Risk Assessment: What's It All About?[1]

1 What is risk assessment?

Risk assessment is a process by which scientists evaluate the potential for adverse health or environmental effects from exposure to naturally occurring or synthetic agents. These agents include (1) chemicals such as those that occur in food naturally, food additives, drugs, and environmental contaminants, and (2) physical agents, such as radiation or electromagnetic fields. Risk assessment typically includes an estimate of the probability of harm, such as the probability of liver toxicity after use of a particular drug or the effect that a chemical in the environment may have on wildlife, and a clear description of the various assumptions and uncertainties that go into the risk assessment.

2 What is the goal of risk assessment?

The goal of risk assessment is to provide risk managers, who might be, for example, government regulatory officials, industry health and safety directors or public health officials, with a rational basis for making decisions about managing the use of chemicals or physical agents in order to protect health and the environment. The decision-making process often involves factors in addition to the risk assessment results, such as social values, technical feasibility and economic factors. Risk assessment is used as part of the decision-making process to ensure public protection against unacceptable risks and to allow the use of products whose benefits outweigh the risks associated with their use. Examples include medicines which may produce side effects.

3 What is involved in risk assessment?

As described by the National Research Council of the National Academy of Sciences[2], risk assessment involves four components:

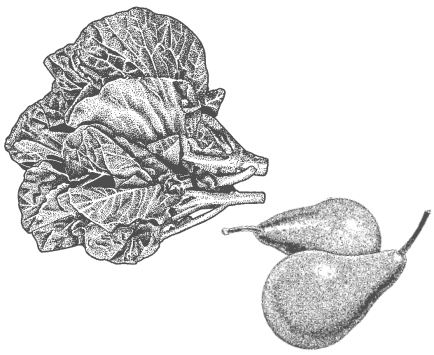
Hazard identification — an evaluation of the adverse health effects the agent is capable of causing. Examples might include the capacity of an agent to cause liver or nervous system damage or to cause cancer.

Dose-response assessment — a determination of how much of an agent is required to cause a toxic effect, and prediction of exposure levels at which risk is likely to be negligible or nonexistent.

Exposure assessment — a determination of how much of an agent people might be exposed to under various conditions such as use of a drug or a consumer product, environmental exposure at a hazardous waste site.

Risk characterization — an integration of the pertinent information from the preceding steps to characterize the risks to the exposed population — e.g., what is the likelihood that there will be an increase in cancer in a population exposed to a particular contaminant in drinking water? What is the likelihood of liver toxicity if an individual uses a particular drug? The risk characterization also includes an explicit description of the assumptions and uncertainties that go into the risk assessment, and the overall confidence in the results of the analysis. It is important to note that even for very toxic chemicals, if the exposures are low enough, the risks may be very low or nonexistent. The principle that "the dose makes the poison" is a basic tenet of toxicology.

It should also be recognized that the longer and healthier life that most of us enjoy can, in large part, be attributed to the proper use of chemicals (including medicines) that benefit people. Toxicology has played a key role by defining the conditions of use under which we may safely employ chemicals for good causes as well as conditions under which the use of a particular chemical should be avoided or eliminated.



1 Why is the Society of Toxicology interested in risk assessment?

Toxicology provides essential information for the risk assessment process. Basically, toxicologists provide much of the underlying scientific data regarding how chemicals might affect humans and the environment. The Society of Toxicology (SOT) believes that risk assessment and its application in decision-making can be greatly improved through the incorporation of sound science in the process and by educating those who use risk assessment in decision-making about the strengths and limitations of the science.

The SOT views the enhancement of the scientific basis of risk assessment as a high priority issue. Accordingly, its strategic plan includes components aimed at stimulating research to improve the risk assessment process, and educating scientists, regulators, the media and the lay public about the importance of the use of sound science in risk assessment. Furthermore, the Society is interested in promoting the use of risk assessments based upon sound science by regulatory agencies. Pursuant to these goals, the Society of Toxicology has adopted a set of Principles for Research Priorities in Toxicology; these are presented below.

SOT's Principles for Research Priorities in Toxicology[3]

Support the advancement of basic and applied research in toxicology, and incorporation of sound science into risk assessment, are the first two items addressed in our Long-Range Plan, adopted in June, 1997. Accordingly, Council has approved the following statement concerning principles for research priorities in toxicology in order to highlight the Society of Toxicology's commitment to research in the context of our concern for human health and the environment. Classic toxicity testing, involving the use of animal models, has served us well and will continue to do so in the future. However, we affirm the need to continue to strive for improvement in accord with the following principles.

1. A focus on basic research aimed at discerning the mechanism / mode of action of the agent of interest is of fundamental importance. Toxicology is a basic biomedical science because the study of mechanisms of toxicity leads to enhanced insight regarding our understanding of essential aspects of biology.
2. Knowledge of mechanisms underlying the toxicity of the agent of interest is required in order to facilitate the incorporation of sound science into risk assessment. This is a critical aspect of our Society's strategic plan. The overall goal is to enhance our ability to make reasonable estimates as to whether or not harm might occur to people, or the environment, under realistic

conditions of exposure. This entails hypothesis-driven research and it is consistent with the notion that it is the dose which makes the poison.
3. The scientific basis of risk assessment can be enhanced by the development of improved test systems (not simply adding to the number of existing "tests") and improved means for interpretation of results. Key aspects of any risk assessment include an emphasis on: (1) dose selection; (2) dose-response relationships, including extrapolation from high to low doses; (3) species to species extrapolation; and (4) exposure assessment.

Research should be judged on the basis of scientific merit, without regard for funding source or where the studies are conducted (e.g., academia, government or industry).

1 *"Risk Assessment: What's It All About?"* is intended for SOT to use on the numerous occasions that we are called upon to present basic aspects of risk assessment to, for example, undergraduates, members of the news media, congressional staff, and high school science teachers. This is a result of a project initiated by the Task Force to Improve the Scientific Basis of Risk Assessment and the Task Force played the major role in its development. Input was received from SOT Council, the Risk Assessment Specialty Section, the Committee for Regulatory Affairs and Legislative Assistance, and the Committee on Public Communication. The contributions that each of these groups made is acknowledged gratefully. The document underwent a number of revisions, based upon the comments received, and was approved by Council on November 11, 1999.

2 *Science and Judgement*, National Research Council, National Academy of Sciences, National Academy of Sciences Press, Washington, DC, 1994.

3 Approved by SOT Council, 1998; published in the Society's newsletter, *Communiqué*, Special Issue, p. 9, 1998.