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2014

SCIENCE IN THE SERVICE OF HUMANITY

Imprint

Annual Report 2014

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Does aluminium in food and consumer products pose risks to health? The BfR addressed this question in its assessments and analyses in 2014. The aluminium content in the test food “tomato sauce” was determined in this context.



Foreword



Prof. Dr. Dr. Andreas Hensel, President



Prof. Dr. Reiner Wittkowski, Vice-President

Dear Readers,

Does the BfR do a good job? This is a question that everyone employed at the institute has to answer through their activities and performance. You are holding the Annual Report 2014 in your hands with a number of selected examples which are intended to show you the fields of consumer health protection in which the BfR is active and the contribution the Institute makes towards improving consumer safety. But how can the quality of the BfR's work be measured? The answers to this question are as varied as the tasks the institute performs. One of the top priority tasks of the BfR is political consulting, but when can it be regarded as successful and what are the assessment criteria? The BfR pursued this question in 2014 and in doing so launched several initiatives which have the goal of defining verifiable criteria on which the institute will focus and by which it can be measured. Other criteria serve to appraise scientific performance in research, assessment and communication. All of these preliminary tasks were taken into account in the evaluation made by the Scientific Council at the beginning of May 2015.

Further confirmation of the quality of the work of the BfR is to be found in the popularity of the events it organises. A good example of this is the main theme of this leaflet: aluminium, which is used in cosmetics, foods and packagings to name but a few examples. The BfR staged a consumer protection forum, including an online dialogue forum, on the question of whether or not this light metal poses any health risks, both of which found broad acclaim in the media. This also applied to the event staged to mark the occasion of the activation of the "AnimalTestInfo" database by federal government minister Christian Schmidt. The website informs about animal testing projects with the help of non-technical project summaries.

The assumption of the tasks of the national committee in line with the Animal Welfare Act was one of the most important elements of the BfR in 2014. By doing so, the Centre for the Documentation and Assessment of Alternative and Supplementary Methods to Animal Experiments (ZEBET) can in future be expanded into a national competence centre and the committee office set up to coordinate the tasks.

Another milestone was the approval of the national Total Diet Study, for which – divided up over several years – a total in excess of ten million euros have been provided. The levels of nutrients, additives, process contaminants and other ingredients in foods prepared in the kitchen are to be determined in the project. The goal is to examine 90 percent of the foods consumed by the general population. Through the study, data on changes to the composition and formation of new substances in the preparation of foods will be acquired – data, which has hardly existed up to now. As the third project, the EU research project “SPICED”, which has the goal of protecting the European supply chain for spices and herbs against biological and chemical contamination – be it intentional, accidental or natural – is mentioned here as an example of many others. The BfR coordinates an international consortium of 15 partners from seven countries in this project.

A personnel requirements survey was started at the BfR in February 2014 by an external consulting company. This measure has the goal of formulating recommendations on personnel requirements, as well as the growth of the BfR's scientific potential and general performance capability. The requirements, and therefore the scope of tasks too, have increased since the BfR was founded and its organisation has also become increasingly more complex. For this reason, it was time to examine whether the BfR is suitably staffed.

Once you have leafed through and read this annual report, we would like to draw your attention to the BfR website. The BfR's “business” is a fast-moving one, because situations can arise within a few days, and sometimes within only a few hours, where the institute has to respond to inquiries. To do so, it makes increasing use of digital communication channels, such as mobile apps, YouTube and Twitter in addition to its classical website.

This brief overview may be sufficient to establish that the work performed in 2014, extracts of which are contained in the following chapters, forms a solid foundation for the next year. The incentive for 2015 is a promise: the BfR will become even better, because a truism of science is that satisfaction can only be achieved by growing beyond that which has already been achieved. The BfR management is aware that to do so requires a high level of commitment from all staff members on which the Institute can rely. Our sincere thanks are due here to all employees.

A truism of science is:
Satisfaction can only
be achieved by
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been achieved.

 BfR website: www.bfr.bund.de/en



Prof. Dr. Dr. Andreas Hensel,
President



Prof. Dr. Reiner Wittkowski,
Vice-President

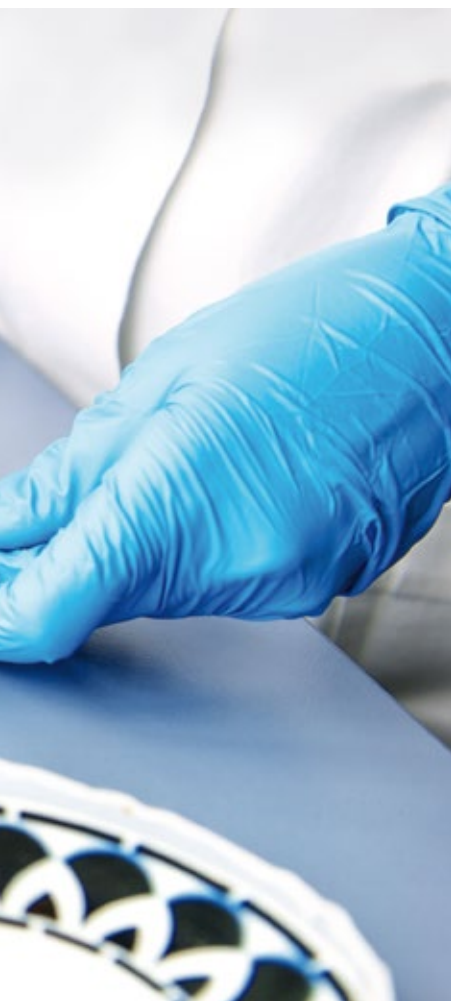


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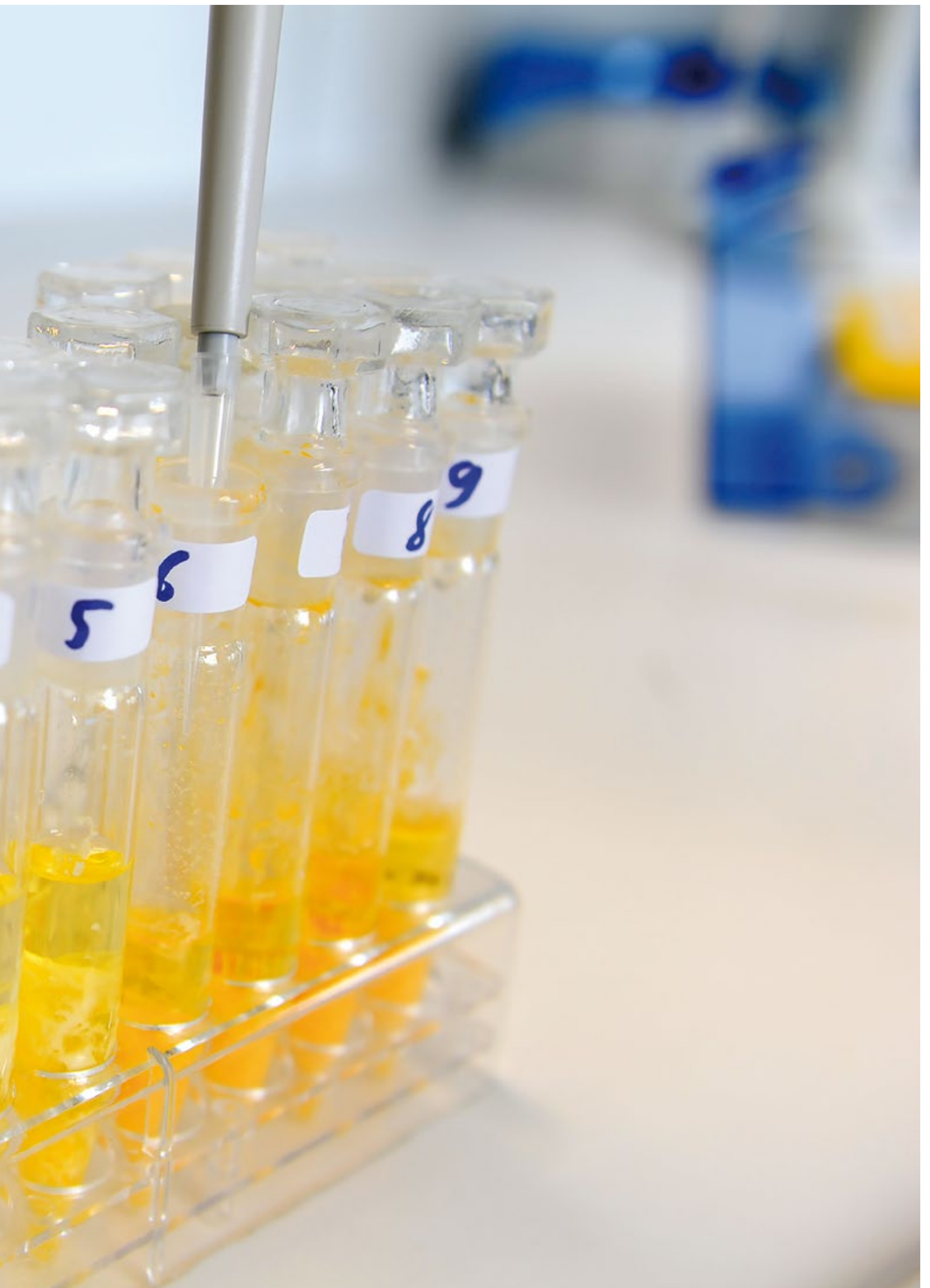
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Organisation chart
Short portrait of the BfR

A row of laboratory test tubes containing a yellow liquid, likely a sample being analyzed. The tubes are arranged in a rack, and the liquid level is visible in each. A blue banner is overlaid at the bottom of the image, containing the text 'About the BfR'.

About the BfR

The Federal Institute for Risk Assessment (BfR) is an independent scientific research institution within the portfolio of the Federal Ministry of Food and Agriculture. It assesses the health risks in the fields of food, consumer products and chemicals, and it prepares recommendations as to how these risks can be restricted. With its work, the BfR makes a decisive contribution towards protecting consumer health.



Objectives and mission

The Federal Institute for Risk Assessment (BfR) was set up in November 2002 to strengthen consumer health protection. It is the scientific agency of the Federal Republic of Germany which is responsible for preparing expert reports and opinions on food and feed safety as well as on the safety of chemicals and products. By doing so, the Institute plays an important role in improving consumer protection and food safety. In its assessments and recommendations, the BfR is free from economic, political and social interests, and it provides its information in a way that can be easily understood by the general public.

Every day, the employees of the Federal Institute for Risk Assessment, or BfR for short, prepare around a dozen reports and opinions assessing the health risks of foods and feeds, consumer goods and chemicals. The BfR communicates its findings and recommendations to policy makers and the general public. The federal government uses the opinions of the BfR as a basis for ensuring consumer health protection. Set up in 2002, the BfR today employs about 760 people in nine departments at three locations in Berlin.

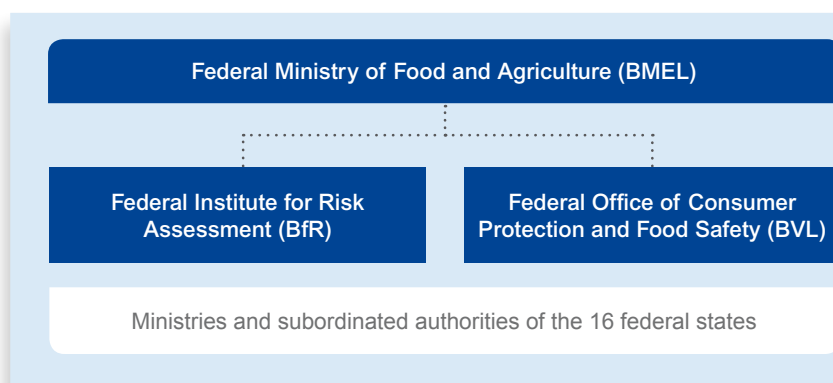
The tasks of the BfR include the assessment of existing and the identification of new health risks, the drawing up of recommendations on risk reduction, and the communication of this process. The results of its work serve as the basis for scientific advice to the relevant federal

ministries and other agencies, such as the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Occupational Safety and Health (BAuA). The work results and recommendations of the BfR serve all interested parties as a decision-making aid for taking the necessary measures. With its scientifically based risk assessment activities, the BfR provides important stimuli for consumer health protection both in Germany and abroad.

In its risk assessment and research work, the BfR is advised by a network of scientific experts made up of committees and the Scientific Advisory Board. As the central national contact or Focal Point of the European Food Safety Authority, the BfR is also integrated into European consumer protection.



With its work, the BfR makes a decisive contribution towards protecting consumer health.



For justified consumer protection measures, the current state of scientific knowledge is first ascertained from the Federal Institute for Risk Assessment. In contrast, the Federal Office of Consumer Protection and Food Safety is responsible for management tasks at the federal level.

Position of the BfR in the field of consumer health protection

The BfR was founded as a federal agency with a legal capacity within the portfolio of the Federal Ministry of Food and Agriculture. The tasks of the Institute are based among other things on the statutory act establishing the BfR. The legislative has also defined the work activities of the Institute in ten further laws – including the German Plant Protection Act, the German Genetic Engineering Act, the German Food and Feed Code, and the Chemicals Act.

i The legal foundations of the BfR in detail:
www.bfr.bund.de/en > **The Institute > Remit**

In a federal system like in Germany, the responsibility for consumer health protection falls to the Federal Government and the federal states. Laws and ordinances designed to promote consumer health protection are enacted by the German government and parliament. The BfR advises the federal ministries on the preparation of legal regulations. It assesses health risks in a scientific process and outlines options for action to minimise risks. These recommendations are translated into protective measures for the consumer by management action on a national government level.

Many statutory provisions for consumer protection are laid down on European level in the meanwhile, and the BfR is also involved in the elaboration of these European provisions for consumer protection. Its experts are represented in numerous EU scientific advisory bodies.

In Germany, it is the job of the surveillance authorities in each federal state to monitor compliance with national and European statutory provisions in the area of consumer health protection. The BfR itself does not perform a monitoring function, but it supports Germany's federal states in this task by developing and establishing analytical methods for monitoring purposes, for example, or by issuing expert opinions on topical issues of consumer health protection. The BfR is also involved in a number of registration and approval procedures.



Members of the Bundestag parliament also regularly keep informed about the work of the BfR.

Principles and working procedures

The BfR is committed to certain principles that ensure the high quality of its opinions. Ever since the Institute was founded in 2002, various measures have been taken which have played a key role in consolidating this science-based approach to risk assessment, thereby contributing to the good reputation of the work of the BfR.

Independence

The independence of experts is a fundamental precondition for guaranteeing independent risk assessment. For this reason, the practice of separating scientific risk assessment from subsequent risk management asserted itself in Europe over ten years ago.


The overall concept of the BfR explicitly provides for the exchange of views with all stakeholders. These include NGOs, consumer associations, trade and industry, politics, science and the media. When scientific standpoints are voiced and substantiated, the involvement of various stakeholders is of particular importance, but the risk assessments themselves are exclusively prepared by employees of the BfR. External experts merely advise the BfR, but they do not make any official decisions. The work results and recommendations of the BfR serve as an important decision-making aid for the planned measures taken by all interested groups. The statements issued by the BfR are based on internationally recognised principles and are also substantiated in a way that can be understood by non-experts. Available knowledge is adequately taken into consideration and presented in an easy-to-understand manner, while any relevant scientific opposing views are also outlined.

Transparency is necessary on all levels of risk assessment. From the objective and area of application of the opinion, through the source, type and evidence of the underlying data, the methods used along with the assumptions, uncertainty and variability, to the result and conclusions, the assessments have to be clear, understandable and reproducible.

Assessment of risks

The assessment of a risk takes into account the probability of the occurrence of an event which will endanger health and the expected extent of the health impairment. Although a health risk can never be ruled out completely, through a series of suitable measures known as risk management, an attempt is made to minimise the risk to the greatest extent possible and to prevent a threat to health.

The job of the BfR is to provide the responsible people with a solid scientific foundation for risk management. Identifying a risk and evaluating it – the two together are known as “risk assessment” – is the first step in the area of consumer health protection. Risk management can use this as a point of reference and initiate suitable measures.



To ensure that independence is maintained, the BfR does not seek or receive any funding from trade and industry; it is financed through funds provided by the national government, as well as from externally funded national and international projects.



The opinions prepared by the BfR are based on internationally recognized scientific principles.

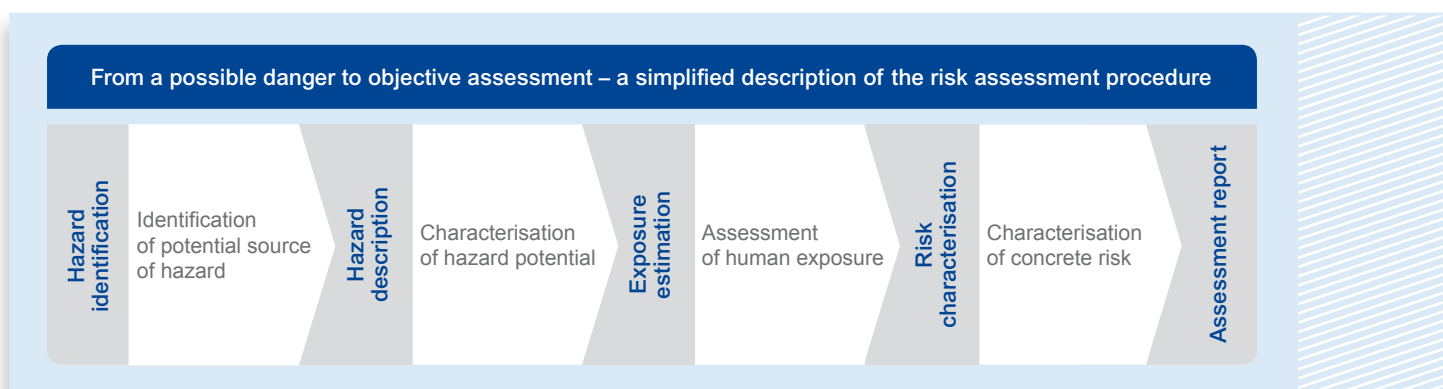
Risk assessment is performed on the basis of internationally recognised scientific assessment criteria (see diagram below). It entails the estimation of a risk using scientific methods.

A distinction is made between qualitative risk assessment, where risks are described verbally – following the pattern outlined in the box – and quantitative risk assessments, which are based at least partly on calculations or mathematical models whereby the risks are described by means of mathematical or statistical methods.

The risk assessments of the BfR are always the subject of the Institute's risk communication activities too. The BfR has the legal mandate to inform the public about poten-

tial, identified and assessed risks. The assessments are presented in a transparent and easy-to-understand manner. The findings are made publicly accessible on the BfR website while maintaining the confidentiality of protected data. At expert hearings, scientific conferences and consumer forums, the Institute enters into a dialogue with representatives from politics, science, associations, trade and industry and non-government organisations.

i The BfR has published a guideline for health assessments in the field of consumer protection which formulates the demands on risk assessments at the BfR: www.bfr.bund.de/en > Publications > Broshures > Guideline





The BfR has a modern laboratory infrastructure, for example for the analysis of exposure to airborne substances such as chemicals, particles and compounds.

Research

The BfR focuses on independent, application-related, targeted research within the scope of its key competences with the help of which the Institute can conduct scientific examinations and assessments in line with its legal mandate. Not least through the BfR's international focus, harmonisation by means of standardisation in the development of methods and procedures plays a prominent role at the Institute.

The BfR is independent in the conception and conducting of all its research activities, thus securing and promoting the scientific expertise for internationally recognised competence in risk assessment and risk communication, which is independent of economic interests. The preparation of new data, methods and procedures helps to close knowledge gaps in the field of food, chemical and consumer product safety, as well as risk communication and risk perception. The results of all research activities flow directly into the risk assessments and opinions of the BfR and underpin the advisory services provided to the three supervisory ministries, the Federal Ministry of Food and Agriculture, the Federal Ministry for the Environment, Building, Nature Conservation and Nuclear Safety and the Federal Ministry of Transport and Digital Infrastructure.

The BfR has a modern experimental infrastructure in chemical analysis, microbial diagnostics, toxicology and food technology. An agricultural business with livestock farming and aquaculture, as well as a facility for conducting experimental work on animals, enable the institute to perform basic research and assessment tasks. In addition to this, the BfR has state-of-the-art molecular and cellular biology, as well as protein biochemistry laboratories for the development of alternative and substitute methods to animal experiments. In the laboratory for large and small animals, work can be done up to safety level S2/L2, while microbiological tasks are possible up to stage L3. This means that the BfR is able to conduct cross-departmental and interdisciplinary examinations and assessments along the entire supply and value chain. In its activities, the BfR orientates on the relevant ISO norms and recognised quality management standards. In its research, the BfR works on the basis of the recommendations of the German research community in line with the principles of good scientific practice.

Presentation: New externally funded projects 2014

- > In the field of nanotechnology, it is being examined in the Franco-German research project "SolNano-Tox" what role the solubility of nanomaterials plays in their enrichment and toxic properties. In this project, the BfR is collaborating with its French sister organisation ANSES, the Institute of Sciences Chimiques de Rennes and the University of Leipzig. The tasks of the BfR include conducting of *in-vitro* tests, analysis of biological samples with regard to the possible enrichment of nanomaterials, and the examination of possible structural changes using imaging methods.
- > The "SEEINGNano" project attracted funding from the EU research programme Horizon 2020 in the area of the risk perception of nanotechnology. Visualisation tools to help improve awareness and understanding of nanotechnology are developed and tested therein.
- > In the main research area of estimating and assessing exposure to biological risks, the Federal Ministry of Education and Research is financing the second promotion period of the two BfR research projects "MRSA in the food chain (Med-VetStaph-2)" and "Molecular epidemiology of the new resistance mechanisms and quantitative risk assessment of ESBL, AmpC- β -lactamase and carbapenemase in *Enterobacteriaceae* from the food chain (RESET 2)".
- > In the area of main focus of identifying alternative methods to experiments with animals, the BfR is contributing two sub-projects as a partner of the Berlin-Brandenburg research platform "BB3R" with integrated postgraduate programme.

BfR-Committees

Fifteen scientific expert committees advise the BfR in questions relating to the safety of food and feed, chemicals and products, nutrition, risk research and risk perception. They consolidate the expertise available in Germany at the highest scientific level to form an external quality assurance system for the assessment of the performance of the BfR. In this way, they can be called upon for advice as an established network also in times of crisis.

The approximately 200 committee members are external, independent experts who support the work of the BfR in an advisory capacity and on an honorary basis. They come from universities and other research institutions, national and regional authorities, trade and consumer associations, private laboratories and industry.

The BfR committees each have at least ten members who elect a chairperson from among their ranks. The BfR supports the committees by taking over management tasks. The minutes of the meetings, which reflect the scientific opinions and recommendations of the committees, are publicly available on the BfR website. Compared to the European Food Safety Authority (EFSA), the BfR committees are advisory bodies only. By contrast, EFSA's committee members prepare their own expert reports and risk assessments.

In 2013, the external appointing panel selected suitable scientific experts who had applied in the open call for tender earlier. The President of the BfR appointed the members for the new term from 2014 to 2017 (by certificate). The appointing panel is made up of members of the BfR Scientific Advisory Board, the chairs of the German Research Foundation's Senate Committees for the Health Assessment of Food and of Substances and Resources in Agriculture and a representative of the Senate of Federal Research Agencies. The committees started to work during the first half of 2014.

i *The tasks of the BfR committees, list of members and rules to ensure independence:*
www.bfr.bund.de/en > **The Institute** > **BfR-Committees**

Other committees at the BfR:
www.bfr.bund.de/en > **The Institute**
 > **National Breastfeeding Committee**

www.bfr.bund.de > **Das Institut** > **ZEBET**
 > **Kommissionsmitglieder** (German only)

Quality management

The quality assurance and quality management of products and processes are not only of importance to industry. Authorities, especially scientific institutes like the BfR, must also be able to prove today that they work in compliance with internationally recognised standards and that this is ensured by means of a functional quality management system (QMS).

The criteria for quality-assured work activities are laid down in international standards. The standard DIN EN ISO/IEC 9001:2008 stipulates how business processes and responsibilities have to be organised in order to guarantee high-quality work and products. The standard DIN EN ISO/IEC 17025 lays down the rules for the management of test and calibration laboratories as well as the technical requirements. Test laboratories which satisfy the standard prove having the technical competence and capability to achieve substantiated results. Since 2010, all work areas of the BfR – science, assessment, communication and administration – have been certified in line with the quality standard DIN EN ISO 9001:2008. The BfR's scientific laboratories have all been accredited in line with DIN EN ISO/IEC 17025 since as far back as 2003.

The two quality official certificates have to be renewed regularly, certification every three years, accreditation every five years. So-called monitoring audits are conducted in the interjacent years. Quality-assured operations in compliance with DIN EN ISO 9001:2008 were last confirmed by the independent TÜV Nord Cert GmbH in May 2014. Compliance with the standard DIN EN ISO/IEC 17025:2005 by the scientific laboratories was most recently assessed one month previously, in April 2014, by the Deutsche Akkreditierungsstelle GmbH (DAKKS).

i *Information on quality management at the BfR:*
www.bfr.bund.de/en > **The Institute**
 > **Quality Management**



BfR Vice-President Prof. Dr. Reiner Wittkowski (l.) receives the "TÜV Nord Cert GmbH" certificate in recognition of the quality-assured working practices and facilities at the BfR.

Internationalisation

Nowadays, food safety can only be assured by means of a global approach. Bilateral cooperation with government ministries and partner authorities on all continents therefore constitutes an important aspect of the work of the BfR. The supervisory authority, the Federal Ministry of Food and Agriculture (BMEL) also puts an emphasis on further strengthening cooperation of this kind. For this reason, the BfR is involved in the ministry's "International Research" work group. The purpose of international cooperation is to convey and transfer knowledge of food and product safety to the mutual benefit of both partner countries. The takeover and application of established methods and procedures in other countries ultimately benefits consumers and businesses throughout Europe too.

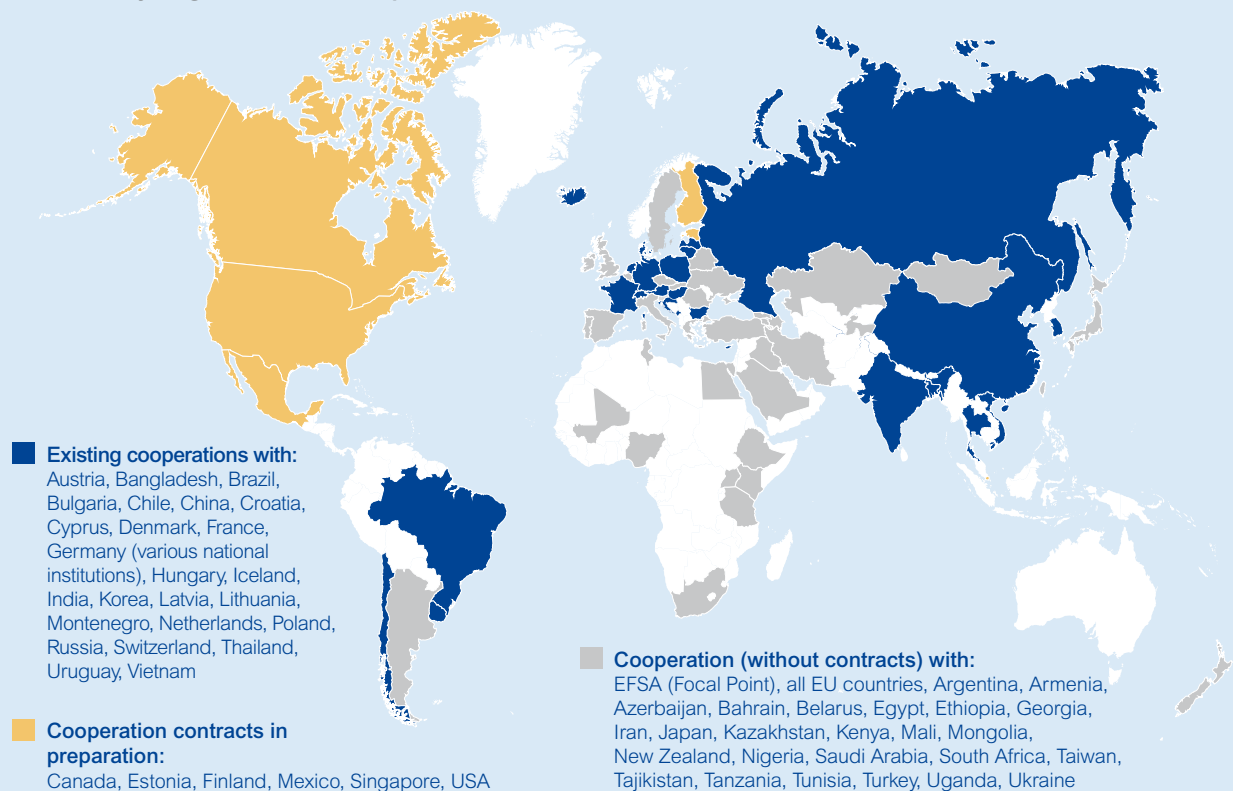
The BfR maintains close contacts with institutions in different countries of the world through such means as mutual visits, joint symposiums, the exchange of information and scientists and through their training at the BfR Summer Academy. The cooperation with most of these institutions has already been placed on a firm, long-term footing by means of appropriate contracts. New contacts develop from these relationships through inquiries from these

countries to the BfR on the one hand and through the activities of the BfR on the other. The Institute conducts anticipatory research in the field of the early recognition of risks in order to identify ensuing and future hazards in a timely manner.

The BfR's close ties with its sister authorities in France (ANSES) and Denmark (DTU) played a special role in 2014. Within this set-up, for example, advances were made in the exchange of PhD candidates. A second area of main activity was China, to which several BfR delegations travelled in 2014 to explain the work of the Institute. Collaboration was established with Estonia, Uruguay, Bulgaria and Montenegro, and discussions on biological hazards, their assessment and prevention were held with institutions of the departments of Health and Homeland Security in the USA.

i *Food Safety in Europe – Who does what?*
The BfR's EU Almanac provides information on the structures and institutions of food safety in 35 European countries and on a European level:
www.bfr.bund.de/en > Publications > Brochures > EU-Almanac

Food safety is globalised – Cooperations of the BfR



Methods for the control and monitoring of foods, chemicals and consumer goods are developed and validated in the BfR reference laboratories.

Reference laboratories

National reference laboratories work on standards for food monitoring in order to ensure the safety of food products throughout the entire EU. For this purpose, 17 reference laboratories in the areas of food and feed safety and food hygiene are attached to the BfR. They are divided into two groups: national reference laboratories in accordance with Regulation (EC) 882/2004 and other BfR laboratories with a reference function.

The reference laboratories pursuant to regulation (EC) 882/2004 attached to the BfR are involved in both food chemistry analysis as well as molecular biological and microbiological testing. They are appointed by the Federal Ministry of Food and Agriculture. Their work is based on various legal regulations such as the German Food and Feed Code as well as laws and regulations on consumer goods.

The main job of reference laboratories is to develop and validate methods and to perform laboratory comparison tests (Interlaboratory Tests) for the purpose of quality assurance. The creation of national reference laboratories guarantees that work is carried out in line with uniform



To determine the presence of mineral oils in food packagings, control laboratories are reverting to the standard methods of the national reference laboratories, for example.

standards all over Europe. This is of particular importance for the monitoring and control of food products, which are fundamentally covered by the principle of the free movement of goods within the European Union. The national reference laboratories also act as a national link between the community reference laboratories of the EU and the food surveillance authorities in the EU member states.

Alongside these national reference laboratories based on EU law, there are also other institutions of the BfR that perform a reference function in other contexts. These include the Reference Laboratory in the “Network of Genetically Modified Organisms”, the Senior Expert Office for the Import Control of Wine in accordance with the Wine Monitoring Ordinance and the Zoonoses Reporting unit.

i *List of the national reference laboratories active at the BfR, as well as the other laboratories with a reference function:*
www.bfr.bund.de/en > **The Institute**
 > **Reference Laboratories**

Reference labs in actual practice: Investigation of a leptospirosis outbreak in Lower Saxony

Leptospirosis is a feverish infectious disease which is transmitted from animals to humans. In the summer of 2014, 45 strawberry pickers in Lower Saxony contracted leptospirosis with 21 of them requiring hospital treatment. In cooperation with the health and veterinary authorities in the administrative districts of Oldenburg and Cloppenburg, the Regional Health Office of the state of Lower Saxony and the State Office for Consumer Protection and Food Safety, the BfR-affiliated consultant laboratory for *Leptospira* examined human blood samples and rodents which had been caught on the cultivated strawberry fields. The consultant laboratory identified mice infected with *L. kirschneri* (sequence type 110) as the probable source of the outbreak. Antibodies against the pathogen type *L. kirschneri* serovar Grippotyphosa were also detected among the strawberry pickers by means of the microscopic agglutination test.

The Executive Board and the Departments

“Identifying risks – protecting health” – this is the central task of the BfR. The Institute is headed by its President, Professor Andreas Hensel, and his Vice-President, Professor Reiner Wittkowski. They are supported in their work by several staff units and the nine departments profiled below.



President
Professor Dr. Dr. Andreas Hensel



Vice-President
Professor Dr. Reiner Wittkowski



Administration Department
Head: Heike Morisse

The Administration Department is the service provider for all the specialist departments of the Institute. It handles infrastructure, personnel recruitment, advice for employees in personnel matters, control and monitoring of revenues and expenditures, and the organisational and technical maintenance of the premises and the Institute grounds. The department publishes organisational regulations for the Institute and is also responsible at the same time for compliance with legal provisions.



Risk Communication Department
Head: PD Dr. Gaby-Fleur Böl

The Risk Communication Department conducts research projects on the perception of risks in the public sphere and their early identification, and on the assessment of their impact. A further focus of its work is crisis prevention and coordination. The department also comprises press and PR activities, the BfR committee system and the BfR Academy. The dialogue with various stakeholders from science, economics, politics, the media, associations, non-government organisations and consumers is also of significance.



Exposure Department
Head: Professor Dr. Matthias Greiner

The department assesses consumer exposure in the areas of food, chemical and product safety and offers interdisciplinary scientific support in such areas as mathematical modelling. The department performs statutory tasks in the areas of chemical safety, dangerous goods transport, poison and product documentation, and good laboratory practice. It also conducts research projects and is a service provider of the BfR's IT requirements.



Biological Safety Department
Head: Professor Dr. Bernd Appel

The department is involved with the health risks to humans due in particular to microorganisms as well as the toxins formed by these microorganisms and other microbial metabolites. The assessments encompass not only food but also feed and consumer products (e.g. food packaging material and tableware), as well as cosmetics – including the processes involved in their extraction, production, processing and distribution – as vehicles of biological risk.



Food Safety Department
Head: Professor Dr. Dr. Alfonso Lampen

The department assesses foods with regard to the risk of the substances they contain, which include natural occurring ingredients, additives and flavourings as well as undesired substances that find their way into foods through production, storage or treatment processes. In addition, nutritional risks as well as the risks of particular population groups are assessed. A part of the assessment consists of experimental projects on the effect mechanisms of the oral intake (bioavailability), internal exposure (biomarker) and molecular effect mechanisms (toxicogenomics) of relevant substances.



Pesticides Safety Department
Head: Dr. Roland Solecki

The focus of the department's work is the health assessment of active substances and formulations of plant protection products and biocides before they are legally authorised. Assessment comprises evaluation of toxicological properties with the aim of classification and labelling, as well as the derivation of limit values. Under consideration of anticipated exposure levels, risk assessments are carried out in order to ensure safe use of the products in question. It also reviews residue monitoring methods and works on the further development of assessment strategies.



Chemicals and Product Safety Department
Head: Professor Dr. Dr. Andreas Luch

The department assesses chemical substances covered by chemicals law and identifies measures to reduce risks. A further task is the identification, investigation, assessment and prevention of health risks emanating from cosmetics, tobacco products and products with which the consumer comes into contact (food packaging, toys, clothing etc). Experimental projects on the migration of, exposure to and toxicity of chemical substances are an integral part of these assessment activities.



Safety in the Food Chain Department
Head: Dr. Monika Lahrsen-Wiederholt

The department assesses the risks resulting from the intake of contaminants, residues and other undesired substances from food and feed products. It houses the National Reference Laboratories for Dioxins and PCBs in Food and Feed, for Mycotoxins, for the Monitoring of Marine Biotoxins and for Additives for Animal Nutrition as well as the Senior Expert Office for the Import Control of Wine. Other areas of main focus are product identity and the traceability of food products.



Experimental Toxicology and ZEBET Department
Head: Professor Dr. Gilbert Schönfelder

The department performs tasks stipulated by the German Animal Welfare Act and the Animal Protection Experiment Regulation. The scientific work also serves to advise political decision makers. Central tasks are the development and validation of alternative methods to animal experiments in line with the 3R principle. The department is also involved in the (further) development of toxicological test methods which include on a regulatory level the Chemicals Programme of the Organisation for Economic Cooperation and Development (OECD).

Personnel and training

The BfR employed a total workforce of 757 at the end of 2014, 439 at the location in Jungfernhede and 318 at the two other locations in Marienfelde. The main tasks of the personnel unit in 2014 included especially the recruitment of qualified staff, training, personnel development and the promotion of the compatibility of family and career at the BfR.

Personnel recruitment

In order to recruit qualified personnel, the BfR presented itself in 2014 at trade fairs and events geared specifically towards the field of natural science. To this end, the personnel unit was again represented with its own stand at two job fairs in Berlin. In addition to this, the BfR attended an international fair for the first time by participating in the 14th annual meeting of the German Academic International Network in the USA. The goal was to reach applicants directly through trade fairs and events and not only via the classical method of job announcements in print and online media. The Institute also released the image film “Working at the BfR”, which provides an insight of the Institute as an employer, on various social media portals in 2014.

The BfR published a total of 120 job announcements – roughly 20 percent more than the previous year. Accordingly, the number of applications rose to 4,800. 110 people were hired. Through organisational measures, it was possible to further shorten the recruitment process to three months on average.



The BfR has a presence at job fairs for the scientific sector several times per year.

Training

The BfR offers training in seven different professions. These include apprenticeships as a chemical or biological lab assistant, animal carer, plumbing and heating installer, office communication and/or office management specialist, media and information services specialist and computer scientist. At the end of 2014, 28 young people had an apprenticeship contract with the BfR.

The BfR is also committed to the “National Plan of Action for Integration” initiated by the national government in 2012 to integrate the number of people with a migration background into the civil service. In its “Training initiative for young people with a migration background” the BfR specifically addresses this target group, for example at training and study course fairs and through its cooperation with associations which provide information on apprenticeships and job announcements at the BfR.

In addition to the apprentices, the BfR granted 166 school children and students an insight into day-to-day practice at the Institute through internships, while also accompanying students' final papers and supervising 23 external PhD candidates.

Personnel development

To ensure that the tasks of the Institute can be performed in top quality, the continuous development of personnel is an essential issue at the BfR. Accordingly, a large number of further training courses were again conducted for all employee groups in 2014 on interdisciplinary and methodical topics such as foreign languages, laboratory appliances and rhetoric. The BfR also continues to promote participation in recognised further training courses in toxicology.



The BfR supports young scientists. It launched a new PhD candidate programme for this purpose in 2014.

For the key group of executives, the “FührungAKTIV” programme kicked off in 2014 comprising lectures, workshops and training courses on subjects such as management (from a distance), communication with employees, personnel recruitment and interculturality. Within the scope of this systematic executive development, the executives at the BfR are offered regular training to continuously further develop their leadership skills.

On top of all of this, a three-year programme to promote an initial number of ten junior scientific staff members was started for the first time at the BfR in April 2014. In addition to the opportunity of studying for a PhD in collaboration with the participating universities, this programme comprises various events and training courses. The BfR also developed a post-doctoral programme especially to promote up-and-coming scientific talents and to increase the cooperation with universities. Among many other things, the participants in the programme are given a detailed career management in the form of individual coaching.

Compatibility of family and career

The BfR considers the term family to mean a way of living where individuals are involved in ensuring the wellbeing, upbringing and care of their children, relatives and partners. To ensure that employees can assume responsibility at work as well as in the family, the promotion of the compatibility of family and career is a matter of importance to the Institute. With the promotion of the compatibility of family and career, the BfR is pursuing the goal of bonding employees more strongly to the Institute and gaining a higher profile in the competition for qualified personnel. The BfR was awarded the “audit berufundfamilie” certificate in 2009 and had it confirmed in a re-audit in 2012. It is to be confirmed yet again in 2015 within the scope of the “Consolidation” re-audit.

Since acquiring certification for the first time in 2009, the BfR has implemented a number of measures to promote compatibility, such as extensive expansion of flexible working hours, the establishment of guest offices and parent-child rooms, the introduction of alternating telework and the preparation of a position paper on the German Family Care Leave Act. In 2014, the BfR also continued to advance the implementation of the plan of measures for further improvement of alternating telework which was prepared in an evaluation workshop. It also made telework even more flexible and strengthened the autonomy of teleworkers with regard to the structuring of their work. There was also a lot of focus on sensitising executives to compatibility issues through discussion groups on the implementation of family-conscious management conduct.

Worthy of special mention too is the introduction of perspective discussions for all temporary employees with their immediate supervisors. The opportunity to clarify future perspectives is of particular importance to junior scientific staff and trainees, especially those who are planning to start a family.

The largest employee group consist of scientific personnel, followed by administrative staff and technical assistants.

Key data for 2014

How many scientists does the Federal Institute for Risk Assessment employ? Which bodies and committees do they serve on? How does the Institute finance itself? The answers to these questions are provided in the following section on the key data of the BfR. The figures all relate to the reporting year 2014.

Personnel



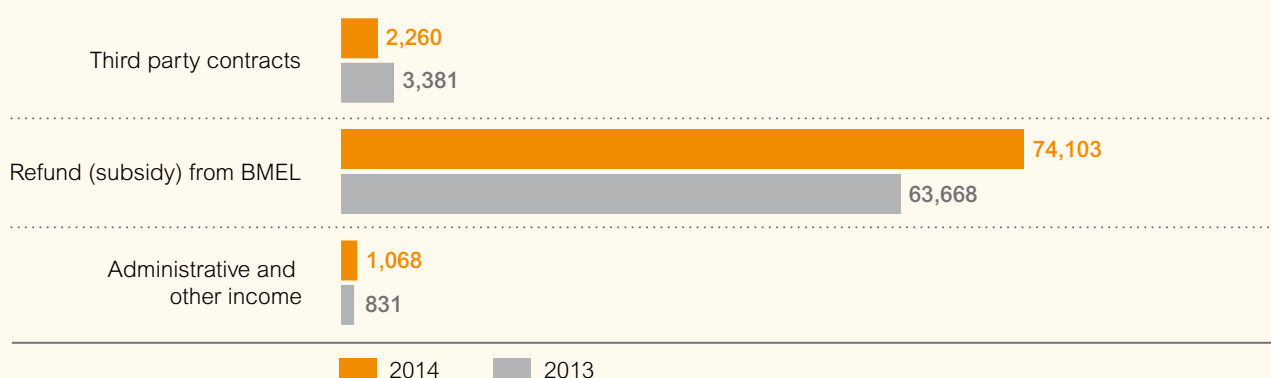
BfR employees are officially involved in **407 committees** to conduct research, give advice and conduct assessments.

Participation in bodies

National	Number
Federal bodies	53
Federal government federal state bodies	42
BVL bodies	21
Bodies of other institutions	103
European Level	Number
Bodies of the European Commission	38
Bodies of the European Food Safety Authority	44
Bodies of the European Chemicals Agency	6
Bodies of other European institutions	23
Worldwide	Number
WHO/FAO: Bodies of Codex Alimentarius	12
WHO/FAO: other bodies	2
Bodies of other United Nations specialised Agencies	9
OECD bodies	43
Other bodies involved in global standardisation activities	11

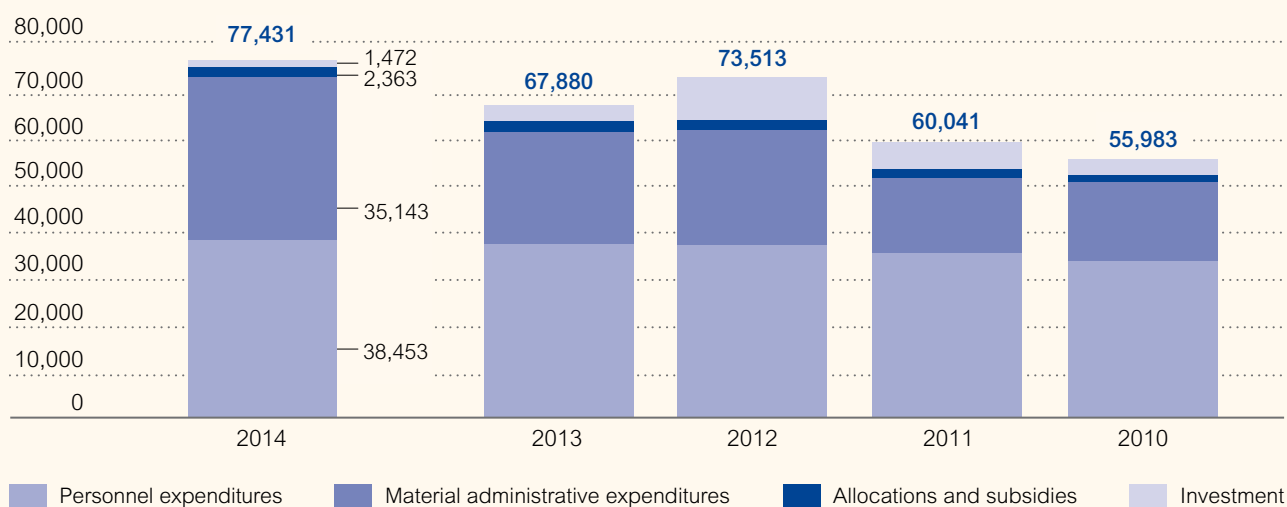
Procurement/Finances

Income (in thousands of euros)



About **77 million euros**
is how much the BfR received in total in 2014.

Expenditures (in thousands of euros)



The increase in material administrative expenditures in 2014 was due mainly to additional rental and operating cost payments, differences in investment caused by the move of a BfR location and the build-up of a new department.

Selected Expenses

Scientific collections and libraries	376,703 €
Initial and further training	295,897 €
Press and public relations, publications and professional information	841,397 €
Conferences, trade fairs and exhibitions	215,888 €

BfR expert opinions and publications

BfR expert opinions

	Number
Assessments in prescribed procedures, e.g. marketing authorisation procedures addressed to the Federal Office of Consumer Protection and Food Safety (BVL) or to the Federal Institute for Occupational Safety and Health (BAuA)	2,180
Expert opinions for supervisory federal ministries (BMEL, BMUB, BMVI)	330
Expert opinions in conjunction with international procedures (EU, OECD, WHO) for the assessment of chemical substances and testing methods, e.g. on alternatives to animal experiments	100
Expert opinions for the European Food Safety Authority (EFSA) and EFSA Focal Points of other Member States	20
Other expert opinions for public authorities and courts outside prescribed procedures	190
Other opinions, mainly for associations, individuals, NGOs	320
Total	3,140

The 2,180 assessments in prescribed procedures include:	Number
Assessments pursuant to pesticides legislation	830
Assessments of intoxication cases pursuant to § 16 e Chemicals Act (ChemG)	460
Opinions on chemicals pursuant to chemicals legislation (REACH)	440
Assessments pursuant to biocides legislation	300
Opinions on feed procedures stipulated in feed legislation	80
Opinions on exemptions from consumer protection provisions in food legislation, §§ 54, 68 Food and Feed Code (LFGB)	30
Other risk assessments in prescribed procedures	40

Note: The figures provide some insight into the type and scale of expert opinions prepared by the BfR in 2014. They describe OUTPUT. A low number of risk assessments may be more valuable for consumer protection – because of the subject matter and scientific quality – than a multitude of risk assessments. The figures do not, therefore, permit any or only limited conclusions about the OUTCOME of the activities of the BfR.

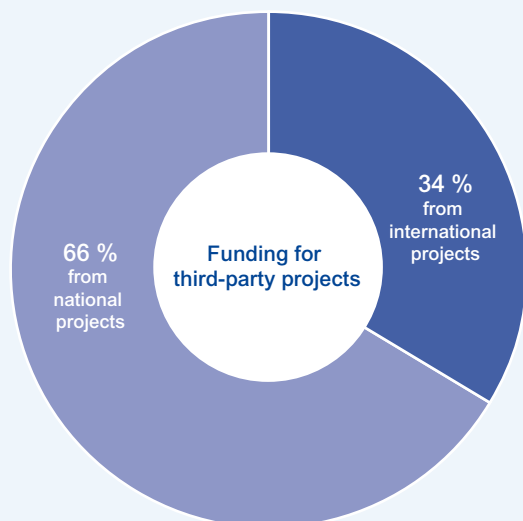


The BfR published approximately **200 articles** in scientific journals in 2014.

Publications

	Number
Books	10
Contributions to compilations	24
Articles in journals	192
Contributions to proceedings	80
Poster contributions	132
Presentations	540
Dissertations/habilitations/ diplomas/masters/bachelors	37

Research



Funding for third-party projects in 2014 amounted to **2.9 million euros**, with international projects accounting for a third of this figure.

Third-party projects	Number	Funds
international (EU, EFSA etc.)	18	974,941 €
national (BMBF, DFG, BLE etc.)	25	1,914,783 €
total	43	2,889,724 €

In recent years, the BfR has increased its third-party projects funds by **20 percent**.

Trend in third-party projects funds (in millions of euros)



Selected events in 2014

The BfR conducts a number of events to present the results of its work and to promote the exchange of ideas, experience and information with representatives of target and interest groups from the fields of science, politics, NGOs, trade and industry, as well as consumers. Since the beginning of 2014, these events have been organised and conducted by the “BfR-Academy”, a unit of the Risk Communication Department. A total of 134 events were staged in 2014, with the participation of experts from other countries at more than every fifth event. Twelve training courses were conducted in 2014 in addition to scientific dialogue and information events.

i More information: www.bfr.bund.de/en > Events

17–26 January 2014

The BfR at the International Green Week in Berlin

The BfR booth focused on the topic of fish and seafood and their health benefits and on what consumers should pay attention to when buying and preparing fish and fish products. The BfR stand was one of the main attractions at the theme farm, attracting around 25,000 visitors of all ages. In addition to the graphic documentation about the proper preparation of fish products, the BfR stand also offered other activities, such as a quiz and a fishing game.

How fresh is the fish? At the BfR stand, visitors to the Green Week 2014 learned about freshness criteria, storage and preparation of fish and seafood.



20 January 2014

BfR-Symposium on the health assessment of plant protection products containing glyphosate



The BfR symposium on plant protection products containing glyphosate attracted a great deal of public interest.

In light of the public discussion of the possible health risks of glyphosate, the BfR discussed questions concerning the health and microbial effects of plant protection products containing glyphosate at a symposium organised within the scope of the International Green Week in Berlin. The main focus of the event was the presentation of the new assessment of the health risks of glyphosate by the BfR. Almost 150 trade visitors of the Green Week participated in the symposium.



Symposium: 50th anniversary celebrations of the BfR-committee “Assessment of Intoxications”

This symposium was dedicated to the significant results and successes of the 1964 founded “intoxication committee”. For example: laying the foundations of clinical toxicology in Germany, the initiation and execution of numerous examination and research projects, the preparation of policy papers and the introduction and accompaniment of several legislative procedures. The committee also compiled a set of information sheets for the diagnosis and treatment of intoxications which has been available for many years as an electronic database. With the National Monitoring of Intoxications, the event offered a look at the future of the committee's work.

26–28 March 2014

Further training event for the public health service

The event for physicians, chemists, pharmacists and specialist personnel from the public health service is conducted every year at the BfR in cooperation with the Federal Environment Agency (UBA) and the Robert Koch Institute (RKI). A total of 30 presentations were held by UBA, RKI and BfR staff members to more than 500 participants who had come from all over Germany. For years now, the further training event has concentrated on directly conveying new scientific findings to a specialised audience, followed by discussions. The topics dealt with in 2014 ranged from the risks posed by the ingredients of jewellery and cosmetics through the health effects of the energy turnaround in Germany to the use of antibiotics in hospitals and livestock farming. An additional workshop for researching literature from special databases, which was offered for the first time, was very well received by the participants.

29 April 2014



In 2014, the “National Committee for the Assessment of Intoxications”, based at the BfR, celebrated its 50-year anniversary with a press conference, symposium and official ceremony.



18–29 August 2014

**Third BfR-Summer School
on the subject of food safety**

During this two-week event, 26 international scientists from eleven different countries studied the principles of health risk assessment and risk communication which the BfR pursues in the field of food safety. In the workshops, the participants focused on food hygiene, residues, contaminants, risk assessments of chemicals and the subsequent adequate communication thereof to the general public. For the guests, the goal was to conduct their own risk assessments and communicate the results. International harmonisation of assessment strategies is being sought by passing on the results to the participants' home countries.

How does risk assessment work? In the BfR Summer School, scientists of various nationalities learn the principles of risk assessment and risk communication.

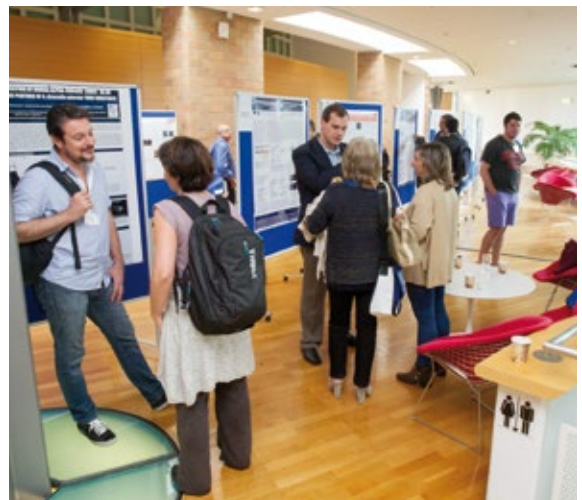



Brucellosis 2014
Berlin

9–12 September 2014

**International Research Conference
on brucellosis**

Even though brucellosis is only a rare occurrence in central and northern Europe due to consistent monitoring, up to 500,000 cases of the disease are still reported every year around the world. This means that even 100 years after it was first discovered, this infectious disease is still one of the most common zoonoses. For this reason, an exchange takes place every year among international experts at a brucellosis conference. In 2014, the BfR organised the event in cooperation with the Friedrich Loeffler Institute, including the 67th Annual Brucellosis Meeting of the International Brucellosis Society. The approximately 250 guests gathered information on the latest results of brucellosis research and discussed them at numerous lectures and poster presentations.





15th BfR-Consumer Protection Forum “Aluminium in Everyday Life”

In 2014, the “BfR-Consumer Protection Forum” was held for the fifteenth time and dealt with the health risks of aluminium. Together with scientists from at home and abroad, the effects of aluminium on human health and the exposure of consumers were discussed. Within the scope of the forum, the BfR experts answered specific consumer questions per livestream. The points of view of representatives of consumer protection organisations and trade associations on the question of how consumers can protect themselves were discussed.

3–7 November 2014

BfR risk assessment module within the scope of specialised toxicology training

For the second time now, the training week on risk assessment and communication, which was attended by 35 participants in the DGPT further training course, was held at the BfR. The instructors, most of whom were from the various BfR departments, offered presentations and interactive exercises. The course participants were able to deepen their acquired knowledge on the basis of practical examples. Due to the great demand and many positive responses, it is planned to establish the module permanently at the BfR.

26–27 November 2014



The BfR answered all sorts of questions in its consumer protection forum “Aluminium in everyday life”, in which approximately 200 people were involved.



BfR events – interactive and broadcast on the internet

In 2014, two BfR events were broadcast in the internet per livestream for the first time, thus making them accessible to an even larger target audience. At another event, the audience was able to answer questions on a specific subject with the help of tablet PCs and special participation software. The spectrum of opinion from the audience was picked up on and discussed directly in the presentations.



Main Topic 2014

Aluminium compounds occur naturally in food. However, they are also used in packaging, cooking utensils, food additives, cosmetics and drugs. In 2014, the BfR calculated how much **aluminium** consumers take in and which health risks could arise from this.



Aluminium in everyday life – a health risk?

Consumers frequently come in contact with aluminium compounds in everyday life. These compounds are already contained naturally in unprocessed foods and they continue to be used in food additives, cosmetic products, food packagings, cooking utensils, drugs, pesticides and in the treatment of drinking water. In 2014, the BfR focused mainly on the question of how much aluminium consumers ingest from various sources. The Institute conducted various exposure estimations, risk assessments and experimental examinations and derived measures to reduce individual aluminium intake.

Possible health risks through aluminium compounds

Aluminium is the third most common chemical element in the earth's crust after oxygen and silicon but it does not play a role in any biological processes in the human body. A high aluminium intake in excess of the health based guidance value – the so-called TWI (tolerable weekly intake) – is not safe from a toxicological point of view. Aluminium can remain in the body for a very long time and enrich itself in the bone substance in particular. A half life of up to 50 years has been estimated from human studies. Aluminium also finds its way into organs such as the brain, liver, skin and lymph nodes, however, and can reach the foetus via the placenta. It is known from studies with animals that the nervous system is particularly sensitive to effects of aluminium exposure, especially in development phases. Aluminium has also been detected in breast milk. In rare instances, skin irritations and sensitisations to aluminium compounds have also been observed.



Aluminium is found in food items, consumer products such as packaging and cookware, and in cosmetic items and drugs.

It has not yet been clarified conclusively whether aluminium plays a role in the development of breast cancer and Alzheimer's disease. The World Health Organisation (WHO) concluded in 1997 that the quantities of aluminium to which consumers are normally exposed are very probably not causally related to Alzheimer's disease. To date, no causal connection between the intake of aluminium from cosmetic products and the emergence of cancer, in particular breast cancer, has been scientifically proven either. →



In experimental studies, the BfR calculates the levels of aluminium that could be transferred to food from aluminium packaging, for example.

As consumers do not ingest aluminium from only one source, however, the BfR assessed the estimated aluminium intake from various sources in 2014.

Aluminium quantities that are safe to health

The European Food Safety Authority (EFSA) has derived 1 milligramme (mg) of aluminium per kilogramme (kg) of body weight and week as the value for a tolerable weekly intake (TWI). This health based guidance value indicates the amount of aluminium a person can ingest orally every week throughout their life without expecting any undesired health effects. The EFSA assumes a mean oral bioavailability of 0.1 percent (%) for aluminium compounds from food. Using this value, the TWI can be converted to a systemic dose of 0.143 micrograms (μg) per kilogramme of body weight. This gives the daily tolerable quantity of aluminium available to the body. This means that systemically available doses up to 8.6 μg per day are regarded as safe for a person weighing 60 kg.

As consumers do not ingest aluminium from only one source, however, the BfR assessed the estimated aluminium intake from various sources in 2014 with the result that consumers already ingest the tolerable weekly quantity of aluminium from their food. Every additional long-term intake has the result that the TWI is permanently exceeded. There is therefore no leeway for additional aluminium intake from other sources.



In the past, the food control authorities of the federal states have regularly determined increased aluminium levels in lye bakery wares. The reason for this could be the use of uncoated aluminium trays in the production of lye pretzel products.

Aluminium intake through food

Aluminium occurs naturally in food and drinking water. Most unprocessed foods contain less than 5 mg of aluminium per kg of food. According to the EFSA, higher concentrations were detected in mushrooms, spinach, radish, chard, garden lettuce and lamb's lettuce, tea leaves, herbs, cocoa and cocoa products, as well as spices, offal and seafood. Processed foods may contain a higher aluminium content if food additives containing aluminium were used. According to the EFSA, bread, cakes and other bakery products – most commonly biscuits and cookies – as well as candied fruits, dairy products, sausages, high-sugar foods and baking mixtures contain an average of 5 to 10 mg of aluminium per kg of food.

The EFSA conducted an exposure estimate for the European population in 2008 according to which, depending on eating habits, an average of approx. 0.2 to 1.5 mg aluminium per kg body weight were ingested through food every week by an adult weighing 60 kg. Children and adolescents showed high intake values (97.5th percentile) in the range of 0.7 to 2.3 mg per kg body weight and week. According to this EFSA data from 2008, consumers already used up the TWI through food. Current legal regulations should ensure that the TWI value is not exceeded. For this reason, the use of certain additives containing aluminium, for example, has been banned since 2014.

The BfR is working on the assumption that aluminium levels in the population in general have already dropped significantly through this measure. The effects have not yet been reflected in current data, however, and have therefore not been quantifiable up to now. The BfR will make a new exposure estimation as soon as values are available on this. →

How is aluminium intake legally regulated?

Several recommendations and regulations are intended to limit the use of aluminium in food, drinking water and items of everyday use.

- > A new regulation regarding the conditions of use and the use levels for aluminium-containing food additives has been in force since 2014. It restricts the use of food additives containing aluminium (Regulation [EU] No. 380/2012 amending Annex II to Regulation [EC] No. 1333/2008).
- > The German drinking water regulation sets a limit value for aluminium in drinking water of 0.2 mg per litre (Regulation on the Quality of Water for Human Consumption – TrinkwV 2001, Annex 3).
- > According to the European Council's resolution on the use of metals and alloys that have contact with food, the release of aluminium into food should not exceed 5 mg per kg.



Acids and salt could release aluminium from consumer products such as aluminium grilling trays that is then transferred to food.



Cosmetic items such as antiperspirants and deodorants can contain aluminium salts.

i Opinions as well as questions and answers on the subject of Aluminium at: www.bfr.bund.de/en > **A-Z Index** > **Aluminium**

Contribution of antiperspirants to aluminium uptake

To determine the sources of human contamination with aluminium, in 2014 the BfR also conducted a risk assessment of antiperspirants contain aluminium salts.

To be able to estimate aluminium uptake, the BfR had to rely on information provided by the manufacturers on the concentrations used in their products, as well as an *in-vivo* penetration study known to the Institute. The BfR arrived at the following values in its model calculation: according to the EU's Scientific Committee on Consumer Safety (SCCS), approx. 1,500 mg of antiperspirant are applied every day. With an aluminium chlorohydrate concentration of 20 %, this equates to a quantity of 75 mg of aluminium applied every day. With an absorption rate of 0.014 %, this in turn equates to a systemically available quantity of 10.5 µg of aluminium per person per day.

According to the EFSA, a systemically available dose of 8.6 µg per day is regarded as safe for an adult weighing 60 kg. This means it is possible that the TWI which was actually derived by the EFSA for oral intake could be fully used up and permanently exceeded alone through the long-term use of an antiperspirant containing aluminium. Although this does not directly lead to health impairments, but initially only to a reduction of the safety margin, permanently exceeding the TWI is not tolerable from a toxicological point of view. In the opinion of the BfR, a reduction of aluminium exposure is desirable, especially intake from avoidable sources. Consumers who want to reduce their aluminium uptake can choose aluminium-free deodorants, for instance.

In its risk assessment, the BfR used a very low experimentally derived absorption rate which was classified as not very robust. It was not possible to take account of real life scenarios such as multiple applications, underarm shaving and details of the exact formulation of the antiperspirants. The BfR will update its risk assessment as soon as new data on the absorption rate of preparations containing aluminium becomes available. The cosmetics industry has announce a corresponding human study for the end of 2015.

Consumers who want to reduce their aluminium uptake can choose aluminium-free deodorants, for instance.

Aluminium intake through articles of everyday use

If not used correctly, aluminium can also be transferred to food from cooking utensils and food packagings. With regard to the increased solubility of aluminium under the influence of acids and salts, the BfR has been recommending for some time now that aluminium foils, trays and uncoated aluminium dishes and utensils should not be brought into contact with acidic or salty foods. Beverage cans, aluminium tanks and lid films for yoghurt cups are coated on the inside, thus preventing the transfer of aluminium ions to the food. Espresso capsules made of aluminium or with an aluminium film lid are also coated on the inside. After making its own examinations in 2014, the BfR is assuming that no transfer of aluminium to the beverage is to be expected here.

The BfR also examined the transfer of aluminium from espresso makers in 2014. When used for the first time, these pots form a protective layer which reduces the transfer of aluminium to a great extent. Cleaning in a dishwasher can remove this coating, however, thus causing an increase in the release of aluminium the next time the pot is used. Even then though, the release remains below the migration value recommended by the European Council and the protective coating forms again the more often the device is used. In the view of the BfR, there is therefore no reason to advise against the use of aluminium espresso makers, but it is advisable not to clean them in a dishwasher. The use of espresso makers made of aluminium contributes only a little to overall exposure to aluminium.

An intake source which is easy to avoid from a technical point of view is the use of uncoated aluminium baking trays for the production of lye pretzels and lye rolls. So far, the food control authorities of the federal states of Germany regularly have determined aluminium levels of more than 10 milligrams per kilogramme of food in lye bakery wares. The BfR already advised back in 2002 against using aluminium baking trays in the production of foods of this kind, especially when dipping the dough into the lye and when baking, as the aluminium is released from of the tray and transfers into the food.

Information to the general public

On the basis of its research and assessment results, the BfR provided the general public with information by various communication means in 2014 about how individual aluminium intake can be reduced if necessary. The Institute organised a consumer forum, for example. In addition, consumers could pose specific questions on the issue to the BfR directly via its website, which the BfR scientists answered in a video. Various BfR studies, such as a media response analysis and a population survey, showed that the topic was picked up on in numerous media articles which sensitised consumers to it. ||



The BfR investigated whether aluminium is transferred from espresso makers to ground coffee.

i The BfR answered consumers' questions on the subject "Aluminium in everyday life – a health risk?" per video at (German only): www.bfr.bund.de > Presse > Mediathek

The public has not yet formed a final opinion on the question of the risks of aluminium.

Interview on perception research of aluminium

In addition to its opinion on aluminium in products of everyday use, the BfR has issued two studies in order to find out more about the knowledge and attitudes of consumers on the subject. To do so, the BfR interviewed a representative number of consumers in November 2014 and analysed reporting in mainstream German media over a period of ten months. In an interview, BfR President Professor Dr. Dr. Andreas Hensel talks about the results of the two surveys.



*Interview with Institute Director
Andreas Hensel*

Professor Hensel, how aware is the general public of aluminium in consumer products?

There is controversial public discussion of the subject of aluminium again and again, and the BfR received many inquiries from concerned citizens last year. Our investigations have shown that the majority of people have heard of aluminium in consumer products and that the media has reported increasingly on the subject.

How high is the level of awareness of the topic compared to other consumer topics?

Compared to other consumer health topics, the subject lies mid-range. It is less well known than antibiotics resistance and pesticide residues, but consumers are more familiar with it than with the EHEC pathogen. That is amazing, because the EHEC outbreak caused by bean sprouts was only four years ago. It just goes to show how quickly topics can disappear from the focus of public attention.

Is the topic fundamentally new to consumers?

It can be assumed that most consumers are aware that they come in contact with aluminium in their everyday lives, because most of them use aluminium film and trays after all for grilling and the like. It wasn't so well known up to now that cosmetics, in particular antiperspirants, are a source of aluminium. Those in the survey who knew about the subject from the media could remember deodorants and antiperspirants even though it is only antiperspirants which contain the aluminium salts which help to make us sweat less. Deodorants merely cover up the smell of sweat. This difference seems to have got lost somewhere in the public debate and not even half of the respondents in the survey knew about it either.

What did the media report about aluminium in consumer products and foods?

The media paid significantly more attention to the subject last year than they did in 2013. What we observed here was not only that more articles were published but also that there was stronger emphasis on the risk potential. Where 54 % of the analysed articles reported on the possible dangers of aluminium in consumer products in 2013, this figure jumped to a total of 87 % in 2014.

Were there other areas of main focus in the reports?

In particular aluminium in cosmetics was a consumer advice and service topic, because the majority of the articles were placed in the service and health sections of newspapers. This is understandable, because it concerns a possible risk where consumers can decide very easily and individually whether or not they prefer to dispense with antiperspirants and switch to aluminium-free deodorants instead. The topic received the most media coverage in the summer months, by the way.

Is the topic regarded overall as a health risk by the general public?

There is no clear answer to that. Even though a small majority of 52 % said that they regard aluminium in consumer products as a risk, as many as 35 % of respondents took up no clear position. The comparatively high number of don't-knows is an indication that the general public has not yet formed a final opinion on the subject of aluminium either.

Why "either"?

I'm referring to research here, because a final decision has still to be reached in scientific risk assessment too due to gaps in the available data. Despite these blind spots, the subject still generates public attention. We have established that it is widely known throughout the population, as has been reported in the media. A peculiarity, by the way, was that the topic attracted the most attention among women and younger people.

Have the respondents changed their behaviour regarding the use of products containing aluminium due to the perceived possible risks?

Yes, there was a distinct difference between the sexes: 36 % of men stated that they had changed their behaviour as opposed to 64 % of women. It can therefore be seen that at least for some consumers, it would appear to be a controllable risk.

Where do you still see a need for clarification?

From the point of view of risk communication, we have to look at the fact that half of the population is unaware of the difference between deodorants and antiperspirants. This means that deodorants overall are associated with a risk. The BfR will make even more reference to this difference in its future communications. Because it is hardly known that food is also an important intake source of aluminium, this aspect has to be addressed more strongly too. ||

Results of the BfR studies

Public perception of aluminium

Aluminium in consumer products is a high-profile topic which is widely known to the general public and which has also been picked up on by the media.

The subject has caught the attention of women and younger people pay in particular.

Just over half of the respondents regard aluminium in consumer products as a health risk.

A third of them have changed their habits with regard to products that contain aluminium by changing to products which do not contain any, for example.

Consumers in Germany want improved labelling and more products without aluminium.



Food Safety

The safety of food is one of the most pressing tasks of consumer protection. One of its prerequisites is safe feed. Be it ingredients, additives, residues and contaminants or bacteria and parasites, the BfR assesses food and feed products and prepares expert opinions on questions concerning their safety. In the field of food safety, the BfR is involved with the toxicological, nutrition-physiological and medical assessment of food.



Food Safety

The BfR works according to the principle “From farm to fork”. This means that the entire food chain needs to be considered in safety concepts if the aim is healthy food. In addition to the Food Safety Department, the Biological Safety and Safety in the Food Chain Departments also work within the food safety field. Results gained from the toxicological, microbiological and nutritional assessments of feed and food provides the scientific basis for the setting of maximum levels or limit values. The Department for Exposure contributes to the characterisation of risks with estimates of intake levels based on consumption studies and with statistical evaluations. Furthermore, external, independent experts from nine committees advise the BfR on issues of food safety on a honorary basis.

Safety assessment of botanicals and botanical preparations in food

Botanicals and botanical preparations are a significant component of human nutrition. We have been consuming fruit, vegetables, spices and herbs for centuries. It is generally known how certain plants need to be prepared in order to avoid undesired effects and which plant parts are edible or poisonous. In the past years, interest has grown in using new plants, extracts or specific compounds of plants in food and, in particular, food supplements. Effects are often attributed to plant extracts based on their levels of secondary plant metabolites. However,

depending on the amount and other accompanying ingredients in extracts and preparations, these substances can be toxic.

Many people regard plant-based products in general as “natural” and “healthy”. Whether health risks could be associated with these products has not always been investigated. Authorities do not generally check the safety of botanicals and botanical preparations in food items before they are marketed. In the European Union, an authorisation procedure including a safety assessment is only in place for foods that have been produced from genetically modified organisms or are classified as novel food.



New plants, extracts or specific compounds of plants are increasingly marketed as food supplements.

Due to the big variety of plant-based products, it is scarcely possible for the federal states' food inspection bodies to check all of them. For this reason, a working group of federal and state governments – the BfR was also a member – compiled a list containing approximately 600 relevant plants and plant parts. This list is intended to help authorities and manufacturers in evaluating these plants and plant parts used in foods if needed. The list was published in September 2014.

From the list, the working group selected 18 examples of plants and plant parts whose use as food could pose risks. These 18 plants and plant parts were subjected to a health assessment by the BfR in accordance with the European Food Safety Authority (EFSA)'s “Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements”.

For example, goji berries, ashwaganda, serpentine root, diviner's sage, Ephedra herb and Yohimbe bark were included. The BfR concluded that nine of the plants or plant parts pose a risk to consumers and should not be used in food. In five cases, use in food might pose risks; in the remaining four cases, no risks have been observed under normal conditions when used in food.

The 18 health assessments were published in a scientific brochure (BfR-Wissenschaft) and aim to provide food control authorities a basis for their safety evaluation of foods.

A number of member states of the European Union also compiled national lists and recommendations or regulations on botanicals and botanical preparations. At a joint conference in November 2014, the National Food Institute of the Technical University of Denmark (DTU), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the BfR called for the harmonisation of approaches and systems in the different member states in order to pave the way for extensive cooperation between risk assessment and risk management bodies. In an initial step, the European Commission sent the BfR's evaluations on Yohimbe bark and Ephedra herb to the EFSA. In 2014, on the basis of the EFSA scientific opinions, the European Commission recommended adding the two plant parts to the Fortification Regulation. Ephedra herb was included in a list of prohibited substances and Yohimbe bark was put for four years under community scrutiny.

i The BfR's risk assessment on 18 botanicals and botanical preparations was published in *BfR-Wissenschaft*, edition 12/2013 (German only): www.bfr.bund.de/en > Publications > BfR-Wissenschaft



KiESEL interviewer in a respondent's home

KiESEL study: What do our children eat?

To assess the safety of food, the BfR needs up-to-date information on what and how children eat. Children are often more vulnerable than adults to various substances contained in food. Previous assessments also show that children have a comparatively higher intake of certain substances when their lower body weight is taken into account. The last comprehensive nutritional survey on this age group was conducted by University of Paderborn on behalf of the BfR in 2001/2002 (VELS Study), so the BfR is conducting a new study since 2014.

The German nutritional survey on children (KiESEL) is a module of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) conducted by the Robert Koch Institute. KiESEL examines which foods in which quantities on a day-to-day basis are consumed by infants, toddlers and children. In preparation to this project, the BfR worked on the improvement of survey methods for the purposes of risk assessment in international working groups and projects for several years and contracted research projects related to these topics. The new methods developed were successfully tested in a pretest and are now being applied for the first time.

These newly generated data will help the BfR to assess the intake of substances from foods. To ensure that the data are as meaningful as possible, the BfR is conducting the interviews throughout Germany, spread over the years 2014 to 2017. By 2017, a total of 1,000 children will be interviewed by the BfR.

i Detailed information on the KiESEL Study, how it works and the methods it uses is available at (German only): www.kiesel-studie.de

Arsenic in rice and rice products

Arsenic is a metalloid that occurs naturally in different concentrations in the earth's crust throughout the world. It can be released through natural processes or human activity. In areas with particularly arsenic-rich sediments, high arsenic levels in ground water used for the production of drinking water can pose risks to health. Plants can also absorb arsenic from the soil through their roots.

It is known that rice can contain more arsenic in inorganic form (inorganic arsenic) than other plant-based foods, including other cereal types. The levels of arsenic in rice depend on a number of factors. These include the arsenic content of the soil and the irrigation water, the type of rice, and the processing and preparation of the rice.

The toxicity of arsenic is primarily determined by the compound in question; inorganic arsenic compounds are highly toxic while organic arsenic compounds are less harmful to human health. Epidemiological studies show that the level of regular intake of inorganic arsenic in drinking water correlates among other things with the degree of risk of developing certain types of cancer. The carcinogenic mechanism of inorganic arsenic is not fully clear either. Nevertheless, there is a consensus within the scientific community that it is not possible to define a safe intake level that is not associated with a possible increase in the risk of cancer. For this reason, inorganic arsenic in any amount is not desired in food.



Rice and rice products can contain inorganic arsenic.

Analyses by the authorities of the federal states responsible for monitoring confirmed that rice and rice products such as rice cakes or creamed rice for children can contain relatively high levels of inorganic arsenic. Considerably higher levels were detected in some of these rice products as compared to rice. These findings are consistent with statements from the EFSA and authorities of other EU member states. The BfR has assessed the health risk posed by the intake of inorganic arsenic compounds through the consumption of rice and rice products for different consumer groups based on the data from the federal states. The result showed that it is possible that the consumption of rice and rice products with the measured arsenic levels over longer periods of time may increase the risk of cancer in consumers. This was based on a model (scenario) for long-term exposure on the basis of the consumption levels of rice and rice products usual in Germany.

For this reason, the levels of inorganic arsenic in food should be kept as low as reasonably achievable (ALARA principle) in order to reduce the exposure of consumers of all age groups to inorganic arsenic. The European Commission's decision to introduce maximum levels of inorganic arsenic in rice and certain rice products in the common market is a first step in this direction.

As an additional measure, the BfR proposes consumption recommendations. For example, parents should not feed their infants or toddlers exclusively with creamed rice or rice milk and should offer snacks such as rice cakes only occasionally. Consumers, including those with a gluten intolerance, should avoid nutrition focusing solely on rice and rice products. Rice should remain part of a balanced diet, however. When selecting food items, consumers should observe the general recommendation of a varied and diverse diet, particularly in terms of the types of cereal they consume.

Parents are advised not to feed their babies or toddlers exclusively with rice-based drinks or food such as creamed rice.

Lead contamination in game meat from lead ammunition

In 2010, the EFSA published an opinion with new data on the exposure to lead of the European population and on the toxicological effect of this heavy metal. In its opinion, the EFSA recommends to uphold no longer the limit for lead in the form of the tolerable weekly intake (TWI), which has been used for decades and instead to minimise the intake of lead as far as possible. Based on data from an earlier project on the intake of environmental contaminants, the BfR was able to show that consumers primarily take in lead through food that is consumed in large amounts and regularly. In contrast, game is eaten relatively rarely, but can sometimes show very high levels of lead. Here, high consumption on a regular basis could lead to a health risk of certain consumer groups, such as pregnant women and children.

To investigate whether lead content in game can be reduced, the BfR conducted the project “Food Safety of Game Meat Obtained Through Hunting” from 2011 to 2014. This project was commissioned by the Federal Ministry of Food and Agriculture and carried out in cooperation with the federal states (Länder), hunting associations, game trade association and the Eberswalde University for Sustainable Development. It is the only project of its size worldwide and it compares the effects of lead ammunition and non-lead ammunition on lead levels in game. For the purposes of this project, samples were taken from the three animal species roe deer, wild boar and red deer from several regions of Germany, with different lead contents in the soil respectively. Per animal, three samples were taken: from the haunch, from the saddle and from the marketable and edible meat near to the wound channel. Overall, sufficient and representative samples were available for roe deer and wild boar.

It was observed that lead ammunition caused significantly higher maximum concentrations of lead in game meat, particularly in the edible tissue close to the wound channel. If such pieces of game meat are regularly consumed in large amounts, this could have adverse effects on the health of pregnant women and children. However, these high values were not found in all animals shot with lead ammunition. The lead contamination caused by lead ammunition was found to be variable, and some game samples contained also lower levels of lead. For example, comparatively low levels were found in the saddle and, particularly, the haunch, which may indicate the significance of ammunition for the contamination of game with lead.

Overall, the BfR found in its project that the use of lead ammunition as compared to non-lead ammunition resulted in a statistically significant increase in the mean lead levels in meat from roe deer and wild boar. This was also the case when the effect of the regions with different lead levels in the soil and thus the lead intake by animals through feeding was controlled for. Wild boar exhibited higher mean lead levels than roe deer in this project.

Based on the results of the project, the BfR concluded in its risk assessment that the additional intake of lead from game as compared to the total intake of lead remains toxicologically insignificant for adults with average consumption patterns. However, this assessment does not apply to children and unborn babies. For this subgroup, the risk of adverse health effects from lead is particularly high. The BfR, therefore, recommends that children up to seven years, pregnant women and women of childbearing age refrain from consuming game shot with lead ammunition. In the opinion of the BfR, action should be taken to encourage the use of non-lead ammunition for hunting because this reduces the content of lead in game.

i Results of the project “Food Safety of Game Obtained Through Hunting” in three conference transcripts (German only):
www.bfr.bund.de > **Publikationen** > **Tagungs- und Abstractbände**

Information on intake of environmental contaminants through food can be found in a brochure (German only):
www.bfr.bund.de > **Publikationen** > **Broschüren**

Clarification of an EU-wide outbreak of hepatitis A

The BfR has a high level of expertise in the area of tracing food chains. The Institute developed the free “FoodChain-Lab” software for the visualisation and analysis of large volumes of delivery data (see BfR Annual Report 2013).

In November 2013, the EFSA therefore appointed a workgroup at the BfR for the clarification of a Europe-wide outbreak of Hepatitis A (HAV). At the time, a large number of cases of HAV had occurred in Italy, Ireland and the Netherlands. A total of more than 1,400 people in different European countries had contracted hepatitis A, and the strain KF182323 was confirmed in 331 of these



cases. Frozen berries were quickly identified as the vehicle of infection for this outbreak. However, the types of berries, the harvest year, and the country or region in which the outbreak originated were still unclear.

To analyse the circumstances of the outbreak, the affected countries collected traceability data for all berries suspected of being contaminated and sent this data via the European Commission to the EFSA as a central evaluation body. The BfR subsequently collated all the data in FoodChain-Lab, checked it for plausibility, and subjected it to an in-depth analysis. During several meetings at the BfR, the members of the EFSA workgroup then simulated various contamination scenarios and decided on further steps for tracing products.

The “HAV Trace” workgroup, which was made up of representatives not only of the BfR but also of the affected countries (Italy, the Netherlands, Ireland, France, Norway and Poland) and of the EFSA, the European Commission and the European Centre for Disease Prevention and Control, came to the conclusion that the most likely sources of the outbreak were redcurrants from a specific region in Poland or blackberries from Bulgaria.

i EFSA report with more detailed information on the outbreak and the results at: www.efsa.europa.eu/en/efsajournal/doc/3821.pdf

More information on FoodChain-Lab at: <http://foodrisklabs.bfr.bund.de/index.php/foodrisk-labs>

Carbapenem resistance in bacteria from livestock

Resistance to antibiotics is relevant to consumer health protection, particularly when it leads to restrictions in treating infections in humans. Research on mechanisms and factors responsible for transferring resistant bacteria from animals to humans through food is therefore of special importance. Generally speaking, antibiotic-resistant bacteria are not more pathogenic in humans than bacteria without this property. However, some of these resistant bacteria can transfer their resistance genes to other pathogens or to the bacteria in the human microflora. When resistant bacteria cause an illness, such as a wound infection or blood poisoning, they may be more difficult to treat.

The BfR investigates the distribution of resistance to carbapenems, inter alia. Carbapenems are a class of substances which are used among other things to treat infections with multi-drug-resistant *Enterobacteriaceae* which are no longer affected by important antibiotics such as cephalosporins. One mechanism leading to resistance of bacteria to carbapenems is the formation of specific enzymes known as carbapenemases. Because bacteria can pass on resistance to carbapenems to other bacteria species, consumers could theoretically take in bacteria with this resistance property through food or through direct contact with animals. In human medicine, an increase of carbapenemase-forming *Enterobacteriaceae* and other gram-negative bacteria has been observed in Germany in recent years.

During studies within the scope of the research project RESET, which investigates the prevalence of cephalosporin-resistant bacteria in animals and food, the BfR confirmed the presence of bacteria with carbapenemases in livestock for the first time in 2011. These were Salmonella isolates from three herds of fattening pigs and one flock of broilers. These resistance properties were also detected in non-pathogenic (commensal) *E. coli* from one of the herds of fattening pigs. A gene for the formation of the carbapenemase VIM-1 enzyme was identified in these bacteria through molecular biological analyses. It is not clear how the resistance genes or modified genes entered the livestock and their environment. Entry through live vectors such as people, wild animals, rodents or livestock or through non-living agents such as feed, water or air is conceivable. Since 2014, more intense checks have been in place EU-wide for the presence of isolates with carbapenem-resistance. It is encouraging that no isolates examined in zoonosis monitoring have been confirmed as capable of forming carbapenemase in Germany since this time.

In the context of EU-wide monitoring, the BfR and the EU Reference Laboratory for Antimicrobial Resistance developed and validated an improved method for detecting carbapenem-resistant bacteria in livestock and in meat in 2014. The testing institutions of the federal states implemented the method in 2015 within the scope of zoonosis monitoring. The method was also used in 2014 for the clarification of an outbreak of illness in a hospital in Hesse, Germany. In this case, food was determined as the vehicle for the transfer of germs of various bacterial species. These germs carried a resistance gene for the formation of the carbapenemase KPC-2 enzyme.

One focal point of the BfR's research is investigating the distribution of resistance to carbapenems.

i The BfR published comprehensive information on carbapenemase-forming bacteria in livestock in information No. 002/2014 at (German only): www.bfr.bund.de > A-Z Index > Carbapeneme



The BfR researches the mechanisms and factors that contribute to the transfer of resistant bacteria from animals to humans via food.

Hydrogen cyanide is released when chewing bitter apricot kernels, linseed and manioc, but legal regulations and consumption recommendations reduce the risk of impaired health.

Bioavailability of hydrogen cyanide from cyanogenic glycosides

Bitter apricot kernels, linseed and manioc contain relatively high concentrations of cyanogenic glycosides. These natural plant ingredients contain chemically bound hydrogen cyanide which is released by chewing through the β -glucosidase enzyme of these plants. Ingestion of a sufficiently high dose of hydrogen cyanide can lead to acute poisoning (see box). The BfR therefore dealt with the question of whether the consumption of bitter apricot kernels, linseed and manioc could be associated with risks to health.

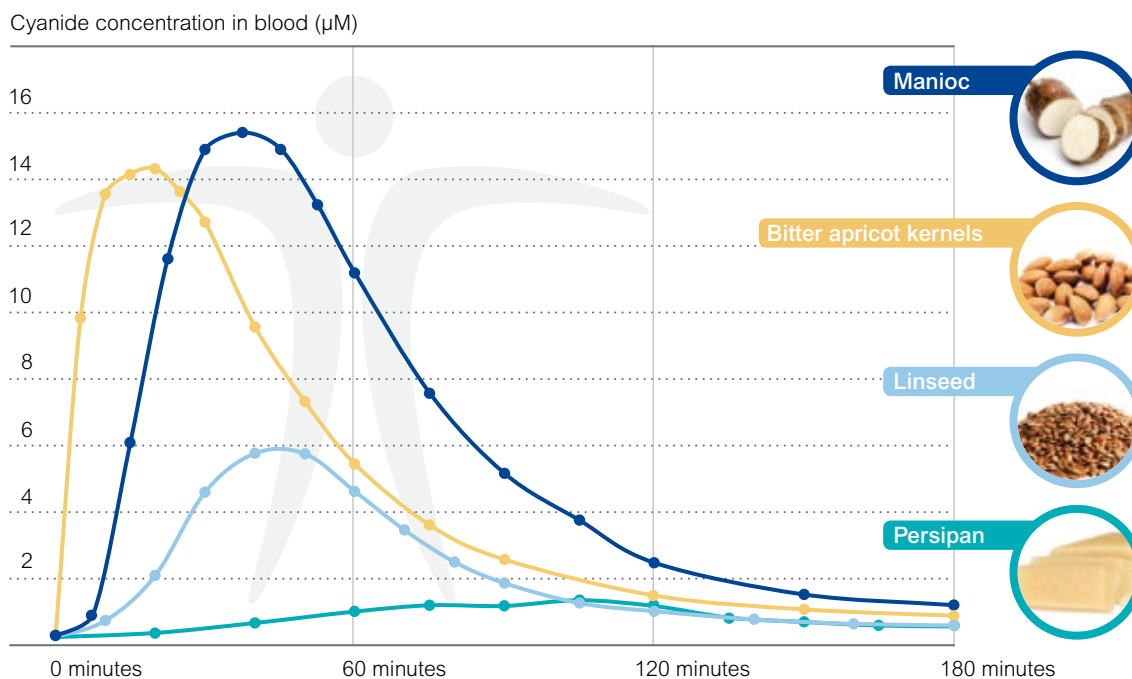
A human study with twelve subjects was conducted for this purpose. The subjects received either bitter apricot kernels (approx. 2 g), linseed (31 g), manioc (approx. 100 g) or persipan (100 g, produced partly from bitter apricot kernels) each morning. All foods used in the study contained the same dose of 6.8 mg hydrogen cyanide. The hydrogen cyanide concentrations in the subjects' blood, which were measured at regular intervals, showed significant differences. While the hydrogen cyanide values only rose slightly after consuming persipan, they were approximately ten times higher in the cases of manioc and bitter apricot kernels, placing them within a range that would be expected after a dose of 6.8 mg of isolated hydrogen cyanide. The hydrogen cyanide values measured after the consumption of linseed lay between the two extremes described above.

The effect of the β -glucosidase enzyme on the toxicity of foods containing hydrogen cyanide was made clear for the first time by the BfR study. Only high enzyme activity leads to the fast release of hydrogen cyanide and thus to toxicity that is comparable with isolated hydrogen cyanide. This can be observed in bitter apricot kernels (or bitter almonds) and in manioc, and the relevant literature confirms this finding: cases of death have been reported after the consumption of these foods in large amounts. In contrast, the natural enzyme activity in linseed is much lower. In persipan, intensive heating during production largely destroys the plant enzyme. In this case, only intestinal bacteria could contribute to the release of hydrogen cyanide.



Linseeds are a very popular addition to muesli and baked goods, but they contain chemically bound hydrogen cyanide.

Hydrogen cyanide blood count after the consumption of foods containing cyanide



Timeline of levels of cyanide in the blood after the consumption of different foods containing the same amounts of bound cyanide (mean values of 12 test subjects)

For the risk assessments of the specified foods, the study results mean in concrete terms that in line with the existing BfR recommendation, bitter apricot kernels should not be consumed at all or only in a quantity of up to two seeds per day. Before eating, large amounts of manioc should be prepared using traditional methods such as soaking, milling or drying in order to reduce the content of hydrogen cyanide. The consumption of linseed is safe, even in the presence of high cyanide contents, as long as the current recommended daily allowance of a maximum of 15 g at a time is observed. Marzipan and persipan, the maximum hydrogen cyanide limit of which is limited to 50 mg per kg food according to EU regulation, are safe in terms of hydrogen cyanide, even when consumed in very large quantities.

Toxic effect of hydrogen cyanide

The first clinical symptoms of hydrogen cyanide poisoning are vomiting and impaired consciousness. The range of concentration from which critical effects can be expected is known from the analysis of cases of hydrogen cyanide poisoning. The toxic effect depends primarily on the maximum blood concentration reached rather than on the total amount consumed.

i The study results were 2015 published in the "Archives of Toxicology" specialist journal: DOI 10.1007/s00204-015-1479-8, open access



Product Safety

Consumers come into contact with products such as cosmetics, food packaging or toys on a daily basis. It is the task of the BfR to contribute to product safety through its recommendations. The field of product safety comprises a variety of different products: cosmetic and hygiene products, food packaging and containers, toys, clothing, detergents and cleaning products, tobacco products and other consumer products such as furniture, mattresses, carpets and hobby products. The results of the BfR's risk assessments are incorporated into recommendations for legislators, manufacturers and consumers.

Eigentum der Behörde
BfR



Product Safety

Product safety is an important aim of consumer protection and involves questions such as: Can toys or cosmetic product pose a health risk? In answering these questions, the Chemicals and Product Safety Department examines not only the substances used, but also the release of these substances. This is because the issue of whether a health risk exists for a particular product depends first and foremost on how consumers come into contact with the substances it contains. The committees for Consumer Products and for Cosmetics as well as the National Reference Laboratory for substances that come into contact with food are attached to the department.

Release of heavy metals from ceramics and glassware

Ceramics and glassware for cooking and baking as well as for storing and serving food can be found in every household. The range of products includes earthenware, porcelain, stoneware, glass and crystal glass. Surface finishes such as engobes, glazes and patterns add to the design of the products.

However, ceramic tableware, coloured glassware and lead crystal glass can contain heavy metals such as lead and cadmium which may release into foods. This is dependent, amongst other factors, on whether the ceramics were fired at high or low temperatures and the type of food that was stored in the container and for what period of time.



Ceramic tableware can contain heavy metals such as lead and cadmium that could be released to food.

In Europe and Germany, limit values have been established for the release of heavy metals from ceramic articles that come into contact with food. For ceramic articles which can be filled, such as cups and bowls, the currently applicable limits are 4 milligrammes per litre (mg/L) for lead and 0.3 mg/L for cadmium. From ceramic articles that cannot be filled such as plates, a maximum of 0.8 mg of lead per square decimetre (dm²) and 0.07 mg of cadmium per dm² can release. In Germany, official control laboratories monitor compliance with these limits.

As a result of a reassessment carried out by the European Food Safety Authority (EFSA), new limits for lead and cadmium for food contact with ceramic articles can now be expected in European legislation. These are significantly lower than the current limits and correspond with the recommendations made by the BfR who had recommended a reduction in the legally permitted limits for the release of lead and cadmium from ceramic articles as early as 2005. Furthermore, in addition to the possible integration of the glassware product group into the new ceramic legislation, an expansion to include elements such as aluminium, arsenic, barium, cobalt and chromium is also part of the discussion.

For the amendment of the existing legislation, the European Commission has assigned several laboratories with the development of the scientific and technical principles, namely the National Reference Laboratory (NRL) for Food Contact Materials located at the BfR, the European Union Reference Laboratory (EURL) and the national reference laboratories of Great



Staff at a National Reference Laboratory based at the BfR develop and validate analysis procedures to check the release of heavy metals from ceramics and glassware into food simulants.

Britain and Belgium. One aim of this cooperation is the establishment of new, robust test conditions for the testing of ceramics and glassware as well as the validation and standardisation of sensitive, modern analytical methods. Using a representative number of different ceramics and glassware, the EURL-NRL network will develop an adequate basis of data for the EU. To this end, in a Europe-wide sample collection the EURL has acquired relevant ceramics and glassware from various manufacturers which can be used by the EURL-NRL network for its investigations. The release of elements such as lead, cadmium, aluminium, barium, cobalt, copper, manganese, nickel, selenium, arsenic, mercury and thallium was analysed using inductively coupled plasma mass spectrometry (ICP-MS). Tomato sauce and food simulants such as 4 % acetic acid and 0.5 % citric acid acted as the test foods.

This analytical method, which was optimised in the EURL-NRL network, was successfully validated as part of a proficiency test in 2014. Further issues such as the harmonisation of test conditions for the release of elements from various ceramics and glassware can now be dealt with using this method. The release of elements from the rims of cups, drinking glasses and drinking containers is just as much a focus as the migration of

elements from ceramics and glass to food under high temperatures or in the microwave.

Primary aromatic amines in paper napkins

Primary aromatic amines can be found in various food contact materials. They can be present in the form of impurities, for example, in paper napkins with colourful print if azo pigments were used in the printing inks as a colouring component. If these napkins come into contact with food, primary aromatic amines can be transferred to the food and therefore ingested by humans.

From a health perspective, primary aromatic amines (PAAs) represent a heterogeneous class of substances. For some members of this class, a potential carcinogenic effect must be taken into consideration. While a large number of PAAs are safe in this respect, some PAAs are known human carcinogens. Based on studies involving animal experiments, others are seen as potentially carcinogenic for humans. The corresponding classifications for the toxicological effect of PAAs are laid down in Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures, the so-called CLP Regulation.

Paper napkins with colourful print can contain primary aromatic amines. These potentially harmful substances are transferred to foods when they are stored in napkins over long periods.

Fundamentally, consumer contact with these substances should be limited as much as possible. The BfR recommends the application of the so-called ALARA principle due to their carcinogenic potential. This means that their presence in materials that come into contact with food should be as low as technically possible. On a European level, a total limit value is currently defined in EU Regulation 10/2011. This applies to migration from plastics and stands at a maximum of 0.01 milligrammes (mg) of PAAs per kilogramme (kg) of food.

Compliance with the limit value is monitored by the laboratories of food control authorities. In order to verify their efficiency, these laboratories must test their methods of analysis on a regular basis. This serves as quality control and takes place via inter-laboratory comparison studies for proficiency testing. In order to determine the transfer of PAAs from napkins, the National Reference Laboratory



Primary aromatic amines enter the printing ink on paper napkins via certain colourants.

for Food Contact Materials which is attached to BfR carried out a proficiency test. Carrying out these proficiency tests is one of the key tasks of reference laboratories. 19 different laboratories from four European countries participated in the BfR's proficiency test.

Cold water extracts are used to simulate the levels at which PAAs from napkins are transferred to food. As part of the proficiency test, the laboratories prepared cold water extracts from four different napkins in accordance with the specifications of European Standard (EN) 645. In each cold water extract, a predetermined PAAs was to be identified. In addition, the laboratories received two pre-made cold water extracts, with four PAAs to be identified in each one. For the analysis of the cold water extracts, the participants used the existing methodology in their laboratories. The results of the proficiency test show that the participating laboratories have a very good command of the creation of cold water extracts and the analysis of PAAs. Additionally, the laboratories were able to determine values which were ten times lower than the total limit value of 0.01 mg/kg.

These results support the BfR's position of introducing a restriction, in addition to the aggregate detection limit, for the individual primary aromatic amines that are classified as carcinogenic or potentially carcinogenic. This is oriented towards values which are still analytically detectable. Accordingly, the value for the transfer of these PAAs into food or food simulant should be limited to 0.002 mg/kg.

i FAQs and the BfR's opinion on primary aromatic amines can be found at:
www.bfr.bund.de/en > **A-Z Index** > **Aromatic Amines**

The BfR's studies were 2015 published in the "Food Additives and Contaminants" specialist journal (Epub):
www.tandfonline.com/doi/pdf/10.1080/19440049.2015.1060661

Studies on ingredients and emissions of e-cigarettes

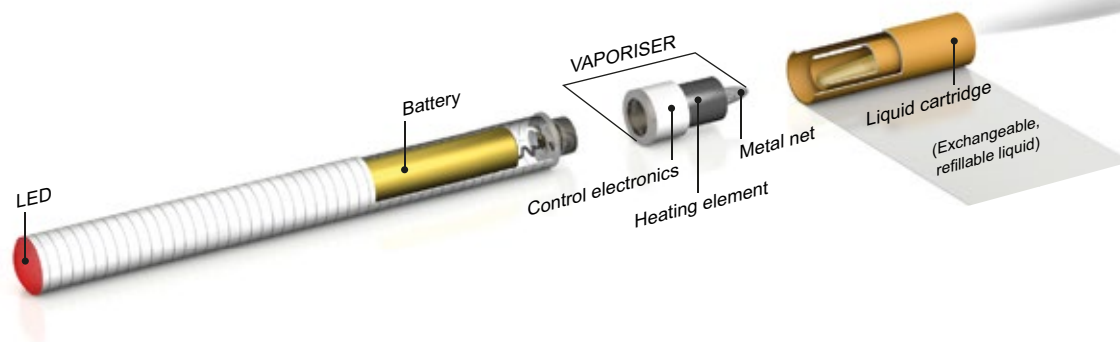
Electronic cigarettes (e-cigarettes) have been marketed in Germany for several years and have since created a new field of work for risk assessment and experimental research. Last year, the BfR published the studies it has carried out thus far regarding ingredients and emissions in order to create a database for the risk assessment of electronic cigarettes. The basis for this was a study involving 28 samples of so-called e-liquids acquired by the BfR at retail in Berlin or over the internet. Nicotine levels, fumigation agents and selected ingredients were studied amongst others. Ten samples were declared “nicotine free” by the manufacturers, yet nicotine was found in seven of them. The levels were between 0.1 and 15 milligrammes (μg) per millilitre (ml) of liquid and were therefore low. It is likely that the nicotine entered into the production and filling machines as a contaminant. There were no references to nicotine on the packaging of the remaining 18 samples, even though in some cases levels of up to 324 μg per ml of liquid were detected. The BfR studies documented the use of a wide variety of scent and aroma substances, with allergenic substances such as eugenol, cinnamaldehyde, linalool or benzaldehyde also detected. Four samples contained coumarin, which is banned in tobacco products and tobacco-related goods. In place of propylene glycol and glycerol, ethylene glycol was used as a fumigation agent in some e-cigarettes, the use of which is not permitted in tobacco products. This unexpected finding illustrates the fact that considerable uncertainty will remain regarding the composition of the liquids until a statutory duty of notification is introduced.

For the BfR study, the Chemical and Veterinary Test Agency (CVUA) in Sigmaringen also investigated the vapours inhaled by users of e-cigarettes. There were indications of exposure to carcinogenic formaldehyde and other harmful carbonyl compounds which are formed from the fumigation agents upon heating. For the carbonyl compounds, a significant increase was found after around 80 puffs using an adapted machine smoking regime. The remaining, 50 further puffs maintained levels of formaldehyde and other carbonyl compounds in the range of conventional cigarette smoke. It can be assumed that the overheating caused by low fill levels in the depots favours the formation of carbonyl compounds. These additional risks could probably be largely minimised by technical safety features such as fill level displays. In light of the large number of newly developed products in recent years, the minimisation of harmful emissions should be considered to a greater extent in the future.

The BfR's investigations showed that, for the analysed samples, no acute toxic risks can be expected and the health risks are significantly lower compared to conventional cigarettes. Nonetheless, many questions remain unanswered concerning both the long-term health risks and the safety of aromas and additives. Although many additives can be used in food, the risks of inhalation have generally not been tested. Like smokers, the users of e-cigarettes need to accept both known and as yet unknown health risks, although these risks are much lower in relation to conventional tobacco products.

i FAQs on the topic of e-cigarettes can be found at: www.bfr.bund.de/en > A-Z Index > Electronic Cigarette

The BfR's studies were 2014 published in the “Archives of Toxicology” magazine: <http://link.springer.com/article/10.1007%2Fs00204-014-1294-7>



Design of an e-cigarette



Chemicals Safety

Chemicals surround us in all areas of our daily life. This means that safety when dealing with them is very important. The BfR assesses risks for consumers, users and all other groups of people who come into contact with these substances. Furthermore, the BfR supports the appropriate labelling of substances, safe transport conditions and reliable detection methods. In the working area of chemicals safety, the BfR assesses the health risk of chemicals, pesticides, biocides and hazardous goods. The BfR also documents cases of poisoning and formulations of chemical products in order to quickly recognise undesirable effects.



Chemicals Safety

The working area of chemicals and pesticide safety affects many areas of consumer and user health protection. The BfR is one of the central institutes for health-related substance assessments in Germany. Multiple departments of the Institute, such as the Departments for Exposure, for Chemicals and Product Safety and for Pesticide Safety, are concerned with this issue.


Omics methods in regulatory toxicology

In the life sciences, the term omics refers to a range of bioanalytical methods which can be used to examine complex molecular changes in biological samples. With such methods, changes of biomolecules in cellular systems can be recorded as a whole. Genomics, for example, are methods which simultaneously analyse genes of a cell or tissue in a single experiment.

As foreign substances such as chemicals can already have an effect on a molecular level, the application of omics methods of toxicology creates new possibilities. Such methods can therefore help to explain mechanisms which have an underlying toxic effect, such as liver damage caused by a particular substance. However, their use for regulatory purposes, such as the authorisation procedures for pesticides, is still in its early stages and is currently subject to considerable uncertainty with regard to reliability and the interpretation of the data.

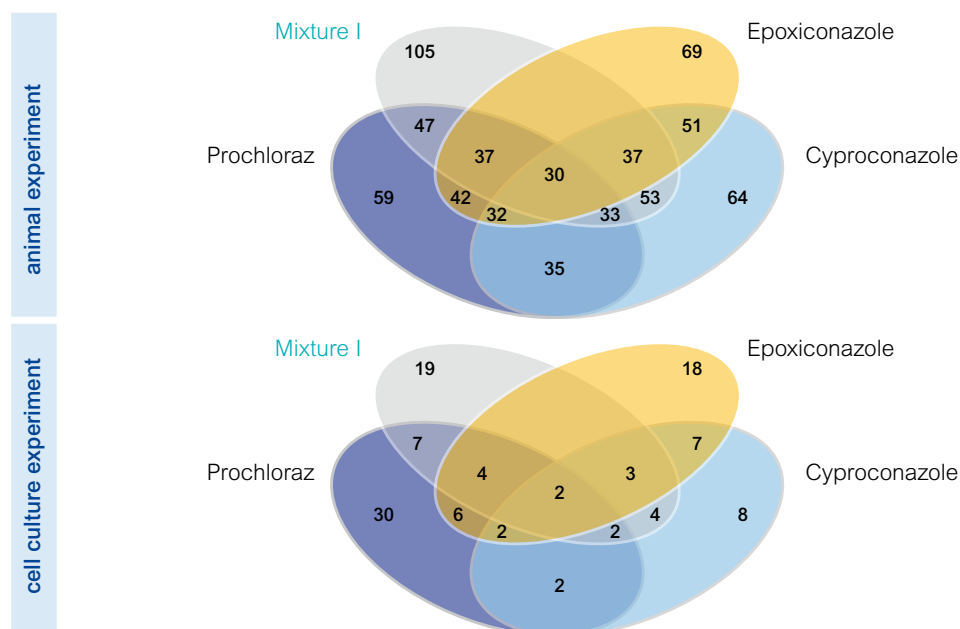
To achieve progress in this area, the BfR conducts its own research. For example, the Institute investigated the combination effects and toxicity mechanisms of fungicides in animal studies and cell culture experiments using omics methods. The aim was to find out whether changes in the cell culture observed with omics methods were similar to those in animal studies and whether cell culture experiments could replace animal testing in regulatory procedures in the medium term. In the BfR study, rats received various test substances over 28 days, both separately and in combination, as did the cell cultures. Using a particular omics method (transcriptomics), the institute then analysed how the individual substances and their combinations influence the expression of certain genes. The focus of BfR's investigation was one main target organ of the substances: the liver and corresponding liver cell lines.

A result is shown schematically in the diagram on page 57. The animal experiment showed that fungicide mixtures influence more genes in total than the individual substances. In mixture 1 there were 105 modified genes compared to the 69 and 64 genes that were altered by separate application of epoxiconazole and cyproconazole. In addition, several genes were found that were modified by all substances and combinations (30 in the animal experiment, two in the cell culture experiment) and could serve as markers for the toxicity of mixtures. The gene expression patterns also allow the detection of similarities and differences in the toxicity mechanism of the various tested substances.



Omics methods analyse all changes of biomolecules in cellular systems at the same time in a single experiment.

The BfR's results on the combination effect of fungicides using omics methods



The diagram shows the number of modified genes in the animal experiment (above) and the cell culture experiment (below) for individual substances and combinations (mixture 1).

The question how results obtained by omics methods can be used for regulatory purposes was the focus of an international experts' workshop at the BfR in October 2014.

The following important conclusions were drawn:

- > Harmful effects of a chemical can currently only be clearly determined in intact organisms. However, the new parameters and methods can help to identify mechanisms of action and to determine their relevance for humans.
- > For more extensive use of omics methods in the future, associations between the obtained data and clinical or pathological modifications must be shown. It will be necessary to use different methods independently and to combine the results for a reliable conclusion. It will not be possible to rely on an individual test.
- > Validation of the individual methods is a prerequisite for their use for regulatory purposes.

i As a result of the conference, the BfR published a workshop report that served as the basis for the discussion of future developments (German only): www.bfr.bund.de/cm/343/omics-methoden-in-der-regulatorischen-toxikologie-experten-diskutieren-moegliche-anwendungen.pdf

Do registration dossiers of chemicals meet the legal requirements?

In the European Union, chemicals may only be used when the risks they pose can be adequately controlled. To this end, they must be registered at the European Chemicals Agency (ECHA). When registering a substance, information regarding the harmful effects of the chemicals on humans and the environment must be provided. What information is mandatory is laid down in the European Chemicals Regulation (REACH).

In a research project, the BfR reviewed 1,932 registration dossiers of chemicals that are produced in particularly large amounts – over 1,000 tonnes per year. It was verified whether the registrants provided all of the required information on the important long-term effects of these chemicals.

In order to systematically compare the information provided with the standard requirements set out in REACH for high tonnage substances, decision trees were developed within the project for a wiki-based software. Using this, the BfR checked which standard requirements were fulfilled or not fulfilled by the registration dossiers or whether no conclusive decision could be made.

The analysis showed that information was missing in more than half of the registration dossiers. For example, in a quarter of the dossiers the data on mutagenicity effects of the registered substances were incomplete (see chart). It also became clear that registrants frequently used the legal option of deviating from the standard requirements. For example, they submitted data collected by using methods that are no longer recognised today. Data regarding structurally similar substances were also submitted in order to predict the effects of a registered substance on human health and the environment.

If the legal requirements for the registered substance are fulfilled by deviating information, then scientific justification is required. As specific data are usually submitted for this, case-by-case assessments must be carried out for

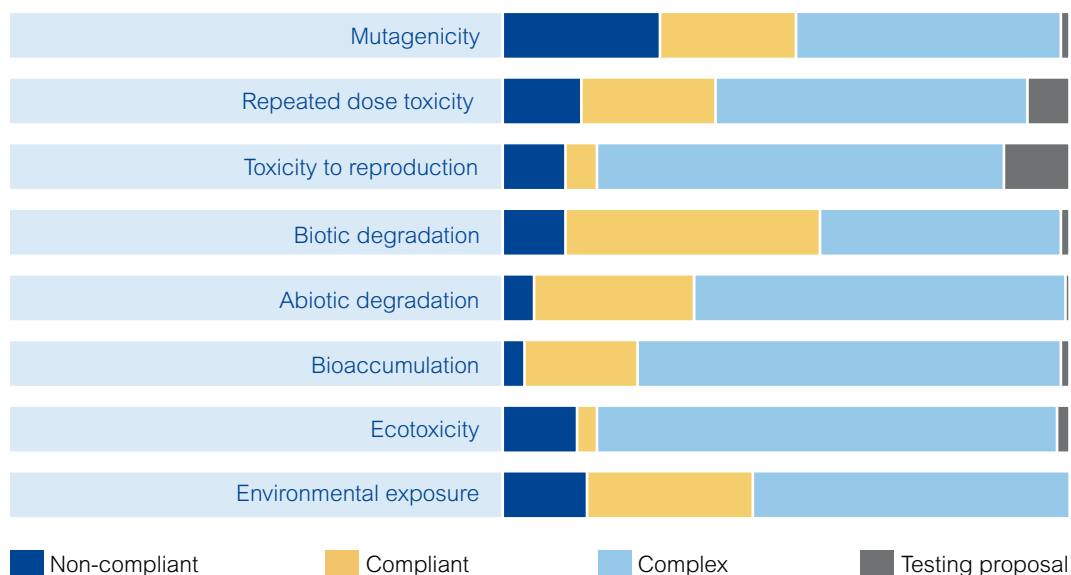
these registration dossiers. In this project, therefore, no conclusive decisions could be made for these cases with regard to the conformity of the data with the standard requirements. However, some of these issues will be now investigated further in a follow-up project.

The BfR, the German Federal Environmental Agency (UBA) and ECHA are using the results of the project to identify substances which require regulation and to carry out risk management measures. The project was carried out in collaboration with UBA and funded by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety.

Long-term effects of chemicals

To be able to draw conclusions on the potential long-term effects of chemicals on health or in the environment, certain toxicity studies for chemicals are required in the REACH Regulation. This includes repeated dose toxicity, mutagenicity, toxicity to reproduction and ecotoxicity. In order to evaluate the environmental fate of a substance, studies are required on biotic and abiotic degradability and bioaccumulation.

Data availability in REACH registration dossiers



The BfR reviewed 1,932 REACH registration dossiers to verify whether they contained the required information regarding potential long-term effects of chemicals. As a result, it was judged whether the available information complies with the REACH requirements (= category "compliant") or not (=category "non-compliant") or whether no conclusive decision could be made within the scope of the project (= category "complex" and "testing proposal").

Setting maximum residue limits for biocides

Biocidal products such as pest control products or disinfectants are used to combat harmful organisms such as bacteria, cockroaches or mice. When these agents are used in animal husbandry or the manufacturing, storing or processing of food and feed, residues can remain in the food. The European Biocidal Products Regulation (Reg. [EU] No. 528/2012) stipulates the setting of maximum residue limits (MRL) in certain cases. These limits guarantee safe food, form the basis for food monitoring and function as trade standards for domestic and imported products.

Key aspects of the exact procedures for setting the maximum residue limits in the EU were discussed by representatives of the European Commission, European and national authorities and European associations at the “European Conference on MRL-Setting for Biocides” in March 2014. As the BfR is involved in various legal procedures concerning the assessment of plant protection products and biocides, the Institute organised the event along with the Directorate-Generals for the Environment and for Health and Consumers from the European Commission.

The main point of discussion was how biocidal applications that can lead to relevant residues in food can be identified as efficiently as possible and for which active substances the setting of MRLs should be prioritised. Data suitable for this purpose from national monitoring programmes and company inspections are scarcely available in the EU. Computational models could serve as an alternative here. The use of default maximum residue limits (see information box) was also discussed. These could create legal certainty for the monitoring of many biocidal active substances with minimal effort and could, if required, be replaced by specific, scientifically verified values.

The regulatory framework into which the MRLs for biocides could be integrated was also discussed. As corresponding values have already been set in other regulatory fields, it is important to pay attention not only to overlaps, but also to synergies. For example, MRLs from biocidal applications in the presence of livestock are already regulated together with veterinary medicinal products in Regulation (EC) No. 470/2009. According to the majority of conference participants, MRLs of all other biocidal applications should be regulated as part of Regulation (EC) No. 396/2005 on residues of active substances from plant protection products. To achieve this, the legal texts must be adapted to the specific application areas of biocides, for example with regard to the definition of the food groups concerned. Cross-pro-



Hygiene during milking is important. However, residues from disinfectants can be transferred to milk during cleaning of the udder and the milking tubes.

cedural coordination would also be important for considering existing values and proposed values from various other procedures (biocides, plant protection products, veterinary medicinal products etc.). The discussion also covered principles of the assessment of residues and the need to finalise harmonised guidelines for the assessment of biocide residues.

i As a result of the conference, the BfR published a workshop report which serves as the basis for the discussion between European member states regarding further measures:
www.bfr.bund.de/en > Events > Archive 2014 > Conference Report “European Conference on MRL-Setting for Biocides”

What are default maximum residue limits?

These are values which automatically apply when no specific maximum residue limit (MRL) has been defined. They are used e.g. in the framework of plant protection products: scientifically-based specific MRLs are derived for the individual active substance(s) contained in the product and apply to certain foods. If no specific value exists, then a default maximum residue limit of 0.01 milligrammes per kilogramme of food (mg/kg) applies. This means there is a concrete legal provision regarding the residues allowed in foods for every active substance.



Risk Communication

The second key task of the BfR is risk communication. It is defined as a continuous and interactive process characterised by a participative dialogue with various target groups. In this way, risk communication goes far beyond the provision of information to all groups involved and all interested parties with regard to the Institute's assessment work and its results. The timely provision of information to the general public concerning possible health risks, research findings and work results forms the basis of this dialogue. In its risk communication, the BfR pursues three principles in order to strengthen the trust of everyone involved in the process of risk assessment: transparency, reliability and the greatest possible openness.





Risk Communication

At the BfR, there is a specific department for Risk Communication which informs the general public about possible health risks and the research results which form their basis. It enters into the dialogue with the various target groups through measures involving classical press and public relations activities, as well as through events such as expert panels, consumer protection forums, conferences and public symposiums. In addition to this, research projects on the perception and early identification of risks and prediction of their consequences are conducted in the department with its interdisciplinary structure. Prevention and coordination of crises is another task of the Risk Communication Department, which receives external know-how through the Risk Research and Risk Perception Committee.



Posters and leaflets for physicians' practices, pharmacies and day care centres further increase awareness of the BfR app "Poisoning accidents among children" among parents and staff.

Transparency, openness and comprehensibility in risk communication

The remit of the department is to present the process of risk assessment as transparently as possible and to make science understandable and usable for all BfR target groups. In addition to classical press and PR work, the BfR enters into an active dialogue with its partners from science, trade and industry, politics, the media, trade associations, non-government organisations and consumer groups through various interactive communication forums. The participative formats include discussions with experts, status seminars, consumer protection forums, stakeholder conferences and public symposiums.

An important instrument of BfR risk communication is the website www.bfr.bund.de where all of the results of the work of the Institute which are relevant to the public are published. Modern, interactive media formats – for the classical website, social networks and also for mobile use on smartphones or tablets – are intended to further increase understanding for questions of consumer health protection and the level of awareness of the BfR.

A mobile offer with great benefits is the app "Poisoning Accidents Among Children" which was developed by the BfR. It was awarded the German Prize for Online Communication in 2014 in the category "Mobile and App". With the aim of preventing cases of poisoning, the app provides important information on potential poisoning with chemical products, drugs, plants and mushrooms and enables a direct connection to the closest Poisoning Information

Centre in the event of poisoning. The app is in great demand among parents and teachers. To further increase awareness of the app, the BfR developed information material, such as posters and memo cards in business card format. Interested physicians, pharmacists and teachers were able to procure and distribute the media free of charge. As a result, the access figures to the app rose by 30,000 downloads.

In 2014, two BfR films appeared in the interactive video format “Consumers ask – the BfR answers”. In this series, consumers ask questions about a predetermined topic before voting on which three questions the BfR should answer in a video. The BfR expanded the format in 2014 by adding an introductory film which explains the content of each topic to the audience.



BfR-film “What to do with the chicken?”

The two-minute film “What to do with the chicken?” was released on the BfR website and in the YouTube video portal in 2014. It explains in entertaining fashion the dangers of cross-contamination by germs and the rules of kitchen hygiene. Due to the continuing demand from public and private institutions in Germany and abroad, the BfR is also making the film available for teaching and training purposes as DVDs in various languages.

Opinions on the film

“I would like to compliment you for the nice initiative.”
(Italian Health Ministry)

“Your film was very helpful and useful for our training sessions with child minders.”
(Weimar City Administration)

Facts and figures about press work

4,284,921	visits to the BfR website
141,605	downloads of the BfR app
85,515	“Poisoning Accidents Among Children” delivered publications (brochures etc.)
21,708	views in the BfR YouTube channel and BfR media library
7,417	subscribers to the BfR newsletter
4,074	mentions of the BfR in newspaper articles
1,119	inquiries from private citizens (in writing)
46	interviews



Antibiotics and antimicrobial resistance in the perception of the general public

The resistance development of germs to antibiotics is one of the most discussed health problems in Germany. Livestock farming and the increased use of veterinary drugs that has been observed there are regarded in the public debate as the main causes of antimicrobial resistance. From the BfR's risk assessment point of view too, the use of antibiotics in animal production should be viewed critically and the husbandry and management of herds and flocks improved so that the animals remain healthy and treatment with antibiotics is not necessary. Slaughter methods should also be further developed in order to reduce the transfer of germs from animals to foods. The use of antibiotics in the field of human medicine should also be viewed critically in some areas as it contributes towards the spread of antimicrobial resistance.

But what does the general public know about antimicrobial resistance, how is it perceived and how do the media deal with the subject? The BfR investigated these questions in two perception research projects. In the first, a media analysis, the BfR examined the print and online media in the period from January 2008 to December 2013. In the second, a population survey, the BfR interviewed 1,005 persons aged 14 and over about their knowledge of

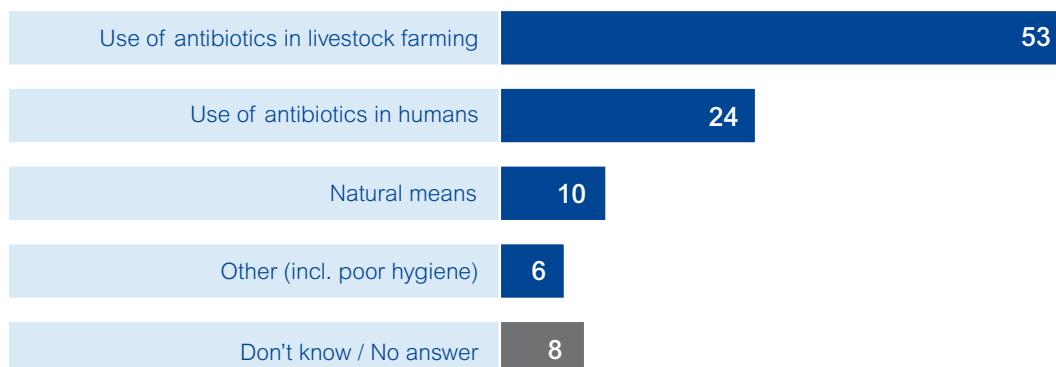
and attitudes towards antimicrobial resistance. The project results serve as a basis for sharpening awareness of the problem among consumers with the help of specific communication measures.

The population survey showed that a large majority of consumers in Germany are aware of antimicrobial resistance and that the topic is at the forefront compared to other consumer topics. 82 % of the respondents stated that they had already heard of it and 64 % of consumers are concerned about it. Although the problem is known in wide sections of the population, only a minority of not quite 20 % considers it likely that they will come into contact with disease pathogens in their own homes. A large majority of those questioned therefore do not expect to encounter resistant bacteria at home. It is considerably more likely, in the view of the respondents, to come in contact with disease pathogens in hospitals (63 %) or in public places, such as when using public transport (59 %). With a level of 90 %, the vast majority of respondents stated that they know how to protect themselves from disease-causing bacteria in their own homes. The most common answers were frequent hand-washing (39 %), observance of hygiene (35 %), the use of disinfectants (34 %) and thorough cleaning (31 %). The cause of the occurrence and spread of antimicrobial resistance is seen by the majority of respondents (53 %) to be the use of antibiotics in livestock

Causes of Antimicrobial Resistance – the perception of the general public

What is the main cause of antimicrobial resistance in your opinion?

predefined multiple-choice



Base: 834 respondents who have heard of bacteria with antimicrobial resistance; all figures in percent

Source: BfR Consumer Monitor Special Antimicrobial Resistance (2015)

There is a growing awareness among the general public and in the media for the occurrence and spread of antimicrobial resistance. The cause of it is seen to lie mainly in the area of livestock farming.

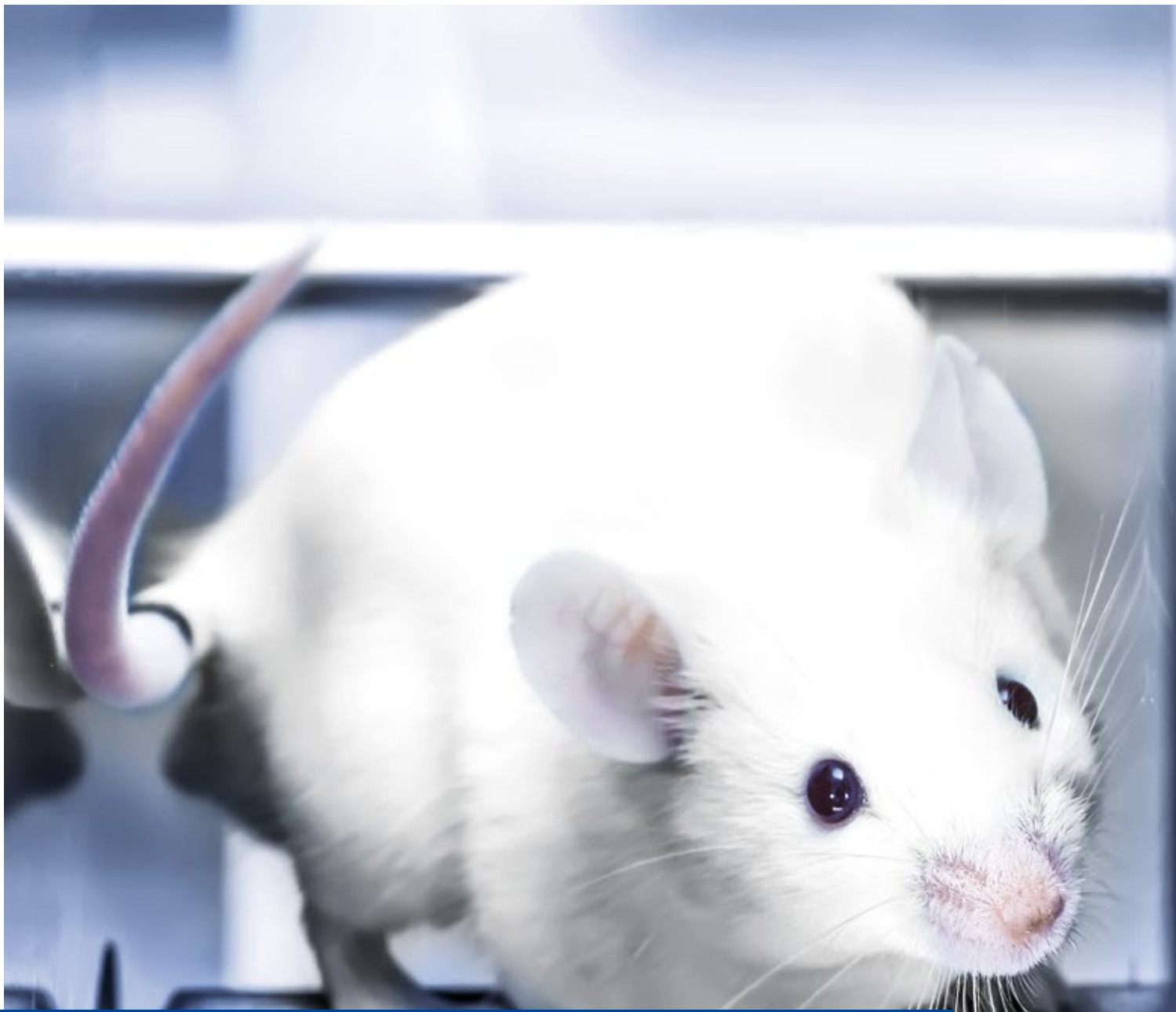
farming, while a minority (24 %) see the causes in the use of antibiotics in humans. Of those who see the cause of resistance in the use of antibiotics in humans, the most common cause is given as erroneous prescription by the doctor (43 %). A third of them suspect incorrect use of the drugs by the patients.

The high level of awareness of the problem among the general public can also be attributed to the presence of the topic in the media. The BfR media analysis of 3,373 articles showed that the number of reports about antibiotics and resistant germs rose steadily in the six years from 2008 to 2013 and reached its climax in 2012 with 789 articles. With articles that gave more detailed information about antibiotics and resistant bacteria (1,922 in total), the number of reports which made implicit reference to the dangers rose by 120 % between 2008 and 2013 to 196 articles, while the number which made explicit reference to the dangers rose by 81 % to 165 articles. Reporting on health hazards focused on topics related to the theme of “People” which presumably attracted more consumer attention to the problems and which also corresponds with the comparatively high level of concern. The transfer of bacteria in hospitals was also mentioned most often in articles which thematised dangers to human health.

Overall, the results show that there is a distinct and in some instances growing awareness of the occurrence and spread of antimicrobial resistance in the general public as well as the media. Although the findings of the population survey and media analysis do not contradict the results of the risk assessment, the general public should be given even more specific options for taking action to stem the problem in future. Accordingly, the BfR is recommending that consumers only eat meat that has been well heated and that they observe the rules of kitchen hygiene in order to prevent the transfer of germs to other foods. The awareness of the problems among the general public and in the media can be seen here as a valuable resource for successful risk communication.

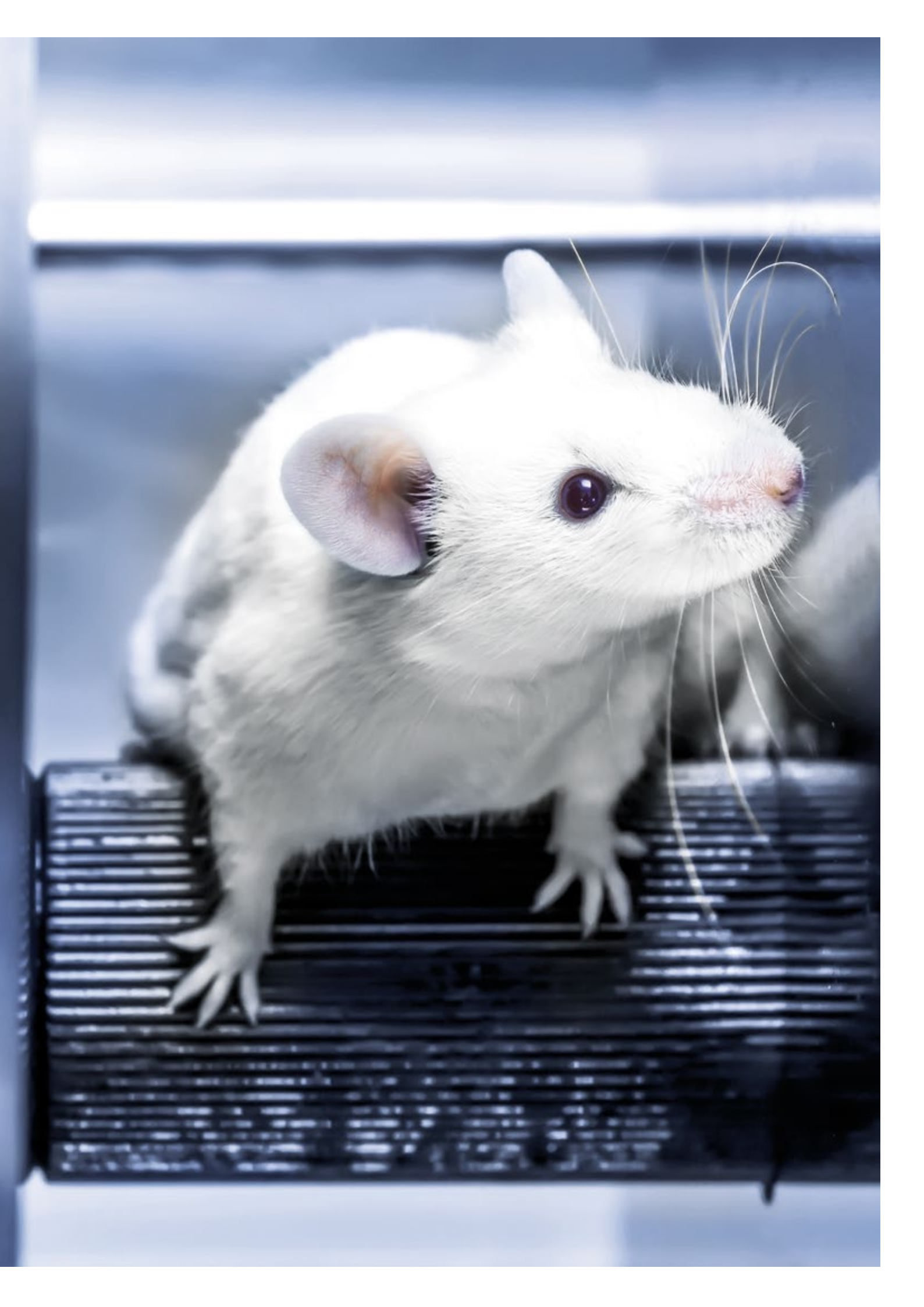


What does the general population know about resistance to antibiotics? The BfR addressed this question in two perception research projects.



Alternatives to Animal Experiments

Scientific experiments using animals are conducted in all areas of life sciences. In basic research in particular, they help to recognise new scientific interrelationships. Current legislation also requires convincing animal experiments within the scope of the toxicological testing of substances. At the same time, however, the requirement to use alternatives to animal experiments when and wherever possible is firmly anchored in the German Animal Welfare Act. The assessment and development of alternative and complementary methods to animal experiments therefore constitute an important task of the BfR. This includes not only fulfilling legal tasks, but also BfR's own research and the support of external projects in this field. In addition, the Institute is committed to improving the living and housing conditions of animals used in experiments.



Alternatives to Animal Experiments

At the BfR, the Experimental Toxicology and ZEBET department develops and evaluates various alternative and complementary methods to animal experiments in line with the 3R principle. It prepares new toxicological assessment strategies and dedicates itself to innovative online-based technologies to search for and assess internationally developed alternative and complementary methods. The department also develops new concepts to reduce the number of animals used in experiments. Through the new Animal Welfare Act, the BfR is obliged to involve itself with ways and means of reducing the pain and suffering of laboratory animals. For this reason, an experimental animal management section, which can draw on high-level expertise in the field of laboratory animal science, is integrated into the department.

BfR database on animal testing projects in Germany

With the third law amending the Animal Welfare Act in 2013, Germany implemented the goals of European Directive 2010/63/EU on the protection of animals used for scientific purposes. Since then, one of the special objectives of the new legislation has been to publish information on all projects in which test animals are used in the form of so-called “non-technical project summaries”.

In this regard, the BfR was given the task of publishing these generally understandable project summaries of approved animal testing projects in Germany on the internet. To do so, the BfR developed the AnimalTestInfo database in close cooperation with the competent authorities of the federal states, who are responsible for authorising animal experiments, and published it on the internet in December 2014 (www.animaltestinfo.de). It is the first web-based database solution in Europe to publish project summaries on animal experiments. AnimalTestInfo contains information on all animal experiments requiring authorisation, which were requested by the scientific research institutes of the universities, industry and national government in Germany.

Basically, the project summaries are prepared by the applicants and sent to the competent authority together with each respective application for project authorisation. If the conducting of the animal test is allowed, the competent authority sends the anonymised project summary to the BfR within three months. The BfR then publishes the data within twelve months. The project summaries may not violate any property rights or contain any institution or person-

related data. The applicants are responsible for ensuring compliance with these stipulations.

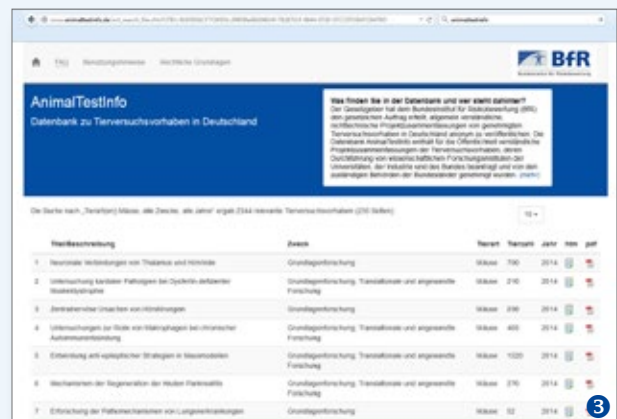
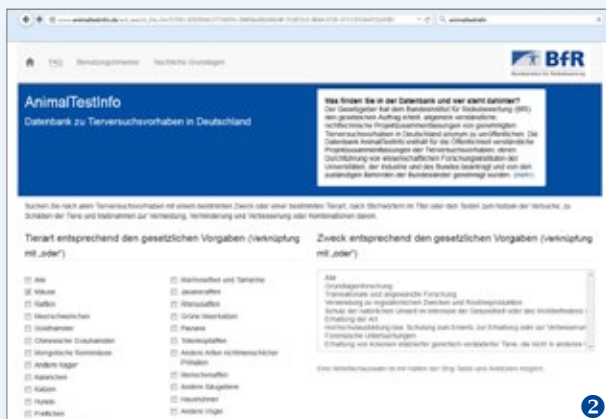
The project summaries provide information on the legally possible purpose that the animal experiments serve, the expected benefits of the experiments and the expected adverse effects on the animals used. Information on the planned number and species of the animals to be used (mice, rats etc) is also given in the summaries along with details of the measures that have been taken in advance to avoid the use of animals, reduce their numbers in the test or improve their wellbeing. Applicants explain the expected benefits of the test project on the basis of the following questions: Which scientific question is to be answered? What scientific progress is being sought? How will the project benefit humans or animals?

The AnimalTestInfo database contributes towards satisfying the interest of the public in objective information on animal test projects. In addition to this, it will provide scientists with valuable information on future research priorities for the field of alternative methods. To this end, the database offers the users different research paths. With the help of various pre-set or freely selectable search functions, a search can be made for the animal species, the numbers of animals used per species, the year of publication, the purpose of the test or for keywords in special fields. These search functions are explained in detail in the user instructions.

 The BfR reported 2015 on AnimalTestInfo in the specialist journal “Nature”:
www.nature.com/nature/journal/v519/n7541/full/519033d.html?WT.ec_id=NATURE-20150305

Navigation through AnimalTestInfo

The start page www.animaltestinfo.de offers interested users a clear and easy introduction searching animal experiments authorised in Germany. Via the “Search” button, users reach a selection mask with the help of which they can narrow down the search. The search results are then displayed as a list and the detailed information on every animal experiment is made available for download as an html page or pdf document. Applicants and approving authorities are guided to the subpages relevant to them via the start page.



Guideline for the preparation of a non-technical project summary

The BfR has prepared a guideline for the preparation of non-technical project summaries for applicants for animal testing projects. It gives information on the purpose, form and content of the project summaries, which is explained in detail and by an example. The BfR also provides a form to document the details of the non-technical project summary. It can be downloaded and sent to the responsible federal state authority together with the application for approval.

i Guideline (German only): www.bfr.bund.de > **Zebet im BfR** > **Nichttechnische Projektzusammenfassungen**



In Germany, the development of OECD testing methods for the toxicological assessment of substances is coordinated by the BfR.

The OECD test guidelines programme at the BfR

Alternative methods to animal testing, in particular *in-vitro* methods, have taken on special significance in Europe within the scope of the REACH chemicals regulation. The most important international organisation for the recognition of toxicological test methods and assessment strategies is the Organisation for Economic Cooperation and Development (OECD). In its test guidelines programme, the OECD deals with the international harmonisation and standardisation of physical-chemical, ecotoxicological and toxicological test methods. The OECD member states develop and improve test guidelines and prepare guidance documents for test methods and related assessment strategies. The national coordinators are of special importance here as they act as mediators between the national expertise and the OECD. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety has appointed the BfR as the national coordinator for the OECD in the field of human health.

The OECD methods serve to forecast the effects of industrial chemicals, nanomaterials, biocides and plant protection products on human health and the environment. Results based on OECD test guidelines are accepted worldwide and contribute towards the avoidance of double testing. They reduce the number and extent of animal tests and dismantle trading obstructions. 24 projects are currently being processed within the thematic area of health in the OECD test guidelines programme. They deal mainly with the (further) development of test guidelines on irritating and corrosive effects on the skin and eyes, mutagenic properties and endocrine-active substances.

The development of animal test-free methods as a substitute for toxicological long-term studies still poses the greatest scientific and technical challenge. As substitution by a single alternative method seems barely possible, the focus from a scientific point of view is on the development of integrated test strategies which can illustrate the various aspects of the effects of toxic substances through the combination of methods.

One of the areas of main emphasis of the OECD in this field lies in the development of so-called adverse outcome pathways (AOPs). This constitutes a chain of reactions which begins with an initial interaction of the chemicals on the molecular level and then reflects the effects in cells, tissue and organs which lead to a health restriction in animals or in humans. The development of AOPs requires detailed understanding of the effects of chemicals. High-throughput and high-content analyses play a major role here as they can test a large number of chemicals for specific effects within a short period of time. Through the development of AOPs and the resultant test strategies, it will be possible in the future to save a large number of test animals and make the testing of chemicals more efficient and economical. The BfR supports and accompanies the process of developing AOPs and integrated test strategies.

i OECD guidelines on the toxicological testing of chemicals at (German only): www.bfr.bund.de > **Chemikaliensicherheit** > **Internationale Programme** > **Prüfverfahren für die Gefahrenbewertung** > **Toxikologische Prüfungen**

In order to take new information on the severity experienced by laboratory animals into account, it is necessary to continuously develop the criteria catalogue, which was compiled in 2013 and is applied throughout Germany.

Criteria for assessment of severity of genetically altered laboratory animals

One of the new provisions of the Animal Welfare Act revised in 2013 stipulates that even the breeding of genetically altered animals is regarded as an animal experiment which requires authorisation. The premise is that, due to their genetic alteration, the animals are likely to experience pain, distress or harm.

To determine the stress levels of animals and establish suitable countermeasures, scientists and approval authorities require the appropriate criteria and specifications. To this end, in collaboration with scientists and representatives of the authorities, the national committee for the protection of animals used for scientific purposes, whose duties are performed by the BfR, developed a first catalogue of criteria for severity classification of genetically altered mouse lines in 2013 (see BfR Annual Report 2013). This catalogue of criteria is already used nationwide.

In order to pay due consideration to the scientific progress, it is necessary to continuously further develop the catalogue of criteria. To do so, a workshop was held at the BfR in October 2014 at which experts shared and discussed their experience with the application of the criteria for severity classification. The updated document now takes into account possible indications of embryonal mortality in the evaluation of a new-born litter of genetically altered mice. This was done because the provisions of the Animal Welfare Act now include the foetuses of mammals in the last third of their normal development before birth. The assessment of severity of the dams is also taken into account in this way.

For future workshops, the plan is to develop special catalogues of criteria on the assessment of severity of genetically altered fish and other animal species.

- i** *The criteria for assessing the severity of genetically altered laboratory animals including the corresponding forms (German only):*
www.bfr.bund.de > **ZEBET im BfR**
 > **Beratung von Behörden und Tierschutzgremien**
 > **Mitteilungen**



Due to their genetic alteration, genetically altered mice can experience pain, distress or harm. The BfR developed a catalogue of criteria to determine severity classification.



Annexes



Third-party funded projects of BfR in 2014

Research for exposure assessment and for the assessment of biological risks

Period	Acronyme	Topic
01/2010–12/2014	SFB Nutrition Intestinal Microbiotica	Nutrition and intestinal microbiota – host interaction in the pig Influence of nutritional factors on the prevalence of viruses, including viruses with zoonotic potential, in faeces of clinically healthy pigs
02/2011–04/2014	FBI Zoo 2	Food-Borne Zoonotic Infections of Humans – <i>Salmonella</i> in the poultry food chain: outbreak potential, evolution, and pathogenicity
11/2010–07/2015	VibrioNet	VibrioNet: Climate warming and the emergence of seafood- and waterborne vibriosis
10/2011–03/2015	Gene transfer	Molecular mechanism of horizontal gene transfer in pathogenic epsilon-proteobacteria
01/2012–12/2014	PROMISE	Consumer: PROtection by microbial risk MItigation through combatting SEgregation of expertise
10/2012–06/2015	e-H@C HUPAction	Developing a system to improve information exchange within the organisational infrastructure in the interest of the more rapid detection, monitoring, and control of EHEC and other human pathogenic bacteria in the value chain, vegetables in the Euregio Rhine Waal
07/2012–08/2015	InnoStep	Development of innovative production integrated microbiological levels control systems in meat production to reduce <i>Campylobacter</i> spp. and <i>Salmonella</i> spp.
01/2014–04/2017	MedVetStaph-2	LA-MRSA spread from food to consumers
01/2014–12/2016	RESET 2	RESET-II: Coordinated project: ESBL and (fluoro)quinolone RESistance in EnTerobacteriaceae

Further Information
DFG (FKZ: SFB 852/1 2010; SFB 852/2)
BMBF (FKZ: 01KI1012I) www.fbi-zoo.de
BMBF (FKZ: 01KI1015A) www.vibrionet.de
DFG (FKZ: STI 201/3-1) http://gepris.dfg.de/gepris/projekt/175974972
EU (FP7-KBBE-2010-4-265877) http://promisenet.wordpress.com
EU (II-2-03=201) http://giqs.org/projekte/hupaction
BLE (FKZ: 2816801511)
BMBF (FKZ: 01KI1301C)
BMBF (FKZ: 01KI1313B)

Abbreviations

BMEL: Federal Ministry of Food and Agriculture
BMBF: Federal Ministry for Education and Research
BMUB: Federal Ministry for Environment, Nature Conservation and Nuclear Safety
BMWi: Federal Ministry for Economy
BLE: Federal Office for Agriculture and Food
UBA: German Federal Environmental
DFG: German Research Foundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

Research for the safety of national and international production chains

Period	Acronyme	Topic
10/2010–09/2014	SiLeBAT	Securing the feed and food supply chain in the event of biological and agro-terrorist (BAT) damage scenarios
07/2013–06/2016	ZooGloW	Zoonoses and food safety along global supply chains
07/2013–06/2016	SPICED	Securing the spices and herbs commodity chains in Europe against deliberate, accidental or natural biological and chemical contamination
12/2013–11/2018	EFFORT	Ecology from Farm to Fork Of microbial drug Resistance and Transmission
01/2014–12/2018	Food Integrity	Ensuring the Integrity of the European Food chain

Research for the detection of contaminants and the assessment of chemical risks

Period	Acronyme	Topic
01/2009–06/2014	Ballast Water	North Sea Ballast Water Opportunity
01/2012–08/2014	Levogluconan	Quantitative analysis of the influence of wood combustion on the concentration of particulate matter in Berlin and Brandenburg using the tracer levogluconan
12/2012–08/2015	Pollutants house dust	Pollutants in house dust: Improving health assessment by determination of the effective dust absorption of children and adults
10/2013–06/2015	GP/EFSA/ CONTAM/2013/03	Occurrence of Pyrrolizidine Alkaloids in food
02/2013–05/2015	ZENOL	Development and validation of an analysis method for the selective determination of zearalenone in vegetable oils

Research for modern methods in toxicology

Period	Acronyme	Topic
11/2010–11/2015	Gastrointestinal Barrier	Interaction between metabolism and transport of toxicologically relevant compounds in the gastrointestinal barrier
11/2013–10/2015	Combiomics	Combiomics – Investigation of mixture effects of pesticides <i>in vitro</i>
12/2013–11/2015	LivSys	Modelling of the toxome of cultivated human hepatocytes

Further Information
BMBF (FKZ: 13N11202) www.silebat.de
BMBF (FKZ: 13N12697) www.bmbf.de/pubRD/Projektumriss_ZooGloW.pdf
EU (FP7-SEC-2012 – 312631) http://spiced.eu
EU (FP7-KBBE-2013-7-613754) www.effort-against-amr.eu
EU (FP7-KBBE-2013-7-613688)

Further Information
EU (InterReg BWO/2010 SA 180) www.northsearegion.eu/ivb/projects/details/&tid=89
Berlin Brandenburg
BMUB (FKZ: 3712 62 204)
EFSA
BMWi (FKZ: 01FS12034)

Further Information
DFG (FKZ: LA 1177/6-1) http://gepris.dfg.de/gepris/projekt/156632571
BMBF (FKZ: 031A267A)
BMBF (FKZ: 3R-474-007)

Abbreviations

BMEL: Federal Ministry of Food and Agriculture
BMBF: Federal Ministry for Education and Research
BMUB: Federal Ministry for Environment, Nature Conservation and Nuclear Safety
BMWi: Federal Ministry for Economy
BLE: Federal Office for Agriculture and Food
UBA: German Federal Environmental
DFG: German Research Foundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

Research for harmonisation and standardisation of exposure assessments

Period	Acronyme	Topic
02/2012–01/2016	TDS_Exposure	Total Diet Study Exposure
01/2014–03/2015	REACH-Compliance	Analysis of the data availability from REACH registrations
07/2014–06/2016	National monitoring of poisonings	Research project: National monitoring of intoxication

Research for alternatives to animal experiments

Period	Acronyme	Topic
09/2010–05/2014	HET-MN	Prevalidation of HET-MN (Hen's Egg Test – Micronucleus Induction) as alternative method to the <i>in vivo</i> micronucleus test in rodents
10/2011–09/2014	3D skin models	Verification of the metabolic competence and prevalidation of the Comet assay in human 3D skin models
04/2014–03/2017	Innovations in the 3R Research	Genetic Engineering, Tissue Engineering and Bioinformatics: Berlin-Brandenburg research platform BB3R with integrated graduate education

Allergy research: effect-based analytics and early risk detection

Period	Acronyme	Topic
12/2014–09/2015	Food carcinogens	Metabolic activation and inactivation of food carcinogens 5-hydroxymethylfuran and furfuryl alcohol in man, mouse and rat

Research for feed safety

Period	Acronyme	Topic
03/2011–08/2014	QSAFFE	Quality and Safety of Feeds and Foods for Europe
06/2013–06/2016	Tannisil	Improving protein quality of roughages in ruminant nutrition by using silage additives on the basis of condensed tannins
01/2014–12/2017	Tender Melamin	Tender Melamin

Further Information
EU (FP7-KBBE-2011-5-289108) www.tds-exposure.eu
UBA (FKZ: 3714 67 420 0)
BMU (FKZ: UM14654010)

Further Information
BMBF (FKZ: 0315803B)
BMBF (FKZ: 0316008A)
BMBF (FKZ: 031A262D)

Further Information
DFG (FKZ: MO 2520/1-1)

Further Information
EU (FP7-KBBE-2010-4-265702) www.qsaffe.eu
BLE (FKZ: 2813804310)
EU (SA/CEN/ENTR/522/2013-11 Contract item: 2013-11.11)

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FKZ: Project reference number

Nanotechnology research: detection, toxicology, risk assessment and risk perception

Period	Acronyme	Topic
04/2012–01/2014	Migration Nanoton	Migration analyses for food contact with nanoclay doped plastic
04/2012–08/2014	Oxid Stress Nano	Classification of nanomaterials for potential oxidative stress at the level of oxidative protein modifications
05/2012–10/2014	Nanopinion	Monitoring public opinion on Nanotechnology in Europe
02/2011–01/2015	QNano	A pan-European infrastructure for quality in nanomaterials safety testing
03/2013–08/2016	NANoREG	A common European approach to the regulatory testing of nanomaterials
11/2013–10/2017	NanoDefine	Development of methods and standards supporting the implementation of the Commission recommendation for a definition of a nanomaterial
10/2014–09/2017	DENANA	Design criteria for sustainable nanomaterials
04/2014–03/2017	SoINanoTOX	The toxicity in intestine and liver for nanoparticles used in food and packaging. Determining factors of the toxicity in intestine and liver for two similar sized nanoparticles used in food and packaging: <i>In vitro</i> and <i>in vivo</i> investigation on uptake and mechanisms involved
03/2014–03/2016	CEFIC	Science-based grouping of nanomaterials for industrial application of safe-by-design
12/2014–11/2016	SeeingNano	Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualization Tools and Guidance for “Seeing at the Nanoscale”

Scientific cooperation

Period	Acronyme	Topic
01/2014–12/2015	EFSA focal point	Germany's national focal point on technical and scientific matters

i Additional information to the projects:
 Federal Institute for Risk Assessment: www.bfr.bund.de/en > Research > Third party projects of the BfR
 Information System for Agriculture and Food Research: www.fisaonline.de > English
 Research database of the BMEL (in German):
www.bmelv-forschung.de/de/startseite/forschung/forschungsprojekte/projektdatenbank.html

	Further Information
	government Rhineland-Palatinate
	government Rhineland-Palatinate
	EU http://nanopinion.eu/de
	EU www.qualitynano.eu
	EU www.nanoreg.eu
	EU www.nanodefine.eu
	BMBF (FKZ: 03X0152E)
	DFG (GZ.: LA 3411/1-1) DFG (FKZ: LA 1177/9-1)
	EU (LRI-N4)
	EU (H2020-NMP-2014-2015, Grant Agreement number: 646141)

	Further Information
	EFSA www.efsa.europa.eu/de/networks/fp.htm

Abbreviations

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BMUB: Federal Ministry for Environment, Nature Conservation and Nuclear Safety
BMWi: Federal Ministry for Economy
BLE: Federal Office for Agriculture and Food
UBA: German Federal Environmental
DFG: German Research Fundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

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B

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E

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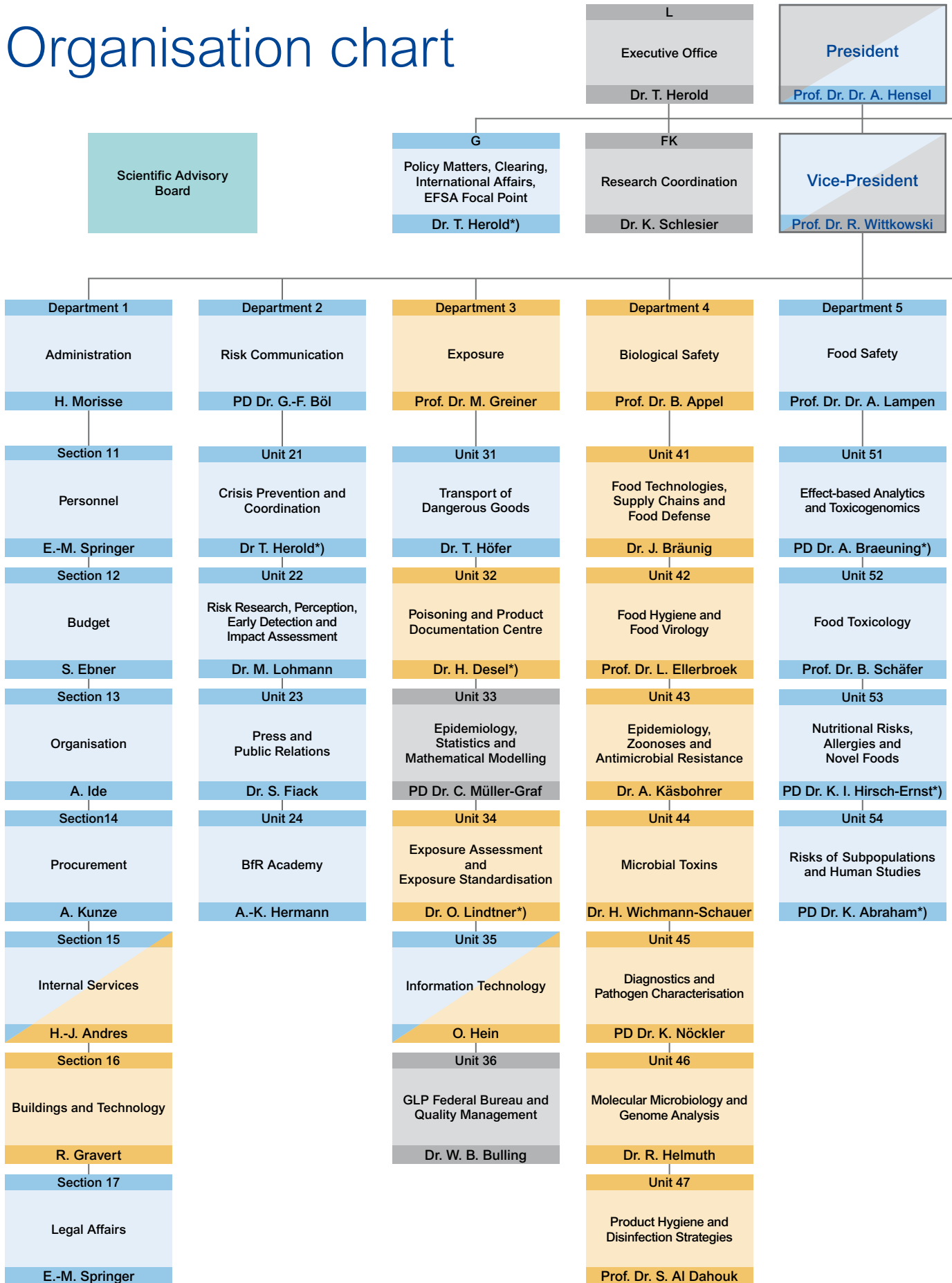
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Organisation chart





GleIB Gender Equality Officer Dr. K. Schmidt
DSB Data Protection Officer ^{Präs)} C. Weigel

SchwV Representative of the Severely Disabled A. Brandt
AB Waste Management Officer ¹⁾ S. Kabbeck

PersRat Staff Council R. Nolte
JAV Youth and Trainee Representatives M. Roß

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^{*)} Temporary appointment/ entrusted with the performance of tasks

) Reporting



Short portrait of the BfR

Do nanoparticles promote the development of allergies? Does apple juice contain harmful aluminium? The Federal Institute for Risk Assessment – in short BfR – is responsible for questions to do with the health assessment of food, consumer products and chemicals. In its work it makes an important contribution to rendering food, products and the use of chemicals safer in Germany.

The BfR was established in November 2002 to strengthen consumer health protection. It is the scientific body of the Federal Republic of Germany that prepares expert reports and opinions on questions of food and feed safety and the safety of substances and products. In doing so, the Institute assumes an important task in improving consumer health protection and food safety. The activities of the BfR are conducted under the responsibility of the Federal Ministry of Food and Agriculture. At the three BfR locations in Berlin, a staff of about 760, among them 300 scientists, is being employed to work in the field of consumer health protection. The scientific expertise needed for its assessment and research activities is provided on a nonpartisan basis.

In our globalised world it is important for the institutions involved in consumer health protection to be part of international networks. The BfR is the national Focal Point of the European Food Safety Agency (EFSA) and a partner of the European Chemicals Agency (ECHA). It cooperates with a number of national and international, governmental and non-governmental agencies.

The BfR sees itself as the advocate of consumer health protection in a context in which many stakeholders make their voices heard. On the scientific basis of its risk assessments, it seeks to strengthen consumer health protection. To this end, the Institute offers policy advice, participates in national and international panels and disseminates consumer information. An important component in its risk assessment activities has consisted in risk communication and the various forms it can take. Risk communication has been provided by BfR by means of various projects and events.

Thanks to the high standard of its work, its scientific independence and its transparent assessments, the Institute has become a recognised player and important driver of consumer health protection on both the national and international stage. Consumers know they can trust its judgements.

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