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PRIVATE STRATEGIES, PUBLIC POLICIES & FOOD SYSTEM PERFORMANCE

HEALTH AND SAFETY REGULATION OF SMALL, HIGH-RISK SUBPOPULATIONS

by

Richard A. Williams, Jr., Ph.D.
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The authors are the Chief, Economics Section and Mathematical Statistician, respectively at the Center for Food Safety and Applied Nutrition, Food and Drug Administration in Washington, D.C.

ABSTRACT

The choice of decision framework used to set regulatory tolerance levels for hazardous substances can be divided into rigid and flexible tolerance levels. Rigid decision frameworks include zero or de minimis tolerances that fix risk levels for some subpopulation. The accelerating identification of highly sensitive and/or highly exposed individuals and the division of the population into ever smaller subpopulations at higher risk could prove to be tremendously burdensome on regulatory systems, particularly for rigid decision frameworks. Rigid tolerance levels, philosophically based on "rights" to zero or arbitrarily low excess risks for individuals, do not contain sufficient flexibility to account for small high-risk subpopulations. Furthermore, the equal protection for all such groups is an illusion, mainly because of the potentially large number of such subgroups and the relatively fixed regulatory resources. Thus, de minimis regulation is seen as a minimal but inadequate improvement over zero risk regulation. With improved measures of the heterogeneous demand for risk reduction by various high-risk subpopulations, augmented cost-benefit analyses leading to flexible tolerances could provide a richer analytic framework for more efficient regulatory decisions. Additionally, it may be useful to attempt to categorize hazards and subpopulations on the basis of the ability to self-protect.

KEY WORDS: De minimis, sensitive, decision framework, cost benefit

Running title: HIGH-RISK SUBPOPULATION REGULATION

"Policymakers should have some concern for any small group of people exposed to very high risk, even if the overall average risk is low."(1)

"... few would feel that it is essential to protect the most sensitive asthmatic or the most compromised individual with cardiovascular disease who decides to exercise heavily on the most polluted day of the year."(2)

1. INTRODUCTION

It has become increasingly clear that estimation of exposure, as a component of the risk equation (potency multiplied by exposure), has the potential to dominate risk management. The problem arises as policymakers are presented with increasingly refined exposure profiles consisting of detailed characterization of risk to high-risk subpopulations. Through new techniques to estimate "internal" dose and more precise survey estimates of external dose, it is possible to identify with greater accuracy actual individual exposure. This development has policy implications because there are a variety of different mechanisms to incorporate this information into risk policy. The two quotations above demonstrate the dilemma regulatory decision makers face with respect to this information. That is, policymakers should be concerned for small high-risk subgroups but should not overprotect them at public expense or as a substitute for individual responsibility. The debate centers on the uncertainty as to what constitutes sufficient concern or overprotection. In the absence of a risk management framework that explicitly

identifies the appropriate amount of concern or overprotection, however, the convenient approach to such uncertainties typically defaults toward overprotection, compelling managers to set tolerances based solely on the risk to the high-risk subpopulation.

Indeed, many federal laws explicitly require risk managers to establish tolerances based on high-risk subpopulations. For example, "the Clean Air Act and the Occupational Safety and Health Act require that standards be set to protect individuals who are highly susceptible to the particular agent being regulated...."[3] This paper takes the view that, for risk managers to be able to make responsible decisions, decision frameworks should explicitly take into account differing effective demand for risk reduction by different high-risk subgroups. Much of the melange of current decision frameworks used in the federal government (such as the Delaney Amendment to the Pure Food, Drug, and Cosmetics Act and de minimis types of regulation) fail to discriminate between population subgroups in a logically consistent manner. By examining the underlying philosophy and practical effects of several accepted frameworks in current use, it will be seen that there are some basic criteria that should be used to discriminate between high-risk subgroup demands for risk protection. First, however, it will be useful to examine more carefully what is meant by a high-risk subpopulation.

2. HIGH-RISK SUBPOPULATIONS

A high-risk subpopulation may be defined as any subgroup of the whole population that is either highly exposed (environmental

predisposition) or highly sensitive (genetic predisposition) to a particular hazard. In statistical terms, small, high-risk subpopulations form the tail of the joint exposure/sensitivity distribution of the whole population.

One example of the first type of high-risk subpopulation is the Maximal Individual Risk (MIR) used by the Environmental Protection Agency. This is, according to EPA "an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years."[4] Another example is the population of statistically defined "eaters" of a particular hazardous substance in the food supply. The Food and Drug Administration defines eaters as those people who have been surveyed and found to eat the product at least once during a survey period; typically, 3 or 14 days. Longer survey periods would therefore define a larger fraction of the population as de facto eaters but would also necessarily produce lower average eater exposures. Thus, in actuality, the population of so-called "noneaters" represents a mixture of both less frequent or sporadic consumers of the product as well as absolute nonconsumers of the product. A smaller, high-risk subgroup of eaters are so-called "heavy eaters," typically defined as persons who consume in the upper 90th percentile of intake of eaters. It is often further assumed that heavy eaters or "preferential consumers" eat the hazardous food every day and never switch to a food not containing the substance (presumably because of brand loyalty) for at least half their lifetimes or longer.[5] In fact, these "preferential

consumers" are yet another subdivision into a smaller, higher-risk subgroup whose exact size is difficult to estimate. It is such subgroups toward which policy is frequently directed.

To be sure, there is normally significant debate as to the appropriate subgroup to use for a specific hazard.[6] The debate for exposure to food substances, for example, may center around the appropriate exposure period and the fraction of the entire population who should be considered at risk; whether to include noneaters and eaters with heavy eaters. The exposure debate does not necessarily end with the debate over the amount and time period of external exposure, however.

Indeed, apparent intake of a hazardous substance (e.g., ambient concentration of a hazard in air, water, and food) is increasingly criticized as a poor indicator of true biological exposure at the target tissue where toxicity occurs. An additional screen for populations at risk is identification of the "sensitive" subpopulation. For example, internal dose (sometimes called biologically effective dose) is "the dose of the active form of the toxic agent at the level of the target cells."[7] Differences among individuals in the absorption, distribution, metabolism, and elimination of toxic agents can result in large variations of delivered or biologically effective dose at the target organ. Perhaps more significant still, large variations in genetic codes among individuals can result in large relative variations of response to the same delivered dose. Increasingly, biomarkers are gradually being developed and recommended as better biological

measures of both individual exposure and response to hazards.[8] With such further development and use of pharmacokinetics[9] exposure and pharmacodynamic[10] response biomarkers, it will be increasingly tempting to further identify and subdivide ever smaller high-risk subpopulations.[11]

There will be strong incentives to increasingly use this information in policy decisions concerning tolerance setting. That the development of information on the heterogeneity of population exposure and response is important is not in question. What is problematical is <u>how</u> this information is used in decisions for tolerance setting. Exposure estimates for use in risk analysis may end up placing stresses on fixed tolerance decision rules that could be similar to those that developed earlier in analytical chemistry, where ever smaller trace levels of more and more toxicants were ubiquitously discovered because of increasingly refined detection methods. So too the accelerating micro-identification of more and more high(er)-risk subpopulations is likely to place unmanageable stress on slightly relaxed but still predominantly fixed tolerance levels. That is, as science improves, regulatory tolerances creep towards greater stringency and away from an "optimal" tolerance level.

3. DECISION FRAMEWORKS

It is precisely this kind of question that any risk-based decision framework must be able to handle. Currently available decision frameworks responsible for producing health and safety

decisions generate either rigid or flexible safety tolerances. Rigid tolerance decision frameworks include zero tolerance (the Delaney Amendment) and de minimis tolerances (i.e., tolerance levels set at a low excess risk level). Rigid tolerance decision frameworks typically establish an "acceptable" level of risk for a broad class of hazards (e.g., 10^{-6} to 10^{-5}). For individual hazards, the decision is whether or not the particular hazard falls within the legal definition for the defined class. Flexible tolerance decision frameworks include more liberally interpreted de minimis tolerances and cost/benefit analyses. In these frameworks, each hazard may have a separate tolerance established based on balancing the various characteristics of the hazard, the population at risk and costs of regulation.

4. DECISION FRAMEWORKS PRODUCING RIGID TOLERANCE LEVELS

The two decision frameworks producing rigid tolerance levels most often used are those that necessitate zero risk levels and those that regulate risk to fixed low excess risk or de minimis levels. The most widely known zero risk law is the Delaney Amendment to the Food, Drug, and Cosmetic Act, which specifies that "no additive shall be deemed 'safe' if it is found...after tests that are appropriate for the evaluation of the safety of food additives to induce cancer in man or animals." With a zero risk standard, no discrimination is possible for any subgroup, including high-risk subgroups as the product is eliminated from the market. In fact, support for the Delaney Amendment came in part from

biomedical researchers who said, "Public health policy has to be based on protecting the most susceptible individuals, which the Clause tends to do."[12] Obviously, the Clause overprotects everyone and this type of decision framework cannot function in the modern world of analytical chemistry, which is capable of detecting carcinogens in the parts per trillion range. In fact, perhaps given the stringency of the Clause and resulting societal inefficiency, the Delaney Amendment has rarely been invoked. One such inefficiency, slowing up the rate of additive development, has been well documented.[13]

In a sense, a de minimis rule that incorporates a pre-set fixed risk level for a class of hazards is an extension of the zero risk standard, i.e., a fixed risk at a higher level. A de minimis risk is defined as one which is so small it is not worth the effort to regulate; it is essentially a legal concept that distinguishes between trivial and nontrivial risks. Agencies such as the Food and Drug Administration and the Nuclear Regulatory Commission have adopted an explicitly narrow approach to deciding de minimis levels based only on toxicity and exposure whereas other regulatory agencies include broader considerations such as the size of the high-risk subpopulation.[14] The narrow approach to de minimis regulation has agencies setting single maximum lifetime risk levels (normally between 10^{-6} and 10^{-5}) for a class of hazards and applying those risks to the sensitive or highly exposed populations.

Like the Delaney Amendment, the uncompromising nature of these de minimis decision frameworks is one of a legislated absolute that

is operatively equivalent to a "rights-based" decision.[15] Rights-based approaches have become central to many political debates involving issues such as the rights of criminals, abortion rights, capital punishment, and the Pledge of Allegiance.[16] The "right" in the case of hazards, is an "inalienable right" not to be harmed by the actions of others (by a manufacturer or originator of the hazard).[17] By framing such problems in terms of rights, there is no room for situational discrimination. For risk from hazards, the problem is that it is impossible under such an approach to discriminate with respect to the size or characteristics of the subpopulation that possesses such rights. There is an enormous difference, for example, between the right of the U.S. population to de minimis risk and the right of an individual to face the same risk.[18]

Once such an absolute right has been legislated, the right becomes the policy, and balance against competing but non-legislated rights becomes largely irrelevant. The effect of such an approach to the regulation of hazards is to transfer policy decisions into a purely zero sum decision in which "single issue proponents can withstand the collapse of the heavens as long as their interest is served."[19] Notwithstanding the lamentable transfer of legitimate social debate from the politics of balance and persuasion to the politics of rights,[19] there is some question if any group should possess an inalienable right to be protected from hazards. When the hazard may be traced directly or indirectly to a pollutant or other risk generated in the manufacturing

process, the right not to be harmed would perhaps arise if it is presumed that a manufacturer has a moral responsibility to prevent harm to buyers because they (the manufacturers) are in "informed control" (over consumers).[20] Informed control is defined to exist when manufacturers know the inherent risks in the products they sell but buyers are ignorant of those risks. When this is true, manufacturers are said to have a moral responsibility to remove all risks from their products and, by extension, government must ensure that they do so.[21]

First, because costs are generally borne in some part by all of society, as well as manufacturers, there is some question as to whether any individual has an absolute right to impose costs on others. Furthermore, for many types of hazards, the risk may be at least partially self-inflicted.[22] Presumably, to the extent that a consumer knows about the risk prior to incurring it, he has given tacit consent to its existence and has willingly participated in incurring that risk. It would be difficult to argue, for example, that persons who started smoking cigarettes in the last five years are not partially culpable in inflicting risk on themselves. Thus, individuals are implicitly "willing participants" in incurring risk if (1) individuals are informed about the nature of the hazard and the risk involved and, (2) once informed, are capable of reducing risk to an individually acceptable level. This claim to a right may even be attenuated to the extent that there is the possibility of becoming informed. For example, if products are labeled with respect to pesticide

toxicity, then an individual consuming those products bears some responsibility for the risk incurred. Furthermore, it is not enough to note that no self-protection activity has been taken on the part of the consumer. For example, a consumer living next to a power plant has the option to move.[23] Thus, the very nature of willing participation creates a strong denial of a claim to a right to risk protection and at least partially absolves manufacturers of the responsibility to reduce or eliminate risk. Whether or not such legitimate rights exist, a rigidly interpreted de minimis risk framework has the potential to enormously disrupt economic markets. With more higher risks and smaller subgroups being identified at risk (through the use of biomarkers, for example), it will become more expensive to regulate for these groups by provision of absolute protection via inalienable rights. By not considering the size of the subgroup to be protected, fixed tolerance decision structures create the potential for enormous social costs because "a myriad of society's essential activities would have to cease" (because of excessive cost).[24]

Furthermore, not only are there potentially large costs but the benefits and costs would potentially become more inequitably skewed as smaller groups become the target population for fixed-risk regulation. If only a small fraction of people are protected to 10^{-6}, for example, yet everyone must pay for the regulatory effort through taxes (or higher prices for some), the distribution of costs and risk-reducing benefits will tend toward greater inequity if few products are regulated. This inequity may not be

perceived if, for example, the public <u>believes</u> that all risks have been or are being regulated to <u>de minimis</u> levels.

Stated otherwise, if all risks could be regulated to a fixed level such as 10^{-6} (lifetime risk), then presumably everyone would enjoy the same low level of risk. However, the use of a fixed-risk level for the most sensitive or most highly exposed group does not necessarily produce equitable social benefits (risk reduction) for all parties. The problem is that with relatively fixed regulatory resources, it is not possible to pass regulations for every small, well-defined subgroup. Furthermore, depending on the method of prioritizing issues, whether deliberate or ad hoc, the distribution of regulatory payoffs (risk-reducing regulation) may be skewed and, in extreme cases, may appear lottery-like with very large payoffs going to very small groups. This lottery-like distribution of payoffs will occur as more high-risk subgroups are defined through product, activity, geographical, or exposure subdivision. In fact, to protect an even larger fraction of such groups at current fixed-risk levels, there would seemingly have to be a tremendous increase in the rate at which regulations are passed, and the required increase in the budget for health and safety regulations seems unlikely.[25]

5. FLEXIBLE TOLERANCE DECISION FRAMEWORKS

Decision frameworks that produce tolerance levels that vary from decision to decision include flexible de minimis and cost-benefit frameworks. The former seeks to improve on rigid de minimis frameworks by recognizing that "we cannot have simple definitions of significant or de minimis risk because acceptability depends on "the consequences of the effect, whether the risk is undertaken voluntarily, which population is at risk, and so forth."[26]

In a flexible de minimis decision framework, the level of risk considered de minimis may vary depending on a wide variety of attributes of the hazard or exposed population although, generally, benefits are not considered.[27] For example, ad hoc suggestions for dealing with the size of the exposed population have been made such as defining a de minimis risk as "less than 10^{-5} per year (probability of death) for a population of 10^{3}, less than 10^{-6} per year for exposed populations of 10^{3} to 10^{6}, and 10^{-7} per year for the entire population."[28] In fact, others have stated that a regulation should not be considered: "For example, if there were an occupational group of 10 or fewer or a population of 100 or fewer, these populations would simply be too small to warrant agency attention."[29]

Alternatively, the cost/benefit analysis allows for flexible tolerances based on all regulatory criteria. The benefit/cost test arises out of economic theory in which a regulatory policy option is deemed appropriate if a "potential Pareto"[30] improvement will

obtain, i.e., the gains from a particular regulation could be distributed in such a manner so as to make all persons at least as well off as they were before the regulation.[31] That is, one group benefits, another group incurs costs, and, at least in principle, the gains in benefits outweigh costs such that the gainers could compensate the losers. Costs of various options are calculated as opportunity costs, i.e., the loss of the next best alternative use of resources. Health benefits (to gainers) are reduced risk of illness or injury. The option selected is that which generates the largest difference in benefits and costs.

In neoclassical economic theory, consumers value a reduction in risk, that is, reduction of risk has positive utility to consumers. All individuals are assumed to be utility maximizers, which means that they are able to make rational choices with respect that payments to reduce risk. Because people do in fact make risk/dollar choices all the time, proponents of this theory hold that the choices made by the government to intervene in markets to reduce risk should be consistent with the choices people make for themselves.

Linking the decision as to the amount of risk that should be reduced to the measurement of actual choices is philosophically based on the "consent" of the affected parties.[32] By taking cues from trade-offs that consumers make, the consent approach is diametrically opposed to the (inalienable) rights-based approach, which does not recognize such trade-offs. With consent-type decision analysis, either measured (hypothetical, estimated from

market actions) or actual (voting) consent (which contains estimates of payments to accept or reduce risk) is obtained from the affected parties. The hypothetical or market approach, for example, scrutinizes the amount or money required to induce workers to accept a riskier job or monetizes the value of time spent by consumers to put on seat belts. Normalizing these monetized amounts for 100% risk reduction is often said (incorrectly) to be an implied valuation of life.[33]

However, as currently practiced, cost/benefit analysis often treats risk to all individuals as homogeneous by summing the benefits expected to occur as a result of preventing a number of illnesses, injuries and/or deaths. In general, neither the characteristics of a hazard nor the types of individual are used to alter valuations placed on morbidity or mortality. Thus, for example, a reduction of risk from certain death to a 90% chance of death would be treated as equal to a reduction of risk from a 20% chance of death to 10%. Failure to consider heterogeneous risk and individuals at risk treats the benefits of risk reduction for a high-risk subpopulation as equivalent to an equal amount of risk reduction for a large group with low risk. Besides the problem of levels of risk being valued differently, there may be other characteristics of the hazard and the exposed population that may cause the benefits of risk reduction to be valued differently.[34] For example, the decision as to whether or not a healthy adult invests the time to put on a seat belt seems to have little relevance to the decision of whether or not to lower the risk from

ingestion of lead by children.[35] Much work has been done, that shows there is a positive discount rate for health effects that occur in the future.[36] This implies differential valuations depending on when in the future the health effect is likely to occur.

In fact, research has shown that consumers do have an eclectic demand for risk reduction which may justify attempts to protect sensitive subgroups.[37] It has been shown that, for example, if a hazard is involuntary, has its effect primarily on children, and is unfamiliar (such as cancer), consumers appear to place a greater weight on reducing these types of risks.[38] Thus, if risk is used in a generic sense such that the types of hazards to the exposed population are weighted equally by using a consensus mean demand estimate, the "consent" obtained in indirect measurements may not be a good indicator of true consent by the affected parties. It is doubtful that a conscientious policymaker could, in fact, use such an estimate.

Yet another problem with cost/benefit analysis is that it is not at all clear who the affected parties are, that is, <u>whose</u> demand for risk reduction should be counted.[39] Direct beneficiaries of risk-reducing regulations for high-risk subgroups include both the subgroup itself and to the rest of the exposed population at lower risk. But there are also indirect benefits accruing both to altruistic members of society as well as those who view their "vote" for such a regulation as part of a policy of protecting subgroups that may ultimately directly affect

themselves. On the latter point, consumers need not be altruistic to favor risk reduction for others if they view the policy of reducing risk to high-risk subpopulations as a type of insurance that would be forthcoming were they themselves ever in such a subgroup. This may be an explanation for some observed altruism.[40] An altruistic vote, then, may actually reflect a wish on the part of some members of society to ensure protection (reduction in risk) should they ever be identified as a part of a high-risk subgroup, similar to an "option" value for a park.[41] However, for such a value, no guarantee exists because there are too few resources to research and protect every well defined high-risk subgroup. In this case, indirect benefits from an option value would be largely illusory.

Thus, to apply cost/benefit analysis to risk decisions affecting high-risk subpopulations that have been identified, it will be necessary to more accurately measure the demand for risk reduction for both the subgroup and altruistic individuals. Although each situation is unique, in a practical sense it will be necessary to categorize types of individuals and hazards to estimate demand for risk reduction. For example, a key variable that should be used to characterize such groups would be the possibility of self-protection.[42] This would, for example, differentiate children and functional adults.

The use of the ability to self-protect as a discriminatory variable may lead to a policy option, under the consent type of approach of information provision, of either taking self-protective

measures or making individual (optimal) risk choices. This policy option could be compared with more stringent regulatory measures. For instance, in a past case confronting the Occupationtional Safety and Health Administration (OSHA), "OSHA (had) available a means of protecting sensitive individuals not available to EPA . . . whereby medical surveillance of workers is possible to detect the early stages of a disease, and workers can be removed from areas of exposure (for cotton dust)."[43] The smaller and more identifiable the group, the less complicated the information, and the more voluntary the nature of the risk, the greater are the net benefits of information provision, compared to those of tolerance setting. By allowing the possibility of self-protection, possibly enhanced by information provision, the dilemma of increasingly stringent regulation resulting from increased identification of ever smaller subgroups is largely avoided.

6. SUMMARY

The accelerating identification of either highly sensitive or highly exposed individuals and their division into ever smaller subpopulations at higher risk could potentially prove tremendously burdensome on regulatory systems, depending on the particular decision framework used for hazardous situations. Current risk-decision frameworks used to regulate risk include rigid tolerance decision frameworks with zero or de minimis tolerance levels and those producing flexible tolerance levels, de minimis or cost/benefit analysis. Rigid tolerance levels, philosophically

based on rights to zero or arbitrarily low excess risks, do not contain sufficient flexibility to account for small high-risk subpopulations. These decision frameworks imply equal absolute minimum protection for all such groups -- an illusion largely due to the potentially large number of such groups -- with relatively fixed regulatory resources.

With improved measures of the heterogeneous demand for risk reduction by various high-risk subpopulations, cost-benefit analysis could provide a richer analytic framework for more efficient regulatory decisions. It may be useful to attempt to categorize hazards and subpopulations on the basis of the ability to self-protect and to discriminately measure demand for risk reduction more precisely. Such efforts should help to improve the political acceptability of cost/benefit analysis.

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6. R. D. Friedman, Sensitive Populations and Environmental Standards (The Conservation Foundation, Washington, DC, 1981), p. 7.

7. I.B. Weinstein, "Molecular Cancer Epidemiology: The Use of New Laboratory Methods in Studies on Human Cancer Causation," in Epidemiology and Health Risk Assessment, (Oxford University Press, New York, 1988), p. 160.

8. Biomarkers are an internal measure of dose or response.

9. The study of the absorption, distribution, metabolism, and

elimination of toxic agents once ingested (i.e., what happens and how fast does it happens.

10. The study of the response of target cells to toxic agents.
11. Biomarkers by their nature take into account intraspecies variation. At present it is ordinary procedure to allow an order of magnitude conservative adjustment for this factor for noncarcinogenic endpoints when extrapolating results of animal studies to humans. To do both would be double counting this effect and result in overly conservative regulation.
12. "Regulation of Cancer-Causing Food Additives-Time for a Change," Report to the Congress of the United States by the Comptroller General, HRD-82-3, December 11, 1981, p. 23.
13. "Regulation of Potential Carcinogens in the Food Supply: The Delaney Clause," Council for Agricultural and Technology, Report No. 89, 1981.
14. J. Menkes and R. S. Frey, "De Minimis Risk as a Regulatory Tool," in C. Whipple (ed.), De Minimis Risk (Plenum Press, New York, 1987), pp. 9-14.
15. One example of a right with respect to a hazard is given by the U.S. Consumer Advisory Council consumer charter presented (1963) to President Kennedy, which included "the right to safety"--that is, to be protected against the manufacture and sale of goods that "may endanger life or health." In "President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: 1983," Securing Access to Health Care. The Ethical Implications of

Differences in the Availability of Health Services, Report, U.S. Government Printing Office (1983-0-401-QL3), Washington, DC; quotation reprinted in H.-M. Sass, "Justice, Beneficence, or Common Sense: The President's Commission's Report on Access to Health Care," The Journal of Medicine and Philosophy 8, 383 (1983).

16. F. Siegel, "Nothing in Moderation," The Atlantic Monthly, May 1990, p. 108.

17. T. J. Brennan in "Rights as Inalienable" (unpublished, University of Maryland, Baltimore County, November, 1989) distinguishes a legal right as based either on equity or efficiency, whereas a moral right is one that is neither alienable by others or by the individual possessing that right.

18. Because of the potentially enormous variance in exposure between the mean of the U.S. population and any highly exposed individual, the regulation could be many orders of magnitude more stringent to set an equivalent level of risk for an individual as for the U.S. population.

19. F. Siegel, "Nothing in Moderation," The Alantic Monthly, May 1990, p. 110.

20. E. V. Magnus, "Rights and Risks," Journal of Business Ethics, February, 1983; see also, National Research Council, Improving Risk Communication (National Academy Press, Washington, DC, 1989), p. 58.

21. Government intervention may take the place of ex ante regulation or ex post enforcement of rights through the courts, which, in fact, have the ex ante effect on manufacturers of removing risk.

22. A. Gewirth, "Human Rights and the Prevention of Cancer," American Philosophical Quarterly, April, 1980.

23. A consumer living next to a power plant will, in general, trade a lower rent for the increased risk of living next to the plant.

24. P. Milvy, "Actual and Perceived Risks from Chemical Carcinogens," in C. Whipple (ed.), De Minimis Risk (Plenum Press, New York, 1987), p. 78.

25. Naturally coupled to the attempt to pass stringent regulations is an exceedingly slow pace of regulation. Because of the slow pace, many problems are never brought to the public forum. This leads to the problem in which "overregulation leads to underregulation." See J. M. Mendeloff, The Dilemma of Toxic Substance Regulation (MIT Press, Cambridge, MA, 1988).

26. J. M. Mendeloff, The Dilemma of Toxic Substance Regulation (MIT Press, Cambridge, MA, 1988), p. 53.

27. J. Fiksel, "De Minimis Risk: From Concept to Practice," in C. Whipple (ed.), De Minimis Risk (Plenum Press, New York, 1987), pp. 3-8.

28. C. Whipple, "Application of the De Minimis Concept in Risk Management," ibid., p. 20.

29. D. Byrd III and L. Lave, "Significant Risk Is Not the Antonym of De Minimis Risk," ibid., p. 56.

30. One distribution of resources is judged "Pareto superior" to another if at least one person prefers it and everyone else is indifferent between the two. A potential Pareto redistribution may be made from one distribution to another if those who prefer the distribution can compensate those who do not.

31. The Kaldor-Hicks test is named after John Hicks and Nicholas Kaldor.

32. T. J. Brennan, "Rights as Inalienable," unpublished abstract, November, 1989.

33. In fact, these estimates are only point estimates of the value placed on minor amounts of risk reduction; the value of life is infinite, but the choice to reduce ex ante risks of death, finite.

34. This is not the problem of interpersonal comparison of the utility of money. In this case, risks of different types and levels and to people in different situations are valued differently and, at least theoretically, are measurable.

35. Using quality-adjusted life years (QALYs) would seem to adjust for differing demands for children and adults although this implies that demand for each year of life is equivalent. For example, the demand for risk reduction from age 18 to 19 would be valued equivalently from age 84 to 85. There is no theoretical justification for this assumption.

36. M. J. Moore and W. K. Viscusi, "Discounting Environmental Health Risks: New Evidence and Policy Implications," Journal of Environmental Economics and Management 18, S51-S62 (1990).

37. See, for example, B. Fischohof, P. Slovic, and S. Lichtenstein, "How Safe is Safe Enough?" Policy Sciences 9, 127-152 (1978).

38. V. T. Covello, P. M. Sandman, and P. Slovic, Risk Communication, Risk Statistics, and Risk Comparisons: A Manual for Plant Managers (Chemical Manufacturers Association, Washington, DC, 1988); reprinted in Improving Risk Communication (National Research Council, National Academy Press, Washington, DC, 1989), p. 35.

39. For a discussion of who "counts" in cost/benefit analysis see, W. N. Trumbull, "Who Has Standing in Cost-Benefit Analysis?" Journal of Policy Analysis and Management, vol. 9, no. 2.

40. J. Mendlehoff (The Dilemma of Toxic Sustance Regulation, MIT Press, Cambridge, MA, 1988) finds that third-party valuations of risk reduction (altruism) do not vary by more than a factor of two or three depending on the situation.

41. Option values for parks are those values placed on retaining the option to use the services of a park at some time in the future. Thus, for example, one might place some positive value on keeping the air in the Grand Canyon clear even though one had no present plans to visit there.

42. In fact, it has been argued that risk assessments often overlook self-protective measures taken by individuals both

prior to and as a result of regulatory measures. These measures have been observed to vary greatly in a population at risk [J. F. Shogren and T. D. Crocker, "Risk, Self-Protection, and Ex Ante Economic Value," Journal of Environmental Economics and Management, vol. 20, no. 1, 1-T5 (1991)].

43. R. D. Friedman, Sensitive Populations and Environmental Standards (The Conservation Foundation, Washington, DC, 1981), p. 31.

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Purpose: The NE-165 Working Paper Series provides access to and facilitates research on food and agricultural marketing questions. It is intended to be a publication vehicle for interim and completed research efforts of high quality. A working paper can take many forms. It may be a paper that was delivered at a conference or symposium but not published. It may be a research report that ultimately appears in full or abbreviated form as a journal article or chapter in a book. Using the working paper series enables a researcher to distribute the report more quickly and in more extensive detail to key research users. A working paper may also be an end product in itself, for example, papers that collate data, report descriptive results, explore new research methodologies, or stimulate thought on research questions.

Procedures: Working papers may address any issues in the food and agricultural marketing area as described in the NE-165: Private Strategies, Public Policy and Food System Performance, project statement. This research agenda is available from Professor Ronald Cotterill, Chair of NE-165 at the address given below. A prospective working paper should be forwarded to the Chair who will coordinate a review of the paper by two research peers. Alternatively authors may submit two independent peer reviews with their paper. Based upon independent reviewer comments the Chair may accept, accept with revisions, or reject the submission. If accepted the Chair will issue working paper covers, and a mailing list to the author who shall have responsibility for preparing and distributing copies to all persons and organizations on the mailing list. Additional copies of working papers are available from the author or from the Food Marketing Policy Center at The University of Connecticut.

Professor Ronald W. Cotterill, Food Marketing Policy Center.
Department of Agricultural Economics and Rural Sociology
Box U-21
The University of Connecticut
Storrs, Connecticut 06269-4021
Tel. No. (203) 486-4394