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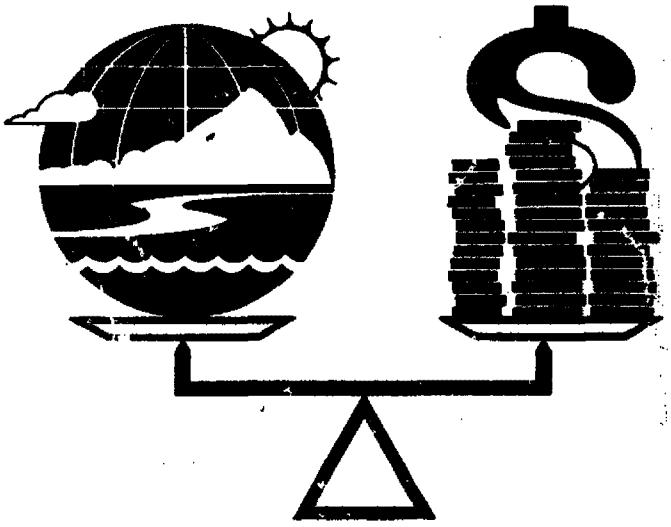
Using Risk Assessments in Policy Decisions



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USING RISK ASSESSMENTS IN POLICY DECISIONS

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The Environment Directorate of the Organization for Economic Cooperation and Development (OECD) has requested that each member country respond to a questionnaire about the use of risk assessment by its public authorities. This paper describes how the United States federal government has been using risk assessment in its public policy decisions.

Because of the broad scope of the OECD questionnaire and the limited time available for response, boundaries had to be established for the paper's coverage. The questionnaire defines risk assessment in terms of attempts to quantify the effects of exposures to individuals. At present, most risk assessment activities performed by government departments within the United States are qualitative, rather than quantitative. Many only identify potential human hazard rather than estimate how many people will be affected by the expected exposures. An attempt has been made to concentrate on quantitative risk assessments, so this paper is not representative of the distribution of types of risk assessment activities in the United States. However, it sometimes is not clear whether a full quantitative risk analysis was conducted, and several examples of more qualitative risk analyses are included.

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*Assisted by Marie Zack

The questionnaire and this paper exclude nuclear risks. In the United States, the Nuclear Regulatory Commission conducts risk assessments because of its responsibility to regulate nuclear reactors and other sites. Other agencies also regulate radioactive materials. Since this type of risk assessment is omitted from the paper, its description of the situation in the United States is incomplete.

The term "public authorities" includes those at the national, state, and local levels. In the United States, there is much cooperative action among these levels. Most of the states have their own environmental agency, public health agency, food safety agency, etc. Larger municipalities often have similar independent departments within their own government. For example, the U.S. Environmental Protection Agency (EPA) has initiated integrated environmental management projects for Philadelphia, Baltimore, and Santa Clara County. In these projects, the state and local governments of Pennsylvania, Maryland, and California are examining the risks from pollutants in each environmental medium (e.g., water, air) to identify the most important sources of risk and the optimal way of reducing these risks. Because, state and local efforts tend to be limited by shortages of funds and expertise, this paper concentrates on the national level.

The depth of information is uneven across types of risk and agencies covered in this paper. The focus is on risks from hazardous substances, whether at the work place or in the general environment. Some information is included for other types of risk, to

provide perspective. A second focus is on risks to people. Within the human health category, quantitative risk assessment (yielding estimates of the number of cases) has been developed far more for carcinogens than for noncarcinogenic toxicants. This is reflected in the paper, even though an attempt has been made to include risk assessments for all health effects.

The questionnaire defines risk assessment to include effects on the environment as well as effects on health. Less information is available for estimating ecosystem risks, although some ecosystem effects can be assessed by estimating changes in the productivity of particular species. Since so many organisms with complex ecological relationships are involved, it is not surprising that knowledge in this area is less developed. Sometimes risks to other significant aspects of society's well-being are evaluated. These include impacts on visibility, recreation, and material goods. A few examples of these other welfare effects are included.

"Use of risk assessment" can have multiple interpretations. At its most basic level, "use" can refer to methodological research designed to improve any of the four steps in the risk estimation process (hazard identification, dose-response assessment, exposure assessment, and risk characterization; [National Academy of Sciences (NAS), 1983, p.3]). Substantial efforts are under way by several agencies to assess and extend the state of the art in risk assessment and to examine research priorities (U.S. Department of Health and Human Services, 1985; Ehrlich, 1985; National Science Foundation, 1984; Risk Science Institute, 1985). At a more

practical level, "use by public authorities" refers to using estimates from risk assessments as input for policy decisions.

RISK ASSESSMENT AS PART OF THE POLICY DECISION PROCESS

A 1983 National Academy of Sciences report established a useful distinction between estimating what the health (or ecosystem) effects would be in alternative circumstances -- called risk assessment -- and selecting an action to address the problem -- called risk management. Thus, risk assessment estimates the magnitude of health and ecosystem effects; risk managers then decide how serious those effects are, and what to do about them.

Public authorities must make two types of risk management decisions. First, because of limited resources, they must set priorities among the many substances over which they have jurisdiction. To do this, they must first use some sort of risk assessment to identify those substances with the greatest relative hazard, so that they can be controlled first. Agencies have been criticized because their risk assessments for setting priorities appear to have been informal and not explained to the public. Some of this fuzziness in the process of setting priorities depends on how much control the agency has over the amount and quality of data available for the risk assessments used to screen substances (Field and McCray, 1983). For example, Section 5 of the Toxic Substances Control Act requires the Environmental Protection Agency to screen new chemicals before production begins. In its premanufacturing notification, the producer must provide any information on toxicity

that it can find, but the firm is not required to conduct any toxicity tests. Since toxicity data often are not available, this forces EPA to consider each new chemical on a judgmental case-by-case basis. The burden of proving that risk may exist falls on EPA. On the other hand, the pesticide program reflects a licensing statute and requires the manufacturer to conduct acute and chronic toxicity tests to obtain registration for a pesticide. In this case, the manufacturer bears the burden of proving that a product is "safe." If the test results exceed qualitative risk criteria set for acute and chronic health and environmental effects and the producer decides to pursue licensing, then the more elaborate weighing of benefits against risks is undertaken in response to EPA's issuing a "rebuttable presumption against registration."

The second major use of risk assessment is in decisions about what method and degree of control should be used for a particular risk. These risk management decisions often are regulatory in nature; they restrict the use of a substance or process in order to reduce exposures to hazardous situations. Other risk management activities are nonregulatory but are designed to lower risk by disseminating information, providing advice to other government agencies, educating the public, conducting emergency and remedial responses (to such things as industrial accidents, spills of dangerous materials, and abandoned hazardous waste dumps), and evaluating the effectiveness of specific risk management activities.

Risk management is only one component in a complex decision process. Ideally, the analytical tools used in risk management

will help determine the most efficient way to reduce risk. In addition to the number of cases reduced, the risk manager often must consider whether the proposed action simply shifts the risk elsewhere (e.g., to the land or air instead of water), whether its overall benefits exceed its costs, and whether the distributions of gains and losses are equitable. For the decisions discussed here, it generally is impossible to tell how important the role of risk assessment was, compared with the roles of other decision factors.

HOW MUCH RISK ASSESSMENT IS REQUIRED?

Actions by Congress, the courts, and the Office of the President have increased the use of risk assessment. Many of the laws passed by Congress to promote safety and protect public health and the environment require some balancing of benefits and costs. Even though risk assessment is not required explicitly by these laws, this balancing is impossible without predicting how risks will change under the proposed action. On the other hand, a few laws, such as the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide and Rodenticide Act, and the Consumer Product Safety Act, have explicit requirements for risk assessments.

Other laws call for mandatory controls once a hazard has been discovered, such as the banning of carcinogenic food additives under the Delaney Clause, and sections of the Clean Air Act that require "an ample margin of safety" in setting emissions standards. The resulting policy decisions clearly require the hazard

identification step, but the rest of the risk assessment process may or may not be used.

A third category of laws specifies that risks be controlled except when this is infeasible, perhaps because technology is not good enough. Examples include sections of the Clean Air and Clean Water Acts that require using "best available technology" and the section of the Occupational Safety and Health Act that requires using the most stringent standards that are "feasible." Hazard identification is essential for such policy decisions, and the additional steps in risk assessment can be used to evaluate the effectiveness of alternative control strategies.

The courts also have promoted the use of risk assessment. For example, in 1980 the Supreme Court struck down the Occupational Safety and Health Administration's (OSHA's) proposed standard for benzene, because OSHA had not demonstrated that the standard would significantly reduce risk. Even when the legislation does not require a risk assessment, this court action has led to an expectation that one will be essential for any court challenges. Similarly, a U.S. District Court decision (City of New York v. EPA, 543 F. Supp. 1084 (SDNY, 1981)) has required EPA to compare risks between ocean dumping of wastes and land-based alternatives, in decisions about issuing ocean dumping permits.

Most federal agencies have to conduct their own risk assessments as needed for policy decisions, since few statutes authorize agencies to require that the regulated parties do so. In general,

for premarket approval programs -- such as those for pesticides and for new drugs or food additives under the Federal Food, Drug, and Cosmetics Act -- the agency has the authority to require the submission of data for a risk assessment, while programs that must show activities to be hazardous before they can be regulated typically are responsible for acquiring their own data (Clement Associates, 1981).

The Office of the President has had an important influence on the use of risk assessment through Executive Order 12291. This order requires benefit-cost analyses of major regulations -- generally defined as those with an annual impact of at least $100 million. Regulatory impact analyses (RIAs) are to be conducted even when the benefit-cost comparison cannot be the basis of the regulatory decision. Part of the reason for a closer examination of regulatory benefits and costs is that firms have been quite vocal about the financial burden of the increased health and safety requirements over the past 15 years. Another part is that the most obvious problems were attacked first, so the incremental benefits of further risk reductions may be small. Advances in technology allow the detection of lower and lower levels of risk, and the accumulation of data shows that an increasing number of substances contain some danger. In practice, many RIAs have not included the full risk assessments needed for a complete benefits analysis.

Administrative law often provides for public participation and comment in regulatory decisions. In addition, some government decisions are made by the White House or Cabinet Council rather

than by the regulatory agency. Although not required to conduct risk assessments, the private sector or other government agencies may do so in order to influence the agency charged with the risk management decision. The sources and types of information on risk that are available to decision makers then are quite pluralistic, with contending interests providing alternative estimates of at least parts of the risk analysis. Risk assessments conducted outside the agency responsible for the management of that risk are not discussed separately in this paper. Instead, it is assumed that the agency incorporates such information in its decision process, and more attention is given to the risk estimates stated to be the basis of the regulatory decision.

GUIDELINES FOR RISK ASSESSMENT

Interagency Coordination

There have been several attempts to upgrade the quality of risk assessments by including state-of-the-art developments in methodology, and to make risk assessment approaches consistent within and across government agencies. Efforts to achieve interagency consistency have been most prominent when the same chemicals are under the jurisdiction of several agencies. For example, asbestos can be regulated under four agencies' programs, vinyl chloride under five, and DDT under two. Part of the reason for this is because each agency has its own constituency. Of the agencies regulating asbestos, for example, OSHA is responsible for protecting workers, the Consumer Product Safety Commission and the

Food and Drug Administration are responsible for protecting consumers, and EPA is responsible for protecting the populace from environmental exposures as well as protecting the environment. Much of this overlap among agencies occurs for carcinogenic substances. When managing risks such as those associated with automobiles, airplanes, or industrial accidents is primarily the responsibilty of a single agency, there has been less of a need for guidelines to ensure consistency among assessments for a particular type of risk.

The Interagency Regulatory Liaison Group (IRLG) was formed in 1979 by five agencies: EPA, the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), OSHA, and the Department of Agriculture (USDA). Their guidelines for identifying and estimating the risks of carcinogens were used widely by the IRLG agencies, although they never were adopted formally (IRLG, 1979).

In response to a congressional mandate, the National Research Council of the National Academy of Sciences (NAS) examined the use of risk assessment in the federal government (NAS, 1983). NAS recommended a clearer separation between the assessment of risks and evaluation of risk management alternatives. It suggested developing a set of guidelines that would indicate how agencies should choose among alternative methods for inferring human risk from limited data. NAS also recommended establishing an independent scientific Board on Risk Assessment Methods. The board would be responsible for assessing the evolving scientific basis for risk assessment, developing and periodically revising the guidelines for

risk assessment that would be used by federal regulatory agencies, evaluating the usefulness of the guidelines, and identifying research needs. However, diversity in the laws for which agencies are responsible, and the differences this implies for the scientific needs across agencies, led NAS to recommend that risk assessments continue to be conducted within the agencies, rather than by an independent risk assessment agency.

President Reagan's Office of Science and Technology Policy (1984) prepared an update of the principles and science of assessing carcinogenic risk. Its proposal includes policy statements about some scientific principles, but leaves most decisions about the selection and use of risk assessment methods to the agencies. During the same time period, then EPA Administrator William Ruckelshaus set up a successor to the IRLG, called the Interagency Risk Management Council. It was to draft its own cancer guidelines and reproductive toxicology guidelines, and coordinate several specific risk management activities across agencies. However the council is inactive at present.

Intra-agency Guidelines

Some individual regulatory agencies have developed risk assessment guidelines for their own use. For example, FDA (within the Department of Health and Human Services (DHHS)) developed acceptable daily intakes for noncarcinogenic substances by applying safety factors to no-observed-effect levels of exposures from laboratory experiments (Lehman et al., 1959). Although FDA has not

adopted formal guidelines for risk assessment, it continues to use this approach for noncarcinogenic food additives, and other agencies use the approach for pesticides and some exposures to occupational and environmental contaminants. More recently, DHHS prepared a document stating policy for the generic use of risk assessment and establishing a boundary separating risk assessment and risk management for all DHHS agencies (DHHS, 1985).

EPA was the first agency to publish internal guidelines for assessing carcinogenic risk (EPA, 1976). It has published updates as new information has become available. The most recent version was proposed in 1984, and was accompanied by proposed guidelines for assessing exposure, mutagenicity risk, and risks from developmental toxicants (EPA, 1984). Shortly thereafter, EPA proposed guidelines for assessing the health risks of chemical mixtures (EPA, 1985a). These five sets of guidelines have been reviewed by EPA's Science Advisory Board, and currently are undergoing final review by EPA and the Office of Management and Budget. EPA also is developing guidelines for assessing risks to male and female reproductive systems, and for making and using exposure measurements.

Other agencies are moving toward using additional steps in the full risk assessment process. For example, in response to recommendations from the NAS and the General Accounting Office, the Food Safety and Inspection Service (within the U.S. Department of Agriculture) is developing an approach for using a hazard index with an exposure index to assess the risks of food ingredients.

DIFFICULTIES OF CONDUCTING RISK ASSESSMENTS

Regardless of whether guidelines are available, risk assessment typically is a complex and costly process. Data often are not ideally suited for the needs of a particular risk assessment. It may be difficult to predict the physical phenomena that will lead to the release or creation of a particular toxicant, or to a particular type of accident. Once released, there often are gaps in the scientific understanding of how a contaminant will move through the air, water, and land, and how it will be attenuated by other influences before it reaches people or the ecosystems of concern. Typically, the dose-response function must be extrapolated far below the responses observed for the exposures used in laboratory animal tests. Since ethical considerations usually preclude experiments with humans, some conversion must be made to find the human dose that is equivalent to the doses used in the experimental animals. Even when epidemiological data are available, it often is difficult to draw inferences for the exposure levels being considered for regulation (Fisher, 1982). Similar problems often exist for assessing accidental risks, in terms of predicting their probability, magnitude, and impacts on people and the environment.

These gaps in our scientific understanding and data limitations imply that it is difficult to conduct a good risk assessment. It is no surprise that they vary in quality. The many stages where judgment must be applied make it very easy for the results to substantially overestimate or underestimate the unknown true risks. Because a government agency's mandate typically is to protect the

public, or to be safe rather than sorry, the cumulative effect of these conservative assumptions may be very large. The resulting risk estimates often are treated as plausible upper bounds. Unless the uncertainty associated with each assumption is stated, risk managers often view these risk estimates as actual risks.

Some gauge of the expected error can be developed by identifying those stages of the analysis where the uncertainties are greatest, and then conducting a sensitivity analysis to see how important errors in those stages would be for the final estimates. Of course, this also can pinpoint where better information would have the greatest pay-off in terms of improving the risk assessment.

USES OF RISK ASSESSMENT

This summary follows the broad outline of the OECD questionnaire, which divides risks into five categories. These are accidental risks, continuous risks, risks occurring in managing natural resources, risks from dangerous installations, and risks associated with alternative strategies for managing hazardous wastes. Attempts were made to categorize the activities properly, but there is considerable overlap in some of these non-exclusive categories.

Accidental Risks

Some contamination occurs more or less continuously, while other contamination results from sudden incidents, or accidents. This section describes activities using risk assessment to control the risks associated with accidents.

U.S. Environmental Protection Agency

At present, there are few risk assessments for manufacturing accidents. Huguenin, Pich, and Elkind (1985) found very few published studies with quantitative risk assessments of chemical manufacturing and associated activities. Of the ones available, most seem to have been conducted to assist in the firm's decision process, rather than for public authorities (e.g., Boykin, Freeman, and Levary, 1984). The studies generally consider the risks of storing or transporting chemicals, rather than the risks of manufacturing or processing them. The risks examined usually are the effects of fires and explosions, rather than potential toxic effects. Huguenin, Pich, and Elkind were able to find only a total of eight studies assessing the toxic risks from storage releases, which include the chemicals ammonia, chlorine, acrylonitrile, sulfur trioxide, and hydrogen fluoride. They found only one risk analysis of chemical manufacturing, and that was for the Netherlands. This indicates a serious information gap, since preliminary analysis of historic release incidents suggests that releases from processing operations are about as large and occur about as often as releases from stored chemicals. It is relatively difficult to conduct risk assessments of process operations, because safety systems and operator procedures and errors tend to differ across plants yet will influence failure rates and quantities released. Much of this information may be proprietary, which would help in explaning why the literature is so sparse.

EPA is working to fill some of the gaps for accidental risks. For example, the Acute Hazardous Events Data Base recently has been assembled to provide information about dangers to the U.S. public and workers from sudden accidental releases of toxic substances (Industrial Economics et al., 1985). This data base was designed to provide perspective on recent accident history in the United States, but is not sufficient as a basis for nationwide estimates of frequencies of events, amounts released, or their consequences. Most of the 3,121 records in the data base are for 1983 and 1984. Although the records report the number of injuries and deaths, most do not have specific information on causation. However, releases of chlorine, ammonia, hydrochloric acid, or sulfuric acid occurred in over one-fourth of the events leading to deaths, and the class of industrial organic chemicals had the most events with deaths. Releases associated with deaths varied from small to large, and inherent toxicity was not uniformly high. Toxicity seems to have caused most of the injuries reported, while fires and explosions are associated with most of the deaths. One-fourth of the events in the data base are transportation releases, accounting for one-third of death or injury events. These shares may change when the data base is expanded to include more records.

An effort to respond to risks from accidental releases of toxic chemicals is EPA's Chemical Emergency Preparedness Program (CEPP). EPA's Science Advisory Board assisted the Office of Pesticides and Toxic Substances (OPTS) in setting up criteria so that companies and communities could identify what chemicals are

of most concern and how to prevent or respond to their accidental release. The criteria rely primarily on acute toxicity effects, with consideration of volume and chemical properties such as flammability, reactivity, and the potential for explosion. EPA has issued a list of 402 chemicals that are considered to be hazardous. EPA's Superfund Office provides site-specific guidance to communities, with OPTS examining the possibilities that the substances will vaporize and how far the plume will travel and be of concern. This does not constitute the full risk assessment process, since the focus is on hazard identification and the number of potential cases is not estimated.

National Environmental Policy Act

The National Environmental Policy Act (40 CFR 1500-1508) requires U.S. federal agencies to prepare an environmental impact statement (EIS) for major federal actions significantly affecting the quality of the human environment (section 102(2)(c)). Examples include issuing federal permits for construction, agency land management plans, and federal construction projects. A larger share of EISs have included risk assessments in the past few years, reflecting the increased use of risk assessment in the regulatory process. When an EIS contains a risk assessment, it usually provides the federal decision maker with an estimate of broadly defined environmental consequences of the proposed action and a range of alternatives. For example, EPA prepares such an EIS as part of its decisions about designating sites for ocean disposal. Each EIS is made available in a public review process.

Many of the EISs that include some form of risk assessment are concerned with accidental risks in energy production. For example, the U.S. Army Corps of Engineers (1984a) evaluated the probability of an oil spill and effects on nearby sensitive ecosystems for the Endicott hydrocarbon development project. For the Georgetown refinery, the Corps (1984b) assessed the effects of a potential oil spill from transportation and operating activities. The U.S. Federal Energy Regulatory Commission's (1983) risk assessment for a natural gas storage plant analyzed the potential for pipelines to rupture. The U.S. Bureau of Land Management (1983a) examined the probabilities of natural gas well blowout and pipeline rupture and the effects on people of H_2S gas. In analyzing the sale of oil and gas leases, the U.S. Mineral Management Service (1983) assessed the individual and joint probabilities of oil spills and the resulting impacts on target ecosystems. The EISs tend to emphasize ecosystem effects, but they also consider human health effects.

Department of Energy

The U.S. Department of Energy (DOE) is completing a facility at the Nevada Test Site that will allow simulation of how winds and gravity affect large scale releases of cryogenic or pressurized flammables, toxic substances, and heavy gas (U.S. DOE, no date). The facility is designed to provide information for risk assessment, regulation, plant design, plant siting, and hazard mitigation. An extensive sensor and data system is available to acquire data on spill characteristics such as rate, volume, temperature and

pressure, [illegible] gas concentration and aerosol characteristics, meteorological parameters, and blast or fire effects.

The facility will provide a site for research and development funded by the private sector although the government agencies also may use it. The user is to coordinate with DOE and provide the funding necessary to perform the work. Although some customers already are waiting to use the facility, no specific plans have come forth to use it for risk analysis.

DOE uses probabilistic risk assessments in many of its activities for planning facilities. Periodic safety analysis reports (SARs) assess risk (probability x hazard) in facility siting and design. DOE requires SARs for its new facilities and major modifications of its existing facilities. Several existing facilities have been evaluated with SARs, including its national laboratories. DOE also is conducting environmental surveys for its facilities. These surveys will allow priorities to be set for problems at DOE sites, based on relative risks to humans as modified by other considerations such as ecosystem damages.

Continuous Risks

EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Department of Agriculture's Food Safety and Inspection Service, and the Occupational Safety and Health Administration (OSHA) are responsible for controlling risks caused by the continuous or repetitive release of pollutants in the environment. Some of them are responsible for addressing the risks

of natural contaminants (such as aflatoxin) or the risks of certain manufacturing practices or additives in food. These responsibilities and some recent decisions are summarized in this section. In order to provide a context for risk estimates, it is helpful to know that there are about 235 million people in the United States. Many of the estimated risks are for cancer. About 472,000 people in the United States are expected to die from cancer in 1986. Roughly 930,000 will have cancer diagnosed for the first time, and about 2 million people have active cancer at any point in time.

U.S. Consumer Product Safety Commission

CPSC regulates consumer products under the Consumer Product Safety Act and the Federal Hazardous Substances Act. The CPSC staff submits risk assessments and other information to the Commission for use in deciding whether to seek mandatory or voluntary standards or to deal with the issue in some other way. These risk assessments become part of the Commission's public record. Only a few of the continuous risks summarized in Table 1 are discussed in this section.

In 1974, CPSC estimated that 6,000 cancers per year would result from the continued use of 200 million spray cans produced annually between 1968 and 1973 with vinyl chloride as a propellant. Even though more cost-effective chlorofluorocarbon propellants were being adopted, CPSC banned the use of vinyl chloride in household aerosol products. When the ban became effective, only about one

Table 1
Consumer Product Safety Commission Decisions

Substance	Type of Risk	Action
Vinyl chloride (propellant)	Cancer	1974: banned use in household aerosol products.
Tris (flame retardant)	Cancer	1977: banned sale of children's garments treated with Tris.
Asbestos fibers	Cancer	1977: banned patching and joint compounds, and artifical emberizing materials, containing asbestos.
Asbestos fibers (other products)	Cancer	1985: aggregate risk estimate of less than 10 cancers per year. Recommendation has not been determined.
Benzene (paint removers)	Cancer	1978: proposed ban on consumer products containing more than 0.1% benzene. 1981: withdrew proposal.
Benzidine dyes and congeners in home dying products	Cancer	Manufacturers voluntarily removed benzidine dyes, and all but one have removed benzidine congener dyes from home dyes.
Nitrosamines in rubber pacifiers and nipples	Cancer	1984: banned rubber pacifiers containing nitrosamine levels higher than 60 ppb (which is consistent with FDA action on rubber nipples).
Urea formaldehyde foam insulation	Cancer	Ban prevents 13 cancers per year.
Methylene chloride	Cancer	Now estimating risks from paint strippers and aerosol paints.
DEHP	Cancer	Industry reportedly has removed DEHP from many children's products; staff is reviewing proposed voluntary standard for pacifiers and teethers.

million cans per year remained to be subject to the action, for an estimated saving of 26 cancers per year. (Most consumer uses of chloroflurocarbon propellants were banned subsequently by EPA and FDA, in cooperation with CPSC.)

In 1977, in response to its estimate that 540 cancers per year year would result from 25 million children's sleepwear garments, the CPSC determined that Tris was banned under the Federal Hazardous Substances Act. Some manufacturers already had eliminated Tris from their products in response to information about the cancer hazard.

Also in 1977, CPSC banned patching and joint compounds containing asbestos for use in wall repairs and dry wall construction after estimating that 680 cancers per year could result from exposure to 40 million five-pound packages. Since then, several other products containing asbestos have been studied by CPSC. Their aggregate risk is small because the use of these products is low and declining. CPSC is considering what additional action, if any, it will take for these products.

CPSC estimated 615 cancers per year would result from benzene in the 1974 formulations of paint removers. By 1978, most producers had switched to methylene chloride, reducing the risks from benzene to 22 cancers per year. In 1981, producers no longer were using benzene in paint removers and CPSC withdrew the proposed ban. Methylene chloride is a less potent carcinogen than the benzene for which it has been substituted, and CPSC is now estimating the risks from its wide use in paint strippers and spray paints.

Although urea formaldehyde foam insulation had been installed in 550,000 homes, with more than a million people estimated to be exposed, CPSC's ban of new installation was estimated to prevent 13 cancers per year. This does not include other acute and chronic health effects that would be prevented. (After a year, the ban was vacated by the 5th Circuit Court of Appeals.)

The Commission's staff also estimated the health effect potential from pressed wood materials made with urea-formaldehyde (fiberboard, particleboard underlayment, and hardwood plywood wall paneling) and used in the construction of single family detached houses. About 24 percent of new houses include some of these pressed wood materials. The 95 percent upper confidence limit estimates indicate an excess risk of 19 to 143 cases per million people exposed. Based on the number of houses built each year, up to 34 excess cancers per year are estimated. The pressed wood industry appears to be taking action to reduce emissions. The CPSC is considering what, if any, additional action is needed.

The plasticizer DEHP has been used for a long time in many polyvinyl chloride products. Studies demonstrated that this carcinogen could leach out of the products and be absorbed readily through ingestion. This led to CPSC concern about vinyl pacifiers, with risk estimates of up to 7 cancers per million live births if all babies use pacifiers containing DEHP. There are about 3.6 million births per year in the United States. The industry reportedly has removed DEHP from nearly all vinyl pacifiers and teethers and is preparing a voluntary standard.

U.S. Environmental Protection Agency

EPA is the U.S. agency with the broadest range of responsibilities for controlling continuous risks. Its programs cover contaminants in the air, water, and land, and include the production of toxic substances, the use of pesticides, and the fate of hazardous wastes. Table 2 lists EPA's regulatory impact analyses (RIAs). Many of these RIAs include risk analysis. However, some of the RIAs that have analyzed risk include only parts of the risk assessment process. In addition, risk assessment sometimes is used in decisions that do not require RIAs. Background documents often are available for these risk assessments.

Perhaps the most extensive use of risk assessment within EPA has been in its air program decisions. Its first use was in the air toxics program, for developing National Emission Standards for Hazardous Air Pollutants (NESHAPs). Decision makers wanted to know whether a particular level of control would eliminate unreasonable risks -- in terms of both aggregate population risk and maximum individual risk. Quantitative risk estimates were not used in setting NESHAPs in the early 1970s for mercury, beryllium, and asbestos. Quantitative risk estimates were used first in setting the vinyl chloride NESHAP in 1976 and have been fundamental to recent risk management decisions on NESHAP actions for benzene, arsenic, and radionuclides.

The role of risk assessment has led to substantial changes in regulations proposed for benzene. For example, a 1980 analysis of emissions from maleic anhydride plants predicted a cancer about

Table 2
EPA's Regulatory Impact Analyses

Air

Listing of Surface Coal Mines for New Source Review, September 1985, draft.

National Ambient Air Quality Standards for Particulate Matter, March 1983.

National Ambient Air Quality Standards for Sulfur Dioxide, forthcoming.

National Ambient Air Quality Standards for Carbon Monoxide, July 1985.

National Ambient Air Quality Standards for Nitrogen Dioxide, June 1985.

Costs and Benefits of Reducing Lead in Gasoline, February 1985.

Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines, March 1985.

Radiation

Final Environmental Standards for Uranium Mill Tailings at Active Sites, September 1983.

Economic Impacts of 40 CFR 191: Environmental Standards for Management and Disposal of Spent Nuclear Fuel and High Level, Transuranic Radioactive Waste, August 1985.

Draft Economic Analysis: Proposed Rules for Radon-222 Emissions from Licensed Uranium Mills.*

Water

Effluent Limitation Guidelines Regulation for the Iron and Steel Industry, March 1982.

Water Quality Benefits of the BCT Regulations for the Pulp and Paper Industry, July 1985, draft.

An Economic Assessment of the Benefits of the Proposed Effluent Limitation Guidelines for Organics and Plastics Manufacturers, September 1984.

Table 2 (Continued)

Proposed Regulations to Control Volatile Synthetic Organic Chemicals in Drinking Water, May 1985.

An Economic Assessment of Reducing Fluoride in Drinking Water, November 1985.*

Solid Waste

Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan, February 1982.

Proposed Standards for the Management of Used Oil, November 1985.

Regulatory Analysis of Proposed Regulations under RCRA for Small Quantity Generators of Hazardous Wastes, June 1985.

Reportable Quantity Adjustments under Sections 102 and 103 of CERCLA, March 1985.

Risk and Cost Assessment of Hazardous Waste Incineration Regulation, 1984, draft.

Regulatory Analysis of Proposed Restrictions on Land Disposal of Hazardous Wastes, December 1985.

Regulatory Analysis of Proposed Restrictions on Land Disposal of Certain Dioxin-Containing Wastes, January 1986, draft.

Regulatory Analysis of Proposed Restrictions on Land Disposal of Certain Solvent Wastes, January 1986, draft.

Toxics

Proposed Regulation of Glycol Ethers, June 1985, draft.

Proposed Rule on the Use of Nitrites in Metalworking Fluids, September 1985, draft.

Final Rule for Nonsubstation PCB Transformers, June 1985.

Final Rule Regulating Inadvertent PCB Generation for Uncontrolled Sources, April 1984.

Final Rule for PCB-Containing Electrical Equipment, July 1982.

Controls on Asbestos and Asbestos Products, August 1985.

* Indicates reports are not formally designed as RIAs.

Table 2 (Continued)

Pesticides

Economic Analysis of Regulations Implementing Certain Portions of FIFRA, Section 3, Concerning Registration of Pesticides, May 1982.

Proposed Rules Governing RPAR Proceedings: Criteria for the Initiation of RPAR Proceedings, May 1982.

RIA of 40 CFR, Part 166: Emergency Exemption Regulation, February 1985.

Data Requirements for Registering Pesticides under the FIFRA, August 1982.

every two years, leading to proposed controls that would reduce the health effects to one cancer about every ten years. Significant changes then occurred in the industry structure and the controls that were in place. A reevaluation in 1984 yielded an estimate of existing emission levels causing one cancer about every 35 years, leading EPA to withdraw its 1980 proposal. Similar analyses for ethylbenzene/styrene plants and benzene storage vessels led to the conclusion that risks to public health are small from these categories of emissions and that there are no significant health benefits from controlling them.

EPA takes several steps before promulgating a NESHAP, and several chemicals are somewhere in this process. Table 3 lists 22 recent decisions relying on risk assessment in the air toxics program, many of which rely on quantitative risk assessment. The one that is closest to final action -- aside from those where the decision is not to regulate -- is the listing of coke oven emissions, for which a NESHAP now is being prepared. (However, RIAs are not prepared for NESHAPs, since they are not classified as major regulations.)

Perhaps the most interesting NESHAP is the proposed rule for inorganic arsenic emissions from copper smelters. On the cost-effectiveness criterion, the proposal calls for using the best available control technology on six of the 14 existing smelters emitting inorganic arsenic, which would save 0.23 lives each year (see Table 4). Since this proposal might mean no additional controls on some smelters that could pose greater health risk, EPA asked for comment on two alternatives.

Table 3
Status of Decisons on Air Toxics

CHEMICAL	ACTION	DATE
Acrylonitrile	Referral	June 1985
1,3-butadiene	Intent to List	October 1985
Cadmium	Intent to List	October 1985
Carbon Tetrachloride	Intent to List	August 1985
Chlorofluorocarbon 113	Not to Regulate	June 1985
Chlorinated Benzenes	Not to Regulate	August 1985
Chloroform	Intent to List	September 1985
Chloroprene	Not to Regulate	September 1985
Chromium	Intent to List	June 1985
Coke Oven Emissions	Listing Notice	September 1984
Epichloronydrin	Not to Regulate	June 1985
Ethylene Dichloride	Intent to List	October 1985
Ethylene Oxide	Intent to List	October 1985
Hexachlorocyclopentadiene	Not to Regulate	October 1985
Manganese	Not to Regulate	August 1985
Methyl Chloroform	Not to Regulate	June 1985
Methylene Chloride	Intent to List	October 1985
Perchloroethylene	Intent to List	December 1985
Polycyclic Organic Matter	Not to Regulate	August 1984
Toluene	Not to Regulate	May 1984
Trichloroethylene	Intent to List	December 1985
Vinylidene Chloride	Not to Regulate	August 1985

Table 4
Analysis for Inorganic Arsenic Provides Additional
Criteria for Regulatory Decisions

Regulatory Criterion	Number of Regulated Plants	Annualized Controlled Costs (10^6)	Highest Remaining Individual Risk	Lives Saved Per Year	Implicit Cost/Life Saved (10^6)
Cost-Effectiveness	6	8.6	3.8×10^{-3}	0.23	37
Population Density	3	3.4	3.8×10^{-3}	0.22	15
Risks to Individual and Total Population	5	7.9	3.8×10^{-3}	0.39	20

Source: U.S. Environmental Protection Agency. "National Emission Standards for Hazardous Air Pollutants: Proposed Standards for Inorganic Arsenic." 48 Federal Register 33112-33180, July 20, 1983.

The first alternative would require controls for plants in areas with high population density and inorganic arsenic emission rates greater than 25 kg/hr. Plants in lower density areas would have to install the controls only if their emissions exceeded 35 kg/hr. Only three plants would have to install controls, and 0.22 lives would be saved each year. In the second alternative, the only sources controlled would be those with unacceptable combinations of maximum individual risk and population risk. The hypothetical combination described in the regulatory package would lead to control on five smelters, yielding the same maximum individual risk as the proposal and the first alternative, but saving 0.39 lives per year. Because different plants would be regulated under each option, Table 4 shows that the cost per life saved varies substantially across options, even though the maximum individual risk stays the same. This shows how risk assessment can be used to illustrate the real trade-offs that must be made in such regulatory decisions.

Six contaminants (carbon monoxide, lead, ozone, nitrogen dioxide, particular matter, and sulfur oxides) have been designated as criteria pollutants, and National Ambient Air Quality Standards have been set for them. The Clean Air Act is relatively explicit about how EPA must deal with criteria pollutants, but some form of risk assessment is beginning to be used for the periodic reviews of these ambient standards. For example, the risk assessment methodology for the lead standard review recently was reviewed by EPA's Clean Air Scientific Advisory Committee, and the ozone risk assessment is underway.

EPA also regulates air pollution from mobile sources. The RIA for the recently proposed regulations for particulate emissions from heavy-duty vehicles includes health benefit estimates based on predictions of cancer and noncancer morbidity and mortality. It turns out that benefits from improved visibility and reduced soiling are higher than the benefits from decreased health damages for this regulation. This illustrates the importance of including all categories of damages, rather than concentrating solely on human health damages.

Another important risk assessment was conducted as part of the RIA for reducing lead in gasoline. Lead has been a common gasoline additive to reduce engine knock and valve wear. However, evidence has accumulated that the level of lead in human blood is closely related to the amount of lead used in gasoline. Lead has been shown to cause anemia, behavioral disorders, mental retardation and nerve damage in children; adult symptoms range from headaches and irritability to stupor, coma, and brain damage. Table 5 shows estimates for the health benefits for the first few years of the lead phasedown. The numbers are smaller for the first year because the standard was lowered from 1.1 grams per leaded gallon (gplg) to 0.5 gplg for only the second half of 1985, and because the standard was tightened further to 0.1 gplg at the beginning of 1986.

EPA recently estimated that 75-80 cancers per year are caused by the combined effects of benzene and gasoline vapors that are released when vehicles are refueled. Although the analysis orig-

inally focused on the volatile organic compounds released in gasoline marketing, it now appears that the regulatory decision may place more weight on the rather substantial ozone releases that accompany gasoline refueling. At this time, EPA is considering a nationwide on-board strategy to control refueling emissions.

Under the Toxic Substances Control Act (TSCA), EPA can prohibit, restrict, or regulate the use of any substance that presents "an unreasonable risk of injury to health or the environment." Risk analyses recently were used to make decisions about priorities under Section 4 of TSCA. The compounds 4,4-methylenedianiline and 1,3-butadiene were found to pose risks primarily in the work place, and EPA has formally referred these to OSHA for action. Also on the basis of (low) risk estimates, EPA informally referred formaldehyde to OSHA.

A combination of risk and economic analyses for glycol ethers showed that they should be banned for consumer use but regulated for industrial use, because of their teratogenic and reproductive risks. EPA's Office of Toxic Substances (OTS) is preparing a formal referral to OSHA for these substances. OTS also has examined the use of nitrites in metal-working fluids where they can form carcinogenic nitrosamines. It may propose a ban, acccompanied by a request for comments since the cost per case avoided is very high for some industries. The language of TSCA has been interpreted to call for balancing the health benefits of restricting chemicals with the costs imposed by the restrictions.

Table 5
Impacts on Adverse Health Effects as Lead Is Reduced in Gasoline

	1985	1986	1987
Reduction in number of children having more than 25 micrograms per deciliter in blood	64,000	172,000	156,000
Reductions in blood-pressure-related effects in males age 40-59*			
Hypertension	547,000	1,796,000	1,718,000
Myocardial infarctions	1,500	5,323	5,126
Strokes	324	1,109	1,068
Death	1,497	5,134	4,942

*Since the study reporting adult health effects had not completed the peer review process when the phasedown decision was made, only child health effects were considered (along with reductions in conventional pollutants, maintenance savings, and improved fuel economy) on the benefit side of the analysis.

OTS also used risk analyses for decisions about PCBs. In addition to the ban on new uses of PCBs, OTS recently issued control regulations for existing high-voltage transformers that could fail and become involved in fires.

EPA's risk assessment for asbestos considered only lung cancer and mesothelioma, omitting asbestosis. Excellent epidemiological information is available for these health effects, compared with that for many other dangerous substances. The asbestos analyses recognize that OSHA may change the occupational exposure standard from two fibers per cubic centimeter (f/cc) to 0.5 or 0.2 f/cc, so risks are estimated under all three potential standards. The number of cases avoided was estimated for each of eight control options and for banning 32 products. The asbestos ban and phase-down rule proposed in January 1986 is estimated to prevent a total of 926 cancers under the more stringent occupational exposure standard. Without EPA's proposal, it is estimated that 1,325 cancers would occur. If OSHA does not tighten the occupational exposure standard, then EPA's proposal is estimated to avoid 1,854 of 2,562 cancers.

EPA also uses risk assessment extensively in its pesticides program. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires EPA to examine whether the risks from using a pesticide are worth the economic benefits (such as increased crop yields or lower costs of achieving a given crop yield). Risks considered range from those affecting endangered species to human cancer effects.

A recent action concerned the use of diamonizide, commonly known as Alar. Its primary uses were on apples, grapes, cherries, and peanuts, mostly to make a crop ripen at a uniform time, improve appearance, and increase storage life. The risks associated with Alar's use are partly attributable to UDMH, the compound formed when Alar breaks down. Initial risk estimates showed a one in a thousand lifetime cancer risk, with an upper bound of one in a hundred. On the basis of these very high risk numbers, EPA was planning to restrict Alar. However, the Science Advisory Panel (of EPA's Science Advisory Board) found serious flaws in the studies behind the risk estimates, and concluded that there simply was not enough information available to calculate the risk from Alar's use. At this time, the only action by EPA has been to require additional health risk testing by the manufacturer. The results are not yet available.

Another recent decision under FIFRA restricted the use of ethylene dibromide (EDB). The major use of EDB has been as a fumigant for application to the soil before planting crops. It also has been used to fumigate crops after harvesting, for spot fumigation of grain milling machinery, and a few other minor uses. Table 6 summarizes the risk estimates for occupational exposures and for the average consumer. As required by FIFRA, these estimates were weighed along with information about economic impacts in the decisions about restricting EDB. The risks that EDB would leach to ground water and contaminate drinking water supplies were high enough that EPA issued an emergency suspension order (followed by cancellation) to discontinue the use of EDB to fumigate soil before

crops are planted, estimated to avoid 65 cancers per year. (As is the case with most risk assessments, the risk estimates based on laboratory animal studies could not be confirmed with epidemiological data. The limited studies available for populations exposed to EDB during its manufacture did not show an excess of cancer.) EPA also cancelled the use of EDB for fumigation of stored grain and for spot fumigation of grain-milling machinery, (avoiding as many as 800 cancers per year), as a quarantine fumigant to eliminate fruit flies from citrus, tropical fruits and vegetables (avoiding up to 325 cancers per year), and for fumigating felled logs to control bark bettles. Registration was continued for other minor uses but with requirements for more restrictive label directions, protective clothing, submission of monitoring and use data.

Under the Clean Water Act, EPA establishes effluent limitation guidelines for industrial and municipal waste-water treatment

Table 6
Cancer Risks from EDB

	Lifetime Probability Estimates	Number Exposed
Occupational Inhalation of EDB		
Soil injection	3.5×10^{-3} - 3.5×10^{-2}	14,000
Quarantine fumigation	3.5×10^{-4} - 2.8×10^{-1}	48-60
Spot fumigation		
applicator	7.7×10^{-3} - 1.0×10^{-1}	2,400-6,000
mill worker	1.7×10^{-2} - 2.0×10^{-2}	16,000
Felled log treatment	9.5×10^{-2}	unknown
Average U.S. Consumer		
Soil incorporation	1.1×10^{-5}	
Wheat grain (bulk fumigation)	3.3×10^{-3}	
Spot (wheat grain - milling machinery	2.4×10^{-4}	
Fruit fumigation	1.7×10^{-5} - 2.8×10^{-4}	

SOURCE: Tables 6 and 11 in Ethylene Dibromide (EDB) Position Document 4, Office of Pesticide Programs, U.S. Environmental Protection Agency, September 27, 1983.

facilities. Since these guidelines are technology-based, risk assessment is not required.

Also under the Clean Water Act, EPA develops water quality criteria and water quality standards. Risk assessment methods are used in evaluating scientific information to find a concentration level that will protect aquatic life and human health. The work is coordinated with other federal agencies such as FDA to develop acceptable levels. The water quality criteria (based on risk assessment) are coupled with the water use objective (aquatic protection, drinking water source, navigation, etc.), and with comments from public hearings. This information leads to a regulatory water quality standard that gives concentration levels that will protect the designated uses of a particular body of water.

EPA also is developing risk assessment methods for the disposal of sewage sludge in landfills, by applying it to land, by incineration, and by ocean dumping. This is an innovative effort to examine one pollution source -- sludge, which contains a variety of pollutants -- and assess its risk across media. In a closely related program, EPA must consider the relative risks of ocean dumping compared with land-based alternatives in its decisions about issuing any kind of ocean dumping permits (Marine Protection, Research and Sanctuaries Act). This requirement was reinforced by a U.S. District Court decision (City of New York v. EPA). EPA is responding to that court decision and is providing guidance on comparative risk assessment as part of its revised ocean dumping regulations.

EPA establishes drinking water standards under the Safe Drinking Water Act (SDWA). For each pollutant, a recommended maximum contaminant level (RMCL) is based solely on health effects and is set at a margin of safety to ensure that no known or anticipated adverse health effects will occur. Each RMCL is a goal, not standard. For conventional toxicants, each RMCL typically relies on the same approach as described for FDA for noncarcinogens, setting an acceptable daily intake. For probable human carcinogens that are treated as nonthreshold toxicants (in the absence of data to the contrary), a RMCL of zero is used. (Exceptions have been made for several substances where the RMCL is larger than zero because the scientific evidence is inadequate to treat them as carcinogenic by ingestion or because of other considerations.) For

enforcement purposes, a maximum contaminant level (MCL) is set as close to the RfCL "as is feasible," considering technological capacity and costs. For example, in 1979 EPA set a MCL for trihalomethanes of 0.1 mg/liter for water systems serving more than 10,000 people. Under the worst case extrapolations this was estimated to avoid up to 320 cancers per year. Reducing the MCL to 0.05 mg/liter for those systems would have avoided another 110 cancers per year. However, this was determined to be too costly and potentially hazardous because it could compromise the disinfection of drinking water, which has well-known benefits of preventing waterborne infectious diseases.

EPA conducted a full risk analysis for the proposed MCLs for nine volatile organic compounds (VOCs). The contaminant levels examined that are closest to the proposed MCLs are estimated to avoid 27-70 cases of cancer per year; most of these are attributable to vinyl chloride. An additional analysis calculated adjusted acceptable daily intakes (ADIS) for noncancer endpoints for all nine VOCs, based on a no-observed-adverse-effect level divided by a safety factor where total exposure is assumed to be from drinking water. Very few public water systems exceed the adjusted ADI for any of the VOCs, so omitting the acute and chronic toxic effects for the noncarcinogens does not bias the risk estimates (for total cases of all effects) by very much (U.S. EPA, May 1985b). Five of these VOCs were regulated as probable carcinogens, one as having equivocal evidence of carcinogenicity, and two as noncarcinogens. So far, no final decision has been made on the last one. In

addition to the nine VOCs described above, the Office of Drinking Water has proposed RMCLs for 43 other substances, including organic and inorganic chemicals and biological contaminants. RMCLs for radionuclides also are being prepared.

Despite the mandate to protect human health and the environment, most of EPA's risk assessments have been applied to human health rather than to ecosystem and other welfare effects. There are some exceptions (although some of the early ones may have relied more on a finding of what concentration would kill half of the test animals after relatively short-term exposures). Under FIFRA, for example, endrin was restricted on the basis of its risk to nontarget species (49 Federal Register 42792), sodium fluoroacetate was restricted on the basis of risk to endangered species (41 Federal Register 52792), and toxaphene was restricted on the basis of its risk to aquatic organisms. Risk of bird poisoning is being considered in the evaluation of diazinon.

EPA is estimating the damages to material goods from SO_2 and its derivatives (e.g., when SO_2 combines with fine particles and forms acid precipitation) using a risk assessment that is less rigorously structured than one would be for human health effects. The results may be used in setting a secondary standard for SO_2. (Primary standards are to protect human health; secondary standards are to protect welfare and the environment.) For the most recent review of the ozone ambient standard, EPA examined available data with respect to its effects on crops. A more sophisticated analysis of crop damages is expected for EPA's upcoming review of the

ozone ambient standard, for which it will conduct a risk assessment of forest damages from ozone.

As part of its review of existing chemicals, the Office of Toxic Substances has made substantial progress in assessing the risks to animal populations (with some consideration of plants) from chloroparaffins. Chloroparaffins are used in about 200 commercial products such as additives in lubricating oils, metal-cutting oils, flame retardants, plastics softeners, sealants, and printing ink. EPA's Office of Research and Development is developing guidelines on how to quantify ecosystem risks; interim guidelines are expected to be available within the next few years.

Food and Drug Administration (FDA)

FDA conducts research and develops standards on the composition, quality, and safety of human and animal drugs, human vaccines, medical devices, food, food additives and colors, and cosmetics. Its regulatory authority was broadened in 1958 and 1960 with the passage of the Food and Color Additive (Delaney) Amendments, which require manufacturers to prove the safety of food and color additives and FDA to prohibit any additive found to induce cancer in humans or animals; in 1962 with enactment of the Drug Effectiveness Amendments requiring that new drugs be proven safe and effective prior to marketing, and in 1976 with passage of the Comprehensive Medical Device Amendment.

Food additives, color additives, and residues of animal drugs in foods are evaluated by FDA primarily as a result of petitions

filed by manufacturers, accompanied by quantitative toxicological testing results. Normally, the company wanting to market the new product will arrange to have an independent lab conduct the risk assessment. FDA evaluates the petition for adequacy, and makes a preliminary assessment of the toxicological data to determine whether all of the potential health effects have been studied. An acceptable daily intake for noncarcinogens is established, and this value is compared with the estimated daily human exposure based on the manufacturer's proposed use and predicted human consumption of the foods in which the additive is to be used. For example, over 150 color additives have been permanently listed with levels established for use in drugs and cosmetics, while over 50 have been banned. These chemicals cross many chemical classes and their changing uses often require new analyses.

At present, carcinogens are treated separately. Some of the substances evaluated for carcinogenicity in the past by the FDA Cancer Assessment Committee include:

Acrylonitrile	1,2-Dichloroethane
Lead acetate	Diethylhexylphthalate
Vinyl chloride	Diethylhexyladipate
Dioxane	Furazolidone
p-Toluidine	Cinnamyl anthranilate
Hydrazine	Trimethylphosphate

In 1982, FDA announced its "constituents policy." The policy states that if a carcinogenic impurity is found in a substance, but the additive as a whole is not carcinogenic, then the entire additive is not necessarily prohibited from use, provided that the risk posed as estimated by risk assessment procedures is found to

be consistent with the Law's general safety standard of a "reasonable certainty of no harm." Recent examples invoking this policy include the ban on Yellow No. 5 in food, drugs, and cosmetics and Green No. 5 in drugs and cosmetics. FDA is currently assessing the risks of many more color additives in food, cosmetics, and drugs that have been on a temporary or "provisional" list.

FDA also has tentatively invoked a de minimis interpretation of the Law's anticancer provisions in connection with the use of methylene chloride in the decaffeination of coffee. In December 1985, based on risk assessment, FDA proposed to ban the use of methylene chloride in hairsprays because it was shown to be a carcinogen by inhalation in mice, while allowing its continued use to decaffeinate coffee because its risk was deemed to be negligible. FDA's Federal Register notice about a regulation describes the risk assessment and a back-up document is available to interested parties.

Most risks from food contamination are addressed by FDA. Some recent examples are baby food containing foreign objects and milk contaminated with heptachlor. FDA's emergency response teams use quantitative risk assessment in the sense that they try to determine exposure and possible effect of contamination quantitatively. They frequently use not only their own risk assessments, but also those prepared for the contaminants (often pesticides) by other agencies.

Unavoidable food contaminants tend to be addressed by setting action levels based on risk assessment, technical feasibility, and economic analyses. An important part of this process for chemicals, such as aflatoxin in cottonseed oil, is the risk assessment for the chemical. Other residues, such as pesticide residues in food, also contain action levels, based on policies influenced by quantitative risk assessment.

Drugs and devices are evaluated on a more qualitative basis, using risk-benefit analyses. These procedures rely heavily on clinical judgment and epidemiological information. Since manufacturers have to prove safety and efficacy, the amount of information available to estimate risks for new drugs and devices usually far exceeds that available for contaminants.

Food Safety and Inspection Service

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) inspects all meat and poultry products in plants that ship in interstate and foreign commerce. As part of its activities to ensure that meat and poultry products do not contain harmful chemical residues from either environmental contamination or animal drug use, FSIS conducts formal risk assessments to determine which chemicals to test for in its residue monitoring and surveillance program. Risk assessment also is used to determine acceptable limits for hazardous chemicals that may be found in a meat or poultry product.

In establishing procedures for inspection of animals before and after slaughter, FSIS uses a risk assessment approach to determine which diseases or conditions to inspect for. The 1985 National Academy of Sciences' report, Meat and Poultry Inspections: the Scientific Basis of the Nation's Program, recommended a quantitative risk assessment approach be taken to support any changes in inspection procedures. This would mean collecting data about why inspection led to rejecting a carcass or product, so that the type and rate of rejection in different inspection procedures can be related to public health effects. Through a NAS contract, FSIS is developing a quantitative model to evaluate different methods of poultry slaughter inspection.

FSIS depends primarily on risk assessments performed by the Food and Drug Administration for making decisions about the safety of substances used in meat or poultry products. As for other federal agencies, the FSIS proposals are published in the Federal Register and its rules and regulations are published in the Code of Federal Regulations.

Occupational Safety and Health Administration (OSHA)

OSHA's primary responsibility under the 1971 Occupational Safety and Health Act is to protect the safety and health of workers. To carry out this responsibilty OSHA regulates workplaces and in response to health hazards, OSHA sets limits on the amount of pollutants or dangerous substances to which employees may be exposed.

OSHA considers regulating organic chemicals and compounds following analysis based on discovery data or upon referral by other government agencies including the National Institute of Occupational Safety and Health (NIOSH) and the Environmental Protection Agency. In the past, NIOSH was responsible for providing OSHA with risk analyses necessary to support a proposed occupational standard. This arrangement has changed in recent years, largely as a result of the Supreme Court's decision on the benzene standard.

In 1980, the Supreme Court decided that OSHA's benzene standard was invalid because the rule was not accompanied by sufficient analysis to document the fact that there was significant risk to workers' health. The Court held that OSHA's policy -- to reduce exposure to the lowest feasible level when there was qualitative evidence of carcinogenicity -- was not sufficient alone to justify regulation. In addition, the Court required that a determination be made that a place of employment was unsafe, and that significant risks could be reduced or avoided by a change in practice. The Court added, however, that the significant risk determination should not be viewed as "a mathematical straight jacket," and that OSHA was not required to support its findings that a significant risk exists with complete scientific certainty. The 1980 Court decision also directed OSHA to review all studies included in the risk assessment supporting a proposed standard.

In response to the Court decision, OSHA's cancer policy was modified in 1981 so that the significance of risk must be

considered before setting a carcinogen standard. All recent OSHA carcinogen standards have used risk assessments in their development. (Table 7 shows the status of recent OSHA health standards activity.) Because of its importance, OSHA has developed its own in-house scientific capability to do risk assessments based on animal and epidemiology studies. Risk assessments done by other government agencies are routinely reviewed and if appropriate, incorporated in an OSHA rule proposal. Outside experts are brought in to review risk assessment models.

Typically, the model will project worker deaths and illnesses expected to occur from exposure to a dangerous substance. Because the empirical conditions of animal and epidemiology studies differ from workplace exposure conditions, statistical formulas are relied upon to extrapolate results expected to occur in an industrial setting. Once the risk assessment model for a given substance has been developed it is applied to the estimated distribution of workers exposed to the substance at various concentrations and time periods. While observed dose-response rates vary among substances, the higher the exposure in terms of length of time and concentration of the substance, the greater the expected frequency of resulting death or illness.

The result of the application of risk assessment models in OSHA is a projection of benefits (deaths and illnesses avoided) from regulating and reducing worker exposures to dangerous substances. For example, in December 1985 OSHA proposed to limit benzene exposures to an 8-hour time-weighted average of 1 part per

Table 7
Summary of OSHA Standards Development Projects

Standards Completed	Standards Proposed But Not Completed	Standards Being Developed
Vinyl chloride[b]	Ethylene dibromide[a]	Methylene chloride
Coke-oven emissions[b]	Asbestos[a]	4,4'-Methylene-dianiline
Lead[a]	Benzene[a]	Laboratories
Cotton dust[a]		Respiratory protection
1,2 Dibromo-3-chloropropane[b]		1,3-Butadiene
Acrylonitrile[b]		
Ethylene oxide[a]		
Health conservation[a] (noise)		
Arsenic[a]		
Hazard communication[a]		

[a]The development of the standard included a risk assessment.

[b]The standard discusses risk, but a formal study was not done.

million (ppm) and to require certain other regulatory duties such as measuring exposures and conducting medical surveillance. OSHA developed a quantitative risk assessment based on epidemiological studies, which was verified by outside experts. The assessment of benefits was based on OSHA's risk assessment and predicted that 18.3 deaths per year would be avoided. OSHA estimated that the cost per death avoided would be $1.6 million for the 1.0 ppm proposal. OSHA has also proposed a revised standard for asbestos that is expected to prevent about 75 cancer deaths and 30 cases of asbestosis per year.

One example of OSHA action in response to the referral of a new hazard by another agency is for 4,4'-methylenedianiline (MDA). Based on available animal data, EPA has concluded that MDA is carcinogenic and presents an unreasonable risk to the health of exposed workers. OSHA's risk assessment indicates that current workplace exposures in the manufacturing and secondary processing sectors are expected to cause about 160 cancers over a 45-year working lifetime. Because of this information, OSHA is drafting a new regulation to protect workers from MDA.

Risks Occurring in Natural Resource Management

The National Environmental Policy Act (NEPA)

Under NEPA, federal land management agencies must prepare environmental impact statements (EISs) for major federal natural resource management activities that may have significant effects on the environment. The Council on Environmental Quality (CEQ)

oversees the implementation of this act and has issued regulations governing the environmental procedures of federal agencies.

Several agencies involved in managing natural resources have conducted risk assessments as part of EISs. For example, the Bureau of Land Management (BLM), within the U.S. Department of the Interior, manages about 300 million acres of land -- approximately 15 percent of all the lands in the United States. BLM is required by law to authorize certain land uses and prepares EISs when developing land use plans for grazing allotments, coal leasing, forest cuttings, and activities involving minerals, oil, and gas. BLM evaluates risks in its coal leasing program to decide what sites are unsuitable for development, given criteria published in its Programmic EIS Document in Coal Leasing. The kinds of risks considered are damages to surface water supplies, aquifers, and endangered resources. The effects are quantified in many cases.

The U.S. Department of Agriculture (1985) has assessed the risks to human health and to nontarget plants and animals from the application of various pesticides to forests. Its U.S. Forest Service manages 191 million acres of national forests and grasslands and regulates the use of forest resources. Management activities include outdoor recreation, timber harvest and reforestation, protecting air and water quality, road construction, minerals activities, wildlife and fish habitat improvement, and livestock grazing. In its planning process, the Forest Service follows both NEPA procedures and those under the National Forest Management Act of 1976. Risk assessments may be conducted at the regional,

forest, or ranger district level for use in forest resource management. National forest plans and other broad program direction provide general guidance, but most of the work is done in the forest and ranger districts where these programs are implemented. The Forest Service is using risk assessment to evaluate such things as the effects of pesticides on human health. The risk analysis methodologies assess different strategies for managing natural resources and their effects. For example, the Forest Service uses a form of risk assessment to determine how close to build a road near a stream or what type of forest cutting to perform, given the expected drainage and erosion impacts.

During the past two years, CEQ has paid particular attention to one of the regulations (40 CFR 1502.22) which, among other things, required federal agencies to include a "worst-case analysis" in an environmental impact statement if the information about significant adverse impacts is incomplete or not available. A worst-case analysis was supposed to identify the most severe possible effects of an action on humans and the natural environment, such as the possibility of cancer to those living and working in the region. CEQ became concerned that the requirement to prepare a worst-case analysis, in certain circumstances, could require federal agencies to go beyond the "rule of reason" in their analysis of potentially severe impacts.

For example, the Bureau of Land Management was ordered to prepare a worst-case analysis assuming a causal effect between the use of certain herbicides in federal forest lands and the development

of cancer in human beings (in Save our Ecosystems v. Clark, 747 F. 2d 1240 [9th Cir. 1984]). BLM contended that such an analysis would be pure guesswork, because no credible scientific data supported the contention that cancer could occur at any dose. Nevertheless, the ruling forced BLM to stop its plan to encourage timber growth by treating 6,400 acres with herbicides.

In a U.S. Court of Appeals for the Ninth Circuit decision on the same issue, the Interior Department was ordered to include an analysis of the herbicide 2,4-D in the environmental assessment prepared before spraying federal timberlands (Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark). The Interior Department estimated that it would take at least five years and $25 million to perform the analysis.

After an intensive review of this issue, including public involvement, CEQ amended the regulation, effective May 27, 1986. The final amendment requires all federal agencies to disclose the fact of incomplete or unavailable information when evaluating reasonably foreseeable significant adverse impacts on the human environment in an EIS, and to obtain that information if the costs of doing so are not exorbitant. If the agency is unable to obtain the information, it must (1) affirmatively disclose that such information is unavailable, (2) explain the relevance of the unavailable information to the decision at hand, (3) summarize the existing credible scientific evidence relevant to the agency's evaluation of significant adverse impacts on the human environment, and (4) evaluate the impacts based on research methods generally

accepted in the scientific community. Impacts that have a low probability of occurring but would have catastrophic consequences should be evaluated if the analysis is supported by credible scientific evidence rather than pure conjecture, and if it is within the rule of reason. The requirement to prepare a worst-case analysis is rescinded.

Natural Resource Damage Assessments

The Department of the Interior proposed a rule in the Federal Register on December 20, 1985, that establishes procedures for assessing damages to natural resources from a discharge of oil or a release of a hazardous substance under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA or Superfund), or under the Clean Water Act. (The President delegated the responsibility for preparing this rule to the Department of the Interior in Executive Order 12316.) The proposed rule is for use by federal and state officials who manage the public's natural resources. Such assessments will be used in court actions and administrative proceedings when seeking compensation for injuries to natural resources. Before an assessment begins, an assessment plan is to be prepared and published, followed by a 30-day period for comments from the public and parties responsible for the damage.

The proposed rule describes alternative methods for conducting assessments on a case-specific basis, but does not provide specific procedures for implementing them. The rule is flexible because of the variations among resources, ecosystems, and hazardous

substances, as well as to enable the incorporation of evolving methods. Each damage assessment involves three major steps: (1) establishing that an injury has occurred and that the injury resulted from the discharge or release, (2) quantifying the effects of the discharge or release on the services provided by the injured resource, and (3) determining the damage.

The proposed rule defines "injury" as a measurable adverse long- or short-term change in the chemical or physical quality or viability of a natural resource, resulting either directly or indirectly from exposure to a discharge of oil or release of a hazardous substance. The number of shore birds killed from oil contamination is an example. The natural resources include surface water, ground water, air, geological resources, and biological resources. Biological resources are defined as fish and wildlife, and include shellfish, terrestrial and aquatic plants, and other living organisms.

Injury determination in this proposed rule is based on a demonstrable adverse biological response from the oil or hazardous substance. Both laboratory and field measurements are required to demonstrate injury. For example, a resource is considered injured:

- if the concentrations and duration of substances in surface water or ground water that was potable before the release are in excess of federal drinking water standards;
- if the air emission concentrations are higher than federal air pollutant standards;

- if the substance causes soil erosion by wind or surface waters; and
- if a biological resource or its offspring has undergone at least one of the following adverse changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions, or deformations.

The second step in damage assessment is the quantification of the effects on the injured resources. This phase requires characterizing the base level for the uninjured resource and comparing this base level to the level existing or anticipated after completing any response actions. Although a formal risk assessment can be used in this step, it is likely that most claims will rely on tables and formulas published to assist in assessing these natural resource damages.

The proposed rule provides that the change in the resource can be quantified in terms of the change in the level of "services" that the resource provides. Services include provision of habitat, food, and other needs of biological resources; recreation; other products or services used by humans; flood control; ground water recharge; and other such functions that may be provided by natural resources. This information is used in the last part of the damage assessment process, which determines the value of damages, using either the reduction in use values or the costs of restoration or replacement.

Dams

The Bureau of Reclamation (BOR), the Soil Conservation Service (SCS), and the U.S. Corps of Engineers use risk assessment to assist them in making decisions concerning the construction, modification, and repair of dams. The analysis considers the probability of dam failure and what the effects would be to human life and the environment.

For example, the SCS (with other agencies) uses a form of risk assessment in establishing criteria for the design of dams. Their approach establishes one set of criteria if the consequences of a dam failure are small (such as for a small farm pond) and correspondingly more stringent criteria as the consequences of failure become greater (such as for a water supply reservoir for a community). If the consequences of a dam failure are expected to be very severe (such as loss of human life), then every known effort is made to design the dam to prevent the most extreme events that are known to be probable. The SCS develops watershed protection and flood prevention projects for 900,000 farmers, and is involved in about 100 projects where it does some type of risk analysis.

The biggest problem with the use of more quantitative risk assessment in designing dams is that flood probabilities for extremely rare events are not well established. In addition, no method is currently available for estimating the probability of dam failure from various other causes. As the capability improves for estimating the frequencies of such rare events, a more quantitative approach to risk assessment may be adopted.

Quantitative risk assessments are used more often when evaluating repairs for existing dams. BOR evaluates the dam's condition to develop probabilities of failure from being overtopped by flooding, from earthquakes, or from static loading of the reservoir. To the extent possible, the effects from failure are estimated in terms of potentially lost lives, destruction or fish and wildlife habitat, property damage, soil erosion, and crop loss. Within the past three years, BOR has conducted such analyses for about 15 dams.

BOR supports the use of a decision analysis framework for evaluating existing or proposed dam projects (U.S. DOI, 1986). Its major components are a hazard assessment and a risk-cost analysis of alternatives to identify what level of protection is economically justifiable. The Fish and Wildlife Coordination Act requires BOR to coordinate with the U.S. Fish and Wildlife Service and the corresponding state agency. To address these responsibilities, BOR has developed a monetary risk-cost methodology for fish and wildlife habitat changes caused by catastrophic flood events.

Risks Associated with Dangerous Installations

In some cases, facilities may have sudden releases, as discussed in the accidental risk section, as well as continuous releases. A few examples are described in this section.

Mines

The Bureau of Land Management (1983b) has analyzed the risks a gold mine poses to surface water quality, climate, air quality,

and public health and safety. More broadly, the Mine Safety and Health Administration (MSHA) (within the Department of Labor) performs risk assessments on how best to reduce and prevent mine accidents and occupational diseases. MSHA develops and promulgates mandatory safety and health standards, including those for airborne contaminants.

MSHA recently used risk assessment in drafting a revision of the radiation standard. It estimated the risk of lung cancer to miners, using international epidemiological studies, information from the scientific literature collected by NIOSH, EPA radiation standards, and national guidelines on safe industry level set by the International Commission on Radiation. MSHA especially balances the risks and costs to small mines.

Energy Installations

Within the Department of Energy, the Health and Environmental Risk Program analyzes the potential health and environmental effects of installing, operating, and decommissioning industries using emerging technologies capable of providing a significant fraction of the nation's energy (Barr, 1983). Analyses of the nature, magnitude and sources of uncertainty regarding potencial health and ecological impacts are published and revised on the basis of comments from interested parties in industry, government and academia. These analyses provide input for planning research to reduce uncertainties that are likely to impede the use of cost-effective control strategies. Analyses have been published for

seven energy technologies (refuse-derived fuel, geothermal, fluidized bed combustion, coal liquefication, liquid metal fast breeder reactor, photovoltaics, and oil shale), two classes of pollutants (nitrogen oxides and airborne particles) common to several energy technologies, and two risk analysis methodologies (treatment of uncertainty and hydrocarbon carcinogenicity) (see references A-K).

As in other agencies assessing ecosystem risks, the Department of Energy has been hampered by the lack of mature methodologies in this area and by the site-specific nature of potential ecological effects. However, it estimated ecosystem risks for mule deer, Indian rice-grass, and plant communities for a one million barrel-per-day (BPD) oil shale industry in the United States (IWG Corp., 1984). Additional potential ecosystem effects were identified but not estimated. For risks to people, Table 8 shows far more accidents than cases of disease; the analysis allows the separation of fatal injuries from those that lead to no work loss or some work loss. Worker health effects also are separated from those for the general public.

Work Place Risks

Besides analyzing continuous work place risks, OSHA also evaluates industrial processes, facilities, and practices that may pose a risk to workers by causing injuries, fatalities, and accidents from fires, explosions and falls. OSHA has proposed four safety standards that have included risk assessments.

Table 8
Risk Estimates for a Million BPD Oil Shale Fuel Cycle

Health or Environmental Effect	Risk Per Year (Uncertainty Range) Cases	Deaths
WORKERS (Population at risk: 41,000 persons)		
Injury, with days lost	2400 (1700-3700)	13 (9-22)
Injury, without days lost	1500 (1200-2200)	NA
Cancer	26 (0-300)	4 (0-49)
Silicosis	232 (0-1070)	76 (0-387)
Pneumoconiosis	100 (33-310)	17 (9-98)
Chronic Bronchitis	41 (13-130)	15 (4-51)
Airway Obstruction	10 (3-36)	5 (1-17)
High Frequency Hearing Loss	3 (0-8)	NA
PUBLIC (Population at risk: 616,000 (Region), 313,000,000 (U.S.))		
Premature Death from Air Pollution	NA	6 (0-47)
Internal Cancers	0.0002 (0-0.001)	0.0002 (0-0.0008)
ECOSYSTEM (Area at risk: 19,000 square miles)		
Mule Deer Decline (Habitat Loss)	4% to 9% (-50% to 200%)	
Indian Rice-grass Injury (Sulfur Dioxide)	0.8%	
Plant Community Decline (Solid Waste Disposal)	3 communities decrease as much as 20%	

Source: IWG Corp., 1984, p. ix.

A major focus is identifying the populations at risk. These are the number and types of workers in those industries that would be significantly affected by a safety standard. OSHA's standards cover the hazards associated with concrete and masonry structures in the construction industry (to reduce the risk that a structure in progress would collapse), grain handling facilities (to reduce the explosions and fires in grain elevators, processing plants, and mills), places of employment that use scaffolding or are in underground locations (such as tunnels, shafts, chambers, passageways and covered excavations), and noisy work places.

OSHA's current activities are concentrated on standards for walking and working surfaces, the handling and storing of flammable and combustible liquids, the communication of hazards, and electrical safety work practices. Some of these categories are quite broad. For example, OSHA's standards for handling and storing combustible and flammable liquids specifically address the following industry sectors and locations: petroleum refineries and distributors, chemical processing plants, gasoline service stations, bulk plants, marine terminals, and distilleries.

Transportation

The Department of Transportation is responsible for several aspects of transportation safety. Its Office of Hazardous Materials Regulation sets national safety standards for transporting all hazardous materials and hazardous wastes by air, water, highway, and rail. The office designates substances as hazardous,

and regulates their transportation in interstate commerce. At present some 2,400 specific materials are listed and labelled as hazardous when transported. The office does not perform specific risk assessments for all of these materials, but regulates them based on known hazardous properties (e.g., flammability, corrosivity, and toxicity). The chemicals that cause the most injuries and fatalities are gasoline (40% of all fatalities, Department of Energy's Battelle Research Lab Study), liquefied petroleum gas, and sulfuric acid. The office sponsors risk assessments to be used in the regulatory process and to identify areas that may need more attention. For example, the office contracted for a risk assessment of the transportation of liquefied natural gas out of a terminal in Boston, Massachusetts.

The Office of Hazardous Materials Regulation follows guidelines for assessing safety risks published by the Secretary of Transportation. It has about 15 ongoing rulemaking actions that are subject to benefit-cost/risk assessment of varying complexity depending on the scope and content of the proposed rule. One current regulatory analysis involves assessing how a package of a certain construction will withstand the rigors of normal transportation. The regulatory action involves conversion from packaging specifications to performance-related requirements. For example, current requirements for carrying various types of hazardous materials specify that a drum must be manufactured in accordance with specified detailed design. The office proposes that drums

pass various performance tests instead, such as drop tests and leak tests.

In developing transportation regulations, the office attempts to estimate conditional probabilities that:

1. the vehicle will have an accident;
2. the accident will result in a spill;
3. the spill will be a certain size; and
4. then, if for example, the substance is flammable, that it will be ignited.

Historical statistics on accidents are used in the estimation procedure.

When proposing new or revised transportation regulations, the office assesses alternative strategies, usually in the form of different modes of transportation (truck, rail, tank, car). Tank trucks have been found to be the riskiest mode, especially in light of safety improvements with rail tank cars over the last two years. On average for the past five years, there have been 14 fatalities per year by all modes of transporting hazardous materials.

When the substances being transported are hazardous wastes, then the Office of Hazardous Materials Regulation shares control responsibilites with EPA. The agencies promulgated closely coordinated standards in 1980. The major change to earlier regulations was the inclusion of intrastate shipments of hazardous wastes.

The U.S. Coast Guard is a branch of the armed forces under the jurisdiction of the Department of Transportation. It regulates vessels, sets and enforces safety standards, prescribes license requirements for merchant marine personnel, and has search and rescue functions. The Coast Guard provides the federal on-scene coordinator for responses to oil and hazardous chemical releases occurring in the coastal zone, Great Lakes waters, and specified inland ports and harbors. The on-scene coordinator is responsible for coordinating federal response activities at the site of the release. Risk assessment is used in the sense that the Coast Guard uses quantified data from a hazardous materials incident to determine the appropriate response. The most appropriate action is determined after assessing various parameters including location, size, chemical type and character of the plume, and the environmental impacts.

Other agencies in the Department of Transportation administer general safety regulations for various modes of transportation. The National Highway Traffic Safety Administration's (NHTSA) programs are designed to increase motor vehicle safety and decrease the threat of death or injury in traffic accidents. Agency research determines which parts of vehicles can be improved to increase crash avoidance capabilities or to provide greater protection in the event of a crash. NHTSA also investigates vehicle defects and can order manufacturers to repair flaws that affect the safe performance of the vehicle.

NHTSA conducts regulatory evaluations for all new rules and regulatory impact analyses for those having a major economic impact (usually $100 million or more). As part of each RIA, the agency performs a risk assessment, which

1. estimates how many people are killed or injured (problem assessment) and
2. determines the effectiveness of countermeasures (i.e., reduction in injuries and fatalities).

This information is then compared to the countermeasures' costs such as higher prices, effects on fuel consumption, and major impacts on the regulated industry.

One recent risk assessment was conducted for the mandatory inclusion of passive restraint systems (i.e., automatic seat belts or air bags) in automobiles. NHTSA officials estimated that passive restraints could prevent as many as 9,000 deaths and 150,000 serious injuries a year and would provide annual savings of up to $2.8 billion in insurance premiums. A benefit-cost analysis performed by a consultant to the insurance industry found the standards to be clearly cost-effective.

NHTSA also investigates reports of vehicle defects not covered by an agency standard, assesses the risk, and often forces the manufacturer to correct the defect as a result of the assessment. For example, a major tire manufacturer's product was recalled due to a safety defect assessed by NHTSA. In performing its RIAs, NHTSA follows in-house policy, the guidelines for Executive Order 12291

and for the Regulatory Flexibility Act, and the requirements in the Motor Vehicle Information and Cost Saving Act of 1972 and in the National Traffic and Motor Vehicle Safety Act of 1966.

The Federal Aviation Administration (FAA) uses risk assessment techniques to learn how to reduce the risk of catastrophic occurrences to the extent possible. A recent risk assessment involved protecting passengers from cabin fires in commercial aircraft. The FAA studied safety procedures and new equipment that will reduce the risk of fires. Currently FAA is developing a regulation on protective breathing equipment for commercial aircraft. The FAA uses methodology that is compatible with the general guidelines set forth in the Department of Transportation document, "Methods for Economic Assessment of Transportation Industry Regulations." The FAA's own methodology for economic analysis, "Economic Analysis of Investment and Regulatory Decisions -- A Guide," does not specify risk assessment procedures per se but describes investment analysis procedures.

The Maritime Administration subsidizes private industry to build ships and manages the sites for the national defense reserve fleet. Based on its risk assessment, the Administration chose a maximum permissible exposure level for asbestos in its ships.

The Federal Railroad Administration (FRA) assesses risks as part of its economic analysis of proposed major regulatory actions. An example is FRA's recent rulemaking for transporting certain hazardous materials in railroad tank cars. The accident record was

analyzed for specific types of tank cars carrying specific materials. Continuation of the historical accident pattern was considered to represent the risk of no regulatory action. Proposed improvements in the safety features of tank cars were matched against historical accidents to determine which adverse consequences could have been prevented or reduced by individual safety features or combinations of them. The differences between the risk of no action and the risk remaining after various combinations of safety features formed the basis for comparing the potential benefits of the various options considered in the economic analysis.

Risks Associated with Alternative Strategies

Decisions about how to deal with hazardous wastes can be viewed as being in a category distinct from the previous four categories. This is because hazardous waste regulations generally pay more attention to alternative ways of managing these substances, rather than simply restricting the amount of air or water emissions from a particular source. EPA has primary responsibility for the management and disposal of hazardous wastes under the Resource Conservation and Recovery Act (RCRA) and its recent amendments. For hazardous waste regulation, the use of formal risk assessment is somewhat new and controversial. Its use is made more difficult since the emphasis in the legislative language is on protecting human health and the environment; EPA has interpreted this emphasis to mean that a balancing of risks and costs is not permissible.

Land Disposal

A review of recent RIAs suggests the extent of risk assessment used to accompany regulatory analyses, even though a full comparison of benefits and costs was not legally feasible. The RIA for the land disposal restrictions of solvent wastes (U.S. EPA, 1986a) considers cancer and other health risks, but provides estimates only for average and maximum individual risk levels rather than characterizing the risk by the number of cases that would occur under each regulatory alternative.

In contrast, the RIA for restricting land disposal of dioxin estimates that there would be small changes in the number of cases if the dioxin wastes were incinerated, rather than disposed of on land under approved Waste Management Plans (U.S. EPA, 1986b). The changes would be small mostly because dioxin is immobile in the environment, unless it is combined with mobilizing compounds such as solvents.

The RIA for the overall land disposal restrictions program (U.S. EPA, 1985f) calculates individual risk for each chemical and each environmental medium (air, water, land) as a measure of probability of harm weighted by a severity factor. Dose depends on distance from the site, source of drinking water, and fish eating habits. This information is combined with several population scenarios to estimate the number of cases for that chemical and medium. Then cases are added over all the waste constituents and all three media to determine the total number of cases. Estimates of cases avoided by prohibiting each of three categories of land

disposal are shown in Table 9, by general waste classification categories. It shows that prohibition of hazardous wastes in treatment impoundments would be relatively ineffective in reducing an already modest risk level. On the other hand, prohibition in landfills, disposal impoundments, land farms, and waste piles would be more effective (except for the K wastes) and would avoid more cases.

Risks also were estimated for the requirements imposed on generators of small quantities of hazardous wastes (U.S. EPA, 1985d). On the basis of the assumptions used, there would be 255 fewer cases of cancer since most of these wastes no longer would be disposed of in ordinary municipal landfills. However, preliminary estimates indicate an increase in noncancer cases of 2,369, which nearly doubles the unregulated number. Most of these are expected to be severe headaches from methanol, which stop when exposure is removed. It should be noted that these estimates of changes in health effects are for a 400-year period, so that the health benefits would be very small on an annual basis.

Used Oil

Although the risk assessments for land disposal restrictions and small quantity generators yield relatively small estimates of total cases, the RIA for managing used oil shows larger baseline cancer estimates and correspondingly larger numbers of cases avoided by the regulatory options considered (U.S EPA, 1985e) (see Table 10). These calculations are for potential cancers rather than expected cancers because conservative population exposure

Table 9

ESTIMATED HEALTH BENEFITS
(AND % REDUCTION FROM CURRENT RISKS)
OF LAND DISPOSAL RESTRICTIONS a/

Waste Type	Current Land Disposal Technology		
	Landfills, Disposal Impoundments, Land Farms, and Waste Piles b/	Storage Impoundments c/	Treatment Impoundments d/
Solvents (F001-F005)	84 (99.9)	16 (99.8)	8 (76.5)
Other F	902 (85.2)	52 (59.2)	52 (29.7)
K	282 (28.4)	25 (99.9)	<1 (1.2)
P and U	27 (93.1)	49 (99.9)	<1 (0.6)
D	281 (99.9)	156 (66.8)	63 (38.7)
X	28 (97.7)	<1 (64.9)	6 (58.8)
Total	1,604 (64.8)	298 (72.3)	129 (31.2)

a/ Weighted cases over seventy years.

b/ There are a total of 16 disposed (landfills, disposal impoundments, land farms and waste piles) wastes by EPA code (and 3 X wastes), that potentially pose increased risks in the treatment technologies initially selected. In the baseline, these wastes contribute 569 cases (over seventy years) to baseline risks, almost 19%.

c/ There are 3 wastes, by EPA code, stored in surface impoundments that potentially pose increased risks. They contribute a negligible portion of baseline risks.

d/ There are 4 wastes, by EPA code, treated in surface impoundments that potentially pose increased risks. They contribute a negligible portion of baseline risks.

SOURCE: U.S. Environmental Protection Agency, 1985f.

Table 10

POTENTIAL CANCER RISK FROM USED OIL IN BASELINE AND REGULATORY ALTERNATIVES

(number of health effects[1])

		Regulatory Alternative			
				Proposal Alternatives	
	Baseline	Full Subtitle C (Alternative 1— 100 ppm Pb)	PROPOSAL (Alternative 2— 100 ppm Pb)	(Alternative 3— 50 ppm Pb)	(Alternative 4— 10 ppm Pb)
Road oiling	[illegible]	0	0	0	0
Urban burning	6,660	3,094	3,094	2,873	1,989
Asphalt plants	112	361	376	380	454
Space heaters[3]	192	19	[illegible]	19	19
Incineration	18	[illegible]	39	39	39
Lined landfills	889	2,303	2,303	2,294	2,226
Unlined landfills	6,813	0	0	0	0
Storage leaks	210	52	135	135	135
Dumping[2]	0	196	50	50	50
Totals	14,982	6,064	6,016	5,790	4,912

[1]Cases of cancer over a 70-year lifetime.

[2]Since all dumping in the baseline is by do-it-yourself oil changers, who are outside the scope of the proposed regulations, risk results reflect only increased dumping caused by responses to regulation. Risks from unregulated do-it-yourself oil changers are estimated as 3,940 health effects and are not affected by the regulations.

[3]Space heaters also cause an estimated 1,700 cases of lead poisoning (over 70 years) in the baseline. These cases are eliminated by the regulation.

SOURCE: U.S. EPA, 1985e.

assumptions may cause upward bias in the estimates. Many of the cancers in the used oil RIA result from ingestion of arsenic (in drinking water). This substance is most closely linked with a form of skin cancer that usually is treatable. In contrast, few data are available about where cancer shows up in the body when other contaminants are ingested. Although cure rates for other sites will vary, the usual assumption for other contaminants is that the cancers they cause will be fatal. There are substances such as lead in used oil that can cause noncancer health effects, but these are not included in the analysis because of the difficulty of aggregating diverse health effects. This would tend to underestimate the total health impact of regulatory action, and these noncancer effects may not be the same across regulatory alternatives. The net importance of these considerations in a regulatory context is not clear, but the estimates in the waste oil risk assessment may have to be interpreted differently from those in other risk assessments.

Incineration

Incineration is a potentially important alternative to land disposal for managing hazardous wastes. EPA compared the risks of incinerating PCB wastes and EDC wastes in land-based incinerators with those for incinerators located at sea (U.S. EPA, 1985c). The analysis considered possible human health effects and environmental effects due to releases from the incinerator, due to fugitive releases from transfer and storage equipment located at the land-based incinerator or at the ship docks, and due to the potential

for spills while the ship is going from the dock to the ocean burn area.

Details of the analysis include estimates that the total incidence of cancer at the two land-based sites in the study ranges from 0.29 to 0.43 cases over 70 years of continuous emissions (p. D-9). Although an explicit estimate is not given for cancers from the ocean-based incinerator, the low individual risk levels imply substantially less than one case per million people exposed over a 70-year period. The health risks from potential marine spills were examined by comparing estimates of ambient pollutant levels with the maximum concentration limits recommended for occupational exposures. Since both short-term and long-term recommended limits could be exceeded if a spill occurred, EPA concluded that nearby spills could pose health risks -- but no estimates of cases are provided (p. E-7).

This analysis also concluded that incinerator emissions would have negligible effects on marine ecosystems. Less information was available for their effects on terrestrial ecosystems, but the expected damages are reported to be minor (p. 1-15). The analysis of environmental effects from an ocean spill show larger impacts, although they are reported mostly in qualitative terms (Table 11).

Other Risk Analyses

Aside from its recent use in RIAs, the tools of risk assessment are coming to be a part of other decisions about hazardous waste management. Examples include: comparative risk analysis as

Table 11

SUMMARY OF MARINE ECOSYSTEM EFFECTS FROM SPILLS OF HALF A TANK

Release Location	PCB Waste: Effect on Biomass	PCB Waste: Bioconcentration Levels	EDC Waste: Effect on Biomass	EDC Waste: Bioconcentration Levels
Mobile Bay				
Floating Case	Small overall, severe reduction for benthos	3 to 5 orders of magnitude	Not Considered	Not Considered
Sinking Case	Uncertain	Uncertain	Minor	Minor
Continental Shelf				
Floating Case	Uncertain	Uncertain	Not Considered	Not Considered
Sinking Case	Small overall, substantial for benthos	2-3 orders of magnitude	Minor	Minor
Burn Zone				
Floating Case	Uncertain	Uncertain	Not Considered	Not Considered
Sinking Case	Minor overall, substantial for benthos	1-2 orders of magnitude for benthos and demersal fish	Minor	Minor

Source: U.S. EPA, 1985c, Exhibit 1-8

part of choosing effective treatment technologies when land disposal is restricted, location guidance, decisions about site-specific exemption of hazardous wastes from regulatory controls, combustion of hazardous wastes, and variances for facilities that exceed background concentration levels in ground water. A final example is the proposed risk model to set up constituent-specific concentration levels to serve as a screen for land disposal of hazardous wastes. If a particular waste exceeds those screening levels, then it must be treated prior to land disposal.

Superfund

Under Superfund, EPA must designate substances as hazardous and set minimum quantities for reporting releases when they would "present substantial danger to the public health or welfare or the environment." EPA is also responsible for updating the National Contingency Plan for remedial action in response to spills of oil or hazardous substances. Although neither of these regulations has been designed as major, RIAs have been prepared. Risks were not estimated in either RIA.

On the other hand, EPA and other agencies (such as the Center for Environmental Health, in the Department of Health and Human Services) examine risk to some extent to learn about the relative dangers of sites that were used for hazardous waste disposal but are no longer subject to the Resource Conservation and Recovery Act. The most dangerous of these sites are put on the National Priorities List (NPL) to be cleaned up under Superfund. With the Hazard Ranking System, EPA's Superfund program uses information

from site inspections to compare the potential risks posed by different hazardous waste sites. Three factors are used to score sites: (1) the possibility that hazardous substances will migrate offsite and reach populated areas; (2) the possibility that people will come into direct contact with hazardous substances; and (3) the possibility of fire or explosion caused by hazardous substances. The first factor is used to put sites on the NPL, and the other factors are used to identify sites that need remedial actions.

Sites are selected for remedial actions based partly on risk and partly on geographic distribution. Risk analysis is used to develop target performance goals that will define an effective cleanup at uncontrolled hazardous waste sites. However, this risk analysis tends to be oriented toward reaching standards set forth under other EPA programs, rather than estimating the change in the number of cases that would occur at alternative levels of cleanup. Additional factors such as engineering feasibility, institutional controls, environmental effects, and costs are used to determine the cost-effective remedy that will meet the performance goals (U.S. EPA, 1985g,h).

Other agencies also consider the relative risks of hazardous waste sites. For example, the Bureau of Land Management has arranged contractors to use the Hazard Ranking System approach for 15-20 sites under its management where there has been unauthorized hazardous waste disposal.

RISK ASSESSMENT IN USE: CONCLUDING COMMENTS

The previous sections have described a multitude of uses of risk assessment by public authorities in the United States. Several caveats needs to be kept in mind, however.

Some of the risk analyses described above do not include all four steps in the risk assessment process (as defined on page 3). This may be because hazard indentitication is all that the statute requires for a decision. Sometimes, exposures are estimated and combined with the "yes" resulting from the hazard identification step. Other analyses have information about the risk to the most exposed individual but no exposure estimates. An attempt has been made to identify those risk studies that do not include all phases of a full risk characterization, but that information has not always been available.

In addition to differing statutory requirements, the extent of risk analysis may be influenced by available resources and expertise. Even before Executive Order 12291 added explicit requirements for benefit-cost analyses, the cost to the agencies for preparing regulatory packages ranged from about $120,000 to $1.5 million (U.S. General Accounting Office, 1982). Of course, only part of this would be for risk assessment. In the regulatory analyses performed in 1979-80, most of the agencies discussed in this paper spent at least 50 percent of their analytical budget for work by outside contractors; in some instances the amount approached 100 percent (U.S. General Accounting Office, 1982). Again, this does not separate the portion of risk assessments that were performed by

contractors, but it suggests that outside consultants may have been an important supplement to agency expertise in this field.

Another limitation of the paper is that it does not examine the quality of the risk assessments. Nearly all of the ones used to support regulatory decisions were made available for expert or public review, but there is no indication in the paper whether risks were reassessed on the basis of such feedback. This leaves open the possibility that a defective risk assessment could have been used for a control decision.

There are a number of research efforts aimed at addressing the deficiencies in quantitative assessment, for instance to limit uncertainty resulting from the use of assumptions. Recent government efforts include: the research recommendations in the Department of Health and Human Services document (DHHS, 1985); the development of a program at FDA, spearheaded by the National Center for Toxicological Research, to address the critical assumptions used in risk assessment and to examine modulators of toxicity; extensive epidemiological studies relevant to cancer risk at the National Cancer Institute/National Institutes of Health (NIH); the National Science Foundation recommendations (NSF, 1984); efforts at the National Institute of Environmental Health Sciences/NIH and evaluation of the extrapolation of chronic bioassays by the National Toxicology Program. In addition, there are a number of efforts by private foundations and institutes. These are all part of a growing effort to improve risk assessment and make it truly quantitative.

As mentioned in the introduction, coverage is intended to be comprehensive, but it may not be complete. The most important next step, however, is to examine the role that risk assessment played, relative to other factors, in the public authorities' decisions. That will have to be the subject of a separate paper.

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List of Acronyms

ADI	-	acceptable daily intake
BLM	-	Bureau of Land Management
BOR	-	Bureau of Reclamation
BPD	-	barrel-per-day
CEPP	-	Chemical Emergency Preparedness Program
CEQ	-	Council on Environmental Quality
CERCLA	-	Comprehensive Environmental Response, Compensation and Liability Act
CPSC	-	Consumer Product Safety Commission
DHHS	-	Department of Health and Human Services
DOE	-	Department of Energy
EDB	-	ethylene dibromide
EIS	-	environmental impact statement
EPA	-	Environmental Protection Agency
FAA	-	Federal Aviation Administration
FDA	-	Food and Drug Administration
FIFRA	-	Federal Insecticide, Fungicide and Rodenticide Act
FRA	-	Federal Railroad Administration
FSIS	-	Food Safety and Inspection Service
IRLG	-	Interagency Regulatory Liaison Group
MCL	-	maximum contaminant level
MDA	-	methylenedianiline
MSHA	-	Mine Safety and health Administration
NAS	-	National Academy of Science
NESHAP	-	National Emission Standards for Hazardous Air Pollutants
NHTSA	-	National Highway Traffic Safety Administration
NIH	-	National Institutes of Health
NIOSH	-	National Institute of Occupational Safety and Health
NPL	-	National Priority List
NSF	-	National Science Foundation
OECD	-	Organization for Economic Cooperation and Development
OPTS	-	Office of Pesticides and Toxic Substances
OSHA	-	Occupational Safety and Health Administration
RCRA	-	Resource Conservation and Recovery Act
RIA	-	regulatory impact analysis
RMCL	-	recommended maximum contamination level
SAR	-	safety analysis report
SCS	-	Soil Conservation Service
SDWA	-	Safe Drinking Water Act
TSCA	-	Toxic Substances Control Act
USDA	-	U.S. Department of Agriculture
VOC	-	volatile organic compound