GUIDEBOOK FOR SUPPORTING DECISION MAKING UNDER UNCERTAINTIES pdf

1: Decision-Making under Certainty, Risk and Uncertainty

This book provides much-needed guidance in making sound business decisions for the business leader or decision maker, especially investment appraisal practitioners such as strategic planners, business analysts, financial partners, and supply chain experts.

In general, the forces of competition are imposing a need for more effective decision making at all levels in organizations. Progressive Approach to Modeling: Modeling for decision making involves two distinct parties, one is the decision-maker and the other is the model-builder known as the analyst. Therefore, the analyst must be equipped with more than a set of analytical methods. Specialists in model building are often tempted to study a problem, and then go off in isolation to develop an elaborate mathematical model for use by the manager i. Unfortunately the manager may not understand this model and may either use it blindly or reject it entirely. The specialist may feel that the manager is too ignorant and unsophisticated to appreciate the model, while the manager may feel that the specialist lives in a dream world of unrealistic assumptions and irrelevant mathematical language. Such miscommunication can be avoided if the manager works with the specialist to develop first a simple model that provides a crude but understandable analysis. After the manager has built up confidence in this model, additional detail and sophistication can be added, perhaps progressively only a bit at a time. This progressive model building is often referred to as the bootstrapping approach and is the most important factor in determining successful implementation of a decision model. Moreover the bootstrapping approach simplifies otherwise the difficult task of model validating and verification processes. What is a System: Systems are formed with parts put together in a particular manner in order to pursuit an objective. The relationship between the parts determines what the system does and how it functions as a whole. Therefore, the relationship in a system are often more important than the individual parts. In general, systems that are building blocks for other systems are called subsystems The Dynamics of a System: A system that does not change is a static i. Many of the systems we are part of are dynamic systems, which are they change over time. Whether a system is static or dynamic depends on which time horizon you choose and which variables you concentrate on. The time horizon is the time period within which you study the system. The variables are changeable values on the system. In deterministic models , a good decision is judged by the outcome alone. However, in probabilistic models, the decision-maker is concerned not only with the outcome value but also with the amount of risk each decision carries As an example of deterministic versus probabilistic models, consider the past and the future: Nothing we can do can change the past, but everything we do influences and changes the future, although the future has an element of uncertainty. Managers are captivated much more by shaping the future than the history of the past. Uncertainty is the fact of life and business; probability is the guide for a "good" life and successful business. In very few decision making situations is perfect information - all the needed facts - available. Most decisions are made in the face of uncertainty. Probability enters into the process by playing the role of a substitute for certainty - a substitute for complete knowledge. Probabilistic Modeling is largely based on application of statistics for probability assessment of uncontrollable events or factors , as well as risk assessment of your decision. The original idea of statistics was the collection of information about and for the State. The word statistics is not derived from any classical Greek or Latin roots, but from the Italian word for state. Probability has a much longer history. Probability is derived from the verb to probe meaning to "find out" what is not too easily accessible or understandable. The word "proof" has the same origin that provides necessary details to understand what is claimed to be true. Probabilistic models are viewed as similar to that of a game; actions are based on expected outcomes. The center of interest moves from the deterministic to probabilistic models using subjective statistical techniques for estimation, testing, and predictions. In probabilistic modeling, risk means uncertainty for which the probability distribution is known. Therefore risk assessment means a study to determine the outcomes of decisions along with their probabilities. Decision-makers often face a severe lack of information. Probability assessment quantifies the information gap between what is known, and what needs to be known for an optimal decision. The probabilistic models are used for protection against adverse uncertainty, and exploitation of propitious uncertainty. Difficulty in probability assessment arises from information that is scarce, vague, inconsistent, or incomplete. A statement such as "the probability of a power outage is between 0. At times, the task may prove too challenging. Difficulties in decision making arise through complexities in decision alternatives. The limited information-processing capacity of a decision-maker can be strained when considering the consequences of only one course of action. Yet, choice requires that the implications of various courses of action be visualized and compared. In addition, unknown factors always intrude upon the problem situation and seldom are outcomes known with certainty. Almost always, an outcome depends upon the reactions of other people who may be undecided themselves. It is no wonder that decision-makers sometimes postpone choices for as long as possible. Then, when they finally decide, they neglect to consider all the implications of their decision. Emotions and Risky Decision: Most decision makers rely on emotions in making judgments concerning risky decisions. Many people are afraid of the possible unwanted consequences. However, do we need emotions in order to be able to judge whether a decision and its concomitant risks are morally acceptable. This question has direct practical implications: Even though emotions are subjective and irrational or a-rational , they should be a part of the decision making process since they show us our preferences. Since emotions and rationality are not mutually exclusive, because in order to be practically rational, we need to have emotions. This can lead to an alternative view about the role of emotions in risk assessment: Most people often make choices out of habit or tradition, without going through the decision-making process steps systematically. Decisions may be made under social pressure or time constraints that interfere with a careful consideration of the options and consequences. When people lack adequate information or skills, they may make less than optimal decisions. Even when or if people have time and information, they often do a poor job of understanding the probabilities of consequences. Even when they know the statistics; they are more likely to rely on personal experience than information about probabilities. The fundamental concerns of decision making are combining information about probability with information about desires and interests. Business decision making is almost always accompanied by conditions of uncertainty. Clearly, the more information the decision maker has, the better the decision will be. Treating decisions as if they were gambles is the basis of decision theory. This means that we have to trade off the value of a certain outcome against its probability. To operate according to the canons of decision theory, we must compute the value of a certain outcome and its probabilities; hence, determining the consequences of our choices. The origin of decision theory is derived from economics by using the utility function of payoffs. It suggests that decisions be made by computing the utility and probability, the ranges of options, and also lays down strategies for good decisions: This Web site presents the decision analysis process both for public and private decision making under different decision criteria, type, and quality of available information. This Web site describes the basic elements in the analysis of decision alternatives and choice, as well as the goals and objectives that guide decision making. Objectives are important both in identifying problems and in evaluating alternative solutions. The systematic study of decision making provides a framework for choosing courses of action in a complex, uncertain, or conflict-ridden situation. The choices of possible actions, and the prediction of expected outcomes, derive from a logical analysis of the decision situation. You might have already noticed that the above criteria always result in selection of only one course of action. However, in many decision problems, the decision-maker might wish to consider a combination of some actions. Visit the Game Theory with Applications Web site for designing such an optimal mixed strategy. An Integrated Approach, Wiley, Rehabilitating Epistemology, Kluwer Academic Publishers, From Data to a Decisive Knowledge Knowledge is what we know well. Information is the communication of knowledge. In every knowledge exchange, there is a sender and a receiver. The sender make common what is private, does the informing, the communicating. Information can be classified as explicit and tacit forms. The explicit information can be explained in structured form, while tacit information is inconsistent and fuzzy to explain. Know that data are only crude information and not knowledge by themselves. Data is known to be crude information and not knowledge by itself. The sequence from data to knowledge is: Data becomes information, when it becomes relevant to your decision problem. Information becomes fact, when the data can support it. Facts are what the data reveals. However the decisive instrumental i. Fact becomes knowledge, when it is used in the successful completion of a decision process. Once you have a massive amount of facts integrated as knowledge, then your mind will be superhuman in the same sense that mankind with writing is superhuman compared to mankind before writing. The following figure illustrates the statistical thinking process based on data in constructing statistical models for decision making under uncertainties.

2: Decision Making in Uncertainty

This book provides much-needed guidance in making sound business decisions for the business leader or decision maker, especially investment appraisal practitioners such as strategic planners, business analysts, financial partners, and supply chain experts. By "supply chain", the authors mean the.

To do so, it is first necessary to understand how decision makers interpret and use uncertainty information. Following a general overview of user types and needs for uncertainty information, Sections 2. The descriptive perspective identifies psychological factors that influence how users perceive risk and uncertainty and process uncertainty information. The prescriptive perspective, statistical decision theory, considers how the major factors inputs, preferences or goals, outputs, etc. While the psychological perspective suggests that the statistical decision theory does not fully describe real-world decision making, such a process may aid decisions and improve understanding of decision making by reducing complexity and focusing the analysis. Following the sections on prescriptive and descriptive approaches, Section 2. There is a vast and growing literature on psychological issues associated with processing of uncertainty information and different methods of communicating user-specific probability and other uncertainty information. The committee did not review and digest this literature and parallel literatures e. Instead, and given that the need for probabilistic forecast products will grow, the committee recommends a process by which NWS can develop an effective system of provider-user interactions that will lead to the design and testing of effective forecast formats. Detailed recommendations about the specifics of the process are distributed throughout the chapter. Some of the recommendations are further developed in Chapter 4. Users of forecasts generated by the Enterprise range from members of the public to those with significant training in statistics and risk management. These different groups of users are diverse in both information desires and needs and their ability to process uncertainty information. NWS, in support of its mission to protect life and property and enhance the national economy, provides forecast information to some users directly, and to some users indirectly through intermediaries such as the media and other private-sector entities. There are two broad categories of NWS forecast users Figure 2. The National Academies Press. Line thickness qualitatively illustrates the relative magnitude of flow. Those include the media, government organizations, and weather services. The psychological factors in interpretation and use of uncertainty information apply mostly to individual end users. However, some intermediaries such as the media can exhibit similar understanding of probabilistic information. In addition, forecast products and formats that work for the NWS scientists who develop them may not be understandable to and usable by less specialized information processors. The decision-support systems and analytic decision methods discussed in Section 2. Whether the decision processes that utilize hydrometeorological forecasts are informal and intuitive or formal and analytic, forecast producers need to be cognizant of how forecast information gets used to decide on how to optimally present its uncertainty. Weather and climate affect nearly all segments of society, and there is a multitude of weather- and climate-related decisions and decision makers. More specifically, decision processes and their consequences vary on at least the following dimensions: In general, users want forecasts to help them make a decision: What clothes do I wear? Do we send out snowplows, and if so, when? Do we purchase additional fuel supplies for the coming months, and if so, how much? Do we order mandatory evacuations? Thus, this section explores user needs for uncertainty information by discussing broad user communities and presenting examples. Specific User Types and Needs for Uncertainty Information Although NWS has not established a comprehensive formal method for incorporating uncertainty information into its services and products based on user needs, 2 it does have 1 As these examples illustrate, many but not all user decisions are binary yes or no , often with some threshold for action. Within this binary decision, however, there can still be a range of alternatives related to type of action e. Page 17 Share Cite Suggested Citation: For example, according to a recent customer satisfaction survey commissioned by NWS, most NWS customers surveyed want uncertainty information, but they are significantly less interested in probability information. With regard to the Advanced Hydrologic Prediction Service, NWS reports that although the available probabilistic information is utilized by specialized users, it has yet to be widely utilized by members of the public or even emergency managers. Nonetheless, these same users do understand and use qualitative uncertainty information. Hydrometeorological forecasts are used in multiple ways that include variations in the time horizon of the forecast, the type s of variables being predicted, their geographic specificity, and other factors. This section discusses the different uses to which hydrometeorological forecasts can be put from a more abstract decision-making perspective. The examples provided differ on three continua. The second continuum ranges from little or no lead time to make a decision to decisions with longer lead time that often allow for adjustments along the way. The third continuum ranges from decisions of little consequence to decisions with severe consequences. Whereas decisions with low stakes occur very frequently e. One of the three examples in this discussion depicts short-term warning of an approaching hurricane Box 2. This example involves high stakes, the loss of human life, and major physical destruction. The second and third examples Boxes 2. In these cases, the time urgency and the targeting of the message at analytically less well trained recipients make it less desirable to transmit the probabilistic nature of the forecast and more important to hit the right emotional tone and level of the message conveyed by the forecast. Their users frequently assess uncertainty by seeking multiple sources of information, given its relatively easy availability on the Internet. Rather than a continuous probability distribution function see Box 1. Many of their customers also want decision-support tools that translate uncertainty forecasts into risk analysis. Finally, much can also be learned from the experience of the international community in understanding user needs. Some of these international experiences may not be directly applicable to NWS, since hydrometeorological services operate differently and have different missions in different countries particularly with respect to roles of public and private sector , but it still can be informative. For instance, state departments of transportation reportedly want probability information on road weather, but researchers find that they may not actually know what they are really asking for. Emergency managers in Los Angeles, for instance, report that they are grappling with more mundane data problems such as accessing, exchanging, and verifying data, not to mention reviewing, understanding, and interpreting such data. Moreover, the information provided must also be compatible with the capabilities of the science. The provision of more information is also not always desirable because additional information can delay or complicate action, with great costs in situations of time pressure and high stakes, especially when information besides hydrometeorological forecast information plays an important role. As noted in Chapter 3 in particular, the capability to produce uncertainty information for users, in and of itself, is valuable and indeed critical for creating forecast products tailored for a specific use. Page 18 Share Cite Suggested Citation:

3: Tools for Decision Analysis

GUIDEBOOK FOR SUPPORTING DECISION MAKING UNDER UNCERTAINTIES Today's Managers, Tomorrow's Business This page intentionally left blank GUIDEBOOK FOR SUPPORTING DECISION MAKING UNDER UNCERTAINTIES Today's Managers, Tomorrow's Business.

Environmental Protection Agency EPA is not the only agency or organization that must make decisions in the face of uncertainty. Other agencies do as well, and, as is the case with EPA, when making a decision those other agencies must consider the likelihood and magnitude of a risk, the number of people at risk, whether some people are more at risk than others, the likelihood that a given intervention will mitigate the risk, the cost of potential interventions, and the potential consequences of inaction. A number of decisions about public health interventions that are now well understood were made at a point in time when there were more uncertainties. For example, it is now well accepted that the pasteurization of dairy products eliminates the risk of infections caused by Campylobacter jejuni, Salmonella species, and other pathogens FDA, a ; that fortification of foods with vitamins and minerals decreases the health consequences of vitamin and mineral deficiencies, e. However, not all of those interventions were unanimously accepted when first proposed or implemented, primarily due to uncertainties surrounding the possible benefits, risks, costs, feasibility, and public values. Many of those uncertainties have been reduced through research, including research on the effects of the interventions or treatments that were implemented. In contrast, other interventions that were once thought beneficial, such as bed rest after childbirth or a heart attack, were found not to be beneficial once uncertainties were reduced. In this chapter the committee reviews the decision-making tools and techniques from a number of different areas of public health, focusing on how uncertainty is taken into account in decisions. What are benefits and drawbacks to these approaches for decision makers at EPA and their partners? The chapter begins with a general discussion of the decision-making processes at a number of government agencies and organizations. It then uses case studies to illustrate how different agencies and organizations have made difficult regulatory or policy decisions while accounting for uncertainties. Table summarizes the processes and methods used by different public health agencies and organizations to evaluate the human health risks and benefits and other factors influencing the decisions, along with their inherent uncertainties. As can be seen in the table, many organizations have no formal guidance materials related to their decision-making processes, and many do not conduct formal uncertainty analyses. Food and Drug Administration FDA , some divisionsâ€”such as the center responsible for overseeing drug approvals and postmarketing safety, the Center for Drug Evaluation and Review, and the center responsible for overseeing medical devices, the Center for Devices and Radiological Healthâ€”have published guidance material on risk assessments. At the international level, the International Agency for Research on Cancer of the World Health Organization WHO evaluates the evidence for the carcinogenicity of different agents and classifies those agents into different categories according to their estimated carcinogenicity; uncertainties are presented qualitatively when discussing the gaps in evidence. Those assessments often contain quantitative analyses of uncertainties and sensitivity analyses. In addition, an interagency working group 1 has published draft guidelines for microbial risk assessments for food and water. The guidelines discuss the analysis and communication of uncertainties in risk assessments. That guidance discusses qualitative and quantitative human health risk assessments and the analyses of uncertainties in those assessments. They also discuss economic analyses to support decision making and the concomitant uncertainties in those analyses. Other uncertainties are not discussed, nor are issues related to the communication of uncertainties in the assessments of health risks and economics. Preventive Services Task Force USPSTF , an independent task force that is supported and administered by the Agency for Healthcare Research and Quality, uses an evidence-based approach to evaluate health care interventions and make recommendations for clinical practices, including medical screening tests. The use of GRADE when making recommendations related to vaccines is briefly discussed later in this chapter. A few organizations discuss the presence of uncertainty in economic analyses, but even those organizations do not explicitly discuss how or whether that uncertainty affected their decisions. Furthermore, they rarely consider factors other than health risks, health benefits, and economic analyses in their decision-making process. Many of the organizations elicit input from stakeholders through public meetings and comments on proposed action, much as EPA does; they do not, however, set forth an explicit process for incorporating uncertainties, such as a heterogeneity of stakeholder perspectives, into decision making. In reviewing the processes of these public health agencies and organizations, the committee identified a number of assessments or decisions that illustrate the techniques and approaches that have helpedâ€”or, in one instance, handicappedâ€”decision makers in their efforts to make decisions in the face of uncertainty. These cases include the following, which are discussed below: The committee did not attempt to develop a thorough evaluation or critique of each case; rather, it focused on aspects of the different cases that demonstrate useful approaches to evaluating and considering uncertainty in regulatory or policy decisions. Those uncertainties are thought to have been generated or at least exaggerated by the tobacco industry Muggli et al. This section discusses what evidence was available on the economic impacts and public acceptance of smoking bans at the time of decisions and what lessons can be learned from the implementation of these bans. Human Health Risks Although many of the human health risks associated with cigarette smoking were well established by the s U. The evidence of the risks from SHS comes from environmental chemistry and toxicology, including animal models of disease, as well from as observational studies most of which were case-control studies or meta-analyses of those case-control studies. Most of the risk-assessment findings were based on quantitative, well-conducted studies, although the findings were not always consistent among the studies see HHS et al. Concerns about variations in findings for a specific condition were allayed by the large number of studies, their general consistency, and the results of a number of meta-analyses conducted. Similarly, public comment periods on health risk assessments and proposed policies and regulations were often dominated by individuals or groups criticizing the studies who were often allied with the tobacco industry, and tobacco industry documents indicate that they had a strategy of maintaining the scientific debate around the health effects of secondhand smoke Bryan-Jones and Bero, To set smoking policies, therefore, decision makers had to distinguish between true uncertainties in the evidence and unfounded criticisms of the evidence motivated by financial interests, and they had to not only consider the results of each study, but also carefully scrutinize the quality of each study under consideration. Economic Factors One economic factor that was taken into account when considering smoking bans was the potential economic effects on the establishments that would be subject to the bans for example, bars and restaurants. Before the advent of state and local regulation, few studies had evaluated the economic effects that smoking restrictions and bans might have on those establishments. Because detailed studies of the economic consequences of likely regulations and policies were often unavailable, there was also no characterization of the uncertainties surrounding those economic factors. Legislatures were left to make decisions on environmental controls for SHS exposure in the face of large uncertainty and intense lobbying. As smoking bans were enacted and implemented, studies have looked at the economic consequences of the bans, for example, on restaurants and bars Glantz and Charlesworth, , which has decreased the uncertainty around the economic factors. Public Acceptance In accordance with national or local rules, decisions on smoking restrictions and bans generally included the opportunity for the public to comment on the proposed policies and on the science underlying them Bero et al. As mentioned above, many of the people commenting spoke out against the policies, but some of that opposition was orchestrated by the tobacco industry and allied parties Mangurian and Bero, Furthermore, the national environmental and public health organizations and agencies that could have supported local and state regulations often did not weigh in strongly, possibly because of a coordination Bero et al. Those aspects increased the uncertainty about the percentage of people and which sectors of the public were for or against smoking bans and restrictions. Further problems with the interactions with stakeholders may have been caused by communication issues, including a lack of communication about the uncertainties surrounding the issue.

Most communication with stakeholders about uncertainty used standard statistical presentations of epidemiological studies and meta-analyses Hackshaw et al. The doseâ€”response phenomenon was also not discussed extensively, with the exception of questions concerning the relevance of studies of home exposures to social exposures. Those discussions could have led the public to believe that the extent and implications of uncertainties in the data and analyses were greater than they actually were. Decisions in the Face of Uncertainty: Lessons Learned Given the lack of any known health benefits from exposure to SHS, health assessments centered on the risks associated with exposure to SHS. Despite a large amount of evidence related to those risks, discussions often focused on the uncertainties in the evidence rather than on its consistencies; individuals and groups with a financial stake in blocking smoking restrictions and bans often drove those discussions Bryan-Jones and Bero, There was large uncertainty about the potential costs from lost revenues to establishments subject to bans and about the financial benefits from avoided medical costs. States and local jurisdictions where there was either the political will or higher public acceptance of bans were the first to implement smoking restrictions and bans. Researchers took advantage of some of those bans to investigate whether they were associated with any health effects, to study the public reaction to the bans, and to see whether the bans had any economic consequences on establishments covered by the bans. Epidemiology studies indicated that smoking bans or restrictions were associated with decreases in adverse cardiovascular events Barone-Adesi et al. Research surveys showed that the public approval of various state and local laws and regulations was generally, although not uniformly, positive after implementation, both in the United States and other countries Borland et al. For example, in Studies of the economic effects of the bans on restaurants and other establishments decreased the economic uncertainties related to smoking restriction and bans Glantz and Smith, , ; Hyland et al. With the decreased uncertainty provided by all these types of studies, other state and local regulators had stronger evidence on which to base their decisions. The passing and implementation of smoking bans provides many lessons for EPA and for other regulators. First, it emphasizes the importance of scientists and policy makers scrutinizing the quality of individual studies as part of appropriately determining the overall weight of the evidence and the uncertainty in it. Second, it demonstrates the need to consider the sources of scientific criticisms and uncertainties that are raised and to separate valid scientific criticisms from invalid ones. Third, it emphasizes that when considering economic factors and other factors, such as public acceptance, uncertainty based on anecdotal concerns about potential financial consequences might not reflect the actual effects of a regulation. Fourth, it illustrates the heterogeneity in public values and how acceptance of health-protective policies can shift over time, leading to new societal norms. Infections during pregnancy can lead to premature delivery, infection of the newborn, or stillbirth. In this section, the committee discusses that risk assessment and the uncertainty analyses in it and also discusses how FDA has used the results of that risk assessment to refine its policies around the control of L. The growth of L. FSIS has a zero-tolerance policy for L. Until FDA published proposed draft guidelines in that established two categories of RTE foods, it had a zero-tolerance policy for L. Under those zero-tolerance policies, the presence of L. The food industry argued that not all RTE foods support the growth of L. The industry also argued that the risk of listeriosis depends on the type and frequency of RTE consumption as well as on home refrigeration factors i. In essence, the industry was arguing that the variability in food susceptibilities and the uncertainty in home refrigeration had not been considered in the regulations. In light of those arguments, FDA reviewed its zero-tolerance policy for L. The agency was faced with determining whether or not to relax the zero-tolerance standard for some foods and, if they were relaxed, what guidance it should issue to industry for controlling L. The assessment evaluated 23 categories of foods considered to be the principal potential sources of L. In particular, it evaluated the heterogeneity among different foods and different age groups of people. The assessment estimated the human health risks for different exposures. It also used various scenariosâ€”different food consumption rates, different growth rates, different contamination rates, and so onâ€”to evaluate which points in the farm-to-table continuum were most susceptible to contamination or had the greatest potential for risk mitigation. Through those sensitivity analyses, the assessment identified five main factors that affect consumer exposure to L. Rather than providing a single risk estimate, the health risk assessment provided a range of estimates using sensitivity analyses and probabilistic methods for the different food categories, the populations with different susceptibilities to listeriosis, and the strains of L. Presenting the different sensitivity analyses allowed decision makers to target strategies to mitigate risks for different populations and food categories. For example, specific strategies could be developed to prevent exposures in pregnant women, the elderly, and susceptible individuals within the intermediate-age group. FDA used the results of the risk assessment and its analyses of variability to develop regulations that differentiated between foods that pose higher and lower risks for listeriosis. That regulation takes into account the conclusions from the sensitivity analyses in the assessment that the risks from foods with a pH less than or equal to 4. The final risk assessment summarized the changes made to the draft in response to the comments received. Many of those changes reflected decreased uncertainties as a result of the feedback received. They included changes to the food categories to better incorporate characteristics that contribute to the support of growth of L. Lessons Learned The assessment of L. The detailed and specific risk characterization allowed FDA and FSIS to develop specific guidance for different foods and to develop outreach strategies to protect the populations at highest risk from consumption of foods contaminated with L. In light of the complexity of the risk assessment, the agency also evaluated methods for grouping the results for communication purposes FDA and FSIS, b. That analysis allowed the development of a matrix to depict five overall risk designations: For example, deli meats are considered very high risk because they were in the high cluster for both per-serving and per-annum consumption. BSE is one of a number of transmissible spongiform encephalopathies that are caused by infectious agents associated with an abnormally folded protein known as a prion IOM, In cattle, the infectious agent is transmitted through ingestion of contaminated feed. Because there are no vaccines against or treatments for BSE or CJD and because it is extremely difficult to destroy the infectious agent, preventing the spread of BSE among cattle and preventing cattle infected with BSE from entering the human food supply are key control mechanisms. The potential human health consequences from CJD are severe, and the costs of an outbreak are high.

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4: Guidebook For Supporting Decision Making Under Uncertainties - PDF Free Download

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Those guidelines are briefly summarized here. The first step more Assessing exposure requires an evaluation of the nature of the population that is incurring exposures to the substances of interest and the conditions of exposure that it is experiencing such as the dose and duration of exposure NRC, Risk assessments are frequently used by EPA to characterize health risks under existing exposure conditions and also to examine how risks will change if actions are taken to alter exposures EPA, b. A clear description of the confidence that can be placed in the risk-assessment resultâ€"that is, a statement regarding the scientific uncertainties associated with the assessmentâ€"should be a feature of all risk assessments. The extent to which uncertainties in data and analyses can be measured and expressed in highly quantitative terms depends upon the types of investigations used to develop scientific knowledge. Highly controlled experiments, usually conducted in a laboratory or clinical setting, if well designed and conducted, can provide the clearest information regarding uncertainties. Even in many experimental studies, however, it is not always possible to quantify uncertainties. Controlled clinical trials, for example, still contain uncertainties and variability that cannot necessarily be predicted or accurately quantified. Risk assessments can address such questions as whether a risk to health will be reduced if certain actions are taken and, if so, by what magnitude and whether new risks might be introduced when such actions are taken. However, the scientific uncertainties associated with such predictive efforts include not only the uncertainty associated with the available knowledge but also uncertainty related to the predictive nature of estimates for example, predicting how much of a decrease in air pollution different control technologies will produce or predicting how many lung cancer cases will be avoided by a given decrease in air pollution. The Red Book highlighted many of the unknowns in a risk assessment, including a lack of understanding of the mechanisms that underlie different adverse effects NRC, The presence of uncertainty in data and analyses, however, is not unique to the chemical risk-assessment world and should not preclude a regulatory decision. For instance, drugs are often used even without a thorough understanding of their underlying mechanism of action. Because of that, the report argues that the limitations in uncertainty analyses should be recognized and considered and that the focus of any such analysis should be on the uncertainties that most affect the decision, and it criticizes characterizations of risks that do not focus on the questions of greatest impact to the decision outcome. Uncertainties in data and analyses can enter the risk-assessment process at every step; the sources of the largest uncertainties include the use of observational studies, extrapolation from studies in animals to humans, extrapolation from high- to low-dose exposures, and interindividual variability. Box , which briefly describes the evidence on the degreasing solvent trichloroethylene TCE , provides an example of how uncertainties arise in risk assessments and of the challenges that those uncertainties present to decision makers. Trichloroethylene TCE is a degreasing solvent used in many industries and a contaminant in all environmental more Studies in humans that evaluate whether exposure to a substance causes specific adverse effects can provide the most relevant information on hazards and dose response. Clinical trials have a greater chance of yielding unambiguous results regarding causality than do observational studies Gray-Donald and Kramer, It is not ethical to intentionally expose people to chemicals at exposure concentrations that are likely to cause adverse effects, even following a short duration of exposure. Moreover, clinical trials are costly and typically are designed to capture the short-term effects of an intervention, whereas many adverse effects of chemicals can take decades to develop. Except under highly limited conditions, clinical trials should not be used to study the adverse health effects of substances regulated by EPA NRC, Because many such studies do not provide evidence that meets the criteria typically used to establish causation rather than associationâ€"that is, the Hill criteria, such as demonstrating a dose response and a temporal relationship between exposure and effect Hill, â€”the results from individual observational studies on their own can, at best, be used to establish associations. For example, in many situations the only information is whether or not participants were exposed to a given chemical, and nothing is known about the magnitude of individual exposures or whether there was differential exposure among individuals, which makes it very difficult to determine doseâ€”response relationships. Observational studies often capture exposures and health outcomes retrospectively, so that the temporal relationship between the exposure and the outcome cannot be determined. Furthermore, regardless of the study type, inconsistent results in a group or body of studies examining a given chemical are common and contribute to uncertainties regarding causality. The types of uncertainties associated with the interpretation of results from observational studies may be described quantitativelyâ€”such as conducting an analysis that estimates the effect and also quantitative assessments of the likelihood of that effectâ€”but the uncertainties are usually expressed in qualitative language, such as describing the range of relative risks across studies and the quality of the individual studies. Data from experimental studies in animals and from a variety of in vitro systems are commonly used, in part, to overcome the limitations in observational epidemiology studies. Experimental studies allow researchers to acquire information about hazards and dose response and, if well designed and well performed, can yield information about causality. Results from such studies, however, can have significant uncertainties regarding their generalizability to humans. Differences between the metabolism and the mode of action of a chemical in animals compared with humans underlie many of the differences between animals and humans, but uncertainty often exists about the magnitude of the differences. For example, it is not currently possible to quantify the extent to which disease processes observed in animal experiments apply to humans, and differences in longevity have to be taken into account when considering the duration of exposure for animal studies. It is important to note, however, that despite those limitations enough is known about the similarities and differences between humans and experimental animals to make them relevant to and critical for assessing human health risks EPA, a. There is also uncertainty associated with exposure information. One such uncertainty comes from extrapolating from exposures in studies to the exposures experienced by the public. There are instances in which the exposure incurred by the population that is the subject of a risk assessment that is, the target population is close to, or even in the same range as, that for which hazard and doseâ€”response data have been collected. For example, studies of exposures to the primary air pollutants ozone, lead, mono-nitrogen oxides, sulfur oxide gases, and particulate matter are often in the same ranges of exposures as occurs with the general population Dockery et al. In many instances, however, the exposure incurred by the target population is only a small fractionâ€”sometimes a very tiny fractionâ€”of the exposures for which it has been possible to collect hazard and doseâ€—response information. Studies of occupational cohorts, for example, typically involve exposures well in excess of general population exposures, and animal studies similarly involve high-dose effects. For the risks to the target population to be described, a method or model must be used to extrapolate from the high-dose scientific findings to infer the risks at much lower doses. That extrapolation can create large uncertainties in risk assessment. The biological bases for selecting among different models for extrapolation are not well established, and different models can yield different estimates of low-dose risk. In other cases very little might be known about the actual exposures in the target population, adding additional uncertainty. Individuals within a population also vary with respect to both their exposures and their responses to hazardous substances. Reliable, quantitative information that allows an understanding of the magnitudes of that variability can be difficult, if not impossible, to acquire Samoli et al. Risk assessments need to account for possible differences in response between the populations that were studied to understand hazards and dose response in the target population, which typically is more diverse than the population studied Pope, Studies of human exposure in limited populations cannot be used to apply to other, more diverse populations without considering the uncertainties from the different populations. Additional uncertainties related to the effects of chemicals at different life stages and different comorbidities, the effects of exposures to complex mixtures, and the effects of chemicals that have received very little toxicological study are also introduced in many assessments EPA, In many cases the analyst or scientist who is conducting the risk assessment is able only to describe those uncertainties in largely qualitative terms, and formulating scientifically rigorous statements about the effects of these uncertainties on a risk result is beset with difficulties EPA, The Red Book emphasized that the uncertainties inherent in risk assessment were so pervasive that virtually no risk assessment could be completed without the use of assumptions or some types of models for extrapolations NRC, Moreover, it recognized that there was little or no scientific basis for discriminating among the range of assumptions or models that might be used in a given case. The report argued that some degree of general scientific understanding, though limited, exists in each of the areas of uncertainty that attend risk assessment. It further argued that, in many of the areas of uncertainty, a range of plausible scientific inferences might be made, although none could be claimed to be generally correct that is, correct for all or most specific cases. The report further stated that the selected set of inference options for risk assessment should not only be justified, but also be set down in written guidelines for the conduct of risk assessments, so that they could be visible to all NRC, As recommended, EPA has developed guidelines for the conduct of risk assessments for many types of adverse effects, and those guidelines include recommendations about what uncertainty factors to use when there are specific uncertainties EPA, , , a , b , d , a , , a. The selected sets of inference options have come to be called uncertainty factors, or defaults. In practice, in reviewing the scientific information available on specific substances or exposures, it becomes clear that there are significant gaps in knowledge or information; agency human health risk assessors adopt the relevant default specified in the guidelines. For example, to account for uncertainties in how to extrapolate from animal data to risks in humans, the default uncertainty factor is EPA, therefore, divides the dose at which no effect is seen in animals by a factor of 10 to estimate a dose at which an effect would not be seen in humans. If there are data on the extent of toxicokinetic differences between animals and humans, then EPA might use a data-derived uncertainty factor rather than using the default uncertainty factor. The Problems with Default-Driven Risk Assessments In addition to helping make risk assessments consistent across agencies, the use of prespecified, generic defaults has a number of advantages. First, although the uncertainties and limitations in the estimate should be characterized for the decision maker, the use of a default does allow the assessor to provide a risk estimate when a decision needs to be made in the presence of some uncertainty. The assessor can use a standard default to extrapolate when there is little or no scientific information available to indicate what the shape of the doseâ€”response curve is in the low-dose region for a carcinogen; the default in this case would be a linear, no-threshold model. Second, defaults are typically protective of health. It is likely to generate the highest, or upper-bound, risk estimate consistent with the data; the actual risk almost certainly will not exceed the upper bound and will likely fall below it. Third, it can provide decision makers with a single, upper-bound point estimate, while acknowledging the uncertainty in that point estimate by indicating that the actual risk could fall anywhere between zero and that upper bound. If that upper bound is itself in the negligible risk range, the uncertainty statement allows the decision maker to assert that any actual risks are likely to be below the negligible range. Fourth, the use of a single point estimate and defaults allows for a simpler risk-communication message. Using defaults to deal with uncertainty does, however, have a number of deficiencies, and that use has been the subject of much discussion and debate in the scientific literature NRC, , , Defaults have been criticized for their lack of an adequate scientific basis. In addition, if the fact that they are used and the implications of their use are not communicated with a risk estimate, they can mask the uncertainty, providing a sense of uncertainty that is inaccurate. The use of defaults has also been criticized for being overly conservative; that is, the regulatory standards that are based on defaults are more restrictive than necessary to protect public health. If, as with the linear, no-threshold default, most of the defaults in risk assessments are selected because they are conservative that is, protective of health and resulting in lower permissible exposures or emissions , very little can be said about exactly how much uncertainty is associated with their cumulative use. As discussed below, these and other criticisms have led to suggestions for alternative ways to treat the problems of uncertainty in risk assessment. The Use of Data, Not Defaults The

Red Book recognized the limitations of defaults and also recognized that any set of defaults, no matter how they were selected, would not likely be generally applicable to all risk assessments NRC, Although substantial research might someday make it possible to justify generally applicable models for interspecies, high- to low-dose, or intraspecies extrapolations, the understanding needed to achieve such a goal remains unavailable and is not likely to be available for a very long time. New research on a specific substance or exposure situation can lead to questions about the applicability of any given default to that substance or situation NRC, Thus the report urged agencies conducting risk assessments to seek data that would supplant the need for a defaultâ€”such as data on the toxicokinetic differences between animals and humansâ€”and to allow scientific knowledge and data on specific substances to hold sway over defaults. For instance, if enough scientific information exists about the differences in the metabolism or mode of action of a chemical in animals versus in humans, then scientifically derived extrapolation factors can be used rather than the defaults. If those factors more accurately reflect the differences between animals and humans than default adjustment factors, the use of such data-derived extrapolation factors would decrease the uncertainty in the risk assessment. EPA agrees with the NRC report that specific knowledge should supplant the use of defaults when appropriate and it has adopted that as a general principle EPA, a. In other words, GAO concluded that although EPA in theory favors using new scientific information to supplant established defaults, in practice it uses defaults more often than not GAO, The continued reliance on defaults is, in part, due to a view that any research data used to deviate from defaultsâ€”such as data on the mode of action of a chemical that indicates that there are no adverse effects below a certain doseâ€”will themselves have uncertainties. Unless those uncertainties are clearly much smaller than those associated with the default, assessors often think that the default should be retained Haber et al. However, because the true uncertainties associated with the standard defaults are generally unknowable, such comparisons are problematic. In any event, the general question remains unanswered of just how convincing the data on specific substancesâ€”such as mode of action dataâ€”should be in order to use the specific information rather than a default. The debate about whether default adjustment factors or specific data should be used occurs even for individual chemicals or other agents. This has occurred, for example, with the dioxin risk assessment NRC, and the formaldehyde risk assessments NRC, Several National Academy of Sciences NAS committees have recommended that EPA develop explicit criteria for when to use research data on specific substances rather than defaults to deal with uncertainties and have also recommended that EPA minimize use of defaults NRC, , For example, Science and Decisions: And, indeed, EPA has adopted a number of those methods to evaluate the uncertainty in many of the components data and analyses of its human health risk assessments. Significant developments have also occurred in characterizing the magnitude of uncertainty in certain types of hazard and doseâ€”response information, particularly for the primary air pollutants NRC, As discussed in Science and Decisions NRC, , EPA uses a number of different approaches to quantify the uncertainty and variability in different components of a risk assessment. One such method is Monte Carlo analysis, a technique that propagates uncertaintyâ€”including variability and heterogeneity as well as model and parameter uncertaintyâ€”in the various components of the human health risk assessment for example, in the exposures, toxicokinetics, and the dose response. The techniques can incorporate a range of values and propagate that range throughout the assessment to create a distribution of risk estimates rather than a single point risk estimate. See the discussion of risk assessment for arsenic in drinking water below for an example. Such efforts are leading to more completeâ€”but more complexâ€”characterizations of uncertainty than have traditionally been provided to decision makers. The techniques can be combined with Bayesian techniques, in which one assesses not simply the potential range of values but also the likelihood of a given value within the range based on expert judgment and available information NRC,

5: Guidebook for Supporting Decision Making Under Uncertainties:Today's Managers, Tomorrow's Busines

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Accelerating technological change Aging population trends in developed economies An increasing sense of uncertainty reflects a changing environment that will impact the choices we make. Recognizing and accommodating these changes provides the opportunity to increase decision making effectiveness. Decision making always involves uncertainty Even the simplest decisions carry some level of uncertainty. Complete certainty would imply carrying out a fixed procedure or algorithm, not making a choice. So, how does decision making impact uncertainty? Decision making can be described as the process of reducing uncertainty about solution options by gaining sufficient knowledge of the options to allow a reasonable selection from among them. Uncertainty is reduced, but never eliminated. If that were possible, we would be able to predict the future without error. Seldom are decisions made with absolute certainty because complete knowledge of the alternatives is not possible or practical. There is also a distinction in levels of uncertainty. In "precise uncertainty" probabilities for solution outcomes can be known or gathered, such as in games of chance. Other risks, such as some of those suggested in the bullet list above, will often have probabilities that are not knowable. Why does it seem like uncertainty is increasing? Events globally and locally, along with a high level of media attention, are revealing some of the risks and uncertainty that underlie decisions that impact our perception of security. In reality, there is no permanent security in this world. Choosing not to take risks does not secure one from changes that can take place in the environment, economy, technology, society, or government. Obvious emotions of fear and anxiety arise whenever we are separated from things that make us feel secure. People experience these emotions, particularly separation anxiety, when they move away from homes and loved ones at many stages during life. It should be expected, and acknowledged, that we will have fear of failure, loss, or rejection when we take on risk or uncertainty. Losing a sense of control over your life can be unsettling. How should we change our decision making when uncertainty increases? Recognizing that uncertainty brings some level of separation anxiety can help reveal some ideas for managing decision making in uncertainty. Here are some ideas to consider for times of high decision uncertainty. Reduce the time horizon for decisions. Build a bridge to the future by taking smaller steps, keeping something familiar and secure with each step. Learn as much as possible about options before choosing. Knowledge makes the new seem more familiar, reducing separation anxiety. When the environment is providing lots of uncertainty, defer risks that are in your control. For example, when there is economic uncertainty, postpone taking on debt for buying a new car. Take one risk at a time when feasible. Combining risks from multiple decisions e. Determine the worst case scenario. Fear of loss is higher when it is unbounded. Knowing the worst is survivable can ease this fear. Estimate the negative and positive consequences of the risk or uncertainty. Knowledge of the potential gains and losses can encourage taking risks for good opportunities. Know your goals and values. The underlying premise of effective decision making is that the decision maker knows their needs and desires. Risk becomes unbounded when this is not the case. Invest in keeping options open. Having a wide range of options increases flexibility to accommodate an uncertain future. Options can be reduced as knowledge is obtained. Avoid emotional risk taking. Take risks for the right reasons based on clear, calm, and rational thought. Increase monitoring and appraisal for decision making in uncertainty. Readily adapt as new knowledge is uncovered. The recurring theme for uncertain times is gaining knowledge. Knowledge provides the basis for security and familiarity. Decisions provide the framework for gaining the knowledge that will reduce uncertainty and enable change.

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