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# The Role of Health Risk Assessment and Cost-Benefit Analysis in Environmental Decision Making in Selected Countries: An Initial Survey

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**Abstract**

This paper seeks to inform the current "regulatory reform" effort in the U.S. by describing how information from risk assessments and cost-benefit analyses is used by decision makers in six other industrialized countries. In Japan, Germany, the United Kingdom, Netherlands, Canada and the European Union decision makers deal with uncertainties associated with risk assessments differently than in the U.S. They are less likely to employ "default assumptions" to bridge uncertainties and instead tailor risk evaluations to the chemical in question. Furthermore, while U.S. agencies are sometimes required to pair information from risk assessments with data from cost-benefit analyses in order to estimate how much it costs to stem or avert environmental and health effects, the decision makers in the six study regimes primarily use such information to set standards, screen chemicals, and identify potential substitutes for hazardous chemicals. Respondents in the study countries say that both quantitative risk assessment and cost-benefit analysis presently contain too many uncertainties to yield meaningful results. However, trade liberalization and shrinking government budgets are stirring greater interest abroad in how the U.S. conducts and uses risk assessments.

Key Words: regulatory reform, risk assessment, cost-benefit analysis, international environmental regulation

JEL Classification No: Q28

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# The Role of Health Risk Assessment and Cost-Benefit Analysis in Environmental Decision Making in Selected Countries: An Initial Survey

Janice V. Mazurek[1]

## INTRODUCTION

This paper is an attempt to help inform the current debate surrounding "regulatory reform" by describing how information from risk assessments and cost-benefit analyses are used by decision makers in other advanced, industrialized countries. Environmental decision makers in Japan, Germany, the Netherlands, United Kingdom, Canada, and the European Union, for several decades, have used both qualitative and more formal quantitative health risk assessment techniques to compare chemicals and set standards designed to protect human and environmental health. By examining how other countries use these tools, we hope to gain a greater understanding of their potential applications, as well as limitations in the U.S.

In the U.S., techniques to assess potential health risks associated with substances such as food hazards were pioneered by the U.S. Food and Drug Administration nearly 40 years ago. Since around 1975, environmental regulators in the U.S. have formalized some of these techniques into complex quantitative exposure assessment models that generate probabilistic estimates on the effects of human exposure to hazardous substances.[2] While health risk assessment tools have been dramatically refined over the past two decades, they nonetheless require the researcher to make a number of scientific and policy assumptions.

To help bridge some of the scientific uncertainties that arise in the process, U.S. regulators have attempted to standardize risk assessment procedures. While the procedures may enable scientists to better conduct the exercise, some say that such procedures have resulted in risk estimates that are based on overly conservative assumptions about the degree of potential hazard. Some maintain that conservative risk assessments result in regulations

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[1] The author is a Research Associate in the Center for Risk Management, Resources for the Future.

[2] Dennis J. Paustenbach. "A Survey of Health Risk Assessment," in D. J. Paustenbach, ed., *The Risk Assessment of Environmental and Human Health Hazards: A Textbook of Case Studies* 27 (1989).

where the additional risk reduction to people is outweighed by the cost of controlling the substance in question.[3]

In response to the perception that risk assessments in the U.S. lead to excessive regulation, approximately twenty proposals regarding the use of risk assessment as a tool for improving environmental decision making were introduced in the U.S. Congress in 1993-1995.[4] The legislative initiatives are designed to improve how federal regulators evaluate health risks and costs associated with reducing risks.

For the most part, the congressional proposals seek to solve the purported problem of overly conservative assumptions by requiring assessors to employ "best" science and "best" estimates, or estimates that deal with averages, instead of outliers, such as "maximally exposed" individuals. Many risk assessment experts counter that in the context of so many bridging assumptions, mandates that require estimates to be based on "best" procedures will do little to reduce the uncertainties embedded in the nascent discipline.[5] Instead of specifying what assumptions risk assessors use, many experts counter that Congress must understand that risk assessment would benefit more from clear, thoughtful statements about the uncertainties involved in a risk assessment and identification of the assumptions that the analyst used to bridge them.[6]

In order to contrast how analysts in other countries attempt to deal with data that are often incomplete or inconclusive, the standard, four-stage U.S. risk assessment paradigm is briefly described below, along with some of the major uncertainties that arise at each stage. Based on this information, the analysis examines how six other regimes use information from risk assessments to make environmental decisions. The paper then examines whether cost-

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[3] *Id.*

[4] Linda-Jo Schierow, "Comparison of Environmental Risk Provisions in the 103d Congress," 5 *Risk* 283 (1994).

[5] See, for example, *Setting Priorities, Getting Results: A New Direction for EPA.* A National Academy of Public Administration Report to Congress, (1995). For a more critical perspective, see Adam M. Finkel, "Who's Exaggerating," *Discover*, May (1996).

[6] *Id.*

benefit analysis is used in conjunction with information from risk assessments to evaluate environmental regulations.

## METHODS

The six regimes were chosen because their economies and environmental management systems most closely mirror those of the U.S. and thus are more likely to make it possible to compare the use of decision-making tools. In each of these regimes, numerous public agencies at the national, regional, and local level, as well as regulated entities conduct health risk assessments to identify potential health effects associated with exposure to certain substances.

The paper's primary focus is on national environmental and health ministries because they are most analogous to the U.S. Environmental Protection Agency (EPA), one of the primary foci of the current Congressional debate on risk assessment and cost-benefit analysis. It is therefore not possible to infer from these results that a country as a whole fails to employ or employs risk assessment or cost-benefit analysis: the results do not apply to firms, regional government, or research institutions which may very well employ techniques identical to those used in the U.S.

Due to time and resource limitations, the data used to make the comparisons among selected countries are from surveys and follow-up telephone interviews. Ideally, the data would be developed through site visits in each country and in-person interviews with relevant scientists and regulatory officials. This study used telephone interviews primarily with representatives in national environment and health ministries in the five countries and the European Union. The names of interviewees appear at the end of the report.

To further narrow the scope of this exercise and focus on risk assessments that deal with human and environmental health, this report focuses primarily on how the national environmental and occupational health agencies select and control the manufacture, use, and licensing of chemicals, especially a subset of suspected carcinogens known as genotoxins. As the name suggests, genotoxins act through genetic mechanisms to trigger cancer. Among the types of analyses conducted by national agencies, health risk assessment of new and existing

chemical genotoxins are common to the six regimes reviewed, and methodologies are thus easiest to compare.

While telephone interviews helped to indicate whether national environmental health and safety agencies use risk assessment and cost-benefit analysis to make decisions, the bulk of data on risk assessment methods is drawn from unpublished manuscripts, draft legislation, and position papers. Three published references to risk assessment methods in other countries were located in the literature.[7] Of these, only one study conducted by the Office of Technology Assessment (OTA) in 1993, employs surveys and interviews to develop a framework to compare how other countries conduct risk assessments. The OTA work appears as an appendix to a study that focuses on health risk assessment in the United States.[8] The limited data reported here are largely consistent with OTA findings. The only notable difference since the 1993 OTA survey involves changes in procedures that have resulted since 1994, when the European Union (E.U.) issued risk assessment guidelines to member states.

The three studies referenced here primarily focus on how other countries conduct risk assessment, but have less to say about how decision makers use the information generated by the procedure.[9] This work focuses more on how decision makers use the information.

## TERMS AND CONCEPTS

Within the United States, there exist many nuances in risk terminology. Internationally, the definitions vary even more due to differences in language, laboratory practices, political and institutional systems, and cultural outlook. Japan, for example, has no equivalent term for "health risk assessment" and "cost-benefit analysis."[10] Where similar terms exist, definitions

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7 Ronald Brickman, Shiela Jasanoff and Thomas Ilgen. *Controlling Chemicals: The Politics of Regulation in Europe and the United States*. Ithaca: Cornell University Press. (1985); "Researching Health Risks," U.S. Congress, Office of Technology Assessment, 1993, 187-207; Dennis J. Paustenbach, "Retrospective on U.S. Health Risk Assessment: How Others Can Benefit," 6 *Risk* 283 (1995).

8 Office of Technology Assessment, *supra* note 7.

9 Paustenbach, *supra* note 7.

10 While it is not among the countries examined for this report, OECD member, Italy, also lacks an established definition of "risk." Italy also lacks an institutional structure designed to deal with environmental risks.

vary dramatically, or are often the source of extreme controversy. For example, some countries sharply differ in how "quantitative risk assessment" (QRA) is defined.[11] The risk lexicon is therefore sufficiently complex to warrant further discussion here. Significant departures from standard U.S. definitions are noted here and in the body of the text that follows.

Of all the following definitions, risk is the most fundamental concept and perhaps the most difficult to precisely define, in part because different people tend to perceive risks differently.[12] Typically, a health *risk* is defined as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. Risks can be calculated for individuals or populations. Sometimes, risk is stated in terms of numeric probability, such as "1-in-1,000,000 lifetime cancer risk associated with exposure to Chemical X."[13] In general, hazards may include natural hazards such as hurricanes, or potentially hazardous technology such as nuclear plants. In the context of this discussion, hazards are understood as certain chemicals.[14]

*Health risk assessment* is a distinct discipline based on toxicology data that is used to make predictions about potential health effects associated with exposure to hazardous substances. As conducted in U.S. federal agencies, the process is designed to identify an environmental hazard; describe the potential adverse effects to of exposure to a hypothetical individual; and to understand the scope of adverse effects to a given population. The assessment also considers the uncertainties involved in making estimates throughout each step of the process (**Figure 1**).

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[11] Office of Technology Assessment *supra* note 7.

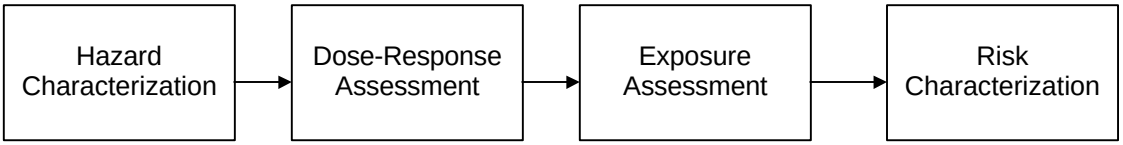
[12] Ortwin Renn," Concepts of Risk: A Classification," in Sheldon Krimsky and Dominic Golding, eds, *Social Theories of Risk*, (London: Praeger, 1992) .

[13] J. Clarence Davies, "Comparative Risk Analysis in the 1990s: The State of the Art," in *Comparing Environmental Risks: Tools for Setting Government Priorities* (Washington, D.C.: Resources for the Future, 1996).

[14] Some countries define environmental risk more broadly. In the Netherlands, for example the term encompasses nuisances such as odor and safety hazards (Dutch National Environmental Policy Plan, 1991).

**Figure 1**

**Four Stages of Risk Assessment**




Source: *Risk Assessment in the Federal Government.* National Research Council, National Academy of Science, 1983.

The first step, *hazard identification*, tends to require the analyst to make the fewest simplifying assumptions.[15] Hazard identification is a process where analysts use available evidence to determine whether a substance is linked to a particular human health or environmental effect. Evidence is derived from three different types of data: human epidemiology, long-term animal bioassay, and short-term mutagenicity tests. Epidemiology data are derived from health effects observed in humans. Data based on how chemicals affect humans are harder to develop in part because it is difficult to know when an observed health problem is linked to an exposure to a certain substance. In the case of carcinogens, making such links is further complicated because it often takes many years after initial exposure for cancer to develop. Human data also are in short supply because it is simply not feasible (or ethical) to administer doses of suspected carcinogens to people in order to see what health effects may result.

As a result, researchers typically use data from long term animal bioassays. Bioassay is often a time-consuming and costly process where researchers administer doses of a substance to lab animals in order to induce tumors. The third data source, short-term mutagenicity testing, is less time-consuming and often more cost-effective method where chemical mutagens are used to further flag potential chemical carcinogens.

Evidence used to identify potential hazards tends to vary in quality, and results are often conflicting. That is, some studies are better than others due to a number of factors

[15] Paustenbach, *supra* note 7.

including sample size and the duration of the experiment. Furthermore, some studies may illustrate a positive association between a dose of some chemical and a health effect, where others may fail to demonstrate a link.

When confronted with conflicting information, the assessor must decide how much weight to place on the available evidence. In the United States, regulators typically deal with such issues by choosing a uniform, or default set of assumptions, which are applied to each substance assessed. So, for example, when assessors are confronted with evidence that shows both a positive and negative association between a substance and a health effect, guidelines might instruct analysts to err on the side of caution and favor studies that show a positive link between exposure and an observed health effect.[16] As illustrated below, most of the countries examined differ from the U.S. in the degree to which analysts employ a "weight of evidence" approach to assess the quality of the data used to identify potential hazards. That is, assessors in other countries would be more likely to employ hazard identification studies that show both negative and positive lab test results.

The second step in risk assessment, the *dose-response assessment* is a way to estimate the relationship between exposure to a harmful substance and the resultant harm.[17] Because data on the human health effects due to exposure are in short supply, dose response assessment typically requires researchers to employ sophisticated mathematical techniques to extrapolate health effects observed in rodents administered relatively high doses to effects which could be observed in humans.[18] In the U.S., such techniques are known as low-dose extrapolation models. Outside the U.S. they are sometimes called quantitative risk assessment (QRA).

Of the four steps, dose response assessment may contain the most uncertainty in the risk assessment process because it is difficult to know whether is it is realistic to assume that effects observed in animals administered high doses will accurately reflect what people

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[16] Brickman, et al. *supra* note 7.

[17] Davies, *supra* note 13.

[18] Daniel Krewski, D. Murdoch & James R. Withey, "Recent Developments in Carcinogenic Risk Assessment," 57 *Health Physics*, 313 (1989).

encounter in their everyday environment. Related to the extrapolation problem is the fact that humans differ so significantly in size, weight, and metabolic function from lab animals. In the context of carcinogens, establishing links between suspected substances and tumor development is further complicated because scientists still do not fully understand all the mechanisms that may trigger cancer. Finally, traditional math models are primarily based on a limited range of carcinogenesis induced by ionizing radiation or one particular class of chemical carcinogens known as "genotoxins," which interacts with DNA in the cancer-formation process. Such models may be inappropriate for other kinds of chemical carcinogens, some of which may operate through different mechanisms.[19]

The methods employed in low dose extrapolation (QRA) are another source of uncertainty for two essential reasons: First, the data are derived from statistical models and not biological information from epidemiological studies that would serve to illustrate actual ways in which exposure to a substance manifests itself in humans. Second, there exist several types of models which employ different types of mathematical equations. The equations yield different results about plausible effects associated with doses in humans. Thus, the predicted incidence of cancer in humans as a result of exposure to a certain substance can vary, depending on the statistical model used.

*Exposure assessment* is the third stage of a risk assessment. At this stage, analysts attempt to identify how much of a population will receive some exposure to a substance. In general, this step is relatively straightforward.[20] Nonetheless, U.S. regulators have been faulted for employing overly conservative assumptions when attempting to discern effects on individuals. In some instances, U.S. assessors have based assessments on assumptions about people who tend to be most exposed to a particular substance (i.e. workers), rather than people who are infrequently exposed to smaller amounts in their everyday surroundings. The characterization is less apt now than in the past since it is now more well-understood that

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[19] Office of Technology Assessment *supra* note 7.

[20] Paustenbach, *supra* note 7.

assumptions about maximally-exposed individuals can lead to conservative results and thus should only be used under certain circumstances, such as initial chemical screens.[21]

After data from steps one through three are collected, analysts must estimate the risks associated with exposure to a carcinogen.[22] *Risk characterization,* is the fourth and final stage of a risk assessment. The stage requires the assessor to explain to the risk manager the previous steps in a way that accurately reflects the potential severity of the risks, the uncertainties in the estimate, and the assumptions that the assessor has employed. From these data, a set of risk management options may be developed and employed.

In the U.S., and now increasingly in some European Union member states, risk assessment methods are broken down and formalized into the four-stage procedure. In contrast to the four-stage model, risk assessments also may be continuous. As the following discussion shows, the European process has tended to be more continuous. That is, experts there traditionally have reviewed scientific data and potentially exposed populations to generate statements about qualitative risks.

## RISK ASSESSMENT METHODS AND USES IN SELECTED COUNTRIES

### Introduction

As mentioned, it is hard to compare how national agencies in different countries assess health risks because terminology, political systems, and lab practices vary among countries. Paradoxically, characterizing practices as largely specific to each country can also lead to oversimplification because information about risk assessment methods flows across borders through journal articles, conferences, and routine communication between professionals in different countries. Programs sponsored by international organizations such as the Organization for Economic Cooperation and Development (OECD) and the World Health Organization (WHO) have helped to further promote uniformity in risk assessment. WHO

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[21] Adam M. Finkel, "Is Risk Assessment Really Too Conservative? Revising the Revisionists," 14 *Colum. J. Environ. L.* 427 (1989).

[22] Paustenbach, *supra* note 1.

develops protocols for risk assessment procedures and has worked with EPA to harmonize risk assessment terminology.[23] The OECD in 1987 developed the Screening Information Data Set (SIDS) project to develop data on high production volume chemicals (HPV).[24] EPA's participation in the OECD program has enabled the agency to increase the volume of chemicals tested under the Toxic Substances Control Act (TSCA).

As a result of such international initiatives, generalizations such as "U.S. assessors do not use a 'weight of evidence' approach while Europeans do," overstates the case somewhat. Where differences occur, it is typically in the relative degree to which analysts employ certain techniques.

It also should be noted that European unification has made assessments for E.U. member states even more uniform because they are now required to follow guidelines designed to harmonize risk assessment procedures (**Appendix I**).[25] Since 1994, E.U. regulations require scientists in Germany, the U.K. and the Netherlands to use a four-stage risk assessment model similar to the U.S. version to assess chemicals covered under E.U. directives. E.U. assigns each member country with a set of priority chemicals to assess. The E.U. risk assessment procedures persist alongside more traditional evaluation methods conducted not within government agencies but primarily by outside experts.

### Findings

Before turning to the E.U. guidelines, the following analysis first examines the more traditional evaluation methods (i.e. pre-unification) in Japan, U.K. Germany, Netherlands and

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[23] George Becking, International Programme on Chemical Safety, World Health Organization, personal communication, April 1994.

[24] Janice Mazurek, *Words to Stir the Sleeping Giant: The Toxic Substances Control Act*, Discussion Paper #11, Pollution Prevention and Education Research Center: University of California, Los Angeles, 1994. On-file with the author.

[25] European Commission Regulation (EC) No. 1488/94 of 28 June 1994, *laying down the principles for the assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC*. L 161, 29.6 **Official Journal of the European Communities** (1994) 3.

Canada, because they better illustrate what people in other countries perceive as the uses and limitations of health risk assessment.

Risk assessment *methods* in other countries differ from the U.S. primarily in the degree to which scientists employ quantitative modeling techniques designed to extrapolate results from lab animals to humans. British and German scientists have expressed skepticism with QRA because they question the validity of models based on mathematics instead of biological data (**Table 1**).[26]

**Table 1: How Other Countries Assess Health Risks**

| | U.S. | E.U. | Canada | Japan | U.K. | Germany | Netherlands |
|---|---|---|---|---|---|---|---|
| Low dose extrapolation model/QRA | ● | ● | ● | | | | ● |
| Case-by-case | | | ● | ● | ● | ● | ● |
| Weight of evidence | | | ● | ● | ● | ● | ● |
| Expert panels | | | | | ● | ● | ● |

Source: Interviews, Center for Risk Management, Resources for the Future, 1995.

In the non-U.S. agencies studied, evaluation of carcinogens tends to be performed by outside experts instead of agency personnel. Risk assessment experts differ from their U.S. counterparts in that they tend to be more willing to employ a "weight of evidence" approach where they consider the quality of the underlying data, as well as lab test results which are both positive and negative. Historically, risk assessors in the U.S. have been sometimes faulted for using evidence selectively as a matter of policy.[27] Europeans also tend to place more

[26] Brickman, et. al. *supra* note 7.

[27] *Id.*

consideration on the mechanism by which the carcinogen acts. In the past, U.S., dose-response models have sometimes been based on data developed from only one or two different cancer mechanisms, such as carcinogenesis induced by ionizing radiation or from genotoxins, a particular class of chemical carcinogens that act through DNA. However, new EPA cancer guidelines allow for different mechanisms and for pharmaco-kinetic factors.[28]

In U.S. agencies, scientists typically deal with uncertainty by following a risk assessment framework or set of procedures. For each substance reviewed, default assumptions tend to be the same, regardless of the evidence. Examples include using test data from the most sensitive species, choosing an extrapolation model that yields the highest estimates of risk, or using exposure models based on individuals who routinely come into contact with a substance, instead of average individuals who infrequently encounter the substance in their daily environment. Other countries tend to review substances on a case-by-case basis, where assumptions vary based on what the evidence suggests as the most appropriate framework.

Once the assessments are conducted, regulators in the countries surveyed also tend to *use* information from risk assessments differently. In the U.S., results generated by a risk assessment may be crudely characterized as having at least four different potential uses. Most commonly, results are used to compare the toxicity of different substances, and to determine standards. In cases where it is deemed that some level of residual risk is impossible to completely eliminate, values from a risk assessment can help to identify appropriate exposure levels. When paired with data from a cost-benefit analysis, risk data also may be used to evaluate regulations. Finally, many advocate pairing the data with agency budget information to develop a relative ranking of how to set spending priorities. While some individual programs use risk information to allocate resources, EPA does not yet systematically employ risk information to set agency priorities.[29]

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[28] Environmental Protection Agency. *Proposed Guidelines for Carcinogen Risk Assessment; Notice.* **61, 79** Federal Register 1996, 17960.

[29] National Academy of Public Administration, *supra* note 4.

Since the early 1980s, the push to use risk assessment information to evaluate regulations and allocate scarce resources has been most pronounced in the U.S. In contrast to its uses in the U.S., the other countries primarily use information from a risk assessment to evaluate and compare chemicals and determine exposure levels to be achieved through the use of technical controls or bans to control potential exposure (**Table 2**).

**Table 2: How Other Countries Use Risk Assessments to Make Decisions**

| | U.S. | E.U. | Canada | Japan | U.K. | Germany | Netherlands |
|---|---|---|---|---|---|---|---|
| Evaluate Regulations | ● | | | | | | |
| Define Acceptable Risk | ● | | ● | | | | ● |
| Set Standards | ● | | ● | ● | ● | ● | ● |
| Evaluate and compare chemicals | ● | ● | ● | ● | ● | ● | ● |

Source: Interviews, Center for Risk Management, Resources for the Future, 1995.

The following discussion examines in greater detail how agencies in each of the six regimes studied conduct risk assessments, and use the information from them to make environmental decisions.

### Japan

The Japanese have no institutional analog for "risk assessment," making comparison to U.S. practices exceptionally difficult. Based on surveys submitted to both the Japanese Environmental Agency and follow-up interviews with Japan's environmental attaché to the U.S., it appears that scientists in Japan's Environment Agency assess toxics using a method where each chemical is subject to an individual evaluation, or "case-by-case" review that considers cancer mechanisms.

**Germany**

The German health and environment ministries traditionally have not sought to quantify exposure risks from carcinogens or other toxic substances because risk assessment admits that some level of risk is acceptable, a principle that runs counter to German environmental law.[30] Thus, the four-stage procedure is typically not employed to generate quantitative estimates that predict the likelihood of adverse human health effects.

Within the E.U., the Germans have the most extensive program on existing chemicals, reflecting high chemical production volumes in Germany. As part of its risk assessment strategy, the German government works with outside experts and with industry to test substances and develop standards. The panels review substances on a case-by-case basis and consider different cancer mechanisms of action. Findings are generally reported in qualitative terms.

While they do not employ quantitative models to estimate health risks, German methods to review evidence from studies of suspected carcinogens have been described as more stringent than those used in the U.S.[31] German toxicologists classify chemicals as carcinogens based on animal tests alone, but each case is reviewed on its own merits. German toxicologists use rigorous formulae to establish animal doses and require that lab animals be observed for longer time periods than in the U.S. Observing animals for longer time periods may be more costly but may also increase the researcher's confidence in the results of the study.

It also may be true that keeping animals alive longer increases the number of observed tumors. Animals in the U.S. are customarily sacrificed at about 24 months of age (the equivalent of 70 human years). One British statistician notes that estimates of carcinogenicity could increase up to seven fold if researchers waited for animals to die naturally.[32]

Based on the results of such studies and the review of all available evidence, expert panels make recommendations on standards based on technological controls such as best

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30 Office of Technology Assessment, *supra* note 7.

31 Brickman, *supra* note 7, 202.

32 Adam Finkel, "Who's Exaggerating?" **Discover** 1996, 48.

available technology (BAT). For drinking water, Germans use E.U. directives.[33] Non carcinogens are regulated according to as low as reasonably achievable standards (ALARA) divided by a safety index.

While Germans have not traditionally employed QRA methods, shrinking public funds and E.U. guidelines have helped to spur interest in U.S. methods.

#### United Kingdom

Like their German counterparts, British regulators and scientific advisors have been generally reluctant to employ quantitative dose-response models to generate estimates about the likelihood of adverse human health effects. Unlike the Germans, the reluctance among British scientists regarding quantitative risk assessment is not motivated by public policy principles, but by scientific skepticism regarding the power of mathematical equations to accurately generate probable cancer risks from chemicals. Most notably, it is believed that models give the impression of precision which cannot be justified from the approximations and assumptions on which they are based.[34] Furthermore, some British scientists maintain that the data which underlie the models tend to be incomplete: That is, models are based on mathematics and not on biological evidence and different models yield different risk estimates concerning the probability of observing an adverse health effect due to chemical exposure.

As in the case of Germany, the British use risk assessments to compare chemicals and set standards. Historically, the British assume that chemicals which appear to act through genotoxic mechanisms are assumed to cause some cancers in the population at any level of exposure. If the chemical does not operate through genotoxic mechanisms, there is generally considered to be a threshold level under which exposure is considered to be safe. Like the Germans, British expert panels evaluate genotoxins using a weight-of-evidence approach that considers all available data including human data, animal studies, and mutagenicity data.

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[33] Brickman, *supra* note 7, 202.

[34] Office of Technology Assessment, *supra* note 7.

If the panel concludes that the chemical appears to operate through a genotoxic mechanism, regulations are developed to reduce exposure to the substance as low as reasonably possible, or the substance is eliminated entirely. For genotoxins that operate through well-understood mechanisms, researchers evaluate animal studies, use these data to determine a no observed effect level (NOEL), and divide this value by a safety factor that reflects the uncertainties of extrapolating from animals to humans.[35]

As in the case of Germany, some groups in the U.K. are increasingly interested in popularizing procedures for four-stage risk assessments that employ low dose modeling techniques (QRA). In 1995, a government-industry consortium released a set of voluntary risk assessment guidelines that closely resemble the U.S. four-stage model. The primary purpose of the guidelines is to promote the use of quantitative risk assessment in the U.K.[36] [37]

#### The Netherlands

The Dutch employ QRA, but the results are a risk assessment that is one tool among many for environmental decision making.[38] Before controlling or mitigating environmental risks, the Dutch prefer to prevent them in the first place. The Dutch have a two-track policy system focused on sources and emissions. Where possible, policy aims to prevent sources, rather than control emissions. The Dutch integrate prevention efforts with other types of decision-making, including regional planning. Examples include land use decisions that minimize driving distances and emissions, or encouraging industry through voluntary covenants to phase out hazardous substances.

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[35] Office of Technology Assessment, *supra* note 7.

[36] *Risk-benefit Analysis of Existing Substances*, UK Government/Industry Working Group (London: Department of the Environment, 1995).

[37] "Costs and Benefits." Statement issued in response to proposed risk-benefit analysis requirement in British Environment Agency Bill by the Advisory Committee on Business and the Environment, United Kingdom, 1995.

[38] Paul Hofhaus, Counselor for Health and Environment, Netherlands Embassy, personal communication, 1995.

The Dutch conduct risk assessments when it is technically or scientifically impossible to reduce all risks to human health from carcinogens that act through a genotoxic mechanism. In the Netherlands, risk assessments are performed both within public agencies and by external expert panels. To compare and evaluate different chemicals, scientists in public agencies use quantitative risk assessments to determine the probability of risks to human health. The Dutch convene expert panels to help formulate regulations.

In the case of suspected chemical carcinogens, scientists first conduct an initial review to determine whether a chemical acts through a genotoxic mechanism. They then review all data from animal bioassay, human studies, and relevant information on chemical structure. The Dutch employ a linear extrapolation model based on the lowest dose of a substance that produces an observable effect. The linear model results in regulations that tend to be conservative, or err in the direction of overstating probable risk. The linear model is typically used, but other models are employed if the underlying data demonstrate that the linear method is inappropriate.[39]

While they have considered employing more sophisticated models than the conservative linear version, the Dutch, like the British, believe that such models contribute to a false sense of security in the accuracy of the results. Thus, they prefer to employ less refined methods that yield more conservative estimates that are then used to determine protective exposure levels. Carcinogens that act by a nongenotoxic mechanism are evaluated with the same process but using different assumptions regarding pathways.

#### Canada

Risk assessment is required under the Canada Environmental Protection Act (CEPA) of 1988. The act sets up a mandate to assess 44 potentially toxic chemicals and to conduct a quantitative risk assessment if the substances are determined to be toxic.[40] The list of potential

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[39] Office of Technology Assessment, *supra* note 7.

[40] Betty Meek, Health and Welfare Canada, personal communication, April 1995; Dwayne Moore, Environment Canada, personal communication, April 1995.

toxic substances is drawn up and revised, as necessary, by a multi-stakeholder panel every three years.

Prior to the enactment of the risk assessment requirements under CEPA, Canadian regulatory bodies relied on exposure standards and occupational exposure limits generated by Sweden, Denmark and the United States, as well as organizations such as the World Health Organization (WHO).[41] However, the Canadian government prefers not to use cancer potency factors and reference doses developed by the EPA because the figures are seen as overly conservative. [42] Furthermore, the Canadian government maintains that the quality of the science of risk assessment in the U.S. is suspect because it is too prone to political manipulation. Canadians attribute the vulnerability of U.S. risk assessment data to what they perceive as an excessively litigious system.[43]

In general, QRA in Canada is performed on a case-by-case basis and the results are used to identify toxic chemicals and not to predict human cancer deaths. The appropriate low dose extrapolation model is selected based on the evidence in each case. For genotoxic carcinogens, the approach under CEPA establishes an "exposure/potency index" (EPI). The index contrasts what part of the population might be exposed with an estimate of a carcinogenic chemical's potency. The potency estimate is based on experimental epidemiological data or animal data and derived by determining the dose that would cause a carcinogenic response in 5 percent of the test subjects in the study.[44]

For nongenotoxic chemicals, uncertainty factors are added to the no-observed-adverse effect level (NOAEL) to calculate a tolerable daily intake similar to the U.S. acceptable daily intake. For genotoxic carcinogens, regulators select one of several policy options designed to reduce health risks as much as possible.[45]

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[41] Paustenbach, *supra* note 7.

[42] *Id.*

[43] Meek, *supra* note 33.

[44] Office of Technology Assessment, *supra* note 7.

[45] Paustenbach, *supra* note 7.

In Canada, the provinces have jurisdiction over most occupational issues and areas such as drinking water. Canada's two primary national agencies, Environment Canada and Health and Welfare Canada, issue guidelines which express potency ranges, instead of single points or "bright lines." The ranges are an attempt to discourage the provinces from challenging the scientific validity of the assessments. Instead, federal agencies simply encourage the provinces to strive to reduce exposure risks to "as low as achievable."

### European Union

Established in 1955 by the Treaty of Rome, the European Union (E.U.) has worked to harmonize health, safety and environmental regulations in an effort to reduce trade barriers and reduce competitive differences among member states. To date, 12 out of 16 eligible countries have officially joined. The organization issues legislation as regulations, directives, decisions, and recommendations. Among these tools, regulations mandate compliance by member states. Directives define procedures and objectives that must be implemented by national legislation in the member countries.

Three, distinct E.U. directives address hazardous substances, new chemicals, and most recently, the 100,000 existing chemicals imported and produced within E.U. territory. They include:

*Seveso Directive*, (82/501/EEC, amended by 87/216/EEC and 88/610/EEC): Adopted in response to a hazardous substance disaster in Seveso, Italy, the directive specifies procedures for major hazard sites and emergency planning.

*New chemicals directive*, (79/831/EEC): Directs countries to modify laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. Countries must develop testing and notification procedures for new chemicals produced in amounts more than 1000 tons per year.

*Existing chemicals directive*, (93/793/EEC): Establishes testing, notification and control procedures for existing chemicals. Requires chemical manufacturers to forward health and safety data to E.U. for chemicals produced in amounts more than 1000 tons per year. From these data, the E.U. establishes a priority chemicals list.

Based on the three directives, the E.U. in 1994 issued a set of guidelines that specify how member countries are to conduct risk assessments to evaluate, compare, and develop control measures for new and existing chemical substances.[46] Jointly developed by member countries, the guidelines are designed to rationalize how risk assessments are conducted, make the procedure more uniform, and reduce reliance on expert panels.[47] They also are intended to minimize duplication of testing among member states.

Countries must develop testing and notification procedures for new chemicals produced in amounts more than 1000 tons per year and test high priority substances from among the 100,000 existing chemicals imported and produced within E.U. territory. The E.U. identifies "priority" chemicals for testing from data submitted by manufacturers. The E.U. then parcels out risk assessment duties to member countries.

For chemicals that are identified by E.U. as being of high priority for testing, the guidelines require each country to conduct a formal, four-stage risk assessment, including hazard identification, dose response assessment, exposure assessment, and a risk characterization (**Appendix I**). The objective of the dose response assessment is to predict the concentration of a substance below which adverse health and environmental effects are not expected to occur. The output is to be expressed as a predicted no effect concentration (PNEC). The PNEC is to be calculated by applying an assessment factor to values that result from tests on organisms, e.g. LD50 (median lethal dose). If it is not possible to develop a quantitative PNEC¸ the directive allows assessors to make qualitative estimates. The directive defines an assessment factor as "an expression of the degree of uncertainty in extrapolation from text data on a limited number of species to the real environment."[48] Agencies are required to record procedures and forward findings to the E.U. if they determine that risk is present. E.U. representatives and representatives from other member countries review results.

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[46] European Commission, *supra* note 22.

[47] John Mumford, Center for Environmental Technology, Imperial College, London, personal communication, April 1995.

[48] *Risk Assessment: Environment* **L** Official Journal of the European Communities **161 9** June 29, 1994. Annex III.

To date, scientists in the environment and health ministries of member states, Germany, United Kingdom, and the Netherlands, report that they have implemented the E.U. guidelines to test chemicals identified by the E.U. as priority substances. For other substances, more traditional risk assessment techniques persist.

The U.K. has used the E.U. guidelines to assess three priority chemicals in 1994 and has plans to assess nine others. When the assessments are complete, member states are required to forward the results of the assessments to Brussels, where member countries can review and, if necessary, challenge the assessments. E.U. representatives have not collected data that illustrate the extent to which member states other than the U.K. have adopted the guidelines.

## COST-BENEFIT ANALYSIS

### Introduction

In the United States, statements about the likelihood of adverse health effects are sometimes paired with data that evaluate the potential economic impacts of regulating or banning a hazardous substance. EPA's 1979 trihalomethane drinking water standard provides an example of such a pairing. In terms of risk, the baseline mortality risk per million individuals exposed to trihalomethane in drinking water is estimated to be about 420. Regulating at such a level of exposure is estimated to cost on the order of $200,000 per premature death averted.[49] Such exercises are conducted in order to determine whether the potential benefits of reducing risks to human health are sufficiently balanced by the costs of regulation.

Before examining in greater detail why the non-U.S. agencies surveyed fail to indicate that they use cost-benefit analysis, is it useful to define the term. Generally speaking, a *cost-benefit analysis* is a tool for comparing the desirable and undesirable impacts of proposed policies and regulations.[50] In the context of environmental laws, "benefits" typically refer to the positive impacts of a regulation such as fewer illnesses or lost work days. Typically, the

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[49] Stephen G. Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Cambridge, Mass: Harvard University Press), 1993.

[50] Kenneth Arrow, Maureen Cropper, and George Eads, et al, "Is there a role for cost-benefit analysis in environmental health and safety regulation?" 272 *Science* (1996) 221.

exercise is conducted as a formal economic analysis where analysts explicitly state risks in terms of numeric probabilities and state net benefits in monetary amounts. Analysts weigh the cost of control (i.e., banning a substance) against the monetary benefits of control (i.e., fewer illnesses, less crop damage).

As with risk assessment, cost-benefit analysis requires researchers to make a number of assumptions because not all potential costs and benefits are easily expressed in monetary terms. Despite the fact that information about costs and benefits can be highly uncertain, many experts in the U.S. nonetheless maintain that estimating the associated impacts of a proposed regulation can provide illuminating evidence to help managers make environmental decisions.[51]

Government agencies in the other countries surveyed routinely use what we understand as cost-benefit analysis to evaluate different transportation options, public works projects, and impacts to ecosystems of proposed developments. However, with regard to chemical carcinogens and other hazardous substances, agencies in the countries studied do not prepare a cost-benefit analysis where benefits (i.e. lives saved) are associated with a monetary value in order to evaluate regulations (**Table 3**). Instead, agencies tend to work with parties subject to potential regulation in order to develop a rough sketch of economic impacts based on a review of immediate evidence. After a review is conducted, the data are used primarily to weigh control options and identify potential substitutes for chemicals that are identified through a risk assessment as hazardous to human and environmental health.[52] In some ways, the exercise can be thought of as analogous to the less formal risk assessment procedures mentioned above that are traditionally conducted in some of European agencies studied.

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[51] *Id.*

[52] Referred to in the United Kingdom and EU guidelines as "qualitative risk-benefit analysis."

**Table 3: Use of Cost-benefit Analysis**

| | U.S. | E.U. | Canada | Japan | U.K. | Germany | Netherlands |
|---|---|---|---|---|---|---|---|
| Evaluate Regulatory Decisions | ● | | | | €€pr o- posed | | |
| Compare Individual Chemicals | ● | ● | | | ● | | |
| Not Used | | | ● | ● | | ● | ● |

For example, the Dutch use ad hoc panels to consider the economic impacts of potential regulation of genotoxins. For non-E.U. priority list hazards, the Dutch instead set nationwide emission reduction goals negotiated through cooperative agreements with industry known as "covenants." The focus of the covenant system is not on efficiency, since every firm is responsible for reducing emissions of a particular chemical to the same level. Similarly, the Germans consult and negotiate with directly effected parties in order to balance different interests.

Canada employs data from risk assessments to compare substances. However, such exercises are not paired with economic analysis. Spokespersons in the national health and environment agencies say that such analyses are unnecessary because regulations are not as subject to legal challenge as in the U.S. For occupational health issues, Canada employs a non-adversarial review process similar to the Dutch model. For example, when Canadian scientists determine through a risk assessment that risk may be present at a particular site or within a firm, they convene "issue tables." Tables typically involve the entire industrial sector where the substance is present. Canada also invites academicians and interest group representatives to the table. Together, they select the most appropriate management strategy. In contrast to regulation, strategies to reduce exposure risks often consist of voluntary agreements negotiated among the firm, regulators, and public representatives.[53]

[53] Meek, *supra* note 33

Of the six regimes examined, the Japanese system is perhaps most unique. The Japanese Environment Agency prior to rulemaking conducts technical hearings with industry. For example, if the agency is contemplating a lower standard for a certain substance from vehicle emissions, the agency will first ask manufacturers whether they can meet the standard. To determine an appropriate policy, industry shares technical data that illustrate reduction capabilities with regulators. Based on information from technical hearings, the Environment Agency works with industry to phase in reduction schedules.[54]

The variation in how other countries employ economic analyses primarily appears to be due to different approaches in the way in which regulators in other countries develop and evaluate regulations. However, there also is a widespread perception among regulators and scientists in other countries that risk assessment and cost-benefit analysis require more methodological refinement than is currently possible. Said one Canadian scientist, "We just don't think science supports presenting risks in terms of a cost per life saved."

According to a 1991 study prepared by the Organization for Economic Cooperation and Development (OECD) environmental managers in Germany, Netherlands, and the U.K., identified the following limitations to cost-benefit analyses:[55]

- They are time-consuming and expensive,
- Data on values are difficult to obtain,
- Money values underestimate environmental benefits,
- They lack a common metric: trees, ponds and people cannot be added,
- While they appear objective, analyses are value-laden. Someone's cost (e.g., a new plant) can be another's benefit (e.g., a new job),
- Government personnel lack the expertise to think in terms of macroeconomic costs.

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[54] David Wallace. *Environmental Policy and Industrial Innovation: Strategies in Europe, the U.S. and Japan* (London: Earthscan Publications, Ltd 1995).

[55] Jean-Phillipe Barde and David Pearce, *Valuing the Environment: Six Case Studies.* (London: Earthscan, 1991).

Despite the perceived limitations of the tool, rising compliance costs are spurring greater interest in the ways in which cost-benefit analysis may be used to evaluate potentially costly new regulations. While environmental managers identified the problems that contribute to the uncertainty of cost-benefit analysis, the OECD study respondents in Germany, Netherlands and the U.K. indicate a growing need for environment agencies to develop a more formal framework to evaluate the impacts of proposed regulations. Thus far, Great Britain is the only country other than the U.S. that has attempted to codify cost-benefit analysis requirements (**Appendix II**).

In a 1995 bill to reorganize the British national environmental regulatory agency, Parliament drafted a provision, "Clause 37," which would have required the new Environment Agency to consider the costs and benefits of all proposed actions. Parliament approved the Environment Act in 1995. However, the cost benefit provision of the Environment Act has been modified significantly from the original language first proposed in draft form. As approved, Section 37 does not require regulators to conduct cost-benefit analyses, but to simply take economic considerations into account. The newly-established Environment Agency is currently preparing a guidance document that discusses how regulators should conduct economic analyses (**Appendix III**).[56]

#### SUMMARY

At the risk of using an hackneyed environmental policy expression, "flexible" best describes how the practice and use of risk assessment and cost-benefit analysis most varies between the United States and its counterparts. Risk assessments for non-E.U. priority chemicals in the Netherlands, Germany, and the United Kingdom are more likely to be conducted on a case-by-case basis, than a set framework based on certain default assumptions. Assumptions employed are based on underlying evidence, which is weighted to reflect the quality of the study and the positive and negative results of lab tests. Among the other countries surveyed, only the U.S. and Netherlands conduct risk assessments based on the

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56 *Environment Act 1995* Sections 4 and 39, London, England.

assumption that some exposure risk to humans is acceptable. The Dutch employ QRA only as a last resort after exhausting other policy options. Among the other national regulatory agencies surveyed, only the Dutch employ low dose models to extrapolate test results from animals to humans, but their linear model yields results that are conservative. Like the British, the Dutch maintain that more sophisticated quantitative models contribute to a false sense of accuracy in the results.

In contrast to the U.S. experience, other countries primarily use data from risk assessments to either identify toxic chemicals, compare chemicals for substitution, or to determine the appropriate level of human exposure. German environmental law in theory rejects the U.S. proposition that some exposure to hazardous substances is acceptable. In contrast, Canadian law requires risk assessments, but Canadian environmental and health agencies use information from risk assessments primarily to identify toxic substances.

While each of the national environmental and health agencies in the five countries employ some method to assess health risks, almost none conduct cost-benefit analysis to evaluate the potential economic impacts of regulation. Those surveyed say that both quantitative risk assessment and cost-benefit analysis presently contain too many uncertainties to yield meaningful results.

However, reluctance is not the same as outright refusal. It is likely that these economic partners of the United States will make greater use of risk assessment and cost-benefit analysis in efforts to control environmental compliance costs and to promote trade liberalization.

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# Appendix I:

## European Commission Risk Assessment Guidelines for Chemicals Identified as Being of High Priority for Testing

From: Official Journal of the European Communities

### *ANNEX III.* RISK ASSESSMENT: ENVIRONMENT

#### 1. Hazard Identification

The objective shall be to identify the effect(s) and/or property (properties) of concern and to review the (provisional) classification in the light of all data available.

#### 2. Dose (Concentration) -- Response (Effect) Assessment

2.1. The objective shall be to predict the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the predicted no effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) -- response (effect) relation would have to be made.

2.2. The PNEC may be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 per cent inhibition of a given parameter, e.g. growth), NOEL(C) (no observed effect level (concentration)), or LOEL(C) (lowest observed effect level (concentration)) or other appropriate methods.

2.3. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.[57]

#### 3. Exposure Assessment

3.1. The objective of the exposure assessment shall be to predict the concentration of the substance which is likely to be found in the environment. That concentration is known as the predicted environmental concentration (PEC). However, in some cases, it may

[57] An assessment factor of the order of 1 000 is typically applied to an L(E)C50 value derived from the results of testing for acute toxicity but that factor may be reduced in the light of other relevant information. A lower assessment factor is typically applied to an NOEC derived from the results of testing for long-term/chronic toxicity.

not be possible to establish a PEC and a qualitative estimation of exposure would have to be made.

3.2. A PEC or, where necessary, a qualitative estimation of exposure need only be determined for the environmental spheres to which emissions, discharges, disposal or distributions are known or are reasonably foreseeable.

3.3. The PEC or qualitative estimation of exposure shall be determined taking account of, in particular and if appropriate:

(i) adequately measured exposure data;
(ii) the quantity in which the substance is produced and/or imported;
(iii) the form in which the substance is produced and/or imported in which the substance is used (e.g. substance itself or as component of a preparation);
(iv) use pattern and degree of containment;
(v) process data, where relevant;
(vi) physico-chemical properties of the substance, in particular melting point, boiling point, vapour pressure, surface tension, water solubility, partition coefficient n-octanol/water;
(vii) breakdown products and/or transformation products;
(viii) likely pathways to environmental spheres and potential for absorption/ desorption and degradation;
(ix) frequency and duration of exposure.

3.4. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure concentrations, adequate models shall be applied. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall then also be considered.

#### 4. Risk Characterization

4.1. For any given environmental sphere, the risk characterization shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived. If the PEC/PNEC ratio is equal to or less than one, the risk characterization shall result that, at present, no further information and/or testing and no risk reduction measures beyond those which are being applied already are necessary. If the ratio is greater than one, the rapporteur shall judge, on the basis of the size of that ratio and other relevant factors, such as:

(i) indications of bioaccumulation potential;
(ii) the shape of the toxicity/time curve in ecotoxicity testing;

(iii) indications of other adverse effects on the basis of toxicity studies, e.g. classification as a mutagen, toxic or very toxic or as harmful with risk phrase R40 ('Possible risk of irreversible effects') or R48 ('Danger of serious damage to health by prolonged exposure');
(iv) data on structurally analogous substances;

if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary.

4.2. If it has not been possible to derive a PEC/PNEC ratio, the risk characterization shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure. Having made such an evaluation and taking into account relevant factors such as those listed in paragraph 4 (1), the rapporteur shall indicate the results of the risk characterization in relation to those effects.

**5. Integration**

In accordance with the provisions of Article 5, a risk characterization may be carried out in relation to more than one environmental sphere. The rapporteur shall judge the results of the risk assessment for each sphere. Having completed the risk assessment, the rapporteur shall review the different results and produce integrated results in relation to the overall environmental effects of the substance.

## *ANNEX IV*. OVERALL INTEGRATION OF RESULTS

1. The results produced in conformity with section 5 of Annex I B, section 4 of Annex II B and section 5 of Annex III shall be reviewed by the rapporteur and integrated in relation to the totality of risks identified in the risk assessment.

2. Further information/testing requirements or recommendations to consider risk reduction measures shall be justified.

## *ANNEX V.* INFORMATION TO BE INCLUDED IN REPORT OF RISK ASSESSMENT

1. The written report submitted to be Commission of the European Communities in accordance with Article 6 shall include the following elements:

(i) the results of the risk assessment produced in conformity with Annex IV;
(ii) if there is need for further information and/or testing in relation to one or more potential adverse effect(s), human population(s) or environmental sphere(s), a description and justification of the further information and/or tests required and a proposal for the time limits within which that further information and/or the results of tests should be submitted;

(iii) if there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already in relation to all potential adverse effects, human populations and environmental spheres, a statement that, on the basis of all available information, at present no further information/testing on the substance is needed and that at present no risk reduction measures beyond those being applied already, are necessary;

(iv) if there is a need for limiting the risks and risk reduction measures are necessary in relation to one or more potential adverse effect(s), human population(s) and/or environmental sphere(s), a statement of the effect(s), human population(s) and/or environmental sphere(s) for which the risk needs to be reduced and an explanation of the need for risk reduction measures. Risk reduction measures which are already being applied shall be taken into account. A risk reduction strategy in accordance with Article 10 (3) of Regulation (EEC) No. 793/93 shall be drawn up and be submitted to the Commission together with the risk assessment as foreseen under this Regulation.

2. Where risk characterization has entailed the use of exposure/effect ratios as described in section 4 of Annex I B and section 4 of Annex III or the use of assessment factors as described in section 2 of Annex III, those ratios or factors shall be stated and methods of calculation used shall be explained.

3. The date considered relevant and therefore as the basis for the risk assessment by the rapporteur on each effect or property and each exposure group listed in Annexes I A and II A and for each environmental property and environmental sphere according to Annex III shall be submitted to the Commission of the European Communities using an appropriate computer program.

## Appendix II:

### Article 37 (economic assessment of regulatory actions) of the British Environment Act of 1995

**Environment Act 1995**

Part I, Chapter 1

4. (1) It shall be the principal aim of the Agency (subject to and in accordance with the provisions of this Act or any other enactment and taking into account any likely costs) in discharging its functions so to protect or enhance the environment, taken as a whole, as to make the contribution towards attaining the objective of achieving sustainable development mentioned in subsection (3) below.

(2) The Ministers shall from time to time give guidance to the Agency with respect to objectives which they consider it appropriate for the Agency to pursue in the discharge of its functions.

(3) The guidance given under subsection (2) above must include guidance with respect to the contribution which, having regard to the Agency's responsibilities and resources, the Ministers consider it appropriate for the Agency to make, by the discharge of its functions, towards attaining the objective of achieving sustainable development.

(4) In discharging its functions, the Agency shall have regard to guidance given under this section.

(5) The power to give guidance to the Agency under this section shall only be exercisable after consultation with the Agency and such other bodies or persons as the Ministers consider it appropriate to consult in relation to the guidance in question.

(6) A draft of any guidance proposed to be given under this section shall be laid before each House of Parliament and the guidance shall not be given until after the period of 40 days beginning with the day on which the draft was so laid or, if the draft is laid on different days, the later of the two days.

(7) If, within the period mentioned in subsection (6) above, either House resolves that the guidance, the draft of which was laid before it, should not be given, the Ministers shall not give that guidance.

(8) In reckoning any period of 40 days for the purpose of subsection (6) or (7) above, no account shall be taken of any time during which Parliament is dissolved or prorogued or during which both Houses are adjourned for more than four days.

(9) The Ministers shall arrange for any guidance given under this section to be published in such manner as they consider appropriate.

Part I, Chapter III

39. (1) Each new Agency--

(a) in considering whether or not to exercise any power conferred upon it by or under any enactment, or

(b) in deciding the manner in which to exercise any such power,

shall, unless and to the extent that it is unreasonable for it to do so in view of the nature or purpose of the power or in the circumstances of the particular case, take into account the likely costs and benefits of the exercise or non-exercise of the power or its exercise in the manner in question.

(2)The duty imposed upon a new Agency by subsection (1) above does not affect its obligation, nevertheless, to discharge any duties, comply with any requirements, or pursue any objectives, imposed upon or given to it otherwise than under this section.

## Appendix III:

### British Environment Agency Guidance Document with Cost-Benefit Analysis Provisions

### Chapter 5: Costs and Benefits

Scope of the duty

5.1 Section 4 of the Environment Act requires the Agency to take into account any likely costs in achieving its principal aim (set out at paragraph 2.4 above). Section 39 places the Agency under a duty, when it considers whether or how to exercise any power, to take into account the likely costs and benefits of its action or inaction. Costs are defined in section 56(1) as including costs to any person (which also means organizations) and to the environment. This duty:

i) does not apply if it would be unreasonable in the circumstances of a particular case. Or there might be cases where it would be unreasonable for the duty to apply to the full extent. For example, it might not be reasonable for the duty to apply in full in an emergency.

ii) does not affect the Agency's mandatory obligations to discharge specific duties, comply with requirements or pursue objectives. Legal requirements (such as the implementation of water quality objectives) remain unaffected by the duty; they must still be observed. But the general duty with regard to costs and benefits will apply whenever there is more than one way of achieving the legal requirements, and if the Agency retains discretion as to how they should be achieved.

Purpose of the duty

5.2 These provisions recognise that sustainable development involves reconciling the need for economic development with that for protecting and enhancing the environment, without compromising the ability of future generations to meet their own needs. Ministers consider that as the Agency is a body with powers to make decisions with significant impacts on individuals, organizations and the environment, it should take account of all types of costs and benefits when making such decisions. This will not only ensure that financial and other considerations are taken into account, but also that environmental considerations are given the central role that is necessary for sustainable development. But the duty does not apply in cases where it would be unreasonable, nor can it be used to override other statutory requirements.

Principals of application

5.3 The principle behind section 39 is that generally in appropriate circumstances -- whether in individual cases or in guiding the Agency's policy-making and executive functions -- the Agency should take account of all types of likely costs and benefits, including environmental impact of a project and the compliance and any other economic costs and benefits. Sometimes this may involve environmental assessment. This is already a statutory requirement in many cases and may also be appropriate in others. While it cannot of itself make decisions, environmental appraisal can when properly applied highlight new options such as remediation. It can also reduce the extent of uncertainty confronting decision makers and improve the quality of the decision making process and inform public debate.

Selection of options

5.4 In discharging its duty, the Agency will need to decide what are the relevant options to consider, for example:

i) whether or not to take action, and

ii) the various options, including the appropriate levels of any controls, for achieving a given environmental outcome.

Quantification

5.5 Whilst the Agency should take into account all likely costs and benefits, Ministers consider that it does not follow that all need to be precisely quantified. For example:

I) where the Agency has no discretion about the outcome it may only be the differences in likely costs and benefits between the particular options that are relevant

ii) the Agency may be able to take account of or establish clear and appropriate precedent for certain classes of activity, for example for the granting of individual fishing licenses or certain types of discharge consents

iii) many likely costs and benefits, particularly in relation to the environment, are inherently difficult to quantify, especially in monetary terms. For example, the possible health effects of exposure to very low levels of pollutants, the value of a forest, the visual impacts of development or global warming. Judgements will therefore often need to be made. The application of the duty in such cases requires the exercise of judgement by the Agency, which should be appropriate to the particular case.

Methodologies and procedures

5.6 When assessing likely costs and benefits in the circumstances of the case, the Agency may consider it appropriate to consider the following:

i) principles, procedures and techniques -- in particular, risk assessment, and economic and policy appraisal[58] -- for giving proper consideration to non-market impacts including those on the environment

ii) the precautionary principle

iii) reliance on sound science

iv) the likely impact on the carrying capacity of the environment, and on natural environmental capital

v) the likely longer-term implications and effects, having particular regard to those which appear likely to be irreversible or reversible only at high cost and over a long time-scale. In the Ministers' view, such analyses should take proper account of long-term environmental benefits as well as immediate financial costs.

vi) the likely costs and benefits of its actions for society as a whole, including the effects on the welfare of people and business, impacts on the environment and changes in the use of resources (labour, capital and natural resources). In so doing the Agency may be guided where appropriate by:

a) the views of the Government's Chief Medical Officers, the Health and Safety Executive and Commission and other interested bodies as to the effects on human health

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[58] Useful guidance is contained in

- *A Guide to Risk Assessment and Risk Management for Environmental Protection*, HMSO, 1995;
- *Economic Appraisal in Central Government: A Technical Guide for Departments*, HM Treasury, 1991;
- *Policy Appraisal and the Environment: A Guide for Government Departments*, Department of the Environment, HMSO, 1991;
- *Environmental Appraisal in Government Departments, Department of the Environment*, HMSO, 1994;
- *Checking the Cost to Business: A Guide to Compliance Cost Assessment, Department of Trade and Industry*, 1992;
- *Policy Appraisal and Health*, Department of Health.

b) evidence within the UK and internationally about proven and likely impacts on the environment

c) the impacts on the economy and on all affected business sectors and individual companies, and

d) the distribution of costs and benefits across the economy. For example, some options open to the Agency may impose particularly heavy costs on particular groups of people or companies or on certain parts of the environment.

Internal guidance

5.7 The Agency should develop and make available practical procedures to ensure that it meets the requirements of the duty having regard to this guidance. Such procedures should be set out in a document which provides internal advice for staff and is made available to others so as to promote public understanding of the principles it adopts. It should include advice to staff on:

i) relevant techniques for assessing costs and benefits

ii) where the Agency's discretion is limited by obligations arising from other duties, requirements and objectives, and

iii) the extent to which detailed consideration of costs and benefits might be unreasonable in particular circumstances.

## Appendix IV:
## Telephone Interview Questions for Environmental Managers in Selected Countries

1) Does your agency conduct health risk assessment?

2) Which (if any) of the following steps comprise a risk assessment?

- hazard characterization
- dose-response assessment
- exposure assessment
- risk characterization

3) Who conducts the risk assessment?

4) Who makes regulatory recommendations? (Outside experts? Agency managers?)

5) Are the steps recorded in formal documents? Who sees the documents?

6) State the relative significance of risk assessments in environmental decision-making:

- Central
- One tool among many. If so, what?
- Marginal importance.
- Not used

Please explain:

7) How is the risk assessment information used? Is it used to:

- Determine if the amount of risk reduced justified by the cost of the regulatory action?
- Define what risk the public will accept, that is, to set standards?
- Compare individual risks (for example, chemical substitutes)?
- Determine where to spend agency money most efficiently?

8) Is the risk assessment information available to people outside the agency?

9) Are cost-benefit analyses conducted in conjunction with risk assessments?

10) Are the cost-benefit analyses recorded in formal documents? Who sees the documents?

11) Why are cost-benefit analyses conducted? (For example, to improve internal accountability, or required by law?) Why are they conducted in this manner?

12) How does your agency use information from cost-benefit analyses? Who uses it? Why is it used in this way?

13) If cost-benefit analyses are not used, state why: