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PART IV

COUNCIL ON ENVIRONMENTAL QUALITY

Toxic Substances Strategy Committee

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Work Plan

[6125–01]

COUNCIL ON ENVIRONMENTAL QUALITY

TOXIC SUBSTANCES STRATEGY COMMITTEE

Work Plan

The work plan for the interagency Toxic Substances Strategy Committee is published here for public comment. This committee was established in response to the President's request, in his Environmental Message of May 23, 1977, that the Council on Environmental Quality develop an interagency program to eliminate overlaps and fill gaps in the collection of toxic chemicals data and to coordinate research and regulatory activities affecting them. This committee will serve as the principal forum for the development of Administration initiatives with respect to government-wide toxic substances strategy and policy.

The Strategy Committee, whose membership is printed below as Appendix A of the work plan, is chaired by CEQ and includes representatives of all agencies with responsibilities for research, regulations or policy relating to toxic chemicals and their effects on human health and the environment. These include 16 member agencies, 5 component parts of the Executive Office of the President as official observers, and 1 interagency group (the Interagency Regulatory Liaison Group) as an ex officio member. These agencies carry out toxic substances responsibilities under at least a dozen major Federal statutes (see Appendix B of the work plan). Although many of the concerns of these agencies and their statutory responsibilities are similar, the various activities have often been developed relatively independently of each other. Some of the research, data and regulatory programs are well-established; some are very new or just now being developed. As demonstrated by several current coordination activities, most can provide useful input to one or more of the other programs; however, better and more effective means for such exchange need to be developed and implemented. In some cases, greater uniformity of approach or elimination of duplication is desirable; in other cases there are legitimate scientific, legislative or administrative reasons for multiple approaches, although these are not always fully understood or communicated to those affected.

The Committee is concerned with development of strategic approaches for carrying out Federal responsibilities in a manner that is both effective in achieving protection from the hazards of toxic substances in the environment and in minimizing unnecessary burdens on outside groups affected by Federal actions, the public, and agencies. Specifically, the Committee will take actions and make recommendations relating to Federal programs for the following:

Advancement of scientific and technical understanding of toxic chemicals problems, including research, testing and monitoring;

Data collection, recordkeeping, reporting and exchange;

Utilization of information and research results in regulatory and policy decisionmaking;

Establishment of mechanisms, plans and priorities for Federal response to potential and actual toxic chemical hazards, including regulatory and nonregulatory preventive measures and handling of toxic chemical crises.

In looking at strategies for identifying toxic chemical hazards relating to human health, an initial high priority task will be to develop a government-wide set of general principles relating to carcinogenesis.

The work plan published below covers the activities of the Committee to achieve its objective in 1978. At the end of this period the need for any further activities of the Committee will be re-assessed. Throughout this period the Strategy Committee welcomes and will solicit information and opinions from the general public, legislative bodies, State and local governments, and interested groups and parties such as industries, labor unions, environmental and consumer groups, and the scientific community. Publicly-held informal meetings with representatives of such groups are expected to begin in December. Later meetings, including ones for the general public, will be held to obtain needed information relevant to the various tasks and comments on proposed actions or draft reports.

At this time the Committee welcomes written comments on the work plan, particularly on the following matters:

1. Which of the areas within the scope of the Committee's concerns and work plan should receive the greatest attention (and why), and what are the priority first steps that might be taken?

2. What are realistic expectations of what should and can be accomplished by development of new Federal strategies for alleviation of toxic substances problems? What benefits would accrue? What are the likely barriers to be encountered in undertaking such efforts and how might these best be overcome?

3. What examples of past effective and ineffective Federal approaches to toxic chemical hazards should be especially noted in considering new strategies? (Please be as specific as possible in providing information or in citing studies or other information of which the committee should be aware, especially for sources outside the Federal agencies.)

4. What specific methods of improved communication might be established between Federal agencies (singly or collectively) and the general public or groups such as legislative bodies, State and local governments, industries, labor unions, environmental and consumer groups, and the scientific community?

5. What mechanisms now exist that are particularly effective (or ineffective) in coordinating the toxics-related activities among the local, regional, State and Federal levels, and what improved approaches should be initiated?

6. The Committee believes that it is vital to its success to have wide participation from all interests at issue in the toxic chemical hazards area. Please identify those groups, associations and others of which you are aware that should have the opportunity to participate in this Committee's activities. Please indicate the contact person and address, if available, and your perception of the nature of the interest of the party and the special information or perspective that it might provide to the Committee's deliberation.

DATE: Comments pertinent to this Committee and its activities are welcome at any time, but must be received on or before December 9, 1977, to be of utility in the pursuit of the major initial tasks of the Committee's work plan.

ADDRESS: Comments or requests for further information should be addressed to the Executive Secretary of the Toxic Substances Strategy Committee: Carroll Leslie Bastian, Senior Staff Member for Environmental Health and Toxic Substances, Council on Environmental Quality, 722 Jackson Place NW., Washington, D.C. 20006, telephone 202–633–7107.

GUS SPETH,
Member, Council on Environmental Quality (Chairman, Toxic Substances Strategy Committee).

TOXIC SUBSTANCES STRATEGY COMMITTEE—WORK PLAN

INTRODUCTION

ESTABLISHMENT AND MEMBERSHIP

The President's environmental message of May 23, 1977 established prevention of toxic substances problems as a high priority of his Administration and instructed the Council on Environmental Quality (CEQ) to develop a coordinated interagency Federal program for control of toxic substances:

The presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering the environment at all.

At least a dozen major federal statutes, implemented by seven different agencies, address this problem in various ways. With the enactment last year of the Toxic Substances Control Act, no further comprehensive federal legislation should be necessary. Now we must inaugurate a coordinated federal effort to exclude these chemicals from our environment.

I am therefore instructing the Council on Environmental Quality to develop an interagency program (1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) to coordinate federal research and regulatory activities affecting them.

Pursuant to the President's directive, the interagency Toxic Substances Strategy Committee has been established to develop a coherent Federal approach. Federal departments and agencies with major policy, research or regulatory responsibilities relating to control of potentially hazardous chemicals have been requested to participate. Members include representatives of the Department of Agriculture (USDA); the Department of Commerce; the Department of Energy (DOE); the Department of Health, Education, and Welfare (HEW), as well as four of its component agencies—Food and Drug Administration (FDA), the National

Cancer Institute (NCI), the National Institute for Environmental Health Sciences (NIEHS), and the National Institute for Occupational Health and Safety (NIOSH); the Department of Interior (DOI); the Occupational Safety and Health Administration of the Department of Labor (OSHA); the Department of State; the Consumer Product Safety Commission (CPSC); the Environmental Protection Agency (EPA); and the National Science Foundation (NSF). Representatives of the Office of Management and Budget (OMB), the President's Reorganization Project (PRP), the Office of Science and Technology Policy (OSTP), the Domestic Policy Staff, and the Council of Economic Advisers (CEA) are official observers. The Chairman of the Strategy Committee and Executive Secretary will be from the Council on Environmental Quality (CEQ).

A list of official members and their designated alternates is attached (Appendix A). Each agency will have one member and one official alternate, both at a high policy-making level. They may invite additional agency personnel to attend meetings of the Strategy Committee (with prior notification to the Executive Secretary) in order to advise on the various broad range of subject areas covered by the Committee. In addition, the lead agency for specific tasks and sub-tasks will request appropriate participation from the various agencies (which may or may not coincide with those participating in the activities of the full Committee). The lead agency should do so in consultation with the Executive Secretary of the Strategy Committee.

SCOPE OF STRATEGY COMMITTEE'S CONCERNS

The scope of the Committee's interests potentially includes those activities that pertain to hazardous or toxic man-made chemicals at every stage of their existence (testing, production, distribution in the environment, use, distribution in commerce, original and ultimate disposal); in the various sectors of the environment (workplace, home, general environment); and their deleterious effects (acute and chronic human health effects, non-human biological and ecological effects, physical/chemical effects such as ozone depletion). For the initial stages of work, concerns relating solely to radiation hazards, to physical and safety hazards, or to exclusively natural substances will be considered to fall outside the scope of the Committee's work, although they may be considered in any cases in which they are closely related to toxic substances concerns. Furthermore, although the adverse health effects from tobacco and alcohol are substantial, issues relating to these substances will not be initially addressed by the Committee. This narrowing of scope is one of expediency and practicality, as well as one of recognition of certain differences between such substances and ones to which exposure is less avoidable. Major statutes containing toxic or hazardous substances provisions within the scope of this Committee's concerns are listed in Appendix B.

OBJECTIVES OF STRATEGY COMMITTEE'S WORK

The Committee will serve as the principal forum for the development of Administration initiatives with respect to government-wide toxic substances strategy and policy. It will focus upon the sufficiency, effectiveness, and coordination of current Federal programs for understanding and addressing toxic substances problems. The Committee will implement appropriate changes in policy and strategy to accomplish its objectives, in such matters as are within its jurisdiction. In other cases it will make recommendations to appropriate decisionmakers, including the President. Actions and recommendations in the various areas of concern will result in written reports on particular subjects. In addition, the Committee will prepare a publicly-available summary report of its activities at the end of one year of effort.

The Committee will review and assess Federal activities relating to the planning, management and analysis of research; data and information gathering and utilization; toxic substances problem identification and prediction; and regulatory and non-regulatory measures for prevention and correction of problems. In doing so, the Committee will analyze specific known problem areas in order to focus on such broader questions as the following:

How should priorities be established for the level of effort and the timing of Federally-coordinated activities relating to particular chemical substances?

What gaps exist in the information base and in basic scientific and technical understanding that are desirable or necessary for rational Federal decisionmaking in regard to prevention and control of toxic chemical hazards? What measures should be taken to fill these gaps?

What unnecessary or undesirable conflict, confusion or duplication exists among the activities of the various agencies engaged in toxic substances-related work? What are the effects of these problems on the efficient use of Federal resources, on the public, and on the parties affected by Federal actions; requirements and regulations? What should be done (e.g. modification of agency missions and responsibility, organizational changes, improved coordination mechanisms) to minimize or eliminate these effects?

For those activities in which multiple or overlapping participation by several agencies is justified, desirable, or unavoidable, what coordination mechanisms exist or should be established to carry out Federal responsibilities most smoothly and efficiently?

Although the principal focus of the Committee's activities will be U.S. domestic strategies, the international dimension of these strategies will be fully considered in each of the Committee's tasks. Assistance will be sought from the State Department and the international affairs staffs of the various agencies in advising the Strategy Committee of the international implications of alternative U.S. strategies. They will also advise on ways by which U.S. policy initiatives can be reflected in U.S. participation in multinational and bilateral discussions of common and global toxics problems. Such advice to the Committee will be on a continual basis as the need arises. In addition, the State Department will be the lead agency for preparing recommendations (for the full Committee's consideration and adoption) of methods by which domestic activities relating to toxic chemicals can best be coordinated with related international initiatives.

Policy options to be adopted or recommended by the Committee may relate to Federal policies, procedures, decisionmaking processes, utilization of resources, organizational structure, and institutional mechanisms, and relationships with the public and with non-Federal groups. Development and review of the detailed documents necessary to implement such recommendations will be handled by the agencies in accordance with normal Federal practices.

RELATIONSHIP OF THIS COMMITTEE TO RELATED INTERAGENCY EFFORTS

1. Interagency Regulatory Liaison Group.

CEQ is encouraged by the recent formation of an Interagency Regulatory Liaison Group (IRLG), consisting of CPSC, EPA, FDA, and OSHA. This group is meeting regularly and frequently to examine common requirements and functions as they pertain to the regulation of potentially hazardous and toxic substances in their agencies and to develop ways to improve present interagency cooperative efforts as necessary. Their goal, in achieving better public health, is to coordinate their efforts in ways that will ensure more effective regulation and will lessen the administrative burden on the regulated industries, the public, and the agencies themselves.

The work of the IRLG and the Federal Toxic Substances Strategy Committee will be closely coordinated and is expected to be mutually compatible. Many of the IRLG activities will implement the objectives for which the Strategy Committee was established. In addition, the detailed work of the IRLG, which is related specifically to those four regulatory agencies, will provide a good background for the broader Federal-wide strategic considerations of the Strategy Committee. For example, the IRLG has agreed to assess research needs in support of regulatory activities, which cannot be fully addressed by the present inhouse capabilities of the four agencies.

2. Other interagency committees.

The Strategy Committee will keep in touch with the activities of relevant interagency groups and utilize their findings and reports wherever possible. Such groups include the TSCA Interagency Testing Committee (established by section 4(e) of TSCA); the *Ad Hoc* Interagency Toxic Substances Data Committee (and its successors); the Interagency Task Force on Environmental Data and Monitoring; the DHEW Committee to Coordinate Toxicology and Related Programs; and other more specialized committees relating to certain types of hazards, data, research or regulatory activities.

3. President's Reorganization Project.

Close liaison will be maintained between the Strategy Committee and the relevant divisions (Natural Resources, Human Resources, and Regulatory Reform) of the President's Reorganization Project (PRP) to avoid duplication of effort and to assure mutually compatible proposals and time schedules. Reorganization proposals which may emerge from the various tasks of the Strategy Committee will be developed in close coordination with the PRP.

DURATION OF STRATEGY COMMITTEE

The Committee is being convened initially for a period to extend through calendar year 1978. After completion of the Committee's initial reports CEQ will determine, in consultation with participating agencies, whether the Committee will continue its activities after 1978. In any case, this Committee's purpose will be to develop policy initiatives, not itself to operate programs.

METHOD OF OPERATION OF STRATEGY COMMITTEE

METHOD OF OBTAINING INFORMATION

The Strategy Committee's activities will focus upon three major areas of concern: Research activities, information and data activities, regulatory and non-regulatory approaches.

The Committee will obtain information on these matters from the interested public, from members of the Committee individually and collectively, from the output from tasks and sub-tasks coordinated by assigned lead agencies, and from review of previous relevant studies.

At the onset of its work, a strong effort will be made by the Committee to solicit the views and suggestions of the public and Congress. The Committee will publish its work plan in the FEDERAL REGISTER and invite comments on the scope and emphasis of the Committee's activities and on specific aspects

of the problem that should receive special attention.

Commentators will be encouraged to present their concerns in terms of known problem areas and how improvements might be made in the future, with reference to specific case histories as appropriate.

As work on specific tasks progresses, public meetings will be held for information gathering purposes as needed, and to obtain comments on draft reports and recommendations. Public participation at these stages may also include solicitations for comments in the FEDERAL REGISTER and by direct mailings.

Shortly after initiation of the Committee's activities and publication of the work plan, a series of initial meetings will be held with representatives of industry, environmental and other interest groups, State and local governments, and the scientific community. Appropriate members of Congress and congressional staff will be consulted concerning their perceptions of needs that led to the passage to TSCA and past and current issues affecting the Executive Branch that are associated with TSCA and other legislation. Informal liaison will be maintained with all of these groups throughout the duration of the Committee's activities.

MEETINGS OF THE STRATEGY COMMITTEE

Meetings of the full Strategy Committee will be scheduled by the Chairman. Additional meetings may be requested by any member agency.

ACTIVITIES OF SUB-GROUPS

Lead agencies have been assigned to the various tasks and sub-tasks of the Committee. The lead agency for a task will arrange for appropriate participation by other agencies and schedule the necessary meetings. The lead agency shall consult with the Chairman and/or Executive Secretary of the Strategy Committee concerning agency participation, work plans, timetables, and meetings. CEQ staff will assist the lead agencies in preparation of common formats and instructions for requests for information to the various agencies and in identification of findings from past studies and interagency efforts that are relevant to the tasks.

TIMETABLE

The Committee plans to take actions and to make reports on its various tasks during calendar year 1978, with an overall status report on all of its activities to be issued in the fall of 1978. Substantial progress on many of the tasks is expected by early 1978. The overall timetable of the Committee's activities and status reports will be distributed regularly to participating agencies by the Committee's Executive Secretary after consultation with the agencies involved in the various tasks. Member agencies plan to follow the schedule unless changes to that schedule are adopted by the Committee. Detailed work plans and timetables may also be needed for some of the tasks and will be developed by the lead agency, in consultation with participating agencies and CEQ.

Every effort will be made to meet major milestone targets, but some adjustments in interim deadlines may be adopted in order to provide earlier initial recommendations on priority topics identified in the course of the investigation, prior to completion of the full investigation; or in order to respond to changes in emphasis suggested during the course of consultation with the public; or in order to coordinate with the work of related committees and groups.

INITIAL STRATEGY COMMITTEE TASKS

I. RESEARCH ACTIVITIES

The Committee will examine the research roles of various governmental organizations; identify major areas of research that should be emphasized; determine how areas for priority attention are or should be selected; and recommend a basis and procedure for coordinating and carrying out such research and utilizing the results.

Task IA. Assessment of research roles and responsibilities (NSF lead). The first step of this task will be for each appropriate Federal agency to submit a report on its existing research priorities and programs of basic, applied and policy-relevant research, testing and monitoring to include the following subject areas:

(1) Dispersion, presence, transport, evolution and accumulation of toxic chemicals in the environment.

(2) Human exposures, including different routes of exposure, and human health effects of toxic chemicals, including individual variations in susceptibility.

(3) Mechanisms of action of toxic effects in man and experimental animals, and the development and testing of animal models that predict human health effects.

(4) Aquatic ecological and environmental effects of toxic chemicals, including effects on sport and commercial fisheries and freshwater or marine flora and fauna.

(5) Terrestrial ecological effects of toxic chemicals, including effects upon individual plant and animal species and upon ecosystems (e.g. agricultural crops, wildlife, grasslands, wetlands).

(6) Mechanisms for the prevention, mitigation or elimination of hazards caused by toxic chemicals.

(7) Impacts of alternative control measures, including socioeconomic effects.

(8) Miscellaneous other research, including programs covering more than one of the above categories, such as studies of the total effects of a given toxic chemical or class of chemicals.

These reports will be prepared according to common formats developed by CEQ staff (in consultation with NSF) and will be of a summary and analytical nature rather than be detailed inventories of individual research items. Topics to be covered concisely in the reports include the following:

Nature of charter or legislative mandate for the research activities;

Current and future research objectives and priorities and how these are established;

Methods for research planning;

Organization for research management;

Description of major research programs (and current and planned levels of effort) and appropriateness and adequacy of these programs;

Methods of funding research and research facilities and the resources available;

Mechanisms for quality control and evaluation of research;

Current and anticipated research management strategic problems;

Assessment of research coordinating mechanisms, within the agency, with other research activities within and outside the public sector;

Recommended mechanisms for research consideration and for linkages between research and regulatory programs.

The Interagency Regulatory Liaison Group will be looking at many of these same issues for its four member agencies. Following receipt of the above information from the IRLG and the other agencies, the lead agency for this task (NSF) with the assistance of other member agencies[1] will pull together the assembled information for each of the eight subject areas listed above and will prepare an analysis of the Federal-wide situation for the full Committee's consideration. This will be the basis for Committee actions and recommendations concerning the adequacy, quality and coordination of Federal research activities relating to toxic chemicals.

Task IB. Assessment of research activities in context of regulatory and policy needs (Strategy Committee lead, with input from IRLG). Insufficient linkage between regulators and researchers is an often-cited problem that has not been fully assessed. Regulatory agencies (IRLG) will outline their needs for research to support their decisionmaking that present research programs cannot fully address. The Strategy Committee will review its assessment of Federal research programs, roles and responsibilities (Task IA) and evaluate the ability of Federal research programs to meet regulatory and policy needs within a balanced overall Federal research program. The Committee will focus not only upon the provision of needed research and its adequacy but also upon ways to improve the incorporation of the results of such investigation into regulatory decisionmaking. Issues for particular attention include the following:

Present and desirable roles of regulatory organizations versus research organizations in the planning and design of research programs;

Mechanisms for coordination betwen researchers and regulators in both research planning and sharing of results;

Apportionment of research among various sectors of the research community (Federal laboratories, academic institutions, private profit and non-profit institutions);

Balance between short-term and long-term research;

Influence of regulatory timetables upon quality and design of research and its utilization;

Factors affecting the relative emphasis given to research relating to prevention of chemical hazards from entering the environment as opposed to mitigation of existing toxic hazards.

The Committee will establish priorities for improvements needed to carry out its recommendations.

II. INFORMATION AND DATA ACTIVITIES (CEQ LEAD)

The research, recordkeeping, and reporting requirements specified in the Toxic Substances Control Act of 1976 and in related authorities are extensive. These data requirements include information on production, testing, characterization, adverse reactions, exports, employment effects, health effects, and environmental effects. The production of these data involves the responsibilities of more than 32 Federal agencies. Moreover, enactment of TSCA has raised the expectation that now the many diverse Federal activities under various legislation can be coordinated in a comprehensive program.

If timely and accurate data are to be collected with the least possible burden on business, industry, and the public, steps must be taken to coordinate the planning and activities of the major Federal producers and users of chemical data. This coordi-

[1] E.g., OSTP and OMB on general analysis; Commerce on transport, HEW on health effects, Interior on aquatic effects, USDA on terrestrial effects, EPA on prevention mechanisms and impacts of controls, and others as appropriate.

nation will require a comprehensive inventory of what agencies are producing what data, by what means, and for what purposes. In addition, attention must be given to barriers that can impede interagency efforts and exchanges of information. Among those barriers are confidentiality provisions that protect identity and trade secrets; the lack of a standard method for classifying chemical substances and uses; and a lack of standard formats for reporting such items as the results of toxicological and epidemiological research.

Task IIA. Review of options paper on trade secrecy and confidentiality of trade secrets data. This task will be carried out for the Committee by a subcommittee on trade secrets and confidentiality (formerly a part of the Ad Hoc Interagency Toxic Substances Data Committee).

Current laws and practices restricting release of information by Federal agencies to other agencies and to the public and are not uniform. The subcommittee, assisted by CEQ staff, will prepare a report evaluating these laws and practices and presenting options for needed improvements, which will be the basis for the full Committee's actions and recommendations in this area. Issues to be addressed include the current ambiguities inherent in existing law on the definition of trade secret or confidential material, the need for uniform and fair criminal sanctions for disclosure of such information, and the implications of removing certain restrictions on interagency exchange of information.

Task IIB. Assessment of mechanisms for addressing information needs and their impacts (Strategy Committee lead, with input from Data Committee, IRLG and Commerce). The Strategy Committee will have the benefit of a report by the Ad Hoc Interagency Toxic Substances Data Committee (or its successor) concerning the needs of Federal agencies for various types of chemicals-related data; the adequacy of existing Federal data systems to meet those needs; and methods and policies for improved exchange of information among Federal agencies. The IRLG will study the area of reporting and recordkeeping requirements and will make recommendations for necessary follow-up; it will also be working on development of compatible testing standards and guidelines. Following review of these reports and activities, the Strategy Committee (with the special assistance of Commerce) will evaluate the adequacy of current efforts relating to chemicals information. The Committee will also look at the impacts on industry, environmental groups, and other interest groups of the various information requirements and programs.

III. REGULATORY AND NON-REGULATORY PREVENTION AND CONTROL APPROACHES

Federal authority over hazardous chemicals now extends over the entire life cycle of chemical products prior to production through disposal and for the first time permits the development of comprehensive preventive regulatory and non-regulatory strategies. Critical needs for design and implementation of such strategies will be addressed by the Committee, in close coordination with the IRLG. The IRLG has completed a review of statutes including triggering mechanisms and is reviewing mechanisms for regulatory action and suggesting regulatory priorities. In addition, the IRLG will look at gaps and overlaps in Federal labelling requirements. (The Strategy Committee will later determine, based on the IRLG's initial work, what further study is needed, if any, of coordination of labelling regulations or of the efficacy of labelling as a preventive toxics strategy.) The focus of the Strategy Committee's initial effort will be on the following tasks:

Task IIIA. Analysis of Historical Lessons as Background for Strategy Development (Committee/CEQ lead). The Committee with the assistance of CEQ staff will review various case studies that have been carried out by agencies, interagency groups, the National Academy of Sciences or others, which examined the governmental reaction to and handling of potential hazards of specific chemicals. The review will include information gathered in previous agency public hearings and congressional testimony, as well as information collected by this Strategy Committee in its own meetings with the public and representatives of interested groups. These case studies will be reviewed by the Committee for insights they provide into the coordination, uniformity and effectiveness of the current Federal approach to chemical hazards and as input into Committee findings and recommendations on such matters as the following:

Adequacy of mechanisms by which agencies seek out and become aware of potential future hazards at the earliest possible stage;

Methods for coordinated Federal determination of which chemical substances should receive what type and level of attention;

Once a potential hazard is identified for attention, what procedures are appropriate for gathering information on the extent and nature of the hazard and its effects; for planning and coordinating further research needed to fill information gaps; for establishing a proposed timetable and plans for decisionmaking; for developing policy options and assessing the likely impacts of those options; for considering factors other than health and safety in regulatory decisionmaking (e.g., availability of substitutes, product utility, impacts of regulation on industry, etc.); for obtaining and allocating resources for these activities; and for coordinating activities of multiple agencies;

Adequacy and effectiveness of present methods for involving the public in regulatory decisionmaking, including alerting the public to pending issues and providing for the participation of private citizens, state and local governments, industry, environmental groups, and other interest groups.

Task IIIB. Policies relating to common approaches for risk assessment (CEQ lead). The desirability of common approaches by Federal agencies to the scientific and technical assessment of certain risks is currently receiving increased attention within the Federal Government. It has been observed that differences in approach toward risk assessment among the regulatory and research agencies have posed barriers to effective cooperation in regard to specific substances and have resulted in some confusion in the regulated industries and among the public. Furthermore, the public dialogue concerning chemical hazards, particularly as they affect human health, has frequently been obscured by the lack of distinction made between scientific methods and principles relating to the detection and measurement of potential hazards on the one hand, and the social, economic, political, legislative, judicial and other factors affecting policy and regulatory decisions on what action to take in regard to a possible hazard once it has been identified. There appears to be a need for greater coordination of Federal agency approaches and for better communication of the reasons for these approaches to the public.

The initial high priority task of the Strategy Committee will be to develop a single set of general principles relating to carcinogenesis for government-wide adoption and use. These principles will be brief statements of the generally agreed upon ways that scientists and agency policymakers view the detection of carcinogenic risk, considering the limits of the present state of the art. For example, the principles would cover the appropriateness of the use of animal laboratory studies in predicting human health risk; handling of dose levels in regard to animal studies and extrapolation to various exposure situations; assumptions about dose-response relationships and threshold levels; the role of epidemiological studies, and others.

This is only a first step in addressing strategies relating to risk assessment. The general policies will need to be backed up by development of detailed policies and procedures, across agencies and within specific agencies. A Risk Assessment Work Group of the Interagency Regulatory Liaison Group is working on analysis and development of alternative procedures for characterizing and quantifying human health risks associated with regulated chemicals. This work will be taken into consideration by the Strategy Committee in addressing government-wide strategies and policies. Topics for the Strategy Committee's attention will be further defined following completion of the initial task on carcinogenesis principles and a review of the IRLG's progress at that time. Future efforts may involve attention to mutagenesis and/or teratogenesis in addition to carcinogenesis.

Task IIIC. Review of non-regulatory incentives for chemical substances control (Commerce lead). Opportunities to strengthen or introduce new non-regulatory approaches to encourage voluntary adoption of preventive practices include market disincentives or incentives (e.g., workers' compensation, tort claims), education and training (for workers and users of hazardous chemicals), consulting services (e.g., on test methodologies, control equipment, monitoring methods) and others.

This task will include the analysis of strengths and weaknesses of such mechanisms and the development of recommendations as to what measures are needed and what form they should take. This effort will be closely coordinated with and make use of the work on non-regulatory incentives being developed by the DOL–OMB task force on occupational health programs, the Interagency Regulatory Liaison Group, the Regulatory Reform Division of the President's Reorganization Project, and research projects of the various agencies.

Task IIID. Recommendations for handling of crisis chemicals (EPA lead). Recent events such as the Kepone and PBB incidents highlight the need for establishing a means for responding to unanticipated but inevitable chemical crises. This task will include identification of the long- and short-term needs for dealing effectively with such crises and an assessment of the adequacy of present Federal programs in meeting these needs.

Recommendations will be developed with respect to (1) mechanisms for mobilizing the diverse Federal resources currently available for assessing, abating, and preparing for contingencies and (2) the need for new authorities, interagency agreements, or other coordinating mechanisms to establish a responsive Federal program.

APPENDIX A—TOXIC SUBSTANCES STRATEGY COMMITTEE MEMBERS, OBSERVERS AND ALTERNATES

CHAIRMAN

Gus Speth, Member, Council on Environmental Quality, 822 Jackson Place NW., Washington, D.C. 20006, 633-7027.

EXECUTIVE SECRETARY

Carroll Leslie Bastian, Senior Staff Member for Environmental Health, and Toxic Substances, Council on Environmental Quality, 722 Jackson Place NW., Washington, D.C. 20006, 633-7107.

USDA

Rupert Cutler (Member), Assistant Secretary for Conservation, Research, and Education, Department of Agriculture, Room 212A Administration Bldg., Washington, D.C. 20250, 447-2796; Errett Deck (Alternate), Coordinator, Office of Environmental Quality Activities, 447-6827.

Commerce

Sidney Harman (Member), Under Secretary, Department of Commerce, Room 5840, Washington, D.C. 20230, 377-4625; Jordan Baruch (Alternate), Assistant Secretary for Science and Technology, 377-3111.

CPSC

S. John Byington (Member), Chairman, Consumer Product Safety Commission, Room 812, 1111 18th St. NW., Washington, D.C. 20207, 634-7740; Don Clay (Alternate), Acting Associate Director for Engineering, 492-6504.

EPA

Steven D. Jellinek (Member), Assistant Administrator for Toxic Substances, Environmental Protection Agency (TS-788), Room 637 East Tower, 401 M St. SW., Washington, D.C. 20460, 755-0310; Andrew W. Breidenbach (Alternate), Special Assistant to the Administrator, 755-0453.

DOE

James L. Liverman (Member), Acting Assistant Secretary for the Environment, Department of Energy, Washington, D.C. 20545, 353-5171; Charles Carter (Alternate), Manager, Biomedical Programs; Division of Biomedical and Environmental Research, 353-5468.

HEW

Julius B. Richmond (Member), Assistant Secretary for Health, Department of Health, Education, and Welfare, Room 5077 North Bldg., Washington, D.C. 20201, 245-7694; Lowell Harminson (Alternate), Special Assistant for Science, 245-6544.

FDA

Donald Kennedy (Member), Commissioner of Food and Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852, 443-2410; Richard Bates (Alternate), Associate Commissioner for Science, 443-3216.

NCI

Arthur C. Upton (Member), Director, National Cancer Institute, 9000 Rockville Pike, Bethesda, Md. 20014, 496-5615; James A. Peters (Alternate), Acting Assistant Director for Special Programs, 496-4963.

NIEHS

David P. Rall (Member), Director, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, N.C. 27709, FTS 629-3201, 910-549-8411 x3201; Raymond Shapiro (Alternate), Assistant Director, FTS 629-3201.

NIOSH

Jack Finklea (Member), Director, National Institute for Occupational Safety and Health, Room 3-30 Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20852, 443-1530; Kenneth Bridbord (Alternate), Director, Office of Extramural Coordination and Special Projects, 443-6437.

Interior

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NSF

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APPENDIX B—LEGISLATION WITHIN SCOPE OF TOXIC SUBSTANCES STRATEGY COMMITTEE

1. Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.

2. Food, Drug and Cosmetic Act, 21 U.S.C. § 301-392 (1938) (as amended).

3. Occupational Safety and Health Act, 29 U.S.C. 65 et seq.

4. Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.

5. Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 et seq.

6. Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.

7. Marine Protection, Research and Sanctuaries Act, 33 U.S.C. § 1401 et seq.

8. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 135 et seq.

9. Clean Air Act, 42 U.S.C. § 1857 et seq.

10. Federal Water Pollution Control Act, 33 U.S.C. 1351 et seq.

11. Safe Drinking Water Act, 42 U.S.C. § 300 (f) et seq.

12. Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq.

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