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Country profiles – how to read the EU Almanac

Each profile provides an overview of public institutions in the area of food and feed safety in the respective country.

Diagram of national institutions: Each profile starts with a simplified diagram showing the organisational structures and hierarchies. The main institutions of each country are listed as acronyms. Institutions at central/national level are highlighted in blue boxes, regional/local institutions in the turquoise ones.

Legal foundation: The national legal foundations for food and feed safety are described briefly at the beginning of the profile.

Institutions at central level (blue boxes): The tasks and activities of each institution are described. The acronym and full name are shown in the blue box. The grey boxes below it list the main activities in the area of food and feed safety, followed by the institution’s location, website, and pictograms depicting its responsibilities.

Responsibilities: 18 pictograms are used to illustrate the areas of responsibilities of each institution.

Regional and local level (turquoise boxes): Institutions at regional and local levels are described in separate sections.

Institutions involved in the EFSA network (yellow boxes): Article 36 Institutions are competent organisations designated by the Member States which may assist EFSA within its mission. Institutions that fall under this category are listed here.

Additional information is available at:
EFSA: https://www.efsa.europa.eu/en
EUR-Lex: https://eur-lex.europa.eu
EU Food Safety Almanac

Bundesinstitut für Risikobewertung (BfR)
German Federal Institute for Risk Assessment

Kei Udagawa, Alina Berendsohn, Dr. Wenna Xu, Julia Schöne, Dr. Majlinda Lahaniatis,
PD Dr. Gaby-Fleur Böl, Dr. Nicole Gollnick
Dear Readers,

The food products we commonly consume are so much a part of our daily life that we hardly think about how much of it originates from other countries. The globalisation of food production and food trading allows for more and more consumer choice. However, it complicates consumer health protection because food and feed safety has to be guaranteed along global supply chains that are increasingly complex. Challenges such as climate change and the recent Covid-19 pandemic have also made their impact on agricultural production and food supply. In Europe, the supply of food from all over the world is still growing. Consequently, stricter requirements have to be met with regard to scientific risk assessments, risk management, and risk communication. Food and feed safety today can only be ensured by taking an international approach.

This new edition provides an updated and comprehensive overview of the competent public institutions and the structures of food and feed safety within 37 countries. The European Food Safety Authority (EFSA) as well as its Focal Point network from all 27 EU Member States, Iceland and Norway, as well as observers from Switzerland and EU candidate countries have considerably contributed to this almanac. I would like to sincerely thank everyone involved for their valuable contributions. This almanac not only facilitates the search for European partners and the clarification of responsibilities, it also helps to avoid the duplication of work and to harmonise existing methods and processes.

The world is changing faster than ever before, not only technologically and economically, but
also politically (e.g. Brexit), socially and environmentally as well. I am pleased to present a printed version of the almanac to my friends and partners. At the same time, it can only provide a current snapshot of the situation. To keep you updated on the latest status, the BfR is currently developing an online version of the almanac, where all national profiles will be updated regularly. The online world food safety almanac will soon be announced on the BfR website.

I hope that all of our readers will find this EU Almanac useful and gain interesting insights into the world of European food and feed safety.

Professor Dr. Dr. Andreas Hensel
BfR President and
German Representative of the EFSA Advisory Forum
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Effective and efficient cooperation between state actors in Europe strengthens food safety. If all parties involved are familiar with the relevant actors and the legal framework in the European Member States, countries are able to work together more efficiently, thus avoiding duplication of work while maintaining consumer protection. Strong and sustainable cooperation activities contribute to harmonised risk assessment methods and improve the control of risks. It also increases the transparency of decision-making processes and facilitates the search for European partners for project collaborations.

The aim of food safety and effective consumer protection is to protect health, prevent fraud and provide proper consumer information. Common European legal regulations offer a uniform and reliable level of protection for European consumers, since national measures alone are not enough to provide sufficient protection in a globalised world.

Without releasing companies and consumers from their responsibilities and due diligence obligations, it is the responsibility of the state to protect consumers in the area of food safety through risk assessment, risk management and risk communication.

As a first step, risks for human health are identified, evaluated and characterised using scientific methods ("risk assessment").

According to the principles and methods for risk assessment established by the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the Organisation for Economic Co-operation and Development (OECD), the German Federal Institute for Risk Assessment (BfR) has revised its “Guidance Document for Health Assessments” again in 2020. With this amended guidance, the BfR contributes to the harmonisation of risk assessment methods in the area of food and feed safety. The document can be found on the BfR website in the ‘Publications’ section.

Based on the results of risk assessments, designated competent institutions decide on the necessary measures ("risk management"). In addition to scientific risk assessments, this process also incorporates social and economic aspects in order to evaluate the suitability and efficiency of these measures.

Consumers are only able to make self-determined purchase decisions if they have been adequately informed ("risk communication"). For this reason, scientifically-based and transparent communication of identified risks is essential in all respects, and information on food safety should be made accessible in an appropriate form. Other affected and involved parties from science, politics, associations, NGOs and public institutions should also be included in the interactive exchange of information and opinions.

At European level, risk assessment and risk communication are tasks assigned to EFSA, while risk management remains with the European Commission and the Council of the European Union.

In the various European states, the task allocation of risk assessment, risk management and risk communication has different legal structures. Some countries, including Germany, prefer to distribute the responsibility for risk assessment and risk management between different institutions. Other countries unite these tasks in a single institution.

The relevant government institutions along with their tasks and legal foundations in relation to
food and feed safety can be found in each country profile. The profiles also state whether (and to what extent) the respective country publishes its risk assessments.

The distribution of responsibility between the national, regional and local levels within a given country also has an impact on efficient food safety regulation. Some countries tend to have their risk assessments conducted by external experts (commissions), whereas in other countries, the institutions largely carry out risk assessments by themselves.

Since very early on in the Withdrawal Agreement negotiations, both the EU and the United Kingdom acknowledged the unique circumstances on the island of Ireland. A special status was given to Northern Ireland through the Protocol on Ireland and Northern Ireland which forms part of the agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the EU. This Protocol ensures the integrity of the EU’s Single Market for goods, along with all the guarantees it offers in terms of consumer protection, public and animal health protection and combatting fraud and trafficking. Its article 5(4) rules that certain provisions of Union law listed in Annex 2 to the Protocol shall also apply to and in the United Kingdom in respect of Northern Ireland. This includes amongst others particular regulations and directives with respect to food, feed and chemical safety. Four years after the start of application of the Protocol on 1 January 2021, the Northern Ireland Assembly (Stormont) can give consent to the continued application of relevant Union law or vote to discontinue its application. In the latter case, the Protocol would cease to apply two years later. Every four years thereafter, Stormont can vote on the continued application of relevant Union law. In case a vote of Stormont gathers cross-community support for the continued application of relevant Union law, the next vote can only take place eight years thereafter.
2 Food Safety in the European Union

In 2000, the EU Commission’s White Paper provided the impetus for a new food safety structure in Europe. A new concept for effective and comprehensive consumer health protection was introduced, whereby food safety is to be guaranteed in all stages of production and processing along the entire food chain (“from the farm to the fork”). In 2002, the European Food Safety Authority (EFSA) was established as an independent scientific body for risk assessment at the EU level. Following that, a network of competent institutions which operate as a link between the national and European levels, as well as between bodies in the various Member States, was created.


In addition, Regulation (EU) 2017/625 which replaces Regulation (EC) 882/2004, lays down general principles of official controls performed to ensure compliance with food and feed law. EU regulations apply directly in all Member States of the EU, without each one having to enact national laws.

Regulation (EC) No. 178/2002 lays down the general principles and requirements of food law within the EU. It covers all stages of food production and processing along the food chain, “from the farm to the fork”. In addition, it establishes and specifies the remits of EFSA and establishes the European Rapid Alert System for Food and Feed (RASFF). Regulation (EC) No. 882/2004 lays down the general principles of official controls performed to ensure compliance with food and feed law. This means that in the EU, in particular, the Member States are required to create a multi-annual national control plan (MANCP) along with the corresponding reporting.

At the EU level, risk assessment and risk communication are formally separated from risk management. While risk assessments are undertaken by EFSA, EU risk management is dealt with by the European Commission (EC). Risk communication, the third element of risk analysis, is a shared responsibility between risk assessors and managers.
Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain – the “Transparency Regulation” – amends Regulation (EC) No. 178/2002, and has become applicable as of 27 March 2021. The aim of the Transparency Regulation is to increase the transparency of the EU risk assessment in the food chain, strengthen the quality and reliability of studies that EFSA bases its risk assessments on, revisit EFSA governance, achieve more coherent risk communication in the EU and improve the sustainability of EFSA’s expertise.

More information about the Transparency Regulation can be found at: https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en

The EC is the only institution with the right of legislative initiative. In practice, the proposals for legislation (regulations, directives and decisions) are prepared by specific EC departments. The EC Directorate-General for Health and Food Safety (DG SANTE) prepares draft legislation in the area of food and feed as well as animal and plant health, for example, while the EC Directorate-General for Environment prepares draft legislation in that area.

Through the activities of Directorate F - Health and Food Audits and Analysis (Regulation (EC) No. 882/2004, Articles 45 and 46), which is part of the EC DG SANTE, the EC assesses how EU regulations related to food and feed safety, animal health, animal welfare, plant health and in the area of medical devices are implemented and enforced within the EU and in non-EU countries that export to the EU. This is achieved mainly through inspections of the competent institutions of the Member States and non-EU countries. The Directorate F - Directorate Health and Food Audits and Analysis provides information on the results of its assessments. Where appropriate, it also recommends measures to remedy shortcomings and monitors their implementation. Inspection reports are published on the Internet along with the comments by the countries inspected.

It is the role of the European Commission (EC) to promote the general interest of the EU as a whole. The “College of Commissioners” (currently one commissioner from each Member State) defines policy and makes decisions.

The EC is the EU’s executive body; as the “guardian of the treaties”, the EC is responsible for ensuring that EU law is properly implemented and applied in all EU Member States. In the event of infringements or doubts about the interpretation on EU law, the European Court of Justice has the final say.
Together with the European Parliament, the Council of the European Union (CEU) is the main decision-making body in the EU. One minister from each national government attends CEU meetings. Which minister attends a meeting depends on the topic to be discussed. The minister represents his/her Member State. Food safety issues, for example, are dealt with at meetings of the “Agriculture and Fisheries” CEU, while food labelling is addressed at the “Employment, Social Policy, Health and Consumer Affairs” CEU.

European legislation in the area of consumer health protection and food and feed safety is adopted through the “ordinary legislative procedure”, the most frequently applied legislative procedure in EU law. The “ordinary legislative procedure” means that draft legislation needs to be adopted by both the CEU and the European Parliament (EP).

EP has the power to approve or reject the nomination of commissioners and also has the right to censure the EC as a whole. The EP shares authority over the EU budget with the CEU and can therefore influence EU spending. At the end of the process, it either adopts or rejects the budget in its entirety.

The EP also prepares draft legislation in the area of food and feed safety. The EP has 20 standing committees and 3 subcommittees. The “Standing Committee on Environment, Public Health and Food Safety” deals with food safety and drinking water issues among others.

The European Parliament (EP) is elected by the citizens of the EU. It has 705 members from 27 EU countries and represents the interests of about 500 million people. The fact that the EP is directly elected by the citizens helps guarantee the democratic legitimacy of European law.

The EP exercises democratic supervision over the other EU institutions, especially the EC. The European Food Safety Authority (EFSA) is an independent European Agency and the keystone of risk assessment regarding food and feed safety in the EU. In close collaboration with national institutions and in open consultation with other stakeholders, EFSA delivers independent scientific advice as well as clear and understandable communication on existing and emerging risks. In its capacity as a risk assessment authority, EFSA prepares scientific opinions and recommendations which form a sound foundation for European policies and legislation to support the EC, EP and EU Member States in taking effective and timely risk management decisions. All risk assessments are published on the EFSA website.
Although EFSA receives requests for risk assessments from the EC, EP and Member States, it also undertakes scientific work on its own initiative. EFSA’s remit covers risk assessments on food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

### EU-RLs

**European Union Reference Laboratories**

- Analytics and diagnostics
- Harmonisation of laboratory methods

European Union Reference Laboratories (EU-RLs) are analytical laboratories designated by EU directives and regulations. Several EU-RLs are part of the Joint Research Centre (JRC), which is a Directorate-General of the EC. EU-RLs provide the EC with technical and scientific support in the area of diagnostic and analytical tests. The remit of EU-RLs includes the set-up of EU-wide test standards, routine procedures and reliable methods, the organisation of comparative tests, training of analysts from national laboratories and networking with National Reference Laboratories. EU-RLs have an overview of international standards and practices, reference substances, reagents and their suppliers.

3 Food Safety in the Member States

3.1 Austria

The Food Safety and Consumer Protection Act is the central legal foundation for food legislation in Austria. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Austria, risk assessment and risk management are largely institutionally separated. Risk assessments are published on the Internet.

The Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) prepares draft legislation in the field of food safety based on scientific risk assessments conducted by the Austrian Agency for Health and Food Safety (AGES). The BMSGPK is responsible for the coordination of state food inspections and can issue national regulations in the area of food safety.

The BMSGPK’s portfolio includes food, novel foods, food supplements, genetically modified organisms (GMOs), zoonoses, mineral water, drinking water, residues of plant protection prod-
The Austrian Agency for Health and Food Safety (AGES) is a limited liability company (GmbH) owned by the BMSGPK and BMLRT. AGES has a mandate from the Republic of Austria to prepare scientific risk assessments and conduct transparent risk communication with the public at large, scientists and other interested or involved groups. Independent of any scientific, political or social interests AGES prepares scientific risk assessments, identifies new health risks and prepares recommendations for risk reduction. AGES risk assessments are used by the BMSGPK and the BMLRT and by local authorities as the foundation for their management measures.

AGES’ remit includes food and feed safety, novel foods, food supplements, GMOs, zoonoses, mineral water, residues of plant protection products and veterinary medicinal products. Furthermore, the BMSGPK is responsible for approving pilot studies with regard to the cultivation of genetically modified plants. It is also responsible for approving the use of GMOs in conjunction with food and feed.

The Federal Ministry of Agriculture, Regions and Tourism (BMLRT) is responsible for agricultural policy and food safety during primary food production. It prepares draft legislation in the field of feed and groundwater based on scientific risk assessments conducted by the Austrian Agency for Health and Food Safety (AGES). The BMLRT is authorised to issue national regulations with regard to feed and groundwater.

The work of the BMLRT is supported by the Federal Office for Food Safety (BAES). The BMLRT’s area of work extends beyond the field of food safety to include plant health and plant protection.

AGES’ remit includes food and feed safety, novel foods, food supplements, GMOs, zoonoses, mineral water, residues of plant protection products and veterinary medicinal products. AGES is also active in the fields of animal health, plant health, plant protection, soil health, fertilisers, seeds, bee health, radiation protection, medicines and medical devices. AGES is also involved in active research. AGES has scientific analytical laboratory facilities for all of its areas of activity.

There are 60 National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 and reference laboratories in the fields of veterinary medicine and human medicine attached to AGES.
The regulatory authority for veterinary drugs is assigned to the Federal Office for Safety in Health Care (BASG). The BASG is also an authority within the organisational structure of AGES. The BASG issues and monitors the market authorisation of medicinal products and other medical devices.

In contrast, the coordination and implementation of animal feed inspections is not delegated to the federal states, it is responsibility of the BAES (national level).

The Federal Office for Food Safety (BAES) was established by the Austrian Health and Food Safety Act. It is associated with AGES. AGES provides the BAES with the manpower and the infrastructure needed to execute its sovereign functions as a federal authority. The BAES is responsible for the coordination and implementation of state inspections of animal feed. It is also the regulatory authority for plant protection products. The area of work of the BAES extends beyond the field of animal feed to include plant health.

The BMSGPK has transferred the coordination and implementation of federal inspections for all aspects of food safety to the federal states of Austria (food safety inspections are conducted at a regional and local level).

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Austrian Agency for Health and Food Safety (Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES) (EFSA Focal Point)
2. Environment Agency Austria (Umweltbundesamt GmbH)
3. University of Natural Resources and Life Sciences Vienna (Universität für Bodenkultur Wien, BOKU)
4. University of Veterinary Medicine Vienna (Universität für Veterinärmedizin)
5. Medical University of Graz (Medizinische Universität)
6. Graz University of Technology (Technische Universität Graz)
Regulation (EC) No. 178/2002 and national food laws are the central legal foundation for food legislation in Belgium. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. In Belgium, several independent organisations are involved in the risk assessment of food and feed safety. However, there is no strict institutional separation of risk assessment and risk management. Risk assessments are published on the Internet unless there are statutory provisions that prohibit it.

The Federal Public Service for Health (FPSH) is the federal authority responsible for policy and legislation in the area of food and feed safety, including novel foods, food supplements, chemical and microbiological contaminants, additives, enzymes, flavourings, processing aids, allergens, labelling and claims, dietetic products and
food for special groups, food contact materials, bottled water, water used by food business operators, zoonoses, plant protection products and their residues, fertilisers, genetically modified organisms (GMOs) and veterinary medicinal products.

The regulatory authority for veterinary medicinal products is the Federal Agency for Medicines and Health Products (FAMHP), which is the competent authority responsible for the supervision of the quality, safety and efficacy of medicines for human and veterinary use (including homeopathic medicines, herbal medicines, pharmacy-made and official preparations), of medical devices and accessories as well as raw materials for the preparation and production of medicines.

The FPSH is responsible for defining policy, drafting legislation, and authorizing products prior to marketing in the area of food and feed safety. According to the General Food Law, the tasks of the FPSH are based on risk analyses. Risk assessments and scientific opinions are carried out by the FPSH, Sciensano or the Belgian Superior Health Council (BSHC), depending on the topics. The BSHC acts as a link between government and the scientific world in the field of nutrition and food safety.

The tasks and missions of the FPSH are also supported by stakeholder consultative platforms.

The FPSH follows an integrated and interconnected approach to health protection that is based on the “One Health” concept.

Other institutions provide the FPSH with scientific opinions on food safety: the Belgian Biosafety Advisory Council (BBAC), the Advisory Commission for Plant Preparations and, in specific cases, the Scientific Committee established at the Federal Agency for the Safety of the Food Chain (FAFSC), as well as external academic departments.

The FPSH provides funding for scientific research in the area of food safety, animal health and plant health. There are yearly calls for project proposals, with both a bottom-up (“free research”) and top-down (“targeted research”) approach.

The areas of missions and tasks of the FPSH extend beyond food safety, including to nutrition policy, breastfeeding policy, animal health, plant health, the environment, cosmetics, biocides, REACH, antibiotic resistance, tobacco, alcohol, human health, and others.

FASFC
Federal Agency for the Safety of the Food Chain

- Risk assessment
- Risk communication
- Risk management
- RASFF contact point
- Multi-annual national control plan

Location: Brussels
http://www.afsca.be/home-en
http://www.favv-afsca.fgov.be/scientificcommittee/

The Federal Agency for the Safety of the Food Chain (FASFC) is the federal executive agency responsible for official controls and inspections as well as for the definition and enforcement of operational legislation related to official control of the food chain (from farm to fork). The agency carries out official controls of food, feed and its raw materials at all stages of the feed and food chain, including production, processing, storage, transport, trade, and import and export of food and its raw materials. The FASFC oversees all official controls on the basis of multi-annual national control plans. In addition, it is also responsible for the control of animal health and plant health.
To fulfil its tasks, the FASFC is supported by two committees. The Advisory Committee includes all FASFC stakeholders and provides opinions on risk management matters. The Scientific Committee is responsible for independent risk assessments and provides scientific opinions on risks affecting the safety of the food chain in connection with the competencies of the FASFC.

Science and health are central to Sciensano’s mission. Our strength and uniqueness lie within the holistic and multidisciplinary approach to health. More particularly, we focus on the close and indissoluble interconnection between human and animal health and their environment (the “One Health” concept). By combining different research perspectives within this framework, Sciensano contributes in a unique way to everybody’s health.

Sciensano provides evidence-based scientific and technical support to the competent authorities (FPSH and FASFC) as well as to professional organisations and front-line laboratories. The institute hosts several NRLs and EURLs.

In the context of EFSA’s remits, Sciensano focuses on food consumption and food safety, (human and animal) health and disease monitoring, and on the link between health and the environment (e.g. pesticides).

Using food consumption surveys, Sciensano analyses citizens’ nutritional habits. Sciensano also identify pathogens in food (and human infections caused by food pathogens) and keeps an eye on GMOs, food contaminants, residues (pesticides, heavy metals, etc.), food contact materials, additives and nanomaterials, for which Sciensano also assesses the risks. In terms of animal health, Sciensano is involved in a broad range of activities (e.g. epizootic diseases, emerging diseases that pose a major socioeconomic risk, but also diseases whose impact is solely economic, such as foot-and-mouth disease). Furthermore, Sciensano also addresses important transversal problems such as antimicrobial resistance and zoonoses.

Regional and local levels

The regional and local levels of the Belgian Federal State consist of three regions, 10 provinces and 589 districts. Local FASFC control units are responsible for conducting food inspections. The central FASFC unit is responsible for coordinating food inspections. The monitoring of drinking water is the responsibility of the regional authorities.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Federal Public Service (FPS) Health, Food Chain Safety and Environment (EFSA Focal Point)
2. Federal Agency for the Safety of the Food Chain (FASFC)
3. Sciensano
4. Walloon Agricultural Research Centre (CRA-W)
5. Own Capital of the Institute for Agricultural and Fisheries Research
6. Ghent University (Universiteit Gent)
7. Centre d’Economie Rurale (CER Group)
8. University of Liege (Université de Liège)
9. Catholic University of Louvain (Université Catholique de Louvain)
10. Hasselt University (Universiteit Hasselt)
The Food Law is the central legal foundation for food legislation in Bulgaria. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Bulgaria, an institutional separation of risk assessment and risk management has been in place since 2016.

In January 2011, the Bulgarian Parliament, following a political decision, established a new public authority by adopting the Law on the Bulgarian Food Safety Agency (BFSA). BFSA, within the Ministry of Agriculture, Food and Forestry (MAFF), is responsible for the official control on safety of food and feed throughout the food chain. Together with the agency, a Risk Assessment Center was created.

Initially the RACFCH was established in 2011 and functioned within BFSA structure until 2016. Since 01 October 2016, following another political decision, the Law on RACFCH was adopted and the center was separated from the agency as an independent legal entity under MAFF. RACFCH is the main authority in Bulgaria engaged in risk assessment and risk communication related to the food chain. Its risk assessments and scientific opinions are published on the Internet unless there are statutory provisions that prohibit it.

MAFF is responsible for agricultural policy along the food chain. It prepares draft legislation related to food and feed safety and is responsible for implementing official controls of food and feed.

Within the Ministry of Agriculture, Food and Forestry (MAFF), the Agro-Food Chain Policy Directorate is responsible for the development, coordination and implementation of the state policy in the fields of quality and safety of food and feed, animal health, plant health and plant reproductive material, and border control on food chain safety. The Directorate is responsible for preparations and is involved in the development and coordi-
nation of draft legislative acts in the respective fields, coordination of control authorities within the Ministry, and in the coordination and preparation of a single multiannual national control plan in implementation of Regulation (EU) 2017/625. It also coordinates activities of the Ministry with the Ministry of Health, other agencies and branch organisations in the context of the quality and safety of food and feed, animal health, plant health and plant reproductive material, and border control along the food chain, and also coordinates activities between the Ministry and Bulgarian Food Safety Agency (BFSA). The Agro-Food Chain Policy Directorate is also responsible for market authorisation of genetically modified organisms (GMOs). It also serves as the national contact point in the Republic of Bulgaria for the following systems: Rapid Alert System for Food and Feed (RASFF), Administrative Assistance and Cooperation System (AAC), Food Fraud Network, the integrated computerised veterinary system called TRACES (Trade Control and Expert System), Plant Protection Products Application Management System (PPPAMS) of the European Commission, International Food Safety Authorities Network (INFOSAN), and maintains their functioning.

The Ministry of Health (MH) is responsible for health policy and safety of bottled natural mineral, spring and table water (Directive 98/83/EC) and the investigation of foodborne outbreaks. In the area of food safety, MH is involved in drafting EU horizontal legislation and is responsible for the harmonisation of that legislation into national provisions as well as the coordination of inspection of control activities, which are carried out by Regional Health Inspectorates. The national centres of public health under MH conduct risk assessment on issues related to human health.

The portfolio of MH encompasses, amongst other things, novel foods, baby food, foods for special medical purposes, health claims, food supplements, GMOs, contaminants and residues of plant protection products and food contact materials. Two National Reference Laboratories are attached to the MH pursuant to Regulation (EC) No. 882/2004 for GMOs and for food contact materials.

The Bulgarian Food Safety Agency (BFSA) is a specialised body under MAFF that is responsible for the official controls of safety of food and feed throughout the food chain. BFSA incorpo-
rates the former National Veterinary Service, the former National Plant Protection Service, and the former National Grain and Feed Service, as well as the regional food health inspectors, who were responsible for the control of food of non-animal origin in the Regional Health Inspectorates (former Regional Inspectorates for Public Health Protection and Control) under MH and the quality compliance of fresh fruits and vegetables (under MAFF) with the European Commission standards for placing on the market.

BFSA is the competent government authority responsible for official controls in Bulgaria with respect to phytosanitary issues, plant protection products and fertilisers, veterinary activities, animal health and welfare, animal by-products not intended for human consumption, feedstuff, raw materials and foodstuff, with the exception of bottled natural mineral, spring and table water, materials and articles intended for contact with food, and the quality compliance of fresh fruits and vegetables with the European Commission standards for placing on the market. BFSA comprises 14 departments/directorates, which are aligned with the above-mentioned activities.

The agency’s central office is in Sofia. It also has 28 regional food safety directorates distributed across the country as well as five specialised structures: the National Diagnostic and Research Veterinary Institute, the Central Laboratory for Veterinary Control and Ecology, the Central Laboratory for Chemical Testing and Control, the Central Laboratory for Plant Quarantine, and the Central Laboratory for Qualification of Grain and Feed.

The Risk Assessment Center on Food Chain (RACFCH) was created by the adoption of the Law on RACFCH and its Code of Organisation in 2016. It is managed by a director and assisted by an Advisory Board (on which MAFF and MH are represented). RACFCH is an independent legal entity within the structure of MAFF, a second level budget unit to the Minister of Agriculture, Food and Forestry. RACFCH provides independent scientific assessments of risks related to food safety, human health, animal health and welfare, food and feed additives, GMOs, dietetic products, nutrition and allergens, materials and articles intended for contact with food, enzymes, flavourings and supporting substances, biological hazards, contaminants, plant health and plant protection. RACFCH carries out activities for the approval, renewal, and review of approval of active substances, safeners and synergists with the terms and conditions of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. RACFCH works in close collaboration with EFSA and other national and international scientific institutions in the food and feed risk assessment area. The EFSA Advisory Forum representative and the national EFSA Focal Point are located within RACFCH.
The National Center of Public Health and Analyses (NCPHA) is subordinate to MH and deals with health protection, health education and nutrition. NCPHA is responsible for the publication of risk assessments in the field of nutrition and hygiene and is also responsible for microbiological hazards, contaminants, biological hazards, chemical contaminants in the food chain, residues of plant protection products, GMOs, food contact materials, heavy metals, food supplements, food additives, novel foods and mineral water.

Regional and local levels

Bulgaria consists of 28 administrative regions with 264 municipalities. Inspections at regional and local levels are conducted by authorities that are subordinate to the central government (headquarters). Both MH and MAFF have 28 regional services which report their activities to the central level in the ministries.
The legal framework for food safety in Croatia is provided by the Food Act, which transposes the provisions of Regulation (EC) No. 178/2002. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Croatia, risk assessment is institutionally separated from risk management. Risk assessment outputs are usually published on the website of the Croatian Agency for Agriculture and Food (HAPIH).

The portfolio of the MP includes drafting legislation in the area of agricultural policy, especially in the area of food and feed safety, quality and hygiene, animal health and welfare, and plant health. MP designates official and reference laboratories to analyse food and feed and to safeguard animal health and welfare as well as plant health. The MP is responsible for informing the public if there are reasonable grounds to suspect that food or feed may represent a risk to human or animal health.
In cooperation with the MP, MZ is responsible for drafting legislation in the area of food safety, covering food of non-animal origin. MZ defines objectives and priorities for public health policy, develops public health plans and national health programmes and ensures their implementation. MZ designates official and reference laboratories to analyse GM food and feed and food contact materials. MZ is also responsible for the registration of food supplements and foods for special medical purposes.

HAPIH is an independent public institution in the field of agriculture and food safety and works within the portfolio of the MP. HAPIH has a remit to implement risk assessments and risk communication relating to food and feed safety. HAPIH provides scientific and technical support based on risk assessments on all matters regarding food and feed safety, plant health, animal health and welfare. Further activities include research in the field of agronomy and related fields, plant protection, seed and seedling production, viticulture, winemaking, oil production, fruit growing, vegetable growing, agricultural land, cattle breeding, quality control of fresh raw milk, honey and feed.

HAPIH works in close cooperation and communication with a broad spectrum of national and international institutions. National independent scientific experts support the work of HAPIH through participation in the expert bodies. HAPIH is responsible

DIRH performs official controls of the entire food chain according to the principle “from farm to fork” by conducting veterinary, sanitary, phytosanitary and agriculture inspections. In addition to food safety, plant health, animal health and welfare, the remit of DIRH extends to agriculture, non-food product safety, trade, services, catering, mining, labour and occupational safety, civil engineering and environmental protection.

DIRH’s structure consists of a central office in Zagreb, regional offices and branch offices.
for establishing and coordinating the national network of institutions in the area of food safety.

**HZJZ**
**Ministry of Health**

- Analytics and diagnostics
- Reference Laboratories
- Research
- Risk communication

**Location:** Zagreb  
[https://www.hzjz.hr/en/about-us/](https://www.hzjz.hr/en/about-us/)

HZJZ is a central public health institute which deals with public health, health promotion and education, disease prevention, microbiology, environmental health, school medicine, mental health care and addiction prevention. It prepares and implements prevention programmes and other healthcare measures aimed at promoting healthy lifestyles. HZJZ carries out epidemiological surveillance and proposes, organises and undertakes preventive and counter-epidemic measures.

HZJZ coordinates the network of regional public health institutes. HZJZ and regional public health institutes have food laboratories which are official laboratories pursuant to Regulation (EC) No. 882/2004.

**HVI**
**Croatian Veterinary Institute**

- Analytics and diagnostics
- Reference Laboratories
- Research
- Risk communication

**Location:** Zagreb  
[http://www.veinst.hr/en/](http://www.veinst.hr/en/)

HVI is an independent public institution within the portfolio of the MP, primarily engaged in the diagnostics of infectious and parasitic animal diseases, analysis of food of animal origin and animal feed, control of veterinary medicinal products and scientific research. HVI consists of the Croatian Veterinary Institute in Zagreb and five branches that comprise the laboratories.

**Regional and local levels**

Croatia is divided into 20 counties and the capital city of Zagreb, which also has county status. At the regional and local level, inspections of food of animal and non-animal origin are conducted by state and border sanitary and veterinary inspectors and agriculture inspections. The regional and local inspections are coordinated and supervised by DIRH.

In total, Croatia has 37 official laboratories and 5 Reference Laboratories for food and feed analyses.

**Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002**

1. Croatian Agency for Agriculture and Food (Hrvatska agencija za poljoprivredu i hranu, HAPIH)
2. Croatian Veterinary Institute (Hrvatski veterinarski institut, HVI)
3. Croatian Institute of Public Health (Hrvatski zavod za javno zdravstvo, HZJZ)
In Cyprus, there is no permanently established coordinating body in the form of a food safety authority; instead a council called the ‘Food Safety Council’ (FSC) was formed under the Ministry of Health. Its members include representatives of all relevant competent authorities (Ministry of Health (MOH), Ministry of Agriculture (MOA) etc.).

For the Public Health Services of the Medical and Public Health Services (PHS of MPHS) within the MOH, which are responsible for controlling the safety of food of non-animal origin at all stages with the exception of the primary production stage, honey, ice cream, and for all food at the retail level except for fresh meat sold at butcher shops, the central legal founding legislation is the Food (Control and Sale) Law, which sets out the definitions, powers and responsibilities of authorities, the main responsibilities of FBOs, and transposes EU food safety legislation in the national context and sets penalties. Violations of this law can be either filed in court through the attorney general or the head of the Public Health Services (PHS) can impose administrative penalties. Competent authority measures are based on EU legislation and the available limits. Occasionally, risk management in the case of an absence of limits or for the escalation of measures requires a risk assessment or risk evaluation. The State General Laboratory (SGL) of the MOH is the official food control laboratory and conducts risk assessment of contaminants and other toxic chemicals in close collaboration with the FSC.

As regards Regulation (EC) No. 178/2002, MOA, through its two subordinate institutions, the Veterinary Services (VS) and the Department of Agriculture (DOA), are responsible for the control of food of animal origin at all stages of production and marketing, feed safety, and microbial controls for food of non-animal origin at the primary production stage. In addition, MOA’s remit includes the responsibility for animal health and welfare as well for the control, monitoring and eradication of animal contagious diseases, plant health and authorisation and use of plant protection products.

In 2003, the FSC of Cyprus was established by the Ministry of Health (MOH). Its members are representatives of all relevant competent author-
The Public Health Services unit of the Department of Medical and Public Health Services within the Ministry of Health (PHS of MPHS) is responsible for controlling the safety at all stages of food of non-animal origin, honey, ice cream, and for all food at the retail level except for fresh meat sold at butcher shops, and is also responsible for risk management and risk evaluation where this is possible. Its portfolio for the above-mentioned products includes food establishment inspections, food product controls (samplings, complaint investigation), import controls, labelling controls, food fraud and food quality controls. Moreover, PHS of MPHS is also responsible for controls related to drinking water.

The head of PHS is also the RASFF national contact point.

The State General Laboratory (SGL) carries out regular official controls and surveillance on foodstuffs, covering all sections of the food production chain, “from the field or farm to the consumer’s table”. For this purpose, it implements various national control programmes with the cooperation of the competent authorities. Controls are of a preventive nature and focus mainly on basic foods that are consumed frequently or may give rise to a specific problem as well as on foodstuffs expected to be consumed by vulnerable groups of the population, such as children and pregnant women. The SGL goes one step beyond analysis. It evaluates the degree of exposure to toxic substances and to related risks, therefore providing scientifically sound advice to the FSC and to competent authorities for risk management through appropriate measures. The SGL of the MOH is the national EFSA Advisory Forum member and the EFSA Focal Point.

The SGL is accredited under ISO 17025 by the Cyprus Accreditation Body (CYS-CYS AB) and six National Reference Laboratories are attached to the SGL pursuant to Regulation (EU) No. 2017/625.
The Ministry of Agriculture, Rural Development and Environment (MOA) aims at promoting sustainable development for agriculture and fishing, while contributing to environmental protection and sustainable management of both the environment and Cyprus’ natural resources through projects, initiatives and actions.

The Ministry consists of ten departments and services.

Its subordinate institutions are the regulatory bodies for the food and feed chain controls listed above. Their remit also includes risk assessments, risk management and risk communication.

The implementation of European and national legislation and the implementation of controls fall under the authorities and responsibilities of its subordinate institutions.

Veterinary Services (VS) are responsible for animal health and welfare and for public health protection by controlling food of animal origin by registering and approving the food-producing and processing facilities. VS are also responsible for monitoring the registration and usage of medicinal products for animal use.

VS design programmes for the control, monitoring and eradication of animal diseases as well as animal welfare in food and non-food producing animals.

Additionally, VS are responsible for implementing public health protection by controlling food of animal origin. Its remit comprises the whole production chain of food of animal origin and control from the primary production to placing the products on the market, except for honey and ice cream. With regard to fresh meat, VS is responsible for the controls at the market as well.

VS also carry out controls on food of animal origin that is imported from third countries. The controls are carried out at the Border Control Posts (BCPs).

VS design annual programmes for the controls, inspections, audits, monitoring and sampling of the products of food of animal origin of the registered and approved establishments that are under their competencies.
The samples collected within the scope of the above-mentioned programmes, are analysed by its accredited laboratories, which are the National Reference Laboratories.

VS have the Animal Health Laboratories (AHL) and the Laboratories for the Control of Food of Animal Origin (LCFAO). All the laboratories are accredited under ISO: 17025 by the Cyprus Organisation of Standardisation (CYS).

The Department of Agriculture (DOA) deals with agricultural policy and food and feed safety in Cyprus. It prepares national legislation in the field of food of non-animal origin at the primary production stage, feed, plant health, marketing of seeds and plant propagating material, marketing standards for fruits and vegetables, eggs, poultry, meat, quality labelling and quality schemes for agricultural products and foodstuffs. It is also responsible for the authorisation of plant protection products and the marketing and use of plant protection products.

It also shares responsibility for the cross-compliance legislation, including the protection of waters against pollution caused by nitrates from agriculture sources.

The DOA is also in charge of the preparation of multi-annual national control programmes, which are based on risk analyses. In addition, it is responsible for implementing the annual national control programmes and their monitoring. It provides guidelines to inspectors as well as training as appropriate.

It is also a decision-making body and responsible for risk communication for the areas that fall within its purview.

The DOA has authorised six BCPs for the import of plants and plant products.

The DOA consists of regional offices and the following five laboratories that deal with controls related to food and feed safety and quality:
1. **Pesticide Residues Laboratory** is the National Reference Laboratory (NRL) for Pesticides Residues in Feed and the official laboratory for the analysis of pesticide residues in conventional agricultural products on the farmer level, for the control of good agriculture practices, as well as for any use of non-authorised plant protection products in accordance with the Plant Protection Products Law. The laboratory has been accredited in accordance with ISO 17025 since 2011.
2. **Pesticide Formulations Laboratory** is the official laboratory for the quality control of pesticide formulations in accordance with the Plant Protection Products Law. Although the lab is not accredited, it implements the same QA system as the accredited laboratories of the DOA.
3. **Animal Feedstuffs and Fertilizers Quality Control Laboratory** is the National Reference Laboratory (NRL) for all official controls in the area of feed and feed additives as well as fertilisers pursuant to the relevant legislation. The laboratory has been accredited in accordance with ISO 17025 since 2011.
4. **Oenology Laboratory** conducts chemical analyses of several vine and wine products within the scope of experimentation and
market monitoring. The laboratory has been accredited in accordance with ISO 17025 since 2009.

5. **Plant Protection Laboratory** deals with the official testing for the diagnosis of harmful organisms (bacteria, fungi, nematodes, viruses and insects) for plants and plant products.

### Regional and local levels

Within the framework of PHS of MPHS, for the implementation of controls in the field, five district offices have been established in the respective administrative districts. In addition, nine municipalities have their own control competencies in the field of food hygiene in certain types of establishments within their boundaries. The activities of both the district offices and the municipalities are monitored by PHS and audited by an internal audit team that is independent of PHS of MPHS.

The Republic of Cyprus has six administrative districts. The regional and local levels are subordinate to the central state of VS and DOA in a direct chain of instruction and are mainly responsible for the implementation of European and national legislation by conducting relevant controls such as audits, inspections and sampling.

### Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Ministry of Health (MOH)
   a. State General Laboratory (SGL)
   b. Environmental Health Services
2. Ministry of Agriculture, Rural Development and Environment (MARDE)
   a. Agricultural Research Institute (ARI)
   b. Department of Agriculture (DA)
   c. Veterinary Services (VS)
3. University of Cyprus (UCY)
4. Cyprus University of Technology (CUT)
Act No. 110/1997 Coll. on food and tobacco products, as amended, is the central legal foundation for food legislation in the Czech Republic. The Food Safety and Nutrition Strategy 2030 is a key document of the Czech Republic in the field of food safety and nutrition.

Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In the Czech Republic, there is no institutional separation of risk assessment and risk management, however there is a procedural separation of risk assessment and risk management. Risk assessments are published on the Internet unless there are statutory provisions that prohibit it.

The Ministry of Agriculture (MZE) deals with agricultural policy and food safety in the Czech Republic. It is responsible for foods of animal and plant origin as well as for state food inspections.

The portfolio of MZE also includes food (including food used in catering services) and feed, animal welfare and health, veterinary medicinal products, plant protection products and their residues, contaminants, drinking water, genetically modified organisms (GMOs), novel foods, food additives, enzymes and aromas, food sup-
lements and food labelling, fortification of food, and nutrition and health claims.

MZE is also responsible for all agricultural commodities issues and organic farming.

Risk communication is another main area of MZE’s remit. The Food Safety Information Centre was set up to provide information, accessible to the general public, on all aspects of food safety (“from farm to fork”).

Competent authorities subordinate to MZE (SZPI, SVS, UKZUZ) play a main role in putting MZE’s policies into effect and implementing official controls.

Scientific advice is provided to MZE by scientific committees:
- Veterinary Scientific Committee
- Scientific Committee on Animal Nutrition
- Scientific Committee on GMO Food and Feed
- Phytosanitary and Environmental Scientific Committee

Some National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 are attached or organisations which are within the portfolio of MZE.

SZPI
Czech Agriculture and Food Inspection Authority

- Risk communication
- Risk management
- RASFF contact point

Location: Brno

The purpose of the State Veterinary Administration (SVS) is primarily the protection of consumers from products of animal origin likely to be harmful to human health, monitoring the animal health situation and maintaining it in a favourable manner, veterinary protection the state territory of the Czech Republic, animal welfare and animal protection.

Risk communication is also a task of SVS.

Another important task of SVS is to ensure the veterinary laboratory diagnostics which is carried out by three state veterinary institutes (SVU) in Jihlava, Olomouc and Prague.

5 National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 are attached to SZPI.

SVS
State Veterinary Administration

- Risk communication
- Risk management

Location: Prague
https://en.svscr.cz/

Czech Agriculture and Food Inspection Authority (SZPI) is a state authority responsible for supervising the safety, quality and labelling of foodstuffs. Within its remit, SZPI inspects foodstuffs, raw materials for their production as well as agricultural and tobacco products. The above-mentioned responsibilities apply to production, storage, transport, and sale (including import).

Risk communication is another task of SZPI, which informs consumers about poor-quality, adulterated or unsafe food identified during the official inspections.

SZPI is also the national contact point for RASFF.
28 National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 are attached to these state veterinary institutes.

**UKZUZ**

Central Institute for Supervising and Testing in Agriculture

- Risk communication
- Risk management
- Risk assessment

Location: Brno  

Central Institute for Supervising and Testing in Agriculture (UKZUZ) performs administrative tasks and carries out other administrative activities, expert and testing tasks, and control and monitoring activities in accordance with special acts in the areas of plant variety testing, feedstuffs, agrochemical testing of soils, soils and plant nutrition, seeds and seedlings of the grown plants, perennial plants (viniculture and hops), protection against harmful organisms, and plant protection.

9 National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 are attached to UKZUZ.

**MZ**

Ministry of Health

- Risk assessment
- Risk communication
- Risk management
- Food hygiene

Location: Prague  

The Ministry of Health (MZ) deals with public health protection and food safety in the Czech Republic. The portfolio of MZ includes food contact materials, contaminants, mineral water and plant protection products and their residues. MZ is also responsible for food for special medical purposes, infant formula and follow-on formula, processed cereal-based food, baby food, total diet replacement for weight control, and microbiological criteria.

MZ is the national competent authority for the surveillance of communicable diseases, including food and water borne diseases, and specifies requirements for irradiated foods (including dose limits).

MZ (together with MZE) shares the responsibility for establishing limits for residues of veterinary medicines in foodstuffs.

The inspection competency of MZ is restricted to food contact materials, food hygiene and, more particularly, the catering trade. The relevant competent authorities are the public health authorities (OOVZ).

Some National Reference Laboratories are attached to MZ.

**SZU**

National Institute of Public Health

- Risk assessment
- Risk communication

Location: Prague  

The main activities of National Institute of Public Health (SZU) comprise science and research, reference and methodological advice, provid-
ing expert opinions on the health safety of various products (including food supplements and items of daily use), systematic monitoring of the environmental impact on population health in the Czech Republic, and promotion of a healthy lifestyle, including nutrition.

Human health risk assessments are provided by SZU – food and food contact materials.

SZU provides MZ with a scientific background, namely expert opinions, scientific advice and assessments concerning human health risks.

**Regional and local levels**

The Czech Republic consists of 14 regions which are further subdivided into districts.

Food and feed inspections are the responsibility of the regions. In all 14 regions, there are regional SVS and OOVZ offices. In seven regions, there are regional SZPI and UKZUZ offices.

Animal welfare is the responsibility of the municipalities, i.e. to inspect, take measures and deal with infringements. SVS ensures the implementation of control activities.

**Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002**

1. Ministry of Agriculture of the Czech Republic (EFSA Focal Point)
2. Mendel University in Brno
3. National Institute of Public Health
4. Veterinary Research Institute
5. Crop Research Institute
6. Institute of Animal Science
7. Czech University of Life Sciences Prague
8. Food Research Institute Prague
9. Biology Centre of the Czech Academy of Sciences
10. University of Chemistry and Technology Prague
11. University of Veterinary Sciences Brno
12. University of South Bohemia in České Budějovice
13. University of Ostrava
14. State Veterinary Institute Jihlava
The Danish Food Act is the central legal foundation for food legislation in Denmark. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts. In Denmark, risk assessment is institutionally separated from risk management. Some risk assessments are published and others are not.

The food-related area of work of the MFAF extends beyond food safety to include, for instance, nutrition, plant health, animal health and animal welfare.

As a subordinate specialist authority of the MFAF, the Danish Veterinary and Food Administration (DVFA) is responsible for risk management in the field of food and feed safety. The DVFA is responsible for food and feed inspections countrywide. The risk assessments conducted by the National Food Institute, Technical University of Denmark (DTU), are used by the DVFA as the basis for management measures in the field of food safety. The risk assessments conducted by the Danish Centre for Food and Agriculture (DCA), Aarhus University, are used by the DVFA as the basis for management measures in the area of feed.
The remit of the DVFA includes novel foods, food supplements, genetically modified organisms (GMOs), zoonoses, mineral water and residues of plant protection products and veterinary medicinal products. The area of work of the DVFA extends beyond food safety to include, for instance, consumer information, i.e. food labelling and nutritional advice.

The National Food Institute, Technical University of Denmark (DTU) researches and communicates sustainable and value-adding solutions in the areas of food and health for the benefit of society and industry.

As a specialist authority that supports the MFAF, the Danish Agricultural Agency (DAA) is responsible for the areas of agriculture, plants and horticulture. The remit of DAA includes the plant health area (National Plant Protection Organization (NPPO)) and monitoring the application of plant protection products in the primary production. One National Reference Laboratory is attached to the DAA pursuant to Regulation (EC) No. 882/2004.

The National Food Institute, Technical University of Denmark (DTU) researches and communicates sustainable and value-adding solutions in the areas of food and health for the benefit of society and industry.

The institute’s tasks are carried out in a unique interdisciplinary cooperation between the disciplines of nutrition, chemistry, toxicology, microbiology, epidemiology and technology.

The institute serves as a National Reference Laboratory for chemical and microbiological food contamination pursuant to Regulation (EC) No. 882/2004. Furthermore, the National Food Institute is also the EU Reference Laboratory for Pesticides in Cereals and Feedstuffs, for Processing Contaminants in Food, for Metal and Nitrogenous Compounds and for Antimicrobial Resistance. The institute also serves as the WHO collaboration centre for antimicrobial resistance for foodborne pathogens and for food contamination monitoring – and as FAO collaborating centre for Antimicrobial Resistance.
Providing scientific advice and risk assessment to the Danish Veterinary and Food Administration is one of the institute’s core assignments and is based on the strong scientific competence and expertise within the institute.

**UCPH**  
**Department of Veterinary and Animal Sciences, University of Copenhagen**

- Research  
- Research-based scientific advice  
- Risk assessment  
- Contingency planning  
- Reference laboratories  
- Education  

**Location: Copenhagen**  
https://www.ku.dk/english/

The University of Copenhagen (UCPH), Department of Veterinary and Animal Sciences (IVH) provides research and research-based advice as well as education in the areas of veterinary and animal science, food safety, antibiotic resistance, animal models and welfare, immune systems and lifestyle diseases. The department covers a wide spectrum of animal and human disease biology in close collaboration with other departments at the University of Copenhagen. The department comprise 9 sections with a total of 360-400 employees.

The main areas in relation to the Danish Food Safety System are infectious livestock diseases, avian influenza and enzootic virus infections, zoonoses, antimicrobial resistance, parasitic infections and diseases of wild fauna, and aquatic diseases.

The Danish Veterinary Consortium, which consists of IVH, UCPH and the Statens Serum Institut (SSI), is responsible for public sector services related to veterinary contingency in Denmark. The consortium conducts research to support and underpin decisions in the area of veterinary contingency, and also provides the DVFA with scientific advice. The public sector consultancy for the DVFA includes advice on a wide range of subjects, including disease surveillance and handling of specific emergency tasks, e.g. suspected disease outbreaks, as well as assistance in the form of risk assessments and replies to questions from the government.

The University of Copenhagen (UCPH) is responsible for the education of veterinarians (DVM) in Denmark. In addition, UCPH offers a range of BSc and MSc programmes in the subjects of animal science, food science and human nutrition.

**DCA**  
**Danish Centre for Food and Agriculture, Aarhus University (AU)**

- Research  
- National and international public sector services  
- Risk assessment  

**Locations: Foulum, Tjele**  
https://dca.au.dk/en/

The remit of the Danish Centre for Food and Agriculture (DCA), Aarhus University (AU), includes research-based risk assessments in the field of feed safety. The DCA provides research-based consultancy and solutions including risk assessments to be used by the MFAF, the Danish Agricultural Agency and the Danish Veterinary and Food Administration as the basis for regulation and legislative work. The DCA cooperates with the DCE to fulfil tasks, i.e. for the MFAF in areas in which their different kinds of expertise are supplementary.

The area of work of the DCA includes:

- Livestock: production systems and management, breeding, health, welfare, feeding and feed safety, cloning, GMOs
Food quality: quality assurance, production systems, supply, processing, storage, nutrition, exposure assessment, nanotechnology
Plant health: plant protection products, including efficacy testing and evaluation
Plants: production management, breeding, biotechnology, climatology, agroecology
Interactions among climate, soil, plants, animals and humans in agricultural systems
Organic farming

The DCE is involved in the development of guidelines for risk assessment and has expertise in antibiotics, growth regulators, and wildlife with regard to the dispersal of emerging diseases.

SSI
Statens Serum Institut

Research
Location: Copenhagen
https://en.ssi.dk/

Statens Serum Institut (SSI) is a governmental research institution within the field of health science. At SSI, we conduct research in epidemiology, microbiology, immunology and biotechnology as a prerequisite for and an integrated part of our core areas in preparedness against infectious diseases, biological threats and control of congenital disorders.

SSI conducts surveillance of infectious diseases and provides counselling to the Danish healthcare system and authorities in the event of, e.g., epidemics that demand urgent action. Specifically, SSI plays a key role in the detection and investigation of foodborne disease outbreaks. All of SSI’s activities are based on research. Data and new knowledge are gathered and produced in all priority areas, communicated to the outside world by SSI employees and published in scientific journals.

Regional and local levels

The regional and local levels in Denmark consist of five regions and 98 districts. The DVFA consists of three local veterinary control offices and five local food control offices. The local offices are an integrated part of the DVFA.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Technical University of Denmark (EFSA Focal Point)
2. Aarhus University
3. University of Copenhagen
4. Statens Serum Institut
The central legal foundations for food and feed safety in Estonia are the Food Act and the Feed Act. These acts contain provisions on food and feed safety as well as specify the competent authorities and control bodies responsible for implementing risk-based measures in the field of food and feed safety. Infringement of these regulations can lead to measures under criminal law and consumer damage claims under civil law. Government measures with regard to food safety are often based on scientific risk assessment. However, the final decision on the legality of governmental measures rests with the courts.

In Estonia, food safety risk assessment and risk management are institutionally separated. Risk assessments, scientific opinions and other statements are conducted by the Veterinary and Food Laboratory. There is no routine publishing of the results of risk assessment, however depending on the importance of the result, they can be published and/or are available upon request.

The Ministry of Rural Affairs (MEM) deals with agricultural policy in Estonia and, more particularly, with food and feed safety. The MEM prepares draft legislation in the field of food and feed and coordinates the performance of state tasks. The Agriculture and Food Board (PTA) facilitates the work of the MEM within its´sm remit as the competent authority and executive body. PTA is responsible for official food and feed control and control of use of plant protection products. With regard to questions on genetically modified organisms (GMOs), the MEM collaborates closely with the Ministry of the Environment (KKM).
The National Reference Laboratories attached to the MEM in accordance with Regulation (EU) 2017/625 are the Veterinary and Food Laboratory and the Agricultural Research Centre. The area of work of the MEM extends beyond food and feed safety to include, for instance, plant health, animal health and animal welfare.

**VTL**
**Veterinary and Food Laboratory**
- Risk assessment
- Risk communication

*Location: Tartu*
https://www.vetlab.ee/en

The Veterinary and Food laboratory (VTL) is subordinate to the MEM. The tasks of VTL include performing risk assessments and risk communication related to food safety and animal health areas and providing scientific advise to the MEM and the PTA.

**PTA**
**Agriculture and Food Board**
- Risk management
- Risk assessment
- Risk communication
- RASFF contact point

*Locations: Tallinn and Saku*
https://www.pta.agri.ee/en

The Agriculture and Food Board (PTA) is subordinate to the MEM. The main focus of the work of the PTA is risk management and risk communication. The PTA monitors and coordinates relevant tasks performed by local offices; the local offices are grouped under 4 regions. Risk assessments on food safety and animal health are outsourced to research institutes, universities and the Veterinary and Food Laboratory, while plant protection products safety is assessed by PTA.

The activities of the PTA focus on ensuring food and feed safety and cover all the major topics, such as feed, food supplements, GMOs, food contact materials, zoonoses, novel foods, residues of veterinary medicinal products and plant protection products. The area of work of the PTA extends beyond food and feed safety to include, for instance, plant health, animal health and animal welfare, organic production, animal breeding and market control.

**SM**
**Ministry of Social Affairs**
- Health policy
- Risk management

*Location: Tallinn*
https://www.sm.ee/en

The Ministry of Social Affairs (SM) deals with health policy in Estonia. It prepares draft legislation in the field of drinking water, mineral water and spring water. The SM, MEM and KKM work together in the field of GMOs. The Health Board (TA) and the State Agency of Medicines (RA) support the work of the SM in their capacity as the competent authorities. The RA is the regulatory authority for veterinary medicinal products in Estonia, except for their use by veterinarians and animal keepers, which is in the remit of responsibility of the Veterinary and Food Board (VTA).

The task area of the SM extends, amongst others, to questions on nutrition in public institutions in Estonia (nutritional value of food, varied and balanced nutrition).
The Health Board (TA) is subordinate to the SM. The TA is responsible for risk assessments, risk management measures and risk communication in the area of drinking water, natural mineral water and spring water.

The TA is the competent authority for natural mineral water and drinking water, and monitors and coordinates tasks of relevant regional and local authorities.

The National Reference Laboratories attached to the TA in accordance with Regulation (EU) 2017/625 perform a range of food safety tests, for example on food contact materials and plant protection product residues in food.

### Regional and local levels

The PTA has 15 local offices grouped under 4 regions of Estonia. These local offices are responsible for enacting food and feed legislation, for food and feed inspections, for plant health and controlling the use of plant protection products, amongst other issues. The TA consists of a central authority and four regional departments which have further divisions in 15 counties.
The Finnish Food Act is the central legal foundation for food legislation in Finland. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Governmental measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

While there is no strict institutional separation of risk assessment and risk management in Finland, procedural aspects of risk assessment and risk management are separated, and risk assessments are done independently from risk management.

Most risk assessments are publicly available.

The Ruokavirasto is a specialist authority within the portfolio of the MMM. It is responsible for planning, steering, developing and undertaking food control on a national basis. It is also responsible for national risk assessments related to food, feed, animal health and plant health. The portfolio of the MMM also encompasses the Natural Resources Institute Finland (Luke), whose remit is to engage in research concerning agriculture and food economy. Luke also focuses on the improvement of farm animal welfare and risk assessments related to it.
There are three National Reference Laboratories attached to the MMM, pursuant to Regulation (EC) No. 882/2004.

STM
Ministry of Social Affairs and Health

- Nutrition policy
- Risk management
- Risk communication

Location: Helsinki
http://stm.fi/en/frontpage

In the food sector, the Ministry of Social Affairs and Health (STM) deals with public health and nutrition policy, including legislation on drinking water, GMO propagation, irradiation and radioactivity. The Board of Gene Technology at STM is responsible for coordinating activities under the EC genetic engineering directives. In addition to this, the STM has coordinated an interdisciplinary network of administrative liaison officers who work on issues related to the safe application of nanotechnology.

The National Supervisory Authority for Welfare and Health (Valvira) is a specialist authority within the portfolio of the STM. The portfolio of the STM also encompasses other government authorities such as the National Institute for Health and Welfare (THL), which undertakes research on public health and conducts nutritional risk assessments, and the Radiation and Nuclear Safety Authority (STUK), responsible for environmental risk assessments and other tasks.

Ruokavirasto (Finnish Food Authority), established in 2019, continues the activities of the Finnish Food Safety Authority (Evira). Ruokavirasto operates under the MMM and is the central authority in the field of food and feed safety in Finland. Ruokavirasto plays a leading role in the development and implementation of the national food control programme covering the food chain from “farm to fork”. Some of the inspections are carried out directly by Ruokavirasto, but the main responsibility for the inspections is assigned to regional and municipal authorities.

Ruokavirasto is also responsible for scientific risk assessments and conducts research on food safety. The risk assessments are conducted independently from risk management. Ruokavirasto also acts as the link to consumers and organises risk communication in the field of food safety.

The Finnish Zoonosis Centre located within Ruokavirasto forms a cooperation body between Ruokavirasto and the National Institute for Health and Welfare (THL). This ensures close cooperation between relevant experts in the field of food safety as well as animal and public health. The centre coordinates the monitoring of zoonoses, foodborne outbreaks, and antimicrobial resistance and also compiles the results.
Ruokavirasto’s area of work extends beyond food safety to include, for instance, veterinary medicinal products. The regulatory agency for veterinary drugs, however, is the Finnish Medicines Agency (Fimea).

### Tukes
**Finnish Safety and Chemicals Agency**
- Risk assessment
- Risk management
- Risk communication

Location: Helsinki, Tampere, Rovaniemi
http://www.tukes.fi/en

The Finnish Safety and Chemicals Agency (Tukes) supervises and promotes technical safety and conformity, together with consumer and chemicals safety in Finland. Tukes is the regulatory agency for pesticides and it assesses the risks of pesticide residues. Tasks related to pesticides are under the remit of Ministry of Employment and the Economy.

### Valvira
**National Supervisory Authority for Welfare and Health**
- Risk assessment
- Risk management

Location: Helsinki
http://www.valvira.fi/web/en/front-page

In the field of food safety, the National Supervisory Authority for Welfare and Health (Valvira) is responsible for the supervision of tap water. In addition to this, Valvira supervises pesticide residues in alcohol products.

### Finnish Customs
- Risk management

Location: Helsinki
http://www.tulli.fi/en/frontpage

Finnish Customs (under the Ministry of Finance) is the competent authority for the import of food of non-animal origin. (Ruokavirasto controls the import of animal-based foodstuffs such as meat, fish and milk). Customs also inspects some of the so-called ‘combined foodstuffs’, which include refined animal-based ingredients in addition to ingredients of a plant origin.

### Regional and local levels
Finland is divided into six regions which are managed by Regional State Administrative Agencies. These regional agencies are under the Ministry of Finance. The regions are further subdivided into self-governing municipalities. Food control as well as control of animal health and welfare is carried out by 62 local environmental health care control units which report to the municipalities.

In addition, controls in the area of animal identification, registration, animal feed and plant health are carried out on behalf of Ruokavirasto by 15 regional Centres for Economic Development, Transport and the Environment (supervised by the Ministry of Employment and the Economy).
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. University of Helsinki (Helsingin yliopisto)
2. Natural Resources Institute Finland (Luonnonvarakeskus – Luke)
3. Finnish Food Authority (Ruokavirasto) (EFSA Focal Point)
4. Finnish Environment Institute (Suomen ympäristökeskus – SYKE)
5. National Institute for Health and Welfare (Terveys ja hyvinvoinnin laitos – THL)
6. University of Turku (Turun yliopisto)

Government measures with regard to food safety take into account scientific knowledge and, more particularly, scientific risk assessments.

In France, in the area of food safety, there is a clear distinction between risk assessment and risk management. Risk assessments are conducted and scientific opinions are prepared by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), and with regard to genetically modified organisms (GMOs), by the High Council for Biotechnology (HCB), and are publicly available through publication on their websites (unless prohibited by statutory provisions).

Risk management is mainly under the authority of three general directorates in three ministries: the Directorate General for Food (DGAL, MAF), the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF, MEF) and the Directorate General for Health (DGS, MSH).

ANSES also has risk management responsibilities in the areas of veterinary drugs and plant protection products.

The ministries use risk assessments prepared by ANSES, and in the case of GMOs, by HCB, as the scientific foundation for risk management measures.

These three general directorates have a dual responsibility:

- ‘political’ – through the development of regulations at the national level and also through a central administration that ensures French representation in international and European authorities.
- ‘operational’ – through decentralised services located in each region and department in France whose mission is to control the implementation of health and food regulations.

Risk communication is conducted by the ministries and by ANSES when relevant. The Codex Contact Point in France is located at the Secrétariat général des affaires européennes (General Secretariat for European Affairs), which is under the authority of the Prime Minister.
In the field of food safety, the Ministry of Agriculture and Food (MAF) is responsible for agricultural policy, the safety of food of animal or plant origin and the safety of animal feed. MAF prepares draft legislation in this area and is also responsible for controls and inspection. MAF is also responsible for fighting food crime.

MAF’s portfolio encompasses plant protection products, including residues, veterinary medicinal products, GMOs and zoonoses.

The area of work of MAF extends beyond food safety to include plant health, plant protection, animal health and animal welfare. In France there are two RASFF contact points, one is at MAF and the other at MEF.

The Ministry of Economy, Finances and Recovery, Directorate General for Competition Policy, Consumer Affairs and Fraud Control (MEF) is responsible for consumer policy, including state food inspections of all products of non-animal origin. The portfolio of MEF includes animal feed, biological hazards (microbiology / hygiene) in food of non-animal origin, GMOs in food of non-animal origin (other aspects with regard to GMOs are covered by MAF), contaminants, emerging risks, food contact materials and packaging, food ingredients, food supplements, nanotechnology, novel foods, nutrition, plant protection products and pesticides (residue).
The Ministry of Solidarity and Health (MSH) Directorate General for Health deals with public health policy, food safety, and mineral and drinking water. MSH defines objectives and priorities for public health policy, sets the legislative and regulatory framework, develops public health plans and national health programmes and ensures their implementation. In collaboration with MAF, MSH is in charge of investigations on foodborne diseases.

In compliance with the European regulatory framework for GMOs, ANSES participates in the assessment of GMO dossiers together with HCB.

The agency also assesses the effectiveness and risks of veterinary medicinal products, plant protection products, fertilisers, growing media and their adjuvants, as well as biocides, with a view to delivering marketing authorisations. It also provides assessments of chemicals within the framework of the European REACH regulations.

ANSES reports to five ministries, three of which have responsibilities in the area of food safety (agriculture, health, economy). These ministries use risk assessments prepared by ANSES as basis for risk management measures.

ANSES undertakes monitoring, alert, vigilance, research and reference activities. It also defines, implements and funds scientific and technical research programmes. The agency relies on a network of nine reference and research laboratories which operate in three main areas: animal health and welfare, food safety (chemical and microbiological), and plant health and hold numerous reference mandates (65 national mandates, 13 EU, and 29 international: WHO, FAO, OIE).

Created on 1 July 2010, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) is a scientific body active in the fields of food safety, occupational and environmental health, animal health and welfare, and plant health. ANSES’s core activity is to conduct independent and pluralistic expert assessments in order to evaluate health risks and provide the competent authorities with scientific data and recommendations that are essential to take the necessary measures preserve public health. These assessments are carried out with the support of 15 scientific expert committees and related ad hoc working groups involving more than 800 external scientific experts.

Established by the Genetically Modified Organisms Act (GMO Act) of 25 June 2008, the High Council for Biotechnology (HCB) gives independent advice to the French government on all issues relating to GMOs and other types of biotechnology. It reports to the ministries responsible for the

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**ANSES**
**French Agency for Food, Environmental and Occupational Health & Safety**

- Risk assessment
- Risk management
- Risk communication
- EFSA Focal Point
- Research, scientific & technical support

Seat: Maisons-Alfort
https://www.anses.fr/en

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**HCB**
**High Council for Biotechnology**

- Risk communication
- Risk management

Location: Paris
http://www.hautconseildesbiotechnologies.fr/en
France consists of 13 regions and 101 departments (five departments and regions are located overseas). Feed and food inspections are carried out by the decentralised services (regional and local offices) of the three ministries in charge of food and feed safety.

To carry out these tasks, HCB consists of two committees: a Scientific Committee (SC) and an Economic, Ethical and Social Committee (EESC).

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. French Agency for Food, Environmental and Occupational Health & Safety (ANSES) (EFSA Focal Point)
2. French National Research Institute for Agriculture, Food and Environment (INRAe)
3. High Council for Biotechnology (HCB)
4. French Agriculture Research Centre for International Development (CIRAD)
5. National Veterinary School of Alfort (EnvA)
6. Institut Pasteur de Lille
7. Institute for Higher Education and Research in Food, Animal Health, Agronomic and Environmental Sciences (VetAgro Sup)
8. Université de Bretagne Occidentale (UBO)
9. National Veterinary School of Toulouse (ENVT)
10. French Research Institute for Exploitation of the Sea (Ifremer)
11. National College of Veterinary Medicine, Food Science and Engineering, Nantes Atlantique (Oniris)
12. University of Burgundy (uB)
13. University of Reims Champagne Ardenne (URCA)
15. French Alternative Energies and Atomic Energy Commission (CEA)
16. University of Rouen Normandy

Regional and local levels

France consists of 13 regions and 101 departments (five departments and regions are located overseas). Feed and food inspections are carried out by the decentralised services (regional and local offices) of the three ministries in charge of food and feed safety.

In particular, HCB has the tasks of:

- assessing the safety of biotechnology: It provides opinions on national biomonitoring and on the risks to public health and the environment of various possible uses of GMOs;
- studying society-related aspects of biotechnology: It specifically gives advice on the social and economic impact of GMOs and considers the ethical issues that they raise.

To carry out these tasks, HCB consists of two committees: a Scientific Committee (SC) and an Economic, Ethical and Social Committee (EESC).

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To carry out these tasks, HCB consists of two committees: a Scientific Committee (SC) and an Economic, Ethical and Social Committee (EESC).
3.11 Germany

The central legal foundation for food legislation in Germany is the Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch*), and the legislative responsibilities lie almost exclusively with the Federal Ministry of Food and Agriculture (BMEL) and its subordinate authorities. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are generally based on scientific risk assessments.

In Germany, risk assessment and risk management are institutionally separated at the federal level. However, at the regional level (i.e. the 16 federal states), risk assessment and risk management are not institutionally separated. Food safety laws are enacted at the federal level, but competence for official food control lies with the federal states.

Risk assessments are usually published on the Internet unless there are statutory provisions prohibiting it.

The Federal Ministry of Food and Agriculture (BMEL) is responsible for agricultural policy and food safety. In the field of food safety, BMEL prepares draft legislation and issues related to statutory regulations. BMEL is assisted by several scientific Advisory Boards (ABs), such as for the Agricultural Policy, Food and Consumer Health Protection, Biodiversity and Genetic Resources. The institutions within the BMEL’s portfolio include higher federal authorities, legally independent institutions, the federal research centres, institutions belonging to the Leibniz Association and recipients of institutional grants.

BMEL is the central competent authority (CCA) for EU legislation in the field of foodstuffs and food hygiene, for GMOs in food and feed, and for negotiations on legislative provisions concerning food safety and their transposition into national law. Furthermore, it is the CCA in the area of plant health, for animal welfare, and for EU legis-
lation related to Maximum Residue Limits (MRLs) in foodstuffs of plant and animal origin.

BMEL is responsible for general food hygiene under Regulation (EC) No. 852/2004. It is also responsible for drawing up the report on the controls carried out by the Länder authorities on the marketing and use of plant protection products, pursuant to Art. 68 of Regulation (EC) No. 1107/2009.

In the field of animal nutrition, it is responsible for drafting legislation at the federal level and for coordinating its implementation with the assistance of the Federal Office of Consumer Protection and Food Safety (BVL). Regarding food safety risks, BMEL receives advice from the German Federal Institute for Risk Assessment (BfR).

BMEL encompasses the federal research institutions involved in the EFSA network pursuant to Article 36, which give advice on various matters. These include the Friedrich-Loeffler-Institut (FLI) in the area of animal diseases, animal welfare, animal husbandry, animal nutrition and farm animal genetics, the Julius Kühn Institute (JKI) with regard to plant health and plant protection matters, and the Max Rubner-Institut (MRI) in the field of nutrition and food. Furthermore, as part of the Article 36 network, the Thünen Institute (TI) provides advice on matters concerning plant health, genetically modified organisms, animal health and welfare, as well as environmental risk assessments.

Well-founded scientific insights are crucial for political decisions. BMEL can draw on its well-positioned specialist research institutions. This departmental research includes the four federal research institutes as well as the German Federal Institute for Risk Assessment (BfR) and the German Biomass Research Centre (DBFZ - Deutsches Biomasseforschungszentrum). Innovative research and competent scientific policy advice are closely linked tasks undertaken by these institutions.

The remit of the German Federal Institute for Risk Assessment (BfR) encompasses scientifically based risk assessments as part of administrative procedures (for instance, marketing authorizations for plant protection products), the compilation of expert reports on issues of food safety and consumer protection based on internationally recognised scientific assessment criteria, and policy advice. In its capacity as a scientific body, the BfR prepares expert reports on risk assessment. The BfR collaborates at the national and international level with other scientific organisations which are active in consumer health protection and food safety. Furthermore, the BfR is tasked with identifying new health risks and drawing up risk minimisation recommendations, it has a legal mandate to conduct research in fields regarding its work on consumer health protection and food and feed safety as well. The BfR is independent regarding its scientific assessment, research and communication. Research findings are used to provide information and scientific advice to BMEL and other ministries as well as to regional and local public authorities.

The BfR’s remit also includes documentation on poisoning incidents, the evaluation of methods to replace or supplement animal testing, and the
assessment of developmental trends of zoonotic pathogens (including antibiotic resistance). Other main areas of its work are research and transparent communication of risks to the public at large, scientific circles and other stakeholders. A list of its responsibilities can be found in the German Act on the Reorganisation of Consumer Health Protection and Food Safety.

In addition, the BfR is also responsible for risk assessments and risk communication in the area of safety of consumer products, cosmetics, biocides and chemicals (REACH). Furthermore, the BfR collects and evaluates notifications of intoxication caused by chemicals. It carries out risk assessments on plant protection products and biocidal products in relation to toxicology and residues. Also methods for residues analysis are evaluated for control purposes.

Fourteen National Reference Laboratories (NRLs), active in the fields of food and feed safety as well as food hygiene, are attached to the BfR pursuant to Regulation (EU) 2017/625. They are NRLs for Salmonella, Monitoring of Marine Biotoxins, Foodborne Viruses, Listeria monocytogenes, Coagulase-positive Staphylococci including Staphylococcus aureus, Escherichia coli including Verotoxin-producing E. coli, Campylobacter, Trichinella, Antibiotic Resistance, Animal Proteins in Feed, Additives for Use in Animal Nutrition, Food Contact Materials, Mycotoxins and Plant Toxins in Feed and Food as well as for Halogenated Persistent Organic Pollutants (POPs) in Feed and Food, respectively. In addition to these NRLs based on EU law, other laboratories with a reference function are also attached to the BfR. These include the reference laboratory in the network of genetically modified organisms (GMO), the top appraisal body for the import control of wine in accordance with the wine monitoring regulation, zoonosis reporting, and the consultant laboratories for Leptospira, Yersinia as well as Vibrios.

An essential part of socio-scientific risk research at the BfR is the development of effective risk communication strategies. Here, the outcomes of scientific risk characterisations are merged with the information needs of relevant target groups from science, economics, politics, public institutions, (consumer) associations, the media, NGOs and consumers. Comparison of individual risk perceptions with results coming from scientific risk assessments and descriptions of scientific uncertainty are prerequisites for conducting subsequent participatory risk communication measures.

BVL
Federal Office of Consumer Protection and Food Safety

- Risk management and communication
- Coordination of food control and monitoring, including zoonoses
- Crisis management, warning systems
- SANTE/f, RASFF and AAC contact point
- Regulatory science
- Food supplements, dietary and novel food
- Cosmetics, tobacco, consumer products
- Food fraud
- Food borne diseases
- Data management

Locations: Braunschweig and Berlin
https://www.bvl.bund.de/EN/Home/home_node.html

The main focus of the Federal Office of Consumer Protection and Food Safety (BVL) is on risk management. In the field of food safety, BVL supports the cooperation between BMEL, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and the federal states. Together with the federal states, BVL coordinates programmes for control of food and monitoring, including monitoring of zoonoses. On behalf of the federal states, BVL hosts the Com-
BVL is the regulatory authority for plant protection products and veterinary medicinal products. In its decision-making process, BVL generally draws on BfR risk assessments except for the authorisation of veterinary medicinal products where the expertise and responsibility are allocated at BVL. Based on risk assessments by other authorities, BVL decides on applications for the experimental scientific cultivation of genetically modified plants. Furthermore, BVL is involved in the EU marketing authorisation of genetically modified organisms (GMOs) in food and feed, feed additives and feedstuffs for particular nutritional purposes (dietetic feed).

The European Union Reference Laboratory (EURL) for residues of veterinary medicines and contaminants in food of animal origin and eight National Reference Laboratories (NRLs) are attached to the BVL pursuant to Regulation (EU) 2017/625. Through their work, comparable procedures and results are ensured.

In addition to food and feed safety, the activities of the BVL extend, amongst other things, to cosmetics, tobacco, and consumer products which come into contact with food or human skin.

The work of the Friedrich-Loeffler-Institut (FLI) focusses on farm animal health and welfare and on the protection of humans from zoonoses, i.e. infections which can be transmitted from animals to humans. These tasks are defined in Section 27 of the Animal Health Act. FLI conducts basic and applied research in different scientific fields.

As a federal research institute and independent higher federal authority under BMEL, FLI provides advice for political decision-making based on its scientific expertise. The institute performs epidemiological investigations during outbreaks of animal diseases and prepares risk assessments on various infectious diseases of farm animals.

FLI acts as the National Reference Laboratory for designated animal diseases and is the national licensing authority for veterinary in vitro diagnostics. Internationally, FLI has been designated as the ‘Collaborating Centre for Zoonoses in Europe’ of the World Organization for Animal Health (OIE) and hosts nine OIE reference laboratories as well as a WHO Collaborating Centre for Rabies Surveillance and Research and two FAO Reference Centres (Classical Swine Fever, Animal Influenza and Newcastle Disease).

Furthermore, FLI is a member of the EU Reference Centre for Animal Welfare. As the national contact point, FLI scientifically supports the com-
The Julius Kühn Institute (JKI) is an independent higher federal authority and research institution. It is subordinate to BMEL. Tasks are stipulated in the German Crop Protection Act and the Gene Technology Act. The main task is to advise the German Federal Government concerning issues related to crop production, soil science, plant genetics, plant breeding, plant protection, plant health and bee protection.

Within the framework of zonal evaluation procedures as well as EU and national approval procedures, JKI evaluates plant protection products and their active ingredients for application on cultivated plants with regard to their efficacy and phytotoxicity. The effects on bees, non-target and useful organisms are also assessed. A further task closely related to the evaluation of plant protection products is the testing and listing of plant protection equipment to assess its suitability to meet application requirements.

JKI develops early warning systems, analyses and evaluates the risks of introduction, spread and harmful effects of quarantine pests and invasive alien species. JKI develops measures to prevent their introduction and spread and for their eradication. As the National Reference Laboratory for the diagnosis of pests on plants, JKI is the central point in the network of EU reference laboratories and diagnostic laboratories in Germany. JKI is involved in the approval procedure for the release and marketing of genetically modified organisms (GMOs). JKI investigates if and how new biotechnological processes should be applied in plant breeding and how they should be integrated into sustainable plant production and what risk potentials and possible need for regulation are associated with this.

The Max Rubner-Institut (MRI) advises BMEL in the field of consumer health protection in the nutrition sector. Important research priorities are the investigation of the nutritional and health-related value of food, work in the field of food safety, and quality and bioprocess engineering. The effect of nutrition is considered from the molecular and cellular level up to the whole organism. Research on nutritional behaviour and the influence of nutrition on the development of children are of particular importance. MRI addresses beneficial nutritional effects of food, food constituents as well as novel foods. It advises BMEL in terms of dietary prevention of non-communicable diseases and contributes to the process of conducting benefit assessments of food. Four of the nine departments conduct research on a specific food category, such as...
cereals, fats and oils, milk, fish, fruit, vegetables and meat. These departments focus on the entire food chain, from harvesting and production up to consumption.

MRI collaborates with the departmental research institutes within the remit of BMEL, especially in the fields of nanotechnology, bacteriophages and pathogens (including zoonoses) in the food chain, trans-fatty acids, mineral oil components, plant toxins and mycotoxins as well as ergot and ergot alkaloids in foods and raw materials, standardization of analytical methods, and development of minimising strategies for undesirable substances in different foods and products. A network of experts in food authenticity as well as the validation of analytical methods relevant for the fight against food fraud is under development.

Germany consists of 16 federal states (Länder) that vary greatly with regard to the size of each state (between approximately 1 and 18 million inhabitants per state). The 16 federal states of Germany are, in principle, responsible for the implementation of laws. Therefore, every state is responsible for the implementation of food and feed safety. The federal government supervises the federal states to ensure correct execution of the federal laws. In this task, the federal states are independent, i.e. not bound by instructions of the federal government.

In Germany, the federal states are responsible for food control. In most federal states, food control is divided into three levels: At the uppermost level, the responsible ministry coordinates the food control. Below that, the provincial authorities or the regional government offices are responsible for the supervisory control of the food control authorities in the district or municipal authorities (‘Kreise und Kreisfreie Städte’). These local offices for food and veterinary control carry out the investigations locally.

EFSA-relevant activities at the TI focus on animal health and welfare, genetically modified organisms, environmental risk assessments, possible contaminants and their impact on humans (e.g. microplastics in fish and soils) and certain areas of plant health. Several of these activities are embedded in co-operations with FLI, JKI, MRI and other scientific partners in Germany and abroad.
4. Julius Kühn Institute (JKI) – Federal Research Centre for Cultivated Plants (Bundesforschungsinstitut für Kulturpflanzen)

5. Max Rubner-Institut (MRI) – Federal Research Institute of Nutrition and Food (Bundesforschungsinstitut für Ernährung und Lebensmittel)

6. Johann Heinrich von Thünen Institute (TI) – Federal Research Institute for Rural Areas, Forestry and Fisheries (Bundesforschungsinstitut für Ländliche Räume, Wald und Fischerei)
Regulation (EC) No. 178/2002 is the central legal foundation for food legislation in Greece. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Greece, there is no institutional separation of risk assessment from risk management in any sector.

MRDF implements horizontal and vertical legislation in the area of food and feed and is responsible for the coordination of food safety inspections, in cooperation with EFET. The bases for MRDF management measures are the risk assessments undertaken by MRDF itself or its supervised organisations. MRDF also engages in transparent communication with consumers on topics of food and feed safety. MRDF is also responsible for feed safety, residues of plant protection products and veterinary medicinal products, genetically modified organisms (GMOs) and zoonoses. MRDF monitors veterinary inspections by local authorities and is the regulatory authority for pesticides (plant protection products and biocides).

The area of work of MRDF extends beyond food safety to include, for instance, plant health, plant protection, animal health, animal welfare and biocides.


The Ministry of Rural Development and Food (MRDF) is responsible for agricultural policy and safety of agricultural (food) products in Greece.
The Ministry of Health (MH) deals with the determination of sanitary conditions and control measures for enterprises subject to public health regulations, the national nutrition policy focusing on health promotion, the surveillance of the quality of water intended for human consumption, and the provision of guidelines regarding:

- quality assurance and surveillance of bottled waters,
- issuance of permits for bottling factories,
- health control of bottling factories.

EFET supervises food inspections in Greece. EFET's central services monitor and coordinate tasks of regional EFET authorities. Risk assessments are compiled by a scientific advisory body (ESET) established within EFET. Risk assessments are the basis for risk management measures and their corresponding communication. The risk assessment work of EFET is performed in an independent fashion.

The area of work of EFET extends beyond food safety to include labelling, nutrition and health claims, nutrition policy, training, communication with stakeholders, etc.

The Hellenic Food Authority (EFET) is a subordinate authority of MRDF. EFET ensures that food produced, distributed or marketed in Greece meets food safety and hygiene standards as described by national and European legislation.

The National Organization for Medicines (EOF) is a public entity administratively under MH. The task of EOF is to ensure public health and safety of medicinal products for human and veterinary use. The remit of EOF also includes foodstuffs intended for particular nutritional uses, food supplements, specific product types of biocides, medical devices and cosmetics. EOF is the regulatory authority for veterinary medicinal products and all health-related products in Greece. It monitors the post-marketing product quality, safety and efficacy. EOF proposes and promotes medical and pharmaceutical research. EOF also supplies the public and health professionals with objective information on medicines (for human and veterinary use) and other health-related
products to ensure their safe and rational use and to support optimal cost effectiveness.

### BPI
Benaki Phytopathological Institute

- Research
- Risk assessment

Location: Athens  
http://www.bpi.gr

The Benaki Phytopathological Institute (BPI) is a research institute, public sector entity that works independently in the field of science and operates under the supervision of the MRDF. BPI is responsible for the evaluation and risk assessment of plant protection products and specific product types of biocides. Regarding plant health, BPI performs risk assessments for emerging harmful organisms.

The research conducted at BPI is aimed to address various needs and requirements of the agricultural sector. The main scientific disciplines covered by BPI are related to phytopathology, entomology & agricultural zoology, pesticide safety for human health, non-target species and the environment.

### ELGO – Demeter
Hellenic Agricultural Organisation – Demeter

- Research
- Risk assessment
- Risk management

Location: Athens  
http://www.elgo.gr

ELGO – Demeter is a public benefit, independent body under the supervision of MRDF, and is governed by private law. The main objective of ELGO – Demeter is to develop and/or support actions aimed at modernizing and developing the country’s agricultural sector, improving production processes, enhancing competitiveness, certifying quality agricultural products and food (e.g. origin and identity of products), establishing and certifying good agricultural practices and implementing controls in the milk and meat production chain in the country. Furthermore, ELGO – Demeter organises and operates vocational educational training and schools.

### NPHO
National Public Health Organization

- Risk assessment
- Risk communication
- Risk management

Location: Athens  
https://eody.gov.gr/

The National Public Health Organisation (NPHO) is a legal entity governed by private law under the supervision of MH. It is responsible for the surveillance of food borne and water borne sporadic disease cases and outbreaks, and for the coordination of investigations of food borne and water borne disease outbreaks at the national level.

### Regional and local levels

Regional and local levels in Greece consist of seven decentralised administrations, 13 regions and 325 municipalities. 13 regional EFET authorities and local authorities are responsible for the implementation of food inspections. MRDF and EFET are responsible for coordinating regional food inspections.
Both the central General Chemical State Laboratory and the regional Chemical Services are under the supervision of the Independent Authority for Public Revenue and are responsible for the laboratory analyses of foodstuffs.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Hellenic Food Authority (EFET) – Ενιαίος Φορέας Ελέγχου Τροφίμων (EFSA Focal Point)
2. Benaki Phytopathological Institute (BPI) – Μπενάκειο Φυτοπαθολογικό Ινστιτούτο
3. National and Kapodistrian University of Athens (NKUA) – Εθνικό και Καποδιστριακό Πανεπιστήμιο Αθηνών
4. University of Crete (UC) – Πανεπιστήμιο Κρήτης
5. Hellenic Agricultural Organisation – DEMETER (ELGO-Demetra) – Ελληνικός Γεωργικός Οργανισμός ΔΗΜΗΤΡΑ
6. Ministry of Rural Development and Food (MRDF) – Υπουργείο Αγροτικής Ανάπτυξης και Τροφίμων
7. National Centre for Scientific Research “Demokritos” (NCSR Demokritos) – Εθνικό Κέντρο Ερευνας Φυσικών Επιστημών Δημόκριτος
8. University of Thessaly (UTH) – Πανεπιστήμιο Θεσσαλίας
9. Aristotle University of Thessaloniki (AUTH) – Αριστοτελείο Πανεπιστήμιο Θεσσαλονίκης
10. University of Patras (UPatras) – Πανεπιστήμιο Πατρών
The Food Chain Act is the central legal foundation for food legislation in Hungary. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Hungary, the National Food Chain Safety Office (NÉBIH) is responsible for risk management and risk assessment. Risk assessments are not published on the Internet yet.

The portfolio of the AM includes soil, plant health, feed, food, genetically modified organisms (GMOs), zoonoses, mineral water and drinking water. The AM also deals with residues of plant protection products and veterinary medicinal products, however the regulatory authority for pesticides and veterinary drugs is the NÉBIH.

The ministry formulates government measures related not only to rural development, but also to the supervision of food chains, environmental protection and the agricultural economy. The ministry’s main goals are the sustainable management of natural resources, diversity of rural land use, rural development and creating conditions for the safe and high-quality production and distribution of food products.
The State Secretariat for Healthcare is responsible for determining the special rules and for the preparation of legislation related to the direction of healthcare provision on the national level and in higher education institutes. It regulates the national public healthcare tasks.

The area of competence of the Ministry of Human Capacities (EMMI) covers legislation in the field of nutritional health (e.g. nutritional health aspects of mass catering) and is primarily responsible for establishing legislation on food supplements, dietetic products, infant and follow-up formulas, health and nutrition claims and nutrition labelling.

The National Institute of Pharmacy and Nutrition (OGYÉI) operates under the supervision of the Ministry of Human Capacities (EMMI). Amongst other things, the OGYÉI is responsible for the notification of food supplements, foods for particular nutritional uses (infant formulas, complementary foods, gluten-free foods, etc.), cosmetics and biocides used in the food industry and mass catering, and also conducts investigations on food supplements and foodstuffs with nutrition and health claims.

The National Public Health Center (NNK) operates under the supervision of the Ministry of Human Capacities (EMMI) and is led by the Chief Medical Officer. NNK is responsible for coordinating the official supervision of food supplements, foods for particular nutritional uses (foods for special medical purposes, infant formulas, follow-on formulas, fortified foods) and mass catering.

With regard to infectious diseases, NNK performs the duties of the microbiological National Reference Laboratory, collects and manages data on foodborne diseases and shares them with other relevant parties, e.g. NÉBIH and ECDC.
Since 2011, the Prime Minister's Office (ME) has been responsible for funding for staffing and infrastructure and for implementation of the operational programmes.

Administratively, the County Government Offices (CGOs) are under the Prime Minister's Office. The ME has other, non-professional management powers (for example: employer rights) as regards the CGOs.

The system management and supervision directorate coordinates the multi-annual national control plan (MANCP) and is responsible for risk assessments, strategic and risk-based planning of official controls, and for IT system development.

As a result of the cooperative preliminary work of the Ministry of Rural Development and the NÉBIH, the Food Chain Safety Strategy 2013–2022 has been accepted by the government. The strategy determines the most important targets and duties connected to food chain safety, as well as provides guidance on the achievement of these desired goals for the next years.

The National Food Chain Safety Office (NÉBIH) is an independent legal entity with nationwide competence and responsibility operating under the direct supervision of the Minister of Agriculture. Its annual budget is allocated by the government. The NÉBIH has a complex organisational structure with various horizontal and professional directorates and testing laboratories. The NÉBIH covers the whole food chain, from soil to retail distribution as well as catering, in order to facilitate the safety of food and feed production with respect to animal and plant health and soil conservation. The NÉBIH is involved in the authorisation of novel foods.

The Risk Management Directorate supports the activities of the competent authorities (quick risk assessments, risk communication, risk management supporting activities in the case of crisis situations). The directorate is the single national contact point for the Commission Service ACN (Alert and Cooperation Network: RASFF, AAC common network). The directorate is responsible for general communication and for providing early warning programmes related to public awareness and education.

Administratively, Hungary is divided into 19 counties and Budapest. The counties are further subdivided into 174 districts, and Budapest is its own subregion comprised of 23 districts.

At the county level, all authorities involved in official controls of the food chain have been merged and integrated into the County Government Offices (CGOs). Since 01 March 2020, the departments responsible for carrying out official controls in relation to food chain safety and animal health have been operating in new structures and under new names.

The ME is responsible for the direction of the CGOs; the AM is responsible for the professional direction of the units responsible for food chain control. Regarding the official food chain con-
trols, the CGOs implement the control plans following the procedures and guidelines that are all provided by NÉBIH and ordered by the AM.

As of 2015, there are 197 district government offices (DGOs) at the local level. At the district level, there are 82 Food Chain Safety and Animal Health Units (on average, each unit is responsible for 2–3 DGOs).

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. National Food Chain Safety Office (Nemzeti Élelmiszerlánc-biztonsági Hivatal - NÉBIH) (EFSA Focal Point)
2. National Institute of Pharmacy and Nutrition (Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet – OGYÉI)
3. Szent István University (Szent István Egyetem – SZIE)
4. Centre for Agricultural Research (Agrártudományi Kutatóközpont)
5. Research Centre for Natural Sciences (Természettudományi Kutatóközpont)
6. University of Debrecen (Debreceni Egyetem – DE)
7. National Agricultural Research and Innovation Center (Nemzeti Agrárkutatási és Innovációs Központ - NAIK)
8. Budapest University of Technology and Economics (Budapesti Műszaki és Gazdaságtudományi Egyetem – BME)
9. University of Veterinary Medicine Budapest (Állatorvostudományi Egyetem – ÁTE)
Most Irish food legislation derives from Ireland’s membership of the European Union. In Ireland, there is no institutional separation of risk assessment from risk management. Risk assessments are in principle published on the Internet unless there are statutory provisions that prohibit it.

The Department of Health (DoH) is responsible for policy issues in the area of food safety, for formulating and transposing EU regulations and for reviewing national legislation. It provides the governance oversight function for the Food Safety Authority of Ireland on behalf of Government. Its remit covers the retail sectors for food and non-retail processing and distribution of foods of animal and non-animal origin.

The Department of Agriculture, Food and the Marine (DAFM) is responsible for policy development, negotiation at the EU level, implementation in national law of EU rules and official controls in the areas of primary production of food, animal health and welfare, feed safety, plant health, fisheries, slaughtering of animals and processing of foods of animal origin up to but not including the retail level. DAFM carries out risk assessments in the field of animal feed and pesticides. DAFM personnel also enforce food law and conduct risk management of food under contract with the FSAI. DAFM’s enforcement of feed law and associated risk management activities are standalone functions. Eight National Reference Laboratories are attached to DAFM pursuant to Regulation
The Food Safety Authority of Ireland (FSAI) is a statutory, independent and science-based body dedicated to protecting public health and consumer interests in the area of food safety and hygiene. Established in 1999, its principal function is to protect consumers and improve compliance through partnership, science, and food law enforcement. It is an independent agency under the aegis of the Minister of Health.

The FSAI enforces food legislation in Ireland. It does this by managing official control activities through service contract arrangements with other bodies – namely, the Health Service Executive (HSE), the Department of Agriculture, Food and the Marine (DAFM), the Sea-Fisheries Protection Authority (SFPA), local authorities, the Marine Institute (MI) and the National Standards Authority of Ireland (NSAI) – as well as scientific and technical support to other bodies through publications and training, and conducting risk assessments to underpin risk management decisions and actions. The FSAI runs the national RASFF contact point and the Administrative Assistance and Cooperation (AAC) national contact point as well as the national EFSA Focal Point.

The FSAI has a remit to carry out risk assessments, risk management and risk communication relating to food safety.

HSE
Health Service Executive

- Public health
- Environmental health
- Food safety

Location: Kildare
http://www.hse.ie

The Health Service Executive (HSE) was established by the DoH as part of the provisions of the Health Act, enacted in 2004. The Environmental Health Service is part of the HSE and provides a range of food safety and food control services on behalf of the FSAI. It is responsible for official controls at retail level and on foods of non-animal origin. The HSE has nine food laboratories which are official laboratories pursuant to Regulation (EC) No. 882/2004. Two of these laboratories have been appointed as National Reference Laboratories.

The HSE is divided into four geographical regions: Southern Region, Western Region, Dublin Mid-Leinster Region and Dublin North Eastern Region. There are between seven and nine environmental health sections in each region and 39 nationally.
The Sea-Fisheries Protection Authority (SFPA) is responsible for the implementation and enforcement of national and EU legislation that deals with health conditions for the production and placing on the market of fish, shellfish and fishery products. Its remit extends from harvesting and catching through to fish and fish products being placed on the market, but excluding products for retail sale, which are supervised by the HSE. The SFPA has six offices in the major ports around the coast.

The Sea-Fisheries Protection Authority

Location: Cork
http://www.sfpa.ie

The National Standards Authority of Ireland (NSAI) is responsible for the development of Irish standards, representing Irish interests in the work of the European and international standards bodies CEN and ISO, the recognition of natural mineral waters and controls on suppliers of food contact materials.

The National Standards Authority of Ireland

Location: Dublin
http://www.nsai.ie

The Marine Institute (MI) is responsible for implementation of aquatic animal health legislation under EU and National legislation and monitors the movement of finfish and shellfish into and within Ireland. The MI is the National Reference Laboratory for finfish, molluscs and crustacean disease. It provides scientific advice and support services to both the FSAI and SFPA.

The Marine Institute

Location: Galway
http://www.marine.ie

The Local Authority Veterinary service is a collective of veterinary inspectors based in local authorities and subject to 25 service contracts with FSAI. They act independently and locally in their work enforcing food law in small slaughter establishments and meat processing plants.

The Local Authority Veterinary Service

Locations: one in each of the 32 counties of Ireland

Food law compliance in small slaughter and meat establishments
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Department of Agriculture, Food and the Marine
2. Food Safety Authority of Ireland
3. Limerick Institute of Technology
4. Marine Institute
5. Maynooth University
6. National University of Ireland, Galway
7. safefood (Food Safety Promotion Board)
8. Teagasc, The Agriculture and Food Development Authority
9. Trinity College Dublin
10. University College Cork, National University of Ireland, Cork
11. University College Dublin
Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law is the central legal foundation for food legislation in Italy. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts.

Government measures concerning food safety are based on scientific evidence and, more particularly, on scientific risk assessments.

In Italy, risk assessment and risk management are institutionally separated. Risk assessments are usually published on the Internet.

In Italy, most of the mandates for food and feed safety, animal health and animal welfare are assigned at the national level to the Ministry of Health (MdS) (reorganised by the Decree of the President of the Council of Ministers No. 59 of 11 February 2014), and, in particular, to the:

- Directorate General for Animal Health and Veterinary Medicine (DGAHVM)
- Directorate General for Food Hygiene, Food Safety and Nutrition (DGFHFSN)
- Directorate General of Collegial Bodies for Health Protection (DGCBHP) (Offices 2 and 3)
- General Secretariat (Office 3).
The Directorate General of Collegial Bodies for Health Protection (DGCBHP) is the national reference authority for the European Food Safety Authority (EFSA) and is the EFSA Focal Point in Italy. Its Director General is a member of EFSA’s Advisory Forum. The DGCBHP is responsible for coordinating risk assessment processes and implementing risk assessments for physical, chemical and biological hazards for food safety purposes.

In addition, the DGCBHP is responsible for consulting with consumer and producer associations, undertaking preliminary investigations and coordinating risk assessment processes. All activities related to risk assessments and consultations with associations are carried out with the support of the two specific sections of the National Committee for Food Safety (CNSA). In particular, the Food Safety Section provides scientific advice at the request of the central competent authorities as well as the competent authorities of the regions and autonomous provinces.

The remit of the MdS includes official controls during import of food and feed, general food and feed hygiene, novel food, food supplements, labelling and nutrition, food contact materials, genetically modified organisms (GMOs), zoonoses, residues of plant protection products, and veterinary medicinal products. The MdS is the regulatory authority for plant protection products and veterinary medicinal products and may conduct audits and inspections of the regional competent authorities.

Italy introduced administrative sanctions against violations of Regulation (EC) No. 178/2002 by Legislative Decree No. 190/2006, and implemented the EU Hygiene Package by Legislative Decree No. 193/2007, which identifies the national competent authorities for official controls. In cases where an identified nonconformity may represent a danger to public health, criminal charges will also be brought.

All control activities performed by the central and local competent authorities are integrated in a multi-annual national control plan (MANCP) developed in compliance with the principles and guidelines laid down in Regulation (EC) No. 882/2004, according to which plans shall be based on risk assessment (Regulation (EC) No. 178/2002) and risk categorisation (Regulation (EC) No. 882/2004).

The MANCP is developed in collaboration with all competent authorities: the Istituto Superiore di Sanità (ISS – National Institute of Health), the Experimental Zooprophylactic Institutes (IZSs), the Ministry of Agricultural, Food and Forestry Policies (MiPAAF), the Ministry of Environment, the regions and autonomous provinces, the Customs Agency, the Carabinieri for Health Protection (NAS), the State Forestry Corps (CUFAA), the port authorities, and the Ministry of Finance’s Police Force.

MiPAAF
Ministry of Agriculture, Foodstuff and Forestry Policies

- Agricultural policy
- Controls on quality, labelling and traceability of food and feed
- Some aspects in the field of plant protection products and fertilisers
- Risk communication
- Risk management
- Codex Contact Point

Location: Rome
http://www.politicheagricole.gov.it

Within the Ministry of Agriculture, Foodstuff and Forestry Policies (MiPAAF), the Department of Competitive Policies is responsible for the coordination of activities related to the quality of agricultural products and food. The Directorate General of Competitive Policies for Rural Development is responsible for plant health, seeds, propagation material, fertilisers and some aspects of the field of plant protection products, as well as for husbandry and products of animal origin.
At the national level, the National Institute of Health (ISS) is a technical and scientific public body of the Italian National Health Service. The ISS (which is under the remit of MH) supervises the laboratories of the Italian National Health Service engaged in food and feed control and performs confirmatory analyses. Its activities include research, control, training and consultation in the interest of public health protection. One of the activities carried out by the institute consists in supporting inspections and quality controls of food products and packaging at the request of the Ministry of Health or the regions.

The Central Inspectorate for Fraud Repression and Quality Protection of the Agri-food Products and Foodstuffs (ICQRF) is the law enforcement body of the MiPAAF responsible for fraud prevention. It carries out controls on labelling and quality of foodstuffs, agricultural product feed, fertilisers and plant protection products via its own laboratory network. All the official laboratories, including those mentioned in the ‘Regional and local levels’ section, are accredited for specific activities by the National Accreditation Body (ACCREDIA), nominated by the government under Regulation (EC) No. 765/2008 and operating under the supervision of the Ministry of Economic Development.

At the national level, the National Institute of Health (ISS) is a technical and scientific public body of the Italian National Health Service. The ISS (which is under the remit of MH) supervises the laboratories of the Italian National Health Service engaged in food and feed control and performs confirmatory analyses. Its activities include research, control, training and consultation in the interest of public health protection. One of the activities carried out by the institute consists in supporting inspections and quality controls of food products and packaging at the request of the Ministry of Health or the regions.

The 10 Experimental Zooprophylactic Institutes (IZS) are official laboratories operating at the local and national level as technical and scientific public sector bodies of the Italian National Health Service, within the remit of the competent authorities (Ministry of Health and regions). One of the activities carried out by the IZSs consists in supporting inspections and quality controls of food products and packaging, at the request of the Ministry of Health or the regions.

Except for the matters explicitly reserved to the central government, responsibility for controls has been devolved to the regional level. The 19 regions and 2 autonomous provinces have responsibility, within their territories, for planning, coordination, guidance, authorisation, and verification, while the operational implementation of controls is handled at the local level by 99 local units with a high degree of managerial autonomy. Local units are responsible for local controls on animal health, animal welfare and food both of animal and non-animal origin.

The analyses are conducted by official laboratories: the network of the 10 IZSs, the network of 27 Regional Agencies for Environment Protection (ARPA) and the network of 16 public health laboratories.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Ministry of Health (MdS), Directorate General of Collegial Bodies for Health Protection (DGCBHP) (EFSA Focal Point)
2. Italian National Institute of Health (Istituto Superiore di Sanita, ISS)
3. Council for Agricultural Research and Economics (Consiglio per la ricerca in agricoltura e l’analisi dell’economia agraria, CREA)
4. National Research Council (Consiglio Nazionale delle Ricerche, CNR)
6. Experimental Zooprophylactic Institute of Abruzzo and Molise Regions (Istituto Zooprofilattico Sperimentale dell’Abruzzo e del Molise ‘G. Caporale’, IZS AM)
7. Experimental Zooprophylactic Institute of Apulia and Basilicata (Istituto Zooprofilattico Sperimentale della Puglia e della Basilicata, IZSPB)
8. Experimental Zooprophylactic Institute of Lazio and Tuscany (Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana, IZSLT)
10. Experimental Zooprophylactic Institute of Piedmont, Liguria and Aosta Valley (Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d’Aosta, IZSPLVA)
11. Experimental Zooprophylactic Institute of Sicily (Istituto Zooprofilattico Sperimentale della Sicilia ‘A.Mirri’, IZZSIC)
12. Experimental Zooprophylactic Institute of Umbria and Marche Regions (Istituto Zooprofilattico Sperimentale dell’Umbria e delle Marche, IZSUM)
13. Experimental Zooprophylactic Institute of Venezie (Istituto Zooprofilattico Sperimentale delle Venezie, IZSVe)
15. Università Cattolica del Sacro Cuore
16. Azienda Socio Sanitaria Territoriale (ASST) Fatebenefratelli Sacco
17. University of Eastern Piedmont (Università degli Studi del Piemonte Orientale ‘Amedeo Avogadro’, UNIPMN)
18. University of Bari Aldo Moro (Università degli Studi di Bari ‘Aldo Moro’, UNIBA)
19. University of Foggia (Università degli Studi di Foggia, UNIFG)
20. University of Milan (Università degli Studi di Milano, UNIMI)
21. University of Palermo (Università degli Studi di Palermo, UNIPA)
22. University of Parma (Università degli Studi di Parma, UNIPR)
23. University of Pavia (Università degli Studi di Pavia, UNIPV)
24. University of Perugia (Università degli Studi di Perugia, UNIPG)
25. Sapienza – University of Rome (Sapienza – Università di Roma, UNIROMA1)
26. Veterinary Public Health Institute of Mezzogiorno (Istituto Zooprofilattico Sperimentale del Mezzogiorno, IZSM)
27. Istituto Superiore per la Protezione e la Ricerca Ambientale (ISPRA)
28. University of Napoli Federico II (Università di Napoli Federico II)
29. University of Modena and Reggio Emilia (Università degli Studi di Modena e Reggio Emilia, UNIMORE)
30. Edmund Mach Foundation
31. University of Turin (Università degli Studi di Torino, UNITO)
32. University of Ferrara (Università degli studi di Ferrara UNIFE)
33. University of Padova (Università degli studi di Padova)
34. University of Brescia (Università degli studi di Brescia)
35. Politecnico di Milano
36. University of Catania (Università degli studi di Catania)
37. Veterinary Public Health Institute of Sardinia
Food businesses have to follow both the EU food safety legislation and the national legal acts in the area of food safety and quality. The Law on the Supervision of the Handling of Food is the central foundation for food legislation in Latvia. Infringement of food safety regulations concerning routine checks of food establishments, consumer complaints and outbreaks of foodborne diseases can lead to measures under civil law and, if necessary, under criminal law. Official controls in the area of food safety are carried out on the basis of the risk assessment approach. However, the final decision on the legality of governmental measures rests with the courts.

In Latvia, there is clear institutional separation with regard to the implementation of risk assessment and risk management functions in the area of food safety. Risk assessments are conducted by the Institute of Food Safety, Animal Health and Environment (BIOR), while risk management rests with the Food and Veterinary Service of Latvia. Urgent information with regard to risk assessment and risk management activities, as well as other relevant information for food business operators and consumers is published on the Internet homepage of the competent authorities on a case-by-case basis unless there are statutory provisions that prohibit it.

The Ministry of Agriculture (ZM) is responsible for the development and implementation of policy in agricultural and food and feed safety sectors, including drafting national legal acts for the sectors mentioned above. The ZM cooperates with BIOR as the risk assessment body and with the Food and Veterinary Service and State Plant Protection Service as risk management bodies to decide on necessary measures for risk management purposes. The ZM is constantly involved in risk communication activities at different levels.

In general, the portfolio of the ZM covers topics such as food safety and quality, plant health and plant protection, animal health and animal welfare.
The ZM’s responsibilities include legal regulation of novel foods, food supplements, genetically modified organisms (GMOs), mineral water, as well as development and implementation of monitoring and control programmes in the area of zoonoses, pesticide residues, residues of veterinary drugs and other food and feed contaminants.

The main task of the Ministry of Health (VM) is to develop and implement national policy to safeguard public health and to promote disease prevention by encouraging healthy lifestyles, as well as to create conditions for citizens to receive cost-effective, accessible and quality health care services.

The VM is responsible for the development, coordination and updating of nutrition policy, analysis of the results of foodborne disease monitoring, as well as the preparation of scientific opinions in relation to solving nutrition problems and providing the public with information on current nutrition topics.

The VM is responsible for elaborating recommendations for nutrient and energy intake for different population groups in Latvia and for the development of standards for nutrient and energy intake for children in preschool and school, as well as for residents of social care houses and patients in hospitals.

The VM is involved in the monitoring of the safety and quality of drinking water, with the exception of internal water supplies for food establishments. The Nutrition Council under the VM was set up to support the activities in the field of nutrition.

The VM is constantly involved in risk communication activities at different levels.

The Institute of Food Safety, Animal Health and Environment (BIOR) carries out scientific activities in the food, veterinary, environmental and fishery sectors, as well as in other sectors related to biology. BIOR provides expertise, scientific substantiation and risk assessments in the sectors mentioned above. BIOR implements projects to assess the risk in the field of food safety and animal infectious diseases, ensuring cooperation with institutions and organisations performing activities in these areas. BIOR performs functions of the National Reference Laboratory in the areas defined in the legislation and conducts laboratory and diagnostic investigations related to state monitoring and food movement control, animal health protection, animal feed and veterinary medicine movement. BIOR is Latvia’s designated National Focal Point for the EFSA.
The Food and Veterinary Service (PVD) operates under the supervision of the Ministry of Agriculture. The PVD is responsible for the realisation of the state's surveillance and control function in the area of food safety and quality, as well as in the area of food labelling throughout the entire food chain, including surveillance and border controls of food (“from the field to the table” concept). The PVD is also in charge of the registration and approval of food establishments.

If there is a threat to human life or health, the state’s chief food and veterinary inspector is entitled to specify restrictions or prohibitions on the distribution of food in the territory of Latvia. The PVD is nominated as the official RASFF contact point in Latvia.

The State Plant Protection Service (VAAD) operates under the supervision of the Ministry of Agriculture. The VAAD is responsible for official surveillance and controls in the area of free movement of plant products, fertilisers, plants and plant protection products, plant varieties, seed and planting material. The VAAD collaborates with international organisations and exchanges information with other countries on issues concerning plant protection, plant quarantine, movement of seeds and variety protection rights. The VAAD is responsible for the control of GMOs within seeds and other propagating material.

The Centre for Disease Prevention and Control (SPKC) conducts epidemiologic surveillance and monitoring and maintains related databases, as well as takes the necessary measures to prevent and localise infectious diseases. It carries out public health monitoring, maintains the related reporting system and advises and informs the public on health and healthy lifestyle issues. The SPKC is responsible for the Early Warning and Response System for communicable diseases in the EU (EWRS), performs the tasks of the coordinator of The European Surveillance System (TESSy) and is designated as a Focal Point for WHO and the European Centre for Disease Prevention and Control.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Institute of Food Safety, Animal Health and Environment – ‘BIOR’ (Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts ‘BIOR’) (EFSA Focal Point)
2. State Plant Protection Service (Valsts augu aizsardzības dienests – VAAD)
3. Food and Veterinary Service (Pārtikas un veterinārais dienests – PVD)
4. Latvia University of Life Sciences and Technologies (Latvijas Lauksaimniecības universitāte – LLU)
5. University of Latvia (Latvijas Universitāte – LU)
6. Riga Stradins University (Rīgas Stradiņa universitāte - RSU)
The Lithuanian Law on Food is the central legal foundation for food legislation in Lithuania. It covers requirements for food placed on the market, handling of food, competencies of public authorities in the area of food safety, duties and liability of food producers, food operators and the food trade.

Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Lithuania, risk assessment and risk management are institutionally separated. Risk assessments are published on the Internet.

The State Food and Veterinary Service (VMVT) is accountable to the Government of the Republic of Lithuania, and prepares and implements regulations in the area of food quality, food safety as well as animal health and welfare. Activities of the VMVT are usually based on scientific opinions from the National Food and Veterinary Risk Assessment Institute (NMVRVI).

The VMVT monitors and controls animal health, including outbreaks of zoonoses and other contagious animal diseases. It is the aim of the VMVT to ensure that all necessary biological measures are applied to prevent the introduction of zoonoses and other contagious animal diseases into the territory of Lithuania and the EU.
The VMVT is responsible for official controls of the entire food chain, according to the principle “from farm to fork”. The VMVT monitors food on the Lithuanian market, as well as food intended for export with respect to safety compliance, labelling and other mandatory legal requirements.

As a subordinate specialist authority of the VMVT, the National Food and Veterinary Risk Assessment Institute (NMVRVI) is responsible for science-based risk assessments, identification of new health risks and recommendations for risk reduction. The remit of the NMVRVI includes assessment of biological, chemical and other risk factors in food and feed, zoonoses, and animal health.

One National Reference Laboratory is an integral part of the NMVRVI in accordance with Regulation (EU) No. 2017/625 and performs laboratory tests in the areas of food and feed safety, quality and animal health.

The Ministry of Health (SAM) is responsible for health policy and food safety in Lithuania. The SAM prepares draft legislation in the area of food and food safety, taking into account scientific assessments of risks to human health. The SAM’s portfolio includes food additives, food supplements, maximum permitted concentrations of contaminants in food, addition of vitamins, minerals and other substances to foods, foods for particular dietary uses, irradiated food, genetically modified food, novel food and food contact materials. The SAM also stipulates mandatory requirements to protect the consumer, i.e. food labelling and use of nutrition and health claims. It also stipulates mandatory requirements with regard to the health of persons handling food, required health examination procedures and obligatory hygiene training.

The National Public Health Surveillance Laboratory (NVSPL) is attached to SAM in accordance with Regulation (EU) No. 2017/625.
The Center for Health Education and Diseases Prevention (SMLPC) is a specialist authority within the portfolio of SAM. The SMLPC organises and implements nutrition and food safety education for residents, communities and professionals. The SMLPC carries out regular monitoring of food consumption in Lithuania.

The Centre for Communicable Diseases and AIDS (ULAC) is a specialist authority within the portfolio of SAM. The ULAC is responsible for organising and implementing communicable disease prevention and control in order to reduce the morbidity, mortality and disability of the Lithuanian population. The ULAC also focuses on the prevention and control of food and waterborne diseases and zoonoses at the national level.

The Ministry of Agriculture (ŽŪM) is responsible for food quality and food safety in Lithuania. This includes regulation of food labelling, handling of food, cultivation of crops for human consumption, use of plant protection products as well as organic farming. In collaboration with the Ministry of the Environment and the Ministry of Health, the ŽŪM is involved in the regulation of the use of genetically modified organisms (GMOs).

The State Plant Service (VATŽŪM) is a competent authority under the Ministry of Agriculture. The VATŽŪM implements the strategic goal of the Ministry of Agriculture – to enhance public health and consumer protection with regard to food safety and quality, to ensure plant and animal health controls. The VATŽŪM is responsible for the implementation and the control of the safe application of plant protection products and phytosanitary (plant health) measures.

The VATŽŪM is responsible for the assessment of active substances at the EU level and the nation-
al authorisation of plant protection products and for post-registration control (import, storage, sale, labelling, package and use of plant protection products). The VATŽŪM also controls the cultivation of GM plant crops and the use of propagating materials (including GMOs). In these areas, the VATŽŪM monitors and coordinates the tasks of the 10 regional divisions and 5 border checkpoints with 13 functioning phytosanitary posts (divisions).

VDU
Vytautas Magnus University

- Research

Location: Kaunas  
https://www.vdu.lt/en/

The Vytautas Magnus University (VDU) is a state institution of higher education and research, awarding diplomas and degrees at the PhD, MSc and BSc levels in a wide range of interdisciplinary programmes: from neurotechnologies to bioeconomics, from creative industries to digital humanities, from law and finance to neurotechnologies, and from smart animal husbandry to agrobiotechnologies.

LSMU
Lithuanian University of Health Sciences

- Research
- Risk assessment
- Risk communication

Location: Kaunas  
https://ismuni.lt/en

The Lithuanian University of Health Sciences (LSMU) is one of the largest universities in Lithuania specialized in health, veterinary and agricultural sciences with integrated studies, research and clinical practice. Different levels of studies (BSc, MSc, PhD) are offered to about 7,000 students each year. Integration of fundamental and applied research is aimed to create new knowledge for the improvement of both human and animal health and life quality.

KTU
Kaunas University of Technology

- Research

Location: Kaunas  
https://en.ktu.edu/

The KTU Food Institute is a research unit of Kaunas University of Technology. Its task is to conduct internationally recognised research in food science as well as to solve the main problems of the Lithuanian food industry and provide scientific, practical and methodical services.

The KTU Food institute is working to expand knowledge and innovative technological solutions for the wellbeing of humans within preventive and sustainable food systems, while also developing food supply capabilities for the growing needs of the world.

Scientific activities: development and improvement of balanced and healthy food and food technologies, development of sustainable food systems, ensuring the effectiveness of interaction between consumers and food producers.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. State Food and Veterinary Service (Valstybinė maisto ir veterinarijos tarnyba – VMVT) (EFSA Focal Point)
2. Center for Health Education and Diseases Prevention (Sveikatos mokymo ir ligų prevencijos centras – SMLPC)
3. State Plant Service under the Ministry of Agriculture (Valstybinė augalininkystės tarnyba prie Žemės ūkio ministerijos – VATŽŪM)
4. National Food and Veterinary Risk Assessment Institute (Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas – NMVRVI)
5. Vytautas Magnus University (Vytauto Didžiojo universitetas – VDU)
6. Centre for Communicable Diseases and AIDS (Užkrečiamųjų ligų ir AIDS centras – ULAC)
7. Kaunas University of Technology (Kauno technologijos universitetas – KTU)
8. Lithuanian University of Health Sciences (Lietuvos sveikatos mokslų universitetas – LSMU)
Luxembourg

Regulation (EC) No. 178/2002 and the national law from 28 July 2018 introducing the control systems and sanctions related to food safety are the central legal foundations for food legislation in Luxembourg. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Luxembourg, there is no institutional separation of risk assessment from risk management.

The Ministry of Agriculture, Viticulture and Rural Development (MAVDR) deals with agricultural policy and prepares draft legislation in specific areas of food and feed safety and food quality. As with all ministries, the MAVDR is supported by competent authorities, such as the Agricultural Technical Services Administration (ASTA) and Veterinary Service Administration (ASV). The portfolio of the MAVDR extends beyond the area of food and feed safety to include plant health, plant protection products, animal health and welfare, and food quality (EU quality schemes, national labels and marketing standards).

MPC
Ministry for Consumer Protection

- Consumer protection policy, food safety
- Risk management
- Risk communication

Location: Luxembourg
http://mpc.gouvernement.lu

The newly created Ministry for Consumer Protection (MPC) deals with general consumer protection policy and food safety and is in charge of the legislation in these areas.

It is supported in its work by the Government Commissariat for Quality, Fraud and Food Safety (COMALIM), which manages the budgets of the
ASV and the Directorate of Public Health (DIR SAN) related to food safety.

MPC has the task of regrouping food control activities into one administration.

**MS**  
**Ministry of Health**

- Health policy
- Risk management
- Risk communication

Location: Luxembourg  
http://sante.lu

The Ministry of Health (MS) deals with health policy.

Official food safety inspections are conducted by subordinate authorities of the MS (SECUALIM, ASV) but are monitored by the MPC. The MS is supported by competent authorities such as Directorate of Public Health (DIR SAN). The portfolio of the MS extends beyond the field of food safety to include, for instance, cosmetics, medical devices and pharmacological substances.

**COMALIM**  
**Commissariat for Quality, Fraud and Food Safety**

- Risk assessment
- Risk management
- Risk communication
- EFSA Focal Point
- COM Contact Point

Location: Strassen  
http://www.securite-alimentaire.lu

The Commissariat for Quality, Fraud and Food Safety (COMALIM) is an administration under the MPC. It is the task of the COMALIM to ensure optimal cooperation between all authorities in the area of food and feed safety. Policy and management measures of all the ministries active in food safety are based on risk assessments prepared by the COMALIM (as well as the ASTA, ASV, and DIR SAN). The COMALIM is responsible for the coordination of official food and feed inspections in the framework of the Multi-Annual National Control Plan (MANCP). It is the contact point for RASFF, AAC, and the Food Fraud Network. In addition, the COMALIM provides training for these authorities, as described in Regulation (EU) No. 2017/625.

The remit of COMALIM focuses on food safety, including novel foods, residues of plant protection products and veterinary medicinal products, food supplements, genetically modified organisms (GMOs), zoonoses, mineral waters and drinking water.
The Agricultural Technical Services Administration (ASTA) is a subordinate authority within the portfolio of the MAVDR and responsible for risk assessments and implementation of state inspections of feed, plant protection products, the EU quality labels PDO, PGI and TSG, organic farming and marketing standards. The ASTA is the regulatory authority for the approval of plant protection products. The ASTA is responsible for the control of primary production and the import of food of non-animal origin and plants.

The Veterinary Service Administration (ASV) is a subordinate authority within the portfolio of the MAVDR and MPC. The ASV is responsible for risk assessments and the implementation of official inspections in the field of food of animal origin as well as animal health and welfare.

The Directorate of Public Health (DIR SAN) is subordinate to the MS. The Division of Food Safety (SECUALIM) within DIR SAN operates under the MPC and is responsible for risk assessments and the implementation of state food safety controls in the area of food hygiene, HACCP, microbiological agents, contaminants, pesticide residues, GMOs, novel food, food supplements, food additives, special dietary food, food labelling, food contact material, irradiation, import of food and beverages of non-animal origin.

In the area of food hygiene, SECUALIM closely collaborates with the customs administration. Common procedures and checklists are in place for inspection and control activities.

The Division of Pharmacy and Medicines (DPM) within DIR SAN is responsible for risk assessments and the implementation of state food safety controls in the area of medicated feed and medicinal products. DPM is one of the regulatory authorities for the approval of veterinary medicinal products.

Feed, food and other types of inspections are implemented by central authorities.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Ministry for Consumer Protection of Luxembourg (MPC)
2. Institute of Health (LIH)
3. Laboratoire national de santé (LNS)
4. Luxembourg Institute of Science and Technology (LIST)
The Food Safety Act is the central legal foundation for food legislation in Malta. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Malta, risk assessment is institutionally separated from risk management. Risk assessments are not published.

Generally speaking, Malta has a national centralised system. Due to the small scale of the services, the offices at the central level are responsible not only for policy and coordination, but also for direct implementation of controls.

The Ministry for Agriculture, Fisheries and Animal Rights (MAFA) deals with agricultural policy and, more particularly, food and feed safety in Malta. It is the competent authority for controls of food of animal origin. The MAFA is responsible for guidance, approval and inspection of all types of establishments for food of animal origin and for import controls on food of animal origin and feed.

The portfolio of the MAFA includes feed, genetically modified organisms (GMOs), zoonoses, and residues of plant protection products and veterinary medicinal products. The MAFA is the regulatory authority for veterinary medicinal products in Malta. The MAFA’s area of work extends beyond food safety to include, for instance, plant health, animal health and animal welfare.

The Ministry for Health (MfH) deals with social policy, health policy and food safety in Malta. It is responsible for controls of foodstuffs and food

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**MAFA**

Ministry for Agriculture, Fisheries and Animal Rights

- Agricultural policy, food and feed safety
- Risk management

Location: Santa Venera  
http://agriculture.gov.mt

**MfH**

Ministry for Health

- Social and health policy, food safety
- Risk management

Location: Valletta  
https://deputyprimeminister.gov.mt/
The Malta Competition and Consumer Affairs Authority (MCCAA) is a government-appointed authority within the portfolio of the Ministry for Tourism and Consumer Protection. The Food Safety Act assigns specific responsibility for risk assessments to the MCCAA. MCCAA risk assessments are used by the MAFA and MfH as the basis for management measures in the field of food safety. The MCCAA assesses risks, identifies new health risks and prepares risk reduction recommendations. The MCCAA provides technical and scientific advice to the FSC. The remit of the MCCAA includes novel foods, food supplements, health and nutrition claims and natural mineral water. The MCCAA is the regulatory authority for plant protection products in Malta. The scope of work of the MCCAA extends beyond food safety to include, for instance, cosmetics, biocides and consumer products.

The MfH’s scope of work extends beyond food safety to include, for instance, nutrition.

The Food Safety Commission (FSC) is an independent government coordinating body which reports to the MfH. The FSC is responsible for risk management and risk communication. The FSC is the coordination office for issues related to food safety and provides a forum for cooperation between the MAFA, MfH and the Malta Competition and Consumer Affairs Authority (MCCAA), as well as other entities involved in food safety. The FSC is responsible for the registration of all food establishments.

In Malta, the Public Health Laboratory is the National Reference Laboratory pursuant to Regulation (EC) No. 882/2004. It draws on the services of National Reference Laboratories in other EU Member States.

The actual controls are carried out by seven regional bodies. The portfolio of the MfH includes hygiene, novel foods, food supplements, mineral water and drinking water.

The FSC’s scope of work extends beyond food safety to include, for instance, nutrition.

The Malta Competition and Consumer Affairs Authority (MCCAA) is a government-appointed authority within the portfolio of the Ministry for Tourism and Consumer Protection. The Food Safety Act assigns specific responsibility for risk assessments to the MCCAA. MCCAA risk assessments are used by the MAFA and MfH as the basis for management measures in the field of food safety. The MCCAA assesses risks, identifies new health risks and prepares risk reduction recommendations. The MCCAA provides technical and scientific advice to the FSC. The remit of the MCCAA includes novel foods, food supplements, health and nutrition claims and natural mineral water. The MCCAA is the regulatory authority for plant protection products in Malta. The scope of work of the MCCAA extends beyond food safety to include, for instance, cosmetics, biocides and consumer products.

Food inspections are implemented by seven regional control bodies which are subordinate to the MfH. Coordination of food and feed inspections is carried out at the Food Safety Commission level.

Regional and local levels

Food inspections are implemented by seven regional control bodies which are subordinate to the MfH. Coordination of food and feed inspections is carried out at the Food Safety Commission level.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Malta Competition and Consumer Affairs Authority (EFSA Focal Point)
2. Ministry for Agriculture, Fisheries and Animal Rights
European regulations and the Dutch Food and Commodities Act are the central legal foundations for food legislation in the Netherlands. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments.

Based on the Dutch “Independent Risk Assessment Act” from 2006, risk assessment and risk management are largely institutionally separated. Risk assessments are published on the Internet unless there are statutory provisions that prohibit it.

The Ministry of Health, Welfare and Sport (VWS) pursues a “good food” policy mainly based on recommendations and guidelines prepared by the Health Council of the Netherlands. VWS is responsible for health policy and safety of food of non-animal origin and prepares draft legislation in this area. VWS bases risk management measures on risk assessments conducted by the Office for Risk Assessment and Research (BuRO), an independent unit within the Netherlands Food and Consumer Product Safety Authority (NVWA). The VWS portfolio includes food supplements, novel foods, mineral water, drinking water, botanicals, residues of plant protection products and veterinary medicinal products and genetically modified organisms (GMOs) in the food of non-animal origin segment. Its area of work extends beyond the field of food safety to cosmetics and consumer products.
The Ministry of Agriculture, Nature and Food Quality (LNV) is responsible for agricultural policy and safety of food of animal origin (i.e. during primary production by farmers, growers and fishermen). LNV prepares draft legislation in this area and ensures the traceability of food of animal origin.

In the Netherlands, it is the responsibility of the food producers to ensure safe foods and to conduct appropriate day-to-day quality controls. The government supervises this self-control system (“supervising the supervisor”).

LNV bases risk management measures on risk assessments prepared by the Office for Risk Assessment and Research (BuRO), an independent unit within the Netherlands Food and Consumer Product Safety Authority (NVWA).

The portfolio of LNV includes zoonoses, GMOs and residues of plant protection products and veterinary medicinal products in animal feed. The area of work of LNV extends beyond food safety to plant health, plant protection, animal health and animal welfare. LNV is the regulatory authority for plant protection products and veterinary medicinal products.

The Netherlands Food and Consumer Product Safety Authority (NVWA) is an independent agency in LNV and a delivery agency to VWS. In April 2010, three authorities (VWA, PD (National Plant Protection Organization, NPPO) and AID) were merged into one authority named NVWA. NVWA has been operating as a single authority since January 2012. The three main tasks of NVWA are the implementation and supervision of food safety control and inspection activities, risk assessment and risk communication. NVWA is also responsible for incident and crisis management, including technical and scientific support and advising LNV and VWS on risks. Within NVWA, risk management is functionally separated from risk assessment.

NVWA has small support offices in the country to provide logistical support to the inspectors. In addition, the number of laboratories has been reduced to two laboratories in Zwijndrecht and Groningen for product safety, and one in Wageningen for plant health (National Reference Centre (NRC) - Plant Health, National Plant Protection Organisation, pursuant to Official Controls Regulation (2017/625/EU)). NRC in NVWA coordinates the European Reference Laboratories (EURLs) for Bacteriology and Virology.
NVWA also has an Intelligence and Investigation Service (NVWA-IOD) that focusses on organised and international crime.

NVWA has access to several National Reference Laboratories in the field of food safety, pursuant to Official Controls Regulation (2017/625/EU).

The area of work of the NVWA extends beyond the field of food safety to animal health, animal welfare, plant health and non-food consumer products.

The independent Office for Risk Assessment and Research (BuRO) conducts risk assessments and advises the ministers of LNV and VWS on food and consumer product safety and on animal health and welfare. BuRO is a scientific unit that is independent, and its scientific opinions are free of political, social or scientific interests. BuRO also identifies new health risks, prepares risk reduction recommendations, and recommends preventive measures to ensure food and feed safety. Another main area for BuRO is the transparent communication with the public. BuRO is active in the areas of food safety, novel foods, food supplements, GMOs, zoonoses, animal feed, animal health, veterinary medicinal products, animal welfare, residues of plant protection products, plant health and non-food consumer products.

Wageningen Food Safety Research (WFSR) is an independent research institute in the field of food and feed safety and human health. WFSR was established in June 2019 and is a combination of the RIKILT- Institute of Food Safety and the Laboratory for Feed and Food Safety of NVWA. WFSR conducts research on substances in food of plant or animal origin and animal feed. WFSR is part of Wageningen UR.

Wageningen Bioveterinary Research (WBVR) is an independent research organisation. WBVR operates in the field of veterinary science and contributes to protecting the health of animals and humans by undertaking research and making recommendations on animal diseases (zoonoses). WBVR is part of Wageningen UR.
of excellence in the area of health, nutrition and environmental protection.

Several National Reference Laboratories and a European Reference Laboratory are hosted by RIVM, WBVR and WFSR.

**Regional and local levels**

The Netherlands is divided in 12 provinces and 355 municipalities. Food and feed inspections are coordinated from the central seat in Utrecht and supported by regional NVWA offices.

**Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002**

1. Netherlands Food and Consumer Product Safety Authority (NVWA) (EFSA Focal Point)
2. National Institute for Public Health and the Environment (RIVM)
3. Vrije Universiteit Amsterdam
4. Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
5. Wageningen Research
6. Utrecht University
7. Wageningen University
8. Erasmus University Medical Centre Rotterdam
9. Rijksuniversiteit Groningen (RUG)
The central legal foundation for food legislation in Poland is the Food and Nutrition Safety Act of 25 August 2006. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on science-based risk assessments. However, the final decision on the legality of governmental measures rests with the courts. In Poland, risk management and risk assessment are institutionally separated. Risk assessments are not published.

The Ministry of Health (MZ) is responsible for public health policy and food safety. The MZ prepares draft legislation in the area of food hygiene, pesticide residues, contaminants and import of foods of non-animal origin, drafts regulation on some issues not covered by EU regulations with regard to food supplements, addition of vitamins and minerals to food, and other special kinds of food. The portfolio of the MZ extends beyond food safety to include, for instance, medicinal products. The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products at the MZ is the regulatory authority for veterinary drugs in Poland.

The Chief Sanitary Inspectorate (GIS) is subordinate to the MZ and is the competent authority for food safety in Poland. It cooperates with the Ministry of Agriculture and Rural Development (MRiRW) on matters regarding food safety and with both the MRiRW and the Ministry of Environment (MS) on matters regarding genetically modified organisms (GMOs). The GIS coordinates and supervises the activities of the State Sanitary Inspectorates (PIS), which are responsible for official control of all aspects of food safety, i.e. food hygiene, pesticide residues, contaminants, import of food of non-animal origin, food contact materials, food additives, GMOs in food, food supplements, food for special groups and novel foods. The GIS is also responsible for monitoring contaminants in food of non-animal origin and prepacked food introduced to the market. GIS risk management measures are based on scientific risk assessments conducted by the National...
Institute of Public Health – National Institute of Hygiene (NIZP-PZH).

The GIS is also the competent authority that monitors food supplements, food for specific groups, food with added vitamins and minerals, and foods being introduced to the market for the first time.


MRiRW
Ministry of Agriculture and Rural Development

- Agricultural policy and safety of food of animal origin
- Risk management
- FAO/WHO Codex Contact Point

Location: Warsaw
https://www.gov.pl/web/rolnictwo

The Ministry of Agriculture and Rural Development (MRiRW) is responsible for agricultural policy and the safety of food of animal origin and prepares draft legislation in this area. The MRiRW is supported by three competent specialist authorities responsible for control and inspection: the General Veterinary Inspectorate (GIW), the Main Inspectorate for Seeds and Plant Health (PIORIN), and the Agricultural and Food Quality Inspection (IJHARS). The FAO/WHO Codex Contact Point for Poland is located at IJHARS.

The work of the MRiRW is mainly focused on risk management on food of animal origin and is based on scientific risk assessments prepared by the National Veterinary Research Institute (PIWET). The portfolio of the MRiRW includes safety of feed, residues of veterinary medicinal products, GMOs and zoonoses. In these areas, the MRiRW monitors the activities of the district and local authorities.

The MRiRW is the regulatory authority for pesticides and plant protection products. In the area of food safety, the MRiRW cooperates with the MZ, and for GMOs with both the MZ and the MS, for example. The portfolio of the MRiRW extends beyond food safety to animal health and animal welfare. The MRiRW is also responsible for the monitoring of contaminants in food of animal origin.

NRA at MF
National Revenue Administration (NRA) at the Ministry of Finance (MF)

- Risk management

Location: Warsaw
Ministry of Finance: https://www.gov.pl/web/finanse

The National Revenue Administration (NRA) is a merger of the tax administration, fiscal control and customs service.

The NRA is subordinate to the Ministry of Finance (MF) and is responsible for the border control of food. The CS cooperates with three specialist authorities: the GIW on controls of export and import of animals, food of animal origin and feed; the PIORIN on controls of export and import of regulated plants and plant material, and the GIS on controls of export and import of food of plant origin.

UOKiK
Office of Competition and Consumer Protection

- Risk management

Location: Warsaw

The Office of Competition and Consumer Protection (UOKiK) is responsible for consumer protection and competition policy. The UOKiK promotes fair conditions of competition and the protection of consumers from anti-competitive practices and misleading commercial practices.
The President of the Office of Competition and Consumer Protection is a central authority of the state administration. The Office is responsible for shaping the antitrust policy and consumer protection policy. It is the task of the UOKiK to ensure that only safe products that meet the essential requirements set forth in Polish regulations are available on the market.

The Office has the power to carry out proceedings concerning practices infringing on collective consumer interests, which may lead to a decision ordering the enterprise involved to cease the practices in question and pay a fine. Further consumer protection activities include ridding B2C contracts of prohibited clauses, i.e. contract terms that set forth consumers’ interests in a way that infringes on the law or good practices. Here, the major instrument used by the UOKiK consists of inspections of contracts used by enterprises. Furthermore, to protect the health and life of consumers, the UOKiK carries out proceedings concerning general product safety. Such proceedings may end in a decision ordering the enterprise involved to withdraw a dangerous product from the market and pay a maximum fine of PLN 100 thousand. The Office also monitors the market surveillance system, which aims to ensure that only safe products which meet the essential requirements set forth in Polish regulations implementing the so-called ‘New Approach Directives’ are available on the market. The Office is also responsible for managing the fuel quality monitoring and scrutinising system.

The primary antitrust instrument used by the President of the Office comprises proceedings concerning competition-restricting practices, i.e. abuses of a dominant position and prohibited agreements (cartels).

The President of the Office is also authorised to control mergers in order to prevent situations where a dominant entity is created on the market as a result of a merger. Since 2004, the Office has been providing its opinion on state aid schemes and individual state aid decisions prior to their notification to the European Commission.

**NIZP-PZH**
National Institute of Public Health – National Institute of Hygiene

- Risk assessment
- Research

Location: Warsaw
http://www.pzh.gov.pl

The National Institute of Public Health – National Institute of Hygiene (NIZP-PZH) prepares scientific risk assessments on food additives, biological risks, added chemical substances, residues of plant protection products, nutrition, novel foods and drinking water. The NIZP-PZH also conducts active research in this area. On 01 February 2020, the Institute merged with the National Food and Nutrition Institute (IZZ).

**PIWET**
National Veterinary Research Institute

- Risk assessment
- Research

Location: Puławy
http://www.piwet.pulawy.pl

The National Veterinary Research Institute (PIWET) prepares scientific risk assessments on feed, residues of veterinary medicinal products and zoonoses. The PIWET also conducts active research.

**Regional and local levels**

In Poland, there is a three-tier division in the public administration: 16 regions (voivodships), 379 dis-
districts (powiats) and 2,478 local authorities (gminas). At the district and local levels, the specialist authorities of the GIS and MRiRW are responsible for enacting food laws and carrying out food inspections. They are instructed and monitored by the GIS and MRiRW in their respective areas of activity.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Chief Sanitary Inspectorate (EFSA Focal Point)
2. National Veterinary Research Institute
3. Institute of Natural Fibres and Medicinal Plants
5. Institute of Plant Protection – National Research Institute
6. Research Institute of Horticulture
7. Prof. Waclaw Dąbrowski Institute of Agriculture and Food Biotechnology
8. Łódź University of Biotechnology
Together with European food laws, Decree-Law No. 113/2006 is the central legal foundation for food legislation in Portugal. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Portugal, there is no institutional separation of risk assessment and risk communication from risk management. Risk assessments are not published.

Within the Ministry of Agriculture (MA), the Directorate-General for Food and Veterinary (DGAV) is in charge of coordinating legislation, preparing bills and the multi-annual national control plan. It is also responsible for the implementation of food safety controls for food of animal origin. Most activities in the area of food safety and food inspections are supervised by the MA.

The MA’s work extends beyond the field of food safety to include, for instance, plant health, animal health, animal welfare and biocides. The National Institute for Agrarian and Veterinarian Research (INIAV) is subordinate to the MA. The INIAV contains several National Reference Laboratories in its structure, pursuant to Regulation (EC) 882/2004.
The Ministry of Economy and Digital Transition (METD) deals with economic and consumer policy, as well as with food safety in Portugal. The Economic and Food Safety Authority (ASAE) is the competent specialist authority that supports the work of the METD.

**ASAE**  
**Economic and Food Safety Authority**

- Risk assessment
- Risk communication
- Risk management
- EFSA Focal Point

**Location:** Lisbon  
http://www.asae.gov.pt/

As a subordinate specialist authority of the METD, the Economic and Food Safety Authority (ASAE) is responsible for risk assessments, risk communication and risk management (food inspection) in the field of food safety.


The ASAE is a criminal police body that operates as the national authority responsible for carrying out inspections to prevent and combat fraud in all economic areas, including food and feed, and National Focal Point of the EU Food Fraud Network (FFN).

It is also responsible for risk assessments and risk communication in relation to food and feed. This is handled by a department that coordinates EFSA-related activities.

The organic structure of the ASAE covers the whole country with one central and several regional control services.

The remit of the ASAE includes the commercialisation chain of plant and animal products, including fishing products (aquaculture, factory ships, vessels, stores, warehouses and wholesale markets). The ASAE competencies also include food supplements, contaminants in meat, fish, plant products and mineral water. The safety of tap water lies within the responsibility of the regulatory authority for water and waste.

The ASAE, through Food Safety Laboratory, has 3 National Reference Laboratories pursuant to Regulation (EC) No. 882/2004: mycotoxins in food, dioxins in food and feed, and polycyclic aromatic hydrocarbons (PAHs) in oils and fats.

**DGAV**  
**Directorate-General for Food and Veterinary Issues**

- Risk assessment
- Risk management
- Codex Contact Point
- RASFF contact point

**Location:** Lisbon  
http://www.dgv.min-agricultura.pt

The Directorate-General for Food and Veterinary (DGAV) is the subordinate specialist authority of the MA. Based on scientific risk assessments, the DGAV implements state food policy and conducts inspections.

As regards the operation of control systems for the safety of food and feed, animal health and animal welfare, plant health and veterinary public health, activities are carried out by five regional...
The powers of the DGAV comprise the areas of genetically modified food, zoonoses, veterinary and plant protection product residues, and food contact materials. The DGAV is the regulatory body for veterinary and plant protection products in Portugal and residues of plant protection products, including pesticide residues in plants. As the national plant protection authority, the DGAV supports the development of regulations on plant protection products and implements the national waste control programmes, including pesticides. The DGAV is also responsible for developing the multi-annual national control plan in compliance with the principles and guidelines laid down in Regulation (EU) No. 2017/625.

The DGAV’s area of work goes beyond food safety to include, for example, animal health, animal feed, transmissible spongiform encephalopathies, animal by-products, veterinary medicines and animal welfare.

**Regional and local levels**

Continental Portugal is administratively divided into 18 districts (308 counties) and two autonomous regions (Azores and Madeira). The Azores and Madeira regions each have an elected assembly with decentralised powers to pass legislation. The evaluation, management and communication of risk in the autonomous regions are dependent on the regional governments; in Madeira it is the ARAE (Regional Authority for the Economic Activities) and in Azores, the IRAE (Regional Inspection Economic Activities), which have the same competencies as the ASAE.

**Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002**

1. Economic and Food Safety Authority (Autoridade de Segurança Alimentar e Económica – ASAE) (EFSA Focal Point)
2. General Directorate for Food and Veterinary (Direção Geral de Alimentação e Veterinária – DGAV)
3. Interdisciplinary Centre of Marine and Environmental Research (Centro Interdisciplinar de Investigação Marinha e Ambiental – CIIMAR)
4. National Institute for Agrarian and Veterinary Research (Instituto Nacional de Investigação Agrária e Veterinária, I.P. – INIAV)
6. Polytechnic Institute of Bragança (Instituto Politécnico de Bragança)
7. Polytechnic of Leiria (Instituto Politécnico de Leiria)
9. Universidade Católica Portuguesa (Universidade Católica Portuguesa – UCP)
10. University of Coimbra (Universidade de Coimbra – UC)
11. University of Porto (Universidade do Porto – UPorto)
12. University of Madeira (Universidade da Madeira – UMa)
Law No. 150/2004 (with amendments) is the legal foundation for food and feed legislation in Romania. Infringement of food and feed regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments.

In Romania there is no institutional separation of risk assessment and risk management. Not all risk assessments are published on the Internet.

The Ministry of Agriculture and Rural Development (MADR) deals with agricultural policy and food safety in Romania. It prepares draft legislation in the area of food and feed of non-animal origin, residues of plant protection products and cultivation of genetically modified organisms (GMOs). MADR also conducts risk assessments in these fields. Activities of MADR with regard to plant protection products are supported by the National Environmental Protection Agency and the Ministry of Health.

Two National Reference Laboratories are part of MADR pursuant to Regulation (EU) No. 2017/625.

The Ministry of Health (MS) is responsible for health protection and partially for food safety in Romania. The MS prepares draft legislation in the field of food safety and is partially responsible for official controls in the area of food safety. The portfolio of the MS includes novel foods, food supplements, food for populations with special nutritional requirements, food additives, enzymes and flavourings, treatment of food with ionising irradiation, food contact materials as well as mineral water. The MS is also responsible for risk assessments in these areas.
The National Sanitary Veterinary and Food Safety Authority (ANSVSA) is subordinate to the Romanian Government, and the activities of the ANSVSA are coordinated by the Prime Minister. The ANSVSA manages all matters in the area of food safety – from raw materials to consumer issues. The ANSVSA is responsible for official controls, preparation of draft legislation as well as preparation of risk assessments in the following areas: food and feed safety, contaminants, residues of plant protection products, import and export of animals and plant products, traceability and labelling of genetically modified food and feed, zoonoses, veterinary medicinal products and their residues, feed, animal health and welfare, and antimicrobial resistance.

The ANSVSA ensures that HACCP and hygienic requirements are implemented in food production and catering businesses.

There are 3 National Reference Laboratories pursuant to Regulation (EU) No. 2017/625 that are attached to ANSVSA: the Institute for Diagnosis and Animal Health, the Institute for Hygiene and Veterinary Public Health, and the Institute for Control of Biological Products and Veterinary Medicines. The ANSVSA also has its own network of 42 official county sanitary veterinary and food safety laboratories.

The Ministry of Environment, Water and Forests (MMAP) deals with environmental policy and is the main competent authority for plant protection products and GMOs. The MMAP authorises and controls the use of GMOs and plant protection products and monitors their impact on the environment. In this area, the MMAP is supported by the National Protection Agency and the National Environmental Guard. Authorisation of plant protection products in Romania requires the approval of three ministries, the MADR, MS and MMAP. The MMAP is also responsible for the management of obsolete pesticides.

The National Authority for Consumer Protection (ANPC) monitors whether food, food advertising, and food labelling conforms to legal requirements. The ANPC also handles consumer complaints.
Regional and local levels

Romania has a unitary government structure with decentralised regional administration offices. The regional level (42 administrative districts) has certain autonomous competencies. The regional administration supervises the work of local authorities. All authorities (MADR, MS, ANSVSA, MMAP and ANPC) have regional offices that carry out inspections and control in the area of food and feed safety, plant protection and plant health as well as veterinary inspections.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. National Sanitary Veterinary and Food Safety Authority in Romania (EFSA Focal Point)
2. Institute for Diagnosis and Animal Health
3. Ministry of Public Health
   Department of Public Health Authority (PHA)
   Department of Sanitary State Inspection
4. Institute for Hygiene and Veterinary Public Health
5. Banat's University of Agricultural Science and Veterinary Medicine
6. County Sanitary Veterinary and Food Safety Directorate in Bucharest – County Sanitary Veterinary and Food Safety Laboratory in Bucharest
7. University of Agricultural Sciences and Veterinary Medicine in Cluj Napoca
8. National Institute of Research and Development for Food Bioresources – IBA Bucharest
9. Dunarea de Jos University in Galati
The central legal foundation for food legislation in Slovakia is the Act on Foodstuffs (No. 152/1995 Coll.). Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts. In Slovakia, risk assessment and risk management are institutionally separated. Risk assessments are published on the Internet.

The Commission of the Food Chain Safety is an advisory body of the Food Safety and Nutrition Department of the MPRV SR. The commission issues advice with regard to food safety throughout the food chain, particularly with regard to the creation and implementation of strategies and policies in this area. Scientific risk assessments are prepared by scientific bodies, research institutions and universities.

Several National Reference Laboratories are attached to the MPRV SR pursuant to Regulation (EU) No. 2017/625.
The Ministry of Health of the Slovak Republic (MZ SR) is responsible for health policy and is the central competent authority for official food controls in the hotel, restaurant and catering sector and for the production and placing of the following products on the market: novel foods, food supplements, foods intended for particular nutritional uses (including foods for infants and young children) as well as natural mineral water, spring water for infants and young children, foodstuffs treated with ionising radiation and food contact materials. The competent authority responsible for coordinating the implementation of official food controls in this sector is the Public Health Authority of the Slovak Republic (ÚVZ SR) and its regional authorities.

The MZ SR has authorised several laboratories to conduct laboratory analyses of samples taken in the course of official food controls. All these laboratories are accredited according to EN ISO/IEC 17025 by SNAS (Slovak National Accreditation Service), DAP (Deutsches Akkreditierungssystem Prüfwesen), or the CAI (Czech Accreditation Institute).

National Reference Laboratories are attached to the MZ SR pursuant to Regulation (EU) No. 2017/625.

The State Veterinary and Food Administration of the Slovak Republic (ŠVPS SR) is subordinate to the MPRV SR and responsible for the official control of animal health and welfare, food of animal and non-animal origin at all stages of production, processing and distribution, except in the catering sector, which is the responsibility of the Ministry of Health (MZ SR). The remit of the ŠVPS SR extends to feed materials of animal origin, feedstuffs used directly at the farm level, medicated feedstuffs, veterinary medicines and their residues, and animal by-products.

The ŠVPS SR manages and coordinates the activities of the State Veterinary and Food Institute, the Institute for State Control of Veterinary Biopreparations and Medicines, and the Institute of Postgraduate Study for Veterinary Surgeons.

The laboratories of the State Veterinary and Food Institute have been designated by the MPRV SR as official laboratories to conduct analyses of samples taken in the course of official controls on animal health and the safety of food of animal and plant origin, including analyses of imported and domestically produced feedstuffs. These laboratories are accredited in accordance with EN ISO/IEC 17025. The regulatory authority for veterinary drugs is the Institute for State Control of Veterinary Biopreparations and Medicines (location: Nitra, http://www.uskvbl.sk).
The Central Controlling and Testing Institute in Agriculture (ÚKSÚP) is subordinate to the MPRV SR and is responsible for the official control of the agricultural sector. The remit of the ÚKSÚP covers plant health, seeds and seedlings, plant varieties, plant protection products, animal feed and animal nutrition. The ÚKSÚP assists with the drafting of legislation and provides advisory services.

The ÚKSÚP performs phytosanitary controls on imported and exported plants and plant materials at three border crossing points. The ÚKSÚP is the competent authority for organic farming in Slovakia, designated by the Department of Environmental Protection and Organic Farming (DEPOF). Analyses of samples taken in the course of official controls are conducted by its own accredited laboratories.

The Public Health Authority of the Slovak Republic (ÚVZ SR) is the competent authority responsible for coordinating the implementation of official food controls in the sectors mentioned in the preceding section. The authority coordinates all food safety activities, including the preparation of control programmes and related reports, the organisation of laboratory capacity, and cooperation with the MPRV SR and on consumer protection issues. Controls are implemented by 36 regional public health authorities.

The Slovak Republic consists of eight regions and 79 districts. Food and feed inspections, as well as veterinary and phytosanitary care are coordinated and conducted by the ŠVPS SR, ÚKSÚP and ÚVZ SR. The ŠVPS SR is supported by eight regional and 40 district veterinary and food authorities, as well as four laboratories and three border inspection posts. The ÚVZ SR is supported by 36 regional authorities and 10 laboratories.
1. Ministry of Agriculture and Rural Development of the Slovak Republic (MPRV SR) (EFSA Focal Point)
2. Public Health Authority of the Slovak Republic (ÚVZ SR)
3. Central Controlling and Testing Institute in Agriculture (ÚKSUP)
4. State Veterinary and Food Institute
5. Slovak University of Agriculture in Nitra
6. University of Veterinary Medicine and Pharmacy in Kosice
7. Institute of Parasitology, Slovak Academy of Sciences
8. National Agricultural and Food Centre (NPPC-VÚP)
Several national laws and governmental regulations represent the legal foundation for food legislation and official controls. Infringement of these regulations can lead to administrative and/or penalty measures being taken by the Administration for Food Safety, Veterinary Sector and Plant Protection (UVHVVR), the Health Inspectorate of the Republic of Slovenia (ZIRS), the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fisheries (IRSKGLR), and the Financial Administration (FURS). Measures can also be taken under criminal law (Public Prosecution Office) and civil law (civil claims). The above measures are based on legal requirements or on risk analyses in cases where no EU or national legal requirements exist. The final decision on the legality of measures taken rests with the courts.

The processes of risk assessment and risk management are institutionally separated.

The Ministry of Agriculture, Forestry and Food (MKGP) is responsible for the policy and legislative framework in the areas of agriculture, fisheries and forestry, including food and feed quality, e.g. marketing standards for food, protected designation of origin, protected geographical indication, traditional speciality guaranteed, and indication of products of higher quality.
Within international trade, the UVHVVR is responsible for market access with regard to food safety, veterinary and phytosanitary requirements. Import and export controls in these sectors are implemented in close cooperation with the customs authority of FURS.

The Administration for Food Safety, Veterinary Sector and Plant Protection (UVHVVR), a body within the MKGP, is the principal competent authority for food and feed safety, animal health and welfare, and plant health. It is responsible for the preparation and implementation of the legislative framework, risk monitoring, managing the public, animal and plant health risks, as well as for official inspection and controls along the entire food and feed chain.

The competencies of the UVHVVR comprise administrative, technical and inspection tasks in the area of the safety, quality and labelling of food (including genetically modified organisms (GMOs), natural mineral waters) and feed; food safety in the catering sector, animal health and welfare, zoonoses, use of veterinary medicinal products, animal by-products, plant health protection, registration and use of plant protection products, and residues of pesticides.

The UVHVVR requests analyses of official samples and risk assessments from appointed scientific institutions and research organisations, such as:

- University of Ljubljana, Veterinary Faculty – National Veterinary Institute
- National Laboratory of Health, Environment and Food
- National Institute of Public Health
- Agricultural Institute of Slovenia
- National Institute of Biology
- Slovenian Institute for Hop Research and Brewing
- Slovenian Forestry Institute
The Ministry of Health (MZ) is responsible for the policy and legislative framework in the area of healthcare, including public health and health insurance. The portfolio of the MZ includes safety of food and drinking water and drafting and implementing a general policy on nutrition. Within the food safety area, the MZ is specifically responsible for the preparation of legislation and overseeing its implementation with regard to food for specific groups, food supplements and food contact materials. The MZ requests risk assessments from appointed scientific institutions, such as the National Institute of Public Health (NIJZ) and the National Laboratory of Health, Environment and Food (NLZOH).

The Health Inspectorate of the Republic of Slovenia (ZIRS) is responsible for the official control of food supplements, food for specific groups, food contact materials and drinking water.

The National Institute of Public Health (NIJZ) is a national scientific organisation responsible for chemical, nutritional, microbiological and novel food risk assessments and risk communication. The NIJZ works in close collaboration with national and international organisations in the field of food safety.

The Financial Administration (FURS) is subordinate to the Ministry of Finance (MF). The FURS is responsible for official import controls regarding:
- Products of animal origin for personal consumption
- Foodstuffs of non-animal origin (except for the increased level of controls)
- Documentary and identity checks on animal feedstuffs of non-animal origin
- Wooden packaging materials
- Detection of illegal imports
The National Laboratory of Health, Environment and Food serves as a National Reference Laboratory pursuant to Regulation (EU) No. 2017/625 and is responsible for sampling, analysis and risk assessment of the official control samples.

The National Veterinary Institute conducts official sampling of food of animal origin for microbiological testing, conducts diagnostic tests for rabies, and performs tasks in the field of animal health. The NVI is designated as the NRL for residues of veterinary medicinal products and contaminants in food of animal origin, and antimicrobial resistance (AMR).

The Republic of Slovenia consists of 212 municipalities and has a centralised structure. The food supervision activities come under the responsibility of the UVHVVVR, which comprises a head office, ten + regional offices and two Border Inspection Posts (BIPs), and the ZIRS, which has a head office and seven regional offices.

1. Ministry of Agriculture, Forestry and Food (Ministrstvo za kmetijstvo, gozdarstvo in prehrano – MKGP) (EFSA Focal Point)
3. Agricultural Institute of Slovenia (Kmetijski inštitut Slovenije – KIS)
4. University of Maribor (Univerza v Mariboru – UM)
5. Jozef Stefan Institute (Institut “Jožef Stefan” – IJS)
7. National Laboratory of Health, Environment and Food (Nacionalni laboratorij za zdravje, okolje in hrano – NLZO)
8. Slovenian Forestry Institute (Gozdarski inštitut Slovenije – GIS)
10. University of Ljubljana (Univerza v Ljubljani – UL)
11. Slovenian Institute of Hop Research and Brewing (Inštitut za hmeljarstvo in pivovarstvo Slovenije – IHPS)
Regulation (EC) No 178/2002, together with Law 17/2011 of 05 July on food safety and nutrition, are the foundations of food safety in Spain. Government measures concerning food safety are, in most cases, based on risk assessments.

In Spain, there is no institutional separation between risk assessment and risk management. Risk assessments are drafted by the Scientific Committee, an independent body within the Spanish Agency for Food Safety & Nutrition (AESAN), and are published in Spanish and English on the AESAN website.

In Spain, AESAN, together with the Ministry of Agriculture, Fisheries and Food (MAPA), are responsible for the coordination at the national level of the organisation and functioning of food safety control systems.

AESAN is an autonomous body of the Ministry of Consumer Affairs and functionally reports to the Ministry of Consumer Affairs, the Ministry of Health, and the Ministry of Agriculture, Fisheries and Food.

The Ministry of Agriculture, Fisheries and Food (MAPA) is responsible for agricultural policy, health in primary production, designation of origin, plant health, animal welfare and animal health and fraud control in the food industry. MAPA prepares draft national legislations and is responsible for the coordination of official controls, including import and export controls within the scope of its competency.

MAPA is the national contact point for food fraud and for the RASFF (feed) and is a user of the Administrative Assistance and Cooperation System (AAC system).

MAPA is also responsible for the preparation of risk assessments with regard to residues of plant protection products and animal feed. MAPA is also in charge of regulating the use of plant protection products.
The scope of MAPA’s competencies also covers national decisions on GMOs, through the Interministerial Council on GMOs, and on zoonoses and veterinary medical products through the Ministry of Health. It is also the regulatory authority for pesticides (registration, authorisation and monitoring of use). However, before MAPA authorises the use of pesticides, AESAN is consulted with regard to residues in foods, the Ministry of Health is consulted to assess the safety of the user, and MAPA assesses the efficacy of the pesticide in question and its safety for the environment.

MAPA has four National Reference Laboratories, in compliance with Regulation (EU) 2017/625.
- Central Veterinary-Animal Health Laboratory
- Central Veterinary-Molecular Genetics Laboratory
- Central Animal Health Laboratory
- EU Reference Laboratory for African Horse Sickness and Bluetongue

The regulatory authority for medicines and medical products for human and veterinary use is the Spanish Agency for Medicines and Health Products, a dependent body in the Ministry of Health.

The Ministry of Consumer Affairs (MC) is responsible for consumer protection, the development of consumer affairs policies, and defending the rights of the consumer. It also prepares draft national legislations and is the contact point for RAPEX and a user of the Administrative Assistance and Cooperation System (AAC system). Within the Ministry of Consumer Affairs, AESAN is responsible for all matters relating to food safety.

The Ministry of Health (MS) deals with public health policy. Furthermore, the Sub-directorate General of Foreign Health, a dependent body in this Ministry’s Directorate General of Public Health is responsible for food safety concerning imports and exports and at Border Control Posts (BCPs), including foods of animal and plant origin, food contact materials, and animal by-products for the manufacture of pharmaceuticals, cosmetics and medical devices for medical purposes.
AESAN is the competent authority for the coordination of food safety within the Ministry of Health and for risk assessments.

AESAN is supported by a Scientific Committee comprised of independent external experts in the area of food safety and nutrition who are commissioned to draft risk assessment reports. The Scientific Committee issues updated scientific reports on biological, chemical, technological and nutritional hazards.

AESAN also prepares recommendations for the reduction of risks and identifies new health risks.

AESAN is also responsible for the risk management of biological, chemical and nutritional hazards and participates in decision-making on GMOs in foods in the Interministerial Council on GMOs.

AESAN is the competent authority for all draft legislations relating to the safety of foods available in Spain, which includes the transposition of EU directives into domestic legislation and the preparation of draft legislations at the national level.

It is also the competent authority in matters relating to food safety responsible for the coordination of official controls in Spain, and for the coordination and programming of official controls on food safety. It also prepares the National Official Control Plan and its corresponding annual reports in collaboration with MAPA and MS.

AESAN also acts as the national contact point for RASFF and is a user of the Administrative Assistance and Cooperation System (AAC system).

The remit of AESAN also includes the design and management of communication strategies in relation to food risk, establishing precise mechanisms that facilitate transparent communication of consumer safety risks to the general public, the scientific community and other involved or interested groups.

AESAN’s area of work extends beyond food safety to nutrition, physical activity and healthy eating habits.

AESAN has two National Reference Laboratories in compliance with Regulation (EU) 2017/625. These are the National Reference Laboratory (National Centre for Food (CNA)) and one EU Reference Laboratory for Marine Biotoxins (EURLMB).

From an administrative point of view, Spain is organised at the regional and local level into 17 autonomous communities, two autonomous cities (Ceuta and Melilla) and 52 provinces. Some regional food safety authorities conduct risk assessments at the local level. The implementation of official controls for food and feed, animal health, animal welfare and plant health is the responsibility of the regional authorities.

Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Spanish Agency for Food Safety and Nutrition
2. University Jaume I
3. ELIKA - Basque Foundation for Agrofood Safety
4. University of Las Palmas de Gran Canaria
5. University of the Balearic Islands
6. Valencian Institute for Agricultural Research
7. Centre for Agro-Food Economics and Development
8. Institute of Agrifood Research and Technology
9. National Institute for Agricultural and Food Research and Technology
10. Complutense University
11. University of Santiago de Compostela
12. University of Valencia
13. University of Leon
14. Autonomous University of Barcelona
15. University of Almeria
16. University of Lleida
17. Spanish Research Council
18. University of Seville
19. University of Castilla - La Mancha
20. Polytechnic University of Cartagena
21. Polytechnic University of València
22. NEIKER - Basque Institute for Agricultural Research and Development
23. University of Murcia
24. University of Granada
25. University of Barcelona
26. University of Burgos
27. University of Vigo
28. University of the Basque Country
29. University of Cordoba
30. Canary Health Service
31. Rovira i Virgili University
32. Ministry for Agriculture, Fisheries and Food
33. Institute of Health Carlos III
34. University of La Rioja
35. University of Alicante
36. University of Oviedo
The Food Act is the central legal foundation for food legislation in Sweden. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Sweden, there is no institutional separation of food risk assessment and food risk management, as both are performed by the Swedish Food Agency (Livsmedelsverket, LV). However, an in-house separation between risk assessment and risk management is in place to ensure independence.

The National Veterinary Institute (Statens veterinärmedicinska anstalt, SVA) is responsible for conducting risk assessments, and the Swedish Board of Agriculture (Jordbruksverket, JV) is responsible for risk management, within their field of expertise.

Within the Government Offices of Sweden, the Ministry of Enterprise and Innovation is responsible for agricultural policy and matters related to the entire food chain, including food safety. In close collaboration with other government ministries, policy issues related to food safety and the entire food chain are handled. As specified by their mandate, public agencies (i.e. LV, JV and SVA) provide support to the ministry.
The Swedish Food Agency (LV) is an independent, non-ministerial government authority. Nonetheless, the LV is accountable to the government and the Government Offices of Sweden.

In the area of food safety, the LV is responsible for risk and benefit assessments, risk communication and risk management. The LV prepares draft legislation on the basis of science-based risk assessments. The LV is responsible for state food inspections and for the subsequent information on the outcome of the control and inspection activities.

Within the LV, the Risk Benefit Assessment Department has the task to conduct independent risk assessments for food safety issues, including biohazards, novel foods, food supplements and botanicals, genetically modified organisms (GMOs), foodborne infections, contaminants and drinking water. The department also conducts risk assessments for plant protection products and veterinary medicinal product residues in food. However, the regulatory authority for plant protection products is the Swedish Chemicals Agency (Kemikalieinspektionen) and the regulatory authority for veterinary medicinal products is the Medical Products Agency (Läkemedelsverket). LV provides laboratory analytical services related to food safety.

The area of the Risk Benefit Assessment Department extends beyond food safety to include, e.g., nutrition and dietary surveys.

The Swedish Board of Agriculture (JV) is an independent, non-ministerial government authority. Nonetheless, the JV is accountable to the government and the Government Offices of Sweden.

In the area of feed safety, the JV is responsible for risk communication and risk management. It prepares draft legislation on the basis of science-based risk assessments. It is also responsible for state feed inspections and if necessary, subsequent information for the government on the outcome of control and inspection activities.

The remit of the JV includes residues of plant protection products and GMOs in feed and extends beyond food safety to plant health, animal health and animal welfare.

The National Veterinary Institute (SVA) is a risk assessment expert authority in animal health, subor-
The responsibility for Swedish food control is divided between the local, regional and national levels. The regional level in Sweden consists of 21 county authorities and the local level has 290 municipal authorities. The county authorities are responsible for the support and management of the municipal food control. They are also responsible for controls with regard to primary production, hunters, fishers and berry pickers. In some cases, the activities of the regional authorities are steered by the government. Municipal authorities are in charge of controls related to food and drinking water producers and handlers at the local level. The municipal authorities work and make decisions independently.

**Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002**

1. Swedish Food Agency (EFSA Focal Point)
2. National Veterinary Institute
3. Swedish Chemicals Agency
4. Swedish University of Agricultural Sciences
5. Linneaus University
6. Karolinska Institutet
The adoption of Law No. 9863 On Food, enacted in 2008, is to a large extent harmonised with the EU Acquis in the field of food safety. It provides the basis and principles for ensuring the protection of food safety standards and consumer interests as well as the requirements for the production and trading of food and feed. With this law, the National Food Authority (NFA) was established and became operational on 1 September 2010, based on the Decision of Council of Ministers No. 1081 On the Organisation and Functioning of the National Food Authority.

Based on the Food Law, secondary legislation was adopted in line with EU requirements. Current legislation dealing with food safety in Albania is partially aligned with EU provisions, namely the Food Hygiene Package. Regulation (EC) No. 178/2002, part of the EC Regulation No. 882/2004 on official controls, has been harmonised, as have Regulations No. 852/2004, No. 853/2004 and No. 854/2004, which were adopted by means of ordinances from the Minister of Agriculture, Rural Development and Water Administration.

The adoption of Law No. 10465 on Veterinary Service in the Republic of Albania in 2011 transferred the responsibilities for animal health and welfare to the veterinary service.

Based on the Law On the Veterinary Service in the Republic of Albania and the Law On the System of Animal Identification and Registration, several secondary legal acts were adopted introducing EU requirements in the veterinary field, such as regulation for the control of diseases in animals, regulation for controlling zoonotic diseases, regulations for the creation and functioning of the animal identification system, regulations for animal welfare, and a regulation on national and international trading conditions for all animals.

Phytosanitary activities are based on Law No. 9362 On the Plant Protection Service, dated 2005, which was amended in 2008 by Law No. 9908. Within the framework of the amended Law On the Plant Protection Service, secondary legislation was adopted in compliance with the EU Directives on plant protection (mainly the two basic directives 2000/29 and 91/414).

There is no separation between risk assessment and risk management, although they are separate departments within NFA.

Risk assessment publications are not published online.
The Ministry of Agriculture, Rural Development and Water Administration (MARDWA) deals with agricultural and food safety policy in Albania. It prepares draft legislation in the field of food and feed safety. The area of work of the MARDWA extends beyond food safety to include plant health, animal health and animal welfare.

Regarding food safety, the MARDWA is responsible for policies, strategies and legislation for food safety and quality of food products. It is involved in risk management and food safety crises management. It formulates policies to control the quality and safety of food products in order to integrate food control as a key function in the protection of consumer health and interests, providing fair competition in the national market, and the introduction of food products in the international market. In addition, the MARDWA is responsible for the fishery sector, including approval of fishery establishments, classification of live bivalve mollusk production areas and monitoring their sampling plans.

Regarding plant protection, the MARDWA is responsible for policies and legislation, implementation of procedures related to the registration of plant protection products, monitoring the plant protection service and representing the international authority in the field of plant protection. The responsible veterinary authority is the Veterinary Directorate within the General Directorate of Agriculture Service. In addition to representing Albania in the World Organisation for Animal Health (OIE), this directorate is responsible for the policies, strategies, legislation and monitoring of the implementation of laws in the area of veterinary service. The regional veterinary services are part of the Regional Agriculture Directories (RADs), which are technically accountable for all their activities to the Veterinary Directorate within the MARDWA. Private veterinarians are contracted by the Regional Agriculture Directories to carry out veterinary-related activities such as vaccination campaigns for national programmes and ear tagging of animals in accordance with the legislation.

Based on the current veterinary and food legislation in Albania, duties and competencies of the MARDWA State Veterinary Services are carried out at the farm level, focusing on the primary production only. Once they leave the farm, the primary products are under the competence of the National Food Authority inspection services.

Pursuant to Law No. 9863 On Food, dated 28 January 2008, as amended, which regulates the food safety system in Albania, the National Food Authority (NFA) is responsible for risk assessments, risk management and risk communication. 13 Border Inspection Posts (BIPs) under the NFA are in charge of the control of plants and plant products, livestock, animal by-products and food of animal and non-animal origin at the borders. The National Food Authority is an integrated part of the programme to create and guarantee a food safety system and consumer protection in the Republic of Albania. It was established by the Decision of the Council of Ministers No. 1081 dated 21 Octo-
NFA is an institution within the Ministry of Agriculture, Rural Development and Water Administration. As part of its organisational structure, NFA has nine regional laboratories which perform lab analyses for food and feed official controls as well as plant protection to verify compliance with the laws in the country, according to the legislation in effect. These labs are categorized into:

- Food safety lab: physical – chemical
- Microbiology lab
- Animal health and welfare lab
- Plant protection lab

The state of play of the NFA labs is defined in Law No. 9863 On Food, dated 28 January 2008, as amended, wherein their authorisation is granted by the Minister of Agriculture after an evaluation performed by the FSVI reference laboratory.

The remit of the NFA:

- Leads the risk assessment process in the fields of food, feed and plant protection; plans, coordinates and realises official controls of food and feed and plant protection
- Ensures the unification of official control practices for food, feed and plant protection at the national level
- Coordinates authorised laboratory activities with regard to official controls for food, feed and plant protection
- Conducts preliminary controls to verify if the technical, technological, hygiene, sanitation, phytosanitary and veterinary requirements are met and also to verify the necessary documentation for registering and licensing food business operators and plant protection
- Blocks, temporarily or permanently, the activities of food and feed business operators in stages of production, processing, delivery and marketing of food or feed when is proven that the food or feed and the respective business operators do not meet food safety standards as specified in the legislation in effect
- Conducts necessary scientific research on risk assessment in the field of food and feed safety and plant protection
- Provides technical, administrative and scientific support to enable the work of scientific committees and scientific panels
- Informs the public on food and feed safety and plant protection

The Food Safety and Veterinary Institute (FSVI) is under the Ministry of Agriculture, Rural Development and Water Administration. FSVI is a national reference centre and laboratory that carries out scientific research and application activities in areas of animal health and food quality, foodstuff residues, veterinary products registration and plant protection.

FSVI serves as a reference centre with the following tasks:

- Confirms diagnoses performed in other laboratories
- Standardises methods of analysis
- Uses and disseminates official methods of analysis
- Organises training courses for specialists in other laboratories
- Supplies other laboratories with new regulations and everything related to the field of research
- Collaborates with reference centres of the European Community
- Provides MARDWA with assistance and scientific laboratory information and suggests further measures to be taken in the field for issues that arise regarding the scope of FSVI.
FSVI implements the quality management system based on the ISO 17025:2005 standard and has been approved for six tests by the General Accreditation Directory and by a foreign accreditation body (Accredia – national accreditation in Italy). The Department of Animal Health in the FSVI comprises six sectors: Bacteriology, Virology, Parasitology, Mycology, Veterinary Epidemiology and the Sector for Veterinary Medical Products. The Sector for the Production of Vaccines and Bio-products is also a part of this institute.

MH
Ministry of Health

- Health services
- Drafting of legislation
- Health development strategies
- Investment programs: infrastructure of health service

Location: Tirana
http://www.shendetesia.gov.al

The mission of the Ministry of Health (MH) is the implementation of health policies of government programmes. The Ministry of Health compiles health policies at the national level and determines the development and planning of health services nationally and regionally. MH is responsible for public health, nutrition and the control of water and specific food products (nutritional purposes).

PHI
Public Health Institute

- Planning/verification of food supply
- Research plans in food sectors
- Monitoring of nutrition of population
- Surveillance/laboratory diagnostic data

Location: Tirana
http://www.ishp.gov.al

Food safety sector:
- Development and application of plans for the verification of food supply.

Nutritional sector (food):
- Development and application of research plans in food sectors: macronutrients and micronutrients.
- Monitoring of nutrition of population.

The enforcement of the legislation for public health and nutrition is carried out by sanitary inspectors who are responsible for issuing health certificates for workers in the industry, inspections in the working environments and the control of water up to the final consumer. The Public Health Institute (PHI) collects surveillance and laboratory diagnostic data from regional public health structures. The PHI reports the number of cases of infectious disease to the Food Safety and Epidemiology Section at the PHI on a monthly basis. The disease categories relevant to foodborne disease are: non-typhoid salmonellosis, botulism, shigellosis, E. coli enteritis, cholera, brucellosis, infection with hepatitis A virus, giardiasis, amebiasis, food poisoning (unknown aetiology, including food toxic infections), unspecified gastroenteric illness, and outbreaks associated with contaminated food and water.

RDA
Regional Directorates of Agriculture

- Collection of agricultural information
- Support of farmers
- Support of Agroindustry/-market
- Statistical information

Location: 12 RDAs in 12 regions

Each region has one Regional Directorate of Agriculture (RDA). RDAs are involved in the enforcement of legislation under the competence of MARDWA at the field level. In addition, plant protection specialists within RDAs are responsible for advising, informing and educating farmers on plant protection issues.
4.2 Bosnia and Herzegovina (BiH)

The Food Safety Law (Official Gazette B&H, No. 54/04) is the central legal foundation for food safety in Bosnia and Herzegovina (BiH). This act transposes Regulation (EC) No. 178/2002. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, however the final decision rests with the courts.

The ‘Hygiene Packet’ is transposed in BiH law with four rulebooks which define the responsibilities of individual institutions in BiH, and entity and cantons involved in the food safety chain.

In Bosnia and Herzegovina, there is procedural separation of risk assessment and risk management. Risk assessments are not published on the Internet.

The Food Safety Agency of Bosnia and Herzegovina (FSA BiH), in collaboration with competent authority of the entity and Brčko distrikt BiH, is responsible for drafting legislation in the area of food and feed safety, quality and hygiene.

The FSA BiH is an independent and science-based authority and provides scientific and technical support on all matters with regard to food and feed safety. It is responsible for risk as-
sessments in this area and the communication of results of risk assessments.

The Food Safety Agency of BiH is the contact point for the DG SANTE EU RASFF system, the INFOSAN network and the Codex Alimentarius pursuant to the provisions of the Food Law (Official Gazette of BiH, No. 50/04).

The FSA BiH works in close communication and cooperation with several national institutions at all levels.

The Veterinary Office of Bosnia and Herzegovina (VO BiH) is the subordinate specialist authority within the MoFTER tasked with animal health and welfare, veterinary public health, veterinary medicines, ensuring a system for risk management in the production and circulation of food of animal origin and, in accordance with the competent authority of the entity and Brčko District, prepares draft legislation in the area of animal health, welfare and feed, and veterinary public health.

The VO BiH monitors and controls animal welfare, including zoonosis. The Veterinary Border Inspection Department is an integral part of the VO BiH and is in charge of official controls of food animal origin and animal feed at the border. The VO BiH is responsible for the cooperation and coordination with the veterinary authorities of other countries in terms of international certification.

At the central level, two institutions within the Ministry of Foreign Trade and Economic Relations (MoFTER), the Veterinary Office of Bosnia and Herzegovina (VO) and the Administration of Bosnia and Herzegovina for Plant Health Protection BiH, have responsibilities related to food safety, animal health/welfare and plant protection. The Department for Agriculture, Food, Forestry and Rural Development within the MoFTER is responsible for the coordination and oversight of the relevant state agencies.

The Administration of Bosnia and Herzegovina for Plant Health Protection (PHPA BiH) was es-
Established as a separate administrative organisation within the MoFTER to determine policy in the area of plant health protection, develop draft regulations and ensure the protection of plant health in the entire BiH territory. The PHPA BiH is an independent administrative organisation within the MoFTER of Bosnia and Herzegovina and represents a National Organization for Plant Protection in accordance with the International Plant Protection Convention (IPPC). The PHPA BiH is responsible for plant health protection in Bosnia and Herzegovina as well as for information exchange/cooperation with international organisations dealing with phytosanitary matters such as IPPC/FAO, EPPO, WTO/SPS, UPOV, OECD, ISTA, etc. The PHPA performs administrative and related technical tasks in line with the Law on Plant Health Protection. It is also responsible for the controls regarding plant protection products, their residues, and registered suppliers/users.

Phytosanitary inspectors carry out obligatory controls on consignments of plants, plant products and regulated objects in accordance with Annex I part B (I) at border crossings (Border Inspection Posts, BIPs) in order to determine the presence of harmful organisms or compliance with phytosanitary regulations, and also conduct phytosanitary inspections of plants, plant products and regulated objects in the interior (where the plants are produced, processed, stored, transported, distributed or otherwise used).

Official controls on food of non-animal origin at border crossings and food and feed in the internal market are carried out by the inspectorates of the entities and the inspectorate of the Brčko District of BiH as follows:
1. Republic of Srpska – Administration for Inspection Affairs of Republic of Srpska
2. Federation of BiH – Federal Department for Inspection Affairs – sanitary and market inspection service, and cantonal inspection service

Institutions of the Government of Republic of Srpska involved in the drafting and implementation of legislation on food and feed safety, agriculture policy are as follows:
1. Ministry of Agriculture, Forestry and Water Management of Republic of Srpska
2. Ministry of Health and Social Welfare of Republic of Srpska

The governmental institutions of the Federation of Bosnia and Herzegovina involved in the drafting and implementation of legislation on food and feed safety, agriculture policy as follows:
1. Ministry of Agriculture, Water Management and Forestry of FBiH
2. Ministry of Health of BiH

Within the Brčko District, the Department of Agriculture, Forestry and Water Management has functions that are broadly similar to those of the entity.

Regional and local levels

Bosnia and Herzegovina consists of two entities, the Republic of Srpska and Federation of Bosnia and Herzegovina and the Brčko District. Entities have a high level of responsibility in the area of agriculture policy, food and feed policy, and quality and official controls. Each governmental level of BiH (entity/district, canton and municipality) has an administration for food safety, animal health/welfare and plant health.
The Food Act is the central legal foundation for food legislation in Iceland. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

Risk assessment and risk management are partly separated. Risk assessments are conducted by a risk assessment committee and by Matis Ltd. (Icelandic Food and Biotech R&D). The risk assessment committee reports to the Ministry of Industry and Innovation. The role of the committee is to provide scientific risk assessments in the areas of food, feed, fertilizers, and seed products. The Minister of Fisheries and Agriculture and the Food and Veterinary Authority may request the opinion of the committee. The committee may also, on its own initiative, carry out a risk assessment in consultation with the Minister of Fisheries and Agriculture.

Risk management decisions are made by the Ministry of Industries and Innovation and the Food and Veterinary Authority. Risk assessments from EFSA or national risk assessment authorities are sometimes used. Risk assessments connected to animal welfare are conducted by the Food and Veterinary Authority.

The Ministry of Industries and Innovation (ANR) is responsible for fisheries and agricultural policy and food safety in Iceland.

Risk assessment comity is under the responsibility of ANR.

The ministry prepares legislation in the area of fish and agricultural products, foods of animal and plant origin and other food and feed, and is responsible for official controls.

The portfolio of ANR includes drinking water, plant health, animal health, feed, animal welfare, seeds, fertilisers and fishing catches.
The Icelandic Food and Veterinary Authority (MAST) consists of a head office, an office for import and export control, and regional offices. MAST supervises the food control activities of the municipalities. MAST is subordinate to ANR and is the central authority in the field of food safety, animal health and animal welfare. MAST is involved in risk communication as well as preparatory work for legislation (in support of ANR activities).

MAST is responsible for inspections and controls during the import and export of food, feed, plants and live animals. In the area of food of animal origin, MAST carries out controls and inspections during primary production, in slaughterhouses, during the processing of meat and fish, and in dairies and during egg production.

MAST cooperates with Matis Ltd. with regard to risk assessment in the area of food safety and human exposure to contaminants. Matis Ltd. provides scientific advice and support in the area of chemical and microbiological food safety, monitoring of food safety risks as well as laboratory diagnostic services in the field of chemical and microbiological risks.

MAST also cooperates with several other scientific and governmental institutions within Iceland, e.g. the Chief Epidemiologist of the Directorate of Health on topics regarding communicable diseases, the Directorate of Customs regarding import and export, and the Icelandic Medicines Agency regarding the evaluation and registration of veterinary medicinal products.

The Icelandic Food and Biotech R&D (Matis Ltd.) is an independent research institute owned by the Icelandic government. Matis Ltd. provides laboratory services as well as risk assessments in the area of food safety. Matis is designated as a National Reference Laboratory in 12 fields covering chemical and microbiological food safety risks.

Iceland is divided into five veterinary districts, each with a regional office of MAST. Ten independent municipal Environmental and Public Health Offices are responsible for food safety controls at the retail level and are supervised by MAST.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. The Icelandic Food and Veterinary Authority (EFSA Focal Point)
2. Matís Ltd.
3. Landspitali – University Hospital and University of Iceland
4. The Institute for Experimental Pathology at Keldur, University of Iceland
4.4 Kosovo

The legal framework for food safety in Kosovo is the Law on Food 03/L-016. Infringement on the provisions of the Law on Food and other legal food safety acts can lead to measures under criminal law and consumer damage claims under civil law, in which case the final decision rests with the courts.

In Kosovo, risk assessment is still being developed. There is no institutional separation between risk assessment and risk management, and risk assessments are not published on the Internet.

The FVA develops, coordinates and implements food and feed safety, veterinary and phytosanitary policies in order to protect public health, animal health, plant health and the environment.

The FVA's activities also include approval and registration of food business operators and ensures that official controls are conducted within the scope of risk-based annual planning. Risk-based assessments are used for controls at border inspection posts when food and feed is imported from other countries.

The Media Relations Unit of the FVA deals with risk communication on a regular basis and in emerging crisis situations as well.

The Food and Veterinary Laboratory (FVL) is part of the FVA, and performs laboratory tests for food, feed and animal diseases.
The Ministry of Agriculture, Forestry and Rural Development (MAFRD) is responsible for the development of agricultural policy, legislation and programming for agriculture, food and feed safety.

MAFRD prepares legal bases for establishing infrastructure, development and strategic planning for implementing safety of food and feed measures, plant protection and aquaculture.

Additionally, MAFRD prepares planning for rural development related to food security and environmental protection.

Within MAFRD, the Agency for Rural Development is responsible for financial support for farmers and producers in order to increase production capacities and implement food safety standards.

MAFRD also comprises the Kosovo Agriculture Institute (KAI) and the Wine Institute. These institutes are accredited under ISO 17025, which ensures high quality standards in laboratory analyses of plant, feed, soil and wine.

MoH Ministry of Health

- Health Policy
- Risk assessment

Location: Prishtina
https://msh.rks-gov.net/en/

The Ministry of Health (MoH) is responsible for matters of public health and healthcare. This includes drafting legislation for foodborne and waterborne diseases. The MoH actively participates in the harmonisation between Kosovo’s national legislation and EU legislation.

MoH is authorised by the National Institute for Public Health (NIPH) to perform laboratory analysis of samples collected during official controls conducted by the FVA.

NIPH laboratories are accredited according to ISO17025:2006 and cover the areas of microbiology, biology and biochemistry, in particular the analysis of food products, beverages and water.
The Law on Food Safety (Official Gazette of Montenegro 57/15) governs the conditions for food and feed safety, duties and responsibilities of food and feed business operators, including traditional products, as well as other issues of relevance for food and feed safety, in order to ensure the protection of human life and health, the environment, consumers and efficient market functioning. Competent authorities for state administration activities in the food and feed safety area are the state administrative authority in charge of food safety, agriculture and veterinary issues (Ministry of Agriculture and Rural Development – MARD) and the administrative authority in charge of food safety (Administration for Food Safety, Veterinary and Phytosanitary Affairs – AFSVPA).

Risk assessments are based on the available scientific evidence and conducted in an independent, objective and transparent manner. Risk assessments may be carried out by scientific research institutions in the area of food safety, agriculture and veterinary issues (Ministry of Agriculture and Rural Development – MARD) and the administrative authority in charge of food safety (Administration for Food Safety, Veterinary and Phytosanitary Affairs – AFSVPA).

In the case that no scientific research institutions meet the requirements, the MARD may authorise a specialised institution of a European Union Member State to assess food and feed risks.

Risk management is carried out to ensure that the preventive measures, supervision and official controls undertaken in order to reduce, eliminate and avoid risk to human and animal health caused by the ingestion of food are based on risk assessment results and other factors relevant to risk elimination, and that they are unbiased, efficient and appropriate. Risk management is carried out by the AFSVPA through surveillance, official controls and preventive measures. In the course of risk management, results of risk assessments and/or scientific opinions prepared by scientific research institutions authorised by the ministry and the European Food Safety Authority (EFSA) and other safety-relevant factors are taken into account.

In the case of a threat where a food or feed may pose a risk to human or animal health, the MARD shall, without delay, through print or electronic media, inform the general public about the type of food and feed, the risk it may pose, as well as the measures undertaken or that are to be undertaken to prevent, reduce or eliminate that risk.
The Ministry of Agriculture and Rural Development (MARD) performs tasks related to the following: agricultural and rural development policies; protection, utilization and promotion of agricultural land; plant production; animal husbandry; organic production; phytosanitary matters; veterinary and food and feed safety policy; beekeeping; freshwater and marine fisheries and mariculture; forestry development policy; hunting; water management; international cooperation; preparation of regulations in the areas for which the ministry was established; administrative and inspection supervision.

The MARD proposes food and feed safety policy, adopts regulations for the enforcement of the Food Safety Law, implements annual monitoring programmes (residues in food of animal origin and feed, pesticide residues in food, zoonoses, microbiological criteria in food, contaminants in food and feed and other programmes), organises the implementation of official controls, adopts a multi-annual official control plan for food and feed, submits annual reports on food and feed safety to the Government of Montenegro and the European Commission, cooperates with international organisations and competent authorities of other states in the field of food and feed safety, and performs other activities in accordance with this law.

Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA) is a single state authority under the supervision of the Ministry of Agriculture and Rural Development of Montenegro. Three departments operate within the administration:

- Food Safety Department (FSD) – performs duties within the competence of the AFSVPA established by the laws on food and feed safety, organises and implements official controls and inspections.
- Veterinary Department (VD) – performs duties within the competence of the AFSVPA established by the laws on veterinary medicine, identification and registration of animals, protection of the welfare of animals, veterinary medicinal products and products of animal origin, and organises and conducts official controls and inspections.
- Phytosanitary Department (PD) – performs duties within the competence of the AFSVPA established by the laws on plant health protection, plant protection products, plant nutrition products, opioid drugs, seed material of agricultural plants, planting material, GMOs, plant variety protection, and plant genetic resources, and conducts official controls and inspections.

The AFSVPA establishes the compliance with the requirements and issues approvals for conducting business operations in establishments for the
production, processing and distribution of food and feed, registers food and feed establishments, sets up and maintains the Central Register of Approved Establishments conducting food and feed business operations, prepares and implements the multi-annual official control plan for food and feed, prepares annual reports on implementation of the multi-annual official controls, prepares the technical basis for adoption of legislation for the enforcement of this law, monitoring programmes, and contingency plans in the area of food and feed safety, cooperates with the European Commission, and performs other technical and administrative tasks in accordance with the law.

The analysis of samples taken in the course of official controls and monitoring of food and feed and food contact materials is conducted by official laboratories authorised by the Ministry. The authorisation may be granted to a laboratory that operates as a legal entity and is accredited pursuant to ISO/IEC 17025 and ISO/IEC 17011 for methods for which the laboratory can prove that it regularly and successfully participates in interlaboratory testing programmes. In the case that Montenegro does not have official laboratories to perform specific analyses, the ministry shall designate an accredited laboratory of a Member State of the European Union.

For specific types of food and specific analyses of food and feed, the ministry shall designate one laboratory as the National Reference Laboratory for such testing purposes. One laboratory may be designated as a reference laboratory for several types of testing. In the case that Montenegro does not have the laboratory for a specific area which complies with the requirements laid down by this law, the ministry may designate a reference laboratory of the Member State of the European Union or of the European Free Trade Association (EFTA).

**Laboratories and Faculties**

There are three public laboratories in Montenegro: the Institute for Public Health (IPH), the Centre for Ecotoxicological Research (CETI), and the Diagnostic Veterinary Laboratory (DVL).

The IPH conducts analyses of food, materials and items coming into contact with food: microbiological, parasitological, chemical, biological, toxicological, biochemical and other laboratory analyses, analyses of drinking water, surface and wastewater, etc.

The CETI is an institution authorised for the control and safety of food and objects in general use as of 1998, for the control of agricultural and food products in foreign trade as of 1999, as well as for the examination of physico-chemical properties of pesticides.

The Diagnostic Veterinary Laboratory has accredited a larger number of methods in the following fields: microbiological analyses of food of animal origin: meat and meat products, milk and dairy products, eggs and egg products; parasitological testing of meat and meat products.

The Biotechnical Faculty of the University of Montenegro (BTF) is a higher education institution that performs scientific research in the field of agriculture. The Biotechnical Faculty accomplishes its mission by improving education and human resources development programmes, modernising technical capacities, and enhancing interdisciplinary and multidisciplinary research by increasing participation in international programmes in the field of agriculture. The BTF is responsible for plant health control programmes.

The Faculty for Food Technology, Food Safety and Ecology (FFTFSE) was established in 2012 and offers bachelor’s and master’s degrees in four areas: food technology, sanitary engineering, HoReCa system engineering, and environmental engineering. The FFTFSE conducts research in areas related to the science of food and nutrition, biotechnology and ecology, in order to improve the theoretical knowledge and research methodologies, with an emphasis on interdisciplinary research.
Food safety, veterinary and phytosanitary inspections are a part of the AFSVPA. Official controls for the implementation of the Law on Food Safety are carried out by food inspectors, official border veterinarians, and border phytosanitary inspectors.

According to the Veterinary Law, veterinary inspectors are responsible for the control of trade of live animals, products of animal origin in the territory of Montenegro, checks at the places of dispatch or final destination of consignment, and in quarantine facilities.

Currently, border veterinary control in Montenegro is carried out at 10 veterinary Border Inspection Posts (BIPs) (8 at land borders, one in the Port of Bar and one at the airport in Podgorica).

Official controls concerning the placing on the market of food and feed are carried out by food inspectors as well as veterinary and phytosanitary border inspectors, while the control of animal by-products is the responsibility of veterinary inspectors.

Official controls with regard to the implementation of laws in the phytosanitary segment are undertaken by phytosanitary inspectors.
In Norway, the central legal foundation for food legislation is the Food Act. The EU Food Law is incorporated in the Norwegian Food Act. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments.

In Norway, risk assessment and risk management are institutionally separated. Risk assessments conducted by the Norwegian Scientific Committee for Food and Environment (VKM) are published on the Internet unless there are statutory provisions prohibiting it.

The Ministry of Agriculture and Food (LMD), the Ministry of Trade, Industry and Fisheries (NFD), and the Ministry of Health and Care Services (HOD) share responsibility for shaping food policy and for the management of foodstuffs from production to the consumer. Mattilsynet (Norwegian Food Safety Authority, NFSA) is a joint subordinate agency under these ministries.

The Ministry of Climate and Environment (KLD) bears special responsibility for environmental policy issues. The Miljødirektoratet (Norwegian Environment Agency, NEA) is a subordinate agency under KLD.

The Ministry of Health and Care Services (HOD) deals with health policy, including nutrition and food safety. It is responsible for legislation in the field of health protection, food safety and food, except for primary production. HOD’s responsibilities include drinking water and cosmetics. HOD is responsible for the Norwegian Directorate of Health, which deals with public health, including nutrition, as well as for the Norwegian Institute of Public Health. HOD finances and appoints the otherwise independent Norwegian Scientific Committee for Food and Environment (VKM).
### NFD
**Ministry of Trade, Industry and Fisheries**

- Risk communication
- Risk management
- Food: aquaculture production

Location: Oslo  
[https://www.regjeringen.no/en/dep/nfd/id709/](https://www.regjeringen.no/en/dep/nfd/id709/)

The Ministry of Trade, Industry and Fisheries (NFD) is responsible for legislation in the area of primary production in aquaculture, both wild and farmed fish and shellfish as well as fish feed. NFD's portfolio also includes feed for marine animals, fish health and welfare, and sustainable use of marine resources.

### KLD
**Ministry of Climate and Environment**

- Risk communication
- Risk management

Location: Oslo  
[https://www.regjeringen.no/en/dep/kld/id668/](https://www.regjeringen.no/en/dep/kld/id668/)

The Ministry of Climate and Environment (KLD) has the main responsibility for ensuring integrated governmental climate and environmental policies. In addition to initiating, developing and implementing its own measures and actions, KLD also acts as a promoter and coordinator to ensure that the authorities in the various sectors implement the environmental policies in their particular areas. KLD is the ministry in charge of Miljødirektoratet.

### LMD
**Ministry of Agriculture and Food**

- Risk communication
- Risk management
- Food: primary production

Location: Oslo  
[https://www.regjeringen.no/en/dep/lmd/id627/](https://www.regjeringen.no/en/dep/lmd/id627/)

The Ministry of Agriculture and Food (LMD) is the main ministry in charge of Mattilsynet (NFSA). It deals with agricultural policy in Norway. It is responsible for drafting legislation concerning the primary (agricultural) production of food and feed. The area of work of the LMD extends beyond food safety to include, for instance, plant health as well as animal health and welfare.

### Miljødirektoratet
**Norwegian Environment Agency**

- Risk communication
- Risk management

Location: Trondheim/Oslo  
[https://www.environmentagency.no/](https://www.environmentagency.no/)

Miljødirektoratet (Norwegian Environment Agency) is KLD’s advisory and executive body in the field of nature management. The agency’s primary tasks and responsibilities are reducing greenhouse gas emissions, preserving nature and preventing pollution.
The Norwegian Scientific Committee for Food and Environment (VKM) is an independent risk assessment body consisting of a secretariat and a scientific committee. 100 experts constitute the committee, which is organised into a Scientific Steering Committee and eleven Scientific Panels, similar to the EFSA structure. The secretariat is organised as an independent unit within the Norwegian Institute of Public Health. VKM is financed and appointed by the Ministry of Health and Care Services. VKM conducts risk assessments at the request of Mattilsynet (NFSA) across the authority’s field of responsibility. Furthermore, on behalf of the Miljødirektoratet (Norwegian Environment Agency), VKM carries out environmental risk assessments of genetically modified organisms (GMOs), microbiological products and alien organisms, as well as endangered species assessments related to the CITES regulations. VKM is the Norwegian Focal Point for EFSA. The director of VKM’s secretariat is a member of the EFSA Advisory Forum. VKM is the Norwegian Scientific Authority under the CITES Convention.

The Norwegian Food Safety Authority (NFSA) is a governmental body whose aim is to implement regulations and controls to ensure that food and drinking water are as safe and healthy as possible for consumers, and to promote plant, fish and animal health. The NFSA’s regulations cover ethical animal husbandry and encourage environmentally friendly production. It also regulates and controls cosmetics and animal health personnel. The NFSA’s role is to draft and provide information on legislation, perform risk-based inspections, monitor food safety as well as plant, fish and animal health, provide updates on developments within its area of responsibility, and plan for emergencies. The NFSA advises and does preparatory work for legislation under the three main food ministries: LMD, NFD and HOD.

The NFSA is the regulatory authority for pesticides, and it is responsible for residues of veterinary medicines. However, the Norwegian Medicines Agency is responsible for the approval of veterinary medicines.

The NFSA is organised into two administrative levels: the head office in Oslo and 5 regions: Northern region, Central region, Southern and Western region, Eastern region, and Greater Oslo region. The regional level includes 32 district offices.
Institutions involved in the EFSA network pursuant to Article 36 Reg. (EC) No. 178/2002

1. Norwegian Institute of Public Health (Folkehelseinstituttet – FHI) – includes VKM, EFSA Focal Point
2. Institute of Marine Research (Havforskningsinstituttet – IMR)
3. Norwegian Institute for Air Research (NILU – Stiftelsen Norsk institutt for luftforskning)
4. Norwegian University of Life Sciences (Norges miljø- og biovitenskapelige universitet – NMBU)
5. Norwegian Food Safety Authority (Mattilsynet)
6. Nofima AS (Nofima AS)
7. Norwegian Institute of Bioeconomy Research (Norsk institutt for bioøkonomi – NIBIO)
8. Norwegian Institute for Water Research (Norsk institutt for vannforskning – NIVA)
9. Norwegian Veterinary Institute (Veterinærinstituttet – VI)
The competent authority for food safety in the Republic of North Macedonia is the Food and Veterinary Agency. Other administrative bodies involved in the food safety system are the Ministry of Agriculture, Forestry and Water Economy represented by the Phytosanitary Directorate and the State Agricultural Inspectorate. The basic legal act is the Law on Food Safety (LFS), which regulates the control over the safety of food at all stages (production, processing, storage, transport, distribution, retail and catering). Infringement provisions of food safety legislation are defined in the LFS. Serious infringements are qualified as criminal offences covered under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Governmental measures with regard to food safety are often based on scientific risk assessments.

The official controls are performed on the basis of previously conducted risk assessments and are based on the provisions laid down in the Law on Food Safety.

As regards risk assessment, in 2015, a National Council for Food and Feed Safety (National Council) was established by the Government of the Republic of North Macedonia. The council consists of members that represent relevant universities and scientific institutions in the country.

The role of the National Council is to provide scientific advice and scientific and technical support in relation to the policies in fields that have direct or indirect effects and influence on food and feed safety and animal health and welfare.

In addition, the National Council is responsible for providing independent opinions and recommendations and for sharing information related to risks in order to increase consumer confidence and improve the harmonisation between risk assessment and risk communication.

The functioning and operation of the National Council is organised into several dedicated Scientific Panels (SP):
- SP for animal health and welfare
- SP for biological hazards
- SP for contaminants in the food chain
- SP for dietetic foodstuffs, nutrition and allergies
- SP for additives and food enrichment products
- SP for plant protection products and residues thereof
- SP for plant health
- SP for feed additives or substances used in the animal feeding stuffs
- SP for food contact materials, enzymes, flavours and technological aids
- SP for genetically modified organisms.

In addition, the Department for Risk Assessment and Communication operates within the organisa-
tional structure of the Food and Veterinary Agency and serves as the secretariat of the National Council.

In the Republic of North Macedonia, there is a functional separation of risk assessment and risk management.

**FVA**
**Food and Veterinary Agency**

- Food and feed safety
- Veterinary policy, public health policy
- Veterinary medicinal products
- Risk assessment
- Risk communication
- Risk management
- EFSA Focal Point
- RASFF contact point
- Codex Contact Point
- OIE Focal Points, CVO
- EC, DG SANTE, contact point and coordinator regarding EU affairs in food safety, veterinary and phytosanitary fields
- WTO SPS Enquiry Point

Location: Skopje
http://www.fva.gov.mk

The Food and Veterinary Agency (FVA) is the central competent authority responsible for performing tasks related to:
- food and feed safety;
- implementation, control, surveillance and monitoring of veterinary activities in the field of animal health and welfare;
- veterinary public health, including veterinary medicinal products, animal feedstuffs and animal by-products;
- control of National Reference Laboratories and authorised laboratories supporting the needs of the FVA;
- control of the quality of food, except for primary agricultural production of food of non-animal origin;
- official controls of feed and food of animal and non-animal origin – during production, processing, storage, transport, trade, import and export.

The FVA is the policy-making authority responsible for coordination of the legislation and control systems in the field of food and feed safety between the relevant institutions in the Republic of North Macedonia, as well as the competent institution for communication with the European institutions responsible for food and feed safety, veterinary and phytosanitary policy.

**MAFWE**
**Ministry of Agriculture, Forestry and Water Economy**

- Agricultural policy
- Risk management

Location: Skopje
http://www.mzsv.gov.mk

The Ministry of Agriculture, Forestry and Water Economy (MAFWE) is responsible for the development and implementation of agricultural policy and safety of food and feed of plant origin during primary production.

As part of the MAFWE, the State Agriculture Inspectorate (SAI) is responsible for the control of primary production of food of plant origin, plant health, and implementation of measures for the prevention and containment of harmful organisms, as well as for control of the use of plant protection products in primary production and associated operations.

The Phytosanitary Directorate (PD) within the Ministry of Agriculture, Forestry and Water Economy
is responsible for the national phytosanitary policy and for drafting legislation in the area of plant health and plant protection products (PPPs).

**FVM**

**Faculty of Veterinary Medicine**

- Laboratory analysis
- Risk assessment

Location: Skopje
https://fvm.ukim.edu.mk/en/

The Faculty of Veterinary Medicine in Skopje (FVM) is a public institution for higher education that operates within Ss. Cyril and Methodius University in Skopje, and is the leading national diagnostic, research and scientific institution in the field of veterinary medicine and food safety in the Republic of North Macedonia. The Faculty of Veterinary Medicine is authorised to perform laboratory analyses of samples collected during official controls conducted by the FVA.

The organisational structure of the FVM consists of the following units:

**Food Institute**, with the following laboratories:
- Laboratory for microbiology of food and feed
- Laboratory for quality control of food and feed
- Laboratory for residues and contaminants
- Laboratory for raw milk quality
- Laboratory for pharmacology and toxicology

**Veterinary Institute**, with the following laboratories:
- Laboratory for microbiology
- Laboratory for serology and molecular diagnostics
- Laboratory for parasitology and parasitic diseases
- Laboratory for transmissible spongiform encephalopathies
- Laboratory for diagnosis fish, bees and hunting wild game diseases
- Laboratory for pathology and patohystology
- Laboratory for pathophysiology
- Laboratory for rabies
- Laboratory for animal hygiene and environmental
- Cabinet for visual diagnostics

**Institute for Reproduction and Biomedicine**

with the following laboratories:
- Laboratory for production, cryoconservation and control of semen
- Laboratory for assisted reproduction
- Plastination laboratory
- Laboratory for histology and embryology
- Laboratory for biochemistry and cell biology
- Animal genetics laboratory

The FVM laboratories are accredited according to MKC ISO/IEC 17025:2006. The FVM is also involved in the FVA’s risk assessment activities.

**IPH**

**Institute of Public Health**

- Laboratory analysis
- Risk assessment

Location: Skopje
http://www.iph.mk/en/

The Institute of Public Health of the Republic of North Macedonia (IPH) is a national health institution in the field of preventive health care. The aim of the institute is to promote the health and general welfare of the human population through scientifically-based knowledge, best practices, information and organisational partnerships and sustainable impact on public health policies. The institute is authorised to conduct laboratory analyses of food and feed samples collected by state food inspectors. The IPH is accredited according to ISO/IEC 17025. The IPH also supports the FVA and risk assessment activities.
### SPL
**State Phytosanitary Laboratory**

- Laboratory analysis
- Location: Skopje
  http://www.mzsv.gov.mk

The State Phytosanitary Laboratory (SPL) conducts laboratory activities (analysis of pesticides formulation and residues of PPPs, seeds, and diagnosis of samples for harmful plant organisms) in accordance with annual phytosanitary monitoring programmes and monitoring programmes for plant protection products and residues of plant protection products in primary agricultural products, as well as testing of seed and seedling materials.

### LI
**Livestock Institute**

- Laboratory analysis
- Risk assessment
- Location: Skopje
  http://www.mzsv.gov.mk

The Livestock Institute (LI), an integral part of Ss. Cyril and Methodius University in Skopje, conducts scientific and applied research and is involved in educational activities. The scientific and research nature of the institute aims towards upgrading the livestock production and related fields in the Republic of North Macedonia. The institute is involved in the coordination and implementation of the identification, control of the production and reproduction features, testing, evaluation and control of the quality of feed for all domestic animal species.

### FASF
**Faculty of Agricultural Sciences and Food**

- Laboratory analysis
- Risk assessment
- Location: Skopje
  http://www.fznh.ukim.edu.mk/

The Faculty of Agricultural Sciences and Food (FASF) is an integral part of Ss. Cyril and Methodius University in Skopje. The faculty is responsible for educational activities for the first, second and third cycles of study, scientific and research activities in the field of biotechnical sciences, soil and hydrology, plant protection, plant production, apiculture, fruit production, livestock production, fishery, forestry, biotechnology, food technology, production of animal products and other fields related to the faculty’s scope of work.

### Regional and local levels

Ten regional independent public health centres/laboratories perform chemical, toxicological and microbiological analyses of food and water.

Control and inspection activities are coordinated and supervised by the FVA’s central headquarters.

28 regional offices of the FVA operate at the regional and local level to inspect food of non-animal and animal origin, animal health and welfare.

Official veterinarians based at 11 Border Control Points (BCPs) perform import controls on food and live animals.
Institutions involved in the food safety system in the Republic of North Macedonia:

1. Food and Veterinary Agency (FVA), Phytosanitary Directorate, MAFWE
2. State Agricultural Inspection, MAFWE
3. Veterinary Institute, Faculty of Veterinary Medicine – Skopje
4. Food Institute, Faculty of Veterinary Medicine – Skopje
5. State Phytosanitary Laboratory, MAFWE
6. Institute for Public Health of the Republic of North Macedonia, Skopje and 10 Regional Centres for Public Health
7. Laboratory for Biochemistry and Molecular Biology, Faculty of Agricultural Sciences and Food
8. Research Centre for Genetic Engineering and Biotechnology, MASA
9. Faculty of Pharmacy, Ss. Cyril and Methodius University, Skopje
10. Faculty of Medicine, Ss. Cyril and Methodius University, Skopje
   - Institute for Microbiology and Parasitology
   - Institute for Medical and Experimental Biochemistry
   - Institute for Epidemiology and Biostatistics with Medical Informatics
   - Institute for Preclinical and Clinical Pharmacology with Toxicology
The Law on Food Safety is the central legal act which prescribes the rules on food and feed safety, responsibilities of food and feed business operators, the rapid alert system, emergency measures and crisis management. This Law is harmonised with Regulation (EC) No. 178/2002. The food safety bylaws are mostly in line with the EU Hygiene package.

Two ministries and their related services share the overall responsibility for food safety: the Ministry of Agriculture, Forestry and Water Management (MAFWM) and the Ministry of Health (MH), mainly in terms of risk management.

MAFWM prepares draft legislation and issues ordinances in the area of food and feed safety, animal health and welfare, and plant health.

MH is responsible for public health, potable water, certain areas of food safety (infant formula, dietetic food, diet supplements, salt, food contact materials, novel food).

The Expert Council for Risk Assessment in Food Safety Area (CRA) is responsible for scientific risk assessments and the development of scientific studies in the field of food and feed safety. CRA provides expert opinions on issues related to the placing on the market of novel foods, nutrient-rich foods, foods for special nutritional needs, animal feed, genetically modified food and animal feed, animal health and welfare, plant health, as well as the identification and characterization of risks.

There is no clear separation between risk assessment and risk management. MAFWM and MH established the Expert Council for Risk Assessment in Food Safety Area with members from all relevant institutions, faculties, and institutes which serve to provide risk assessments on request.

**MAFWM**

**Ministry of Agriculture, Forestry and Water Management**

- Agricultural policy
- Food and feed safety policy
- Risk management
- Risk communication
- RASFF contact point
- EFSA Focal Point
- OIE Focal Point
- Codex Focal Point

Location: Belgrade

http://www.minpolj.gov.rs

The Ministry of Agriculture, Forestry and Water Management (MAFWM) is the central competent authority for policy and legislation on the enforcement of laws on food safety, veterinary and phytosanitary matters. Veterinary Directo-
The Veterinary Directorate (VD) is responsible for the safety of food of animal origin throughout all stages of production, processing and distribution, including import and export. It is also responsible for animal health, animal welfare, animal reproduction, animal feed, veterinary medicinal products and residues, as well as animal by-products. Legislation and cooperation with other relevant competent authorities in these fields are in the remit of VD. VD is the central point for coordinating activities related to OIE, EFSA and RASFF.

The Veterinary Inspection division is an integral part of VD and veterinary inspectors carry out official controls on holdings and in establishments dealing with food of animal origin and feed.

VD implements all necessary measures to protect the spread of animal diseases and zoonoses, foodborne diseases and antimicrobial resistance.

The Veterinary Institutes located throughout the whole country support the work of VD and the Faculty of Veterinary Medicine.

The scientific and expert support to VD is provided by the Scientific Veterinary Institutes (SVI) in Belgrade, Novi Sad and Kraljevo for certain animal diseases – as well as by the Faculty of Veterinary Medicine, which performs diagnostic tests related to animal health, food and feed testing, and participates in scientific work and training.

The National Reference Laboratory for VMP (veterinary medicinal product) residues is the Institute for Meat Hygiene and Technology in Belgrade.

Besides these institutions, there are designated state and private laboratories involved in the official testing of food of animal origin.

The Plant Protection Directorate (PPD) of MAFWM is the competent authority for phytosanitary matters, including plant health (harmful organisms), seed and propagating material, plant breeders' rights, genetically modified organisms (GMOs), plant protection products (PPPs), plant nutrition products and soil improvers. PPD is responsible for establishing test methods for residues of PPPs in food and feed of plant and animal origin,
the control of residues of PPPs in food of plant and composite origin, and the control in the area of the safety of non-processed and processed food of plant origin upon import, and feed of plant origin upon import.

PPD monitors the implementation of legislation and the enforcement of official controls in these areas.

The Phytosanitary Inspection division is an integral part of PPD. Phytosanitary inspectors are in charge of official controls on plant origin products in primary production. Plant protection institutes and agricultural services throughout the country support the work of PPD.

The Directorate for National Reference Laboratories (DNRL) was established for the purpose of performing tasks within the area of food safety, plant health, residues of pesticides, milk hygiene and quality, and plant gene banks. DNRL has cooperations with the reference laboratories in other countries. It also establishes uniform criteria and methods, implements standards for the operation of authorised laboratories, and provides training for authorised laboratory staff. It is responsible for the testing of pesticides, certain plant diseases and plant gene banks, milk hygiene and certain foodborne pathogens.

The Ministry of Health (MH) is the competent authority for drafting policy and the adoption and implementation of regulations for enforcement of legislation in the area of novel food, dietary products, infant formulas, dietary supplements and salts for human consumption, additives, flavourings and enzymatic preparations and supplements of non-animal origin, food contact materials, drinking water and public water supply systems. The Sector for Inspection Supervision (SIS), the Department for Sanitary Inspection within MH, carries out official controls within designated food safety tasks and in the case of food outbreak/epidemiology investigations. Public health institutes are tasked with the official testing of food and water.

The portfolio of MH also encompasses other research institutions – National Institutes for Public Health “Batut” (ECDC Focal Point), the Institute of Virology, Vaccines and Sera (“Torlak”), and regional public health institutes.
4.9 Switzerland

The Federal Act on Foodstuffs and Utility Articles is the central legal foundation for food law in Switzerland. Also relevant in this area is the Federal Act on Agriculture and related ordinances on feed, animal health, animal welfare, as well as the import, transit and export of animals and food of animal origin.

Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

In Switzerland, there is no institutional separation of risk assessment and risk management. However, different divisions of the Federal Food Safety and Veterinary Office (FSVO) are in charge. While food safety laws are enacted at the national level, implementation and control at the regional level is the responsibility of the cantons.

Risk assessments are published on the Internet only occasionally.

The Federal Food Safety and Veterinary Office (FSVO) is part of the Federal Department of Home Affairs. The office is responsible for risk assessments and risk management in the area of animal health and welfare, food safety and consumer protection and has its own laboratory research facilities.

The FSVO is also responsible for the safety of utility articles, such as toys and cosmetics. In addition, the FSVO monitors and controls the import, export and transit of livestock and domestic animals, animal products, food, and internationally protected flora and fauna (CITES Convention). In
close collaboration with the Swiss Federal Customs Administration, the FSVO is responsible for the control of foodstuffs and utility articles at the border.

In cooperation with importing countries, the FSVO also issues veterinary documents for the export of animals and animal products.

The regulatory authority for veterinary drugs is the Swiss Agency for Therapeutic Products (Swissmedic), while risks associated with residues of veterinary drugs in food of animal origin are covered by the FSVO.

**FOAG**
Federal Office for Agriculture

- Risk assessment
- Risk management

Location: Bern
http://www.blw.admin.ch

The Federal Office for Agriculture (FOAG) is an office of the Federal Department of Economic Affairs, Education and Research and is responsible for agricultural policy, safety of food of plant origin during primary production and safety of animal feed. Together with the cantons and farmers' organisations, the FOAG implements decisions by the people, the parliament and the government.

The FOAG is responsible for risk assessments and risk management in the area of animal feed. Actual control and inspection activities are carried out by the research institute Agroscope.

The FOAG’s remit includes residues of plant protection products, GMOs and plant health. The FOAG is the regulatory authority for pesticides, while risks associated with pesticide residues are covered by the FSVO.

**FFCU**
Federal Food Chain Unit

- Risk management

Location: Bern
http://www.blk.admin.ch

On behalf of the FOAG and FSVO, the Federal Food Chain Unit (FFCU) audits the implementation and enforcement of national legislation by federal and cantonal authorities in the area of feed safety, food safety, animal health and animal welfare. The FFCU also prepares and coordinates the implementation and evaluation of the multi-annual national control plan.

Switzerland consists of 26 federal states, the cantons. They are responsible for the enforcement of food safety and agricultural legislation. Cantonal food control authorities are responsible for food safety inspections. Cantonal veterinary offices are responsible for the enforcement of legislation concerning animal health, animal welfare and veterinary medicinal products. They inspect livestock prior to slaughtering and conduct meat inspections. Both cantonal authorities report to the FSVO.

Institutions involved in the EFSA network: Switzerland has observer status for various EFSA working groups, the Focal Point network and some of the scientific networks, in which mainly delegates of the FSVO participate.

Access to the Rapid Alert System for Food and Feed (RASFF) is limited to notifications concerning food of animal origin.

Infringement of food regulations can lead to measures under criminal law and consumer damage claims (under the Law No. 6502), whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessments. However, the final decision on the legality of governmental measures rests with the courts.

Although there is no institutional separation in Turkey, risk management is procedurally separated from risk assessment, which is undertaken by scientific commissions. Risk assessment results are not yet regularly published.

The Ministry of Agriculture and Forestry (TOB) is responsible for food and feed safety, including veterinary and phytosanitary tasks, forestry. TOB aims to protect public health, plant and animal health, animal welfare and consumer interests, taking into consideration the protection of the environment. The TOB is responsible for official controls and inspections at all stages of the food and feed chain.

To protect human and animal health, the TOB cooperates with the Ministry of Health (SB) and other relevant institutions with regard to the monitoring of certain zoonotic diseases and agents, foodborne outbreaks and antimicrobial resistance.
The TOB in Ankara consists of twenty-one units, three of them are involved in the development and enforcement of food and feed safety, veterinary policy and phytosanitary policy (i.e. the General Directorate of Food and Control (GKGM), General Directorate of Plant Production (BÜGEM), General Directorate of Agricultural Research and Policies (TAMEM)).

**GKGM**

**General Directorate of Food and Control**

- Food and feed safety
- Risk assessment
- Risk communication
- Risk management
- Codex Contact Point
- EFSA Focal Point
- RASFF contact point

Location: Ankara

https://www.tarimorman.gov.tr/GKGM

Laboratory services for animal health, plant health as well as food and feed safety are provided by eight veterinary control and research institutes, eight plant protection research institutes, four quarantine laboratories, 39 provincial control laboratories, one food control and central research institute, and one National Food Reference Laboratory under the supervision of the GKGM. There are also 98 private laboratories operating with the authorisation of the GKGM. Most of the practical implementation and enforcement activities are carried out by 81 Provincial Agricultural and Forestry Directorates (PAFDs) and 914 District Agricultural and Forestry Directorates (DAFDs), with a vertical chain of command between the two.

The Ministry of Health (SB) is responsible for specific aspects in the area of food safety. The SB prepares legislation and is responsible for inspection and control of the quality of water intended for human consumption, natural mineral water, health claims, dietary foods for special medical purposes, as well as products which do not require a prescription but have been scientifically and clinically proven to be used as drugs, including enteral nutritional products. In addition, epidemiologic research is coordinated by the General Directorate of Public Health. The SB is represented by Provincial Health Directorates (PHDs) in the provinces and District Health Directorates (DHDs) at the district level.

**SB**

**Ministry of Health**

- Health policy, foodborne outbreaks, health claims
- Nutrition, drinking and mineral water, dietary foods for special medical purposes
- Risk assessment
- Risk management
- Risk communication

Location: Ankara

http://www.saglik.gov.tr

The General Directorate of Food and Control (GKGM) is a unit within the TOB which is responsible for developing policies and preparing legislation, as well as for the subsequent enforcement, control and inspection of food and feed safety, animal health, animal welfare and plant health at the central level (‘from farm to fork’). The GKGM is also responsible for conducting scientific risk assessments which are carried out by scientific commissions under the umbrella of the Risk Assessment Department.
The General Directorate of Plant Protection (BÜGEM) is a unit within the TOB which is responsible for the determination and inspection of standards and the convenience of use of agricultural inputs and production technologies, such as the organic production of agricultural products. Additives and microbiological criteria are studied in research institutions and laboratories, such as the Plant Protection Central Research Institute and the Veterinarian Central Research and Control Institute.

Some of the laboratories associated with TAGEM conduct laboratory analyses of samples collected during food, feed, animal health and phytosanitary control and inspections under the supervision of the GKGM.

The tasks of evaluating applications related to GMOs and their associated products, performing the secretarial tasks of the committees and other duties specified in the Biosafety Law and related regulations are carried out by the TAGEM.

There are 81 provinces and 919 districts in Turkey. The TOB is represented by local TOB offices (PAFDs and DAFDs) in all provinces and 914 districts. PAFDs consist of nine units responsible for food, feed, animal health, breeding, fishery, plant production and plant health. Four of them are involved in the enforcement of food and feed safety, veterinary policy and phytosanitary policy.
### 5 Description of Pictograms

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<tr>
<th>Pictogram</th>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>🐂</td>
<td>Animal feed</td>
<td>Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.</td>
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<tr>
<td>🐂</td>
<td>Animal health and welfare</td>
<td>All aspects of animal diseases and well-being of food-producing animals during breeding, rearing, transportation and slaughter (integral part of the EU's Farm to Fork strategy). Analysis of the impact that the conditions and treatment of animals can have on both animal and human health.</td>
</tr>
</tbody>
</table>
| 🐄         | Biological hazards and zoonoses | Biological hazards: also known as biohazards, refer to biological substances that pose a threat to the health of living organisms, primarily that of humans. This can include medical waste or samples of a microorganism, viruses, or toxins (from a biological source) that can affect human health.  
   Zoonoses: any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans. |
| 🌐         | Biotechnology and genetic engineering | Biotechnology: the use of biology to solve problems and make useful products. The most prominent area of biotechnology is the production of therapeutic proteins and other drugs through genetic engineering.  
   Genetic engineering: all modern molecular biology techniques used to isolate, manipulate and transfer genes from one organism to another in order to create novel traits in plants, animals, bacteria and fungi. |
| 🌞         | Contaminants          | Any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination.  
   Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition. |
| 🌂         | Drinking water        | All water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers. Drinking water includes also all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption, unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form. |
| 🚨         | Emerging risk        | A risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard. |
| **Environmental risk assessment (ERA)** | A scientific process that identifies and evaluates stress to the environment in particular, to living microorganisms, habitats and ecosystems. ERA considers the impact on the environment caused by, for example, the introduction of GM plants, the use of certain substances in food, feed and plant protection products, or the introduction and spread of plant pests. ERA helps policy makers and regulators take sound decisions that protect the environment. |
| **Food contact materials and packaging** | All materials and articles intended to come into contact with food, such as packaging and containers, kitchen equipment, cutlery and dishes. These can be made from a variety of materials including plastics, rubber, paper and metal. They also include materials used in processing equipment, such as coffee makers or production machinery, as well as containers used for transport. |
| **Food ingredients** | Chemical substances which are used as food additives, enzymes, flavourings, processing aids and other substances intentionally added to food (commonly called ‘nutrient sources’). |
| **Food supplements** | Nutrients or other substances with a nutritional or physiological effect aimed to supplement the regular diet. Food supplements are usually on the market as capsules, pastilles, tablets, pills, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. |
| **Mineral water** | Bottled water for human consumption that is either 

a) natural mineral water (groundwater that has emerged from the ground and contains a certain amount of minerals),

b) natural spring water (also groundwater that has emerged from the ground, but which contains a lower amount of minerals) or

c) processed tap water. This does not include bottled water intended for medicinal purposes. |
| **Nanotechnology** | Field of applied sciences and technologies involving the control of matter on the atomic and molecular scale (normally below 100 nanometres). Nanotechnology products could have a substantial impact on the food and feed sector in the future. It may also be used in food packaging. |
| **Novel food** | Foods and food ingredients that have not been used for human consumption to a significant degree within the EU before 15 May 1997. In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. Only those products considered to be safe for human consumption are authorised for marketing. |
| **Nutrition** | Nutrition is the study of nutrients in food and how the body uses them. Nutrition also focuses on how people can use dietary choices to reduce the risk of disease associated with poor nutrition, such as chronic metabolic diseases. |
| **Plant health** | Plant health is concerned with ecosystem health, with a special focus on plant pests (such as fungi, bacteria, viruses and insects) among food crops, natural vegetation and landscape plants, which are often introduced to areas previously unaffected through plant imports and can have far-reaching economic, social and environmental consequences. |
| **Plant protection products or pesticides** | Active substances and preparations containing one or more active substances intended to protect plants (or plant products) against harmful organisms. The term ‘plant protection product’ (or pesticide) implies that the active substances are present in a form or product which can be supplied to the user. Active substances in plant protection products may also destroy undesired plants or influence life processes of plants in a way other than as a nutrient (for example as growth regulators). |
| **Residues of veterinary medicinal products** | Substances contained in plants, plant products, edible animal products or drinking water which originate from the use of veterinary medicines, including metabolites, decomposition and reaction products. |
## 6 Overview of Institutions

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