

Approaches to Risk Assessment

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At the present time there is no consensus on a uniform risk assessment model for use in animal health and associated human health issues. Harmonization of models for risk assessment are desirable for several reasons. Harmonization of the approaches followed by the various organizations and disciplines will result from scientific discussions, information exchange, and understanding each other's goals and objectives. It is not at all standardization but rather a sharing of information on what approaches and definitions are being used.

First, the development of an approach exclusive to animal health could undermine the credibility of our risk assessments in the eyes of other disciplines, especially those conducting risk assessments on biological agents. Second, the possibility of duplication of efforts in performing risk assessments on a given hazard could be minimized if an understanding existed on approaches used. Third, the acquisition of methods developed in other disciplines would be facilitated by the use of shared or common approaches to risk assessment. In recent years the World Trade Organization (WTO) has been encouraging governments to base their national measures on the international standards, guidelines and recommendations developed by WTO member governments in other international organizations. These agencies include for animal health, the Office international des épizooties (OIE); for food safety, the Codex Alimentarius Commission of the FAO/WHO; and for plant health the International Plant Protection Convention (IPPC). As an example, the risk assessment paradigm developed by a committee of the National Research Council, an agency of the National Academy of Science (NAS) in 1983, is being used by an FAO/WHO expert consultation on the application of risk analysis to food standards issues (WHO 1995).

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NAS-NRC MODEL

The National Academy of Science (NAS) through the Committee on Institutional Means for Assessment of Risks to Public Health of the National Research Council derived a uniform risk assessment model for use by all USA federal regulatory agencies (NAS, 1983). This model is now widely used by several U.S. government agencies. The Committee adopted the following terminology for use in this report.

Risk assessment: the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

Risk management: the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision making process that entails consideration of political, social, economic, and engineering information with risk related information to select the appropriate regulatory response to a potential chronic health hazard.

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The selection process necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control.

STEPS IN THE NAS-NRC MODEL OF RISK ASSESSMENT

Risk assessment can be divided into four major steps: hazard identification, dose response assessment, exposure assessment, and risk characterization. A risk assessment might stop with the first step, hazard identification, if no adverse effect is found or if an agency elects to take regulatory action without further analysis, for reasons of policy or statutory mandate.

1. **Hazard identification:** is defined as the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (abortion, birth defect, etc.). It involves characterizing the nature and strength of the evidence of causation.

2. **Dose-response assessment** is the process of characterizing the relation between the dose of an agent administered and the incidence of an adverse health effect as a function of exposure to the agent. It takes account of intensity of exposure, age pattern of exposure, and possibly other variables that might affect response, such as sex, lifestyle, and other modifying factors. A dose-response assessment usually requires extrapolation from animals to humans. A dose-response assessment should describe and justify the methods of extrapolation used to predict incidence and should characterize the statistical and biologic uncertainties in these methods.

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3. Exposure assessment is the process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new infectious agents into the environment. In its most complete form, it describes the magnitude, duration, schedule, and route of exposure; the size, nature, and classes of the populations exposed; and the uncertainties in all estimates. Exposure assessment is often used to identify feasible prospective control options and to predict the effects of available control technologies on exposure.

4. Risk characterization is the process of estimating the incidence of a health effect under the various conditions of exposure described in exposure assessment. It is performed by combining the exposure and dose-response assessments. The summary effects of the uncertainties in the preceding steps are described in this step.

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COVELLO-MERKHOFFER MODEL

Another model adapted from the NAS-NRC model was developed by Covello and Merkhofer (1993). It is a more general model and more adaptable to animal health risk assessments.

In this model a risk assessment must determine, characterize, and quantify the following factors: (1) the potential of the source to release a risk agent; (2) the intensity, frequency, and duration of exposure, and the nature of the populations (or other valued entities) that might be exposed; and (3) the relationship between exposure and the resulting health or environmental consequences. Finally, the combined influence of these factors on risk must be determined, characterized, and quantified. The final outputs of this process are estimates of the magnitudes of possible adverse health or environmental consequences, including always a characterization of the probabilities, uncertainties, or degree of confidence associated with these estimates (Covello and Merkhofer 1993).

Based on the Covello-Merkhofer model, a complete risk assessment consists of four interrelated but conceptually distinct steps:

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1.Release assessment. Release assessment consists of describing and quantifying the potential of a risk source to introduce risk agents into an environment accessible to human and animal populations. Release assessments typically include (a) a description of the types, amounts, timing, and probabilities of the release of risk agents, and (b) a description of how these attributes might change as a result of various actions or events. Determinants such as susceptible species, age and breed of animals, average incubation period, mortality and morbidity, duration of disease course, stage of infection, vaccination, sensitivity of diagnostic tests, proportion of carrier animals and duration of carrier state, agent predilection sites, ease of agent contamination, processing procedures, additives and treatments, are generally considered to generate probability estimates. Certain risk reduction options such as vaccination, testing, treatment are included in the release assessment step to allow quantification of minimal risk in presence of the risk sources.

2.Exposure assessment. Exposure assessment consists of describing and quantifying the relevant conditions and characteristic for exposure to risk agents produced or released by a given risk source. In animal health the exposure assessments typically would include (a) a description of the intensity, frequency, and duration of exposure (e.g. nature and properties of the agent, the inherent nature and intended use of the release source (b) routes of exposure, modes of transmission and portals of entry, (c) the number, nature, and characteristics of the populations that might be exposed (e.g. primary, secondary and intermediate hosts of the agent, human and animal demographics, customs and cultural practices compliance with human and animal health legislation), and (d) any other conditions that might affect exposure (e.g. the presence of potential vectors).

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3.Consequence assessment. Consequence assessment consists of describing and quantifying the relationship between specified exposures to a risk agent and the health, economic and environmental consequences of those exposures. Consequence assessments typically include (a) a specification of human/animal fatalities and disease outbreaks sustained under given exposure scenarios, and/or (b) a specification of ecological damage or adverse effects on the natural environment under given exposure conditions.

4.Risk estimation. Risk estimation consists of integrating the results from release assessment, exposure assessment, and consequence assessment to produce quantitative measures of health and environmental risks. These measures typically include (a) estimated numbers of animals experiencing health impacts of various severities over time, (b) measures indicating the nature and magnitude of adverse consequences to the natural environment, and (c) probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates (Covello and Merkhofer 1993)

Preceding the risk assessment is the hazard identification, which identifies the potential risks agents and the conditions under which they may produce adverse reactions. Each hazard necessitates a risk assessment. A diagrammatic comparison of the two models presented below portrays the similarities and the differences. The dose-response assessment is similar to the consequence assessment yet the latter is more general in that animal and human health and environmental impact are all considered, not just human health.

Risk Assessment Models

NAS-NRC

Hazard
Identification

Dose-response
Assessment

Exposure
Assessment

Risk
Characterization

Covello-Merkhoffer

Hazard
Identification

Release
Assessment

Exposure
Assessment

Consequence
Assessment

Risk
Estimation

Hazard Identification
Identifying the risk agents and the conditions under which they potentially produce adverse consequences

Risk Assessment Model *

*Adapted from the Covello-Merkhofer
Risk Assessment Model

Risk Assessment

Release Assessment
Describing and quantifying the potential of a risk source to introduce risk agents into accessible animal and human populations

Exposure Assessment
Describing and quantifying the exposures to risk agents released from the risk source

Consequence Assessment
Describing and quantifying the economic and health consequences associated with the exposure to the risk agents

Risk Estimation
The final step in risk assessment that integrates the results from the release assessment, exposure assessment and consequence assessment to produce quantitative measures of the likelihood, timing, nature and magnitude of adverse consequences

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Advantages of the Covello-Merkhofer model for animal health risk assessment

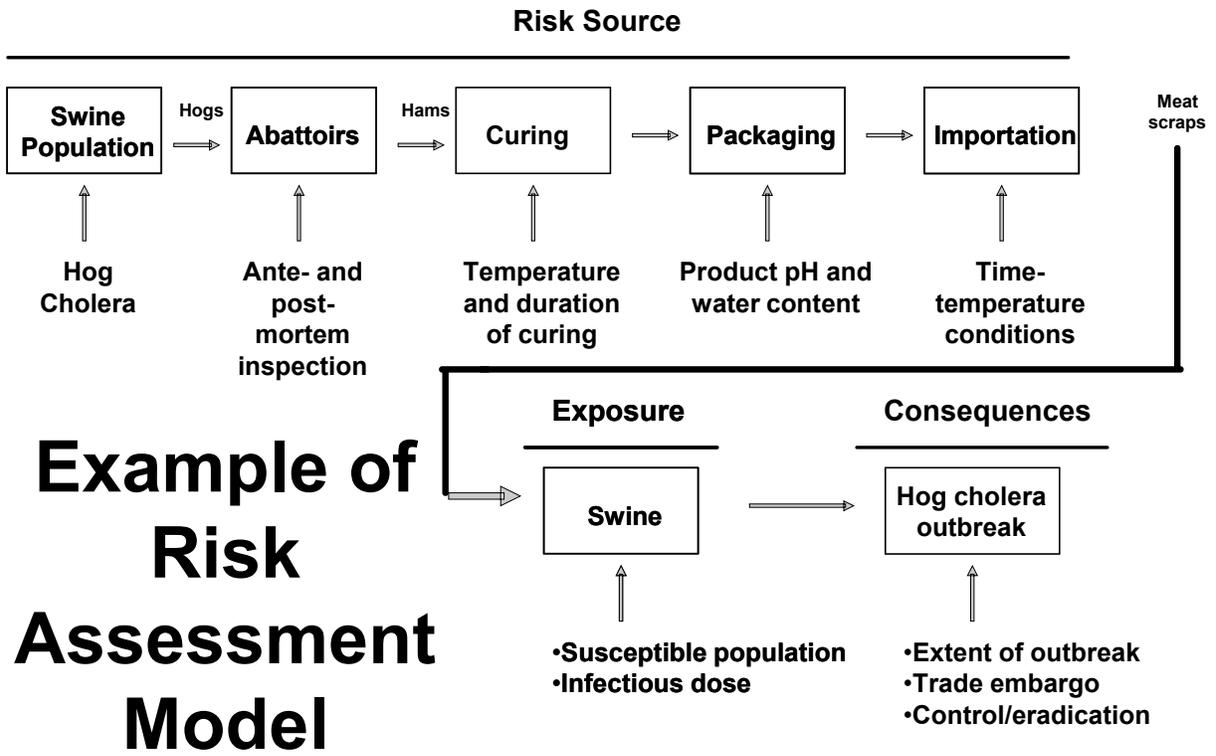
There are numerous advantages for adopting the Covello-Merkhofer risk assessment model over the NAS-NRC model. First, the NAS-NRC risk assessment model includes hazard identification as the first step in risk assessment. In the Covello-Merkhofer model, hazard identification is an altogether separate process that is necessarily conducted prior to the risk assessment. Hazard identification provides the essential foundation for and must precede the risk assessment. It is a qualitative process which has equal importance to the quantitative process of risk assessment. Second, the Covello-Merkhofer model presents a release assessment step not included in the NAS-NRC model. Release assessment is considered as a step on its own since for important types of risk quantifying and describing the potential of a risk source to release risk agents may consume as much or more effort than the other steps of the risk assessment. Even the word 'release' appropriately suits the idea of the risk source being the tangible location of one or more hazards. Third, exposure assessment is presented as the second step in the Covello-Merkhofer model to keep it in the sequential order of events (risk source release exposure consequences). Fourth, the NAS-NRC model has a dose-response assessment as a second step. The step called consequence assessment in the Covello-Merkhofer model corresponds to the dose-response but is more general. In animal health issues, dose-response is not being used, at least not in animal health risk assessments to date. Finally, the terminology of the last step in the Covello-Merkhofer model has been changed from risk characterization to risk estimation to emphasize that the goal of risk assessment is to communicate a risk estimate and not some abstract output.

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In general a risk exists when three conditions are satisfied. First, a source of risk must be present-that is, a system, process or activity must exist that can release or otherwise introduce a risk agent into the environment. Second, an exposure process must exist by which people or the things they value may be exposed to the released risk agent. Third, a causal process must exist by which exposures produce adverse health or environmental consequences (Covello and Merkhofer 1993).

An animal health example is presented graphically below - a source of risk achieves exposure through the importation of an animal product infected with hog cholera virus and the consequences of disease introduction follow. The risk source constitutes a parent population that is infected with hog cholera. The swine population sources young pigs for slaughter which are used to produce ham. The hogs are subjected to ante-and post-mortem examinations. Hams are produced and the agent is influenced by the temperature, duration of curing, the product pH, water content and time and temperature in-transit.

For exposure to occur some means to facilitate exposure of the commodity to susceptible animals and an infectious dose is required. The consequence assessment evaluates the extent of a hog-cholera outbreak, the cost of control and eradication and the losses from a trade embargo.



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