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Maine, like the nation, has focused a great deal of recent attention on determining acceptable levels of environmental and human health risk. Barbara Knuth, associate professor of Natural Resources at Cornell University, discusses the role and uses of scientific information in risk assessment and public policy debate. Similar to Kevin Boyle's previous article (featured in our December,1994 issue), Knuth discusses the 1992 Maine Board of Environmental Protection hearings which focused on the human consumption of fish potentially contaminated with dioxin.

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Introduction

In 1992, the Maine Board of Environmental Protection (BEP) conducted a rule-making hearing on dioxin (2, 3, 7, 8-tetrachlorodibenzo-p-dioxin) emissions from Maine paper mills. A portion of that hearing process was reviewed by Kevin Boyle (1994) in a previous issue of *Maine Policy Review*. Through his presentation, Dr. Boyle implied that the BEP's decision to defer ruling on the proposed dioxin regulation pending the U.S. Environmental Protection Agency's review of the toxicity of dioxin reflected an inability of citizens to make good judgments about regulating toxic substances potentially posing a risk to humans. Boyle asserted that "The success of the public hearing process depends on the ability of the BEP to avoid overestimating the risks associated with human exposure to toxic substances." The key issues he addressed were:

- the likelihood of harm occurring is the major relevant criterion that should be considered in public decisions; and
- the success of public decisions rests solely on the ability of those involved to estimate likelihood of harm, or to accept such estimates from "experts" without necessarily examining the quality of the estimate provided.

This article suggests that the scope of public policy considerations related to environmental and human health risks often is, and should be, much broader than focusing simply on estimates of likelihood. Rather, risk policy and risk management should consider type or severity of harm, and to whom the harm (and any associated benefits) will accrue, as well as ensure that estimates of likelihood of harm are calculated for the most appropriate, most highly affected human population, and are as accurate as possible. Furthermore, those involved in policy-making, particularly citizen boards, must be prepared to question and consider the assumptions and value judgments underlying any of the estimates and other information presented in the policy debates.

Scientific information should be used appropriately in public policy decisions. Both science and policy involve assumptions and value judgments. Science (as well as policy) is based on choices; researchers make numerous choices that affect the type and quality of data gathered, and

therefore the kinds of conclusions that will be (or even can be) reached. It is critically important, particularly when public health policy is involved, to identify the assumptions on which scientific methods and conclusions are based, and to ask if those assumptions are the correct ones to be using as policy is debated. This article emphasizes that the role of the citizen board in a democratic society is precisely to consider the appropriateness of each of those assumptions and judgments, not just to accept blindly the quantitative estimates of harm produced by "experts."

I offer a different perspective about some of the issues that the BEP may have considered in reaching its decision in the 1992 dioxin rule-making hearing. I will not review the detailed testimony that was provided by all sides at the dioxin rule-making hearing; that information is available elsewhere in the public record. Similar to Boyle's approach, I will focus on fish consumption estimates and other elements of the testimony presented to the BEP to illustrate the host of factors that should be considered when evaluating the quality of the BEP decision in the context of public policy.

Choices in risk assessment

The testimony considered by the BEP focused on a proposed rule that was based on a particular risk assessment equation. Every such equation involves several choices and assumptions, reflecting underlying values about who should be protected by risk policy, and how conservative that protection should be. When considering the reasonableness of the decision reached by the BEP, it is necessary to understand each of the assumptions in the risk assessment equation and their associated implications, as well as the full scope of testimony the BEP considered in its deliberations.

The general process of risk assessment involves four basic stages: 1) hazard identification; 2) dose-response assessment; 3) exposure assessment; and 4) risk characterization (National Research Council, 1983). Each of these stages involves choices and assumptions.

In the *hazard identification* stage, assessment focuses on determining if a particular chemical is or is not causally linked to particular adverse health effects. This determination relies on the quality and abundance of basic scientific analyses about the potential toxicity of the chemical of concern. In many cases, these analyses involve inferences from animal studies to human health effects, and associated assumptions about the quality and transferability of such information. Choices involve deciding which adverse health effects are the most appropriate to study, e.g., cancer, reproductive impairments, immunological deficits. With some types of health outcomes (e.g., reproductive and developmental impairments), moral and ethical questions involving intergenerational responsibilities and equity may be important but are not addressed through the risk assessment process.

The *dose-response assessment* determines the relationship between the magnitude of exposure (dose) and the probability of adverse health outcomes (response) in the population of interest. Choices include which outcomes are studied, which human populations are defined as of interest, and whether to use inferences from animal studies to human application or from acute human exposure to chronic human exposure.

Exposure assessment estimates the likelihood of human exposure to the chemical of concern. In the case of the dioxin rule-making, the fish consumption estimate was a key feature of exposure assessment. Choices include which human population's behaviors (and therefore probability of exposure) are studied to derive exposure assessments, as well as the completeness of data regarding potential routes of exposure.

Risk characterization synthesizes the information from the first three stages to produce a description of the likelihood of exposure and severity of consequences for the population of concern. Choices and assumptions from the earlier stages carry forward to this final stage of risk assessment.

In spite of all of these assumptions and associated uncertainties, risk assessment still can be a useful tool in public policy decisions. Risk assessment provides a synthesis and summary of the risk-related information available about a certain chemical for decision-makers to consider. It is not, however, the sole decision criterion. Risk assessment can effectively inform public policy discussions about managing risks if the uncertainties and assumptions are presented clearly, if the reasons for certain choices are explicitly described and agreed to, and if uncertainties are reduced as much as possible. Risk assessment, like all scientific endeavors, is a process that involves human judgment. Thus, it becomes important for decision-makers (e.g., BEP) to consider the choices, assumptions, and uncertainties involved in rule-making procedures based on quantitative risk assessments. Boyle (1994) noted that the "predisposition of the public to overestimate the likelihood of low probability events" is the "major problem involved in risk assessments." I argue other aspects of risk assessment deserve equal or more attention than the estimation of likelihood of harm, including the variety of choices and assumptions that are made, often implicitly and without critical debate. The role of a citizen policy board should be, at least in part, to review those judgments and ensure they are reflective of the society's own views regarding ethical, responsible treatment of human life and the quality of the environment.

Choices in the dioxin rule-making equation

The risk assessment equation on which the proposed Maine dioxin rule was based included several components, such as acceptable risk, cancer potency factor, weight of an average person, fish consumption, and a bioaccumulation factor (Frakes, 1990). Each element of the equation reflects choices and uncertainty, some of which are described below.

Acceptable Risk. Clearly the choice of an "accept-able" risk level is laden with value considerations. Scientific studies by risk assessors can produce some evidence related to the level of harm associated with certain levels of exposure, but someone ultimately has to judge what is an acceptable level of harm to those who will experience it.

The notion of acceptability implies a reasoned judgment by those in society who will be affected and/or those who have the responsibility to make such judgments. Thus, it is certainly within the scope of the BEP to apply its considered judgment, as representatives of the Maine citizenry, to selecting an acceptable risk level in the rulemaking procedures. At debate was a proposed level of acceptable risk of 10^{-5}, which translates into one additional cancer case per 100,000 people due to exposure to dioxin in contaminated fish. Is this a reasonable level, or should the level be

more or less protective of the Maine citizenry? What should BEP consider in making its decision? Finkel (1989) suggested a variety of issues should enter into decisions about acceptable risk levels, including the voluntariness of the risk, the probability relative to other environmental or lifestyle risks, and the costs and benefits associated with either reducing or continuing production of the chemical of concern. Consideration of the distribution of those costs and benefits also may be included. Are the risks to be distributed through the society, or to a particular segment most heavily? Does society have special obligations to that segment to be especially protective of human health?

Cancer Potency Factor. Although the proposed rule was based on a risk assessment equation in which cancer risks were considered, expert testimony indicated that dioxin also may be associated with a host of non-cancer risks (e.g., reproductive, developmental, hormonal, immunological). Would it be reasonable for the BEP to regulate dioxin solely upon its association with cancer, when evidence exists that non-cancer risks may be a greater concern than cancer risks? As Locke (1994) noted, "emphasis on cancer means that other health effects may be downplayed, or even worse, ignored." This issue also relates to the notion of acceptable risk. What should policymakers consider when weighing cancer risks that would affect the current older generation vs. noncancer risks that would affect the current younger generation and future generations? Does such a consideration influence how conservative or protective a regulation should be?

Weight of an Average Person. This factor includes assumptions about the age, sex, etc. most important to consider in the risk equation, and explicitly undervalues those on the ends of the spectrum (e.g., children who weigh less than the average adult weight).

Fish Consumption. Any estimation process involves choices regarding what parameters are estimated, what sampling strategies are used, what measurement methods are employed, etc. Choices made at every stage in the estimation process reflect the underlying values of the estimators. The fish consumption estimation processes used in the dioxin rule-making illustrate some fundamental differences in values that were made apparent to the citizen board during the testimony. It was up to the citizen board to consider the various approaches and conclusions presented, and the values underlying those approaches, and then determine which of those was most appropriate in a decision process with potentially great impact on human health.

The appropriateness of the fish consumption figure used in the rule-making equation (6.5 g/d/p) was addressed via testimony by the kraft mill industry, which had funded a study of fish consumption among Maine licensed anglers (ChemRisk, 1992). Portions of the industry testimony at the rule-making hearing focused on explaining the methods, results, and implications from that study, and were reported again by Boyle (1994). Other testimony, however, raised questions about the adequacy of the ChemRisk study as the basis for setting public policy.

The ChemRisk study was not designed to assess fish consumption rates specifically for river anglers downstream of kraft mills (Boyle 1994). No statewide study of that type existed at the time of the hearing (such a study would be very costly), but the Penobscot Nation presented data based on their own study of river fish consumers downstream of a kraft mill on the Penobscot

River. The Penobscot Nation is located on the Penobscot River. In testimony at the BEP hearings, representatives of the Penobscot Nation discussed the findings of a fish consumption survey they had conducted in their community. Their findings indicated that fish consumption among members of the Nation could be substantially higher than that indicated for licensed anglers in the ChemRisk study.

The Penobscot data reported at the hearing indicated that fish consumption among Penobscot Indians at the 90th percentile may be as high as one fish meal per week (about 30 g/d), and at the 95th percentile may be two to four meals per week (about 60 to 120 g/d). (Percentiles indicate what percent of the population is represented by using a specific fish consumption rate. The percent of the population above a given percentile is not represented by that consumption rate, and is therefore not protected by water quality regulations based on that consumption rate.) The ChemRisk study estimated Native American fish consumption at the 95th percentile as about 22 g/d. These studies differed in methods, and each involved its own set of choices and assumptions that should be considered by decision-makers when judging the quality and implications of the data for policy decisions. In any case, both of these values are clearly greater than the 6.5 g/d fish consumption rate on which the proposed dioxin rule was based. Is it possible the BEP citizen board took this into consideration in arriving at its final decision? Should the BEP seek to apply a fish consumption estimate reflective of the general licensed Maine angler, or reflective of a segment of society with strong cultural ties to the affected fishery resource?

Other testimony regarding the adequacy of the ChemRisk study as a basis for setting public policy focused on the confusing way in which some questions were posed to the anglers who participated in the study, and the resulting uncertainties in the data. For example, one question asked how much fish had been consumed in the past year "by you and/or a household member." Using "and/or" questions in studies such as this severely compromises the utility of the data gathered. The researcher cannot be sure if the person responding to the survey is reporting the fish consumption for him/herself, or for some other portion of the respondent's household. Such ambiguous wording is usually avoided in quality mail survey research, particularly if the data will be used as the basis for public policy affecting human health.

Testimony also focused on the appropriateness of basing fish consumption estimates on current consumption rates that may already be reduced because of environmental pollutants. Basing the fish consumption rate on current fish consumption by currently licensed anglers (e.g., as reported in the ChemRisk study) does not consider how much fish people would eat if water quality had not already been degraded or was improved in the future. Some of the waters on which kraft mills were located had been subject to fish consumption health advisories, i.e., some potential fish consumers were advised to limit or avoid consumption of fish caught from those waters due to potential negative health effects from contaminants. If anglers and fish consumers are adhering to the fish consumption advice provided by the State of Maine, current fish-eating activity may represent fish consumption rates lower than that desired by those people who fish the rivers downstream of kraft mills. Public policy-makers must decide if it is appropriate to: 1) base regulatory decisions on a baseline level of fish consumption that may already be lower (because of water pollution) than that desired by the public; or 2) use a level of fish consumption that may be more representative of the desired level of fish consumption within society. The

former approach would produce water quality standards that allow more pollutants to be released to the environment than allowed by the latter approach.

As noted throughout this discussion, decision-makers must evaluate the quality of data, and decide how to interpret and apply the data available from fish consumption studies. Scientific studies help describe the range of probable fish consumption rates. Choosing a particular fish consumption rate within that range for use in the rule-making equation, however, is clearly a policy decision. It is a policy decision for the BEP to determine if the State of Maine should protect frequent or infrequent fish consumers. Should consumption for the "average" person be used as the estimate in the equation? Or should the estimate be based on the consumption rates for those on the upper end of the consumption spectrum who, for whatever reason, are eating a comparatively greater amount of fish than the average person? If the more frequent fish consumers should be considered, should the 90th, 95th, or 99th percentile fish consumption rates be the basis for setting policy? Are Maine licensed anglers the most appropriate segment of the population that regulations are designed to protect, or are there other segments for whom society may have special obligations? The Penobscot Nation may be one group to which special obligations exist. In any case, each of these questions merits careful consideration by the citizen board.

Each element of the equation underlying the proposed dioxin rule involved choices and assumptions. I argue it is an appropriate function of the citizen board to consider and question each of these in its deliberations, and not just accept one "expert" recommendation.

Values, acceptable risk, and public policy

Risk assessment is not the final stage in public policy-making. Rather, the process of *risk management* involves considering the results of the risk assessment process in light of social, economic, political, and other issues relevant to public policy debates. In risk management, values underlying the decision process should be recognized explicitly. This was the role of the citizen board (BEP) in the dioxin rule-making hearing. If public policy is to be based, even in part, on the results of the risk assessment process, some public procedure is needed to: 1) analyze the appropriateness of the assumptions that entered into each stage of the risk assessment process; and 2) consider what information beyond the results of the risk assessment should be applied to the public policy decision. Risk assessment is not value-free. Open public policy debates about risk regulation/management must therefore also be able to critique openly the values and assumptions underlying the risk assessment process, as noted above.

In addition, public policy-makers should consider how the notion of risk should be defined in public policy debates. A key element of Boyle's argument was that citizens, including citizen boards (and experts working outside their area of expertise), over-estimate small risks, a phenomenon Boyle argued is fundamentally undesirable and should be changed through education. In a discussion of public judgments about low-probability, high consequence events, Fiorino (1989) presented an alternative view: "...the expert's focus on technological variables fails to account for such factors as human and organizational error, statistical vulnerabilities of low-probability estimates, and errors or variability in estimation techniques. *The lay public may be prudent in ways that the more specialized experts cannot"* (emphasis added). The testimony

considered by the BEP in the dioxin rule-making included critiques of the quality of the estimation techniques used to develop the low-probability estimates of fish consumption referred to by Boyle, including concerns about the validity of some of the questions used to assess fish consumption rates among the surveyed population, as discussed earlier. Perhaps the citizen board exhibited reasonable caution when interpreting the low-probability estimates provided.

As noted earlier, Boyle's definition of risk seems to center on estimates of the likelihood that harm will occur. In the last decade, a host of researchers, public policy analysts, and ethicists have questioned the fundamental assumptions on which this argument rests: 1) that likelihood (probability) of harm is synonymous with the concept of risk; and 2) that the best public policy decisions are those that focus only on quantitative estimates of the likelihood of harm. Otway (1987) examined the reliance on quantitative estimates in the context of public decisions in a democratic society.

He wrote: *[Quantitative risk studies] were inspired by the fact that, contrary to the expectations of technical experts, the public were not convinced by probabilistic risk calculations that their concerns about new technologies were groundless...Public fears were often ridiculed as being "irrational," apparently because they weren't expressible in technical jargon. Later research showed that there are other, objective characteristics of risk besides death and injury which matter to people (such as voluntariness, control, delay, catastrophic potential), and that it is perfectly normal to care about them. The view of decision making implicit in [quantitative] acceptable risk studies could be called technocratic, elitist...but it did nothing to further democratic process because the judgment of acceptability was seen as a matter for risk experts--that we could tell people what was best for them.*

Social scientists who have analyzed notions of risk and risk management related to public policy have recognized that "'riskiness' means more to people than 'expected number of fatalities'" (Slovic, 1987).

Differences in risk definition between experts and citizens are not surprising. It is logical (and has been demonstrated empirically) that people view risks in terms of how their own lives will be affected, and what is important in their way of life (Rayner and Cantor, 1987; Wildavsky and Dake, 1990). In the case of citizen boards, this may translate into considering how the lives of the citizens to whom they are responsible will be affected, going far beyond the quite limited notion of probability of harm. When considering the severity of harm, it is quite important to consider who will be affected. Judging the acceptability of seriousness and distribution of harm involves fundamental social and moral values, and so must be done by the public and not by technical experts (Lee, 1981).

Boyle noted that "The question for decision makers is how much effort should be involved in regulating choice versus nonchoice exposures to hazardous substances," emphasizing his view that "Exposure to dioxin through consumption of sport-caught fish...is a choice of the angler/consumer." This view reflects the assumption that every potentially exposed or affected individual has a completely free choice to subject themselves to that exposure or not. Those individuals who rely on fish from contaminated waters for subsistence purposes may not have a choice of relocating their fishing activities to another body of water, due to limited income or

other resources. Communities whose cultural and historical ties are linked to a particular geographic location or a specific body of water do not have the choice of relocating that cultural history to another, cleaner, location. The ChemRisk survey was not designed to identify and assess fish consumption rates nor cultural impacts for those who may not have the choice of shifting their activities to other fishery resources. A quantitative estimate of these factors would be very costly to obtain, but could be addressed qualitatively by those involved in the decision-making process.

Shrader-Frechette (1990) noted that one of the fallacies associated with relying solely on expert characterizations of risk is assuming that risk can be defined purely probabilistically, ignoring other important considerations in risk management judgments such as the distribution of benefits and costs, whether individuals have a choice about being exposed or not, and other factors not easily quantified. Indeed, the importance of each of these factors varies with the type of cultural norms of the society. Judgments about risk are socially and culturally constructed, based on shared beliefs of the members of society (Armour, 1993). For example, as Wildavsky and Dake (1990) demonstrated, "egalitarians" who value equal and fair treatment of all members of society may be very reluctant to judge any risks acceptable that involve a disproportionate distribution of benefits to one group and costs to another group in society. "Individualists" who value absence of constraints as paramount may be more accepting of risks to avoid placing burdens on technological development. The values and norms of the society, presumably reflected by the members of the citizen board, will inevitably (and appropriately, I argue) enter into public policy decisions.

Ethical issues enter into debates about risk management and related regulatory processes. In the four prescribed stages of the risk assessment process, moral questions are ignored, such as "the right to impose risks on some for the benefit of the common good" (Armour, 1993). The risk management process (i.e., including the rule-making hearing) should be a forum for debating those questions.

In the case of the dioxin rule-making, these questions relate to the obligations of the State of Maine toward any groups who would be at greatest risk--those with the highest levels of fish consumption; those who by necessity, desire, or cultural heritage seek to be subsistence fishers; those with strong cultural and historical ties to the fishery resource. In making their determination, then, the BEP should consider the appropriateness of exposure estimates (fish consumption rates) reflecting the average or avid Maine licensed angler, or those with cultural ties to the impaired fishery resource (e.g., Penobscot Nation), or other actual or potential subsistence users. Moral questions about who should bear the harm and who should experience the benefits center on concepts of distributive justice and cannot be addressed by efforts to educate citizens to be more rational in their perceptions of likelihood of risk.

Conclusion: The quality of the dioxin rule-making hearing process

In most rule-making procedures of any controversy, contradictory information will be presented. Such was certainly the case in the BEP dioxin hearing. It is the role of the citizen board members to hear and weigh all of the evidence presented, then apply their understanding of the implications of various alternatives for Maine society as the BEP makes its decision.

Key testimony presented to the BEP centered around the level of acceptable risk that should be used for policy decisions, the health effects of dioxin, and the accuracy and appropriateness of certain fish consumption estimates. Each of these types of information must be considered when evaluating the reasonableness of the BEP decision, not just the "ability of BEP to avoid overestimating the risks associated with human exposure to toxic substances," as Boyle argued.

Only BEP members would be able to explain how various testimony actually was interpreted and weighed in the decision process regarding how to regulate the risks of dioxin in Maine. The preceding discussion has illustrated the richness of the concept of "risk," a concept that goes far beyond quantitative estimates of the likelihood of harm. Boyle described his article as providing "a flavor of the risk assessment process in the hearing," focusing on how estimates of fish consumption and likelihood of harm were considered during the hearing. I have argued that a full taste of all aspects of the notion of risk, of the risk assessment process, and of the testimony considered by the Board is necessary to judge the success of the public hearing process.

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