

# National Advisory Committee on Microbiological Criteria for Foods "Principles of Risk Assessment for Illnesses Caused by Foodborne Biological Agents"<sup>†‡</sup>

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## ABSTRACT

The National Advisory Committee on Microbiological Criteria for Foods has been developing a concise document that provides key definitions and principles related to the application of quantitative risk assessment techniques to illnesses caused by foodborne biological agents. Key components of the document are outlined, and its status is reported.

Key words: Quantitative risk assessment, risk analysis, public health

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At the recommendation of the National Academy of Sciences, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was established in 1988 to serve as a scientific resource for the Departments of Agriculture, Health and Human Services, Defense, and Commerce on issues related to the microbiological safety of foods. The committee operates under the auspices of the Department of Agriculture. Its principle mode of operation is to respond to specific scientific inquiries by the four sponsoring agencies. The committee has responded to such requests primarily through the issuance of a series of reports and recommendations on subjects such as principles and practices for the application of hazard analysis/critical control point (HACCP) to different segments of the food industry, examples of generic HACCP plans, microbiological criteria for different seafood, and scientific status and research needs for several emerging foodborne pathogens.

Approximately 3 years ago, the committee received a request to "provide advice of the 'current state of the science' relative to the development of techniques for the quantitative assessment of risk posed by the microbial

pathogens associated with meat and poultry." The committee believed this was an important emerging approach and responded to the request by establishing a quantitative risk assessment working group. The application of quantitative risk assessment techniques to food safety microbiology is a scientific discipline that is in its infancy. To date, there have been a limited number of published assessments in which investigators have attempted to estimate quantitatively the risks associated with pathogenic microorganisms in foods (2, 3). Further, the extension of risk assessment principles developed for chemical agents to biological agents is not straightforward because of differences in some of the basic underlying scientific principles. One of the most obvious differences is that the levels of a microorganism in a food change drastically as a result of growth or death of the biological agent. It became apparent during the committee's initial review of the subject that too often experts in risk assessment and food safety microbiology did not have an adequate appreciation of the basic concepts in each others' disciplines or were using the same terms to describe different ideas. Accordingly, the risk assessment working group concluded that its first task in responding to the request for advice was the development of a document that provides definitions and general principles for the quantitative assessment of risks of illness from biological agents in food. A summary of the NACMF document, "Principles of Risk Assessment for Illness caused by Foodborne Biological Agents," is reported here.

In fulfilling this initial objective, the working group established three general criteria/goals for the report. The first was that the report should be internally consistent with the previous work of the committee. For example, terms and concepts that had been defined or accepted in the committee's earlier work on HACCP would not be changed unless there was a significant scientific reason the previous deliberations were inadequate. A second goal was to keep the document concise and the language as straightforward as possible. This goal reflected the assumption that the report would be read by a diverse range of individuals. Finally, the third self-imposed criterion was that all pertinent foodborne microorganisms of public health concern should be encompassed in the document; hence the focus on biological agents

and not just pathogenic bacteria. The term "biological agent" was intended to include the pertinent bacteria, viruses, fungi, helminths, protozoa, parasites, and algae and the toxic products that these agents produce.

The document is divided into two major sections. One provides key definitions adopted by the working group, and the other outlines the general steps and principles for conducting a risk assessment for a foodborne biological agent.

## DEFINITIONS

The eight definitions listed below are included in the document. In developing these definitions, the working group attempted to the greatest extent possible to harmonize the definitions with those developed at the WHO/FAO Expert Consultation on Risk Analysis (4). Where differences do occur, the working group believed either that a concept could be expressed in a simpler manner or that a definition needed modification to include all biological agents of food safety concern.

**Biological agent.** Infectious, toxicoinfectious or toxigenic foodborne organisms or their toxic products.

**Food.** Any substance, whether processed, semiprocessed, or raw, that is intended for human consumption, including drinks, chewing gum, nutritional supplements, and any substance that has been used in the manufacture, preparation, or treatment of "food" but excluding cosmetics, tobacco, and substances used only as drugs (4).

**Hazard.** A biological, chemical, or physical agent in or property of a food that may cause a food to be unsafe for consumption.

**High-risk populations.** A segment of the population that has increased likelihood of exposure to a hazard, increased likelihood of illness due to exposure to a hazard, or increased likelihood that the illness resulting from exposure to a hazard will be life threatening.

**Risk.** The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

**Risk assessment.** The process of identifying hazards and characterizing the risk of illness.

**Severity.** Seriousness of the effect(s) of the hazard. Estimates of severity include, but are not limited to, proportion of cases hospitalized, case/fatality ratio, impact of sequelae, and duration of illness.

**Transparent.** The process wherein the rationale, logic of development, constraints, assumptions, value judgments, decisions, limitations, and uncertainties of the expressed determination are fully stated, documented, and accessible for review (1).

## PRINCIPLES OF QUANTITATIVE MICROBIAL RISK ASSESSMENT

The working group concurred with the WHO consultation and others concerning the division of risk assessment into four components: hazard identification, exposure assessment, dose-response assessment, and risk characterization. These four components are used in a five-step process to

establish the risks associated with the hazard being considered.

### Step 1. Goal of the risk assessment

Quantitative risk assessments should be initiated with a clear statement of the purpose of the evaluation. Such statements are particularly important when the assessment will be performed by a team of individuals. The statement should define the scope of the assessment, establish key assumptions and parameters to be considered, and provide guidance in relation to the degree of latitude that can be taken in making additional assumptions. This step should be detailed enough to establish the *transparency* of the underlying goals and basic assumptions. Assurance of transparency also requires consideration of the precautions taken to minimize bias in the selection or interpretation of scientific data.

### Step 2. Hazard identification

The second step involves the use of epidemiological, biological, and other information and expert knowledge pertinent to the biological agent, the food, and the presence of illness in consumers. Initial estimates concerning the amounts, frequencies, and sources of the biological agent that lead to illness should be made during this phase. Some of the principal sources of information used in hazard identification include biological surveillance, process evaluations, epidemiological surveillance, and epidemiological investigations. In many instances, the hazard is already well established, particularly when the purpose of risk assessment is to evaluate the relative risks associated with a change in a food system.

### Step 3. Exposure assessment

The purpose of an exposure assessment is to estimate the actual numbers of a biological agent ingested by consumers. This usually requires consideration of the probability that the biological agent will be present in the food, the impact of food handling and processing on the biological agent, and the duration and frequency of exposure. Some of the factors and information sources that may have to be considered include host population demographics, consumption patterns, consumer handling practices, biological agent distributions, and predictive models for estimating the effects of processing, marketing, and preparation.

### Step 4. Dose-response assessment

Dose-response assessments estimate the quantitative relationship between the quantity of the biological agent consumed and the frequency and magnitude of adverse health effects in a population. Typically, dose-response assessments include estimates for rates of infection, morbidity, and mortality. Some of the potential sources of information that may be used to estimate dose-response relationships include human volunteer feeding studies, epidemiological data, animal model data, and clinical and laboratory studies of virulence determinants. Additional factors that may have to be considered are sequelae, secondary infections, the physiological state of specific

subpopulations, and substrate effects (changes in dose-response relations associated with characteristics of the food). The working group included severity assessments as part of the dose-response assessment. This is based on the conclusion that dose-response assessments that include estimates of multiple biological end points (i.e., rates of infection, morbidity, mortality, and other adverse effects) provide a means for assessing the relative impact of a health effect.

#### *Step 5. Risk characterization*

This final step in conducting a quantitative microbial risk assessment involves integration of the results from the exposure and dose-response assessments to provide an overall estimate of the likelihood and magnitude of the hazard. In a fully quantitative risk assessment, the product of the assessment is a mathematical statement. In its simplest form, the risk is an exposure function times a dose-response function:

Risk = Probability of Illness

$$= F(\text{exposure}) \times F(\text{dose-response}).$$

An integral part of risk characterization is adequate description of the scientific and statistical uncertainties associated with the assessment. As with each of the steps, risk characterization must be transparent; risk assessments are most effective when all assumptions, results, analyses, and interpretations are adequately described and discussed. In addition to providing information needed for making informed risk management decisions, a good risk characterization also identifies key data currently unavailable that

would enhance the accuracy of future evaluations. Risk assessments for biological agents have finite life spans and may need to be augmented or replaced when scientific knowledge or the factors influencing risk change.

### CONCLUDING REMARKS

The final step in the NACMCF's Working Group on Microbial Risk Assessment's development of its "Principles of Risk Assessment for Illnesses Caused by Foodborne Biological Agents" was a recent review to consider the document in relation to a similar one being developed by Codex. This review has been completed, and the working group's document has been forwarded to the full NACMCF for adoption. Once adopted, the report will be forwarded to the committee's sponsoring agencies. Copies of the draft document are available by contacting Dr. Bonnie Rose, USDA, FSIS, Room 101, Cotton Annex Building, 300 12th Street SW, Washington, D.C. 20250 USA. Tel: (202) 205-0212; Fax: (202) 720-4662.

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