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March Sadowitz

John D. Graham

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A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy

March Sadowitz & John D. Graham *

Introduction

The analytic tools of risk assessment are designed to determine how much risk to human health might be caused by various exposures to chemicals and agents such as radiation. Once risk levels are estimated, risk management is the process of determining whether risks should be controlled by standards, including how much, if any, risk should be allowed. Risks permitted by standards are sometimes called "residual risks" because they represent the levels of risk that may persist after 100% compliance with standards is achieved.

This paper describes residual cancer risks permitted in the U.S., focusing on numerical levels authorized specifically by statute or regulation under various national and state policies. It also identifies residual risks permitted only implicitly. Finally, for areas where change is on the horizon, it discusses potential new policies. Although we do not predict what new law and regulation will provide, we consider the possibilities and suggest general policy guidelines.

Earlier surveys of risk management decisions have been published. One examined cost-effectiveness in risk management, finding risks of 1 in 1,000 to be fairly consistently regulated. Yet, it found several factors other than magnitude, e.g., population size and cost of control, to play varying roles in regulating smaller risks.¹ Another examined cancer

* March Sadowitz is a Research Specialist at the Center for Risk Analysis, Harvard School of Public Health. She received a B.S. (Management Information Systems) from Rensselaer Polytechnic Institute, an M.S. (Environmental Studies) from Bard College and an M.A. (Public Policy) from SUNY, Albany. She is also a candidate for the J.D. at Boston University.

Dr. Graham is Director of the Center for Risk Analysis and received his B.A. (Economics) from Wake Forest, his M.A. from Duke University and Ph.D. (Public Policy) from Carnegie Mellon University.

¹ C.C. Travis et. al., *Cancer Risk Management*, 21 *Env'l Sci. & Tech.* 415 (1987).

risk management in three regulatory agencies and found no uniformity on the level of risk considered insignificant.² Almost eight years later, such differences continue among and within agencies.

The legal and policy communities use various phrases to describe the regulatory status of cancer risks. If a risk is deemed “significant” or “unacceptable,” risk managers are generally expected to take steps to reduce or eliminate it. A “de minimis” or “negligible” risk is one that can be ignored. If a risk is judged to be insignificant or acceptable, however, it is not necessarily de minimis or negligible. Cancer risks too small to exceed the “significance” threshold but too large to fall below the “de minimis” threshold have a discretionary status in the U.S. Allowability is determined by considerations such as the weight of the scientific evidence, the feasibility and affordability of control, the size of the population at risk and the cost-effectiveness of control.

Quantitative risk assessments were first used by agencies to allocate resources among an array of health and environmental problems. Since then, several federal cases challenged its use, but debate may now be coming full circle. Congress and state legislatures no longer include only narrative directions for risk management but increasingly add numerical values to risk standards and directions for calculating them.

Standards for Radiation Protection

In the U.S., cancer risk management was first used for radiation. One of the earliest and most famous was in the 1975 “Rasmussen Report” on the public health risks of a nuclear reactor accident.³ U.S. policy makers still struggle with how much cancer risk should be tolerated from various man-made sources of radiation.

The International Commission on Radiological Protection (ICRP) currently recommends limiting excess environmental radiation to a total of 100 mrem per year. If continued over a lifetime, 100 mrem per

² Joseph V. Rodricks et. al., *Significant Risk Decisions in Federal Regulatory Agencies*, 7 Regul. Tox. & Pharmacology 317 (1987).

³ Reactor Safety Study: An Assessment of Accident Risks in U.S. Nuclear Power Plants (1975).

year produces a dose of about 7 rems. Using the radiation cancer risk coefficient of the U.S. Environmental Protection Agency (EPA), 7 rems poses an incremental lifetime cancer risk of about 3 in 1,000.⁴ Besides the 100 mrem guideline, ICRP calls for exposures to be kept as low as reasonably achievable (ALARA) and recommends that technologies causing exposure have a net positive benefit, taking into account economic and social factors.⁵

In 1986 the Nuclear Regulatory Commission (NRC) adopted a variety of qualitative and quantitative safety goals for the operation of nuclear power plants.⁶ For example, the risk of latent cancer fatalities from living within 10 mi of such plants should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes. According to NRC calculations, this translates into an allowable cancer risk of about 2 in 1M per year (or about 1.4 in 10,000 per lifetime).

In 1990, the NRC attempted unsuccessfully to promulgate a policy statement on the amounts of public risk from various nuclear-related activities that would be considered "below regulatory concern" (BRC).⁷ Thus, for decommissioned facilities or sites, NRC proposed to use 10 mrem per year for limiting residual radiation doses. According to NRC, this proposed standard corresponded to an annual cancer risk of about 5 in 1M (or about 3.5 in 10,000 in a lifetime).⁸ It was never adopted because of public objections.

The cancer risks allowed by NRC's current policies vary considerably. For example, the NRC's criteria for protection of the general population from releases of radioactivity from a low-level waste disposal site includes an annual dose limit of about 25 mrem to the whole body. According to NRC calculations, this corresponds to an

⁴ Stephen L. Brown, *Harmonizing Chemical and Radiation Risk Management*, 26 *Env'l Sci. & Tech.* 2336 (1992).

⁵ *Radiation Protection: 1990 Recommendations of the ICRP* (1990).

⁶ *Safety Goals for the Operation of Nuclear Power Plants: Policy Statement*, 51 *F.R.* 28,044 (1986).

⁷ *Below Regulatory Concern; Policy Statement*, 55 *F.R.* 27,522 (1990).

⁸ Statement by Forrest J. Remick, Commissioner, NRC, *Regulatory Risk Coherence*, American Nuclear Society Topical Meeting on "Risk Management: Expanding Horizons," Boston, MA, June 8, 1992.

annual cancer risk of about 1.25 in 100,000 (or about 8.75 per 10,000 in a lifetime). Yet NRC's newest rules limiting doses of ionizing radiation (from routine plant operation) to the general public permit an annual cancer risk of 5 in 100,000 (or about 3.5 per 1,000 in a lifetime). For nuclear power plant workers, NRC rules permit an annual total effective dose of about 5 rem, which corresponds to an annual risk of about 2.5 in 1,000. The corresponding lifetime risk is well above 1 in 100, although general plant practices typically provide workers much more protection than is prescribed by NRC.⁹

Because EPA also regulates radiation releases in a variety of contexts, NRC and EPA conducted a harmonization effort on risk assessment and management. They found that NRC's approach to cancer risk management is different from EPA's. The differences in technical approaches appeared to be less important than those in risk-management goals. EPA is inclined to set highly ambitious risk limits (with little regard for cost and practicality) but then permit variances or exemptions on a case-by-case basis. NRC is inclined to set pragmatic risk limits while requiring plants to go beyond these limits as cost, technology and practicality permit. In May 1993 NRC issued the following statement in conjunction with EPA:¹⁰

Although the practical effect of these two regulatory approaches is largely the same, there remains a difference of about a factor of ten between NRC's acceptable lifetime risk level of excess cancer (1 in 1,000), as embodied in the public dose limit... and EPA's acceptable lifetime risk range (1 in 10,000 to 1 in 1,000,000) for Hazardous Air Pollutants and in the Superfund Program. It is this fundamental difference in acceptable risk and regulatory approaches that the agencies need to explore in seeking harmony in public and environmental protection.

EPA recently issued a final rule for radiation-protection standards for the management and disposal of spent nuclear fuel, and of high-

⁹ *Id.*

¹⁰ Memorandum from James M. Taylor to the NRC Commissioners, Status of Risk Harmonization with the Environmental Protection Agency under the 1992 Memorandum of Understanding, May 14, 1993, at 7.

level and transuranic radioactive wastes.¹¹ The new rule changes the calculation of dose from a whole body/specific organ dose to a committed effective dose (CED), which is the risk-weighted sum of the dose to each organ. EPA chose a 15 mrem/yr standard which corresponds to a 5 in 10,000 lifetime risk. It acknowledges that this seems higher than other programs, but programs such as Superfund and air toxics use single pathway, single medium exposures while the CED uses a total body exposure. EPA anticipates that a very small number of people will actually be exposed at the maximum allowable risk.

Radon is handled differently. First addressed by federal legislation in 1988, EPA has since used a lifetime cancer risk of 1 in 100 as the recommended action level. This is not a strict requirement.¹² A new proposal would require property sales disclosures. It would also require EPA to establish standards and radon priority areas if there is:¹³

a reasonable likelihood that the average indoor radon level in the area is likely to exceed the national average indoor radon level by more than a de minimis amount.

Standards for Carcinogens in the Food Supply

Beginning in the 1930's, the Food and Drug Administration (FDA) approved tolerances for food additives that met a standard of "reasonable certainty of no harm when used as intended." Later, the famous Delaney Clause governing carcinogenic food additives (1958), color additives (1960) and animal drugs (1968)¹⁴ provided that no additive or animal drug shall be deemed safe if found, after appropriate tests, to induce cancer in man or animal.

The plain meaning of the Delaney Clause would seem to require zero cancer risk from additives. However, the 1968 law contained a statutory exception called the "DES proviso." Diethylstilbestrol (DES),

¹¹ U.S. Environmental Protection Agency (EPA), Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes, 58 F.R. 66,398 (1993).

¹² Kenneth L. Mossman & Marissa A. Sollitto, *Regulatory Control of Indoor Rn*, 60 Health Physics 169 (1991).

¹³ S. 657, 103d Cong., 1st Sess. (1993).

¹⁴ Federal Food Drug and Cosmetic Act § 409, 21 U.S.C. § 348(c) (1988).

a drug used to prevent miscarriages in livestock, left a residue in meat. The DES proviso authorized FDA to approve carcinogenic animal drugs or additives in animal feed, provided that “no residue” of the drug or additive will be found in meat or meat products by an analytical method prescribed by FDA. The first recorded use of carcinogen risk assessment in the U.S. occurred when FDA defined an amount of carcinogenic residue in meat that was so tiny that it could be considered “no residue” under the DES proviso.¹⁵

When developing this so-called “sensitivity of method” (SOM) procedure, FDA in 1973 rejected reliance on the limits of analytical methods of detection. Instead it proposed that quantitative risk assessment be used to define a level of extra cancer risk in a lifetime — originally, 1 in 100,000,000 or essentially zero.¹⁶ Several years later, when FDA replaced a less conservative model with a more protective, linear dose-response model, it relaxed the negligible risk level from 1 in 100M to 1 in 1M.¹⁷ Although FDA’s interpretation of the DES proviso has never been reviewed in the courts, one court ruled that FDA has general authority under the Food, Drug and Cosmetic Act (unless Congress specifically states otherwise) to ignore de minimis risks.¹⁸ It did not define de minimis risk.

In the 1980’s, FDA tried to apply the same 1 in 1M standard to small amounts of carcinogenic color additives. This came to a halt when a court ruled that Congress, in writing the Delaney Clause, intended to require zero cancer risk from color additives.¹⁹

Meanwhile, FDA and EPA faced a curious “Delaney Paradox” in their efforts to register pesticides. If the residues of a carcinogenic

¹⁵ Robert J. Scheuplein, *SOM and Food Safety Policy*, in *Safety Evaluation of Drugs and Chemicals*, 405 (W. Eugene Lloyd ed. 1986).

¹⁶ U.S. Food and Drug Administration (FDA), *Compounds Used in Food Animals: Proposed Rule*, 38 F.R. 19,226 (1973).

¹⁷ FDA, *Chemical Compounds in Food Producing Animals: Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals*, 42 F.R. 10,412 (1977).

¹⁸ *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979).

¹⁹ *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987).

pesticide do not concentrate in processed foods, the permissible amount of residues on raw and processed foods can be regulated under a flexible risk-benefit balancing law: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

FIFRA uses a narrative standard to prevent “unreasonable adverse effects” from pesticide applications. All pesticides sold in the U.S. must be registered under FIFRA. Whereas food and drug requirements are strictly health based, FIFRA defines “unreasonable” in a way that includes the “economic, social and environmental costs and benefits of the use of the pesticide.”²⁰ This has given the EPA more flexibility.

In effect, FIFRA permits slight amounts of cancer risk from raw foods if necessary to achieve the benefits to farmers and consumers that pesticides provide. But if the carcinogenic residues are known to concentrate in processed foods, then the tolerance level for processed foods must be set in accordance with the Delaney Clause.

EPA and FDA attempted to evade the Clause by using the 1 in 1M standard as a practical definition of negligible risk for residues on both raw and processed foods.²¹ The government was supported in this by a major recommendation from the National Research Council of the National Academy of Sciences (NAS–NRC).²² Despite this support, FDA and EPA lost a major challenge when a Court of Appeals determined that the *de minimis* policy was incompatible with the Delaney Clause.²³ While the Clause has little scientific and political support, there is no consensus about how a new law governing pesticide registration should be written.

Proposals seeking to reform pesticide regulation can be characterized along a continuum from completely numerical risk-based standards to a narrative standard that allows full consideration of pesticide risks and benefits. One proposal would require completely risk-based registration and reregistrations including a bright line of 1 in

²⁰ FIFRA § 2(bb), 7 U.S.C. § 136(bb).

²¹ EPA, Regulation of Pesticides in Food: Addressing the Delaney Paradox: Policy Statement, 53 F.R. 41,104 (1988).

²² Regulating Pesticides in Food: The Delaney Paradox, (1987).

²³ *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 U.S. 1361 (1993).

1M residual risk in food, without regard to benefits.²⁴ This health-based proposal would require risk assessment for specific age categories using conservative assumptions. On the benefits end of the continuum is a proposal which would allow EPA to consider the benefits of pesticides when making registration decisions. This would create a narrative negligible-risk standard, placing the determination of negligible risk upon the Administrator of the EPA.²⁵ Greater than a negligible risk would be allowed if it “provides an adequate, wholesome and economical food supply.” Finally, the Administration proposal would require conservative assumptions, but does not specify a bright-line number, instead using a narrative standard of “reasonable certainty that no harm would occur.”²⁶ This does not explicitly phase out consideration of benefits but would give EPA flexibility in choosing a risk standard and method of implementation.

Standards to Protect Workers

The Occupational Safety and Health Administration (OSHA) is authorized to set workplace standards to provide “safe and healthful working conditions.”²⁷ In 1977 it proposed to regulate carcinogens to the lowest levels technologically and economically feasible.²⁸ When industry objected, a fierce battle ensued. Ultimately, the U.S. Supreme Court ruled that OSHA must demonstrate that a risk is “significant” before adopting a regulation to reduce exposures. In this case, Justice John Paul Stevens opined that a reasonable person might consider a lifetime cancer risk of 1 in 1,000 to be significant while a risk of 1 in 1B could not be so considered.²⁹ However, Justice Stevens was silent on risks between 1 in 1B and 1 in 1,000, indicating that OSHA had

²⁴ H.R. 4091, 103d Cong., 2d Sess. (1994).

²⁵ H.R. 1627, 103d Cong., 1st Sess. (1993).

²⁶ H.R. 2084 and S. 2050, 103d Cong., 2d Sess. (1994).

²⁷ OSH Act § 3, 29 U.S.C. § 651 (b).

²⁸ U.S. Occupational Health and Safety Administration (OSHA), Occupational Exposure to Benzene Emergency Temporary Standards, 42 F.R. 22,516 (1977).

²⁹ Industrial Union Dept. AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 655 (1980).

flexibility to weigh various factors such as the size of the exposed population, the severity of the adverse effects and the quality of the scientific evidence.³⁰ Although OSHA has not articulated a strict definition of significant risk, it has generally used 1 in 1,000 as a benchmark of significance.³¹

Labor groups have been concerned that 1 in 1,000 has been interpreted by OSHA (and some industry lawyers) as a level of de minimis rather than significant risk. They would like to grant OSHA the flexibility to initiate rule making to reduce residual risks in the range from 1 in 1,000 to 1 in 1M. Now that the Occupational Safety and Health Act is being rewritten, labor advocates support a bill that would allow but not require OSHA to regulate any cancer risk greater than 1 in 1M calculated using conservative methods.³²

Standards Governing Environmental Exposures

The Supreme Court's 1980 ruling that OSHA must conduct quantitative risk assessments to support rules caused EPA to consider a similar approach. As early as 1976, it had published interim guidelines on how cancer risks from environmental exposures should be computed. When William Ruckelshaus returned to EPA in 1983 to restore public confidence, he announced that the principles of risk assessment and management would govern. Risk assessment practice at EPA grew rapidly in the 1980's, although none of the environmental laws administered by EPA mentioned risk assessment explicitly.

In assessing practice at EPA, it is important to remember that FDA had used the 1 in 1M lifetime cancer risk standard to assure essentially zero risk for 200M American consumers of meat. Several EPA program offices have used the 1 in 1M standard quite differently, in some cases to provide this same degree of protection to a hypothetical, maximally-

³⁰ John D. Graham & March Sadowitz, *The Role of Significant Risk in OSHA Reform*, Risk in Perspective, Harvard Center for Risk Analysis, Aug. 1993.

³¹ OSHA, Occupational Exposure to Ethylene Oxide: Final Standard, 49 F.R. 46,936 (1984); Occupational Exposure to Inorganic Arsenic: Supplemental Statement of Reasons for the Final Rule, 48 F.R. 1,864 (1983).

³² H.R. 1280, 103d Cong., 1st Sess.(1993).

exposed individual. The variability in risk-management standards throughout the federal agencies is interesting, particularly since this variability is not completely explainable by differences in their regulatory mandates as prescribed by Congress.

Hazardous Air Pollution

The Clean Air Act Amendments of 1990 (CAA) require stationary sources of hazardous air pollutants (including carcinogens) to meet residual-risk standards after industry has implemented the maximum achievable control technology. Sources with risks to maximally exposed individuals are below 1 in 1M do not require residual-risk standards. Those that do not meet this test are governed by standards that "protect the public health with an ample margin of safety."³³ This has been interpreted by EPA, a federal appeals court and Congress to mean that the most-exposed individual is protected against risks greater than 1 in 10,000 (regardless of feasibility and cost) — and as many citizens as possible are protected against risks as small as 1 in 1M (taking into account scientific uncertainty, feasibility and cost considerations).³⁴ This approach has been used by EPA for benzene and radionuclides.³⁵ Congress will consider revisions to the residual risk standards for air toxics based on reports prepared by the NAS-NRC and a bipartisan Commission on Risk Assessment and Management.

Toxic Water Pollution

Under the Federal Water Pollution Control Act (FWPCA), better known as the Clean Water Act, states are required to develop surface water quality standards that protect public health.³⁶ EPA guidance to

³³ CAA, § 112, 42 U.S.C. § 7412.

³⁴ *Natural Resources Defense Council v. EPA*, 838 F.2d 1224 (D.C. Cir. 1987); Clean Air Act Amendments, Conference Report to Accompany S. 1630, 101st Cong., 2d Sess., Oct. 26, 1990.

³⁵ EPA, National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke by-Product Recovery Plants, 54 F.R. 3,804 (1989); National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Chemical Manufacturing Process Vents, Industrial Solvent Use, Benzene Waste Operations, Benzene Transfer Operations and Gasoline Marketing System, 54 F.R. 38,083 (1989).

the states indicates that carcinogenic risk from each contaminant in surface water should be reduced into the range from 1 in 100,000 to 1 in 10M, with a preference for 1 in 1M.³⁷ However, some states, such as Maryland and Virginia, have had water quality standards for dioxin approved by EPA with acceptable-risk levels in the range from 1 in 10,000 to 1 in 100,000. EPA's decision to approve these standards under the Clean Water Act was approved by the federal courts.³⁸ Beginning in 1990, EPA has promulgated ambient water quality criteria for those states which did not have their own water quality criteria at a lifetime risk level of 1 in 1M.³⁹

Health Standards for Drinking Water

The Safe Drinking Water Act (SDWA), last amended in 1986 and under current debate, requires EPA to set two types of standards for drinking water. First, nonenforceable "maximum contaminant level goals" (MCLGs) are levels at which no adverse human health effects are anticipated while enforceable "maximum contaminant levels" (MCLs) are to be set as close to MCLGs as is "feasible with the use of best available technology."⁴⁰ For carcinogens, MCLGs are typically set at zero and thus the real basis for regulation under the SDWA is technological feasibility. The MCLs, although not based on risk assessment, are very important because they are imported for use in other environmental laws such as Superfund. Proposed amendments to the Safe Drinking Water Act would specifically allow EPA to use risk assessment and incremental cost-benefit analysis when setting levels for new contaminants.⁴¹

Hazardous Waste Management

Risk assessment and management is used in the regulation of

³⁶ FWPCA § 303(c), 33 U.S.C. § 1313(c).

³⁷ EPA, Water Quality Criteria Availability of Document, 49 F.R. 5,831 (1984).

³⁸ Natural Resources Defense Council v. EPA, 806 F.Supp. 1263, (E.D. Va. 1993).

³⁹ EPA, State Compliance with Clean Water Act Requirements for Adoption of Water Quality Criteria for Toxic Pollutants, 55 F.R. 14,351 (1990).

⁴⁰ SDWA § 1412g-1(b)(5), 42 U.S.C. § 300g-1(b)(4).

⁴¹ H.R. 3392, 103d Cong., 2d Sess. (1994).

hazardous wastes at both abandoned sites and active, permitted waste-management facilities. There are, however, subtle differences in the risk management approach at abandoned sites versus active facilities.

Superfund

The Comprehensive Environmental Response Compensation and Liability Act (CERCLA) or "Superfund" requires selection of cleanup strategies which "protect human health and the environment."⁴² Risk assessment plays a dual role in the implementation of the Superfund Program. A baseline risk assessment conducted at the site determines whether cleanup is required but risk assessment also may be used to set site-specific cleanup standards at a site. EPA's risk management policy for Superfund has been evolving since the passage of the original statute in 1980. The implementing regulations at first proposed a risk range of 1 in 100,000 to 1 in 10M. Now the National Contingency Plan has designated an acceptable risk range of 1 in 10,000 to 1 in 1M.⁴³

This "range-of-risk" approach gives site managers flexibility to choose whether or not to remediate when site risks fall within the range. In 1991 the Agency published a policy directive stating that risks within the risk range should not be remediated without adequate justification.⁴⁴ The risk-management standards in the Superfund program have contributed to extensive debate about the cost of cleanup at hazardous waste sites. The guidelines for Superfund risk assessments have evolved with the risk-management policy and have been formalized in the Risk Assessment Guidance for Superfund.⁴⁵

CERCLA is now up for reauthorization, and the use of risk assessment in setting an acceptable level of risk has become a focus of debate. Novel state policies have sprung out of the debate, such as the

⁴² CERCLA § 121(b), 42 U.S.C. § 9621(b).

⁴³ EPA, National Oil and Hazardous Substances Pollution Contingency Plan, 55 F.R. 8,715 (1988).

⁴⁴ EPA, Role of the Baseline Risk Assessment in Superfund Remedy Decisions, Office of Solid Waste and Emergency Response (1991).

⁴⁵ EPA, Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual, (Part A): Interim Final, Office of Emergency and Remedial Response, Dec. 1989.

New Jersey law we discuss below, that attempt to return contaminated industrial properties to use and set different standards for residential and industrial land use.

The Administration's proposal for Superfund reauthorization does not include a numerical risk standard but requires that chosen remedial actions protect human health and the environment.⁴⁶ This would require EPA to establish a formula to yield permissible concentration levels that reflect reasonably anticipated land uses. The cleanup levels would represent concentrations below which action is not required. Some site-specific variables will be used in applying these generic standards. For contaminants that do not have generic standards set, or if unusual site characteristics exist, parties may petition for a site-specific risk assessment. This is likely to downplay the use of site-specific risk assessment. In response to accusations that Superfund risk assessments are extremely conservative, EPA would be required under the Clinton plan to promulgate a national risk protocol for conducting risk assessment based on realistic assumptions.

The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act (RCRA) requires hazardous waste management practices to be protective of human health and the environment.⁴⁷ EPA regulates hazardous wastes and the cleanup of currently active industrial facilities which hold RCRA permits. Classification of a chemical as "hazardous" is determined either by maximum contaminant levels set by EPA under the Safe Drinking Water Act or by use of risk assessment if no MCLs are available. If the lifetime risk associated with the leaching of wastes is more than 1 in 100,000, the wastes are classified as hazardous.⁴⁸ Standards for delisting wastes as hazardous are stricter, requiring a level of risk below 1 in 1M.

⁴⁶ H.R. 3800, 103d Cong., 2d Sess. (1994).

⁴⁷ RCRA § 102, 42 U.S.C. § 6902 (a).

⁴⁸ EPA, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revision, 55 F.R. 11,813 (1990).

Corrective action at active sites is triggered by a risk assessment as well. Current EPA regulation requires the study of cleanup options if the risk is greater than 1 in 1M, calculated in a specific manner. However, the cleanup options selected must bring risk within an acceptable risk range of 1 in 10,000 to 1 in 1M.⁴⁹

Residual Cancer Risks Permitted by U.S. Environmental Standards

<i>Policy</i>	<i>Law and Language</i>	<i>Regulatory Approach</i>
Hazardous Air Pollution	CAA: an ample margin of safety	1 in 10,000 individual and 1 in 1M for the most people possible
Toxic Water Pollution	FWPCA: to protect public health and welfare	1 in 10,000 to 1 in 10M
Drinking water contaminant levels	SDWA: MCLGs within an adequate margin of safety	0
Superfund	CERCLA: protection of human health and the environment	1 in 10,000 to 1 in 1M
Hazardous waste management	RCRA: protective of human health and the environment	<i>listing:</i> 1 in 100,000 <i>corrective action:</i> 1 in 10,000 to 1 in 1M <i>incinerators:</i> 1 in 100,000, group C, to 1 in 1M groups A and B carcinogens

Risk assessment and management practices under RCRA are far from consistent, despite a unifying statute and implementation by one agency through one office, the Office of Solid Waste. When setting standards for waste incineration, industrial boilers and furnaces, EPA makes a distinction between carcinogen classifications. Group A and B carcinogens are to be regulated to a risk level of 1 in 1M, while group C to 1 in 100,000. In addition, for carcinogenic metals, the limit is established at an aggregate lifetime risk of 1 in 100,000.⁵⁰

⁴⁹ EPA, Corrective Action for Solid Waste Management Units (SWMUs) at Hazardous Waste Management Facilities: Proposed Rule, 55 F.R. 30,800 (1990).

⁵⁰ EPA, Standards for Owners and Operators of Hazardous Waste Incinerators and Burning of Hazardous Wastes in Boilers and Industrial Furnaces, 55 F.R. 17,862

The States Enact Their Own Laws and Standards

Beginning in the 1980's, many states became disgruntled with the federal government's slow and fragmented approach to environmental protection. Hence, state legislatures and agencies began to adopt their own standards, which were frequently different from those enforced by the federal government.

New Jersey's Hazardous Site Remediation Act

The use of a numerical risk level in the Clean Air Act Amendments of 1990 was not just a historical fluke. In 1993 the state of New Jersey passed an act regulating contaminated sites that contains a numerical risk level. The Hazardous Site Remediation Act attempts to answer the "how clean is clean" question by requiring that separate remediation standards be developed for residential and nonresidential property.

The New Jersey law requires the State Department of Environmental Protection and Energy to adopt minimum remediation standards for soil, groundwater and surface water such that "the potential harm to public health and safety and to the environment is minimized to acceptable levels."⁵¹ This section requires the department to use "reasonable" exposure assumptions and to "avoid the use of redundant conservative assumptions." The Department is required to set "minimum remediation standards for both residential and non-residential uses that will result in an additional cancer risk of 1 in 1,000,000."⁵² It is unusual for a state to specify risk standards in statutes. New Jersey has, however, issued such risk standards before, requiring the state agency in charge of drinking water standards to set maximum contaminant levels at risk levels of 1 in 1M.⁵³

Michigan Air Pollution Laws

The state of Michigan uses a narrative health standard to regulate air contaminants which are not already regulated by EPA. Air pollution is defined as air contaminants which are "injurious to human health or

(1990).

⁵¹ N.J. Stat. Ann. Tit. 58, Ch. 10B, § 12(a).

⁵² *Id.* § 12(d).

⁵³ N.J. Stat. Ann., Tit. 58, Ch. 12A, § 13(b).

welfare, or that interfere with the enjoyment of life and properties.”⁵⁴ The state Air Pollution Control Commission is charged with establishing ambient air and emission standards. The Commission has done so by setting standards for new and modified sources.

The maximum allowable emission rate cannot be in excess of the initial risk screening level of 1 in 1M. Carcinogens may be exempt from the initial risk screening level if the ambient impact would be less than the secondary risk screening level of 1 in 100,000.⁵⁵ The Michigan Air Pollution Control Rules prescribe the use of the linearized multistage₁ model for cancer risk assessment and even specify the statistical procedure to be used in determining whether a potency estimate is based on a good fit to the data.

California's Proposition 65 and Toxic Hot Spots Law

The state that has been most aggressive in requiring risk assessment is California. California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, passed as a ballot initiative. It requires the Department of Health Services to establish a program which is “more protective of public health than the minimum federal requirements” by promulgating primary and secondary drinking water standards. The Department set levels for “no significant risk” in regulation. The burden is upon the regulated community to prove that a release will pose “no significant risk” or, in this case, a risk of less than 1 in 100,000.⁵⁶ Exceptions to 1 in 100,000 can be made to address competing public health risks such as in the use of chlorine disinfection to eliminate bacteria. Economic affects and technological feasibility are not of consideration when setting standards.

A list is compiled by the Department of all human carcinogens and reproductive toxics on which there is scientific consensus. The list has been criticized for regulating unused substances or ones used, e.g., for medical research.⁵⁷ California's focus on reproductive toxins appears

⁵⁴ Mich. Comp. Laws Ann. § 336.

⁵⁵ Mich. Admin.Code, r.336 § 1231.

⁵⁶ Cal. Health & Safety Code, D. 20, Part 1, Ch. 7 § 12,703.

⁵⁷ William S. Pease, *Identifying Chemical Hazards for Regulation: The Scientific*

to be unique and has thus served as a source of hazard identification for other regulatory bodies.

The California Toxic Hot Spots Law requires industrial facilities to inventory air emissions of designated chemicals under normal operating conditions and to report the emissions to the local air pollution control district.⁵⁸ Facilities with emissions deemed by the local districts to pose a significant risk are required to inform the exposed communities. A proposed rule of the South Coast Air Quality Management Commission would deem a 1 in 100,000 cancer risk as significant.⁵⁹ Facilities have five years to reduce total plant emissions to below the significant risk and action risk levels or face a fine. If the cost would make the facility unable to continue operating or if the cost per cancer averted is over \$6M, the operator could defer the requirement.⁶⁰

Conclusion

Both the federal and state legislatures and agencies have defined negligible, acceptable, significant or de minimis risk differently. Levels from 1 in 100 to 1 in 100M have regulatory importance in various contexts. Even when risks are managed through similar numerical definitions, the assumptions about toxicity and exposure used in the risk assessment process may differ under individual statutory and regulatory requirements. Some laws and regulations contain rigid requirements for the risk assessment process and others do not. In some programs, risk assessors may have wider latitude than in others, making simple numerical comparisons difficult.

The curious feature of current health, safety and environmental policy is that actors in the standard-setting process often invoke phrases such as significant or negligible risk without any shared numerical

Basis and Regulatory Scope of California's Propositions 65 List of Carcinogens and Reproductive Toxicants, 3 Risk 127, 154 (1992).

⁵⁸ Cal. Health & Safety Code, D. 26, Part 6, Ch. 3 § 44,340.

⁵⁹ California Air Pollution Control Officers Association, Air Toxics "Hot Spots" Program Risk Assessment Guidelines, Jan. 1991.

⁶⁰ South Coast Air Quality Management Commission, Proposed Rule 1042, Dec. 1993.

understanding of what the words mean. Indeed, our central finding is that the current approach to allowing residual cancer risks does not reflect any coherent or uniform process of risk assessment and management. Levels of cancer risk that are considered significant (or negligible) in one federal or state program would not necessarily be considered significant (or negligible) in another program. It should not be assumed that such inconsistencies are compelled by legislators in the statutes that govern risk-management decisions.⁶¹ In most cases U.S. statutes provide only narrative guidance to agencies, which gives risk managers broad flexibility to define numerical definitions of significant or negligible risk. Only in rare instances has Congress expressly stated a required risk level (e.g. the Delaney Clause requirement of zero risk) or has court stepped in to constrain the way risks are handled by federal agencies (e.g., the Supreme Court's 1980 benzene decision involving OSHA). Risk management practices have evolved to reflect the strength of particular personalities and the power of bureaucratic factors at least as much as legislative direction.

The more subtle message is that the search for a uniform numerical determination of significant or negligible cancer risk is unrealistic. If the magnitude of cancer risk to an exposed individual were the only relevant factor in making a decision, then a uniform and numerical risk-management standard would be sensible. America's apparent confusion about allowable cancer risks reflects the reality that numerous factors are considered on a case-by-case basis when making risk-management decisions. Such case-specific factors may include the number of citizens exposed to the risk, the demographic and ethnic traits of the citizens at risk, the degree of public concern about the risk — and the controllability, affordability and cost-effectiveness of risk management. While risk-based policy has not achieved a coherent, explicit and rigorous consideration of these various factors, any process that seeks to sidestep a careful evaluation of numerous factors appears unlikely to survive political challenges in the long-run.⁶²

⁶¹ Alon Rosenthal, George M. Gray & John D. Graham, *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 *Ecol. L.Q.* 324 (1992).

The use of cancer risk assessment and management by federal and state agencies is coming under increasing scrutiny by the public. Legislators are beginning to understand that risk assessment and management practices are critical in determining how much protection against risk is provided to the public and what the costs of the protection are likely to be in the public and private sectors of the economy. Recently, legislative bodies at the federal and state levels have begun to debate and create statutory policy which deals specifically with risk assessment and management. Today a major piece of environmental legislation cannot be considered by the U.S. Congress without a vigorous debate about both how risks will be calculated and how much protection will be considered sufficient.

The admittedly chaotic approach to cancer risk management in the U.S. reflects the reality that no single risk number is likely to be judged as significant or negligible in all circumstances. A numerical risk level that seems protective yet reasonable in one decision context may seem draconian or dangerously permissive in another context. There are numerous factors relevant to a risk-management decision other than the level of risk. Such factors include the weight of the scientific evidence about risk, the number of citizens at risk, the demographic and ethnic mix of the exposed population, the severity of the adverse health effect, the degree of public concern about the risk, and the feasibility, affordability and cost-effectiveness of risk management.



⁶² John D. Graham, Laura Green & Marc J. Roberts, *In Search of Safety: Chemicals and Cancer Risk*, (1988).

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