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COMPARISON OF RISK MANAGEMENT IN U.S. REGULATORY AGENCIES

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Summary

Although regulatory agencies in the United States have achieved substantial uniformity in the assessment of risks to human health from hazardous substances, it is not difficult to identify what appear to be quite different approaches to the agencies' management of these risks. One of many examples appears in the different levels of cancer risk (and corresponding levels of allowable exposure) found acceptable by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) for the human carcinogen vinyl chloride. Even within EPA, permissible vinyl chloride exposure levels differ among programs. Thus, one can experience quite different levels of permitted vinyl chloride exposure depending upon whether one is breathing air near a manufacturing facility, working within that facility, drinking contaminated water, or ingesting beverages stored in certain plastic bottles. Inconsistencies such as these are partly explained by differences in statutory requirements, but also exist because of inadequacies in technical analyses regarding the meaning of terms such as "significant risk".

1. Introduction

Although regulatory agencies in the United States have achieved substantial (be it not complete) uniformity in the assessment of risks to human health from hazardous substances, it is not difficult to identify what appear to be quite different approaches to the agencies' management of these risks. One of many examples appears in the different levels of cancer risk (and corresponding levels of allowable exposure) found acceptable by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA), for the human carcinogen vinyl chloride. Even within EPA, permissible vinyl chloride exposure levels differ among programs. Thus, one can experience quite different levels of permitted vinyl chloride exposure depending upon whether one is breathing air

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near a manufacturing facility, working within that facility, drinking contaminated water, or ingesting beverages stored in certain plastic bottles.

Although it is easy to perceive a regulatory system that yields such results as irrational, its basis can be readily explained by an examination of both the scientific and legal bases for regulation; these bases are reviewed in the next two sections. These sections are followed by a section dealing with specific regulatory actions on carcinogens, and a comparison of agency approaches. Apparent inconsistencies in agency actions are noted; we close with a discussion of our own views of some of these inconsistencies.

2. No single scientific definition of safety

If scientists could declare with confidence that a given level of human exposure to an environmental agent were safe, and that exposures above that level were certain to be unsafe, regulatory decision-making might be greatly simplified. The only issue of consequence would be the scientific identification of the safe exposure level; risk management could then simply involve insuring the safe level were achieved.

If safety could so easily be defined, it would suggest that not all is well with a regulatory system that yields the types of results exemplified in the case of vinyl chloride. One of the reasons the vinyl chloride case does not necessarily reflect a regulatory system gone awry is that scientists are unable to draw sharp lines between safe and unsafe levels of exposures to environmental agents. Scientists are thwarted in such efforts either because such distinctions probably do not in fact exist, or because there are no scientific means available to identify the lines of demarcation.

Based on currently available scientific knowledge, it appears that environmental agents can be categorized into two groups: those that exert their hazardous effects only after a certain minimum exposure level is reached (threshold agents), and those that appear to pose a non-zero risk at all non-zero exposure levels, with the magnitude of risk increasing with increasing exposures (no-threshold agents). This categorization scheme has had the practical effect in the regulatory arena of placing agents having carcinogenic properties in the second category and all other agents in the first. Although such categorizations are likely simplified and distorted representations of what are exceedingly complex scientific issues, they form the basis for risk assessment in U.S. regulatory agencies [1,2]. It is probable that some carcinogens act through threshold mechanisms, and it may even be true that some non-carcinogens act through no-threshold mechanisms. There are no widely accepted means available to make these distinctions on a generic basis.

For the threshold agents, it would seem that identification of safe intake levels would be possible. Unfortunately, it is possible neither to identify thresholds with precision and accuracy in toxicology experiments, nor to spec-

ify the threshold for the agent in large populations of individuals. Thresholds for the same agent vary among individuals, and no means exist to quantify this variability for most agents. The response to these uncertainties is to divide experimentally estimated threshold values by certain generic safety factors to obtain "acceptable intake levels" for the human population to be protected. There is no strictly scientific basis for the safety factors that are commonly used, so it is not possible to conclude that acceptable intake levels established with them are the only true "safe" levels [3].

For carcinogens the generic assumption of "no-threshold" implies that there is no single criterion for safety; exposures differ only in the degree of risk associated with them. Under the "no-threshold" assumption, safety becomes some level of tolerable or acceptable risk.

In the absence of a single criterion for safety based on purely scientific assessments, for either threshold or no-threshold agents, it is clear that regulatory decision-making must involve the use of certain policy considerations. The necessary policy choices depend upon the dictates of the various statutes under which environmental agents are regulated, together with the precedents developed as the regulatory agencies have implemented those statutes.

3. Statutory requirements and decision models

Although all laws under which U.S. regulatory agencies operate require protection of public health and, in some cases, of the environment as well, some allow for consideration of technical constraints on risk reduction, the cost of risk reduction, or the benefits conferred by the agent. Table 1 contains a list of U.S. laws pertaining to exposures to hazardous substances, together with the responsible agencies and the regulatory model that these agencies must use in decision-making. These laws were enacted at different times and their requirements were dictated by different political forces and interests. It is thus not surprising that they differ both in the degree of health protection they seek and in the types of factors unrelated to health protection that regulators are allowed to consider in establishing limits on exposures.

There are other significant differences among these laws. One of the most important concerns burdens of proof. Thus, for example, manufacturers of food additives, drugs, pesticides and certain new industrial chemicals are required to perform studies to demonstrate that certain safety criteria are met prior to the marketing of their products. In such cases the role of the regulatory agencies is to specify testing requirements and to judge the data submitted by manufacturers. The amount and type of test data required under these various statutes differ, and it is by no means an easy task to master the detailed specifications of these laws and the regulatory requirements promulgated under them.

In contrast to statutes that place such burdens on manufacturers are those

TABLE 1

Some U.S. Laws related to exposures to toxic substances (adapted from the Office of Technology Assessment: Technologies for Determining Cancer Risks from the Environment, Washington, D.C., 1981)

Legislation	Administering agency	Regulated products	Regulation model (see text)
Food, Drug and Cosmetic Act (1906, 1938, amended 1958, 1960, 1962, 1968)	FDA	Food, drugs, cosmetics, food additives, new drugs animal and feed additives, and medical devices	Risk (food additives, cosmetics) Balancing (drugs/medical devices)
Federal Insecticide, Fungicide and Rodenticide Act (1948, amended 1972, 1975, 1978)	EPA	Pesticides	Balancing
Atomic Energy Act (1954)	NRC	Radioactive substances	
Federal Hazardous Substances Act (1960, amended 1981)	CPSC	Toxic household products	Risk
Poultry Products Inspection Act (1968)	USDA	Food, feed, color additives, and pesticide residues	Risk
Occupational Safety and Health Act (1970)	OSHA	Workplace toxic chemicals	Technology
Poison Prevention Packaging Act (1970, amended 1981)	CPSC	Packaging of hazardous household products	
Clean Air Act (1970, amended 1974, 1977) Sec. 109, Sec. 112	EPA	Criteria pollutants	Risk (Sec. 112)
		Hazardous air pollutants	Technology (Sec. 202)
Hazardous Materials Transportation Act (1972)	DOT	Transport of hazardous materials	Risk

Clean Water Act (formerly Federal Water Control Act) (1972, amended 1977, 1978)	EPA	Water pollutants	Technology
Marine Protection, Research and Sanctuaries Act (1972)	EPA	Ocean dumping	
Consumer Product Safety Act (1972, amended 1981)	CPSC	Hazardous consumer products	Balancing
Lead-Based Paint Poison Prevention Act (1973, amended 1976)	CPSC, HEW (HHS), HUD	Use of lead paint in federally assisted housing	
Safe Drinking Water Act (1974, amended 1977)	EPA	Drinking water contaminants	Balancing
Resource Conservation and Recovery Act (1976)	EPA	Solid waste, including hazardous wastes	Risk
Toxic Substances Control Act (1976)	EPA	Hazardous chemicals not covered by other laws, includes pre-market review	Balancing
Federal Mine Safety and Health Act (1977)	DOT, NIOSH	Toxic substances in coal and other mines	
Superfund Amendment and Reauthorization Act (1986)	EPA	Hazardous substances, pollutants, and contaminants at waste sites	Risk/Technology

that require regulatory agencies to develop the information base, through published studies or through their own studies, necessary to establish a need for regulation. Most of the statutes governing air, water and dietary pollutants, workplace agents, and consumer products are of the latter type. One interesting effect of this legal distinction is that, in most cases, the amount and quality of data supporting regulation are greater for agents requiring premarket approval than it is for those for which regulatory agencies seek to initiate regulation.

Inspection of Table 1 reveals three broad types of regulatory models under which limits on exposures or releases are established [4].

3.1 No risk/minimal risk model

In establishing limits on food additive exposures, the FDA is required to consider health risk only; no consideration of technological or social benefits is allowed to enter the agency's decision-making. For food additives that are carcinogenic, the Delaney Clause of the Food Additive Amendments appears to impose a zero-risk standard; such agents are not allowed to be added to food in any amount (although see below for a recent FDA attempt to reinterpret this requirement). For non-carcinogenic food additives, a minimal-risk standard is imposed; the additive must "be shown to be safe", where "safe" is defined as the "reasonable certainty of no harm" under conditions of use. The criterion for safety FDA has developed involves the use of safety factors to establish Acceptable Daily Intakes (ADIs).

Other classes of agents that are regulated purely on the basis of risk considerations are hazardous air pollutants from stationary sources (Section 112 of the Clean Air Act), hazardous wastes regulated under the Resource Conservation and Recovery Act, and household products regulated under the Federal Hazardous Substance Act. EPA is required to regulate hazardous air pollutants from stationary sources by ensuring "an ample margin of safety to protect the public health...". (Criteria air pollutants regulated under Section 109 require an "adequate margin of safety.") Under RCRA, the agency must set limits "that are necessary to protect human health and the environment...". It is not unexpected that, operating under such vague language, quite different limits on human exposure could emerge for the same agent under different regulatory programs, even when a "risk only" model is the governing requirement.

3.2 Balancing models

A variety of "balancing" statutes exists. Some require balancing the risks of using a particular agent against the risks of not having the agent available. The principal example of such a statute is that controlling regulation of pharmaceutical agents. At EPA, pesticide registration decisions depend upon a risk–benefit balancing. The agency is asked to balance the risks posed by a pesticide against those posed by other pesticides available for the same purpose and the

risks that might arise (such as loss of food crops) if the pesticide were not available. EPA is required to set limits on drinking water contaminants by considering not only health protection, but also feasibility and cost. The language of Section 6 of the Toxic Substances Control Act (which pertains to regulation of industrial chemicals) directs EPA to limit exposures "to protect adequately against such risk using the least burdensome requirement...". Similar balancing language exists in the Consumer Product Safety Act.

3.3 Technology-based models

Although health protection goals of various types are specified in all statutes governing hazardous substances, some require regulators to consider the technology available to reduce and control risk. Toxic pollutants listed under Section 307 of the Clean Water Act, for example, must be controlled by applying the "best available technology" economically achievable, although limits must also ensure an "ample margin of safety". Air pollutants from motor vehicles are to be controlled using "standards which reflect the greatest degree of emission reduction achievable...through...technology...available...".

OSHA's actions to control occupational hazards must "adequately assure(s) to the extent feasible that no employee will suffer material impairment of health or functional capacity...". This OSHA language is a singularly impressive example of Congressional attempts to accomodate all interests while leaving the regulatory agency in an almost impossible position. It is apparent that the dual requirements of "feasibility" (which presumably accomodates management interests) and assurance that "no employee" will be harmed (the worker interest) may in many cases be impossible to reconcile. Some of the OSHA decisions on occupational carcinogens to be reviewed in the next section will reveal the difficulty facing regulators operating under broad and sometimes ambiguous legislative mandates.

4. Regulatory decision-making

A close examination of the regulatory process will reveal that actual decision-making is influenced by considerations even beyond those explicitly called for in U.S. laws. Priorities for regulation are many times influenced by political and social events over which regulatory agencies have little control and to which they can only react. Public perceptions of risk, which may or may not correspond to the results of calculations by experts, play a significant role in decision-making, although this influence has not yet been the subject of systematic study. Regulatory decision-making, wherever it occurs, also typically involves efforts to accommodate the many conflicting interests that make themselves felt during the process of rule development. The real world of regulation is frequently much more complex than is indicated in the pages of the Federal

Register, and can only be understood by exploring the motives and actions of those who are involved in the process.

It is instructive to examine the outcomes of some important regulations, because this will provide some insight into how agencies think about their duties under law. In the following we describe and comment on several important decisions of FDA, EPA, and OSHA regarding carcinogens. Even though the agents discussed are regulated under different statutes, the agencies have been forced to make decisions about significant and insignificant levels of risk – i.e., the levels of risk that need to be achieved to protect public health. Some interesting patterns emerge from this summary.

The risks discussed below are those associated with carcinogens. The risks described are hypothetical and are based on a variety of as yet untested assumptions about interspecies and high-to-low dose extrapolation; they should not be confused with risks based on actuarial analyses. The risk assessment methodologies used by the three agencies are nearly equivalent (though not identical), so that a given risk predicted by EPA has roughly the same meaning and uncertainty as that predicted by OSHA and FDA.

4.1 Food and Drug Administration

Risk assessment has been used by FDA primarily as a basis for regulating substances added to or contaminating food, although FDA has extended this practice to other classes of products. Indeed the FDA was the first government agency formally to incorporate risk assessment into regulatory decision-making. In 1973 FDA proposed to define the maximally acceptable concentration of food residues of carcinogenic drugs used in food-producing animals as that which would produce a lifetime carcinogenic risk no greater than one-in-one hundred million (10^{-8}). FDA concluded that food residues of carcinogens in this particular class of regulated agents could be present below the maximally acceptable concentration without jeopardizing the public health. Although in response to public comments FDA later changed the maximally acceptable lifetime risk to one-in-one million (10^{-6}), risk assessment became firmly lodged as a regulatory tool. FDA has since adopted this same approach for other classes of regulated agents [5].

In all these cases FDA has insisted its goal has been to satisfy the statutory requirement that color additives and substances added to food must be "safe", which, in the context of food law, has generally been defined as "reasonable certainty of no harm." A position has evolved within FDA that a carcinogen can be considered safe as long as exposure to it is restricted to levels posing insignificant risks.

The agency has also attempted to extend this approach to cover directly introduced food additives, in apparent defiance of the "zero-risk" requirements of the Delaney Clause. Recently the courts have found this extension inconsistent with the Food, Drug and Cosmetic Act.

Predicted lifetime cancer risks less than 10^{-6} have been defined by the agency as insignificant in several decisions. In a 1979 reproposal of the animal drug residue regulation, FDA stated that "a risk level of one-in-one million over a lifetime imposes no additional risk of cancer to the public" [5]. FDA has also stated that a level of a substance that presents no more than a one-in-one million lifetime risk of cancer "can properly be considered of insignificant public health concern" and is "the level that represents no significant carcinogenic burden in the total diet of man" [5,6].

FDA has found lifetime cancer risks greater than 10^{-6} for certain classes of inadvertent food contaminants – polychlorinated biphenyls, polychlorinated dioxins, aflatoxins – to be acceptable, given the technical and cost limitations on reducing such risks. FDA has not, however, labeled any risks greater than 10^{-6} as insignificant. The agency has also held that contaminants such as these are not to be considered direct food additivities, which are regulated under the Delaney Clause.

4.2 Environmental Protection Agency

4.2.1 Pesticides

The EPA has, in recent years, accepted food residue levels of carcinogenic pesticides posing lifetime risks as high as 10^{-6}. Agency decisions on dicamba, cyromazine and thiodicarb were based on the same position taken by FDA on the safety of food residues of carcinogens [6].

For carcinogenic pesticides that are subject to the Federal Insecticide, Fungicide and Rodenticide Act, EPA is required to perform a risk–benefit analysis. It appears that in most cases EPA has used the 10^{-6} lifetime risk level as a rough guide to significant risk decisions, but the agency has allowed risks greater than 10^{-6} when benefits were large, and has acted against pesticides posing risks less than 10^{-6} when benefits were seen as negligible. It is not clear what the upper limit in risk acceptance is for pesticides regulated under FIFRA, but there are several decisions in which EPA has accepted lifetime risks as high as 10^{-4} [6].

4.2.2 Carcinogenic air pollutants

EPA's treatment of non-occupational risks in its regulatory decisions under Section 112 of the Clean Air Act is stated to be based in part on the Supreme Court's view, expressed in the *Benzene* decision (see below), that "safe" is not equivalent to "risk-free". The agency determined that "standards under Section 112 should protect against *significant* public health risks" [6].

EPA explained in its notice withdrawing proposed regulations of radionuclides from elemental phosphorus plants and other sources that two measures of risk provide important information about significance. The first, "nearby individual risk," refers to the estimated increased lifetime risk from a source

that is faced by individuals who spend their entire life (*sic*) at the point where predicted concentrations of the pollutant are highest. The second, "total population impact," refers to the aggregate risk to all exposed persons in terms of total yearly fatalities.

EPA has held that these two estimates – individual risk and population impact – together provide a superior description of a risk than either alone [7].

EPA has found the maximum individual risks and total population risks from a number of radionuclide and benzene sources too low to be significant. For instance, benzene emissions from maleic anhydride process vents created maximum individual risks of 7.6×10^{-5}, and an aggregate public health impact of ca. 0.03 extra cancer cases [8]. Radionuclides from Department of Energy (DOE) facilities expose a person who accrued lifetime exposure to a plant's most concentrated emissions to a risk of 1×10^{-4} to 8×10^{-4}, while, in the aggregate, only 0.08 extra cancer cases would be predicted to occur yearly, or roughly one case every 13 years [7]. In those two cases, EPA found risks to be insignificant when the most exposed individual faced a risk in the range of 10^{-4} to 10^{-3}, based on a hypothetical 70 years (lifetime) of exposure. Of course, account must be taken of the fact that *average* personal risk would be below the maximum risk. In view of the maximum risks found insignificant by EPA, 10^{-5} seems to be in the range of what EPA might consider to be an insignificant average lifetime risk at least for air pollutants. This may be true at least in cases where aggregate population impact does not exceed a fraction of a cancer yearly. It may not apply if population impact is large.

All of the decisions taken under Section 112 may have to be revised, because of a recent Court decision (below).

4.2.3 Drinking water

In a recent interpretation of the Safe Drinking Water Act, EPA has proposed that, for "non-threshold toxicants" contaminating drinking water, such as carcinogens, no safe level of exposure can be established. The agency proposed zero exposure as the goal for such contaminants, and then proposed Maximum Contaminants Levels (MCLs) based on considerations of technical feasibility. Under this approach it can be presumed MCLs would have to be reduced whenever it became technically feasible to do so. This approach explicitly rejects the use of risk assessment and any notion of a non-zero risk that can be considered insignificant [9].

4.2.4 Superfund clean-up

Although no clear pattern has yet emerged, EPA appears generally to seek clean-up levels for carcinogenic contaminants of Superfund sites that ensure lifetime risks $< 10^{-6}$. In the agency's official Superfund guidance documents, risk goals are stated to fall in the range of 10^{-4} to 10^{-7}, but so far emphasis has been placed on the 10^{-6} figure [10].

4.3 Occupational Safety and Health Administration

OSHA is required to find workplace risks significant before it may seek to regulate them. As the Supreme Court ruled in *Industrial Union Department, AFL-CIO vs. American Petroleum Institute* (the *Benzene* case), the Secretary of Labor, before promulgating any safety or health standard, must "make a finding that the workplaces in question are not safe." However, "safe" is not the equivalent of "risk-free". There are many activities that we engage in every day – such as driving a car or even breathing city air – that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities "unsafe." Similarly, a workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm [11].

A one-in-one thousand risk level is in the range of other fatality hazards in jobs commonly thought of as "safe." On the basis of data collected by the Bureau of Labor Statistics for 1984, the average lifetime risk of a work-related death in private sector establishments with 11 or more employees is 2.9 per 1000 (assuming 45 years of employment). For persons working for 45 years in the mining and construction, transportation, and public utilities industries, the lifetime occupational fatality rates are 18.6, 10.3 , and 7.6 per 1000, respectively, while those employed in the wholesale and retail trades have risk of 1.4 per 1,000, and those employed in finance, insurance, and real estate have a lifetime risk of fatality of just under 1 in 1,000. It should be remembered that these are directly measured, not predicted risks. Note also that the figures assume little variation in the risks from year-to-year [6].

OSHA has used fatality rates such as those described above as "benchmarks" for evaluating the significance of worker health risks.

Health standards promulgated by OSHA generally have stopped short of regulating occupational cancer risks below 1 in 1,000, largely because of feasibility limitations. The residual lifetime risks (i.e., those remaining after implementation of the OSHA's revised Permissible Exposure Limit) associated with the agency's inorganic arsenic and ethylene oxide standards are, in OSHA's estimation, 8 per 1,000 and 1 to 2 per 1,000, respectively. Further, the residual risks associated with the proposed benzene standard are, according to OSHA, 5 to 16 per 1,000. For other occupational carcinogens OSHA has not sought to reduce risks below 1 to 10 per 1,000. Note that OSHA has not made any statement about what it considers an "insignificant" occupational risk [6].

These risk levels, while in the range of those of other types found in many occupations considered safe, would not appear to satisfy the legal standard that "no employee" will suffer harm, and it is not clear how OSHA reconciles these decisions with the strict language of the law.

4.4 Summary of agency significant risk decisions

Although our review of significant risk decisions is not exhaustive, several trends emerge. With one important exception two federal regulatory agencies

(EPA, FDA) now appear to recognize the notion of "insignificant" risk. At least in the past 5 years there appears to be no case in which predicted lifetime cancer risks $< 10^{-6}$ have been subjected to regulation, with the possible exception of some pesticides judged to provide insignificant benefits. Although agencies and offices within those agencies have described the concept of insignificant risk in different ways and with varying degrees of explicitness, there appears to be almost universal acceptance of the concept.

The exception to this trend is the EPA's Drinking Water Office, which rejects as unsafe, at least in principle, any non-zero risk of carcinogenesis, no matter how small. The Office is forced, however, to accept non-zero exposures to carcinogens because of technical limitations in achieving zero exposure.

OSHA has not judged any occupational carcinogenic risk to be clearly insignificant but has not sought to force predicted lifetime risks below ca. 10^{-3}. It appears that, at least in principle, OSHA is prepared to find some level of occupational risk insignificant.

The other emergent trend is that the regulatory agencies have found lifetime risks to the general population greater than 10^{-6}, sometimes up to approximately 10^{-4}, as acceptable, either because of cost or feasibility constraints or because the size of the exposed population was small. Even the Office of Drinking Water accepts risks in this range for the trihalomethane contaminants produced as a byproduct of chlorination [6]. Except for decisions made by EPA for certain air pollutants, as described above, we can find no evidence that agencies regard general population risks greater than 10^{-6} as clearly insignificant; rather, risks greater than 10^{-6} are often described as "acceptable" because reductions to the clearly negligible range are either technically infeasible or too costly.

5. Inconsistency in risk management: A problematic case

The preceding discussion suggests why variations in risk management occur – uncertain science, different statutory policies, differences in the feasibility of risk reduction – but also the striking degree of commonality among agencies and programs in their willingness to ignore estimated cancer risks in the vicinity of 10^{-6}. There *is* an element of rationality in our system of environmental risk regulation despite the appearance at times of inconsistency or even the occasional hint of chaos.

In July 1987, however, two court cases involving EPA, decided only three days apart, demonstrated that problems of inconsistency do remain. The cases involved regulation of vinyl chloride as a "hazardous air pollutant" under Section 112 of the Clean Air Act [12] and volatile organic compounds (VOC's) in drinking water under the Safe Drinking Water Act [13].

Section 112 of the Clean Air Act requires the Administrator of EPA to set emission standards for hazardous air pollutants "at the level which in his judg-

ment provides an ample margin of safety to protect the public health." In considering an emission standard for the presumably non-threshold carcinogen vinyl chloride, EPA set a non-zero emission standard based in part on consideration of what emission level was considered achievable using "best available control technology." Clearly implicit in EPA's position was the judgment that "an ample margin of safety" could be achieved with some level of exposure to vinyl chloride, despite the Agency's view that any exposure to a non-threshold carcinogen must be assumed to pose some risk of cancer. Safety does not mean zero risk.

In the Safe Drinking Water Act case, EPA seemed to take another view. That statute instructs EPA to set "recommended maximum contaminant levels" (RMCL's) for potentially hazardous pollutants "at a level which, in the Administrator's judgment...no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." RMCL's are non-enforcable health goals, but they provide the basis for promulgation of legally binding maximum contaminant levels (MCL's), which must be set as close to the RMCL "as is feasible." In the case of the VOC's EPA set zero RMCL's for the ones found to be "known" or "probable" carcinogens, reasoning that:

> ...the zero level is necessary to prevent known or anticipated effects from human or probable human carcinogens including a margin of safety. No other margin of safety would be adequate since EPA does not believe a threshold for carcinogens exists [9].

According to the Court reviewing EPA's decision, the Agency did not consider itself legally bound to establish zero RMCL's for carcinogens, but instead "made an expert judgment that there is no safe threshold level for known or probable carcinogens" and set recommended levels accordingly.

But see how different this is from the judgment apparently underlying EPA's position in the Clear Air Act case. There, a non-zero level of exposure to a known human carcinogen was apparently found to provide "an ample margin of safety to protect the public health," in direct conflict with EPA's reasoning under the SDWA [12,13].

In EPA's defense, there are statutory and practical differences in these cases that help explain the apparent inconsistency. For example, in the drinking water case, EPA knows that RMCL's are only goals and that practical considerations could come into play in setting the binding MCL's for these contaminants. The fact remains, however, that these cases reflect differing approaches within the same agency toward managing the risks posed by environmental carcinogens. In one case EPA has abandoned the goal of zero exposure/zero risk based on the judgment that neither is required to provide a safe environment, even an "ample margin of safety." This is consistent with the prevailing body of expert opinion and public health judgment.

In the safe drinking water case, however, EPA retains the zero exposure/

zero risk goal. The logic of this is elusive. If exposures to other classes of agents posing *de minimis* cancer risks can be judged safe, why not similar exposures to drinking water contaminants?

One answer might be that, as long as we are talking about aspirational goals, we should stick with zero exposure, recognizing that practical considerations can come into play in setting binding limits. This notion has appeal, especially to the lay public and those whose role it is in our political system to respond to public perceptions and desires.

But there are problems with zero exposure/zero risk even as a goal of environmental risk regulation. One is that it goes beyond what science suggests is necessary and is unattainable. There is something to be said for not kidding ourselves when it comes to deciding what is needed and possible in this critical area of public health regulation.

At a more practical and important level, the problem with pursuing absolutes in environmental risk regulation is that it slows agency decisionmaking and wastes regulatory resources. Over the last decade or so, EPA and FDA both have spent enormous time and energy grappling with problems of *de minimis* risks, deciding how to regulate them and defending decisions not to regulate. For FDA much of this has been driven by the apparent zero-risk mandate of the Delaney Clause, while for EPA much of the pressure has come from environmental groups pressing zero-risk interpretations of the Clean Air Act, the Safe Drinking Water Act and other environmental statutes. When considered in light of increasingly constrained agency resources and the large inventory of more important public health and environmental problems waiting to be addressed, much of this effort seems wasted.

This is not to say *de minimis* risks should be ignored. Indeed, they must be evaluated and identified as part of the process of assuring that we avoid significant risks. But the agencies should adopt, and be supported in their adoption, of consistent, practical tools of risk management that permit them to pass over *de minimis* risk with minimal effort and controversy. Progress has been made in this direction, but much more remains to be done, including further development of the scientific and social consensus required for sound risk management.

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