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INTRODUCTION

This overview has been drawn up by the Directorate for Health and food audits and analysis of the Directorate-General for Health and Food Safety of the European Commission based on information supplied by Germany.

The aim is to present, in summary form, the latest information on how control systems for food and feed safety, animal health, animal welfare and plant health are organised in Germany.

Chapter 1 describes the overall organisation of the German authorities and the respective responsibilities of the ministries and government agencies in relation to the different components of the control system. A chart is used to help the reader better understand the inter-relationships between the responsibilities of the different bodies.

Chapter 2 gives a more detailed description of the main responsibilities for each of the twelve separate systems that form the complete range of control systems in Germany, covering the whole chain of plant, animal and food production. As in Chapter 1, organisation charts are used to help the reader.

Annex I provides details on the number of control staff in Germany. The statistics on staff resources have been provided by the Member States on a non-standardised basis.

The overview was updated following the most recent general follow-up audit in November 2015 and will be updated at regular intervals based on relevant information received by the Commission services from the German authorities.

Acronyms are used extensively throughout this overview for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex II as a guide for the reader.
SUMMARY

Germany is a Federal State with 16 Länder. The general responsibilities at federal and Länder levels in the areas of food and feed safety, consumer goods, animal health, animal welfare and plant health are laid down in Article 30 of the Basic Law of 1949. This is complemented by Articles 70 to 75 (legislative powers of the Federation) and Articles 83 to 85 (execution of federal laws).

The Federal Government is responsible for policy and federal legislation. The Länder are responsible for official controls to comply with the legislation in the relevant areas. The Federal Government has no authority to instruct the Länder in these areas.

At national level, the Federal Ministry of Food and Agriculture (BMEL) has almost exclusive competence for food and feed safety, animal health and animal welfare. Its remit encompasses higher federal authorities, public institutions and federal research institutions, including in particular the Federal Office of Consumer Protection and Food Safety (BVL), the Federal Institute for Risk Assessment (BfR), the Federal Agency for Agriculture and Food (BLE), the Friedrich Loeffler Institute (FLI), the Julius Kühn Institute (JKI) and the Max Rubner Institute (MRI).

Furthermore, certain responsibilities pertaining to food safety lie within the remit of the Federal Ministry for Environment, Nature Conservation, Building and Nuclear Safety (BMUB), the Federal Ministry of Finance (BMF) and the Federal Ministry of Justice and Consumer Protection (BMJV).

The basic national rules are laid down in the Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB - Food, Feed and Consumer Goods Code), the Tiergesundheitsgesetz (TierGesG - Animal Health Act) and the Tierschutzgesetz (TierSchG - Animal Welfare Act).

Pursuant to Article 84 of the Basic Law, several General Administrative Regulations have been issued for the official controls. The most important one for food and feed monitoring is the General Administrative Regulation on compliance with food, wine, feed and tobacco legislation, known as the Framework Control Regulation (AVV RÜb). The aim of this Regulation is to provide for a nationwide, uniform and high level of consumer protection.

Section 1 of this document, under Legal basis for controls, contains more details on AVV RÜb, as well as on other General Administrative Regulations on: the rapid alert system for feed and food (AVV SWS); zoonoses (AVV Zoonosen); data exchange related to food safety (AVV DATA); hygiene rules for foods of animal origin (AVV LmH); and monitoring (AVV Monitoring):

http://www.verwaltungsvorschriften-im-internet.de/Teilliste_Bundesministerium_f_r_Ernhrung__Landwirtschaft_und_Verbraucherschutz.html

As shown in Annex I, at federal level there are in total 3 434 full-time equivalent staff, including about 135 in the relevant BMEL departments, and 358 in the relevant BVL departments.

The period of validity of the German MANCP is five years (2012-2016). The framework plan is updated every year. The contact point for the plan is the BMEL. The co-ordination centre for compiling and updating the plan is the BVL. All 16 Länder plans and the federal plan are published on the website of the BVL.
1 ARRANGEMENTS FOR THE IMPLEMENTATION OF CERTAIN REQUIREMENTS OF REGULATION (EC) No 882/2004

A general audit took place in relation to Germany in 2008. The following is a summary of the findings of the general audit report 2008-8744, as updated to take account of developments over the intervening years.

Designation of competent authorities

Distribution of responsibilities between administrative levels

The Federation and the Länder

Germany is a Federal State with 16 Länder:

Baden-Württemberg (Land capital: Stuttgart), Bayern (Bavaria, Freistaat Bayern, Land capital: Munich), Berlin (Land capital: Berlin; capital of the Federal Republic of Germany), Brandenburg (Land capital: Potsdam), Bremen (Freie und Hansestadt Bremen, Land capital: Bremen), Hamburg (Freie und Hansestadt Hamburg, Land capital: Hamburg), Hessen (Hesse, Land capital: Wiesbaden), Mecklenburg-Vorpommern (Mecklenburg-Western Pomerania, Land capital: Schwerin), Niedersachsen (Lower Saxony, Land capital: Hannover), Nordrhein-Westfalen (North Rhine-Westphalia, Land capital: Düsseldorf), Rheinland-Pfalz (Rhineland-Palatinate, Land capital: Mainz), Saarland (Land capital: Saarbrücken), Sachsen (Saxony, Freistaat Sachsen, Land capital: Dresden), Sachsen-Anhalt (Saxony-Anhalt, Land capital: Magdeburg), Schleswig-Holstein (Land capital: Kiel), Thüringen (Thuringia, Freistaat Thüringen, Land capital: Erfurt).

Responsibilities at federal and Länder levels are laid down in Article 30 of the Basic Law of 1949. This is complemented by Articles 70 to 74 (legislative powers of the federation) and Articles 83 to 85 (execution of federal laws).

Food safety, animal health, plant health, plant protection and animal welfare are listed as areas of concurrent legislation in Article 74 of the Basic Law. This means that, in these areas, the Länder have legislative competence as long as the Federal Government does not adopt laws in the respective areas. However, the Federal Government has, to a very large extent, used its legislative power so that most of the legislation applies uniformly throughout Germany.

The Federal Government exercises supervision over the Länder to ensure that they implement federal laws correctly. Article 84 of the Basic Law provides that, for the execution of federal laws, the Federal Government may issue individual instructions for particular cases. These instructions must be addressed to the highest Land authorities. Pursuant to Article 84 of the Basic Law, several General Administrative Regulations (Allgemeine Verwaltungsvorschriften) have been adopted.

Certain responsibilities pertaining to food safety and under the Plant Protection Act lie within the remit of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and its subordinate authorities, as well as the Federal Ministry of Justice and Consumer Protection (BMJV).
At national level, legislative responsibilities for food and feed safety under the German Food and Feed Code (LFGB), for animal health under the Animal Diseases Act (TierSG), for animal welfare under the Animal Welfare Act (TierSchG), and for plant health under the Plant Protection Act (PflSchG) lie almost exclusively with the Federal Ministry of Food and Agriculture (BMEL) and its subordinated authorities. Its portfolio encompasses higher federal authorities, institutions established under public law and federal research institutions.

Should any shortcomings which the Federal Government identifies in the execution of Federal laws in the Länder not be corrected, the Bundesrat decides, on the application of the Federal Government or the Land, whether the Land has acted unlawfully. The decision of the Bundesrat may be challenged in the Federal Constitutional Court.

Under the Basic Law, the Länder are responsible for ensuring implementation of the laws. The various Länder ministries and senate administrations co-ordinate monitoring within their respective Land. In some Länder with provincial authorities, the latter have responsibility for supervising individual monitoring agencies, e.g. the offices of veterinary medicine, food and health. These authorities are controlled by the Land Ministries.

In the area of plant health and plant protection, monitoring is performed by the plant protection services of the Land. Federal authorities sometimes participate in the monitoring.

**Federal Ministries**

**Federal Ministry of Food and Agriculture (BMEL)**

The BMEL represents the Federal Republic in EU-level negotiations in the following policy areas.

The principal concerns covered by the BMEL, within its area of responsibility, are the further development of effective approaches to producing safe food and preserving animal health, a strong and sustainable agricultural industry and a promising outlook for rural areas.

The BMEL is responsible for drawing up legislative initiatives and General Administrative Regulations (Allgemeinen Verwaltungsvorschriften), as well as for issuing related statutory regulations (Rechtsverordnungen). This work also includes the food, animal feed, animal health and animal welfare sectors covered by the Multi-Annual National Control Plan (MANCP), as well as the plant protection sector.

Within the Federal Government, the BMEL works particularly with the departments whose responsibilities pertain to environmental protection, health and industry.

Responsibility for external representation lies with the Federal Government.

Detailed information on the BMEL can be found on the Internet at [www.bmel.de](http://www.bmel.de). As of September 2015, the BMEL, in its two locations in Bonn and Berlin, has six departments with 14 sub-departments.

The areas of nutrition, food and feed safety, animal health and animal welfare are dealt with by Department 3. The Head of Sub-department 32 is the German Chief Veterinary Officer and the representative in the World Organisation for Animal Health (OIE).
The following table shows an extract from the BMEL organisation chart.

<table>
<thead>
<tr>
<th>Department 3</th>
<th>Department 2</th>
<th>Department 4</th>
<th>Department 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition, food safety, animal health</td>
<td>Consumer protection</td>
<td>Rural development, agricultural markets</td>
<td>Bio-based economy, sustainable agriculture and forestry</td>
</tr>
<tr>
<td><strong>Sub-department 31</strong></td>
<td><strong>Sub-department 32</strong></td>
<td><strong>Sub-department 21</strong></td>
<td><strong>Sub-department 22</strong></td>
</tr>
<tr>
<td>Safety of the food chain</td>
<td>Animal health, animal welfare</td>
<td>Food policy</td>
<td>Consumer policy in the community, research coordination</td>
</tr>
<tr>
<td>Unit 311 Strategy and coordination of Department 3; international food safety policy</td>
<td>Unit 321 Animal welfare</td>
<td>Unit 212 Food information, food prevention</td>
<td>Unit 222 New technologies</td>
</tr>
<tr>
<td>Unit 312 Food monitoring, crisis management</td>
<td>Unit 322 Animal health</td>
<td>Unit 214 Specific foodstuffs, food supplements, food additives</td>
<td>Unit 432 Milk</td>
</tr>
<tr>
<td>Unit 313 Residues and contaminants in food, food contact materials</td>
<td>Unit 323 Animal diseases; EU trade and international issues; crisis centre</td>
<td>Unit 215 Food information, food labelling</td>
<td>Unit 433 Plant products</td>
</tr>
<tr>
<td>Unit 314 Meat hygiene, food hygiene</td>
<td>Unit 324 Veterinary matters relating to exports</td>
<td></td>
<td>Unit 434 Wine, beer, beverages sector</td>
</tr>
<tr>
<td>Unit 315 Feed safety, animal nutrition</td>
<td>Unit 325 Legal issues in Department 3; legal issues related to the veterinary profession</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit 316 Food law, emergency food supply</td>
<td>Unit 326 Veterinary medicines, residues of pharmacologically active substances in food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Unit 311 Strategy and coordination of Department 3; international food safety policy

Unit 321 Animal welfare

Unit 212 Food information, food prevention

Unit 222 New technologies

Unit 431 Animal products

Unit 512 Plant protection

Unit 312 Food monitoring, crisis management

Unit 322 Animal health

Unit 214 Specific foodstuffs, food supplements, food additives

Unit 432 Milk

Unit 513 Plant health, plant health matters relating to exports

Unit 313 Residues and contaminants in food, food contact materials

Unit 323 Animal diseases; EU trade and international issues; crisis centre

Unit 215 Food information, food labelling

Unit 433 Plant products

Unit 516 Organic farming

Unit 314 Meat hygiene, food hygiene

Unit 324 Veterinary matters relating to exports

Unit 434 Wine, beer, beverages sector

Unit 315 Feed safety, animal nutrition

Unit 325 Legal issues in Department 3; legal issues related to the veterinary profession

Unit 316 Food law, emergency food supply

Unit 326 Veterinary medicines, residues of pharmacologically active substances in food
Unit 512 is responsible for plant protection and Unit 513 for plant health and plant health matters relating to exports. The Head of Unit 513 is the German Chief Officer for Plant Protection (COPHS), and the representative for the International Plant Protection Convention (IPPC). In particular, these units are responsible for legislation on plant protection and plant health, policy contacts at national level with other Federal and Land ministries, international contacts and the promotion of research programmes as the basis for decisions on plant protection and plant health.

Unit 434 is responsible for the wine, beer and drinks industries.

Unit 222 is responsible for GMO policy-making and legislation for GM food, feed and seeds controls.

The BMEL is assisted by three scientific advisory boards, namely for Consumer and Food Policy, for Agricultural Policy and Sustainable Agriculture and for Genetic Resources.

The federal ministry has two locations: Berlin and Bonn. Department 3 is primarily located in Bonn.

The BMEL controls the lower-level bodies at Federal level. These include, in particular, the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Risk Assessment (BfR), which were established in 2002 as a result of the BSE crisis. The Julius Kühn Institute (JKI), the Federal Agency for Agriculture and Food (Bundesanstalt für Landwirtschaft und Ernährung, BLE), the Friedrich Loeffler Institute (FLI) and the Max Rubner Institute (MRI), among other bodies, are also within the portfolio of the Ministry.

Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)

Under § 13(5) of the German Food and Feed Code, the BMUB has responsibility within the Federal Government for preventing risks to consumers from foodstuffs affected by air, water and soil impurities (environmental contaminants).

Within the Ministry, Sub-department IG II (Environment and health, chemicals safety) of Department IG (Environment and health, pollution control, installation safety and traffic, chemicals safety) is responsible for food safety issues.

The area of environmental contaminants in food is dealt with by the Environment and Health Unit (IG II 2) Unit IG II 2 also receives significant specialist support in carrying out its tasks from the BVL and the BfR.

Unit IG II 5 (“Plant Protection Products, Biocides, Pharmaceuticals”) falls under the Sub-department “Environment and Health, Chemicals Safety”. Unit IG II 5 receives technical assistance for its work from the BVL and the BfR where appropriate.

The BMUB is located in Berlin and in Bonn. Department IG is located in Bonn. Detailed information on the BMUB can be found on the Internet at www.bmub.bund.de.
Federal Ministry of Justice and Consumer Protection (BMJV)

Once applications made in accordance with Regulation (EC) No 1151/2012 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs have been inspected by the German Patent and Trade Mark Office [Deutsches Patent- und Markenamt] (DPMA), the BMJV forwards them to the European Commission. Monitoring is carried out by the competent bodies of the Länder.

Further information is available at http://www.bmj.bund.de.

Federal Ministry of Finance (BMF)

The BMF and its designated customs offices play their part in monitoring compliance with the law in the areas of food and feed safety, food contact materials, animal health, animal welfare and plant health as far as possible within their powers (e.g. in the area of food and feed safety in accordance with Article 24(4) of Regulation (EC) No 882/2004 in conjunction with Articles 27–29 of Regulation (EC) No 765/2008 and § 55 LFGB).

The customs authorities consist at regional level of five Federal Finance Directorates, which were created on 1 January 2008 as new intermediate authorities of the German tax administration and are under the Federal Ministry of Finance.

Operational tasks by customs at the local level are carried out by 43 main customs offices, linked to 271 subordinate offices.
The following chart provides an overview of the organisation and linkages between federal ministries, associated authorities and the Länder.
Higher federal authorities, federal research institutions and institutions established under public law

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) – Federal Office of Consumer Protection and Food Safety

The BVL is an independent higher federal authority affiliated with the BMEL. It undertakes a number of functions as part of cooperation between Federation and Länder.

It is located at two sites:
- Braunschweig: headquarters and authorisation of plant protection products
- Berlin: food and feed safety; food contact materials (FCM); RASFF; veterinary medicinal products; genetic engineering; standardisation of methods, reference laboratories and antimicrobial resistance

The BVL is organised into five specialised departments and one 'Central Services' department. Tasks are carried out by units as set out in the table below. The specific activities of the BVL are described under point 2 in the individual control systems.
<table>
<thead>
<tr>
<th>Department 1: Food safety</th>
<th>Department 2 Plant protection products</th>
<th>Department 3 Veterinary medicines</th>
<th>Department 4 Genetic engineering</th>
<th>Department 5 Standardisation of methods, reference laboratories and antimicrobial resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1 – Crisis management</strong></td>
<td><strong>Group 2 – Safety of the food chain</strong></td>
<td><strong>Unit 201 Basic issues</strong></td>
<td><strong>Unit 301 Central management of veterinary medicine authorisation</strong></td>
<td><strong>Unit 401 Basic genetic engineering issues</strong></td>
</tr>
<tr>
<td>Unit 104 Crisis management, rapid alert systems</td>
<td>Unit 101 Basic issues, food</td>
<td>Unit 202 Process control for products</td>
<td>Unit 302 Pharmaceutical regulatory compliance, quality assessment</td>
<td>Unit 501 Basic issues</td>
</tr>
<tr>
<td><strong>Unit 107 Data management, data analysis</strong></td>
<td><strong>Unit 102 Feed</strong></td>
<td><strong>Unit 203 Process control for active substances</strong></td>
<td><strong>Unit 303 Veterinary medicine assessment, environmental impact assessment</strong></td>
<td><strong>Unit 502 EU Reference Laboratory for residues</strong></td>
</tr>
<tr>
<td><strong>Unit 108 Crisis cell, prevention</strong></td>
<td><strong>Unit 103 Strategy and coordination in monitoring</strong></td>
<td><strong>Unit 204 Natural environment</strong></td>
<td><strong>Unit 304 Monitoring and supervision after authorisation (post-marketing)</strong></td>
<td><strong>Unit 503 National reference laboratories for pharmaceutically active substance residues and GMOs</strong></td>
</tr>
<tr>
<td><strong>Unit 105 Consumer products</strong></td>
<td><strong>Unit 205 Plant protection product applications</strong></td>
<td><strong>Unit 305 Pharmacologically active substance residues Antimicrobial resistance team</strong></td>
<td><strong>Unit 405 Traceability, detection methods, Biosafety Clearing House</strong></td>
<td><strong>Unit 504 National reference laboratories for pesticides, PAHs and heavy metals</strong></td>
</tr>
<tr>
<td><strong>Unit 106 Food hygiene, inspections, veterinary issues</strong></td>
<td><strong>Unit 206 Product chemistry and analysis</strong></td>
<td><strong>Unit 207 Health</strong></td>
<td><strong>Unit 208 Health</strong></td>
<td><strong>Unit 505 Antimicrobial resistance monitoring</strong></td>
</tr>
</tbody>
</table>
The BVL also provides logistical and organisational support to the Länder. In addition, it supports the flow of information between federal and Länder level in the field of food safety and consumer protection, processes data from official food and feed monitoring from the Länder and draws up reports. As part of the dioxins rapid alert system it also collects the test results submitted by food and feed businesses on dioxin levels in food and feed and evaluates them for quarterly situation reports.

The BVL is also the national contact point for the Directorate for Health and food audits and analysis of the Directorate-General for Health and Food Safety of the European Commission and thus responsible for, among other things, preparing, monitoring and following up on audits and updating the country profile.

From 2016, following a pilot phase, the BVL will in the long term run the joint Zentralstelle der Länder zur Überwachung des Internethandels mit Lebensmitteln, Futtermitteln, Bedarfsgegenständen und Tabakerzeugnissen (Central Authority of the Länder for monitoring online trade in food, feed, consumer goods and tobacco products).

For export issues, it acts essentially as advisor and coordinator in relation to exports of animals, animal products and feed to various third countries. This includes maintaining various establishment listings, processing complaints, assisting with pre-notification procedures and preparing for and accompanying inspections and audits in Germany by authorities from third countries. In addition, the BVL coordinates the work of the Federal and Länder Veterinary Group on exports on the subjects of 'exports to the Russian Federation and Eurasian Economic Union', 'exports to the USA' and 'exports to China'. This basically compares the relevant legislation of the third countries in question with that of the European Union.

It also plays a part in drawing up general administrative provisions.

In addition, the BVL actively shares specialist knowledge and experience at international level as a member of committees and other bodies of authorities and organisations.

A list of the BVL's international activities can be found at http://www.bvl.bund.de/DE/07_DasBundesamt/02_Aufgaben/03_International/dasBundesa mt_aufgaben_international_node.html.

Detailed information on the BVL can be found on the Internet at www.bvl.bund.de.

Federal Institute for Risk Assessment (BfR)

The BfR is the scientific institution which compiles expert reports and statements on issues of food safety and consumer protection on the basis of internationally recognised scientific assessment criteria. It enjoys independence in respect of its scientific assessments, research and communications.

The Institute collaborates with other scientific organisations at national and international level, as well as with institutions from other countries which are active in consumer health protection and food safety. As EFSA Focal Point, the BfR publishes the EU Food Safety Almanac, which shows how food safety is organised in each Member State: http://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf

Its responsibilities are listed in legal regulations pertaining to food and plant protection, as well as in the German Act on the Reorganisation of Consumer Health Protection and Food Safety (Gesetz zur Neuorganisation des gesundheitlichen Verbraucherschutzes und der Lebensmittelsicherheit), in particular:
• compiling scientific statements and expert reports on food and feed safety, including issues related to nutrition and preventative nutrition;
• assessing the risk to health from chemicals, from plant protection and pest control products, and from selected products (i.e. consumer goods, such as food packaging, and tobacco products) and the safe use of these products;
• documenting and providing information on poisoning incidents;
• recording and evaluating methods to replace or supplement animal testing;
• carrying out risk assessments with regard to genetically modified organisms and new types of food;
• participating in the monitoring of food, cosmetics and commodities and in national surveys in the area of feed and feed additives;
• recording and assessing the developmental trends of zoonotic pathogens, including antibiotic resistance, and the sources of zoonotic infections;
• development of methods and validation activities of the National Reference Laboratories;
• communicating risks and advising the public of risks.

Based on an analysis of the risks, the BfR formulates action proposals for risk reduction. Its assessments are presented in a manner that aims to be transparent and comprehensible to the public, scientists and other stakeholders or interested parties. The outcomes of assessments are made accessible to the public, although the confidentiality of protected data is preserved.

In all its fields of activity, the BfR informs and advises the federal ministries and notifies the various Länder authorities, EU bodies and both public- and private-sector bodies of its findings.

Fourteen reference laboratories in the field of food safety, food hygiene and feed safety pursuant to Regulation (EC) No 882/2004 are attached to the BfR. In addition to these EU law-based NRLs, there are other BfR bodies which have a reference function in other contexts. These include the reference laboratory in the GMO network, the Senior Expert Office for the import control of wine under the Wine Control Regulation (Weinüberwachungsverordnung), zoonoses reporting to the European Food Safety Authority (EFSA) and the Reference Laboratories for Leptospira and for Yersinia.

The BfR conducts its own research in fields closely linked to its work on consumer health protection and food and feed safety. The research findings are used to provide scientific advice to the BMEL, the Federal Ministry of Transport and Digital infrastructure (BMVI) and the Federal Ministry for Environment, Nature Conservation, Building and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit, BMUB).

Detailed information on the Institute can be found on the Internet at www.bfr.bund.de.

Federal Office for Agriculture and Food (BLE)

The BLE is an institution established under public law, within the portfolio and subject to the legal and expert supervision of the BMEL.

It is a market regulation centre for the common market organisations within the European Union (e.g. grains, rice, sugar, fruit and vegetables, seeds, wine alcohol, beef, pork and mutton, milk and milk products and fishery products). In this capacity, it is responsible for market intervention and the implementation of private storage measures and subsidy measures.
As the licensing body for cross-border traffic in goods and services using products of the food, agriculture and forestry industries, the BLE issues import and export licences and authorisations in accordance with Regulation (EC) No 376/2008 and, additionally, the rules on the organisation of the market in wine, rice and sugar. It carries out specific conformity checks for fruit and vegetables.

In the context of securing adequate food supplies, it administers provisions of food products as a civil emergency reserve. It monitors marine fishing outside coastal waters and compliance with the fish quotas which it administers, and operates the Federal Government’s fishery protection vessels and fishery research ships. It also controls the use of renewable raw materials cultivated on land that has been set aside and the use of energy crops cultivated on land not set aside. Under the German Organic Farming Act (Öko-Landbaugesetz, ÖLG) in line with Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (Basic EC Organic Regulation), the BLE is, in addition to other tasks in this area, also responsible for granting and revoking authorisations for private control bodies in the area of organic farming.

As part of the Leader+ programme, the BLE also houses the German networking centre and the Information and Coordination Centre for Biological Diversity. The BMEL has assigned the BLE the following temporary special projects: the implementation and coordination of the Federal Organic Farming Scheme; the promotion and monitoring of research projects in the area of agricultural production and processing; and the management of the National Action Plan on Food and Movement (Nationaler Aktionsplan Ernährung und Bewegung).

A detailed description of the responsibilities and an organisation chart of the Federal Agency can be found on the Internet at http://www.ble.de/DE/00_Home/homepage_node.html.

Friedrich Loeffler Institute (FLI)

The health and welfare of farm animals are the focus of the work of the FLI, as well as the protection of humans from zoonoses. The objectives of the research are: to protect against infectious diseases through better and faster diagnoses; to develop preventive measures and establish modern strategies to combat animal diseases and zoonoses; to develop welfare-friendly farming systems; to conserve genetic diversity in livestock; and to ensure efficient use of feed for production of high-quality food of animal origin.

The FLI's tasks with regard to infectious animal diseases and zoonoses are laid down in § 27 TierSG, § 2 TierImpfStV (Animal Vaccine Regulation), and § 16(4) GenTG (Genetic Engineering Act).

It conducts research in the field of animal diseases, animal welfare, animal husbandry, animal nutrition and farm animal genetics and notifies and advises the Federal Government in these areas. It is responsible for authorising in vitro diagnostic medical devices, drawing up risk assessments in the field of combating animal diseases and observing the worldwide animal health situation with reference to the risk of introducing animal diseases into the country through live animals or products. The Friedrich Loeffler Institute plays a part in drawing up plans for monitoring and in assessing its results, in testing animals or products intended for import or export, and in epidemiological testing in the event of a suspected or actual outbreak of an animal disease.
It acts as a national reference laboratory for a series of infectious animal diseases and animal illnesses and, as such, operates reference laboratories. The complete list of all national reference laboratories is set out in the Notice of the National Reference Laboratories for notifiable infectious animal diseases and notifiable animal illnesses on page 4701 of the German Federal Gazette [Bundesanzeiger] of 5 December 2008, as last amended.

The reference laboratories are accredited by the German Accreditation Body (DAkkS) according to ISO/IEC 17025. They clarify suspected cases, advise the veterinary authorities and conduct ring trials or similar measures for quality assurance of animal disease diagnostics in Germany. As part of this activity, the FLI publishes a collection of official methods for sampling and testing for notifiable animal diseases, as well as the annual animal health report.

At international level, the FLI runs a series OIE reference laboratories and reference centres for various animal diseases. The FLI is also an OIE Collaborating Centre for Zoonoses in Europe and runs a WHO Collaborating Centre for rabies.

As the contact point referred to in Article 20 of Regulation (EC) No 1099/2009 on the protection of animals at the time of killing, the FLI supports the competent authorities in implementing the provisions of that Regulation, in particular regarding the humane stunning and killing of animals.

The FLI is divided into 11 specialist institutes and a central department spread over five sites. Located at the headquarters on Riems Island are the Institutes of Molecular Biology, Cell Biology, Diagnostic Virology, Infectology, Novel and Emerging Infectious Diseases, Immunology and Epidemiology, and, as a joint facility, the Department of Experimental Animal Husbandry and Biosafety, while the Institutes for Bacterial Infections and Zoonoses and for Molecular Pathogenesis are at the Jena site. The Institute of Animal Nutrition is in Braunschweig and the Institute of Animal Welfare and Husbandry in Celle. The Institute of Farm Animal Genetics is in Mariensee.

http://www.fli.de/de/home/

**Julius Kühn Institute (JKI)**

The JKI is an independent Federal authority that reports to the BMEL, advises the Federal Government on plant health and plant protection matters, carries out research for that purpose, is the designated authority for coordination and contacts under Article 1(4) of Directive 2000/29/EC and is the authority that assesses the effectiveness of plant protection products and their impact on plants and bees as part of the approval procedure for those products.

With regard to plant protection and plant health, the JKI focuses on contributing to the creation of national and international standards, risk analyses and assessments of plant protection products and the phytosanitary field. It tests plant protection equipment and evaluates the resistance of plants to pathogens. The JKI is involved in procedures under genetic engineering law and participates in inspection and approval procedures for plant protection products.
Within the JKI, the Institute for National and International Plant Health Affairs is responsible for the exchange of technical information on plant health between the Federal and Länder plant protection services. It is also responsible for technical coordination of plant health measures, in cooperation with the Länder, for risk assessments, guidelines, technical bases for monitoring programmes and the development of their scientific basis.

It houses the body that investigates incidents of bee poisoning. Under the Plant Protection Act (§ 57(2)(11)), it has the task of examining bees for harm caused by the use of plant protection products. The investigation body for incidents of bee poisoning was established in accordance with its statutory duty to test bee and plant samples in suspected cases of poisoning through the use of plant protection products. Biological tests are also carried out: Aedes biotest, pollen analysis, disease studies, including nosemata analysis.

The JKI has sites in Quedlinburg (where its main office is located), Braunschweig, Berlin and Kleinmachnow. There are also JKI institutes at seven other locations (Bernkastel-Kues, Darmstadt, Dresden-Pillnitz, Dossenheim, Groß Lüsewitz, Münster and Siebeldingen).

Max Rubner Institute (MRI)

The MRI is the research and advisory institution of the BMEL in the areas of food, nutritional effects of food, improvement of nutritional behaviour, consumer health protection in the food sector, and the assessment, safeguarding and improvement of food product and process quality.

Research focuses on health and nutritional assessment of food ingredients, the investigation of low-impact food processing methods, and quality assurance for food of plant and animal origin. Other areas of work include research on the economic and sociological parameters of nutrition, and on the improvement of nutrition information.

The main research areas on the safety and quality of meat also include projects with special relevance to animal welfare, since, in particular, the choice of stunning methods has a significant impact on the quality of the meat of slaughtered animals.

The MRI is responsible for developing and carrying out national nutrition monitoring on the basis of the second national study of consumption. It deals with questions of food safety and carries out public authority tasks related to the Agricultural Statistics Act and the Law on Precautionary Protection of the Population against Radiation Exposure.

The work of the MRI is of particular relevance to that of the Federal Institute for Risk Assessment and the Federal Office of Consumer Protection and Food Safety.

The MRI has eight institutes spread over four locations (Karlsruhe headquarters, Detmold, Kiel, Kulmbach), and an experimental station at Schädtbek.
Administration in the Länder

At Land level, food and veterinary affairs are administered on up to three levels.

1. Land level

The Ministry/Senate Administration in charge of food, feed and veterinary affairs (LM/SV) is the supreme authority. Its competence comprises control, planning, steering, co-ordination and instructions in all areas of food, feed and veterinary administration of the respective Land.

In some Länder (e.g. Brandenburg, Lower Saxony, North Rhine-Westphalia, Thuringia), the implementing tasks lie with the higher Land authorities (Obere Landesbehörden, OL) in the area of food and feed control, as well as partially in the areas of animal welfare and plant protection.

2. Intermediate Land level

Some Länder have an intermediate administrative level between the Land food, feed and veterinary control authority and the district and municipal monitoring authorities (DMAs):

- North Rhine-Westphalia: Düsseldorf, Münster, Arnsberg, Cologne, Detmold.
- Bavaria: Schwaben, Oberpfalz, Unterfranken, Mittelfranken, Oberfranken, Niederbayern, Oberbayern
- HH; Hesse: Giessen, Kassel, Darmstadt
- Baden-Wurttemberg: Stuttgart, Karlsruhe, Freiburg, Tübingen
- Saxony-Anhalt Landesverwaltungsamt (Land Administration Office)

The intermediate administrative levels/higher Land authorities (e.g. provincial authorities, regional government offices, Land directorates and offices) are subject to supervisory control by the highest-level food and feed monitoring and/or veterinary authority of the Land in question.

3. Lower Land level

The food and feed monitoring and veterinary authorities of the district or municipal authorities (Kreise und kreisfreie Städte, DMA) constitute the third administrative level within a Land, with the exception of the Land of Saarland, where there is one competent authority, a Landesamt (Land Office) at the lower administrative level.

The DMA food monitoring and veterinary authorities carry out monitoring tasks in a district or municipality, with the exception of the Land of Saarland, where the Landesamt carries out the supervisory tasks. In Germany, there are 431 food monitoring and veterinary authorities at this level. The district or municipal authorities are generally audited in the context of technical supervision by provincial authorities (where applicable) and otherwise by the Land authorities/ministries or senate administrations (i.e. the highest-level food monitoring and veterinary authorities) (The Land of Saarland, where the Landesamt is
subject to technical surveillance, is an exception to this general principle.). There are also 36 public (chemical and) veterinary testing authorities (*Veterinäruntersuchungämter*) that are subject to technical supervision by the *Länder*. Four *Länder* (Lower Saxony, Bavaria, Thuringia and Baden-Württemberg) have Land institutes or offices carrying out laboratory testing. In North Rhine-Westphalia there are also four test offices operating in the form of a public institution (*Anstalt des öffentlichen Rechts - AöR*) and run jointly by the Land and municipal authorities.

**Cooperation between competent authorities**

**Co-ordination and communication between Federal and Land level**

There are several types of coordination and communication between federal and Land level. The BMEL or BMUB organises federal/Land officer meetings with the competent Land ministries to discuss legislative issues. With a view to achieving harmonised implementation at national level, and serving as an interface between the Federal and Land levels, the Länder have also developed co-ordination and communication structures (working groups). Political, strategic and working-level bodies have been established to support the co-ordination and communication process.

Standing Conferences of the Agriculture Ministers and Consumer Protection Ministers (political level) were established to advise on changes in legislation and new enforcement procedures across all Länder. They comprise high-level officials from the Land ministries and Federal ministries concerned. The Federal Government takes part in these meetings and has a right to vote (except on questions relating only to Land matters). Meetings take place at least once a year and deal inter alia with the health and economic aspects of consumer protection as well as the regulatory aspects of consumer protection and nutrition. Every year the chair of the meetings changes (in alphabetical order of the Länder).

As a result of these meetings, requests for further checks related to the health and economic aspects of consumer protection are then forwarded to the Länder Working Group on Consumer Protection (LAV), while requests for further checks related to plant protection and plant health are forwarded to the Land plant protection officers. Within the LAV, the Länder authorities responsible for consumer protection and veterinary matters work together. The LAV is responsible for co-ordinating the implementation of legal provisions. The responsibilities of the LAV include the topics of food and feed safety, animal health, animal diseases, veterinary medicinal products, animal welfare, relevant occupational law, and topics (within the remit of the VSMK and AMK) related to economic and regulatory aspects of consumer protection and nutrition. Twelve sub-groups have been set up, on:

- Animal health and animal diseases (AGTT)
- Animal welfare (AGT)
- Feed (AFU)
- Food, food contact materials, wine and cosmetics (ALB)
- Meat and poultry meat hygiene and technical issues concerning food of animal origin (AFFL)
- Veterinary medicinal products (AG TAM)
- Healthy diet and dietary information (AG GEE)
- Import and transit (AG ED)
- Economic consumer protection (AG WV)
- Training and professional issues for people subject to food and veterinary law (AfAB)
- Information and communication (AG IuK)
Quality management in health-related consumer protection (AG QM)

The working groups comprise the directors of the departments responsible for consumer protection and veterinary matters within the relevant ministries in the Länder. They meet at least twice a year. Every year the chair changes (in alphabetical order of the Länder). The BMEL and BMJV are permanent observers at the meetings. Moreover, where necessary they can invite representatives of federal ministries and other authorities, organisations, associations and scientific institutions. These working groups are chaired in rotation by a Land and the chair generally changes every second year. The working groups draw up recommendations based on majority decisions and deliver proposals to the Standing Conferences. After adopting a recommendation, each Land applies the adopted rules in the performance of its duties. To deal with time-limited specific issues, the LAV or its working groups can create project working groups, which then present a report for adoption. In accordance with their internal rules of procedure, all members of the working groups must meet at least once a year, but meetings generally take place twice a year.

During the 2010 general follow-up mission, the German authorities indicated that a decision had been taken at LAV level to require all working groups to systematically discuss follow-up measures to Commission services’ report recommendations. During the same mission, most of the LAV working groups referred to above confirmed that they were including the progress made by Länder in addressing Commission services’ recommendations as an agenda item in their regular co-ordination meetings.

The conclusions of Section 4.2 of General Audit report 2008-8744 were that co-ordination and cooperation were generally ensured both at federal level, through the LAV and its sub-working groups, and within the Länder.

The General Audit report found that: the BVL was responsible for communication between the competent Land authorities and the Commission, and the JKI operated as the authority defined in Article 1(4) of Directive 2000/29/EC. In the sectors covered by the specific audits, co-ordination and cooperation was ensured through LAV working groups. In terms of information exchange, Germany had created an "Information System for Consumer Protection and Food Safety" (Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit, FIS-VL) which contains, inter alia, the MANCPs, minutes of meetings of the working groups, annual reports on controls provided for in Article 44(1) of Regulation (EC) No 882/2004 and other relevant data.

In addition to information on bodies operating under the LAV framework, information may be found in this information system on the following coordination bodies:

- Federal-Länder working group on plant protection product control (Arbeitsgemeinschaft Pflanzenschutzmittelkontrolle, AG PMK)
- Research Group of Experts in Food Chemistry (Arbeitskreis Lebensmittelchemischer Sachverständiger der Länder und des BVL, ALS)
- Research Group of Experts active in the Field of Food Hygiene and Foods of Animal Origin (Arbeitskreis der auf dem Gebiet der Lebensmittelhygiene und der Lebensmittel tierischer Herkunft tätigen Sachverständigen, ALTS)
Delegated specific tasks related to official controls

In relation to delegation, as covered by Article 5 of Regulation (EC) No 882/2004, the conclusions of Section 4.3 of the General Audit report 2008-8744 were that the requirements of Article 5 were not relevant to the official controls carried out in the areas under review. Recommendation 2007-7430-5 (of the Country Profile 2010-8366) showed that action had been taken by the Baden-Württemberg, Bavarian, and Schleswig-Holstein authorities in relation to the accreditation of identified control bodies for meat and milk controls.

Contingency planning

The amendment to the Framework Control Regulation (AVV RÜb) of 1 June 2008 provided inter alia for arrangements for cooperation between authorities in crisis situations and for the implementation of relevant contingency exercises. Further agreements to optimise Federal/Länder cooperation in the event of inter-Land and/or cross-sectoral crises can be found in the agreement on cooperation between the Federal Government and the Länder in crisis situations relating to food and feed safety, which came into force on 1 August 2013. The office of the permanent crisis management team was set up within the BVL on the basis of this agreement. Should a food and feed safety task force be convened, it will be set up within the BVL.

In crisis situations in the food and feed sector, the BVL unit responsible for crisis management provides support for the department concerned, or the crisis centre of the BMEL, through an emergency response centre (Lagezentrum). The BVL also provides logistical and organisational support to the Länder. If an event or crisis arises, the BVL is allocated the task of crisis management. To address these tasks, it establishes an additional two-level special organisational structure (BAO). The main organisational units relevant to crisis management are the BVL Lagezentrum, the crisis management team office and the "Food and Feed Safety" Task Force. The tasks, organisation and operation of the BAO are detailed in the BVL Crisis Guidelines: http://www.bvl.bund.de/SharedDocs/Downloads/07_Bundesamt/krisenleitfaden2015.pdf?

In crisis situations in the area of animal health, the Länder receive support from the task force working group and the FLI. For animal disease control there is a national manual on combating infectious animal diseases (Tierseuchenbekämpfungshandbuch, TSBH) with Land-specific supplements. A special crisis management programme is available to support the veterinary authorities.
The following chart gives an overview of the distribution of responsibilities in relation to control systems and specialist technical levels. More detailed descriptions of the allocation of tasks between authorities in relation to each control system are given in the following chapters.

<table>
<thead>
<tr>
<th>Sector</th>
<th>Policy coordination</th>
<th>Coordination of controls</th>
<th>Implementation of controls</th>
<th>Laboratories</th>
<th>Risk assessment, scientific advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Animal health</td>
<td>BMEL</td>
<td>LM-SV/PA</td>
<td>DMA</td>
<td>Official laboratories, FLI, PEI (sera, vaccines) Private laboratories</td>
<td>FLI, PEI (sera, vaccines)</td>
</tr>
<tr>
<td>3. Imports of animals and foods of animal origin</td>
<td>BMEL</td>
<td>LM-SV/PA</td>
<td>DMA</td>
<td>Official laboratories</td>
<td>FLI</td>
</tr>
<tr>
<td>4. Feed and animal nutrition</td>
<td>BMEL</td>
<td>BVL/LM-SV/OL/PA/DMA/PPS</td>
<td>BMEL</td>
<td>Official laboratories</td>
<td>BfR/FLI</td>
</tr>
<tr>
<td>5. TSEs/ABP</td>
<td>BMEL</td>
<td>LM-SV/PA</td>
<td>DMA</td>
<td>Official laboratories, FLI</td>
<td>FLI</td>
</tr>
<tr>
<td>6. Veterinary medicinal products – authorisation, marketing, distribution</td>
<td>BMEL/BMG</td>
<td>BVL/LM-SV/PA</td>
<td>DMA/PVP</td>
<td>Private laboratories</td>
<td>BM/UBA</td>
</tr>
<tr>
<td>Veterinary medicinal products – residues</td>
<td>BMEL/BMG</td>
<td>BVL/LM-SV/PA</td>
<td>DMA</td>
<td>Official laboratories</td>
<td>BM/BfR</td>
</tr>
<tr>
<td>7. Foodstuffs and food hygiene</td>
<td>BMEL</td>
<td>BVL/LM-SV/PA</td>
<td>DMA</td>
<td>Private laboratories</td>
<td>BfR</td>
</tr>
<tr>
<td>GMOs</td>
<td>BMEL</td>
<td>BVL/LM-SV/OL/PA/DMA/PPS</td>
<td>BMEL/LPPS</td>
<td>Official laboratories</td>
<td>BM/UBA/BfR/JKI/UBA</td>
</tr>
<tr>
<td>Plant protection products – residues</td>
<td>BMEL</td>
<td>BVL/LM-SV/LPPS/BL/PPL</td>
<td>LPPS</td>
<td>Private laboratories</td>
<td>BM/UBA/BfR/UBA</td>
</tr>
<tr>
<td>10. Animal welfare</td>
<td>BMEL</td>
<td>LM-SV/PA</td>
<td>DMA</td>
<td>-</td>
<td>BfR/MRI/FLI</td>
</tr>
<tr>
<td>11. Plant health</td>
<td>BMEL</td>
<td>LM-SV/LPPS/JKI</td>
<td>LPPS</td>
<td>Official laboratories</td>
<td>JKI</td>
</tr>
</tbody>
</table>
Resources for the performance of controls

Legal basis for controls

The legal basis for controls in the food and feed sector is constituted by Regulation (EC) No 882/2004; the Food, Feed and Consumer Goods Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, LFGB); and the implementing laws of the Länder.

The first version of the General Administrative Regulation on Framework Controls, laying down the principles underlying the official surveillance of compliance with provisions of food, wine, feed and tobacco legislation (Allgemeine Verwaltungsvorschrift Rahmenüberwachung, AVV RÜb), was adopted by the Federal Government with the approval of the Bundesrat in December 2004. With regard to food monitoring, it regulates activities according to uniform risk-based criteria, the flow of information and reporting between Federal and Land level, measures to avoid the duplication of work, and the linking of the control activities of the Länder (nationwide control plan).

Subsequent amendments to the AVV RÜb concerned, among other things:

- requirements for establishing and standardising quality management systems in all Land authorities, improving information flow using a new Internet-based information system (FIS-VL);
- introduction of a rotation system for inspectors and of the two-pairs-of-eyes principle during inspections;
- arrangements for cooperation between authorities in crisis situations and the implementation of simulation exercises;
- establishment of nationwide criteria for risk-based official sampling of foodstuffs;
- more specific details on the procedure for import checks on foods of non-animal origin;
- the inclusion of the feed sector in the scope of the Framework Control Regulation in so far as quality management rules are concerned;
- procedural instructions for controls of pesticide residues and for related reporting.

A further amendment to the AVV RÜb on 14 August 2013 included feed monitoring within its scope.

Other important General Administrative Regulations are:

- General Administrative Regulation implementing the rapid alert system for food, food contact materials and feed (Allgemeine Verwaltungsvorschrift für die Durchführung des Schnellwarnsystems für Lebensmittel, Lebensmittelbedarfsgegenstände und Futtermittel [AVV Schnellwarnsystem, AVV SWS]).
- General Administrative Regulation on the collection, evaluation and publication of data on the occurrence of zoonoses and zoonotic agents along the food chain (Allgemeine Verwaltungsvorschrift über die Erfassung, Auswertung und Veröffentlichung von Daten über das Auftreten von Zoonosen und Zoonose erregern entlang der Lebensmittelkette, AVV Zoonosen Lebensmittelkette).
• General Administrative Regulation on the exchange of data in the field of food safety and consumer protection (Allgemeine Verwaltungsvorschrift über den Austausch von Daten im Bereich der Lebensmittelsicherheit and des Verbraucherschutzes [AVV Datenaustausch, AVV DatA])

• General Administrative Regulation on the performance of official monitoring of compliance with hygiene rules for foods of animal origin and on the procedure for reviewing guidelines for good procedural practice (Allgemeine Verwaltungsvorschrift über die Durchführung der amtlichen Überwachung der Einhaltung von Hygieneverordnungen für Lebensmittel tierischen Ursprungs und zum Verfahren zur Prüfung von Leitlinien für eine gute Verfahrenspraxis [AVV Lebensmittelhygiene, AVV LmH]).


The Feed Regulation (Futtermittelverordnung, FMV) was amended on 15 October 2015 with regard to Implementing Regulation (EU) No 2015/1607.

In relation to the requirements for competent authorities to have legal powers of access to food business premises and documentation (under Article 8 of Regulation (EC) No 882/2004) the conclusions of Section 4.6 of the General Audit report were that these legal powers of access were adequately ensured and satisfactorily applied.

**Staffing provision and facilities**

The findings of Section 4.2 of the General Audit report 2008-8744 were that the AVV RÜb contained specific provisions on avoidance of conflicts of interest and required, inter alia, that any secondary functions which might constitute such a conflict must be declared, and could only be carried out after prior verification and upon agreement by the CA. In addition, individual Länder could have their own additional provisions in this respect. Examples of such provisions were obtained in some of the Länder visited by Commission services’ audit teams for animal welfare and residue controls.

In most sectors and Länder, sufficient resources, equipment and facilities, including adequate laboratory capacity, were available to enable the performance of official controls.

The conclusions of Section 4.2 of the General Audit report were that the operational criteria for official controls, including the avoidance of conflicts of interest, were generally complied with.

**Staff qualifications and training**

The conclusions of Section 4.4 of the General Audit report were that the CAs had introduced measures which largely ensured that staff performing official controls were trained, and were being kept sufficiently up to date in their areas of competence as required by Article 6 of Regulation (EC) No 882/2004. Appropriate minimum educational requirements and training programmes were established. The authorisation to perform controls only after completion of compulsory training ensured basic competence levels. Staff performing official controls were trained and competent. In the plant health area, staff had the qualifications necessary for the proper application of Directive 2000/29/EC.
Organisation and delivery of official controls

Registration/approval of businesses

Information on registration and approval of businesses may be found in this overview part of the Länder profile:

- for food of animal origin, in Chapter 2.2
- for feed, in Chapter 2.4
- for ABP, in Chapter 2.5
- for foodstuffs and general food hygiene, in Chapter 2.7.

Prioritisation of official controls

The findings of Section 4.1 of the General Audit report 2008-8744 were as follows:

"Under German constitutional law, each Federal State (Land) has the responsibility for planning and implementation of the official controls under Regulation (EC) No 882/2004 within its jurisdiction. In order to assist in a uniform and coordinated implementation throughout Germany of the requirements of Regulation (EC) No 882/2004, in particular Articles 4 to 10, as well as other requirements for animal health and welfare, legislation was adopted which establishes commonly agreed principles on systems and structures, but leaves the actual development and implementation to the States (Länder): the General Administrative Provision on the Framework of Controls of 24 December 2004 (Allgemeine Verwaltungsvorschrift Rahmen-Überwachung, AVV RÜb) sets the general principles for official controls and the main requirements for inspection performance and reporting, as well as surveillance of compliance with provisions of food, wine, feed and tobacco legislation as provided for in the Regulation. It also lays down the principles for carrying out official monitoring to check compliance with regulations, in line with the provisions of Regulation (EC) No 882/2004 as regards risk-based controls.

The AVV RÜb provides that food businesses to be monitored/controlled shall first be classified into risk categories. This risk-oriented system contains both general criteria, such as product risk, as well as individual ones, such as the past performance of the FBO, the reliability of the FBO’s HACCP programmes and other relevant factors, and on that basis it sets up the inspection frequency for FBOs. The risk assessment is supported by a rating, whereby the more points assigned to businesses on the basis of the above-mentioned general and specific criteria, the higher the frequency of inspections."

The AVV RÜb is supported by the LAV’s work on harmonisation and coordination, involving several working groups. Project groups may be formed to deal with individual issues. The LAV working group 'Quality management system in consumer health protection' (AG QM) has drawn up a QM framework for the Länder which contains inter-Länder QM documents in the form of policy documents, procedural instructions and other QM-relevant rules. The framework covers the food, feed, animal health and animal welfare sectors. The following groups are involved in designing the framework: the LAV, the AG QM and the other LAV working groups on consumer health protection. All inter-Länder QM documents, except technical ones, are drawn up by the AG QM. Technical inter-Länder QM documents are written by the relevant LAV working group. Progress in implementing the QMS and carrying out audits, including the status of QMS in the Länder, is described annually in the MANCP annual report in accordance with Regulation (EC) No 882/2004.

Additional information on the AVV RÜb may be found under the heading 'Resources for the performance of controls: Legal basis for controls'.

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The conclusions of Section 4.1 of the General Audit report 2008-8744 were that, in the areas under review, the provisions of Article 3 of Regulation (EC) No 882/2004 in respect of risk-based controls, appropriateness of their frequency and coverage of the production chain were, overall, adequately implemented, and the provisions of the AVV RÜb were respected. Some initial shortcomings observed in terms of considering past performance by FBOs were addressed through the revision of the AVV RÜb in June 2008. Overall, the requirement for unannounced controls appeared to be adhered to.

Since the completion of the General Audit, more recent audits have found that official controls in the Länder visited in accordance with AVV RÜb were carried out regularly taking a risk-based approach. Given the current rating system, the weight assigned to HACCP plans can lead, under certain circumstances, to a higher frequency of controls being carried out in cases of inadequate or non-implemented HACCP programmes.

**Sampling and laboratory analysis**

**Laboratories**

In accordance with Article 33 of Regulation (EC) No 882/2004, Germany has designated the following institutions as National Reference Laboratories in the fields of food, feed and animal health:

The Federal Office of Consumer Protection and Food Safety (BVL) houses the national reference laboratories (NRL) for: pesticide residues in cereals and feedingstuffs; pesticide residues in foods of animal origin and products with a high fat content; pesticide residues in fruit and vegetables, including products with a high water and high acid content; single pesticide residues; heavy metals in food and feedingstuffs; polycyclic aromatic hydrocarbons (PAHs); genetically modified organisms (GMOs) and residues of veterinary medicinal products and harmful substances in foods of animal origin (residues of group A and B substances listed in Annex I to Directive 96/23/EC).

The Federal Institute for Risk Assessment (BfR) houses the national reference laboratories (NRL) for: viruses and bacteria in bivalve molluscs; marine biotoxins; Campylobacter; Escherichia coli, including verotoxigenic E. coli; Listeria monocytogenes Trichinella; antimicrobial resistance; dioxins and PCBs in feed and foodstuffs; zoonoses (Salmonella); coagulase-positive Staphylococcus, including Staphylococcus aureus; mycotoxins; materials that are intended to come into contact with foodstuffs (food contact materials); animal protein in feedingstuffs; and additives for use in animal nutrition.

The Friedrich Loeffler Institute (FLI) is the National Reference Laboratory (NRL) for notifiable infectious animal diseases and notifiable animal illnesses under relevant EU legislation.

The FLI carries out examinations and tests for: African swine fever and classical swine fever; avian influenza; bluetongue and African horse sickness; brucellosis; echinococciosis; fish diseases (koi herpes virus, infectious salmon anaemia, infectious haematopoietic necrosis and viral haemorrhagic septicaemia); foot-and-mouth disease; shellfish diseases; Newcastle disease; swine vesicular disease; rabies; and transmissible spongiform encephalopathies (TSE).

The FLI also operates a number of National Reference Laboratories for infectious animal diseases for which there are no control measures under EU law but which, for example, are notifiable according to World Organisation for Animal Health (OIE) standards and for animal illnesses notifiable under German law. The complete list of all national reference
laboratories is set out in the Notice of the National Reference Laboratories for notifiable infectious animal diseases and notifiable animal illnesses, as last amended.

The Max Rubner Institute performs tests on milk, milk products and Anisakis.

The Julius Kühn Institute fulfils in some areas the role of a national reference laboratory for plant health, particularly with regard to organisms subject to monitoring throughout the EU and to the directives for combating harmful organisms (e.g. *Clavibacter michiganensis subsp. sepedonicus* and *Bursaphelenchus xylophilus*).

Within their respective area of competence, the 16 Länder designate laboratories for official food, feed, animal health and plant health analyses. A list of laboratories in individual Länder can be found in the individual control plans: [http://www.bvl.bund.de/mnkp](http://www.bvl.bund.de/mnkp)

Section 4.2 of the General Audit report 2008-8744 found that in most sectors and Länder sufficient resources, equipment and facilities, including adequate laboratory capacity, were available to enable the performance of official controls.

**National accreditation body**

Under Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, since 1 January 2010 accreditation may be carried out only by a single national accreditation body exercising public authority in each Member State.

In Germany, on the basis of the Accreditation Body Act (AkkStelleG), in conjunction with the AkkStelleG authorisation ordinance (AkkStelleG-Beleihungsverordnung), the Deutsche Akkreditierungsstelle GmbH (German Accreditation Body, DAkkS) is entrusted with the duties and powers of the national accreditation body. The DAkkS performs mandatory and voluntary accreditation of conformity assessment bodies in all sectors (industry, construction, agriculture, transport, healthcare, telecommunications, etc.) as an official task of the Federal government. It is under the technical supervision of each of the relevant ministries.

Regarding accreditation activities in the nutrition, agriculture and consumer protection sectors, including food safety, the DAkkS is under the supervision of the Federal Agency for Agriculture and Food (BLE). This concerns in particular the areas of feed, food, cosmetic products, consumer goods and tobacco products as well as certain agricultural products as defined in Article 1 of Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets.

The DAkkS performs accreditation of official laboratories, as required under Article 12 of Regulation (EC) No 882/2004.
Procedures for performance and reporting of control activities

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out official controls in accordance with documented procedures, containing information and instructions for staff performing official controls. These procedures must be kept up to date.

The findings of Section 4.6 of the General Audit report 2008-8744 were that, generally, all official controls including supervision within the area of food safety and animal health legislation were being carried out in the context of the Länder QMS. The objective of the QMS is, inter alia, to provide instructions for all areas of control as required by Article 8(1) of Regulation (EC) No 882/2004.

The conclusions of Section 4.6 of the General Audit report 2008-8744 were that the development of the requirements of Article 8 (in relation to documented procedures, procedures to verify the effectiveness of controls and the drawing up of reports on official controls carried out) was in a number of areas directly linked to progress made in the development of the QMS and/or the work emanating from working groups under the LAV. As a result, considerable variation was seen, particularly in the development and use of documented procedures. In a number of areas and/or Länder, the requirements for documented procedures could be considered to comply with Article 8, whereas in others, much work remained to be done. While it was acknowledged that differences in the progress of work under the LAV (further developed in the food safety area than in others) may explain some of the variation, there was also ample evidence that CAs at Land or local level had developed and progressed procedures on their own initiative, usually linked to a more rapid development of the Land QMS.

In the meantime, the introduction of QMS in the Länder and the Federal government is substantially complete (see Section 3.2 of the 2014 Annual Report on the MANCP).

Progress in carrying out audits, including the status of QMS in the Länder, is described annually in the MANCP annual report in accordance with Regulation (EC) No 882/2004. (See recommendation 2008-8744-6 in this Länder profile, in the part on follow-up measures).

Reporting on control activities

Article 9 requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action taken by the business operator concerned. At least in the case of non-compliance, a copy must be given to the business operator.

Progress in relation to the preparation of reports on controls is also linked to completion of QM systems in all sectors in each Land. Since 2013, the obligation to draw up control reports has been included under points 4.4.1 and 4.5 of the inter-Länder procedural guideline on official controls and in other documentation.

Enforcement measures

The conclusions of Section 4.7 of the General Audit report were that in the areas under review, the requirements of Articles 54 and 55 of Regulation (EC) No 882/2004 were largely complied with. A solid legal framework was in place at Federal level, complemented by measures in the Länder, and including an indication of enforcement measures to be taken and sanctions to be imposed. Application of these mechanisms was evidenced in practice in most Länder visited and in most areas under review, and appeared both proportionate and effective in the majority of cases.
Verification and review of official controls and procedures

Verification

The inter-Länder procedural guideline on ‘Official controls’ was amended and adopted by the LAV in autumn 2012. The paper prepared by the AG QM describing the process of ‘Ensuring and verifying the effectiveness of official controls’ was adopted by the LAV and included in the Multiannual National Control Plan (MANCP) for Germany in line with the decision of the LAV.

The paper sets out tools and procedures that form the basis for administrative actions in all the Länder.

A number of examples of measures were presented during the 2013 GFA in an annex (‘3.A.5. Wirksamkeit (Effectiveness)’). The AG QM indicated that while the list was no more exhaustive than the position paper itself (as it was not possible for the AG QM to present all aspects of technical supervision), it provided an overview of the main tools for technical supervision.

In Länder with intermediate (provincial level) governments/provincial councils, the same tools are used to ensure the effectiveness of controls; there is merely an additional level of authority. The role of the provincial governments/provincial councils particularly involves a consolidation and coordination function.

Examples of the operation of the provincial level verification process were provided by BW and BY:

- BW belongs to the group of Länder with provincial governments as a mid-level authority. These are the authorities that exercise technical supervision over the lower-level administrative authorities in their government region. The Ministry of Rural Affairs and Consumer Protection (Ministerium für Ländlichen Raum und Verbraucherschutz) of Baden-Württemberg is the highest supervisory authority and also exercises technical supervision over the provincial governments.

  The same tools are used to ensure the effectiveness of controls; the only difference is that there is an additional level of authority here. The technical supervision tasks also always include on-site elements.

  Target agreements are one element of the exercise of technical supervision. There have therefore been target agreements between the Ministry of Rural Affairs and Consumer Protection and the provincial councils in Baden-Württemberg for several years. These agreements stipulate, inter alia, that in maintaining their steering role the provincial councils make on-site visits to 50% of their subordinate authorities each year.

Audit

Responsibility for carrying out audits in accordance with Article 4(6) of Regulation (EC) No 882/2004 lies with the Länder. They decide on the type of audits to be conducted, the planning cycle, follow up, transparency and other requirements laid down in Commission Decision 2006/677/EC.

The inter-Länder procedural guideline on internal audits was revised by the AG QM and adopted by the LAV on 5 November 2012.
According to the AVV RÜb (German “Framework Control” regulation), all Länder must introduce quality management systems which include quality standards for the implementation of the audit procedure pursuant to Article 4(6) of Regulation (EC) No 882/2004.

Länder carry out independent audits, which may be attended by observers from other Länder and the Federal Government in line with the decision of the LAV. Länder audit procedures are prepared in accordance with the requirements of the inter-Länder procedural instruction on "Independent scrutiny" (Unabhängige Prüfung).

During the period from January to August 2013, internal audits in Lower Saxony, Rhineland-Palatinate, Saxony-Anhalt and Bavaria were attended by observers from other Länder and the Federal Government for the first time. In 2014 and 2015, observers visited or planned to visit five other Länder and the Federal Government. Planning for the participation of observers for the following reporting period takes place at the AG QM's autumn meeting.

A process-based review of progress in carrying out audits, including the status of QMS in the Länder, is carried out annually in each sector. This is carried out through the MANCP annual report in accordance with Regulation (EC) No 882/2004.

In October 2015, the AG QM presented an updated overview table of audits performed in the Länder.

The variations in the number of audits carried out in each Land was explained by the fact that the number of authorities to be audited in each Land varied. At the lower administrative level the number of competent authorities varies from less than 10 to more than 90.

Some Länder also have an additional middle management level, and this level will also be audited. In the overview provided to the Commission services, there was no distinction between audits in the various levels of government; all audits were recorded equally.

In addition, the following points emerged during the general follow-up audit:

- The operational capability of the audit system is under the control of the Highest Land Authority (Oberste Landesbehörde).
- The Commission services were shown harmonised documents from the AG QM, including a standard form for a report by an observer of an independent audit in another Land or at Federal level.
- The AG QM has drawn up principles for the conduct of audits.
- An on-the-spot element is being increasingly incorporated into the audit and technical supervision processes.

A Federal/Länder working group was also established independently of Regulation (EC) No 882/2004 to conduct audit procedures in the plant health sector. In principle, this group can conduct audits in all Länder.

**Multi-annual National Control Plan (MANCP)**

The period of validity of the German MANCP is five years (2012-2016). The framework plan is updated every year. The contact point for the plan is the BMEL. The co-ordination centre for compiling and updating the plan is the BVL. The framework plan and all 16 Länder plans are published on the BVL website:

http://www.bvl.bund.de/mnkp
The strategic objectives of the multi-annual national control plan are:

- optimising the QM systems in all competent authorities, including verification by means of suitable audit systems to ensure their effectiveness;
- greater networking for control strategies, and increased interdisciplinary control procedures;
- developing concepts for the early detection and minimisation of residues, contaminants, undesirable substances and zoonotic pathogens in the entire food and feed chain;
- further development of effective concepts for preserving the health of animals and plants to create safer food and feed;
- developing and implementing control concepts for minimising the use and ensuring the correct use of veterinary medicines, in particular for reducing residues and resistance;
- developing and implementing control concepts to ensure animal welfare-compliant husbandry conditions, particularly for farm animals;
- optimised analysis and evaluation of the effectiveness of controls pursuant to Regulation (EC) No 882/2004;
- better information and transparency for consumers and citizens.

Due to the federal administrative structure in Germany, there is no national MANCP covering all control activities in Germany. In line with the devolution of control competencies, Germany drew up a federal framework MANCP, underpinned in the consumer health protection sector by individual plans for each of the 16 Länder, with the BVL playing a coordinating role. A “Federal/Länder MANCP Drafting Group” coordinated by the BVL, annually reviews the framework MANCP. It makes proposals for its further development and, after the production and evaluation of the annual report provided for in Article 44 of Regulation (EC) No 882/2004, for amendment as appropriate. These proposals are submitted to the Länder for their agreement or observations. The review and development of the Länder plans is the responsibility of the Länder.
2 COMPETENT AUTHORITIES AND DISTRIBUTION OF RESPONSIBILITIES IN RELATION TO INDIVIDUAL CONTROL SYSTEMS

2.1 Control system for animal health

CDB Central database for animal identification and registration
FLI Friedrich Loeffler Institute
LAV Länderarbeitsgemeinschaft Verbraucherschutz [Länder Working Group on Consumer Protection]
AG TT LAV-Arbeitsgruppe Tierseuchen, Tiergesundheit [LAV animal diseases and animal health working group]
TSN Tierseuchennachrichtensystem [Electronic animal disease reporting system]
PEI Paul Ehrlich Institute (sera, vaccines)

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<td>Mobiles Tierseuchenbekämpfungszentrum</td>
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<td>LAV Arbeitsgruppe Tierseuchen, Tiergesundheit (AG TT)</td>
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<td>16 Landesministerien/Senatsverwaltungen</td>
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<td>CDB Central database for animal identification and registration (HIT), operated by Bavarian Ministry</td>
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### Competent authorities

The BMEL is the CCA in the animal health sector. Within the BMEL, Unit 322 is responsible for animal health matters. Its tasks include in particular: EU and national animal disease issues, financial issues of EU animal disease compensation, prevention and control of other animal diseases not covered by the State animal disease control scheme, animal disease identification for bovine, ovine and caprine animals, swine and equidae, issues related to the production, analysis and application of veterinary medicinal sera and vaccines, and disposal of animal by-products not destined for human consumption. In the framework of regularly convened meetings of animal disease administrators, particular aspects of the implementation of existing or draft legislation are addressed.

Unit 323 is the National Crisis Centre for Animal Diseases, and is also responsible for animal health issues related to intra-Community trade and imports. The Crisis Centre for Animal Disease has the following tasks:

- Monitoring and assessing the animal disease situation in Germany and abroad; animal disease eradication in cooperation with EU Member States and third countries; animal disease notification system in Germany and abroad.
- Animal disease statistics, development and updating of animal disease crisis plans.
- Expert group on disease eradication, including epidemiological examinations in the event of outbreaks, led by the Federal-Länder “Animal Diseases” Task Force; management of the national crisis staff at the level of office head, involving the respective economic operators and experts.

### Holding registration, animal identification and movement controls

The central database (CDB) is part of the system for guaranteeing the origin of and providing information on animals (Herkunftssicherungs- und Informationssystems für Tiere, HIT), introduced in accordance with the provisions of EU law, firstly for bovine animals,
then for pigs, sheep and goats and finally for equidae. In addition to animals, the CDB also covers the market as the basis for EU single payments (cross-compliance).

In accordance with the agreement concluded between the 16 Länder, the CDB was established at the Bavarian State Ministry for Food, Agriculture and Forestry in Munich. Although the Bavarian Ministry operates the CDB, each Land remains responsible for its own data. The responsibility of the Bavarian Ministry is limited to operation of the CDB.

Animal health controls

In all Länder, responsibility for implementing tasks within the context of animal health and combating infectious animal diseases lies with the administrative districts and independent municipalities (exceptions: HB and SL: carried out at Landesamt level). These possess appropriate specialist staff, plans for raising the alarm in the event of an outbreak of an infectious animal disease and for combating the disease, as well as appropriate equipment and technical resources. In addition, some Länder have established administrative districts and created cross-cutting resources networks.

A Federal-Länder “Animal disease eradication” Task Force has been established to examine all aspects of animal disease eradication and to support the Länder. The Task Force is chaired by the head of the Crisis Centre for Animal Diseases at the BMEL. Animal diseases experts from the Länder, a representative from the Federal Ministry of Defence and from the FLI are also members. All Länder signed up to participate in this process by providing resources and expertise and to implement the recommendations made.

Some Länder have also established task forces at their level. In terms of crisis management, new structures have been set up on the basis of the Task Force Agreement to enhance cooperation between the federal and Land levels. Four experts operate in the BMEL and FLI, paid by the Länder, to liaise between the BMEL and the Länder. The “Animal disease eradication” Task Force has the following tasks:

- Recommendations on combating highly contagious animal diseases, in particular with regard to cross-border implications; collating and assessing epidemiological findings; drawing up standards for implementing animal disease eradication measures and updating these standards with the assistance of the FLI.

- Proposals for the establishment of rapid and, in particular, inter-Länder information sources, in view also of information obligations towards the EU and third countries; establishing and continuously updating a list of persons available in cases of outbreaks or suspected outbreaks of highly contagious diseases (crisis case) in the respective Länder.

- Establishing and maintaining an Internet-based handbook on combating infectious animal diseases (Tierseuchenbekämpfung- TSBH) to standardise animal disease crisis management; recording and coordinating diagnostic capacity, disposal capacity, material resources, protection policies, proposals for implementing training measures and inter-Länder exercises.

- Recommendations regarding the establishment of crisis and combat centres; establishing, maintaining and updating a list of experienced experts in the area of animal disease eradication in order to appoint them as members of an expert group on the basis of proposals from the Federal government and the Länder for their respective area; in the event of a crisis, to appoint the members of expert groups.
A Mobile Disease Eradication Centre has been created, based on a written agreement by all 16 Länder. It comprises predominantly a mobile container unit (about 40 containers including furnishings and IT equipment) to be deployed in the event of an outbreak. Furthermore, there is a stock of protective clothing and equipment for animal disease eradication.

At national level the FLI (Institute for Epidemiology, Insel Riems) is responsible for technical implementation and monitoring of TRACES as “Member State Administrator”. Further information is available at http://www.fli.bund.de.

The national electronic animal disease reporting system (Tierseuchennachrichtensystem, TSN) is the standardised computer-supported national reporting system for infectious animal diseases and other animal illnesses and has been used in all veterinary authorities within Germany since 1995.

Contingency plans

In line with the decision of the Task Force on combating infectious animal diseases, a standardised joint crisis plan has been developed. The electronic handbook on combating infectious animal diseases (Tierseuchenbekämpfung - TSBH), an Internet-based collection of plans, checklists, tables, factsheets and information material compiled and updated by Task Force working groups, forms an essential part of this. The catalogues are designed to support the veterinary authorities, who can access it via TSN.

However, the Länder adapt their plans and procedures to their specific requirements (Länder emergency plans).

Laboratories

Details of the FLI's tasks as a National Reference Laboratory for notifiable infectious animal diseases and for animal illnesses notifiable under German law can be found in Chapter 1, under the sub-heading 'Sampling and laboratory analysis', in the section on the Friedrich Loeffler Institute.

Within their respective area of competence, the 16 Länder have designated laboratories for official animal health analyses. Information about laboratories within all Länder can be found in individual control plans: http://www.bvl.bund.de/mnkp
2.2 Control system for food of animal origin

**AFFL**  LAV working group on meat and poultry meat hygiene and technical issues of food of animal origin

**ALTS**  Food Hygiene and Food of Animal Origin Research Group

**BfR**  Federal Institute for Risk Assessment

**BVL**  Federal Office of Consumer Protection and Food Safety

**LAV**  Länder working group for Consumer Health Protection

**MRI**  Max Rubner Institute

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Competent authorities

The BMEL is the CCA for food of animal origin. The BMEL and the BMUB are competent for legislation at Federal level in this area. In the BMEL, Unit 314 is responsible for food hygiene and meat hygiene. In the BMUB, Unit IG II 2 is responsible for prevention/limitation of environmental contaminants in food, including those in food of animal origin.

The Federal Office of Consumer Protection and Food Safety (BVL) provides data to the BMEL and the BMUB and executes tasks in cooperation with those Ministries. The Federal Institute for Risk Assessment (BfR) performs risk assessments and advises the BMEL, BMUB, BMVI, BVL and the Länder.

The BfR has a legal mandate to conduct independent research, directed towards specific applications. The objective of such research is to fill in knowledge gaps with regard to: the safety of food, chemicals and food contact materials; the development, evaluation and validation of alternative and replacement methods for animal testing; as well as risk communication and risk perception. The findings of the BfR's research are used to provide scientific advice to the BMEL, BMUB and BMVI.

Research in the area of food of animal origin is carried out by the Max Rubner Institute, also known as the Federal Research Institute of Nutrition and Food, which reports its findings back to the BMEL.

Compliance for implementing controls, and for enforcement of relevant legislation lies with the Länder. Consequently, the BMEL cannot issue instructions to the Länder. The LAV is a Länder body that discusses issues affecting all the Länder at the level of department head. With the Federal authorities as guests, it acts as a key interface between Federal and Land level. In particular, technical questions relating to food of animal origin are also addressed in AFFL, the LAV working group for food of animal origin. Apart from control of the implementation of legislation in the area of food of animal origin, the Länder Ministries and Senate Administrations can issue provisions on the implementation of Federal law as long as it is in accordance with Federal and EU law. At district and municipal authority level, the respective veterinary and food control authority (DMA) is responsible for the control of establishments on the spot. (This is the case in all Länder except Bremen and Saarland, where implementation takes place at the level of a State Office (Landesamt)).
The Food Hygiene and Food of Animal Origin Research Group (ALTS) is a committee comprised of representatives from the Federal Government and the Länder, and experts. Its role is to harmonise the assessment of investigative outcomes, and the exchange of scientific experience and opinion in relation to the composition of food of animal origin, food hygiene, food microbiology, viruses in foodstuffs, and animal drugs in accordance with the National Residue Control Plan, and in relation to parasitological, histological and immunological analysis of foodstuffs.

**Registration and approval of establishments**

The Länder are responsible for the approval of establishments (including meat, poultry meat, milk, fish and egg products establishments and egg packing centres) where approval is compulsory. According to the respective Land, approval is granted by the Länder Ministries and Senate Administrations, the Provincial Authorities, a State Office (Landesamt) or by a special authority.

The procedure for the approval of establishments usually comprises the following steps:

- Application (by the respective establishment) for approval
- Checking and discussing the administrative and technical file
- Checks on the spot by the competent approval authority
- Decision on approval
- Informing the BVL, which publishes an up-to-date list on the Internet, with a link to the relevant page of the European Commission

The rules governing the authorisation procedure are set out in the German General Administrative Provision on Food Hygiene (AVV-LmH) and in the German Regulation Implementing the Provisions of Community Food Hygiene Law. This is a consolidation and implementation of the EU food hygiene legislation for the authorisation of establishments dealing with food of animal origin.

The list of approved establishments producing food of animal origin for the internal market is accessible on the Internet: [http://www.bvl.bund.de/bltu](http://www.bvl.bund.de/bltu).

**Official controls and inspections at establishments**

Responsibility for official inspections and food monitoring programmes lies with the Länder. In all Länder except Bremen and Saarland (where implementation takes place at the level of the State Office), the food monitoring and veterinary offices in the administrative districts, and in the municipalities independent of the administrative districts, are responsible for implementing controls, in their capacity as lower-level administrative authorities. In Bavaria, Baden-Württemberg, and Schleswig-Holstein, the competent authority has delegated specific tasks in relation to meat inspection, inspections in milk-processing establishments and controls of raw milk deliveries to a control body.

Competent authorities in the Länder designate laboratories to carry out analyses of official food samples. The supreme authorities in the Länder having responsibility for consumer health protection collaborate in the Länder Working Group for Consumer Health Protection Länderarbeitsgemeinschaft Verbraucherschutz (LAV).

For food surveillance, the Framework Control Regulation (AVV RÜb) sets uniform risk-based principles for official control activities of food establishments. The General Administrative Regulation on Zoonoses along the Food Chain was adopted by the Federal Ministry of Food and Agriculture (BMEL) and came into force on 3 June 2008. This
administrative regulation is the legal basis for zoonoses monitoring, a programme for monitoring of antimicrobial resistance in zoonotic agents and zoonotic and other pathogens which pose a health risk (see http://www.bvl.bund.de/ZoonosenMonitoring).

A Monitoring Programme for Food, Cosmetic Products and Food Contact Materials has been implemented jointly by the Federal Government and the Länder. It is a programme with the aim of collecting representative data on undesirable substances in foodstuffs, cosmetic products and food contact materials and consists of two parts: shopping-basket monitoring; and project monitoring, on selected issues, carried out on the basis of proposals from the Federal Government or the Länder: www.bvl.bund.de/monitoring.

The National Monitoring Plan (NMP) is a plan, agreed among the Länder and established for one year, of official inspections to monitor compliance with food, wine and tobacco regulations, including protection against fraud. It may contain programmes for product and establishment inspections, or a combination of the two. The National Monitoring Plan is a risk-based monitoring programme. The testing of food, cosmetic and non-food consumer products falls within the NMP’s scope.

For more information on the NMP and the programmes implemented so far, see www.bvl.bund.de/buep.

For these investigation programmes, and in order to meet reporting obligations to the Commission, the Federal Government must draw together data for the entire Federal Republic. In order to facilitate handling and administration of the large quantities of data, general conditions for the standardisation of data formats for foodstuffs and feed monitoring were agreed between the Federal Government and the Länder. These data formats were described and fixed in the General Administrative Regulation on the exchange of data in the field of food safety and consumer protection (AVV Datenaustausch – AVV DatA).

Official controls on identification mark and traceability

Controls over the application of identification marks are included in the annual control plan and should be covered during inspections. Traceability is included as a specific issue in control plans.

Laboratories

Germany has designated National Reference Laboratories for food of animal origin.

The National Reference Laboratories for Salmonella, Campylobacter and Listeria monocytogenes, for marine biotoxins, viruses and bacteria in bivalve molluscs, coagulase-positive Staphylococcus, including Staphylococcus aureus, Escherichia coli, verotoxigenic E. coli, and for Campylobacter, parasites (particularly Trichinella), dioxins and PCBs in foodstuffs are located at the Federal Institute for Risk Assessment.

The BVL operates the national reference laboratories for residues and contaminants in foods of animal origin. The MRI carries out analysis and tests of raw milk and milk products, and for the Anisakis parasite.

The 16 Länder within their competence have designated laboratories for official food analyses. Information about laboratories within all Länder can be found in individual control plans: http://www.bvl.bund.de/mnkp.
2.3 Control system for imports of animals and food of animal origin

**BIN** Federal Agency for Nature Conservation  
**BMUB** Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety  
**BVL** Federal Office of Consumer Protection and Food Safety  
**LAV** Länder working group for Consumer Health Protection  
**AGED** Import and transit working group of LAV  
**FLI** Friedrich Loeffler Institute

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Competent authorities

The BMEL is the CCA for issuing Federal legislation for import controls of live animals and food of animal origin. The competent units are Unit 323 (Animal diseases - Crisis centre; Intra-Community trade and imports) and Unit 314 (meat hygiene, food hygiene) for imports of food of animal origin.

The customs authorities are involved in checking compliance with animal health regulations during import and export controls and can stop consignments of the relevant animals and goods for this purpose. The legal bases for action by the Customs administration are § 29 TierGesG (or Article 24(4) of Regulation (EC) No 882/2004 in conjunction with Articles 27-29 of Regulation (EC) No 765/2008), and § 55 LFGB. The Federal Ministry for Finance and its designated customs offices collaborate with Land or district and municipal authorities at border inspection posts and entry points with regard to import and export controls of products of animal origin. The customs offices are also involved in monitoring the import and export of live animals under § 14(1) TierSchG.

The BfN, under the BMUB, provides expertise on species protection, and in particular concerning the Convention on International Trade in Endangered Fauna and Flora (CITES list).

Under § 27 TierGesG, the FLI takes part in the examination of animals or products of animal origin intended for import or export.

Import controls

The national Regulation on the import of food of animal origin, the Lebensmitteleinfuhr-Verordnung, was adapted to address Community law on food hygiene by means of the Order of 8 August 2007 implementing the provisions of Community Food Hygiene Law. Responsibility for implementation of veterinary import/transit controls lies with the Länder. The Länder implement Federal legislation including the directly applicable legislation of the EU.

Consultations are carried out between the 16 Länder, the Ministry of Food and Agriculture, and the Federal Ministry of Finance. With regard to the role of the police, the Federal Ministry of the Interior is also involved in the consultations. The legally binding task for Customs to carry out a joint risk analysis is an essential part of the EU's security initiative. The main objective of this security initiative (and thus also of the risk analysis) is to ward off potential threats to EU citizens and to the EU environment at the external borders of the EU. The concentrated central risk analysis carried out in Germany by the Customs Criminal Investigation Department, as part of the risk management of the EU Member States' customs administrations, aims to carry out targeted checks in cases where there is a risk of an irregularity or a fraud. Where applicable, relevant findings during the customs clearance of products or animals are communicated to the competent control authorities in the framework of customs' powers for co-operation.
Coordination and cooperation between the veterinary authorities and Customs on import controls is laid down in administrative order SV 0802 and in specific circulars, in particular those giving instructions on cooperation with respect to Regulations (EC) No 136/2004, No 206/2009 and No 998/2003. While the enforcement of legislation on food safety, animal diseases and animal welfare is not dealt with at Federal level, the implementation of customs matters is a centralised, Federal responsibility. Customs are entitled to stop passengers when carrying out animal health-related controls on products of animal origin in passenger luggage and on pet animals in order to enable the competent veterinary authorities of the Länder to monitor animal health. It falls within the remit of the veterinary authorities to take decisions on whether meat, milk and derived products may be imported or seized, or to issue orders concerning subsequent disposal.

The LAV’s AG ED is designed *inter alia* to ensure that all BIPs apply the law uniformly. One of its tasks is the development of a handbook/manual of procedures for imported products of animal origin and live animals from non-EU countries. The manual was finalised at the time of the 2011 Commission services' audit 2011-8918 on import controls.

The AG ED has the following objectives:

- aligning procedures across all Länder, particularly in relation to official import and transit controls;
- updating the "Border inspection posts" (*Grenzkontrollstellen*) manual, in which all veterinary border inspection procedures are described, for an administrative regulation laying down valid procedures for all border inspection posts (BIPs). This should help the authorities to conduct supervision in a uniform manner;
- establishing a training programme for BIP staff;
- drafting and updating a National Import Monitoring Plan in accordance with point 1 of Annex II to Regulation (EC) No 136/2004;
- reaching agreement on legislative projects (nationally and at EU level) as well as participating in the preparation and follow-up of Commission services' audits in the field of food and feed imports.

On the basis of the National Monitoring Plan, each Land draws up a specific monitoring plan for its BIPs.

Responsibilities for controlling the correct disposal of waste products of animal origin lie within the local veterinary authorities.

General information on importing products of animal origin and non-commercial pet animals is published on the websites of the CCA and Customs as well as in a brochure published by Customs (*Reisezeit – Ihr Weg durch den Zoll*).

As of November 2015 there are 14 approved BIPs in Germany as shown in the latest amendment of Decision 2009/821/EC. These are under the supervision of 10 Länder as follows: **Bavaria**: 1 – (Munich Airport); **Berlin**: 1 – (Tegel Airport); **Brandenburg**: 1 – (Schönefeld Airport); **Bremen**: 3 – (Bremen and Bremerhaven ports); **Hamburg**: 2 – (Hamburg Airport and Hamburg Port); **Hessen**: 1 – (Frankfurt/Main Airport); **Lower Saxony**: 2 – (Cuxhaven Port1, Wilhelmshaven JadeWeserPort, and Hannover-Langenhagen Airport); **North Rhine-Westphalia**: 1 – (Cologne Airport); **Rhineland-Palatinate**: 1 – (Hahn Airport); and **Saxony**: 1 – (Leipzig-Halle Airport).

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1 The Cuxhaven BIP belongs to Lower Saxony but comes under the supervision of Bremen on the basis of an inter-Länder co-operation agreement.
2.4 Control system for feedingstuffs and animal nutrition

BfR Federal Institute for Risk Assessment
BVL Federal Office of Consumer Protection and Food Safety
FLI Friedrich Loeffler Institute – Federal Animal Health Research Institute
LAV Länder working group for Consumer Health Protection
AFU Animal feed working group of LAV
VDLUFA Association of German Agricultural Investigation and Research Centres
FG VI Animal Feed Group (Futtermitteluntersuchung) of the Association of German Agricultural Investigation and Research Centres

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<td>AFU (Animal feed working group of LAV)</td>
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In the field of animal nutrition, the BMEL is mainly responsible for drafting legislation at Federal level, and for coordination of implementation, assisted by the BVL.

Within the BMEL, Unit 315 deals with animal feed. In the BVL, Department 102 is responsible for animal feed safety and animal nutrition.

In particular, the BVL coordinates, drafts guidelines and provides advice to the Länder as regards implementation of control programmes. Other relevant bodies in this area are the Federal Institute for Risk Assessment, which is responsible both for the assessment and communication of risks to public health in respect of feed, and the Friedrich Loeffler Institute (FLI).

Registration and approval of establishments and intermediaries

The Länder authorities are responsible for the authorisation and registration of feed businesses. The Länder keep registers of all feed businesses that have been approved or registered and of intermediaries in the animal feeds sector, and ensure that these registers are up to date. In 2014, a total of around 327,000 operators had been identified as carrying out activities in the feed chain, including around 298,000 primary producers, 1,971 producers of compound feedingstuffs, 120 producers of feed additives, and 192 producers of pre-mixes.

The list of registered feed businesses is published in the Electronic Federal Gazette (Elektronischer Bundesanzeiger). Further information is available at the following website: http://www.bvl.bund.de/DE/02_Futtermittel/03_AntragstellerUnternehmen/01_Zulassungs_Registrierungspflicht/02_Futtermittelbetriebe Verzeichnis/fm_FMBetriebeVerzeichnis_node.html

Official controls

Implementation of animal feed controls rests with the Länder. The Länder implement Federal legislation, including directly applicable EU legislation.

The basis for the implementation of official controls on animal feed within the Länder is the "Feed Control Programme for 2012 to 2016", which was adopted in October 2011 (within the framework of the Conference of Agriculture Ministers of the Länder) by the agriculture ministers from the Federal Government and the Länder.
The Feed Control Programme forms part of the MANCP. It contains recommendations on the number and distribution of risk-based official controls, including the inspection parameters for controls on products, through sampling and analyses. It contains the requirements for risk assessments of feed establishments. It is reviewed annually, with the participation in the Länder, BMEL and BVL, and updated continuously in order to adapt to specific conditions in individual Länder, and to current problems in the animal feed sector. It is published on the BMEL internet site at: http://www.bmel.de/DE/Tier/Tierernaehrung/tierernaehrung_node.html

On a national basis, coordination on the implementation of animal feed controls and on the transposition of feedingstuffs legislation is carried out through meetings of representatives from the national and Länder Ministries of Food and Agriculture, and meetings of the LAV AFU.

The state or private laboratories, official or designated, form part of Specialist Group VI (Fachgruppe VI – FG VI), on Animal Feeds, of the Association of German Agricultural Investigation and Research Centres Verbandes der Deutschen Landwirtschaftlichen Untersuchungs- und Forschungsanstalten (VDLUFA). Generally, each Land/laboratory is represented within the specialist group by one representative of the assigned laboratory. One representative from each of the BMEL, the BVL, the BfR, the German Agricultural Society (DLG) and the Land representative of the AFU are permanent observers in specialist group meetings. The task of the specialist group is to discuss analytical topics with relevance to feed law and to develop and implement tested and standardised analytical procedures. For special analysis, FG VI works in very close collaboration with FG VIII, the Specialist Group for Environmental and trace elements analysis.

Laboratories

The competent Länder authorities designate accredited laboratories to carry out feed analysis. There are 25 laboratories carrying out feed analyses, including both state and private laboratories.

Germany has designated National Reference Laboratories for feed related analyses. The BfR is the National Reference Laboratory for animal protein, mycotoxins, dioxins and PCBs in animal feed, and for additives for use in animal feed. The BVL is the National Reference Laboratory for pesticide residues, heavy metals, polycyclic aromatic hydrocarbons and GMO in animal feed.

The 16 Länder, within their competence, have designated laboratories for official feed analyses. Information about laboratories within all Länder can be found in individual control plans: http://www.bvl.bund.de/mnkp.
2.5 Control system for TSEs and Animal-By-Products (ABPs)

**TSE**

- **BfR** - Federal Institute for Risk Assessment
- **CDB** - Central database for animal registration
- **FLI** - Friedrich Loeffler Institute
- **LAV** - Länder working group for Consumer Health Protection:
  - **AGTT** - Animal health and animal diseases working group of LAV (Epidemiosurveilliance)
  - **AFFL** - Meat and poultry meat hygiene and technical issues of food of animal origin working group of LAV (SRM)
  - **AFU** - Feed working group of LAV (Total feed ban)
- **TSN** - Animal Disease Notification System
Competent authorities

The BMEL is the CCA in the field of transmissible spongiform encephalopathies (TSE). Within the Ministry, Units 322, 314 and 315 deal with TSE issues, in particular with respect to legislation and coordination of epidemiological surveillance.

Other relevant bodies in this area are the BfR, which is responsible both for the assessment and communication of risks to public health related to feed, and the FLI, which is responsible for risk assessment with regard to TSE in live animals.

Epidemio-surveillance

Responsibility for implementation and controls on epidemiological surveillance, removal of specified risk material (SRM) and the feed ban, lies with the Länder. A national control programme for TSEs includes monitoring of cattle, sheep and goats.

The central database for animal identification and registration (CDB) contains all identification and animal movement data. Monitoring of active surveillance is supported by using the CDB, which contains data on animal movements, confirmation of carcasses received at animal by-products processing plants for category 1 and 2 by-products, and BSE test results. The CDB is always consulted to control the eligibility for BSE testing on the inspected premises. A further control is that the CA at district level is automatically alerted by the CDB system, in case a BSE test result has not been recorded in the database two days after the slaughter notification or 28 days after the fallen stock notification.
The BMEL coordinates the TSE sampling requirements for sheep and goats. The number of samples required to be taken by each Land is allocated on the basis of their small ruminant populations. Each Land then further allocates the numbers of samples to be taken so that each slaughterhouse or relevant ABP plant has a target number of samples that has to be taken. As there are relatively small numbers of goats slaughtered, efforts are made to sample all goats over 18 months of age that die on-farm, or are slaughtered for human consumption.

The German National Reference Laboratory (NRL) for TSE is the FLI. Confirmatory tests carried out at the NRL include: histopathology, detection of Scrapie associated fibrils, immunocytochemistry and immunoblotting. The NRL can also carry out primary molecular testing to differentiate BSE and Scrapie strains. All government and private laboratories conducting TSE tests are approved and accredited. In order to supervise and control the quality of TSE tests, all laboratories have to participate in a ring-test each year conducted by the NRL. After a positive rapid test, the confirmation through confirmatory methods has to be done by the NRL.

Specified risk material (SRM)

The removal of SRM in the slaughterhouses and cutting plants, the collection and staining of SRM, and the reconciliation of SRM, is carried out by the food business operator under the supervision of the district and municipal competent authority.

Total feed ban

The feed ban is monitored by the Länder. Controls are carried out by the authorities responsible for feedingstuffs monitoring on the basis of the Feed Control Programme for 2012 to 2016 in the feedingstuffs sector. Länder competent authorities have indicated that, in the organisation of controls for the feed ban, they take account of the risks posed by the use of organic fertilisers and soil improvers (OF/SI) on farms.
LAV  
*Länder* working group for Consumer Protection

AG TT  
Animal health and animal diseases working group of LAV

AFFL  
Meat and poultry meat hygiene and technical issues of food of animal origin working group of LAV

AFU  
Animal feed working group of LAV
Competent authorities

The central competent authority for ABPs is the BMEL (Unit 322). The Länder are responsible for the application of Regulation (EC) No 1069/2009 and Regulation (EC) No 142/2011 as laid down in the corresponding Federal implementation act.

Approval of ABP plants and other premises

The ABP Order of 27 July 2006 (Tierische Nebenprodukte-Beseitigungsverordnung – TierNebV) implemented authorisations under the 2004 ABP Act (Tierische Nebenprodukte-Beseitigungsgesetz – TierNebG). The Act is the overall legal basis for mandatory disposal in ABP plants in Germany. The ABP Order (TierNebV) contains particular requirements for approval and registration of ABP plants and also specific requirements for catering waste, biogas and composting plants. The responsibilities of the different authorities within the Länder are defined in the respective legislation of each Land. Depending on the structure in the Land, one or two Ministries and different departments may be responsible for the application of the ABP rules. Biogas and composting plants historically are under the responsibility of the environmental administration, but the veterinary authorities are involved where animal by-products are used. Depending on the Land, approval of establishments for Category 1, 2 and 3 material in accordance with the ABP Order is given either at the relevant Land Ministry or Senate Administration, the Provincial Authority or at the lower administrative levels (ie at District (Kreise), Municipal (kreisfreie Städte) or State Office (Landesamt) levels).

Information concerning the issuing or withdrawal of approvals and other relevant information is notified promptly to the Federal Ministry of Food and Agriculture. The Ministry maintains a constantly updated list of plants approved according to the ABP Regulation. The list of approved ABP plants and establishments is published in the Animal Disease Information System of the FLI at the following link: http://tsis.fli.bund.de/Home/BMEL/List.aspx?ref=322
Official controls

The competent authorities in the Länder are responsible for the control and supervision of: processing, intermediate-treatment and storage plants using raw animal by-products; producers of feedingstuffs; and pet food and ABP processing plants (Categories 1, 2 and 3).

The collection, transport, storage and processing of Category 1 and Category 2 materials in defined areas is ensured in all 16 Länder. The end products, in particular meat-and-bone meal and animal fat, are either sent for incineration or co-incineration or, in the case of fat, used for technical purposes or sent to other Member States. Incineration of MBM takes place in dedicated incinerator or co-incinerator plants (e.g. cement kilns) which also receive material from other Member States.

Issues relating to ABP are discussed in the LAV AGTT.
2.6 Control system for veterinary medicinal products (VMPs) and residues

Veterinary medicinal products

**Database on authorised VMPs**

**BfR** Federal Institute for Risk Assessment

**BVL** Federal Office of Consumer Protection and Food Safety

**LAV** Länder working group for Consumer Protection

**AGTAM** Veterinary medicines working group of LAV

**VMP** Veterinary medicinal products

**ZLG** Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices

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Competent authorities

The BMEL (Unit 326 - Veterinary medicines, residues of pharmacologically active ingredients in food) is the central competent authority for legislation on trade in VMPs.

Authorisation of VMPs

The Federal Office of Consumer Protection and Food Safety (BVL) is responsible for issuing marketing authorisations for veterinary medicinal products (VMPs) in Germany. The legal basis is laid down in the Federal Pharmaceuticals Act. Individual Länder may not issue authorisations for VMPs. Private veterinary practitioners may subscribe to an on-line database of all nationally authorised and registered VMPs. As of October 2007, all VMPs for treatment of food producing animals are classified as “prescription only medicines”. Exceptions to this principle, in accordance with the criteria of Directive 2006/130/EC, are laid down in an Order. As of 31 December 2014, 3,261 veterinary medicinal products were marketable (authorised or registered) under the competence of BVL, of which 1,738 were for at least one food-producing species.

Official controls on marketing and use

The Länder are responsible for controls on: the storage, distribution and use of veterinary medicinal products on farms and by private veterinary practitioners; the sale of medicated premixes; and the production of medicated feedingstuffs.

All establishments involved in veterinary medicinal product issues are subject to inspections by Länder competent authorities, underpinned by the Federal Pharmaceuticals Act and related Land-specific provisions. Further to the legal obligations for control, there is a standardised Federal quality system elaborated and continuously updated by the Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices - Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

National legislation lays down a routine inspection frequency for veterinary pharmacies of one inspection every two years. For the other establishments, including farms, the inspection frequencies are to be risk-based and carried out according to risk, as deemed fit by each competent authority. In principle, inspections are unannounced, including checks of medicines records, stocks held on farm or by veterinarians, and compliance with prescription requirements and other requirements relating to medicines.

Pharmaceutical manufacturers and wholesalers may supply VMPs to pharmacies and to private veterinary practitioners provided that they have an in-house veterinary pharmacy registered by the CA pursuant to the Pharmaceuticals Act. Farmers may obtain medicines with prescriptions from pharmacies or directly from their private veterinary practitioner.
Private veterinary practitioners are only allowed to receive and deliver VMPs for animals they are treating. Records must be kept at all levels - pharmacies, private veterinary practitioners and farms. National legislation requires private veterinary practitioners to retain proof of the application and supply of medicines for five years. Copies of prescriptions for food production animals must also be kept for five years.

Medicated feedingstuffs may only be delivered under prescription (a prescription template is defined in national legislation). Medicated premixes are allowed to be used for the production of medicated feed premixes only in establishments that manufacture compound feedingstuffs and have a production authorisation by the CA pursuant to the Pharmaceuticals Act. In principle, medicated premixes can not be supplied directly to the farmer.

Issues relating to veterinary medicinal products are discussed in the LAV veterinary medicines working group, AG TAM, which is used mainly for aligning Länder with each other. Amongst other things, it adopts the procedures, prepared by the ZLG, for the nationwide quality assurance system.

Laboratories

Germany has one National Reference Laboratory for residues of pharmacologically active substances in food of animal origin. The NRL is part of the Federal Office of Consumer Protection and Food Safety (BVL). The 16 Länder within their competence have designated laboratories for official veterinary medicinal product analysis.

Since 2001, the BVL has been testing the resistance to antibiotics of bacteria that are pathogens to animals, as part of a national German monitoring programme (GermVet). Data on antimicrobial resistance from these testing activities will be considered in the authorisation process or during the renewal of the authorisation.
RESIDUES (of pharmacologically active substances)

BfR  Federal Institute for Risk Assessment

BVL  Federal Office of Consumer Protection and Food Safety

EU RL  European Union Reference Laboratory

LAV  Länder working group for Consumer Protection

AFFL  Meat and poultry meat hygiene and technical issues of food of animal origin working group of LAV

NRL  National Reference Laboratory
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**Competent authorities**

The BMEL (Unit 326 - Veterinary medicines, residues of pharmacologically active ingredients in food) is the CCA for veterinary residues. Unit 106 of the Federal Office of Consumer Protection and Food Safety carries out specific tasks on veterinary residues, as the central body under Article 4.1 of Council Directive 96/23/EC, prepares the National Residues Control Plan (NRCP), collects and analyses data on results from the Länder. It summarises the data, reports it to the European Commission and publishes it. Unit 106 is supported in this task by Unit 107 of BVL: "Data Management and Analysis".

**Official controls on residues**

The Residue Monitoring Plan (RMP) is drawn up each year by the BVL in cooperation with the BMEL, the National Reference Laboratory (NRL) and the 16 Länder. It contains specific requirements for each Land, with regard to the number of animals or animal products to be inspected, the substances to be inspected, the methodology to be applied, and sampling. The Länder organise sampling in accordance with the requirements set out in the plan. For some samples, Länder are free to choose the substances in accordance with their current requirements and as appropriate for their particular situation. The annual slaughter and production figures and the size of the livestock populations constitute the basis for determining the level of sampling for each Land. The CA in each Land except Bremen and Saarland (where implementation takes place at the level of the State Office (Landesamt)) allocates the number of samples to be collected for the various tests to their district or municipality authorities.

The Residue Monitoring Plan is implemented by the Länder as an independent statutory responsibility within the framework of official monitoring of food and veterinary medicine. It is regulated at national level in the Food and Feed Code (LFGB) and in the Food of Animal Origin Regulation (Tier-LMÜV).
Data collected by the monitoring authorities in the Länder is gathered and evaluated in the Federal Office of Consumer Protection and Food Safety, forwarded to the European Commission and published. The Federal Institute for Risk Assessment evaluates the results from the Residue Control Plan.

Issues relating to veterinary residues control are discussed in the AFFL.

Laboratories

Germany has one NRL for all commodities and all substance groups listed in Annex I to Council Directive 96/23/EC. The NRL is part of the Federal Office of Consumer Protection and Food Safety. The NRL responsibilities are dealt with by three Units. Unit 502 acts as the NRL for the substance groups for which it is also designated as EU Reference Laboratory. Unit 503 and 504 are responsible for the other substance groups. The NRL does not perform any routine testing under the Residue Control Plan – this is the responsibility of the 29 official laboratories operating in the 16 Länder.

All of the official laboratories are designated by their respective Länder as official laboratories. Since 1 January 2010, in common with the NRL, these laboratories are being accredited to ISO 17025 by a single uniform accreditation body (AkkStelleG) as described in Part 1 of this document. The NRL is responsible for, inter alia, performing the NRL functions under Article 14 of Council Directive 96/23/EC. It also carries out referee and confirmatory analyses (Schieds- und Bestätigungsanalysen) as required under Article 15 of this Directive.

At present, the NRL tasks are dealt with by 10 scientists and 12 technicians subdivided into nine competence areas and organised according to substance groups and areas such as animal studies, and production of reference materials for proficiency tests.
2.7 Control system for foodstuffs and general food hygiene

ALS Working Group of Experts in Food Chemistry from the Ländere and the BVL
BfR Federal Institute for Risk Assessment
BVL Federal Office of Consumer Protection and Food Safety
LAV Ländere Working Group for Consumer Protection
ALB Food, Food Contact Materials, wine and cosmetics working group of LAV
AFFL Meat and poultry meat hygiene and technical issues of food of animal origin working group of LAV
ALTS Food Hygiene and Food of Animal Origin Research Group
MRI Max Rubner Institute (Federal Research Institute of Nutrition and Food)
RASFF Rapid alert system for food and feed
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**Competent authorities**

The BMEL is the CCA for legislation in the field of foodstuffs and food hygiene. Within the BMEL, Unit 314 is responsible for general food hygiene under Regulation (EC) No 852/2004, Unit 312 is responsible for policy on official food monitoring, Unit 313 is responsible for residues and contaminants and Unit 434 is responsible for wine monitoring.

The BVL cooperates with the BMEL and assists by providing data and information. Within the BVL, Unit 101 is in charge of plant foodstuffs and Unit 106 is in charge of animal foodstuffs and food hygiene. Applications for marketing novel foods and novel food ingredients must be submitted to the BVL. The initial assessment is also carried out by the BVL, where necessary with the assistance of the BfR. The BVL grants derogations on request or issues general administrative measures for food. In this respect, the BVL, as a Federal authority, contributes to drafting general administrative regulations, coordinates control programmes, organises ALS and ALTS meetings, and attends meetings of LAV working groups as a guest.

The BfR is the central scientific institute. In the area of general food hygiene, it is responsible as an independent institute for producing opinions and comments about the safety of foods, substances and commodities (risk assessment). It advises the BMEL and the BVL, and produces scientific opinions on food safety and consumer protection. It is also responsible for the evaluation of risks to public health of plant protection and pest control products, chemicals and novel foods. The BfR tasks include risk communication to the public.

The BfR has a legal mandate to conduct research. The objective of such research is to fill in knowledge gaps with regard to the safety of food, chemicals and commodities, risk communication and risk perception. The findings of the BfR’s research serve to improve the risk assessment and scientific advice to the BMEL, BMUB and BMVI.

The MRI covers research aspects of food quality.
Registration and approval of establishments

In Germany, there is no central registration or approval of FBOs at Federal level. The Länder are responsible for the registration and approval of establishments. Depending on the Land concerned, registration and approval may be granted by Länder Ministries, Senate Administrations, ProvincialAuthorities, the higher Länder Authorities, a State Office (Landesamt) or by the monitoring bodies of the district/municipal authorities. The BVL publishes the list of approved establishments in accordance with Article 31.2 (f) of Regulation (EC) No 882/2004.


The Working Group on Foodstuffs and Food Contact Materials, Wine and Cosmetics (ALB) of LAV has published guidelines on "Registration of businesses in accordance with Regulation (EC) No. 852/2004 on the hygiene of foodstuffs". In 2014, the German authorities identified 1,208,889 food premises, with the greatest share (55.6 %) being in the service sector.

Official controls and inspections at establishments

Responsibility for official inspections and food monitoring programmes in this area also lies with the Länder. The food monitoring and veterinary offices in the administrative districts, and in the municipalities independent of the administrative districts, are responsible for implementing controls, in their capacity as lower-level administrative authorities, with the exception of Bremen and Saarland (where implementation takes place at the level of the State Office (Landesamt)). The competent authorities in the Länder designate laboratories to carry out the analysis of official food samples. The supreme authorities responsible for consumer health protection in the Länder collaborate in the LAV. The ALS is a Federal/Länder committee of experts whose members serve as scientific experts in the field of non-animal foods and commodities. The tasks of the ALS include the harmonisation of how test results are assessed under food law, and the exchange of scientific knowledge and opinion in relation to non-animal foods. Each Land is represented in the research group with one senior employee from an investigative office. One employee from the BMEL and one from the BVL are permanent observers. Invitations are also issued to the ALB and the BfR.

The AVV RÜb sets up a system for establishing a risk-based inspection frequency for food establishments, general principles for the nationwide Federal Monitoring Plan and obligations for reporting data. The criteria for sampling plans are also laid down in the AVV RÜb. According to these, five food samples per 1,000 inhabitants have to be taken each year.

The Monitoring Programme for Food, Cosmetic Products and Food Contact Materials is implemented jointly by the Federal Government and the Länder. The programme aims to collect representative data on undesirable substances in foodstuffs, cosmetic products and food contact materials, and consists of two parts: shopping-basket monitoring; and project monitoring on selected issues, carried out on the basis of proposals from the Federal Government or the Länder.
The National Monitoring Plan is a plan of official inspections, set for one year and agreed between the Länder, to monitor compliance with food, wine and tobacco regulations, including protection against fraud. It may contain programmes for product and establishment inspections or a combination of the two. The National Monitoring Plan is a risk-based monitoring programme. The testing of food, cosmetic and non-food consumer products comes within the scope of the National Monitoring Plan. For the aforementioned investigation programmes and in order to meet reporting obligations to the Commission, the Federal Government has to draw its data together for the entire Federal Republic. In order to facilitate handling and administration of the large quantities of data, general conditions for the standardisation of data formats for foodstuffs and feed monitoring were agreed between the Federal Government and the Länder. These data formats were described and fixed in the General Administrative Regulation on the exchange of data in the field of food safety and consumer protection (AVV Datenaustausch – AVV DatA).

The German Regulation implementing specific provisions of EU food hygiene legislation, which has been in force since August 2007, lays down inter alia additional, specific national rules on food hygiene (e.g. at retail level).

In 2006, the AFFL adopted a decision on the application of risk-based HACCP principles in Germany; this decision was confirmed by the ALB in 2007. This decision provides for risk-based application of HACCP requirements (with establishments being classified in various risk categories on the basis of objective criteria). The decision takes account of the European Commission Guidance Document on the use of HACCP principles, and food industry guidelines.

**Good hygiene practice guides**

In Germany, there are two types of guides to GHP and two different procedures for their production: guides prepared by the relevant industry sectors in accordance with Regulation (EC) No 852/2004; and DIN-based guides which are produced by the German Standard Institute in Berlin.

These GHPs are drafted by the respective Federal association of the industry sector, and are harmonised with Länder competent authorities by the Association for Food Law and Food Science (BLL), the industry coordination body. A Land coordination body is designated for each sector. It assesses the guide in agreement with the Länder and the competent Federal authorities in a procedure set out in the General Administrative Provision on Food Hygiene (AVV-LmH). The assessed guide is then sent back to the industry coordination body via the BLL for their further opinion. If consensus is reached between all concerned, the guides are then forwarded to the BMEL, which then sends them on to the Commission. The procedure for the production of such guides has been published in a notice in the Official Gazette. Currently, there are 27 guides of GHP in Germany. These are listed on the homepage of the coordination body acting for the food industry (BLL-Federation of Food Law and Food Science): [http://www.bll.de/de/lebensmittel/sicherheit/hygiene](http://www.bll.de/de/lebensmittel/sicherheit/hygiene).

The competent authorities at the Land level have access to GHP guides prepared by relevant industry sectors, through the electronic information system for consumer protection and food safety (FIS-VL).
Rapid Alert System for Food and Feed (RASFF)

Unit 104 of the BVL is the National Contact Point for the RASFF in Germany. General administrative rules for the implementation of the RASFF rapid alert system (AVV SWS) came into force in January 2006 and were most recently updated in January 2010. They lay down the procedures for notifications from the Länder via the National Contact Point in the BVL to the European Commission, and from the Member States of the European Union via the Commission and the National Contact Point to the Länder. On the basis of these implementing rules, the National Contact Point is responsible for making a summary of incoming notifications from the EU Member States via the Commission, and, after classifying them according to risk categories and translating the key content into German, passing them on to the contact point in each Land by e-mail. The BMEL, the Federal Ministry of Defence (BMVg), the BfR, and the Federal Office of Consumer Economics and Export Control (BAFA) are also informed about every RASSF report. Depending on the subject matter of the alert, the BMUB, the Robert Koch Institute (RKI), the Friedrich Loeffler Institute (FLI) or the Federal Institute for Drugs and Medical Devices (BfArM) may also be informed. The BVL also summarises the alerts received on a particular day as a daily report which it makes available to the Länder, the BMEL and other Federal authorities in a web-based specialised information system (FIS-VL). An anonymised version of the report is also posted to the BVL website every day. The border inspection posts (veterinary) and the competent body in each Land have their own access to the RASFF Portal website of RASFF alerts and can download individual alerts. RASFF information relevant to imports (e.g. the right to sign certificates) is sent directly to the competent border inspection post authorities in accordance with § 12 AVV SWS. These general administrative rules set out clear responsibilities and criteria in relation to the preparation of notifications as regards food, food contact materials and feedingstuffs.

Laboratories

Germany has designated National Reference Laboratories in the field of food of plant origin.

The Federal Institute for Risk Assessment carries out analysis and tests for zoonoses, mycotoxins, dioxins and PCBs in foodstuffs as well as of food additives and food contact materials.

The BVL carries out analysis and tests of pesticide residues (grains and foodstuffs, products with a high fat content, fruit and vegetables, including products with a high water and high acid content; single residue validation), polycyclic aromatic hydrocarbons, heavy metals in foodstuffs.

The 16 Länder within their competence have designated laboratories for official food analyses. Information about laboratories within all Länder can be found in individual control plans: http://www.bvl.bund.de/mnkp.
GMOs

AFU Animal feed working group of LAV
ALB Working Group of Foodstuffs and Food Contact Materials, Wine and Cosmetics of LAV
ALS Working Group of Experts in Food Chemistry from the Länder and the BVL
BN Federal Agency for Nature and Conservation
BfR Federal Institute for Risk Assessment
BSA Federal Office of Consumer Plant Varieties
BVL Federal Office of Consumer Protection and Food Safety
FLI Friedrich Loeffler Institute
JKI Julius Kuhn Institute
LAG German National and Federal/Länder Joint Committee on Genetic Engineering
PEI Paul–Ehrlich Institute
RKI Robert Koch Institute
ZKBS Central Committee for Biological Safety

### LEGEND

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GM in food and feed
Propagating materials
GVO in Lebensmitteln und Futtermitteln
Vermehrungsmaterial

Competent authorities

The BMEL, through Unit 222, is the CCA for GMOs in food and feed and is thus responsible for shaping policy and legislation relating to genetically modified food, feed and seeds.

The BVL is the competent higher federal authority within the portfolio of the Federal Ministry for GMO. The BVL has an advisory function for law-making for GM food, feed and seeds, and coordinates the Federal Monitoring Plan (Bundes-überwachungsplan – BÜP) and control activities for GM food and feed. The BVL is the responsible authority for accepting, processing and forwarding applications under Articles 5(2) and 17(2) of Regulation (EC) No. 1829/2003 and for approving applications for deliberate release into the environment and placing on the market of GMOs under Directive 2001/18/EC.

The Central Committee for Biological Safety (ZKBS) is an independent commission of experts whose office is located within BVL. As laid down in § 4 of the Gentechnikgesetz, the ZKBS is composed of 20 members and their substitutes (scientists from a variety of disciplines, as well as representatives of non-governmental organisations). The ZKBS is responsible in particular for advising the Government and the Länder on safety questions related to GMO.

The assessment of applications for authorisation of placing GMOs on the market is the responsibility of several authorities: BVL (overall responsible), BfR, JKI, RKI, BfN, and, in certain cases, the Friedrich Loeffler Institute (FLI) and the Paul Ehrlich Institute (PEI). The Federal Office of Consumer Plant Varieties is responsible for approval of GM varieties.

The BVL is also within the meaning of Regulation (EC) No 1946/2003, the German authority responsible for the Biosafety Clearing House (BCH) and in case of notification of unintended cross border movements of GMOs, the relevant contact point where Germany is concerned. If GMOs are exported from Germany to countries outside the EU, BVL as the competent authority must be notified before export.

Official controls on GMOs in food, including import

The supreme authorities at Länder level are responsible for implementation of GMO controls. Their legislative area is restricted to legislation concerning the implementation of GM food, feed and seed controls. The National Monitoring Plan (Bundesweiter Überwachungsplan – BÜP), which targets the surveillance of all areas of food safety, includes controls of food businesses (including importers) for GM labelling, including sampling for analysis of GMOs. The Federal Monitoring Plan specifies which Land takes part in the programme.
The *Länder* organise regular meetings of expert working groups which are also attended by representatives of the Federal Government such as the BVL: the Working Group on Foodstuffs and Food Contact Materials (ALB) and the Working Group on Monitoring of Genetically Modified Foods of the Working Group of Experts in Food Chemistry (ALS). Legal issues, sampling schemes, testing methods and labelling issues are discussed during these meetings.


In the § 64 LFGB working group "Development of methods to identify foods manufactured with the help of genetic engineering", and in the § 28b working group, GenTG, new methods of analysis are devised, defined and standardised with the assistance of experts from official GMO monitoring bodies, science and industry. Suitable test methods are added to a collection of methods pursuant to § 64 LFGB and § 28b GenTG.

**Official control of GMOs in feed**

The *Länder* are responsible for monitoring compliance with GMO regulations in the area of feed. The scope and content of GMO inspections are described in the Feed Control Programme for 2012 – 2016 (see Section 2.4).

**Official control of GMOs in propagating material**

The *Länder* check seeds for levels of genetically modified organisms according to an agreed system. Seed consignments are sampled, preferably on the producers premises, in parallel to the sampling carried out with regard to the official licensing of seeds. In the case of imported seeds, controls are usually not possible before the consignments are on the market.

Since 2009, no genetically modified maize varieties have been approved in Germany for cultivation due to the application of the safeguard clause for MON810. The areas on which a cultivation of GMO crops would take place would have to be notified to the BVL. These are made accessible to the public in a register of locations.

**Laboratories**

The national reference laboratory for GMOs is based within the BVL. Twenty-two Land laboratories and one contracted private laboratory are responsible for official monitoring. In Germany, 26 laboratories are members of the European Network of GMO laboratories (ENGL). One further laboratory is designated as an associate laboratory of the ENGL. The GMO NRL and the Land laboratories develop and validate methods for GMO analysis. Appropriate methods are published in the Official Collection of Methods established pursuant to § 64 LFGB. Information about the Land laboratories can be found in the individual Land control plans: [http://www.bvl.bund.de/mnkp](http://www.bvl.bund.de/mnkp).
2.8 Control system for imports of food of non-animal origin

BVL Federal Office of Consumer Protection and Food Safety
LAV Länder working group for Consumer Protection
AG EAD Import, export and transit working group
ALB Working Group of Foodstuffs and Food Contact Materials, Wine and Cosmetics of LAV

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<td>Eingangsorte (einschl. Einfuhrorte und Orte der ersten Einführung)</td>
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Competent authorities

The BMEL is the CCA responsible for negotiations on legislative provisions concerning food safety and for their transposition into national law. Within the Ministry, the units for Food monitoring, crisis management and emergency food supply (Unit 312), for Residues and contaminants in food and food contact materials (Unit 313) and for Wine (Unit 434) are responsible for individual aspects relating to the import of food of plant origin.

The BVL has a wide range of responsibilities. Its overarching task is cooperation with the Federal BMEL in the areas of crisis management and food safety.

The Customs services are involved in monitoring compliance with food law under powers pursuant to Article 24(4) of Regulation (EC) No 882/2004 in conjunction with Articles 27-29 of Regulation (EC) No 765/2008 and pursuant to § 55 LFGB. In this regard, the customs offices work together with the competent food monitoring authorities.

Import controls

The Länder are responsible for the implementation of official controls on food. They are also responsible for import controls on food of non-animal origin.

In accordance with the provisions of Regulation (EC) No 669/2009, the Länder have designated points of entry to implement the increased level of official controls pursuant to Article 8 of this Regulation. A list of all designated points of entry in Germany was submitted to the Commission services and is publicly accessible on both the Internet domains of the European Commission and the BVL. In accordance with the requirement of Regulation (EC) No 669/2009 entry points were designated in 11 of the 16 Länder. The other 5 Länder do not handle the clearance of any consignments falling under the scope of Regulation (EC) No 669/2009. (See attached BVL website: http://www.bvl.bund.de/EingangsorteLM)

The requirements of Articles 15 to 17 of Regulation (EC) No. 882/2004 concerning the organisation of official controls on imports of food of non-animal origin are specified in the Food Import Regulation (Lebensmitteleinfuhr-Verordnung), the Food and Feed Code (LFGB) and the AVV RÜb. The procedural rules contained therein serve to implement a nationwide approach to risk-based control at import in accordance with Article 15(1) and Article 15 (5) of Regulation (EC) No 882/2004. For goods covered by Commission Decisions, the nature and frequency of controls are laid down in the Decisions.

Consignments subject to stricter controls under Regulations (EC) No 669/2009, EU No 884/2014, or EU No 885/2014 are to be notified to the competent food monitoring authority, at the point of entry or first point of introduction, for a Common Entry Document (CED). Following completion of the official controls, that authority completes the Common Entry Document (CED) to be presented to the Customs office when releasing goods for free circulation.

The Customs authorities are responsible for Customs clearance. Goods from third countries (cf. Article 4 Nos 6 to 8 of the Customs Code (CC)) may be assigned to different customs treatments or uses (Article 4 No 15 of the CC). They may be placed under various Customs procedures (Article 4 No 15(a) of the CC) in conjunction with Article 4 No 16 of the CC), such as free circulation, Customs warehousing or transit, etc. An export or re-export declaration is required for the export of goods to a third country. The procedure is based on the provisions of the CC, the CC Implementing Provisions (CCIP) and national Customs law.
As regards the import of food of non-animal origin, the Customs authorities work within the powers granted to them by law (see above). As regards monitoring compliance with specific safeguard measures and an increased level of controls on food of non-animal origin under Article 15(5) of Regulation (EC) No 882/2004, the Customs authorities are involved in releasing the goods for free circulation under specific powers granted by law (see, for example, Article 10 of Regulation (EC) No 669/2009 and Article 11 of the Implementing Regulation (EU) No 1884/2014). Coordination and cooperation between the competent food monitoring authorities and the Customs services for food import controls are governed by Instruction No SV 0630 (which was published on 15 October 2014) and possibly by specific administrative circulars and official decisions agreed with the BMEL. Some products of non-animal origin are subject to conditions before they can be released for free circulation. These are detected by a plausibility check in the ATLAS clearance system.

The import procedure for wine is laid down in the Wine Monitoring Regulation. It lays down that the Customs authorities should contact the respective control authority (within the Land of the recipient of the consignment) which is responsible for these controls at local level, and for an import clearance statement in respect of official controls on wines.

Specific issues in connection with import control of food of non-animal origin are discussed in the AG ED.

**Laboratories**

Within their competence, the 16 Länder have designated laboratories for official food analyses. Information about the laboratories in the Länder can be found in the Länder control plans: [http://www.bvl.bund.de/mnkp](http://www.bvl.bund.de/mnkp).

Depending on the thematic focus, issues relating to the validation and accreditation of official testing laboratories are addressed not only in AGED, but also in other specialist LAV working groups, e.g. ALB, covering the area of food, food contact materials, wine and cosmetics.
2.9 Control system for plant protection products (PPPs) and residues

PPPs (marketing and use)

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**BfR** Federal Institute for Risk Assessment
**BVL** Federal Office of Consumer Protection and Food Safety
**JKI** Julius Kühn Institute
**LPPS** Länder Plant Protection Services
**UBA** Federal Environmental Protection Agency
**AG PMK** Federal Länder working group on PPP control (not part of LAV)
Competent authorities

The BMEL is responsible for the plant protection area. Within the Ministry, Unit 313 (residues and contaminants in food and food contact materials) has overall responsibility for legislation on residues of plant protection products in products of plant origin and animal origin, while Unit 512 (plant protection) has overall responsibility for the placement on the market and use of plant protection products. The Ministry, through Unit 512, is also responsible, pursuant to Article 68 of Regulation (EC) No 1107/2009, for drawing up the annual report on the controls carried out by the Länder authorities on the marketing and use of plant protection products.

The BVL is the competent authority for authorisation of plant protection products. In relation to Regulation (EC) No 1272/2008 and Commission Regulation (EU) No 547/2011, the BVL is the competent authority for checking the classification, packaging and labelling of plant protection products. Department 2, within the BVL, deals with all issues related to plant protection products. Unit 201 is responsible for managing the Federal-Länder working group on plant protection product control (AG PMK).

The area of Special Projects, which is directly subordinate to the head of Department 2, is responsible for the central procedures function and quality management. The coordination of the national authorisation procedures is dealt with by Unit 202 while Unit 204 is responsible for environmental monitoring after authorisation. The laboratory for chemical formulations belonging to unit 206 is responsible for sampling of plants in collaboration with the Länder. The Unit for Feedingstuffs (Unit 102) provides support for the implementation of legislation on residues of plant protection products in feedingstuffs.

Risk assessment on plant protection products is carried out by:

- the BVL (Unit 206), in relation to physical and chemical properties and identity;
- the BfR, in relation to toxicology, residues and methods for residues analysis for control purposes;
- the UBA, in relation to the environment;
- the JKI, in relation to effectiveness and phytotoxicity and the impact on honeybees.
Authorisation of PPPs

The authorisations issued by the BVL also include classification, packaging and labelling.

Authorisation of plant protection products involves the detailed evaluation of a data package supplied mainly by the applicant. In the authorisation procedure, the Federal Office of Consumer Protection and Food Safety can request samples from the applicant and check whether the established specifications are complied with. The evaluation and risk assessment is conducted by the Federal Institute for Risk Assessment, the Federal Environmental Protection Agency and the Julius Kühn Institute. The Federal Office of Consumer Protection and Food Safety, in its capacity as risk management authority, issues the authorisation in accordance with the provisions of Regulation (EC) No 1107/2009.

A BVL website ([www.bvl.bund.de/infopsm](http://www.bvl.bund.de/infopsm)) contains a database of all plant protection products registered in Germany.

Interested parties, those involved in the marketing and use of plant protection products, and those responsible for the control of such products obtain an overview on the website, (which is updated quarterly) of the end dates of authorisations and the deadlines for sale and use of PPP. Information is also provided in a timely manner on the website and in the form of a newsletter on the withdrawal of authorisations or on approvals for parallel trade. At Länder level, in the framework of advisory activities, information on the authorisation status of PPPs is sent by email or posted on the information portal of the Länder (ISIP). For advice and controls, the on-line database “Plant Protection Product Analysis and Information” is used.

Official controls on marketing/use

The Länder are responsible for implementation of controls, inspections and sampling for the market control of plant protection products; the BVL is responsible for testing of samples.

The Federal-Länder working group on plant protection product control (AG PMK), under the management of BVL, coordinates official controls and proposes nationwide priority control areas. This body has prepared the Control Manual, updated whenever necessary and published on the BVL website. The manual stipulates how controls on the marketing and use of plant protection products are to be performed. The AG PMK also arranges the exchange of up-to-date information. In the event of incidents occurring in connection with cross-border trade in plant protection products, the BVL is informed directly. It then forwards the information to the competent authorities in other Member States.

The Control Handbook was drafted following consultation between the BVL and the authorities of the Länder. It specifies how controls on the marketing and use of plant protection products should be conducted.

In the Länder, there are 109 full-time equivalent staff for the planning, implementation and evaluation of controls (not including laboratory personnel). Within the BVL, the equivalent of 4.9 full-time employees (1.4 scientists and 3.5 technicians) are involved in the plant protection product programme. (Situation as of 3 September 2015).
Laboratories

The BVL laboratory at Braunschweig is responsible for examining plant protection products for their composition and their physical and chemical properties. In organisational terms, the laboratory belongs to Unit 206 and operates in various areas:

- it analyses samples of plant protection products taken by the Land authorities during market controls to verify whether the goods on the market have the composition and specification stated on the authorisation or permit. In the procedure for the parallel trade permit, it verifies whether the plant protection product, in respect of which the permit is requested, matches the reference substance approved in Germany;
- in the approval procedure and in the procedure for the parallel trade permit, the BVL can request samples from applicants and test them to determine whether the specifications have been complied with.

The laboratory also participates in international programmes for the new and continued development of test procedures and analysis methods.

As of 3 September 2015, the laboratory is operated by three scientists (equivalent to 1.2 full-time staff) and five technicians (4.5 full-time equivalents).

Within their sphere of competence the 16 Länder have designated laboratories for analysing samples which are to be tested in connection with controls on use. The Residues and Analysis Working Group, which is chaired by the BVL’s Unit 206 and to which representatives of the Länder laboratories are appointed, works on the further development and validation of methods, and on resolving general analytical questions arising in connection with controls on use.
Pesticide residues in food (for feed, see Part 2.4)

BfR Federal Institute for Risk Assessment
BVL Federal Office of Consumer Protection and Food Safety
ALB LAV Working Group on food, commodities, wine, cosmetics

<table>
<thead>
<tr>
<th>LEGEND</th>
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<tbody>
<tr>
<td>FEDERAL MINISTRY OF FOOD AND AGRICULTURE (BMEL)</td>
<td>BUNDESMINISTERIUM FÜR ERNÄHRUNG UND LANDWIRTSCHAFT Referat 313</td>
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<tr>
<td>Provincial authorities (if existing)</td>
<td>Bezirksregierungen/Regierungspräsidien (falls vorhanden)</td>
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</table>
Sampling | Probenahme
---|---
Wholesalers, retailers, import control | Großhändler, Einzelhändler, Einfuhrkontrolle
Advice | Beratung
Scientific assessment | Wissenschaftliche Bewertung
Residues Plan | Rückstandsplan
Advice | Beratung
Food Safety Monitoring Committee | Ausschuss zur Überwachung der Lebensmittel-sicherheit ("Ausschuss Überwachung")

Competent authorities

The BMEL is the central competent authority for legislation relating to MRLs in foodstuffs of plant and animal origin. Unit 313 of the Ministry is responsible for residues and contaminants in food as well as for food contact materials.

The BVL supports the 16 Länder, through coordination and assisting in the flow of information. The BfR carries out risk assessment and provides advice to the BMEL, the BVL and the Länder.

Official controls on residues

The multi-annual national control programme for pesticide residues in and on food of plant and animal origin is drawn up on a joint Federal-Länder basis for a three-year cycle in accordance with Article 30(1) of Regulation (EC) No 396/2005. It is updated annually, and is submitted to the Commission services and EFSA at least three months before the end of each calendar year. The objective is to carry out official controls in order to ensure that pesticide residues remaining in or on food of plant or animal origin do not present an unacceptable health risk; the controls are aimed at assessing consumer exposure and compliance with legislation.

To meet these two objectives, a proportion of samples is examined within the framework of the Monitoring Programme for Food, Cosmetic Products and Food Contact Materials on the basis of the control concept: "Residues of plant protection products in or on foods, under Regulation (EC) No 396/2005". Sampling is conducted on a representative basis and takes account of biostatistical factors as regards the origin of the samples, and covers conventional or organic farming, taking account of the particular features of the German market.

A much greater number of samples are tested to check compliance with legislation. Sampling takes place, on a risk basis, at all stages of the marketing process (importation, wholesaling, retailing, production), applying uniform criteria which enable the sampling plans, drawn up in the Länder on a decentralised basis, to be combined into a uniform national plan.

During monitoring and also during risk-based official food monitoring, sampling and analysis are carried out by the competent authorities of the Länder, with the analysis results being forwarded to the BVL. The BVL combines the data from the Länder, evaluates them and, in accordance with Article 31(1) of Regulation (EC) No 396/2005, forwards them to the European Commission, EFSA and the other Member States. In addition, the results are published annually in the "National Report on Residues of Plant Protection Products in Food" and serve as the basis for consultations on risk-minimising measures in the food-safety area.
Inter-Länder coordination on pesticide residues in food of plant origin takes place through ALB (the LAV Working Group on Food, Commodities, Wine, Cosmetics). At its meetings, ALB discusses action taken by Länder to address recommendations arising from Commission services' reports.

Laboratories

The BVL laboratory (Department 5) carries out the work of the four national reference laboratories for pesticide residues.

Within their sphere of competence, the 16 Länder have designated laboratories for official residue controls. Information about the laboratories in the Länder can be found in the control plans of the Länder: http://www.bvl.bund.de/mnkp.
2.10 Control system for animal welfare

AMK Conference of Agriculture Ministers of the Länder
BfR Federal Institute for Risk Assessment
BVL Federal Office of Consumer Protection and Food Safety
FLI Friedrich Loeffler Institute - Federal Research Institute for Animal Health
MRI Max Rubner Institute
AMK Conference of Agricultural Ministers of the Länder
ACK Official Conference of Heads of Länder (Part of AMK proceedings)
VSMK Conference of Ministers for Consumer Protection of the Länder
AG T LAV Working Group on Animal Welfare

<table>
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<th>LEGEND</th>
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<td>Tierschutzkommission</td>
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<td>BUNDESMINISTERIUM FÜR</td>
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<td>ERNÄHRUNG UND LANDWIRTSCHAFT</td>
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<tr>
<td></td>
<td>Participation as observer</td>
<td>Teilnahme als Gäste</td>
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</table>
Competent authorities

The BMEL is the central competent authority for animal welfare. It has the power to propose and prepare national laws and to transpose EU legislation into national law. Within the Ministry, Unit 321 is responsible for animal welfare matters. Unit 322 announces the authorisation of animal transport companies under animal health legislation, in each case publishing the registration number issued in the Federal Gazette or in the electronic Federal Gazette. Any changes are announced in the same way.

Unit 106 of the BVL is Germany’s national contact point within the meaning of Article 24(2) of Regulation (EC) No 1/2005 on the protection of animals during transport. The contact point draws up the annual report on the animal transport controls carried out in Germany in accordance with Article 27(2) and sends it to the Commission services.

The Federal Institute for Risk Assessment deals with issues relating to animal welfare (in particular animal testing and alternative methods) both in the context of the remit of this institute and, in collaboration with the Unit for animal welfare within the BMEL, in advising the CA of the Länder.

The Friedrich-Loeffler Institute (FLI) – Federal Research Institute for Animal Health - conducts research projects and provides scientific advice in response to queries from the BMEL and Länder in the field of animal welfare. As the contact point referred to in Article 20 of Regulation (EC) No 1099/2009 on the protection of animals at the time of killing, the FLI assists the competent authorities in implementing the provisions of Regulation (EC) No 1099/2009, in particular in scientific issues related to stunning and killing methods.

The Max Rubner Institute (MRI) – the institute for meat safety and quality – conducts research into meat-quality factors that are relevant to animal welfare (including the continued development of slaughtering methods, alternatives to pig castration without anaesthetics such as the rearing of boars) and provides scientific advice in this field.

There are Advisory committees for animal welfare at BMEL and Länder level. The animal welfare committee in BMEL is responsible for advice on legislative proposals. The advisory committees in the Länder implement different tasks.

Inter-Länder coordination on animal welfare issues takes place through AGT. At their coordination meetings, AGT regularly discuss follow-up action being taken by Länder to address recommendations arising from Commission services’ reports. AGT coordination meetings usually take place twice a year.

AGT has coordinated the preparation of handbooks related to controls on farms, during transport, and at slaughter.
Official controls on farms

For animal welfare, the Länder are responsible for implementing the legal requirements. Each Land is responsible for supervision, planning guidance, coordination and providing instructions for animal welfare checks. With the exception of Bremen and Saarland, (where implementation takes place at the level of the State Office (Landesamt)), the veterinary authorities at local level have responsibility for the enforcement of animal welfare legislation and liaise with agricultural administrations and other offices concerned with animal holdings (e.g. construction authorities).

Animal welfare monitoring and enforcement measures are implemented on the basis of general monitoring regulations contained in EU law, particular provisions of animal welfare law, especially Articles 16 – 20a of the German Animal Welfare Act (Tierschutzgesetz) and the requirements of general administrative and criminal law. Since the year 2000, the General Administrative Regulation for the implementation of the Animal Welfare Act (Allgemeine Verwaltungsvorschrift zur Durchführung des Tierschutzgesetzes) has been in force which is intended to ensure that animal welfare provisions are applied uniformly across the Länder:
http://www.verwaltungsvorschriften-im-internet.de/bsvwbund_09022000_32135220006.htm

The lower-level administrative authorities carry out periodic controls on a representative number of animal holdings. These are selected and the frequency is set on the basis of the highest risk potential. The establishments with the highest risk potential are prioritised for controls. In order to permit an evaluation of the risk analysis, the animal holdings selected in accordance with the risk factors are compared with a random selection made in advance from the basic set of establishments (20% of the establishments to be controlled). The procedure is described in the handbook “Monitoring Animal Welfare in Production Animals” (Tierschutzüberwachung in Nutztierehaltungen), developed by the AGT.

As part of on-site controls, animal holdings are inspected with regard to compliance with the provisions of animal welfare law. The information on the holding which is required for the control is ascertained from the documents of the competent authority prior to the control. In this context, particular consideration is accorded to the type and number of animals in the establishment, the means of production, any losses that have occurred, the date and the outcome of the previous control and any conditions imposed by the authorities.

Where necessary, representatives of other specialist areas in the competent administrative authorities and experts from within the authority or from third party organisations may be called upon to provide support with the control. The control includes inspection of: documents on the holding; the facilities for accommodating the animals; and feeding and condition of the animals. In addition to routine controls, additional controls may be carried out as circumstances require.

Official controls during transport

Cross-border transport movements are controlled with regard to the completeness and plausibility of documentation, the condition of the means of transport, the fitness of the animals for transport, and the expertise and reliability of the carriers. Furthermore, cross-border and inter-state transport movements are also subject to random controls during road transport on the road, at-destination, in markets and at stopping and transhipment points. These controls take place with police involvement and, where appropriate, also with the involvement of the customs authorities. The involvement of the customs authorities set out in § 14 of the Animal Welfare Act, is however limited to controls of imports and exports from or to a third country. Under § 14(1)(2) TierSchG, customs offices can detain...
animals and their means of transport for surveillance in connection with importation. Under § 14(1)(2)(2) and 14(1)(2)(3) TierSchG they can report suspected infringements of the Animal Welfare Act to the competent authorities, and order animals to be presented for controls, where such suspicion arises during customs clearance.

In addition, feeding of animals during transportation is inspected, using the journey log, and further documentation is checked against the route plan where appropriate, within a period of eight weeks following completion of cross-border transportation.

In order to guarantee the uniform enforcement of Council Regulation (EC) No 1/2005 and of the TierSchTrV (Tierschutztransportverordnung - German national regulation on the protection of animals during transportation and implementing Council Regulation (EC) No 1/2005), the LAV Animal Welfare Working Group (AGT) has compiled a manual on animal transport to which the subordinated authorities must refer as an aid to interpretation.

**Official controls at slaughter**

Animal welfare during the slaughter process is inspected by means of regular controls of establishments, with the frequency of controls being predominantly determined by the number of animals slaughtered and the number of non-compliances recorded previously.

Within the context of monitoring animal welfare requirements, the principles that apply to controls on-farm and on animal transport are also implemented for slaughter. Since 2014 a nationwide coordinated manual "Animal Welfare Monitoring at Slaughter and Killing" (to be found on FIS-VL and AGT) is available to the law enforcement agencies. It contains, inter alia, contains procedures for official inspections at slaughterhouses.

The Official Veterinarian in the slaughterhouse controls whether any findings made as part of the inspection of the animals to be slaughtered allow one to conclude that animal welfare law has been infringed in the source establishment, during transport or during the stay at the abattoir. The Official Veterinarian monitors compliance with the legal requirements with regard to transport and slaughter. Breaches of animal welfare law are reported to the competent lower-level administrative authority, which institutes regulatory offence proceedings or passes on the case to the competent public prosecution service, as appropriate. The lower-level administrative authority regulates and monitors the activities of the Official Veterinarian.
2.11 Control system for plant health

Competent authorities

The BMEL is the central competent authority in the area of plant health. It is responsible for formulating and introducing new legislation (laws, regulations and general administrative regulations) in the field of plant health, collaboration with other departments, particularly in the areas of environmental protection, health and industry, and for external relations in the field of plant quarantine (bilateral contacts with other countries, consultations at EU level, and regional and international contacts). Within the Ministry, Unit 513 is responsible for plant health and plant protection matters, and phytosanitary issues related to exports.
The JKI is the designated authority for coordination and contacts according to Article 1(4) of Directive 2000/29/EC. It coordinates and informs the Länder Plant Protection Services on technical issues, records and processes data on phytosanitary matters, sends results to the Länder, other Member States and the European Commission, and deals with notifications, interceptions and plant health risk analyses. The JKI also covers research in the area of plant health.

The responsibilities of BMEL, JKI and the Länder Plant Protection Services (LPPS) are established in the Plant Protection Act (Pflanzenschutzgesetz).

In 2005, the BMEL, JKI and LPPS jointly established a phytosanitary audit control group to evaluate official plant health controls carried out by the LPPS, including import controls. The intention is to carry out up to three audits each year on a voluntary basis. At present, only one to two audits are being carried out per year owing to a lack of human resources. The audited LPPS is provided with a detailed report, which includes concrete recommendations for improvement measures. A short form of the report is also submitted to the Länder which have not been audited.

Plant passport system and internal market checks

The CAs in the Länder are responsible for implementation of plant health controls. The Länder Plant Protection Services are the responsible official bodies as referred to in Article 2(1)(g) of Council Directive 2000/29/EC. Each of the 16 Länder has its own official LPPS, which carries out inspections, takes measures, pursues infringements and produces the technical Land reports. The LPPS have official laboratories at their disposal for the diagnosis of quarantine harmful organisms, and issue plant passports and plant health certificates.

The LPPS report to the competent Länder Ministries or the competent Senate (in Bremen, Hamburg, and Berlin). In some Länder (e.g. Lower Saxony, North Rhine-Westphalia and Schleswig-Holstein), the LPPS are attached to the respective Chambers of Agriculture. In these cases, they are also bound by instructions from the competent Land Ministries and entrusted by them with execution of the legal tasks in accordance with the Plant Protection Act and related provisions.

The plant passport is issued on request by the competent authority, provided that the plants, plant products and other objects are not subject to a transport ban under Article 13a of the Phytosanitary Ordinance and comply with the requirements of Article 13b of the Phytosanitary Ordinance. Provided certain conditions are met, the competent authority may, on request, approve the issuing by an establishment, registered under Article 13n, of plant passports for plants, plant products or other objects listed in Annex V, Part A, Chapter 1, to Directive 2000/29/EC.

The Länder should comply with the phytosanitary control system which is described in the Compendium on Plant Health Controls in Germany. This compendium was compiled, based on a joint initiative between the State and the Länder, with the aim of harmonising phytosanitary measures in Germany on the basis of the EC Plant Quarantine Directive (Directive 2000/29/EC). As part of a project financed by the Länder, the Institute for National and International Affairs of the Plant Health Department of the Julius Kühn Institute coordinated the compilation, combination and standardisation of the specialist contributions that are drawn up by experts in the Länder plant protection service offices and employees of the Institute. The compendium contains descriptions of the control processes, including plant health measures, references to applicable legislative provisions, data sheets...
for the most important harmful organisms subject to quarantine, and templates of forms and documents.

A general administrative regulation addressing the issue of notifications and the flow of information between the Ländere Plant Protection Services and the JKI was adopted in January 2007. This is currently being revised and adapted to the Commission Implementing Decision 2014/917/EU.

In the Länder, 277 full-time equivalent staff work in the area of plant health; at the Julius Kühn Institute there are 14 staff (scientists) and at BMEL 5.32.

The JKI organises about 5-8 meetings each year with the Länder Plant Protection Services. The meetings are chaired by the Julius Kühn Institute which proposes the agenda on the basis of the information and experience gained. Coordination meetings usually address the actions being taken by Länder in response to Commission services' report recommendations.

Import controls

The Länder are responsible for conducting import and export controls. Plant health import controls are carried out at the points of entry or, in accordance with EU regulations, at the place of destination. In total, 88 points of entry have been designated, 48 of which are ports and airports. The large majority of regulated consignments arrive at Frankfurt-Main, Bremerhaven, Munich and Hamburg. In accordance with Directive 2004/103/EC, identity checks and phytosanitary controls may be carried out at the place of destination rather than at the point of entry. In Germany there are 217 registered places of inspection in 12 Länder. In these cases, the plant protection service at the point of entry carries out a document check and verifies whether the preconditions for control at the place of destination are in place (Article 8b(1) of the Phytosanitary Ordinance/Directive 2004/103/EC). If this is the case, the identity check and the plant health inspection take place at the place of destination.

If the goods to be imported are subject to plant health regulations, they are controlled by the plant protection service. In principle, the goods can only clear customs when the plant protection service has determined that they comply with plant health requirements and has confirmed in writing that the goods are suitable for import.

In the event of non-compliance with phytosanitary requirements in plants, plant products and other objects originating from non-EU Member States, a report of interception is sent to the plant protection service in the country of origin. The plant protection services in Germany are informed of this, as are the European Commission and the competent offices in the Member States (using the Europhyt electronic system).

Laboratories

The plant health diagnosis laboratories are part of the official plant protection services in most Länder. In Rhineland-Palatinate, the laboratories are assigned an official advisory function; one laboratory, which is owned by the Land but organised under private civil law, conducts various analyses (RLP Agroscience). In addition, one private laboratory carries out partial examinations in Bavaria under the supervision and control of the official laboratory of the plant protection service (Südzucker; Rain/Lech), which is under contract to and supervision by the Bavarian State Research Centre for Agriculture, Plant Protection Institute. It is competent for initial laboratory tests in potatoes for the Clavibacter michiganensis subspecies sepedonicus, and for Ralstonia solanacearum). Information about laboratories within all Länder can be found in individual control plans: http://www.bvl.bund.de/mnkp
2.12 Quality labelling

Organic farming


Article 27 of the EC Basic Organic Regulation provides for a system of controls to be set up in conformity with Regulation (EC) No 882/2004. More detailed provisions are set out in Article 27(8).

Under the Basic Law of the Federal Republic of Germany, the Länder are responsible for implementing national and EU legislation. There is a competent authority for organic farming in each Land.

In its Organic Farming Act Germany opted for a system of authorised private control bodies to carry out the controls laid down in Regulation (EC) No 834/2007, Regulation (EC) No 889/2008 and Regulation (EC) No 1235/2008 in respect of individual operators. The controls on operators are carried out in accordance with Title V, Articles 27-31 of Regulation (EC) No 834/2007, in conjunction with Regulation (EC) No 889/2008 and Regulation (EC) No 1235/2008. The private control bodies are authorised, or have such authorisation withdrawn, by the BLE in accordance with the allocation of powers in the Organic Farming Act. The competent Land authorities monitor the activities of the private control bodies on the basis of Article 27 of Regulation (EC) No 834/2007 and the German Organic Farming Act. The Land authorities have a mutually agreed, harmonised, risk-oriented system for monitoring the control bodies. The Land authorities conduct office audits, inspect control documents and accompany control operations, thereby ensuring fulfilment of the requirements of Article 27(8) and (9) of Regulation (EC) No 834/2007.

Import controls

Importers wishing to place on the market an organic product need to notify their activities to the competent authority of the relevant Land and also need to be certified by an authorised control body. For products to be imported under transitional rules stipulated in Article 19 of Commission Regulation (EC) No 1235/2008, importers shall make an application to BLE. BLE evaluates such applications and, where the conditions laid down in Article 19 are fulfilled, an authorisation is issued. Such authorisation shall always be submitted together with the inspection certificate for every consignment to be released into free circulation.

In accordance with Article 13 (1) (b) of Regulation (EC) No 1235/2008, the Customs services check organic consignments and endorse the original certificate of inspection submitted.
PDO, PGI and TSG

Qualified geographical indications of origin (protected designations of origin (PDO) and protected geographical indications (PGI)) currently enjoy particular protection in the EU, under Regulation (EU) No 1151/2012, Commission Delegated Regulation (EU) No 664/2014 and Commission Implementing Regulation (EU) No 668/2014. The rules also apply to geographical indications of origin from non-EU countries which are protected in the EU. Products are entered in one of the registers of protected indications kept by the European Commission ('DOOR' database).

The *Traditional Speciality Guaranteed* (TSG) label is purely a quality indication. Products which are produced using traditional methods and recipes may be so labelled. Neither the place of production nor the origin of the ingredients needs to be associated with a particular geographical area. The decisive factor is that the traditional recipe or production process is followed. Production may, however, take place anywhere. Like protected geographical indications, TSG are also registered in the DOOR database.

**Competent authorities**

In Germany, implementation of the rules for PDO and PGI comes under the auspices of the Federal Ministry of Justice and Consumer Protection (*Bundesministerium der Justiz und für Verbraucherschutz* (BMJV)) and the German Patent and Trade Mark Office (*Deutsches Patent- und Markenamt* (DPMA)). The BMEL provides technical assistance. Monitoring with regard to fraud is carried out in Germany by the food monitoring authorities of the various federal states (*Länder*).

For TSG, under the *Lebensmittelspezialitätengesetz* [German Food Specialities Act] and the *Lebensmittelspezialitätenverordnung* [German Food Specialities Regulation], the *Bundesanstalt für Landwirtschaft und Ernährung* (BLE) [Federal Office for Agriculture and Food] is responsible for implementing the procedures regarding TSGs provided for in Regulation (EU) No 1151/2012. Surveillance and monitoring are the responsibility of the competent offices under the legislation of the *Länder*. 
ANNEX I: STAFF RESOURCES

The following tables give a summary of the data on staff resources at Federal and Länder level in Germany. The numbers reflect full-time equivalent staff (FTE).

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<td>31 Safety of the Food Chain and 32 – Animal Health and Animal Welfare</td>
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<td>Total</td>
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</table>

Länder staff resources in areas of food, feed, animal health, animal welfare and plant health (full-time equivalents)

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<td>RHEINLAND-PFALZ*</td>
<td>660</td>
</tr>
<tr>
<td>SAARLAND*</td>
<td>105</td>
</tr>
<tr>
<td>SACHSEN*</td>
<td>447</td>
</tr>
<tr>
<td>SACHSEN ANHALT*</td>
<td>483</td>
</tr>
<tr>
<td>SCHLESWIG-HOLSTEIN*</td>
<td>404</td>
</tr>
<tr>
<td>THÜRINGEN*</td>
<td>494</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>14 600</strong>*</td>
</tr>
</tbody>
</table>

* Full-time equivalents

** Official veterinarians and specialist assistants; it is not possible to give exact full-time equivalents for this occupational group.

*** Includes official veterinarians and specialist assistants from Niedersachsen and Bayern and Brandenburg.

Note: Staff resources data varies over time. The reference dates may differ for each *Land.*
ANNEX II: ACRONYMS, ABBREVIATIONS AND SPECIAL TERMS

Annex II is composed of three tables:
- Table 1: General acronyms
- Table 2: Acronyms relating to German structure and organisation
- Table 3: Acronyms relating to Länder Working Groups for Consumer Health Protection

Table 1 - GENERAL ACRONYMS

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABP</td>
<td>Animal By-Products&lt;br&gt;Tierische Nebenprodukte</td>
</tr>
<tr>
<td>AG</td>
<td>Working Group&lt;br&gt;Arbeitsgruppe</td>
</tr>
<tr>
<td>AkkStelleG</td>
<td>German Accreditation Body Act&lt;br&gt;Akkreditierungsstellengesetz</td>
</tr>
<tr>
<td>ALB</td>
<td>LAV Working Group &quot;Food, Commodities, wine, cosmetics&quot;</td>
</tr>
<tr>
<td>ALS</td>
<td>Research Group of Experts in Food Chemistry&lt;br&gt;Arbeitskreis Lebensmittelchemischer Sachverständiger der Länder und des BVL</td>
</tr>
<tr>
<td>ALTS</td>
<td>Research Group of Experts active in the Field of Food Hygiene and Foods of Animal Origin&lt;br&gt;Arbeitskreis der auf dem Gebiet der Lebensmittelhygiene und der Lebensmittel tierischer Herkunft tätigen Sachverständigen</td>
</tr>
<tr>
<td>AMG</td>
<td>Pharmaceuticals Act&lt;br&gt;Arzneimittelgesetz</td>
</tr>
<tr>
<td>ATLAS</td>
<td>Automated tariff and local customs clearance system&lt;br&gt;Automatisiertes Tarif- und Locales Zollabwicklungssystem</td>
</tr>
<tr>
<td>AVV</td>
<td>General Administrative Regulation&lt;br&gt;Allgemeine Verwaltungsvorschrift</td>
</tr>
<tr>
<td>AVV-LmH</td>
<td>General Administrative Regulation on Food Hygiene&lt;br&gt;Allgemeine Verwaltungsvorschrift über die Durchführung der amtlichen Überwachung der Einhaltung von Hygieneverordnungen für Lebensmittel tierischen Ursprungs und zum Verfahren zur Prüfung von Leitlinien für eine gute Verfahrenspraxis</td>
</tr>
<tr>
<td>AVV DatA</td>
<td>General Administrative Regulation on Data Transfers Relating to Food Safety and Consumer Protection&lt;br&gt;Allgemeine Verwaltungsvorschrift über den Austausch von Daten im Bereich der Lebensmittelsicherheit und des Verbraucherschutzes</td>
</tr>
<tr>
<td>AVV Monitoring 2011-2015</td>
<td>General Administrative Regulation for the implementation of monitoring of foodstuffs, cosmetics and consumer goods over the years 2011 to 2015&lt;br&gt;Allgemeine Verwaltungsvorschrift zur Durchführung des Monitorings von Lebensmitteln, kosmetischen Mitteln und Bedarfsgegenständen für die Jahre 2011 bis 2015</td>
</tr>
<tr>
<td>AVV RÜb</td>
<td>General Administrative Regulation on Framework Control&lt;br&gt;Allgemeine Verwaltungsvorschrift über Grundsätze zur Durchführung der amtlichen Überwachung der Einhaltung lebensmittelrechtlicher, weinrechtlicher, futtermittelrechtlicher und tabakrechtlicher Vorschriften</td>
</tr>
<tr>
<td>AVV SWS</td>
<td>General Administrative Regulation implementing the early warning system for food and feed and for feed notifications&lt;br&gt;Allgemeine Verwaltungsvorschrift für die Durchführung des Schnellwarnsystems für Lebensmittel, Lebensmittelbedarfsgegenständen und Futtermittel</td>
</tr>
<tr>
<td>AVV Zoonosen Lebensmittelkette</td>
<td>General Administrative Regulation on the collection, evaluation and publication of data on the occurrence of zoonoses and zoonotic agents along the food chain&lt;br&gt;Allgemeine Verwaltungsvorschrift über die Erfassung, Auswertung und Veröffentlichung von Daten über das Auftreten von Zoonosen und Zoonoseerregern entlang der Lebensmittelkette</td>
</tr>
<tr>
<td>ACRONYM</td>
<td>DESCRIPTION</td>
</tr>
<tr>
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<td>-------------</td>
</tr>
</tbody>
</table>
| CCA     | Central Competent Authority  
Zentrale zuständige Behörde |
| CDB     | Central Database for Animal Identification and Registration 
Zentrale Datenbank für die Identifizierung und Registrierung von Tieren |
| CED     | Common Entry Document |
| CEN     | Comité Européen de Normalisation, European Committee for Standardisation |
| CIRCA   | Communication and Information Resource Centre Administrator  
Verwalter des Kommunikations- und Informationsressourcenzentrums |
| CITES   | Convention on International Trade in Endangered Fauna and Flora  
Übereinkommen über den internationalen Handel mit gefährdeten Arten frei lebender Tiere und Pflanzen |
| CO2     | Carbon dioxide |
| COPHS   | Chief Plant Health Officers |
| CRL     | Community Reference Laboratory  
Gemeinschaftliches Referenzlaboratorium |
| CSF     | Classical Swine Fever  
Klassische Schweinepest |
| CVMP    | Committee for Medicinal Products for Veterinary Use |
| DAkkS   | Deutsche Akkreditierungsstelle GmbH |
| DiätV   | Dietetic Foods Order  
Diätverordnung |
| E. Coli | Escherichia coli |
| EC      | European Community |
| EEC     | European Economic Community |
| EFSA    | European Food Safety Authority  
Europäische Behörde für Lebensmittelsicherheit |
| EMA     | European Medicines Agency |
| EN ISO  | European Standard ISO |
| ENGL    | European Network of GMO Laboratories  
Europäischen Netzwerk der GVO-Laboratorien |
| EU      | European Union |
| EURL    | European Union Reference Laboratory |
| FIS-VL  | Technical information system for consumer protection and food  
Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit |
| FG      | Specialist Group  
Fachgruppe |
| FIS-VL  | Technical Information System for Consumer Protection and Food  
Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit |
| FMD     | Foot and Mouth Disease |
| FMV     | Feed Regulation  
Futtermittelverordnung |
| GAP     | Good Agricultural Practice  
Gute Praxis in der Landwirtschaft |
| GenTG   | Genetic Engineering Act  
Gentechnikgesetz |
| GMO     | Genetically Modified Organism  
Gentechnisch veränderte Organismen |
| HACCP   | Hazard Analysis and Critical Control Points  
Gefahrenanalyse und kritische Kontrollpunkte |
| HIT     | System Providing Information on Animals  
Herkunftssicherungs- und Informationssysteme für Tiere |
| ID      | Identification System  
Identifizierungssystem |
| IPPC    | International Plant Protection Convention |
| ISO     | Internal Organisation for Standardisation |
| ISO/IEC | ISO/International Electrotechnical Commission |
| Land/Länder | Federal State/Federal States |
| LFGB    | Food, Feed and Consumer Goods Code  
Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch |
<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANCP</td>
<td>Multi-annual National Control Plan</td>
</tr>
</tbody>
</table>
| MBM     | Meat-and-bone Meal  
*Fleisch- und Knochenmehl* |
| MON810  | Monsanto 810 |
| MRL     | Maximum Residue Level  
*Rückstandshöchstwert* |
| NCP     | National Control Plan  
*Nationaler Kontrollplan* |
| NemV    | Food Supplements Order  
*Nahrungsergänzungsmittelverordnung* |
| NPCDB   | National Pig Central Database  
*Nationale Zentrale Schweinedatenbank* |
| NRCP    | National Residue Control Plan  
*Nationaler Rückstandskontrollplan (NRKP)* |
| NRL     | National Reference Laboratory  
*Nationales Referenzlabor* |
| OFFC    | Regulation (EC) No 882/2004 |
| OIE     | Office International des Epizooties  
*Internationales Tierseuchenamt* |
| PAH     | Polycyclic aromatic hydrocarbon |
| PCB     | Polychlorinated biphenyl |
| POM     | Prescription only medicines  
*Vorschreibungspflichtige Arzneimittel* |
| PPP     | Plant Protection Products  
*Pflanzenschutzmittel* |
| PVP     | Private Veterinary Practitioner  
*Praktizierender Tierarzt* |
| QM      | Quality management |
| QMS     | Quality management system |
| RAPEX   | Rapid Exchange of Information System  
*Europäisches Schnellwarnsystem für gefährliche Verbraucherprodukte* |
| RASFF   | Rapid Alert System for Food and Feed  
*Schnellwarnsystem für Lebensmittel und Futtermittel* |
| RMP     | Residue monitoring plan |
| SRM     | Specified Risk Materials |
| TierImpfStV | Animal Vaccine Regulation  
*Tierimpfstoffverordnung* |
| Tier-LMÜV | Food of Animal Origin Regulation  
*Tierische-Lebensmittel-Überwachungsverordnung* |
| TierNebG | ABP Order  
*Tierische Nebenprodukte-Beseitigungsverordnung* |
| TierNebV | ABP Act  
*Tierische Nebenprodukte-Beseitigungsgesetz* |
| TierSchG | Animal Welfare Act  
*Tierschutzgesetz* |
| TierSchTrV | German national regulation on the protection of animals during transportation  
*Tierschutztransportverordnung* |
| TierGesG | Animal Health Act  
*Tiergesundheitsgesetz* |
| TSE     | Transmissible Spongiform Encephalopathy |
| TSN     | National Animal Disease Notification System  
*TierSeuchen-Nachrichten* |
| VMP     | Veterinary medicinal product  
*Tierarzneimittel* |
Table 2:
ACRONYMS RELATING TO GERMAN STRUCTURE AND ORGANISATION

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>Name of Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACK</td>
<td>Conference of Directors of Public Offices (part of the proceedings of Conference of the Agriculture Ministers of the Länder (AMK)) Amtsschöffenkonferenz</td>
</tr>
<tr>
<td>AG PMK</td>
<td>Working Group on PPP Control Arbeitsgemeinschaft Pflanzenschutzmittelkontrolle</td>
</tr>
<tr>
<td>ALS</td>
<td>Working Group of Experts in Food Chemistry from the Länder and the BVL Arbeitskreis Lebensmittelchemischer Sachverständiger Länder und des BVL</td>
</tr>
<tr>
<td>ALTS</td>
<td>Food Hygiene and Food of Animal Origin Research Group Arbeitskreis der auf dem Gebiet der Lebensmittelhygiene und der Lebensmittel tierischer Herkunft tätigen Sachverständigen</td>
</tr>
<tr>
<td>AMK</td>
<td>Conference of Agriculture Ministers of the Länder Agrarministerkonferenz</td>
</tr>
<tr>
<td>BAFA</td>
<td>Federal Office of Consumer Economics and Export Control Bundesamt für Wirtschaft und Ausfuhrkontrolle</td>
</tr>
<tr>
<td>BB</td>
<td>Brandenburg</td>
</tr>
<tr>
<td>BE</td>
<td>Berlin</td>
</tr>
<tr>
<td>BIARM</td>
<td>Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte</td>
</tr>
<tr>
<td>BIfN</td>
<td>Federal Agency for Nature Conservation Bundesamt für Naturschutz</td>
</tr>
<tr>
<td>BfR</td>
<td>Federal Institute for Risk Assessment Bundesinstitut für Risikobewertung</td>
</tr>
<tr>
<td>BIP</td>
<td>Border Inspection Post Grenzkontrollstelle</td>
</tr>
<tr>
<td>BLE</td>
<td>Federal Agency for Agriculture and Food Bundesanstalt für Landwirtschaft und Ernährung</td>
</tr>
<tr>
<td>BLL</td>
<td>Federation of Food Law and Food Science (coordination body acting for the food industry) Bund für Lebensmittelrecht und Lebensmittelkunde</td>
</tr>
<tr>
<td>BMEL</td>
<td>Federal Ministry of Food and Agriculture (known until end of 2013 as BMELV) Bundesministerium für Ernährung und Landwirtschaft</td>
</tr>
<tr>
<td>BMELV</td>
<td>Federal Ministry of Food, Agriculture and Consumer Protection (until end of 2013) Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz</td>
</tr>
<tr>
<td>BMF</td>
<td>Ministry of Finance Bundesministerium der Finanzen</td>
</tr>
<tr>
<td>BMG</td>
<td>Ministry of Health Bundesministerium für Gesundheit</td>
</tr>
<tr>
<td>BMI</td>
<td>Ministry of the Interior Bundesministerium des Inneren</td>
</tr>
<tr>
<td>BMJV</td>
<td>Federal Ministry of Justice and Consumer Protection Bundesministerium für Justiz und Verbraucherschutz</td>
</tr>
<tr>
<td>BMUB</td>
<td>Federal Ministry for Environment, Nature Conservation, Building and Nuclear Safety Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit</td>
</tr>
<tr>
<td>BMVI</td>
<td>Federal Ministry of Transport and Digital Infrastructure Bundesministerium für Verkehr und digitale Infrastruktur</td>
</tr>
<tr>
<td>BMVg</td>
<td>Federal Ministry of Defence Bundesministerium der Verteidigung</td>
</tr>
<tr>
<td>BSA</td>
<td>Federal Office of Consumer Plant Varieties Bundessortenamt</td>
</tr>
<tr>
<td>BVL</td>
<td>Federal Office of Consumer Protection and Food Safety Bundesamt für Verbraucherschutz und Lebensmittel sicherheit</td>
</tr>
<tr>
<td>BW</td>
<td>Baden-Württemberg</td>
</tr>
<tr>
<td>BY</td>
<td>Bavaria</td>
</tr>
<tr>
<td>CS</td>
<td>Customs Services Zoll</td>
</tr>
<tr>
<td>Department IG</td>
<td>Environment and health, pollution control, installation safety and traffic, chemicals safety</td>
</tr>
<tr>
<td>ACRONYM</td>
<td>Name of Body</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| DIN       | German Institute for Standardisation  
*Deutsches Institut für Normung* |
| DLG       | German Agricultural Society  
*Deutsche Landwirtschafts-Gesellschaft* |
| DMA       | District and municipal authorities  
*Überwachungsbehörden der Kreise und kreisfreien Städte* |
| DPMA      | German Patent and Trade Mark Office  
*Deutsches Patent- und Markenamt* |
| FIS-VL    | Technical Information System for Consumer Protection and Food  
*Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit* |
| FLI       | Friedrich Loeffler Institute (Federal Research Institute for Animal Health)  
*Friedrich-Loeffler-Institut (Bundesforschungsinstitut für Tiergesundheit)* |
| FVO       | Food and Veterinary Office, now known as the Directorate for Health and Food audits and analysis, of the Directorate-General for Health and Food Safety of the European Commission  
*Lebensmittel- und Veterinäramt* |
| HB        | Bremen  |
| HE        | Hessen  |
| HH        | Hamburg  |
| JKI       | Julius Kühn Institute  
*Julius-Kühn-Institut* |
| LAG       | German National and Federal/Länder Joint Committee on Genetic Engineering  |
*Landesamt für Natur-, Umwelt- und Verbraucherschutz Nordrhein-Westfalen* |
| LAV       | Länder working groups for Consumer Health Protection (12)  
*Länderarbeitsgemeinschaft Verbraucherschutz (12 Arbeitsgruppen)* |
| LM        | Ministries of the Land (16)  
*Landesministerien (16)* |
| LPPS      | Plant Protection Services of the Land  
*Landespflanzenschutzdienste* |
| MRI       | Max Rubner Institute (Federal Research Institute of Nutrition and Food)  
*Max-Rubner-Institut (Bundesforschungsinstitut für Ernährung und Lebensmittel)* |
| MV        | Mecklenburg-Western Pomerania  |
| NI        | Lower Saxony  |
| NW        | North-Rhine Westphalia  |
| OIE       | World Organisation for Animal Health (Office International des Epizooties)  |
| OL        | Higher Land Authorities  
*Obere Landesbehörden* |
| ÖLG       | German Organic Farming Act  
*Öko-Landbaugesetz* |
| PA        | Provincial authorities/Provincial offices  
* Bezirksregierungen/Regierungspräsidien* |
| PEI       | Paul Ehrlich Institute  |
| priv. Lab.| Private laboratories  |
| RKI       | Robert Koch Institute  
*Robert Koch Institut* |
| RP        | Rhineland-Palatinate  |
| SH        | Schleswig-Holstein  |
| SL        | Saarland  |
| SN        | Saxony  |
| ST        | Saxony-Anhalt  |
| StMLF     | Bavarian State Ministry for Agriculture and Forestry  
*Bayerisches Staatsministerium für Landwirtschaft und Forsten* |
| SV        | Senate administration  
*Senatsverwaltung* |
| TH        | Thuringia  |
| UBA       | Federal Environmental Agency  
*Umweltbundesamt* |
<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>Name of Body</th>
</tr>
</thead>
</table>
| VDLUFA  | Association of German Agricultural Investigation and Research Institutes  
*Verband Deutscher Landwirtschaftlicher Untersuchungs- und Forschungsanstalten* |
| VSMK    | Conference of Ministers for Consumer Protection  
*Verbraucherschutzministerkonferenz* |
| WBR     | Scientific Advisory Board  
*Wissenschaftlicher Beirat* |
| WHO     | World Health Organisation |
| ZKBS    | Central Committee for Biological Safety  
*Zentrale Kommission für die Biologische Sicherheit* |
| ZLG     | Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices  
*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten* |
| ZORA    | Central Authority for Risk Analysis (Customs)  
*Zentralstelle Risikoanalyse (Zoll)* |
### Table 3: Länder Working Groups for Consumer Health Protection (LAV) Länderarbeitsgemeinschaft Verbraucherschutz

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
</table>
| AFFL     | Working Group on Meat and Poultry Meat Hygiene and Specific Questions related to Food of Animal Origin  
Arbeitsgruppe Fleisch- und Geflügel fleischhygiene und fachspezifische Fragen von Lebensmitteln tierischer Herkunft |
| AFU      | Animal Feed Working Group  
Arbeitsgruppe Futtermittel |
| AG ED    | Working Group: Import, and Transit  
Arbeitsgruppe Ein-, und Durchfuhr |
| ALB      | Working Group on Foodstuffs and Food Contact Materials, Wine and Cosmetics  
Arbeitsgruppe Lebensmittel und Bedarfsgegenstände, Wein und Kosmetika |
| AG TAM   | Veterinary Medicines Working Group  
Arbeitsgruppe Tierarzneimittel |
| AG TT    | Animal Diseases, Animal Health Working Group  
Arbeitsgruppe Tierseuchen, Tiergesundheit |
| AG T     | Animal Welfare Working Group  
Arbeitsgruppe Tierschutz |
| AG GEE   | Healthy Diet and Nutritional Information Working Group  
Arbeitsgruppe Gesunde Ernährung und Ernährungsinformation |
| AfAB     | Working Group on Training and Professional Issues for People Active under Food and Veterinary Law  
Arbeitsgruppe Ausbildungs- und Berufsangelegenheiten der im Rahmen des Lebensmittel- und Veterinärrechts tätigen Personen |
| AG IuK   | Information and Communication Working Group  
Arbeitsgruppe Information und Kommunikation |
| AG WV    | Economic Consumer Protection Working Group  
Arbeitsgruppe Wirtschaftlicher Verbraucherschutz |
| AG QM    | Working Group on Quality Management  
Arbeitsgruppe Qualitätsmanagement im gesundheitlichen Verbraucherschutz |