TOXICS INTEGRATION WORKPLAN

This workplan describes a set of activities related to development of an EPA-wide strategy for toxics control. The plan covers the remainder of FY 1981. It is based on the work to date of the Toxics Integration Strategy Committee and the concept paper prepared by the DAA's serving on the committee. The plan leads to initial design of an integrated toxics strategy that can be fleshed out and refined (along with initial implementation steps) in FY '82. It reflects commitments made to OMB in EPA's reply to the budget passback:

1. Design of operational mechanisms to coordinate regulation, data gathering, and analysis of toxic substances.
2. Design and testing of prototype geographic and industry-wide approaches to toxic pollutant problems.
3. Identification of legislative changes needed to effectively integrate toxics control.
4. Organizational changes needed to implement the Agency's integrated toxics strategy.
5. Resource allocation recommendations for FY '82 and FY '83.

In the second year, we will complete the analysis of integration strategies, and begin implementation.

GOALS

The goals of EPA's toxics integration strategy will be:

- to set priorities for regulation of toxic substances in a manner that is logically consistent across programs and based on coordinated research and analysis of scientific, health, and economic data.
- to develop a systematic agency process for identifying and responding to toxic substances so that the combined effect of Agency actions on specific areas and industries achieves the most important environmental objectives at reasonable costs.
- to delineate the proper roles of EPA headquarters, EPA regions, and state/local governments in dealing with toxic problems.

The rationale for developing a strategy is simply that the worst threats to health and environment should be controlled first; that this needs to be done, as much as possible, on an Agency-wide basis; and that limited resources are most likely to make a significant impact if used as part of a well thought out Agency-wide strategy.

ACTIVITIES

The FY 1981 workplan consists of six activities:

1. Analysis of Toxics Control in Different Agency Programs
2. Analysis of Exposure and Risk Assessments
3. Analysis of Integration Based on Specific Pollutants
4. Analysis of Integration Based on Industrial Categories
5. Analysis of Integration by Geographic Area
6. Preparation of Recommendations to the Administrator

Activity 1: Analysis of Toxics Control in Different Agency Programs

This is an analysis of how different EPA programs deal with toxic substances. Seven programs will be analyzed: air quality, water quality, drinking water, hazardous waste, toxic substances control, pesticides, and radiation.

The objective of this study is to identify similarities and differences in procedures which programs use to regulate toxics and ascertain how these can help or hinder Agency efforts to develop an agency-wide toxics strategy. The analysis will include evaluation of each program's completed regulatory action, its current work in progress, and longer term plans for toxics control. Program-specific regulatory schedules, timetables, and priority activities will be identified in order to determine compatibility with other program plans.

As part of the study, the Office of General Counsel will provide a quick analysis of the enabling statutes to determine legislative differences and opportunities for toxics integration.

The task will lead to identification of problems and opportunities and recommendations for legislative, organizational, and procedural changes which will be used in Activity 6.

Issues to be addressed in this activity include:

- what are the major procedural differences among programs in controlling toxic substances?
- what has been each program's regulatory record to date in

controlling toxic substances, what activities are currently underway, and what is planned beyond FY 81?

- to what extent have different programs developed non-regulatory approaches to the control of toxic substances?
- which program activities are mandated or discretionary and what flexibility does the agency have in this regard?
- what are the implications for changing the Steering Committee process?
- are toxic or hazardous substances defined differently in the enabling statutes?
- do the statutes give different weights to consideration of health, welfare and economic concerns including benefits and costs in dealing with toxic substances?
- to what extent are programs reacting to emergency situations or able to take anticipatory action?
- how are the conclusions to be integrated with legislative reauthorization studies?
- how do different programs involve EPA regions and state and local governments?

Activities 1 and 2 need to work closely together since both deal with scientific and economic data collection and analysis. Details will be worked out in the workplan for each activity.

Schedule:

Task 1 Analyze current EPA approaches to toxic

pollutant control in the various programs. Based on OTI work currently underway analyzing toxics decisionmaking in major EPA programs. Interim report by 3/15/81; Final Report by 4/30/81.

Task 2 Analyze major EPA legislation to identify and compare legislative mandates for toxics control, based on OTI-OGC evaluation of EPA legislation related to toxics issues. Complete by 3/15/81, revised by 5/15/81.

Task 3 Identify constraints to integration and features that facilitate or promote integration. Complete by 4/15/81.

Task 4 Identify the organizational, procedural, resource allocation, and legislative changes that could eliminate or reduce the constraints. Complete by 6/1/81.

Task 4 Review and revision of report. Complete by 7/1/81.

Staff Requirements:	Full time leader from OTI	(24 work-mos.)
	One half-time person from OPE	(4 work-mos.)
	One person for one months each from seven program offices	(7 work-mos.)
	One work-month from OGC	(1 work-mos.)
	Total: 36 work-months	

Contract Resources: $80,000

Activity 2: Analysis of Exposure and Risk Assessments Employed to Determine Adverse Health and Ecological Effects

Program offices have developed different approaches in assessing health and environmental dangers and economic benefit-cost impacts as a step in preparing regulatory decisions. The programs also differ in their use of outside experts for reviewing data and assessments.

The goal of this activity is to review existing approaches to the conduct of science, health, and risk and economic assessments, risk reduction efforts, document differences and their causes, identify possible changes to promote integration, and prepare recommendations that will be used in the output of Activity 6.

Issues to be addressed in this activity include:

- what are the methods used by different program offices for collection and analysis of scientific data, and assessment of health and environmental risks?
- what differences exist in the methods used for collection and analysis of economic data and assessment of benefits and costs?
- what methods for quality control of assessments are used?
- how do EPA's approaches differ from those used by other federal agencies?
- are there differences in reliance on outside experts and weight given to their testimony and why?
- are there meaningful differences in methods used to measure or estimate exposures from monitoring data,

° are there meaningful differences in methods used to measure or estimate dose,

° are there meaningful differences in methods used to interpret and extrapolate results of bioassays,

° are there significant differences in methods used to interpret and extrapolate results of long-term whole animal tests,

° are there significant differences in methods used to interpret and extrapolate acute toxicity data,

° are there significant differences in methods used to collect and interpret clinical and epidemiological data. (Examples of interpretative issues are: the use of such concepts as the lowest observed effect level (LOEL); the treatment of negative results as compared to positive results; and the discrimination made among populations according to age, sex, susceptibility and life-stype in identifying effects and estimating risks.),

° are there significant differences in models used to translate emissions into exposure estimates,

° are there differences in methods used to translate exposure to dose,

° how are results of assessments used for information to regions, states, and the public?

° how should the agency be organized to prepare short-term risk assessments which are needed in support of regional responses to environmental incidents? can we prepare a model for this purpose?

° could acceptable criteria be proposed for determining the level of acceptable quality for risk assessments?

° should formal risk assessments be prepared for all toxics programs?

° should assessments be done in more than one office, and if so, how do we ensure consistency and credibility?

° what risk assessment methodologies are acceptable; are relative risk analyses acceptable?

° could acceptable criteria be proposed for determining the level of acceptable quality for risk assessments?

Schedule:

Task 1 Description of current EPA approaches in collecting effects data. Complete by 3/15/81.

Task 2 Analysis of the reasons for differences in approaches to risk assessment. Complete by 4/15/81.

Task 3 Analysis of needs for changes. Interim report by 5/15/81. Complete by 8/1/81.

Task 4 Analysis of approaches used by FDA, CPSC, OSHA and NCI. Complete by 5/15/81.

Task 5 Recommendations for organizational, procedural and resource allocation changes that would facilitate consistency, integration and efficiency. Complete by 6/1/81.

Task 6 Submission of final report. Complete by 8/1/81.

Staff Requirements: One full-time leader from OPE (9 work-mos.)
One full-time person from ORD (9 work-mos.)
One quarter-time person from
OANR, OTS, OWWM, SAB (9 work-mos.)
Total: 27 work-months

Activity 3: Analysis of Integration Based on Specific Pollutants

The agency has in the past made decisions on what chemicals to control on an uncoordinated basis, with each program reacting to a different set of pressures, constraints, and environmental insults. It is therefore not surprising that instances can be cited in which EPA action has merely transfered pollutants from one environmental medium to another, in which minor emissions of a chemical are stringently controlled while major emissions are untouched, in which the last environmental medium to be regulated receives a waste, etc. A symptom of this problem is that the programs' priority lists for new regulatory actions show unexplained variations.

The focus of this activity will be on development of a mechanism to identify gaps and inconsistencies among the actions of the programs with respect to particular chemicals. Once these are identified, the Agency will need an issue resolution process to ensure consistent non-duplicative Agency action.

The focus of this activity is on consistent priority setting, regulation, enforcement, and information on a chemical by chemical basis. The effort will attempt to define: (1) the decision criteria for selecting priority chemicals (or groups of chemicals); (2) the feasibility of developing agencywide regulatory strategies for individual chemicals, (3) what kinds of gaps and inconsistencies among control action we wish to detect and how they can be found, (4) what internal institutional mechanism should perform the analysis,

(5) the role of external review and public participation in the process being developed, (6) the role of non-regulatory control mechanisms such as the setting of action levels, and (7) the potential for coordination of information gathering and analysis (especially contracted work) functions among program offices.

To start this process, EPA has set up several working groups to develop an intermedia analysis for particular substances. The DAA Toxics Integration Strategy Committee, in addition, is working on an interim list of about 20 chemical substances on which it will prepare chemical support documents, primarily for use by programs and regions for FY '82. The FY 1982 guidance package will reflect the coordinated approach toxic substances across EPA. Other current Toxic Substances Priorities Committee (TSCP) projects (control options analyses, dioxin coordination) under this activity, such as the respective program treatment of substitutes and volatility of solvents.

Issues to be addressed in this activity include:

- how should "new" chemicals be identified?
- what has been the experience to date with priority listing of individual chemicals?
- what should be the relative weight of various criteria for priority ranking, such as toxicity, exposure, health risk, or economic benefits and costs of regulation?
- how can priority ranking established either by interagency or agency-wide groups be meshed with program-specific activities?
- should groups of chemicals, rather than individual substances, be identified for priority action?
- what information on priority chemicals should be passed on to EPA regions and state and local governments?

° how does the chemical-by-chemical approach relate to alternative strategies, such as those discussed under Activities 4 and 5?

Schedule:

Task 1 Assess current practices for identifying and ranking of priority chemicals by EPA and other federal agencies. Complete by 3/15/81.

Task 2 Finish current work on recommendations for agency cancer policy criteria for priority-setting and regulation (based on consideration of toxicity, risk, exposure and economic impact), but scoped to cover all effects (not just carcinogens). Complete by 4/1/81.

Task 3 Complete first round of agency-wide work group process for developing strategies for chemicals and chemical categories. Complete by 5/1/81. Additional work groups to complete their assessments by 10/1/81.

Task 4 Develop chemical support documents identifying health and environmental effects of selected priority chemicals and Agency-wide as well as program-specific regulatory actions and plans. Complete first two model documents by 2/1/81. Prepare additional chemical support documents by 8/1/81..

Task 5 Based on experience of Tasks 3 and 4 make recommendations on whether and how EPA should develop Agency-wide strategies for specific pollutants and a suggested approach to selecting and scheduling them. As part of this assessment alternatives to matrix and work group approaches for integrating agency actions on chemicals will be considered. Complete interim report by 6/1/81. Final report by 8/1/81.

Staff Requirements: (OTI staff requirement does not include OTI staff devoted to TPSC management and work groups.)

Full-time task leader/support staff from OTI	(36 work-mos.)
Full-time person from OAQRT	(9 work-mos.)
6 months from other offices (OPM, OTS, OWWM, ORD)	(6 work-mos.)
Total: 51 work-months	

Contract Resources: $150,000.

Activity 4: Analysis of Integration Based on Specific Industrial Categories

This activity will attempt to develop an approach to prioritizing multi-pollutant, multi-program concerns for given industries to assure that the most important waste stream or chemical problems are dealt with first in limited resource situations and to ensure consistent regulation across programs. One or two approaches to assessing the combined effects of multiple current and future regulations on an industry will be designed and applied to two sample industries (organic chemicals and copper smelters). They will draw on the experience of the alternate Fuels Group in dealing with multi-program guidelines for controlling pollution from synfuel plants.

Both of the industry studies will identify the nature and magnitude of the toxic pollutant problems specific to the industry, identify available information on exposure and risk from these pollutants, assess the environmental and, particularly, the economic impact of various levels of regulation, and attempt to draw conclusions on the need for priority-setting among media and pollutants. Each industry study should lead to design of a sample intermedia strategy for the particular industry. The most important use of the case studies will be to assess the utility of the approach taken and to decide whether EPA should develop a general strategy for coordination of and priority-setting among multiple regulations affecting an industry and, if so, to suggest an approach for doing so. A special effort will be made to explore the industry-by-industry approach with representatives from industry.

Issues to be addressed in this activity include:

- what are meaningful industry categories for the purpose of this approach?
- can effective industry prioritization be carried out on the basis of available information?
- how can the industry-specific approach be made consistent with the pollutant-specific and geographic-specific approaches?
- what data requirements limit the applicability of this approach? how can those data deficiencies be overcome, and at what cost to industry and the Agency?
- can the agency identify industries which cannot afford all the toxic and non-toxic requirements we might place on them and concentrate on the most important? How should EPA deal with industries in order to make these assessments.

° how would the industry strategy relate to OSHA, CPSC, FDA or other regulations?

° does the industry strategy provide a vehicle for combining media-, effluent-, and product-oriented controls?

° do we need more emphasis on research and development efforts on ways to reduce toxics problems through changed industrial processes or materials?

° what roles would EPA regional offices play in implementing the industry strategy?

° how can the industry-wide strategy be best advanced in consultation with industry representatives and organizations?

° which industries should be selected for second-round studies (during FY '82)?

Schedule:

Task 1 Define data needs and conceptual approaches to industry-by-industry strategy. Assess experience of alternate fuels group. Initial analysis complete by 2/1/81.

Task 2 Design and conduct industry assessment studies, including benefits and costs of current and likely future environmental requirements for the organic chemicals industry and the copper smelting industry. Complete study designs by 2/15/81. Interim report by 6/1/81. Complete studies by 8/11/81.

Task 3 Organize industry consultations on the concept and implementation plan for industry-wide control strategies. On-going with other tasks.

Task 4 Assess potential of industry-wide approach and design appropriate strategy. Develop additional study program for FY '82. Complete by 8/15/81.

Staff Requirements:	Full-time leader from OPM	(9 work-mos.)
	Full-time person from a program office staff (OAQPS)	(9 work-mos.)
	Full-time technical person from another major program office (OE?)	(9 work-mos.)
	Two months of time from two other relevant program offices (ORD & OTS?)	(4 work-mos.)
	Total: 31 work-months	
Contract Resources:	$450,000 ($225,000 for each of two studies)	

Activity 5: Analysis of Integration by Geographic Area

Attacking toxics problems nationally substance-by-substance, program-by-program may not resolve many of the problems posed by local concentrations of toxics and toxic exposures. Control of toxics problems in specific geographical areas-- and by regional, state and local governments located in those areas-- can provide another alternative to national regulatory action. The working hypothesis underlying this Activity is that many toxic problems are not amenable to solution via national regulations. National perspectives and priorities may overlook localized problems and solutions.

One approach to geographic control is to determine the distribution loadings and locations of critical redlaws of toxic pollutants in specific geographical areas and evaluate the likely benefits of national regulatory programs now in place or currently under development. Several geographic toxics assessments are currently underway and will be useful in developing the approach. We would then determine whether further action is needed, looking at the full range of federal, state, and local actions such as regulation, monitoring, data collection, and public awareness. Under what conditions and how this approach might work will be explored by conducting two pilot studies. Each study will assess the nature and magnitude of the toxics problem in the area selected for study, the scientific data base currently available, and the options for further clean-up if necessary. The pilot studies will be used to develop a general strategy for the geographic approach. Different models need to be identified, both for a general use of the geographic approach and its use in response to contamination incidents.

The main purpose of this activity is to conceptualize and evaluate the geographic approach and determine its utility and feasibility. Subsequently, we must determine if the approach should be routinely applied to a number of areas or held in reserve for use when clear problems arise.

Other issues to be addressed in this activity include:

- to what extent are regional and local toxics problems regulated nationally but not controlled locally? what are the reasons for this?
- alternatively, are localized regulations necessary to deal with special situations? what role should EPA assume?
- what are the roles of EPA headquarters, regional offices, other federal agencies, and state and local governments in response to different situations, such as toxics incidents of known nature, incidents that are not understood for their principal causes, and high concentrations of media or effluent toxic pollutants due to particular local circumstances?
- what is the agency's policy for preparation and release of information to the public with regard to local toxics problems?
- what data exists for "desk top" studies at the Federal, State, and local levels?

Schedule:

Task 1 Explore concept and approach to geographic regulation with regional, state and local representatives. On-going with other tasks.

Task 2 Design and conduct two pilot studies of specific geographical areas. Coordinate with ongoing geographic pilot studies, such as

Great Lakes, Chesapeake Bay, and Kanawha Valley projects. Design completed by 3/1/81, interim reports complete by 6/15/81, 2 pilots complete by 8/1/81.

Task 3 Develop a catalog of regional, state and local approaches that don't require national regulation. Complete by 7/1/81.

Task 4 Analyze success of the 2 pilot studies and design general strategy. Complete by 8/31/81.

Task 5 Complete the analysis of toxic "Hot Spots" in the aquatic environment and integrate with output from Task 2. Interim report by 5/15/81. Revised report by 8/1/81.

Task 6 Analyze several case studies of emergency toxic problems to determine where Agency responses were integrated and where they were not. Identify the factors that contributed to both integrated efforts and failure to integrate. Recommend approach to integrated emergency response. Complete by 8/1/80.

Staff Requirements:	Full-time leader from OWWM	(9 work-mos.)
	Full-time person from Region III	(9 work-mos.)
	Full-time person from ORD	(9 work-mos.)
	Half-time person from OPM	(4 work-mos.)
	Total: 31 work-months	
Contract Resources:	$450,000 ($225,000 for each of two studies)	

Activity 6: Recommendations to the Administrator

The various activities listed above will be used in developing a report on toxics integration for the Administrator. This will be the central document which discusses the concept of toxics integration, its applicability to the mandate of the Agency, and various approaches to implement the strategy. The report will recommend an agency-wide strategy and steps for its implementation. In addition, a workplan and resource allocation plan for the next two fiscal years will be prepared. OPE/OPM will assist the project manager in preparing resource allocation estimates and operating plans for all activities. The report will be based on the results of Activities 1 through 5 above and will require a strong effort to weave together the various study results and to identify clearly the legislative, organizational, and procedural changes that will lead to the new strategy. The direction of the report, as well as the goals of the agency's integrated toxics strategy, will be developed in close consultation with the DAA's committee.

Schedule:

Task 1 Work on key issues jointly with other task forces. January thru September 1981.

Task 2 Explore key concepts and approaches to toxics integration with outside experts. Ongoing with other tasks.

Task 3 Develop strategy and prepare report to the Administrator. The timetable for this task is as follows:

February 15	Complete outline of report. Revise workprograms for activities 1-5 as necessary to bring them in line with development of central strategy.
April 1	Revise outline of report. Incorporate progress reports from Activities 1-5.
May 1	Drafting of report begins
July 15	draft report submitted to the Toxic Integration Strategy Committee
August 1	work begins on final draft of the report.
Sept. 15	Toxics Integration Committee forwards report to the Administrator. Agency and regional briefings.

Task 4 Resources Allocation plan for FYs '82 and '83.

Work on components ongoing with other tasks.

Comprehensive plan due September 1.

Task 5 Preparation of workplan on toxics integration for FY '82. To be completed September 1, 1981.

Staff requirements:		
	Project manager	(9 work-mos.)
	Full-time (or equivalent) person from OTI	(9 work-mos.)
	Full-time person from OPE	(9 work-mos.)
	One-half person from ORM	(4 work-mos.)
	Full-time secretary (OE?)	(9 work-mos.)
	Total: 40 work months	

Contract Resources: $150,000

Resources and Management Plan:

(a) Staff and Contract Resources requirements are as follows:

Activity 1	36	work-months	$80,000
Activity 2	27	work-months	---
Activity 3	51	work-months	150,000
Activity 4	31	work-months	450,000
Activity 5	31	work-months	450,000
Activity 6	40	work-months (includes project mgr.)	150,000
TOTAL	216	work-months	$1,280,000

(b) Project Manager: The project manager will oversee the development and implementation of the workplan. He will serve as executive secretary of the Toxics Integration Strategy Committee and will direct the staff working on toxics integration.

(b) Toxics Integration Strategy Committee:

The Committee, with representation at the DAA level from all program offices and one DRA, will act as the steering committee for the various activities related to toxics integration. In particular, the committee will approve the workplan, review the reports prepared by the different task forces, and approve the final report on toxics integration to the Administrator.

(c) Task Forces:

For each of the six activities listed above a task force will be established, consisting of a task force leader and staff, as necessary. Task force leaders will spend full time on their assignment. They will be part of the central group in charge of work on

toxics integration. Other staff members will join the core group or will remain attached to their individual program offices. Each task force will develop a detailed workplan.

(d) Consultants and Contract Work:

Each task force will develop plans for the use of outside advisers and consultants. Use of expert advice in defining different approaches to toxics integration is encouraged. In particular, new strategies for industry-wide and geographical controls will be discussed with industrial and state and local government representatives.

(e) Management and Integration Mechanisms.

We anticipate holding monthly meetings of the Toxics Integration Committee from January through June, and bi-weekly meetings from July through September. Marilyn Bracken, Roy Gamse, and the project manager will meet with the Task Force leaders at a regularly scheduled weekly meeting. The project manager will work on a daily basis with the Task Forces and as needed with the TISC members.

(f) Update of Workplan:

Once the various activities described in the workplan are fully staffed, the project manager and the task force leaders will review the workplan and make changes as necessary. The Toxics Integration Committee will be kept fully informed.

(g) Scheduling Problem:

How to develop FY '83 resource needs in time to affect the ZBB process this summer. May need to assume a continuation of FY '82 levels if we can't solve this problem.

DRAFT

March 6, 1981

INTEGRATED TOXICS STRATEGY

Workplan for Activity 1: Analysis of Toxic Substances in Agency Programs

Statement of Objectives

One focus of the Integrated Toxic Strategy workplan is determining a means to integrate Agency activities pertaining to toxic substances given the current environmental statutes and EPA organization; therefore a comprehensive analysis of current toxic substances activities within Agency programs is a requisite first step. The specific objective of Activity 1 is to identify similarities and differences in procedures used to regulate toxic substances and to ascertain how these can help or hinder efforts to develop an Agency-wide toxics strategy.

The analysis will evaluate the completed regulatory action of each program, current work in progress, and longer term plans for toxics control. Program-specific regulatory schedules and priority activities will be identified in order to determine compatibility with other program plans. Activity 1 will identify various constraints and opportunities in toxic substances activities and will suggest legislative, organizational, programmatic, and procedural changes pursuant to the preparation of recommendations to the Administrator in Activity 6.

GENERAL SCHEDULE:

interim drafts	4/30
final drafts	6/1
finished report	7/1

GENERAL STAFFING:

Full time Leader from OTI	9 work-months
OTI staff support	18 work-months
One half-time person from OPE	4 work-months
One person for one month each from seven program offices *	7 work-months
One work-month from OGC *	1 work-month

Total: 36 work-months

CONTRACT RESOURCES: $80,000

* Not currently being used.

TASK 1: ANALYZE CURRENT APPROACHES

Analyze current EPA approaches to toxic pollutant control in the various programs.

Task 1-A: Analyze Toxic Substances, Assessment and Control Processes

Address past allegations of ineffective policy and procedures in each sub-task. Notable among these alleged shortcomings are: lack of consensus on health and environmental risk, inconsistent response to risk, overlapping pre-regulatory assessment activities, differences in weighing costs and benefits of regulation, missed opportunities for integrated enforcement, uncoordinated monitoring strategies, and a tendency to respond to the first exposure route encountered rather than the most significant one.

Develop program-specific profiles (for the air, water quality, drinking water, solid waste, pesticides and toxic substances programs) and conduct item-specific comparisons of key program activities. The general focus of these profiles will be: regulatory history, selection of chemicals for regulation, selection of control options, regulatory strategy, and analysis of risk. The emphasis of this task will be to identify inconsistent and overlapping activities within EPA. Specific areas of examination include:

- Procedures for Setting Priorities
  Compare the priority setting processes used by each major program. Distinguish between priority setting for assessment and for control action. Identify opportunities for improving consistency across programs.

- Assessment Processes
  Identify consistencies/inconsistencies. This sub-task must be coordinated with Activities 2 and 3.

- Procedures for Economic Analyses
  Examine various types of economic analyses performed during assessment and control processes, and the weight placed on analysis of costs and benefits during regulatory decision-making.

- Toxic Substances Control Processes
  Examine the following areas:
  - the regulatory development processes
  - non-regulatory alternatives (e.g., incentives, information bulletins, etc.)
  - incident response processes
  - implementation mechanisms/processes
  - inter-program coordination efforts
  - fate of chemicals or problems dropped from the regulatory queues.

- Status of Control Activities
  Examine the current status of toxic substances control activities in major EPA programs. Specify:
  - progress made toward regulation of toxic substances
  - regulatory plans
  - scope of future of remaining problems

- Agency Monitoring Systems
  Compare monitoring and other related problem identification processes across EPA programs; use the Integrated Monitoring Strategy as a primary resource.

- EPA Enforcement Programs
  Compare toxic substances enforcement processes across media. Examine the program office/Office of Enforcement relationship in setting priorities for enforcement under each statute.

This information will be developed from interviews of senior management in each program office. The interview material will be developed into progam profiles, which will be the information base for Tasks 3 and 4. Furthermore, information and ideas from the interviews will be used to refine the areas of analysis to be conducted in Tasks 3 and 4.

SCHEDULE: draft profiles 3/15
final report 4/30

Task 1-B: Intergovernmental Coordination

Examine in each major EPA program current and possible roles of EPA Regional Offices, State governments and local governments in problem identification, assessment, development and implementation of controls, and enforcement. Input should be solicited from Regional Offices, State government and local government sources. Describe involvement of headquarters offices in regional or other activities involving toxic substances integration. Describe and critique plans of current regional integration efforts. Review and summarize the National Governors' Association report on state toxics integration activities. Discuss possible models for integration progress. Propose ways of coordinating the ongoing toxics integration efforts with Regional, State, and local authorities, and identify expected problems in doing so.

SCHEDULE: draft report 3/30
final report 4/30

Task 1-C: Current Integration Mechanisms

Identify and analyze basic mechanisms in-place within EPA to integrate regulatory development activities. Present programmatic perspectives on the success of such integration mechanisms.

Examine the role of the Work Group/Steering Committee/Red Border

process as an integration mechanism. Identify weaknesses and strengths of the process, and opportunities for improving the process.

Examine the Toxic Substances Priorities Committee (TSPC) as an integration mechanism. Identify strengths, weaknesses and opportunities for improvement. Describe and analyze the Integrated Waste Management (OWPO) and Integrated Risk Assessment (OHEA) initiatives and examine their relationship to the integrated toxics strategy.

SCHEDULE:	draft report	3/15
	final report	4/30

Task 1-D: Enhanced EPACASR -- Developing an Industry File

The Chemical Activity Status Report (EPACASR) is an interactive data base, accessible by chemical name/CAS number, containing a description of each Agency activity relating to chemical substances. The types of activities listed include: regulations, technical assistance information, preregulatory assessments, chemical and biological testing and monitoring programs and labeling requirements - both completed and ongoing. Making this data base accessible by industrial cross-reference would provide valuable assistance in assessing impacts of industry-specific regulations.

The task manager will identify, develop, and select means of accessing EPACASR by industry and will subsequently begin compilation of necessary information.

SCHEDULE:	preliminary reports	4/81
	begin compilation	5/81
	no completion date identified	

TASK 2: ANALYZE EPA LEGISLATION

Analyze major EPA legislation to identify and compare legislative mandates for toxics control. Survey toxic substances control mechanisms available to the Agency and describe definitions of toxic substances as established by statute and as interpreted by the Agency. This analysis will identify constraints to and opportunities for integration in the statutes EPA implements.

Control mechanisms and their bases will be described for each statutory provision as follows:

- purpose of the provision
- control mechanism employed
- criteria for development of the control mechanism
- the point at which the control mechanism is applied in the life cycle of the toxic chemical
- deadlines imposed by statute.

The definition of a toxic substance will be described:

- in the language of the statutes
- as interpreted by the agency

SCHEDULE: interim draft 3/30
final report 5/15

TASK 3: IDENTIFY LEGAL AND ADMINISTRATIVE CONSTRAINTS/ OPPORTUNITIES

Identify legal and administrative constraints to integration as well as opportunities to facilitate or promote integration in the Agency programs pertaining to toxic substances. This analysis will cut across Agency procedures for setting priorities, assessment processes, procedures for economic analyses, control processes, agency monitoring systems, and enforcement programs.

The specific analyses to be performed in this task are based in part upon the information gathering of Tasks 1 and 2 and will therefore be developed in parallel with them. A dialectical comparison of procedural and statutory aspects identified in preceeding tasks will serve as the basis for the recommendations of Task 4. Because the candidates for analysis are expected to be numerically unmanageable, a subset will be chosen for immediate attention based upon: 1) potential for near-term impact on Agency activities, 2) relevance to other parts of the Integrated Toxics Strategy, and 3) managability given current resources.

SCHEDULE:

compare and contrast profiles to identify issues	3/30
selection of analyses	4/6
draft analyses	
final report	6/1

TASK 4: IDENTIFY DESIRABLE MODIFICATIONS

Identify changes in organization, procedures, resource allocation, and legislation that could lead to improved integration of toxic substances assessment and control activities. Analyze Tasks 1-3 to develop recommendations for changes to improve Agency integration efforts involving toxic substances. These recommendations will be developed in concert with Activities 2, 3, 4, and 5.

SCHEDULE:	draft report	6/1
	final report	7/1

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

20 FEB 1981

OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Draft Work Plan for Activity 2 Under the Toxic Integration Program

FROM: James W. Falco, Director James W. Falco
Exposure Assessment Group (RD-689)

TO: See Below

Attached is a draft work plan for activity 2 of the Toxic Integration Program. Please review this draft in preparation for a work group meeting to be held on Monday, February 23, 1981 at 9:30 am in Room 3802. At this meeting I would like to receive any recommendations for changes you wish to offer. I have also attached a copy of the overall program work plan for your information. I look forward to working with you on this project.

Please contact me if you have any questions.

Attachment(s)

Addressees:

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Detailed Work Plan for Accomplishment of Activity 2 Under the Toxics Integration Work Plan

To accomplish the objectives of activity 2 of the Toxics Integration Project, the following work plan is proposed. The time and resources allocated for the accomplishment of these goals require that the exposure and risk assessment activities conducted by each operating program within the Agency be aggregated into fairly broadly defined categories. These categories of assessment activities can be evaluated and compared with similar activities in other operating programs. In addition to evaluating the Agency's exposure and risk assessment activities in a manner that is consistant with the Agency's resources, the aggregation of activities in to broad categories should provide a reasonable number of recommendations that have a significant impact on improving the quality and efficiency of the Agency's operation.

We propose that a separate report be written for each of the tasks outlined in the Toxics Integration Work Plan under Activity 2. Each of these reports would be written in a style and format such that at the end of the project one final report could be published by assembling each task report as a chapter and adding a summary chapter.

We propose to address the following issues in task reports.

Task 1 Report - EPA's Approach to Exposure and Risk Assessment

This report will contain a brief description of the requirements for exposure and risk assessment specified by each major legislative act. Major operating programs involved in the implementation of exposure and risk assessments will be identified.

The report will also contain as individual sections a description of the implementation strategy employed to satisfy regulations. Specific topics included for each major exposure and risk assessment category are:

1. Description of procedures for conducting cancer risk assessments.
2. Description of procedures for conducting mutagenicity risk assessments.
3. Description of procedures for conducting risk assessments for other health effects.
4. Description of procedures for conducting exposure assessments.
5. Description of procedures for conducting environmental risk assessments.
6. Description of procedures for independent review of assessments and quality assurance of data.

This report will also identify the program offices that collect and analyze economic data and that assess benefits and costs. Methods used to perform economic evaluations will also be described.

Task 2 - Analysis of the Reasons for Differences in Approaches to Exposure and Risk Assessments

This report will highlight the differences in management and technical approaches for conducting exposure and risk assessments. Specific topics will include:

1. Description of differences in reliance on outside experts and weight given to their testimony and statement of reasons for differences.
2. Description of differences in methods used to measure or estimate exposure based on monitoring data and statement of reasons for differences.

3. Description of differences in methods used to measure or estimate dose and statement of reasons for differences.
4. Description of differences in methods used to interpret and extrapolate results of bioassays and statement of reasons for differences.
5. Description of differences in methods used to interpret and extrapolate results of long-term whole animal tests and statement of reasons for differences.
6. Description of differences in methods used to interpret and extrapolate acute toxicity data and statement of reasons for differences.
7. Description of differences in methods used to collect and interpret clinical and epidemiological data and statement of reasons for differences.
8. Description of differences in models used to translate emissions into exposure estimates and statement of reasons for differences.
9. Description of differences in other methods used in exposure and risk assessments and economic evaluations discovered during task 1 and statements of reasons for these differences.

Task 3 - Analysis of Needs for Changes

This report will briefly describe how each major category of exposure and risk assessments is used by the Agency. It will also define needs for administrative and technical changes. Specific topics to be discussed include:

1. Description of use of exposure and risk assessments by each program

office highlighting needed changes related to this use.

2. Description of use of exposure and risk assessments by regions highlighting needed changes related to this use.
3. Description of use of exposure and risk assessments by states highlighting needed changes related to this use.
4. Description of use of exposure and risk assessments by the public highlighting needed changes related to this use.
5. Description of other needed changes that become apparent during task 1 and task 2.

Task 4 - Report Analysis of Approaches Used by FDA, CPSC, OSHA, and NCI

This report will briefly describe the legislative requirements for exposure and risk requirements for exposure and risk assessment that must be addressed by FDA, CPSC, OSHA, ad NCI. Guidelines and procedures used by each Agency will be described. Specific topics addressed will include:

1. Description of procedures for conducing cancer assessments
2. Description of procedures for conducting mutagenicity assessments
3. Description of procedures for conducting risk assessments for other health effects.
4. Description of procedures fo conducting exposure assessments.
5. Description of procedures for independent review and quality assurance of data.
6. Description of economic analyses performed.

This report would highlight similarity and differences in management and technical approaches among agencies and the reasons for those differences.

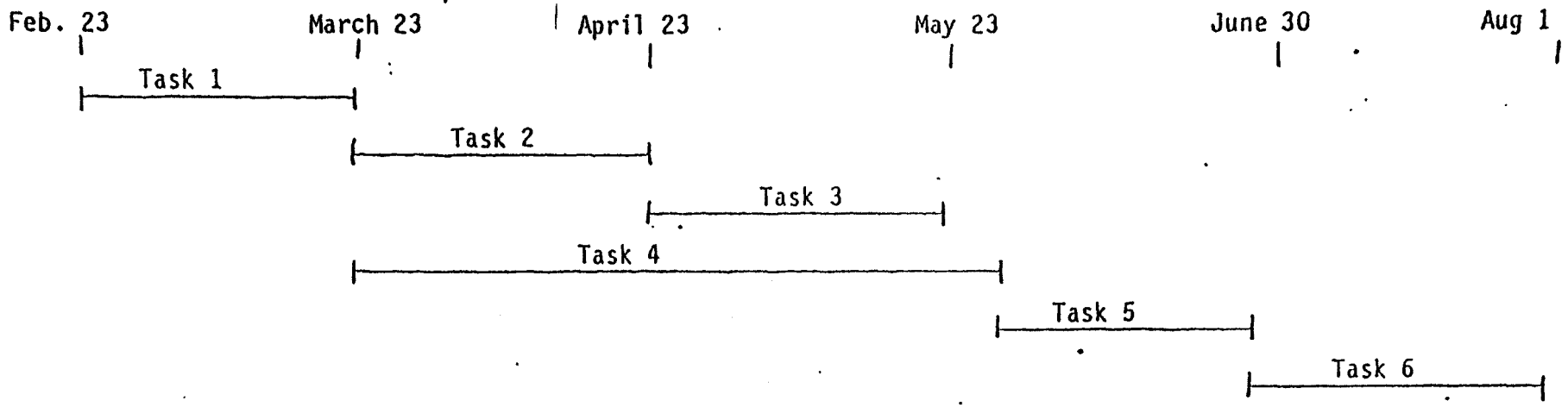

FIGURE 1. SCHEDULE OF COMPLETION OF ACTIVITY

Task 5 - Recommendations for Changes

This report will suggest changes in organizational, procedural and resource allocations that would improve consistency, integration and efficiency of exposure and risk assessments conducted by the Agency. Specific issues that will be addressed in this report are as follows:

1. Organization to prepare short-term risk asseessments that are needed to support regional responses to environmental incidents.
2. Development of criteria to determine the level of acceptable quality for exposure and risk assessment.
3. Organization and management of program office (offices) involved in exposure and risk assessment to insure consistency and credibility
4. Recommended chages to minimize legislative barriers to consistency of assessment and efficiency of conducting assessments.
5. Definition of changes to improve and expand economic evaluations.
6. Definition of changes needed to address other problems discovered in tasks 1 through 4.

Task 6 will involve review and editing of each task report to form an integrated final report.

Table 1 lists the responsibilities for completion of each task. The assignment of responsibilities reflect the need to organize work to maximize efficient execution of the tasks and to retain responsibility for decisions within the Agency. Figure 1 shows the schedule of completion of tasks. Although this schedule shows tasks completion dates for individual tasks later than originally proposed, it indicates a final report delivery date of August 1, 1981. Thus, completion of activity 2 will occur on target if this schedule is approved.

TABLE 1. ASSIGNMENT OF RESPONSIBILITIES

Task 1 - This task will be done by Clement Associates. In-house activity 2 team will review and comment on this report and offer technical information in their areas of expertise.

Task 2 - This task will be the responsibility of the in-house team. Clement Associates will assist the team by summarizing team opinions into a report and providing professional technical consultation in their areas of expertise.

Task 3 - This task will be the responsibility of the in-house team. Clement Associates will assist the team by summarizing team opinions into a report and providing professional technical consultation in their areas of expertise.

Task 4 - This task will be done by Clement Associates. The in-house team will review and comment on this report and offer technical information in their areas of expertise.

Task 5 - This task will be the responsibility of the in-house team. Clement Associates will assist the team by summarizing team opinions into a report and providing professional technical consultation in their areas of expertise.

Task 6 - The in-house team and Clement Associates will be jointly responsible for editing the five task reports to form the final report.

DRAFT

INTEGRATED TOXICS STRATEGY

Analysis of the Chemical Approach to Toxics Integration/Control

:TIVITY 3 -- WORKPLAN

ıe intent of this activity is to evaluate EPA's optimal :hemical" approach (including chemical "classes") to ntegrating/controlling toxics, particularly with regard to the roper "mix" with other feasible integration approaches. Since his activity is especially intertwined with the subjects of ctivities one and two, there should be a considerable amount of ubstantive interchange among them.

:. Evaluation of Traditional Agency Practices

The intent of this section is to assess to some degree the problems EPA's traditional chemical approach have produced. This information will provide (1) an inventory of the specific problems that need to be alleviated by this strategy; (2) internal Agency support for any changes recommended by this analysis; and (3) the basis for future evaluations of how well the recommendations that are implemented have succeeded.

II. Evaluation of Recent Innovations in Applying this Approach

Several major innovations to the traditional "chemical approach" have been recently initiated by the TSPC and OTI, and deserve particular analytic attention in light of their potential broader application (with modifications resulting from their present "field testing"). These activities include the TSPC Solvents work group and the development of the unified guidance packages on the 20 Intermedia Priority Pollutants (IPP). It is important to note that the Solvents work group is the first coordinated, Agency-wide effort to develop an Agency Control Strategy for a whole use class of major chemicals. Likewise, the IPP process is the first time the Agency has integrated its major activities and resolved outstanding issues on the Agency's 20 agreed-upon priority chemicals.

III. Recommendations for FY 1982 and Beyond

This will be the major section of the final report. The first two sections will support the development of options for improving the Agency's present toxics-related programs. Options will be developed that range from incremental improvements to present procedures to major changes to the Agency's policies, laws, and organization.

TIVITY 3 -- TASK OUTLINE

SK 1 -- Evaluation of present chemical priority setting actices of EPA

:e intent of this task is to (1) describe how EPA program 'fices presently set their toxic chemical priorities, (2) ıalyze differences in their priority setting and (3) define the ıtegration problems that have arisen as a result of these fforts. The following subtasks are intended to provide base-ine information on major areas requiring greater integration ttention.

ASK 1A -- Priority List Development Evaluation (This task will e closely coordinated with Activity 1)

'his task will address how the various program "priority lists" ıave been developed (and are updated/revised) and how they have ɔeen/are coordinated/integrated among offices. This effort and the resulting analyses will "piggyback" interviews conducted ınder Activity 1. Any necessary, more detailed interviews will ɔe conducted by Ed Lillis, Larry Reed, Elaine Bild and John Gevertz.

TASK 1B -- Analysis for consistency of all major agency documents on three chemicals (cadmium, arsenic, trichloroethylene).

This subtask is being conducted by Elaine Bild and John Gevertz. The first draft will be completed by March 15th. All major support documents have been gathered and are being reviewed to identify specific and generic redundancies and inconsistencies among program offices. This analysis will be provided to the Activity 2 leader to assist in the overall risk assessment reiew.

TASK 1C -- Consistency of Cost per Unit of Pollution/Risk Reduction

This subtask will assess the cross-program, cross-media consistency of costs imposed by EPA program office regulations on chemicals of concern. Realizing the critical constraints (such as different exposure pathways, risks, and legal authorities), we will try to "standardize" cross-Agency costs on each chemical. This information will allow an assessment of how consistent across-media EPA's regulatory costs are, and provide the basis for policy recommendations if the consistency is less than appropriate. Hollis Call of OTI will lead this contract study.

Schedule/Cost

OTI is providing $145 K, supplemented by $55 K in Agency contract funds to conduct this study. A pilot methodologyical analysis should be successfully completed on a few chemicals by April 1st, with a broader study on a larger universe of chemicals to be completed by July 1st.

TASK 1D -- Target Populations

This subtask addresses issue of whether or not EPA offices are consistent in defining the "target populations" (populations at risk) that they are intended to protect (e.g., in terms of amount of food and water intake, adult and child weight classes, etc.). This subtask will identify any inappropriate inconsistencies and policy needs. The completed task will provide a major input to Task 2. Sandi Lee and Avis Robinson of OTI will conduct this analysis. The initial draft should be completed by March 15th.

TASK 2 -- Agency Cancer Policy (and other health effects)

This task was initiated as a committee effort in 1980 under the auspices of the TSPC, and is addresseing major cancer-related issues, including:

-- Should the Agency have a generally agreed upon carcinogen risk "ceiling" and "floor" to assist setting priorities among chemicals?

-- Should the Agency set toxics priorities based on individual or aggrgate population risk?

Since this is a major, ongoing task with high level Agency staff participating, and lies conceptually somewhere between activities 2 and 3, it will in fact function as an autonomous activity "feeding into" activities 2 and 3

TASK 3 -- TSPC Task Group Pilot

3A -- TSPC Solvents Task Group

The TSPC Solvents Task Group, chaired by Arnie Edelman of OTI, is a pilot effort initiated in August, 1980 to assess the cross-Agency integration issues involved with these 6 organic solvent degreasers. After the task group's initial issue/status report to the TSPC in December, the work group was charged to develop an Agency control strategy for these chemicals and to act as a "mini-steering committee" to ensure that any related regulations are consistent with the developing control strategy. The solvents work group will also act a as a sounding board in reviewing/assisting OTI analyses of (1) intentional and unintentional intermedia transfer of chemicals, especially volatiles; and (2) the effect of EPA controls on the use of chemical substitutes that may be of equal or greater risk.

The TSPC Solvents task group is a major, pilot attempt to integrated Agency-wide all major activities on this important class of chemicals. The final product will be an Agency control strategy that will recommend the appropriate actions to ensure a

consistent scientific regulatory and non-regulatory approach. (The task group will also attempt to coordinate its activities with the IRLG).

Schedule

The solvents work group's draft work plan entails $100 K in OTI contract support and an additional $190 K in needs. The schedule is dependent on TSPC approval and funding. If tasks are not initiated in March, final work group results will not be until Fall, 1981

Staffing

Arnie Edelman (plus OTI staff support) - Solvents
Jim Casey -- Volatility and Intermedia Transfers
Ginny Steiner -- Substitute Chemical Impacts
Solvents Task Group Members

3B -- TSPC Chlorinated Dioxins Task Group

The Chlorinated Dioxins Task Group, cochaired by Paul Brown of OTI and Don Barnes of OTS, is an ongoing TSPC coordinative work group with three subgroups that are addressing the various dioxins related issues in EPA Headquarters and Regional Offices. The generic implications of this work group's role, accomplishments and limitations will also be factored into the analysis under Task 5.

Schedule

A draft Dioxins issue paper will be prepared by April 1st.

3C -- Additional TSPC Task Groups

Any needed additional TSPC task group candidates will be identified under Task 4, intermedia priority pollutant support document development. Completion of any additional work groups would obviously be dependent on when they were initiated and the nature of the integration issues raised.

TASK 4 -- Intermedia Priority Pollutant Support Documents

The first major action in support of the Integrated Toxics Strategy was the identification of 20 Intermedia Priority Pollutants (IPP) that were of concern to a large number of EPA offices. OTI has the lead in developing brief, consistent support documents that outline the major Agency findings and concerns for each priority pollutants.

Dr. Viviani of OTI with other program office assistance will coordinate the development of the 20 intermedia priority pollutant support documents. The support documents will consolidate in a concise format all major Agency exposure, risks

hysical/chemical characteristics, regulatory, and action levels n these chemicals to assist EPA Regions to set program riorities and to inform the public how EPA is responding to hose chemical risks. In addition, OTI will identify major chnical and policy issues for the Integrated Toxics Strategy committee to resolve, assign program office responsibilities for esolving, or establish additional TSPC work group(s) to resolve.

The overall IPP process will be evaluated in terms of its effectiveness in promoting greater toxics integration and potential "stronger" variants of the process that could be more effective.

Staffing

-- OTI -- 2 workyears plus $115 K in OTI contract support
-- Support in identifying and abstracting information on the 20 chemicals from OAQPS, OWRS, ODW, OSW, ORD, OTS and OPP

Schedule (schedule attached)

-- The benzene and arsenic documents are in draft form and should be in final by the end of February
-- The remaining packages will be completed by August.

TASK 5 -- Options for Better Integration of Agency Toxics Activities

The previous four tasks will provide a basis for assessing (1) where and to what extent the Agency is not properly integrating its toxics-related activities, and (2) the utility of the ongoing, pilot integration efforts (or modifications of these pilots) for broader application in FY 1982 and beyond.

In addition, Task 5 will "map out" the generic decision-making processes that lead to assessment and control (when appropriate) of toxic substances. This decision-making outline will help in the development of Agency-wide toxics priority-setting schemes for the short and long term.

Task 5 will incorporate these findings into a full array of optional approaches for improving Agency procedures for controlling/integrating toxic chemicals (while trying to incorporate considerations for the chemical and geographic approaches.

An initial list of options would include the following:

Options for An Agency Toxic Integration Strategy

I. Use Existing Pilot Efforts on a Wider Scale

A. TSPC work groups on all major chemicals

B. Intermedia priority pollutant process for additional chemicals of concern.

C. Require control options analyses on all toxics regulations prior to ANPRM

D Reiew and evaluate agency toxics-related contracts for overlap and potential inconsistencies

E. Require each program to maintain its toxics-related activities up-to-date in a central data system (a la EPACASR)

Pro

- Results in least distrubance to present programs

Con

- Suffers from severe weaknesses of Agency work groups (regulatory or TSPC); lack of interest and attention from other EPA offices.

Increased Integration Authorities

A. Develop detailed guidance for all materials balance, exposure, health, and risk assessments done by EPA.

- One central office to review/approve all such documents

B. Form a series of standing work groups (based on chemical "classes" and/or industries) responsible for all regulation-development in that category.

- Incorporate responsibilities as a major component of performance standards.

C. Require more specific and directed analyses of intermedia impact of regulations prior to their proposal and promulgation.

Pro

- Provides enhanced capability for integration

Con

- Still does not ensure integration among work groups or supporting program offices

II. Centralized Toxics Integration Function

A. Toxics priorities for entire Agency set by one office (probably OTI)

- Individual program offices then assigned specific or lead responsibilities

B. All toxics-related assessment activity conducted by one office (probably in ORD)

C. All toxics-related analyses conducted by one office (probably in OPE)

D. Standing control work groups using products of B. and C.

- Each work group to develop a control options analysis for review/evaluation/approval by A. before developing an Agency-wide control strategy

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DRAFT WORK PLAN FOR ACTIVITY 4: ANALYSIS OF TOXICS INTEGRATION BASED ON INDUSTRY-SPECIFIC APPROACHES

This activity will attempt to develop industry-specific strategies for control of conventional and toxic pollutants. The goal of these strategies is to identify the most cost-effective way to minimize health and environmental risks associated with industrial discharges. The FY 81 focus of this activity will be two case studies, one dealing with a portion of the organic chemicals industry and the other with a subsector of nonferrous metals.

Each of these studies will characterize the nature and magnitude of the pollution problems specific to the given industry, identify available information on exposure and risk from the pollutants, assess the combined environmental and economic impact of various levels of regulation, and attempt to draw conclusions on the need for priority-setting among environmental media and pollutants. Each study will lead to the development of a sample intermedia strategy. Together, they should enable EPA to design a preliminary strategy for coordination and priority-setting among the various regulations that could be imposed on any industry.

TASK 1 Select Appropriate Subsectors for Analysis

Criteria for selecting the subsectors will include:

- Availability of data on the economics of manufacturing operations and data on environmental loadings, exposure, and effects;
- Existence of intermedia tradeoffs;
- Existence of interpollutant tradeoffs;
- Possible tradeoffs among different parts of the subsector (e.g., "big" versus "little guys"); and
- Logical factors that make the candidate subsectors either particularly coherent or interesting.

Staffing: All members of the project team plus delegates of each of the major program offices (Air, Water, Solid Waste, Hazardous Waste, Toxics, and Drinking Water).

Schedule:

- Separate meetings will be held on February 18 for organic chemicals and nonferrous metals.
- By February 23, a memo providing analysis of options and recommendations will be sent to Dan Beardsley, Roy Gamse, and Marilyn Bracken.
- By February 27, the selection of subsectors will be finalized.

TASK 2 Collect Data for Each Selected Subsector

Both the data for the risk assessment and the economic analysis should be developed according to three scenarios:

- Assume that no Federal pollution controls were mandated.
- Assume that only controls already installed are required in the future.
- Assume that all Federally-required controls are installed according to schedule.
- Assume that (for organics) that generic controls replace chemical-by-chemical controls in the air media.

To the extent they may be relevant, the study teams should also consider the environmental effects of other Federal programs (such as OSHA regulations).

These scenarios will enable the study team to determine:

- What "baseline" emissions would be in the absence of Federal pollution control regulations;
- The magnitude of current untreated pollution or residuals; and
- The magnitude of pollution problems in the future according to a "business as usual" scenario.
- The magnitude of the air pollution problem if generic controls replace chemical-by-chemical controls on the organics industry.

By assessing the cost implications for these scenarios, it will be possible to determine the "economic burden" of current and projected pollution controls that might be shifted to more important health and environmental problems without increasing the anticipated level of control-related expenditures.

Given that the various subsectors of the nonferrous metals ndustry are less diverse (fewer plants, products, and pollutants) an the subsectors of the organic chemicals industry, analysis the former will probably deal with specific facilities while nalysis of the latter will probably focus on surrogates, such s "generalized plant configurations".

Staffing:

1. The follcwing EPA offices will develop information on environmental loadings for each of the above scenarios:

--For air emissions: Office of Quality Planning and Standards (OANR).

--For effluents: Effluent Guidelines Division (OWWM).

--For drinking water quality: Office of Drinking Water (OWWM).

--For solid waste: Office of Solid Waste (OWWM).

--For hazardous waste: Office of Enforcement.

2. Health effects data and information on population exposure will be provided primarily by the Office of Research and Develcpment and the Office of Pesticides and Toxic Substances.

3. Cost data will be provided by the individual program offices and will be further refined by Putnam, Hayes, and Bartlett, Inc. and appropriate subcontractors. Fred Talcott and Jim Titus, both of OPM, will supervise the economics effort for organic chemicals and nonferrous metals, respectively.

Schedule:

1. Complete the environmental assessment by April 1.

2. Compile basic health effects data by April 15.

3. Develop baseline manufacturing costs for the nonferrous metals subsector by April 21. To the extent possible, provide information specific to individual facilities.

4. Develop "generalized plant configurations" for the selected subsector of the organic chemicals industry by April 1.

5. Develop the cost information on the other three regulatory scenarios by late April.

ASK 3 Calculate and Prioritize the Risks to Public Health and other Environmental Values for Each Pollutant Stream

This effort will build on the data collected in Task 2. ave Patrick of CAQPS will head this portion of the organic hemicals study. Michael Gruber of the Office of Intergovernmental ffairs will do the same for the nonferrous metals subsector. ave Graham of the Office of Research and Development will work ith both risk assessment groups to assure that the prioritization f environmental risks is internally consistent between media in ach subsector and between the two studies. Putnam, Hayes, and artlett, Inc. will be aid in the design of the assessment and will erform the actual calculations.

This analysis should be based on the best scientific evidence vailable within EPA and the Federal government, but it should lso highlight differences between existing programs' different erceptions of exposure, risks, and other factors. The assessment should be as extensive as possible, uncovering differences based on plant location and other factors, such as different credible assumptions about carcinogenity, mutagenicity, teratogenicity, and other health and environmental effects.

The initial objective will be to explore with each program office how it would evaluate the risks and significance of exposure of each waste stream. The second goal would be to develop a plausible way for resolving these differences. This would involve:

- Consistency of treatment between all environmental media;
- Reduction of total environmental damage (rather than mere conversion of a problem from one medium to another); and
- A scheme for dealing with imperfect information.

Although a cardinal ordering of environmental problems would be most desirable, it is assumed that large information gaps will be indentified. It may therefore be necessary to settle for an ordinal ranking of problems into categories that reflect the relative desirability of requiring pollution control.

Staffing: see above.

Schedule: To be completed by mid-May.

TASK 4 Develop Alternative Regulatory Scenarios and Additional Pollution Control Cost Estimates

Given assessments of alternative levels of pollution, pollution control costs, and risk factors, it should be possible to develop a strategy that: (a) within the expected "pollution control economic

arden" and a possibly higher level of resource constraints, ttacks the worst public health and other environmental problems irst, (b) treats public health threats consistently between vironmental media, (c) considers economic impacts on both the rosperous and less prosperous segments of the industry, and d) reflects the differences in environmental risks associated ith different plants due to their individual locations. This ask is meant to pull together Tasks 1 through 3. It will require erging the risk assessment with the economic analysis, and will mphasize concepts such as cost-effectiveness and trade offs etween various pollutants. This will be a major focus of the iscussions with industry and the individual program offices. o be most useful, it should clearly articulate all major assumptions, alternatives, and caveats.

Designing the sample intermedia strategies (including process changes that could be ordered under the Toxic Substances Control Act) may require the development of new control cost estimates. To the extent this is done, it may be necessary to use crude approximations, rely on the experience of other industries, or make orders of magnitude judgments. The basis for such estimates should be clearly articulated.

Staffing: This aspect of the study will involve the whole work group. The managers and consultants responsible for the risk assessments and economic analyses will be particularly important in this exercise, as will George Provenzano of the Office of Research and Development, who will provide guidance on how best to merge the two types of assessments for each industry.

Schedule: This activity will produce a draft report by mid-June and a final report by late July.

TASK 5 Evaluate the Applicability of the Approaches Taken and Develop Recommendations for a General Industry-Wide Approach

Based on the preceeding tasks, it should be possible to:

- Identify industries that should be studied in FY82 to continue this research effort, and
- Develop general conclusions about toxics integration that will be useful.

Further industry case studies should be more representative of the total range of industries and provide a better basis for generalizing about needed changes in regulatory, statutory, or analytical approaches. The goal of such studies will be to develop well-supported conclusions for improved integration of toxic control strategies in FY 83.

By August 1981, however, it should be possible to offer preliminary conclusions for consideration by senior management at EPA and the Office of Management and Budget. For example, for the industries studied, it should be possible to state whether control of conventional pollutants should be de-emphasized to free up resources for better control of toxic pollutants in certain circumstances. It should also be possible to identify data gaps that prevent analyses of this sort from being as complete as one might like for regulatory purposes; analyze whether toxics problems can adequately be addressed through a multi-media regulatory development approach; and shed light on resource and other implications of adopting such an approach across other industries.

Staffing: the whole project team and the consultants.

Schedule:

1. Develop a draft report summarizing the results this task and the preceeding ones by late July.

2. Issue a final version of the report by August 11, 1981.

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TOXICS INTEGRATION PROJECT

Geographic study: Workplan

I. General Goals of the Geographic Approach

The general goal of the geographic approach is to define and test a methodology whereby geographic studies could be made a prime means through which the agency's toxics control activities are carried out.

Both the pollutant-by-pollutant and the industrial approach to integration seek internally consistent and nationally appropriate systems of regulations. The geographic approach looks at the issues from the opposite direction, seeking unique and locally appropriate solutions to toxics problems. These solutions may or may not depend on the existing national control programs to achieve their goals: certain aspects of existing programs may be either irrelevant or even counterproductive in responding to local problems as defined by this approach.

This activity will therefore develop a methodology through which state and local participation--and control authority--might be enlisted more effectively to serve national pollution control goals. It will seek ways to integrate the federal and non-federal resources in such a way as to maximize public health benefits locally, and minimize costs to all participants (industry as well as all levels of government).

In the current year, the project will be concerned both with the general methodology for organizing and administering a geographic study, and with the analytical tools necessary to conduct them. Methodological studies will concentrate on administrative, political and legal designs of geographic studies--how intra- and intergovernmental roles and responsibilities can be defined, how administrative and political ties with states can be tightened, how state and local laws can be utilized to support national public health and environmental goals. Analytical studies will concentrate on the task of producing cost-effective tools for analyzing local toxics problems accurately, and for defining efficient controls. These are discussed in turn below.

Methodological Studies

EXHIBIT A shows our prototype methodology in schematic form. Absent from this flow diagram is any discussion of technical assessment issues: these are presented in the following section under "Analytical Studies." The key here is to define the interrelationships of EPA with the states and local governments, and in the later stages of strategy development, with industry and the public.

Since toxics problems are known to be usually most severe in metropolitan industrialized areas, where concentrations of industries discharge effluents into confined ecosystems near concentrations of population, testing of the methodolgical approach will emphasize urban situations--both in terms of methodology development and analytical techniques. But ultimately the methodology should be generally applicable, even to contexts where toxics problems are

minimal and existing control programs (perhaps) excessively stringent.

Costs are discussed as a methodological issue because of the crucial role they play in allocating emphasis, and responsibility, between segments of this methodology. Cost estimates for most elements of a geographic study will come from the analytical studies (pilot studies) conducted, but the overall methodology must offer strategic guidance on how to allocate limited resources between activities. Overall estimates of costs are also critical in determining a general strategy for when and where to do geographic studies (Step A) and how often. It may be that such studies could become a regular part--even a predominant part--of agency activities, or it may be that they would be employed very seldom.

The following sections briefly discuss the methodological and study issues involved in each of the prototypical steps listed on EXHIBIT A.

STEP A

Before geographic studies can be routinely conducted as part of a toxics control program, a methodology or procedure for identification of potential problem areas will need to be devised. THe methodology would essentially consist of a procedure that would, through the use of existing data, screen out those geographic areas that are likely to have sub-population groups exposed to higher than tolerable levels of toxics (however defined) in one or more media.

Some constraints on formulation of the methodology would be:

- o it should not require collection of new data, i.e., should utilize existing data bases.
- o potential problems should be quantified such that priority lists can be developed.
- o in view of the fact that the selection methodology will be applied in a large number of cases, it should be relatively simple and non resource intensive.

Study Issues for FY 81:

- o Study technical factors to be used in formulating the selection criteria
- o Examine the adequacy of existing data bases for making site selections
- o Define the role of federal agencies (EPA and others), states and locals in the sites selection process. (Should the selection process be left to the states with EPA and other federal agencies merely providing technical support and input?)

STEP B

Following selection of a site (using procedures in Step A), the next step would attempt a preliminary analysis of existing data designed to show probably sources, pathways and exposure levels for a selected group of

toxics. The group or list of chemicals to be subjected to further studies should be identified in this step, and will likely be taken from the list of 20 intermedia priority pollutants and any other local chemicals of interest. hese "table-top" analyses should also provide indications of the problem media around which field sampling and data collection efforts would be designed.

While it would seem logical for EPA to take the lead in the development of standardized modeling and forecasting techniques, the role of local and state governments would probably be greater in actual application of the techniques and the ensuing analysis of data and results. States could concievably take the responsibility for performing these analyses (as they presently do for water-quality based effluent limitations) with technical support from EPA.

Study Issues for FY 81:

- o To the extent possible, define the most efficient allocation of responsibiliteis for this task among the federal agencies, states, and local governments.
- o Assess the adequacy of existing techniques and data bases to perform such desk-top analyses, identify deficiencies and remedial measures, and their costs.
- o What are the costs of the studies to EPA and the states?
- o What are appropriate sources of funding to support these activities?

STEP C

It is likely that in many cases, existing data are insufficient to adequately assess and define local problems. Presumably, the table-top analyses will show up these deficiencies and also provide information on areas/media requiring more study and/or data.

This step should produce, through a cooperative effort between federal, state, and local entities, a field sampling program designed to fill data gaps revealed in the previous step. Methodological questions will include examination of appropriate divisions of effort between participating parties, estimates of unit costs for various types of studies conducted, establishment of standard sampling protocols in various media, and so forth. Political questions may arise as to public involvement in this phase, particularly if media to be sampled are publically conspicuous and may arose public interest or anxiety.

As is discussed below under Step F, this step may be iterated repeatedly in order to arrive at conclusive evidence. Either in the first or in subsequent iterations, health studies may be indicated, including direct sampling of tissues (hair, blood, urine, adipose), or other types of epidemiological work. Due to the costs and legal issues involved, and the interests of other agencies (CDC), analysis of the health study issue should be a special sub-element of this part of the study.

Study Issues for FY 81:

- o Define types of survey or field sampling techniques that may be useful, including standard unit costs.
- o Tackle the health issue directly, determining criteria for undertaking such studies and for not undertaking them.
- o Establish formal relationships with health organizations and other with special authority or expertise in relation to any of the study activities affected.
- o Examine relative roles of EPA, states, and localities.
- o Define protocols for inserting obtained data into existing EPA systems (TOXET, STORET, etc.)

STEP D

Once a plan has been developed to obtain further environmental or health data, protocols for analysis must then be defined. At this point we assume that this step is a minor issue, since most tests will have to have national uniformity, and thus EPA is expected to have sole authority in defining these protocols or in reviewing the protocols of other federal agencies with jurisdiction (CDC, OSHA, etc.).

Study Issues for FY 81:

- o Review availability of existing protocols for categories of tests described in Step C.
- o Commission development of protocols where gaps or technical problems exist.
- o Coordinate as necessary with other agencies involved.

Step E

At this step, analysis of samples and interpretation of results will begin to yield indications of the true extent of problems tentatively identified in Step B. It is important that the interpretation of test results be made in relation to uniform risk assessment protocols, using, for example, consistent assumptions about population sizes and distributions, consumer habits, and other factors affecting exposure. (See also workplan for Activity 2 of this project.) Establishment of these protocols should presumably be solely an EPA function, since they should be uniform across the country and based on the most advanced risk assessment methodologies.

Other methodological questions of importance here include who pays for lab work, using what funds: certain costs may be assumed by states or localities, others may be reimbursed through federal grants (including those from non-EPA sources). How much should these responsibilities be formalized across studies, to what extent should they be ad hoc?

FY 81 Study Issues:

- o Identify uniform risk assessment protocols
- o Analyze costs of basic analysis methods for reference use in regions

- o Determine requirements of quality assurance program
- o Determine approaches to equitable distribution of burden between participating groups
- o Identify appropriate sources of grant funding (EPA, non-EPA)

Step F

At this step, EPA and participating state and local groups would decide whether the data gathered offer conclusive evidence one way or another about the nature and extent of potential toxics problems. Improved data could, if necessary, be fed into the models used in Step B. If data are found to be to any extent inconclusive, the methodology would at this point cycle back to Step C, where new sampling or study techniques would be commissioned, such as body burden or other epidemiological work on selected individuals or subpopulations.

To the extent that national health standards or other external criteria do not guide decisions to conduct more studies, how should these decisions be made. In the absence of consensus, should EPA have the deciding role, or the states? What weight should the opinion of other federal agencies (e.g. CDC) be given? How formal should this process be? What tradeoffs should be made between costs of additional data gathering and conclusiveness of existing study results? Finally, once conclusions are reached, what criteria should be used to rank the problems identified in order importance? in order of treatment?

FY 81 Study Issues:

- o All above issues will be addressed empirically within the pilot studies. Experience there will guide the strategy recommendations.

STEP G

Once the identity of problems is known to the desired degree of accuracy, control options for correcting them can be developed. Some control options could operate through the regular EPA problems, but we expect that degrees of control above and beyond customary levels will be needed in certain cases.* Alternative control techniques, especially those that could be imposed by states or localities, must be considered. Generically, responses could include technical controls on sources, modifications of source/receptor relationships (from relocating sources to relocating populations, and steps in between), and modifying receptor characteristics (treating drinking water rather than controlling industrial effluent into streams). Each option should be costed out, and its benefits estimated.

At this point it may be desirable to involve the public in listing options. It will almost certainly be necessary to consult directly with industrial representatives where industries are identified as problem pollution sources.

Key methodological questions will revolve around the type and degree of guidance needed in defining technical and non-technical control options, and in estimating the efficacy of each. Should EPA be the final arbitor of

* The pilot studies, for instance, will be conducted in metropolitan areas where unusual toxics problems will probably exist after imposition of all normal controls.

efficacy (enforceability as well as technical effectiveness)? To what extent to the existing acts influence the permissable range of control options, especially those which are alternatives to customary program controls?

Study Issues for FY 81:

- o Compile a catalog of alternative control measures
- o Review current legal constraints on their use (especially in terms of laws EPA administers--see Activity 1)
- o Evaluate EPA/state/local roles empirically through the pilot studies

STEP H

In the final step, a control strategy or strategies for identified problems will be developed jointly between EPA and the affected state and locality. At this point, cost/benefit assessments must be made, and must be balanced against all other relevant considerations: political acceptability; distribution of costs among different levels of government, industry, and the public; enforceability, potential adverse intermedia effects, and so forth. It will probably not be possible to develop detailed guidance on most of these issues; rather the intent will be to devise a methodology for making issues and tradeoffs explicit, and for structuring judgments for decision. As before, we must attempt to define appropriate relationships between the various parties affected: who has the last word? what is the relationship between this process and the regular administration of EPA programs?

In order to approach the issues here, we must study the relationships between EPA and state/local authorities in some detail. Where controls applicable to toxics are concerned, are there any gaps where no authority exists to regulate a class of problem? Are there overlaps between authority, where one would have to choose the level of government at which control is exerted? Are there instances of actual interference between state and federal authorities over a certain class of problem?

Also included in the strategy must be explicit assignments of responsibility for monitoring and enforcement. We must include consideration of accountability mechanisms between EPA and the states and local governments: these could build on present SEAs, but could also include other devices (MOUs, contracts, new state legislation or planning programs, commitment of local police powers). These accountability mechanisms must be carefully examined to determine the degree to which their use is consistent with EPA's legislative mandates.

Study Issues for FY 81:

- o If possible, create guidelines for cost/benefit evaluations
- o Investigate types of possible accountability mechanisms, and their legal status in relation to EPA legislative mandates

Analytical Studies

Steps B through F involve complex analytical examinations of local ambient environmental conditions in relation to toxics exposures and risks. In the past, EPA has attempted various approaches to geographic analysis of this kind, generally in areas where under the existing programs it is unlikely that observed or suspected toxics problems can be adequately corrected: in such areas, local concentrations of industry and population can be expected to lead to undesirable levels of toxics-related health and environmental risk, <u>despite</u> the application of nationally appropriate environmental standards and controls. In various ways, the projects previously sponsored have sought to answers to the following questions:

(a) What are ambient levels of toxics now, and what apparent health and environmental risks do they impose?

(b) What are the sources of these toxics?

(c) What are the potential pathways between sources and receptors?

(d) Will the normal application of EPA programs reduce ambient toxics levels to acceptable levels (are we regulating the key toxics pathways stringently enough)?

Building on past experience with projects of this sort will directly aid the development of a geographic strategy.

We know from past experience, however, that trying to analyze geographic areas to answer such questions is time consuming, expensive, and usually inconclusive. Our limited aim for the first year is therefore to test the general feasibility of existing tools and existing data. How far do these carry us toward the requirements of Steps B through F? What are the costs involved? How can we overcome data gaps and methodological problems? How expensive will it be to gather conclusive evidence? What innovative alternative techniques are available to fill gaps in our current knowledge?

We propose to focus our first year efforts as follows:

1) <u>Evaluate past geographic studies</u>

Past attempts at geographic analysis offer technical and procedural lessons, especially on identifying avoidable problems. We will document these in brief case studies. (Task 5.0)

2) <u>Commission two pilot case studies</u>

Proposed sites are north Philadelphia PA, and the Kanawha Valley in West Virginia. Principal elements will be:

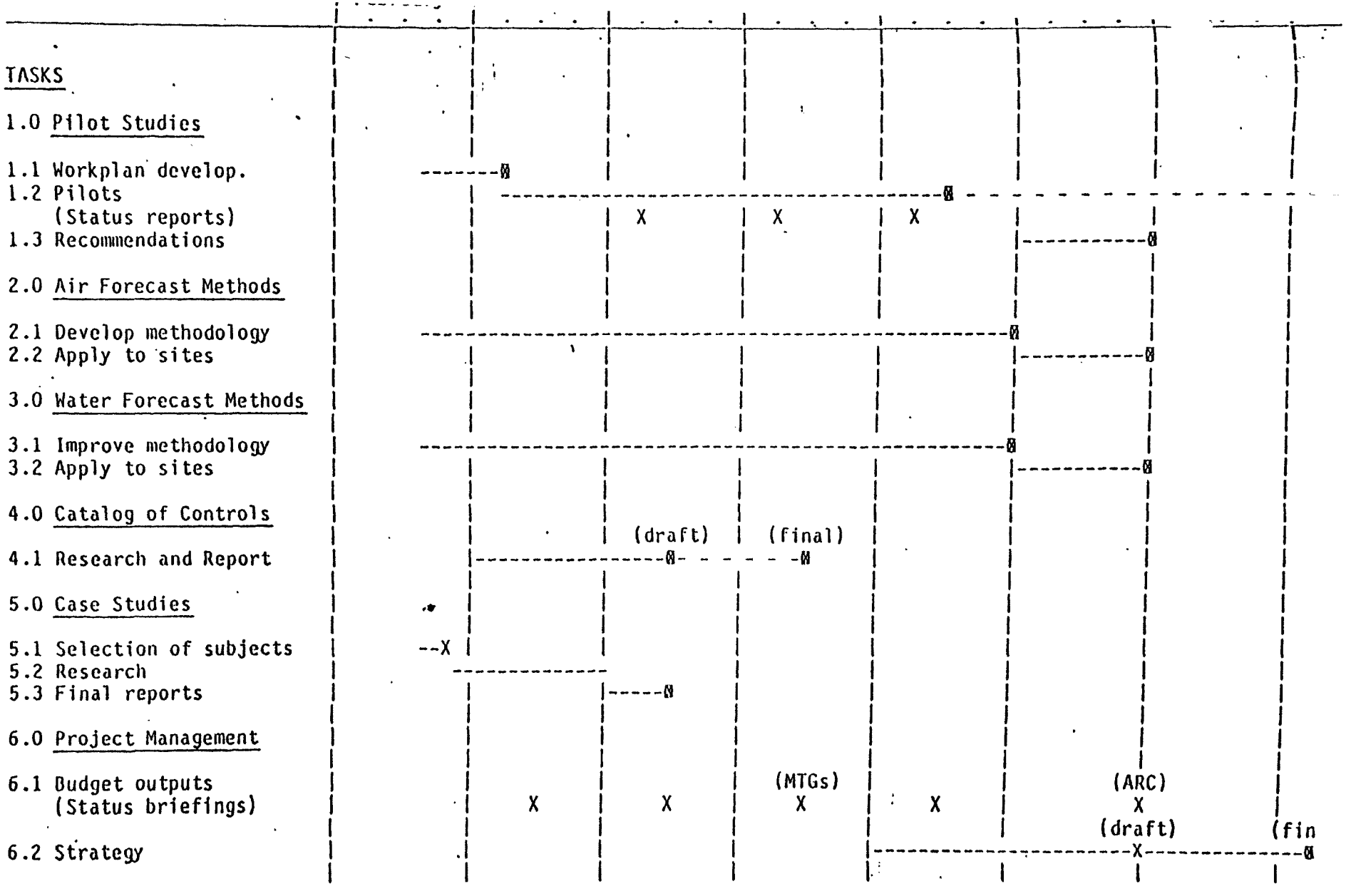
a. To assess sources and ambient toxics quality in the case study areas (Task 1.0);
b. To forecast (if possible) the future effects of current programs in the study area (Tasks 2.0 and 3.0); and

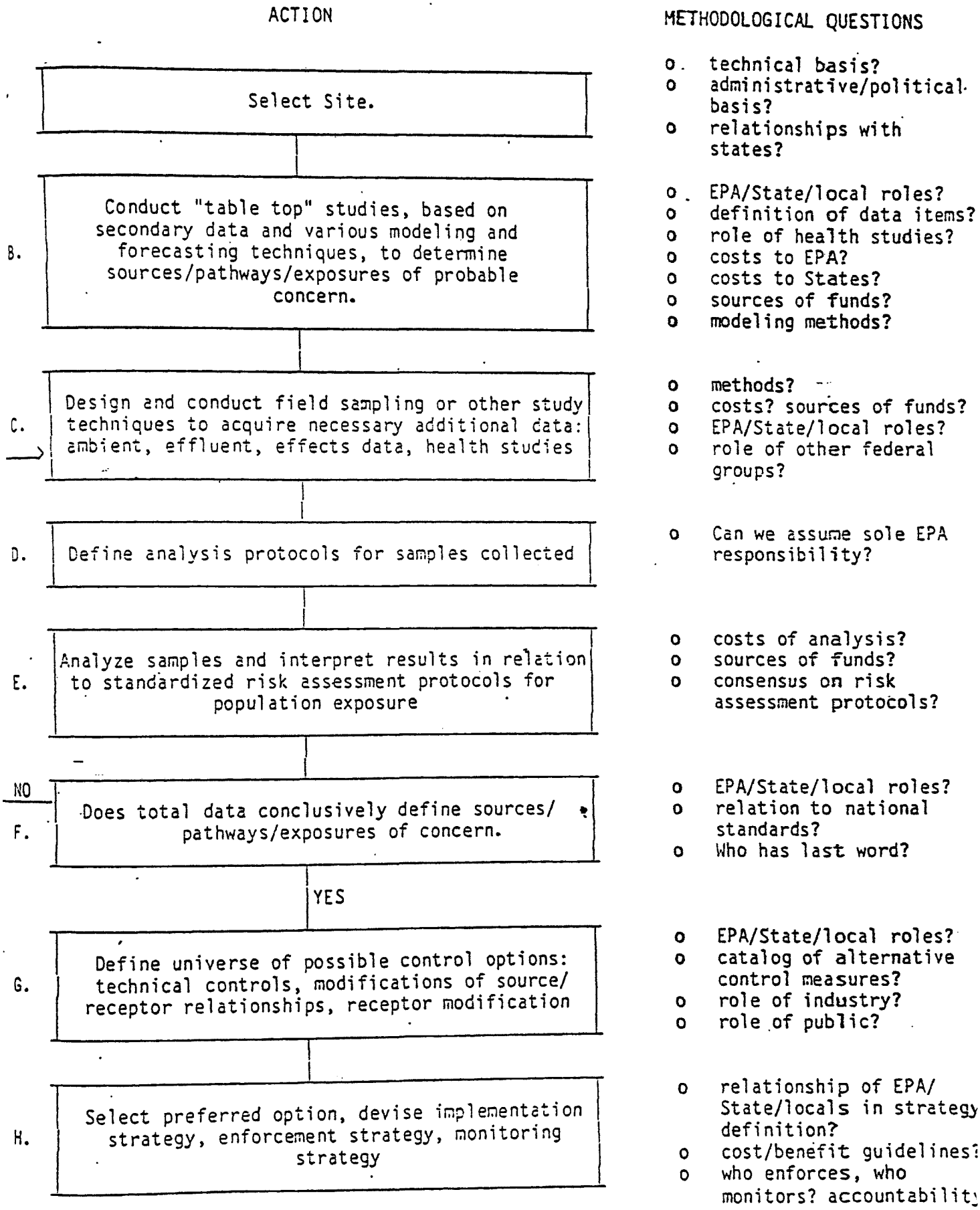
c. To research innovative methods for controlling discovered toxics problems (Task 4.0).

3) Integrate the findings of these activities into the general methodology

II. Structure of this Workplan

This workplan incorporates all the elements of the general toxics integration project workplan, but has not yet ennumerated more general tasks related to dealing with all the methodological questions raised above. In some cases the schedule has been changed: at this point it appears that the detailed pilot study design (which now will involve considerable contractor input) will not be complete until March 14, although the general pilot study design will probably be approved ahead of schedule; the catalog of alternative controls is now scheduled to be complete two months earlier than originally planned.


TASKS
1.0 Pilot Studies
1.1 Workplan develop.
1.2 Pilots
(Status reports)
1.3 Recommendations
2.0 Air Forecast Methods
2.1 Develop methodology
2.2 Apply to sites
3.0 Water Forecast Methods
3.1 Improve methodology
3.2 Apply to sites
4.0 Catalog of Controls
4.1 Research and Report
(draft)
(final)
5.0 Case Studies
5.1 Selection of subjects
5.2 Research
5.3 Final reports
6.0 Project Management
6.1 Budget outputs
(Status briefings)
(MTGs)
(ARC)
(draft)
(fin
6.2 Strategy
X = briefing, informal report
M = formal written report


ACTION
METHODOLOGICAL QUESTIONS
Select Site.
o technical basis?
o administrative/political basis?
o relationships with states?
B.
Conduct "table top" studies, based on secondary data and various modeling and forecasting techniques, to determine sources/pathways/exposures of probable concern.
o EPA/State/local roles?
o definition of data items?
o role of health studies?
o costs to EPA?
o costs to States?
o sources of funds?
o modeling methods?
C.
Design and conduct field sampling or other study techniques to acquire necessary additional data: ambient, effluent, effects data, health studies
o methods?
o costs? sources of funds?
o EPA/State/local roles?
o role of other federal groups?
D.
Define analysis protocols for samples collected
o Can we assume sole EPA responsibility?
E.
Analyze samples and interpret results in relation to standardized risk assessment protocols for population exposure
o costs of analysis?
o sources of funds?
o consensus on risk assessment protocols?
NO
F.
Does total data conclusively define sources/ pathways/exposures of concern.
o EPA/State/local roles?
o relation to national standards?
o Who has last word?
YES
G.
Define universe of possible control options: technical controls, modifications of source/ receptor relationships, receptor modification
o EPA/State/local roles?
o catalog of alternative control measures?
o role of industry?
o role of public?
H.
Select preferred option, devise implementation strategy, enforcement strategy, monitoring strategy
o relationship of EPA/ State/locals in strategy definition?
o cost/benefit guidelines?
o who enforces, who monitors? accountability

TASK 1.0 PILOT STUDIES

The pilot studies will have limited goals.

1. To establish how far existing data and methods can take us in analyzing geographic areas and prescribing solutions.

2. To describe deficiencies in existing data and methods.

3. To define (as far as possible) how these deficiencies might be remedied, and at what cost.

4. To catalog innovative and alternative approaches to control applicable to these and other sites, especially in relation to intermedia effects.

Many problem areas are already visible. The following are among the major ones; others will undoubtedly arise.

Actual "effects" information is not part of the study: it is hard to document toxics-related health and environmental effects, especially since these usually have long latency periods. We will therefore have to design the study primarily around desired ambient levels (e.g., water quality criteria) and estimated exposure-related risk levels. We may be able to link with such groups as NIH for limited reviews of local health effects.

It is impossible to analyze all toxic compounds of interest: even the "short lists" of toxics (NESHAPS, consent decree, TIP list of 20, RCRA) may exhaust all available funds for analysis; some protocol for defining substances for geographic consideration is necessary.

Toxics-related ambient standards have many problems: inconsistencies between standards (e.g., water quality criteria vs. MCLs), poorly defined definitions of compliance/non-compliance, uncertain numerical values.

Ambient toxics data is generally poor: the Chesapeake Bay study has unusually good toxics data on water, but most other ambient toxics data, especially for air and groundwater, is sketchy at best.

Effluent data on toxics is not much better: some estimates can be made on the basis of permit and process data, but this is unlikely to be hard enough use for an enforceable control strategy.

Modeling techniques have serious methodological and definitional problems: the water dilution studies, for instance, tend to overestimate projected problems; methodological improvements are needed, but corroborating monitoring is also needed.

Before committing to further work on a geographic approach in FY 82, we must determine if problems such as the above invalidate the entire concept of a geographic approach to toxics analysis. We hope that the first year's experience will provide us with a practical methodology that can be fully developed over the second project year.

Design of the pilot studies

Our preliminary plan for the pilots follows. We will focus in parallel on defining ambient quality in air, surface water, groundwater, and soils, and on characterizing all effluent sources contributing to these media. Solid waste sites--including regulated and unregulated (abandoned) sites-will be treated as sources to these media. Once this data is explored, we will attempt to predict changes in ambient quality due to the controls imposed by the various environmental programs using techniques refined in Tasks 3 and 4.

Most of the technical work will be done under contract under the technical direction of Dr. Alvin Morris, Deputy Regional Administrator of Region II.

TASK 1.1 Develop workplan for conduct of geographic pilots

The geographic approach is to be tested through one or two pilot studies of selected areas. These areas will be selected within Region III, and will be selected by that Region's staff.

Goals of the pilots are to:

- To determine the adequacy of existing data and methods for definition of multi-media toxics problems in given geographic areas,
- To describe deficiencies in existing data and methods,
- To define remedies to these deficiencies and the costs of correcting them, and
- To determine the magnitude and nature of toxics problems likely to persist following the implementation of most stingent regulatory controls (see also Tasks 2 and 3).

Major elements of the pilots studies will be:

- Determination of present ambient quality for air, water, and land/groundwater,
- Inventory of existing sources of pollution to these media,
- Estimation of of likely emission rates following imposition of regulatory controls,
- Effects of these continued emission on future ambient quality, and
- Development of remedial control strategies, including cost estimates.

In this task, the contractor will be directed by the EPA project officer in development of a detailed workplan designed to complete each major element listed above. The workplan will include:

1. Specific activities (sub-elements) needed to complete each element above for the selected area(s).

2. Scheduled dates of completion of each activitiy.

3. Resources to be allocated to each element and sub-element.

4. Identification of individuals/offices responsible for each sub-element.

This task must be completed in consultation with a list of EPA staff and officials to be provided to the contractor upon commencement of work. The final workplan must be explicitly approved by the Deputy Regional Administrator for Region III.

Output: Workplan document

Period of Performance: Three calendar weeks from commencement of work

Estimated level contractor effort: Five person weeks

TASK 1.2: Conduct Pilots

A. AIR ASSESSMENTS

Produce those air assessment outputs assigned to contractor in TASK 1.1.

Under the air assessment element of the workplan, not all sub-elements will be assigned to the contractor. Major activities under this task will be directed at the following:

Ambient Air Studies

a. Existing monitoring data from all sources
   - ORD
   - SAROAD (NAMS, SLAMS, National Air Survey Network (metals))
   - Research Triangle Institute

b. Link to health data
   - OHEA estimates of risk for chemicals identified

Air Pollution Sources

a. Inventory all sources
   - Majors (program listings, check local data for non-filers).
   - Minors (program listings, presumed higher prob. of non-filers)

b. Toxic effluent profiles
   - Majors: source by source (based on permit files, process assumptions, monitoring data as available)
   - Minors: characterize by groups if technically necessary

c. Contrast (a) and (b) against expectations--i.e., knowledge of Regional/State permitting personnel

d. Contributions of other sources
   - Area (mobile source, small retail establishments; etc.)
   - Hazardous waste sites/sanitary land fills (may link to other contract)

Forecasting Program Effectiveness

a. Methodology development: contractor may consult in development of methodology under Task 2.

b. Application to sites

The number of hours devoted to this task and the scheduled dates of completion of each output will be provided in the workplan.

B. WATER ASSESSMENTS

Produce those outputs assigned to contractor in TASK 1.1.

Major activities in this task will be directed at the following:

Ambient Water Studies

a. Existing monitoring data from all sources
   - Chesapeake Bay study
   - STORET
   - Enforcement data files
   - others as available

Water Pollution Sources

a. Inventory all sources
   - Majors (program listings, check local data for non-filers)
   - Minors (program listings, presumed higher prob. of non-filers)

b. Toxic effluent profiles
   - Majors: source by source (based on permit files, process assumptions, monitoring data as available)
   - Minors: characterize by groups if technically necessary

c. Contrast (a) and (b) against expectations--i.e., knowledge of Regional/State permitting personnel

d. Contributions of other sources
- Area (urban runoff study for Baltimore, application of general soil loss equation and runoff estimates for Kanawha)
- Hazardous waste sites/sanitary land fills (may link to other contract)

Forecasting program effectiveness

a. Consult as required in Task 3.

b. Apply improved methodology to pilot study sites.

The number of hours devoted to this task and the scheduled dates of completion of each output will be provided in the workplan.

C. SOLID WASTE/GROUNDWATER LINKAGES

Produce those outputs assigned to contractor in TASK 1.1.

Major activities in this task will be directed at the following:

a. Source assessment
- Map known Superfund candidates
- Map known hazardous waste/sanitary landfill sites
- Review existing aerials for other sites
- Review whatever technical data exists on all located sites (site contents, depth to groundwater, site integrity)
- Estimate loadings to groundwater (in conjunction with next task)

b. Groundwater quality assessment.
- Review monitoring data on public (private?) water supplies
- State geologic survey assessment--perhaps data on contributions to local aquifer flow, degree to which contamination from outside local area is significant

c. Drinking water assessment
- Statement on extent to which drinking water is derived locally (contrast ambient data to MCLs, if applicable; some linkage to project 5 is possible)
- Map against population for areas exposed

The number of hours devoted to this task and the scheduled dates of completion of each output will be provided in the workplan.

D. INVESTIGATE INTERMEDIA CONTROL RESPONSES

Produce those outputs assigned to contractor in TASK 1.1.

Major activities in this task will be directed at the following:

a. Develop approach for using assembled data to define potential intermedia effects.

b. Assemble catalog of models for analyzing intermedia flows, especially after imposition of alternative abatement assumptions.

c. Conduct analysis of intermedia flows under alternative abatement assumptions.

d. Recommend selected options with most beneficial environmental effects.

The number of hours devoted to this task and the scheduled dates of completion of each output will be provided in the workplan.

TASK 2.0 AIR FORECASTING METHODS

In this task, headquarters staff in Washington and Durham (OAQPS) will confer on the design of methods for forecasting the effects of projected controls on ambient toxics concentrations of particular localities, such as the selected pilot study sites.

This work will build on work already under way by OAQPS, partially under a past contract with SAI Incorporated. A new contract may be let to translate exposure assessment techniques applicable to national risk assessment studies to a local context.

Tasks for the development of this methodology have not been described as yet. Feasibility of this effort will be studied in parallel with the development of the workplan, with suitable input from the Task 1 contractor. Proposed tasks sub-elements are:

Task 2.1 Develop Methodology

Task 2.2 Apply to Pilot Sites

In conjunction with Task 1 contractor.

TASK 3.0 WATER FORECASTING METHODS

At least one method now exists for predicting the effect of future controls on ambient environmental toxics levels. Developed by OWWM for surface water studies, this method first estimates current emissions of toxics from known sources in a given river network, using permit and process data available in-house. It then estimates the abatement expected for each source under BAT controls. The resulting new values for toxics emissions are then assumed to be diluted in the known 10-year, seven day low flow of the river system. The ambient values for toxics thus obtained are compared to present water quality criteria; OWWM is thereby able to screen for stream reaches that are likely to exceed water quality criteria values after imposition of BAT.

This task will build on work completed in the Monitoring and Data Systems Division. It will use past "dilution study" efforts as a basis for developing a refined method of modeling the effects of improved point-source treatment technology on ambient toxics concentrations in receiving waters of the pilot study sites.

Produce those outputs assigned to contractor in TASK 1.1.

Major activities in this task will be directed at the following:

Task 3.1 Improve Methodology

a. Identify deficiencies and inaccuracies in methodology.
- Does methodology attempt to account for all sources and sinks of pollutants?
- What simplifying assumptions have been used--what effect are these assumptions likely to have on accuracy of the results?
- Can some, all, or any of these assumptions be eliminated without overcomplication of the methodology, thus improving accuracy?
- Are data available to replace assumptions with reliable estimates?

b. Develop improved methodology.
- Examine identified deficiencies in existing methodology, assess the magnitude of error likely to be induced by each deficiency, and attempt to correct or minimize it.
- Determine appropriate applications of the method.
- Based on findings of preceding steps, formulate new methodology designed to maximize accuracy while minimizing data needs. (Likely to involve use of EXAMS model.)
- Describe data needs for the new methodology.
- Describe simplifying assumptions used in new methodology and the likely sources of error.
- Focus new methodology on new applications.

Task 3.2 Apply to Sites

In conjunction with Task 1 contractor.

TASK 4.0: EVALUATION OF PAST GEOGRAPHIC STUDIES

The agency has undertaken several "geographic" studies over the past several years, all of which will offer significant lessons both in relation to the pilot studies and to the more general evaluation of the potential of the giographic approach as a whole. This task will compile uniformly formatted case studies of at least three such instances, and will review others as they come to light.

The most important case studies (especially Memphis, perhaps also Beaumont) will be done in cooperation with the contractor working on the pilot studies, since the approach and methods used will be important to the design of the pilots. Other cases will be addressed by in-house staff; we estimate that approximately one person week will be necesary for each. Staff exists to compile approximately 12 case studies; if more are needed or if compilation time exceeds one person week per site, additional staff will be required.

Task 4.1 Identify candidate sites for examination (February 19 - 25)

a. Call Regions for names of sites, names for interviews.

Regions divided into groups. Will call S&A lab directors and consult HQ personnel as necessary to identify sites.

Site selection to be final by 24 Febraury.
Presume inclusion of Memphis, Beaumont, Great Lakes, Louisville, Birmingham, Love Canal.

Task 4.2 Develop uniform data requirements, final report outline (already complete in draft)

a. Uniform data plan attached (draft 19 February). Includes provision for primary (interview) and secondary data (existing reports, in-house documents, etc.). Assume no travel required. Exception may be Memphis, for general study purposes.

b. Final report outline due 25 February

Task 4.3 Conduct studies (February 25 through April 15)

a. Preparations (review of HQ data, phone calls): identify respondents, necessary reports. Estimate 1 person-day per case.

b. Conduct interviews and review secondary sources (one person per case, average 2 person-days per case)

c. Draft report (10-20 pp. max.; keep short; 2 person-days per case)

d. Regional review, redraft in final

e. Prepare executive summary, general conclusions, as necessary.

TASK 5.0 CATALOG OF ALTERNATIVE CONTROLS

A geographic approach to toxics integration is intended to discover problems that the ordinary operation of programs may have missed, or will be unable to correct. It follows that controls to correct these problems may have to rely, at least in part, on methods unavailable to the Federal regulatory programs, specifically regional, state, or local methods that do not require national regulation.

Much work has been done in the area of innovative and alternative controls for environmental pollutants. This task will compile and evaluate tools that have already been researched and developed in some detail.

The task will be completed in-house, using staff on the toxics integration project.

TASK 5.1 Research Available Methods and Complile Report

a. Research available Federal-developed tools for toxics controls
   - Controlled trading
   - Bubble/banking
   - other innovative controls as available

b. Research available State/local tools for toxics controls (especially those applicable for Maryland and West Virginia)
   - Non-point source runoff controls (sedimentation and erosion control ordinances, subdivision ordinances, zoning, performance standards)
   - Emergency powers
   - State pollution control legislation (assess degree that it offers more stringent control of water pollution, air pollution, etc.)
   - Locally enforceable special purpose controls (subdivision ordinances, special purpose zoning (e.g., emission density zoning), performance standards, etc.)

c. (If possible) Link selected control possibilities to recommended abatement recommendations from previous task.

Draft report will be complete by April 15, final report one month later. This is a considerable acceleration of the original schedule, which called for completion of this task effort by July 1.

The level of effort for this task has not been assigned; in order to complete it by the date stated, additional staff are likely to be necessary. No contract support is now contemplated, but could conceivably be used if time constraints require it.

TASK 6.0 PROJECT MANAGEMENT

This general task will produce two main products: (1) budget reports and briefings (as necessary) to both the media task groups and the Agency Ranking Committee, and (2) the strategy itself.

Task 6.1 Budget Outputs

In coordination with TIP Activity 6, budget memos and briefings will be prepared as necessary to allow the Agency to:

a. Assess current resources being expended on activities related to geographic assessments.

b. Cost out options being developed under this Activity.

c. Integrate (to the extent possible) the developed strategy into the FY 83 budget request.

These materials will be compiled by the TIP staff in-house. No level of effort has been assigned. MTG briefing materials will be available by mid-May, ARC materials by the end of July.

Task 6.2 STRATEGY

The final strategy document will summarize the findings of all tasks of this Activity, and include at least the following elements in relation to the pilot studies:

a. Statement on links between sources and ambient quality

b. Identification of sources
   - Unregulated
   - Underregulated

c. Statement on further data needs

d. Statement on desired spot monitoring/other desirable analysis

e. Specify FY 82 workplan for two sites, if recommended:

   - Development of further analytic tools, potentially including:

   (1) Aerial surveys (use of Enviro-pods, remote scanning, overflights)
   Purpose: dump site location, remote scanning for all types of visible and invisible plumes in all media, etc.
   Sources of expertise: NEIC, Las Vegas lab and other ORD sources, Regions, contractors, other agencies, States.

(2) Existing monitoring networks (air and water ambient monitors on State and local levels; effluent monitoring)
Purpose: general data review

(3) Existing data bases (SAROAD, STORET, TOXET, Toxics Inventory, etc.)
Purpose: detailed ambient quality and exposure estimates

(4) Original sampling and monitoring (dumps, abandoned sites, air and water quality, groundwater, water supply, sludge quality, federal facilities, human and animal tissues)
Purpose: multiple

(5) Epidemiological studies
Purpose: estimate effects of identified local exposures

(6) Mathematical models (SEAS, air diffusion models, etc.)
Purpose: multiple

- Development of cost estimates for all of above.

Any other documents or reports required under Activity 6 will also be produced.

TASK 4 ATTACHMENTS

Evalution of Past Geographic Studies

Background information for respondents

EPA is investigating the possibility of using a geographic approaoch to integrating its toxics programs: this would involve any number of techniques aimed at investigating localized problems with toxics in the ambient environment, rather than only applying nationally appropriate regulations and controls to local problems. Over the past several years, EPA has sponsored various studies of local toxics problems (often emergencies). In our current investigation of the geographic approach to integration, we want to use as much experience from past studies as possible.

If any version of a geographic approach to controlling toxics is to become institionalized, it is important to be thorough in identifying the costs and benefits of such past studies. The following questions are intended to elicit information related to the costs of previous studies, as well as to assess the relative success or failure of past efforts.

In this exercise of looking into past studies we want to identify what led to each study--was it a particular health problem, odor problem, citizens' complaints, or the Agency's independant concern about a potential problem? What were the actual problems found (if any), and could they be documented well? What were the benefits of the effort? If problems were identified but not resolved, what prevented application of suitable controls: was there insufficant data to define the problem, were there questions about the interpretation of the data, were there institutional or cost problems related to cleaning up the problem? Or were there no standards, no criteria, or no legislation or regulatory support for actions?

Your assistance in providing the following information is appreciated. Please recommend the names of others who might assist us in obtaining necessary information.

INFORMATION WORK SHEET

SITE_____.

NAMES AND TITLES OF RESPONDENTS (Phone)

(1)_____
(2)_____
(3)_____
etc.

SECONDARY SOURCE MATERIAL

(1)_____
(2)_____
(3)_____
etc.

A. What was study area: town or city, county, state?

B. When was study conducted?

C. What caused the study to take place?

1. Did a specific problem exist, if so what?

2. When was the first indication that a problem existed?

3. Were local and state agencies aware of potential problems and how early?

4. Were citizens aware that problems existed and how was this expressed?

5. Why did EPA undertake study?

D. What activities did the study involve?

1. What actions did local agencies take? (increased monitoring, increased inspections, described situation to public, other.)

2. What actions could have been taken by local agencies but were not?

3. What actions did state agencies take? (increased monitoring, increased inspections, described situation to public, other)

4. What actions could have been taken by state agencies but were not?

5. What were EPA's actions?

6. Which offices in EPA became involved: Regions, ORD, others?

E. What were the technical/scientific issues?

1. What was technical nature of problem?

2. Were data adequate to define problems?

3. Did EPA have adequate expertise to assess the significance of the problem in terms of risks or exposure? Explain.

4. In general, what did the environmental data show?

5. If data was inadequate, what were the inadequacies?

data quality unknown?

disagreement on the interpretation of the data?

insufficient number of stations?

unsatisfactory distribution of monitoring stations?

how was adequacy or inadequacy of data determined?

6. What other information was used (could have been used) to define problem (e.g., aerial photographs, ground photos, site investigations, etc.)

7. What were the recommendations for correcting problems?

F. What were the political issues? (with public, with local government, with state government)

G. What were the administrative/institutional issues?

1. Why couldn't local agencies respond? (lack of expertise, funds, authorization, etc.)

2. Why couldn't state agencies respond? (lack of expertise, funds, authorization, etc.)

3. Did public accurately understand the problem being addressed? If not, how did they perceive it?

4. How could communications with the public have been improved?

5. Was there adequate time to design the study?

   How much time was there?

   What was the driving force behind the study?

6. Were adequate funds available for the study?

H. What were the costs of the study?

1. Cost to local agencies in work years?

2. Cost to state agencies in work years?

3. Cost to EPA in terms of work years and contracts? (fill in table)

	Work years	dollars	
		in-house	contracts
ORGANIZATION			
Regions			
ORD			
NEIC			
Other (list)			
ACTIVITIES			
Planning			
Sampling			
Data analysis			
Quality assurance			
General analysis			
Source inspections			
Enforcement action			
Other (list elements)			

4. If funds were inadequate, what is the estimate of how much an adequate study would cost?

5. What type of work would be done with additional funds?

6. What type of control actions could possibly result from the additional effort?

I. What were the results of the study?

1. Did problem actually exist?

2. Was there a concensus between agencies of exactly what the problem or problems were? Explain.

3. Were any controls or remedial actions taken to correct problems?

What type of actions or controls?

Who provided the funding for the corrective action?

If control actions were taken by private industries did they do it voluntarily?

Was legal action considered before action taken by industry?

Was action taken by industry after legal action initiated?

4. Was problem actually corrected?

J. General Conclusions

1. What recommendations would you make to someone conducting similar study?

2. What, from your perspective, were the weaknesses of this study? How would you would advise people initiating similar studies in order to avoid these problems?

3. Even if the problem was corrected as a result of this study, could a similar result have been obtained through some other means, such as the routine operation of existing EPA or state control programs?

4. Has the Region developed a general plan or procedure to follow for future studies/responses?

TOXICS INTEGRATION: OUTLINE OF THE REPORT TO THE ADMINISTRATOR

In addition to an Executive Summary, the report will contain an Introduction and sections on Information Collection and Analysis, Control Strategies, and Recommendations. This outline identifies major features in each of those sections; we cannot at this point, of course, detail conclusions.

The Introduction will discuss past and on-going efforts at toxics integration, such as development of risk-assessment methodologies and intra-agency work groups on pollutants. Also, we will identify the important assumptions and goals of the current study: the need to set collective agency priorities on the worst threats to the environment; the need to focus better EPA's limited resources; the need to factor economic impacts more directly into the regulatory development process.

A. EPA Must Make Its Data Collection and Analysis Procedures Consistent for all Programs

EPA can never achieve an integrated and efficient regulatory process as long as its programs have individualized procedures for identifying problems, acquiring information, and analyzing risk and economics data. We need to improve consistency and prevent duplication. No matter what integration strategy -- and what speed of implementation -- is chosen, this project will review with the expectation of standardizing such basic procedures as:

- o more directed and coordinated priorities for information collection on pollutants and industries;
- o an agency-wide cancer policy;
- o agency-wide risk assessment methodologies;
- o review procedures by independent experts;
- o as much as possible, economic impact and cost-effectiveness analytic procedures.

In trying to establish these agency-wide procedures, EPA will be making a number of difficult technical and policy choices. A cancer policy, for instance, will require balancing of economic criteria as well as risk information to establish the appropriateness and extent of regulation. Similarly, any agency-wide policies about risks and costs imply making judgments on the basis of

imperfect data and not fully tested analytic tools. Methods for applying the standardized tools developed under this section will be elaborated in Section C of the report.

B. Toxics Integration Project (TIP) Studied Three Strategic Approaches Which Could be Used to Guide Future Integration

Common sense suggested that any eventual integration strategy will consist of parts of all the approaches considered in this study: regulation by pollutant, by industry, and by geographic area. Given the great number of toxic chemicals, it is likely that selected compounds may require in-depth analysis or intermedia review. It is also likely that controlling such pollutants may be most economically feasible if approached on an industry-wide basis. Finally, there is an important potential role for geographic analyses to play in stucturing responses to specialized intermedia toxics problems.

Nevertheless, each of these three strategic approaches is being developed as though it were the single, dominant integrative force upon which the agency would, in the future, depend. Each approach will be evaluated in isolation.

What would be the strengths and weaknesses of that method of integration? What is the catalogue of issues with which that integrative methodology would need to deal? What are the immediate problems -- such as availability of data -- in testing the usefulness of the strategy? What are the resource, organizational, and legislative impacts of using this approach? This section of the report will present findings of those kinds of questions for each strategy.

1. Integration by Chemical Pollutant.

This approach has been dominant historically in EPA partly because of legislative mandate and partly because analysis of health and environmental risks must begin with specific pollutants. Two overriding difficulties of the pollutant control model have been 1) the vast numbers of pollutants to be controlled, and 2) the difficulty in setting agency-wide toxics priorities given the variety of requirements of each program's differing legislation.

The current strategy proposes to:

- o strengthen the agency-wide chemical priority ranking process;
- o standardize the methodology for calculating pollution control costs and comparing control costs for each chemical across media;
- o consider the effectiveness of the work group format for developing agency-wide control strategies;
- o develop support documents which consolidate exposure, risk, chemical characteristics, regulatory action level, and cost-related information on selected priority pollutants;
- o develop a strategy for analyzing and taking regulatory, or non-regulatory, action for each priority chemical.

2. Integration by Industry.

Toxics integration by industry would force regulators to consider assessment and control technologies from an intermedia perspective; and would increase the visibility of economic considerations. This strategy will describe the total pollution problem created by a specific industry, then assess the health and environmental risks of that pollution. Traditional and innovative control options will be priced. Finally, this approach will compare risk data with control costs for each option and recommend a regulatory decision tailored to that industry and to the population exposed.

Critical factors in developing the strategy are:

- o proposing criteria for industry selection, such as nature of intermedia pollution discharges, technical feasibility of control options, and economic condition of the industry;
- o modeling the extent of a selected industry's toxics emissions;
- o estimating economic impacts;
- o developing methods for intermedia risk assessment for a given industry (based on other TIP work) and a means for selecting regulatory priorities;

- developing industry analytic work groups or other organizational devices to implement this approach.

The report to the Administrator will summarize findings of the industry case studies which are testing this approach.

3. Integration by Geography.

Toxic pollution problems vary in severity across the country. A geographic approach will examine the feasibility of applying intermedia analytic and control strategies (particularly non-regulatory devices) to the unique problems of particular geographic areas.

This year the project will identify and develop the primary components of a geographic approach to toxics control. This approach will include such elements as site selection and planning procedures, development of analytic tools, and definition of control strategies appropriate to the special problems of a particular area.

Control strategies which are cost-effective and suitable for a given geographic area must be devised on the basis of defensible and fairly comprehensive descriptive information. Analytic tools currently available lack the necessary sophistication to provide such information. Therefore, in addition to describing basic requirements of a geographic approach, this project will focus on developing the requisite analytic techniques, using to the maximum degree data which is already available. Testing these analytic tools will be an important function of several case studies to be conducted in sites suspected of having unusually severe toxic problems.

The final report will summarize the utility of the geographic approach, drawing from past geographic analyses and the two case studies in addition to answering questions such as the following:

-How adequate are available data bases for routine geographic analyses?

-What are the appropriate roles of Federal, state and local governments in targeting analyses, in developing, and finally in implementing control options?

-How feasible is implementation of such an approach within EPA?

C. TIP Will Recommend Changes in a Number of Areas

1. The Most Promising Strategic Approach

The report will recommend criteria for when, based on our current knowledge, each strategy can best be used (e.g. when a particular chemical is of compelling health concern and to which there is wide exposure; when an industry emits many toxic pollutants whose regulation can most effectively and cheaply be accomplished collectively; where a localized pollution problem exists for which a national regulatory control would be inappropriate). If possible, the report will also suggest ideas for combining parts of two or all three strategies (e.g., an industry based regulatory strategy, but with intermedia work groups on top priority pollutants on the assumption that all of an industry's waste streams cannot be regulated cost-effectively; and with alternative control measures for high priority geographic problems.)

2. Implications of Strategy Choice.

This section of the report is perhaps the most important because it will articulate the management decisions and procedural changes necessary to implement the preferred integration strategy. This portion of the report will define an array of possible changes in statute, in organization, and in decision-making process. It will suggest criteria for applying the tools and making the policy judgments raised in earlier sections of the report, including such considerations as:

- o what rules to develop and when they should be issued;
- o what standards to use which consider cost or risk trade-offs and against which regulations should be evaluated;
- o how and when to evaluate intermedia effects and relationships.

The organizational implications of changes such as these might range from expanding the number of pollutant-specific and industrial workgroups, to creation of offices of specific industry regulation empowered to initiate all controls affecting that industry. The summary of legislative issues will highlight obstacles to implementation of the strategy.

3. Time Table

The report will present a timetable with options related to speed of implementation of the selected strategy or strategy elements. Gaps in necessary information will exist when the final report is prepared, and we will need more time before we understand the full implications of each strategic approach: that knowledge shortfall will brake immediate implementation. The Administrator, however, will be presented choices for EPA resource allocation and focus, legislative initiatives, allocations of authority, etc., which could determine the pace of integration activity.

D. The Report Will Present a Draft FY82 Toxics Integration Project Workplan.