Appendix B.— "Unreasonable Risk"

To learn more about the concept of "unreasonable risk, " the assessment made inquiries of a group of experts and cosponsored a workshop about the subject. The inquiry was directed to *36* individuals, selected by the Assessment Advisory Panel and OTA Staff, and the workshop was held in March 1980 at the New York Academy of Sciences (NYAS).

Responses to Letter Inquiries About Unreasonable Risk

Informed individuals were asked to comment on unreasonable risk. Each individual received the letter and attachments shown in figure B-1. The *22* who responded are acknowledged in table B-1.

Responses ranged from telephone calls or notes, to reprints of papers and speeches, to discursive letters. No attribution of a particular opinion to a specific individual is made in the description of responses that follows. The inquiry letter was couched in reference to the Toxic Substances Control Act (TSCA), but it did not specify that discussions of "unreasonable risk" were to be restricted to a balancing approach to controlling carcinogens. Both zero-risk and balancing approaches were mentioned in the responses, but no response mentioned a technology-based approach to regulation.

Zero-Risk Approaches to Unreasonable Risk

A number of respondents treated cancer, especially workplace-related cancer, as an unreasonable risk, regardless of the number of people affected. Proponents of a purely health-based reading of unreasonable risk contend that workers should suffer no impairment of health as a result of workplace exposures.

These responses did not reflect a naive position that all workplace exposures can be eliminated immediately. Instead, it represented a starting position for regulatory efforts. A respondent said that, "currently when a carcinogen is identified, the first step is to estimate how much of it can be tolerated. " He would favor instead that the first step be to set as a goal the elimination of exposure. If that is impossible, each "essential" exposure could be considered in turn to construct a pattern of allowed exposures above zero. Every effort should then be made to reduce the allowed exposure.

Another respondent likened the present workplace situation to Thomas More's Utopian caste system, in which laborers may be sacrificed for the greater societal good:

> Not accepting the caste system, only ***necessary*** risks would be taken and a standard would be promulgated acceptable to labor, but not to management . . . [Workers] want standards set so there will be no increased risk of getting cancer as a result of their exposure to chemicals in the working environment.

Recognizing that zero exposure levels will not be possible in all situations, limiting exposure to low levels is seen as an intermediate goal to be accomplished by imposing every available control measure. There is no balancing in this approach and the respondent objected to "the entire process of weighing dollar costs to employers against the value of a human life. "

Another respondent advocated applying all available controls for workplace exposures to known *carcinogens* and specifically concludes that the time for quantitative risk assessment has not yet arrived. He cited the continued presence of such obvious and indisputable hazards as asbestos, benzidine dyes, and aluminum-reduction pot-room carcinogens as examples of risks which need immediate attention. He stated that even when control techniques are available, they are not required or applied to the fullest extent.

Interestingly, an alternative health-based approach to unreasonable risk involves a very different methodology and leads to different actions. Quantitative risk assessment would be used to estimate human risk for each identified hazardous substance. All estimates would be expressed as the risk that a person might develop cancer during his lifetime as a result of exposure to the substance at the level now encountered. The risks would be expressed as 1/10, 1/100, 1/1,000, etc. Some value for the risk factor, would be designated **as a** critical value. Risks less than that value would be tolerated; risks greater than that value would be declared unreasonable and candidates for regulation. Costs of regulation would not intrude into the decision to regulate.

Balancing Approaches to Unreasonable Risk

The majority of respondents indicated a preference for a form of balancing some combination of risks, costs and benefits. The spectrum within this ideological grouping however, ranges from suggesting very subjective, case-by-case determinations, to the use of formal quantitative calculations that could be applied to all cases. Individuals who place little faith in quantitative risk assessment and economic analysis of costs and benefits cluster around the "subjective and qualitative" position. The "objective and quantitative" position is occupied by people who are more

Figure B-I.

Dear

We **would like** your **help in attacking a particularly vexing problem as part** of the ongoing Assessment of Technologies for Determining Cancer Risks from the Environment. For your information, a one page description of the Office of Technology Assessment, a one page description of the assessment, and a list of the members of the Assessment Advisory Panel are included.

In order to move against a substance under the Toxic Substance Control Act, the Administrator of the Environmental Protection Agency must determine that the substance poses an "unreasonable risk." The legislative history of TSCA states that Congress decided not to attempt a definition of the term, and intended that its use as an operational term would allow the administrator flexibility in dealing with toxics.

We are asking a number of individuals and organizations (list enclosed) to comment on their impressions and thoughts about unreasonable risk as a concept and an operational term. The enclosed list of questions may be useful to you. If you like, you may, of course, answer each one, or you can use them as a general guide, or ignore them.

We will acknowledge all people and organizations that respond to this request in the assessment report to be published in November, 1980. We will not attribute your comments and ideas to you unless you ask us to do so.

I know that you are busy, and on behalf of the Assessment Advisory Panel and OTA staff, I thank you in advance for your time and consideration.

Sincerely yours,

Michael Gough

1. Unreasonable risk, most probably, represents estimating the projected harm from continued use of substance and balancing that against the benefits of continued use.
   a. What sorts of information would you use in making estimates of the projected harm (short-term tests, animal studies, epidemiology, specific tests. . . ?)
   b. What sorts of information would you use in making estimates of the costs of restricting use of substance?
   c. How would you balance a against b?
   d. Whom would you trust to supply you with the information and make the comparison?
2. What components go into determining an unreasonable risk?
   a. How would you weigh each component?
   b. Must the components be quantitative?
3. Isa decision about unreasonable risk tantamount to a cost-benefit or risk-benefit decision?
4. Is there an approachable numerical level for unreasonable risk?
5. Do you think we have gained anything by introduction of the term "unreasonable risk" in decision making?
6. Have you or has your organization ever conducted an exercise that you consider to have a determination of unreasonable risk? If so, we would appreciate your describing it (or we'll be glad to talk to you on the phone, or if it's already printed somewhere, just tell use the reference.)

Table B-1.

The OTA thanks the following individuals who responded to a letter inquiry about unreasonable risk.

John T. Barr,	Air Products and Chemicals, Inc.
Jan Beyea,	Audubon Society
Eula Bingham,	Occupational Safety and Health Administration
Ralph Engel,	Chemical Specialties Manufacturers Association
P. J. Gehring,	Dow Chemical Co.
Harold P. Green,	Fried, Frank, Harris, Shriver, and Kampelman
Fred Hoerger,	Dow Chemical Co,
Peter Hutt,	Covington and Burling
Kenneth L. Johnson,	Clement Associates, Inc.
Lorin E. Kerr,	United Mine Workers of America
Arnold Kuzmack,	Environmental Protection Agency
Linda B. Kiser,	Consumer Products Safety Commission
Lester Lave,	The Brookings Institution
William J. McCarville,	Monsanto Co.
Richard A. Merrill,	University of Virginia
Franklin E. Mirer,	United Auto Workers
F. W. Mooney,	The Proctor & Gamble Co.
Parry M. Norling,	E. 1. du Pent de Nemours & Co., Inc.
Glenn Paulson,	Audubon Society
David P. Rail,	National Institute of Environmental Health Sciences
Sheldon W. Samuels	American Federation of Labor/Congress of Industrial Organizations

confident of the precision of quantitative risk assessment and economic analysis.

A representative of the Consumer Product Safety Commission (CPSC) described CPSC interpretation of unreasonable risk:

> The legislative history of the Consumer Product Safety Act (CPSA) indicates that unreasonable risk of injury is to be determined by balancing the probability that the risk will result in harm and the gravity of the harm against a rule's effect on the product's utility, cost, and availability to the consumer. Thus, in addition to an assessment of the risk that a rule will eliminate or reduce, an important component of unreasonable risk of injury is the economic impact of a planned regulatory initiative. The legislative history explains that an unreasonable risk is one which can be prevented or reduced with little or no economic impact; or one where the rule's effect on a product's utility, cost or availability is outweighed by the need to protect consumers from the hazard associated with the product.

One respondent made the point that our knowledge of carcinogenicity forces a balancing approach. As a policy matter, there is no recognition of a "threshold dose:" the safe haven of a "no effect" level does not exist for carcinogens.

The subjective qualitative approach is exemplified by a lawyer who wrote: "A substance constitutes an 'unreasonable risk' only where the probability and/or the severity of harm are deemed to outweigh its utility." He explained that all pertinent elements, "probability, severity, harm, utility, " in that statement are highly subjective, and that their definitions are shaped by participating individuals, who may include: "legislators, regulators, business persons, voters, writers of letters to the editor, interested citizens, etc. " This type of balancing emphasizes subjective judgments in qualitative determinations and limits to purely objective determinations.

Another lawyer describes the process of unreasonable risk determinations as:

> . . . paramount to a cost-benefit or risk-benefit decision. In *essence,* it relies as much on procedure as on substance for correct decisions. The concept is that, if all potentially relevant information is taken into account and all interested parties have an opportunity to contribute to the proceedings, the ultimate decision will be rational and as sound as it possibly can be in an area where there is no certainty. While that is perhaps not acceptable to a mathematician, 1 see little possibility of improving upon it as long as the concept remains in statutory language.

Another respondent sees the language of TSCA as allowing a broad range of options for regulatory approaches. He suggests that TSCA rulings might follow the pattern of the Food and Drug Administration's development of criteria for drug effectiveness tests, beginning as loose, intuitive, ad hoc decisions, later becoming codified into lengthy regulations. Once that state is reached, it is difficult to depart from the formula.

A variation on this theme came from an industrial executive, who feels that determinations should be qualitative, and decided on a case-by-case basis. However, he calls for explicit criteria to be addressed in balancing, listing as examples:

- level of hazard inherent in exposure to the chemical;
- types of exposure which create the hazard;
- populations likely to be exposed;
- extent of the exposed populations;
- whether the exposure would be voluntary or involuntary;
- availability of substitutes;
- the worth to society of continued availability of the substance;
  cost inherent in various levels of control or elimination;

- nature of the data suggesting the existence of a hazard;
- ability to extrapolate from those data to predict the hazard in other situations; and
- relative importance of regulating the particular chemical in view of the risks presented by other as yet unregulated chemicals.

A chemical trade association representative addressed the issue broadly:

> Many criteria or approaches for one substance will not be appropriate for another. We believe that there is no formula for such an assessment, but that each case must be decided on its own merits. This is not to say that scientific methodology should not be used, but it does say that the foundation and assumptions that lead to the determination of "unreasonable risk" should be clearly identified, along with their limitations, by the regulatory agency on a case-by-case basis and not through a generic approach.

A public interest advocate deplored the high degree of quantification of risks, costs, and benefits emanating from the Environmental Protection Agency (EPA), which are seen as based on methods inadequate to the task. The large areas of uncertainty surrounding these estimates are rarely specified, especially for economic evaluations. Risk estimates, he feels, are good only for the grossest distinctions between the most and least potent carcinogens. Balancing, therefore, should rely heavily on qualitative decisions, in which doubts must be resolved, by the language of the law, in favor of greater protection.

A middle ground position is taken by many respondents, who would like to see all of the available quantitative information enter into the final regulatory decision, but modified by such factors that are less readily and more controversially quantified. Within this group, there are those who feel that eventually all factors will be quantified, and that more energy should be directed at methodologies for reaching that goal. Others feel that certain measures, especially the value of a human life, cannot be converted to monetary terms.

Some industry respondents lean toward quantitative approaches to deciding unreasonable risk. One expressed his belief that risks from hazardous chemicals are overstated, and that regulation probably will not materially benefit health. This respondent places confidence in risk assessment:

> The question of "risk" can be assessed with some certainty. "Unreasonable" is by definition a matter of perception, and would include consideration of the benefits of a substance and the cost to regulate it.

As **a** part of risk analysis, respondents from across the spectrum advocate risk comparisons of different types. An industry representative thinks it would be useful to compare the risk from exposure to a carcinogenic chemical to other risks we accept willingly in daily life.

A highly quantitative cost-effectiveness approach is promoted by one economist. Measures that achieve the greatest risk reduction, most economically, would be the first to be required. This method requires risk assessments for known carcinogens and identification of carcinogens with exposures that can be reduced. This respondent suggested a 2-stage approach, accepting reductions to an intermediate level which maximize risk reduction for each dollar spent, However, final limits would be set requiring an explicit valuation of life. He acknowledges that an implicit value for life is found abhorrent by some, but, he says: "it is inherent in all toxic substance regulation. " This suggested scheme would not allow for a regulation that was less cost effective than an alternative, nor any final regulation which cost more per human life saved than the value placed on a life.

Acceptable Risk and Consumer Choice

Unreasonable risk determinations were not always discussed in the context of a deliberative body making a decision. Individuals, it is pointed out, make risk-benefit decisions continuously, and much might be learned from those behaviors in which individuals decide what risks are acceptable. Some respondents prefer to approach unreasonable risk from a perspective of "acceptable risk. "

An industry representative expressed the view :

> . , . this more positive direction of attack is useful in considering prospectively the extent to which regulation should be carried, as opposed to a retrospective review to see if regulatory actions were adequate.

Amplifying, he explains:

> In the long run, acceptable risk is the perceived risk to which informed persons do not object. That statement implies a higher level of knowledge than the general population now has, and acknowledges the emotional issues present in any cancer controversy.

This respondent joins those who call for improvements in present methods of risk and benefit estimation, but adds:

> It seems probable that them is no general answer to acceptable risk, and no numerical value that is correct for all situations.

The issue of whether a risk is taken voluntarily or involuntarily is a major determinant of levels of hazard that are considered acceptable. It is supposed, in general, that higher risk is acceptable for a purely voluntary exposure than for an involuntary one, and different approaches to regulation may be appropriate for different degrees of voluntarism.

A member of the legal community, concerned particularly with consumer products, advocates a "consumer choice" approach:

> . , . under which the Government would assess the risks but would not have authority to ban on the basis of this risk assessment, would be responsible for assuring that information about risk is provided to consumers through product labeling and other educational techniques, and would leave the ultimate risk-benefit judgment to consumers. The uniqueness of this approach is that the consumer, rather than the government, would make the "regulatory" decision of whether human exposure would occur. Some consumers would conclude that their benefits outweigh the risks and would use the product; others would conclude the opposite and would not use it.

Concerning the benefits derived from consumer goods, he explains:

> Most benefits are psychological or in any event nonobjective and nonquantifiable in nature. In the area of food . . . virtually all people eat not for health or nutrition reasons but rather for pleasure. If one eats enough of virtually anything that one likes, one will, after all receive sufficient nutrition. Thus, choice of food—i.e., consumer benefit—is wholly subjective and personal in nature. With the exception of a very few essential nutrients, in our country no food can be said to have any "benefits" in the sense that they are in any way essential or irreplaceable. And if you define "benefits" to include simple consumer desire for pleasure, the term soon becomes meaningless.
>
> 1 believe this same analysis holds true not just in the area of food, but indeed for all consumer products. And because TSCA deals with chemicals broadly, it ultimately impacts upon all consumer goods.

Opinions Expressed in the Responses Parallel the Diversity of Laws

From banning of carcinogens based only on consideration of risk, to balancing risks, costs, and benefits, to an antiregulatory position of letting the consumer decide, the responses parallel developments and discussions in regulatory law. This range of attitudes is not surprising because many respondents have testified before the legislature or been party to lawsuits about carcinogen regulation. On the other hand, the spectrum of opinion confounds conclusions that environmental laws can be fit into an evolutionary pattern and that some approaches, for instance, zero-risk laws, no longer have adherents.

The evolutionary analysis suggests that more sophisticated laws, such as TSCA, with its balancing, have now displaced risk-only approaches. Overall, responses received by OTA indicate that risk-only regulations are favored by some for the workplace and that "evolution" has not displaced all interest in risk-based regulations. In fact, the responses show that the breadth of carcinogen regulatory approaches, including the old and the new laws, reflects the spectrum of current thinking. The responses did not produce a "new" approach to determining unreasonable risk. Quantitative risk assessment is an integral part of many of the responses, and its frequent mention reflects the perceived importance of this technique.

The New York Academy of Sciences Meeting

The title of the NYAS meeting, "Workshop on Management of Assessed Risk for Carcinogens, " was chosen to show that the focus of the meeting was not risk assessment. The meeting lasted 2-1/2 days. There was some overlap between participants in the meeting and respondents to the OTA letter, and because of that and the inherent problems of capturing a long meeting in a few pages, no attempt will be made here to summarize the meeting. This short description will highlight some points made there that did not arise in any other context in this assessment.

William Ruckelshaus of the Weyerhaeuser Co., a former EPA Administrator, was asked why industry does not remove risks in advance of regulation. His answer had two parts. First, he said, "industry leaders often do not know the extent of the health or environmental problems. " Second, a "company that spends money on a problem in advance of regulation may fall behind its competitors who make the same product but do not spend for risk reduction. " He suggested that regulations are sometimes welcomed because all competitors are affected.

Peter Preuss described CPSC's approach to regulation of carcinogens. Each of CPSC's actions has originated from a petition asking for agency action. All but one of the chemicals had been regulated by another agency. His analysis of CPSC actions led him to conclude that CPSC has employed no overarching method to settle unreasonable risk questions; each decision was largely independent of the others.

A number of speakers made the point that many chemicals are carcinogens when tested and that there are perhaps hundreds of candidates for regulation. Lively discussions broke out between those who want to order carcinogens on the basis of their potency and those who hold that extrapolation is too imprecise to estimate potency.

Surprisingly enough, there was general agreement about the value of cost effectiveness as a method to plot regulatory strategy. Cost effectiveness involves ordering the risks, estimating the cost of reducing or eliminating the risk, and deciding which expenditure of resources will accomplish the largest reduction in

risk. A perhaps essential difference between cost effectiveness which found favor, and benefit-cost analysis which did not, is that cost effectiveness presupposes that risk reduction is a goal, and the method guides efforts toward that goal.

There were few advocates of benefit-cost analysis at the workshop, and many participants attacked the method. It was characterized as expensive and as ignoring values, costs, and benefits that cannot be converted to dollars. And, for those interested in regulation, benefit-cost analysis does not set a goal of reducing risks. Instead, it puts each projected regulation to a test of whether or not it should be promulgated.

Proceedings of the workshop have recently been published. *Management of Assessed Risks for Carcinogens* (276a) is a valuable source of information about approaches to risk management.