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Analysis and Application of Risk Assessment And
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THE BENEFITS OF FOOD SAFETY REGULATION: ANALYSIS AND APPLICATION OF RISK ASSESSMENT AND BENEFIT VALUATION TO PCBs.

By

Marion Secrest Gold

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ABSTRACT

THE BENEFITS OF FOOD SAFETY REGULATION:
ANALYSIS AND APPLICATION OF RISK ASSESSMENT AND BENEFIT VALUATION TO PCBs.

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This thesis examines the question of whether it is useful to measure the benefits of food contamination regulations in monetary terms. To answer the question, a conceptual framework is developed to identify the range of benefits that might result from food safety regulations. The study then narrows its focus to the problem of valuing in dollar terms the reduction of cancer risks from polychlorinated biphenyl (PCB) contamination of fish.

The research first compiles low, medium and high estimates of the risk from PCBs. Then three estimates of the value of risk reduction, developed using variations of willingness to pay methodology, are applied to the PCB data resulting in a set of estimates of the dollar value of PCB regulations based on different risk assumptions and benefit estimates. The research concludes that benefit quantification can be a valuable adjunct to, but not a replacement for, other approaches of regulatory evaluation.

To Arthur

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To Eileen Van Ravenswaay, for her unfailing support and guidance throughout the research, I offer many heartfelt thanks. I also gratefully acknowledge Larry Libby for his long term supervision, John Godderis for his assistance with economic theory and Michael Kamrin for help with the toxicological issues. Thanks also to all my family, including Burt and Amanda, and to Larry, Ann and Leny for their encouragement and support. Finally, special thanks for everything, to Arthur.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

Table

1 INTRODUCTION

This thesis examines methods of valuing the economic benefits of regulating chemical contamination of food. The central question posed in the research is whether it is useful to attempt to measure the benefits of such regulations in monetary terms. To answer the question, the theoretical and empirical issues surrounding the process of benefit valuation are explored. Then, the benefits of regulating one chemical contaminant in food, polychlorinated biphenyls (PCBs) in fish, are quantified to provide a basis for critique and evaluation of the benefit valuation process.

1.1 The Research Problem and Research Objectives

The problem of unintentional chemical contamination of food has become increasingly widespread in the United States. Mercury in seafood, polybrominated biphenyls in meat and milk, and lead in canned food products are well-known examples of contamination incidents. The increased use of chemicals in modern society is one obvious reason for the growth of the problem - over 70,000 chemicals are in commercial production in the U.S. today. (1) Additionally, awareness of the problem has grown because of the availability of analytical methods that can detect minute amounts of contamination in food. The new

methods reveal that contamination of food is more widespread than previously realized.

Unfortunately the ability to measure the health, environmental, and economic impact of contaminants in food has grown much more slowly. Yet, all of these impacts must be well documented if the problem is to be effectively managed. Of particular interest in this thesis is whether the economic benefits of regulations designed to control the food contamination problem can be estimated with enough accuracy and reliability to be useful in the regulatory decision-making process.

Methods of economic analysis and examples of empirical studies of food safety regulations are limited however, especially with respect to analysis of regulatory benefits. The reasons for this are threefold: 1) legal constraints on the use of economic analysis to make food safety decisions; 2) conceptual controversies surrounding the economic theory of benefit valuation; 3) empirical difficulties in valuing benefits. To provide a better understanding of the research problems associated with economic analysis of food safety regulation, each of these problems are briefly addressed below.

Legal constraints are the first reason that few economic studies of food safety regulation have been

conducted (2). The mix of administrative, judicial and legislative rules that govern food safety policy calls for little formal economic input. Food safety decisions tend to be made on the basis of other criteria that have evolved over the course of almost 80 years and generally leave little room for consideration of economic ramifications (3). Some more recent regulations including regulation of contaminants in food, do include consideration of the costs of regulation versus the benefits of reduced risk in nonmonetary terms. However, because such regulations are so recent, and because most food safety decisions do not call for economic input, few economic studies have been conducted to date. Some examples of economic studies that have been carried out include an analysis of sulfa regulations and the swine subsector by Kramer (4), and an analysis of the impact of deboning regulations in red meat by Bullock and Ward (5).

The second reason for the lack of economic analysis is the conceptual difficulty associated with developing economic theory to value the type of benefits that stem from food safety regulations. The primary benefit is reduction of the risk of adverse impacts to human health -- an impact that is difficult to measure and value for a variety of reasons. There is a controversy over whether it is ethical to measure benefits of regulations affecting

human life in dollar terms (6, 7, 8). The basis of the argument against such measurement is that no amount of money is adequate to compensate for the loss of a human life -- a life is a resource of infinite value. The counter argument is that while it is indeed impossible to place a value on human life, it is often necessary to make choices among government policies or programs which aim to save lives, or more accurately to reduce the statistical risk of injury, disease or death within a given population (9). In order to allocate regulatory resources most efficiently and equitably some measure of the magnitude of risk reduction achieved by alternative programs is necessary. Since the costs of the programs are expressed relatively easily and accurately in dollar terms, it would be best if benefits could also be expressed in dollars. Experience has shown that when costs are precisely quantified, while benefits are only expressed qualitatively, the costs receive more attention and weight (10). Thus, while it may be impossible to measure the "value of life", it may be worthwhile to attempt to more precisely quantify the extent to which regulations reduce risk, and if possible, express the value in dollar terms. The methods to do the quantification are limited, however, in part because of the reluctance of many analysts to become involved in the controversial subject.

Underlying the perspective that reduction in risk cannot be expressed in dollar terms is the belief that such efforts would underestimate the value of "lifesaving" regulations and would be used to support decisions biased against environmental health and safety regulations in general. In fact, there are many examples of overly simplistic applications of benefit measurement which have underestimated the value of risk reducing regulations (11). However, recent evidence indicates such bias is not the norm. Rather, benefit quantification studies tend to uphold the validity of lifesaving regulations. In a recent review of 35 studies involving cost-benefit comparisons of 57 sets of policy options, the benefits of lifesaving programs were found to exceed costs in over 3/4 of the cases (12). In other words, in the majority of benefit quantification studies, quantification of benefits supported the regulatory effort. Thus, even if the value of the benefits of reducing risk to life were underestimated, the benefit values were still found to be greater than the costs of the regulation.

The third reason for the lack of economic analysis of food safety regulatory benefits is that such studies are difficult to conduct from an empirical standpoint. One difficulty is that the level of risk associated with exposure to even the most thoroughly studied environmental

contaminants is highly uncertain. In many cases one set of scientific data will indicate that a substance is hazardous while another indicates absence of hazard (13). Economic methods are unable to meaningfully incorporate this uncertainty in the economic analysis.

Another empirical problem is that the benefits of food safety regulation tend to involve small, long-term reductions in risk spread out over a large population. The cummulative risk reduction is significant, but the statistical reduction in risk per individual is small. Measurement and valuation of the benefits of reducing such risks is difficult. A related problem is that there are many different types of risks -- voluntary vs. involuntary; reversible vs. irreversible (14). Distinctions between such risks are usually not considered in quantitative analysis of risk reduction (15).

Despite problems associated with analyzing the benefits of food safety regulations, and the lack of methodology to conduct such analysis, the need for economic information is apparent. As the problem of environmental contamination grows, the need to carefully allocate limited resources to control the contaminants increases. Systematic economic analysis including benefit quantification can facilitate the control effort.

This research will attempt to improve understanding of both the methods and limitations of quantifying the benefits of food safety regulations, specifically regulations involving environmental contaminants. The specific objectives of the research are listed below:

1. To develop a conceptual framework to use in identifying the benefits of food safety regulations.
2. To use the framework to delineate and describe the benefits of PCB regulations.
3. To examine and critique current methods of risk assessment and the theory and application of benefit valuation.
4. To estimate the value of the benefit of reduced risk to human health from regulation of PCBs in fish using a range of estimates of the risk posed by PCBs and a range of empirical estimates of the value of reductions in risk to health.
5. To conclude whether benefit estimation can contribute meaningful information to the regulatory decisionmaking process.

1.2 The Research Approach

Several approaches could be taken to explore the problem of food safety benefit estimation. One approach would be to select or develop a theoretical model to value

regulatory benefits and then gather the data necessary to generate original estimates of the value of PCB regulation. This method requires time and financial resources beyond the scope of this study. Moreover, as demonstrated here, limitations in the available methods of benefit quantification preclude selection of one method as the most theoretically valid and empirically feasible.

The approach taken instead involves the application of existing empirical estimates of the value of reductions in risk to the analysis of PCB regulations for fish. Three estimates of the value of risk reduction are used and a range of values is obtained for each estimate based on different risk assumptions. As an alternative approach to placing a dollar value on human life, the cost per cancer prevented, is also calculated. Sensitivity of estimates to changes in assumptions and methods are examined in order to understand variation in estimates obtained.

The regulation of PCBs was selected as a case study because of the relatively large amount of risk data available on the chemical. Since the major exposure of people to PCBs through food is in the consumption of fish, the benefit assessment is confined to four alternative regulatory standards, called tolerances, for PCBs in fish

(i.e., No tolerance, 1 ppm., 2 ppm., and 5 ppm.).* Since the major health risk associated with exposure to PCBs is cancer, the benefit assessment concentrates on the cost savings of reduced cancer risk associated with each of the four regulatory standards.

The research will not result in a definitive dollar figure for the value of PCB regulations. Rather, the research will show the range of benefit estimates which may be obtained through application of state-of-the art economic research and best available scientific information. It must be stressed at the outset that serious informational and conceptual limitations exist in both the scientific and economic aspects of benefit estimation which the study will attempt to clarify. A list of some of the most serious constraints considered in the thesis illustrates the problem:

1) Limitations in scientists' ability to accurately assess the health hazards of prolonged exposure to multiple, low-level toxins in food.

2) Difficulties in determining exposure in terms of which foods are likely to contain a toxin and what combinations and quantities of food are consumed.

*The tolerance standard now in place for PCBs in fish is 2 ppm.

3) Problems in determining the economic value of safety created by the public goods qualities associated with food safety.

4) Specification problems of economic estimation methods including choice of economic variables, discount rate and time horizon, and method of addressing income distribution questions.

1.3 Organization of Thesis

The thesis will first review in Chapter 2 the theoretical rationale for regulation of food safety problems in general and describe three broad categories of regulation. Although this thesis examines only one of these categories, examining the broader range of food safety regulations indicates how the subject of study differs from closely related areas. Chapter 2 will also focus on identification of the range of benefits which may result from the three categories of food safety regulations. A general framework will be developed to assist in the conceptualization of the benefits of regulating PCBs in food and the environment. Again, a wider range of benefits are identified than those concerned with the regulation of PCBs in food. This broader focus on benefits indicates how benefit assessment of food safety

differs from other types of regulations which seek to control environmental contaminants.

Existing methods for valuing reductions in risk are examined in Chapter 3. Four methods are presented. Estimates for the value of risk reductions that have been obtained in studies using these methods are summarized and critiqued.

Chapter 4 examines the process of risk assessment and benefit valuation. The issues and controversies surrounding the risk assessment process are first explored based on a review of the literature. These issues are addressed because assessments of the economic benefits of regulation first require quantitative risk assessments by scientists. Benefit analysts must be aware of the scientific uncertainties concerning this basic data source. Following this discussion the risk estimates used in this study for the four tolerance standards for PCBs in fish are presented.

In Chapter 5 the four existing methods for valuing reductions in risk are applied. These methods are used to develop empirical estimates of benefits of the four regulatory standards for PCBs in fish. Sensitivity of estimates to method and assumptions is examined. Benefit estimates are compared to existing cost estimates of PCB tolerances to examine the policy implications of the benefit estimates.

Chapter 6 summarizes results and presents the conclusions of the study.

2 BENEFITS OF FOOD SAFETY REGULATIONS AND THE CASE OF PCBS

2.1 Rationale for Food Safety Regulations

Food safety can be conceptualized as a continuum of risk involved in the consumption of food items (16). Absolute safety, meaning zero risk or hazard, represents one extreme of the safety spectrum. Few food items are completely risk free. More often, a tradeoff is involved between use of a food, or food constituent, which poses some risk, and avoiding use of the substance to achieve absolute safety. Often, individuals consider a small risk acceptable when compared to the cost of forgoing the benefits afforded by the food item.

If the marketplace functioned efficiently in terms of providing information about food safety, then theoretically, each individual could balance the benefits and the risks of a food and make their purchases accordingly. However, there are significant information costs associated with determining the safety of food. Most food safety problems are imperceptible visually or through taste or smell. A consumer cannot rely on experience with a food to determine if it is safe. Most hazards involve infinitesimal levels of chemical additives or contaminants the impact of which will not be manifest for

years at which point it is too late to decide whether the costs of the food outweigh the benefits. It is obviously impractical for a consumer to analyze each food item before purchase to determine degree of risk. As a result, in an unregulated marketplace, most food safety problems escape detection by consumers. Consumers may purchase less safety and more risk than they might given full safety information. Or, they may underconsume the good, thinking it is unsafe when in fact it is safe. Both cases result in a loss to consumers. High information costs are one significant justification for government regulation of food safety.

The high information costs also influence the actions of food producers and processors with respect to food safety. As noted by Kramer (4), in the absence of regulation, some producers may, in self interest, withhold safety information from consumers in order to maximize sales of their product. These producers have a cost advantage over producers who do provide accurate safety information. Moreover, if this lower product safety is discovered by consumers, all producers bear the costs of reduced sales since consumers cannot detect differences in product safety. Producers may therefore support imposition of food safety regulations. The unregulated marketplace

offers perverse incentives to the open exchange of food safety information.

Even if all existing information was available to consumers, two other arguments could be made in favor of food safety regulations. The first argument is based on the total cost to society stemming from risks taken by individuals. Many food safety problems involve situations with potentially adverse consequences for which the underlying probability is highly uncertain. These types of problems termed "environmental risks" by Talbot Page (17), involve collective risks to society which cannot be adequately evaluated on the individual level. For example, consider a situation where an individual is faced with the decision of whether or not to consume a substance which will increase the chance of getting cancer from 1 in 100,000 to 1 in 10,000. The change in risk may appear small to the individual, but it is significant when summed over many individuals. From society's viewpoint, the cost is great in terms of lost productive labor, higher health costs, and higher insurance payments. In some cases, society may decide that the social costs are significant enough to override individuals' freedom to choose to take the risk. At what level, and in what manner, this intervention should occur is a policy question involving property rights allocation.

An additional argument for food safety regulation is based on the highly uncertain nature of the risk posed by food safety problems and how individuals evaluate risk. Research on risk has shown that for a variety of reasons, individuals tend to underestimate the probability of hazardous events happening to them (18). The underestimation leads to riskier behavior than if the probabilty of the adverse consequence had been correctly estimated. Individuals may want collective rules to thwart underinvestment in health and to promote more health protecting investment. Another related point is that many risks involve a latency period between exposure to a hazard and manifestation of the effect. The latency period masks the costs of a particular risky action while the benefits of taking the risk are immediately available. In these types of situations society may wish to arbitrate either to protect the interests of future generations or to protect individuals from hidden future costs. Such regulations would also make individual lawsuits to collect damages less likely.

2.2 Food Safety Regulations

In the U.S., decisions on when and how to intervene in food safety issues are based on a regulatory system that has evolved over the last 80 years. Regulatory

alternatives can be grouped into three broad categories: product performance standards; process performance standards; and provision of information.[1] Each of these categories are discussed below and illustrated with examples of how the regulations impact consumers, producers and government.

2.2.1 Product Performance Standards

Product performance standards regulate the attributes of the final output of a production or manufacturing process and are often used to regulate the quality and safety of food products. Product performance standards can be implemented separately or together with other types of standards. Examples of product performance standards include the various regulations governing meats and poultry. Before meat products can be marketed they must meet certain safety and quality specifications such as described in the Wholesome Meat Act and other regulations. Product performance standards, in fact, exist for almost all categories of food products marketed in the U. S. Product performance standards are based on a governmental decision as to what constitutes an acceptable level of safety in food. Consumer choice is to some extent limited,

[1] Based on taxonomy developed Kramer in An Economic Analysis of Food Safety Regulation. The Case of Sulfa and the Swine Subsector, Unpublished Ph.d. Dissertation, M.S.U., 1982.

as all food marketed theoretically meets the same safety criteria. The level of safety may be greater or less than some consumers would prefer. However, as discussed earlier, in the absence of such regulations, food safety information is typically not available to consumers at all; product performance standards attempt to protect consumers from these hidden food safety problems.

Product performance standards limit producers' autonomy of action. The cost of food production may increase in order to meet higher levels of safety and/or to cover costs of food inspection. Significant government expenditures, paid by taxpayers, may also be required to enforce product performance standards. Costs of the standards may also be reflected in higher product prices.

2.2.2 Process Standards

Process standards place constraints on the processes and materials which can be used in food production and manufacturing. Requirement of specified manufacturing practices or of certain technologies are both types of process standards. Examples in food safety include regulations governing the meat packing process (meat packing plants must follow guidelines developed by the Packers and Stockyard Administration) and the "Current Good Manufacturing Practices" with which commercial feed firms

must comply under a Food and Drug Administration (FDA) regulation.

Process standards have many of the same implications with respect to impacts on consumers and producers, as do product performance standards. The autonomy of the food producers is again reduced, but more directly in this case as specific manufacturing processes are often required. The acceptable, or desirable, level of safety is again set by the government, in order to protect consumers from hidden safety costs, and consumer choice is thus curtailed. Costs to the government may be less with process standards, in that enforcement entails checking the overall process rather than inspecting each item produced. Costs to taxpayers may thus also be less. It is uncertain how much of the increased costs to producers would be reflected in higher food prices.

2.3 Provision of Information

The rationale behind the third regulatory category, provision of information, is to facilitate market functioning by providing consumers with more information about the relative safety of food products. Labeling requirements, such as the warning of carcinogeneity in animal tests on saccharin packages, are one example of information regulations in the food system. Warnings in

brochures and in the media against heavy consumption of certain types of Great Lakes fish are another example.

With information regulations, no particular level of safety in food is set by the government. Rather, the government provides, or requires industry to provide, information on the safety or risk of a food product. Consumers can then choose among levels of safety according to their own risk preferences. Assuming that sufficient and accurate information is provided, consumers' freedom of choice is maximized. Consumers also freely bear the cost of their own risk taking behavior in terms of adverse health or other impacts. Nonconsumers also bear the costs of risk taking behavior in terms of the social impacts of death, disease, or environmental degradation. The incidence of costs and benefits associated with this type of regulation will vary according to the characteristics and magnitude of the risk involved.

In this study, a performance standard known as a tolerance, is examined. Performance standards are the primary type of regulations governing environmental contaminants in food. Generally speaking, enviromental contaminants in food cannot be limited by process standards such as good manufacturing processes. By definition, environmental contaminants are unavoidable. Information provision, such as labeling, is also limited in the case of

environmental contaminants. For example, each fish cannot be screened and labeled as to its PCB content. General information, such as warnings to sport fishermen and suggested cooking techniques, however, can be made publicly available.

The use of a performance standard as a case study on the benefits of food safety regulations makes obtaining the risk estimates needed in order to value benefits somewhat easier. If all fish must contain no more than a specified tolerance level of PCBs such as 2 ppm, then the upper limit of risks of PCB exposure varies directly with the amount of fish consumed. In constrast, it would be more difficult to predict the risk levels produced by a process standard or a labeling requirement. A benefit estimation approach other than that taken in this study would have to be used for the other two categories of food safety regulation.

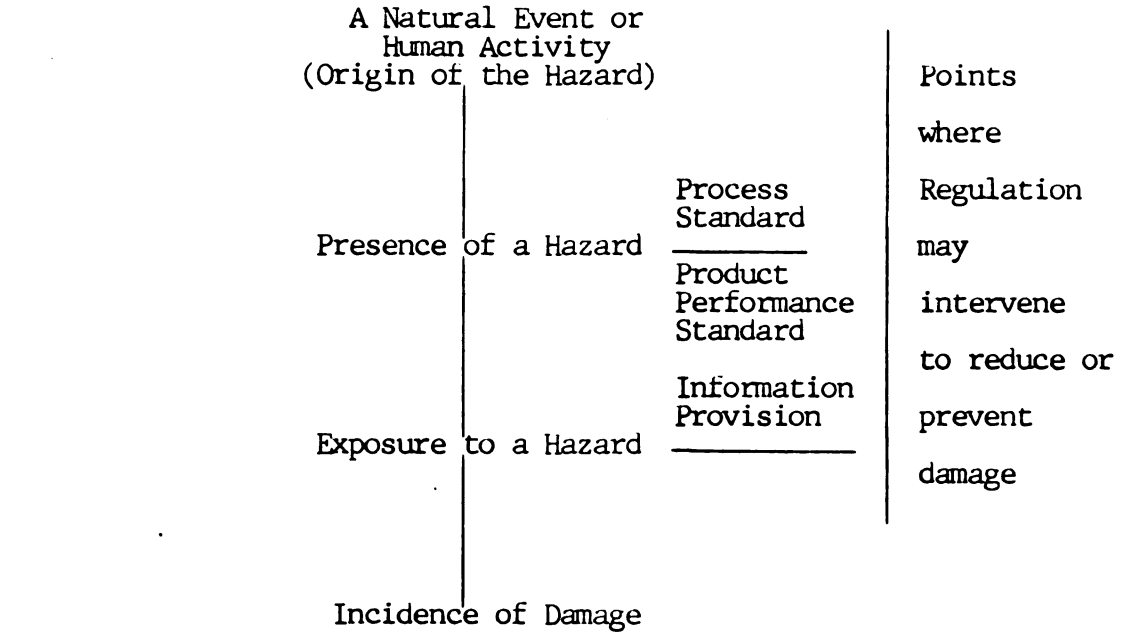
2.4 Framework for Benefit Identification

Given this overview of justifications for and alternative types of food safety regulations, a generalized framework for conceptualizing the benefits of regulation can be developed. The purpose of the framework is to facilitate consideration of the full range of potential positive consequences of food safety regulations.

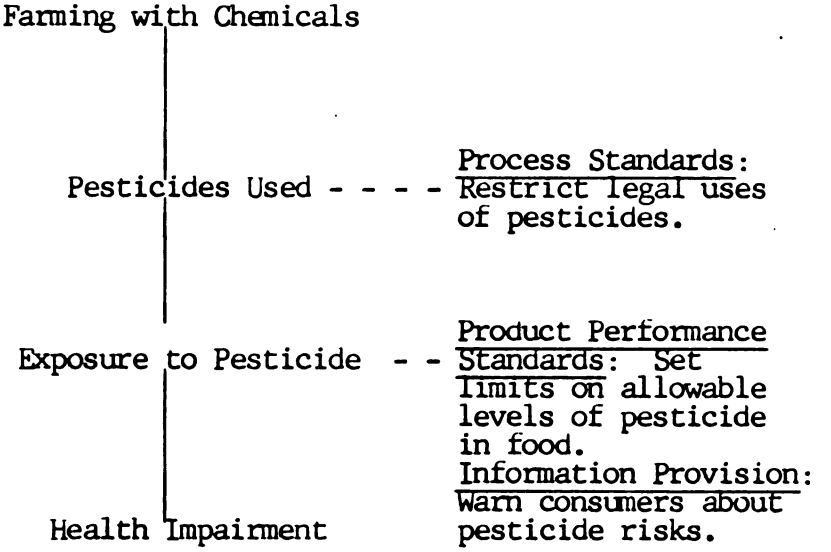
A simple model showing the linkage between the origin of a hazard and the incidence of damage is used as the starting point of the benefit indentification process. A hazard is defined here as a component of the food system that poses a threat to human health and/or the environment. A benefit is then defined as the impact of a regulation that reduces or prevents the damage caused by a hazard.

Figure 2.1 illustrates the linkage between the origin of a hazard (i.e., some natural event or human activity) and the incidence of damage. As shown in Figure 2.1, natural events, such as the development of aflatoxin molds, or human activities, such as industrial production, manufacture of food using chemicals or farming with pesticides, are the origins of hazards in the environment. People or the environment may then be exposed in a variety of ways to the hazard. Exposure, in turn, leads to some amount of damage, such as disease, injury, or reduced environmental quality. Regulations may intervene at various stages of the linkage system to reduce the presence of, or exposure to, hazards and thus reduce the incidence of damage. Beneficial changes may occur at one or more levels of the system depending on the design and enforcement of the regulation.

The types of regulations described earlier vary in the way they reduce exposure to a hazard. Product performance



Example



Note: Figure adapted from The Benefits of Environmental, Health, and Safety Regulations (MIT, 1977) (19).

Figure 2.1. Model of How Human Activities Introduce Hazards to the Environment.

standards reduce exposure by placing legal limits on the level of exposure to a hazard from units of a single source. Thus, exposure varies depending on the number of units consumed. Similarly, provision of information regulations aim to reduce exposure to hazards by providing people with information on the presence of the hazard, assuming they will choose to avoid it. Process standards intervene earlier in the linkage system. For example, process standards may reduce the presence of hazards by stipulating manufacturing practices which eliminate the possibility of the hazard entering the food supply. A process standard may also forbid the use of a particular substance in the production of a food item, again eliminating the entry of a hazard into the food supply.

2.5 Categories of Benefits

Given this simple conceptualization of how human activities introduce hazard to the environment the next step is to identify more specifically the nature of the benefits of regulating the hazard. There are few studies which undertake either a classification or a comprehensive listing of the benefits of health, safety and environmental regulations. Even fewer studies refer to food safety specifically. Many discussions quickly define regulatory benefits as "reduced risk to human life" and then proceed

directly to questions of measurement and valuation of the reduced risk (7, 20, 21, 22). While "reduced risk to human life" is undoubtedly the major direct benefit of regulation, additional benefits do exist and should be identified.

For the purposes of this paper, benefits were divided into the following five categories:

1. Reduced risk to human health.
2. Lowered costs of information to consumers.
3. Protection of the environment.
4. The development and adoption of new, more productive, industrial processes and more effective products.
5. Improvements in society such as the formation of new institutions in industry, government, and labor unions and more equitable distribution of income.

In order to illustrate more clearly how these categories are useful in the identification of food safety regulatory benefits, the PCB case study is now presented. PCBs are regulated in many ways besides setting performance standards for food items. Following a brief overview of the hazards posed by PCB, and the various ways it is regulated, the benefits of a variety of PCB regulations are delineated using the framework presented above.

2.6 PCBs

PCBs are a class of toxic, highly stable industrial chemicals that have been manufactured and sold in the U.S. since 1929. The properties of chemical stability and insolubility made PCBs a valuable and widely used industrial chemical. From the 1930s through the 1970s PCBs were a common component of manufacturing equipment, paint and other protective coatings for wood, metal and concrete, adhesives, and carbonless reproducing paper. During the period from 1930 to 1975, U.S. commercial sales of PCBs totaled nearly 570,000,000 kg from domestic sources and about 14,000,000 kg from imports (22). No special steps were taken to control or monitor use, handling, or disposal of PCBs.

In the mid 1960s, scientists discovered accumulation of PCB compounds in tissues of fish taken from the Baltic Sea. This discovery prompted monitoring efforts in the U.S. and by 1972, significant levels of PCBs had been discovered in many foods including milk, poultry, dairy products, eggs, animal feed and freshwater fish. Sources of the PCBs included industrial leaks and accidents, contamination from agricultural uses of PCBs (such as farm equipment and PCB-containing coatings in silos, etc.) and contamination from food-packaging materials which contained PCBs. The most significantly contaminated food was

freshwater fish which accumulated PCBs released into the water via land runoff and industrial effluent in their tissues.

Initially, the presence of PCBs in food and the environment received attention because it appeared to be such a ubiquitious problem and because the compound was extremely persistent. It was not until the late 1960s that information became available showing conclusively that PCBs were harmful to human health. One incident in particular provided powerful evidence that PCBs could be highly toxic. In 1968, in Yusho, Japan, PCBs from heat transfer fluid leaked into rice oil during the manufacturing process. Over 1,000 persons consumed the contaminated oil. Mild to severe symptoms of poisoning appeared. Skin diseases, blindness, gastrointestinal illness, reproductive disorders, and possibly cancer were associated with the accident (23).

Following the Yusho incident, the distribution of PCBs in the environment and the risks to health associated with them came under extensive study. By the early 1970s, the need for PCB control became clear.

2.7 PCB Regulation

After information became available in the early 1970s suggesting that long-term exposure to PCBs could be hazardous, the sole producer of the substance in the U.S.,

Monsanto Company, voluntarily banned sales of PCBs for "open-ended" and "closed" applications. The relative use of PCBs in these categories versus other uses is shown in Table 2.1. At the same time, stringent controls were placed on ongoing industrial uses of PCBs, and the loss rate from industrial sources was eventually greatly reduced (22). In 1977, Monsanto Company voluntarily discontinued production of PCBs, two years before production would have been banned under the Toxic Substance Control Act. PCBs in food were first regulated in 1973 when tolerance levels were established for fish, eggs, dairy products, meat and poultry.

Large amounts of PCBs still remain in the environment, in materials containing PCBs still in service (e.g., transformers), in landfills and dumps, in water, and the bottom sediments of water bodies, in the soil and in the air. Table 2.2 shows the distribution of PCBs in-service as of 1975. It is expected that on land disposal of obsolete electrical equipment will constitute the primary source of PCB entry to the environment in the future.

Regulatory efforts to control PCBs remaining in the environment are of three types:

1. Regulations aimed at reducing the flow of additional PCBs into the environment;

Table 2.1 Domestic Uses of PCBs

Category	Type of Product	Percent of New Total Use
Closed Electrical Systems	Transformer, capacitors, other (minor) electrical insulating/cooling applications	61 until 1971; 100 after 1971
Nominally Closed Systems	Hydraulic fluids, heat transfer fluids, lubricants	13 until 1971; 0 after 1971
Open-End Applications	Plasticizers, surface coatings, ink and dye carriers, adhesives, pesticide extenders, carbonless copy paper, dyes	26 until 1971; 0 after 1971

Note: NAS. Polychlorinated Biphenyls, 1979. (22)

Table 2.2 Environmental Distribution of PCBs Not in Service as of 1975

	Amount ($\times 10^6$ kg)
Mobile PCBs in the Environment	68.2
Degraded or Incinerated	25
Landfills or Equipment Dumps	130

Note: NAS. Polychlorinated Biphenyls, 1979. (22)

2. Efforts to reduce stocks of PCBs in the environment;
3. Regulations aimed at control of exposure of populations to PCB.

These three types of PCB regulations can be related to the general categories of food safety regulation and model of hazard introduction presented earlier. The first of these types of regulations reduces the flow of PCBs into the environment and thus, affects the presence of the PCB hazard. Regulations of this type are essentially process standards and include such measures as eliminating industrial discharges of PCBs by requiring certain waste control processes and controlling the manner in which PCB-containing materials still being used are disposed. The second type of regulations aim to reduce stocks of PCBs. Such regulations limit presence of a substance and are, also process standards. However, in this case, the standard may be placed on governmental, rather than private, organisations, and funded publicly. Examples of these activities include measures such as dredging river and lake sediments contaminated with PCBs or cleaning contaminated land fills.

The third type of regulatory effort attempts to reduce exposure to the PCB hazard. Setting limits on the allowable or tolerated levels of PCBs in foods (product

performance standards) is one example of this category of regulation. Warnings against consumption of certain foods contaminated with PCBs (information provision regulations) are a second example. Figure 2.3 illustrates how these types of regulations can minimize the hazard posed by PCBs.

2.8 Benefits of PCB Regulations

Given this broad overview of the types of regulations used to control PCB, it is possible to identify the range of benefits which could stem from the regulations. Using the categories of benefits presented earlier as a framework, the beneficial effects of PCB control are outlined below. The discussion is general at this point; the benefits of a specific PCB regulation must be more precisely identified based on the specific objectives of each regulation.

2.8.1 Reduced Risks to Human Health

A major objective of all PCB regulations is to reduce the risks to human health posed by exposure to PCBs. The reduction in the costs associated with the removal of risks to health is a primary benefit of PCB regulations. The cost savings involve both tangible and intangible costs. Examples of reductions of tangible costs include decreases in medical care costs and reductions in "foregone earnings" by persons who become ill. Decreases in intangible costs

		REGULATORY INTERVENTION
A Human Activity - PCB PRODUCTION		
*[Not produced in U.S. since 1977]	- - - - - - - -	*Ban Production
Presence of PCBs in Environment		
*PCBs still"in service" in manufacturing plants, agriculture production: some discharge to environment	- - -	*Eliminate industrial discharge of PCBs *Control PCB disposal
*PCBs present in soils, sediment of lakes, in the air	- - - -	*Reduce stocks of PCBs in environment (by dredging lake sediments for example)
Exposure to PCBs		
*PCBs found in food products	- -	*Set limits on allowable levels of PCBs in foods *Provide warnings against consumption of certain foods contaminated with PCBs

Figure 2.3. Model of How Human Activities Introduce Hazards to the Environment - PCB Examples

include such things as the reduced pain and suffering experienced by the injured person and their family and friends or prevention of an employer's loss of an experienced, trained worker.

2.8.2 Lowered Costs of Information to Consumers

The second category of benefits pertains primarily to regulations of PCBs in foods. These regulations provide the benefit of lowering the cost to consumers of obtaining food safety information. For example, the FDA has set limits on allowable levels[2] of PCBs in any foods, including fish, meat and poultry, eggs and dairy products. Consumers are thus theoretically guaranteed a minimum level of safety in the food and are spared the cost of finding information and the cost of the anxiety of not knowing if the food was safe. Another example of a regulation which lowers the cost of obtaining information is a regulation requiring public dissemination of food safety information. If the nature and severity of of the hazard is made available to consumers, then they can decide whether or not

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[2]Under Section 406 of the Federal Food, Drug and Cosmetic Act (FDCA), the FDA can set either tolerance or action levels that limit allowable levels of contaminants in a food. A tolerance level is a stronger action based on more scientific data and carrying more weight in court. Only substances whose presence in foods is "unavoidable" by good manufacturing practices are eligible for tolerance-type regulations.

to consume an item based on their own risk preferences. An example of this type of regulation is information on PCB levels in fish that is made available to people who fish for sport in the Great Lakes.

2.8.3 Protection of the Environment

Some of the PCB regulations also provide the significant benefit of environmental protection. Although PCB's acute toxicity is minimal for most forms of life, except some aquatic invertebrates (22), the long-term toxic effect on environmental systems is potentially serious. By controlling entry of PCBs into the environment, the costs of such long-term adverse impacts are avoided.

2.8.4 Development and Adoption of Safer Products

Some of the PCB regulations can stimulate development of less risky substitutes for hazardous products. A range of substitutes are replacing PCBs in their various applications. A detailed comparison of PCBs with these substitutes is required to assess relative performance, relative hazard, and relative cost. If however, as would be assumed, PCBs are replaced with less hazardous substances, such a substitution constitutes another regulatory benefit.

2.8.5 Improvements in Social Institutions

Sometimes regulations create changes beyond the scope of the regulated concern. In the case of PCBs, one

significant social benefit stimulated by regulation of PCBs in food was the development of the regulatory mechanisms and procedures to control unintended contamination of food. Prior to the "PCB problem," no regulatory means existed to control food that was "accidently" contaminated. Regulation of all environmental contaminants is based on procedures first developed and applied to control of PCBs.

2.9 The Benefits of Food Safety Regulations for PCBs

This chapter has explored general types of food safety regulations, presented a framework for conceptualizing the benefits of such regulations, introduced the PCB case study, and applied the benefit framework to analyze the potential benefits of several different types of PCB control. The range of possible beneficial effects of all types of PCB regulations are summarized in Table 2.3.

The remainder of this study will focus on the process of valuing regulatory benefits for a food safety regulation involving a performance standard. Thus, the valuation is restricted to one category of benefits, that of reduced costs of injury, disease or death. In this case, the major disease problem is cancer.

In standard economic texts, benefits are defined as "resources saved" or "resources produced" (24). In this study, benefits are defined as the cost savings (resources

Table 2.3 Beneficial Effects of PCB Regulation

1. Reduced incidence and costs of damage to human health:
   - disease
   - illness
   - death

2. Lowered information costs to consumers: consumers protected against hidden costs and guaranteed minimum level of safety in food.

3. Protection of natural systems - avoidance of environmental damage.

4. Replacement of toxic substance with safer substitute.

5. Development of regulatory mechanisms for control of environmental contaminants.

saved) associated with limits on exposure to PCBs in fish and consequently with fewer cancers. In other words, if the cost of cancers from PCB was calculated to be $10 million, the benefit of regulating PCBs in fish would be the cost saved, e.g., $10 million.

Economic texts further break down benefits into direct and indirect. Direct benefits are those immediately related to the main objective of the regulation; indirect benefits are the by-product or spin-off benefits. For the purpose of this report, the reduction in number of cancers is considered the major direct benefit of regulations on PCBs in food . Indirect benefits include such things as the development of safe substitutes for PCB and improvements in society such as the formation of new mechanisms for controlling toxic substances. Indirect benefits are not considered in this valuation process.

3 VALUATION OF REDUCTIONS IN RISK

Benefit valuation in this study involves the process of estimating the value of reductions in risks to human health in economic terms. The purpose of benefit valuation is to provide information on the benefits of a regulation in a form useful for policy assessment. In particular, estimating benefits in economic terms allows comparison of the benefits and costs of alternative regulatory options.

Traditionally, benefit valuation refers exclusively to efforts to value risk reduction in dollar terms. However, because of the types of conceptual and empirical difficulties mentioned in Chapter One, many analysts stop short of placing a dollar value on the reduction in risk, choosing instead to look at the cost associated with each increment of risk reduction. This approach, technically labeled "cost-effectiveness," avoids the problem of putting a dollar value on human life and is thus favored by some economists. Because of the large number of empirical studies of regulatory benefits which use the cost-effectiveness approach, it is considered in this study.

There are two major methods used to value reductions in risk, the human capital (hk) approach and the willingness to pay (wtp) approach. Until recently, the hk approach has

been the more frequently used method because the necessary data is relatively easy to obtain. However, the hk approach is easily criticized for reasons discussed below. In light of these criticisms, the wtp approach is coming into more widespread use, despite difficulties in empirical application. There has also been an effort to develop a theoretical rationale (consistent with the theory behind the wtp approach) for using hk data in valuing risks to life. This a methodology is known as the adjusted hk/wtp approach.

A review of the hk, wtp and adjusted hk/wtp theories and empirical estimates of the value of risk reduction produced by these theories is presented here in order to clarify the differences, the strengths and the weaknesses of each method. Based on the review, rationale is developed for using particular approaches to develop low and high estimates of the value of reducing risk.

3.1 The Human Capital Approach

The human capital (hk) approach assumes that the value to society of a human's life is measured by future production potential, usually calculated as the present discounted value of expected labor earnings.[1]

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[1]Early work on the methodology was carried out by Fein, Mushkin and Collings, Weisbrod, Klarman and Rice (25, 26, 27, 28).

The hk values are based on income foregone by persons of a given age, sex and occupation who are affected by a risk. Thus, in contrast to the wtp approach which attempts to measure the value of saving one statistical life, the hk approach seeks to measure the value of saving the lives of particular individuals or groups in society.

There are several variations of the hk approach. In one variation of the standard hk methodology the value of life is calculated by estimating foregone earnings net of consumption. The variation aims to calculate the net loss to society from death or illness based on the idea that when an individual dies, or is ill, not only is future production lost, but future consumption as well (29). Another variation of the hk approach adds the medical expenses associated with illness diagnosis and treatment to the foregone earnings to obtain a total cost estimate (30, 31). The hk approach is criticized for its lack of foundation in economic theory. It has no necessary relationship to an individual's willingness to pay to avoid risk, nor does it recognize individual attitudes or preferences towards risk. The approach relies on the assumption that individuals' utility functions are based solely on maximization of income, specifically in terms of contribution to GNP. This narrow definition of the utility function is difficult to defend on theoretical grounds. Dimensions of illness and

death beyond economic output, such as pain and suffering, the value of leisure, and other intangible dimensions of life are completely ignored. Moreover, such a description of the utility function with respect to risk valuation does not reflect how people actually behave. If the full value of life is actually measured by GNP contribution, people would, if given the choice, work more than a 40 hour week sacrificing leisure for higher income. While some people do behave in such a fashion, most do not. This is just one example showing how the complexities of the value of life cannot be fully captured by measurement of contribution of GNP.

Most users of the hk method do not argue that the approach produces estimates of the value of life based on economic theory. Supporters of the hk approach instead maintain that the hk estimates were never intended to measure the full value of life. Rather, they simply represent the impact of loss of given lives on the GNP.

Support for using the hk approach is based on the advantage of the information gained using full age specific accounting to evaluate the impact of disease and death. The numbers generated with the hk method provide precise information because they are based on actuarial data. Most analysts agree that hk studies produce numbers which are fairly accurate estimates of what they are trying to measure

-- estimates based on life expectancy, labor force participation and projected earnings of the impact of death and injuries on GNP. However, it is also widely acknowledged that these estimates are not the most appropriate measures of the overall value of risk reduction.

A final point is that application of the hk approach leads to unacceptable policy conclusions. For example, because white, middle-aged men earn, on the average, more than nonwhites, women and young people, use of the hk estimates leads to the conclusion that a program that saves white, middle-aged men's lives is more worthwhile than programs which save the lives of people in other demographic groups. The underlying assumption of the hk approach, that people are worth as much as they earn in the marketplace, is not accepted as valid by most members of society.

In the final analysis the drawbacks of the hk approach are significant. Although the numbers are viewed as representing only a part of the value of life, they are often used without regard to this qualification. The advantage gained by using actuarial data to obtain more precise and accurate estimates is thus negated because the hk measure neglects so many components of the value of life. The accuracy gained by using actuarial data is

irrelevant given the magnitude of error caused by other limitations of the approach.

The value of one life obtained in existing hk studies range from under $100,000 (1975 $) to around $400,000 (1975 $) (11). Values are sensitive to choice of discount rate used in calculations and to the demographic group considered (age, sex and income level). For further discussion of the method and its empirical application, see Mishan (29), Cooper and Rice (30) and Hartunian, Smart and Thompson (31).

3.2 The Willingness to Pay Approach

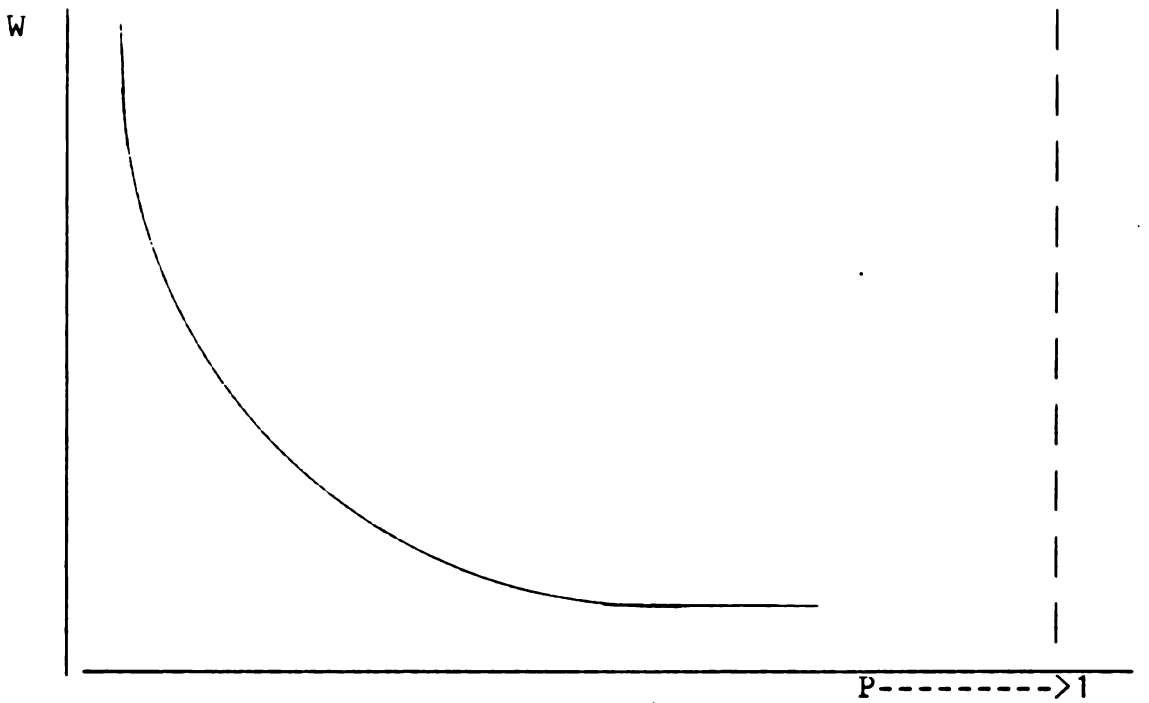
An approach to valuing life which is more consistent with economic theory is the willingness to pay (wtp) approach. The method is based on the thesis that valuation of loss of life applied in safety decisions should be based on the same criterion used by economists in other areas of cost-benefit analysis, namely that the worth or value of a thing is determined by what a person is willing to pay for it (29). It is widely agreed that wtp estimates of the value of risk reduction are conceptually more appropriate than the traditional hk estimates.

As discussed by Mishan, the issue in the willingness to pay question is not the value of an identified person's life as in the hk approach; rather it is the value of the

reduction in the probability of death for a given population. The appropriate benefit measure is the aggregate value a population at risk places on programs that save statistical lives, or the sum of the amounts individuals are willing to pay ex-ante to buy small reductions in the probability of their own death (29).

3.2.1 Economic Conceptualization of WTP

A simplified model showing the tradeoffs between wealth and survival probability illustrates the concepts underlying the wtp approach to assessing the value of risk reduction. Figure 3-1 presents an indifference function showing the tradeoff of wealth for survival probability in a one-period situation. In this case, survival can be thought of as a probabilistic term for an increase in life expectancy; the demand for survival would then be willingness to pay for this increase. The problem is to determine an individual's preferences with respect to survival versus wealth choices. In other words, the price at which wealth can be exchanged for enhanced survival probability, or vice versa, must be determined. The basic behavioral assumption is that individuals make choices so as to maximize their expected utility. The actual choices that will be made will depend on the initial endowment of wealth and the initial



P = Probability of survival.

Figure 3.1 An Indifference Function Showing the Tradeoff of Wealth for Survival Probability

probability of survival. Other factors likely to influence the wealth-survival tradeoff would include anticipated lifetime, the number of dependents and family, and the nature and timing of the probabilistic death.

Based on this simplified model some initial observations about the value of risk reduction can be made. Consider a situation where an individual is faced with an increase in risk, all other factors held constant. There are two approaches to determining the impact of the risk increase on an individual's welfare. One approach is to assess the compensating variation (cv) which is the amount of compensation required to induce the individual to voluntarily accept the risk increase. Obviously as the level of risk increases the amount of compensation will go up (in a nonlinear fashion) until, when asked to accept certain death, no amount of compensation will be adequate. The second approach is to measure the amount of money an individual would pay to avoid a risk increase or the equivalent variation (ev). Again, as the level of risk rose, a person would be willing to pay more and more, until when faced with need to avoid certain death, a rational person would likely give up all wealth to save their life.

From these concepts, it can be seen that the value of a risk reduction is theoretically bracketed by the amount a person is willing to pay to avoid it (up to all their wealth) and the amount of money required to fully compensate a person for the risk (which is infinite for certain death).

Comprehensive models have been developed to describe individuals' behavior concerning wealth-survival tradeoffs. Some of the models attempt to incorporate bequest motivation (utility derived from unconsumed wealth remaining at time of death) and insurance behavior. For examples, see Jones-Lee (32), Conley (33), Thaler and Rosen (34).

Other models are based on specific types of risk-income tradeoffs such as observations of risk-income tradeoffs in the labor market or in consumption activities. Thorough reviews and critiques of these models are presented in Freeman (35), Mishan (29), and Linneroth (36).

A question of interest to many researchers is the relationship between a person's willingness to pay for an increased chance of living and a person's lifetime earnings. Improved understanding of this question would lead to improved understanding of the relationship of the theoretically correct wtp approach and the more easily applied hk approach. Several researchers have developed

models that show that lifetime earnings do in fact represent a theoretically correct estimate of wtp for a small reduction in risk (33, 37). The models, sometimes referred to as the adjusted wtp/hk models, rest on two restrictive assumptions about behavior: 1) that the individual's objective function is based solely on the maximization of the expected value of discounted lifetime income; 2) that the individuals are risk averse and deal with economic losses associated with risk symmetrically with risks to financial and other assets. Given these two assumptions, these models conclude that the welfare-based aggregate value a population would be willing to pay ex ante to save a statistial life is equal to an hk based estimate of the lifetime income of the person.

The authors of these models, as well as subsequent reviewers, generally conclude that such estimates can, at best, serve as lower bound estimates of wtp for decreased chance of death. The reasoning is that lifetime earnings are not the only component of most people's utility functions. Rather, there are other aspects of living which are not represented by income measurement. (It is also pointed out by some analysts that for any person with an income who commits suicide, lifetime earnings overestimate

the value of life. However, such situations are not the norm.)

It should be noted that the process of aggregating individual wtp values to estimate the market demand for risk reduction requires several restrictive assumptions about income distribution and risk preferences that can be criticized on theoretical grounds. For a discussion of these issues see Freeman (35).

3.2.2 Empirical Estimates of WTP

Attempts to obtain estimates of willingness to pay have proceeded along two general lines: 1) analysis of direct survey responses of individuals' wtp, followed by aggregation of the results to obtain a societal wtp value; 2) statistical estimation of peoples' revealed preferences based on either studies of the labor market or studies of consumption services, again followed by aggregation of the values to obtain a societal wtp estimate. The two methods produce a wide range of estimates of the value of reductions in risk. No concensus exists as to which method is the most valid.

3.2.2.1 Survey Approach

Three major studies have been conducted using the survey method to obtain estimates of the wtp for risk reductions. Acton (38) posed open-ended questions about individuals' wtp for a coronary care unit that would provide a small (.002) reduction in the risk of death from heart attack. Two different formulations of the question led to values of a statistical life of $28,000 and $43,000 (1972$). Jones-Lee (32) asked a similar question concerning individuals' wtp higher air fares to travel on airlines that had lower probabilities of a fatal crash. The value of a statistical life saved in his study was approximately $5 million (1975$). Landefeld (39) surveyed individuals on their wtp to reduce cancer mortality. He found a value of $1.2 million (1977$) per statistical life saved.

The survey approach has several methodological problems that may account, to some extent, for the variability of the benefit estimates. The first and most obvious drawback is the inability of individuals to determine their preferences with respect to risk in hypothetical and complex situations. Individuals may respond (honestly) to questions in one way, but act entirely differently when actually faced with the risk situation.

A second problem surrounds how individuals expect the survey information to be used. If a person thinks they will

be charged their wtp for a program, they may understate their wtp in the survey, hoping that others will pay and they will be able to ride free. On the other hand, if individuals do not believe that they will ever be charged, they may overstate the wtp value in order to ensure that the program is initiated (36). Such strategic behavior in response to survey questions can seriously bias results. Careful phrasing of survey questions may minimize the extent of strategic answering, but it is difficult to eliminate altogether.

A final problem with the survey approach is that individuals do not evaluate very small changes in risk in a consistent fashion, even if the risk information is clearly presented. Empirical studies support this insight, indicating that predictable biases are observable in individual's risk assessments. For example, people tend to underestimate the chance that a low-probability, high loss event will happen to them, while overestimating the likelihood of high-probability, low-risk events (40).

Some economists feel that the above criticisms are serious enough to preclude obtaining reliable estimates of wtp from surveys. Other economists, however, accept the variability of survey results as a reflection of the fact that different types of risks (i.e. higher vs. lower; voluntary vs. involuntary) are valued differently. Also, people's risk preferences vary. As stated earlier, wtp for

risk reduction varies with income level, age, life expectancies, number of dependents and the nature and timing of the risk. Therefore, it is possible that some of the variation in risk values is a function of either the differences in type of risk, or the risk preferences of the individuals questioned.

3.2.2.2 Revealed Preference-Labor Market Approach

Estimates of the value of life obtained from labor market studies provide the most accessible direct evidence of the amount people are wtp for their own safety. The method is based on the observable wage differentials between risky and less risky work. In theory, a worker with a given skill and education level can choose from among several types of jobs having markedly different accident rates. Risky jobs typically pay more for a given skill requirement than less risky positions. By examining the wage differential between the two jobs, theoretically, the value placed on a given increment of risk can be estimated.

Landefeld and Seskin (11) have summarized the most common criticisms of the labor market approach in five points:

1. Wage premiums may not accurately reflect worker risk preferences if workers have incomplete information regarding risks to which they are exposed.

2. Wage premiums may not provide accurate measures of worker preferences if there are significant imperfections in the labor market (i.e., an immobile labor force).
3. Sample self-selection may bias results. Because of low incomes, lack of economic opportunities, or specific individual preferences, those who work in riskier jobs may exhibit less risk adverse behavior than the population as a whole. Wtp valuations based on risk premiums paid such persons will understate the correct values applicable to the general population.
4. Statistical problems occur when trying to separate risk of death from risk of injury since compensating wage differentials will try to account for both.
5. Data constraints may bias statistical evidence, for example, using aggregate industry data instead of data from an individual firm.

Analysis of the labor market to generate estimates of the value of a statistical life has been conducted by Dillingham (41), Smith (42), Viscusi (43), Thaler and Rosen (41), and Olson (44). The estimates of the value of saving a statistical life range from $140,000-$260,000 (1967$, 34), to $1.5 million (1967$, 42). The variation in the

methodologies used in the different studies may account for some of the variability in estimates. The list of problems cited above may also contribute to the wide variability of labor market values. However, the labor market, approach has been more thoroughly formulated, critiqued and applied than any other methodology. Also, as will be seen in Chapter 5, careful study of the estimates makes it possible to somewhat narrow the range of risk reduction values.

3.2.2.3 Revealed Preference - Consumption Studies Approach

As an alternative to the labor market estimates of the value of a statistical life, analysts have attempted to assess risk preferences in a larger, general population. The approach typically involves estimating the value of risk reductions by observing how much people are willing to pay in the marketplace for various goods or services which reduce the risk of death or injury. Blomquist (45) has estimated the value of life based on the use of automobile seatbelts. Dardis (46) estimated the value of life based on use of smoke detectors, and Portney (47) developed estimates based on housing values and environmental risks.

The range of values obtained from the consumption activity method are narrower than those from the labor market studies. The values range from approximately $100,000 (1973$, 46) to approximately $355,000 (1977$, 45).

However, according to Landefeld and Seskin (11), many of the same data statistical problems that weaken labor market studies also affect consumption activity estimates. As with labor market studies, it is statistically difficult to separate risk premiums from other confounding factors such as income and education level. Extrapolation of the value of risk from the narrow "study group" (i.e., seatbelt users, smoke detector consumers, etc.) to the general population may not be valid. It is also extremely difficult to obtain data on purchase or use of risk-reduction items. A final point is that it is unlikely that people who make such purchases are aware of the statistical implications in terms of risk at the time of purchase.

3.2.2.4 The Adjusted WTP/HK Approach

The theoretical appeal of the wtp approach and the operational strengths of the hk approach have prompted research efforts to meld the 2 methodologies. The result is the "adjusted wtp/hk approach" which was discussed earlier. Empirically, the adjusted wtp/hk approach is identical to the hk approach except for two points. First, in adjusted wtp/hk estimates, the individual's, as opposed to society's opportunity cost of investing in risk-reducing activities forms the basis for choosing a discount rate. A low discount rate can thus be justified. Secondly, a risk aversion factor is included in the adjusted wtp/hk model

to reflect the assumption that persons should be at least as risk averse with respect to loss of life as to other financial assets. Based on these two adjustments and their underlying assumptions, it is argued that foregone earnings provide a theoretical correct estimate of an individual's wtp to avoid risk. This argument rests, in turn, on the assumption that the only variable entering individual's lifetime utility function is lifetime income (36). This is an unlikely assumption for the same reasons that the assumptions underlying the traditional hk estimates are assumed not to fully reflect the value of life, i.e., the utility of living cannot be measured simply by contribution to GNP. However, it does seem reasonable to accept the assumption that individuals are at least as risk averse with respect to loss of life as to other financial assets. Given this assumption, the adjusted wtp/hk estimates represent a lower bound value of risk reduction activities. It should be noted that this approach could be more accurately labeled the adjusted hk approach for it simply involves use of hk estimates, weighted by a risk aversion factor and discounted at a low rate. Therefore, the adjusted wtp/hk estimates of the value of risk reduction are subject to the same criticisms as traditional hk estimates.

Only one study has been conducted to estimate value per statistical life using the adjusted willingness to pay method. Landefeld and Seskin derived estimates for males and females by 19 age categories. They found, as expected, that the estimates with the wtp/hk method were consistently larger than those based on the hk approach. For example, the adjusted wtp/hk estimate for a male, aged 40-44, is $660,193 (1977$) versus $180,052 (1977$)using a hk method (11). As pointed out above, the difference in value is associated with the use of a lower discount rate of 3% versus 5% in this example and with inclusion of risk aversion factor.

3.3 Using the Methods to Assess PCB Tolerances for Fish

Based on the discussion presented in this chapter, consideration of which benefit values to apply to the PCB case is narrowed to those based on the wtp approaches. The decision stems from the overwhelming limitation of the hk approach - the equation of lifetime earnings with value of life.

The key piece of information sought in wtp studies is the value of the reduction in probability of death for a given population. The appropriate benefit measure is thus the aggregate value a population at risk places on programs that save statistical lives, or, the sum of the amounts

individuals are wtp ex ante to buy small reductions in the probability of their own death (or sum of the amounts they will accept to voluntarily undergo the risk). For the purposes of this study, it will be assumed that such values are appropriate for use in the evaluation of policies which affect the health and safety of the entire population, such as PCB regulatory policies. The wtp values are used, in this sense, as average values of risk reduction for the entire population - i.e., for persons of all ages, sex and income level.

The emphasis of this study is on the empirical utility of the benefit quantification approach. Therefore, development of a range of benefit estimates versus application of one estimate has been selected as the most appropriate methodology. If only one benefit value were to be used in the study the reliability of the estimate would be overstated given the wide variation in wtp empirical results. Application of a range of values on the other hand, provides quantitative information on the value of risk reduction yet clearly indicates the uncertainty inherent in the valuation process. The empirical estimates selected for use in developing the range of values and the rationale for their selection are discussed below. The methodology will be more fully explained in Chapter 5.

Selection of the methodology to use to develop a theoretically correct lower bound estimate is relatively straightforward. As discussed earlier, the adjusted wtp/hk approach provides a lower bound value of the benefit of risk reduction, based on a model consistent with economic theory. The model has the advantage of ease of calculation and also provides useful information on the impact of risk on GNP based on fairly detailed actuarial data. Also, because the objective of this research is to asses the overall benefits of PCB regulations, third party medical costs stemming from PCB related health risks are added on to the basic adjusted wtp/hk estimates.

Selection of an upper bound value is more difficult. The value that an individual places on risk reduction is dependent, among other things, on the level of risk and the risk preferences of the individual. The higher the risk, the greater the wtp to avoid it or the greater the amount of compensation required for the individual to voluntarily accept the risk. In the extreme case, where death is certain, an individual would give up all wealth to avoid the risk or, would not agree to any amount of compensation to accept the risk. Thus, the upper value of risk reduction is infinite in some cases. In light of the possibility of an infinite value, it could be argued that very high values of risk reduction are theoretically valid. The values could be

very large because people highly value living. However, an infinite upper bound does not provide much useful information in terms of valuing small reductions in risk. Yet, there is no theoretical rationale for any upper bound values besides infinity. Because of the lack of theoretical support for a set upper bound, the term "high" value will be used instead of upper bound value. The "high" value cannot be assumed to represent an absolute upper bound since the wtp value will increase as the risk increases, possibly until it reaches infinity. The high value used here simply represents an estimate that is large relative to other empirical estimates.

Two labor market studies are used to develop middle and high estimates of the value of risk reduction. The rationale for selecting values derived from labor market studies is that more of these type of studies have been conducted, with more consistent results than either the survey or the revealed preference wtp approaches. As with the adjusted wtp/hk approach, the basic labor values are adjusted to reflect third party effects including medical costs and lost indirect business taxes. These modifications and the details of the labor market studies are discussed more specifically in Chapter 5.

3.4 Cost Effectiveness

The last approach to benefit valuation considered is cost effectiveness. As mentioned earlier, cost effectiveness is not a benefit quantification approach. Rather, it is an alternative approach to evaluating the impacts of policy. The advantage of the cost effectiveness approach is that it avoids the controversial task of valuing reductions in risks to life. Use of the cost effectiveness method to evaluate the benefit of risk reduction can involve any of several approaches. The most well known approach is to compare several alternative actions to determine which achieves a given level of benefits at the lowest cost, or alternatively, which action generates the most benefits at a given cost. In health and safety program evaluation, this method is operationalized by examining the cost per life saved, calculated by dividing the costs generated by the program by the number of statistical lives the program will protect. This calculation allows policymakers to pinpoint which programs save lives most inexpensively. The cost per life saved figure may also be compared to empirical estimates of the values of a statistical life to see if the cost falls into a "reasonable" range.

A unit of measure other than statistical lives saved is sometimes used in cost-effectiveness studies. For example, some analysts prefer to consider changes in longevity within

a population rather than the number of statistical lives saved (9, 20). The longevity method incorporates more actuarial data into the calculations. It would, for example, differentiate between a program which saved young peoples lives and one which saved the lives of older persons. The former program would obviously increase longevity more than the latter. The actual number of lives saved however, would be identical.

One researcher has gone a step farther than life-years saved by measuring "quality adjusted life years" (QALY) saved. As in the longevity approach, the QALY method attempts to provide more information to decision-makers on the type of benefit stemming from an action. In order to provide more information, the method values reductions in risk, taking into account the age of an individual, the number of life years saved and the quality of those years. The effects of changes in risk of death or injury are measured in terms of an individual's utility function where the amount of output is QALYs. According to this approach, the appropriate measure for the output of a health-promoting program is the total gain in discounted QALYs it provides to all members of the population (14). As when program impacts are measured in terms of numbers of lives saved, the cost per QALY saved can be used to evaluate a program or to

choose between programs. Both the longevity and the QALY approaches must be calculated separately for each risk-reducing regulation.

In Chapter 5, the cost per life saved under various PCB tolerance regulations will be calculated. The purpose of the exercise is to compare the policy implications stemming from this type of analysis to those obtained by quantifying risk reductions in dollar terms.

4 METHODS AND ISSUES IN RISK ASSESSMENT

Because risk assessment is a crucial aspect of the economic analysis, a discussion of the process is presented before the four methods of benefit assessment are applied. Particular attention is given in this chapter to sources of uncertainty in the risk assessment process and to how the uncertainty is addressed. Then the risk assessment for PCBs is presented. It will be used in the next chapter to develop estimates of the benefits of regulatory standards for fish.

4.1 Risk Assessment and Benefit Valuation

Within the context of this study, the term risk assessment refers to 1) the process of identifying substances which are hazardous to human health; and 2) evaluation, both quantitative and qualitative, of the risks posed by the hazardous substance.[1] A second term,

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[1]Note that the term risk assessment has many interpretations. Sometimes, it is defined as encompassing both the physical risk assessment and benefit valuation processes. In other cases, risk assessment refers to methods of quantitatively estimating risk of cancer using mathematical models. Here, the term refers to the overall process of identifying and evaluating risks, but does not include the benefit valuation process.

benefit valuation, is used to describe the process of evaluating the reduction in risk achieved by regulating a given hazard.

Figure 4.1 illustrates the process of risk assessment and benefit valuation. The risk assessment stage begins with hazard identification - the step of pinpointing potentially harmful substances and attempting to document their toxicity using a variety of tests. The second step in the risk assessment process is to evaluate the test results and to determine whether or not, based on available data, the risk to humans can be estimated. The hazard evaluation stage results in either a decision to attempt to quantify the risk to humans, or, a judgment that available information is inadequate for quantitative risk assessment. As shown in Figure 4.1, quantitative risk assessment is usually attempted only for suspected carcinogens. Estimates of other risks to health, such as mutagenic or teratogenic effects, or adverse impacts on reproduction, can only be qualitatively estimated if at all. Because quantitative risk assessment data is required for economic valuation of risk reduction, only reduction of carcinogenic risks is easily valued in economic terms. For substances which pose a risk of uncertain magnitude, other decision criteria, besides the value of the risk reduction, must be used to analyze the impacts of regulation.

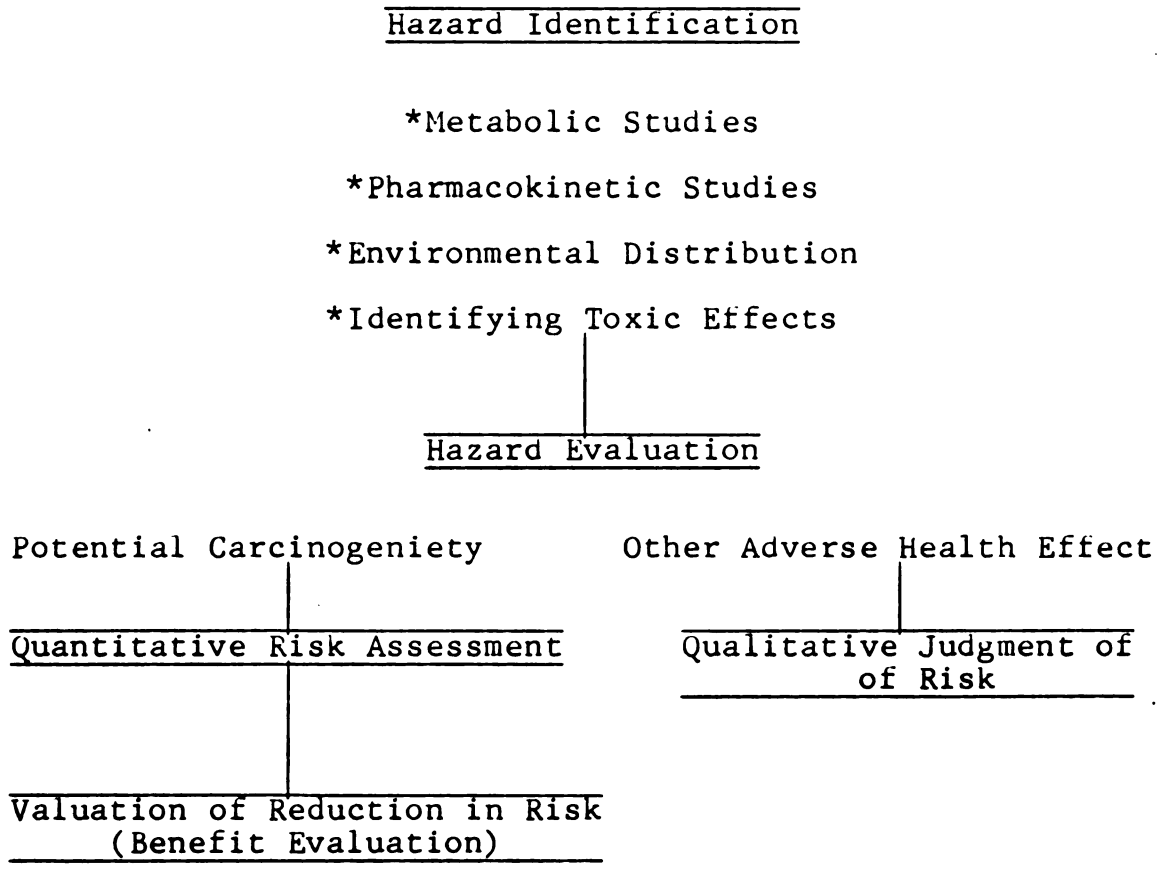

Figure 4.1 The Risk Assessment-Benefit Valuation Process

Before undertaking a description of the specific steps and issues encountered in the risk assessment process, the scientific uncertainties underlying the process should be addressed. The most important point is that the risk posed by a substance is never known with absolute certainty. The risk assessment process is often considered to be objective because it is based on scientific studies. However, the methods and interpretations of the procedures are actually subject to considerable controversy and debate. The methodologies are still in the developmental stage.

As pointed out by Crandall and Lave (15), at best, science and scientists can search for the best data, identify the range of uncertainty involved in a given problem, and isolate the areas where assumptions and judgments are needed. In most cases, a complete review of scientific evidence does not provide definitive, clear answers to questions about the risk a substance poses. The lack of scientific certainty carries over to the economic analysis of the benefits of risk reduction. Economic analysis can provide a range of estimates of the value of regulating a hazardous substance, based on the best available risk data, and clearly identifying the range of uncertainty surrounding the estimates. With these qualifications in mind, the stages of the risk assessment process are now discussed in more detail.

4.2 Hazard Identification

Hazard identification is the process of determining which substances potentially will have an adverse impact on human health. Adverse impacts are defined to include effects such as carcinogenic, mutagenic, teratogenetic or reproductive effects, or other acute or chronic toxic impacts.

Hazard identification typically encompasses 4 steps: 1) conducting metabolic studies to learn how a substance changes chemically in the body; 2) conducting pharmacokinetic studies to determine the substances absorption rate, how much of the substance and its metabolites reach and are maintained in the body tissues, and their rates of elimination; 3) determining the distribution of the substance in the environment, and; 4) identifying toxicological effects of the compound. A discussion of all of these steps is beyond the scope of this project. However, a review of the fourth step, methods of identifying the toxicological effects of the compound is presented here to provide a sense of the types of uncertainties and controversies involved in the risk assessment process. Similar types of issues to those discussed below, arise in the other 3 steps of the hazard

identification process, though they perhaps are not as widely discussed.

There are three major methods used to identify toxicological effects: epidemiological studies; animal experiments; and short-term tests. Unfortunately, no one method is sufficient to provide a full understanding of the potential impact of a substance on human health. All of the types of tests have drawbacks. Moreover, testing often proceeds in a haphazard fashion, stimulated by available funding or by popular reaction to a recent event, rather than according to systematic scientific thinking. The major strengths and weaknesses of each type of test are briefly reviewed here.

4.2.1 Epidemiological Studies

Epidemiological studies of human populations exposed to a given substance provide the most certain identification of a hazard. As one scientist phrased it:"epidemiological studies, by exploiting 'natural experiments' that people perform on themselves, or that society or the environment inflict on them, are as close as we can reasonably get to performing actual experiments on humans" (48).

The obvious strength of epidemiological studies is that the subjects are humans; there is no need to

extrapolate results from animal species to people. Another advantage is that these studies assess "real life" risk situations where synergistic effects may be in play which could not be duplicated in the laboratory. Epidemiological evidence of a substance's toxicity eliminates much of the uncertainty in the hazard identification process.

Epidemiological studies, however, can seldom provide a fully adequate basis for assessment of risk for several reasons. First, the adverse health effect is often manifested only long after the exposure to the hazard has occurred. Tracing the causal relationship between exposure and health impact is therefore difficult. Epidemiological studies are also weak in detecting and identifying causes of small degrees of excess risk.

Moreover, exposure levels are often not known and groups for exposure and non-exposure are difficult to delineate (13).

4.2.2. Animal Studies

Lack of adequate epidemiological data forces reliance on other methods. Animal studies, based on the similarity between animal species and humans in terms of body organs, their functions, and disease processes, remain the most highly regarded and often used alternative. When epidemiological data is available to compare with animal

study data, the results usually show high agreement. For example, all the chemicals known to cause cancer in humans, with the exception of arsenic and benzene, also do so in experimental animals (48). Animal studies also have the advantages of shorter testing periods, the ability to administer high doses to test for significant response at low level exposures, and the relatively greater ease with which confounding factors can be examined (49).

One drawback of animal tests is their simplicity. Practical considerations dictate that scientists must test chemicals one at a time. Therefore, the experiments do not reflect real world situations of concurrent and sequential exposures to a wide array of toxic substances. Animal studies are also extremely costly. A full complement of commonly used animal studies could cost $12 million or more and require 3-4 years to complete (50). The techniques of animal testing also are subject to uncertainty and debate. Some of the most difficult issues include:

* how to compare test results from animals of different sex, strain, species and age
* the unclear role of diet, nutrition and diet contaminants in test outcomes
* the impact of contaminants in test chemicals on results

* metabolic overloading and implications for result interpretation
* differences between humans and animals in terms of how chemicals are modified in the body
* statistical difficulties in all stages of testing
* lack of agreement on how to deal with non-positive results

Despite these undertainties and limitations, there is a general concensus in the scientific community that animal experiments provide a valid method for first order identification of hazards. Additionally, recommended procedures for conducting animal tests have been recently published that attempt to standardize testing methods and thereby minimize or at least contain the uncertainty within bounds (51).

4.2.3 Short-term Tests

The high cost and time involved with epidemiological and animal studies has stimulated a search for rapid and inexpensive ways of identifying hazards. A number of short-term methods have been developed to assess genetic toxicity, neoplastic (tumor) cell transformation and chemical structure-activity relationships (52). To date, the studies are used primarily to provide supportive or

suggestive evidence of the toxicity of a substance, particularly of carcinogenicity. In a recent survey of 273 carcinogens of a wide range of different structures, an overall correlation with mutagenicity of 77% was found. The prevailing opinion on short-term tests is that a positive result can be used as supplemental information regarding carcinogenicity, but a negative result can not be taken as presumptive evidence that a substance is not a carcinogen (48).

4.3 Hazard Evaluation

After a hazard has been identified and the nature of the toxic effect delineated, the toxicological data must be evaluated. This step of the risk assessment process produces either qualitative or quantitative expressions of the hazard to human health associated with a substance at given exposure levels. Hazard evaluation is the most controversial aspect of the risk assessment process. Whether and how risks can be measured quantitatively is the major source of controversy. As mentioned earlier, from the perspective of the economist attempting to value the benefits of risk reductions, quantitative risk data is essential. Lack of reliable risk data is one reason why more economic analysis has not been done on food safety regulatory benefits. Since methods of quantitative risk

estimation for non-carcinogenic health effects are not well developed, the focus here is narrowed to issues surrounding evaluation of carcinogenic health effects.

4.4. Issues in Evaluating Carcinogenic Health Effects

There are three major questions that must be addressed in evaluating carcinogenic health effects: 1) what constitutes adequate proof that a substance is a human carcinogen; 2) is there a threshold level below which a carcinogen will not cause cancer; 3) can carcinogenic risks to humans be quantified. Each of these questions is discussed below.

4.4.1 Adequate Proof

There appears to be a general concensus in the scientific community that if a substance is demonstrated to be a carcinogen for any mammalian species in an appropriately designed and performed carcinogenesis bioassay, then the substance is likely to pose a potential cancer risk to humans (51, 52). However, while this statement sounds straightforward, to determine when the conditions of the definition are met is a controversial task. For most substances, multiple sources and types of test evidence are available that lead to conflicting conclusions about carcinogeneity to humans. It is often

difficult to determine which of the studies are correct, or even the most valid. The operational definition given above of when a substance poses a cancer risk to humans provides little insight into how conflicting test results should be handled.

In practice, a conservative approach is usually taken in interpretation of carcinogenic studies. For regulatory purposes, decisions on carcinogen risk tend to place the most weight and credence on the data that shows the strongest carcinogenic responses. The intent of the "worst case" approach is to allow the assumption that "estimated risk always exceeds real risk" (53).

4.4.2 The Question of Thresholds

A second, widely debated question in carcinogenic risk assessment concerns whether there is a threshold level below which a carcinogen will not cause tumors. The two main arguments in support of the threshold theory are: 1) the apparent existence of threshold effects for other types of toxicity and; 2) the theory that the high dose exposures used in animal studies overwhelm the ability of cells to repair damage to their chromosomes, thus leading to mutations (leading to cancer), a reaction that would be absent at low dose exposures (54).

There appears to be agreement in the literature that resolution of the threshold question is not possible at

this time because there are too many biologically reasonable mathematical models, both implying and denying the existance of thresholds, that fit observed results (13). Most scientists therefore consider the burden of proof to be upon those who argue for the threshold model.

4.4.3 Can Cancer Risk Be Quantified?

There is ongoing debate over whether it is possible to quantify the risk of cancer to humans. Arguments against quantitative risk assessment (QRA) point to the tremendous uncertainty and error encountered in efforts to express cancer risk in quantitative terms, such as the number of new cancers per year. It is pointed out that uncertainty surrounding the estimates may involve degrees of magnitude as much as 1,000-10,000 but this uncertainty is often not adequately documented when the risk data is applied. Further, in cases where the uncertainty is adequately documented by the researchers it may be overlooked by decision-makers eager for numbers. For these reasons, many researchers conclude that numerical estimates of potential human cancer incidences are not valid.

As an alternative to QRA, proposals have been developed to qualitatively assess carcinogens by ranking substances in terms of their relative carcinogenic activity (49,51,53). Such approaches permit distinctions to be made, between the potential cancer risks posed by various

substances based on the weight of available evidence. For example, Squire (51) has proposed a regulatory approach which uses a scoring system to rank animal carcinogens. Based on the most relevant toxicological information, chemicals are placed into one of 5 classes according to 6 different factors associated with carcinogen testing. It is proposed that the classification of a compound could be used to select the appropriate regulatory option, and to establish priorities for public and scientific concerns. The information could even influence how a QRA were to be conducted. For example, a chemical classified in a "very hazardous" class might require application of a more conservative model to extrapolate risk than a chemical classified in a less hazardous category.

There are however, many researchers who believe that numerical estimates of the incidence of cancer are valid and necessary. This stance is taken for example, in a study of carcinogeneity and drinking water in which quantitative risk estimates are developed for over 100 compounds identified in drinking water (expressed in number of new cancers per year) (55). In order to produce valid estimates, the study stresses the need for good data on population exposure, use of valid, precise, accurate and reproducible assay procedures in animals, and use of appropriate statistical techniques for extrapolation. It

is stressed in the study that no rigid, generally applicable procedure could be recommended for all toxic agents as the substances differ too much in their overall effects. If the appropriate techniques are used however, the study concludes that QRA is a useful and valid tool for risk evaluation.

There are 2 steps in the QRA process that are often questioned: 1) extrapolation from high dose test experiments to low dose exposure situations; 2) extrapolation from animal studies to humans. Each of the steps introduces uncertainties and the possibility of increasing the error in the final risk estimate. The steps are briefly reviewed.

4.4.4 Extrapolation from High Dose to Low Dose

Constraints of time and money dictate that animal carcinogen studies be carried out with small numbers of animals - generally fewer than 100 and sometimes less than 20. Consequently, to maximize the probability of detecting a positive tumor response, very high levels of the test compound are administered. The practice is accepted as reasonable by the scientific community. The use of high doses however, poses the problem of extrapolating from effects at high doses to carcinogenic responses anticipated at extremely low doses typical of human exposure.

Numerous mathematical extrapolation models have been developed to predict low dose responses. Each model is based on a different set of assumptions about the nature of carcinogenesis and, therefore, results in different estimates of the number of tumors expected to occur after low dose exposure. Each model can be justified with data drawn from animal studies. In other words, the variety of dose-response patterns available from animal studies is such that a given model can usually fit some set of observed data.

The most frequently used model in risk assessment is the linear model. The model assumes there is no absolute "safe dose" for a carcinogen (i.e., the dose-response curve commences at the origin and the probability of cancer varies directly with dose). The linear model has become standard practice as the conservative method of extrapolating animal data from high to low doses because it generates results that are more likely to overestimate than underestimate risk (48). The linear model is generally presumed to represent an upper bound on risk extrapolation estimates (53).

Numerous other models have been developed to extrapolate risk, based again on varying assumptions about the chemical mechanisms underlying cancer and about the shape of the dose-response curve at very low exposure

levels. In some cases, where the linear model does not fit the available data, the other models, conservatively applied, could be used to estimate risk.

4.4.5 Extrapolation from Animal to Human

A second major decision involved in extrapolating cancer data to humans is how to adjust the dose measured in an animal assay to the dose experienced by humans. Four methods have been developed to adjust exposure estimates. These "scaling factors" result in estimates of human risk which can vary as much as forty-fold (13). Agreement has not been reached in the scientific community over which scaling factor is most appropriate. The four methods are listed below.

*Exposures may be adjusted on the basis of relative body weight, milligram of agent per kilogram of body weight per day (mg./kg/day) for animals and humans. This is the method generally used by toxicologists.

*When chemicals are administered to animals in the diet, doses are measured as percent dietary intake or parts per million (ppm), and require no further adjustment. This method is often used by the FDA.

*A third method involves adjusting exposures on the basis of relative surface areas of the test animal and humans (mg./m^2/day).

*A fourth scaling factor involves adjustment of exposure on the basis of relative body weight over lifetime (mg./kg./lifetime). This method is less frequently used than the other methods. (13).

No matter which extrapolation methods are used,the resulting risk estimates must include a discussion of the degree of uncertainty involved. All of the available extrapolation models are based on a set of biological and statistical assumptions which cannot be verified experimentally. It is not known with any certainty which set of assumptions is most accurate.

The wide range of uncertainty is well illustrated with an example. Table 4.1 shows extrapolations made to estimate human risk of cancer from saccharin. Risks are calculated for a population that ingests one can of diet drink containing 120-150 mg. of saccharin per day per person. It is assumed that the population at risk is 200 million people, the life expectancy is 70 years and human sensitivity is the same as the rat. Factors not considered in the extrapolation include individual variability in the human population in response to carcinogens, effects of intercurrent diseases, various forms of interactions between carcinogens, co-carcinogens, promoters and other factors. As can be seen from the data in Table 4.1, the methods chosen for dose adjustment and for extrapolation from high

Table 4.1 Estimated Risks from Saccharin Consumption

Estimate 1
Dose adjusted to surface area by the expression mg/kg/day (human)=5.6 mg/kg/day (rat)

Method of extrapolation

	Number New Cancers/year
a. linear (71).....	3,400
b. quadratic (a multistage model) (71).....	15

Estimate 2
Dose adjusted to body weight by the expression mg/kg/day (human) = mg/kg/day (rat)

Method of extrapolation

	Number New Cancers/year
a. linear (146).....	600
b. linear (153).....	600 to 1200

Estimate 3
Lifetime dose adjusted to body weight by the expression mg/kg/lifetime (human)=mg/kg/lifetime (rat)

Method of extrapolation	Number New Cancers/year
a. linear (23).....	15,000

Note: Table adapted from OTA Report, #55, Cancer Testing Technology and Saccharin, Oct. 1977 (56).

to low doses have a sizable effect on the estimated human risk. As mentioned above, there is no scientific evidence that one method is more valid than another. All that can be done is to include consideration of the wide variation in risk estimation when using the data to make any type of decision.

4.5 Hazard Identification and Hazard Evaluation for PCBs

As discussed in Chapter Two, the problem of widespread contamination of the environment with PCBs was first recognized in the 1960s. By the 1970s, the problem of PCB contamination had been well documented. Comprehensive surveys reported the existence of PCBs in the atmosphere, soil, water, sediment, fish, wildlife and human blood and tissue (22, 57, 58).

The effects of PCBs on human health have also been extensively examined but interpretation of test results remains the subject of much controversy. Thorough reviews of the effects of PCBs on human health have been conducted by NAS (22), Hutzinger (57), Drill et al. (59), Kimbrough (60), Khan and Stanton (61), and Rodericks (23). The major health impacts appear to take the form of "subtle impairments rather than gross morphological or pathological changes" (22). Acute toxicity to either humans or wildlife rarely occurs, and those effects that have been observed

are the result of cumulative contacts over a long period of time.

There is a significant body of evidence indicating that PCBs are animal carcinogens (62, 63, 64, 65, 66). While the evidence is not conclusive, the compound has been classified as "probably carcinogenic for humans" by the International Agency for Research on Cancer (IARC). Table 4.2 shows the IARC carcinogeniety evaluation for a variety of chemicals and industrial processes. As indicated in the Table, IARC judged the degree of evidence regarding cancer and PCBs as "sufficient" from animal studies, but "inadequate" from human studies (13). Lack of sufficient epidemiological evidence is not surprising considering the generally low concentrations of PCBs in the environment, and the long time horizon for manifestation of carcinogenic effects. Inability to prove carcinogeneity conclusively from human studies is thus an insufficient basis to conclude whether PCBs are carcinogenic. Taking a conservative perspective, PCBs can be considered as potential human carcinogens.

Other health effects of PCBs suggested by animal studies include reproductive effects such as alterations in the menstrual cycle, births of abnormally small infants and greater frequency of early abortions. Infants born to primate mothers exposed to PCBs during gestation and

Table 4.2 Chemicals and Industrial Processes Evaluated for Human Carcinogenicity by the International Agency for Research on Cancer (IARC)

	Degree of Evidence	
	Humans	Experimental Animals
Chemicals and processes judged carcinogenic for humans		
4-aminobiphenyl	Sufficient	Sufficient
Arsenic and certain arsenic compounds	Sufficient	Inadequate
Abestos	Sufficient	Sufficient
Manufacture of auramine	Sufficient	Not applicable
Benzene	Sufficient	Inadeuqate
Benzidine	Sufficient	Sufficient
N,N-bis(2-chloroethyl)-2-naphthylamine (chlornaphazine)	Sufficient	Limited
Bis(chloromethyl)ether and technical grade chloromethyl methyl ether	Sufficient	Sufficient
Chromium and certain chromium compounds	Sufficient	Sufficient
Diethylstilboestrol (DES)	Sufficient	Sufficient
Underground hematite minine	Sufficiet	Not applicable
Manufacture of isopropyl alcohol by the strong acid process	Sufficient	Not applicable
Melphalan	Sufficient	Sufficient
Mustard gas	Sufficient	Limited
2-naphthylamine	Sufficient	Sufficient
Nickel refining	Sufficient	Not applicable
Soots, tars and mineral oils	Sufficient	Sufficient
Vinyl chloride	Sufficient	Sufficient
Chemicals and processes judged probably carcinogenic for humans		
Group A: Chemicals and processes with "higher degrees of evidence."		
Aflatoxins	Limited	Sufficient
Cadmium and certain cadmium compounds	Limited	Sufficient
Chlorambucil	Limited	Sufficient
Cyclophosphamide	Limited	Sufficient
Nickel and certain nickel compounds	Limited	Sufficient
Tris(1-aziridnyl)phosphine sulphide (thiotepa)	Limited	Sufficient
Group B. Chemicals and processes with "lower degrees of evidence."		
Acrylonitrile	Limited	Sufficient
Amitrole (aminotriazole)	Inadequate	Sufficient
Auramine	Limited	Limited
Beryllium and certain beryllium compounds	Limited	Sufficient
Carbon tetrachloride	Inadequate	Sufficient
Dimethylcarbamoyl chloride	Inadequate	Sufficient
Dimethyl sulphate	Inadequate	Sufficient
Ethylene oxide	Limited	Inadequate
Iron dextran	Inadequate	Sufficient
Oxymetholone	Limited	No data
Phenacetin	Limited	Limited
Polychlorinated biphenyls	Inadequate	Sufficient
Chemicals and processes that culd not be classified as to their carcinogenicity for humans		
Chloraphenicol	Inadequate	No data
Chlordane/heptachlor	Inadequate	Limited
Chloroprene	Inadequate	Inadequate

Note: Modified from OTA-H-138. Technologies for Determining Cancer Risks from the Environment. June, 1981 (13).

lactation also show some loss of immunological competence and learning and behavioral deficiencies (59).

Additionally, nonspecific health effects possibly attributable to PCBs include dermatological abnormalities, abnormal fatigue, abdominal pain, numbness of limbs, swelling of joints and chronic cough (22). Abnormal tooth development and anemia have also been associated with PCB exposure (66).

Methods to quantify noncarcinogenic health effects are not currently available. For pragmatic reasons, therefore, this study will focus on carcinogenic effects. If the benefits of reducing cancer risks to humans from PCBs appear substantial on their own, it will not be necessary to measure other benefits quantitatively. However, if the benefit of cancer risk reduction appears minor, other benefits should be considered.

4.6 Quantitative Risk Assessment for PCBs

The estimate of risk of cancer from PCBs used in this research is based on a FDA study (23). The study develops four estimates of the risk of cancer per year from PCBs based on two experimental studies; Kimbrough et al. (62) an a National Cancer Institute (NCI) study (23). In this research the risk estimates based on the Kimbrough data are relied upon most heavily, but one set of data from the NCI data is also used.

The NCI study is procedurally flawed in that the sample size used was smaller than that recommended by standard protocol for carcinogenic tests (24 animals versus the recommended minimum of 100). However, the results of the NCI test are consistent with the procedurally valid Kimbrough study in that both studies indicate that the liver is the target organ for toxicity, and a high incidence of proliferative lesions occurred in both studies (23). The NCI data is used here as a upper bound risk estimate of cancer risk posed by PCBs. It is interesting to note that the NCI risk data was used by the FDA in 1979 as the basis of their estimate of PCB-related risk (67).

In the Kimbrough study, Sherman female rats were fed Aroclor 1260 at 100 mg/kg in their diet for 21 months and sacrificed at 23 months. At this dosage, 26 of 184, and one of 173 in the control group, exhibited heptacellular carcinomas (62). The NCI study involved groups of male and female Fisher 344 rats (24 of each sex per group). They were administered Aroclor 1254 in the diet at 25, 50, and 100 pp for a period of 104-105 weeks. At the high dosage, 21 out of 48 rats from both groups exhibited heptacellular proliferative lesions and 4 out of 48 exhibited liver carcinomas and adenomas (25).

To extrapolate risk of cancer to humans from the Kimbrough study and the NCI study, the FDA used a linear

model. The model was justified by the assumption that it was the model least likely to underestimate risk. Although it was not specifically stated in the study, it appears that the risk estimates were corrected for species conversion on the basis of total lifetime exposure divided by body weight. It should be noted that the model used by the FDA -- linear, no threshold extrapolation, and relating animal and humans on the basis of total lifetime exposure divided by body weight -- has been reported to estimate human cancer incidence within a factor of 10 to 100 when compared to incidence measured by epidemiologic studies (13).

In order to calculate cancer risks to humans, the next step is to estimate exposure to PCBs. The FDA assumed that the PCB in fish was the same compound (Aroclor 1260) used in the lab test. To calculate human exposure, data on PCB in fish was obtained from FDA surveys conducted in 1978-1979. Mean PCB levels were calculated for the 11 species that contained the highest levels of PCBs. All other fish types were put in a 12th category. PCB contamination in fish was estimated for the situation of no tolerance, 2 ppm, 3 ppm, and 5 ppm. Rough approximation of the effect of a given tolerance level on mean PCB levels for each species was arrived at by eliminating samples with PCB levels greater than the assumed tolerance and recalculating the mean.

Data on the type, and mean daily amount of each type, consumed by the population was obtained from the National Marine Fisheries Service Study. The study included 25,947 eaters selected as a sample of all U.S. fish eaters. Total estimated daily exposure to PCBs was then calculated for the estimated 15.2% of the U.S. population assumed to eat the species of interest. Using the risk extrapolation and the exposure data, the number of new cancers/year in eaters of fish species of interest was calculated.

For the purpose of this study three levels of risk are delineated: high, medium and low. The purpose of using three estimates is to examine the sensitivity of the benefit valuation process to the risk estimates. The high risk estimate is based on total malignancy data from the NCI bioassay and a "heavy fish consumption" assumption. The low estimate is based on the Kimbrough data, assuming light fish consumption. The medium level estimate is based on the Kimbrough data but assuming heavy fish consumption. The risks, expressed as numbers of new cancers per year, are shown in Table 4.3.

4.7 Summary

This chapter has reviewed methods of identifying and evaluating the risks posed by hazardous substances and discussed some of the controversies and uncertainties surrounding the process. While the discussion is

Table 4.3 Number of New Cancers Per Year* - High, Medium, Low Estimate

Risk Level	Number of New Cancers Per Year			
	No Tolerance	5 ppm	2 ppm	1 ppm
High	50.6	46.8	34.3	21.0
Medium	16.3	14.7	10.0	6.7
Low	6.2	5.8	3.8	2.4

*Numbers of new cancers per year in the 15.2% of the U.S. population assumed to consume freshwater fish.

necessarily cursory, it serves to provide an understanding of the type of problems encountered in risk assessment. An important point made in the chapter was that many types of adverse health impacts posed by hazardous substances cannot easily be quantified. Methods do exist to quantify cancer risks, though even they are controversial.

Efforts to quantify the benefits of risk-reducing regulations must work within the constraints of available scientific data. Most importantly, the uncertainties surrounding the risk assessment process must be addressed in the economic analysis. This is most appropriately accomplished by using a range of risk estimates in the economic analysis and clearly identifying the assumptions on which the estimates are based.

It is in light of the above discussion, that the PCB risk data is presented. Use of three estimates of risk (high, medium and low) allows examination of the change in benefit estimates due to a change in the risk estimate. Moreover, use of a range of risk estimates acknowledges the range of uncertainty associated with the data.

5 APPLICATION TO PCBs

In this chapter, estimates derived from three benefit valuation studies are used to assess the value of reductions in risk from PCBs in fish. The specific focus is on the benefits of reducing the risk of cancer under four different tolerance levels for PCBs: 1 ppm, 2 ppm, 5 ppm, and no tolerance. As discussed in Chapter 3, lower-bound, middle-range, and high estimates of the value of reducing PCB risks are developed.

The chapter begins with a discussion of methodological issues. The three approaches to assessing the value of risk reduction, including some modifications, are then presented and compared and the overall range of estimates discussed. Whether the range can be narrowed is considered and best "point" estimates of risk reduction are developed. The policy implications of the risk reduction estimates are then addressed by examining the net benefits of each risk/tolerance scenario. Finally, the alternative approach to evaluating benefits, cost-effectiveness analysis, is applied and the results evaluated. The chapter concludes with a summary of the usefulness of the estimates for policy decisions.

5.1 Methodology

Before presenting the specific methods applied to generate the benefit estimates, some comments on the methodology are required. The basic theory is described in Chapter 3. Three points are considered here including the application of existing data, the terminology used to describe the results, and conversion of estimates to 1982$.

5.1.1 Application of Existing Data

The first issue to consider is that the study approach used here applies existing estimates of the value of risk reduction. Data was not collected on individuals' willingness to pay to reduce the risk of cancers from PCB exposure. This research instead applies existing empirical estimates of the value of reducing risk from each of the three models and multiplies that value times the various PCB risk estimates. In some cases, existing estimates are modified to develop more inclusive estimates of the value of risk reductions.

An important point concerning use of existing estimates is the type of risk reduction considered differs in the three studies. The adjusted wtp/hk model addresses the value of preventing one liver cancer, the exact risk considered in this study. The two wtp studies however, deal

with the value of preventing one statistical death. The risk of a liver cancer is obviously different from the risk of death, but the actual difference may not be great. Cancer can be assumed to eventually lead to death, perhaps after a painful illness. It is not improbable that some people would be willing to pay more to avoid cancer than some other quick and painless death. In any case, comparison between the value of avoiding cancer and death may not be far out of line.

5.1.2 Terminology Used to Describe Results

The definition of a benefit used in this study is somewhat confusing and is restated here to minimize the confusion. The benefits of a given tolerance level are defined here as the costs saved under the particular tolerance versus under a no tolerance level situation. These benefits, or cost-saved figures, are not presented until the end of the chapter. The numbers presented throughout the first sections of the chapter represent the dollar costs stemming from PCB-related cancers under a particular tolerance level. To reduce repetition, only the costs of the no tolerance situation are given in some cases. The no tolerance values represent the maximum dollar costs that would result from cancer if PCBs in fish were not regulated at all.

5.1.3 Conversion to 1982$

The estimates of the value of risk reduction applied to the PCB data were originally expressed in dollars ranging from $1967 to $1979. For purposes of evaluation, all values are converted to $1982 using the Consumer Price Index (CPI) with one exception--medical costs were converted to 1982$ using the Medical Price Index of the CPI.

5.2 The Lower Bound Estimate: The Adjusted WTP/HK Approach

The lower bound estimate of the benefits of PCB regulations is calculated using the adjusted wtp/hk methodology. As applied here, the process involves first developing an hk based estimate of the costs of cancer and then multiplying the present value of the hk values (i.e., foregone earnings estimates) discounted at the individual's opportunity cost of investment, and weighted by a risk aversion factor. The hk estimates include both foregone earnings and the estimated medical costs due to PCB cancers. This approach differs from that of Landefeld and Seskin who do not include medical costs in their figures. They are added here on the grounds that these costs are likely to be borne outside the family and thus not accounted for in an hk estimate based on foregone earnings only

The initial hk estimates are developed from data collected in an hk study by Hartunian, Smart and Thompson (hereafter referrred to as Hartunian).

As will be seen, the foregone earnings and medical costs are initially calculated by age and sex categories. For purposes of developing a lower bound value per life saved however, the foregone earnings and medical costs data for males, aged 35-44, are used as representative of one statistical life. This decision is necessary in order to make the lower bound value comparable to the middle and high bound benefit values of the range, which use one number based on empirical studies of middle aged men as the value per life saved for people of all ages and sex. (See section 5.2.4 below for further discussion of the implication of this choice.)

The initial hk estimates are then converted into adjusted wtp/hk estimates using Landefeld and Seskins estimates of individuals' opportunity cost of investment and risk aversion.

In order to apply the Hartunian hk model to the PCB case, the high, medium and low risk estimates of total new cancers per year from PCB in fish are broken down into number of new cancers per year by sex and age group. To illustrate the process Table 5.1 presents calculations of the age-sex breakdown for cancers from PCBs based on the medium risk estimate and a no tolerance situation. Data presented in Hartunian (based on data from the Third National Cancer Survey) are used for the disaggregation.

Table 5.1 Incidence of PCB-Related Cancers by Age and Sex, No Tolerance, Medium Risk Estimate.

Age/Sex Group	Incidence	Proportion	Cancers From PCBs/Age Group
Male			
0-14	145	.169	.014*
15-24	301	.342	.029
25-34	768	.873	.074
35-44	2241	2.548	.217
45-54	9673	11.000	.936
55-64	21130	24.028	2.045
65-74	28802	32.752	2.788
75+	24879	28.291	2.408
Total Males			8.512
Females			
0-14	84	.104	.008
15-24	175	.218	.017
25-34	634	.794	.062
35-44	2052	2.550	.199
45-54	7643	9.498	.740
55-64	15689	19.496	1.518
65-74	24440	30.370	2.365
75+	29750	36.969	2.879
			7.79

*This figure is produced by multiplying the actual proportion of cancers occurring in each age-sex group by the number of new cancers from PCB (at medium risk level, no tolerance). In this case, 16.3 new cancers are expected. Of these, 8.51 would occur in males, 7.79 would occur in females. Thus, for males, multiplying 8.51 times the proportion would result in the cancers from PCBs/age group.

Note that it is necessary to specify the type of cancer expected to result from PCB exposure in order to develop these calculations. In the animal experiments, the liver is the organ affected by PCB (62). Lacking further information, it is assumed that the liver is also the target organ in humans. In Hartunian, specific data on liver cancers is not presented; liver cancer costs are instead included in the broader category of digestive system cancers. It is likely that liver cancer costs would be slightly different than general digestive system cancers (personal interview, Michael Kamrin). However, in comparison with other data variability and uncertainties, the variation is considered insignificant to this research.

5.2.1 Calculation of Medical Costs

The Hartunian approach first entails estimation of total medical expenditures for each type of cancer by age, sex and stage of cancer when diagnosed. The model used by Hartunian to calculate medical costs is presented below in order to clarify how the cost estimates were developed. The model is as follows:

$$\text{Present value of costs (PVC)} = \sum_{n=1}^{99} (P^{i}_{L,s}(n) \cdot DC^{i}_{L,s}(n-L+1)) \qquad 5.1$$

where: n = the various ages of the individual (99 is the maximum age we considered)

L = the age at impairment onset

(n) = the probability that a person of sex s who acquires cancer i at age l will survive to age n

$DC^{i}_{L,s}(n-L+1)$ = the dollar value of the average annual medical costs generated by such persons during year (n-L+1) following cancer onset.

r = the discount rate

The variable $P^{i}_{L,s}(n)$, the probability that a person of sex s who acquires cancer i at age L will survive to age n, is calculated based on the survival rates of persons who get liver cancers as compared to the survival rates of persons in the general populations of the same age and sex. Hartunian obtained the survival data from U.S. Census life tables; and the statistics on survival from cancer from the Third National Cancer Survey (68).

The medical cost figures are based on hospital costs plus non-hospital costs. Hospital payment data was obtained by Hartunian from an indepth study of hospitalization and payment patterns by Scotto and Chiazze (69). Average hospital costs during the first and second years following diagnosis were calculated and used to project cost estimates for subsequent years. Non-hospital costs as calculated by Hartunian included cost of physicians services, private nursing, nursing home and attendant care, drugs, physical therapy, special equipment and prosthetics and other miscellaneous services. This data was primarily from the Third National Cancer Survey.

Using the model, Hartunian produces estimates of costs per cancer for persons of a given age and sex as shown in Table 5.2. As explained above, the cancer costs for the male, aged 35-44, will be used as the estimate of medical costs from PCB-related cancers.

Table 5.2 Estimated Medical Costs Per Cancer by Age and Sex

Age Group	Medical Costs of 1 Cancer by Age Group (1975$)	Medical Costs of 1 Cancer by Age Group (1982$)
Males		
0-14	5488.00*	9329.60**
15-24	11276.00	19169.20
25-34	10986.00	18676.20
35-44	11186.00	19016.20
45-54	10510.00	17867.00
55-64	8340.00	14178.00
65-74	7875.00	13387.50
75+	7341.00	12479.70
Females		
0-14	5172.00	8792.40
15-24	10721.00	18225.70
25-34	11351.00	19296.70
35-44	11615.00	19745.50
45-54	11480.00	19516.00
55-64	9987.00	16877.90
65-74	8669.00	14737.30
75+	7921.00	13465.70

*Estimate of total medical expenses required to treat one cancer diagnosed in 1975 in a male, aged 0-14. The cost estimates were developed by Hartunian et al (31) and are based on estimates of total hospital plus non-hospital costs generated by cancer victims and estimates of how long a person of a given age and sex will survive after getting the disease.

**Costs converted to 1982$ using the Medical Costs Index.

5.2.2 Calculation of Foregone Earnings Associated with PCB Related Cancers

The second step in the Hartunian model is to calculate lost or foregone output of patients suffering premature death or disability. Hartunian measures this in terms of the wages that would have been earned by the individuals if they had not become ill. Hartunian also attempts to include in the estimate the computed market value of unperformed housekeeping services.

Factors not included in the valuation include output losses generated by family members, friends and co-workers of the cancer patient and non-economic costs of disease and injury including pain, emotional deprivation, anxiety, etc. Although the researchers acknowledge these costs as potentially significant they maintain that "empirical difficulties associated with data collection and, in certain instances, attribution of cause, virtually always prevent their estimation" (31, pp. 7).

To calculate earnings foregone as a result of cancer, Hartunian compared earnings expectations of the patient at the time of initial cancer diagnosis with those realized

after diagnosis. Using information from mortality analyses and on the functional status of cancer survivors from the Third National Cancer Survey Project, they calculated the mean number of weeks during the first year that a previously employed patient with cancer would be out of work. Based on these results, they calculated the fraction of potential first-year productivity lost by cancer patients working before illness who survived and returned to work one year after diagnosis.

Using the Third National Cancer Survey, Patient Interview Book (PIB) unpublished data, and incorporating mortality/survival information, Hartunian estimated by age, sex and cancer type: (1) the fraction of potential first-year productivity actually generated by cancer patients ($\alpha^{i}_{L,s}$);(2) the proportion of previously employed cancer patients (including both previously employed patients and those engaged in homemaking activities) who survive and return to work one year after diagnosis ($\beta^{i}_{L,s}$). Incorporating the two parameters, they modeled the expected postmorbid earnings of a cancer patient as:

$$\text{Present Value of Postmorbid Earnings} = [\alpha^{i}_{L,s} \cdot Y_s(L) \cdot E_s(L)] + \{\beta^{i}_{L,s} \cdot [\sum_{n=L+1}^{85} P^{i}_{L+1,s} \cdot Y_s(n) \cdot E_s(n) \cdot (\frac{1+\delta}{1+r})^{n-1}]\} \quad 5.2$$

where:

$\alpha^{i}_{L,s}$ = fraction of potential first year productivity actually generated by cancer patients

$\beta^{i}_{L,s}$ = proportion of previously employed cancer patients (including previously employed patients and those engaged in homemaking activities) who survive and return to work one year after diagnosis

L = age at onset (+/or death)

s = sex

δ = average annual rate of growth in labor production (assumed 1%)

$Y_s(n)$ = mean annual earnings of employed people and homemakers in general population of age n and sex s measured at incidence year 1975

$E_s(n)$ = proportion of general population of age n and sex s employed in labor force or engaged in housekeeping

$P_s(n)$ = probability of a person in general population of age L and sex s surviving to age n

r = discount rate

The first term on the right side of the equation represents the present value of average earnings, and the second term represents the present value of average earnings generated in subsequent years by cancer patients.

Using the model described above, the Hartunian study estimates average postmorbid earnings for cancer patients of different ages, sexes, and diagnostic types and combined and averaged them to yield results for each of nine diagnostic

categories. They next subtract a cancer patient's postmorbid earnings from the estimate of his/her expected future earnings had he/she not contracted the disease to find the estimated net foregone earnings owing to the disease. Table 5.3 shows forgone earnings from cancer by age and sex. Again costs for a male, aged 35-44, will be used in this report.

5.2.3 Converting the HK Values to Adjusted WTP/HK Values

The estimated cost of foregone earnings from cancer for the representative group considered (male, aged 35-44) is $230,155 (1982$). The medical costs associated with the cancer are $19,016 (1982$). Two other adjustments must be made to convert these hk values to adjusted wtp/hk estimates: 1) the foregone earnings figure must be multiplied by a risk aversion factor to reflect assumed risk preferences; 2) the figure must be adjusted upward to reflect application of individuals' opportunity cost of investment as opposed to the social opportunity cost rate.

Application of the risk aversion factor is justified by the assumption that the value of a person's life, based on private decisions, is substantially greater than the discounted present value of future earnings. Evidence to support this assumption can be found by examining the purchase of life insurance. For a representative life insurance policy, premiums are approximately 1.6 times the

Table 5.3 Estimated Foregone Earnings per Cancer by Age and Sex

Age Group	Foregone Earnings per Cancer $1972, r = 6%	Foregone Earnings per Cancer $1982, r = 6%
Males		
0-14	117720.00*	188352.00**
15-24	159551.00	255281.60
25-34	172638.00	276220.80
35-44	142847.00	230155.20
45-54	95982.00	152571.20
55-64	34690.00	55504.00
65-74	3740.00	5984.50
75+	373.00	596.80
Females		
0-14	83372.00	133395.20
15-24	103735.00	165976.00
25-34	101095.00	161752.00
35-44	82148.00	131436.80
45-54	54208.00	86732.80
55-64	24334.00	38934.40
65-74	7095.00	11352.00
75+	1456.00	2329.60

*This figure refers to the estimate developed by Hartunian of earnings foregone by one male, aged 0-14, who got cancer in 1975. As explained in the text, the estimate is calculated based on expected years of survival, first year productivity following cancer onset, expected productivity in subsequent years, and expected income during those years.

**Costs converted to 1982$ using the Consumer Price Index.

value of claims. In other words, people are willing to pay a premium on life insurance in excess of the payout of claims that they expect to receive (21). The benefit of the life insurance protection is apparently worth at least 1.6 times the amounts paid for the policy. Given this observation, it is reasonable to conclude that people would value a reduction in some type of risk to life in a similar risk averse fashion. In fact, paying for risk reduction protection, such as a PCB regulation, would actually keep an individual alive longer, which insurance would not do. The actual aversion factor for valuing the risk reduction from PCB programs may be higher than the life insurance factor. The figure of 1.6 will be used here however.

To adjust the foregone earnings and medical cost data to reflect application of a lower discount rate, a sensitivity analysis conducted by Hartunian was used. Hartunian found that use of a 2% versus a 6% discount rate in calculation of foregone earnings, raised estimates by 34%. The foregone earning estimate is therefore multiplied by 1.34 to incorporate the difference. For medical costs, Hartunian found that using a 2% vs a 6% discount rate, raised the estimates by 11%. The medical costs are thus multipled by 1.11 to reflect the cost increase.

The adjustments to the hk figures to obtain an adjusted wtp/hk estimate are summarized in Table 5.4. The final

Table 5.4 Adjusted WTP/HK Estimate of the Value of Saving One Life

1.	Hartunian estimate of the earnings foregone by a male, aged 35-44, who gets cancer, calculated at a 6% discount rate (1982$)	$230,155
2.	Adjust figure upward to reflect use of individual's opportunity cost of investment (2%) vs the social opportunity cast of investment (6%); multiply by 1.34	x 1.34 = 308,408
3.	Multiply by risk aversion factor of 1.6	x 1.6 = 493,452
4.	Adjust medical costs by 1.11 to reflect individual's vs social opportunity cost of investment and add	19,016 x 1.11 + = 21,108 514,560

LOW ESTIMATE = $514,560

figure of cost per cancer is $514,560. This value will be the lower bound estimate used in this study. The value is multiplied by the number of new cancers from PCBs under various tolerance levels (see Table 4.3) to obtain total costs from PCB related cancers. The lower bound estimates are shown in Table 5.5.

5.2.4 Summary Comments -- Medical Costs

Medical costs per cancer as estimated by Hartunian are shown in Table 5.2. As can be seen in the Table, these costs range from a low of approximately $9000 (1982$) for a female, aged 0-14, to a high of approximately $20,000 for a male, aged 35-44. In general, women generate slightly more medical costs as a result of cancer than do men, primarily because of their higher survival rates (reflected in variable $P_{(n)}$ in equation 5.1). The sensitivity of costs to age at diagnosis (variable L) is reflected in the higher costs associated with patients under age 65, compared with patients 65 years of age and older.

Table 5.5 Cost of PCB-Related Cancers Adjusted WTP/HK

	No Tolerance	5 PPM	2 PPM	1 PPM
Low Risk	3,190,272	2,984,448	1,955,328	1,234,944
Medium Risk	8,387,328	7,564,032	5,145,600	3,447,552
High Risk	26,036,736	24,081,408	12,503,808	10,805, 760

It must be stressed that while the disaggregated data appears useful to help understand the distribution of costs between age groups and sexes, the degree of confidence which can be placed on such relatively small cost variations is limited. For one thing, there is a high degree of uncertainty surrounding many of the assumptions on which the estimates are based, such as the assumption that the liver is the target organ for any PCB-related cancer. While the assumption represents best efforts to describe the risk process, it is not of sufficient strength to permit reliable comparisons of very small cost variations. Similar types of assumptions are made throughout the risk assessment process. A second point concerning putting too much weight on the variations in medical costs is that the fluctuations are insignificant compared to the variations expected when different benefit valuation estimates are employed (i.e., the adjusted wtp/hk approach versus one of the wtp approaches). For example, it is likely that the estimate of the value of preventing one cancer, obtained using the wtp method, will be many times greater than the value obtained using the adjusted wtp/hk method. In comparison, the variation in medical costs of cancer between men and women is only around $7,000. The effect of age and sex on the cost estimates thus appears far less important than the choice of benefit value used. Given this observation, the

use of medical costs from one age and sex group apply to all PCB cancers seems reasonable.

5.2.5 Summary Comments -- Foregone Earnings

The estimated earnings forgone per cancer are shown in Table 5.5, disaggregated by age and sex. The age-related distribution of foregone earnings reflects the rapid reduction of earnings with age. Also, as expected with this methodology, earnings foregone by males are almost twice as great as those foregone by females.

The problems associated with the medical costs data in terms of not being able to place too much reliance on the disaggregated values also apply here. Again, while the disaggregated values are useful to point out general trends (or biases) in the hk valuation approach, the variations between age groups and sexes are neither very reliable given the risk data, or significant in the context of the variations between benefit estimates from different studies. Therefore, the use of foregone earnings from one age group and sex seems a reasonable approach. Again, the group consisting of men aged 35-44 was chosen because it is the group most similar to those examined in the labor market studies.

5.3 Middle Estimate: Thaler and Rosen, Labor Market Survey

The second set of data used to estimate the benefits of PCB regulations is taken from a well known labor market

study by Thaler and Rosen (34). The study was selected both because the estimates from the study seem to represent the middle range of values obtained in research of this type and because the research effort is one of the earliest and most carefully done studies of its type.

Thaler and Rosen estimated the influences of numerous variables, including risk, on occupational wage differentials. They applied data on 900 male workers in 37 risky occupations from the Survey of Economic Opportunity to identify the industry and occupation of a sample of workers, along with their earnings and other job characteristics. Data provided by an insurance industry organization was used to measure the occupational risk associated with each industry/occupation category. Occupational risk was measured by excess mortality from all causes. Other variables were used to control for the influence of age, education, race, geographic location on wage rates within the sample. Regressions were run in both linear and semilog linear form. There was no statistical basis for choosing one functional form as superior to the other (34). Note that because of the numerous formulations of the Thaler and Rosen estimating equation, it is only discussed in general terms here.

Thaler and Rosen estimated each functional form in two alternative specifications with differents sets of socioeconomic control variables. The linear functional form dictated a constant marginal wtp for all members of the sample. When this estimate was applied to calculate the

aggregate value of a statistical life, the results are $176,000 and $160,000 (1967$) for two alternative specifications. When the semilog form was used, the marginal wtp varied across the sample. Marginal wtp was evaluated at the mean, resulting in aggregate values of a statistical life of $136,000, or $189,000 for the two specifications. Thaler and Rosen conclude that their best estimate of a statistical life is $200,000 plus or minus $60,000. The upper bound value of 260,000 is used here in order to develop a conservative, middle range estimate.

Based on work by Bailey (21), several adjustments are made to the Thaler and Rosen estimate. First, it is noted by Bailey, that workers in risky jobs, such as those studied by Thaler and Rosen, have lower wages than other workers despite compensation for risk. A straightforward way to adjust for the income difference between high-risk and all workers is to multiply the wtp value obtained by Thaler and Rosen by the ratio of national income per worker to the Thaler-Rosen earnings figure per worker. In 1967, the national income per worker was $8,089; the Thaler and Rosen figure was $6,600. The Thaler-Rosen figure is adjusted upwards by multiplying by 1.23 (8089/6600 = 1.23).

A second adjustment suggested by Bailey is to consider the third party affect of the loss of indirect business taxes as a result of workplace mortality. The reasoning is

that the sum of all household incomes is national income; the sum of all final products, net of depreciation of capital, valued at market prices is net national product. Net national product exceeds national income by the amount of indirect business taxes - sales and excise, primarily. The value of the loss of a worker's contribution to output includes these indirect taxes as well as the loss of his income. Because society loses the worker's labor earnings but not the income from other sources, the adjustment should be based on labor income only, not on national income per worker.

Bailey develops a figure to use to adjust for the loss of indirect business taxes in the following manner. In 1972-74 indirect business taxes added an average of 11.5% to the value of the product. The ratio of national product to national income, on the average, was .1115. Labor income was about 80% of total national income. Hence the indirect business taxes on labor income added 0.8 times 0.1115 to the total value of the product or approximately 9% (21, p. 62). Thaler and Rosen's estimate of the value of risk reductions is adjusted to account for for the third party effect of lost indirect business taxes by multiplying by 1.09.

A final adjustment is to add the third party effect of medical costs associated with a risk assuming that they are

not borne by the family of the victim. The medical costs of liver cancer, as calculated by Hartunian and cited earlier in this chapter, are used for this adjustment.

The Thaler and Rosen estimate of the value of saving one statistical life and the adjustments to the figure are shown in Table 5.6. The final figure of $925,329/life saved is used as the middle range estimate.

Estimates of PCB-related cancer costs are obtained by multiplying the Thaler and Rosen estimate by the number of new cancers from PCBs under various risk and tolerance assumptions. Table 5.7 shows these cost figures.

5.4 High Estimate: Smith, Labor Market Survey

The data used to generate a high estimate of the value of saving a statistical life is from a labor market survey by Robert Smith (42). Like the Thaler and Rosen study, the Smith research is often cited in reviews of the value of life literature. It is usually used as a high estimate.

Smith's study relies on the assumption that, in the absence of full ex post compensation for injuries, workers would obtain ex ante compensation in the form of wage premiums that would be sufficient to cover the losses imposed on them by injuries. An estimating equation is developed where an individual's wage is regressed against the probability of his sustaining an injury resulting in

Table 5.6 Adjusted Thaler and Rosen Estimate of the Value of Saving One Life

1.	High estimate of the wage differential associated with the riskiness of a job (Range: $140,000 - $260,000)	$260,000
2.	To reflect average worker income in 1967 (vs income of risky job workers): multiply by 1.23	x 1.23
3.	Adjust for indirect business tax losses: multiply by 1.09 (third party effect)	x 1.09
4.	Convert to 1982 dollars	x 2.6
5.	Add medical costs (third party effect)	+ 19,016
	MEDIUM ESTIMATE =	$925,329

Table 5.7 Cost of PCB-Related Cancers Medium Estimate - Thaler and Rosen

	No Tolerance	5 PPM	2 PPM	1 PPM
Low Risk	5,737,039	5,366,908	3,516,250	2,220,789
Medium Risk	15,082,863	13,602,336	9,253,290	6,199,704
High Risk	46,821,647	43,305,397	31,738,785	19,431,909

death. Independent variables included as determinants of wage are education, union membership, experience, class of worker, occupation, demographic characteristics, geographical dummies, migration variables, and industry dummies. Owing to the lack of data on occupational disease (the type of occupational risk most relevant to this study), only job safety risks were considered.

Smith's equation is as follows:

$$\text{Ln } W_{ij} = r^{A}P_{ij}B_{ij} + \text{Ln}W^{n}(H_j, Z_j) \qquad 5.3$$

where:

- W_{ij} = gross (observed) wage of the ith worker in the jth class of worker (class = type of industry)[1]
- W^{n} = net wage stated as a function of human capital (H) and other variables (Z)
- P_{ij} = probability of injury resulting in death during any hour of work[2]
- B_{ij} = hourly injury rate
- r^{A} = loss in wages associated with death
- Z = other independent variables including education, experience, union membership, class of worker, occupation, demographic characteristics, geographical dummies, migration dummies, and industry dummies.

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[1] Data on W_{ij} and determinants of W^{n} were obtained for 3,183 white males from May 1967 Current Population Survey.

[2] Obtained by Smith from SIC code from U.S. Department of Labor, Bureau of Labor Statistics, Injury Rates by Industry, 1966 and 1967, Report No. 360, 1969. Smith originally calculated values of reducing injuries that did not result in death. The value of such reductions was not found to be significant.

Using equation 5.3 Smith calculated that workers would be willing to sustain a 64% cut in wage to reduce the hourly chances of death by one in one million. At $4.00 per hour (1967 wages) this implies that 1,000,000 workers would be willing to pay $2.56 a piece or $2,560,000 in total, to avoid the loss of one life. Thus, according to Smith's study, workers act as if the value of saving one life is around $2.6 million (1967$).

Smith noted that the $2.6 million figure was several orders of magnitude greater than values calculated in other labor market studies. To check his numbers, he recalculated the equation under slightly different assumptions. The major change was to include only employees in the manufacturing industries versus all industries to eliminate as much as possible variation in job disability or union strength correlated with job safety. Such biases might exist if "strong union" industries such as coal mining or construction workers were included. With this revision, the total amount workers were willing to pay to save one statistical life was $1.5 million dollars (1973$).

Several adjustments can be made to the Smith figure to improve the estimate. The first adjustment is for the third party effect of the loss of indirect business taxes and involves adjusting Smith's value upward by multiplying by 1.09 (as discussed in section 5.3). The second adjustment,

also for third party effects, involves the addition of medical costs. The adjustments are shown in Table 5.8. The final, high bound value of saving one statistical life is $3,125,516.

To obtain estimates of PCB-related cancer costs, the Smith value is multiplied by the number of new cancers from PCBs under various risk estimates (note again that this calculation assumes that one cancer equals one death). The final high estimates of the value of PCB tolerances in fish are shown in Table 5.9.

5.5 Summary - Range of Estimates of PCB-Related Cancer Costs

Based on these three studies a range of the value of saving one statistical life is constructed. The low value, based on an adjusted wtp/hk approach is about $514,560. The middle level, based on Thaler and Rosen's labor market analysis, is $925,329 and the high value, based on a labor market study by Smith, is approximately $3,125,516 per life saved. The range is shown on Table 5.10.

The range of estimates of the maximum cancer costs from PCBs in fish (i.e., under a no tolerance situation), obtained using the three valuation studies and three risk assumptions, is shown in Table 5.11. The values seen to be slightly more sensitive to the level of risk assumed versus

Table 5.8 Adjusted Smith Estimate of the Value of Saving One Statistical Life

1.	Estimate of the wage differential associated with the riskiness of a job	$1,500,000
2.	Adjust for indirect business tax losses (third party effect): multiply by 1.09	x 1.09
3.	Convert to 1982 dollars	x 1.9
4.	Add medical costs (third party effect)	19,016
	HIGH ESTIMATE =	$3,125,516

Table 5.9 Cost of PCB-Related Cancers, High Estimate - Smith

	No Tolerance	5 PPM	2 PPM	1 PPM
Low Risk	19,378,199	18,127,993	11,876,961	7,501,238
Medium Risk	50,945,911	45,945,085	31,255,160	20,940,957
High Risk	158,151,110	146,274,150	107,205,200	65,635,836

Table 5.10 Range of Values for Saving One Statistical Life

Low	Medium	High
$514,560	$925,329	$3,125,516

Table 5.11 Cost of PCB-Related Cancers - No Tolerance*

	Adjusted WTP/HK	Thaler & Rosen	Smith
Low Risk	3,190,272	5,737,039	19,378,199
Medium Risk	8,387,328	15,028,863	50,945,911
High Risk	26,036,736	46,821,647	158,151,110

*These figures represent the range of maximum estimated costs of PCB-related cancers. The benefits of the PCB tolerance levels will be determined in terms of how much each tolerance reduces costs relative to the no tolerance situation.

the benefit value applied. Changing the risk estimate applied, from low to high, causes the cost estimates to increase approximately seven- to eight-fold. Changing the estimate of the value of a statistical life from low to high, on the other hand, causes the estimates to increase approximately six-fold.

Looking at the data more closely, it can be seen that the cost of not regulating PCBs in fish at all, based on a low level of risk, ranges from $3,190,272 using the adjusted wtp/hk approach to $19,378,000, using the Smith's labor market estimate. If the high level estimate of risk is used, total cost estimates range from $26,036,736 (adjusted wtp/hk estimate) to $158,151,110 (Smith's estimate). Application of the intermediate risk estimate leads estimates of $8,387,328 (adjusted wtp/hk approach) to $50,945,911 (Smith's estimate).

5.5.1 Narrowing the Range of Estimates and Developing A "Best Point" Estimate

The range of maximum costs of the PCB-related cancers (from $3,190,272 to $158,151,110) is too great to provide much meaningful policy information to decision-makers. If some of the sources of variation between the estimates of cost per life saved could be clarified it might be possible to narrow the range of estimates somewhat, and perhaps indicate when a lower or a higher estimate should be applied. Additionally, a most useful or "best point" estimate could be indicated.

Looking first at the lower bound estimates, the reasons for it being so much lower than the middle and high estimates are obvious. The estimate is based on the assumption that an individual's wtp to reduce risk can be derived from foregone income. The individual is assumed to be risk averse and a low discount rate is applied in calculating the present value of the risk reduction (so that the adjusted wtp/hk estimate is higher than traditional hk estimates). However, the reliance on foregone income measurements keeps the estimate low. Other components of the value of living are not included in the measure. Although presented here as a lower bound, most analysts agree that such income based measures underestimate the value of risk reduction.

Understanding the variation between the two labor market studies requires a harder look. Some possible reasons for the variation can be discerned by looking at the methodologies employed. For example, Thaler and Rosen considered only high risk industries. It is possible that workers in such industries self-selected the risky jobs and are less risk averse than the general population. This would be one factor in the lower Thaler and Rosen estimate. On the other hand, the Smith study used occupations as a control variable in the analysis. This approach may have made it difficult to distinguish between the part of the wage that was due to risk and that due to other

characteristics of the job, possibly resulting in some upward bias in the estimate. Another comment about the Smith study is that Smith originally sampled all industries and then later, redid the study focusing soley on manufacturing industries. All other methods and assumptions were kept the same in the two analyses yet a difference in the value of risk reduction of over $1 million was observed. While some of the variation could be attributable to the difference in the two groups studied, another possibility is that the use of aggregated occupational data led to error. The underlying idea is that with job risks reported only for industry averages, the wage differentials could be smaller and, because they were averages, could mask actual variation among occupational categories (again, making it difficult to discern that part of high wages due to risk versus other job characteristics).

It is worth noting how other researchers' estimates of the value of life compare with the Thaler and Rosen and Smith estimates. Two analyses of the labor market report estimates fairly close to the Smith figures. Viscusi (43) found an average (unadjusted) value of life of $2.5 million (1979$). Olson (44) found a value of life of about $3.2 million (1979$). Another labor market study by Dillingham (41), on the other hand, reported a value of life saving of approximately $458,000 [1978$, as adjusted by Bailey (21)].

Blomquist (45) in a study of seatbelt use reported a value of $715,000 (1978$, as adjusted by Bailey for third party effects).

Given this evidence from other studies supporting both the Smith and the Thaler and Rosen estimates, it is not possible to definitively identify one value as more valid than the other. However, for the purposes of assessing the PCB regulations it would be useful to suggest a best point estimate. Based on the criticisms of the two studies presented earlier, the midpoint value between the Thaler and Rosen and the Smith estimate would be a reasonable best point estimate. The Thaler and Rosen value is possibly a low estimate because it is based only on workers who self-selected risky occupations. The Smith estimate, on the other hand, may be biased upwards because of the aggregated data used and the difficulties in separating out the component of wage attributable to risk versus other job characteristics. The midpoint value between the Thaler and Rosen and the Smith estimates represents a compromise between the two points. The best point estimates, calculated for various tolerances and risk estimates, will be referred to throughout the discussion of the PCB benefit calculations. The values are shown in Table 5.12.

Table 5-12 Best Point Estimates - Costs of PCB-Related Cancers

Risk Level	No Tolerance	5 PPM	2 PPM	1 PPM
Low	12,557,619	11,747,451	7,696,606	4,861,013
Medium	33,014,387	29,773,711	20,254,225	13,570,331
High	102,486,379	99,789,771	69,471,992	42,533,873

5.6 Calculation of Benefits

The values presented in Table 5.12 are estimates of the maximum costs of PCB-related cancers expected with no tolerance regulation of PCBs in fish. With this information the benefits of alternative PCB tolerance levels can be calculated. As discussed in Chapter 3, benefits are defined as the savings in health costs achieved under each regulatory option. The benefit stemming from a given tolerance level is the difference between the health costs incurred at the tolerance level and the health costs of a no tolerance situation. For example, to find the benefit (i.e., cost savings) of a 5 ppm tolerance, using the adjusted wtp/hk method and a low risk assumption, the cost of cancers at the 5 ppm tolerance is subtracted from the cost of no tolerance: $3,190,272 - $2,984,448 = $205,824. Table 5.13 a, b, c presents estimates of the benefits of each tolerance level, using the three valuation methods and risk assumptions.

Given the benefit estimates, the question becomes how can the information facilitate the policy-making process. One approach to answering the question is examine the net benefits associated with each tolerance. In order to consider net benefits, cost data is now introduced.

Table 5.13 Calculation of Benefits - Cost Savings

	No Tolerance	5 PPM	2 PPM	1 PPM
a) Adjusted wtp/hk				
LOW	3,190,272	$2,984,448	$1,955,328	$1,234,944
C.S.*		(205,824)	(1,234,944)	(1,955,328)
MEDIUM	8,387,328	7,564,032	5,145,600	3,447,552
C.S.		(823,296)	(3,241,728)	(4,939,776)
HIGH	26,036,736	24,081,408	12,503,808	10,805,760
C.S.		(1,955,328)	(13,532,928)	(15,230,976)
b) Thaler and Rosen				
LOW	5,737,039	5,366,908	3,516,250	2,220,789
C.S.		(370,131)	(2,220,789)	(3,516,250)
MEDIUM	15,082,863	13,602,336	9,253,290	6,199,704
C.S.		(1,480,527)	(5,829,573)	(8,883,159)
HIGH	46,821,647	43,305,397	31,738,785	19,431,909
C.S.		(3,516,250)	(15,082,862)	(27,389,738)
c) Smith				
LOW	19,378,199	18,127,993	11,876,961	7,501,238
C.S.		(1,250,206)	(7,501,238)	(11,876,861)
MEDIUM	50,945,911	45,945,085	31,255,160	20,940,957
C.S.		(5,000,826)	(19,690,751)	(30,004,954)
HIGH	158,151,110	146,274,150	107,205,200	65,635,836
C.S.		(11,876,960)	(50,945,910)	(92,515,274)
d) Best Point				
LOW	12,557,619	11,747,451	7,696,606	4,861,013
C.S.		(810,168)	(4,861,013)	(7,696,606)
MEDIUM	33,014,387	29,773,711	20,254,225	13,570,331
C.S.		(3,240,676)	(12,760,162)	(19,444,056)
HIGH	102,486,379	99,789,771	69,471,992	42,533,873
C.S.		(3,240,676	(33,014,388)	(59,952,507)

*C.S. = Cost Savings

5.6.1 The Costs of PCB Tolerances

Cost data on the economic impact of the tolerances is available from studies by the FDA (70). The FDA estimates are based on the premise that if a certain percentage of fish species in a given area is violative, then a valid estimate of the economic loss would be to assume that the same percentage of the total catch would be condemned. It is acknowledged that this approach could lead to some over and underestimation of costs. For example, it would be unlikely that a fisherman would risk catching and selling any fish if 30% were expected to be inspected and found violative. In such cases, he would perhaps stop fishing, so that there would actually be a 100% loss. This underestimation would, however, be balanced by cases where a smaller percentage of fish were violative but were not inspected or condemned.

Using this approach, the FDA calculated that approximately 2% of total catch of freshwater fish would be condemned under a 5 ppm tolerance.[3] Under the 2 ppm tolerance, approximately 14% of the total catch would be lost and about 35% would be lost under a 1 ppm tolerance. Based on these figures, the landed valued of the condemned fish

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[3] Freshwater fish are the most highly contaminated with PCBs. Very few marine species have detectable levels of PCBs though some loss of shellfish is included in the cost estimates.

was calculated. These costs, adjusted for inflation, are shown in Table 5.14. Note that no adjustments were made for indirect costs such as potential unemployment or loss of income in the fishing and fish processing industry. These costs were considered secondary, and not relevant for use in comparisons with the primary (quantified) benefit of risk reduction. It is also important to point out that the fishing industry would likely act to minimize losses from a PCB tolerance level by shifting resources to a different type of fish, or perhaps fishing in an area where PCB contaminated fish were not common. The cost of the tolerance levels might thus drop the year following initiation of the regulation.

5.6.2 Net Benefits

To calculate net benefits, the estimated costs of condemned fish under each tolerance level are subtracted from estimated benefits (costs saved). The results are presented in Table 5.15a, b, c and d which shows net benefits using low, medium and high risk estimates and the adjusted wtp/hk, medium, high and best point estimates of benefits respectively.

Table 5.14 Cost of PCB Tolerances in Fish

	No Tolerance	5 PPM	2 PPM	1 PPM
One Year Cost* (1982$)	--	$ 790,000	$ 7,520,000	$21,120,000

*Landed value of commercial fish condemned because of PCB contamination over tolerance level.

Table 5-15 Net Benefits (Cost Saved - Cost of Fish Condemned)

	5 PPM	2 PPM	1 PPM
a) Adjusted wtp/hk			
LOW	* -$584,176	-6,285,056	-19,164,672
MEDIUM	* 33,396	-4,278,272	-16,180,224
HIGH	-1,165,328	* 6,012,928	-5,889,024
b) Thaler and Rosen			
LOW	* - 419,869	-5,299,211	-17,603,750
MEDIUM	* 690,527	-1,690,427	-12,236,841
HIGH	2,726,250	* 7,562,862	6,269,738
c) Smith			
LOW	*18,588,199	- 18,762	-9,243,039
MEDIUM	4,210,826	*12,180,751	8,884,954
HIGH	11,086,960	43,425,910	*71,395,274
d) Best Point			
LOW	* 20,168	-2,658,987	-13,423,394
MEDIUM	2,450,676	* 5,240,162	-1,675,944
HIGH	1,906,609	25,494,388	*38,832,507

*Indicates the maximum net benefit (or minimum net cost) for a given risk level and method of calculation. For example, net benefits are highest at the 1 ppm level for the high risk level of the best point estimate ($38,832,507).

The results are not uniform. Rather, the tolerance level that offers the greatest net benefit (or lowest net cost) seems to vary depending on which benefit value and risk estimate is applied. When the low (the adjusted wtp/hk value) or the medium (the Thaler and Rosen estimate) benefit values are applied, the 5 ppm tolerance provides the greatest net benefits based on the low and medium risk estimates while the 2 ppm tolerance offers the greatest benefits based on the high risk estimate. When the high bound value (the Smith estimate) or the best point estimates are applied, the 5 ppm tolerance provides maximum benefits based on the lost risk estimate, the 2 ppm tolerance provides maximum benefits based on the medium risk estimate, and the 1 ppm tolerance provides maximum benefits based on the high risk estimate.

From an overall perspective, the 5 ppm tolerance produces maximum net benefits (or minimum cost) no matter which benefit value is considered, in 6 out 12 cases. Two of these cases are negative, indicating the tolerance should be higher than 5 ppm. The 2 ppm level leads to maximum net benefits in 4 out of 12 cases and the 1 ppm tolerances produces maximum net benefits 2 times out of 12.

Looking at the best point estimates, the selection of the most appropriate tolerance level in terms of maximum dollar benefits, varies depending on the level of risk assumed. The difference in net benefits between the 5 ppm

and the 2 ppm tolerance levels for the low and medium risk levels is relatively small - about $2.5 million. However, the difference between the 2 ppm and 5 ppm tolerance levels based on a high assumption of risk is quite large -- the 1 ppm tolerance provides about $13 million more benefits than the 2 ppm tolerance. The final selection of tolerance thus appears to depend on the level of risk assumed. However, a 2 ppm tolerance is probably most appropriate if a high level of risk is assured.

5.7 Cost Per Cancer Prevented Estimates

The final approach considered to assess the benefits of PCB regulations in fish is cost-effective analysis. This is a straightforward method in which the estimated net cost and the reduced human risk at each of the proposed tolerances levels are estimated and compared. Specifically, the net change in cost from moving from one tolerance to the next is divided by the net change in number of new cancers to obtain a "cost per cancer avoided" figure.

The cost data used to generate the cost per cancer estimates is the same as the cost data used in the last section. It is shown in Table 5.16, along with the estimated marginal changes in costs of moving from one tolerance to the next. Given these marginal cost figures, the cost per cancer prevented is calculated.

Table 5.16 Direct Cost of Commercial Fish in Violation of PCB Tolerances

Tolerance	One Year Cost (1974$) of Commercial Fish (Landed Value)	% CPI 1974 - 1982	One Year Costs 1982$	Increase in Costs
No tolerance				
5 PPM	0.6 million	1.32	.79 million	.79
2 PPM	5.7 million	1.32	7.52 million	6.73
1 PPM	16.0 million	1.32	21.12 million	13.6

Results are shown in Table 5.17. The lowest cost is $210,000 per cancer prevented from changing from a no tolerance situation, to a 5 ppm tolerance, assuming a high risk level. The highest cost figure is almost $10,000,000 per cancer prevented when moving from a 2 ppm to a 1 ppm tolerance, assuming a low risk situation.

To see how the cost per cancer values compare to the estimated value of a statistical life used in this report, it is necessary to refer back to the benefit data before it is coupled with the PCB risk data. As discussed earlier, the benefits of preventing one cancer range from approximately $514,560 to $3,125,516. As can be seen in Table 5.16, the cost per cancer prevented at almost all of the tolerance levels, falls under the highest estimate of benefit per cancer averted of $3,125,516. However, if the low level of risk is used, the cost per cancer at the 2 ppm and 1 ppm tolerance, exceeds the maximum benefit value of preventing one cancer.

5.8 Summary

This chapter has applied the risk assessment/benefit valuation process to analysis of regulation of PCBs in fish. The results of the analysis vary depending on the level of risk assumed, and on the method used to quantify the value of risk reduction. Benefit values vary as much as eightfold through use of alternative risk estimates. Values

Table 5.17 Cost Per Cancer Prevented

Risk Level	NUMBER OF NEW CANCERS Prevented*				COST PER CANCER Prevented**			
	No Tolerance	5 PPM	2 PPM	1 PPM	No Tolerance	5 PPM	2 PPM	1 PPM
High	3.8	12.5	3.3		210,000	540,000	1,000,000	
Medium	1.6	4.7	3.3		490,000	1,400,000	4,000,000	
Low	.4	2	1.4		2,000,000	3.400,000	9,700,000	

*Change in number of new cancers prevented moving from a given tolerance to the next.
**Change in costs (value of fish condemned) moving from one tolerance to the next.

vary up to sixfold through application of alternative approaches to benefit quantification. By comparison, use of alternative discount rates or detailed demographic data has little effect on benefit values.

The value of preventing one cancer applied in this study ranges from $514,928 (the adjusted wtp/hk estimate) to $3,125,516 (the wtp estimate developed by Smith). Estimates of total benefits (costs-saved) if all PCBs could be eliminated (i.e., if all the cancers predicted under a no tolerance situation could be prevented) range from $3,190,272, based on a low estimate of risk and the adjusted wtp/hk benefit values, to approximately $158,151,110 based on a high estimate of risk and the Smith wtp values. The best "point" estimates of the benefits of such "100% effective" PCB regulation range from $12,557,619 under low risk assumptions, to $102,486,379 under high risk assumptions.

To evaluate the policy implications of the various tolerance levels, net benefits have been calculated. Again, the conclusions reached from analyzing net benefit data are

sensitive to both type of valuation method used and to level of risk. Based on the adjusted wtp/hk and the Thaler and Rosen estimates, the 5 ppm tolerance provides the greatest net benefits when the low and medium risk estimates are used while the 2 ppm tolerance maximizes net benefits when a high risk estimate is used. If the Smith or the best point estimates are applied however, the 5 ppm tolerances leads to maximum benefits based on a low risk estimate, the 2 ppm tolerance provides maximum benefits based on the medium risk estimate and the 1 ppm tolerance provides maximum net benefits based on the high risk estimates. Thus which tolerance level should be selected based on the benefit measures clearly depends on the level of risk assumed. However, it appears that overall the 2 ppm tolerance is the most appropriate tolerance assuming low or medium risk levels and the 1 ppm tolerance best based on a high risk estimate, according to the best point approach.

Finally, if the cost per cancer prevented is compared with the estimated benefit per cancer prevented, using the medium and high risk estimates, the cost are less that the maximum benefit estimate for all tolerances except for the 1 ppm tolerance with the medium risk estimate. If the low risk estimate is applied, costs per cancer exceed benefits per cancer avoided.

These estimates of benefits represent the cost-savings from preventing PCB-related cancers under different assumptions concerning risk level and type of benefit calculation used. Policy choices will depend ultimately on which risk and benefit assumptions are deemed most valid. It must also be remembered that there are many impacts not included in the numbers, both in terms of other benefits, such as discussed in Chapter 2, and additional costs (although many of the intangible benefits concerning reducing risks to life are included in the wtp estimates). These factors should be included in a final policy decision.

To put this analysis of the benefits of alternative tolerance levels in broader perspective it can be compared to a study conducted by the National Academy of Sciences (22), which included an analysis of the cost and benefits of all types of PCB regulations. The NAS study did not quantify the costs and benefits of each tolerance level in fish. Rather, a cost and benefit figure per kilogram of PCBs removed from the environment was estimated. Based on these calculations, PCB tolerance levels in fish were concluded the most cost effective approach to removing PCBs from the environment and thus minimizing their hazard to human health. Information such as this (i.e., comparison of the benefits of tolerance levels with other types of PCB

regulations) is important to final selection of tolerance level because it places the decision in a broader policy perspective.

6 CONCLUSIONS

6.1 Summary of Research

The central question posed in this thesis is whether it is useful to measure the benefits of food contamination regulations in monetary terms. To answer the question the study first developed a conceptual framework to facilitate identification of the range of benefits that might result from food safety regulation. The focus was then narrowed to the problem of valuing in dollar terms the reduction of cancer risks from PCBs in fish.

The research approach entailed extensive review of the literature on risk assessment and on valuation of reductions in risks to human health. A range of estimates of the risk of PCBs to human health was gathered from existing risk studies of the compound. A review of the economic valuation literature quickly revealed that there was little agreement in economic circles as to whether and how reductions in risks to health could be quantified. None of the available approaches seemed superior overall, leading to the first conclusion of the research, that application of a range of benefit estimates using several approaches, was the most appropriate method of quantifying regulatory benefits. To learn whether such an approach could yield useful information became a primary research objective.

To implement the study, estimates of the value of risk reduction developed using three variants of willingness to pay methodology were selected and applied, with some modifications, to the PCB data. The results were discussed in light of their sensitivity to a number of variables. The conclusions to the research are summarized in the next section.

6.2 Conclusions

6.2.1 Sensitivity of Results to Benefit Valuation Method

The estimates of the cost of health damage from PCBs in fish (and therefore the benefits of reducing the costs) vary up to sixfold through application of low, medium or high estimates of wtp for risk reduction. The adjusted wtp/hk values produce the lowest estimates of PCB related cancer costs. This is because the method only measures the impacts of the health damage on GNP, in terms of foregone income and medical costs. The approach assumes that these tangible impacts provide an adequate reflection of the value of life. However, when such an estimate is applied without regard to other components of the value of life, the overall benefits appear much smaller than they actually are. The adjusted wtp/hk estimates, at best, represent the lower bound value of preventing one death.

A second problem with the adjusted wtp/hk approach is that it requires information on the specific type of risk and the age and sex of the people affected by the risk. A major problem arises when this risk information is not readily available.. With many problems involving a health risk, including the PCB problem, the nature of the risk is not known with certainty. To develop the adjusted wtp/hk estimate therefore, assumptions have to be made as to what type of health risk is involved including the specific type of cancer anticipated, the degree of impairment caused by the cancer, the number of years of survival after onset of illness, etc. The validity of the assumptions and usefulness of the detailed data used in the the adjusted wtp/hk approach is questionable in analysis of PCB regulations. The degree of uncertainty surrounding the PCB risk estimates overshadows the precise cost data the adjusted wtp/hk estimates attempt to provide. The estimates thus may end up being "precisely wrong".

The adjusted wtp/hk approach does produce estimates of the value of risk reduction slightly higher than traditional hk estimates. The approach attempts to capture the empirical feasibility of the hk method while incorporating consideration of individual's preferences towards risk

the valuation process. In the adjusted wtp/hk approach, individuals are assumed to be risk averse, to value risks to life equivalently to other economic risks and to be income maximizers. These assumptions are incorporated in the valuation model through use of a low discount rate and a risk aversion factor. The resulting estimates are perhaps a more accurate reflection of how individuals value the possibility of losing future income. However, the adjusted wtp/hk estimates remain low because they are based only on foregone output and ignore other components of the value of life. However, the adjusted wtp/hk values remain more appropriate lower bound estimates of the value of risk reduction than the unadjusted hk estimates.

According to the adjusted wtp/hk approach, the value of preventing one cancer is about $514,560. The total possble costs of PCB-related cancers range from $3,190,272 (no tolerance, low risk) to $26,036,736 (no tolerance, high risk).

The medium and high benefit estimates are based on labor market application of wtp theory. These estimates attempt to measure both tangible and intangible values of risk reduction. The estimates used here are based on actual risk vs. income choices made by workers. Theoretically, all of the components of the value of living are implicitly included in these wtp values.

As pointed out in the review of labor market research in Chapter 3, different applications of the method have produced wide ranging estimates of the value of reducing risks and it is difficult to reproduce or verify any of the estimates. However, an individual's valuation of risk reduction would be expected to vary depending on the type of risk, the degree of pain and suffering involved, the expected quality of life after the risk occurred (if it wasn't death), a person's income and family situation etc. Therefore, it is possible that some of the variation in labor market wtp estimates is a result of actual differences in wtp for risk. However, some of the variation is also undoubtedly due to methodological and statistical problems.

Estimates developed by Thaler and Rosen were selected as the medium range benefit values. According to the Thaler and Rosen work, the value of preventing one statistical death (after adjustments for third party affects and income differences between the study group and workers at large) is $925,329. The estimated value of PCB rgulations ranges from $5,737,039 (no tolerance, low risk) to $46,821,647 (no tolerance, high risk).

An estimate developed by Smith was selected for the high benefit value. According to the Smith study (adjusted for third party effects) the value of preventing one

statistical death is $3,125,516. The estimated value of PCB regulations ranges from $19,378,199 (no tolerance, low risk) to $158,151,110 (no tolerance, high risk).

The calculation of a range of estimates expresses the uncertainty inherent in the process of valuing reductions in risks to life. This study has indicated that the endpoints of the range represent conservatively low and high risk value estimates. This implies that some value in between the end points of the range is likely to be the best point estimate dictated by the study.

The midpoint values between the Thaler and Rosen and the Smith estimates are selected as the best point estimates of the value of PCB regulations. These best point estimates range from about $12,557,619 (no tolerance, low risk) to $102,486,379 (no tolerance, high risk).

6.2.2 Sensitivity of Estimates to Risk

Estimates of the value of risk reduction varied approximately seven to eightfold as the risk assumption varied from low to high. The final choice of risk assumption is the responsibility of decision-makers, based (theoretically) on the perceived risk preferences of society.

It should be pointed out that the most crucial risk uncertainty in this study, is whether or not PCBs are carcinogenic. This study has proceeded under the

conservative assumption that they are carcinogenic. Only additional research will provide the final judgment on this question.

6.2.3 Net Benefit Estimates

The net benefits associated with each tolerance level were calculated to put the risk valuation data in a form useful for policy comparisons. It was found that if the low or medium benefit estimates were used, the 5 ppm tolerance offered the greatest net benefits for low and medium risk assumptions and the 2 ppm tolerance maximized benefits based on a high risk assumption. Based on both the high and best point estimates, the tolerance level which offered the highest net benefits varied according to risk assumption. Overall it appeared that the 1 ppm tolerance would be the best conservative choice if the low or medium risk assumption was used but the 2 ppm tolerance would be most appropriate based on a high risk estimate.

6.3 The Usefulness of Benefit Quantification

A key question of this research is whether the benefit quantification process has yielded information useful for analysis of regulation of PCBs in fish and more generally, whether it is a useful tool for food safety regulatory analysis. Based on this research, it is concluded that

quantification of risk reduction using a range of estimates is a valuable adjunct to, but not a replacement for, a broader policy evaluation process. Use of a range of quantitative estimates allows benefits to be expressed in concrete terms, yet does not downplay the uncertainty involved in such expression. Application of a range of values such as developed in this study can also be carried out quickly (if the appropriate risk data is available), an advantage when time and financial resources for policy analysis are limited. A broader approach than benefit quantification is required because so many regulatory impacts, such as the type of benefits discussed in Chapter 2, and other central issues such as the irreversibility of damage and the property rights of future generations are not taken into consideration. Additionally, the question of who will pay the costs of the regulations and who will receive the benefits, is not addressed in the quantification process. For example, in the PCB case, the short-term, dollar costs of the condemned fish are borne entirely by the fishing industry. The cost of health-related PCB damage is borne by the fish-consuming public, especially consumers of freshwater fish, primarily from the Great Lakes, and also by society at large through lost productivity, higher medical costs, etc. The cost of regulation of PCBs would be borne by all taxpayers. Also, importantly, regulation of PCBs would

require resources that might otherwise go to control some other toxic substance problem, perhaps affecting an entirely different group of people. Distributional questions such as these must be considered in the policy analysis process.

Ideally, benefit quantification would be just one aspect of the regulatory evaluation process. The process should begin with complete identification of likely impacts of regulation. Each of the impacts should then be described as fully as possible and, if feasible, expressed in some physical unit (such as number of people affected, number of new cancers, etc.). The distribution of the benefits should also be discussed. This information could be prepared for several alternative designs of a particular regulation and the alternative designs compared. Then, in conjunction with the above analysis, the value of the anticipated risk reduction could be expressed in dollar terms, using a range of values with the adjusted wtp/hk estimates as the lower bound and a wtp estimate as the high bound. The adjusted wtp/hk estimates would provide an estimate of the <u>minimum</u> cost to society, in terms of impact on GNP, stemming from a health hazard such as PCBs. The wtp estimates would provide a more inclusive and probably more realistic estimate of the value which society places on reduction of certain types of risks to health.

6.4 Future Research Needs

As stated above, it is felt that application of a range of benefit estimates, coupled with a descriptive impact analysis, is the most appropriate approach to regulatory analysis. Key factors in such an approach include: 1) quality of descriptive analysis; 2) accuracy and reliability of risk data; 3) use of the same range of benefit estimates in the various regulatory analyses conducted; 4) appropriate explanation of the benefit estimates used.

A key area in future economic research is to learn more about preferences and behavior in risk situations. Such research will facilitate more precise quantification of the value of specific types of risk reduction. Through better understanding of people's wtp for certain types of risk, application of more precise, risk reduction values could be supported with greater confidence. At this point, the dollar value of risk reduction can only be expressed with a range of values such as developed in this study.

The economics of risk reduction rests ultimately on accurate information on the nature of various risks. Only more research in toxicology and better data on human exposure to toxins will lead to a better understanding of risk, and therefore, to a better understanding of how risk reduction should be valued.

A final important field of research concerns overall improvement of the policy analysis process in the area of toxic substance regulation. This research must address the difficult issues of identifying and managing the multitude of risks of uncertain magnitude that exist in modern society.

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