**Online Training Curriculum**

**Confirmation Methods for Food contaminants**

# General Background on food contaminants and food regulatory management

## Principles of main international regulations about food contaminants

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# Overview

# Risk analysis Principles

At the international level, **risk analysis principles** are applied to ensure that food is safe and can be traded among countries. The risk analysis process comprises three separate elements: **risk assessment, risk management and risk communication**. It is widely recognized as the fundamental methodology underlying the development of food safety standards. Decisions are needed to determine what the hazards are and to identify their immediate, interim and long-term effects on human health (risk assessment); to establish the appropriate measures of control to prevent, reduce or minimize these risks (risk management); and to determine the best way to communicate this information to the affected population (risk communication) [1].

The risk to the world's population from hazards in and on food depends largely on the degree of control exercised by producers, processors and official food control authorities to prevent or minimize the risks to acceptable safe levels. Unfortunately, there is no such thing as "zero risk" for food. Understanding the association between a reduction in hazards that may be associated with a food and the reduction in the risk of adverse health effects to consumers is of particular importance in development of appropriate food safety controls.

Food authorities are responsible for the assessment of risks to human health from exposure to food-borne chemical contaminants and other adulterating substances.

## Risk assessment

Risk assessment is a quantitative evaluation of information on potential health hazards from exposure to various agents. It involves four interrelated steps [2]:

- Identification of the hazard and comprehension of the danger it represents, the impact in terms of human health and the circumstances under which the danger is present (hazard identification)
- Qualitative and/or quantitative evaluation of the adverse effects of the hazard on human health (hazard characterization)
- Qualitative and/or quantitative evaluation of the likely degree of consumption or intake of the hazardous agent (exposure assessment)

- Integration of the first three steps into an estimate of the likely adverse effect in the target population (risk characterization)

The entire risk assessment process requires the use of scientific information and the application of established scientific procedures carried out in a transparent manner. Unfortunately, scientific data are not always available for the qualitative and quantitative evaluations necessary for an absolutely sure final decision. Consequently, a degree of uncertainty must be factored into the decision.

The importance of risk assessment lies not only in its capacity for estimating human risk, but also in its function as **a framework** for organizing data as well as for allocating responsibility for analysis. The risk assessment process can include a variety of models for reaching conclusions; for example, the concept of **acceptable daily intake (ADI)** may be considered a component of risk assessment. Chemical risk assessment is a well-established process and in general permits the assessment of risks from long-term chronic exposure to a chemical. It includes the assessment of food additives, residues of pesticides and other agricultural chemicals, residues from veterinary drugs, chemical contaminants from any source and natural toxins such as mycotoxins and ciguatoxin. When sufficient data are not available to support a quantitative assessment of risks associated with food contaminants, a qualitative approach to characterizing risk may be the only current alternative.

Risk assessment requires evaluation of relevant information and selection of the models to be used in drawing inferences from that information. Further, it requires recognition of uncertainties and, when appropriate, acknowledgement that alternative interpretations of the available data may be scientifically plausible. Data uncertainties arise both from limitations on the amount of data available and from evaluation and interpretation of actual data obtained from epidemiological and toxicological studies. Model uncertainties arise whenever attempts are made to use data concerning phenomena that are likely to occur under other sets of conditions for which data are not available.

Risk assessments provide a basis for developing appropriate strategies to mitigate the risk of adverse health effects from exposure to contaminants in foods. However, the outcome of the risk assessment process should be combined with the evaluation of available risk management options in order that a decision on management of the risk can be reached.

## Importance of the update

As technology continues to expand and change, new substances, additives and ingredients may be identified in foods. Synthetic (man-made) chemicals continue to be developed for a variety of industrial and commercial uses and these chemicals can find their way into the food chain. New food growing conditions, processing techniques, equipment and packaging materials can introduce new toxins producers and potentially harmful chemicals to foods. Furthermore, substances that are naturally present in foods are still being identified for the first time, some of which may have harmful impacts on human health. In addition, new food products, additives and ingredients in foods can allow the production of new toxins that were not produced before. As a result of the ever-changing nature of foods, it is important to evaluate the human health risks associated with food contaminants in foods on a regular basis [3].

Human health risk assessments for well-known substances and toxins may be updated as new information becomes available. For example, new toxicological studies that illustrate that a given compound possesses a greater or lesser health risk than previously thought would warrant an update to a previous health risk assessment. New data on the concentration of a substance in food would also require the re-evaluation of health risks, particularly if concentrations are higher than previously reported.

## Risk management

When a potential safety concern is identified, appropriate risk management measures must be taken to reduce the risk of adverse health effects from exposure to the chemical. Risk management is defined within the Codex Alimentarius as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options including regulatory measures. The goal of the risk management process is to establish the significance of the estimated risk, to compare the costs of reducing this risk to the benefits gained, to compare the estimated risks to the societal benefits derived from incurring the risk and to carry out the political and institutional process of reducing the risk.

The outcome of the risk management process is the development of standards, guidelines and other recommendations for food safety. In the national situation it is likely that different risk management decisions could be made according to different criteria and different ranges of risk management options. Risk managers, in developing approaches to managing risk, use the risk characterization

that results from the risk assessment process. Risk management decisions can be based on establishing safe handling procedures and practices, food processing quality and safety assurance controls and food quality and safety standards to control hazards in food. These standards must take into consideration the proper use of food additives which have been determined to be safe and their permitted levels and scientifically determined acceptable safe limits for contaminants and agricultural chemical residues in food, using the risk assessment process.

**Risk management strategies vary depending on the situation**. These types of actions can include:

- setting maximum levels for contaminants in foods.

One risk management measure is the development of maximum levels (MLs) for chemical contaminants in retail foods. Maximum levels are established by food regulatory agencies and should be enforceable (by the same or another agency). Those MLs should be communicate to all stakeholders in a clear form. However, even if a safety concern is identified and risk management action is required, the establishment of an ML may not necessarily be considered the best approach to reducing the risk associated with the food-borne chemical. For example, the presence of a contaminant in a food may be the result of an incident that was temporally or geographically isolated and that could have been avoided. In this case, appropriate risk management may involve removal of the contaminated food from retail shelves and corrective action at the food manufacturer or farm level to ensure that such contamination does not occur again. Short-term monitoring to ensure that the corrective action was successful would be required but the establishment of an ML may not be considered necessary.

Maximum levels are established in an effort to reduce exposure to a particular contaminant. Exposure is affected by the concentration of the chemical in food and the amount of the food consumed. Therefore, both the concentration and the amount of food normally consumed must be considered when developing an ML. As a result, MLs for a particular chemical may differ depending on the food. The toxicity of the chemical in question must also be taken into account in the establishment of MLs for contaminants in food, because different chemicals affect human health in different ways. For example, a certain level of exposure to one food contaminant may not have an adverse impact on human health, whereas similar exposure to a different contaminant may be very harmful. When

establishing MLs for contaminants in food, the primary concern is human safety, although the availability, nutritional value, and importance of the food in the Canadian diet are also considered.

There are a limited number of retail foods for which maximum contaminant levels have been developed. There are several reasons for this. The finding of a chemical in food does not automatically lead to the conclusion that there is an unacceptable health risk to humans. Most chemicals are found in food at such low levels that they do not pose a safety concern and therefore the establishment of MLs is not required. Levels of chemicals in food are monitored through regular surveillance activities by regulatory agencies. Surveillance data are used to help identify potential contamination issues and, when warranted, appropriate risk management strategies are developed [4].

In the same way, the absence of an ML for a particular chemical contaminant does not mean that it is safe for consumption. If an elevated concentration of a chemical contaminant is found in a food for which no ML exists, a human health risk assessment must be conducted to determine if there is a potential safety concern and whether risk management measures are required.

For certain adulterating substances, a "zero tolerance" approach may be taken, which means that no amount of the substance in question would be considered acceptable in foods. Implementation of the management decision should be followed by **monitoring of both the effectiveness of the control measure and its impact on the risk to the exposed consumer population**, to ensure that the food safety objective is being met.

- providing direction on how to reduce contaminant levels, or

This is particularly the case for Food-Processing-Induced but all food contaminants are mitigated through this option notably via the Good manufacturing process and Good Agricultural Practices.

- providing advice and guidance to consumers on the risks and benefits of particular food choices,

While research and scientific studies continue to provide the answers needed for making informed decisions in risk analysis related to hazards in food, the uncertainty and unresolved questions continue to cause concern to decision-makers. Only continued research and scientific study can provide the necessary answers. Until these answers are available, much of what is known about

hazards and assessing and controlling risks is based on only partial information, with uncertainties factored into the analysis.

## Risk communication

Risk communication is the third and final element of the risk analysis process. The Codex Alimentarius definition of risk communication is narrow: "an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties". A definition with broader scope is that of the United States National Academy of Sciences: "an interactive process of exchange of information and opinion among individuals, groups and institutions... [which] involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions or reactions to risk messages or to legal and institutional arrangements for risk management" [5].

Communicating the results of risk assessment and risk management serves many purposes. The quality and safety of food depends on responsible action by all involved at all stages in the food chain, including consumers. Consumers require access to adequate information about potential hazards and appropriate precautions to be taken in the final preparation and serving of food. In addition, consumers need to be aware of and to understand food safety control measures implemented by their government in the interest of consumers' health.

Communication provides the public with the results of expert scientific review of food hazard identification and assessment of the risks to the general population or to specific target groups such as infants or the elderly. Certain people, such as those who are immunodeficient, allergic or nutritionally deficient, require particular information. **Communication provides the private and public sectors with the information necessary for preventing, reducing or minimizing food risks to acceptably safe levels through systems of food quality and safety management by either mandatory or voluntary means**. It also provides sufficient information to permit the populations with the greatest level of risk from any particular hazard to exercise their own options for achieving even greater levels of protection.

# The pesticides example

## Risk assessment

We know for sure that pesticides have harmful effects on health since many studies identify all these health impacts. When applied on food and feed crops, pesticides have the potential to remain in the products where they are applied, with more or less persistence. The remaining amounts of pesticides on a food or feed crop are known as pesticide residues. While pesticide use has positive impacts on food security through improvement of yields in crop products, such use should not result in negative health impacts. As a result, pesticides residues should not be present in food or feed at levels that may cause a health concern.

## Risk management

Regulated pesticides are applied on crops under conditions designed to protect human health both for farmer and producers as well as consumers. These conditions are determined after a thorough study of the potential health impacts of these chemical substances and the determination of conditions of use: amounts to be applied, concentration, protective equipment, withdrawal period etc. that minimize their potential risks. If such directions are not followed or if illicit substances are used, the latter may pose unacceptable risks to health or to the environment.

Regulatory control of pesticides is based on determining their conditions of use such that:

- They are effective for the purposed they were applied,
- They are safe for producers (farming practices) and consumers (consumption of crops by animals and humans).

Regulations such as pre-harvest intervals also often prevent harvest of crop or livestock products if recently treated in order to allow residue concentrations to decrease over time to safe levels before harvest.

The regulation of pesticides generally relies upon three numerical values:

- **The restricted-entry interval (REI)** which is the amount of time between the **application** of the pesticide and when workers can do **hand labour** tasks on the crops;

- **The preharvest interval (PHI)** which is the minimum amount of time between the last application of a pesticide and when the crop can be harvested. Harvest is the cutting of the crop or removal of the produce from the plant; and
- **The Maximum Residue Levels (MRLs)**, representing the maximum amount of pesticide residues that are expected to remain on a food product when the pesticide is used according to label directions.

The traces that pesticides leave in treated products are called "residues". A maximum residue level (MRL) is the highest level of a pesticide residue that is legally permissible in or on food or feed when pesticides are applied correctly (Good Agricultural Practice) and the lowest consumer exposure necessary to protect vulnerable consumers. Most food competent authorities regulate the use of pesticides through imposing a compulsory registration of their active substances. This registration includes the demonstration of safety and the determination of conditions of use and the MRL. This level is defined as a key risk management measure ensuring the safety of consumers and workers, but also to minimize the application of pesticides to the minimum amounts that would ensure their effectiveness.

These MRLs are determined using:

- toxicological assessment of the pesticide and its residue to determine an Acceptable Daily Intake (ADI);
- review of residue data from supervised trials and supervised uses including those reflecting national food agricultural practices, and
- consideration of the various dietary residue estimates both at the national and international level in comparison with the Acceptable Daily Intake (ADI).

These legal limits also apply to imported food. The maximum allowable levels of these residues in foods are often stipulated by regulatory bodies in many countries.

## Risk communication

Several countries proposed their own MLRs as food diet can be very different from one country to another. MRLs set by different jurisdictions can be found below:

- Europe: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
- Canada: https://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php)
- USA: https://www.epa.gov/pesticide-tolerances/how-search-tolerances-pesticide-ingredients-code-federal-regulations

In order to prevent a high level of inconsistency in pesticide management, and in an attempt to harmonize food regulatory measures, the Codex Alimentarius Commission (CAC) has developed a set of MRLs for a number of pesticides through its Codex Committee on Pesticide Residues (CCPR), which relies upon the assessment of safety of these substances developed by the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR).

Codex MRLs are considered the international reference for pesticide standards in food traded internationally.

Codex MRLs are available through the link below: http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/

# References


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5. http://www.fao.org/3/x1271e/X1271E03.htm