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DE MINIMIS CONSIDERATIONS IN HEALTH RISK ASSESSMENT*

P.F. RICCI and L.A. COX, Jr.

Arthur D. Little, Inc., Acorn Park, Cambridge, MA 02140 (U.S.A.)

with contributions from M. BARAM.

Boston University Law School, 765 Commonwealth Ave., Rm. 866, Boston, MA 02215 (U.S.A.)

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Summary

Federal statutes concerned with health and safety are attempts by Congress to establish goals and principles for regulatory agencies to use in setting standards and making other decisions.

However, statutory language often provides inadequate guidance or mandate. In some cases, absolute requirements are stated which cannot be satisfied. In other cases, the language is ambiguous as to agency responsibilities and the responsibilities of industry, leaving final interpretations to the courts. This can be costly.

One critical issue resulting from this situation is how to set "*de minimis*" limits for the regulation of chronic health risks from exposure to hazardous substances. Absence of statutory guidance for determining "*de minimis*" threshold levels of risk which do not merit regulatory efforts has been identified as a critical regulatory problem by many, including recently the U.S. Supreme Court.

The consistency, effectiveness, and benefits of regulatory programs will be enhanced if a "rational" approach can be made available to agencies for establishing *de minimis* risk levels. Setting these levels requires consideration of both individual and population risks as well as risk management principles for allocating scarce resources.

The development of a formal *de minimis* approach requires resolution of several legal and technical issues. In this paper, we provide conceptual and legal rationales for a *de minimis* policy to determine plausible risk bounds for chronic health risks. We also develop a conceptual framework for adopting generic *de minimis* policies. Our findings suggest that there are several opportunities for applying this concept under existing statutory mandates.

Introduction

The statutes that authorize federal regulation of risks to human health are attempts by Congress to provide intelligible goals and principles to guide the

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regulatory agencies. However, the statutory language in some instances sets absolute requirements that cannot realistically be satisfied, while in many other cases, only ambiguous statements and inadequate guidance are provided (see Table 1). As a result, the regulatory process has difficulty interpreting the intent and substance of the statutes. This is particularly true in the context of chronic health risks.

Several critical issues for regulatory agencies arise from these statutory inadequacies. Two are dealt with here: the problem of selecting which hazards are to be regulated, and the problem of determining the level at which the concomitant risks are to be judged "acceptable". The effectiveness of regulatory decisions might be enhanced if agencies had available a consistent, systematic approach for determining when risks are *de minimis* or trivial. Such an approach could avoid triggering wasteful regulatory efforts, private sector expenditures of resources, and social opportunity costs from benefits of production inappropriately foregone. Where the regulatory process has been initiated, a *de minimis* cutoff threshold could help determine at what level the risk has been reduced enough to make more stringent regulation unnecessary. Development of a systematic *de minimis* approach requires resolution of several legal, technical, economic, and policy issues. We address some of these issues and develop a conceptual basis for using the *de minimis* concept to set reasonable bounds on risk regulation of chronic health hazards in selected statutory contexts.

De minimis has its origins in the ancient legal maxim, "*de minimis non curat lex*", i.e., "the law does not concern itself with trifles". The maxim is applied under the circumstances of the case at bar where various procedural safeguards guarantee some freedom from arbitrariness.

Although *de minimis* risk has not been directly addressed by Congress, the concept is well-grounded in American case law involving hazardous materials. The U.S. Supreme Court, and other Federal courts, have recently exhorted agencies to consider the significance of risk findings, in cases involving OSHA, EPA, and the FDA. EPA has sought to establish "trigger levels" for regulatory action in areas such as hazardous waste cleanup, control of carcinogens, and FDA is using a *de minimis* rationale in recent actions involving food additives. We discuss these actions later in this paper.

We develop some of the principles pivotal to establish a formal, generic policy for *de minimis* risk, under which trivial risks would not trigger regulatory efforts or more stringent standards, unless new and compelling facts were to come to light.

A. The risk regulation process

Risk-governing statutes may be viewed in terms of the three main stages for risk regulation that they mandate for agency implementation:

1. Identifying hazards and selecting those which warrant or trigger regulatory efforts.
2. Fact-finding on the risk attributes of the selected hazards including, for example, carcinogenicity, exposure conditions, and dose–response relationships.
3. Taking regulatory action on the selected hazards to reduce risk to a particular level on the basis of the findings of fact.

Examination of the statutory language of several risk management statutes, and interpretations of statutes by the agencies and courts, leads to our initial finding: that, in most instances, agencies have sufficient discretion to formulate and apply *de minimis* risk policies which are consistent with statutory provisions.

1. Hazard identification and selection

When a statute specifies that an agency must consider for regulation the complete universe of substances or activities (e.g., food additives, pesticides), the agency has limited discretion to screen out those *substances or activities which are quantitatively de minimis* to avoid wasting limited resources, and thereby focus its efforts on those substances or activities more likely to have significant impacts. But a federal court ruled that the Food and Drug Administration (FDA) may decline to regard a substance as a food additive "if the level of migration into food...is so negligible as to present no public health or safety concerns", *Monsanto* v. *Kennedy*, 613, F.2d 947, 955 (D.C. Cir., 1979).

Numerous courts have upheld agency decisions that federal actions proposed on the basis of a preliminary screening process do not merit full environmental impact review under the *National Environmental Policy Act*, 42 U.S.C. 4321 *et seq.*, because the apparent measurable impacts on the environment were insignificant. For example, *Carolina Environmental Study Group* v. *United States*, 510 f.2d 796 (D.C. Cir., 1975), held that the probability of a class 9 reactor accident was so low as to be "almost totally unworthy of consideration". Nuclear Regulatory Commission (NRC), 524 F.2d 1291, 1300 (D.C. Cir., 1975), held that routine low-level emissions of radionuclides were acceptable.

When the substances or activities subject to regulation have been statutorily defined so that probability of occurence alone cannot serve as a basis for exclusion from regulatory consideration, as in the cases of "hazardous air pollutants" or "toxic water pollutants", the implication is that the agency's screening process will be based on some *quantitative threshold of risk*. An agency is permitted to screen out such substances or activities from further regulatory consideration only when the exposure circumstances and other risk conditions indicate that: (a) disease, or other health impact endpoints, will not amount to any significant number of harms in the general population or in any partic-

TABLE 1

Synopsis of selected criteria for regulating public, occupational and environmental risk

Criteria	Implication	Remarks
Zero risk	Absolute control, through ban (substances demonstrated to be carcinogenic are banned). Substance must be generally shown to be safe (*Certified Color Maftrs* v. *Mathews*, 543 F.2d 284 (D.C. Cir. 1976)).	Delaney Clause to the Federal Food, Drug, and Cosmetic Act (approval of food related additives) (FDA), 21 *U.S.C.* §348(c)(3)(A); also see the 21 *U.S.C.* Sec. 376(b)(5)(B) and 21 *U.S.C.* Sec. 3606(d)(1)(H).
To the extent feasible	"Capable of being done". Cost-benefit analysis is inappropriate; emphasis on human life and workers' health protection against toxic or harmful agents. Economic and technical feasibility is the standard.	(OSHA), §6(b)(5), 21 *U.S.C.* §655(b)(5) and *American Textile Manufacturers Association* v. *Donovan*, 101 S. Ct. 2478 (1981).
De Minimis	Level of risk that can be ignored. From the Common Law maxim, *de minimis non curat lex*: trivial findings are of no legal consequence.	In *EDF* v. *EPA*, 636 F.2d 1267 (D.C. Cir. 1980) in a case involving the Clean Air Act and TSCA, the court held that the agency can "overlook circumstances that in context may ... be *de minimis*", but "it must find the concentration at which there only "trivial" benefits to be denied from regulation". (Also see *Monsanto* v. *Kennedy*, 613 F.2D 947 (D.C. Cir. 1979)).
Natural Standards	Risks from naturally occurring events serve as a benchmark for man-made events.	Pervades the law and human behavior.
Unreasonable Risks	Considers cost and benefits of proposed action to reduce risk. Balancing of costs and benefits may include cost of burden imposed by regulation probability of harm, and severity of harm.	(TSCA)5(f), 15 *U.S.C.* 2604(f).
Significant Risk	No explicit consideration of costs or benefits but technology forcing. Significance is determined case-by-case; the Agency must find such significance before proceeding further,	Highest degree of safety is called for (OSHA) §(6)(b)(5), 29 *U.S.C.* §655(b)(5).

	Ind. Union Dept., AFL-CIO v. *Am. Petroleum Institute*, 449 U.S. 609, 642 (1980).	
Adequate margin of safety	Clean air pollutants (e.g., SO_2, CO, TSP, HC, etc.) Protects health of the less resistant segments of population. No consideration of costs or benefits are required to justify environmental standard, but some (e.g., 0.005% of population at risk from airborne lead) can be at risk after imposing standard.	Clean Air Act for Primary and Secondary National Ambient Air Quality Standards. (CAA) §§108, 109, 42 *U.S.C.*, §§7408, 7409. (Also see *Lead Industrial Association Inc.* v. *EPA*, 647 F.2d 1130 (D.C. Cir.), *cert. denied* 449 U.S. 1042 (1980).
Reasonably Necessary or Appropriate	Cost and Benefit balancing with substantive evidence requirement (relevant to safety issues rather than carcinogens) against "risk of material health impairment". Particularly applicable to standards that do not involve toxic agents.	See (TSCA) §4(f), 15 *U.S.C.* §§2603(f) and §(5)(f), 15 *U.S.C.* 2604(f).
Ample Margin of Safety	Air pollutants not covered under CAA §§108, 109, (e.g., Be, Hg, asbestos, etc.). Emphasis on serious or incapacitating illness or mortality. No explicit consideration of costs or benefits to justify ambient air quality standards. Practical application include Best Available Technology (BAT) and some form of risk-benefit or cost-benefit trade-off.	Includes consideration of risk remaining after BAT control of pollutant. Clean Air Act, section for hazardous pollutants (CAA).
As Low as Reasonably Achievable (ALARA)	Individual and societal risks; the former on a low annual probability; the latter at the expected value. The consequences may be raised to either 1.0 or other exponent > 1.0, depending on nature of consequence (e.g., cancers or delayed deaths).	Societal risk at set at a limit; ALARA cost-effectiveness to further reduce societal risk. The NRC proposes a safety goal - but does not regulate on this basis - for nuclear power plants, such than an increase greater than 0.1 percent in cancers over background, without a reactor, is sufficiently to trigger NRC's action.

ular population subgroup; or (b) that the harms themselves are intrinsically trivial in terms of their impacts on the health of any individual.

2. Fact-finding for risk estimation

Hazards which are not screened out in the prior stage then enter the fact-finding stage of regulatory process. Since findings of fact are needed to support any regulatory standard-setting action under all statutes, a hazard may not be susceptible to regulation if (a) scientific uncertainty prevents the reaching of any conclusive findings as to risk, or (b) the findings indicate that the risk falls below some threshold of health importance which is considered too trivial to regulate. Ideally, a *de minimis* policy deals with the latter circumstance. It consists of two parts; (i) an operational specification of how risk is to be measured numerically; and (ii) a numerical threshold below which risks are to be considered *de minimis* and excluded from regulation. In practice, the fact of scientific uncertainty must be recognized and dealt with in the formulation of pragmatically useful *de minimis* criteria.

For example, if the findings of risk required by statute are to be based on *probability of occurrence* of a health effect in the most exposed individual and the health significance or the *magnitude of the health effect* if it occurs, then too remote a probability, or too insignificant a health impact, or both could lead to the use of agency discretion in finding the risk *de minimis*. This finding would exclude it from further regulatory consideration (at least for the moment).

Now suppose, realistically, that the change in occurrence probability of an adverse health effect is uncertain, e.g., because of scientific uncertainties about the biological mechanisms at work and the form of the dose–response function. Then the *de minimis* rule would have to be modified to account for this uncertainty. For example, it could state that if the *probability* that an uncertain risk exceeds a *de minimis* level is sufficiently low, based on substantial evidence, then the uncertain risk will also be considered *de minimis*. These are essentially the same kinds of tests employed in the first screening stage, the major difference being that the facts are more conclusively established. Few statutes limit agency discretion in this regard. (The Delaney Clause of the Food, Drug, and Cosmetic Act, 21 U.S.C. 348(c)(3)(A), is a well-known exception: risk is significant, and the substance causing it subject to regulatory ban, if evidence indicates carcinogenicity.)*,**

Agencies setting standards under most statutes, therefore, have the oppor-

*But see the proposed action by the FDA: (a) to ban methylene chloride (in aerosol cosmetic products) based on significant risk, but, (b) not lowering the maximum permitted residue level of methylene chloride in decafinated coffee as that "level is considered safe", although methylene chloride is an additive. 50 *Fed. Reg.* 51551 (December 18, 1986). The FDA justifies this latter action on the basis of *de minimis* risk, avoiding the Delaney Clause, 50 *Fed. Reg.* 51555. This decision is now being challenged as a violation of the agency's statutory mandate.

**Also see *Scott* v. *FDA*, 728 F.2d 322, 325 (6th Cir., 1984) extending *Monsanto* to proven carcinogens, as impurities in color additives, if these cause a negligible impact.

tunity to use their discretion in establishing a *de minimis* risk policy based on a balanced assessment of the probability of occurrence and magnitude of harm components of their risk estimate. However, controversy is certain to arise following the enunciation of such a policy if it articulates a proclaimed "acceptable" trade-off between probability and magnitude of harm. Many will contend that finding a risk *de minimis* on the basis of a remote probability of occurrence was not intended by statutes that emphasize regulation on the basis of the significance of the health or safety risks involved (e.g., for airborne chemical carcinogens, under the Clean Air Act). There is also the relatively sophisticated objection that estimated occurrence probabilities usually depend primarily on what is known, rather than on the probabilistic nature of the health and safety phenomena involved. This implies that using an estimated probability as a criterion for decision-making requires the adequacy of the evidential basis for the estimate to be assessed. Probabilities must be credible as well as small to pass this extended *de minimis* test. But debates over the credibility of risk assessments can stymie decision-making nearly indefinitely.

Rather than deal with these arguments *de novo* in each case and face legal challenge and suboptimal allocation of resources, agencies should establish general, clearly stated *de minimis* policies, and engage in a single process, open to all views and scrutiny, in applying it to particular cases. Such a generic policy would avoid or reduce future conflicts over the elimination of specific risks from regulatory considerations. For example, in *Baltimore Gas and Electric Co.* v. *Natural Resources Defense Council, Inc.*, (U.S., 82-524 and 555, 1983), the U.S. Supreme Court affirmed NRC's use of its generic policies on reactor risks for the particular power plant challenged.

An agency's policy toward *de minimis* risk may reflect the economic context in which the risk being regulated arises. For example, an agency such as CPSC or OSHA that regulates risk from economic transactions (e.g., consumption or employment agreements) may wish to adopt a different *de minimis* threshold than an agency, such as EPA, that protects members of the public against risks from production externalities – like chronic health effects from power plant emissions – over which victims have no control.

The adoption of a general *de minimis* risk policy, specifying conditions under which risks will be considered *de minimis*, for application to particular risk cases, is consistent with the recommendations of experts on administrative and regulatory law: namely, that agencies should structure their discretion by adopting formal policies, on a generic basis, to prevent *ad hoc* decision-making which is prone to subjective factors, pressures, and abuses.

3. Taking appropriate regulatory action

Risks that are not eliminated in the preceding two stages now enter the last stage of the process, in which appropriate regulatory action is determined. The levels of risk are set here.

There may be little need for a *de minimis* risk policy at this point, since most of the issues of risk occurrence and magnitude will have been dealt with in the preceding two stages. However, to the extent *de minimis* risk determination was not done earlier, it could be done here. This could result in the suboptimal use of the *de minimis* policy; it would be less cost-effective – in a regulatory sense of proper allocation of scarce resources – if done in this last stage. Any *de minimis* test would involve the considerations appropriate for the fact-finding stage, and the test would be applied to determine the risk level at which more stringent regulation is not warranted.

B. *De minimis* risk as a regulatory concept

The *de minimis* risk concept has received limited judicial and executive endorsements. In this section and the next, we briefly review recent relevant case law history that lends legal support to and helps define the concept.

In his concurring opinion in the OHSA benzene standard case, *Industrial Union Dept., AFL-CIO* v. *American Petroleum Institute,* 448 U.S. 607, 663-664 (1980), U.S. Supreme Court Chief Justice Burger noted:

"Inherent in [the OSHA] statutory scheme is authority to refrain from regulation of insignificant or *de minimis* risks. See *Alabama Power Co.* v. *Costle,* 204 U.S. D.C. Cir. 41, 81-89, 636 F.2d 323, 360-361 (1979) (opinion of Leventhal, H.). When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation."

The plurality opinion in this case, in which Burger joined, held that, before the Occupational Health and Safety Administration (OSHA) could issue its revised benzene standard under the *Occupational Safety and Health Act,* the Act requires a threshold finding that a significant risk from benzene is present in the work place, and can be lessened by the proposed standard. 448 U.S. at 642. The Burger concurrence, however, appears to state a slightly different proposition: the Act permits OSHA to refrain from regulation when it finds a risk to be insignificant or *de minimis* and "responsible administration" compels it to do so.

The Chief Justice cited, in support of his statetement, the discussion of the *de minimis* concept offered by D.C. Circuit Judge Harold Leventhal. In *Alabama Power* v. *Costle, supra* 636 F.2d at 360-361 (a case requiring interpretation of some sections of the Clean Air Act), Judge Leventhal considered EPA's prospective exemption of certain categories of stationary sources of air pollution from its regulatory requirements, to prevent the significant deterioration of ambient air quality. Judge Leventhal stated:

"Categorical exemptions may ... be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis*

....The law does not concern itself with trifling matters, and this principle has often found application in the administrative context. Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort .... The ability .... to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.

Determination of when matters are truly *de minimis* naturally will turn on the assessment of particular circumstances, and the agency will bear the burden of making the required showing. But we think most regulatory statutes, including the Clean Air Act, permit such agency showings in appropriate cases (footnotes omitted)."

The court thus accepted the *de minimis* risk rationale to grant exemptions from even absolute statutory language, although it found the particular exemptions made by EPA to be invalid. The use of the *de minimis* risk concept as an administrative management tool has also received the support of federal regulatory agencies and advisory groups. The Department of Commerce, in a critique of EPA regulatory policies under Section 112 of the Clean Air Act, illustrated how the *de minimis* concept could be used to foster such a risk-efficiency objective:

"The public health and welfare would be better served by channelling regulatory efforts and the resulting private investments into programs having a higher risk level than about 10-20 in the U.S. population of about 225 million. We urge EPA to establish some *de minimis* risk, below which EPA can determine that there is no significant risk to the public ... Even if there are "considerable uncertainties" in quantitative risk assessment, the *de minimis*, if properly set, can prevent the Agency from directing its own and private efforts towards the reduction of risks with a very low probability of occurrence to an even lower probability." (Commerce Department, Memorandum of Comment on EPA's Proposed Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer (draft 3) [EPA Doc. OAOPS 79-14, No. IV-D-181].)

The Office of Management and Budget has similarly endorsed the use of *de minimis* risk thresholds in EPA's implementation of Section 112.

"EPA may find that there are administrative advantages to establishing a *de minimis* risk level. This would allow EPA to direct its attention toward those source categories posing the greatest public health risks. In addition, ... an explicit *de minimis* threshold for public health risk at an initial stage in the standard setting process would seem to screen out a number of cases where regulation would achieve only negligible gains in public health." (Office of Management and Budget, EPA's Standard-Setting for Toxic Pollutants (Dec. 1983) reprinted at 14 Env. Rptr. 1594, 1603 (Jan. 13, 1984).

EPA's Carcinogen Assessment Group, CAG, evaluates cancer risks for numerous substances and has frequently concluded that certain levels of risk are too minimal to warrant further consideration. For example, an individual lifetime cancer risk of 5×10^{-6} from Ortho-Scram Dog Repellant was considered "minimal", *Carcinogenic Risks of Safrole Contained in Ortho-Scram Dog*

Repellant (June 3, 1977). A 1×10^{-6} individual lifetime risk of cancer from N-nitroso compound exposure was deemed by EPA to meet "currently acceptable risk criteria". 45 *Fed. Reg.* 42856 (June 25, 1980).

The *de minimis* or insignificant risk concept has also been used at the state level. Michigan's Water Resources Division in the Department of Natural Resources, recently proposed in its Rule 57 that it will not regulate the discharge of carcinogenic substances into surface water when the substances have a 1×10^{-5} level of individual lifetime cancer risk, or less, because this level is "generally below that of common, everyday risks". "Pollution: The Acceptable Risks", *Detroit Free Press* (Feb. 26, 1984).

Despite these views, the *de minimis* risk concept has not been formally proposed or adopted for generic use, even in well-defined classes of similar risks. As a result, agencies regulating similar risks continue to determine on an *ad hoc* basis the risk levels they will regulate or act upon. Thus, EPA has recommended zero as the contaminent level for seven chemicals in drinking water, *Current Developments* 15 *Env. Rptr.* 163 (June 8, 1984). It has taken the position that hazardous waste cleanup actions must be considered and taken (on the basis of various factors) at a finding of a 10^{-6} individual lifetime risk of cancer. *Current Developments,* 14 *Env. Rptr.* 2270 (April 20, 1984). In contrast to the Michigan Division of Water Resources proposed Rule 57, that state's Divisions of Air Quality and Groundwater Quality, also in the Department of Natural Resources, use an individual lifetime cancer risk of 1×10^{-6} to trigger regulatory action. *Detroit Free Press, supra,* at 1.

There is little evidence that the federal courts, which review agency standards and other final actions, have any clear understanding of the probabilistic aspects of *de minimis* risk, or that they apply any uniform criteria in evaluating whether agency requirements stop at a *de minimis* risk level. Thus, in the *United States* v. *General Motors,* 561 F.2d 923, 924 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1033 (1978), the D.C. Circuit Court of Appeals upheld a NHTSA recall of 1959–1960 model year Cadillacs in 1977. This occurred although there was no government showing of any injury or death from "pitman arm" failures. General Motors had given evidence that no unreasonable risk was posed because failures occurred only at low speed; that there were few 1959–1960 Cadillacs still in use in 1977; and that its forecast showed less than a one percent chance of fatality, and only two injuries. T. Schwartz, *Product Recalls: A Remedy in Need of Repair* 7 (Adm. Conf. U.S., Dec. 1983).

More recently, several federal courts have enjoined federal agencies from undertaking projects (e.g., spraying timber with herbicides), because their analysis, under the *National Environmental Policy Act,* did not include a "worst case analysis". (See, e.g., *Save Our Ecosystems* v. *Clark,* 13 ERC 1607 (9th Cir. Jan. 27, 1984). This recent judicial test of NEPA compliance appears to show preoccupation with severity of harm (consequence) but inadequate attention to probability of harm.

In summary *de minimis* risk is a concept available for agency decision-making, but is not now a general practice. Agency failure to advance *de minimis* risk from concept to practice – through a generic policy – is due to at least two major considerations:

1. The meaning of the concept is uncertain. In some cases it is related to "significant risk", "acceptable risk", and other concepts or criteria used by agencies; in other cases it conflicts with such concepts. This issue turns on scientific uncertainty about the extent of risk, and on the failure to clearly distinguish between risk and uncertainty about risk. Both must be addressed in practical formulations of the *de minimis* risk policies.
2. The agencies have no clear statutory mandate to use or even to consider the concept, since neither Congress nor the Office of the President (e.g., Office of Management and Budget) have defined it, or called for its generic use.

C. Toward convergence: judicial discretion

At common law, courts have occasionally used the *de minimis* concept to dismiss a suit on the ground that it presents a trivial matter, or does not merit the court's attention and resources. In this sense, there is little ambiguity:

"This law is not concerned with trifles. *Loeffer* v. *Roe* (Fla.) 69 So.2d 331 .... A maxim leading to the rule that accepts substantial performance as sufficient performance of a contract, 17 *Am. Jur. 2d,* Contr. Section 370; sometimes applied to exclude the recovery of nominal damages, where no unlawful intent or disturbance of a right or possession is shown and where all possible damage is expressly disproved. 22 *Am. Jr. 2d,* Damages Section 2 ... (Definition of *De Minimis Non Curat Lex, Ballantine's Law Dictionary,* at 331)."

The common law has used the concept to deal with cases involving trifling damages or breaches of duty. Nevertheless, there also are seemingly innocuous situations where the maxim has not been invoked (e.g., where an unintentional trespass on land without measurable damage is nevertheless subject to civil penalty). Further, the concept has not been used by the courts to describe an inadequate evidentiary showing by a plaintiff as to a defendant's fault or as to causation of plaintiff's injury. Nor has it been used to dismiss claims which the common law deems inactionable even though actual damages may be involved (e.g., emotional distress; loss of consortium; injuries caused by government but not actionable because of sovereign immunity). Finally, the concept has not been invoked – perhaps wisely – in cases involving health or safety risk, even if the plaintiff represents a distinct minority (e.g., a person who reacts abnormally to a usually harmless product or exposure). At common law, there is no statistical or quantitative measure of *de minimis* when it comes to adjudicating the basic individual rights of injured parties against tortious defendants.

Federal court use of the *de minimis* concept, as exemplified by the Burger and Leventhal opinions, has expanded upon this limited common law tradition. The Leventhal opinion reflects an extension of the *de minimis* concept from judicial use to administrative use.

Judge Leventhal concluded that the *de minimis* risk concept is a matter for an agency's reasoned discretion, provided it does not conflict with applicable law and is supported by the facts before the agency. His opinion is silent on the definition of *de minimis* risk, but his consideration of the concept, applied to small contributions to air pollution, indicates that an agency can consider a *de minimis* level based on the probability of harm, and not only one based on the magnitude of the consequences arising out of that harm.

The U.S. Supreme Court has carried the *de minimis* concept further, at least with regard to the OSHA. In Chief Justice Burger's view, it is an agency's *duty* to avoid wasting its resources on what it finds to be a *de minimis* risk and to develop a rational scheme of priorities for regulation. This "management duty" view of *de minimis* is obviously more forceful than Leventhal's, but it is also more problematic, since an agency's duty to manage its resources may arguably be at odds with its statutory mandate or Congressional funding directives. If Congress enacts legislation and provides funds to promote agency regulation there appears to be no basis in Constitutional or administrative law to enjoin the agency from responding accordingly.

Nevertheless, the Burger view has distinct appeal as a guide for improving agency efforts to reduce health risks. The existence of such a duty finds support in the Supreme Court's plurality opinion in the benzene case, *supra,* 448 U.S. at 643-644. That opinion enunciated a "significant risk" threshold for OSHA standards:

"Before he can promulgate any permanent health or safety standard, the Secretary [of Labor] is required to make a threshold finding that a place of employment is unsafe - in the sense that significant risks are present and can be eliminated or lessened by a change in practices."

This threshold was derived by construing the Occupational Safety and Health Act's definition of the term "occupational safety and health standard":

"... a standard which requires conditions, or the adoption or use of one or more practices, views, methods, operation, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 *U.S.C.* Sec. 652(8).

The Supreme Court plurality opinion also added:

"The Act implies that, before promulgating any standard, the Secretary must make a finding that the work places in question are not safe. But "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 entails some risk of accident or material health impairment; nevertheless, few people would

consider these activities "unsafe". Similarly, a work place can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm." 448 U.S. at 642.

Thus, the Court derived the requirement of a threshold finding (above which risks are significant) from an implication it found in the quoted section and from the use of the word "safe". If so, then it is arguable that the duty to disregard *de minimis* risks exists in virtually every health, safety, and environment statute, at least in the absence of language expressly directing action on such risks.

The outcome of this case may be the result of judicial conservatism or dissatisfaction with the broad mandate of the Occupational Safety and Health Act. On its face, the Act appears to provide OSHA with broad discretion to set standards to reduce risks to individual workers, within the limits of economic and technical feasibility:

"The Secretary [of Labor], in promulgating standards dealing with toxic materials ... shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity ..." 29 *U.S.C.* 656(b)(5).

This mandate also seems to permit regulation of risks, no matter how limited or insignificant their incidence. Thus, the Act stresses the seriousness of health effect to the individual worker, but appears to ignore the probability of occurrence. Any uses of the "significance" test can therefore be read as a judicial effort to instill some consideration of the probability of occurrence into OSHA regulatory decision-making.

Indeed, a number of federal courts have embraced the significant risk concept precisely because it "looks equally to the likelihood of the potential harm", *Pratt and Whitney, Inc.* v. *Donovan*, 715 F.2d 57, 64 (2d Cir. 1983), and, therefore, is in accord more with modern concepts of risk management than with traditional judicial views "which have focused primarily on the seriousness of the accident should it occur, ... [giving] only low level scrutiny [to the likelihood of the accident itself]". *Kelly Springfield, Inc.* v. *Donovan*, 11 OSHA 1889, 1893 (5th Cir. 1984).

Nevertheless, the significant/*de minimis* test has thus far figured only in court cases involving OSHA regulatory actions, and with mixed results. In *United Steelworkers, AFL-CIO* v. *Marshall*, OSHA's lead standard was challenged on several grounds including the lack of a proper "significant risk" finding. It was argued by petitioners that, by extrapolating from high-dose results to low-dose conditions in the work place, by setting a regulatory standard to prevent an adverse biological response, and by failing to give more weight to the variability of these responses to various levels of lead exposure, OSHA had regulated lead exposure too far. It had gone beyond the level of significant risk, into the insignificant: OSHA had crossed the *de minimis* level. In applying the

significant/*de minimis* test, the D.C. Circuit Court found that OSHA had used a valid scientific model to provide the best available evidence for correlating subclinical responses with significant risks of "material impairment" to worker health. The court also ruled that OSHA's dose–response model justified extrapolating health effects from high-doses to low-doses. The court noted that there was substantial evidence, in OSHA's administrative record, to establish the need for the standard to be issued. It determined that this agency had avoided making those arbitrary assumptions of significant risk which had led to the earlier invalidation of the benzene standard by the U.S. Supreme Court. Thus, the court found that OSHA had met the significant risk test.

However, in the line of cases involving challenges to OSHA's findings of violations of the OSHAct's general duty clause, the significant/*de minimis* risk test has been essentially discarded as inconsistent with the statutory language. Although courts have differed somewhat in construing the test, and determining its applicability, the essential outcome is that "the task of speculating is not central to determining whether a violation finding is proper". A finding of violation will be supported by evidence that the hazard at issue is one that is "recognized in the industry", or "known to the firm"; not that it is "possible", "reasonably foreseeable", or probable to some degree.

All that can be concluded now is that the federal courts are using a significant/*de minimis* risk test in reviewing OSHA regulations, but not in the decisions involving risks controlled by other agencies. In part, this reflects the fact that the enabling statutes of these agencies sometimes contain their own demarcations of risk for regulatory action (e.g., acceptable/unacceptable; reasonable/unreasonable) which call for agency consideration of both the seriousness of harm and the probability of occurrence. Alternatively, the enabling statutes are silent about what threshold findings of fact must be made to support a regulation, or what balancing analysis must be followed by the implementing agency. In those cases, the agency is free to formulate its own action thresholds and to consider both magnitude and probability of harms. In judicial review of the risk standards set by agencies other than OSHA, the courts have typically looked to see if the agency has met the statutory criteria and balancing requirements, and whether the decision is "arbitrary and capricious" or is otherwise invalid under the *Administrative Procedure Act,* Sec. 5, *U.S.C.* 551, *et seq.* The *de minimis* risk concept has not found a place in these judicial evaluations, possibly because some of the enabling statutes offer clearer guidance on the element of risk to be considered, or because the agencies involved have interpreted statutory silence on the matter and exercised their discretion to permit consideration of probabilities of occurrence in setting their standards.

The application of *de minimis* risk by the federal courts can thus be seen as a judicial attempt to refine Congressional mandates (such as those in the *Occupational Safety and Health Act,* the *Clean Air Act,* and the Delaney Clause of

the *Food, Drug, and Cosmetic Act*) which ignore probabilistic considerations (e.g., frequency of occurrence, incidence) required for proper decision-making under uncertainty. The concept has not been used by the courts to rescind agency determinations of risk significance, however, since in all cases the Congressional enactments are quite clear as to which types of risk are serious enough to merit regulatory consideration, and the courts cannot rewrite statutory language by declaring certain types of risk as *de minimis*.

E. A basis for generic *de minimis* policies

A number of motivations lead to the attempt to develop a "rational" approach to regulating health risks through *de minimis* considerations. These include the impossibility of completely eliminating risks without incurring undesirable economic consequences, public concerns, the increasing sensitivity of chemical detection techniques, the multitude of suspected carcinogens and other toxic agents, and the desire for mechanisms to simplify agency decision-making. A *de minimis* criterion may under certain conditions strike a fair balance between the desire to reduce risks and the efficient utilization of scarce resources.

The generic *de minimis* risk policy is a process based on qualitative objectives for an agency. These include the determination of whether the risk alleged is one that is within the agency's statutory mandate, whether the petitioner or claimant has made out at least a *prima facie* case that a risk exists, and whether the risk may be reasonably expected to be significant in terms of environmental or health consequences for a particular target population and a most susceptible individual in that population.

On the face of it, it is not always clear why or whether a threshold rule of the *de minimis* form is compatible with other principles of risk management such as cost-risk-benefit or decision-analytic approaches. There seems to be no purely logical implication that risks that are small should be ignored if resource allocation criteria such as cost-benefit ratios or marginal expected utilities are used. However, these sorts of criteria for "rational" risk management decision-making can be reconciled with the *de minimis* approach under some plausible statistical assumptions. For example, if it is plausible that cost per unit risk reduction is *strongly (and negatively) correlated* with size of risk for small risks, e.g., because of a fixed-cost component, then risk magnitude will be a good predictor for cost per unit risk, and a *de minimis* threshold for the former may effectively express an implicit threshold and confidence level for the latter. Similar correlational justifications can be used to reconcile the simple *de minimis* approach with other more sophisticated decision criteria if the required assumptions about the joint statistical distribution of problem characteristics are met.

To develop a sound basis for establishing numerical *de minimis* risk levels,

TABLE 2

Science-policy issues in risk acceptability

Choice (and example)	Issues		Regulatory Fiat (example)
	Science	Policy	
Risk level (10 $^{-5}$/lifetime)[a]	–	✓	Yes (EPA)
Epidemiological results (negative)[b]	–	✓	Yes (EPA, OSHA)
Animal test results (negative)[b]	–	✓	Yes (EPA, OSHA)
Dose-response function (linear or not)[c]	✓	✓	Yes (EPA, OSHA)
Species conversion formulae (area)[d]	✓	✓	Yes (EPA)
Statistical confidence level (0.05)[e]	✓	✓	–
Sample size (small sample)[f]	✓	–	–

Source: P.F. Ricci: *Society at Risk; Cancer Risks in America* (forthcoming).

[a]Normally set by policy fiat on the basis of conservative assumptions. The value may derive from a Maximum Likelihood Estimate (MLE) of potency or it can be asserted on the basis of analogy to involuntary risks.

[b]Negative test results may be used in "weight-of-evidence" considerations.

[c]The choice of a conservative dose-response function is justified by safe-guarding health and welfare.

[d]Alternative conversion formulae attempt to approximate metabolic differences.

[e]The reason for choosing a specific confidence level is a matter of scientific judgement; however, it lends itself to abuse and to increases in type II error (false negative rates).

[f]Most estimates of carcinogenic potency are based on small samples and inference to a population is warranted only under specific assumption about the asymptotic properties of the estimator (e.g., MLE).

a variety of other factors must be considered that modify the correlational/economic approach. For example:

- Quantification of risk from an activity must explicitly include a definition of the unit of activity being considered (risk per unit of benefit), bound the range of regulatory concern, and fairly portray science-policy issues (Table 2).
- Establishment of numerical *de minimis* risk levels may require the use of numerical "proxy variables" such as average concentration levels, which can be quantified, in place of underlying non-numerical variables, such as the time pattern of exposure.
- A three-way distinction must be preserved between those risks that are assumed voluntarily, those that are accepted as part of an economic transaction or negotiated agreement, and those that are imposed upon third

parties. Comparing risks across categories for "acceptability" leaves out the political and rights-based aspects of risk regulation.

- Individual risk and aggregate population at risk must be considered separately. Similarly, a distinction between "catastrophic" risks and distributed (statistically independent) risks which have the same magnitude must be maintained. Note that a widely distributed product with *uncertain* risks poses elements of "catastrophic" risk – many potential victims from a common cause – even though individual health responses are statistically independent once the risk is known.
- Potential for unacceptable accumulation of residual risks due to multiple *de minimis* exemptions. This reinforces the need to specify the unit of activity to which a judgement of *de minimis* is applied.
- Potential for unacceptable risk, even though the risk is nominally *de minimis*, when additional *de minimis* risks are introduced into the portfolio of risk activities every year.

F. Conclusions

There has been increasing recognition that it is inefficient for regulatory agencies to expend resources on controlling risks that might be considered "trivial". Although absolute language in some health and safety statutes appears to constrain agencies from taking into account the "significance" of risks, there appears to be sufficient precedent for the interpretation of such language in terms of general *de minimis* policies. The use of such policies could permit agencies to focus their efforts on cost-effective risk reduction, without having to resort to elaborate justifications for ignoring trivial risks. Since complete elimination of a risk is frequently impractical, unwarranted if the activity is beneficial, or impossible, a *de minimis* policy would be a formal recognition of the pragmatic limitations of risk management. At the same time, the simple form of the policy would tend to expedite risk management decision-making. If certain statistical assumptions hold, moreover, the decisions made on the basis of a simple *de minimis* test should be good predictors for the decisions that would result from more elaborate and expensive decision procedures.

A possible basis for a *de minimis* policy is found in the law. This paper has developed the legal and conceptual backbone for the next step: determination and justification of *de minimis* risk levels for adverse health effects in particular application domains. The concepts developed here are applicable to both individual and population risks.

The selection of *de minimis* risk levels will require consideration of analytic models (e.g., for exposure pathways, population susceptibility, and carcinogenic potency) and their uncertainties; definition of the unit of activity being regulated, and identification of appropriate numerical proxy variables. It has also been shown that while *de minimis* risk levels, based on the rationale of

protecting individual rights, could perhaps be derived from comparisons with the risks imposed on individuals by existing activities such as industrial emissions, the consideration of broader societal objectives raises some unresolved technical difficulties. By applying a statistical cost-effectiveness rationale, it may be possible to derive a *de minimis* risk level that reflects agency policy and risk attitude and that allows for explicit recognition of uncertainty in decisions not to regulate.

Finally, there are a number of science and policy issues that will need to be resolved if a *de minimis* approach is to be pursued as a regulatory instrument. These include:

- Acceptability of the approach to regulated parties and to Congress.
- Monitoring of the cumulative effect of the portfolio of residual risks left unregulated.
- Reconciliation of the *de minimis* rationale with economic decision-making principles, e.g., through *de minimis* confidence levels for certain types of risk estimates.
- Treatment of uncertainty in the quantification of low-level risks.
- Availability of non-regulatory means for managing residual risks, such as tort law and private and social insurance mechanisms.
- Treatment of equity concerns, such as protection of high-risk groups.

The challenging social risk management duties and problems facing regulatory agencies may be dealt with more easily with the help of consistent, formalized policies and procedures for translating statutory directives into regulatory decisions. The *de minimis* concept appears to be a potentially useful step in this direction.

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