

Appendix D

FOOD SAFETY RISK ANALYSIS

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It's important to consider hazards and risks in food processing. Hazards are often thought of as the same as risks, however, hazards are quite different from risks. The differences between them are outlined in more detail in this appendix.

1.0 Risk in Food Processing

In food processing, a hazard is a biological, chemical, allergenic or physical substance that has the potential to harm. It may also be a condition (e.g. high humidity) that could cause harm.

Not all hazards are as serious, or as immediate a threat, as others. Some situations can be more 'hazardous' depending on the levels, sizes, quantities, or doses of unwanted substance or conditions.

When it comes to food and food processing, just how hazardous a substance or condition is may vary greatly. The level of danger can depend not only on the type hazard, but also on who might consume a food product. There usually is a threshold level below or above which the presence of a hazard is considered tolerable, or acceptable.

1.1 Risk Analysis

Risk is a measure of the likelihood of a hazard doing harm and how much harm the hazard could do. Or, another way of looking at it is to consider risk an estimate of the probability of a hazard being present.

All activities related to food production and handling involve some hazards. However, how we do something or what we do determines the level of risk.

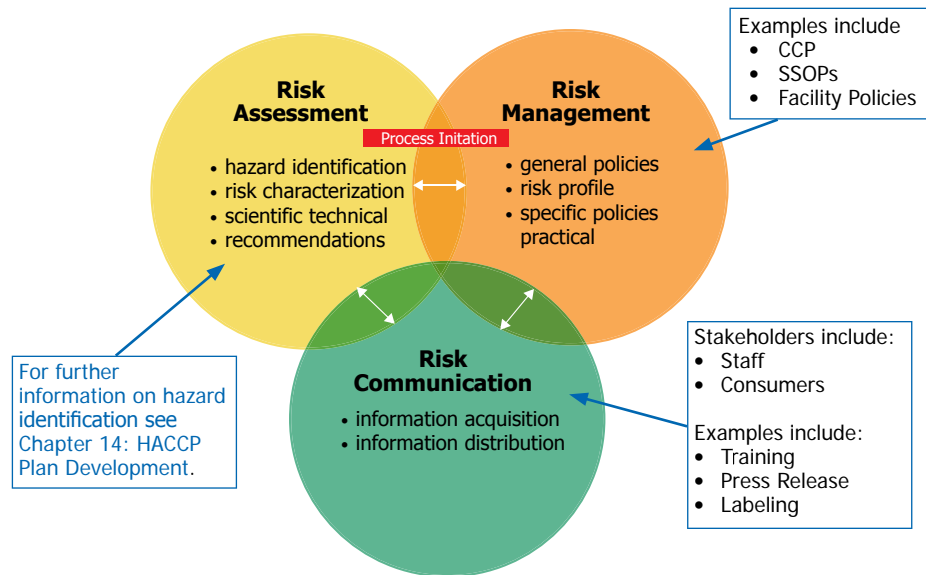
By understanding how to reduce or eliminate food hazards, it's then possible to set up food safety controls. These will lower risks to consumers and these actions are an important part of risk analysis.

A food safety risk analysis directs time and attention to greatest safety concerns in a facility. Not every food safety issue will need a formal risk analysis. It may be possible to deal with many issues in-house with well-trained staff. Depending on the situation, the facility may need the knowledge or services of an outside consultant.

Risk is an estimate of the chance of a hazard being present and the chance of it causing harm.

Risk analysis deals with:

- Assessing the risk;
- Managing the risk; and
- Risk communication.

Figure 1: Schematic Diagram of Risk Analysis

Begin the risk analysis by identifying and describing any hazards, problems or situations in the facility and its food production process. Look for anything that could be a risk to human health.

To make this list of risks, use information from:

- Consumer feedback;
- Audit results;
- New scientific research; and
- Staff comments and input.

Potential risk factors might include the food processing operation, post-preparation handling or even food safety practices in the home of consumers.

The level of risk could also relate to how retailers and distributors handle, store and process the facility's products. Consider the cause and effect relationship between the identified substance, agent or event, and how this might affect food safety.



To find more information on food safety risk analysis, visit the University of Maryland's Joint Institute for Food Safety and Nutrition (JIFSAN) at their Online Resource for Food Safety Risk Analysis at www.foodrisk.org.

1.2 Risk Assessment

The first step in risk analysis is risk assessment. This helps the facility to decide on the level of risk for each hazard. Risk assessment should provide complete information to allow the risk management team to make the best possible decisions.

Begin the risk assessment by answering three basic questions:

1. What could go wrong?
2. How likely is the event to happen?
3. What would be the outcome or impact if this event happened?

A risk assessment is never exact. The results of the risk assessment point toward probable outcomes that describe the population risk (e.g. look into density, distribution, disease and/or death).

Always think about science and public values when looking at food safety.

1.3 When to do a Risk Assessment

Ingredients, processes, consumers and other product factors are important in deciding if a formal risk assessment is needed. In general, do a risk assessment for products, processes and activities that could result in an increase in a health risk. Do so for anything that could have a direct affect on food safety.

Examples might include:

- The use of new additives in the facility's food products;
- Facility changes that affect exposure and product safety;
- Environmental changes at the facility that could affect product safety;
- Changes to the process or facility that might affect the microbiological or chemical safety of food supplies or the food supply chain; and
- Assess existing facilities, procedures, processes and policies to improve existing risk prevention.

Risk assessments can be very complicated and take a lot of time. Don't hesitate to get help from an expert.

1.4 Risk Assessment and HACCP

Risk assessment is very important in developing a HACCP (Hazard Analysis Critical Control Point) system.

Hazard Analysis is the first principle of HACCP plan development. A hazard analysis looks at the hazards that might affect a food product or raw ingredient in a processing operation. It includes collecting and evaluating information on each hazard and looks at the conditions that may cause the hazard to be present or to increase.

Once the facility decides that one or several hazards are present, do a food safety risk assessment. This will help to decide which hazards are great enough to affect food safety. These must be dealt with in the HACCP plan.

The facility's risk assessment should be based on the presence of the hazard, agent, or cause. It should also be based on how serious the hazard is, and how likely it is to reach unacceptable levels.

For example, the facility might come to the following conclusions:

- If an agent isn't present in the raw materials, production lines, or environment, it may be safe to assume it's not a hazard;
- If an agent is known to be in the facility's environment, but it can't contaminate the product, it may be safe to assume it's not a hazard;
- If the agent can contaminate the product it may become a hazard; and
- If the agent can survive, stay or increase, it may become a hazard.

This type of food safety risk assessment can often be done quickly. But sometimes the issue may be large and complicated. It may involve major health concerns and in these situations, the facility may need outside help.

1.5 The Health Risk Assessment Model

The Canadian Food Inspection Agency (CFIA) and Health Canada have developed a health risk assessment model. It lets the facility assess food safety by ranking risks on how severe they are. This assessment model offers a simple method that processors can use to look into food safety concerns.

The CFIA approach:

- Is based on current science;
- Allows for an assessment of the significance of any given risk; and
- Uses common sense.

This assessment tool has been developed to be used in all commodity (product) groups. It's clear and straightforward.



For more information on the Health Risk Assessment Model visit <http://www.inspection.gc.ca/english/fssa/polstrat/haccp/manue/app3e.shtml>.

When estimating health and safety matters, the CFIA assessment model takes into account:

1. Impact of consequences;
2. Probability; and
3. Population at risk.

CFIA Risk Assessment Summary

1. Identify the problem.
2. Determine if product safety is affected.
3. Identify the concern or hazard.
4. Evaluate the probable outcomes.
5. Determine if a sensitive population is likely to be affected.
6. Assess what controls are currently in place to deal with the hazard or concern.

7. Based on current controls, place a value to the chances of something harmful happening.
8. Decide whether the risk is remote, low, major or critical.

Identify the Problem

Keep in mind, studies have shown that 90 percent of problem solving is spent on:

- Dealing with the wrong problem;
- Describing the concern in a way that can't be answered; and
- Trying to get agreement on a solution before the problem has even been identified.

In deciding whether or not to do a formal assessment ask:

1. What is the concern or hazard?
2. Why is it a concern or hazard?
3. How urgent is this concern?
4. What do consumers think of this concern?

Determine if Product Safety is Affected

The CFIA has also developed a process to help decide what's most important. It looks at the immediate effect on human health and considers other possible impacts, like business reputation and financial impact.

The CFIA process gives the highest priority to figuring out the expected immediate impact on health. Give priority to anything where an expected emergency could immediately endanger human health.

To deal with this step, ask:

- What can go wrong?
- What disease agents, pests, hazards could be involved?
- What end results are concerns (e.g. infection, clinical disease, death, lost trade, recall)?

Evaluating the Outcome

To determine the probable outcome, look into both human concerns and financial impacts. In the CFIA assessment model, human concerns and financial impacts are noted on the X or horizontal axis (see Figure 1 below).

Health and Safety Concerns:

The health and safety effects of hazards on consumers (e.g. illness, injury, etc.) fall into one of the following groups:

- **Low** – no medical attention required;
- **Medium** – medical attention required, but recovery of the consumer expected; and
- **High** – medical attention required, no chance of recovery of the consumer expected.

The seriousness of a hazard might increase for people who are sensitive to certain situations or materials (e.g. allergens). For example, the outcome related to a hazard may be more serious if a product is used mainly by a sensitive population like newborns or the elderly.

Business Impact

The impact on the facility's business can be measured in dollars (e.g. lost sales or revenue). It can also be measured in reduced output. The impact of lost sales in a year can be grouped as:

- **Low** – minimal effect to sales, or costs for recovery;
- **Medium** – noticeable loss in sales, large expense for recovery; and
- **High** – loss or closing of the business.

The impact of a hazard affects not only consumers, but also the facility's business.

The elderly, newborns, small children and people with severe allergies or poor immune systems are examples of sensitive populations.

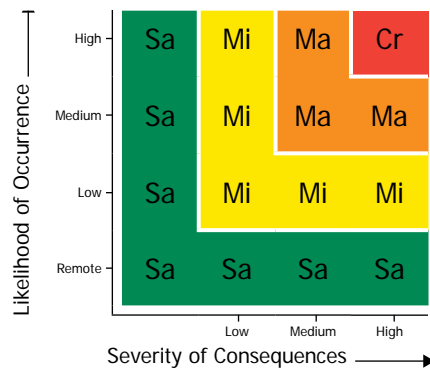
Likelihood of Occurrence

The Y or vertical axis of the assessment model (see Figure 1 below) lists the probability or chance of something happening. The chance of an undesirable outcome can be listed as:

- **High**
- **Medium**
- **Low**
- **Remote**

The chance of an unwanted outcome happening tends to increase as control over products and processes decreases.

Figure 2: CFIA Risk Assessment Model



Significance of the Hazard

Figure 1 shows how a food safety hazard is decided using the CFIA assessment model. By looking at each axis and combining their results, the facility can see different outcomes of the various combinations (Sa = Satisfactory; Mi = Minor; Ma = Major; Cr = Critical).

There are four levels in this risk assessment model:

- **Satisfactory** – a **REMOTE** (small) possibility of health or economic risk
- **Minor** – a **LOW** health or economic risk
- **Major** – a **MODERATE** health or economic risk
- **Critical** – a **HIGH** health or economic risk

2.0 RISK MANAGEMENT

Risk management was originally considered a separate part of risk analysis. However, risk analysis experts now realize that risk management and risk assessment overlap. Risk management is about choosing the best way to reduce the risk.

The main goal of food safety risk management is to protect public health. This is done by controlling risks as much as possible. Risk assessment results allow the facility to decide how to manage its own unique risks.

Since it isn't possible to eliminate risk, the facility must reduce it to an acceptable level.

2.1 Steps of Risk Management

The five steps of risk management are:

1. Evaluate the risk;
2. Determine a course of action;
3. Put a plan in place;
4. Monitor and review; and
5. Document all actions.

1. Evaluate the Risk

Most information needed for risk evaluation comes from the risk assessment. Next, use the following steps to decide how to reduce the risk:

1. Identify the food safety problem;
2. Put together a risk profile;
3. Rank each hazard for risk assessment priority (importance);
4. Rank each hazard for risk management priority; and
5. Consider the risk assessment result.

2. Determine a Course of Action

New control measures for one hazard might affect the probability of risks for other hazards. For each risk management option considered, evaluate how much the risk is reduced. Also look at how each change being considered could affect other processes and hazards.

The CFIA risk assessment model recommends making human health the priority. When human health is at immediate risk, it must be the facility's first concern.

Risk to human health must be managed through the facility's recall program. It will also be managed through the facility's product protection procedures or HACCP plans. After dealing with all human health concerns, consider other factors. Look at economic costs (e.g. lost profits), benefits (e.g. improved shelf life) and consumer preferences (e.g. use of preservatives).

3. Implement a Plan

Once the facility decides on the action to take, develop a plan. Set specific tasks and timelines. Make sure to carry out the plan.

4. Monitor and Review

Monitored and re-evaluate all activities so that that they achieve the facility's goals. The feedback from monitoring and reviewing the risk management program will let the facility know how well the program and process work.

5. Document Actions

As with all other parts of the facility's food safety system, thorough record keeping is important for risk analysis. Be clear in identifying and keeping records of all parts of the risk management process. Be sure to include the decisions made and the reasons for making them.

3.0 RISK COMMUNICATION

Risk communication lets the facility identify and weigh options during the risk analysis process. Open communication among all stakeholders (from employees to consumers) will improve the overall risk management. When the facility decides on a course of action, make sure that the decision and the reasons for it are explained clearly to everyone involved.

Risk communication is very important during food safety emergencies. However, to help make sure the message stays constant and clear, communication is also very important when there is no crisis.

The main goals of risk communication are:

1. Promoting awareness and understanding of risks (amongst employees, government officials and consumers);
2. Promoting consistency and clarity about the risk analysis process;
3. Providing an understanding for risk management decisions;
4. Strengthening good working relationships and promoting respect;
5. Promoting appropriate involvement of all stakeholders groups; and
6. Exchanging information, knowledge, attitudes, practices and perceptions of those involved.

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