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DIFFERENCES IN THE REGULATION OF CHEMICALS AND RADIONUCLIDES

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INTRODUCTION

Government regulations limiting public exposure to radionuclides and chemicals have historically been developed by regulatory agencies using different approaches with the result that levels of protection vary for the two classes of contaminants. These differences create difficulties in determining equitable regulatory measures when both radionuclides and chemical pollutants are involved. Generally, radiation exposure is not regulated as stringently as chemical exposure (Travis et al, 1989). The International Commission on Radiological Protection (ICRP) recommends limiting excess environmental radiation exposure to the general public to 100 millirem per year (mrem/yr) (ICRP, 1991), a lifetime cancer risk of about 3.5E-3. An acceptable level of risk for chemical exposures is generally considered to be below 1E-6. Differences in regulatory approach for radionuclides and chemicals evoke debate over why they are different and which regulation strategy is better. Because these pollutants often coexist (mixed waste sites, contaminated metals and facilities, etc.), it is important to analyze inconsistencies in the regulation of chemicals and radionuclides and establish a more consistent approach to defining an acceptable level of exposure for these contaminants.

DEFINING THE DIFFERENCES

Historical Development

A major factor in the historical development of public radiation protection standards is that radiation exposure by the general public is inevitable. Natural background radiation exposure is in the range of 70 to 250 mrem/yr, giving rise to a lifetime cancer risk of 2.5E-3 to 8.8E-3. Early risk reduction strategies for radiation exposures were cognizant of high background exposure levels and attempted to limit additional exposures to the same order of magnitude as background (100 mrem). Reduction of radiation exposure significantly below background was considered unnecessary.

Chemical risk assessments do not account for a naturally occurring background level of exposure. Historically, chemical exposure was recognized to be a purely man-made condition resulting from the increased use of chemicals by industry and the public. Chemical exposure was thought to result from point sources of pollution. This perspective led to the opinion that any man-made chemical can (and therefore should) be regulated to a point of near-zero exposure. This type of reasoning was affirmed, and precedents set, by legislation such as the Delaney Clause (Food Additives Amendment) of the 1958 Federal Food, Drug and Cosmetic Act which stated: "No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal." From a practical point of view, the absolute ban on human exposure to chemical pollutants has been functionally replaced with a generally accepted de minimis (below regulatory concern) risk level of one in a million (1E-6) lifetime cancer risk.

More recently, it has been recognized that a background level of human exposure to hazardous chemicals does exist (Travis and Hester, 1991). Because of the widespread use of chemicals in our everyday life (e.g., paints, gasoline, cleansers), the entire U.S. population is exposed to a large and persistent level of chemical pollution. The total risk of exposure to the global background chemical pollution is on the order of 1E-3 (Travis and Hester, 1991), the same level of risk associated with background radiation exposures.

Scientific Foundations for Regulation

Major differences exist in the data upon which radiation and chemical risk estimates are based. Radiation risk assessment developed as a framework for protecting radiation workers and for predicting residual health impacts from the use of nuclear weapons (SAD/RAC, 1992). Scientists have studied first-hand the effect of acute and chronic radiation exposures such as Japanese atomic-bomb survivors, uranium miners, medical patients, and radium dial painters. Therefore, risk estimates for radiation exposures are based on relatively precise human data, with the result that scientists are more confident in the regulatory limits and do not believe over-conservatism is necessary.

Compared to radiological studies, little is known about the biological effects of human exposure to chemicals. While epidemiological data do exist for a few chemical carcinogens, they do not exist in general. What data do exist are of poor quality because of the difficulty in determining the extent of historical exposure. Chemical risk assessments are therefore based primarily on the results of animal bioassays rather than human data.

The use of animal data in chemical risk assessments leads to a great deal of uncertainty in the risk estimates. Test results must be extrapolated from the high doses to which animals are exposed to the low doses which humans generally experience.

other variables that increase uncertainty in using animal data are differences in metabolic processes, tumor sites, and sensitivities among species. Because of these uncertainties, health scientists have tended to adopt very conservative procedures in estimating risk of human exposure to chemical contaminants.

Levels of Regulation Stringency

The ICRP recommendation of limiting public excess radiation exposure to 100 mrem/yr is generally interpreted as an upper bound for public exposure. It is explicitly acknowledged that excess exposure should be reduced below the 100 mrem limit when possible so that doses are kept "as low as reasonably achievable" (ALARA) (Kocher and Hoffman, 1991). In applying the ALARA principle, factors such as cost, technical feasibility, and societal concerns are taken into account.

Because no historical basis for assuming background chemical exposure exists, scientists have attempted to establish a practical equivalent to absolute safety for chemical exposure. A one in one million (1E-6) risk level for lifetime individual exposure to chemicals has been generally accepted as appropriate and negligible, or a *de minimis* level. This minimal level does not take into account existing chemical background levels, potential benefits of chemical use, cost, or technical feasibility. In practice, however, the actual risk level associated with regulated chemical exposures is higher. The target range for clean up of hazardous sites as identified by the EPA Superfund Project is 1E-4 to 1E-6. A review of 132 federal regulatory decisions showed that the median individual risk *after* regulation was 8.6E-6 but that some post-regulatory risks ranged as high as 4E-3 (Travis et al, 1989).

HARMONIZING THE STANDARDS

The concept that similar risks should be treated in a similar manner is not unreasonable; however, attempts to apply acceptable chemical risk standards to radiation result in standards that are far lower than natural background radiation. Radiation scientists see such limitations on radiation exposure as unreasonable and unnecessary; by comparison, chemical risk assessors see current regulatory standards on radiation as posing a risk too high to be tolerated (SAB/RAC, 1992). These situations call for harmonization of risk-reduction strategies for chemicals and radiation. Harmonization does not necessarily imply identical treatment, but it does imply that any differences in treatment be clearly explained and justified (SAB/RAC, 1992).

To resolve the discordance in regulatory approaches for chemicals and radionuclides, regulators must first understand and clarify the fundamental differences in the two separate philosophies of regulation. Each standard has a sound historical basis of development, and in fact, there may be a way to harmonize them. Kocher and Hoffman (1991) propose 1E-3 as a level of risk above which public exposure to either radionuclides or chemicals would never be allowed to occur. This level of risk is compatible with the background level of risk for both radionuclides and chemicals; therefore, it would not significantly increase the *existing* level of risk. It is also compatible with the existing regulatory approach for chemicals and radionuclides whereby every chemical with an individual risk above 4E-3 is regulated (Travis et al, 1987), and public exposure to radiation is regulated at 100 mrem. Kocher and Hoffman further propose that 1E-3 only serve as a ceiling; every effort should be made to reduce exposures to ALARA. Therefore cost, technical feasibility, and societal concerns can be taken into account. This approach would supply a harmonizing framework for the regulation of both radionuclides and chemicals. It would not dramatically change our current approach to regulation but would provide a more consistent and equitable manner to regulate environmental pollutants.

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