Risk Assessment and Communication in Food Safety

Edited by
Maria Longeri

Milano University Press

RISK ASSESSMENT AND COMMUNICATION IN FOOD SAFETY

Definitions, Legal Framework and Training in Italy and in the Context of the European Union

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They wish to assert that the views expressed are personal and in no way reflect the official policies of the Ministry of Health or other administrations.

Credits

This handbook is designed to educate and disseminate knowledge. It stems from a collaborative initiative, inspired by the same purposes, undertaken by the Ministry of Health's General Directorate of Health Protection Collegiate Bodies, Office 3, the Italian EFSA Focal point, and the University of Milan, the competent organisation pursuant to Article 36 EFSA ("Collaboration Agreement for Educational Seminars 2021"). In keeping with this agreement, a training day entitled "Risk assessment: from Training to Work" was held on 11 November 2021 at the Lodi Teaching Centre University of Milan (Department of Veterinary Medicine and Animal Sciences). The work presented coincides with the resulting training manual.

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Preface

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In general terms, risk is defined as "the possibility of suffering damage related to more or less foreseeable circumstances" (the Treccani Encyclopaedia). In complex situations involving multiple processes, it is necessary to identify and quantify possible adverse circumstances, estimate their likelihood of occurrence, and determine the harm they could cause. Thus, Italian legislation on the protection of workers' health and safety defines risk as "*the probability of reaching a potential level of harm under the conditions of use or exposure to a given factor or agent or their combination*" (Legislative Decree 81/2008). It also defines the term *hazard* as 'the property of a factor that may result in harm,' thus distinguishing it from risk.

Therefore, inherent in the definition of risk is the concept of quantifying and estimating the likelihood that harm will be caused by 'something' capable of doing so. If we break down this 'something,' we see that risk depends on several factors or hazards: the intrinsic properties of things, events or technologies, behavioural characteristics, organisational characteristics, etc. If a risk is to be assessed, all these components must be considered, and, not least, we must also consider their associated level of harm that must be avoided.

Risk assessment is important and is applied in countless areas and processes affecting daily life, from politics to economics, from finance to disaster risk management. It can be expressed on different scales for various levels of damage.

Among the many areas in which risk assessment is implemented, the protection of human health is undoubtedly of primary importance. The many hazards that threaten health are classified according to the source (e.g., food, task, machinery), nature (e.g., chemical, physical, biological, behavioural), or also according to the harm they may cause (e.g., cancer, malformation, injury). Risk assessment mandates thorough consideration of all possible hazard parameters (source, nature, and harm).

This volume deals with food safety risk assessment, with a major focus, in the illustrative passages, on animal health. Indeed, this was the first area that saw the implementation of food safety risk assessment methodologies in use today and is an important chapter in the broad, integrated approach scenario to such assessment practices known as '*farm to fork*' within the European Union.

In this regard, the EU Legislature, in establishing the principles and requirements of Food Safety in EC Regulation No. 178/2002, defined risk as "a *function of the likelihood and severity of an adverse health effect resulting from the presence of a hazard*," identifying the 'hazard or element of danger' as any "*biological, chemical or physical agent contained in food or feed*," or their condition, "*capable of causing a harmful effect on health*;" (Art. 3, EC Reg. No. 178/2002).

The concept of 'Risk Analysis' is the foundation of EU food law, which aims to ensure a 'high level of protection of human life and health' and, at the same time, constitutes a process based on scientific elements: every legislative provision and every measure adopted at the institutional level (EU and national) must be justified and supported by scientific evidence.

In addition to Food Safety, risk analysis has also been 'extended' to Animal Health (EU Reg. No. 429/2016) and the system of Official Controls covering legislation to protect Public Health (EU Reg. No. 625/2017). In Food Safety, food hazards are classified as chemical, physical or biological, depending on the nature of the food-related hazard. More recently, the nutritional composition of food has also been grouped under these hazards, Due to the unbalanced food consumption behaviour of consumers.

The complexity of risk assessment in food safety is intrinsic to the need for reliable information (often to be acquired rapidly) at every level of a long and complex supply chain, characterised by a high diversity in environments, technologies, and professionalism. The internationalisation and globalisation of commodities add a layer of complexity, related to the need for technical and regulatory dialogue and harmonisation among nations, the local realities of which often differ from one another significantly.

To structure and integrate sources of information, the European Union (EU), in consultation with the governments of Member Countries, has established bodies and initiatives to coordinate the professionalism required to provide and evaluate such information. This structuring and harmonisation endeavour, intended to start at the local level, involves national coordination and, ultimately, community integration, including links with third-party international organisations (such as the U.S. Food and Drug Administration).

In addition, the EU promotes and shares with the public, especially with professionals operating at all levels of food safety risk assessment processes, technical knowledge on risk assessment practices, as well as information about national and international organisations dedicated to risk management. The EU also promotes initiatives that, through specific programmes, train professionals capable of operating at various levels, in the immediate and in the short term, to ensure the monitoring and assessment of such risk.

Precisely in the spirit that inspires the EU and the National Authority to raise awareness of food safety risk assessment and knowledge, the Authors of this volume have endeavoured to adhere to a didactic and popular approach capable

of addressing a broad target of novices and students engaged in all fields of expertise. The text covers the definition of food safety risk assessment, how it is performed, the body of applicable legislation and its international scope of application, what knowledge and skills are needed for effective assessment, the relevant training and support programmes, including economic ones, and, finally, how risk should be communicated and conveyed. This corpus is presented in easily identifiable, well-characterised and independently readable chapters, with robust bibliographic support and tools to aid comprehension such as examples and practical advice, all enhanced by the professionalism and experience of the authors.

This volume is an excellent starting point that can provide insights for specialists in the field. It is also a useful universal tool for a general understanding of the topic and to learn about the actions that Italy and the EU are taking to address the global health challenges of the coming decades in a coordinated and effective manner.

Chapter 1
Risk analysis: definition of risk and scope of application

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Risk analysis is an iterative process, employing techniques that use scientific data and statistical calculations to produce reliable estimates of the occurrence of specific hazards under certain conditions.

The phases

The risk analysis process comprises three interconnected phases:

1. *Risk assessment* makes it possible to describe, both qualitatively or quantitatively, the likelihood and potential impact of certain risks; this process estimates the risk resulting from a given hazard, expressed in qualitative or quantitative terms;
2. *Risk management* envisages the proposal of solutions or alternative corrective actions;
3. *Risk communication* envisages the exchange of risk assessment information with all stakeholders and their engagement in the decision-making process and applicable corrective actions.

Relevant scenario

The scenario is the reference context in which the risk analysis is conducted, i.e. it is the series of events considered for which a given risk must be estimated. For example, to estimate the risk of listeriosis (a foodborne bacterial infection) to smoked salmon consumers, we would consider the entire chain of production, storage, and distribution of the "smoked salmon" product, from its raw state to final purchase and consumption. This context sets the reference scenario for defining all variables that may affect the final estimate of risk. Regarding animal health, another example might address the risk of introducing a previously absent disease into a free country with the shipment of live animals from abroad (the so-called "*import risk analysis*"). In this case, the reference scenario would comprise all the steps involved in the introduction of

a given number of animals from a specific country of origin, the selection of animals to be introduced (e.g., randomly from several herds or specific groups of animals), and the relevant health conditions of these animals (e.g., whether or not the animals were vaccinated, whether or not specific laboratory tests were carried out on all or a representative or non-representative subset of the animals themselves). Once introduced into the country, the animals may be destined for a few specific herds or distributed to multiple destinations; they may or may not be subjected to a period of quarantine and further testing. This series of interconnected parameters constitutes the baseline scenario (World Organisation for Animal Health, WOAH, 2010). One way that is often used to represent the chain of events is to define the so-called tree of events ("*scenario tree*"). Figure 1.1 shows a hypothetical tree of events related to the introduction of the African swine fever virus through the importation of contaminated pork from a foreign country.

As shown in Figure 1.1, the event tree chronologically describes everything that must happen for the final risk to materialise. This also makes it possible to indicate, at each junction of the tree, the probability that must be considered for the next event to be determined. New branches and nodes can be added to the core of the event tree, such as applicable corrective actions. This type of representation is very useful for representing and clearly identifying all the variables that must be considered and evaluated in order to obtain the final risk estimate.

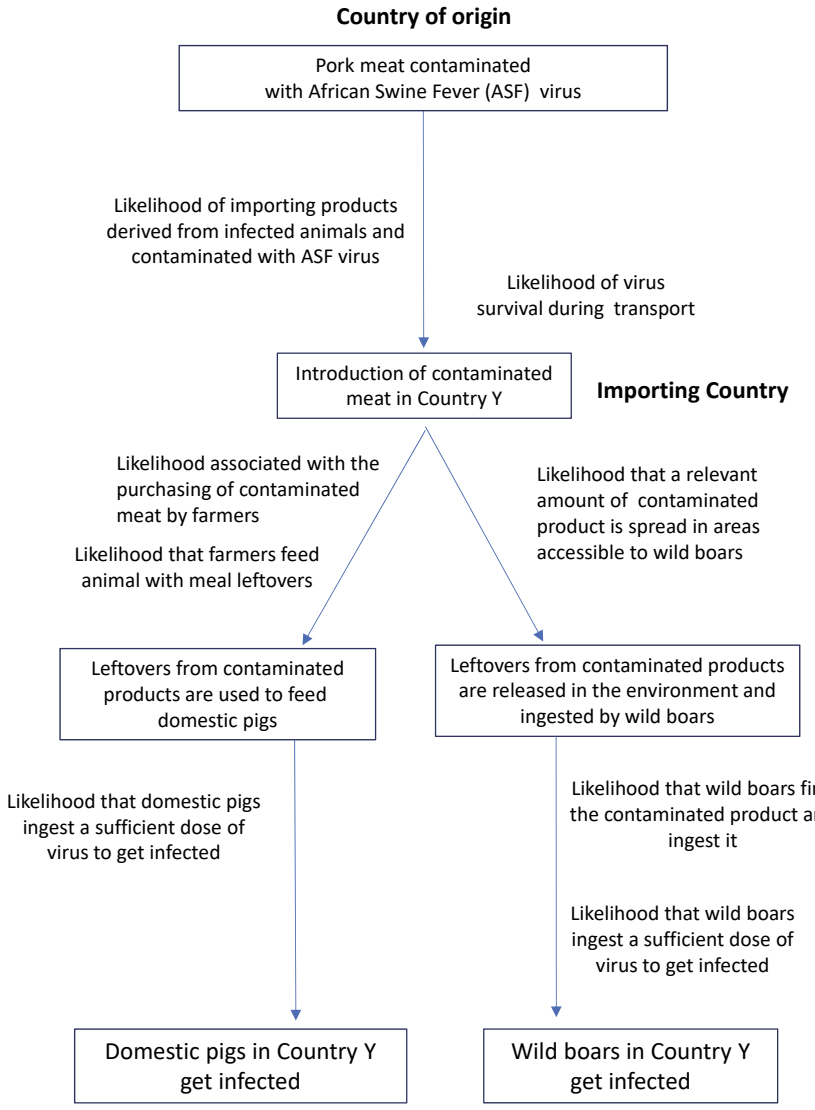

Figure 1.1 Event tree related to the introduction of African swine fever virus through the import of contaminated pork from a foreign country.

The risk

But what is risk? Risk is defined both by the probability of the occurrence of a given hazard and by the consequences 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 to happen = probability

It follows from the above definition that risk can rarely be described by probability values alone, but it is also necessary to associate each level of probability with any expected consequences. In order to adequately represent risk in quantitative terms, therefore, we must use at least one curve (the so-called risk curve) (Figure 1.2). For example, if the curve in Figure 1.2 represents an estimate of the risk of introduction and countrywide spread of a previously absent causative agent of an infectious animal disease, the x-axis could refer to the number of autochthonous outbreaks expected as a result of this introduction, and, in that case, we could assert that this introduction would almost certainly cause at least 1 or 2 outbreaks, while the probability of more than 10 outbreaks would be very low or close to zero (recalling that zero risk does not exist).

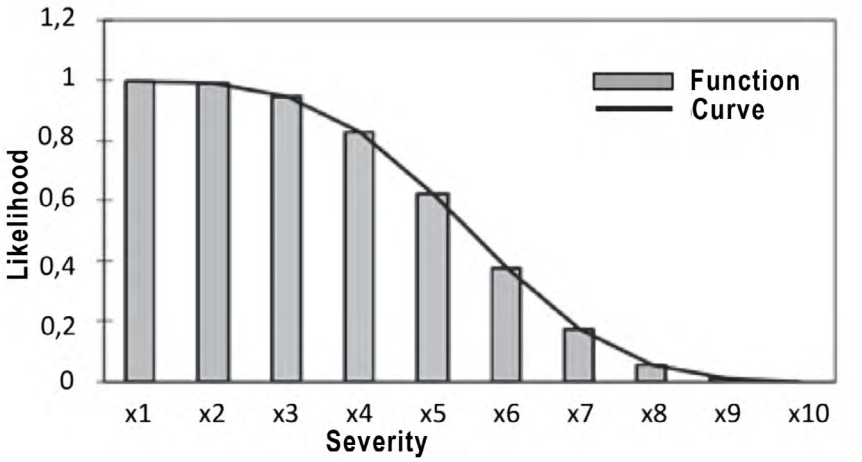

Figure 1.2 Risk function and risk curve.

Sometimes, it is useful to hypothesise different, alternative scenarios ("*what if scenarios*"), compare them, and derive the elements needed to decide what to do. Each scenario may have a range of possible consequences (damage levels). Each level of damage has its own probability of occurrence. For example, different risk curves for the spread of a given animal disease can be estimated by assuming different values of vaccination coverage in the population and estimating the number of new cases expected for each vaccination scenario. This approach is a useful decision-making tool to guide the search for the most cost-effective control strategies.

Risk can be expressed not only quantitatively (e.g., through risk curves) but also qualitatively. In the latter case, specific standard methods should be adopted to reduce the degree of subjectivity during the process. Qualitative risk

estimation, in fact, involves describing the various levels of risk through terms such as "high risk," "low risk," "negligible risk," etc.

When both the probability and the consequences of an event, or a chain of events, are to be described together, a so-called "risk matrix" is sometimes used (Figure 1.3). This is a qualitative representation of the levels of the probability, consequences and risk resulting from their combination (Food and Agriculture Organisation of the United Nations FAO, 2021).

			Consequences				
			1	2	3	4	5
			Insignifi cant	Minor	Moderate	Great	Catastro phic
Probability	A	Quite certain	Moderate	High	High	High	High
	B	Likely	Moderate	High	High	High	High
	C	Possibile	Low	Moderate	High	High	High
	D	Unlikely	Low	Low	Moderate	High	High
	E	Extremely rare	Low	Low	Moderate	High	High

Figure 1.3 Example of qualitative risk matrix.

A third approach is the so-called semi-quantitative (or semi-qualitative) method. Here, the qualitative description of the levels of probability and consequences is associated with a numerical reference to a possible range of values, the function of which is to aid understanding of the meaning of the terms used (Table 1.1).

Finally, the terms "risk" and "hazard" should not be confused. While "risk", as mentioned above, comprises aspects related to the probability of occurrence of a series of specific events (scenarios) and the estimation of the resulting consequences (harm or damage), on the other hand, "hazard" expresses a characteristic potentially related to an object, or, more often in the case of food safety, to an animal or food. For example, the possibility for pathogenic bacteria to grow in contaminated food is related to the various biochemical properties of the food itself, which may or may not encourage the growth of such pathogens (in the latter case, the risk is far lower, even if the bacterium is a pathogen). Consider another example, trichinosis, a parasitic zoonosis, can be caused by eating undercooked pork, but not by eating cheese. In terms of hazards, the same reasoning can be applied to animal species that are susceptible to infection by specific etiological agents and not by others.

Table 1.1 Example of probability levelsand consequences described semi-quantitatively.

Level	Category	Definition	Quantitative description
Probability			
1	Rare	It can happen only under exceptional circumstances	< 1% probability
2	Unlikely	It can happen but not in the majority of cases	1% – 33% probability
3	Probable	It can happen in the majority of cases	34% – 66% probability
4	Very likely	It is expected to happen frequently	> 66% probability
Consequences			
1	Irrelevant	Few animals infected and affected by mild forms of the disease	< 1% of the susceptible animal population is affected with no lethality and mild production declines
2	Minor	Few animals infected but affected by severe forms of disease that can lead to significant production losses and high mortality OR Hundreds of animals infected and affected b y mild forms of the disease	1% of the susceptible animal population is affected with high lethality and significant productive losses OR 5% of the susceptible animal population is affected with no lethality and mild production declines
3	Moderate	Few animals infected but affected by severe forms of disease that can lead to significant production losses and high mortality OR A large proportion of the animal population infected and affected by mild forms of the disease	5% of the susceptible animal population is affected with high lethality and significant productive losses OR 10% of the susceptible animal population is affected with no lethality and mild production declines
4	Severe	Large proportion of an animal population infected and affected by severe forms of disease that can lead to significant production losses and high mortality	>10% of the susceptible animal population is affected with high lethality and significant production losses

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Chapter 2
Risk assessment along the food production chain

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Introduction

Risk assessment has always been a powerful tool for epidemiological analysis. It is an approach that relies on predictive techniques but often requires the availability of detailed data of excellent quality. In the course of human endeavour, we have always sought to assess or estimate the risk impact arising from certain actions or events. From a certain point of view, also the recourse to haruspices in the ancient world was a way of attempting to predict the future by assessing the risks of a given undertaking to some degree. More articulate and scientific risk assessment approaches, however, did not emerge until the late 19th century when they were developed to estimate risks associated with financial investments in national stock exchanges. However, it was with the advent of space exploration in the mid-20th century that the need for reliable risk assessment and forecasting techniques became more pressing, and various techniques and methodologies still in use today were developed, thanks in part to the use of electronic computers.

Conventionally, 1995 is considered the year in which risk analysis-based approaches were first formalised in the veterinary and food safety fields. Indeed, from a holistic perspective, the modern approach to food safety considers the health of the animals from which food is derived to be an integral part of the overall health guarantees that protect consumers and, therefore, an essential aspect of risk assessment. On 1 January 1995, the Agreement on the Application of Sanitary and Phytosanitary Measures (also known as the SPS Agreement) entered into force as part of the existing agreements among the member countries of the World Trade Organisation.

According to this Agreement, WTO member states may impose import restrictions on goods, foodstuffs, plants, and live animals only when such measures are necessary for the protection of the health of the human, animal or plant populations of the importing country. The appropriateness of the level

of a sanitary or phytosanitary measure must be objectively proven, and the sanitary measures themselves must have a sound, factual scientific basis. The appropriateness of a level of protection may be questioned at any time if there is a lack of scientific data that can demonstrate a possible adverse health effect resulting from such importation. The levels of protection chosen must be consistent and commensurate with the highlighted risk, avoiding unjustified discrimination between countries.

Each government can choose the level of protection it deems most appropriate (Appropriate Level of Protection, ALOP) in relation to degrees of risk considered acceptable or tolerable. The SPS agreement does not impose limits on protection levels countries set for themselves. Such choices may be determined by political and social criteria. The measures chosen by countries to implement their ALOP, however, must be:

- scientifically justified;
- applied in a consistent, continuous and non-discriminatory manner;
- based on risk analysis methodology.

International Reference Bodies have established international standards, guidelines and recommendations to ensure that sanitary and phytosanitary measured are harmonised on a global scale. These reference bodies include:

- The World Organisation for Animal Health (WOAH), for aspects related to Animal Health and Zoonoses;
- the Codex Alimentarius, jointly coordinated by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), for areas related to Food Safety;
- The International Plant Protection Convention (IPPC) based at FAO, with regard to plant health aspects.

These bodies have developed their own guidelines for risk analysis and assessment in recent years, which are to be considered true international reference standards.

The stages of risk analysis

The World Organisation for Animal Health (WOAH) has formally defined the components of risk analysis and developed specific guidelines.

According to WOAH, the risk analysis process should include the following steps [WOAH, 2021]:

- *Hazard identification*, which is the activity of identifying and listing all pathogens that could potentially be introduced through the importation of live animals or their biological products (eggs, semen, embryos);
- The *Risk assessment*, which, in turn, includes:

  - *Entry assessment*, that is, the description of all possible ways or pathways by which a particular pathogen could be introduced and the estimation of the probability that such a chain of events will occur;
  - *Exposure assessment*, i.e., the description of the possible ways or pathways by which, once entered, the pathogen could come into contact with the animal population (or human population, in the case of zoonoses) of the importing country and the estimation of the likelihood of such an exposure occurring;
  - *Consequence assessment*, which is the description of the possible consequences resulting from exposure to the pathogen and the estimation of the expected level of consequences;
  - *Risk estimation*, i.e. the activity of aggregating the results of the previous steps to produce a final risk estimate arising from the specific import scenario considered;
- *Risk management*, is, the decision-making process of evaluating possible risk reduction measures, which, in turn, includes:
  - *Risk evaluation*, i.e. the comparison between the risk as estimated by the risk assessment process and the possible risk reduction values that would apply if different control measures were implemented;
  - *Option evaluation*, is the process of identifying and evaluating the effectiveness and feasibility of specific risk reduction measures. Effectiveness is measured through 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 assessment of the feasibility of the measure must consider technical, operational and economic aspects;
  - *Measure implementation*, which ensures the application of the risk reduction measures as defined;
  - *Monitoring and review*, i.e., the ongoing monitoring of proper measure application practice, the results obtained, any deviation between them and the expected results, and, if necessary, the application of essential changes in pursuit of improved risk reduction;
- *Risk communication*, is the process by which information regarding hazards and risks is collected and disseminated to all *stakeholders* throughout the risk analysis process. A separate chapter will be devoted to the fundamentals and principles of risk communication.

As is evident from the above description of the steps in risk analysis, the WOAH refers primarily to risks arising from international trade in live animals and their biological products (eggs, sperm, embryos): the so-called "*import risk analysis*." However, the same steps and approach can be applied to contexts other than international trade, for example, to decide on the most effective strategies for control or eradication of a disease by comparing the residual risk of permanence

or spread of a specific infection (e.g., the number of expected disease outbreaks), depending on the control strategies applied (e.g., vaccination or stamping out[1]).

For the sake of completeness regarding food safety in relation to animal health, we should further emphasise that various approaches have been used over time to estimate the probability of introduction and spread of infectious diseases in a given area. For example, spatial models have been used to draw up risk maps; today, this well-established practice remains a valid method for identifying and quantifying the effects of a set of explanatory variables on the spatial distribution of a specific event or disease [Tran et al, 2013].

In the context of risk analysis in animal health, we should mention the most renowned infection transmission epidemiological models (e.g. the SIR or SEIR compartmental models[2]) [Keeling & Rohani, 2008; Keeling & Ross, 2008; Keeling & Eames, 2005; Barthélemy et al., 2005; Wasserman & Faust, 1994].

For an in-depth discussion of the various approaches used in epidemiology to model infection transmission and that can be used for risk analysis, please refer to the bibliography cited at the end of the chapter.

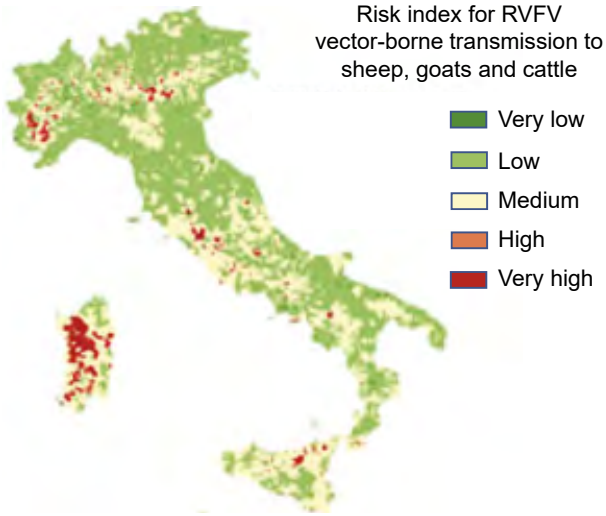

Figure 2.1 Map of areas at highest risk of Rift Valley fever transmission in case of its introduction into Italy (source: Tran et al., 2013).

1 Stamping out is the culling of all diseased, infected, or suspected infected animals in a outbreak. In many cases this results in the culling of all animals present in the outbreak and belonging to species susceptible for that pathogen.

2 SIR models breakdown population into compartments: Susceptible to infection (S), those Infected (I) and those Recovered (R). SEIR models also consider those who are infected but not yet infectious, i.e. those only Exposed to infection (E).

Regarding the application of risk analysis in food safety, the reference document is the one published in 1999 by the Codex Alimentarius Commission [Codex Alimentarius, 1999]. This document defines the following steps for conducting risk assessments:

- **hazard identification** is the identification of biological, chemical and physical agents capable of causing an adverse effect on public health and which may be present in a particular food or food group;
- **exposure assessment** is the qualitative and/or quantitative assessment of the likelihood of intake of biological, chemical and physical agents through food, as well as exposure to other possible sources, if relevant;
- **hazard characterization** is the qualitative and/or quantitative assessment of adverse health effects. This assessment is achieved with dose-response models that enable the determination of the relationship between levels of exposure (dose) to a chemical, biological, or physical agent and the likelihood of adverse health effects to a person;
- **risk characterization** is the qualitative and/or quantitative determination of the probability (and its uncertainty) of potential adverse public health effects occurring and the severity of the consequences, in a given population, as defined in the previous steps.

Risk assessment methods

In food safety, risk assessment can take several approaches.

One of these is the so-called *farm-to-fork* approach (https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en), which takes into account all aspects of the food production, processing, and marketing chain [European Commission, 2000]. The advantage of this type of approach lies in the possibility of evaluating the effectiveness of any safeguard measures that have been introduced. It is, in fact, possible at any time to include new variables in the risk analysis model and see how the final risk changes. This provides valuable insights to decision-makers (i.e., risk managers), who can also evaluate the effectiveness of risk control/reduction options.

The farm-to-fork risk analysis approach is certainly the most comprehensive, but it is also very complex and difficult to implement because of the amount of required contamination frequency and contamination level data pertaining to the entire food production chain (Figure 2.2). For this reason, the estimated uncertainty generally increases with progress along the production chain.

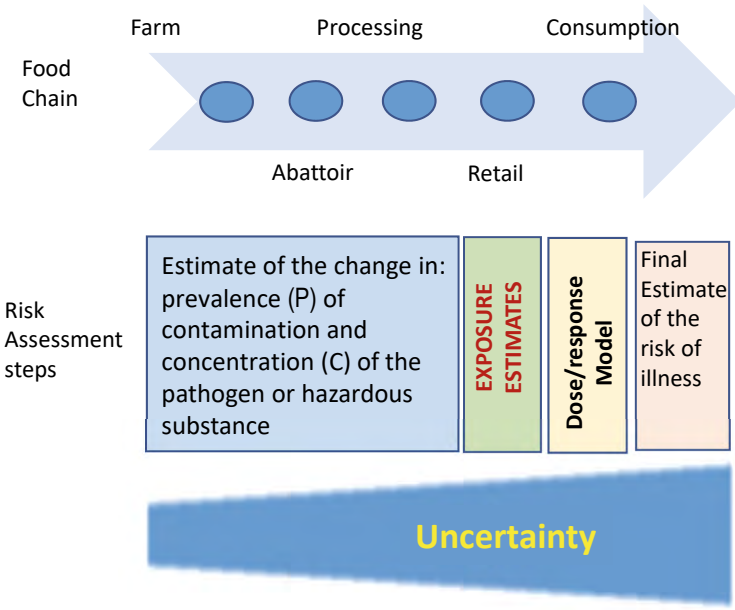

Figure 2.2 Diagram of risk assessment steps in case of farm-to-fork models.

At times, it may be advisable to rely solely on the exposure assessment. In this case, the risk assessment is made by considering only the effects of exposure to various sources of contamination, without taking into account the entire food production chain. The result is not a true estimate of risk, but a categorisation of the various sources or vehicles of infection, taking into account the number of cases in humans determined by each.

A particular form of exposure assessment study, which applies in cases of food-related risks, is the so-called "source attribution" [EFSA, 2019; EFSA, 2008]. This is based on the use of applicable statistical techniques to compare the number of human cases caused by various pathogen "subtypes" against the distribution of the same "subtypes" in the various food/animal sources. In order to apply this type of assessment, it is necessary that some segregation of "subtype" populations exists (e.g., certain *Salmonella* variants are almost exclusively found in certain animal species, the so-called "typical types" or "anchors") and such detailed information on the distribution of "subtypes" in humans, animals, and food is available. Although this approach does not provide indications of the effectiveness of possible risk reduction actions, it has the advantage that it does not require detailed data related to the entire food production chain and provides useful indications for setting priorities for action against various sources of risk.

We should recall that, these days, pathogen typing is almost always genomic. The availability of powerful techniques and tools for whole genome sequencing ("Whole Genome Sequencing" WGS) makes it possible to characterise not only the pathogen but also its "subtypes" or sub-populations ("molecular subtyping"), at very low cost. Conversely, this approach produces large amounts of data and thus requires large storage capacities and solid specialist skills (bioinformatics) for their analysis [Rantsiou et al., 2018; WHO, 2018].

It was not until 2000 that the European Commission codified the need for risk assessment in food safety with the publication of the White Paper [European Commission, 2000]. On the White Paper, see also Chapter 3.

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Chapter 3
The regulatory framework

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Introduction

European legislation on food safety and consumer protection stems from the need for the European Union (at that time European Community EC) to respond to the emergency following the food crises of the 1990s, in particular, dioxin contamination and cases of "mad cow disease" (Bovine Spongiform Encephalopathy). In January 2000, the European Commission published the White Paper, a milestone in the renewal of European legislation on the subject, implemented via Regulation (EC) No. 178/2002, which establishes the general principles and requirements of food legislation and sets out the procedures to be used in the field of food safety, seeking a high level of protection of human and animal health, with the control of food and feed along the entire chain, *"from farm to fork,"* maintaining the free movement of products.

In order to be able to take appropriate measures to ensure food safety, Regulation (EC) No. 178/2002 introduced the risk analysis process, comprising three interconnected components: risk assessment, risk management, and risk communication, which provide the systematic methodology for establishing health-protective interventions that are targeted, proportionate, and effective. In 2002, the European Food Safety Authority (EFSA), based in Parma, Italy, was established to provide an independent scientific reference point in the assessment of existing and emerging risks associated with the food chain. This chapter exclusively examines the parts of the Regulation related to risk assessment and risk communication and the tasks and functioning of the EFSA.

Twenty years after its enactment, the adequacy review (i.e., the

"adequacy screening of the general food law" or "refit") of Regulation (EC) No.178/2002 has shown that its implementation has achieved its intended goals of ensuring a high level of human safety protection and the proper functioning

of the internal market. In particular, the scientific approach has increased the overall level of protection against food safety risks.

However, weak consumer confidence in risk analysis outcomes has revealed a need for improved risk communication, compared to the past. Indeed, concerns expressed by citizens regarding transparency in scientific studies and the risk assessment process materialized in October 2017, with the European Citizens' Initiative "*Banning Glyphosate and Protecting People and the Environment from Toxic Pesticides*," which focused on the plant protection products sector and was supported by more than one million signatures.

Addressing these concerns, the European Commission proposed a specific revision of Regulation (EC) No. 178/2002, which covered the entire food chain and all associated products, amending the sector's eight dedicated legislation measures, such as genetically modified organisms, additives in food**,** smoke flavourings**,** food contact materials**,** food additives**,** food enzymes and flavourings**,** plant protection products, and novel foods.

The essential elements of the proposed revision were:

a. greater transparency, with immediate and automatic public access to all non-confidential information related to the safety of a product scheduled for market placement that has been submitted to EFSA for evaluation. In short, when an industry is interested in placing one of its products on the market, it must submit the research work done on the product (the "dossier") to the European Authority for its assessment to enable the risk assessment process. As part of this goal, a common European studies register was established at the EFSA, commissioned by companies engaged in applying for product marketing authorisations. Before a product is placed on the market, the EFSA is required to consult stakeholders (manufacturers and the public) on these studies;
b. authority granted to EFSA to request additional studies at the request of the Commission and the Union budget;
c. greater participation of Member States in the *governance* structure of the EFSA and its scientific-technical committees;
d. strengthening of risk communication to citizens through joint actions to raise awareness and improve understanding of scientific opinions and risk determination decisions.

Regulation (EU) No. 2019/1381

March 2021 saw the enactment of Regulation (EU) No. 2019/1381 (hereafter referred to as the Regulation), which addresses the transparency and sustainability of risk analysis practices in the food supply chain throughout the EU. It clearly pursues the goal of increasing the transparency of the regulatory

process, thus strengthening the EFSA and its mission of providing the scientific basis necessary for decision-making in Europe.

First and foremost, the Regulation has comprehensively regulated communication (as mentioned above, an essential element of the risk analysis process), which must be transparent, uninterrupted and inclusive while providing for the participation of risk assessment managers at EU and national levels, as well as broader public participation. This is intended to restore their greater trust in institutions and ensure a high level of protection of human health and consumer interests.

Risk communication must contribute to an open and participatory dialogue among all stakeholders to ensure that public interest, completeness, transparency, and consistency of information, as well as the accountability of those who release it, are taken into account in the risk analysis process.

Risk communication should pay special attention to explaining in an accurate, clear, complete, consistent, adequate, and timely manner not only the findings of risk assessment endeavours but also how these findings are used. Information should be provided in the communication on how risk management decisions were arrived at beyond the results of the assessment, what factors were considered by the managers, and how all these factors compared with each other.

In the event of reasonable grounds for suspecting that a food or feed may pose a risk to human or animal health, National Authorities are required to implement, to the greatest extent possible, all mechanisms to reduce that risk and to inform the public in a timely manner.

Risk communication

Regulation (EU) No. 2019/1381 establishes the goals and general principles of risk communication, considering the respective roles of risk assessors and risk managers while ensuring their independence.

Based on these general goals and principles, the Regulation provides for the development of a risk communication master plan in close cooperation with the EFSA and member states. The master plan promotes an integrated framework for all those responsible for risk assessment and management, both at EU and national levels, on all issues concerning the food supply chain.

The master plan identifies the main factors to be taken into account when considering the type and level of necessary risk communication activities, such as the different levels and nature of the risk, the potential impact on human health, animal health, and, where appropriate, the environment, levels of exposure to a hazard, the degree of urgency and the ability to control the risk, and other factors affecting the perception of the risk itself, including the existing legal framework and the market environment.

The master plan also identifies the communication tools and channels to be used and defines the appropriate mechanisms for coordination and cooperation among the risk assessors and risk managers involved. This is essential to ensure consistent communication and open dialogue among all stakeholders (assessors, risk managers, and the public).

The role of Member States

The Regulations also address changes made within some of the bodies that make up EFSA. In particular, in order to enhance the role of member states and the participation of civil society, regulations have also been drafted to cover aspects related to the designation, composition, duration, and voting procedures for the Management Board, as well as the designation, duration, and operations of the Scientific Committee and its Scientific Panels.

Authorisation procedures

The Regulation determines which food and animal feed goods are subject to the EFSA's jurisdiction, as well as related areas and matters such as genetically modified food and feed, additives intended for animal feed, smoke flavourings for food, food contact materials, food additives, enzymes and flavourings, plant protection products, novel foods, and the release of GMOs into the environment.

With regard to product authorisation procedures, it is up to the applicant (or notifying party) to demonstrate, based on the available scientific knowledge, that the subject of an application (or notification) complies with EU standards. The underlying principle is that "human and animal health and the environment are better protected by assigning to the applicant (or notifying party) the burden of demonstrating a priori (i.e., before placement on the market) that the subject of the application (or notification) is safe," and not by obliging Public Authorities to prove a posteriori that it is dangerous, and then having to ban its sale. In keeping with this principle and current regulatory provisions, it is the responsibility of applicants (or notifying parties) to submit pertinent studies, including tests performed and analytical results obtained, to demonstrate the safety and, in certain cases, the effectiveness of the subject of the application. The application (or notification) submitted to the Authority for risk assessment purposes must be procedurally compliant and aligned with the EFSA's mission to conduct scientific evaluations of excellent quality.

Applicants and notifying parties do not always clearly understand these procedures. It is, therefore, appropriate that when the EFSA is asked to provide scientific advice, it should guide the potential applicant or notifying party. The Authority issues the information upon request before the application or notification is formally submitted. Guidance provided by EFSA before the

application is submitted should refer only to the applicable standards and the subject matter of the application or notification and shall not address the nature and type of studies to be submitted, as this remains the responsibility of the applicant.

It is also necessary and appropriate that when applicants commission or carry out studies for an application (or notification), they notify EFSA of the conduct of such studies. Information on notified studies should be made public only after the publication of the corresponding application, in accordance with applicable transparency rules.

In the case of an application or notification requesting renewal of a permit, the studies intended to support the renewal application, including information on the nature and type of studies, should be submitted for consultation with a third party to ascertain whether additional scientific data or studies are available.

The Regulations assert the obligation of transparency regarding the governance of the EFSA's activities, listing all the acts, documents, scientific data, and information that must be made public, as well as the relevant conditions and arrangements.

However, requirements for transparency must not prejudice confidentiality, which is the prerogative of concerned parties in relation to information that, if fully or partially disclosed, could demonstrably cause them significant damage.

The protection and confidentiality of personal data

The regulations set out specific requirements regarding the protection and confidentiality of the applicant's personal data. Personal data must not be made public unless disclosure is necessary, in which case disclosure must be proportionate to ensure the transparency, independence, and reliability of the risk assessment process while preventing conflicts of interest. Standard formats are developed for data and their storage systems to ensure high security conditions.

The European Commission's assessment

The Regulations also address the need for the European Commission to evaluate the effectiveness and efficiency of the EFSA (see also below). Part of the evaluation is a review of the procedures for selecting members of the Scientific Committee and Scientific Panels, which must assess their degree of transparency, cost-effectiveness, and ability to ensure independence, competence, and absence of conflicts of interest.

Finally, studies comprising analytical results are submitted in support of authorisation applications. To avoid problems of non-compliance with applicable standards, the Regulations require the Commission to conduct audits in the Member Countries where the application was made. Such audits enable the Commission to verify that the laboratories and other facilities tasked with

conducting the analyses are compliant with the applicable standards. In addition, the Commission had means to identify any systemic deficiencies and detect other cases of non-compliance. If necessary, the Commission may propose appropriate legislative measures aimed at improving compliance with existing sector regulations.

The European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) is the EU body responsible for assessing food and feed safety, risks associated with its consumption, and animal health and welfare. The EFSA operates independently of European legislative and executive powers (Commission, Council, Parliament) and EU member states.

All areas and activities of EFSA are based on a set of values: **scientific excellence** of the advice provided based on the expertise of its network of scientists, its staff, the quality of its scientific information and methodologies, founded on internationally recognized standards; **independence** of its experts, methods and data, which are not exposed to any undue external influence, thanks to the application of well-defined and controlled operational mechanisms; **openness to the outside world**, through the transparent, clear and prompt sharing of the outcomes of its scientific work, with the aim of increasing trust in it; **innovation**, in the sense of the ability to anticipate new challenges, keeping pace with the changes occurring in science, industry, and society, through the development and adaptation of data and working methods, and thus ensure that the EU food safety system is at the forefront of theory, as well as scientific and administrative practice; **cooperation**, in the sense of collaboration and exchange of knowledge among institutions and experts within the EU and around the world, while optimizing the capacity and potential of available risk assessment. The EFSA publishes opinions on existing and emerging food risks. These opinions feed into European legislation, regulations and policy strategies, helping to protect consumers from potential food chain risks.

The EFSA's mission comprises engagement in the following areas:

- Food and animal feed safety
- Nutrition
- Animal health and welfare
- Plant protection
- Plant health.

The EFSA's tasks include:

- The collation of data and scientific knowledge
- The provision of independent and up-to-date scientific advice on questions concerning food safety

- The provision of information to citizens about the scientific activities carried out
- Cooperation with EU countries, international bodies and other stakeholders
- Building confidence in the EU food safety protection system through the provision of reliable advice.

The EFSA Bodies

There are three EFSA bodies:

1. the Management Board (MB).

Until the entry into force of Reg. (EU) 2019/1381 on 1 July 2022, the Management Board consisted of 14 members appointed by the Council of the European Union.

The aforementioned Regulations changed the composition and manner of Management Board appointments. In fact, each Member State designates one standing member and one alternate member as its representatives, all with voting rights.

In addition to the standing and alternate members appointed by the Member States, the MB is composed of two standing and two alternate members, appointed by the European Commission as its representatives, both with voting rights; two standing members nominated by the European Parliament, both with voting rights; four standing and four alternate members, with voting rights, as representatives of civil society and food chain interests, namely one full and one alternate member for consumer organisations, one standing and one alternate member for environmental nongovernmental organisations, one standing member and one alternate member representing farmers' organisations and one standing member and one alternate member representing industry organisations.

In addition to setting the EFSA's budget, the MB

- establishes EFSA's rules of procedure based on a proposal from the executive director;
- ensures that EFSA performs its functions and carries out the tasks assigned to it in the manner set forth in Reg. (EU) No. 2019/1381;
- before 31 January of each year, adopts EFSA's work programme for the following year and implements a multi-year programme subject to revision;
- ensures that these programmes are consistent with the EU's legislative and policy priorities in the field of food security;
- before 30 March of each year, endorses the general report on EFSA's activities for the previous year.

2. The Executive Director.

The Executive irector is appointed by the MB and is the legal representative of the EFSA with responsibility for

- take care of the EFSA's day-to-day business;
- developing the proposal for EFSA's work programmes in consultation with the European Commission;
- implementing the work programmes and decisions of the MB;
- ensuring that adequate scientific, technical and administrative support is provided to the scientific committee and scientific panels;
- ensuring that EFSA performs its tasks in accordance with the needs of users, with particular regard to the adequacy of services provided and the time spent;
- preparing the draft revenue and expenditure estimates and executing the EFSA budget;
- handling all EFSA personnel matters;
- developing and maintaining contact with the European Parliament and ensuring regular dialogue with its relevant committees;
- submitting the following projects annually to the MB for approval: a draft general report, covering all activities carried out by the EFSA during the previous year;
- draft work programmes.

After endorsement by the MB, the executive director forwards

- work programmes to the European Parliament, the Council, the Commission and the Member States and arranges for their publication;
- the general report on EFSA's activities to the European Parliament, the Council, the Commission, the Court of Auditors, the Economic Committee and the Social Committee and the Committee of the Regions (by 15 June of the current year) and orders its publication;
- any useful information regarding the results of the valuation procedures to the Budget Authority on an annual basis.

3. The Advisory Forum.

This body is chaired by the Executive Director of the EFSA.

It includes representatives of national food safety agencies from all EU Member States. Each country designates one standing member and one alternate member.

For Italy, the member of the EFSA Advisory Forum is the Director General of the Directorate General of Collegiate Bodies for Health Protection of the Ministry of Health (DGOCTS).

Members of the Advisory Forum cannot serve on the Management Board. The Advisory Forum is a mechanism for the exchange of information on potential risks and concentration of scientific knowledge. It ensures full cooperation between the EFSA and the competent bodies of the Member States, in particular through

- the promotion of interaction, through European networks, of organisations active in the EFSA's areas of expertise;
- the coordination of risk communication actions;
- the coordination of activities aimed at avoiding duplication;
- timely and effective cooperation following the identification of emerging risks.

Through the Advisory Forum, the EFSA and Member States can join forces to address risk assessment and risk communication issues in Europe. The Advisory Forum addresses controversial issues and conflicting opinions raised by member states. This body also supports the execution of the Executive Director's duties, in particular with respect to developing the EFSA work programme. It meets regularly at least four times a year. During the forum sessions, one representative from each Member State may participate along with representatives of the Commission services. Additionally, if specific issues related to animal welfare, health or plant health are being discussed, representatives of the competent bodies in the respective Member States may also attend. The Executive Director has the authority to invite representatives from the European Parliament and other competent bodies to participate in the sessions.

Coordination of support activities for Italy's participation in the Advisory Forum is provided by Office 3 of the DGOCTS of the Ministry of Health. The latter also:

- collaborates with the EFSA in the execution of its functions;
- identifies, directs and coordinates the Italian Focal Point (see below) and related activities;
- updates the national list of scientific bodies (Article 36 of RE (EC) No. 178/2002 – see below) to be submitted to EFSA and the list of national experts and related networks.

The Scientific Committee and Scientific Panels

These are the scientific bodies in charge of all risk assessment activities carried out by EFSA. It is composed of independent experts with three years of tenure who perform risk assessments by developing relevant assessment methodologies.

The Scientific Committee is responsible for the overall coordination necessary to ensure the consistency of the procedure for formulating scientific opinions, with particular regard to the adoption of operating procedures and the harmonisation of working methods. It shall formulate opinions on multisectoral issues involving the expertise of more than one scientific panel and on issues that do not fall within the competence of any scientific panel.

The Scientific Panels are responsible for most of the scientific assessment work that takes place at the EFSA in the fields of human food and animal

feed chains (animal feed, animal health and welfare, biological hazards, chemical contaminants, food ingredients and packaging materials, genetically modified organisms, nutrition, plant health, pesticides) and consist of independent scientific experts. The number and professional competence spectrum of Panel members are constantly updated by the Commission at EFSA's request in light of scientific and technical developments.

In addition, in cooperation with member states, the EFSA ratified the establishment of a database of external scientific experts with the aim of

- improving its ability to perform food and animal feed safety risk assessments;
- increasing the transparency of procedures in relation to experts invited to participate in the Authority's scientific activities;
- developing a more effective and flexible response to its growing workload, especially in the event of highly specialised, unexpected and urgent assignments.

The working groups and networks

To ensure proper operation, the Scientific Committee and Panels are supported by working groups, each competent for one specific area of the 13 in which EFSA operates (animal feed, animal health and welfare, biological hazards, chemical contaminants, food ingredients, and packaging materials, genetically modified organisms, nutrition, plant health, pesticides,

methodologies, data, cross-sectoral science).

To support the work of scientific expert groups, while simultaneously enhancing cooperation among Member States and the EFSA, the latter also oversees a network of competent national organizations in EFSA-related scientific domains (the network). Within their respective roles as organizers of national scientific networks, Office 3 of the DGOCTS and the Italian focal point of the EFSA coordinate these national networks.

Scientific Projects and Activities

EFSA secures itself the necessary scientific and technical support from organisations in the MSs through a system of funding and co-financing of scientific projects and activities, based on Grants and Procurements according to the European rules of funding and tendering.

Grants are funds allocated by EFSA to finance projects and initiatives in the area of data collection, scientific opinion preparation work and scientific and technical assistance to complement EFSA's scientific evaluations. Only bodies designated by their Member States under Article 36 of Regulation (EC) No. 178/2002 (so-called "Article 36" entities for short) are eligible to participate in calls for Grants.

Procurements are funds awarded through public tenders, through which the EFSA purchases supplies and services in accordance with EU legislation and in compliance with the fundamental principles of transparency, equal treatment, non-discrimination, the broadest possible scope for competition, proportionality, and sound financial governance. When appropriate, scientific organisations can also participate in Procurement calls.

The EFSA National Focal Points

In 2006, the EFSA established a number of national Focal Points (FPs). FPs act as an interface between EFSA and national food safety authorities; they are identified by EU member states in line with their own internal organisations. The FP network ensures the exchange of food safety information between EFSA and national stakeholders and comprises members from all 27 EU Member States, Iceland and Norway. This network enables member states and the EFSA to exchange scientific information and data, coordinate work programmes, share resources, and cooperate on joint projects.

National FPs hold statutory meetings four times a year. In addition, meetings on specific aspects of collaboration are also organised. The FPs submit annual reports on their activities to the EFSA, which are summarised in EFSA's FP activities report.

The Focal Points were established, among other things, to support the endeavours of EFSA's Advisory Forum. On 5 October 2016, the functions of the FPs were further defined by the EFSA Board Decision (Article 5 of the Advisory Forum Operating Procedure); thus, the latter shall

- represent the interface between EFSA and the various National Food Safety Authorities;
- promote cooperation among bodies identified under Article 36 of EC Regulation No. 178/2002, among national experts and networks of scientific experts;
- coordinate the activities of EFSA's scientific networks at the national level;
- carry out international scientific cooperation activities;
- assist in the exchange of scientific and expert information;
- provide advice on cooperative activities and scientific projects;
- promote training in risk assessment;
- increase EFSA's scientific visibility and broaden the scope of its activities in the member states, with the ultimate goal of significantly improving scientific cooperation and networking between two or more member states and EFSA.

The Focal Points enter into a four-year collaboration agreement with EFSA, which is funded by EFSA on an annual basis (*Grant Agreement*) following the

submission of a report of the activities carried out on the basis of what is outlined in the annual agreement.

The Italian EFSA Focal Point

In Italy, EFSA's FP role is established at the Direzione Generale degli Organi Collegiali per la Tutela della Salute (DGOCTS) of the Ministry of Health. It is tasked with the following mandates:

Supporting the Advisory Forum

As previously mentioned, the role of the Italian FP is primarily to support the work of the EFSA Advisory Forum. In particular, it assists the Italian representative of the Advisory Forum by improving the Authority's data collection systems, providing for the exchange of information between the EFSA and the national competent bodies under Article 36, supporting the exchange of information between countries through their FP networks, and aiding the information and dissemination of calls and training programmes proposed by the Authority.

Exchange information

The FP ensures the exchange of scientific information on initiatives, research projects, risk assessment results, and risk communications related to food, animal feed, and other topics within EFSA's remit. One of the tools used for this exchange of scientific information is the EFSA's platform known as the *Knowledge Junction*, which provides open access to scientific models, tools, and publications within EFSA's remit.

The FP replies to risk assessment query questions from Member States or forwards them to relevant ministries, authorities, institutions or experts. The FP organises regular meetings at the national level with institutions and experts who cooperate with EFSA.

Information exchanged between national FPs and EFSA mainly concerns

- the development of major risk assessment and communication initiatives in Italy and by the EFSA;
- the results of major scientific research projects;
- ongoing risk assessments and opinions in preparation;
- aspects that may cause potential differences of opinion between Italy and the EFSA;
- the work programmes of the National Authority and leading research institutions in areas of interest to the EFSA;
- requests for specific information.

Management of national competent organizations under Article 36 of Regulation (EC) No. 178/2002 and their national experts

The competent organizations referred to in Article 36 of Regulation (EC) No. 178/2002 support EFSA in the performance of its functions by participating in calls for proposals for research projects for which the EFSA can provide financial support (Grants). The FP informs these organisations about calls for cooperation published by EFSA and supports them with specific training and information activities.

The FP has developed databases subject to continuous updating by scientific experts and national research organisations qualified to assist the EFSA and national authorities in risk assessment, risk communication, and food and feed safety.

In Italy, the network of Competent Organisations under Article 36 of Regulation (EC) No. 178/2002 is currently composed of 38 scientific organisations [the full list is available at the link provided in the bibliography]. With the support of the Italian FP of EFSA, the DGOCTS verifies their eligibility according to the criteria outlined under Regulation (EC) No. 2230/2004. If eligible, the organisations are then designated as competent by the Member States and, subsequently, included in a list drawn up by EFSA's Board of Directors following a proposal of the Executive Director and published on the EFSA's website. In Italy, as of late February 2022, 650 experts are belonging to the 38 organisations and, on the basis of their professional experience, they appear in the national database distributed in 14 lists of experts, 13 of which are associated with the EFSA areas of competence and one comprising gathering experts in risk communication.

In cooperation with the relevant organisations mentioned in Article 36, the FP organises scientific and training events for national experts to foster cooperation with the EFSA and provide opportunities for scientific and technical collaboration between it and national institutions.

One of the Italian FP's priorities is the promotion of training activities for young risk assessors, particularly EFSA's EU-FORA program. Prominent among the activities of the Italian *FP* is the collaboration to the update of the *European Union Food Safety Almanac* (see bibliography), which will be published in 2021 by the Bundesinstitut für Risikobewertung (BfR), the German Federal Institute for Risk Assessment, to facilitate the understanding of the organisation in Europe in the field of food safety.

The Directorate General of Collegial Bodies for Health Protection of the Ministry of Health (DGOCTS)[1]

The Directorate General of the Collegial Bodies for Health Protection (DGOCTS) of the Ministry of Health acts as EFSA's National Reference

1 Regarding the reference national organization for the European Authority, the Ministry of Health is undergoing reorganization pursuant to the national legislation (DPC - Decreto del

Authority and National FP. It performs Food Safety Risk Assessment, ensures liaison with the Regional Authorities and consults with Consumer and Producer Associations.

As the Competent Authority for Risk Assessment, the DGOCTS provides support and advice to risk managers and provides them and stakeholders with the most appropriate guidance for the improvement of food safety practices. On its own initiative or upon specific request, it identifies the existence of actual or potential risks and independently schedules its risk assessment activities.

Through the Consumer and Producer Associations Advisory Section of the National Committee on Food Safety (CNSA), the DGOCTS also holds discussions with interested parties to detect special risk communication needs.

These Directorate functions are assigned to Office 2 and Office 3 as follows:

Office 2 – Risk Assessment and Communication in Food Safety.

This section ensures the coordination of chemical, physical and biological procedures comprised in the food safety assessment process through

- liaison with the Regions and Autonomous Provinces, also for the planning of food chain risk assessment activities;
- liaison with the CNSA secretariat;
- liaison with the relevant directorates general of the Ministry of Health for activities pertaining to the CNSA;
- detection of relevant needs and planning of risk communication activities in cooperation with the General Directorate of Communication and European and International Relations.

The CNSA is a technical advisory body on risk assessment. It is chaired by the Minister of Health, or his delegate, and has two sections:

- The Food Safety Section.
- It provides technical and scientific advice to risk management administrations, formulating scientific opinions in food safety-related matters. It conducts risk assessment activities, both for contingent needs, as well as on the basis of programmes. The Minister of Health appoints 13 experts drawn from universities and research institutes. The CNSA collaborates with national reference centres, reference laboratories, and competent organisations under Art. 36 of Reg. (EC) No. 178/2002 and other national research institutes of proven expertise;
- The Consumer and Producer Associations Advisory Section.

It ensures confrontation between public institutions and Consumer and Producer Associations on food safety issues, promoting the exchange of information among them and facilitating citizens in their choices regarding

Presidente del Consiglio dei Ministri, dated October 30, 2023, no. 196 (Gazzetta ufficiale - special series number n. 295 dated December 19, 2023, in force from January 3, 2024).

conscientious consumption and a correct nutrition lifestyle. It comprises representatives of the Ministry of Health, the Ministry of Business and Made in Italy, the Ministry of Foreign Affairs and International Cooperation, the Ministry of Agriculture, Food Sovereignty and Forestry, the State-Regions Conference and Consumer Associations, as well as representatives of the Producers' Associations, identified by the National Council of Economy and Labour (CNEL). An important function of the Advisory Section is to represent specific risk assessment needs of stakeholders to the Food Safety Section. The establishment of the Consultative Section is particularly significant in light of the provisions of (a) Regulation (EC) No. 178/2002, which places special emphasis on the safeguarding of consumers interests as well open and transparent consultation with consumers themselves, either directly or through representative bodies; and (b) EU Regulation 2019/1381, which provides for the adoption of a Master Plan on Risk Communication by the European Commission, comprising specific mechanisms to ensure dialogue between consumers, food and feed businesses, and all relevant stakeholders.

Office 3 – the EFSA and Focal Point – ensures cooperation with the EFSA by
- participating in and supporting the activities of the EFSA Advisory Forum;
- identifying, directing and coordinating the EFSA Italian Focal Point;
- updating the national list of scientific bodies to be submitted to EFSA (Art. 36 of RE (EC) No. 178/2002) as well as the list of national experts and related networks.

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EFSA structure and objectives: https://www.salute.gov.it/portale/ r i s c h i o A l i m e n t a r e / d e t t a g l i o C o n t e n u t i R i s c h i o A l i m e n t a r e. jsp?language=italian&id=4847&area=Assessment%20risk%20chain%20 food&menu=authority

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Chapter 4
The risk assessor profile

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Background, skills and responsibilities

Risk assessment in food safety and animal health is a multidisciplinary endeavour. In fact, the application of internationally adopted methodologies requires evaluators to have a broad spectrum of knowledge in different fields ranging from food microbiology to toxicology, statistical modelling, epidemiology, medicine and nutrition, etc. Imagine, for example, the need for a quantitative opinion on the risk of listeriosis associated with the consumption of a certain cheese in a certain country. Developing a predictive model requires expertise in food microbiology and possibly knowledge about the specific microorganism. The assessment would also require a professional with experience in model building and food technology to outline the sequence of events/processes that determine the level of consumer exposure to the micro-organism. It would also require collecting appropriate data (data mining) from appropriate sources and knowing how to process it using sound statistical and epidemiological techniques, perhaps with the advice of experts in other specific fields, chosen according to the nature of the information (e.g. doctors, nutritionists, veterinarians, etc.). The risk assessor guides and supervises the entire process and must, therefore, be capable of generating and mastering risk assessment techniques and combining them with the specific expertise needed. For these very reasons, the first step after a client requests a risk assessment is usually to form a team that can provide the appropriate knowledge in relation to the submitted *risk question*. The above is particularly applicable in complex and accurate risk assessment cases, usually supported by significant investment and/or sufficient time to recruit and coordinate different specialists. In reality, this is not always possible, i.e., there may not always be sufficient resources available to compose a team of professionals or sufficient time (e.g., in case of emergency

situations) to dedicate to the assessment. In such cases, all of the above skills and activities must be provided by one or a few professionals. It follows that the educational background of modern risk assessors must be multi-sectoral and must be consolidated through the in-depth study of very diverse disciplines. Multidisciplinary training is, moreover, an important requirement because it favors the acquisition of the "overall picture" with respect to the work to be completed and enables actors to skillfully handle the abundant data and information used to provide a risk estimate and possible control options.

Unlike other fields, such as the financial and nuclear sectors, applying risk assessment principles to food safety and animal health issues is a relatively recent approach. Probably for this reason, there are still no academic courses specifically dedicated to the comprehensive training of professionals able to work in these fields in the European context, although several academic courses in related disciplines have expanded their curricula to include risk assessment topics and/or relevant basics. This is evident from the highly diversified educational background of most risk assessors working today. Granted that many of the *modus operandi*, techniques, and methodologies used to assess risk are cross-cutting and deployed across multiple fields, operators dedicated to assessing risks associated with biological hazards generally have academic backgrounds grounded in undergraduate courses in biomedical or agri-livestock fields such as biology, medicine, veterinary medicine, biotechnology and food technology.

While not specifically exhaustive, such studies certainly foster greater familiarity in the area of microbiological risk assessment, i.e., the risk of disease in humans caused by hazards of a biological nature (bacteria, viruses, parasites, etc.) present in food. For the same reason, professionals with training in veterinary/animal husbandry are facilitated in the study of risks related to animal pathogens or, for example, in the development of models for estimating the probability of importation of exotic diseases or the dynamics of the spread of a pathogen in an animal population.

On the other hand, the training of operators primarily engaged in chemical risk assessment is often grounded in undergraduate courses in chemistry, pharmacy and pharmaceutical techniques, toxicology, etc. In this case, risk assessors tend to focus on chemical risk assessment, such as studies of population exposure to foodstuff contaminants or the characterisation of the toxicity of substances for human consumption.

In any case, all risk assessment is based on the use of data to create predictive models, sometimes very complex ones. It follows that many professionals whose university degrees denote a strong mathematical bias (mathematics, statistics, engineering, etc.) also frequently work in the food and agri-livestock sector, in both public and private companies, precisely in biological and chemical risk assessment at all levels.

As mentioned, an orientation towards risk assessment or one of its specific areas in line with a certain university study profile is not necessarily professionally restrictive. Indeed, the skills needed by risk assessors are highly specialised and require in-depth effort and supplementary post-graduate studies. A risk assessment, whether qualitative or quantitative, is founded on the available data, which allow a given chain of events to be studied to be described with a given degree of accuracy. Therefore, it is evident that professional engagement as a risk assessor implies considerable knowledge in the collection, analysis, and management of relevant data.

Information collation may draw on several potential sources on a case-by-case basis, but initially always from the international scientific literature (*peer-reviewed* journals). The risk assessor, therefore, must be skilled in the precise consultation of well-known bibliographic databases (e.g., PubMed, Scopus, Web of Knowledge, etc.), knowing how to select and examine useful studies through extensive or systematic reviews, and archive references using bibliographical management software (e.g., *Refwork, EndNote, etc.*). The extraction of data from scientific studies implies understanding how these were obtained and whether they can actually be suitable for the development of the expected assessment. In this sense, the risk assessor needs to have a solid foundation in epidemiology to ensure the correct interpretation, use and adaptation of epidemiological investigation outcomes in a scientifically correct manner, applying appropriate assumptions when integrating them into an assessment model. Mastery of epidemiological methodologies is also very useful when *ad hoc* studies are required, i.e., in those relatively infrequent yet possible cases in which information essential for assessing a given risk is not available and dedicated unprecedented research is required. Information collation for risk assessment is a logical and systematic process involving vast amounts of data, which must be stored using computer databases. This activity obliges risk assessors to know how to create databases in line with applicable good practices and how to independently and effectively master the software tools needed to accomplish such operations (e.g., MS Excel, LibreOffice suite, R Studio, etc.).

Data collection is followed by the analysis phase, which is aimed at studying, and then defining, the values to be assigned to the parameters governing the sequence of events in the risk assessment. It is, therefore, evident that a risk assessor must be able to apply the primary techniques relating to descriptive and inferential statistics, which are indispensable for exploring the available data and assessing their robustness and possible integration into the model. For example, the calculation of measures of position (mean, quartiles, etc.), variability (variance, standard deviation, etc.) and their representation through appropriate graphs are indispensable for understanding the order of magnitude and distribution of the values collected and used to describe a certain variable. Inferential statistics are indispensable for discerning and quantifying relationships between

variables pertaining to a certain event; they also predict their behaviour and the associated probability of error (e.g., regression models and hypothesis testing). Equally essential, a risk assessor must possess some knowledge of probability theory. Indeed, stochastic risk assessments, i.e., those that are not limited to a point estimate of risk but provide ranges that take into account its variability and/or uncertainty, make use of distributions that define the probability of an event occurring in relation to the available data. Meta-analysis methods are another widely used tool in view of the fact that risk assessment, in order to value certain parameters, often makes use of data from many different sources. Such mathematical-statistical techniques make it possible, in fact, to summarise results from a large number of similar studies, taking into account their inherent limitations and differences.

Finally, it will be necessary to adopt various techniques to manipulate or transform the data to be integrated into the model under construction. For example, it is very important to know how to apply regression or fitting methodologies to characterise the data by distributions that will later be used in the assessment model. In certain cases, additional specialist skills are needed, such as notions of predictive microbiology in the food sector. The latter consists of deploying mathematical relationships to describe the behaviour of a microorganism over time under predetermined ecological conditions (e.g. type of food, temperature and pH), using real data previously collected in other studies or derived from a specifically devised experimental study. In some cases, it is possible to make direct use of currently available predefined software (tools) (e.g., COMBASE, SSSP), select the microorganism of interest, and query the application, simulating the conditions under which the microorganism will presumably be found. However, such tools cannot be used in all cases; for example, when describing the behaviour of an uncommon microorganism or simulating extremely specific conditions not covered by a standard application. In such cases, the risk assessor must be able to garner the experimental data of microorganism growth or decay in relation to the factors to be studied and apply primary and secondary regression models that fit the microbial behaviour and enable predictions of relevant foodstuff concentrations (Figure 4.1).

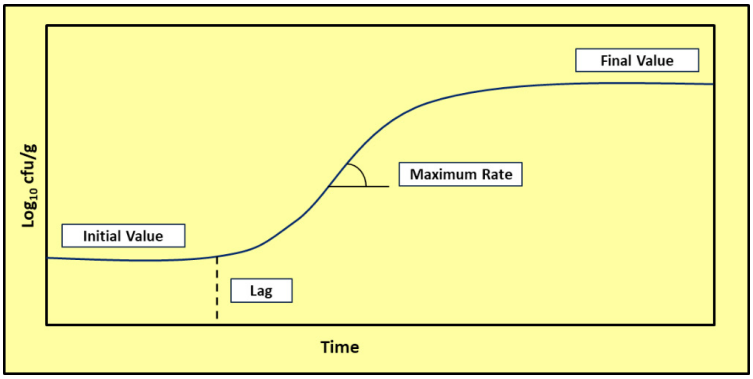

Figure 4.1 The Baranyi and Roberts model (1994) is one of the most widely used to predict the behaviour of a microorganism over time under constant conditions (Initial value – the contaminant bacterial load of interest for evaluation present in the food at the start of the detection period; Lag – the time taken for the contaminating bacteria of interest in the evaluation to start replicating. It depends on various factors including food matrix, temperature and pH; Maximum rate – the maximum growth/replication of the contaminating bacteria of interest in the evaluation. It corresponds with the straight-line curve gradient and depends on various factors, including nutrient availability, free water, temperature and pH; Final Value – final concentration of Contaminated Bacteria of interest for evaluation in the considered matrix)(COMBASE, 2021).

Finally, in order to provide an adequate response to the demands of risk managers, in the vast majority of cases, the risk assessor will be called upon to develop a model, i.e., a simplified representation of the reality to be represented. The risk assessor is primarily responsible for the conceptual development of the model and, possibly in collaboration with other specialists, will proceed to estimate the sequence of events or phases to simulate a future evolution (e.g., Figure 4.2). This involves

- estimating the probability of occurrence of a certain adverse event;
- determining the factors that most influence such an event;
- exploring possible risk mitigation scenarios.

In qualitative risk assessment, models generally tend to be simple because iterations through various components or factors are defined by simple logical operations or because probability matrix-based approaches are adopted. Quantitative risk assessment, on the other hand, and even more so stochastic and/or spatial risk assessments, tend to be more complex; the resulting models, possibly based on highly complex mathematical relationships, must be developed using dedicated software capable of simulating certain phenomena in a probabilistic manner. Hence, most risk evaluators must know how to use software tools such as R Studio, WinBugs, @Risk, Matlab, Analytica, etc.

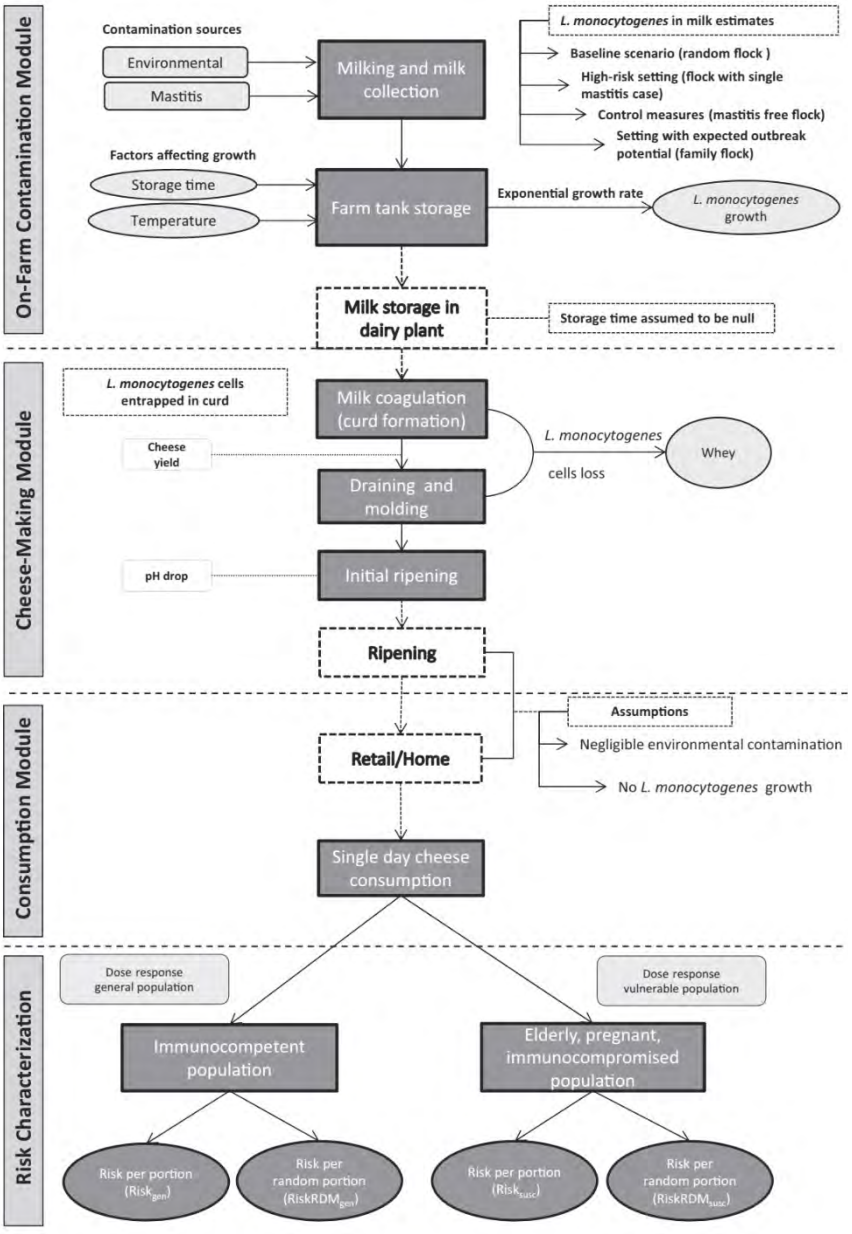

Figure 4.2 Diagram of a quantitative assessment model regarding the risk of listeriosis associated with the consumption of unpasteurised milk or cheese (Condoleo et al., 2017)

Risk Assessor roles and prospects

As mentioned above, risk assessment is a complex process involving various institutions and professional figures. Its purpose is to produce scientifically correct and useful results for risk management and prevention initiatives. Risk assessors must possess skills that facilitate interaction and mutual understanding among the experts involved in risk assessment and coordinate the collation, management, aggregation, and dissemination of information necessary for the assessment itself. Excellence in relevant scientific fields is an essential prerequisite, but knowledge of the entire risk analysis process, food legislation, social sciences (necessary to consider consumer behaviour), international relations and risk communication are other areas that must be considered in order to perform the role of risk assessor at the best possible level. To manage future challenges related to food safety risk assessment in an ever-changing and increasingly complex environment, it is necessary to identify a training model for young aspiring operators in the field and a system for training and updating experts that fosters the continuous evolution of skills. Hence, it is not sufficient to identify experts with skills that may be appropriate in a given historical moment and context; rather, we must envisage adaptive training mechanisms capable of addressing the evolution and new challenges that food safety and risk assessment practices will face in the future.

One of the interdisciplinary skills considered indispensable today is knowledge of technology and its applications in science and communication. In light of the ongoing "digital revolution," technical and scientific professions are undergoing and will continue to undergo frequent changes, and professionals must be prepared and stay updated.

The ability to read and evaluate scientific data and information remains a critical skill for risk assessment work. Risk assessors may face either an excess or a shortage of data and information; in both cases, they must be able to identify and evaluate relevant information and identify data that is necessary and useful. The ability to identify the best scientific evidence and quality information is an essential skill that should not be underestimated in the training of future risk assessors. Indeed, such skills are becoming increasingly important, considering that whereas scientific publication is subject to a peer review process that, within certain limits and with due care, assures a measure of quality, "free" data, i.e., those published without peer review entail more complex evaluation because their usefulness depends on aspects related to motive, context, methods, collection and sharing tools, and the evaluation and validation steps to which they have been subjected.

One particular type of data is so-called "big data", computerised information so numerous, dynamic or complex that it is difficult or impossible to process by traditional methods. Big data has been termed as "an invaluable source of

value," but merely collecting it or processing it with the best available technologies does not guarantee the extraction of valuable and, above all, useful knowledge. Big data is useful only to the extent that it can be transformed into meaningful information, and this requires high-quality data sets, communication between information systems (IT – information technology), and standard data formats that can be easily processed. These new types of data require new skills and interpretation capabilities, especially with a view to their use for risk assessments.

The increasing level of risk assessment complexity, coupled with the EFSA's optimisation of resources and its cooperation with Member States, based also on the new Regulation (EU) 2019/1381 and the 2022-2027 EFSA Strategy, has led to the creation and management of multidisciplinary teams dedicated to risk assessment and communication aspects, composed of EFSA staff and experts from the Member States themselves. Knowing how to work in multidisciplinary teams, managing different management styles, problem-solving or attitude becomes, therefore, a skill to be learnt, cultivated and implemented constantly, together with the ability to organise one's work according to the activities of the group and to meet deadlines.

Food safety is complex and multidimensional in nature; it is subject to public regulation mechanisms required to satisfy and balance multiple interests. Food safety governance entails implementing a set of principles, legislation and international, national and local regulations. These regulations consider food and products intended for human and animal consumption; they protect a multiplicity of values and sometimes conflicting legal interests such as human, animal and plant health, but also trade and marketplaces, consumer information and respect for the development of the agricultural sector and food traditions, the environment, economic growth and sustainable development. Such complexity requires experts in the field who are also endowed with legal and regulatory knowledge; risk assessors cannot ignore the legal aspects of their work. Without expecting ultimate legal expertise, the main regulatory framework and the most important legal aspects should be well known in order to facilitate interaction with legislative specialists and promote understanding of the legal framework within which risk assessment work is conducted.

Excellent knowledge of at least one foreign language, especially English, is mandatory for those who want to work in an international scientific context today. Knowing how to deal with environments outside one's native culture, fosters that openness and embrace of "the outside" that forms the basis of one's ability to mediate reality with broader horizons and, therefore, to participate more actively in the processes of cultural, social and technical innovation. In the world of work and in a multiethnic and multicultural context such as the EFSA and risk assessment, this ability is indispensable for all those activities that include relations with experts of different nationalities and the use and

drafting of written documentation in foreign languages. This ability is closely associated with communication skills, which are also necessary considering the difficulty of ensuring rapid and correct translations, both in scientific and linguistic terms, and the need to avoid doubts or misinterpretations.

Risk assessors are often called upon to provide information, updates, and explanations of ongoing assessments, which must be clear, comprehensible, and scientifically correct. With regard to public interaction skills and the specific aspects of risk communication, the required specialised skills can only be mastered with specific training beyond the scope of a risk assessor's basic technical education.

In conclusion, food safety risk assessment demands a multidisciplinary and interdisciplinary approach; excellence in relevant scientific fields is a prerequisite, which must be supplemented with detailed knowledge of different aspects of food risk assessment, EU food legislation, consumer behaviour, international relations and risk communication expertise. Food safety is developing in an ever-changing and increasingly comprehensive environment, and it requires appropriate skills, which must eventually be defined and updated to meet the future challenges that risk assessment will entail.

Current educational options for risk assessors

The educational offer available to *risk assessors* working in food safety and animal health fields is extremely specialised and still rather limited. As previously mentioned, the degree programs currently available throughout Europe do not offer the relevant basic training. Therefore, in order to respond to the immediate need for experts for risk assessment, the European Commission and the EFSA are funding risk assessment training programmes for experts from public administrations and Article 36 Competent Organisations. At the European level, discussions are currently underway on the need to create special university-level training courses for this subject.

EU-FORA

The European Food Safety Risk Assessment Fellowship Program (EU-FORA) is currently one of the most comprehensive and relevant European Risk Assessment initiatives. EU-FORA is a European training programme intended to run for four years. The EFSA has run yearly 12-month courses since 2017, and the original programme format (EU-FORA 1.0) ended in 2021. At the time of writing, the call for proposals regarding the new four-year format (EU-FORA 2.0) has just been published; as before, it envisages funding for several fellowships on an annual basis, albeit with certain procedures and requirements that differ from the previous edition. The purpose of the initiative

is to provide high-level food risk assessment training for operational or interested professionals. European Union citizens who have worked for at least 12 months for an organisation active in areas under the EFSA's expertise ("Art. 36 Competent Organisations", the full list of which is available at the link provided in the bibliography) are eligible to participate in the call. Candidates (*fellows*) must have a bachelor's degree in a field related to food safety, English language ability to B2 level (CEFR classification) and between 3 and 15 years of experience in food safety work. In addition, preferential fellow characteristics include practical knowledge of useful risk assessment tools (modelling tools, statistical software, etc.) and authorship or co-authorship of scientific publications.

Participation in EU-FORA 2.0 involves the establishment of a consortium between an institution that proposes a candidate with the above-mentioned requirements (*Fellow-sending organisation*) and an international-level institution that will administer the training (*Hosting organisation*). The consortium then applies for programme membership by proposing a project aimed at the *fellow*'s professional growth. The two organisations must necessarily belong to two different EU member countries and be recognised as "Article 36 Competent Organisations". The project should provide details of the work programme (for example, indicating the risk assessment activities in which the fellow will participate), and outline the stays at the host institution. In the EU-FORA 2.0 programme, in fact, the fellow does not have to spend the entire fellowship period abroad; approximately no more than one-third of the fellowship is spent at the host organisation to gain first-hand experience, enhance knowledge exchange, and create or consolidate bilateral relationships. The remaining period involves the fellow performing remote collaborative work. The general and ultimate goal of the EU-FORA project is to increase expertise on risk assessment in each of the EU countries and enhance the development of international expert networks strengthened by direct knowledge among scientists. If the consortium's application is accepted, the EFSA will provide the necessary funds to cover all costs of the proposed programme, such as travel and living expenses at the hosting site, risk assessor training fees, administrative charges and course fees.

Training of fellows (Figure 4.3) is based on a "*learning by doing*" approach. Fellows have the opportunity to gain specialist knowledge and experience by operating as full members of working groups ("teams") composed of senior risk assessors. They will work hands-on with risk-related food safety and animal health issues. The topics of the various projects reflect the variety of risk assessment scenarios dealt with by EFSA and cover specific issues, such as, for example, the introduction of an exotic infectious disease in a country, the exposure of humans to certain harmful substances through food contamination, the behaviour of pathogenic microorganisms in the food chain following to technological treatments, the evolution of antibiotic resistance phenomena, the development of studies for the collection of data concerning food consumption

in certain countries, etc. At the end of each EU-FORA cycle, a special issue of the EFSA journal is published with a detailed description of the conducted projects and their results (https://www.eufora-alumni.org/science-research/publications/).

At the initial phase of the project, a summer workshop might be organised during which fellows can meet each other, exchange their experiences and get acquainted with the topics they will address during the year. This is followed by an intensive course lasting several weeks at the EFSA headquarters in Parma (induction course), during which, with the collaboration of experienced risk assessors, all participants in the cycle become familiar with the essential components of risk assessment: they acquire notions of statistics, modelling, microbiology, and food chemistry and familiarise themselves with the main risk assessment tools and software available. In addition, four one-week training events are scheduled throughout the year where in-depth discussions with top European specialists cover specific topics such as risk assessment techniques in animal health and welfare, evaluation of novel foods, analysis of emerging risks, and data collection and representation.

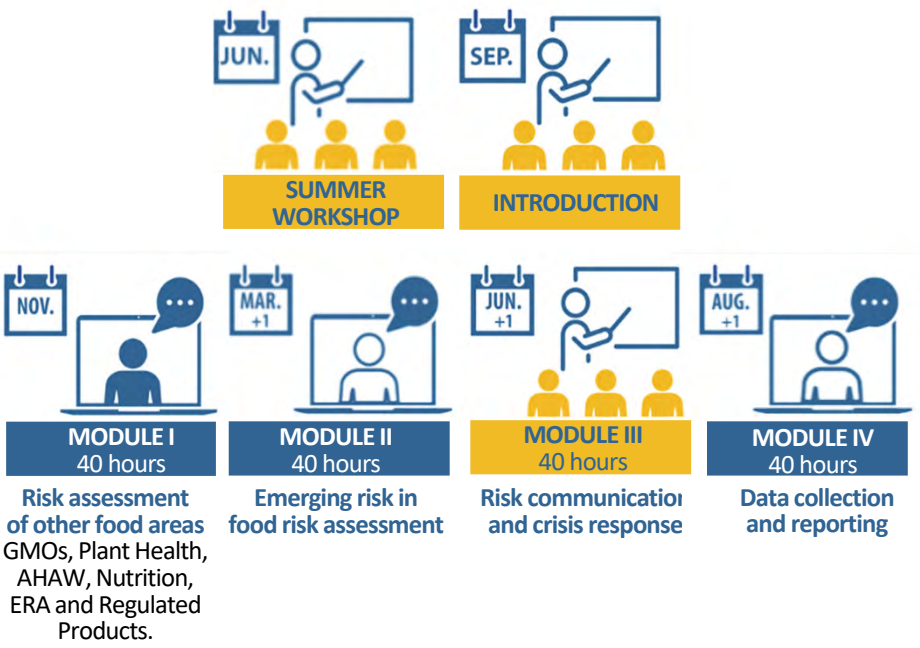

Figure 4.3 Specialised training for fellows during the EU-FORA 2.0 programme (EFSA, 2022)

Although the ultimate goal is to strengthen cooperation among European food safety organisations, and between them and the EFSA, thereby contributing to the harmonisation of food risk assessment practices throughout Europe, EU-FORA also offers participants several individual benefits. Indeed, the programme enables participants to acquire relevant practical skills and experience regarding many scientific aspects of risk assessment. Such achievements are rare, considering the training offerings currently available in the European context. Fellows can train and work with the support of professionals of proven scientific renown and can, therefore, establish working relationships that will be extremely useful also after the conclusion of the project. In addition, since EU-FORA is an international project, participants will have the opportunity to experience a variety of cutting-edge operations in various European countries and replicate them in their own countries. The benefits are not limited to the fellows alone: their home organisations will ultimately benefit from the increased skills and knowledge, the broadening of the network to include prestigious scientific entities, and the staffing of personnel belonging to a strong EU-wide network of food safety scientists.

Traineeships

Traineeships organised by the European Food Safety Authority (EFSA) offer a high-level educational experience to young people who want to approach food safety risk assessment. In fact, the EFSA regularly provides paid traineeships mainly to young graduates holding a university degree at the beginning of their careers. Trainees may opt for a field of their choice, and the programmes last for periods between 5 and 12 months. This is a valuable opportunity to gain initial professional experience with a specialist European organisation in the various risk assessment areas. Traineeships are accessed by applying on the occasion of specific calls, which are published at varying intervals on the European Authority's website. Applications are open to all nationals of EU member states, EFTA countries, countries benefiting from the EU's pre-accession programme, and, in limited numbers, nationals of non-EU countries, subject to available resources and consistent with EFSA's operational priorities. Essential prerequisites are a bachelor's degree and good communication skills in English (minimum CEFR level B2). The EFSA's candidate selection process is based on background, curriculum, and the profile of the Agency's target department assignment target.

As stated by the EFSA, trainees may participate in the Authority's activities and, in general, acquire on-the-job experience while learning about the European food safety system, an experience that can sustain numerous career possibilities. In addition to the evident advantage of acquiring operational skills at a highly-recognised agency, trainees get to work in a multicultural environment and approach a multitude of diverse themes. The activities conducted

during the traineeship can cover any topic related to risk analysis and depend on the unit or team to which the trainee is assigned. For more information, see the EFSA Young Professionals website (https://www.efsa.europa.eu/en/careers/youngprofessionals).

Better Training for Safer Food (BTSF)

Better Training for Safer Food (BTSF) is a training initiative funded directly by the European Commission with the aim of furthering knowledge about the implementation of EU standards relating to food and feed, animal health and welfare, and plant health and plant protection products. The courses offered by BTSF are intended for all professionals already working in National, Regional and Local Authorities and experts from Article 36 Competent Organisations. BTSF course programmes are structured according to proposals from the EFSA. They are short training modules (maximum of five days), which can take place in e-learning mode or in person. At the European level, BTSF courses are managed by a cultural-scientific body known as the BTSF Academy. The academy periodically disseminates the calls through its own national contact point (the BTSF National Contact Point) and the EFSA's National Focal Point. These are tasked with divulging the calls and encouraging the participation of experts.

All courses are thematic and conducted by tutors from different European countries with extensive and proven experience in their fields. All training BTSF activity can be tracked on the BTSF Academy portal. In recent years, BTSF has cyclically organised courses focusing on the application of risk assessment in food safety. For example, courses regarding microbiological risks focus on hazards of a biological nature (bacteria, viruses, parasites, etc.), using the steps defined by the international Codex Alimentarius methodology as an outline and providing the basic skills that enable a quantification of a pathogen-specific risk to the public associated with the consumption of a given food product. Courses on chemical risk assessment, on the other hand, focus on exposure to undesirable substances in food and their impact on consumer health. Other courses cover the assessment of risks of environmental, biotechnological, nutritional, animal health and welfare origin.

All courses include hands-on practical work, which enables participants to familiarise themselves with the techniques used to assess risks. One of the additional purposes of the BTSF program is to stimulate what is known as cascade training: once participants have returned to their home institutions, they are asked to disseminate what they have learned to their colleagues through seminars, presentations, scientific papers, projects, and to share course materials.

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Chapter 5
The characterisation of toxicological risk, this unknown

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Toxicological risk

In Europe and almost all countries, risk assessment and characterisation follow procedures based on well-defined scientific information in order to provide the assessor and the legislator with reliable elements of judgment.

Consequently, food safety can be said to consist of a set of standards and procedures designed to assess possible hazards to health deriving from exposure to synthetic or natural substances and contaminants present in food, environmental toxins, residues from the processing and transformation of raw materials into food, and residues of food preservation processes.

In particular, in accordance with the recommendations of Regulatory Bodies and Agencies, these procedures help to determine Health Based Guidance Values (HBGVs), such as the Acute Reference Dose (ARfD), the Acceptable Daily Intake (ADI), the Tolerable Daily Intake (TDI), and the Margin of Exposure (MoE) (Table 5.1). These values provide a guide to the safe consumption of chemicals in food, taking into account the latest data on their safety, the uncertainties in such data, and the likely duration of exposure.

Risk assessment is a process designed to estimate the risk to a given target organism, system, population or sub-population as a result of exposure to a particular agent, taking into account the intrinsic (toxic) characteristics of the agent in question, as well as the characteristics of the specific target. The process comprises four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation.

The first step, hazard identification, identifies the type, nature, and potency of adverse effects that an agent has the inherent capacity to cause in an organism, system, population or sub-population. The experimental methods that characterise this step range from the use of in silico approaches (computational analysis, such as the quantitative structure-activity relationship or QSAR), to *in vitro* and *in vivo* assays and epidemiological observations.

This is followed by the hazard characterisation step, which involves gathering information on the toxicokinetics and toxicodynamics of the substance and its mechanism of action to identify a dose-response and no-effect dose.

The No Observed Adverse Effect Level

The no-observed adverse effect level (NOAEL), is one of the pillars of risk assessment procedure and applies in many fields of evaluation. It corresponds to the highest concentration or amount of a substance, identified by experimental studies or epidemiological observations, and expressed in mg/kg of body weight, that does not cause toxic (adverse) effects, morphological or functional alterations or changes in corporeal growth, development and lifespan of the experimental subject under study. It must be derived from experiments involving repeated administrations of the test substance. The NOAEL is particularly important because it is the basis for all *Health Based Guidance* Values *or* HBGVs, albeit by different processes, such as those established by EFSA.

Table 5.1 Guideline values for the protection of human health or HBGVs.

Acronym	Meaning	Application examples
ADI	*Acceptable Daily Intake*	Food additives, biocides and pesticides
TDI/TWI	*Tolerable Daily/Weekly Intake*	Food contaminants (metals, toxins, etc.).
MoE	*Margin of exposure*	Unadded genotoxic carcinogens
MoS	*Margin of Safety*	Cosmetic ingredients
PDE	*Permitted Daily Exposure*	Residues of drugs, homeopathic products

The "oldest" HBGV, in terms of its appearance on the food safety scene, is definitely the ADI, which is the amount of a substance, expressed in mg/kg body weight, that can be ingested daily by an individual even over a lifetime without any appreciable risk. It is mainly used for non-genotoxic and non-carcinogenic substances in food.

The ADI (like the TDI) is calculated by dividing the NOAEL by defined safety factors (SFs) or uncertainty factors (UFs), according to the formula: ADI or TDI or TWI = NOAEL/UF

Uncertainty factors take into account interspecies variability (in fact, NOAEL is mainly observed in animal experiments, whereas ADI is established for the human species) and intra-species variability (ADI is valid for the entire population, i.e., men, women, children, old and young, healthy and sick, etc.).

In general, a safety factor of 100 is used. This value is the product of a value of 10 assigned to inter-species variability times a value of 10 for intra-species variability, but, in special cases, higher safety factors may be used.

The NOAEL of a substance is determined by performing a complex toxicological protocol, that may vary depending on the intended use of the tested substance and the applicable regulations.

Figure 5.1 illustrates the toxicological protocol that is implemented for pesticides, biocides, food additives, and *novel foods*. *As* can be seen from the implementation of this test battery, not only the NOAEL, but also information on the possible acute oral, inhalation, and topical toxicity of the substances, as well as the possible genotoxic, carcinogenic, reproductive, and endocrine toxicity potential can be obtained.

In some cases (metabolites present at very low concentrations) *in vitro* or *in silico* approaches (such as Threshold of Toxicological Concern or TTC, read-across, etc.) may be used. Both are computational approaches whereby molecules without toxicological information are compared with others with known activity, simply based on chemical structure. Therefore, TTC is not a safety value, but a "concern" value.

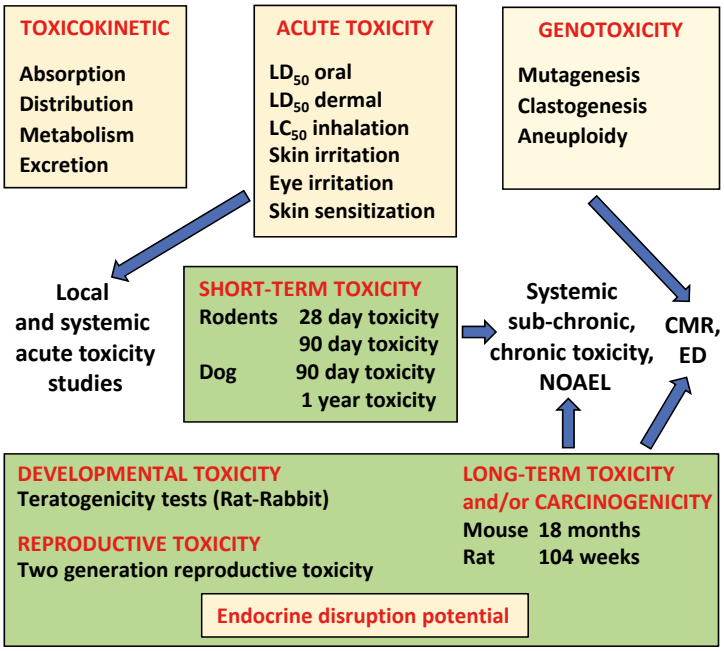

Figure 5.1. Hazard identification and characterisation: toxicology protocol. NOAEL: No Observed Adverse Effect Level; CMR: Carcinogenic, Mutagenic, toxic to Reproduction; ED: Endocrine disruptor. Modified from Galli C.L., Corsini E. & Marinovich M. (2016).

Experimental tests (both *in vitro* and *in vivo*) must be conducted following internationally shared and harmonised guidelines. In addition to EU countries, many others (such as the USA, Canada, Japan and Australia) refer to the Organisation for Economic Co-operation and Development (OECD). The OECD page devoted to "Test Guidelines for Chemicals" (https://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm) provides information on protocols for performing toxicological assays. Generally, for substances of industrial interest (i.e., substances for which a company applies for marketing authorisation), Regulatory Authorities accept dossiers that contain only tests performed according to these guidelines.

Although simple and intuitive, the determination of NOAEL is marked by several critical issues. The first is the choice of the most appropriate doses to be used in the experiment: the highest dose should produce a harmful effect, but the latter should not be observed at the lowest dose. To determine the possible dose-effect correlation, at least three dosages are used on three distinct treated groups, in addition to the untreated control group.

A second critical issue is the definition of "adverse effect" and the evaluation of the significance of toxic effects on the human species.

Regarding the adverse effect, the difficulty lies in the fact that the identification of a harmful effect in a specific study depends on several factors: the doses used, the type of parameters measured, and the ability to distinguish between truly harmful effects, false harmful effects (false positives), and adaptive effects.

For example, when there is a slight change in a parameter after administration of a substance at the highest dosage, a change that is absent at the lowest dosages, it is difficult to distinguish whether this change is due to actual harm or instead to a possible overload of physiological processes in the species used. Just as a reduction in body weight associated with decreased food consumption could be due to altered organoleptic properties of the food to which the test substance was added rather than from a toxic effect of the substance itself.

In general, substances are tested on animals of different species; in these cases, NOAELs are calculated for each study. The NOAEL used to derive the guideline value for human health protection, such as the ADI, is typically the lowest, and the species in which this effect was observed is considered to be the most sensitive species. It should be noted that, in selecting the NOAEL for establishing the ADI, preference should be given to the results of studies of high scientific quality, conducted over a long period of time, and where metabolic and pharmacokinetic data are available, to the most human-like rather than preferred to the most sensitive species.

Finally, when analysing the results of a toxicological study and defining the NOAEL, it is necessary to distinguish between reversible changes in parameters caused by temporary modifications related to normal physiological processes, or homeostasis-maintaining mechanisms, and irreversible responses that are

truly toxic. Examples of the first type of response include hepatic hypertrophy and microsomal enzyme induction, resulting from high dosages of liver-metabolized substances, laxative effects from osmotic overload, resulting in reduced weight gain or enlargement of the caecum resulting from high levels of non-nutritive substances, alteration of kidney weight directly related to the amount of water filtered by the kidney itself, and finally, as already mentioned, slowing of weight gain, resulting from reduced consumption of an unpalatable diet.

For the third step, exposure assessment, i.e. the evaluation of the quantities of the substance to which the population is exposed, the agency or company that requests the evaluation for a given substance must provide experimental estimates based on expected residues (for this purpose, field tests are performed in the case of pesticides) or expected use (in the case of food additives). Otherwise, for example, when the EFSA evaluates a contaminant present in food (e.g. a naturally occurring toxin such as aflatoxin), it asks EU Member States to provide the data available to them from monitoring campaigns.

The final step in the whole process is the comparison of the accumulated hazard knowledge with the human exposure data collected, i.e. the risk characterisation, which is the quantitative determination of the probability of occurrence of adverse effects caused by a synthetic or natural chemical agent in a given organism, system or population or subpopulation under defined exposure conditions.

Obviously, the greater the distance between the ADI and the exposure value, the higher the safety threshold will be. A high safety threshold means that the exposure of a population to a given compound will not result in an appreciable health risk.

In the case of plant protection products, for example, the following are taken into account when determining exposure to a given substance:

- he levels of the substance as a residue in agricultural products, derived foods and water;
- consumption of specific foods that may contain the substance as a residue;
- consumption of specific foods in sensitive groups (children, pregnant women, etc.);
- the frequency of consumption of specific foods (daily, occasional).

For this purpose, the EFSA uses standard diets, which are also typified on a national basis. For example, if a plant protection product leaves residues in wheat, the Italian population, with its high consumption of pasta, could be more exposed than others.

In the case of toxicological risk assessment of plant protection products, use is made of actual field data defined as MRLs (Maximum Residue Levels) found on specific crops at the time of harvest. Since the same residue can be contained in more than one crop and, therefore, more than one food, the sum of residues

is used for comparison with the ADI. If, for example, a certain molecule is present in wheat, bananas and spinach, based on how much our diet includes these crops, the total amount that can potentially be consumed daily is calculated and compared with the ADI (i.e., maximum acceptable daily intake). Under optimal conditions, the total residue is no more than 30-40% of the ADI.

The acceptable risk

It is possible that the exposure, in terms of intake of mg of a substance/kg of body weight per day, may exceed the ADI. This event, if transient, must be evaluated with caution. Indeed, it must always be remembered that the ADI is derived from a NOAEL, i.e. a dose with no toxic level identified in a repeated dose experiment, divided by a factor of at least 100.

In other words, the ADI should in no way be considered a toxicity threshold. Legislators must be aware and bear in mind that exceeding the "legal limits" does not immediately imply an increased toxicological risk. The legal limits are usually very conservative from a health safety point of view. It is therefore essential to consider a number of factors before concluding that a substance is hazardous.

But when is a risk acceptable? The acceptability of a risk depends on its importance, order of magnitude and the nature of the activity under consideration. In general, risks associated with activities that are voluntary, enjoyable or associated with benefits, such as smoking or driving vehicles, are more acceptable to individuals, even if the associated risks are high. In contrast, risks associated with activities that are perceived to have no direct or that are beyond individual control (e.g., the presence of chemicals in food) are more likely to be considered unacceptable. Table 5.2 shows some risk estimates in relation to different kinds of events.

Table 5.2 Estimated risk associated with daily living habits and natural phenomena. Risk is expressed as the probability of death for one year of exposure, rounded up.

Activities	**Risk**
Cigarette smoking (10 cigarettes/day)	1/400
Accidents in general	1/2000
Driving (15,000 km/year)	1/5000
Car accidents	1/8000
Workplace accidents	1/30,000
Natural disasters	1/50,000
Death by lightning	1/1,000,000

When considering, for example, cancer as a result of a genotoxic-carcinogenic contaminant, an increased risk of one in a million was chosen as acceptable for the consumer. Thus, epidemiological evidence suggests that the possibility that one in a million people exposed to a specific genotoxic-carcinogenic substance over a lifetime may develop cancer is considered an "acceptable" level of risk.

With regard to workplace environments, i.e. in the case of occupational exposure, the U.S. Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) consider an increment of one in a hundred thousand to be an acceptable level of risk, that is, one cancer-affected individual per 100,000 exposed workers.

Ultimately, determining a particular level of risk is a risk management decision that is the responsibility of each country.

Despite a highly regulated situation in Europe and Italy, daily exposure to synthetic chemicals cyclically provokes alarmist reactions in the public, which tends to believe that safety assessment is an arbitrary process driven solely by economic interests. This is due to several factors, the most important of which is the lack of effectiveness in risk communication, and the failure to communicate the relevant benefits of the appropriate use of chemicals in all fields.

The following facts must be clearly understood:

- safety assessment of chemicals is carried out BEFORE they are approved;
- no chemical substance can be placed on the market without a safety assessment;
- chemicals are highly regulated on a global level (European Chemical Agency ECHA, EFSA, EMA, FDA, etc.);
- the applicant (Company) must provide safety data, which must be produced strictly following defined quality standards (good laboratory practice-GGLP, quality assurance-QA, established by the OECD, in EU guidelines, etc.);
- scientific evaluation committees, which include scientists and regulatory authorities with a wide range of expertise, are ultimately responsible for safety assessments.

Accordingly, professionals who are responsible for assessing toxicological risks possess a multidisciplinary background that combines toxicological knowledge applied in the regulatory field. One of the training courses that can help individuals enter this profession is the Master's programme "Safety Assessment of Xenobiotics and Biotechnological Products" (https://www.unimi.it/en/education/safety-assessment-xenobiotics-and-biotechnological-products) offered by the University of Milan.

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Chapter 6
Risk communication

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Hazards and risk perception

The term "risk" has been studied in various fields, including epidemiology, statistics, economics, and the social sciences (psychology, sociology, anthropology). The definition most widely used to identify and evaluate risk (R) is statistical/probabilistic and refers to the likelihood (L) of harm (H) occurring. In this framework, risk is taken as the product of the factors L and H, R=L x H and differs from the concept of hazard, which refers instead to the intrinsic capacity of an object or situation to cause harm. Risk is a complex concept in that it cannot always be measured, quantified, and readily identified, due to the L factor, i.e. the likelihood of exposure to a hazard, the likelihood of the hazard actually causing harm, and the estimated severity of the harm.

Consequently, risk is often associated with the concept of uncertainty, particularly when it involves people rather than just objects or phenomena. Over time, none of the many approaches to objective risk estimation has understood people well enough to convince them to react and behave correctly. For example, at equal objective risk (based on statistical/probabilistic estimates), most individuals are more afraid of risks that are less likely to happen, but have serious consequences, than they are of risks that are highly likely to happen but are less impactful (for example, a plane crash compared to a car accident). To that effect, the social sciences approach stresses the importance of factoring subjective aspects of risk into the analysis, including psychosocial, cultural, and sociopolitical beliefs held by groups or individuals which can give rise to different perceptions and can, in some cases, appear to lack objectivity (Cerase, 2017).

The term "risk perception" is defined as a cognitive process guiding people's decision-making behaviour vis-à-vis potential risks and stems from individual, subjective assessment of the likelihood of a negative event occurring with a harmful outcome. This process involves different dimensions, including for example the immediate or future consequences of an event and its rational and emotional implications. Given the very nature of these dimensions, there is

often a discrepancy between risk perception and risk assessment (Slovic, 2000). As a result, objectively harmful phenomena or activities may not be deemed such by some people, who fail to perceive them as risky and vice versa.

Psychosocial research (Cigognani, Prati & Zani, 2011) has shown that people perceive some activities to be riskier than others for various reasons and that perception differs among people, in some cases to a considerable extent (Slovic, 2000). Several factors are known to highly influence people's perception of a specific activity, including:

- capacity to control a potentially harmful event: for example, people feel highly in control when driving a car but far less so during a natural disaster;
- degree of intentionality in the decision to tackle a risky situation;
- seriousness of the possible consequences;
- familiarity with a specific risk (Slovic, 1987).

It follows that people's attitude to risk is a "socially oriented" process, yet the matrix is never irrational (Douglas, 1996).

Contemporary society, characterised by the advent of the knowledge age, the rise of the information society, accelerated innovation, and new technologies, has been described by scholars as "post-modern" (Beck, 2000). Its defining phenomena are rooted in culture and scientific knowledge and have become the driving force behind change, both in material and daily life and in each person's perception of the world.

The perception of scientific phenomena, for example, is closely linked, on the one hand, to prior knowledge and sociocultural dynamics and, on the other, to information and representations circulating in the media. Some people are overtly hostile towards certain scientific products, perceiving innovation to be managed inappropriately and in a socially inacceptable manner, as demonstrated by the food and health crises of the last twenty years. The advent of bovine spongiform encephalopathy (BSE), or avian flu, in addition to the recent SARS-CoV-2 pandemic are cases in point.

In the health domain, risk takes on two main meanings (Lupton, 1995). The first refers to external human health hazards, including viruses, pollution, industrial waste, and the presence of toxic additives in food. Individuals have very limited control over these phenomena. The second is associated with an internal dimension and considers the risk to be the result of certain behaviours or lifestyles, such as eating habits, physical activity, or smoking. Hence, the study of risk and its perception means examining and bringing together different dimensions and factors. Discrepancies in risk assessment between experts and non-experts can, however, represent a point of disconnect in the process. These differences can create unjustified alarmism which occurs when individuals or the media greatly overestimate a risk compared to expert appraisal.

Considering the above premise, inconsistent, contrasting risk perceptions inevitably develop. These differences are most visible between experts from a

specific field (doctors, biologists, chemists, etc) and non-experts, i.e. individuals lacking specific scientific knowledge. Experts build their risk representation on consolidated, validated scientific evidence while non experts inevitably draw inspiration from subjective experience and solid examples. In a study performed in the UK in the 1990s, Lupton (1995) observed that some mothers refused to send their children for statutory vaccination not because they were misinformed or irrational, but because they perceived the risk differently from medical experts (Bucchi, 2002). The women reported to have opted against vaccination because they were personally acquainted with other mothers whose children had become seriously ill after inoculation. Numerous studies have researched the mechanisms underlying these dynamics (see, for example, Sjoberg, 2000; Pidgeon, Kasperson & Slovic, 2003; Slovic 2016), finding that discrepancies in perception among different social groups or between experts and non-experts were not attributable solely to cognitive deficits or inadequate communication but also to an elaborate process of sharing and selecting information, in which the mass media also naturally play a key role. The media actively contribute to defining new images and perceptions by introducing numerous specialists into the mediatic scene, i.e. technical and scientific experts and consultants, who participate in public debates, political decision-making, and social issue management. In this framework, scientists, politicians, journalists, and many other categories enter a process of public visibility, where they are called upon to explicitly or implicitly build new knowledge in their own right, ultimately contributing to different perceptions of risk (Peters, 2021).

The study of risk perception helps to understand the assessment process adopted by individuals and society not only when the risk becomes real but also when it is simply perceived. Studying this mechanism means defining its acceptability, which is instrumental to grasping how individuals address a given risk. Communication seeks to fill the gap between real risk and perceived risk by developing communication strategies and interventions aimed at aligning perception and reality and promoting full risk awareness, management, and prevention. In Italy, the first studies of risk perception date back to the 1970s, while only recently have systematic reviews been conducted to explore the role played by risk in people's perceptions and attitudes. The initial research focused on social and health care (numerous studies were conducted in the 1970s on the use of narcotics) and the environment (associated with the ecological disasters of the 1980s and 1990s). Following more recent socioeconomic transformations, also affecting the food and livestock sector in the 1990s (the use of GMOs, food globalisation, etc), studies of risk perception have also addressed new domains and areas of analysis, including food safety.

Determining individual perception requires investigation at both the micro level, i.e. each person's subjective viewpoint, and the macro level, associated with the environmental, social, and educational setting to which people belong.

This is done using psychosocial research methods, techniques and specific data collection tools, and is designed to record and reveal the various components of perceptions, from the latent, personal meanings each person attributes to a specific risk, to the social representations attributed to that risk by a given cluster of individuals.

In parallel, qualitative and quantitative research tools are used to collect individual cases or aggregated data, with the aim of revealing commonalities or controversies about the risk in question. The most widely used tools are:

- narrative interviews, which use a discursive-narrative approach to explore and discuss viewpoints, feelings, and meanings held by each interviewee. The analysis focuses both on the verbal dimension of the discussion (analysis of meanings, lexis, content, etc.) and non-verbal codes (e.g. intonations, movements, body language) (Mazzara, 2002);
- structured questionnaires: through completion of a questionnaire specially built to identify and measure social perceptions (e.g. based on a psychometric approach, see Slovic, Fischhoff, Lichtenstein, 1986), information can be transformed into data and relationships identified between factors/characteristics/attributes of the sample.

Conversely, to explore risk perception shared by and common to a given group, the social sciences have developed participatory tools envisaging the direct involvement of several people in the same data collection process. These include:

- focus groups, which use a structured conversation between a group of interviewees (6-10 people) and an interviewer to deeply explore and understand participants' viewpoints on a specific topic (Mazzara, 2002);
- world cafés, which use a creative process to facilitate the exchange of different opinions, knowledge, and perceptions within a group of people, stimulating spontaneous, informal discussion among them (Brown, 2002).

In addition, rather than addressing people directly, some data collection methods, based on specific text and/or content analyses, address artefacts, i.e. textual and visual sources that provide information on perceptions at several levels. Web pages, social media posts, blogs and fora can summon up "common feelings" or any controversies existing at a given moment in time on a given topic. Analysis of newspaper and popular press articles can instead provide information and clues about the development of new perceptions closely associated with what is being transmitted to society by the mass media. One example is the use of scaremongering to communicate medical facts/news and its consequences.

Hence the use of various psychosocial research methods and approaches, often combined, helps to glean extensive information on risk perception, from the micro level of the individual to the macro level of the public as a whole.

Risk communication

We have seen that studying risk perception is pivotal to understanding people's predisposition to risk, from both an individual and a societal perspective. This assessment process is the starting point on which to build risk communication. So, what *is* risk communication? Risk communication refers to the exchange of information among individuals, groups, and organisations in relation to risk assessment and decisions on the behaviours to adopt to avoid or reduce said risks (Leiss, 1996).

Risk communication must not be seen as an attempt to convince or persuade people to adopt the experts' or communicator's judgement of risk tolerability or acceptability. The aim is rather to help people formulate more informed opinions and enable them to deal with risks encountered in their daily lives. Communicating risk therefore means communicating uncertainty about the occurrence of a given risk, bearing in mind different acceptability estimates and bridging the information asymmetry between experts and society due to their different perceptions. Although risk communication emerged as a distinct concept within the scientific community in the early 1970s, the term was used for the first time in the scientific literature in 1984, due to growing interest in risk perception, which used psychological research to explain judgement formation about risk acceptability among individuals and groups. It was initially conceived as a top-down process, whereby experts transmitted their risk assessment to the public through the mass media. However, the food and environmental crises of recent decades called this vertical communication process (deficit model) into question because it excluded the public from participating in the risk assessment and definition process, leading to interpretation and information asymmetries invalidating any attempt to communicate risk to society (Balog-Way, McComas & Besley, 2020).

One of the first changes in outlook was marked by the publication in 2002 of the article, "From PUS to PEST," in the journal *Science,* by a group of British scientists. It acknowledged the need to shift from public understanding of science (PUS), on which the deficit model was based, to public engagement with science and technology (PEST), i.e. a communication model based on listening to and actively involving the public in scientific debates. The debate on risks gradually morphed into an ecosystem populated by many actors: experts, institutions, public authorities, the media, interest groups, politicians, and citizens. Today, public risk communication can be defined as "a series of information exchanges among different social players participating in the debate on risks to health and the environment, involving not only experts and institutions, but also a plurality of stakeholders […] motivated by specific objectives, values and interests" (Sturloni, 2018, p.35)

Over time, therefore, the definition of "risk communication" has broadened its scope to encompass the skills, know-how, and techniques of diverse professional figures (psychologists, sociologists, communicators, statisticians, epidemiologists). This integration and sharing constitutes the very strength of risk communication.

Food safety was among the first sectors to institutionalise risk communication, deemed an essential part of transparent, responsible risk management. Article 3 of EU Regulation No. 178/2022 (European Parliament, Council of the European Union, 2002; Venturi, 2008), commonly known as the General Food Law, defines risk communication as "the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions". EU Regulation 2019/1381, Chapter II – Section Ib (European Parliament, Council of the European Union, 2021), modifies and extensively integrates the General Food Law, including a section on risk communication, detailing its objectives (art. 8b) and general principles (art. 8c), and selecting transparency, inclusion, and trust as key words. In light of this important integration, the European Food Safety Authority (EFSA), was recently tasked by the European Commission to conduct a scoping review (EFSA et al., 2021) to describe the state of the art of the discipline, with the aim to obtain harmonised, shared guidelines on the meaning and scope of risk communication, to be used to develop the General Plan on risk communication, provided for by EU Regulation 2019/1381.

Within the risk communication ecosystem, the media play a crucial role in creating and transmitting information to the public. They have switched from a predominantly informative to an actively risk-building role, a shift driven in part by their agenda-setting function within the public domain. They often adopt strong, alarmist language, which can negatively distort perceptions. Vice versa, messages conveyed by the media are also often used to heuristically make sense of complex situations: epidemic emergencies being a case in point. Furthermore, compared to the opportunities afforded by traditional mass media, the advent of new media has radically changed the way citizens find information, and discuss and decide whether and how to address risks. Institutional information is now accompanied by a plurality of sources and actors tasked with producing different types and styles of communication interventions. This prompts the need for researchers and public institutions to become more and more convincing and reliable in order to guarantee the social acceptability of science and consolidate the role of institutions as official sources of expertise.

Lastly, to function, the complex risk communication ecosystem requires one crucial element, namely trust, which society places both in those responsible for risk assessment and management, and in communication sources. Besides being considered reliable by virtue of their expertise, it therefore follows that these actors must also be capable of producing and disseminating credible, truthful, transparent messages.

Types of risk communication and fields of application

The literature has identified three main types of risk communication (Lundgren & McMakin, 2013):

- care communication: this applies when the reported hazards and related precautions have already been scientifically validated and are generally accepted by the public. The aim of care communication is to educate or improve the health of the intended audience, by reminding and encouraging them to adopt the appropriate preventive behaviours proposed (e.g. the presentation of guidelines). Examples include campaigns to fight tobacco, drug or alcohol abuse, or campaigns on the road or workplace safety.
- consensus communication: this applies to decision-making about risks that are still relatively unknown or highly controversial, such as the construction of an incinerator, the disposal of nuclear waste, or the need to be vaccinated. Here it is preferable to discuss the various stakeholder viewpoints and to negotiate and agree - alongside the risk managers – on the most appropriate approach to solving the problem, thanks to the active, inclusive participation of the various stakeholders involved.
- crisis communication: this refers to communication activities carried out in the event of sudden, unexpected emergencies, such as natural disasters, epidemics, and food crises. Given its urgency, this type of communication must be timely and informative since it serves to alert the population and specify the precautions to be taken.

These three types apply, based on need, to three key domains:

- environmental communication
- health communication
- safety communication.

Communicating risk

Daily life abounds in examples of risk communication: a politician informing citizens about a new waste disposal system; a doctor informing a patient about the risks of a certain behaviour or a particular therapy; scientists reporting the findings of an investigation into the harmfulness of a given substance. Nonetheless, communicating risk remains a major challenge for institutions and experience has shown there are no proven recipes for its implementation. Research and practice have likewise taught us that there are some hard and fast principles to follow to ensure the good outcome of communication.

First and foremost, risk communication is not something to be improvised when an emergency strikes. Considering the delicate balance in play between the parties, based on mutual trust, risk communicators must be competent both in a crisis and in "peace time". In "peace time," the role of risk communication

is strategic in that it paves the way to a lasting/sustainable relationship with the intended audience. It serves to build trust and reputation, to be redeemed in an emergency, and must be ongoing and clearly recognisable.

Risk communication in peacetime requires:

- critical analysis of the context and target audience, which is a prerequisite for defining objectives, strategy and key messages;
- ability to design, develop, promote, and evaluate communication based on professional knowledge of communication techniques and tools;
- resources (people, services and equipment);
- continuous collaboration among communication and content experts.

We will now consider in detail the various stages leading to the production of risk communication interventions.

Context analysis. This first step aims to gain insight into the risk communication setting. Supported by social research tools, context analysis is designed to identify opportunities, resources, weaknesses, interests, and actors involved, in addition to identifying their risk perception and their information and communication needs. It is helpful to also explore the risk representations the intended audience has been exposed to. Analysis of content conveyed by the media can reveal which information has been disseminated and is circulating on a given risk/issue, how the information has been presented to readers, and how it has shaped their perception. In parallel, to objectively describe the risk to be communicated, it is also necessary to collect available scientific data and evidence, using for example reports or studies conducted by research facilities and risk assessment organisations or systematic literature reviews.

Defining the objectives. The second step is to define the communication objectives, dividing them into strategic and operational. The former refers to the three types of risk communication identified above (care, consensus, and crisis communication), while the latter defines which tools and channels to engage to implement the strategy. "Which of the target audience's attitudes/behaviours do we seek to influence? Which risk information and knowledge do we wish to disseminate? How will we evaluate the effectiveness of the communication intervention?" are some of the questions underlying the development of the pathway connecting strategic planning, communication implementation, and impact evaluation.

Defining the target. Alongside the context analysis, it is pivotal to identify the intended targets of the risk communication and their starting positions (knowledge, risk perception, information needs) and, based on the objectives and risk in question, to select the engagement tools to use in the risk analysis process. This may include participatory processes and knowledge and message co-creation. Social research, based on qualitative-quantitative (focus groups, interviews, sample surveys) or participatory techniques (ethnographic studies, consensus methods), provides the communicator with input to efficiently guide the communication to fit the characteristics of the intended audience, allowing it to be split into uniform

groups to be reached through targeted initiatives, messages, and tools. This will generate detailed information on the target's evident (demographics, sociocultural traits, habits, lifestyles, educational level) and non-evident characteristics (perception of the problem and any specific concerns, perception of and faith in risk managers and the source of communication). When the target audience cannot be analysed in depth (due to time or material constraints), the communicator can make use of previously published studies and research or grey literature[1] data.

Building the message. Consistent with the objectives and target audience, the message will contain the communication's key concepts, expressed clearly, transparently and in language as close as possible to the language used by the recipient. In developing the message, it is important to bear in mind the psychological and perceptual factors described by research in the field. Ignoring them could potentially thwart the entire communication effort. Specifically:

- avoid making messages technical: use an explanatory approach and make information accessible;
- limit the communication to a few key messages (typically no more than three), to be repeated for reinforcement, supported by examples and visual tools (graphs, pictures, infographics, videos), particularly to accompany numerical information;
- avoid comparing risks, especially if they are different from each other;
- in crisis situations, messages must also communicate the situation's characteristic uncertainty;
- the way the message is framed can influence its reception and comprehension.

When building the message, communicators can also use insights previously collected through social research tools to study the intended audience's mental representations and models of the risk in question. To maximize communication effectiveness, it may be helpful during the design stage to test out the messages on a sample of the target audience (using social research tools), to evaluate whether they are understandable, credible, and acceptable.

Defining the strategy and communication plan. The next step is to outline the communication strategy, creating a communication plan detailing the engagement

1 According to the definition accepted in 2006 at the 8th International Congress on grey literature, "Harnessing the Power of Grey," held in New Orleans, the term "grey literature" refers to "information produced on all levels of government, academics, business and industry in electronic and print formats, not controlled by commercial publishing, i.e. where publishing is not the primary activity of the producing body." Examples of grey literature are: university degree and doctoral theses, technical and research reports, internal publications of organisations (public or private), proceedings or abstracts of congresses, conferences and seminars, course handouts, patents, guidelines on laboratory techniques and analysis methods. While often not on a par with scientific publications, grey literature can nonetheless be a source of valuable, undoubtedly important information.

tools and channels as well as the timelines for producing and distributing materials. Communicators have a wealth of tools and channels available to them, offering various options for reaching the target audience. There is often no absolute best way to convey messages, with the most effective solution being instead to use an integrated approach, taking into consideration the audience's familiarity with the selected means of communication and the estimated time taken to implement the activities. In the document, "When food is cooking up a storm – Proven recipes for risk communications," EFSA reviewed a wide range of communication tools, specifying the best situations in which to use or avoid using each of them (see website).

Evaluating the communication. When designing the communication activity, it is important to incorporate periodic evaluations to check the correctness, efficacy, and effectiveness of the strategic planning. The timing of valuation and appraisal can vary as follows:

- *ex ante*, to adjust activity planning and review the suitability of the selected indicators;
- *in itinere*, to correct any steps or problems arising during the implementation of the activity;
- *ex post*, to assess the work as a whole and improve similar future initiatives, learning from experience. When possible and envisaged among the project objectives, it can be helpful to assess the communication's impact on the target audience's perception and behaviours.

Data and evaluation judgements can be collected using performance indicators specific to the medium and channel used (e.g. number of page views on websites, number of downloads of informative material, number of interactions with social content, number of registrations to a newsletter/event), or social research techniques, particularly to assess the communication's impact on perception and behaviour. Lastly, in planning the evaluation, it is important to ensure that the selected indicators are capable of measuring the achievement of the operational objectives.

Defining the budget. Communication activities need dedicated funding, requiring the allocation of resources to conduct the work either independently, where the organisation has its own competent, dedicated staff, or through a communication agency. Where an organisation works independently, the budget must cover the cost of equipment, software, staff, and the production, distribution, and promotion of materials (online or offline, depending on the selected communication strategy).

Research and practice in risk communication in the field of food safety

Below are some examples of research projects on risk communication applied to food safety. They are studies funded by the Italian Ministry of Health

and conducted by the Istituto Zooprofilattico Sperimentale delle Venezie (www.izsvenezie.it) to convey correct scientific information to specific audiences and to promote the adoption of mindful habits and behaviours to prevent or limit exposure to food risks (Ravarotto, 2015).

This was achieved by selecting and applying the social research methods and communication solutions that had proven most responsive to each of the needs identified during the study and met the project objectives. These solutions are used as survey and communication tools also in the animal health or epidemiology sectors, considering that a global approach encompassing and evaluating social, psychological, and economic information is increasingly required to effectively solve public health issues linked to biological, medical, and veterinary sciences.

*Development of a multistrategy model for creating and disseminating information on microbiological risks in foods for pregnant women (*RC IZSVe 02/2015)

Objectives: to pilot a multistrategy approach to disseminating information on microbiological risks in foodstuffs during pregnancy, based on an analysis of the target audience's information needs on food safety in pregnancy; development of communication tools designed to increase knowledge and awareness of food risks among pregnant women.

Analysis of the phenomenon and study of the target audience: the project envisaged a data collection and analysis phase on pregnant women's exposure to specific food risks during pregnancy. The analysis was structured as follows:

a. review of the related scientific literature;
b. study of the target audience through two social research activities, divided as follows:
   - a quantitative survey at the national level addressed to women aged between 18 and 50 years: a semi-structured questionnaire was completed online by a selected sample of 1000 respondents, to map knowledge, opinions, and information needs of pregnant and non-pregnant women;
   - a participatory survey based on three World Café sessions: three meetings were organised for a total of 28 participants (pregnant women), to collect information on the food risk perceptions and information needs of pregnant women and to enhance their knowledge on the subject.

Definition and production of communication tools: the most appropriate scientific content and communication tools were defined based on the results of the two social surveys. This led to the production of the *Alimenti&Gravidanza* (*Food&Pregnancy*) (www.alimentigravidanza.it) website, designed and developed through the implementation of search engine optimisation (SEO) techniques. The content of the project website was presented and divided into several thematic pathways:

- Microbiological risks;

- Risky foods;
- Risk reduction;
- Exercises & brochure;
- Video-interviews.

A brochure was also produced summarising all key information posted on the project website, from which it can be downloaded. The brochure was produced in several languages (English, French, Romanian, Russian, Arabic, and Chinese) to encourage access to the information by non-Italian-speaking pregnant women. For this reason, numerous copies of the brochure were printed and sent to all local health authorities in the Veneto Region, requesting its distribution to facilities and services dedicated to women (hospital gynaecology and obstetrics units, family planning clinics, health centres, etc.).

Dissemination of the communication resources. The website was promoted and publicised nationally through:

a. digital public relations activities envisaging the involvement of several Italian bloggers working in the maternity and pregnancy field, inviting them to talk about the Food&Pregnancy project in their blogs and to directly share the website content;
b. a publicity campaign using the Facebook Advertising tool, designed for a specific audience (pregnant women, aged 18-50 years, television programmes and journals specialising in pregnancy and maternity);
c. organisation of an informative conference in Padova to publicise the website and, more generally, the project at the local level.

Monitoring and evaluation of the communication material: web analytics tools were used to separately analyse the number of hits coming from the various selected promotional channels to see which channel was most effective in promoting the campaign.

Results: Different sources of scientific, social, and communications expertise were combined to develop a multidisciplinary strategic framework for food risk communication, aimed specifically at pregnant women but of interest to all fertile women. The study findings confirmed and strengthened the need to increase the development of effective, targeted communication to be promoted throughout the area.

The communication campaign promoting the Food&Pregnancy website succeeded in widely disseminating, via the web and at a regional level, the scientific content and information, validated by experts, on the main food risks and possible strategies to adopt to eat safely during pregnancy. In addition, the production of a multilingual brochure emphasized the importance of reaching as many people in the community as possible and making medical-scientific topics more understandable.

Notably, thanks to the SEO techniques implemented in the portal, the website has continued to rank at the top of Google's search results for keywords

on food risks and eating during pregnancy. In the first six months of 2022, the website averaged almost 1,000 hits per day, without support from other promotional activities.

The success of the project was due in part to close multidisciplinary collaboration across all implementation phases with various professionals, including veterinarians, biologists, gynaecologists, infectious disease doctors, and dieticians, in addition to sociologists, statisticians, and communication experts. The collective expertise positively contributed to the detailed and in-depth exploration of the issue and to ensure the scientific validity of the communication resources created and disseminated in the community.

Impact analysis of a community-centred educational intervention aimed at disseminating good domestic food preparation practices over the web (RC IZSVe 05/2013)

Objective: to disseminate good practices related to food handling to internet users, with the help of food bloggers and their online pages. The specific objective of the project was to:

a. analyse the Italian food blog world and food blogger profiles;
b. pilot an online educational pathway to provide Italian food bloggers with knowledge about food risks to convey to internet users;
c. promote the communication of correct, useful information on food safety via the web.

Analysing the phenomenon. Food blogs were studied and mapped and Italian food bloggers were profiled to define their key characteristics. Data collection took the following forms:

a. review of the scientific literature on the phenomenon;
b. study of the food blog phenomenon: Italian food blogs were mapped using the Google search engine (search based on the string <Italian foodbloggers>), which served to build a dataset to analyse the structure and characteristics of the selected blogs and to create a list of contacts to engage in the project;
c. profiling of Italian food bloggers. Two different surveys were performed:
   – quantitative, national survey: a selected sample of 277 food bloggers completed a semi-structured online questionnaire with the aim of determining: the communication purposes of food bloggers, the level of interest in food safety and risk perception, the level of knowledge about the main microbiological risks associated with food handling, and the use of information sources on food safety;
   – qualitative, in-depth survey: four narrative interviews were conducted with food bloggers, to more closely explore some of the themes emerging from the questionnaire and to define the topics to address in the online training course.

Definition and production of teaching and communication material to disseminate online: under the supervision of scientific experts, the analysis findings were used to

prepare the content of the training course for food bloggers and the related editorial resources.

*Designing and implementing the online training/communications programm*e: An online course for food bloggers was designed and implemented, envisaging the following: individual learning spaces (supported by video lessons, additional background materials, and interactive reinforcement exercises); development of a Project Assignment based on the creation of a recipe accompanied by good hygiene practices to ensure safe food preparation; interactive sessions with experts and among peers. In total, 132 food bloggers registered for the training course and 47 completed it. At the end of the training pathway, the teaching resources, provided to the food bloggers through the e-learning platform, were published on the www.salepepesicurezza.it (*www.saltpeppersafety.it*) portal to promote the spread of good food safety practices.

In addition, all users were given access, through the portal, to the information/summary handouts produced during the course, which they were invited in turn to share on their own Facebook and Twitter accounts, using the hashtag #salepepesicurezza.

Monitoring the training and evaluation: the evaluation covered the entire project. Its purpose was therefore not simply to analyse the learning outcomes but also to monitor *in itinere* the entire pathway and to adopt any necessary corrective/integrative actions. The focus of the activities was to:

- assess the knowledge (*ex ante* and *ex post*) of the target audience, through a multiple-choice questionnaire administered at the start of the activities and repeated at the end, to monitor the difference between baseline knowledge and acquired knowledge;
- assess proficiency, through both a qualitative analysis of the fora (thread content) and the development of the Project Assignment.

Analysis of the online dissemination of communication resources: Communication efficacy was assessed at two analysis levels:

- spread of the project hashtag #salepepesicurezza on social media, particularly on YouTube and Twitter;
- user interaction with the project website www.salepepesicurezza.it (*www.saltpeppersafety.it*), by means of the Google Analytics tool.

Results: The analysis of project effectiveness was positive, showing an increase in scientific knowledge on food safety among the food bloggers participating in the training course.

Long-term monitoring also revealed constant use of the available resources: the project website was visited in part by referral traffic (i.e. websites directly linking up to www.salepepesicurezza.it *www.saltpeppersafety.it*), which served as a sounding board. Likewise, online interaction with website content (worksheets, videos, recipe books) remained constant over time. Hence, the production of online video material proved an effective means of disseminating content over

the web. In addition, IZSVe's institutional communication channels also played a key role in the visualization and spread of the www.salepepesicurezza.it (*www.saltpeppersafety.it*) website and consequently in the online dissemination of scientific information on food risks in the home setting.

Lastly, the final Project Assignment produced by the training course participants led to the development of a further communication tool, namely the "Safe recipes" book, distributed in both hard and digital format and downloadable from the IZSVe website (Figure 6.1).

As with Foods&Pregnancy, this project also made use of expertise in food safety, social research, training, and communications, thereby enhancing the study design and ensuring that the phenomenon was explored competently and professionally, while bearing in mind the various challenges and viewpoints involved.

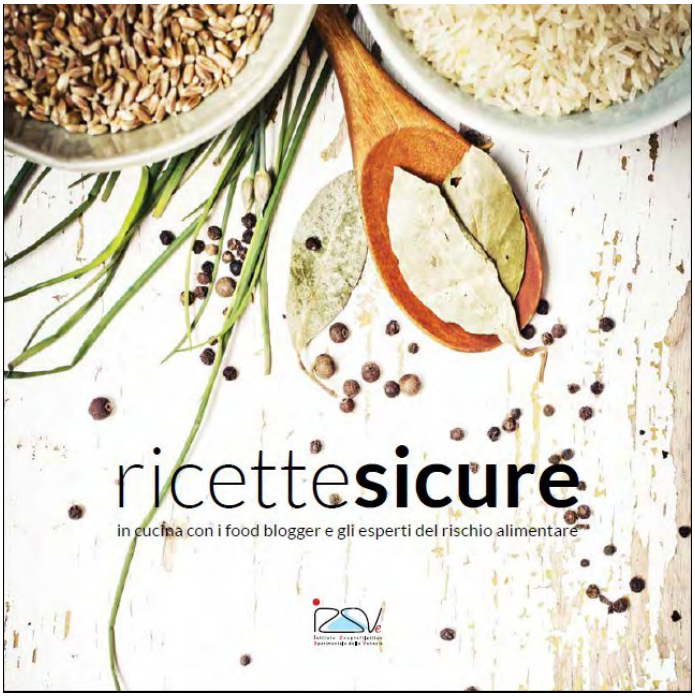

Figure 6.1 "Safe recipes" recipe book cover. https://www.izsvenezie.it/documenti/comunicazione/materiale-editoriale/1-comunicazione-scientifica/rischio-alimentare/ricettario-sps.pdf

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EU Food Safety Almanac

https://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf

Risk Assessment and Communication in Food Safety

Edited by Maria Longeri

Thanks to its didactic and informative approach, this volume is a comprehensive resource for those who are new to the subject of risk assessment in food safety. It describes the knowledge and skills needed for effective risk assessment and communication, starting with the body of regulations and the international scenario in which these are embedded. The text also outlines available basic training courses and the economic support provided to attend them. The chapters are written by highly professional and experienced specialists. The chapters are independently readable, and each is accompanied by up-to-date bibliographical support. The volume is an excellent starting point for gaining both a general understanding and specialised insights into the topics in question and the actions that Italy and the European Union are implementing to address imminent global health challenges in a coordinated and effective manner.

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