

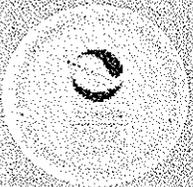
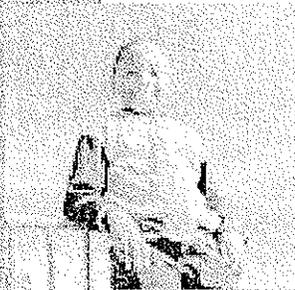
WARNING

CAUTION: This fish is a symbol of a health hazard. It is a warning that the fish is contaminated with a substance that is known to be a carcinogen. The fish is a symbol of a health hazard. It is a warning that the fish is contaminated with a substance that is known to be a carcinogen.

ADVERTENCIA!

ADVERTENCIA: Este pez es un símbolo de un peligro para la salud. Es una advertencia de que el pez está contaminado con una sustancia que se sabe que es un carcinógeno. El pez es un símbolo de un peligro para la salud. Es una advertencia de que el pez está contaminado con una sustancia que se sabe que es un carcinógeno.

A Guide to Health Risk Assessment



California Environmental Protection Agency
Office of Environmental
Health Hazard Assessment



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The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see California's official "Flex Your Power" Web site at www.flexyourpower.ca.gov.

A Guide to Health Risk Assessment

In recent years, the public has become increasingly aware of the presence of harmful chemicals in our environment. Many people express concerns about pesticides and other foreign substances in food, contaminants in drinking water, and toxic pollutants in the air. Others believe these concerns are exaggerated or unwarranted. How can we determine which of these potential hazards really deserve attention? How do we, as a society, decide where to focus our efforts and resources to control these hazards? When we hear about toxic threats that affect us personally, such as the discovery of industrial waste buried in our neighborhood or near our children's school, how concerned should we be?

Health risk assessment is a scientific tool designed to help answer these questions. Government agencies rely on risk assessments to help them determine which potential hazards are the most significant. Risk assessments can also guide regulators in abating environmental hazards. Members of the public who learn the basics of risk assessment can improve their understanding of both real and perceived environmental hazards, and they can work more effectively with decision makers on solutions to environmental problems.

The purpose of this booklet is to provide a basic explanation of risk assessment for laypeople involved in environmental health issues, including policymakers, businesspeople, members of community groups, news reporters, and others with an interest in the potential health effects of toxic chemicals.

In memory of Harold Russell (1937-2008)

who dedicated his career to serving the public and protecting public health and the environment by his steadfast efforts to create and communicate timely, accurate, and understandable public health information.

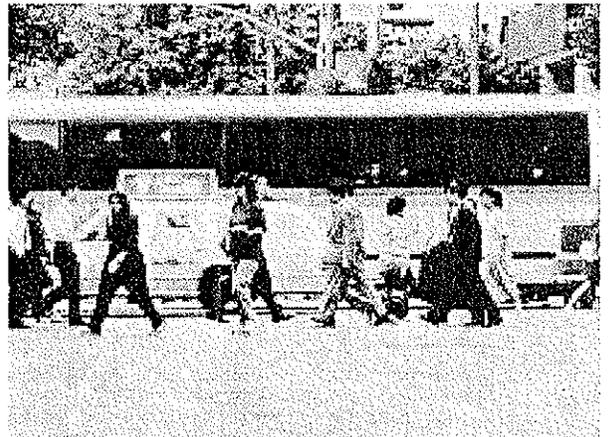
Introduction

Chemicals can be either beneficial or harmful, depending on a number of factors, such as the amounts to which we are exposed. Low levels of some substances may be necessary for good health, but higher levels may be harmful. Health risk assessments are used to determine if a particular chemical poses a significant risk to human health and, if so, under what circumstances. Could exposure to a specific chemical cause significant health problems? How much of the chemical would someone have to be exposed to before it would be dangerous? How serious could the health risks be? What activities might put people at increased risk?

If it were possible to prevent all human exposure to all hazardous chemicals, there would be no need for risk assessment. However, the total removal of harmful pollutants from the environment is often infeasible or impossible, and many naturally occurring substances also pose health risks. Risk assessment helps scientists and regulators identify serious health hazards and determine realistic goals for reducing exposure to toxics so that there is no significant health threat to the public.

Estimating the hazards posed by toxic chemicals in the environment involves the compilation and evaluation of complex sets of data. Government regulators, therefore, turn to specialists to perform or assist with risk assessments. These specialists include scientists with degrees in toxicology (the study of the toxic effects of chemicals) and epidemiology (the study of disease or illness in populations) as well as physicians, biologists, chemists, and engineers.

The term "health risk assessment" is often misinterpreted. People sometimes think that a risk assessment will tell them whether a current health problem or symptom was caused by exposure to a chemical. This is not the case. Scientists who are searching for links between chemical exposures and health problems in a community may conduct an epidemiologic study. These studies typically include a survey of health problems in a community and a comparison of health problems in that community with those in other cities, communities, or the population as a whole.



Health risk assessment estimates how current or future chemical exposures could affect a broad population.

Photo: Air Resources Board

Although they are both important, health risk assessments and epidemiologic studies have different objectives. Most epidemiologic studies evaluate whether *past* chemical exposures may be responsible for documented health problems in a specific group of people. In contrast, health risk assessments are used to estimate whether *current* or *future* chemical exposures will pose health risks to a broad population, such as a city or a community. Scientific methods used in health risk assessment cannot be used to link individual illnesses to past chemical exposures, nor can health risk assessments and epidemiologic studies prove that a specific toxic substance caused an individual's illness.

The U.S. Environmental Protection Agency (U.S. EPA) is a leading risk assessment agency at the federal level. In California, the Office of Environmental Health Hazard Assessment (OEHHA) in the California Environmental Protection Agency (Cal/EPA) has the primary responsibility for developing procedures and practices for performing health risk assessments. Other agencies within Cal/EPA, such as the Department of Pesticide Regulation and the Department of Toxic Substances Control, have extensive risk assessment programs of their own but work closely with OEHHA (see the table below).

The Department of Pesticide Regulation uses risk assessments to make regulatory decisions concerning safe pesticide uses. The Department of Toxic Substances Control uses risk assessments to determine requirements for the management and cleanup of hazardous wastes. OEHHA's health risk assessments are used by the Air Resources Board to develop regulations governing toxic air contaminants and by the Department of Health Services to develop California's drinking water standards. These agencies' decisions take into account the seriousness of potential health effects along with the economic and technical feasibility of measures that can reduce the health risks.

Health risk assessment requires both sound science and professional judgment and is a constantly developing process. Cal/EPA is nationally recognized for developing new procedures that improve the accuracy of risk assessments. Cal/EPA also works closely with U.S. EPA in all phases of risk assessment.

Cal/EPA and Other Agencies' Cooperation With Risk Assessment Activities

| Department or Office | Risk Assessment |
|--|---|
| Office of Environmental Health Hazard Assessment | Chemical contaminants in air, water, food, and fish |
| Department of Pesticide Regulation | Pesticides: regulation and safe use; residues in food, water, soil, and air |
| Department of Toxic Substances Control | Hazardous waste: mitigation of site contamination; safe operation of treatment, storage, or disposal facilities |

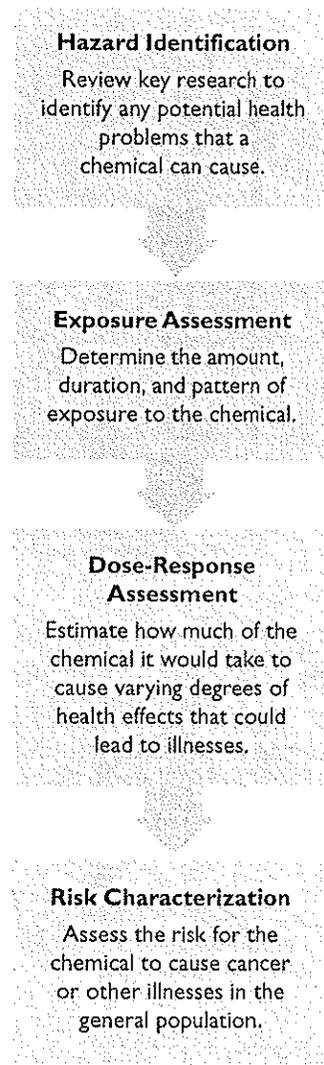
The Four-Step Process of Risk Assessment

The risk assessment process is typically described as consisting of four basic steps: hazard identification, exposure assessment, dose-response assessment, and risk characterization. Each of these steps will be explained in the following text.

Step 1 Hazard Identification

In the first step, hazard identification, scientists determine the types of health problems a chemical could cause by reviewing studies of its effects in humans and laboratory animals. Depending on the chemical, these health effects may include short-term ailments, such as headaches; nausea; and eye, nose, and throat irritation; or chronic diseases, such as cancer. Effects on sensitive populations, such as pregnant women and their developing fetuses, the elderly, or those with health problems (including those with weakened immune systems), must also be considered. Responses to toxic chemicals will vary depending on the amount and length of exposure. For example, short-term exposure to low concentrations of chemicals may produce no noticeable effect, but continued exposure to the same levels of chemicals over a long period of time may eventually cause harm. (See “Dose-Response Assessment” on page 8.)

An important step in hazard identification is the selection of key research studies that can provide accurate, timely information on the hazards posed to humans by a particular chemical. The selection of a study is based upon factors such as whether the study has been peer-reviewed by qualified scientists, whether the study’s findings have been verified by other studies, and the species tested (human studies provide the best evidence). Some studies may involve humans that have been exposed to the chemical, while others may involve studies with laboratory animals.

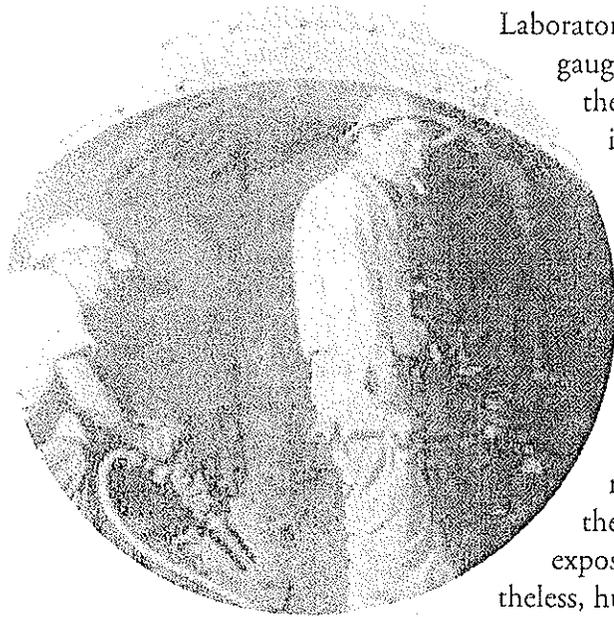


Human data frequently are useful in evaluating human health risks associated with chemical exposures. Human epidemiologic studies typically examine the effects of chemical exposure on a large number of people, such as employees exposed to varying concentrations of chemicals in the workplace. In many cases, these exposures took place prior to the introduction of modern worker-safety measures.

One weakness of occupational studies is that they generally measure the effects of chemicals on healthy workers and do not consider children, the elderly, those with pre-existing medical conditions, or other sensitive groups. Since occupational studies are not controlled experiments, there may be uncertainties about the amount and duration of exposure or the influence of lifestyle choices, such as smoking or alcohol use, on the health of workers in the studies. Exposure of workers to other chemicals at the same time may also influence and complicate the results.

Laboratory studies using human volunteers are better able to gauge some health effects because chemical exposures can then be measured with precision. But these studies usually involve small numbers of people and, in conformance with ethical and legal requirements, use only adults who agree to participate in the studies. Moreover, laboratory studies often use simple measurements that identify immediate responses to the chemical but might miss significant, longer-term health effects. Scientists can also use physicians' case reports of an industrial or transportation accident in which individuals were unintentionally exposed to a chemical. However, these reports may involve very small numbers of people, and the level of exposure to the chemical could be greater than exposures to the same chemical in the environment. Nevertheless, human studies are preferred for risk assessment, so OEHHA makes every effort to use them when they are available.

Because the effects of the vast majority of chemicals have not been studied in humans, scientists must often rely on animal studies to evaluate a chemical's health effects. Animal studies have the advantage of being performed under controlled laboratory conditions that reduce much of the uncertainty related to human studies. If animal studies are used, scientists must determine whether a chemical's health effects in humans are likely to be similar to those in the animals tested. Although effects seen in animals can also occur in humans, there may be subtle or even significant differences in the ways humans and experimental animals react to a chemical. Comparison of human and animal metabolism may be useful in selecting the animal species that should be studied, but it is often not possible to determine which species is most like humans in its response to a chemical exposure. However, if



Family medical history, occupation, and personal habits, such as smoking, all influence an individual's risk of contracting cancer and other diseases.

*Photo: History and Science Division,
Sacramento Archives and Museum
Collection Center*

similar effects were found in more than one species, the results would strengthen the evidence that humans may also be at risk.

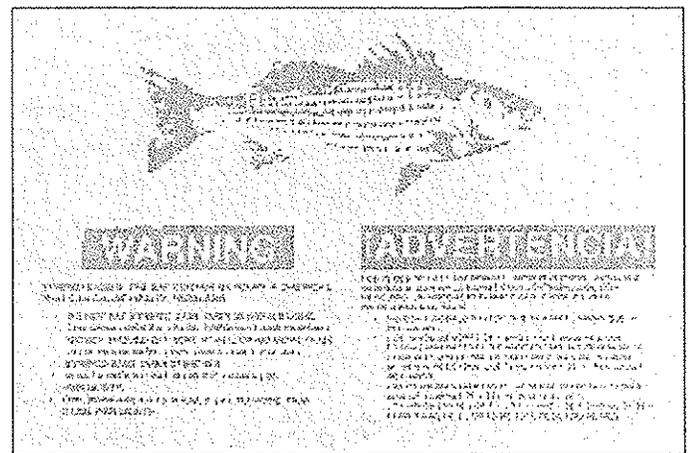
Exposure Assessment

In exposure assessment, scientists attempt to determine how long people were exposed to a chemical; how much of the chemical they were exposed to; whether the exposure was continuous or intermittent; and how people were exposed—through eating, drinking water and other liquids, breathing, or skin contact. All of this information is combined with factors such as breathing rates, water consumption, and daily activity patterns to estimate how much of the chemical was taken into the bodies of those exposed.

People can be exposed to toxic chemicals in various ways. These substances can be present in the air we breathe, the food we eat, or the water we drink. Some chemicals, due to their particular characteristics, may be both inhaled and ingested. For example, airborne chemicals can settle on the surface of water, soil, leaves, fruits, vegetables, and forage crops used as animal feed. Cows, chickens, or other livestock can become contaminated when eating, drinking, or breathing the chemicals present in the air, water, feed, and soil. Fish can absorb the chemicals as they swim in contaminated water or ingest contaminated food. Chemicals can be absorbed through the skin, so infants and children can be exposed simply by crawling or playing in contaminated dirt. They can also ingest chemicals if they put their fingers or toys in their mouths after playing in contaminated dirt. Chemicals can also be passed on from nursing mothers to their children through breast milk.

To estimate exposure levels, scientists rely on air, water, and soil monitoring; human blood and urine samples; or computer modeling. Although monitoring of a pollutant provides excellent data, it is time consuming, costly, and typically limited to only a few locations. For those reasons, scientists often rely on computer modeling, which uses mathematical equations to describe how a chemical is released and to estimate the speed and direction of its movement through the surrounding environment. Modeling has the advantage of being relatively inexpensive and less time consuming, provided all necessary information is available and the accuracy of the model can be verified through testing.

Computer modeling is often used to assess chemical releases from industrial facilities. Such models require information on the type of chemicals released, facilities' hours of operation, industrial processes

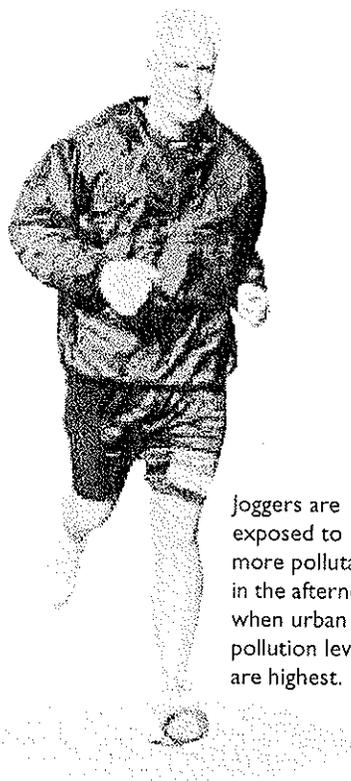


OEHHA sport fish advisory

that release the chemicals, smokestack height and temperature, any pollution-control equipment that is used, surrounding land type (urban or rural), local topography and meteorology, and census data regarding the exposed population.

In all health risk assessments, scientists must make assumptions in order to estimate human exposure to a chemical. For example, scientists assessing the effects of air pollution may need to make assumptions about the time people spend outdoors, where they are more directly exposed to pollutants in the ambient air, or the time they spend in an area where the pollution is greatest. An assessment of soil contamination may require scientists to make assumptions about people's consumption of fruits and vegetables that may absorb soil contaminants.

To avoid underestimating actual human exposure to a chemical, scientists often look at the range of possible exposures. For example, people who jog in the afternoon, when urban air pollution levels are highest, would have much higher exposures to air pollutants than people who come home after work and relax indoors. Basing an exposure estimate on a value near the higher end of a range of exposure levels (closer to the levels experienced by the jogger than by the person remaining indoors) provides a realistic worst-case estimate of exposure. These kinds of conservative assumptions, which presume that people are exposed to the highest amounts of a chemical that can be considered credible, are referred to as "health-protective" assumptions.



Joggers are exposed to more pollutants in the afternoon, when urban air pollution levels are highest.

Step 4 Dose-Response Assessment

In dose-response assessment, scientists evaluate the information obtained during the hazard identification step to estimate the amount of a chemical that is likely to result in a particular health effect in humans.

An established principle in toxicology is that "the dose makes the poison." For example, a commonplace chemical like table salt is harmless in small quantities, but it can cause illness in large doses. Similarly, hydrochloric acid, a hazardous chemical, is produced naturally in our stomachs but can be quite harmful if taken in large doses.

Scientists perform a dose-response assessment to estimate how different levels of exposure to a chemical can impact the likelihood and severity of health effects. The dose-response relationship is often different for many chemicals that cause cancer than it is for those that cause other kinds of health problems.

Cancer Effects

For chemicals that cause cancer, the general assumption in risk assessment has been that there are no exposures that have "zero risk" unless there is clear evidence otherwise. In other words, even a very low

exposure to a cancer-causing chemical may result in cancer if the chemical happens to alter cellular functions in a way that causes cancer to develop. Thus, even very low exposures to carcinogens might increase the risk of cancer, if only by a very small amount.

Several factors make it difficult to estimate the risk of cancer. Cancer appears to be a progressive disease because a series of cellular transformations is thought to occur before cancer develops. In addition, cancer in humans often develops many years after exposure to a chemical. Also, the best information available on the ability of chemicals to cause cancer often comes from studies in which a limited number of laboratory animals are exposed to levels of chemicals that are much higher than the levels humans would normally be exposed to in the environment. As a result, scientists use mathematical models based on studies of animals exposed to high levels of a chemical to estimate the probability of cancer developing in a diverse population of humans exposed to much lower levels. The uncertainty in these estimates may be rather large. To reduce these uncertainties, risk assessors must stay informed of new scientific research. Data from new studies can be used to improve estimates of cancer risks.

Noncancer Effects

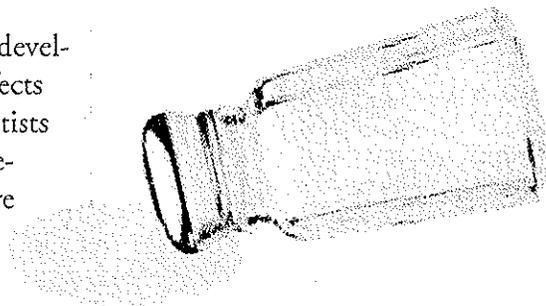
Noncancer health effects (such as asthma, nervous system disorders, birth defects, and developmental problems in children) typically become more severe as exposure to a chemical increases. One goal of dose-response assessment is to estimate levels of exposure that pose only a low or negligible risk for noncancer health effects. Scientists analyze studies of the health effects of a chemical to develop this estimate. They take into account such factors as the quality of the scientific studies, whether humans or laboratory animals were studied, and the degree to which some people may be more sensitive to the chemical than others. The estimated level of exposure that poses no significant health risks can be reduced to reflect these factors.

Risk Characterization

The last step in risk assessment brings together the information developed in the previous three steps to estimate the risk of health effects in an exposed population. In the risk characterization step, scientists analyze the information developed during the exposure and dose-response assessments to describe the resulting health risks that are expected to occur in the exposed population. This information is presented in different ways for cancer and noncancer health effects, as explained below.

Cancer Risk

Cancer risk is often expressed as the maximum number of new cases of cancer projected to occur in a population of one million people due



The dose makes the poison—even table salt can be toxic in large doses.

to exposure to the cancer-causing substance over a 70-year lifetime. For example, a cancer risk of one in one million means that in a population of one million people, not more than one additional person would be expected to develop cancer as the result of the exposure to the substance causing that risk.

An individual's actual risk of contracting cancer from exposure to a chemical is often less than the theoretical risk to the entire population calculated in the risk assessment. For example, the risk estimate for a drinking-water contaminant may be based on the health-protective assumption that the individual drinks two liters of water from a contaminated source daily over a 70-year lifetime. However, an individual's actual exposure to that contaminant would likely be lower due to a shorter time of residence in the area. Moreover, an individual's risk not only depends on the individual's exposure to a specific chemical but also on his or her genetic background (i.e., a family history of certain types of cancer); health; diet; and lifestyle choices, such as smoking or alcohol consumption.

Cancer risks presented in risk assessments are often compared to the overall risk of cancer in the general U.S. population (about 250,000 cases for every one million people) or to the risk posed by all harmful chemicals in a particular medium, such as the air. The cancer risk from breathing current levels of pollutants in California's ambient air over a 70-year lifetime is estimated to be 760 in one million.

Noncancer Risk

Noncancer risk is usually determined by comparing the actual level of exposure to a chemical to the level of exposure that is not expected to cause any adverse effects, even in the most susceptible people. Levels of exposure at which no adverse health effects are expected are called "health reference levels," and they generally are based on the results of animal studies. However, scientists usually set health reference levels much lower than the levels of exposure that were found to have no adverse effects in the animals tested. This approach helps to ensure that real health risks are not underestimated by adjusting for possible differences in a chemical's effects on laboratory animals and humans; the possibility that some humans, such as children and the elderly, may be particularly sensitive to a chemical; and possible deficiencies in data from the animal studies.

Depending on the amount of uncertainty in the data, scientists may set a health reference level 100 to 10,000 times lower than the levels of exposure observed to have no adverse effects in animal studies. Exposures above the health reference level are not necessarily hazardous, but the risk of toxic effects increases as the dose increases. If an assessment determines that human exposure to a chemical exceeds the health reference level, further investigation is warranted.



Health risk assessment takes into consideration children, the elderly, and other groups that may be particularly sensitive to a chemical.

How Health Risk Assessment Is Used

Risk managers rely on risk assessments when making regulatory decisions, such as setting drinking water standards, or developing plans to clean up hazardous waste sites. Risk managers are responsible for protecting human health, but they must also consider public acceptance, as well as technological, economic, social, and political factors, when arriving at their decisions. For example, they may need to consider how much it would cost to remove a contaminant from drinking water supplies or how seriously the loss of jobs would affect a community if a factory were to close due to the challenge of meeting regulatory requirements that are set at the most stringent level.

Health risk assessments can help risk managers weigh the benefits and costs of various alternatives for reducing exposure to chemicals. For example, a health risk assessment of a hazardous waste site could help determine whether placing a clay cap over the waste to prevent exposure would offer the same health protection as the more costly option of removing the waste from the site.

One of the most difficult questions of risk management is: How much risk is acceptable? While it would be ideal to completely eliminate all exposure to hazardous chemicals, it is usually not possible or feasible to remove all traces of a chemical once it has been released into the environment. The goal of most regulators is to reduce the health risks associated with exposure to hazardous pollutants to a negligibly low level.

Regulators generally presume that a one-in-one million risk of cancer from life-long exposure to a hazardous chemical is an "acceptable risk" level because the risk is extremely low compared to the overall cancer rate. If a drinking water standard for a cancer-causing chemical were set at the level posing a "one-in-one million" risk, it would mean that

not more than one additional cancer case (beyond what would normally occur in the population) would potentially occur in a population of one million people drinking water meeting that standard over a 70-year lifetime.

Actual regulatory standards for chemicals or hazardous waste cleanups may be set at less stringent risk levels, such as one in 100,000 (not more than one additional cancer case per 100,000 people) or one in 10,000 (not more than one additional cancer case per 10,000 people). These less stringent risk levels are often due to economic or technological considerations. Regulatory agencies generally view these higher risk levels to be acceptable if there is no feasible way to reduce the risks further.

For example, a regulatory agency may determine that the only water-treatment technology capable of reducing a given water contaminant to the one-in-one million risk level would be so prohibitively expensive that drinking-water suppliers would have to raise their rates to levels that their customers could not afford. At the same time, the regulatory agency may determine that several treatment technologies could economically reduce the contaminant to the "one-in-100,000" risk level. By setting the drinking-water standard at the one-in-100,000 level, the regulatory agency could reduce health risks to acceptable levels while ensuring that water rates remain affordable.

Health risk assessment helps regulatory agencies establish drinking water standards that protect human health while ensuring that water rates are affordable.

Photo: State Water Resources Control Board

For Further Information

OEHHA and other Cal/EPA departments are dedicated to helping the public understand the risk assessment process as a way of encouraging public participation in decisions involving environmental matters. OEHHA has compiled *The Toxics Directory*, a list of information sources on many aspects of health risk information. To obtain this directory and find out more about OEHHA's risk assessments, visit the OEHHA Web site at <http://www.oehha.ca.gov>, or contact OEHHA at the address listed below:

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