to health and the environment associated with their activities.

STRATEGY

Almost every EPA office with program, research, or legal responsibilities is involved in some way with efforts to control toxic substances. Since the toxic substances activities of most offices are integrated into the overall program strategies of the respective offices, the strategy reflected in this Report is limited to the approaches of the Office of Toxic Substances. In a sense the strategy of this Office can be considered as a core strategy of the overall Agency's efforts to control toxic substances.

The Office of Toxic Substances emphasizes the health and environmental effects of individual and combinations of toxic substances. This approach contrasts with earlier emphases of the Agency and its predecessor organizations on the broader gross pollution effects. The Office's sustained overview of the many dimensions of toxic pollutants involving a critical mass of specialists includes the following types of activities:

-- Staff function: coordination and support of Agency-wide efforts in toxic substances, with particular attention to multi-source and multi-media pollutants, consistency and interrelationships of standards set under different authorities, and coordinated approaches with other agencies (e.g. FDA, Consumer Products Safety Commission).

-- Line function: lead responsibility for gap areas including assessment of risks of and controls for new products, monitoring strategy, and research need assessment.

-- Crisis function: mobilization of Agency resources to clarify the dimensions of the problem, development and implementation of control strategies, and coordination with other agencies.

These activities are carried out through the following program elements which are described in some detail in subsequent sections of the Report:

-- Restrictions

-- Testing

-- Reporting

-- Early Warning

-- Monitoring

-- Crisis Response

-- Strategy and Coordination

-- Research Needs

Each program element is designed to make substantial contributions to realization of one or more of the long-range goals. The distribution of effort among these activities will vary, according to legislatively mandated deadlines, unexpected crises, and shifting Agency priorities. No precise formula can be used in determining resource distribution among program elements beyond assurance that a nucleus of staff resources will be directed to each area at all times. As experience is gained in this program, and if the Toxic Substances Control Act is enacted, it may be appropriate to distribute the emphasis among program elements in a more rigid fashion.

TABLE 1
EXAMPLES OF FOOD CONTAMINATION FROM TOXIC SUBSTANCES

FOOD	SUBSTANCE	SOURCE
Fish	Mercury	Chemical Industry Effluent
	Phthalates	Dump
	Copper, Zinc	Mine Runoff
Cattle	HCB	Chemical Industry By-product
	Lead, Zinc	Mine Runoff
Grains and Cereals	Arsenic	Dump
	Cadmium	Fertilizer Contaminant
Poultry	PCBs	Heat Exchange Fluid
Fruits	Phenols	Petrochemical By-product
Leafy Vegetables	Nitrates	Fertilizers
	Lead, Cadmium	Sewage Sludge

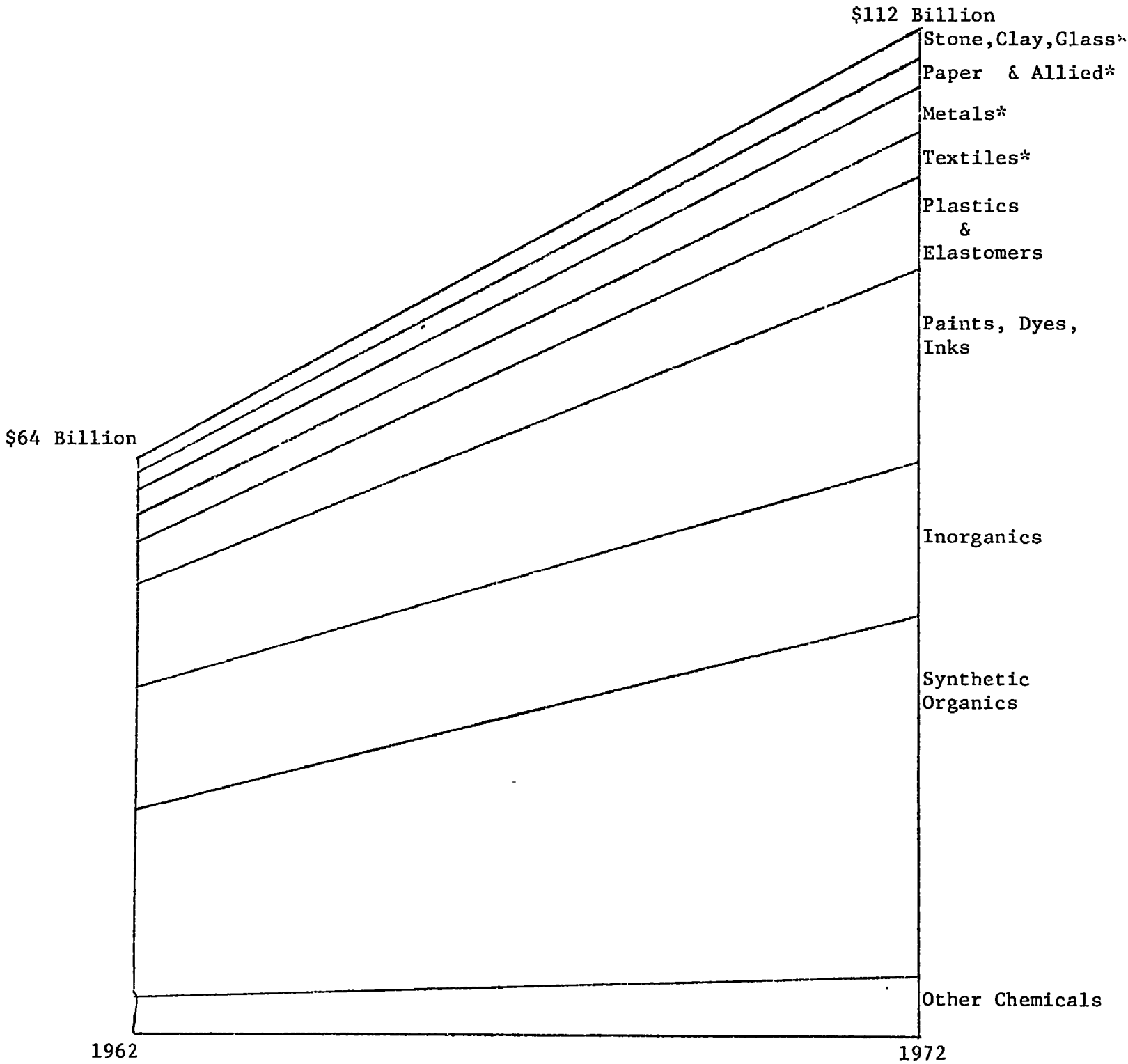
TABLE 2
EXAMPLES OF ENVIRONMENTAL DAMAGE FROM TOXIC SUBSTANCES

EFFECT	SUBSTANCE	SOURCE
AQUATIC DAMAGE		
Fish Kills	Hypochlorites, Fly Ash	Lagoon Ruptures
Change Lake Ecology	Copper, Zinc	Mine Runoff
Destroy Fish Population	Phenols, Ethanol	Refinery Products & By-products
WILDLIFE DAMAGE		
Bird Reproduction	PCBs	Plasticizers
Duck & Geese Populations	Lead	Shot
Botanical Species	Sulfuric Acid	Chemical Industry Wastes
LAND DEGRADATION		
Forest Destruction	Lead, Zinc	Smelters
Groundwater Contamination	Arsenic, Cyanide	Disposal Sites
Soil Fertility	Chlorides	Landfills
DESTRUCTION OF ANIMALS		
Cattle	Fluorides	Phosphate Lagoon Wastes
rses	Tetraethyl Lead	Landfills

TABLE 3
EXAMPLES OF TOXIC SUBSTANCES IMPLICATED IN SELECTED DISEASES IN THE UNITED STATES

CAUSE OF DEATH IN HUMANS	PERCENT OF DEATHS	DEATH RATE PER 100,000 POPULATION	SUBSTANCE WHICH CONTRIBUTES TO SOME DEATHS
Heart Diseases	38.5	366.1	Cadmium
Cancer	16.8	160.0	Benzidene, nitrosamines, beta naphthalamine, benzopyrene, asbestos, chromates
Infant Mortality	2.2	21.4	Heavy metals, nitrates, nitrites
Lung Diseases	1.6	15.4	Asbestos, beryllium, toluene diisocyanate, cadmium
Liver Diseases	1.6	14.8	Carbon tetrachloride, chlorinated phenols
Congenital Anomalies	0.9	8.4	Mercury
Kidney Diseases	0.5	4.7	Lead, ethylene glycol, cadmium sulfate

TABLE 4
ANNUAL VALUE ADDED TO SELECTED CLASSES OF
CHEMICAL AND RELATED PRODUCTS



*Only that portion of industry involved in chemical processes included.

II. RESTRICTIONS

PROBLEM

During the past several years the necessity of Federally imposed restrictions to reverse environmental degradation and to protect human health has been repeatedly demonstrated. The main problem in the area of toxic substances is to select the substances of greatest concern and then to determine how the hazards associated with these substances can be most effectively controlled or reduced, given the dearth of information about the behaviour of toxic substances and their distribution in the environment. The Toxic Substances Control Act would give the Agency far reaching authority to intervene in the chemical industry in a variety of ways. Care must be taken to insure that such intervention does not disrupt the industry unnecessarily. Of particular concern is the continued viability of the technological base undergirding the industry's momentum.

Intertwined with the regulatory authorities and actions of the Government are the attitudes, activities, and voluntary actions of industry in assessing the safety of products and exercising restraint in the development and marketing of products which might pose risks. Given the size of the sector of industry involved in commercial chemicals not currently subject to regulatory authorities -- with an annual value of products exceeding $150 billion -- it seems totally unrealistic to expect direct Governmental intervention to regulate a large fraction of these products. In a sense, each of the more than 20,000 commercial chemicals is a unique case -- both with regard to chemical behaviour and in marketing and economic considerations.

Central to consideration of regulatory options is the balancing of the risks with the benefits related to specific actions. The diversity of the tradeoffs make this a formidable task. For example, the benefits from employment of workers in chemical plants must be balanced against occupational risks; U.S. competitive ability in world markets weighs against environmental testing costs or requirements of expensive effluent or emission controls; and quality of life benefits from chemical substances bear on the degree of risks which can be tolerated. Restrictions placed on existing activities will affect past investments and established patterns of commerce and employment. With respect to those chemicals which have yet to be offered for commercial use, barriers to market entry could be created through premarket testing and screening requirements. If research and development of new chemicals becomes so difficult that it is no longer profitable, the advantages to society, in terms both of new products and development of less toxic alternatives to existing products, are lost. In short, environmental protection is not free.

Attention must be given to the impact of corrective actions on the direction, configuration, and diversity of the chemical industry as well as on the benefits to society of chemical products.

GENERAL PROGRAM ELEMENT GOAL

To mitigate, through direct regulatory actions and through encouragement of voluntary actions, the most serious environmental problems posed by currently uncontrolled entry into the environment of chemical substances.

INDUSTRIAL STEWARDSHIP

Subgoal

To heighten industrial concern over the necessity to clarify the risks to man and the environment associated with chemical substances and to take appropriate action to reduce these risks.

Strategy

A principal thrust of the Agency's efforts to reduce the probability of adverse incidents affecting health or the environment as the result of chemical substances entering the environment is to encourage voluntary steps by the chemical and allied industries to identify and limit those activities that pose a risk. Ideally, such voluntary steps should become a fundamental consideration in the decision-making process of industry concerning the desirability of developing and manufacturing chemical substances.

The Agency's approach involves both the carrot and the stick -- i.e., public recognition of positive steps taken by industry to reduce environmental risks (e.g. Monsanto restrictions on PCB production) and regulatory actions to force a reorientation of industrial decision-making processes (e.g. limitations on mercury discharges into navigable waterways). When necessary, EPA will take direct restrictive actions. More often, efforts will be directed to encouraging industrial actions on a much broader front than is usually feasible through specific regulatory measures. The approach to industrial stewardship relies heavily on the following types of activities:

-- Repeated articulation in speeches, news conferences, and published articles by senior agency officials of (a) the responsibility of industry in insuring the

safety of its products, and (b) the successes and failures of industry in this regard.

-- Encouragement of trade associations and professional societies such as the Manufacturing Chemists Association and the American Chemical Society to provide leadership in stimulating a greater degree of industrial responsibility, both in a general sense and with regard to specific toxic substance problems that are particularly significant.

-- Consultations with individual companies, and particularly the medium-sized and small companies, to sharpen their awareness of the need for a greater degree of stewardship at both the working and decision-making levels.

The measurement of the current degree of industrial concern, changes in this concern as the result of Agency efforts, and the reflection of this concern in activities in the market place as well as in the plant will of course be difficult. However, assessments will be a valuable adjunct to efforts to stimulate industrial stewardship.

Three-Year Milestones

Assess to the extent possible the scope and effectiveness of voluntary industrial restrictions on the manufacture, use, distribution, and disposal of chemical substances.

Assess the trends within selected companies to incorporate environmental considerations into the decision-making process concerning the introduction of new products into commerce.

REGULATORY

Subgoal

To restrict a selected number of activities associated with the manufacture, use, distribution, and disposal of chemical substances in a way that will not only reduce serious environmental problems but will also demonstrate the favorable benefit/cost ratio of such restrictive actions, trigger both industrial and public concern over other related activities, and generally focus broader attention on the toxic substance problem.

Strategy

Restrictive actions under the Toxic Substances Control Act during the initial years can serve several purposes. They should be designed to (a) mitigate severe environmental problems not currently being addressed by other regulatory authorities, (b) prevent future environmental problems of large magnitude, (c) demonstrate a number of types of restrictions that are appropriately promulgated under the law, and/or (d) address activities involving a wide spectrum of industrial firms. In short, in addition to addressing environmental problems, deliberate efforts should be made in selecting restrictive actions to test the parameters of the law, thus clarifying whether there is need for further legislative refinements, and to awaken industry to the EPA's commitment to toxic substances, thus stimulating voluntary steps on the part of the industry.

Among the high priority candidate substances to be considered for possible regulatory action are:

-- Organic Chemicals: PCBs, NTA, HCB, HCBD, bis(chloroethyl) ether, polytetrafluoroethylene, tributyltin

-- Toxic Metals: cadmium, mercury, arsenic, vanadium

-- Chemical Classes: halogenated aromatic hydrocarbons, phosphate esters, benzenepolycarboxylates, fluorocarbons, azo compounds, aromatic hydrocarbons

-- Use Classes: detergent builders, plasticizers, printing ink pigments, hydraulic fluids, heat transfer media, highway de-icers, dry cleaning solvents

-- Other: asbestos

As discussed below, criteria for selecting substances for regulation and for determining the shape of the regulation will be developed. Initially, these criteria will probably be crude. They will be continually refined as experience is gained.

Three-Year Milestones

Promulgate 15 sets of restrictions on existing chemicals.

Promulgate five sets of restrictions on new chemicals.

CRITERIA

Subgoal

To develop and refine the procedures, techniques, and criteria for determining the need for, the character of, and the impact resulting from restrictions on the production, use, distribution, and disposal -- as well as associated activities -- of toxic substances.

Strategy

The ground rules for determining the need for, the character of, and impact resulting from restrictions required or recommended by EPA should be clearly understood in advance by Government, industry, and other interested parties. In the absence of such understanding, in many instances industry probably would be basing R and D and other investment decisions on wrong assumptions concerning those factors affecting subsequent Governmental decisions. Whether or not industry agrees with Governmental decision-making criteria, it should be aware of the criteria in order to make intelligent investment decisions. On the other hand, industry, as well as other interested groups, should have an input into the development of the criteria.

The new legislation sets forth in general terms the criteria to be used (e.g. health effects, environmental effects, economic considerations, alternative materials). The initial approach in elaborating these criteria will be development of weighted checklists. These checklists will be distributed for comment and periodically refined as experience is accumulated. In the future, development of a more elaborate approach to criteria may be possible, but in any event the useability of the criteria must be a paramount concern.

Three-Year Milestones

Publish an initial criteria document, and a subsequently revised version, articulating the considerations involved in determining the need for, character of, and impact resulting from restrictions on chemicals.

PROBLEM ASSESSMENT

Subgoal

To assess the environmental risks and societal benefits associated with selected chemical substances as a basis for determining the appropriateness of restrictions.

Strategy

As chemicals, chemical classes, and use classes that should be of particular regulatory concern are identified, in-depth analyses of the appropriateness of restrictions will be conducted, using the criteria described above. In some cases, such as PCBs and mercury, most of the analytical work may have been completed by other organizational units and the principal task will be the packaging of the information into a form which will facilitate regulatory decisions. At the other extreme it may be necessary to carry out laboratory work, field surveys, and literature searches to generate the data needed for sensible decision-making.

These analyses will include considerations of factors such as:

-- risks posed by the substance, in terms of toxicity, exposed populations, and geographic distribution

-- current and projected market trends

-- available and projected technologies for controlling the substance

-- extent and effectiveness of current regulations on the substance imposed at the Federal, state, and local levels

-- available regulatory options and the practicality, effectiveness, and impact of each

-- current level of voluntary restrictions and feasibility of encouraging additional voluntary actions.

The central purpose of these assessments is determination of the appropriateness of regulatory action. They are not intended to be scientific publications to advance general understanding, but rather will be decision oriented studies. At the same time they must have technical credibility so they can serve as supporting documentation if regulatory action is taken.

Related to these in-house and EPA-funded contract activities will be a parallel effort to stimulate industry to increase its efforts to assess the need for restrictions. This approach will include sharing with industry the methodologies used in problem assessment, publication of EPA supported assessments, and encouragement of publication by industry of its methodologies and assessments.

Three-Year Milestones

Analyze the need for, character of, and impact resulting from possible restrictions on thirty chemicals.

III. TESTING

PROBLEM

The inadequacies of current testing activities are reflected in (a) the lack of data for setting standards and tolerances on a number of substances of near-term concern (e.g. benzidine, HCB, asbestos), (b) environmental incidents revealing previously unsuspected harmful properties of chemicals (e.g. PCB, dioxin, methyl mercury), and (c) the conspicuous absence of information for identifying potentially harmful substances that can cause future incidents. The problem is two-fold: lack of test data and deficiencies in capabilities to interpret the test data.

At the same time, the testing programs of some of the larger companies are impressive, recognizing that their basis for assessing test results and incorporating such assessments into corporate decision-making is profit-oriented. The testing programs of the medium-sized and smaller firms are not well developed due to the lack of R&D resources. Much industrial test data is not released by industry, thus limiting the capability of the Government and public to participate in assessments of risks of commercial chemicals. For some chemicals in wide usage no single company is willing to finance the cost of testing.

Testing by Government laboratories and by the university community is more often than not science oriented, with results that are difficult to adapt to regulatory decisions. When Governmental testing of specific substances for regulatory purposes is needed, there are frequently delays in acquiring funding and the needed priorities to displace on-going testing.

Testing covers a broad gamut of activities -- the standard toxicological test methods are relatively well understood but tests for stability, degradation and breakdown products, bioaccumulation, environmental transport, and ecological effects are uncertain areas at best. In addition, determining which types of tests to be applied to which substances is usually far from obvious.

In the past, problems with toxic substances have usually been identified after the fact. With hundreds of new chemicals being introduced into commerce each year, and with production levels of many others growing rapidly, the need for greater reliance on predictive testing seems clear. While the burden of testing of specific products falls squarely on industry, EPA has a responsibility to insure that the extent, quality, and timeliness of such testing is commensurate with potential environmental problems.

GENERAL PROGRAM ELEMENT GOAL

To improve the approaches by Government, industry, and the scientific community to testing of chemical substances entering commerce.

INDUSTRIAL STEWARDSHIP

Subgoal

To encourage increased industrial concern and appropriate action in testing both new and existing chemicals

Strategy

Continuing consultations with representatives of industry will provide a basis for assessing the extent and effectiveness of industrial testing procedures, for sensitizing industry to EPA testing concerns, and for determining the types of mandatory test requirements which can have the most significant impact on industrial testing practices. During these consultations efforts will be made to identify model industrial test patterns and practices which should be publicized and otherwise disseminated. Also, industry will be encouraged to increase its efforts to publish and otherwise make available test data.

There will be continuing discussions with industry concerning proposed EPA approaches to test requirements. These discussions should enable EPA to draw on industrial experience in developing EPA regulations, stimulate industrial concern over testing with or without EPA regulatory actions, and broaden industry's perspective as to the range of environmental concerns. More specifically, EPA will establish a few broadly based model testing recommendations which should affect at least one product of most of the large and intermediate-size chemical manufacturers. Industry will then be requested to provide comments as to how it would assess the results of such model tests, thus assisting EPA in determining the adequacy of the prepared approaches.

Three-Year Milestones

Complete assessment of the effectiveness and adequacy of testing activities of large and medium-size manufacturers.

Complete assessment of the trends in industrial concern for adequate testing as indicated by factors such as the types and number of tests, the types and number of chemicals subjected to tests, and the role of test results in decision-making.

REGULATORY

Subgoal

To require or encourage, as appropriate, industrial testing of specific chemicals for which inadequate data concerning the risks associated with the chemicals are available but which are suspected to pose a hazard to man or the environment.

Strategy

The two key tasks are the determination of the chemicals which are to be subjected to testing, and the actual test requirements. A related testing issue concerns division of industrial responsibility for testing of substances of interest to more than one firm.

Selection of the initial chemicals and chemical classes requiring testing will be based largely on subjective judgements within very general criteria such as known problem substances of current concern, production levels and trends, inadequacy of available test data, widespread presence of the chemical in the environment, and environmental incidents involving the chemical. Meanwhile, methods for prioritizing chemicals that should be subjected to testing will be developed to provide a better basis for subsequent selections.

In general, the Agency will not prescribe test requirements in great detail but rather will provide guidelines concerning the types of test data needed for decision-making. Thus, several different specific test protocols could satisfy the test requirements for a specific chemical although each protocol would have to consider the types of effects of concern to the Agency.

Supporting these activities will be continuing reviews of test methodologies. These reviews should be helpful both in developing test requirements and assisting concerned parties in being aware of the most effective test approaches to determining different effects.

Three-Year Milestones

Promulgate 10 to 15 standards for test protocols for selected chemicals, chemical classes, and use classes.

Assess results and reach decisions concerning the need for restrictions for three of the chemicals, chemical classes, or use classes for which standards were promulgated.

EXPERIMENTAL

Subgoal

To provide experimental data needed to determine appropriate standards or restrictions for specific chemicals of near-term concern.

Strategy

Through participation on interagency committees, and through redirecting EPA supported testing activities, efforts will be made to orient Governmentally supported testing more sharply to regulatory needs. Both the types of experiments and the structuring of experiments are of concern. The activities of NCTR will be particularly important in this regard.

In addition an on-call testing capability at one or more industrial laboratories will be developed to provide the response capability needed for addressing specific chemicals which become of near-term concern. This capability will be used to demonstrate structuring of experiments that are more responsive to standard setting needs. In addition, this capability will provide opportunities for experimenting with proposed regulatory approaches to assess their feasibility. Finally, it will be available to generate supplemental data if questions arise concerning the test results submitted by industry under regulatory authorities.

Three-Year Milestones

Provide test data needed to set standards or to take other restrictive actions on three chemicals of near-term regulatory interest.

Demonstrate how two or three types of routine testing can be more sharply oriented to providing data of maximum value in arriving at regulatory decisions.

PUBLIC AWARENESS

Subgoal

To bring test data concerning the safety of chemicals into public view, in a way that will not compromise trade secrets,

to facilitate a broader base of understanding and inputs for evaluating the necessity for restrictions for such chemicals.

Strategy

Low-key but conscious efforts will be made to better acquaint the public with the strengths and weaknesses of testing and with the relationship of testing to visible environmental problems. As specific problems arise, the public will be made aware of available test results and of the significance of these results (e.g. as was the case with hexachlorobenzene).

Three-Year Milestone

Establish a smoothly operating system for responding to public requests for test and related data that does not contain trade secrets, for identifying trade secrets, and for resolving uncertainties as to what constitutes trade secrets.

IV. INDUSTRIAL REPORTING AND DATA PROCESSING

PROBLEM

An essential input to identifying and evaluating those potentially troublesome chemicals or classes of chemicals which should be given high priority attention is authoritative and timely information on their levels of production, use, and by-products and on the geographical distribution and the trends of these activities. Such information, together with information on the physical and biological properties of the chemicals, serves as the basis for assessing risks and weighing the appropriateness of alternative control strategies.

Limited information is currently routinely available from the reports of the Bureau of Census, Bureau of Mines, FTC, Tariff Commission, and Stanford Research Institute, as well as from the EPA permit program. Also, individual company reports include a vast amount of unaggregated data. However, the information is not packaged in a manner oriented to regulatory decision-making, with the exception of the waste stream information in the permit program. It is diffuse, often out of date, and spotty. It seldom, if ever, relates to new chemicals. Finally, while EPA access to much of the data is difficult, public access is further complicated by lack of awareness of available sources and by bureaucratic reluctance to release unpublished information prior to actual publication.

At present, regulatory decisions are being made on specific chemical substances using only a small fraction of the data on industrial activities and trends that should undergird such decisions. Data are not readily available to support analyses of known problem substances which are candidates for regulatory actions. Similarly, industrial data are not available in a useable form for rapid identification of previously unsuspected chemicals that should be of regulatory concern.

In short, available data bases on industrial activities are seriously deficient. On a case-by-case basis more detailed industrial data can be obtained at considerable time and expense, but even then such data are more often than not inadequate. At the same time, if the Agency decides to exercise its full authority for industrial reporting under the Toxic Substances Control Act, the volume of data could be so overwhelming as to make the data almost useless.

GENERAL PROGRAM ELEMENT GOAL

To improve the ready availability in a useable form of authoritative information concerning the manufacture, use, distribution,

and disposal of chemical substances which together with data on the physical and biological properties of chemicals is needed to assess the necessity for, character of, and impact resulting from possible steps to restrict or to encourage voluntary restrictions on chemical substances which pose a risk to man or the environment.

GENERAL

Subgoal

Promulgate the regulations required to implement the annual reporting, premarket notification, and related sections of the Toxic Substances Control Act.

Strategy

Within six to twelve months following passage of the Toxic Substances Control Act proposed regulations will be promulgated setting forth the ground rules for industrial reporting to EPA of information concerning the manufacture, distribution, use, and disposal of chemical substances. A number of terms will be defined with more precision (e.g., manufacturer, commercial quantity, new use, intermediate, chemical substance, by-product), confidentiality aspects will be elaborated, and reporting requirements for exports and imports will be set forth. Both annual and premarket reporting requirements will be covered. In short, the regulations will cover who reports, what is included in the reports, when reports are made, and what format is to be used for reports.

Initially, the general approach will be to delimit the reporting requirements to data that will be directly useable for premarket screening, regulatory, or early warning purposes as described below. The emphasis will be on obtaining data that will be used rather than obtaining data to cover every substance that has been in commerce for some time. The cost/effectiveness benefits from this emphasis should more than outweigh the information gaps that are not filled.

The reporting requirements will be reviewed and updated annually. During these reviews the desirability of broadening or narrowing the reporting requirements based on past usage of data will be considered.

PREMARKET

Subgoal

To provide information needed to identify those new chemical substances entering commerce which deserve in-depth analyses to determine whether they pose a threat to man or the environment.

Strategy

Given the uncertainty of the risks associated with new chemical products which may have toxic properties and the lack of available information about these products, the premarket notification authority in the legislation will be invoked to the fullest practical extent. This information must be clearly identifiable when it arrives at the Agency, be expeditiously handled, and be quickly but carefully analyzed. In addition, industry will be encouraged to provide the Agency with as much notice as possible concerning new chemical substances and uses and any available information in addition to the mandatory information.

EPA should have a unique repository of current information on new chemicals entering commerce and on new uses of old chemicals. Given the Congressional and environmental concerns over new commercial chemicals and the uniqueness of this EPA data capability, the data processing complications associated with obtaining all available information on these new products are warranted . However, the data system must be able to provide the information to the analysts in a useable form, and in particular be able to flag chemicals (a) belonging to chemical classes that have caused past problems, (b) being used in a way that there is large exposure to man or the environment, or (c) being produced in large quantities.

Three-Year Milestones

Develop methodologies for identifying in advance to the extent practicable the types of new chemicals or new use categories of particular concern, for presenting data in a form that will allow rapid premarket screening to determine the need for more intensive analyses, and for obtaining additional information needed for carrying out such detailed analyses.

Provide the data needed to analyze 10 to 20 new chemicals of particular concern.

EXISTING SUSPECTED CHEMICALS

Subgoal

To provide information on selected chemicals currently in commerce which due to their properties, production levels, and/or uses might pose a threat to man or the environment.

Strategy

For chemicals strongly suspected of posing environmental risks, and hence prime candidates for regulatory actions, extensive data from a variety of sources will be necessary. The identification and prioritization of these substances will initially be based largely on the use of best judgement within rather general criteria, with parallel efforts initiated to develop more refined criteria. The reporting requirements levied on industry will reflect a reporting emphasis on predetermined classes of particularly troublesome chemicals.

The types of industrial data of particular interest include aggregated data on production levels including trends, uses and the environmental exposure associated with each use, and manufacturing processes which produce the substances of concern as by-products. In addition, to assess the impact of restrictive actions, information on individual manufacturers will be necessary. Initially, aggregated data will come largely from other Government organizations while the detailed breakdown of this data will come from the required annual industrial reports and also voluntary information submitted to EPA by industry.

Three-Year Milestones

Establish and have operating a system that presents both aggregated data and data broken down as appropriate which can provide the industrial information base needed for making regulatory decisions.

Provide the industrial information needed to reach regulatory decisions on 10 to 20 suspected chemicals.

EARLY WARNING

Subgoal

To provide information concerning other chemical substances in commerce which, due to their levels of production, uses, and/

or chemical and biological properties, may warrant in-depth analyses to determine whether they pose a threat to man or the environment.

Strategy

At one extreme the amount of data submitted by industry on unsuspected chemicals which are in commerce could be overwhelming, and hence almost useless. On the other hand, some type of broad data net is needed to identify the potential problem substances. Therefore, a close match must exist between data analysis procedures and capabilities and reporting requirements. The basic approach is to provide enough information to alert a trip-wire, rapid screening process which signals the substances that warrant in-depth analysis. Specifically, the industrial information should help pinpoint chemicals with production and use patterns which should be of concern. Thus, the mandatory industrial reporting requirements will cover all substances exceeding a certain production level or destined for particular uses.

The format of early warning data is critical if it is to be useful for rapid screening. Reporting requirements will specify such a format.

Three-Year Milestone

Establish and have operating a system that provides the industrial information needed to identify previously unsuspected chemicals that should be of environmental concern.

PUBLIC ACCESS

Subgoal

To provide easy and rapid access by other agencies and by the public to data submitted to the Agency without compromising trade secrets.

Strategy

Adequate resources will be provided to process rapidly public requests for data submitted by industry although it is highly unlikely that regular Agency reports containing collected data will be possible. The procedures used by the EPA fuel additive program for responding to requests for information claimed to be trade secrets by industry will be adopted. In short, the data identified by industry as confidential will be

considered confidential. If public requests are received for such data, determinations will be made by EPA on a case-by-case basis as to whether the requested information is indeed in the category of trade secrets or can be freely disseminated. The affected company will be provided an opportunity to submit supporting documentation for his claim of confidentiality prior to the determination.

Three-Year Milestones

Establish and have in operation procedures for providing rapid public access to industrial information that does not involve trade secrets, for sorting out trade secrets, and for resolving uncertainties as to what constitutes trade secrets.

V. EARLY WAPNING

PROBLEM

More than 20,000 chemical substances are presently in commercial production. Many of these are entering the environment in substantial amounts, and there is some environmental exposure to most of them. In most cases, the potential toxicity of these materials is unknown. Even when pertinent data are available, they are frequently buried in the scientific literature or in industrial or government reports and have never been collected and analyzed with a view to implications they may have regarding threats to health or the environment.

Review of all data on all chemicals, or even limited data on most chemicals, is not practical. The time and resources required would be astronomical. It is necessary to concentrate resources on a few chemicals, hopefully those with the greatest potential for causing mischief in the environment.

The purpose of the early warning activity is to survey the universe of chemicals and to select those which warrant special attention. Substances selected would be those showing potential for causing adverse effects. Determination of the need for regulatory action is not the immediate purpose in this activity; it is limited to the preliminary step of identifying substances for more careful investigation and evaluation. If the selections are well made, a rather large fraction of the substances recommended for further investigation should prove to be good candidates for regulatory action.

The system should serve to alert the Agency to incipient crises which may soon reach levels of public concern. In some cases, there may be enough lead time to permit the Government to take steps to avert the crisis; in others, at least the Agency would not be caught totally unaware when the crisis breaks. However, it is not suggested that the system could eliminate unanticipated crisis situations.

The need for such an activity and the lack of ongoing efforts in this area have been cited by a number of groups. For example, the Panel on Hazardous Trace Substances of the CEQ-OST Committee on Environmental Health Research (the "Rall Committee") has recommended the establishment of an "Assessment Program for Hazardous Environmental Chemicals" to help fill this void. Support for such a program has been voiced by NAS, NSF, CEQ, USDA, and NIH. While recognizing the difficulty of the task, all of these groups agree that a major effort to identify unsuspected hazardous environmental chemicals is needed.

GENERAL PROGRAM ELEMENT GOAL

To identify and prioritize previously unsuspected chemicals entering the environment which are most likely to pose a significant hazard to man or the environment in the near future.

CRITERIA

Subgoal

To develop criteria and techniques for determining on the basis of minimal information which chemical substances should be of greatest concern.

Strategy

Two types of chemical properties are of concern: those properties which are likely to cause trouble in the environment, and those properties that can serve as early warning indicators. These two sets of properties will not be the same, although sound correlations between them may exist. The search for these correlations and for correlation methodologies is the essence of the early warning activity. For instance, persistence may be a property of environmental concern, but information on persistence is not sufficiently available to make it directly useful for early warning searches. However, if correlations can be established between persistence and certain structural or physical properties which are readily ascertainable, these properties could serve as the keys for early warning on persistent chemicals.

Past toxic substances incidents (e.g. dioxin, DDT, PCB, HCB, mercury) will be reviewed to identify the salient features that might be useful in anticipating future crises. When possible, convenient measures or indicators of these features will be developed and verified, and then applied against other materials or situations to determine where similar situations may exist or be created.

Supporting efforts to develop selection systems which are relatively objective, using formal ranking schemes, mathematical modelling, or other approaches will be undertaken.

Three-Year Milestones

Assess the utility of several quantitative and pseudo-quantitative techniques for predicting future problems with toxic substances.

Identify and begin to prioritize those properties of chemicals which are suggestive of health or environmental threats based on correlations that can be derived from past experience and from theoretical considerations.

EXPERT OPINION

Subgoal

To mobilize and use expert opinion to assist in rapidly screening large numbers of chemicals and in predicting potential problem substances.

Strategy

A panel of experts conversant with environmental problems, industrial technology, and chemically-induced health effects will meet on a regular basis to assess possible problem areas, to flag chemical problems on the horizon, and to advise on areas which may warrant early investigation.

A series of seminars on various industries which are potential sources of toxic substances (e.g. detergents, plastics) will also be supported in cooperation with other interested agencies. These will consider innovations in the industry, those activities or products that may be troublesome, and measures that could be taken to reduce environmental exposure to these products. These seminars could include retrospective case histories. The seminar reports should be useful guidebooks for future analyses of the selected industries.

Three-Year Milestone

Establish and convene on a regular basis a panel of experts to provide advice on unsuspected chemicals which deserve investigations and on the significance of the results of such investigations.

DATA ANALYSIS

Subgoal

To collect, collate, and analyze data from sources such as monitoring, trend assessment, and industrial reporting, as well as the open literature, on those chemicals which appear to deserve the highest priority in a manner that will facilitate

judgements as to whether the chemicals should be candidates for further investigations, testing, and/or control.

Strategy

Data analysis includes (a) awareness of current happenings on a limited scale, and (b) trend analysis of likely future developments. Both of these depend on indicators and parameters developed in the criteria activity.

Current problem awareness includes (a) surveys of engineering, trade, and business journals and government reports, (b) data collected from other federal agencies which have specific relevant responsibilities such as reports of occupational incidents to the Department of Labor, reports of animal or crop damage incidents to the Department of Agriculture, and reports of human disease incidents to the Center for Disease Control of HEW, and (c) reports of local incidents obtained by extension services of universities, newsletters of local environmental organizations, and EPA offices. The third type of information is the most difficult to acquire because it is so disperse, and the feasibility of developing either a network manned by trained regional personnel or a centralized clearing house will be explored.

Trend analysis requires data pertaining to less specific economics, growth, and new-product indicators. Economic data are obtained from standard published sources as well as directly from the Department of Commerce. Growth data are obtained from market journals and federal effluent permits. New product data are available through the General Services Administration and the Department of Defense (Defense Services Administration) primarily through their new product applications and specifications program.

When this network signals an alert, an analysis of information pertinent to the problem will be undertaken. The depth of these analyses will depend on the nature of the data and the apparent urgency of the problem. If this analysis confirms the presence of a significant problem, it will be referred to the restrictions or crisis response activity as appropriate.

Three-Year Milestones

Establish a current awareness network covering scientific, trade, and business journals and Government reports to identify potential problems and to analyze trends in technology and commerce that could result in new types of problems.

Complete preliminary analyses on twenty substances.

VI. MONITORING

PROBLEM

Adequate, timely, and reliable monitoring data is critical to the assessment of the risks posed by existing substances already in the environment and by new substances entering the environment. Such data are required to determine the need for and effectiveness of standards and tolerances for specific chemical substances, to shape responses to actual or alleged crises, and to target enforcement activities. In short, monitoring data provide the most reliable barometer of the potential impact of substances in the real world on man and the environment whether viewed on a national or a limited geographic basis. Also, such data can indicate the incremental change in the status of the environment as the result of Agency actions.

Despite extensive Federal and State monitoring programs, at present there is little useable information on background levels, geographic description, and trends for most toxic substances. At standard setting time the monitoring data needed to assess the incremental impact that the standards will have on ambient levels are not generally available. This void is particularly noticeable when information on organic chemicals and many heavy metals is sought. Buildups of toxic substances in the environment are almost always signaled after the fact by environmental incidents; only then is monitoring activity focused on the problem substances. Virtually no effort has been directed to the systematic use of monitoring data for early warning purposes.

A principal deficiency within EPA is the lack of a sustained effort to (a) articulate prioritized program needs for monitoring data on toxic substances in relation to standard setting activities, and particularly the types of information needed, the specific substances of concern, and the timetable, (b) incorporate into existing networks these and other toxic substances requirements, and (c) extract, analyze, and present in a useable form information from the monitoring data banks that can respond to program needs.

To a large extent the Agency's principal monitoring concerns have centered on criteria pollutants and on gross pollution effects. Only recently has attention been given to specific toxic substances -- and this attention is largely single media oriented.

While many Federal and State agencies have active monitoring programs, the feasibility of influencing these programs is difficult at best. Also, as the Agency shifts the central responsibility for monitoring to the States and to permit recipients, the practicality

of effectively orchestrating a unified multimedia national monitoring approach targeted on selected toxic substances will become even more difficult. However, a better job of ferreting out data available from existing programs and using this information to meet Agency needs is clearly in order. A selective approach to specific substances and specific geographical areas within the confines of acceptable sampling and analytical methodology is essential lest the Agency's toxic substances program drown in a sea of uninterpretable data.

GENERAL PROGRAM ELEMENT GOAL

To identify and quantify to the extent practicable the levels, distribution, and buildup of toxic substances in man and the environment.

REGULATORY ACTIONS

Subgoal

To provide in a useable form data needed to assess the necessity for and character of steps to control toxic substances of particular concern.

Strategy

Clearly, comprehensive monitoring for all toxic substances in all media, or even a significant fraction of these substances in most media, is impractical. Thus, a close correlation between the targetting of the monitoring effort and the perceived risk posed by various substances as well as opportunities for regulatory actions to limit these substances is imperative. In short, the end user of the data should have a significant input in determining what data are collected.

Monitoring activities should be designed to determine the appropriateness of regulatory actions. Such activities may be characterized as follows:

-- reasonably comprehensive monitoring efforts targetted on substances that are prime candidates for regulatory actions under the Toxic Substances Control Act, the Hazardous Waste Management Act, or the toxic and hazardous pollutant provisions of the Clean Air Act and FWPCA during the next several years; such efforts would cover a broad geographic area, using to the fullest extent possible data from existing networks.

-- more limited monitoring, using selected networks in selected geographical areas, for other toxic substances which are also of particular concern and which could be regulated under other Federal and State statutory activities.

The first step is to identify those chemical substances of concern. Criteria for selection of toxic pollutants which should be regulated are set forth in a variety of Agency documents, and include such factors as toxicity, persistence, production levels, and a history of past problems. To these criteria should be added practical monitoring considerations that determine cost/effectiveness ratios, such as state of monitoring technology, geographical distribution of sources, and opportunities to piggyback on existing programs.

Once the initial list of target substances has been developed -- a list that will be continuously refined and updated -- a specific monitoring strategy for each substance will be developed. These strategies will be integrated to the extent possible. In addition to using existing monitoring networks, careful consideration will be given to use of the permit program and the attendant opportunities for requiring monitoring of toxic substances.

Three-Year Milestones

Identify, characterize, and quantify to the extent possible background levels and current releases into the environment on both a national and localized basis of 10 to 15 toxic substances of near-term regulatory concern.

Develop and have in operation a systematic approach to incorporating toxic substances monitoring requirements into existing monitoring networks and to exploiting data collected from these networks for toxic substances regulatory purposes.

EARLY WARNING

Subgoal

To alert the Agency and other interested parties to the presence or buildup in the environment of previously unsuspected chemicals which might pose a significant threat to man or the environment.

Strategy

The search for unsuspected problem substances, which individually or in combination may create environmental problems, will require a great deal of ingenuity and perception. Monitoring and analytical technology is often substance-specific, and the indicators of problems may vary from substance to substance.

The basic approach is for the EPA regional offices to serve as the initial trip wire, following up leads from a variety of monitoring sources. Buttressing this trip-wire mechanism will be the following activities:

-- development, initially on a pilot basis, of a system of biota indicators which can serve as the basis for keeping abreast of environmental trends on a national basis of selected classes of chemicals

-- development, initially on a pilot basis, of an approach to selecting geographical areas that are likely candidates for environmental problems and to searching out the latent chemical substances that should be of concern in these areas

-- provision of teams of monitoring and assessment specialists who can respond to trip-wire alarms and assist in determining if an environmental problem is indeed developing.

This combination of field sense, tuned to the idiosyncrasies of specific geographic areas, together with adequate backstopping from headquarters, hopefully will uncover physical evidence that can lead to better anticipation of environmental incidents. Of particular interest in this regard are a variety of localized monitoring efforts, often classified as research, funded by EPA, other Federal agencies, the States, and universities which can be of considerable help in pinpointing problem areas. Clearly, physical monitoring data are only one input -- but an essential input -- to an early warning system.

Three-Year Milestones

Develop and have in operation on a pilot basis a system of biota indicators which can serve as the basis for identifying environmental trends indicating adverse environmental effects resulting from specific chemical substances entering the environment.

Develop and implement in one geographic area a physical monitoring approach to locating and assessing potential "hot spots" due to the unsuspected buildup of chemical substances.

VII. CRISIS RESPONSE

PROBLEM

The increasing frequency during the past several years of incidents of environmental contamination from toxic substances strongly suggests that in the months and years ahead a quick response to such incidents must become a way of life in EPA. The sources of such problems may be traced to natural occurrences of the substances; to the use, misuse, or disposal of commercial products; or to industrial or transportation activities involving chemical substances. The substances may contaminate air, water, soil, or living organisms; may cause problems in food or drinking water; and may be biomagnified.

The EPA regional offices are the Agency's principal response capability. These offices have developed considerable experience in dealing with air pollution alerts, spills of oil and hazardous materials in waterways, and misuse of pesticides. However, they are not equipped to handle effectively many other contaminants, and particularly the less familiar contaminants that build up over time and contaminants which tend to fall between program areas.

Usually, responding to a toxic substance crisis involves three related types of activities: assessing the immediate risks posed by the substance and taking steps to reduce the risks, identifying the source and extent of the problem substance and taking steps to turn off the source, and developing and stimulating appropriate actions to help insure that the problem does not reoccur in other areas of the country. More often than not the problem substance will be ubiquitous, persistent, and toxic; will come from poorly defined multiple sources; and will be affecting animals, fish, plants, and other biological components of the environment. Also, the scientific data needed for specific regulatory actions will probably be sparse.

Further complicating responses are the regulatory, programmatic, and other bureaucratic, ambiguities and overlaps within EPA and among Government agencies. Also, the responsibilities and response capabilities of the States will vary. In each case these must be sorted out -- usually a relatively easy task in the field but a more difficult task in Washington.

The experiences with PCBs, HCB, and asbestos involved all of the foregoing considerations. In each case the immediate crisis response has been followed with longer range action plans involving reallocation of Agency resources. In this regard, the absence of Agency contingency funds (notwithstanding the revolving fund for water spills) can cause considerable delay in responding and program disruption through shifting priorities.

GENERAL PROGRAM ELEMENT GOAL

To provide an effective on-call capability for (a) assisting EPA regional offices to respond to unanticipated buildups in the environment of chemical substances that pose a substantial hazard to man or the environment, and (b) developing and carrying out long-term action programs to mitigate recurrent problems involving the same substances on a nation-wide basis.

PROBLEM ASSESSMENT

Subgoal

To mobilize and deploy appropriate specialists for clarifying the character and extent of specific crisis problems and evaluating the short- and long-term impact of the problem substances on man and the environment.

Strategy

In developing a quick response capability for assisting the regional offices, the States, and other interested parties to assess the extent and severity of newly erupted problems, the following requirements will be emphasized:

-- Versatile monitoring and data analysis capability for determining the distribution and levels of the problem substance.

-- Rapid access to relevant reports and scientific data concerning the properties of the substance, its sources, and past incidents.

-- Standing arrangements with other interested Federal agencies that will facilitate rapid coordination, division of labor, and sharing of information.

-- Availability of a range of specialists who can analyze highly technical aspects of the problem.

Except in unusual cases the regional offices will take the lead in orchestrating EPA's involvement in a localized problem. The headquarters on-call capability will be available to assist with a limited number of problems, with the number dictated by budgetary and manpower constraints.

On the other hand, coordination of the longer range effort to reduce the probability of similar incidents in other parts of the country will be centered in headquarters. In addition to insuring consistency among the efforts of EPA offices and of Federal Agencies, the following types of considerations may be important:

-- Necessity for guidelines for identifying and sampling potential hot spots around the country.

-- Availability of adequate laboratory capability to analyze monitoring samples.

-- Needed research to clarify the properties of the substance.

-- Opportunities for using the contaminated area as a research test bed.

-- Mobilization of the best expertise to assess the problem on a national basis.

-- Priority that the problem deserves relative to other toxic substances problems.

All regional offices will be invited to participate in development of the nation-wide plans, and special efforts will be made to keep them advised of developments in one region that may be relevant to another region.

Three-Year Milestones

Develop the necessary analytical and monitoring resources needed to assess a wide variety of unanticipated incidents involving the buildup of chemicals in the environment.

Develop and carry out action programs to clarify the risks posed on a nation-wide basis by six crisis chemicals.

REGULATORY

Subgoal

To identify the regulatory and related steps needed for reducing or eliminating the source of crisis problems, develop the necessary information for carrying out the most appropriate steps, and encourage the appropriate remedial actions.

Strategy

The choice of the appropriate regulatory tools for alleviating localized toxic substance problems must be tailored to the specific situations. Frequently, State authorities or voluntary actions on the part of the polluter will be more effective and rapid than cumbersome Federal approaches. However, in addressing the nation-wide problems, a Federal approach may have many advantages.

As in the case of the problem of assessment, the regional office should usually take the lead in sorting out the most appropriate near-term response for a localized problem, with headquarters providing the necessary support and also a perspective of national implications of the various options. With regard to the national problem, headquarters should take the lead in collaboration with other interested agencies and with opportunities for regional office inputs.

Three-Year Milestone

Foster development and implementation of restrictive actions (either under Federal or State laws or on a voluntary basis) to reduce the source of the problems associated with six crisis chemicals.

VIII. STRATEGY AND COORDINATION

PROBLEM

Responsibility for toxic substances activities is fragmented within the Agency, and the policies governing these activities are largely determined by the broader responsibilities and interests of the concerned Assistant or Regional Administrator. More often than not toxic substance activities are considered as just one subset of more general pollution concerns, and relatively little effort has been made to link the common toxic substance interests of different offices. Program offices tend to concentrate on that portion of the problem which directly relates to their statutory authorities. This focus of attention is usually dictated by deadlines, with resources deployed to address the urgency of setting standards or responding to crises. Typically, rotating specialists work in spurts on toxic substance problems, usually without the opportunity to evaluate the total hazard posed by a given substance. Communication among offices working on the same problems has not been good, coordinated planning scarcely attempted, and the usefulness of the work of one office to other offices usually minimal.

At present several EPA offices are independently assigning priorities to problem substances, carrying out in-depth studies, and promulgating regulations, with minimal attention to coordination until most of the work has been completed. With the enactment of new authorities, the Agency effort may become further fragmented. Given the constraints on available Agency resources and the complexity of toxic substance problems, the Agency can ill afford wasted motion in this area.

There are many interfaces among existing regulatory authorities, and the passage of new legislation will further extend the options for addressing specific problems. Implementation of the air and water acts, for example, involves selecting the most appropriate legislative provisions within these acts for addressing particular problems. The pesticide act controls the use of certain pesticides while point source discharges of these same chemicals are being considered for control under the water act. Further complicating effective choice of regulatory options is the tendency to search for problems to be controlled under specific authorities, rather than searching for the best authorities to most effectively control specific problems. This approach of controlling the "accessible" aspects of the problem, which may or may not be the "critical" aspects, can hamper efforts to focus on the core of environmental and health risks posed by the manufacture, use, and disposal of toxic substances.

The setting of standards and tolerances, the issuing of permits, and the taking of other types of regulatory actions inevitably involve the balancing of risks and benefits. There are no Agency guidelines as to how this balancing is to be carried out with regard to toxic substances -- a particularly difficult area in view of the uncertainties as to the health and environmental impact of the substances and the incremental environmental gains which might reasonably be attributed to actual or proposed EPA actions. This problem is further complicated by differences in the language of different laws and uncertainties concerning legislative intent. As a result, different criteria are being used depending on the specific legislative framework and the biases of the concerned office.

GENERAL PROGRAM ELEMENT GOAL

To improve the Agency's approach to control of toxic substances through more effective utilization of statutory authorities and manpower and financial resources.

PROGRAM COHERENCE

Subgoal

To insure that diverse program efforts designed to clarify and mitigate the risks associated with toxic substances are consistent and mutually reinforcing.

Strategy

The Steering Committee/Work Group process provides the best existing mechanism for (a) insuring consistency in the standard setting and related regulatory approaches of different offices, and (b) stimulating improved interactions among offices at the working level. However, if this process is to be effective the following aspects need particular emphasis:

-- better and more comprehensive Development Plans which are rigorously followed

-- greater opportunities through the Work Group process for interested offices to participate in developing, rather than merely rubber stamping, proposed standards

-- minimizing current tendencies to circumvent the Steering Committee process

The Toxic Substances Control Act calls for an Annual Report to Congress on efforts to control toxic substances under a variety of authorities. Whether or not the legislation is enacted, such an Annual Report (albeit not necessarily to Congress) should promote greater coherence to these presently fragmented program

activities. At a minimum it can serve as a catalog of on-going programs. More importantly, it can provide an opportunity to articulate policies that affect all programs.

An area of particular concern is the apparent gap in a number of areas between the activities at the EPA research facilities and program interests. The reality and extent of the gap are frequently blurred in the welter of bureaucratic documents surrounding the research process. Therefore, a more systematic effort by program offices to visit and assess research efforts on a continuing basis should improve not only the process for setting research priorities but also foster better working level interactions between program and research personnel at the working levels.

Three-Year Milestones

Publication of two Annual Reports on EPA activities in toxic substances.

Completion of two annual in-depth evaluations of current and potential contributions of EPA research facilities to program needs in toxic substances.

PROBLEM ASSESSMENT

Subgoal

To improve problem assessments through more deliberate ordering of priority substances, better problem definition, and improved interaction among program elements supporting assessment activities.

Strategy

As a number of EPA offices and other agencies devote an increasing amount of resources to in-depth analyses of toxic substances -- particularly in support of regulatory and early warning activities -- there is a need for more deliberate processes for selecting the substances of priority concern. While each program office must establish its own list of priority substances to be regulated under different legislative authorities, each can benefit from a clearer understanding of the criteria being used by other offices for selecting the substances. Also, it is important that the results -- both published and unpublished -- of such analytical efforts be broadly distributed on a timely basis within the Agency.

An early order of business in implementing the Toxic Substances Control Act will be selecting the toxic substances that deserve priority attention and assessing the appropriateness of the new legislation as the regulatory vehicle for addressing these substances. This activity should serve as a catalyst in stimulating Agency-wide efforts toward more deliberate priority ranking of toxic substances.

In addition to activity directed to implementation of the new legislation, the following steps are planned;

-- a series of seminars on the efforts of EPA and other agencies, as appropriate, directed to analyzing for regulatory purposes, specific substances and on EPA efforts to develop criteria for prioritizing substances.

-- annual summaries of the principal EPA efforts in this area with appropriate bibliographies.

-- more deliberate attention during the Steering Committee/Work Group process to criteria for selecting toxic substances for regulatory consideration.

Three-Year Milestone

Have in place and operating a system of seminars, annual summaries, and Agency review procedures which will help insure that selections of toxic substances for in-depth evaluations are made within the context of the totality of the Agency's interests and activities.

REGULATORY ACTIONS

Subgoal

To develop and implement control strategies that (a) address the most critical aspects of toxic substance problems, and (b) balance in a consistent manner the costs of control with the reduction in risks from such control.

Strategy

Closely related to problem assessment is the choice of the most appropriate regulatory authority to reduce the problem. Insofar as choice among EPA authorities for addressing the most critical aspects of problems of national dimensions is

concerned, the Steering Committee/Work Group process is the best existing mechanism, subject to the previously noted caveats. Also, implementation of the Toxic Substances Control Act should give impetus to a more deliberate selection process.

While different laws set forth differing criteria for standards, tolerances, and other limitations on toxic substances, all the existing laws give EPA some flexibility in this regard, and there should be some consistency in the Agency's overall approach. To this end Agency-wide guidelines are needed, particularly with regard to balancing uncertain health and environmental impacts of toxic substances with both direct and indirect economic impacts of regulations.

Three-Year Milestone

Prepare annually Agency-wide guidance concerning the balancing of risks and economic impact in setting standards and tolerances, issuing permits, and imposing other limitations on toxic substances.

IX. RESEARCH NEEDS

PROBLEM

As regulatory activity for toxic substances continues to expand in scope and complexity, the results of mission-oriented EPA research efforts take on added significance. Not only is there a need for research into new areas, but of equal importance is the need to orient more sharply current research efforts to program needs. Also, much of the EPA research effort traditionally identified as related to toxic substances has been oriented to specific single-media problems of very limited scope while equally important multimedia concerns have been largely neglected.

The most significant gaps in current Agency research programs -- taking into account research activities supported by other organizations as well -- are development of (a) improved test methods that are more responsive to near-term and longer-term regulatory needs, (b) techniques for estimating the level of human and environmental exposure to specific chemicals entering the environment, and (c) techniques for assessing economic, technological, and market trends that will provide insight into the severity of future problems that are associated with chemical substances entering the environment.

Classical evaluation of toxic effects involves acute, subchronic, and chronic tests on experimental animals, and extrapolation of results to the effects (or "no effects") on man. This extrapolation relies very heavily on the incorporation of "safety factors". Such tests have proven useful in the past and will certainly continue to be in the immediate future. However, many of them are very expensive and time consuming. Structuring of tests for specific research purposes often results in inconsistencies among different investigators so that applicability to regulatory activity is limited. Similarly, there is a definite lack of tests optimally designed for generating results useful in the development of numerical standards. Seldom are animal and epidemiological investigations conducted on the same materials to improve the extrapolation process. Finally, the substances being tested frequently have little relevance to the substances of regulatory interest.

The Agency's approach to toxic substances regulation places the prime responsibility for the testing of substances with the producers of those substances or others who derive economic benefit from them. At the same time, the Agency has an interest to insure that tests performed to comply with regulations are meaningful, reliable, and standardized to the point that the results can be interpreted within the established regulatory framework. Thus, although a certain amount of

testing must still be done by the government, the major responsibility of EPA in this area is to insure that reliable and practical testing procedures exist and are being used. Therefore, the primary objective of the research effort should be the development and verification of new or improved test methods, rather than the collection of data on a large number of compounds.

Rapid and relatively low cost testing methods for predicting chronic effects including carcinogenic, mutagenic, and teratogenic potential are particularly needed. Such testing would allow for an initial screening of many more chemicals to identify those chemicals which require more elaborate testing.

Similarly, there is an urgent need for development of new test methods which will indicate environmental effects from chemicals. Such tests at present are few in number or nonexistent, and substantial research resources will be necessary to close this gap. Given the potential magnitude of these activities, special efforts must be made to insure close coupling of research work and priority program needs.

Extensive efforts have been made to estimate the levels of human exposure to chemicals which are ingredients in foods, drugs, and cosmetics. Little serious effort has been made to estimate levels of human exposure to these or other chemicals via other routes such as inhalation, drinking water contamination, food contamination, and skin absorption of pollutants. Even less effort has been directed to assessing exposure of environmental flora and fauna to chemicals. This is a difficult area, and meaningful quantification will be the exception rather than the rule. For example, primitive steps have been made in considering human exposure to mercury, but only very crude estimates were possible. Research is needed to develop techniques for estimating exposure levels of the known problem substances and for signalling high exposure levels of potential problem substances.

Economic and market forecasts are central to the activities of all aggressive companies. Similarly, the research for better manufacturing and related technologies is never ending. However, these industrial activities are inevitably cast in profit-making and not environmental impact terms. Economic and technological forecasting techniques which combine both profit and environmental concerns are particularly important in a field dependent on long lead-time R&D requirements. It is important that the Agency learn how to use such techniques to anticipate activity that may lead to environmental degradation.

GENERAL PROGRAM ELEMENT GOAL

To improve the experimental and analytical techniques and data base needed to assess the necessity for, character of, and impact resulting from regulatory and other steps to restrict chemical substances.

TEST METHODS

Subgoal

To stimulate development of more rapid, less expensive, and/or more reliable test methods with particular emphasis on approaches that provide data needed for specific types of regulatory actions.

Strategy

The approach to improving toxicological test methods through EPA research activities should emphasize development of

-- short-term and low cost methods for rapidly screening large number of chemicals and for identifying those biologically active chemicals which should be subjected to more detailed testing.

-- improved methods for extrapolating from animal test results to human health effects, including the design and execution and toxicological and epidemiological studies on the same substances.

-- better models for extrapolating toxicological test results to lower levels on the dose/response curve with particular attention to orienting the activities at NCTR more sharply toward regulatory requirements.

-- tests for detection of chronic and delayed effects other than carcinogenesis and mutagenesis.

-- standardization of tests for chronic and delayed effects such as teratogenesis and mutagenesis.

Environmental test activities should center on improved methods for assessing (a) the impact of selected chemical classes on different types of plants and animals, (b) the movement of chemicals through the environment -- and particularly through the soil and across media interfaces, (c) the ability

of chemical insults to cause serious imbalances in natural ecosystems, and (d) the utility of micro-ecosystem models to evaluate the interaction of selected chemicals with the ecosystem. Methods that could be adopted and used by industry as a basis for predicting environmental fate of toxic substances should be emphasized. Clearly, cost and reliability will be central considerations.

Critical to a successful research effort in this field is participation in selection and design of tests by program offices -- to help insure their relevance, and by industry -- to help insure that the results of the research will be used.

Three-Year Milestone

Have under development three new approaches to testing that will provide an improved basis for assessing the risks associated with chemical substances.

ESTIMATION OF EXPOSURE

Subgoal

To develop and apply methods and background data needed for assessing the extent of environmental and human exposure to selected chemical substances, including consideration of environmental transport, persistence, routes of entry into the environment, magnification and bioaccumulation, environmental degradation, and retrospective monitoring through sample banking.

Strategy

The approaches involved are of two types: those more general approaches which consider factors common to all types of chemicals for assessing exposure, and specific approaches which are directed to particular chemicals or classes of chemicals.

Analytical models which make use of monitoring and other types of data should be designed and developed for both general and specific approaches to exposure estimation. Factors such as production quantity, use patterns, persistence, environmental transport characteristics, and degradation patterns will be considered and should form the basis for various proposed models. Experimental and theoretical techniques for predicting,

assessing, and verifying environmental properties such as persistence and transport characteristics are generally lacking, and should be developed to support this effort.

The development of analytical models of predictive value involves relating experimentally obtained values of different types to one another. For example, a physical-chemical measurement such as a partition coefficient may have a statistical correlation to the degree of storage of a compound in certain biological compartments. This approach can be applied to many chemicals and chemical classes, but may develop particular significance for a specific group such as chlorinated hydrocarbons.

Development of new monitoring methodology and monitoring data to assess the presence and distribution of chemicals in the environment is a vital input to these approaches. Such activities should involve research on methods to monitor actual exposures to humans and natural ecosystems to environmental chemicals.

Comparative analysis of theoretical and actual exposure levels is a concurrent activity which can serve to strengthen both general and specific approaches to exposure estimation by revealing the consistencies or inconsistencies of observed correlations. Verification of analytical models will necessitate the development of monitoring strategies, and in many cases will demand extremely sensitive analytical chemical techniques which may not be readily available. Feedback from this activity will impact on both monitoring method and analytical model development.

A sample bank system should be established to provide baseline information on actual exposures in selected locations. Initially, the sample bank should be limited to human tissues but later expanded to environmental samples such as crops, soils, water, or selected plant and animal tissues.

In addition, these efforts should include some input from related EPA activities such as the CHESS program and pesticides community studies.

Three-Year Milestones

Develop and test on a limited number of chemical substances a system for estimating and/or producting the level of human and

environmental exposure to such substances, taking into account use patterns, environmental transport, degradation, and food chain effects.

Establish and maintain a sample bank for retrospective monitoring of selected chemical substances.

TREND ASSESSMENT

Subgoal.

To improve assessments and forecasts of technological developments, economic and market trends, and material production and use patterns which can assist in anticipating environmental problems resulting from chemical substances entering the environment.

Strategy

Well established market and related economic forecasting techniques provide the framework for this activity. Technological forecasts within this framework can serve as the basis for estimating the character and direction of the chemical and allied industries in the years ahead. The major effort should then be directed to estimating the interaction of these projected trends with environmental concerns. The following types of considerations are particularly relevant:

-- At what levels will known problem substances be entering the environment?

-- What currently unsuspected chemicals will be entering the environment and at what levels?

-- What will be the geographic distribution of manufacturing and use?

-- Which types of manufacturing and use activities lead to appreciable amounts entering the environment?

-- Which types of technological innovations heighten environmental concerns and which types reduce concerns?

-- What risks are involved with substitute and alternative materials?

-- To what extent will economic trends and other market factors influence technological developments and how will these developments interact with environmental concerns?

-- To what extent can use patterns be predicted from economic and growth indicators?

Initially, conceptual approaches and analytical techniques should be developed. They would then be available to assess specific industries, specific chemical classes, and specific use classes.

Three-Year Milestone

Develop and apply to a range of selected industrial classes economic and market indicators that can signal those chemical substances which should be of particular concern.

EPA REGULATORY AUTHORITIES OF PARTICULAR RELEVANCE TO TOXIC SUBSTANCES

CLEAN AIR ACT

Ambient Air Quality - National air quality standards based on geographic regions establish the maximum amount of each pollutant that will be permitted in the atmosphere consistent with public health and welfare. Standards have been set for sulfuroxides, particulate matter, carbon monoxide, hydrocarbons, photo chemical oxidants, and nitrogenoxides.

New Stationary Sources - EPA directly regulates new stationary sources by setting uniform national standards for new air polluters. Standards have been devised to require the application of the best available technology for five sources: fossil fuel fired steam generators, incinerators, cement plants, and sulfuric and nitric acid manufacturing operations.

Hazardous Air Pollutants - EPA has the authority to set national standards for materials discharged into the atmosphere that have a proven relationship to severe human health problems. Standards have been set for mercury, asbestos, and beryllium.

Fuel and Fuel Additives - EPA may regulate fuel and fuel additives which endanger public health, such as leaded gasoline.

FEDERAL WATER POLLUTION CONTROL ACT

Effluent Limitations - EPA is directed to publish regulations establishing guidelines for effluent limitations which identify the best practicable control technology for various industrial categories. Industrial discharges must meet these standards by 1977. Also, EPA must identify the best available technology which will reduce discharge of pollutants with industrial discharges obliged to meet these standards by 1983. Among the industries of particular relevance to toxic substances are plastics, petroleum, rubber, organic chemical, asbestos, fertilizers and phospates, soaps and detergents, and inorganic chemical.

Water Quality Standards - States must submit to EPA water quality standards which are consistent with Federally established water quality criteria, including criteria for limitations on toxic substances. In addition, where effluent limitations will not be stringent enough to meet water quality standards, States are required to establish

maximum daily loads of pollutants in waters that will allow the propagation of fish and wildlife.

New Source Performance Standards - EPA is required to set standards for new industrial point sources, based on best available demonstrated control technology.

Toxic and Pretreatment Effluent Standards - EPA is directed to publish a list of toxic pollutants and effluent limitations, including prohibition if appropriate, for these substances.

Oil Spills and Hazardous Substances - EPA is directed to clean up spills of oil and hazardous substances, make the polluter pay the cost of clean up, and levy fines and penalties against him. As a first step in the area of hazardous substances, a list of pollutants is to be promulgated with subsequent determination of penalty rates.

PUBLIC HEALTH SERVICE ACT

Drinking Water Quality - EPA has responsibility for drinking water standards for public water supplies used by interstate carriers.

MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT

Ocean Dumping - EPA issues permits for dumping in the ocean of sewage sludge, garbage, and chemical and construction wastes and approves permits for dredged materials.

FIFRA, FEPCA, AND FOOD, DRUG, AND COSMETIC ACT

Registration - Under FEPCA, the distribution, sale, offer or holding for sale, shipment, delivery, or receipt within any State of any pesticide which is not registered is prohibited. Additionally, FEPCA calls for labelling of registered pesticides and the registration of pesticide-producing establishments.

Certification of Applicators - EPA is authorized to prescribe applicator certification standards requiring that the individual to be certified is competent to handle the pesticide. A related provision is the prohibition against the use of a pesticide in a manner inconsistent with its labelling.

Tolerances - Under the Food, Drug, and Cosmetic Act, if the pesticide in normal use leaves residues on crops that provide food for man and animal, a tolerance must be established. Where the supporting data is inadequate or a health hazard may be present, EPA must establish a "zero" tolerance.

Cancellation - Cancellation is the major tool in implementing the decision that the benefits of using a pesticide are outweighed by its risks. Cancellation can result in removal from the market. Other enforcement sanctions include: a change in classification from general to restricted use: stop sale, use, or removal orders; seizures; and civil and criminal penalties.

REGULATORY AUTHORITIES OF OTHER AGENCIES OF PARTICULAR RELEVANCE TO TOXIC SUBSTANCES

There are a number of regulatory authorities bearing on toxic substances administered by other agencies. The most significant laws and administering agencies are:

Food, Drug, and Cosmetics Act - Department of Health, Education, and Welfare

Lead Based Paint Poisoning Prevention Act - Department of Health, Education and Welfare

Federal Meat Inspection Act - Department of Agriculture

Egg Products Inspection Act - Department of Agriculture

Poultry Products Inspection Act - Department of Agriculture

Flammable Fabrics Act - Federal Trade Commission

Occupational Safety and Health Act - Department of Labor and Department of Health, Education and Welfare

Federal Hazardous Substances Act - Consumer Product Safety Commission

Consumer Product Safety Act - Consumer Product Safety Commission

EXAMPLES OF MONITORING NETWORKS SUPPORTED BY OTHER AGENCIES

Food and Drug Administration:

surveys of raw agricultural products and market basket purchases

Department of Agriculture:

sampling of livestock feed, livestock, and selected crops

Forest Service:

surveys of toxic effects on trees and on nearby areas

Geological Survey:

base line monitoring of rivers and streams and periodic sampling for specific substances

Bureau of Sport Fish & Wildlife:

analyses of contamination of fish and wildlife, including sampling for heavy metals

Bureau of Mines:

surveys of mine tailings and related runoffs

National Oceanographic & Atmospheric Administration:

monitoring of near shore, estuarine, and lake quality including spot sampling for heavy metals

Smithsonian Institution:

analyses of marine and wildlife biology

Department of Health, Education, and Welfare:

Communicable Disease Center's efforts in epidemiological monitoring, including diseases related to heavy metals

STRATEGY FRAMEWORK

FRAMEWORK FOR AN EPA STRATEGY

FOR THE

CONTROL OF TOXIC SUBSTANCES

July 12, 1973
HMC/OTS

PREFACE

This Report is an early step toward development of an EPA strategy for controlling toxic substances. It is intended to serve as the framework for a more comprehensive and definitive strategy statement to be prepared during the next several months. Thus, at this stage the Report is largely descriptive of problems and activities relevant to such a strategy statement. In some cases general policy approaches are suggested although further refinement of these approaches is clearly in order.

The Report is directed primarily to chemical substances exhibiting adverse effects on man or the environment at relatively low concentration levels. At the same time it is recognized that almost any substance can be toxic if exposure levels are sufficiently high, and therefore it is not practical to specify which chemicals or chemical classes are or are not included. Additionally, the concern here is only for toxic effects resulting from sustained chemical or biological activity, and other hazardous effects, such as fire, explosions, and radioactivity, are not considered.

The EPA approach to controlling toxic substances must be carefully integrated with the myriad of related activities of other Federal and State agencies -- including regulatory, monitoring, and research activities. While better integration of all national efforts is a central concern, this Report does not set forth in detail the activities of other organizations which are described in various reports of these organizations.

One purpose of this Report is to provide a broad perspective for the toxic substance activities of a number of interested EPA offices, and particularly the recently established Office of Toxic Substances. Therefore, the most relevant activities of these offices and the additional activities required to implement the pending Toxic Substance Control Act are briefly outlined, with more detailed statements of specific activities presented separately in EPA program documents.

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I. THE PROBLEM OF CONTROLLING TOXIC SUBSTANCES

More than 10,000 chemical substances are commercially produced and used in the United States, with 500-700 new substances entering commerce annually. They find a wide variety of uses as industrial chemicals, in consumer products, and in specialized uses such as drugs, food additives, and pesticides. 1972 sales of chemicals and allied products were about $70 billion, or about eight percent of total U.S. manufacturing sales.

The problems presented by the presence in the environment of some of these substances are all too well known (e.g. mercury, lead, asbestos). Others are believed to pose a latent health or environmental threat, while the effects associated with many of the remaining chemicals, acting individually or synergistically, are almost completely unknown. However, it seems clear that the problems associated with the presence of many chemical substances in the environment -- such as food and drinking water contamination, destruction of biota, and water and soil degradation -- will undoubtedly continue to grow in number, severity, and complexity in the years ahead.

Some of the hazards associated with chemical substances have been recognized and are controlled by the Government, e.g. pesticides and drugs. Other aspects of the toxic substances problem have only recently been identified, and appropriate regulatory measures do not yet exist. Still other pieces of the problem have yet to be identified. Many gaps remain in understanding why, how, and when a substance can have a negative impact on health or the environment, and how best to control or prevent such hazards.

Thus, the concern of EPA with toxic substances is twofold: identification and assessment of the risks associated with the manufacture, distribution, use, and disposal of chemicals which could adversely affect health and environmental quality; and practical steps, including regulatory actions as appropriate, to prevent or mitigate the problems posed by such chemicals.

The risks associated with toxic substances are related to many factors including the size of the dose, duration of exposure, form of the substance when released, and presence of other substances that also contribute to environmental stresses. Problem assessment is further complicated by the many unknowns that surround the characteristics

and behaviour in the environment of most toxic substances, including such aspects as persistence, degradation, accumulation, and movement among environmental media. Good information is not readily available concerning levels, distribution, and trends in the environment of many substances of concern. With regard to the adverse effect of toxic substances, testing approaches for measuring chemical properties and acute toxicity are reasonably well developed. However, similarly well developed test methods for determining chronic toxicity and for estimating environmental impact are not in hand.

The success of past efforts to reduce these deficiencies and uncertainties has been spotty. Monitoring systems generally lack the capability to relate effects to specific substances, and research efforts are only now beginning to address many core issues. Lack of effective integration of the many Federal monitoring and data systems further impedes rapid progress.

In seeking to control specific toxic substance problems, the Government can draw on three types of regulatory authorities:

-- Consumer protection statutes which have as their primary mission the prevention of acute risks to human health. They, however, do not address problems of environmental protection nor human exposure to toxic substances through environmental routes.

-- Media-oriented statutes which focus primarily on problems at the point where they become environmental contaminants, typically, after they are manifested at the end of an outfall pipe or smokestack.

-- Statutes dealing with a particular phase of the existence or use of a toxic substance such as risk to workers, transportation-related accidents, and use of pesticides which are toxic by design.

Pending legislation is directed to enabling EPA to deal with problems which do not currently fall within the existing regulatory framework, and particularly with regard to drinking water standards, disposal of toxic wastes, and problems associated with use and distribution

of chemical substances. In addition, EPA would have authority to control certain types of problems before they appear in the environment. In the absence of such legislation, efforts to cooperate with industry on a voluntary basis in addressing specific problems beyond the reach of current authorities must continue although the results of past efforts have been somewhat uneven.

There are many interfaces among existing regulatory authorities, and the passage of new legislation will further extend the options for addressing specific problems. Implementation of the air and water acts, for example, has involved selection of the most appropriate legislative provisions within these acts for addressing problems of toxic substances in addition to development of criteria to determine if regulation is needed or appropriate under specific provisions. Another example is the control of the use of certain pesticides under the pesticide act while point source discharges of these same chemicals are being considered for control under the water act. Further complicating effective choice of regulatory options is the tendency to search for problems to be controlled under specific authorities rather than searching for the authorities that will most effectively control problems. This approach of controlling the "accessible" aspects of the problem, which may or may not be the "critical" aspects, can hamper efforts to cope with the core of the environmental and health risks posed by manufacture, use, and disposal of toxic substances.

Central to consideration of regulatory options is the balancing of the risks with the benefits related to the action. The diversity of the tradeoffs make this a formidable task. For example, the benefits from employment of workers in chemical plants must be balanced against occupational risks; U.S. competitive ability in world markets weighs against environmental testing costs or requirement of expensive effluent or emission controls; and quality of life benefits from chemical substances bear on the degree of risks which can be tolerated. Restrictions placed on existing activities will affect past investments and established patterns of commerce and employment. With respect to those chemicals which have yet to be offered for commercial use, barriers to market entry could be created through pre-testing and screening requirements. If research and development of new chemicals becomes so difficult that it is no longer profitable, the

advantages to society, in terms both of new products and development of less toxic alternatives to existing products, are lost. In short, environmental protection is not free. Care must be exercised in assessing the impact of corrective actions on the direction, configuration, and diversity of the chemical industry as well as on the benefits to society of chemical products.

II. AGENCY GOALS

The overall EPA goal in the toxic substance area is the protection of man and his environment from adverse effects which may result from the manufacture, use, distribution, and disposal of chemical substances without unduly jeopardizing the societal benefits derived from such substances. While this goal is very broad, and not uniquely the responsibility of EPA, it can serve as the standard for measuring the success of EPA efforts in this area.

The following subgoals are directed to an enhanced EPA capability to assess the risk and benefit aspects of toxic substances and to take appropriate steps to control existing or potential problems posed by these substances:

(1) Development of improved methods to identify and assess problems, including anticipation of problems before severe environmental or human health problems arise. Monitoring and testing data must be combined with analytical efforts and expert judgements in forecasting likely problem areas as well as clarifying known problems.

(2) Articulation of actual or potential health and environmental effects of particular concern. In individual cases careful consideration must be given to the concepts of a permissible level vs. a no effects level, to protection of individual organisms vs. protection of populations of organisms, and to irreversible vs. temporary effects.

(3) Improved use and coordination of monitoring and data systems to ensure that maximum benefit is derived by all concerned program elements from such activities. Ready access to a broad range of available scientific, technical, and economic data can greatly improve and facilitate decisions concerning specific toxic substance problems.

(4) Stimulation of priority research activities, both in the public and private sector, to clarify the problems associated with toxic substances and to develop less hazardous alternatives to these substances.

(5) Improved understanding of the economic framework surrounding the production, use, distribution, and disposal of toxic substances and the regulations affecting these activities. Not only are the direct costs associated with determining toxicity and with controlling substances important, but also the costs to individuals and to society of failure to control the toxic substances must be described in at least a qualitative fashion.

(6) Development of criteria for determining when a specific regulatory authority or combination of authorities should be used to control identified problems, and particularly multi-media problems.

(7) Development of organizational procedures within the Agency to ensure that individual actions taken with respect to a particular toxic substance are consistent and compatible with other activities dealing with the same substance. As the regulatory options for controlling substances increase, there is a growing need to ensure that the authorities that are used go to the core of the problem.

III. THE STRUCTURE TO DEAL WITH TOXIC SUBSTANCES

A. Regulatory Authorities

There are a variety of existing authorities which can be used to control toxic substances. Some cover a broad range of pollutants while others have been specifically designed to address toxic substances. Appendix 1 describes the relevant provisions of the following statutes administered by EPA: Clean Air Act; Federal Water Pollution Control Act; Public Health Service Act; Marine Protection, Research, and Sanctuaries Act; and FIFRA, FEPCA, and Food, Drug, and Cosmetic Act. Appendix 2 identifies a number of statutes covering various aspects of the toxic substance problem which are administered by other agencies.

The proposed Toxic Substances Control Act of 1973 would give EPA new authority for (a) information acquisition, and (b) restrictive actions. EPA could require testing of chemical substances (both existing and new) which are suspected to pose unreasonable risks and also require other information from manufacturers including the name of the substance, chemical formula, amounts produced, actual or intended uses, and known by-products. EPA could then restrict the use and distribution of chemical substances found to pose unreasonable risks. The Agency could prescribe the amounts of a chemical which may be sold to processors, limit the type of processor to whom it may be sold, restrict the amount a given type of processor may use, or limit the sale or manner in which a substance may be used, handled, labelled, or disposed by any person.

This new authority is important from two standpoints. First, the Federal Government is given direct authority to restrict substances presently in commercial use that are known to cause health or environmental hazards, and (when effects) information is lacking, to require testing of the substance by the manufacturer to assess human or environmental impact. Second, for substances not yet in commercial production, the Agency could require premarket testing and review of chemicals suspected to be hazardous. The Agency would have the opportunity to assess the risks before the new substances are commercially produced and to take appropriate regulatory action to prevent toxic incidents.

The proposed Hazardous Waste Management Act of 1973 would create a joint Federal-State program to regulate the treatment and disposal of hazardous wastes. This legislation would authorize EPA to designate waste substances or waste streams of particular concern and to specify performance and design standards for disposal facilities. Wastes not identified as posing the most serious hazards, but which still present disposal problems, would be controlled by State programs established in accordance with Federally specified guidelines.

This new authority is particularly important as presently established regulation of air and water discharges and of ocean dumping makes land disposal of toxic wastes more attractive. The Agency could require generators of hazardous wastes to use environmentally sound disposal techniques and could insure compliance.

The pending Safe Drinking Water Act would expand Federal coverage of drinking water standards from the current 700 systems serving interstate carriers to 40,000 community water supplies and 200,000 non-community systems serving the travelling public. Mandatory national primary standards would apply to all health related constituents as well as certain operating and monitoring requirements. Enforcement authority would rest primarily with the States, subject to EPA support if State programs fail to meet Federal guidelines. A more direct Federal role would exist in the presence of an imminent hazard.

B. Research, Monitoring, and Data Systems

Three EPA research areas of particular significance are: Transport Processes, including the fate of pollutants in ground water and fresh surface water and the mechanisms of formation and decay; Health Effects, including development of improved toxicological tests; and Ecological Effects, including the impact of toxic substances on fish and wildlife. A number of other Federal agencies also support research on toxic substances, including the Department of Health, Education, and Welfare (e.g. Food and Drug Administration and National Institutes of Health), the Department of Agriculture (e.g. Agriculture Research Service, Forest Service), the Department of Interior (e.g. Bureau of Mines, Bureau of Sport Fish and Wildlife, Geological

Survey), the Department of Commerce (e.g. NOAA, National Bureau of Standards), and the National Science Foundation.

In a number of cases entire research programs or laboratories are directed to toxic substances, such as the NSF program on trace metals, the National Center on Toxicological Research, several laboratories of the National Environmental Research Centers, a number of programs of the National Institute of Environmental Health Sciences and the National Cancer Institute, and a number of other Federally supported university programs. In addition, attention to highly toxic materials is frequently subsumed in programs encompassing a broader range of pollution concerns.

Similarly, many Federal and State agencies are involved in monitoring. For example:

-- FDA surveys of raw agricultural products and market basket purchases

-- USDA sampling of livestock feed, livestock, and selected crops

-- Forest Service surveys of toxic effects on trees and on nearby areas

-- USGS base line monitoring of rivers and streams and periodic sampling for specific substance

-- Bureau of Sport Fish and Wildlife analyses of contamination of fish and wildlife, including sampling for heavy metals

-- Bureau of Mines surveys of mine tailings and related runoffs

-- NOAA monitoring of near shore, estuarine, and lake quality including spot sampling for heavy metals

-- Smithsonian Institution analyses of marine and wildlife biology

-- HEW Communicable Disease Center's efforts in epidemiological monitoring, including diseases related to heavy metals.

The objectives, and hence the geographic spread and data collection requirements, of these networks vary considerably. Nevertheless, they offer extensive opportunities for environmental sampling on either a routine or an ad hoc basis. In some cases toxic pollutants are a principal concern of the network collection activities. In other cases, toxic substances are but a subset of a broader range of pollutants that are analyzed. Timely access by EPA to the monitoring data is often difficult, however, and adjustments of the systems to accommodate quick responses to short-term EPA needs is usually not feasible. In short, when the needs of EPA mesh with the needs of the other agencies, the systems are very valuable. However, when there is not a good meshing, there are considerable difficulties in acquiring and using the needed data.

EPA's highest priority monitoring needs are currently associated with characterization of known geographical problem areas and the contributing pollution sources and with the evaluation of compliance with standards. Monitoring to assess overall environmental quality, national or regional environmental trends, and new pollutants emerging as problems is of secondary priority. Responsibility for the National Air Sampling Network is being transferred to the Regions, with emphasis on evaluation of state air monitoring networks, review of adequacy of state-collected data, and special surveys. Similarly, the major responsibility for water quality monitoring is being placed on the States, with the EPA emphasis on characterization of water segments where water quality standards dictate discharge permit conditions. In the years ahead, the States are expected to begin providing the majority of information on the overall status and trends in water quality. None of these efforts are at present deliberately oriented toward acquiring data on toxic substances although in specific air or water bodies where problem substances are suspected, they obviously are prime targets. With the designation of toxic pollutants under Section 112 of the Clean Air Act and Section 307(a) of FWPCA, monitoring for these substances should increase. Pesticide residue monitoring (for soils, crops, biota, surface runoff, human tissues) provides data for evaluation of label regulation applications and residue tolerance petitions, rather than an overall assessment of pesticide levels in the environment.

Many federally funded data systems potentially provide a rich reservoir of information on toxic substances (e.g. TOXICON, SIE, NTIS). A number of data systems are used in EPA to handle information collected through monitoring activities and from other sources (e.g. ENVIRON, STORET, NEDS, SAROAD, Pesticide Data Base). However, these systems have been developed largely independently of one another, and there is little commonality among them, thus inhibiting integration of data from various systems. Despite the numerous attempts at bibliographies, common indexing, and formal and informal coordination mechanisms, effectively tapping available data banks remains a formidable task.

C. Interests of EPA Headquarters Offices

Toxic substances currently permeate the activities of many EPA program offices with responsibilities for administering existing legislation. They are of major concern to the Offices of Pesticides, Solid Waste Management (and particularly the Division of Hazardous Wastes), Air Quality Planning and Standards, Mobile Source Air Pollution Control, Water Programs Operations (and particularly the Division of Oil and Hazardous Materials), and Water Planning and Standards. Each of these offices is involved in developing control strategies, standards, and/or guidelines. In addition, these offices are concerned with technical assistance to the states and responding to emergency problems and inquiries bearing on toxic substances. Other offices, and particularly the Offices of Research and Development, Toxic Substances, Technical Analysis, and Program and Evaluation also devote considerable resources to direct support of legislative requirements and enforcement activities.

Several examples illustrate the spread of EPA activities. More than twenty EPA working groups are currently addressing both policy aspects and technical details of particularly troublesome toxic substances, including consideration of unleaded gasoline, fuel additives, drinking water standards, toxic water pollutants, and spills of hazardous materials. With regard to crisis response, the Office of Technical Analysis is currently heavily involved in asbestos problems, the Pesticides Office in Agent Orange, and the Office of Toxic Substances in hexachlorobenzene. Two of the longer range EPA activities involve current analyses of problems associated with disposal of specific hazardous wastes

being conducted by OSWMP and strategy planning of OAWP for coping with toxic air pollutants, including a series of supporting studies of specific pollutants by the National Academy of Sciences.

D. Role of the Office of Toxic Substances

In 1971 several EPA task forces recommended establishment of a central office to serve as a focal point for shaping an overall EPA approach to the assessment and control of toxic substance problems. A particular need was identified for analyzing the effects of toxic substances on the total environment and relating these effects to regulatory authorities, strengthened research and monitoring activities, coordination of the activities of various EPA offices concerned with toxic substances, and cooperation with other Government agencies.

The initial framework for the Office's activities reflects these concerns. At present the Office's efforts are directed to:

-- supporting the activities of other EPA offices responsible for regulating toxic substances under existing statutory authority with particular attention to criteria for determining when, and under what authority, toxic substances should be controlled.

-- developing and improving techniques for anticipating and identifying problem areas, including monitoring approaches and investigations of specific chemicals suspected to pose risks to health and the environment.

-- improving the analytical base for decision-making, with particular attention to the adequacy of existing test methods, the economic and related framework for the manufacture, use and distribution of chemicals, and the timely availability of technical data to decision makers.

-- clarifying the most important research needs including assessment of the value and useability of past research efforts and identification of priority research gaps.

-- support of EPA field units, through provision of technical information tailored to specific problems and timely response to ad hoc requests.

-- support for the "Toxic Substances Control Act of 1973" with particular attention to the industrial reporting requirements, the character and scope of test requirements, and relationship of the proposed legislation to existing laws.

-- response to crisis situations such as the problems associated with hexachlorobenzene that do not neatly fall into a single program area.

Many of these activities are still embryonic, and the Office's involvement in each area is increasing rapidly. In particular, the role of supporting other EPA offices will continue to expand as additional regulations are developed to control toxic substances. Should the Toxic Substances Control Act be enacted, a major new dimension will be added to the Office's responsibilities.

IV. POLICY ISSUES

A. The Level of Agency Resources Devoted to Toxic Substances

The increasing frequency of emergency situations involving toxic substances, as well as the implementation of the Toxic Substances Control Act and the Hazardous Waste Management Act, will undoubtedly require resources beyond those currently devoted to this area. Indeed, the level of additional resources programmed into the area of toxic substances will have a decisive effect on the character and scope of implementation of an Agency strategy. Since it is unlikely that a sizeable increment of new resources will become available to EPA for toxic substances, the Agency will probably have to support a significant part of the resultant activities from within its existing base.

Although a portion of the Agency's resources are currently directed toward the toxic substances area--in regulatory and research and supporting activities--the current commitment is not sufficient to support even minimal implementation of either bill. The resource constraints dictate that toxic substances related programs clearly define their priorities and carefully consider means of making maximum use of existing analytical, research, and monitoring facilities as well as regulatory and enforcement personnel and resources.

B. Organizational Responsibilities and Coordination within EPA

The EPA program offices tend to concentrate on that portion of the toxic substances problem which directly relates to their statutory authorities. The focus of this attention is usually dictated by deadlines as resources are deployed to address the immediacy of standard setting or crises. As a result, a number of rotating specialists are working in spurts on toxic substance problems usually without the opportunity to evaluate the total hazard which may be posed by a given toxic substance. Related to these activities of the program offices is a myriad of activities of the Regional Offices, the Enforcement Offices, and ORD, including the NERCs. Many of these activities are directly tied to program concerns; others are not. The

disparate nature of EPA toxic substances responsibilities complicates an already complicated problem, and better organizational unity seems essential if resources are to be wisely used, and if the total environmental approach is to be a reality.

The EPA Regional Offices should further develop a strong capability to cope with single media problems and some capability to address a wide range of toxic substance concerns. Hopefully, this capability will grow as the Regions gain experience without the necessity of deploying significant additional resources directed specifically to toxic substances. However, a strong centralized system for policy and standard setting and for assessing highly specialized problems is essential. Both headquarters personnel and specialists from the NERCs can play an important role in this regard. The pesticides program exemplifies how decentralization of enforcement and local response capabilities are backstopped by specialized central staffs. Also, in the air monitoring area, the regions are assuming new responsibility but much of the specialized analyses will undoubtedly continue to be guided by centralized staff.

Related to these organizational concerns is the responsibility within EPA for technical assistance and for responding to crises, and particularly crises which involve multi-source and multi-media pollutants. Many EPA offices -- and particularly the Regional Offices -- are continuously involved. Clearly, an important objective of an EPA response capability should be to use efficiently the best available expertise with the minimal disruption to ongoing activities. Usually, much, but not all, of the relevant headquarters expertise resides with the headquarters office that has primary responsibility for resolving the problem. At the same time the office is generally so engaged with the problem that it is not difficult to overlook the interests, capabilities, and resources of other offices. Toxic substances represent a formidable and complicated array of problems, and there are a number of EPA units which can contribute to solving specific problems.

C. Selection of Problem Substances for Detailed Attention

Identifying and assigning priority to problem substances is fundamental to the success of several Agency programs. At present several EPA offices are independently

carrying out studies of various toxic substances with minimal attention to coordination. With the enactment of new authorities, the Agency effort may become further fragmented.

When assessing new chemicals which have not yet been introduced into commerce, the traditional tools, such as monitoring and reliance on past human experience, are not available. Test results and other predictive measures to assess potential impact must be used. It is in this area that the Toxic Substances Control Act is uniquely appropriate, and the Office of Toxic Substances is a logical focus for such concerns.

With respect to existing chemical substances, monitoring and epidemiological experience can be used to complement test and other analytical information for identifying those substances which are causing health or environmental problems. Responsibility for identifying and assigning priorities to problem substances in one of the media or with regard to a specific use rests with the office responsible for the relevant authority. Nevertheless, a more conscientious effort must be made by all offices to (1) communicate throughout the Agency their efforts to identify and establish priorities at an early date, and (2) define more precisely criteria for identifying hazardous chemicals. The Office of Toxic Substances and the Office of Research and Development can play strong supporting roles in this second area.

D. Selection of Appropriate Regulatory Authority

Related to the selection and analyses of specific substances and problems attendant to the presence of these substances in the environment is identification of the best approach in resolving the problems. In many cases, this relates to a choice of regulatory authorities.

At present the starting point for almost all EPA efforts to control toxic substances is a legislative authority, and that authority in large measure dictates the problem or piece of the problem to be solved. In many cases, of course, this approach goes to the core of the problem. In other cases, however, only a small piece of a far broader problem posed by a substance can be addressed. Even with individual laws, such as FWPCA and the Clean Air Act, there are several routes for controlling single media problems. In some instances regulation under more than one authority may be desirable.

In selecting the appropriate authority, a variety of factors should be kept in mind such as maximizing reduction of the problem while minimizing adverse economic impact, ease of enforcement, and precedents set by the use of a particular authority. Schemes developed in addressing one class of problems may have direct relevance to other classes. Meanwhile, the current limited efforts to isolate the key elements of toxic substances problems and then to search out the most appropriate regulatory authorities should become a useful complement to the approaches of other offices.

E. Limited Reliance on State Capabilities

It seems neither wise nor practical to place primary reliance on the States for controlling toxic substances -- certainly not in the near term and probably not in the longer run. While the States are assuming an ever greater role in monitoring and regulating the activities of many types of polluters, several of the characteristics of toxic substances suggest that in this area a program which is in large measure Federally directed is essential.

-- The use, sale, and distribution of chemical substances are generally interstate in character, and consistency of regulation is necessary to prevent economic imbalances and to enable meaningful enforcement.

-- Given the scientific and technical uncertainties surrounding the behaviour and detection of many toxic substances, it is highly unlikely that many States can develop the capability to address these problems in a credible fashion.

-- The hazards associated with toxic substances are potentially of such magnitude that the Federal Government has a special obligation to take steps to mitigate these hazards.

While State participation in some aspects of monitoring and enforcement should be encouraged, clearly the Federal Government must assume the leadership in these areas as well as in standard setting and general policy direction.

F. Improved Approaches to Research, Monitoring, and Data Systems

There has been relatively little effort to review the pieces of the total research activity in toxic substances for determining where duplicative work might be alleviated, or for identifying neglected areas. The toxic substances-related research needs of the various EPA program offices have not been consolidated into an effective plan to fill in critical gaps. Both within the Agency and in the overall federal research effort, a concerted rather than a fragmentary approach to toxic substances problems is needed.

Federal record keeping (e.g. Tariff Commission production data), data gathered through regulatory efforts (e.g. EPA's pesticides and water permit programs), and the results of federal monitoring programs (e.g. FDA's market basket surveys) are all potential sources of valuable information on the manufacture, use, distribution and disposal of toxic chemicals. To date, however, these sources have served primarily the parochial interests of the office conducting the effort. Potential users of such information are discouraged by specialized systems, barriers to access to information such as confidentiality requirements, and general agency reluctance to allow outside use of information. Even more fundamentally, it is often difficult to ascertain what kinds of information exist within the federal system. At the very least, EPA must ensure that information collected by one office will be available to the rest of the Agency. With its own house in order, the Agency can then call for increased linking within the overall federal information acquisition and storage system.

The following approaches should be developed and articulated in support of further elaboration of the overall strategy for controlling toxic substances:

-- A framework for identifying the highest priority research needs, including elaboration of the areas of greatest concern, analysis of the effectiveness of on-going programs, and estimates of the payoff of new approaches if they are successful.

-- A detailed approach to monitoring toxic substances in the environment, identifying with some precision specific types of monitoring

activities that should be augmented, and estimating the anticipated usefulness of the data from such augmentation.

-- Steps for more effectively utilizing existing information sources on toxic substances, with particular emphasis on how one or more centralized information switching points can facilitate access to relevant data.

G. Priorities in Implementing the Toxic Substances Control Act

Given the extensive scope of the legislation, the number of areas of initial emphasis will depend to a significant degree on the staff and resources available for implementation activities. In selecting areas for priority attention consideration should be given to Congressional mandates, severity and urgency of existing problems which can be alleviated by the new authority, opportunities to reduce future problems of major dimensions, and necessity for establishing long-term viability of implementation procedures.

While the final version of the legislation may influence the choice of initial activities, it seems clear that the following activities should be high on the agenda for early attention:

-- Elaboration and articulation of the criteria or sets of criteria to be used in weighing risks versus benefits, and in determining when regulatory action is needed. Clear understanding by both industry and Government of the ground rules for restrictions is essential to the viability of industrial R & D activities.

-- Determination of the character and scope of initial testing requirements, including the possibility of umbrella testing requirements for a broad range of chemical classes and identification of specific chemicals or classes of chemicals of particular immediate concern. While the selection of substances covered by the standards for test protocols that are initially promulgated will in large measure reflect intuitive judgements concerning likely hazards and inadequacy of current

data, concurrent work is needed to provide a basis over the longer term for selecting areas of concern.

-- Development of regulations setting forth timing, coverage, content, and format of the reporting requirements for chemical manufacturers and processors, including both annual reporting and premarket notification.

-- Establishment of a data system for handling the industrial reports and test results that are submitted. Experience in the pesticide area underscores the importance of early attention to establishing efficient and decision oriented procedures to be effective when the first reports arrive.

There are, of course, a considerable number of other requirements that will require attention from the outset. However, if choices must be made, less extensive efforts would be devoted to the following:

-- Development of a detailed system for classifying chemicals.

-- Analyses of the risks associated with existing chemicals.

-- Establishment and meaningful operation of the Toxic Substances Board.

-- Analyses of exports of chemicals.

-- Annual report on coordination of activities under this legislation with activities under other authorities.

V. FUTURE STEPS

As a step toward a more coherent approach to the control of toxic substances -- and particularly to clarify consistency of policy directions of different offices, to assist in selection of regulatory tools for addressing specific toxic substance problems, and to ensure most effective use of limited resources being devoted to toxic substances -- the strategy described in previous sections will be further developed during the coming months. In elaborating the overall approach careful attention will be directed to (a) various methodologies currently being used within EPA for setting tolerances and standards, (b) complimentary and duplicative efforts within EPA to analyze problems associated with specific substances, and (c) the rationale for selecting the appropriate legislative authority for solving specific problems.

Clearly, the further delineation of needs and opportunities in research, monitoring, and data systems that has been described previously should support the development of a more definitive strategy statement. Also, the preparation of FY 1975 program documents, including the program submission for the Office of Toxic Substances, should assist in further illuminating the spread of EPA interests and activities in toxic substances and in assessing the effectiveness of current efforts toward more effective meshing of the efforts of a large number of offices. Meanwhile, standard setting through the Steering Group mechanism can be improved through greater involvement of all interested offices early in the working group process, particularly in relation to developing the methodologies for standard setting.

Should the two pending bills be enacted, major new dimensions will be added to EPA responsibilities. Thus, prompt attention should be given to analysis and resolution of

-- the principal policy and implementation issues associated with the Toxic Substances Control Act, including the extent and character of industrial testing requirements for both new and existing substances, criteria for determining whether and how substances should be controlled, criteria for designating a substance as an

"unreasonable threat" and subject to industry testing, and criteria for determining whether the new law is the most appropriate law for controlling a substance.

-- the principal policy and implementation issues associated with the Hazardous Waste Management Act, including clarification of State responsibilities, disposal site standards, and initial funding requirements.

In addition to the foregoing policy issues there is need for a better organizational approach which will add coherence to broadly dispersed regulatory attacks and supporting activities on pieces of the same problem. The newly established Office of Toxic Substances -- with responsibility for broad overview of EPA activities in toxic substances and for coordination of such efforts -- should give high priority to improving such organizational cohesion.

EPA REGULATORY AUTHORITIES OF PARTICULAR RELEVANCE TO TOXIC SUBSTANCES

CLEAN AIR ACT

Ambient Air Quality - National air quality standards based on geographic regions establish the maximum amount of each pollutant that will be permitted in the atmosphere consistent with public health and welfare. Standards have been set for sulfuroxides, particulate matter, carbon monoxide, hydrocarbons, photo chemical oxidants, and nitrogenoxides.

New Stationary Sources - EPA directly regulates new stationary sources by setting uniform national standards for new air polluters. Standards have been devised to require the application of the best available technology for five sources: fossil fuel fired steam generators, incinerators, cement plants, and sulfuric and nitric acid manufacturing operations.

Hazardous Air Pollutants - EPA has the authority to set national standards for materials discharged into the atmosphere that have a proven relationship to severe human health problems. Standards have been set for mercury, asbestos, and beryllium.

Fuel and Fuel Additives - EPA may regulate fuel and fuel additives which endanger public health, such as leaded gasoline.

FEDERAL WATER POLLUTION CONTROL ACT

Effluent Limitations - EPA is directed to publish regulations establishing guidelines for effluent limitations which identify the best practicable control technology for various industrial categories. Industrial discharges must meet these standards by 1977. Also, EPA must identify the best available technology which will reduce discharge of pollutants with industrial discharges obliged to meet these standards by 1983. Among the industries of particular relevance to toxic substances are plastics, petroleum, rubber, organic chemical, asbestos, fertilizers and phospates, soaps and detergents, and inorganic chemical.

Water Quality Standards - States must submit to EPA water quality standards which are consistent with Federally established water quality criteria, including criteria for limitations on toxic substances. In addition, where effluent limitations will not be stringent enough to meet water quality standards, States are required to establish

maximum daily loads of pollutants in waters that will allow the propagation of fish and wildlife.

New Source Performance Standards - EPA is required to set standards for new industrial point sources, based on best available demonstrated control technology.

Toxic and Pretreatment Effluent Standards - EPA is directed to publish a list of toxic pollutants and effluent limitations, including prohibition if appropriate, for these substances.

Oil Spills and Hazardous Substances - EPA is directed to clean up spills of oil and hazardous substances, make the polluter pay the cost of clean up, and levy fines and penalties against him. As a first step in the area of hazardous substances, a list of pollutants is to be promulgated with subsequent determination of penalty rates.

PUBLIC HEALTH SERVICE ACT

Drinking Water Quality - EPA has responsibility for drinking water standards for public water supplies used by interstate carriers.

MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT

Ocean Dumping - EPA issues permits for dumping in the ocean of sewage sludge, garbage, and chemical and construction wastes and approves permits for dredged materials.

FIFRA, FEPCA, AND FOOD, DRUG, AND COSMETIC ACT

Registration - Under FEPCA, the distribution, sale, offer or holding for sale, shipment, delivery, or receipt within any State of any pesticide which is not registered is prohibited. Additionally, FEPCA calls for labelling of registered pesticides and the registration of pesticide-producing establishments.

Certification of Applicators - EPA is authorized to prescribe applicator certification standards requiring that the individual to be certified is competent to handle the pesticide. A related provision is the prohibition against the use of a pesticide in a manner inconsistent with its labelling.

Tolerances - Under the Food, Drug, and Cosmetic Act, if the pesticide in normal use leaves residues on crops that provide food for man and animal, a tolerance must be established. Where the supporting data is inadequate or a health hazard may be present, EPA must establish a "zero" tolerance.

Cancellation - Cancellation is the major tool in implementing the decision that the benefits of using a pesticide are outweighed by its risks. Cancellation can result in removal from the market. Other enforcement sanctions include: a change in classification from general to restricted use: stop sale, use, or removal orders; seizures; and civil and criminal penalties.

REGULATORY AUTHORITIES OF OTHER AGENCIES OF PARTICULAR RELEVANCE TO TOXIC SUBSTANCES

There are a number of regulatory authorities bearing on toxic substances administered by other agencies. The most significant laws and administering agencies are:

Food, Drug, and Cosmetics Act - Department of Health, Education, and Welfare

Lead Based Paint Poisoning Prevention Act - Department of Health, Education and Welfare

Federal Meat Inspection Act - Department of Agriculture

Egg Products Inspection Act - Department of Agriculture

Poultry Products Inspection Act - Department of Agriculture

Flammable Fabrics Act - Federal Trade Commission

Occupational Safety and Health Act - Department of Labor and Department of Health, Education and Welfare

Federal Hazardous Substances Act - Consumer Product Safety Commission

Consumer Product Safety Act - Consumer Product Safety Commission

MONITORING STRATEGY

Ed Brooks
Howard Leathers
Glenn Schweitzer
June 19, 1973

TOXIC SUBSTANCES MONITORING STUDY

I. If not closely and carefully pre-considered, a monitoring effort can easily become a white elephant. This study will attempt to realistically determine whether, in fact, there are any special, significant, and feasibly met monitoring needs peculiar to toxic substances; special to warrant a unique effort; significant to warrant the allocation of scarce resources; and feasible to avoid a search for the Holy Grail. The first step, through staff discussions and studies, will be to enumerate those anticipated information requirements that might, at least theoretically, be met by monitoring.

Presently, several offices within EPA are involved in monitoring (e.g., Offices of Air, Water, and Pesticides). This study will seek to clarify and where possible establish priorities for EPA in the area of toxic substance monitoring. Short term steps to respond to these needs will be recommended.

A. Specifically, we will assess the extent to which and exactly how, monitoring might:

1. Anticipate toxic substance problems by;

a. Locating substances of possible or known toxicity in the environment,

b. Measuring the concentrations of these substances in the environment,

c. Signaling changes in the concentrations of these substances,

d. Measuring accumulated concentrations of toxic substances in human and animal tissue, and

e. Observing biological effects (especially on "indicator species").

2. Identify the chemical causes (where unknown) of observed toxic crises by;

a. Locating substances of possible toxicity in the environment,

b. Measuring accumulated concentration levels of known or suspected toxic substances in human and animal tissue;

c. Observing anomolies in concentration levels or trends of these substances.

3. Provide background data to aid in setting, justifying, and defending standards and regulations by;

a. Correlating observed biologic effects with concentration levels and trends in tissue samples and environmental media,

b. Gathering information on use, distribution, and transport patterns,

c. Discovering sources and paths of toxic substances into the environment,

d. Gathering specific data regarding physical and/or chemical properties (e.g., bioaccumulation) of individual substances,

e. Measuring the effectiveness of regulations and their enforcement -- are the target concentration levels reached? Do anticipated environmental effects occur?

4. Detect violations and enforce compliance by;

a. Frequent trend monitoring near known sources of toxic substance pollution,

b. General level monitoring to establish when prescribed concentration levels in specific media are being exceeded.

5. Gain an overview of the extent and components of toxic substance contamination by;

a. Locating known toxic substances in the environment,

b. Measuring concentration levels and trends of these substances,

c. Monitoring for inter-media differences and trends in the same geographical area and for inter-areal differences and trends in the same medium.

B. The alleged potential advantages of each tentatively indicated monitoring use category will be rigorously and critically evaluated. Illustratively, monitoring has been touted as an "early warning" system to detect emerging toxic threats in the environment.

1. Is this practical - e.g., if such a system had been in place would it have alerted us to the NTA, PCB, mercury or HCB problems any earlier? If so, to what advantage?

2. For such an enterprise to be worthwhile, how many, and specifically which, chemicals substances, organisms, media and tissues would it be necessary to monitor?

3. Assuming an "early warning" system is deemed both workable and within the bounds of reason, would it necessarily be our best choice?

a. Are there either more efficient or less costly ways to discover potential toxic threats -- e.g., via the production and test data anticipated from industry after passage of the Toxic Substances Control Act?

b. How essential is such monitoring? To what extent would offices and operations within EPA be defined differently in the absence of such data? Are the alternative definitions clearly less desirable?

II. Once the priority information requirements of EPA have been enumerated, and those amenable to monitoring identified, the next step will be to survey the real world of available monitoring programs, facilities and activities to determine their capacity and willingness to meet our needs. This will involve consultation with, and evaluation of, among others, the monitoring programs operated by:

A. Within EPA, Offices of;

1. Monitoring,

2. Air,

3. Water, and

4. Pesticides.

B. Other Agencies;

1. National Oceanic and Atmospheric Administration,

2. Bureau of Sport Fisheries and Wildlife,

3. Geological Survey,

4. Department of Agriculture (animal inspection), and

5. Food and Drug Administration (market basket surveys and agricultural surveillance).

C. States;

1. Air,

2. Water, and

3. Soil.

These programs will be examined for:

D. Comprehensiveness.

1. What chemicals, substances, organisms, media and tissues are sampled? How extensively and intensively are these samples analysed?

2. How many sampling sites are there in the U.S., and how are they distributed geographically in the land, air and (ground, surface, navigable, and contiguous) waters?

E. Consistency and timeliness;

1. Are these sites sampled;

a. Periodically,

b. Consistently,

c. Frequently, and

d. In a standard, prescribed manner?

2. Are the data reasonably current? What is the typical lapsed time from sample collection through analysis to data processing and storage?

F. Comparability and compatibility.

1. Are the data derived from these several monitoring efforts comparable through time?

2. Are they uniformly collected, analysed, processed and reported from sampling site to sampling site?

3. Are the data reported in compatible terms from one system to another?

G. Availability;

1. Are the derived data processed and stored on computer tapes or discs?

a. If so, can EPA have access to these data,

i. via terminal hook-up,

ii. by periodically acquiring copies of the tapes, discs and related software, or

iii. in hard copy responses to ad hoc requests?

b. If not, can the data be made available to EPA in any form?

2. Assuming the data can be made available in some form;

a. How long would it take from request to receipt, and

b. How much would it cost?

H. Form of presentation - is it tailored to decision makers needs?

III. Environmental Monitoring is a burgeoning field; its ability to meet information requirements of EPA will depend not only upon the present state of existing monitoring systems, but also upon future developments in these systems. Our survey will therefore try to anticipate the probable near term qualitative and quantitative increments to currently available monitoring information that can be expected to accrue from such factors as;

A. More demanding legislation, as exemplified by the increased monitoring requirements imposed by;

1. Section 305(a) and (b) of the Federal Water Pollution Control Act Amendments of 1972, and

2. Section 110(a)(2)(C) and Section 114(a)(1)(C) and (D) of the Clean Air Act of 1970, and

B. Improved instrumentation and technology;

C. Implementation of proposals to integrate -- or at least render compatible -- the several data systems established to service the independently operated monitoring programs.

IV. Once we have a fairly accurate fix on what information EPA will require, and the existing and probable near term national monitoring capabilities, means will be sought to increase, enhance, modify and exploit these capabilities. Possible avenues to be explored, here, using both staff and contract resources, include:

A. Encouraging integration of the diverse information systems into a universal network;

B. Promoting legislation to require the conduct of autopsies (the result of which would be sent to a

nationally centralized data bank) in all deaths where toxicity is a suspected cause. Special emphasis would be placed upon gaining such information in deaths due to diseases of chronic exposure (such as mesothelioma);

C. Exploring the desirability of collecting and storing data from regularly reported bioassays on rats, pigeons, dogs, cats, etc., living in urban, industrial, and other contaminated environments. These data would be used to ascertain base levels and detect changes in the accumulated toxic burden in these animals as means of;

   1. Estimating the total doses to man in these specific locales, and

   2. Signaling, early on, potential threats to man due either to the sudden and inadvertent introduction of a toxic substance into the environment, or to the gradual bioaccumulation of such a substance, in that area, to dangerous levels.

D. Establishing a national water, air, soil, food and tissue "bank: to receive, identify, index, and store samples that would be regularly collected and submitted from locations throughout the nation. Samples from such banks should be of inestimable value to epidemiological studies initiated in the future in response to toxic catastrophes, by allowing retrospective comparative analyses of the toxic exposures in a particular area, through time;

E. Articulating data needs more carefully in a more elaborate strategy statement;

F. Encouraging research to improve monitoring techniques.

V. Finally, our estimates of (1) EPA toxic substances information needs, (2) the ability of monitoring programs to meet them, and (3) the likelihood of our favorably modifying that ability, will all be incorporated into an overall Plan for Monitoring Toxic Substances. This plan will set forth those categories of information to be addressed through monitoring and, for each such category, a detailed indication as to:

A. Exactly how the data will be collected, analysed and reported, and

   1. By whom,

   2. With what (and whose) resources, and

   3. Within what time frame, and

B. Precisely how, and for what purposes, the received data will be utilized.