

# Regulation of Environmental Pollutants: Introductory Remarks

by **Shahbeg S. Sandhu\***

The environmental problems we face today are multifold and complex. The emission of pollutants in the atmosphere, the discharge of effluents in lakes and rivers, the disposal of hazardous materials in ecosystems, and the use of pesticides on crops and food products are serious problems that are not yet fully understood. More recently, the industrialized nations of the world have been confronted with the critical environmental issue of toxic waste products management. The most pressing requirement today is to identify and assess the toxicity of these substances, particularly their carcinogenic and mutagenic effects. Our modern society has introduced vast numbers of toxic substances into the environment. The American Chemical Society has listed more than four million different chemical compounds; thousands more are being made each year; 70,000 are in common use, produced and distributed by some 115,000 industries and firms. Billions of gallons of industrial effluents are discharged to our lakes, rivers, and oceans each year. In 1977, 190 million tons of criteria air pollutants were emitted in the atmosphere; this quantity does not include the other unregulated and potentially hazardous particles, gases and aerosols emitted by industrial and energy-related processes each year. And, with solid waste, again we are faced with several billion tons of unwanted materials—some harmful, some innocuous—that are disposed of, legally and illegally, each year.

The regulatory initiative to clean up the environment began slowly in the 1960's with the passage of five different pieces of environmental legislation addressing the problems of air and water pollution. The earliest regulation to control human

exposure to carcinogens was the Delaney Amendment to the Food, Drug, and Cosmetic Act which prohibited the introduction into food additives that had been found to induce cancer in animals or man. The 1970's saw the passage of a number of comprehensive environmental laws and extensive amendments to earlier regulations. Today, there are 42 major Federal legislative acts that have been passed with the expressed purpose of controlling the hazardous/toxic substances released into our environment.

Since 1970, the primary responsibility for the control of environmental pollutants has rested with the Environmental Protection Agency. Creation of EPA consolidated the environmental activities of the federal government into a single agency with far-reaching legislative authority to control air and water pollution, including the effects of noise, radiation, and toxic substances. EPA's responsibilities are not all-encompassing however, and a number of Federal and, in some instances, state organizations have responsibilities that require consideration of environmental contaminants. Regulatory emphasis has shifted from the control of traditional pollutants to more hazardous/toxic pollutants. One of the highest priorities of EPA research today—and, indeed of most environmental organizations—is the identification and assessment of toxic substances.

Efforts have been made in the last several years to coordinate the research and regulatory activities of the Federal agencies that have responsibilities for controlling hazardous materials. These agencies include the EPA, the Food and Drug Administration, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Food Safety and Quality Service. The Toxic Substances Strategy Committee Group, formed in 1977, and the Regulatory Council, established by President Carter in 1978, are two groups that have

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\* Genetic Toxicology Division, Health Effects Research Laboratory, U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

been formed to promote and improve coordination of regulatory activities and to reduce or eliminate duplication of scientific studies. Another joint effort is the Interagency Regulatory Liaison Group which includes EPA, CP, FDA, and OSHA and has established a series of work groups to deal with many of the regulatory and research issues in an effort to better coordinate carcinogen regulatory programs.

The focus of the government's efforts in toxic substances research and control is, of course, to limit the exposure of people to chemicals potentially harmful to human health, including cancer-causing substances. To accomplish this objective, the regulatory agencies must determine whether a chemical may cause cancer, assess the risk of cancer to humans, establish regulatory priorities, and then undertake regulatory activities. The technical and economic feasibility of control, the availability of less hazardous substitutes, and cost-benefit analyses are other considerations that play important roles in regulatory actions.

The methods in use or under development to determine whether a substance can cause cancer include the traditional epidemiological studies and animal bioassays, as well as short-term testing to help establish priorities for the investment of limited research facilities and funding. The pollen systems to be discussed at this workshop are representative of the exciting developments that are being made with short-term test procedures. Regulatory decisions have been and, probably will continue in the foreseeable future, to be based on the results of epidemiological and animal studies. The "suggestive" evidence presented by short-term screening processes will, however, help to support regulatory actions dealing with groups of substances having similar chemical or biological properties.

A substantial number of genotoxins, including cancer-causing chemicals, has already been identified. Regulatory priorities are generally assigned to substances for which there is substantial evidence that the substance will cause cancer in man, principally as determined by epidemiological data or animal tests. Priority is also given to regulating substances when there is reason to believe that the level of human exposure or risk is high or if the exposed population is large. The potential for alleviating other environmental effects, other than cancer, and evidence that the social and economic costs of control will be small also lend priority to regulatory decisions.

Much of the effort to coordinate carcinogen policies has focused on the scientific issues involved in testing carcinogenic substances and assessing

carcinogenic risk. Efforts to promote quality testing and consistency have also been initiated. The Interagency Regulatory Liaison Group is currently developing a set of testing standards that will be accepted by the member agencies; this effort should preclude the possibility of different agencies requiring slightly different test procedures to be used for their specific regulatory programs. Similar efforts are being made to ensure that qualitative assessments of risk are consistent.

Until recently, environmental monitoring methodologies have been limited to physical and chemical characterization of specific pollutants. Refinement in bioevaluation techniques has revealed that chemical analysis alone is not sufficient to identify the potentially toxic chemicals. Moreover, since people are not exposed to single chemicals but to complex environmental mixtures, it is important that we develop and implement test systems that can effectively evaluate the effects not only of single compounds but of the interactive effects of complex chemical mixtures.

Particular attention and considerable resources have been devoted to the research and development of short-term tests over the last several years. This allocation of resources has reflected our recognition of the limitations of whole animal and epidemiological studies. As a rapid, effective, and inexpensive means to identify the impact of toxic substances, short-term testing can play a critical role in monitoring the environmental media for presumptive health hazards. By efficiently using short-term bioassays and through the development of approaches that combine the use of various bioassay systems, we can screen large numbers of potentially harmful compounds in a systematic and effective manner.

The past few years have seen great strides in the short-term bioassay field, marked by an increase in the application and utilization of short-term procedures and by the validation of these bioassays. In spite of their suitability as environmental monitoring tools green plants have not been the beneficiary of the boom in bioassay development and utilization. However, as this workshop will reveal, considerable effort is now being made to establish plant systems as valid monitoring and screening mechanisms for mutagens. There are currently about a dozen reliable plant genetic systems that can increase the scope and effectiveness of chemical and physical mutagen screening and monitoring procedures. The advantages of plant systems are numerous:

- Plant tissue is much more complex than bacteria and, as such, is more similar to that of man.

- Some plants have demonstrated a capacity to transform promutagens into mutagens.
- Researchers enjoy the same numerical advantages with pollen systems that have proven so beneficial with the microbial tests, i.e., scoring of mutation events on a per-million-cell basis.
- Hereditary effects can be studied by growing plants from germ cells such as exposed pollen grains.
- Qualitative extrapolation of pollen bioassays appears to be no worse than has been achieved with bacteria.
- Plants are easy and inexpensive to culture and can exhibit numerous genetic and chromosomal changes for determining the effects of mutagens.
- And, finally, plants offer unique potentials for use as on-site monitors for mutagenic pollutants in the atmosphere.

Plants can be used as *in situ* monitors to identify both the acute and the chronic effects of environmental contaminants. The United States Environmental Protection Agency has used a few plants systems, such as the *Tradescantia* stamen hair, to evaluate the quality of ambient air in several cities in the United States. Also plant bioassays, includ-

ing the *Tradescantia* micronucleus, waxy maize, and *Arabidopsis* are being validated for potential use in environmental monitoring.

In conclusion, I would like to say that plant systems will be very important to future assessment research efforts, particularly since they can be used on site to provide an indication of the potential damage of ambient conditions in air and water, and since they can provide a relatively inexpensive way to study the chronic effects of pollution.

Effective regulation requires that we first complete the task of identifying, qualitatively and quantitatively, the harmful health and ecological effects associated with environmental agents. Plant systems will complement our efforts in this direction by providing, in comparison with other short term test systems, results that may be more extrapolatable to man.

Recognition of the magnitude of the problem is but a small first step toward the development of environmental regulation required by legislation. The overwhelming task confronting us now is to play "catch-up." We must develop effective, efficient, and economical ways to identify the chemicals as they appear in emissions, effluents, or ambient environmental media.