

# **RISK-BASED ENVIRONMENTAL DECISIONS**

**Methods and Culture**

# **RISK-BASED ENVIRONMENTAL DECISIONS**

**Culture and Methods**

by

**Douglas J. Crawford-Brown**

Department of Environmental Sciences and Engineering

Curriculum in Public Policy Analysis

Carolina Environmental Program

University of North Carolina at Chapel Hill



Springer Science+Business Media, LLC

**Library of Congress Cataloging-in-Publication Data**

Crawford-Brown, Douglas J.

Risk-based environmental decisions : culture and methods / by  
Douglas J. Crawford-Brown.

p. cm.

Includes bibliographical references and index.

ISBN 978-1-4613-7382-7 ISBN 978-1-4615-5227-7 (eBook)

DOI 10.1007/978-1-4615-5227-7

1. Environmental risk assessment.

GE145.C73 1999

333.7'14--dc21

99-40710

CIP

---

**Copyright** © 1999 Springer Science+Business Media New York

Originally published by Kluwer Academic Publishers in 1999

Softcover reprint of the hardcover 1st edition 1999

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher, Springer Science+Business Media, LLC.

*Printed on acid-free paper.*

Dedicated to my Mother and Father, who have seen me through to here and sent me on my way; to my sister, who has cared for us all over the years; and to my wife and son, who make life worth exploring.

---

# CONTENTS

---

<b>Preface</b>	ix
<b>Chapter 1. Risk, Rationality and Decisions</b>	1
1.1. Analysis of Risk	1
1.2. Conceptions of Risk	4
1.3. Rationality and Risk	13
1.4. Rationality and Logic Trees	16
1.5. The Uses of Risk Analysis	22
1.6. Risk, Values and Culture	30
<b>Chapter 2. The Structure of Environmental Risk Assessments</b>	39
2.1. Formulating the Problem	39
2.2. Hazard Identification	44
2.3. Risk Characterization	59
2.4. Risk Communication	65
<b>Chapter 3. Assessing Exposure</b>	69
3.1. Emerging Pathogens	69
3.2. Identifying Sources and Characterizing Strength	70
3.3. Dispersion and Fate	73
3.4. Dispersion Coefficients and Equilibrium Ratios	75
3.5. Areal-weighted, Time-weighted and Population-weighted Averages	80
3.6. Exposure Pathways	81
3.7. ADRI and MIR	84
3.8. Data and Models	89
3.9. Summarizing Exposure	92

<b>Chapter 4. Exposure-Response Assessment</b>	<b>95</b>
4.1. Environmental Radon	95
4.2. Pharmacokinetics	96
4.3. Pharmacodynamics and Dose-Response	103
4.4. Missing Steps	110
4.5. Human Equivalent Concentrations	112
4.6. Intersubject Variability	115
4.7. The Social Construction of the Causes of Risk Variation	119
<b>Chapter 5. Regulatory Science: Risk and Decisions</b>	<b>123</b>
5.1. Decisions and the Precautionary Principle	123
5.2. NOELs, NOAELs, LOELs and LOAELs	128
5.3. RfDs and RfCs	134
5.4. Benchmark Doses	141
5.5. Hazard Quotients and Hazard Indices	143
5.6. Linear Carcinogens	144
5.7. Nonlinear Carcinogens	146
5.8. Exposure Limits and Ample Margin of Safety	148
5.9. Risk, Science and the Courts	154
<b>Chapter 6. Uncertainty and Variability Analysis</b>	<b>159</b>
6.1. Protecting Against Risk	159
6.2. Principles of Uncertainty for Discrete Options	162
6.3. Uncertainty for Continuous Variables	173
6.4. EPA Guidelines on Monte Carlo Analysis	179
6.5. Sensitivity Analysis	180
6.6. Variability Analysis	182
6.7. Nested Analyses	185
6.8. Risk-Based Decision Under Variability and Uncertainty	186
<b>Chapter 7. Risk, Systems Analysis and Optimization</b>	<b>191</b>
7.1. Risk Management Options	191
7.2. A Decision Problem	194
7.3. Optimization Principles	205
7.4. Applying the Lessons	209
7.5. Closing Comments	213
<b>Index</b>	<b>221</b>

---

## PREFACE

---

Risk analysis lies somewhere between a science and a professional practice; between a pure discipline and an application of other disciplines; between an analysis of the world and an analysis of our understanding of that world. It certainly has developed sufficiently far to have its own methods which, while they may also be found elsewhere, are used so routinely in risk analysis as to be identified primarily with that field. It has a language all its own, although again borrowed from other disciplines and modified to fit the needs of risk analysts. It has its own professional societies, with applications ranging across almost the entire galaxy of decisions.

The methodologies of risk analysis in general, and of environmental risk analysis in particular, draw heavily on scientific models and data. To determine the risk from a source of pollution such as an incinerator, there is a need for scientific data and models concerning the rate of release of the pollutant; the movement of the pollutant in the air, water, soil, etc.; the ingestion and inhalation of the pollutant into the body; and the relationship between this intake into the body and the various adverse health effects that might be found in human and other populations. All of these data and models must (or at least should) satisfy standards of best scientific practice. In this sense, risk analysis looks like any other applied area of science, drawing on fundamental science to make predictions used in applications more reliable.

At the same time, risk analysis is linked strongly to decisions made by society. The major applications of risk analysis are found in attempts to examine alternative societal policies, to assess those policies, to rank the policies with respect to their effectiveness at reaching goals, and to select the policy that is in some sense optimal. It is hard to imagine risk analysis existing without the need for decisions, without the need for a systematic approach to aiding those who make decisions. Given the close connections to decisions, it is not surprising to find that risk analysis has been infused with methods associated with decision analysis such as uncertainty analysis, variability analysis, sensitivity analysis, logic trees and influence diagrams (all discussed later in this book).

A central feature of modern risk analysis is explicit consideration of the quality of decisions, and the ability of existing science to provide at least an acceptable level of quality. It is possible to perform a risk analysis without ever

asking about the quality of the information used in that analysis, simply following formal procedures of using data and models without ever addressing the reliability of the resulting predictions. But with the need for public decisions comes the need to justify the analysis leading to those decisions. Without such an analysis, the decision-maker is open to charges of being arbitrary and capricious. This justification rarely is allowed to rest solely on the qualifications of the analyst. Instead, it rests on a systematic analysis of the degree of support for predictions of risk, and on a public discussion of whether that support is sufficient to justify particular decisions. This leads the debate into an area somewhat foreign to scientific discourse: consideration of the quality of understanding and prediction that must underlie beliefs before those beliefs are allowed to drive decisions. It leads the debate into the border between science, philosophy and policy.

When is a decision justified? This seems on the surface a matter for purely rational analysis, so at the least a risk analyst needs an understanding of rationality and its relationship to decisions. A decision is justified rationally when the goals have been met with adequate confidence. Such a statement, however, hides, or at least does not confront directly, a core issue of culture. When we make decisions, we say something about ourselves. We tell the world how we justify decisions, how much evidence we require to justify actions that affect a wide range of people, how we select and weigh the many goals to be met, how we confront the limits of our knowledge, and how we manage to struggle through to a decision even in the face of uncertainty. All of these are issues of culture because they go beyond methodologies and strike at the heart at what makes us human. They define not only how we will act, but how we express our visions of proper action.

This book examines the links between risk analysis, decision, philosophy and culture. It is not, strictly speaking, a work of philosophy or of cultural analysis. It is too oriented towards the science of risk analysis and the methodologies of that science to qualify as a work on culture or on philosophy (even philosophy of science). But the book is informed throughout by my personal conviction that methodologies can hide philosophical positions that are best examined in full light, and that the selection of methodologies and the willingness to express uncertainty says as much about us as a people as they say about scientific practice. Risk analysis becomes a cultural activity when a group begins to ask fundamental questions about the nature of their methodologies and how those methodologies assist in reaching decisions. In a sense, when we use a particular risk analysis to guide decisions, we are stating not only what the world is like and what we would like it to be, but how we as a people confront uncertainty and factor that into the decisions which define us.

St. Augustine, arguing from the relative darkness of the 5<sup>th</sup> century, spoke of the Drama of Salvation. He saw the world as fundamentally unknowable to humans, populated by laws we could grasp only in sketch. He saw our existential condition as one of uncertainty concerning the stage on which we live, with that

uncertainty only informed partially by what we now call science. What mattered in the end was how we lived within that uncertainty and still managed to choose actions that we thought good or bad. This was the drama we acted out on the stage of uncertainty. How we acted within that drama, how we made the decisions needed to carry us through life without knowing what lay ahead, defined our souls. It brought us salvation or damnation. His time is gone, and the language we use today is not so filled with fire and brimstone. But his message can be given modern form in risk analysis: we define ourselves and our culture daily as we confront the limits of knowledge in defining risks and embrace those limits while deciding how to act on the stage we are given. Risk analysis is the closest thing science has given us to a method for analyzing our existential condition of uncertainty and doubt in the face of decisions.

What is in this book? First, there are methodologies, and the science which informs these. To master risk analysis means to understand how characterizations of risk are generated and transmitted. Second, this is a book of philosophical analysis. As will be described later, risk is tied intimately to uncertainty, and uncertainty is tied to the analysis of evidence and rational belief. Philosophical analysis in general, and epistemological analysis in particular, provide the tools by which uncertainty can be understood (or is that an oxymoron?). Thirdly, it is a book of at least partial cultural reflection, since I want to consider where the adoption of methodologies says something about us as a culture, and how we might select methodologies that most closely conform to the visions we have of ourselves. Finally, it is a book of applications, providing numerous examples of the ways in which risks are assessed in practice and this assessment used to rank and select alternative environmental policies. I have chosen examples on which I have worked over the years, not because they are the most important issues (although I think they are very important), but because I know these better and can provide the most detailed picture.

Chapter 1 sets the stage by considering the relationship between risk and decisions, using the example of endocrine disruptors in the environment. The goal is to understand how it is possible to make rational decisions in the face of uncertainty, and how risk analysis informs that rationality. It is in this chapter that the broadest philosophical issues are raised before plunging into specific methodologies. Chapter 2 defines the structure of environmental risk analyses as these analyses typically are practiced. It considers the components of a risk analysis, and how these are linked to both guide the analysis and justify particular decisions.

This structure leads naturally to the discussion in Chapter 3 of the models and data used in assessing exposure to risk factors in the environment. An example is used to explore the methodologies needed to understand how much of a pollutant makes it through the environment to the point where it comes into contact with an organism. Chapter 4 continues this consideration of data and

models for understanding the relationship between exposure and the various measures of risk in a population.

Chapter 5 examines a series of issues and definitions that arise in regulatory science, or the application of science to regulatory decisions. This chapter bears most directly on the tasks that an analyst would face in performing a risk assessment for an organization such as the Environmental Protection Agency, where a specialized language has developed to ensure consistency in public decisions. Chapter 6 turns to the methods of uncertainty analysis and sensitivity analysis, and to the applications of these methods in reaching rational decisions. The example of society's attempt to balance the risk from microbes and disinfection by-products in drinking water is used to explore how uncertainty in risks from different sources can be compared.

All of the tools developed in the first six chapters are combined in Chapter 7 by considering principles of systems analysis and optimization. The goal is to understand how risk analysis can be used to assess and rank alternative environmental policies when there are multiple sources of risk, multiple effects produced by pollutants, and multiple pathways by which a population is exposed. The example of risks from solid and liquid waste is used, since this is one of the most complex analyses currently being performed in the field of regulatory risk assessment.

So many people have contributed to this book, either with their ideas or review, that I find it impossible to mention them all. Those that stand out through extensive collaboration over the years are Werner Hofmann of the University of Salzburg; Terry Pierson, Zach Pekar and Steve Beaulieu of Research Triangle Institute; Larry Reiter, Bob Hetes and Rick Cothem of the EPA; Hwong Wen Ma of National Taiwan University; Ken Brown of Chapel Hill; Sylvaine Cordier of INSERM in Paris; Jeffrey Arnold; and the students in one of my courses, Analytic Thought and Environmental Risk, who have studied this material without the benefit of a text and have guided my writing through their weekly discussions.

---

## **CHAPTER 1**

### **Risk, Rationality and Decisions**

---

#### **1.1. Analysis of Risk**

In August of 1997, the Environmental Protection Agency (EPA) formed an advisory committee to consider how the Agency should respond to the issue of endocrine disruptors in the environment. Such committees are formed under the Federal Advisory Committee Act (FACA), which specifies that government agencies will bring together relevant outside experts to advise them whenever decisions must be reached that involve significant technical issues. The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) was formed under FACA to advise the Agency on the design of a program to determine which substances in the environment pose a risk to health through endocrine disruption (i.e. disruption of the endocrine system controlling the many hormones produced by the body, and which in turn control processes of development, reproduction and metabolism).

The charge to EDSTAC was fairly narrow: find a system of measurements that would tell the Agency whether or not a substance was capable of disrupting the endocrine system in ways that were bad for health. Like all FACAs, this one consisted of members of the various stakeholder groups, or organizations that had something to gain or lose from the final decision by the Agency, in addition to a group of scientists who were chosen for their neutrality. In such a setting, it is to be expected that there will be disagreements over both the facts and the interpretation of those facts.

At an early stage in the discussions, the stakeholder groups representing citizens' concerns raised an issue which went far beyond the collection and interpretation of facts about the risks from potential endocrine disruptors. Their more fundamental concern was over the rational framework under which the discussions of EDSTAC should take place. The position of these groups was that any measurement system developed by EDSTAC, and any system in which these measurements would be interpreted by society, should not be tied intimately to risk assessment. Their concern was that risk assessment had become a tool of industrial groups to justify decisions in which cleanup of pollution, particularly

at Superfund sites, stopped once an acceptable risk level was reached. They argued that there was no “acceptable” level of risk, and that the rule should be to continue cleaning the environment until the pollution was gone, or risk a day in court. Presumably, the regulatory agencies such as the EPA were implicated by agreeing to the use of risk assessment as a framework for decisions in such cases. These citizen groups preferred that the EDSTAC methods be placed in some framework other than risk assessment, given what they saw as the historical trend in risk-based regulatory decisions that seemed to justify higher levels of pollution than they were willing to accept.

Their concern was at a level deeper than the facts and interpretations used in risk assessment. They were calling into question whether risk assessment itself was appropriate, whether it was a rational way to arrive at the goals of society in protecting health and the environment. Their concern leads to three issues that are central to this book. One might first ask how these groups were defining risk, and why this conception of risk gave them reason to distrust decisions rooted in risk assessment. Or one might ask what these groups thought of the process by which risk was analyzed and used in decisions, and why this process seemed to them to be so corrupted. Or, finally, one might ask how these groups felt about the picture of our culture that emerges when we choose to use risk assessment as a partial basis for our decisions; how we display who we are as a people in the use of such tools.

Without putting words in their mouths, it is safe to say that these groups either were concerned about incorrect conceptions of risk within the regulatory process, improper use of information about risk, or a distortion of our culture that arises when risk becomes the primary basis for decisions. They could not have been concerned primarily with the facts and interpretations that would be produced by the methods developed through EDSTAC, since their concerns arose before those facts and interpretations were even on the table. We turn in this section to the first issue, or the conception of risk, and explore the other two issues in later sections and chapters.

What we want to do here is to analyze risk. We want to determine, or perhaps assign, a meaning to the word “risk” so everyone will share this meaning and we can avoid confusion. We want to know when risk has been properly assessed and how this is related to decisions. Modern analytic philosophy is devoted to the idea that a concept can be understood by examining the more fundamental concepts that underlie it and which are combined in specific patterns that bring sense to the original word or concept. In discussing whether a chemical such as dioxin poses a risk to health through endocrine disruption, therefore, analytic philosophy begins with the questions: *What is Risk? How would we know a risk when we see it? How is the idea of risk built up from more fundamental concepts such as threat, possibility and severity?*

In answering these questions, we can begin with two broad philosophical traditions, exemplified by the early and later writings of Ludwig Wittgenstein. Wittgenstein spent much of his life trying to understand how science came to create such powerful concepts, concepts that seemed to work so well and to be agreed upon by essentially all scientists. In his *Tractatus Logicus-philosophicus* [1], published early in his career, he thought he had found the answer in the way in which science reduced the world to a few fundamental concepts and then combined those concepts logically to create the rich texture of modern scientific theory. These fundamental concepts were the bedrock of reality, and more complex ideas could be understood by analyzing how they were created from combinations of these fundamental truths. Molecules could be understood by referring to atoms and molecular forces, atoms could be understood by referring to neutrons and protons and electrons, and so forth. Science had found the building blocks of reality, had given each of these blocks a name, and proceeded to construct amazingly complex ideas from these blocks. The truth of the ideas was established by the fact that they were built on concepts that correspond perfectly to the way in which the world is put together.

Following in this tradition, one could argue that a concept like risk is to be understood by analyzing it into its more fundamental concepts, which in turn requires an understanding of how reality is constructed. The proper fundamental concepts are those that correspond perfectly to the parts of reality that are bundled together under the term “risk”. For this early Wittgenstein, the reductive process of science can analyze a phenomenon such as risk into the proper parts, and provide a meaning for risk that is a logical combination of those parts. Everyone who then understands the world truthfully, using only the fundamental concepts science has found and the rules of logic, will come to the same definition of “risk”.

The later Wittgenstein, writing in *Philosophical Investigations* [2] was less certain about this project. He began to question whether there were any fundamental concepts, any concepts that corresponded perfectly to the ways in which the world is put together. In examining words and the concepts to which they refer, he came to believe that they were in many ways dependent on their use. Rather than corresponding directly to features of the world, concepts instead helped us perform tasks. Rather than asking if these concepts are true in the way his early writings implied, he found it more interesting to ask whether they served a useful purpose. Two people might then disagree about a concept like “risk” because they were intending to use the word in different activities. From the later Wittgenstein we get the modern idea of words and concepts as having utility, rather than being truthful to the world. This is not to say that definitions of risk are purely subjective, since once you specify the use to which a word will be put there are rules about the definition which are appropriate for that use. Still, the idea of definitions of risk as being objective, as referring directly to parts of the

world rather to human experience and action, is weakened by these later views of Wittgenstein.

Risk analysis may be thought of as the process by which the basic building blocks of the concept of risk are determined and then built back into a more complex understanding of risk; in short, risk analysis includes analysis of the concept of risk and of the ways in which risk is determined. Risk assessment is the more technical field, striving to place numerical values onto the concepts revealed by risk analysis. Two definitions follow from this:

- *Risk analysis* is both a philosophical and scientific activity. On the philosophical side, it is the process by which we determine the fundamental characteristics of risk and the ways in which those characteristics are combined to produce the full meaning of the term “risk”. On the scientific side, it is an analysis of the physical conditions and processes that cause risk and of the ways in which we can measure, predict and quantify risk. It focuses on theoretical understanding of these conditions and processes, and understanding of the concepts, physical processes and methods used to characterize situations involving risk..
- *Risk assessment* is a purely technical activity. It is the application of methods that measure and/or predict risk to specific situations. The result is quantification of risk for particular substances (such as dioxin) in particular situations (such as exposure through the air). It focuses on practical problems that arise as society attempts to deal with specific threats.

Later chapters focus on the process of risk assessment. In this chapter, we will continue with the analysis of risk as a concept and as a tool for making decisions.

## 1.2. Conceptions of Risk

The word “risk” has at least three broad meanings that can be identified and which refer to different aspects of the world and of our experience [3]:

- the objective conception of risk
- the subjective conception of risk
- the psychologistic conception of risk

### 1.2.1. The Objective School

The first school, or *Objective School*, considers risk an objective property of the world, in the same way we might speak of weight as being a property of a car. To understand risk conceptually within this school, one must understand what exists objectively in the world and how these parts of existence come together to create a risk. These parts of the world are to be found in exactly the way science discovers all aspects of the world: through observation, experiment, measurement, statistical analysis, etc. In the objective school, any more fundamental concept from which the concept of risk is composed must refer to such measurable properties of the world. These are properties such as frequency, severity, variability, and so on, all of which will be discussed later. No concept which does not refer to the outside world, such as emotions or belief, can be allowed into this conception of risk. They cannot be allowed because these are properties of us and not of the world we are trying to understand in analyzing and assessing risk.

A person in the objective school might adopt the following definition:

*Risk is a combination of the frequency with which an adverse effect occurs in the world and the severity of that effect. Risk increases as the frequency, severity, or both, increase. Both the frequency and severity may also vary from person to person, and so risk includes a measure of this variability.*

The idea of frequency is introduced because a risk implies the effect does not occur at all times and in all people, but rather is only one of several possible outcomes. If an effect is certain (death and taxes) we don't say we *risk* it happening, we say it *will* happen. Risk also implies that the effect is adverse. Again, if an effect is desired (e.g. a longer life), we don't say we *risk* it happening, we say we *hope* it will happen. Assessing risk, then, requires assessing both the frequency of an effect and the severity, or degree of adversity, represented by that effect. Risk can be analyzed into these more fundamental concepts.

The objective school believes that *frequency* and *severity* are measurable, objective, properties of the world and, therefore, so is risk. In addition, this school allows for the concept of *variability*, since there is recognition that the frequency of an effect may be different in different populations and at different times, as may the severity. So this school allows discussion of the variability of risk. Properties that are not allowed into the objective definition of risk are *uncertainty* (we are uncertain, the world is not); *fear* (we may be frightened of the risk, but the risk itself has no aspect of fear); and so on. These words refer to us and not to the risk. The objective school would argue that such words are appropriate for analyzing us, or for analyzing our response to risk, but are not appropriate ways to analyze risk itself.

If risk is an objective property of the world, *where* does it exist? We know where a car exists (it is outside my window as I type). We know where the weight of the car exists (it is a property of the car itself). But where does the risk of an endocrine disrupting molecule exist? Is it in the molecule itself? This can't be true, since the molecule by itself shows no signs of the frequency, severity and variability discussed earlier. Is it in a population of people? Again, this can't be true since the population doesn't show the frequency, severity and variability of the effect without the presence of the molecule. So, risk must a property of the combination of the molecule and the population. It makes no sense to speak of the risk from an endocrine disruptor. It only makes sense to speak of the risk from a *situation* in which the molecule comes into contact with the population. This "risky situation" is made up of both the molecule and the population; risk is a property of the situation and not of either of the parts alone.

Populations consist of individuals. If the risk is in the population, is it also in each individual within that population? It would seem to make little sense to talk about risk as being in the population but not in each of the individuals. Imagine a situation in which people are exposed to an endocrine disrupting molecule. We take a measurement of the effects in the population and find that of the 1000 people exposed, 30 show an adverse effect. So the frequency appears to be 30/1000 or 0.03. Is this a property of the population or of the individuals in the population or both? One possibility is that the effect is completely random, like the rolling of dice. In that case, each person might be said to have a *probability* of the effect equal to 0.03. They are not certain to develop the effect, it is only more or less likely to develop. When the dice were rolled, 3% of the people developed the effect and 97% did not. But before the dice were rolled, each individual had the property of a 3% probability of developing the effect. This property manifested itself in the population as a frequency. We measure the frequency, but it is really the probability in each individual prior to the rolling of the dice that constitutes the risk.

This way of thinking about risk, of assigning it as a *propensity* to each individual rather than to the population, requires that we think of the effect as being purely random. If we ran the world again and again, different people in the population might develop the effect, but the frequency would stay at 3% (assuming the population is very large) because each individual in the population has this probability of developing the effect. It is perfectly conceivable that a given person would develop the effect in one rolling of the dice, but not develop it in another. In fact, that person would develop the effect in 3% of the rolls of the dice. Nothing has changed in these different rolls. In each, the person had a propensity or probability of 3%. In each, the risk was the same. All that changed is how this risk played itself out. Since this probability is a property of each individual, we will refer to it as an *ontological probability*.

An alternative way of thinking about the situation is that frequency is simply our way of saying we don't fully understand why some people develop the effect and others don't. Perhaps some people are more sensitive to the endocrine disruptor than others, and we don't know how to identify these people. If the population is exposed, perhaps 3% of the people are fated to develop the effect (their ontological probability of the effect is 100%) and 97% are fated to stay free of the effect (their ontological probability of the effect is 0%). If we ran the experiment again and again, we might find that it is always the same 3% of the population developing the effect. Since we are ignorant of which people are ill-fated and which are not, all we can say is that 3% will develop the effect. If we want to talk of this as a probability, and assign it to each individual in the population, we should refer to it as an *epistemological probability*, where epistemological means a probability that is assigned only because of imperfections in our state of knowledge.

In this case, the probability of 3% does not really apply to the individuals in the population. If we insist on applying epistemological probability to individuals, we must admit that we no longer are talking about an objective property of that individual, since the probability results from an analysis of our knowledge, not an analysis of the person. To be objective in this case, we would need to refer to the probability as a frequency, and to think of that frequency as being a property of the population of people rather than of any one individual. We summarize this by saying the risk to the population is characterized by a frequency of 3%, and that all we can say is 3% of the population will develop the effect. We cannot really say anything more about an individual's chance of developing the effect.

The difference between ontological probability and epistemological probability or frequency lies in whether the risk is a property of the individual (ontological probability) or the population (frequency). It also lies in whether you think the number of people developing the effect in a population could have been different if the "experiment" were to be run again. Under the concept of ontological probability, with the metaphor of rolling dice, a probability of 3% might produce 30 people out of 1000 showing the effect in one experiment, and then 26 people out of the same 1000 showing the effect in another experiment, and then 50 people out of the same 1000 showing the effect in a third. All of these results are consistent with a world in which the true probability is 3%. Turning the problem around, an observation of 50 people out of 1000 developing the effect does not mean the ontological probability of the effect was really 5%. The risk is measured indirectly and imperfectly, since the outcome is different in each rolling of the dice even though the underlying ontological probability in each person has not changed. If frequency is a property of the population, however, with some people fated to develop the effect and others fated to remain free of the effect, the

measured frequency is exactly the same as the fraction of people fated to develop the effect, and this fraction does not change from experiment to experiment (unless different groups of people are used in the different experiments). The risk is measured directly and perfectly in this case so long as the fraction of people with the properties that make them ill-fated remains constant.

This leaves only the question of how the components of risk (frequency, severity and variability) are combined logically to assess risk in the objective view. One possibility is to simply leave them as separate components and say that risk is some combination of these to be left to the discretion of the assessor. The argument is that the components of risk are *incommensurable*, unable to be combined into a single measure of risk. This seems to be too subjective to fall within the objective school, but if these components really are distinct and cannot be combined, then perhaps the objective components must be combined subjectively.

Another possibility is some sort of calculus for combining the components, some formula for computing risk. In this approach, variability first is dealt with by calculating the average, or mean, or expectation value of the frequency (all of these terms are discussed in later chapters). For example, if there are 100 people divided into two populations, 30 of whom have a frequency of 3% and 70 of whom have a frequency of 9%, the expectation value for this combined population of 100 people is  $(0.3 \times 0.03) + (0.7 \times 0.09) = 0.072$  or 7.2%. We might then assign some measure of the severity of the effect. A very adverse effect would be assigned a high measure of severity (e.g. 1.0) and a less adverse effect would be assigned a lower measure of severity (e.g. a 0.2). The risk would then be the product of the frequency and the severity:

$$(1) \quad \text{Risk} = \text{Frequency} \times \text{Severity}$$

If the frequency were the same in two populations, but the effect differed in the way mentioned above (i.e. a severity of 1.0 in the first population and 0.2 in the second), the risk in the first population would be  $0.072 \times 1 = 0.072$ , and the risk in the second population would be  $0.072 \times 0.2 = 0.0144$ . Even though the frequency of the effect is the same in the two groups, the risk is higher in the first since the severity of the effect is worse.

The calculation of risk above focuses on the risk to individuals in the population. Such a measure of risk is referred to as *individual risk* (remembering that it strictly applies to an individual only in the case of ontological probability). The goal of a regulatory decision might be to keep the individual risk below 1 in a million ( $10^{-6}$ ). Another goal might be to keep the total number of people developing the effect below 100. To calculate the total number of effects, the frequency must be multiplied by the number of people in the population:

$$(2) \quad \text{Total Effects} = \text{Frequency} \times \text{Population Size}$$

We could even weight this number by the severity to obtain a measure of the overall risk in the population. When the total number of effects (or some version of this number weighted by severity) is produced, we speak of *population risk*.

### 1.2.2. The Subjective School

The *Subjective School* rejects the claim that risk is an objective property of the world. The school agrees that there is such a thing as the frequency, severity and variability of the effect. Their argument, however, is that there is no necessary reason why these properties should be conflated with the idea of risk. To the subjective school, risk is a state of mind, a sense one develops in the face of uncertainty, of adversity, of the possibility that the world will produce undesired effects. Analyzing risk requires analyzing us. Risk exists inside us and not in the outside world. It is our response to that world. It should be informed by estimates of frequency, severity and variability, but it is not possible to measure the risk outside of the human mind. The subjective school might adopt the definition:

*Risk is a condition of the mind characterized by uncertainty about the future, a sense that this future might hold undesired outcomes, a sense that these outcomes cannot be fully controlled, etc. As this condition of the mind becomes more severe, the risk is increased.*

The measurement tools of the subjective school are those of psychometrics. Analysis of risk requires analyzing the components of subjective experience that cause us to feel dread, uncertainty, etc. Some of the more important subjective characteristics of a risky situation are shown in Table 1.1.

The objective school finds most of these characteristics to be irrelevant to the analysis of risk. Take, for example, the degree of dread or anxiety felt by a person when thinking of endocrine disruption. To the subjective school, this dread is a characteristic of the risk; as the dread increases so does the risk. To the objective school, this dread is not a property of the risk, it is a property of the human mind *responding to* the risk. They want to keep distinct the analysis of risk and the analysis of human response to risk. The subjective school finds this distinction useless and wrong. Their argument is that if they had wanted a description of the frequency and severity, they would have asked for the frequency and severity. Risk to them is a much richer concept; it is a word that came first from analyzing human responses to the world and should remain rooted in those

responses. They will agree that this response should be related in some way to the frequency and severity, but that it will be tempered by all of the factors shown in Table 1.1. The objective school agrees that it will be tempered in this way, but thinks of this tempering as being irrational as distorting understanding of the “true” risk. The subjective school finds this talk of distortion misleading. They argue that this state of mind doesn’t *distort* the understanding of risk, it is the *source* of risk. The debate on the endocrine disruption FACA over the use of risk as an organizing principle stemmed in part from the feeling amongst some members that the technical, objective, definition of risk that dominates regulatory discussions fails to capture some of the most important features of risk as the word is used in public discussions.

**Table 1.1.** Characteristics of a situation that cause it to be perceived subjectively as risky.

Characteristic	Condition Associated with Feeling of High Risk
Severity	adverse effect
Probability	high probability
Catastrophic	effect clustered in space/time
Reversibility	irreversible effect
Age	effect appears in children
Victim Identify	able to specify sufferer
Familiarity	effect unfamiliar
Understanding	large uncertainty
Dread	situation evokes fear
Voluntariness	involuntary exposure
Controllability	no known control measure
Equity	uneven distribution of effect
Trust	lack of trust in source
Personal Stake	effects highly personal
Attribution	can’t attribute blame
Attention	high media attention

**1.2.3. The Psychologicistic School**

The objective and subjective schools seem to be at an impasse. They not only disagree about the definition of risk, they disagree about where risk is located