

EUROPEAN LEGISLATION ON FOOD SAFETY WITH SOME ELEMENTS OF COMPARISON

The precarious balance between the right to protection of food safety – and Public health – and the trade interest for the free movement of products within the EU and the member countries of the WTO

SPS Agreement, Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of **minimizing negative trade effects**.
6. When establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such **measures** are **not more trade-restrictive than required** to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility

Reg. EU/178/2002, Article 5

General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.
2. Food law shall aim to achieve the **free movement** in the Community of **food** and **feed** manufactured or marketed according to the general principles and requirements in this Chapter.
3. Where **international standards** exist or their completion is imminent, they shall be taken into **consideration in the development or adaptation of food law** [Omissis]

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Reg. EU/178/2002, Article 6

Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. **Risk assessment** shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. **Risk management** shall take into account the results of **risk assessment**, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the **precautionary principle where the conditions laid down in Article 7(1) are relevant**, in order to achieve the general objectives of food law established in Article 5

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Reg. EU/178/2002, Article 7

Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional **risk management measures** necessary to ensure the high level of health protection chosen in the Community **may be adopted**, pending further scientific information for a more comprehensive **risk assessment**.

2. **Measures adopted** on the basis of paragraph 1 **shall be proportionate and no more restrictive of trade than is required** to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration [Omissis]

Precautionary principle

The Precautionary principle is a notion which supports taking **protective action** before there is complete scientific proof of a risk; that is, action should not be delayed simply because full scientific information is lacking.

The Precautionary principle or precautionary approach has been incorporated into several **international environmental agreements**, and some claim that it is now recognized as a general principle of international environmental law.

Precautionary principle

The Precautionary principle has its beginnings in the German principle of *Vorsorge*, or foresight.

At the core of early conceptions of this principle was the belief that society should seek to avoid environmental damage by careful forward planning, blocking the flow of potentially harmful activities.

The Vorsorgeprinzip developed in the early 1970s into a fundamental principle of German environmental law. It was subsequently incorporated into a number of regional environmental agreements in Europe.

Reg. EU/178/2002, Article 7
Precautionary principle

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Government
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Allergen-free, gluten-free and cross-contamination statements

Food allergen cross-contamination (or precautionary) statements

A cross-contamination statement is a declaration on the label of a prepackaged product that alerts consumers of the possible presence of an allergen in the food.

Cross-contamination statements may be declared by food manufacturers and importers when, despite all reasonable measures, there is the unintended presence of food allergens in the food. Cross-contamination statements are not a substitute for good manufacturing practices.

The precautionary principle applied to GMO food

This approach is prominent in the European Union's regulation of GMOs, where it allows for stricter oversight and management of potential risks associated with genetic modification technologies.

Uncertainty and risk: The principle is invoked because there is significant uncertainty about the long-term, broad-scale, or irreversible harm GMOs might cause

Balancing risks and benefits: A key challenge is balancing the potential risks against potential benefits, such as increased food supply and quality

Potential for harm: The principle is applied in situations where there is a threat of harm, uncertainty about the extent of that harm, and therefore, a need for action. Actions can range from a complete ban to various control measures like segregation and cleaning to prevent cross-contamination of non-GMO crops.

Risk communication: Effective risk communication is also crucial when applying the precautionary principle, involving an interactive exchange of information and opinions throughout the risk analysis and management process

RISK, TOOLS AND INSTRUMENTS TO CONTROL IT

RISK ANALYSIS

The concept of **Risk Analysis** represents the foundation of European food legislation, which aims to guarantee a high level of protection of human life and health and, at the same time, constitutes a process based on scientific elements: each **legislative provision** and each measure adopted at institutional level (Community and national) must be motivated and supported by scientific evidence.

RISK ANALYSIS

In addition to **Food Safety**, risk analysis has also been extended to **Animal Health** (EU Regulation 429/2016) and to the system of **Official Controls** concerning legislation for the protection of Public Health (EU Regulation 625/2017).

RISK ANALYSIS

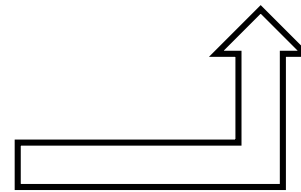
In Food Safety, food are classified at risk from:

- chemical contamination,
- physical contamination,
- biological contamination,

depending on the nature of the **hazard** present in the food.

More recently, the risk due to the **nutritional composition** of foods has also been added, associated with unbalanced behaviors in their use.

*Therefore, the importance of
nutrition declaration on the label*



But, what is risk?

Risk is defined both by the probability of occurrence of a certain hazard and by the consequences that it entails.

Schematically we could define risk as the combination of the following three factors:

1. what can happen = **scenario**
2. if it happens, what are the consequences = **damage**
3. how likely it is that it will happen = **probability**

When both the **probability** and the consequences of an event or a chain of events (**damage**) need to be described together, a so-called **risk matrix** is sometimes used.

This qualitatively indicates the different levels of probability, consequences and risk resulting from their combination (Food and Agriculture Organization of the United Nations - FAO, 2021).

Risk analysis

Risk assessment

Hazard identification

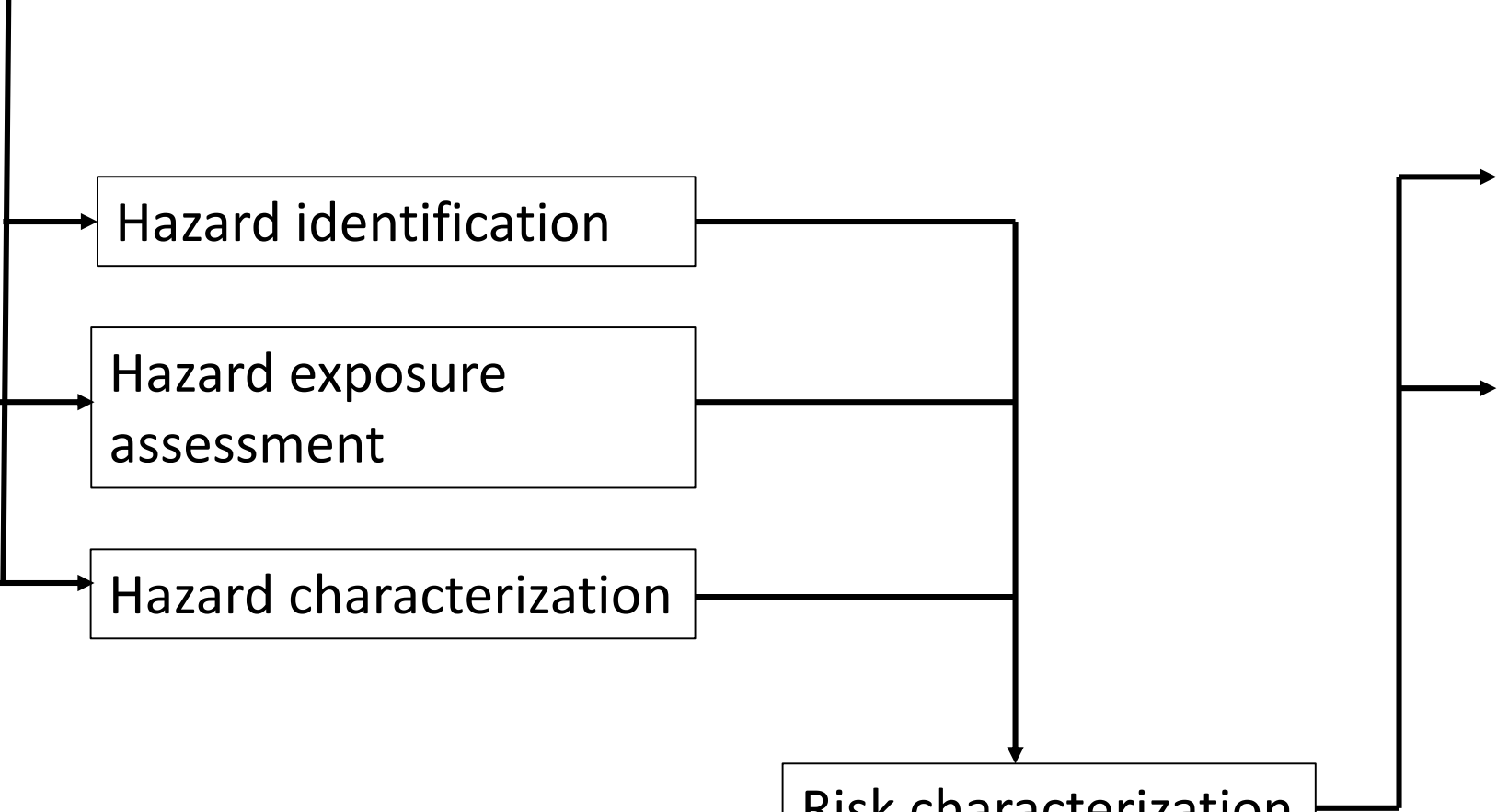
Hazard exposure
assessment

Hazard characterization

Risk characterization

Risk communication

Risk management

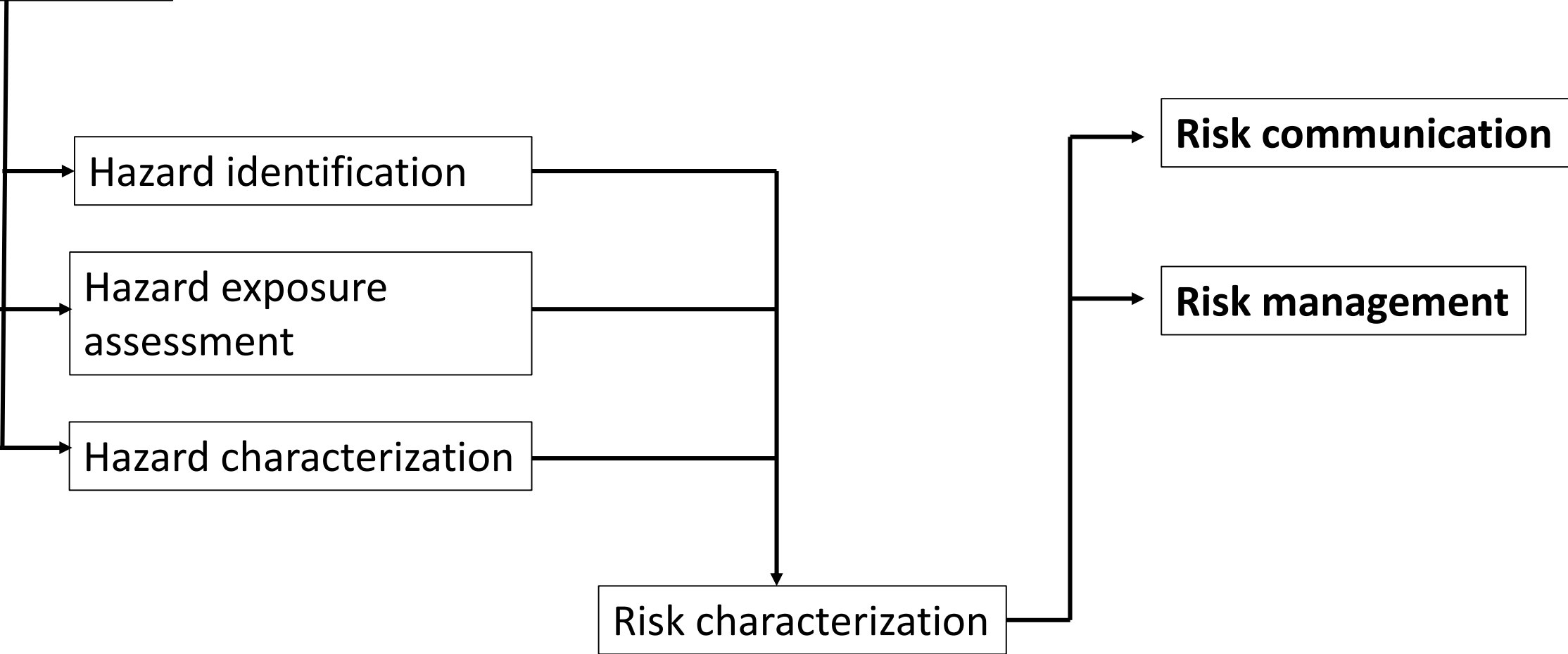


As regards the application of risk analysis in food safety, the document that represents the reference text is the one published in 1999 by the Codex Alimentarius Commission [Codex Alimentarius, 1999].

This document defines the steps for conducting the risk assessment

Risk analysis

Risk assessment



1. **Hazard identification:** is the identification of biological, chemical and physical agents capable of determining an adverse effect on public health and that may be present in a given food or group of foods

2. **Exposure assessment:** is the qualitative and/or quantitative assessment of the probability of intake of biological, chemical and physical agents through food, as well as exposure to other possible sources, if relevant

3. Hazard characterization: is the qualitative and/or quantitative assessment of adverse health effects. This assessment is obtained with dose-response models that allow to determine the relationship between the levels of exposure (dose) to a chemical, biological or physical agent and the probability that harmful effects on the health of the person may occur

4. **Risk characterization:** it is the qualitative and/or quantitative determination of the probability (and its uncertainty) that potential adverse effects on public health will occur and the severity of the consequences, in a given population, as defined in the previous phases.

Risk $R = f(P, D)$ = function of:
Probability of occurrence of damage (P)
Severity of damage (D)

P

The probability that the risk factor causes a damage

It can be assessed based on the frequency data of the damage caused by the consumption of the food in question

D

The severity of the pathology caused to the consumer

It is strictly related to the pathogenicity and toxicity of the agent considered and is linked to the consequences of the occurrence of the event, i.e. the extent of the possible intoxications that may occur

It also depends on the preventive measures

D is also referred to as Impact or Magnitude



THE RISK MATRIX (there are several)

Probability of occurrence/FREQUENCY

I = UNLIKELY

B = LOW PROBABILITY

M = MEDIUM PROBABILITY

A = HIGH PROBABILITY

Damage severity/MAGNITUDE

L = MILD

M = MEDIUM

G = SERIOUS

GG = VERY SERIOUS

	L	M	G	GG	
I	A	A	B	M	Frequency
B	A	B	M	M	
M	B	M	M	E	
A	M	M	E	E	
	Magnitude				

Value for risk class: A minimum; B low; M medium; E high

Ex. Threshold beyond which intervention is necessary

Frequency (P)

Rare	May only happen in exceptional circumstances	< 1% probability
Unlikely	May happen but not in the majority of cases	1% - 33% probability
Likely	May happen in the majority of cases	34% - 66% probability
Very likely	Expected to happen frequently	> 66% probability

Damage magnitude (D)

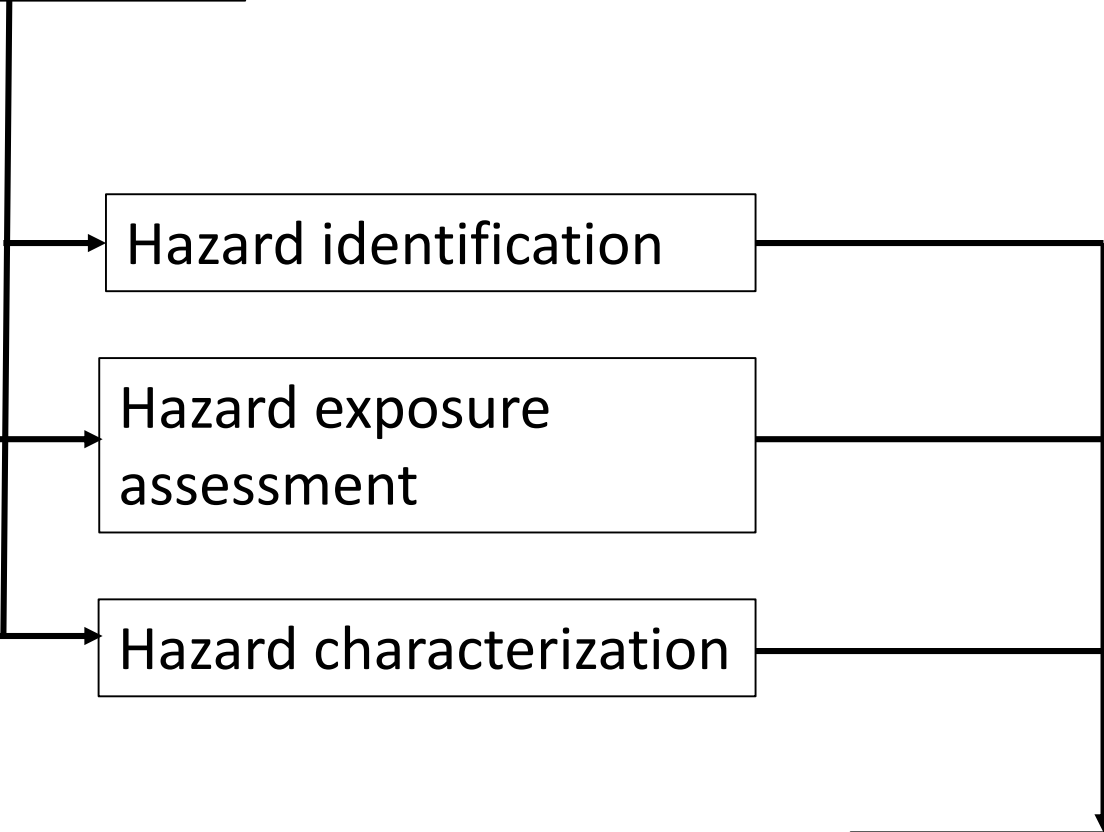
Score 3 = risk of death or irreversible effects on the health of the consumer

Score 2 = danger to health but completely reversible

Score 1 = presence of the danger but without any consequences for the consumer

Risk analysis

Risk assessment



Risk communication

Risk management

Risk characterization



Risk management is the decision-making process of evaluating possible risk reduction measures, which includes:

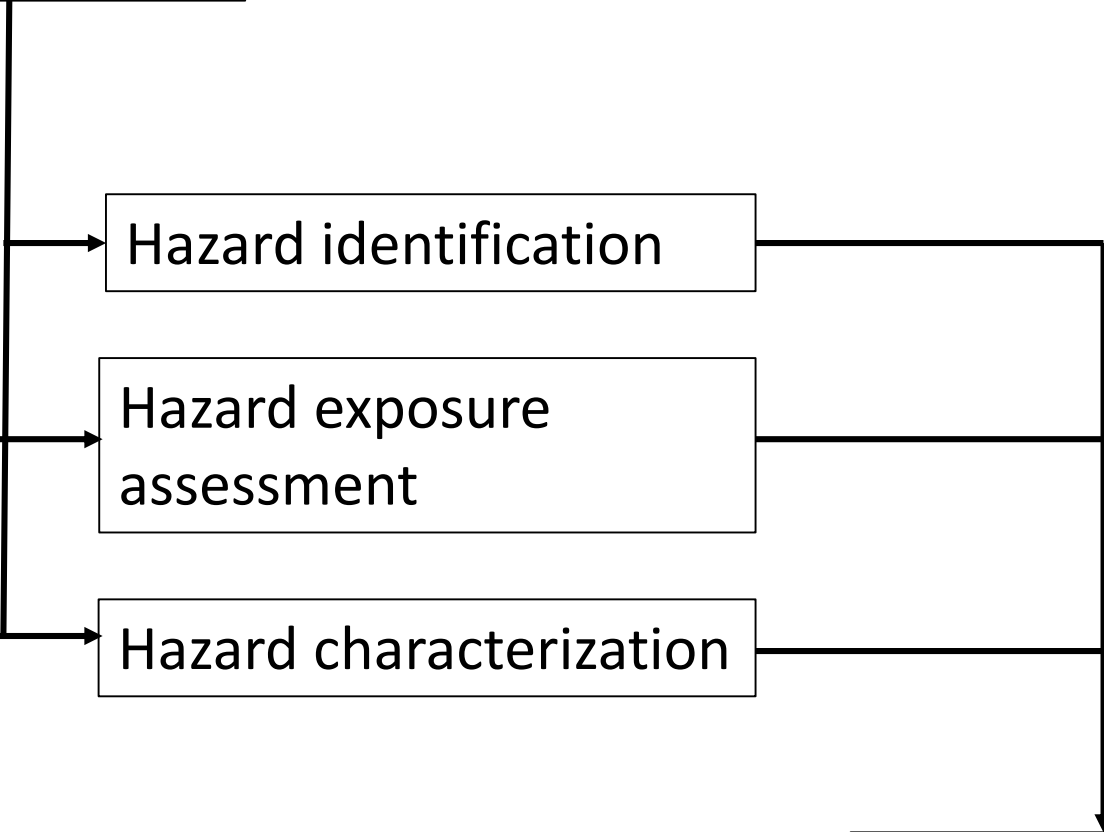
- the evaluation of risk reduction measures (“Risk evaluation”), i.e. the comparison between the risk as estimated by the risk assessment process and the possible risk reduction values for the application of different **control measures**;
- the evaluation of options (“Option evaluation”), i.e. the process of identifying and evaluating the **effectiveness and feasibility of specific risk reduction measures**. Effectiveness is measured by the degree of risk reduction that such an option can ensure, and is estimated by incorporating the measure itself into the risk assessment model. The evaluation of the **feasibility** of the measure must take into account **technical, operational** and **economic** aspects;
- the application of measures (“Implementation”), which ensures the application of the **risk reduction measures** as defined;
- monitoring and review, i.e. the process through which the correct application of the measures, the results obtained, any deviations between the results and those expected and, if necessary, the application of the essential changes for a better reduction of the risk are continuously monitored;

In others words, **risk management** is the process that evaluates and “weighs” the different **policy alternatives** (technical, commercial, economic, etc.) in the light of the risk assessment, and, where required, selects and implements the appropriate **control options**, also on the basis of **legislative mandates** or internal management controls.

It is at this level that the match between the different needs of **official control** and **commercial requests** must occur.

Risk analysis

Risk assessment



Risk communication

Risk management

Risk characterization



Risk communication, which is the process by which information about hazards and risks is collected and disseminated to all stakeholders, throughout the risk analysis process.

Risk communication should not be considered an attempt to convince or persuade people to adopt the judgment of experts or the communicator regarding the tolerability or acceptability of risks, but rather, an attempt to help people make more informed judgments and enable them to act in the face of risks in their lives.

Communicating risk, therefore, means communicating the **uncertainty** related to the possibility that that risk will manifest itself, taking into account the different estimates of acceptability and bridging the information asymmetry between experts and society, due to their different **perceptions**.

**Food Risk
Consumer**

**Food Risk
Authority/Science**

High risk

Chemical contaminants

Additives

Poor nutrition

Microbes

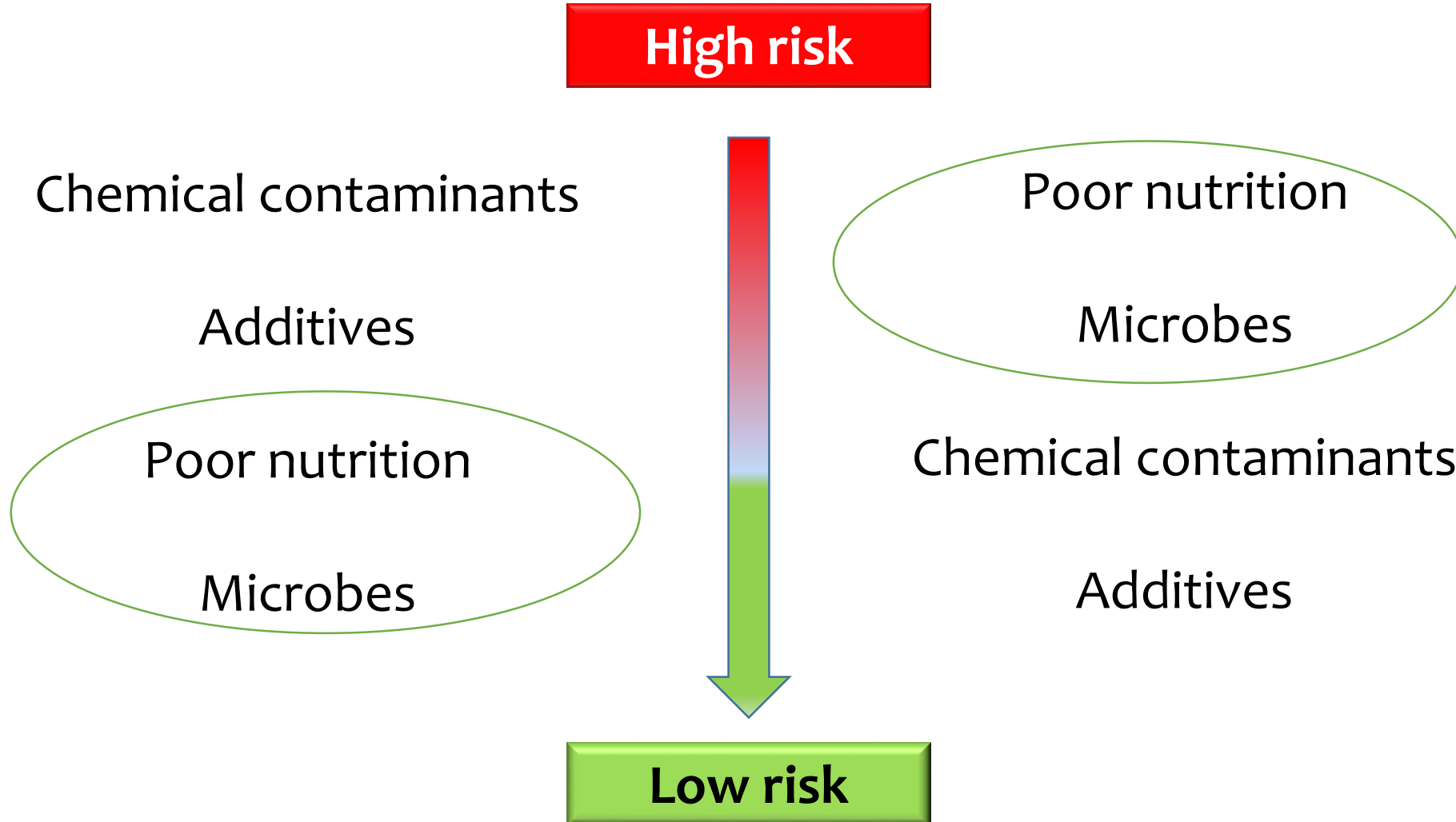
Poor nutrition

Microbes

Chemical contaminants

Additives

Low risk



Physical hazard

Radionuclide

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Wed, Mar 20, 2024 page2

Radioactive residue found in mushrooms from Japan

SMALL PERCENTAGE: Since March 15, 2011, a total of 228,142 shipments of food imported from Japan were tested and 254 contained trace amounts of radiation

Staff writer, with CNA



The Food and Drug Administration (FDA) yesterday reported that radioactive residue had been detected in a shipment of sliced mushrooms imported from Japan, marking the first such instance of a Japanese food product being found to contain such traces this year.

Cesium-137 was detected at a level of 7.9 becquerels per kilogram (Bq/kg) in the shipment of sliced mushrooms imported from Shizuoka Prefecture, which was sent for testing on Feb. 29.

Under the FDA regulations, the maximum permitted levels for cesium-134 and cesium-137 combined are 10Bq/kg in beverages and packaged drinking water, 50Bq/kg in baby food and formula, and 100Bq/kg in other food products.

Pathways of Radioactive Contamination to Agricultural Products

1. Air Contamination

- Surface contamination of plants and animals
- Inhalation by animals

2. Water Contamination

- Rainfall carries radioactive fallout to surface water
- Fishery products contaminated
- Plants and animals contaminated through water uptake

3. Soil Contamination

- Plant and feed uptake of contamination
- Animal ingestion of contaminated soil and plants

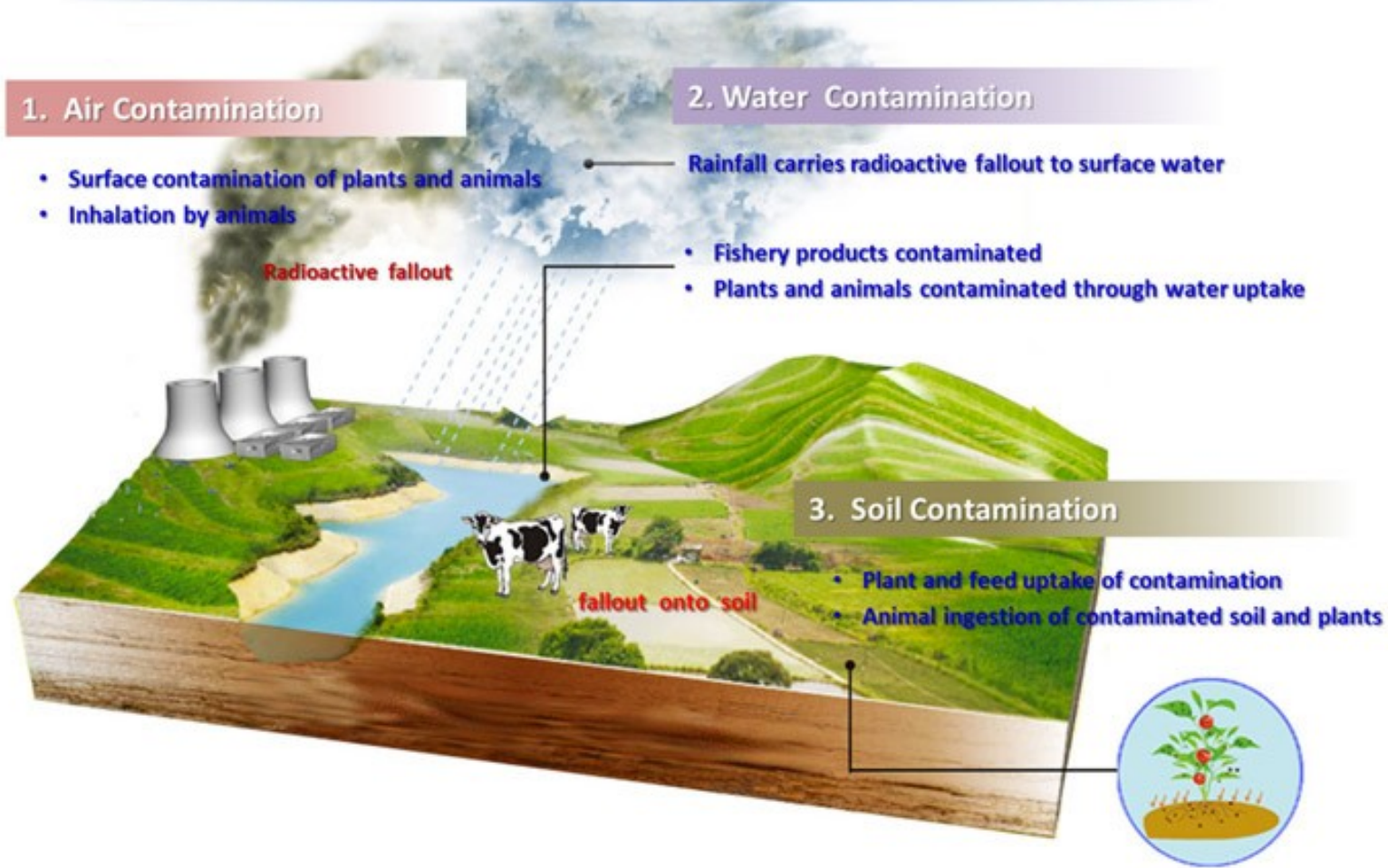


Figure 1. Major pathways of radioactive contamination to food

The radionuclides with the greatest known biological impact are the radioisotopes of:

iodine (^{131}I , ^{132}I , ^{134}I , ^{135}I)

caesium (^{134}Cs , ^{137}Cs)

strontium (^{89}Sr , ^{90}Sr)

Radioactivity

Becquerel (Bq): The SI unit for radioactivity, representing one radioactive decay per second.

Radioactive decay is the process by which an unstable atomic nucleus loses energy by radiation

Absorbed dose

Gray (Gy): The SI unit for absorbed dose, which is the amount of radiation energy absorbed per unit of mass (1 Gy = 1 joule/kilogram).



Maximum levels of radio-caesium in food

		Codex	Japan	EU Euratom 2018/52	US FDA DIL
Annual radiation dose limit [†]		1 mSv	1 mSv	1 mSv	5 mSv
Assumed ratio of contaminated food		10 % ^{††}	50 %	10 %	30 %
Maximum levels of radio-caesium in food	Drinking water		10 Bq/kg	1,000 Bq/kg (or liquid food)	
	Milk		50 Bq/kg	1,000 Bq/kg (Dairy product)	
	Infant food	1,000 Bq/kg ^{†††}	50 Bq/kg	400 Bq/kg	
	Other than the above food	1,000 Bq/kg ^{†††} Food consumed in small quantities^{††††} 10,000 Bq/kg	100 Bq/kg (General food)	1,250 Bq/kg [100 Bq/kg - Imported food from Japan EU (2018/6) 600 Bq/kg - from Chernobyl accident affected countries EU (2020/1158) Minor food 12,500 Bq/kg]	1,200 Bq/kg (All food)

[†] The dose limit should be expressed as an effective dose of 1mSv in a year. (ICRP, Publication103, 2007, p98)

^{††} The ratio of the amount of the foodstuffs per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration(CXS 193-1995).

^{†††} The food under the Codex guideline level should be considered as safe for human consumption (CXS 193-1995).

^{††††} For food consumed in small quantities that represent a small percentage of total diet and hence a small addition to the total dose, the Codex guideline Levels may be increased by a factor of 10. (Called 'minor food' in EU) (CXS 193-1995).

Note: The Japanese maximum levels of radio-caesium in food are set also in consideration of other radionuclides released by the accident namely ⁹⁰Sr, ¹⁰⁶Ru, ²³⁸Pu, ²³⁹Pu, ²⁴⁰Pu and ²⁴¹Pu.

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF MINOR FOOD

1. List of minor food

CN code	Description
0703 20 00	Garlic (fresh or chilled)
0709 59 50	Truffles (fresh or chilled)
0709 99 40	Capers (fresh or chilled)
0711 90 70	Capers (provisionally preserved, but unsuitable in that state for immediate consumption)
ex 0712 39 00	Truffles (dried, whole, cut, sliced, broken or in powder, but not further prepared)
0714	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets; sago pith
0814 00 00	Peel of citrus fruit or melons (including watermelons), fresh, frozen, dried or provisionally preserved in brine, in sulphur water or in other preservative solutions
0903 00 00	Maté
0904	Pepper of the genus <i>Piper</i> , dried or crushed or ground fruit of the genus <i>Capsicum</i> or of the genus <i>Pimenta</i>
0905 00 00	Vanilla
0906	Cinnamon and cinnamon-tree flowers
0907 00 00	Cloves (whole fruit, cloves and stems)
0908	Nutmeg, mace and cardamoms
0909	Seeds of anise, badian, fennel, coriander, cumin or caraway; juniper berries
0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices
1106 20	Flour, meal and powder of sago or of roots or tubers of heading 0714
1108 14 00	Manioc (cassava) starch
1210	Hop cones, fresh or dried, whether or not ground, powdered or in the form of pellets; lupulin
1211	Plants and parts of plants (including seeds and fruits), of a kind used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes, fresh or dried, whether or not cut, crushed or powdered, except plants or parts of plants used for food production
1301	Lac; natural gums, resins, gum-resins and oleoresins (for example, balsams)
1302	Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners whether or not modified derived from vegetable products

COUNCIL REGULATION (Euratom) 2016/52

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FOOD

The maximum permitted levels to be applied to food shall not exceed the following:

Isotope group/Food group	Food (Bq/kg) ⁽¹⁾			
	Infant food ⁽²⁾	Dairy produce ⁽³⁾	Other food except minor food ⁽⁴⁾	Liquid food ⁽⁵⁾
Sum of isotopes of strontium, notably Sr-90	75	125	750	125
Sum of isotopes of iodine, notably I-131	150	500	2 000	500
Sum of alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239 and Am-241	1	20	80	20
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137 ⁽⁶⁾	400	1 000	1 250	1 000

The maximum permitted levels to be applied to the minor food as listed in point 1 shall not exceed the following:

Isotope group	Bq/kg
Sum of isotopes of strontium, notably Sr-90	7 500
Sum of isotopes of iodine, notably I-131	20 000
Sum of alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239 and Am-241	800
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137 ⁽¹⁾	12 500
⁽¹⁾ Carbon-14, tritium and potassium-40 are not included in this group.	