

## THE GROWING NEED FOR RISK ANALYSIS

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### ABSTRACT

Risk analysis has been increasingly receiving attention in making environmental decisions. For example, in its May 18, 1993 Combustion Strategy announcement, EPA required that any issuance of a new hazardous waste combustion permit be preceded by the performance of a complete (direct and indirect) risk assessment. This new requirement is a major challenge to many engineers who are involved in waste incineration activities. This Paper presents the highlights of what is required for a risk analysis from a practical engineering point of view. It provides the regulatory basis for it to provide the rationale as to why risk analysis is needed.

### INTRODUCTION

"Nothing would be done at all if a man waited till he could do it so well that no one could find fault with it"--Cardinal Newman. Cardinal Newman's statement is very pertinent to the subject of "Risk Analysis." The assessment of environmental risks posed to human health is an incredibly complex undertaking. Because of this complexity, it is very difficult to do much more than identify sources and effects of potential concern and, in a rough manner, to quantify transport along major pathways (Martin-86). In addition, risk analysis has been basically developed by scientists. This makes it more difficult for engineers to apply the risk models developed by these scientists to their "real-world" waste treatment problems, because of the different disciplines and terminologies involved.

Basically, the authors used the documents contained in the "References Section" to derive the information for this Paper. The objective of this Paper is to summarize the highlights of what is required for a risk analysis from a practical engineering point of view. It emphasizes the documentation of risk analysis requirements from various environmental statutes. The purpose is to establish the regulatory basis relative to why risk analysis is needed, and how risk analysis should be conducted. It is believed that the understanding of the statutory provisions is important and that the only way to formulate the proper risk analysis approach is to comply with the regulatory requirements under the specific environmental laws that apply. For example, in the past, risk assessments were not required for obtaining a hazardous waste incineration permit. However, in its May 18, 1993 Combustion Strategy announcement, EPA required that any issuance of a new hazardous waste combustion permit be preceded by a complete direct and indirect risk assessment (EPA-93/5). This new requirement is a major challenge to many engineers who are involved in waste incineration activities.

### REGULATORY BASIS FOR RISK ASSESSMENT

Risk is the probability of injury, disease, or death under specific circumstances (Lee-92/6). Risk assessment is a cornerstone of environmental decision-making. EPA defines risk assessment as: (1) the determination of the kind and degree of hazard posed by an agent (such as a harmful substance); (2) the extent to which a particular group of people has been or may be exposed to the agent; and (3) the present or potential health risk that exists due to the agent (Lee-92/6). Risk assessment is a complex process by which scientists determine the harm that an individual substance can inflict on human health or the environment. For human health risk assessment, the process takes place in a series of four major steps as follows (EPA-90/6; NAC-83):

- (1) Hazard identification: In identifying hazards, two kinds of data are gathered and evaluated: (A) data on the types of health injury or disease that may be produced by a chemical; and (B) data on the conditions of exposure under which injury or disease is produced. The behavior of a chemical within the body and the interactions it undergoes with organs, cells, or even parts of cells may also be characterized. Such data may be of value in answering the ultimate question of whether the forms of toxicity known to be produced by a substance in one population group or in experimental settings are also likely to be produced in humans.
- (2) Dose-response assessment: The next step in risk assessment describes the relationship between the amount of exposure to a substance and the extent of toxic injury or disease. Even where good epidemiological studies have been conducted, reliable quantitative data on exposure in humans are rarely available. Thus, in most cases, dose-response relationships must

be estimated from studies in animals, which immediately raises three serious problems: (A) animals are usually exposed at high doses, and effects at low doses must be predicted by using theories about the form of the dose-response relationship; (B) animals and humans often differ in susceptibility (if only because of differences in size and metabolism); and (C) the human population is heterogeneous, so some individuals are likely to be more susceptible than the average.

- (3) **Human exposure assessment:** Assessment of human exposure requires estimation of the number of people exposed and the magnitude, duration, and timing of their exposure. The assessment could include past exposures, current exposures, or exposures anticipated in the future. In some cases, measuring human exposure directly, either by measuring levels of the hazardous agents in the ambient environment or by using personal monitors, is fairly straightforward. In most cases, however, detailed knowledge is required of the factors that control human exposure, including those factors that determine the behavior of the agent after its release into the environment.
- (4) **Risk characterization:** The final step in risk assessment combines the information gained and analysis performed during the first three steps to determine the likelihood that humans will experience any of the various forms of toxicity associated with a substance. The risk characterization then becomes one of the factors considered in deciding whether and how the substance will be regulated.

In the 1980s, as health risk assessment became more widely used across U.S. EPA programs, the need for consensus and consistency in the areas of hazard identification and dose-response assessment became clear. In 1986, EPA work groups were convened to establish consensus positions on a chemical-by-chemical basis for those substances of common interest and to develop a system for communicating the positions to EPA risk assessors and risk managers. This effort resulted in the creation of EPA's Integrated Risk Information System (IRIS) in 1986. In 1988, the IRIS was made available to the public.

IRIS currently contains summaries of EPA human health hazard information that support two of the four steps--hazard identification and dose-response evaluation--of the risk assessment process. It currently contains information on approximately 500 specific substances. Questions such as "what is the potential human health hazard of exposure to benzene?" and "what are the possible cancer and/or non-cancer effects?" can find answers from IRIS (EPA-93/1).

A key factor affecting the regulatory coverage of a statute is the definition of the substances subject to regulation. The statutes use several descriptive terms, not necessarily having the same meaning, to identify "harmful substances." These include pollutant, toxic pollutant, hazardous substance, contaminant, hazardous material, and hazardous waste. The Toxic Substances Control Act (TSCA), for example, defines "chemical substances" and "mixtures" subject to regulation if certain criteria are met; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Marine Protection, Research, and Sanctuaries Act (MPRSA) specify categories of substances [FIFRA defining "pesticides," and MPRSA "materials"].

In general, three aspects of risk are addressed in each statute. They are: type of harm, type of risk, and required considerations between the chemical and the harm that may result (Martin-86).

**Type of Harm:** The type of harm is usually explicitly described by terms that define the chemicals or the substances to be addressed (e.g., a hazardous substance that may cause injury to health or the environment). The harm components of a statute's risk definition generally consist of a description of an undesired outcome (death, injury) and/or a description of the population (public, wildlife) at risk or the objective of the regulation, such as protection of the environment.

**Type of Risk:** Considering risk when developing federal regulations encompasses the probability of harm occurring. The probability of harm presented by a chemical may be considered zero, insignificant, or significant. A term such as "significant risk" will then be addressed by the rule-making process.

**Required Considerations:** The statutory language may guide the designation and setting of technical or control standards for explicitly specifying a basis for making regulatory decisions and also for indicating what factors must be, may be, or may not be considered when developing regulations. The statutes discuss the amount of protection or risk reductions to be addressed through the issuance of standards "necessary,"

"adequate," or "sufficient" to protect health or the environment by providing detailed guidance (e.g., ample margin of safety) and/or by prescribing partial factors (e.g., risk and cost) that must be considered.

#### REGULATORY BASIS FOR RISK MANAGEMENT

EPA is responsible for implementing environmental statutes. Although, the statutes generally do not prescribe risk assessment methodologies, many environmental laws do provide very specific risk management directives, and these directives vary from statute to statute. EPA defines risk management as the process of evaluating alternative regulatory and non-regulatory responses to risk and selecting among them. The selection process necessarily requires the consideration of legal, economic and social factors (Lee-92/6).

Statutory risk management mandates can be roughly classified into three categories: (1) pure risk; (2) technology-based standards; and (3) reasonableness of risk balanced with benefits (EPA-93/1).

##### (1) Pure-Risk Standards

Pure-risk standards are, sometimes, termed zero-risk standards. This category allows an adequate margin of safety, however, requires the protection of public health without regard to technology or cost factors. For example, the National Ambient Air Quality Standards (NAAQS) of the Clean Air Act belong to this category.

##### (2) Technology-Based Standards

Technology-based environmental standards focus on the effectiveness and costs of alternative control technologies rather than on how control actions could affect risks. For example, industrial water pollution standards, where the installation of a single control system can reduce risks from a variety of different pollutants, belong to this category.

Consider the several technology-based standards in the Clean Water Act. The Act requires industries to install several levels of technology-based controls for reducing water pollution. These include best practicable control technology, best conventional technology, and best available technology economically achievable for existing sources. New sources are subject to the best demonstrated control technology. Total costs, age of equipment and facilities, processes involved, engineering aspects, environmental factors other than water quality, and energy requirements are to be taken into account in assessing technology-based controls.

##### (3) No Unreasonable Risk

This category calls for the balancing of risks against benefits in making risk management decisions. The following are two examples in this category:

- The Federal Insecticide, Fungicide, and Rodenticide Act requires EPA to register (license) pesticides which, in addition to other requirements, it finds will not cause unreasonable adverse effects on the environment. The phrase refers to any unreasonable risks to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.
- Under the Toxic Substances Control Act, EPA is mandated to take action if it finds that a chemical substance presents or will present an unreasonable risk of injury to health or the environment. This includes considering the effects of such a substance on health and the environment and the magnitude of the exposure of human beings and the environment to such a substance; the benefits of such a substance for its various uses and the availability of substitutes for such uses; and the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

#### THE ROLE OF COMPARATIVE RISK ANALYSIS

EPA's support for using comparative risk analysis to help set its regulatory priorities has been no secret. Unlike risk assessment, which for years has provided regulators the basis for deciding whether or not an individual substance needs to be controlled, comparative risk analysis and its derivative, relative risk, have arrived on the scene only recently. Very simply described, comparative risk analysis is a procedure for ranking environmental problems by their seriousness (relative risk) for the purpose of assigning them program priorities. Typically, teams of experts put together a list of problems; then,

they sort the problems by types of risk--cancer, non-cancer health, materials damage, ecological effects, and so on. The experts rank the problems within each type by measuring them against such standards as the severity of effects, the likelihood of the problem occurring among those exposed, the number of people exposed, and the like. The relative risk of a problem is then used as a factor in determining what priority the problem should receive. Other factors include statutory mandates, public concern over the problem, and the economic and technological feasibility of controlling it.

EPA's Science Advisory Board urged the Agency to order its priorities on the basis of reducing the most serious risks. The Board argued, in part ... There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower priority problems at the expense of higher priority risks, then society will face needlessly high risks. If priorities are established based on the greatest opportunities to reduce risk, total risk will be reduced in a more efficient way, lessening threats to both public health and local and global ecosystems....(EPA-93/1).

#### THE ROLE OF RISK COMMUNICATION

Basically, risk communication deals with the approaches to communicate with the public on various environmental issues. Some recommended communication checklist items are provided as follows (EPA-90/6): (1) Be prepared; (2) Review the facts; (3) Anticipate likely questions; and (4) Consider what the audience wants to know.

#### THE ROLE OF RISK UNCERTAINTY

Uncertainty means the quality or state of having possible variations. In risk analysis, uncertainty factors include: (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; (4) the inability of any single study to adequately address all possible adverse outcomes in humans.

#### SUMMARY

By way of summarizing, the following key questions concerning the above-described "risk" terms might be asked:

- (1) Risk assessment: What do we know about risk? or how risky is this situation?
- (2) Risk management: What do we wish to do about risk? or what shall we do about it?
- (3) Comparative risk: What is the ranking (priority) of the various risks?
- (4) Risk communication: What and how should a risk assessor communicate with the public on risk analysis?
- (5) Risk uncertainty: What is the quality or state of having possible variations in conducting risk analysis?

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