Welcome to the second lesson on the first module. During the presentation, I will explain the main principles supporting the legislation regarding food contaminants.
The learning objectives are to acquire knowledge about risk-based regulations. Indeed, food legislation in the European Union and elsewhere includes both hazard- and risk-based approaches for ensuring food safety. In hazard-based approaches, the presence of a potentially harmful agent at a detectable level in food is used as a basis for legislation and/or risk management actions. Risk-based approaches allow consideration of exposure in assessing whether there may be unacceptable risks to health.

IMPACTS OF FOOD CONTAMINANTS

Food contaminants have impact on society

- Food safety
- Food security
- Public Health
- Nutrition
- Economic impact (food waste)

As presented in lesson 1, food contaminants may cause immediate effects, or may be associated with potential long-term effects after chronic exposure to the chemical. One example of an immediate effect is gastrointestinal illness such as nausea, which can be caused by high levels of industrial chemicals. Examples of long-term effects include impaired cognitive development in children chronically exposed to relatively low levels of lead and liver cancer resulting from chronic exposure to mycotoxins like aflatoxin.

However, the impact of food contaminants can easily be extrapolated to broader issues such as food safety, food security, food waste etc.
For all these reasons there is a need for a legislative framework allowing the production of safe food and mitigating the presence of food contaminants.

WHY A LEGISLATIVE FRAMEWORK?

To protect public health

- From chemical and microbiological hazards
- Through proactive, preventative programmes based on scientific evidence
- By enabling better prioritisation of food control resources
- By regular evaluation of efficacy of existing food safety measures

To facilitate food trade

- By providing a scientific base to support food safety decisions
- By developing consumer or importer trust through demonstrated commitment to food safety
- Through improved transparency by making contaminant data widely available

European Commission

The primary purposes of food legislation are to protect the health of the consumer, to protect the consumer from fraud, and to ensure the essential quality and wholesomeness of foods.

Food law must first provide the legal authority and an adequate legal framework for the food-control activities.

Generally, food law prohibits importation and distribution of food products that are adulterated, or have labels that are false or misleading in any context.

Food regulations can also be thought of as catalysts to developing countries' participation in trade.

Regulatory measures that address risk in food production and food consumption underpin the structure of market transactions within countries and influence competitive advantage among trade partners.

The proper implementing of such regulations encourages fair trade practices through compliance with the basic provisions of the food law. This protects the honest manufacturer and dealer against unfair competition. It also stimulates development of the

food industry, because quality control along sound scientific lines tends to promote better consumer acceptance of foods.

In other words, regulations are important for other stakeholders (including consumers but also Food business operators) to maintain trust in your capability to produce safe food.

An effective food safety system requires effective regulations, policies and procedures along the entire farm to fork continuum. It also requires co-operation by a multitude of partners, including governments, international standard-setting bodies such as the Codex Alimentarius Commission, industry (farmers, producers, processors, importers, exporters, and retailers) and also individual consumers.

To illustrate, governments are responsible for establishing food safety requirements for industry to meet. Governments should ensure compliance with food safety requirements

Food industry is responsible for ensuring that food produced is safe and meets all requirements established by government

BASIS OF INTERNATIONAL REGULATIONS

Framework of risk analysis (Théolier et al., 2020)

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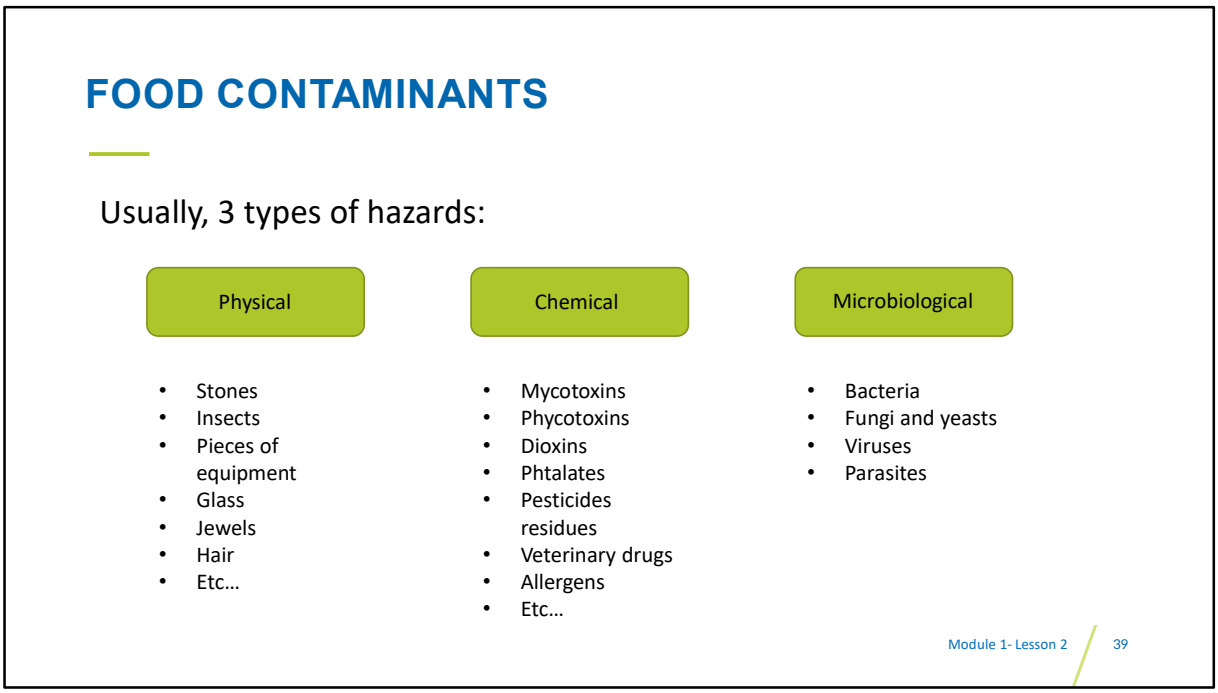
However Food laws are not intended to guarantee that all food is safe because achieving that goal would be too expensive. Instead, food safety laws are intended to reduce the risk of unsafe food. At least this is the case for legislative framework in developed countries but also at the global level through the mandate of WHO and the Codex Alimentarius Commission.

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.

According to the Food and Agriculture Organization of the United Nations, risk analysis is used to identify hazards, assess their effects, establish the appropriate control measures to prevent these risks, and to communicate those risks and measures.

Risk communication must be included to present the analysis to consumers and other stakeholders. At the global level, risk analysis principles are applied to ensure that food is safe and can be traded among countries.

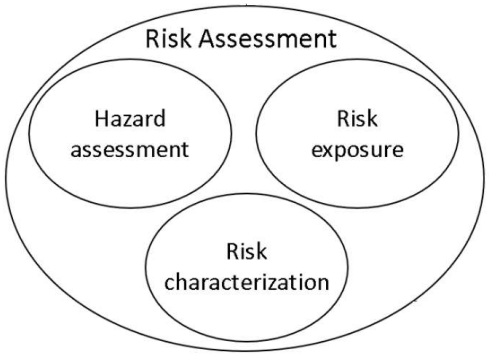


To start, it is really important to make the difference between "hazard" and "risk". A hazard is an agent in food with the potential to cause harm. On the contrary, a risk is the estimated probability and severity of adverse health effects in exposed populations consequential to hazards in food.

From a global standpoint, a food safety hazard refers to any agent with the potential to cause adverse health consequences for consumers.
Food safety hazards occur when food is exposed to hazardous agents which is the result of the contamination of foodstuff. Food hazards may be biological (or microbiological), chemical or physical.
Sometimes, some other categories are added like nutritional and biotechnology-related hazards. In some case food allergens are separated from chemical hazards and are categorized as allergic hazards

So, each individual food contaminant is not a risk but a hazard.
So if we come back to the basic principles of main legislations regarding food contaminants in food, the first things to do is to identify food contaminants.

RISK ASSESSMENT



- Hazard assessment: Potential health effects
- Risk exposure: Quantity of contaminant absorbed by consumers

The presence of chemical contaminants or other undesirable substances in food and feed is often unavoidable as these substances may occur ubiquitously (like dioxins and dioxin-like compounds or heavy metals) or are of natural origin (e.g. inherent plant constituents such as alkaloids, or mycotoxins such as aflatoxins) as seen in lesson 1. Therefore, human exposure to such substances is also unavoidable.

The risk assessment of chemical contaminants in food relies on the integration of two components: knowledge about the human exposure to these substances via food and other routes, and their potential to cause adverse health effects. The risk characterization is the likelihood of the occurrence of adverse health effects at a given exposure.

To perform a robust risk assessment there is a need for sufficient knowledge on human exposure (like occurrence data in food and food consumption data) and a sufficiently sound toxicological database. Manufacturers do not provide toxicological information for most of chemical contaminants, with the exception of substances that are intentionally used for specific purposes in food production (e.g. pesticide or veterinary drugs).

Chemical risk assessment is a well-established process and in general permits the assessment of risks from long-term chronic exposure to a chemical.

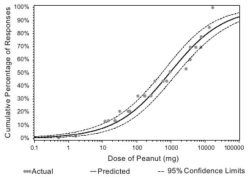
It includes the assessment of food additives, residues of pesticides and other agricultural chemicals, residues from veterinary drugs, chemical contaminants from any source and natural toxins such as mycotoxins and phycotoxins.

When sufficient data are not available to support a quantitative assessment of risks associated with food contaminants, a qualitative approach to characterize risk may be the only current alternative. The risk assessment process can include a variety of models for reaching conclusions; for example, the concept of acceptable daily intake may be considered as a component of risk assessment.

RISK ASSESSMENT

Hazard assessment

Distribution of individual peanut thresholds



Taylor et al.2009

Toxicological information:

- identification of the toxic substance(s);
- metabolism by humans and animals, as appropriate;
- toxicokinetics and toxicodynamics;
- information about acute and long term toxicity and other relevant toxicity data;
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable.

The hazard assessment process require knowledge about a specific hazard including the identification of the toxic substance(s);
It can be done for a group of molecules like dioxins or aflatoxins for example

It also require knowledge about the metabolism by humans and animals, as appropriate;
Sometimes, the culprit molecule become toxic only after modifications

Toxicokinetics and toxicodynamics are also relevant like the information on possible carry-over of the toxic substance from feed to edible animal tissue/products; Another example may be food allergens. It is known that allergic consumers will not react the same way to the exact same dose of allergen. Some of them will react when they ingest few mg of a food allergen while others will only react after the ingestion of several grams.

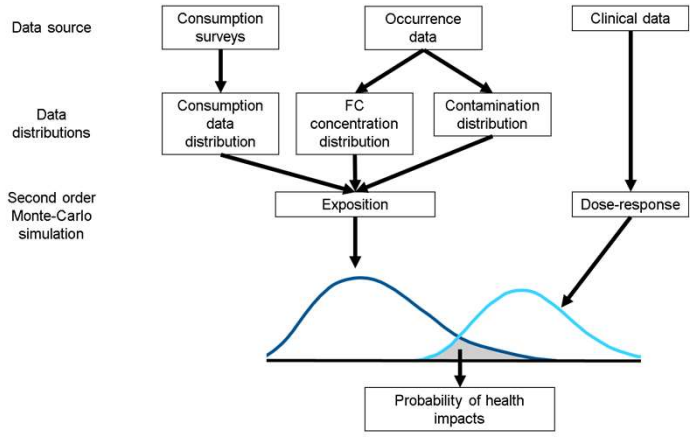
Obviously, information about acute and long term toxicity and other relevant toxicity data are relevant and should be considered.

Finally, integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable should also be included in the data to assess the risk.

When there is uncertainty, these gaps have to be documented.

RISK ASSESSMENT

Risk exposure and risk characterization



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The risk exposure has to be done via the obtention of consumption data. These data is to be done by using tools like surveys and should include the different population of a country or a region. For example, in Algeria, you need consumption data from people close to the Mediterranean sea but also from people who live in the desert. In the same way, in countries with mountains, isolated population should not be excluded. On the contrary, these populations are often at risk because they often have a specific type of diet.

Risk exposure can also be done by performing total diet studies which are food surveillance programs that monitors the concentrations of chemical contaminants in foods that are typically consumed by a population.
Food is prepared for consumption as it would be at home. This provides realistic information about contaminant exposure from the diet. Preparation steps include washing, peeling, and cooking. Similar types of foods are combined into composite samples.

Once the hazard assessment and the risk exposure are done, the next step is the risk characterization.
It is defined as an estimation of the probability of occurrence and severity of known or potential adverse health effects in a population based on the preceding steps of hazard identification, hazard assessment, and risk exposure.

RISK MANAGEMENT

- Identification of available management options.
- Selection of preferred management option, including consideration of an appropriate safety standard

Once the risk assessment is performed, the risk must be controlled or mitigated via risk management.

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.

RISK MANAGEMENT

Potential options:

- Providing advice and guidance to consumers on the risks and benefits of particular food choices;
- Preventing food and feed contamination at the source, e.g. by reducing environmental pollution;
- Applying appropriate technology control measure(s) in food and feed production, manufacture, processing, preparation, treatment, etc…
- Establishment of Maximal Limits or Maximal Residue Limits.
- Recalls and safety alerts, etc…

The control of chemical contamination of food is clearly in development. But if there is a key part of the current process, it is the international harmonisation of controls. To this regard, The Codex Committee on Food Additives and Contaminants developed a Codex General Standard for Contaminants and Toxins in Food.

Risk management strategies vary depending on the situation. These types of actions can include "providing advice and guidance to consumers on the risks and benefits of particular food choices".
For example, consumers should be aware that biological agriculture reduces the risk of being exposed to pesticides

It may include providing direction on how to reduce contaminant levels.
This is the case for food-processing-induced chemicals for example

A classic of risk mitigating measures is of course the setting of maximum levels for contaminants in foods.
This is the case for several mycotoxins, pesticides residues, and many others food contaminants. For certain 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.

RISK MANAGEMENT

Establishment of Maximum Levels in Food

The maximum level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by a food safety authority to be legally permitted in that commodity.

- The Codex Alimentarius Commission (CAC)
  - 2466 Codex MRLs for pesticides
  - 289 Codex MRLs for veterinary drugs
- Health Canada
- The European Food Safety Agency (EFSA)
- Etc.

Among the several options that risk management offers, the development of maximum levels for chemical contaminants in retail foods is an important one.

Maximum levels are established by food regulatory agencies and should be enforceable (by the same or another agency). Which means that there no interest to establish a ML which can not be detected with current analytical methods.

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 is successful would be required.

RISK MANAGEMENT

Establishment of Maximum Levels in Food

Principles:

- MLs should be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer.
- MLs should be set in such a way that the consumer is adequately protected.
- MLs should be based on sound scientific principles leading to levels which are acceptable worldwide, so that there is no unjustified barrier to international trade.
- MLs shall be clearly defined with respect to status and intended use.

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 national diet are also considered.
There are a limited number of retail foods for which maximum 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. Indeed, 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 should be developed.

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.

MONITORING AND REVIEW

- Compliance with risk management solutions
- Effectiveness of risk mitigating measures
- Effectiveness of the system (reaction time, potential flaws, consumers' awareness, etc..)

Risk management is not a project to complete or a task to check off the to-do list. It is ongoing and should become part of an continuity culture. As with most activities, continual attention provides better and more efficient execution, less effort overall, and better results. Monitoring risk management strategies is actually one of the most important activities in risk analysis.

Monitoring and review are the gathering and analyzing of data so as to give an overview of compliance in food safety requirements. It includes verifying compliance with the risk management decisions by ensuring that stakeholders implement the options that were chosen. This also include determination of the ongoing effectiveness of risk management measures, and the identification of any changes that would impact the risk analysis.

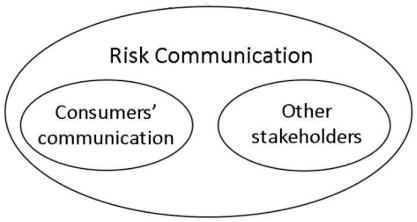
Ongoing review of the risk mitigation plan is required to ensure that it is meeting the needs of the regulatory framework. This review concerns all mitigation strategies, including the status and effectiveness of the actions that were taken.

Ensuring that all requirements of the risk management plan are being implemented is critical – otherwise the mitigation strategy can become an unconscious acceptance of the risk, and may be identified as an additional risk itself.

RISK COMMUNICATION

Principles:

- Communication about risk assessment and risk management
- Increase awareness and reinforce confidence
- Allow consumers to exercise their own options



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".

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.

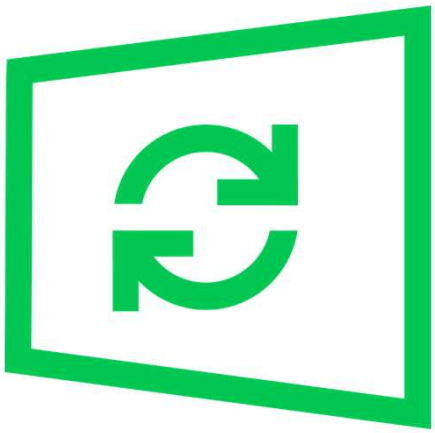
Risk Communication provides the results of expert scientific review of food hazard identification and assessment of the risks to the general population or to specific target groups such as infants or the elderly. Indeed, certain people, such as those who are immunodeficient, allergic or nutritionally 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.

For example, MLs for any particular food contaminant, should be communicate and accessible to all stakeholders in a clear form.

UPDATE

- Deciding what new contaminants might be of public health concern
- Providing new data for risk assessment of contaminants
- Allowing assessment of risk management options for handling specific problem
- Allows continual evaluation of adequacy of existing food safety measures/suitability of food handling practices
- Can facilitate pro-active food safety programming



Finally, all the regulative frameworks in the world need to be updated from time to time. This is also the case for risk-based framework.

The monitoring of contaminants in food and the surveillance of foodborne diseases should identify new food safety problems as they emerge. A risk analysis strategy will be ineffective if new risks are not tracked based on stakeholders communications. Updating the list of emerging hazards is a critical part of maintaining an effective risk analysis strategy.

Besides, the modus operandi of risk analysis is always evolving as new scientific data became available to affine the hazard assessment. The risk exposure could also vary as food diets are constantly evolving.

Basically, there are always new data to enhance a risk assessment. It is essential to adjust the risk's priority accordingly. It is also a good idea to validate previous assumptions and state any new assumptions as this will help for the monitoring of the risk over time.

In the same way, new mitigation options could be setup when a new risk characterization is produced. When there is a change on the risk or its probability, it may make sense to adjust the risk management options already in place. A complete change in the strategy may not

be necessary.

This presentation covered the basic of risk analysis and its application to food contaminants. To illustrate with an example, in the word document, you will find the principle of risk analysis applied for the control of pesticides in foodstuffs with an emphasis on risk management.