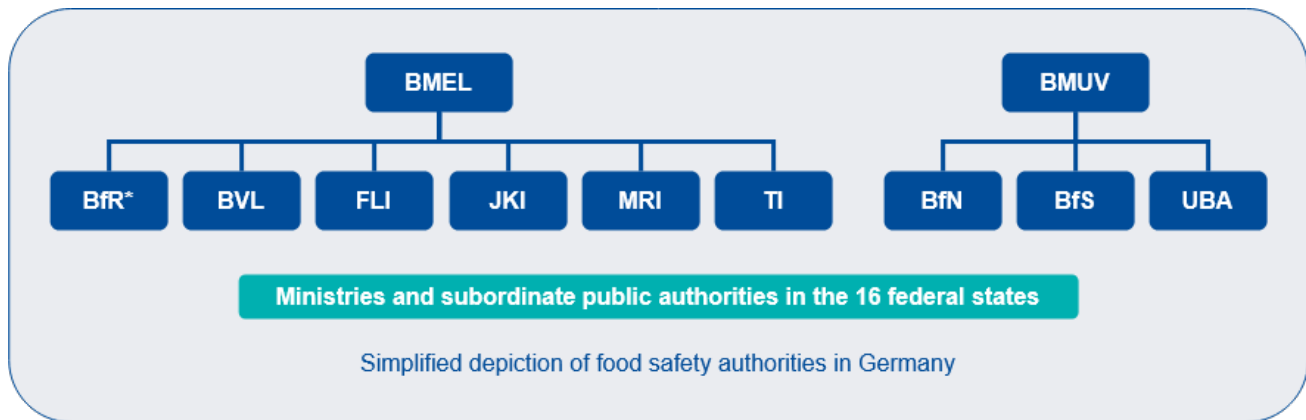


Germany

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* Host institution of the national EFSA Focal Point. For information on the EFSA Focal Point network, please see the EFSA website.

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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 this.

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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 and food policy as well as food and feed safety. In the field of food safety, the BMEL prepares draft legislation and issues related to statutory regulations. The 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 institutions, institutions belonging to the Leibniz Association.

The BMEL is the central competent authority (CCA) for EU legislation in the field of food and feed safety as well as hygiene, GMOs in food and feed. Furthermore, it is the CCA for plant health and for animal welfare, and is involved in the development of EU legislation related to Maximum Residue Limits (MRLs) in foodstuffs of plant and animal origin, contaminants in foods and food contact materials.

The BMEL is the ministry in charge of matters of general food hygiene that are regulated in Regulation (EC) No 853/2004. The BMEL is also responsible for drawing up the report on the controls carried out by the Länder on the marketing and use of plant protection products, pursuant to Art. 68 of Regulation (EC) No 1107/2009.


In the field of feed safety and 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, the BMEL receives advice from the German Federal Institute for Risk Assessment (BfR).

The BMEL is responsible for 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
Activities	<ul style="list-style-type: none">• Environmental aspects of food safety
Responsibilities	
Locations	Bonn and Berlin
URL	https://www.bmu.de/en/

The Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) is responsible for a range of government policies that are reflected in the name of the ministry itself. The ministry has been working for over 30 years to protect the public from environmental toxins and radiation, to promote the wise and efficient use of raw materials, to advance climate action and to ensure that natural resources are used in a way that protects the diversity of animal and plant species and preserves their habitats.

The BMUV is responsible for preventing food safety risks resulting from anthropogenic impacts from the air, water and soil (environmental contaminants). The ministry's work is supported by specialist authorities within its remit; these include the Federal Environmental Agency (UBA), the Federal Agency for Nature Conservation (BfN) and the Federal Office for Radiation Protection (BfS). Effective environmental protection is key for the production of healthy, largely uncontaminated food. The BMEL is responsible for all other areas of food safety. The BfR and the BVL, the competent technical authorities in food safety, support the BMEL and the BMUV in the performance of their respective tasks.

The structure and name of the ministry was changed by the organisational decree of the Federal Chancellor of 8 December 2021. Since then, the BMUV has been responsible for consumer protection policy as well as environmental protection and nature conservation. The BMUV therefore shapes the future of issues related to people and their living environments. It drives economic, environmental and social modernisation. Climate action also remains a key issue for the BMUV with a focus on natural climate solutions, climate adaptation and resource policy.

German Federal Institute for Risk Assessment

Name	German Federal Institute for Risk Assessment
Acronym	BfR
Activities	<ul style="list-style-type: none"> • 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 and feed 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 and feed 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.

15 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, Food Additives and Aromas, 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. The National Study Centre for Sequencing in Risk Assessment is also located at the BfR.

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	<ul style="list-style-type: none"> • Risk management • Risk assessment and communication (veterinary medicines) • Coordination of food control and monitoring, including zoonoses • Crisis management, warning systems • SANTE/F, RASFF and AAC contact point • Regulatory science • Food supplements, novel food and food for special groups • Food additives, flavourings and enzymes • Food contact materials • 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 Federal Office of Consumer Protection and Food Safety (BVL) is the national management body for risks along the food chain. 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. BVL runs a watching and warning system for crisis prevention. In times of crisis, it serves as a situation centre for the crisis management group of BMEL and acts as information hub. It regularly organises crisis exercises with all relevant players. BVL is the regulatory authority for plant protection products and veterinary medicinal products. BVL collaborates with risk managing bodies around the globe, and is involved in standard-setting at national and international level. Together with the Federal States, BVL coordinates programmes for control of food and of plant protection products, and monitoring, including monitoring of zoonoses. BVL collects and analyses data of official food and feed control as well as foodborne outbreaks and forwards them to EU. BVL manages the Official Collection of Methods of Analysis. 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. It serves as the contact point for the EU Food Fraud network. BVL is also the national competent authority in the EU authorisation of food additives, food flavourings and food enzymes. 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) as well as the Central Unit for Surveillance of Online Trade of Plant Protection Products (ZOPf). BVL also supports competent authorities and relevant business associations in export matters and accompanies the registration process of establishments exporting in third countries.

For authorisation of plant protection products, BVL draws on risk assessments by BfR, JKI and UBA. For the authorisation of veterinary medicinal products the expertise and responsibility are allocated at BVL. In both fields, BVL is involved in the establishment of maximum residue limits of active substances. 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. The BVL performs the national antibiotic resistance monitoring of animal pathogens.

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	<ul style="list-style-type: none"> • 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 (WOAH) and hosts ten WOAH reference laboratories as well as a WHO Collaborating Centre for Rabies Surveillance and Research and FAO Reference Centres for Classical Swine Fever, for Animal Influenza and Newcastle Disease as well as Reference

Centre for Emerging Zoonotic Pathogens and High Biosecurity/Biocontainment Facilities.

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.

FLI is according to **Regulation (EC) No 1831/2003 on additives for use in animal nutrition** involved in the review of feed additive approvals.

Julius Kühn-Institut - Federal Research Centre for Cultivated Plants

Name	Julius Kühn-Institut - Federal Research Centre for Cultivated Plants
Acronym	JKI
Activities	<ul style="list-style-type: none">• 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 the BMEL in the field of consumer health protection. The scientific advice is provided in the fields of nutrition and food and is based on both basic and applied research. MRI's research covers the areas of quality, safety and authenticity of food, healthy and sustainable nutrition, nutritional and health effects of food on humans and, in particular, the nutrition of life-stage-specific groups in the population, such as children and senior citizens. Of great importance is the overall consideration of the food consumed depending on the degree of processing and over a longer period of time. The mode of action of food ingredients is considered from the molecular and cellular level to the whole organism. Food group-specific departments at the MRI conduct research on food categories such as cereals, fats and oils, milk and fish, fruits and vegetables, and meat. The period under consideration extends from harvesting or production to consumption of the food by humans. The study of nutritional behaviour is also of particular importance. Overall, the results of the research activities are used to derive recommendations for a health-supporting diet.

MRI is responsible for the further development and implementation of the National Nutrition Monitoring and the German Nutrient Database (BLS). It performs sovereign functions under the Agricultural Statistics Act and the Radiation Protection Act. In addition, the National Breastfeeding Commission (NSK) is located at the MRI.

The MRI cooperates with the departmental research institutions in the portfolio of the BMEL, especially in nutrition-related studies, in the fields of sustainable agricultural and food systems, digitalization, new crop production systems, plant-based nutrition, biodiversity, nanotechnology, bacteriophages and pathogens (including zoonoses) in the food chain, trans fatty acids, mineral oil components, plant toxins and mycotoxins, among others ergot and ergot alkaloids, in food and raw materials, standardization of analytical methods, and development of minimization strategies for undesirable substances in various foods and products. Another aspect concerns cooperation in the field of food authenticity, e.g. in the case of fish and seafood, in order to combat food fraud.

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.

Federal Agency for Nature Conservation

Name	Federal Agency for Nature Conservation
Acronym	BfN
Activities	<ul style="list-style-type: none"> • Enforcement of nature conservation law • Advice • Funding • Research • Information
Responsibilities	
Location	Bonn
URL	https://www.bfn.de/en

BfN performs tasks in the enforcement of nature conservation law, including marine and species conservation. BfN supports the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) in all questions of nature conservation and landscape management and in international cooperation and provides advice for policymakers. In order to perform these tasks, BfN conducts scientific research and supports various funding programs.

Federal Office for Radiation Protection

Name	Federal Office for Radiation Protection
Acronym	BfS
Activities	<ul style="list-style-type: none"> • Environmental hazard analysis • Selected food measurements • Information • Policy advice
Responsibilities	
Location	Salzgitter
URL	https://www.bfs.de/EN/home/home_node.html


BfS works for the safety and protection of man and the environment against damage due to ionising and non-ionising radiation. In the field of ionising radiation there are, e. g. safety in the handling of radioactive substances in nuclear technology and the protection against enhanced natural radioactivity. Here, the BfS also collects measurement results, e.g. for food, and informs the population. The work in the field of non-ionising radiation includes the protection against ultraviolet radiation as well as public information about the subject. The BfS also focuses on radiation in medicine e.g. x-rays and the effects of mobile communication.

The BfS covers natural and artificial radionuclides occurring in drinking water, mineral

water and groundwater and in other environmental areas (such as agricultural products). It has conducted nationwide studies, particularly on the levels of natural radionuclides in drinking water and mineral water, in order to incorporate the knowledge gained from these studies into policy advice (Drinking Water Ordinance, emergency planning, hazard analyses) and work in international bodies (WHO, IAEA). The data on drinking water and groundwater as well as on the other environmental areas are collected and checked by the Integrated Measurement and Information System (IMIS) operated by the BfS and can be viewed publicly at <https://www.imis.bfs.de/geoportal/> or at <https://www.geoportal.de/map.html>.

A classification of the drinking water and groundwater data and the data from the other environmental areas by the BfS is additionally made in the annual report on environmental radioactivity and radiation exposure published by the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection. The BfS also collects data on radioactive substances in food as part of its environmental monitoring, for example on radioactive contamination of wild mushrooms, and publishes studies on this. It also deals with game meat in connection with radioactivity.

German Environment Agency

Name	German Environment Agency
Acronym	UBA
Activities	<ul style="list-style-type: none">• Regulatory activities: environmental hazard and risk assessment, socioeconomic analysis• Scientific work, research• Data collection, database management• Public awareness raising
Responsibilities	
Location	Dessau-Roßlau
URL	https://www.umweltbundesamt.de/en/

The German Environment Agency (Umweltbundesamt - UBA), which was set up on 22 July 1974 through the Act establishing a German Environment Agency, supports the Federal Environment Ministry in matters relating to immission control, soil conservation, waste management, water resources management and health-related environmental issues. Other areas include, in particular, the preparation of legal and administrative provisions, research and development of foundations for suitable policies and the review and examination of procedures and institutions.

UBA is also involved in the enforcement of a number of laws, for instance, in the field of emissions trading, the Plant Protection Act, the Electrical and Electronic Equipment Act and the EU REACH regulation.

One of UBA's important tasks is raising awareness of environmental issues. To this end, UBA provides access to extensive databases, regularly publishes the "Data on the Environment" indicator report and runs the largest environmental library in a German-speaking country.

UBA provides central services and support for the environmental research of the Federal Environment Ministry and for coordinating environmental research by federal authorities. The agency also assists in awarding the "Blue Angel" eco-label.

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 (Umweltbundesamt, UBA)
8. Bavarian Health and Food Safety Authority (Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, LGL)

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