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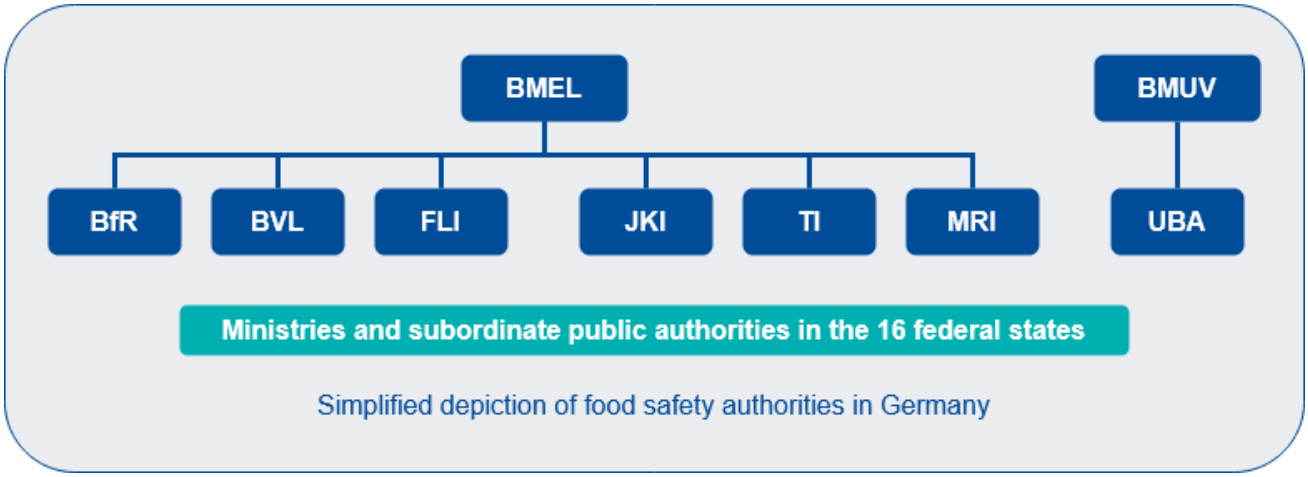

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Contents

Germany (Test)

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.

Federal Ministry of Food and Agriculture

Name	Federal Ministry of Food and Agriculture
Acronym	BMEL
Activities	• Agricultural policy and food safety
Responsibilities	
Locations	Bonn and Berlin
URL	https://www.bmel.de/EN/Home/home_node.html

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 those for Agricultural Policy, Food and Consumer Health Protection and for 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 legislation 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 of Regulation (EC) 178/2002, 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-Institut (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 Johann Heinrich von Thünen-Institut (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). Innovative research and competent scientific policy advice are closely linked tasks undertaken by these institutions.

Federal Ministry of the Environment, Nature Conservation, Nuclear Safety and Consumer Protection

Name	Federal Ministry of the Environment, Nature Conservation, Nuclear Safety and Consumer Protection
Acronym	BMUV
Locations	Bonn and Berlin
URL	https://www.bmuv.de/en/

German Federal Institute for Risk Assessment

Name	German Federal Institute for Risk Assessment
Acronym	BfR
Activities	• Risk assessment • Risk communication • Risk benefit assessment • Regulatory service • EFSA Focal Point • Research
Responsibilities	
Location	Berlin
URL	https://www.bfr.bund.de/en

The remit of the German Federal Institute for Risk Assessment (BfR) encompasses scientifically based risk assessments as part of administrative procedures (for instance, marketing authorisations 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 the 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: Registration, Evaluation, Authorisation of Chemicals). 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*, *Campylobacter*, *Trichinella*, Antimicrobial Resistance, Animal Proteins in Feed, Additives for Use in Animal Nutrition, Materials in Contact with Food, Mycotoxins and Plant Toxins as well as 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.

Federal Office of Consumer Protection and Food Safety

Name	Federal Office of Consumer Protection and Food Safety
Acronym	BVL
Activities	• 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
Responsibilities	
Locations	Braunschweig and Berlin
URL	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 the BMEL, the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and

Consumer Protection (BMUV) 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 Common Central Unit 'Control of Food, Feed, Cosmetics, Consumer Goods and Tobacco Products Traded on the Internet' (G@ZIELT). BVL is the German national contact point for the inspections of the European Commission, for the Rapid Alert System for Food and Feed (RASFF) as well as the Administrative Assistance and Cooperation System (AAC) of the European Union, and in this role secures the flow of information between the EU and the Federal States. In times of crisis, it serves as a situation centre for the crisis management group of BMEL, and regularly organises crisis exercises with all relevant players. BVL collects and analyses data of official food and feed control and forwards them to EFSA. It serves as the contact point for the EU Food Fraud network. BVL also supports competent authorities and food associations in export matters and accompanies the registration process of food business operators in third countries.

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.

Friedrich-Loeffler-Institut – Federal Research Institute for Animal Health

Name	Friedrich-Loeffler-Institut – Federal Research Institute for Animal Health
Acronym	FLI
Activities	• Research • Risk assessment
Responsibilities	
Location	Greifswald – Island of Riems
URL	http://www.fli.de/en

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 competent authorities in the implementation of Council Regulation (EC) No 1099/2009, Article 20, regarding the protection of animals at the time of killing.

Julius Kühn-Institut – Federal Research Centre for Cultivated Plants

Name	Julius Kühn-Institut – Federal Research Centre for Cultivated Plants
Acronym	JKI
Activities	• Risk assessment • Risk benefit assessment • Regulatory science • Research
Responsibilities	
Location	Quedlinburg
URL	http://www.julius-kuehn.de/en

The Julius Kühn-Institut (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.

Max Rubner-Institut – Federal Research Institute of Nutrition and Food

Name	Max Rubner-Institut – Federal Research Institute of Nutrition and Food
Acronym	MRI
Activities	• Research
Responsibilities	
Location	Karlsruhe
URL	https://www.mri.bund.de/en/home/

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 also 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.

Johann Heinrich von Thünen-Institut – Federal Research Institute for Rural Areas, Forestry and Fisheries

Name	Johann Heinrich von Thünen-Institut – Federal Research Institute for Rural Areas, Forestry and Fisheries
Acronym	TI
Activities	• Risk management • Regulatory science • Research
Responsibilities	
Location	Braunschweig
URL	https://www.thuenen.de/en/

In general, the Johann Heinrich von Thünen-Institut (TI) carries out research and long term-monitoring and provides policy advice with regard to natural resources, protected assets as

well as respective production systems and economic and societal issues in agriculture, fisheries, forestry and rural areas (see Thünen Institute homepage > TOPICS).

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.

German Environment Agency

Name	German Environment Agency
Acronym	UBA
Location	Dessau-Roßlau
URL	https://www.umweltbundesamt.de/en/

Regional and local levels

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.

Article 36 institutions

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

1. German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) (EFSA Focal Point)
2. Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL)
3. Friedrich-Loeffler-Institut (FLI) – Federal Research Institute for Animal Health (Bundesforschungsinstitut für Tiergesundheit)
4. Julius Kühn-Institut (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-Institut (TI) – Federal Research Institute for Rural Areas, Forestry and Fisheries (Bundesforschungsinstitut für Ländliche Räume, Wald und Fischerei)
7. German Environment Agency (UBA) (Umweltbundesamt)