

2.0 Interpretation of the Commodity Risk Assessment Ratings

The interpretation of the ratings used in the Commodity Risk Assessments described below, is based on the Ontario Ministry of Agriculture and Food's "A General Framework for Food Safety Risk Assessment" which may be viewed at:

<http://www.gov.on.ca/OMAF/english/research/risk/frameworks/index.html>

Risk Characterization and Estimation

Risk assessors are responsible for risk characterization. Risk is characterized by estimating in qualitative or quantitative terms, the probability and magnitude of the impact (or consequence) of the adverse effects of the disease. Risk is further characterized by noting the attendant uncertainty of the estimates, given the available data.

When reliable quantitative data are available, assessors use quantitative multiplicative mathematical models to estimate risk. Often, the desired quantitative data are not available and a more qualitative approach is used. In either case, quantitative and qualitative assessments are summarized using a rating system to help categorize risks. The final rating assigned to a given hazard and commodity situation is derived from six sub-ratings, each rated "negligible", "low", "medium", or "high".

The first three sub-ratings are concerned with the probability of an impact on human health, influenced by several factors including the exposure characteristics of the situation. The final three sub-ratings are concerned with the impact of the disease, which is influenced by several factors including dose-response characteristics. This scoring system is used to help categorize risks in terms of their general importance. It is not used to rank individual risks in numerical sequence, but does attempt to place them in broad categories of negligible, low, medium, or high risk.

2.1 Probability of Exposure (exposure characterization)

The probability of exposure is considered under three headings:

- a) The **probability of contamination** of food along the food chain by disease agents. This may require consideration of pathways for contamination of source animals or crops and of the product during processing, storage, distribution, and preparation.
- b) The **probability of significant exposure** of susceptible human hosts to a dose sufficient to cause disease.
- c) The **potential for broad distribution and/or secondary spread** of the disease.

These headings are described in greater detail below.

a) Probability of Contamination:

The probability of contamination along the food chain by the disease agent is estimated for the specific disease agent, commodity/product, source, pathway, and destination in question. Evaluators consider:

- animal or plant source
- prevalence and distribution of agents
- harvest, processing, storage, distribution, preparation
- food safety codes of practice
- preventative programs along the food chain

Guidelines for rating the probability of contamination:

Rating = N = Negligible: The probability of contamination is extremely low or negligible given the combination of factors previously described.

Rating = L = Low: The probability of contamination is low but clearly possible given the combination of factors previously described.

Rating = M = Medium: The probability of contamination is likely given the combination of factors previously described.

Rating = H = High: The probability of contamination is very likely or certain given the combination of factors previously described.

b) Probability of Significant Exposure:

It may be appropriate to estimate the critical threshold of exposure or inoculum that is required to cause disease. In many cases such estimates will not be available and it may be appropriate to simply state the threshold that is assumed to cause a negative impact. Alternatively, when solid data describing the critical exposure are not available, risk assessors may only be able to describe process factors that are believed to influence exposure.

The probability of significant exposure of susceptible people to a hazard is estimated by considering:

- agent survival, potential for growth, decline or dilution in the food, processing, storage, distribution and preparation factors influencing temperature, time, pH, water activity, microbial competition and interaction, and chemical breakdown
- effectiveness and timing of process controls to remove or inhibit hazards
- intended use and food consumption patterns
- variability and distribution of susceptible people

Guidelines for rating probability of significant exposure:

Rating = N = Negligible: The probability of exposure to susceptible people is extremely low or negligible given the combination of factors previously described.

Rating = L = Low: The probability of exposure to susceptible people is low but clearly possible given the combination of factors previously described.

Rating = M = Medium: The probability of exposure to susceptible people is likely given the combination of factors previously described.

Rating = H = High: The probability of exposure to susceptible people is very high or certain given the combination of factors previously described.

c) Distribution and Secondary Spread Potential:

Factors influencing disease agent distribution and secondary spread are important to disease impact and control. The potential for broad distribution of significant exposure levels and secondary spread from the initial outbreak are assessed. This is influenced by the particular food distribution scenario and the biology of the disease. It can be summarized by describing the number of cases per food poisoning incident observed in epidemiological studies of similar scenarios. This may include many of the same elements considered in probability of significant exposure. Analysis may involve the use of geographic information systems (GIS) for modeling and mapping potential disease distributions.

Guidelines for rating distribution and spread potential:

Rating = N = Negligible: The probability of broad distribution and/or spread from the initial outbreak is negligible.

Rating = L = Low: The probability of broad distribution and/or spread is low and disease would tend to occur only very locally.

Rating = M = Medium: The probability of broad distribution and/or spread is moderate.

Rating = H = High: The probability of broad distribution and/or spread is high with potential for occurrences in multiple areas of Ontario from a point source.

2.2 Impact of Disease (response characterization)

The impact (or consequence) of a hazard is the second component of risk. Currently, only negative human health impacts need to be described in a food safety risk assessment for the purposes of trade. As a result, the emphasis of the OMAF impact-assessment is on impact to human health. Disease impact is described in terms of its severity and frequency of debilitation, and its impact on quality of life. The OMAF framework also briefly describes economic and environmental impacts of food safety hazards.

OMAF assesses impact under three headings:

- a) The **host spectrum and impact** on quality of life including disease frequency.
- b) The basic **economic impact** of disease.
- c) General **environmental impacts**.

These headings are described in greater detail below:

a) Host Spectrum and Health Impact:

The biological impact of the hazard (including dose/response) is described by noting the range of people potentially affected and the impact of disease on their health and quality of life, including the acute and chronic nature of the disease. The severity of impact may vary between age groups (e.g. children vs. adults vs. elderly) and concurrent health status (e.g. immune compromised individuals). A broad host range increases the biological importance of an agent. An extremely detailed explanation of the pathophysiology of the disease is not required. The mechanisms involved are described generally, noting expected severity of disease, morbidity, and case mortality rates among various hosts and age groups.

Guidelines for rating host spectrum and health impact:

Rating = N = Negligible: Disease occurs in a limited group and/or has negligible impact on health and quality of life.

Rating = L = Low: There is a limited range of people who suffer disease, with minor impact on health.

Rating = M = Medium: There is a moderately broad range of people who suffer disease and/or moderate impact on health.

Rating = H = High: Disease occurs in a broad range of people and/or with severe impact on health and quality of life.

b) Economic Impact:

Guidelines for rating economic impact:

Rating = N = Negligible: Little or no impact in terms of treatment or clean-up costs, lost work or trade.

Rating = L = Low: Minor impact on the above factors.

Rating = M = Medium: Moderate impact on the above factors.

Rating = H = High: Severe impact on the above factors.

c) Environmental Impact:

The expected environmental impact of the agent is assessed, should it escape from the food chain to other ecosystems. This may include subjective consideration of direct biotic effects on other species. It may also be appropriate to consider potential negative environmental impacts of risk management options (e.g. use of disinfectants or run-off from clean-up activities).

Guidelines for environmental impact ratings:

Rating = N = Negligible: No potential to degrade the environment or otherwise alter ecosystems.

Rating = L = Low: Limited potential impact on environment.

Rating = M = Medium: Potential to cause moderate environmental impact, with change in the ecological balance and affecting several attributes of the ecosystem.

Rating = H = High: Potential to cause major damage to environment with significant losses to ecosystems.

Please note the following information regarding the interpretation of the Risk Assessment Framework as used by the Food Inspection Branch regarding the impact on the Environment:

Using the risk assessment framework, the expected environmental impact of the agent or hazard is assessed should it escape from the food chain to other ecological systems. Environmental impacts may be substantial where new agents are introduced into Ontario. In these risk assessments, most of the hazards or agents considered are already naturally occurring in Ontario. To help clarify our ratings for environmental impact, the impact of the hazard at levels found in foods on the environment is considered, rather than assessing the direct impact of the hazard on the environment.

2.3 Overall Risk Rating and Uncertainty Assessment

Risk characterization and estimation are summarized in a statement noting the probability and impact of disease. The sources and magnitude of uncertainty of the estimation of risk are summarized in a description of the nature and quality of the data, and a discussion of the supporting and conflicting evidence. Finally, an overall risk rating of negligible, low, medium, or high is assigned.

2.4 Quick Reference Table for Interpretation of the Ratings

Rating	Risk Characterization						Risk Summary	
	Probability (Likelihood of Going Wrong)			Impact (Consequences of Going Wrong)			Uncertainty of Data	Summary of Risk and Uncertainty
	of contamination	of consumer exposure	of secondary spread among humans	on human health	economic (treatment and/ or trade)	environment		
Nglg	very unlikely	very unlikely	very unlikely	Very low few people affected	none to little	no potential	certain considerable evidence	unlikely contamination and exposure, limited impact, no previous concerns
Low	unlikely but possible	unlikely but possible	unlikely but possible local spread	minor limited range of people affected	minor	limited potential	moderate certainty some evidence	Unlikely but possible contamination and exposure, limited impact, some evidence of potential concern
Med	likely	likely	likely moderate spread	moderate moderate range of people affected	moderate	moderate potential	limited certainty little evidence	expect some contamination, exposure, and impact. strong evidence of potential concern or previous concern(s)
High	very likely	very likely	very likely wide spread	severe broad range of people affected	severe	major potential	no certainty no evidence	likely or certain contamination and exposure, serious impact, known concerns