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2015

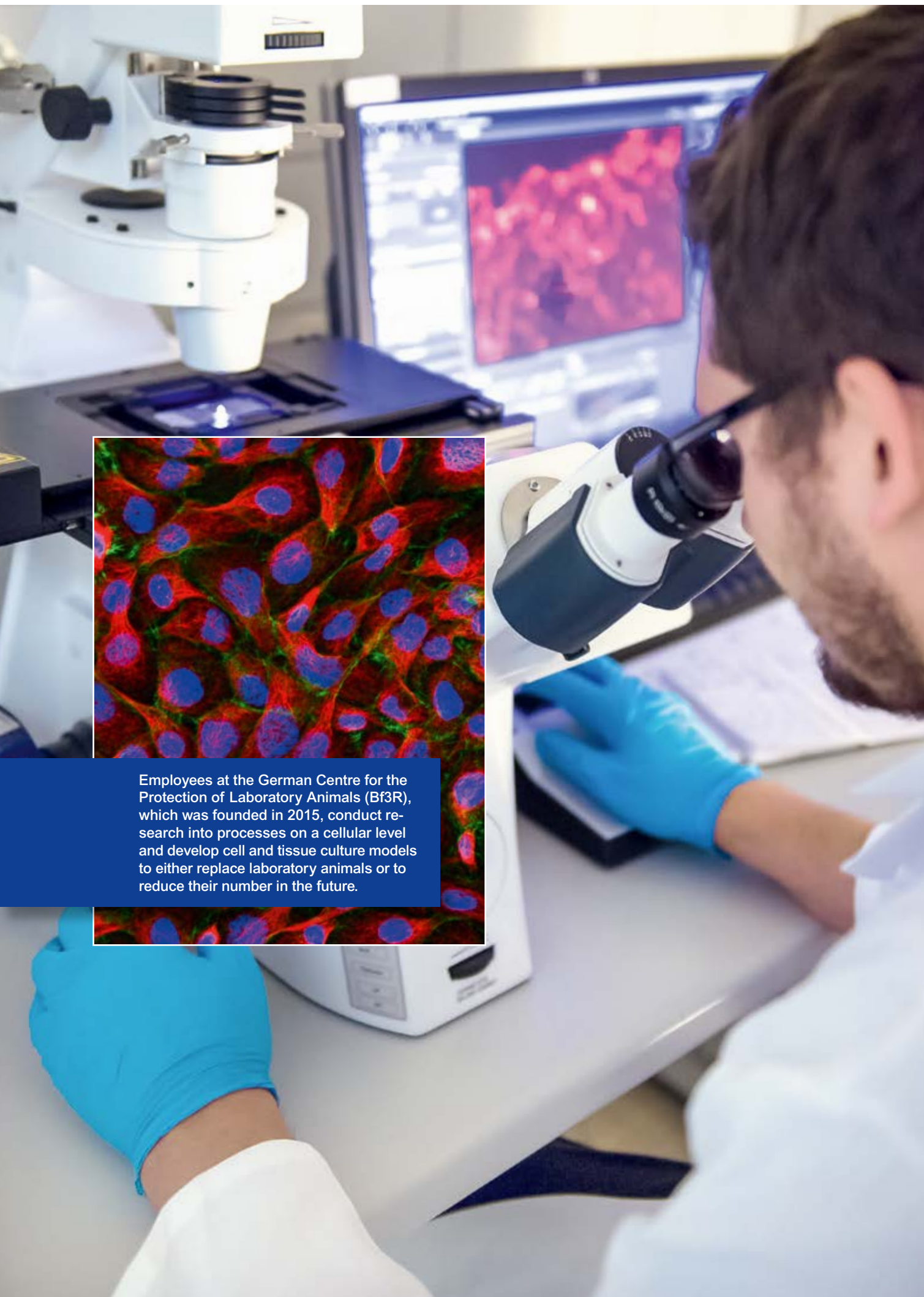
SCIENCE IN THE SERVICE OF HUMANITY

Imprint

Annual Report 2015

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Employees at the German Centre for the Protection of Laboratory Animals (Bf3R), which was founded in 2015, conduct research into processes on a cellular level and develop cell and tissue culture models to either replace laboratory animals or to reduce their number in the future.

Foreword



Prof. Dr. Dr. Andreas Hensel, President



Prof. Dr. Reiner Wittkowski, Vice-President

Dear Readers,

Science, independence and transparency are the three pillars of risk assessment at the BfR. This was also acknowledged by the Scientific Council in their evaluation report published at the end of 2015 in which the assessment group described our federal institute as one of the leading institutions of science-based risk assessment at international level. This annual report documents BfR's work in providing sound scientific advice to policy makers while maintaining transparency and traceability. In reading you will be able to prove this for yourself.

One example of the important work carried out at the BfR is the founding of the German Centre for the Protection of Laboratory Animals (Bf3R) and its integration into our institute. With the opening of the Centre on 25 September 2015 by Federal Minister Christian Schmidt, Germany took on a pioneering role in the development of alternatives to animal experiments. The goal of all activities coordinated nationwide by Bf3R is to reduce animal experiments to the absolutely essential minimum and guarantee the best possible protection of animals. Bf3R instigates research activities all over the world and promotes scientific dialogue e.g. by intensifying research of alternative methods, by promoting scientific research in this area, by harmonising alternative methods at international level, advising authorities and research institutions and by providing information to professionals and the general public. The Federal Ministry of Food and Agriculture (BMEL) provides annual funding of roughly 1.5 million euros for this purpose. This enables us to further intensify our commitment to providing laboratory animals with even better protection against pain, suffering and impaired health in the future.

The distinguishing features of risk communication within the BfR strategy are independence, transparency and comprehensibility. We have portrayed the communicative work we performed within the scope of the legally prescribed process for the renewal of approval of the use of glyphosate in Europe. The assessment of glyphosate was discussed in politics and in public more intensively than any other approval process of a pesticide active substance. BfR was a central point of contact for information on this subject and received numerous inquiries in 2015. The emotional debate about plant protection products and their residues shows once again how important properly conducted scientific studies and the correct communication of results are in providing consumers with appropriate information and avoiding unnecessary uncertainty.

Science, independence and transparency are the three pillars of risk assessment at the Federal Institute for Risk Assessment.

In the evaluation report of the Scientific Council published on 19 October 2015 it is stated, “The BfR has great scientific expertise, provides important consultancy services and makes a significant contribution to consumer health care”. The evaluation group, which is currently acquiring insight into all of the departmental research institutions within the portfolio of the Federal Ministry of Food and Agriculture (BMEL), visited the BfR at all three of its locations on 7 and 8 May. In the course of the visit they talked to staff members, cooperation partners from Germany and abroad, including our scientific advisory board, stakeholders and representatives of the supervisory boards of leading BMEL departments and BfR committees.

The members of the Scientific Council evaluation board rated the BfR staff as very competent and committed. We agree with this assessment report because competence and commitment are very high standards in our institute. We would like to express our thanks to every single staff member for their work in achieving these goals. A further fundamental prerequisite which enables us to weather the occasional storm is internal cohesion, because the BfR is always perceived as a single entity from the outside. This perception is set to remain just as positive in the future too, as the Scientific Council has certified. Good reasons for this are offered by the numerous examples of the work of the BfR which you will find on the following pages. We wish you stimulating reading!

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



Prof. Dr. Dr. Andreas Hensel,
President



Prof. Dr. Reiner Wittkowski,
Vice-President

Evaluation of the Scientific Council 2015

After 2005 and 2009, the Federal Institute for Risk Assessment (BfR) was evaluated again by the Scientific Council in 2015. With the publishing of its opinion in October 2015, the evaluation was completed after a one-year appraisal procedure with a very positive result. The Scientific Council certifies the high level of efficiency and scientific expertise of the BfR: “The BfR performs the legal tasks assigned to it competently and reliably. By doing so, the BfR makes a significant overall contribution towards consumer health care in the Federal Republic of Germany”.

The Scientific Council stresses that the BfR provides important scientific advisory services to political decision-makers, in particular the Federal Ministry of Food and Agriculture (BMEL) and various other stakeholders. The scientific risk assessment performed by the BfR guarantees political consultancy that is independent of any social, political or economic interests.

The BfR has also established itself as one of the leading institutions for science-based risk assessment at international level. The work it performs enables the further development of risk assessment and risk communication on a national and international level. Special praise was given here to the very good international link-up with cooperation partners, as well as the committed and competent BfR personnel whose further qualifications are continuously promoted. The training function of the BfR is extremely important for non-European countries too and is exemplified by the annually organised BfR Summer Academy, which focuses on the further training and networking of risk experts from all over the world in the field of food safety.

Explicit praise was reserved for the scheduled and already realised filling of certain BfR positions and professorships with joint appointments, such as that with the University of Veterinary Medicine Hannover, the University Clinic Charité and Freie Universität Berlin, as well as the close cooperation with our French sister authority ANSES and the food institute at the Technical University of Denmark (DTU). The certification of all BfR work areas in line with DIN EN ISO 9001 and the accreditation of the laboratories in line with DIN EN ISO/IEC 17025 were also given special mention.

 You will find the complete opinion (in German) of the Scientific Council at: www.wissenschaftsrat.de/en

The Scientific Council recommends that the institute align its research activities even more strategically and to do so, the BfR will actively involve the scientific advisory board. Joint appointments with universities should also be sought on the level of the institute's specialised units. As with the previous evaluations, the BfR will give thorough consideration to the recommendations of the Scientific Council.

The BfR makes a significant contribution towards consumer health protection in Germany.

The BfR is one of the leading institutions for science-based risk assessment on a European and international level.

The institute provides important scientific advisory services to political decision-makers.

With this specific task, the BfR has a unique feature which distinguishes it throughout Germany.

The BfR personnel is competent and committed.

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 Short portrait of the BfR



About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). It advises the Federal Government and Federal States ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks. 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 matters, 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 research, assessments, recommendations and communication, the BfR is free from economic, political and social interests, and it provides them in a way that can be easily understood by the general public.

Every day, the employees at the BfR prepare around a dozen reports and opinions assessing the health risks of foods and feeds, consumer goods and chemicals. The institute communicates its findings and recommendations to policymakers and the general public. The opinions of the BfR serve the federal government as a basis for maintaining consumer health protection. Today, the BfR employs roughly 800 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 science-based risk assessment, 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 (EFSA), the BfR is also integrated into European consumer protection.



With its work, the BfR makes a decisive contribution to consumer health protection.

Position in the field of consumer health protection

The BfR was founded as a federal authority with a legal capacity within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). Its remit is based among other things on the statutory act establishing the BfR. Legislation has also defined the work activities of the institute in more than ten other laws – including the German Plant Protection Act, the German Genetic Engineering Act, the German Food and Feed Code, and the laws governing chemicals.

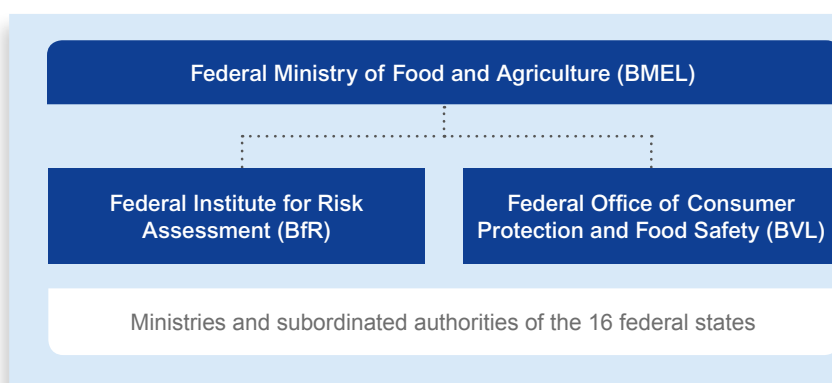
i *The legal foundations of the BfR in detail:*
www.bfr.bund.de/en > *The Institute* > *Remit*

In a federal system like the one in Germany, responsibility for consumer health protection is divided up between the national and regional levels. Laws and regulations that serve consumer health protection are established 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.

The BfR assesses health risks scientifically and marks out courses of action to minimise risks.

Many legal regulations governing consumer protection are prepared on European level in the meantime, and the BfR is also involved in the drafting 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 authorities in each federal state to monitor compliance with national and European legal regulations 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 taking a stance with regard to evaluation on topical issues in the field of consumer health protection. The BfR is also involved in a number of registration and approval procedures.



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 and the Federal Ministry of Food and Agriculture are responsible for management tasks at the federal level.

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.

Impartiality

The impartiality 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. For reasons of independence, the BfR does not seek any funding from trade and industry. It is financed exclusively by funds provided by the federal government and through national and international, publicly funded third party projects.

The overall concept of the BfR explicitly provides for the exchange of views with many different 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 prepared exclusively 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 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. Existing knowledge is given adequate consideration and is presented in a manner which is easy to understand. Relevant opposing scientific opinions are given in full.

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 endangers health and the anticipated 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.

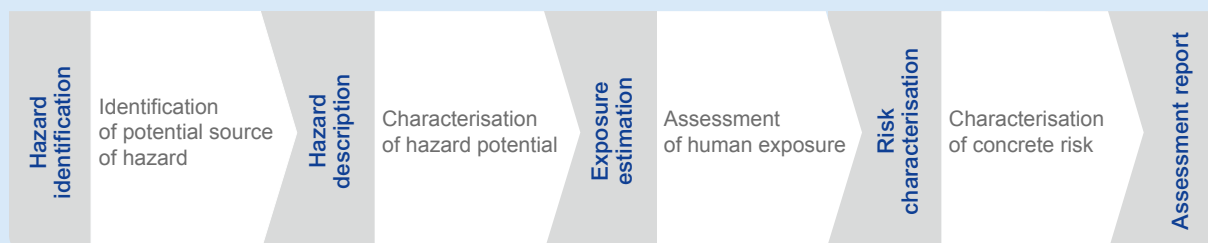
The task of the BfR is to provide the responsible people with a sound scientific foundation for risk management. Identifying a risk and evaluating it – the two together are known as “risk assessment” – is the first step in the area of consumer health protection. Risk management can use this as a point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

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, in which risks are described verbally in line with the diagram outlined in the box, and quantitative risk assessments. The latter are based at least partly on calculations or mathematical models, and the risks are described using mathematical or statistical methods.

The risk assessments made by 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 potential, identified and assessed risks.

From a possible danger to objective assessment – a simplified description of the risk assessment procedure



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, NGOs and the media.

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 > Brochures > Guidance Document for Health Assessments



The BfR also uses Twitter and other social media to inform the general public about risks.



The BfR conducts cross-departmental, interdisciplinary examinations and assessments along the entire supply and product chain.

The BfR is independent in the planning, structuring and conducting of all research activities.

Research

The BfR conducts its own, application-related, targeted research within the scope of its key competences. With the results the institute can conduct scientific examinations and assessments in line with its legal mandate. Against the background to the international focus of the BfR, standardisation in the development of methods and procedures plays a prominent role at the institute.

The BfR is independent in the planning, structuring and conducting of all its research activities. It so ensures and promotes the scientific expertise for internationally recognised competence in risk assessment and risk communication, which is independent of economic interests. The collection of data, development of new 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 (BMEL), the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and the Federal Ministry of Transport and Digital Infrastructure (BMVI).

The BfR has a modern experimental infrastructure in the fields of 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 modern molecular and cellular biology laboratories, as well as protein biochemistry laboratories for the development of alternative and replacement 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 product chain. In its activities, the BfR orientates itself on the relevant ISO norms and recognised standards for quality management. In its research, the BfR works on the basis of the recommendations of the Deutsche Forschungsgemeinschaft in line with the principles of Good Scientific Practice.

Presentation: New Third-Party Funded Projects 2015

Within the scope of its main areas of research, the BfR acquired third-party funding for various new projects in 2015. Here is a selection:

- > In the main area Nanotechnology, the Federal Ministry of Education and Research (BMBWF) is financing the research project “Nanostructured materials – Grouping regarding worker, consumer and environment safety and risk mitigation (nanoGRAVUR)”, which aims to observe specific developments of grouping approaches to the important aspects of exposure and hazard potential for humans and the environment and to explore joint aspects for the testing and assessment of nanomaterials.
- > In the field of the Risk Assessment of Nanotechnologies, the project “Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks (NANoREG II)” was procured which picks up on the process from the EU NANoREG project and dedicates itself to the build-up of a regulatory system which is flexible enough to integrate new objects and requirements. This is to be achieved through the development and introduction of the Safe-by-Design (SbD) principle.
- > In the main research area on the Safety of National and International Supply Chains, the EU is funding the project “Ensuring the Integrity of the European Food Chain (Food Integrity)”. The goal of the EU consortium is to ensure the safety, authenticity and quality of food and to protect the food chain from adulteration. To achieve this, the partners from universities, research institutions, industrial corporations and authorities are collaborating on the harmonisation and standardisation of processes.
- > The project in the main area of Detecting Contaminants and Assessing Chemical Risks “European Test and Risk Assessment Strategies for Mixtures (EuroMix)” is funded within the scope of the EU research programme Horizon 2020. An experimental, verified and graduated strategy for the risk assessment of mixtures of various chemicals is to be developed here.
- > In the main research area on the Harmonisation and Standardisation of Exposure Estimations, the European Commission is funding the project “Study on hazardous detergents mixtures contained in soluble packaging for single use (LiquiTabs)”, in which water-soluble packaging of LiquiTabs are being examined for health-damaging substance mixtures.

BfR-Committees

Fifteen scientific expert committees advise the BfR in questions relating to the safety of food and feed, chemicals and products, as well as risk communication. They consolidate the expertise available in Germany at the highest scientific level to form an external scientific quality assurance system for the assessment tasks undertaken by the BfR. In this way, they can be called upon for advice as an established network not only 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, as well as trade and consumer associations.

The BfR-Committees each have at least ten members who elect a chairperson from among their ranks. The BfR provides support by taking over management tasks. The minutes of the meetings, which produce the scientific opinions and results of the committees' consultations are made available to the general public on the BfR website. What makes them fundamentally different from other institutions in the EU, such as the European Food Safety Authority (EFSA), is that in line with their rules of procedure, BfR committees play a purely advisory role and do not make any risk assessments.

In 2013, suitable experts who had previously applied in an open process, were selected by the external appointing panel for the new appointment period 2014 to 2017 and appointed by the BfR president with a 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.

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

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

Quality management

How well does the BfR work? The institute's employees have to face this general question every day. Modern quality management structures help here to fulfil the BfR's legal remit to prepare high-quality, science-based risk assessments.

Since 2010 all work areas at the BfR have been certified, in line with the quality standard DIN EN ISO 9001:2008. This international standard promotes the establishment of work processes and responsibilities so that high quality can be achieved with regard to the work performed and products produced. This applies to the scientific work of the BfR as well as the administration and communication. The quality standards are monitored for compliance and constant improvement is sought in internal and external audits.

The standard DIN EN ISO/IEC 17025 for test and calibration laboratories specifies additional technical and personnel requirements. These regulations enable very high, comparable quality demands on an international level.

The BfR's scientific laboratories have been accredited since 2003 in accordance with DIN EN ISO/IEC 17025. The accreditation places emphasis on technical and professional competence of test laboratories and serves as confirmation of high-quality, reliable results.

These two quality certifications require regular, independent verification. The certification must be reconfirmed every three years and accreditation every five. In addition to this, so-called monitoring audits are annually conducted. The performance of the tasks in line with DIN EN ISO 9001:2008 was last confirmed in May 2015 by the independent TÜV Nord Cert GmbH. The compliance of the scientific labs holding the standard DIN EN ISO/IEC 17025:2005 was last reviewed by German accredited body (DAkkS) in November 2015.

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



Food and product safety can only be achieved through an international approach.

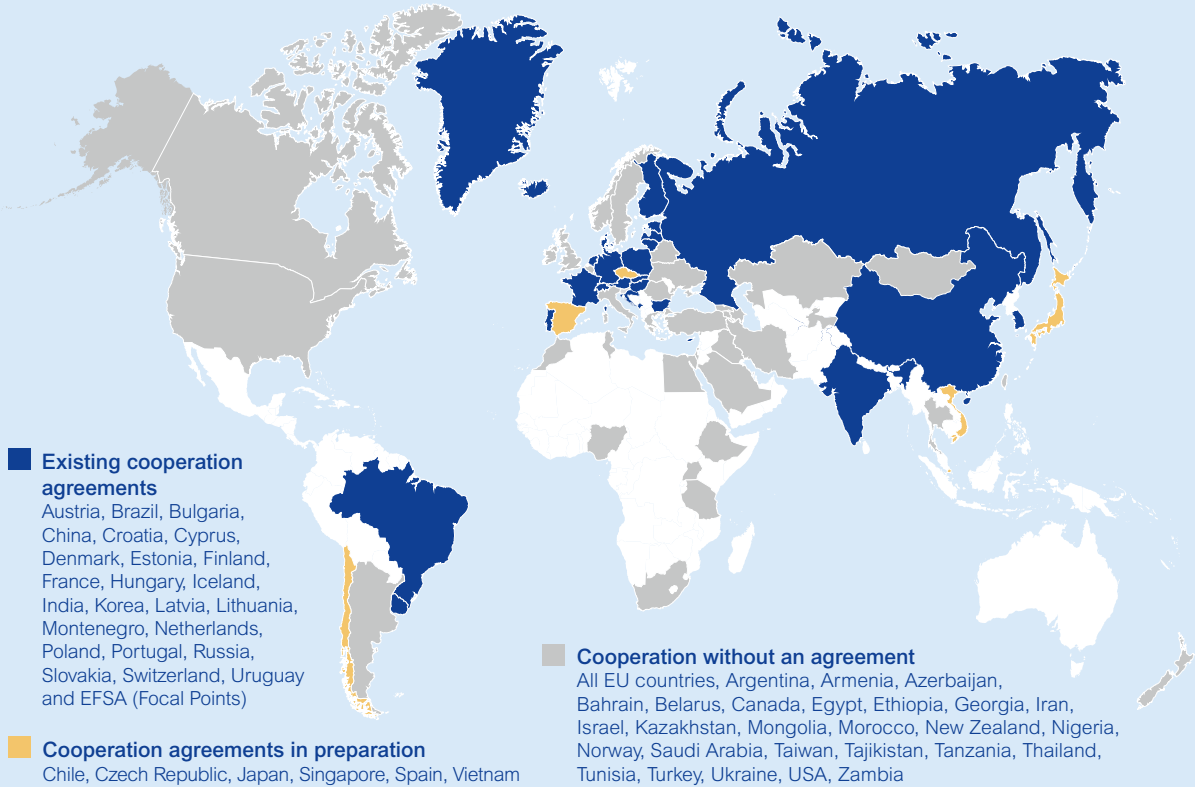
International cooperation

Goods flows have fundamentally changed through globalisation and are now subject to quick changes. New raw materials and products are reaching the German market. As the quality and safety standards in the countries of origin are often not comparable with those that apply here, food and product safety can only be assured nowadays through an international approach.

The BfR faces up to this challenge through close cooperation with ministries and partner authorities on all continents. The exchange of information and establishment of uniform procedures and standards contribute directly to a high level of safety, even with imported products. In addition to this, the establishment of effective structures for risk assessment and risk management in the partner countries leads to a sustainable improvement of the situation, thus benefitting consumers all over the world.

The supervisory ministry, the Federal Ministry of Food and Agriculture (BMEL), places great importance on the further strengthening of cooperations of this kind. International activities and regions in focus are closely coordinated between BMEL and BfR. The BfR currently has cooperation contracts with 42 partners in 26 countries. One focus is on maintaining close contacts with European sister authorities. Whereas the BfR has enjoyed many years of partnership with ANSES (France), DTU (Denmark), AGES (Austria) and NVWA (Netherlands), cooperation is still being built up with other agencies, such as AECOSAN (Spain), ASAE (Portugal) and EVIRA (Finland). Another focus is on collaboration with important non-European trading and cooperation partners. Worthy of special mention here are China and South Korea, partners with whom we conducted many joint activities once again in 2015. A new focal point is India, with whose food safety authority FSSAI a cooperation contract was signed in 2015.

Food safety is globalised – BfR cooperations



Cooperation with partner institutions takes the form of mutual visits, joint symposiums, the exchange of information and the training of scientists at the BfR within the scope of initiatives such as the BfR Summer Academy. BfR employees are also sent out to support the partner countries with know-how in the build-up of capacities in the field of food safety within the scope of twinning projects or bilateral agreements.

Cooperation with the European Food Safety Authority (EFSA) deserves a special mention at this point. The BfR is represented in many EFSA committees, thus making a decisive contribution towards food safety in Europe. As the EFSA Focal Point, the BfR coordinates the exchange of scientific information between EFSA and the authorities responsible for food and feed safety in Germany, as well as players from trade and industry, politics, science and consumer associations.

i The BfR's EU Almanac, the third edition of which is now available, gives information on the structures and institutions of food safety in 35 European countries and on a European level. The German edition has been translated into English, Chinese, French and Spanish: www.bfr.bund.de/en > Publications > Brochures > EU-Almanac



The National Reference Laboratories ensure that work is performed throughout Europe in line with uniform standards, an aspect which is of particular importance where the monitoring and control of foods are concerned.

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 attached to the BfR pursuant to regulation (EC) 882/2004 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 (BMEL). 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 (ring trials) for the purpose of quality assurance. The creation of national reference laboratories guarantees that work is carried out in line with uniform 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 monitoring authorities of 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.



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

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**

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, Prof. Dr. Dr. Andreas Hensel, and his Vice-President, Prof. Dr. Reiner Wittkowski. They are supported in their work by several staff units and the nine departments profiled below.

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 regulations.

Risk Communication Department

Head: PD Dr. Gaby-Fleur Böl

The Risk Communication Department with its interdisciplinary make-up conducts research projects on the perception of risks and their early identification, and on the estimation of their impact. A further focal point of its work is crisis prevention and coordination. The department also handles press and PR activities, the BfR committee system and the BfR Academy. The dialogue with stakeholders from science, trade and industry, 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 cooperation in such areas as mathematical modelling. The department performs legally prescribed tasks and conducts research projects in the areas of chemical safety, dangerous goods transport, toxicity 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, 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 posed by the substances they contain, which include natural 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 also assessed. An integral 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 department devotes itself to the health assessment of active substances and formulations of plant protection products and biocides prior to legal approval. This involves the 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.

Chemical 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 consumer products (e.g. food packagings, 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 Lahrssen-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 marine biotoxins and for additives in animal feed 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 Animal Welfare Act and regulations on the protection of animals used in experiments. 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 with 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).



From top left to bottom right: Prof. Dr. Gilbert Schönfelder, Prof. Dr. Dr. Andreas Hensel, Dr. Roland Solecki, Dr. Monika Lahrssen-Wiederholt, Prof. Dr. Dr. Alfonso Lampen, Prof. Dr. Bernd Appel, Prof. Dr. Matthias Greiner, PD Dr. Gaby-Fleur Böl, Heike Morisse, Prof. Dr. Reiner Wittkowski, Prof. Dr. Dr. Andreas Luch

Personnel and training

The BfR showed a significant increase in personnel in 2015. Whereas there was a total workforce of 757 at the end of 2014, this figure rose to 801 a year later and comprised 25 trainees, 113 civil servants and 663 salaried employees subject to collective agreements. Two thirds of the BfR staff are women.

In addition to the operative work of the Personnel Section, the implementation of an online application management system, the conception of target group-specific programmes for refugees, postdocs and guest scientists formed the areas of main focus in 2015 along with re-auditing by berufundfamilie GmbH.

Personnel acquisition: Start of the online application management system

Online application management was launched in April 2015. Where only postal application was previously possible, applicants now have the opportunity not only to find out about job offers at the BfR via the internet, but also to apply online. In this way, applicants can apply easily and irrespective of the place or time, an advantage above all to applicants from abroad. The online application management system has been very well accepted right from the start. In the first six months since its introduction, the share of postal applications has been reduced to a mere 17 %. With around 5,000 applications a year, the Personnel Section has not only established a modern means of addressing applicants, they have also achieved significant gains in efficiency.

Working at the BfR

To fulfil its tasks, the BfR is particularly reliant on a committed and motivated workforce who contribute their specific knowledge and skills in each field to make the BfR an internationally recognised institute for consumer protection.

People with different professions and experiences, most of them with a background in scientific disciplines, such as medicine, veterinary medicine, pharmacology, biology, chemistry, biochemistry, food chemistry and nutritional sciences, work together at the BfR. Cooperation is distinguished by a focus on objectives, self-reliance, loyalty and performance orientation.



Personnel development: Programmes for postdocs, guest scientists and refugees

To do justice to the needs of the different target groups at the BfR as well as the expectations that are placed on them, three new programmes were introduced in 2015 in addition to the ones that already existed for executives, doctorate candidates and newly hired employees. Ten new postdoc positions were advertised with the goal of promoting up-and-coming talent as well as experienced scientists and strengthening cooperation with the universities. An essential component of this programme is the support of postdocs in their further career planning in the form of individual coaching.

To boost international cooperation and promote scientific talent, a guest scientist programme was also announced which is aimed primarily at scientists abroad. Of the 43 applications received, ten applicants were selected for a three-month guest visit to the BfR with assumption of costs. The BfR welcomed scientists from many coun-



The BfR guest scientist programme serves to strengthen international collaboration and promote scientific talent.

tries, including China, Iceland and Uruguay in 2015. The second announcement was made at the end of the year and the number of applications rose to a pleasing 89. In 2016, the BfR looks forward to welcoming guest scientists from Ethiopia, Brazil, China, France, Ireland, Kenya, Nigeria, South Korea, Uganda and Ukraine.

Over and above this, the BfR advertised an internship programme for refugee scientists in 2015 which also involves individually adapted further training options. To date, refugees from Syria and Pakistan have started an internship of this kind.

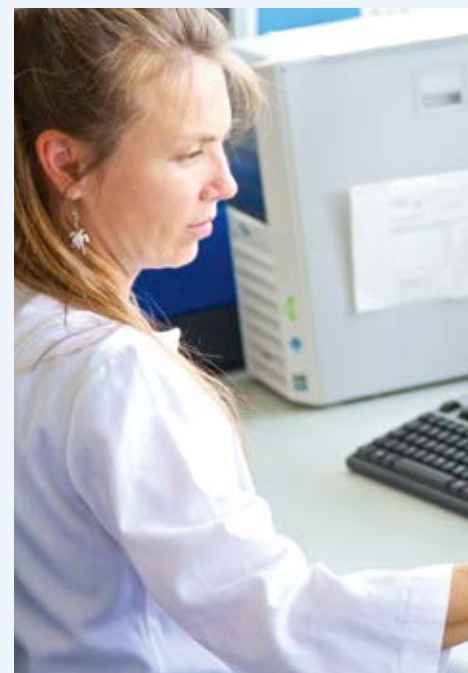


The BfR supports the compatibility of career and family and has been certified as a family friendly employer since 2009.

Compatibility of career and family: re-auditing process

The BfR promotes the compatibility of career and family and has been certified as a family friendly employer by berufundfamilie Service GmbH since 2009. On top of the compatibility enhancing measures that already existed (such as flexibility of working hours, parent-child offices at all locations, further training opportunities for employees absent for family reasons and part-time work offers), the option was added in 2015 of taking half-days of annual leave. The BfR has also been working closely with a family service provider since 1 July 2015. Employees can now make use of additional services, such as the mediation of regular, emergency and holiday child-care, as well as consultancy and mediation services for looking after family members who are in need of care.

Re-auditing and confirmation of the certificate for the next three years were done in 2015. The success of the audit confirms the previous efforts of the BfR to create a family friendly and attractive working environment. We will be continuing along this path in future.



Get moving at the BfR

Staying healthy at the workplace and protecting employees from job-related health impairments are the focus of personnel management at the BfR. In addition to strict compliance with occupational safety requirements through the conducting of continuous joint inspections of workplaces together with the in-house medical service and health and safety officer, offers for employees to get active and stay active form the focus of our health management. The BfR offers its workforce a number of in-house physical conditioning opportunities such as back exercises and Pilates courses at its locations in Marienfelde and Jungfernheide. Running events are also enjoying increased popularity. The BfR supports participation here by paying the registration fees and providing sports kit. The BfR entered its own teams at three Berlin running events in 2015, including the “CrossChallenge”.

Apprenticeships

The BfR offers apprenticeships to become an animal carer, office management clerk or chemical/biological lab assistant. Eight trainees completed their apprenticeships in 2015 with good to very good results.



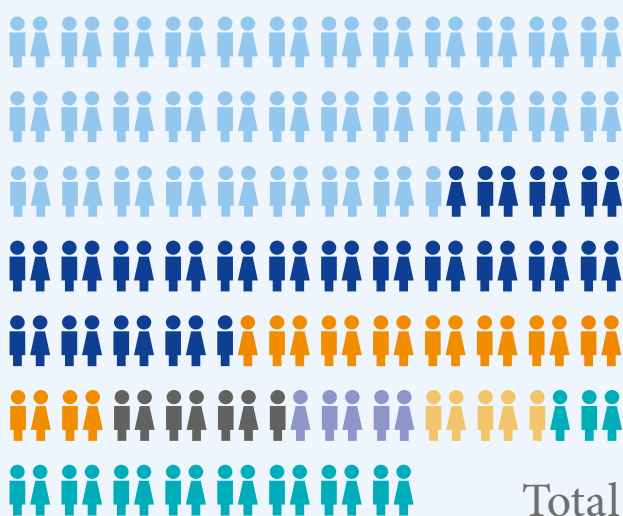
BfR staff at the Cross Challenge.



Key data for 2015

How many scientists does the Federal Institute for Risk Assessment employ? Which committees do they serve on? How does the institute finance itself? The answers to these questions are provided in the following chapter on the key data of the BfR. The figures all relate to the reporting year 2015.

Personnel



Scientists	324
Administrative staff	202
Technical assistants	95
PhD candidates	35
Apprentices/trainees	25
Animal carers	24
Other	96

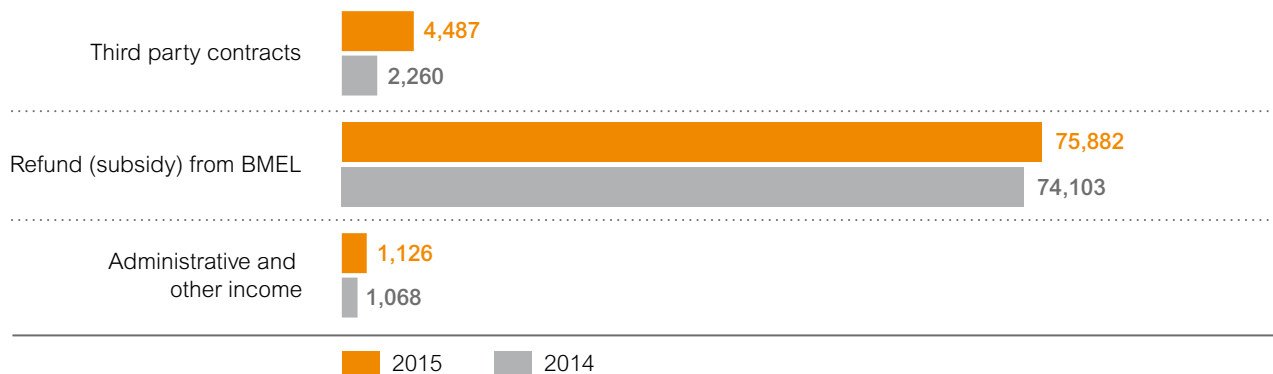
Total 801 employees

Participation in bodies

National	Number
Federal bodies	45
Federal government federal state bodies	49
BVL committees	26
Committees of other institutions	107
European level	Number
Bodies of the European Commission	39
Bodies of the European Food Safety Authority	38
Bodies of the European Chemicals Agency	15
Bodies of other European institutions	28
Worldwide	Number
WHO/FAO: Bodies of Codex Alimentarius	13
WHO/FAO: other bodies	3
Bodies of other United Nations specialised Agencies	9
OECD bodies	43
Other bodies involved in global standardisation activities	9

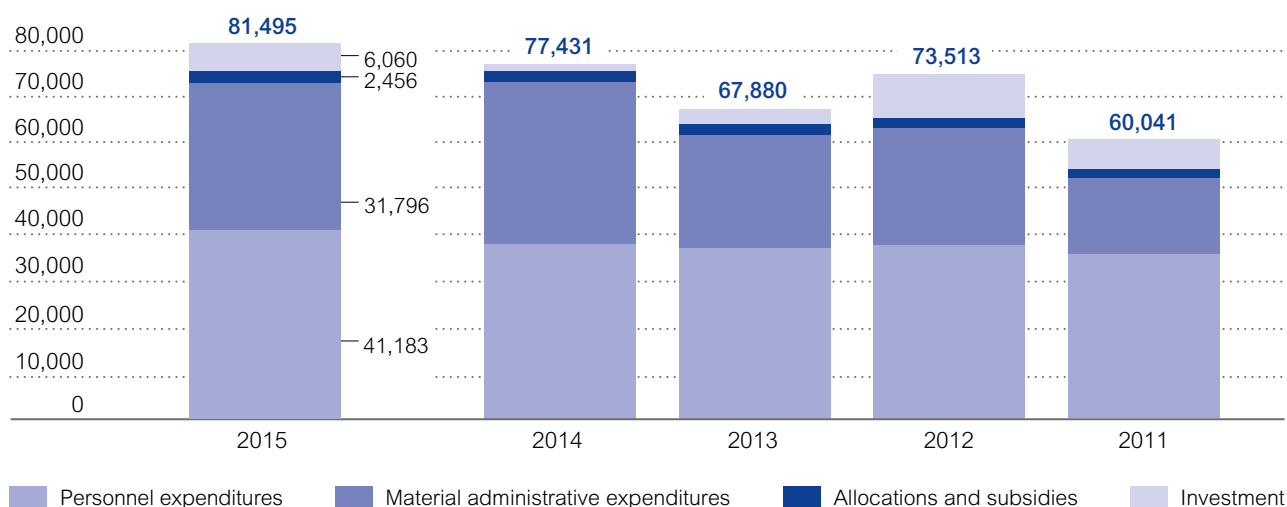
Procurement/Finances

Income (in thousands of euros)



About **81 million euros**
is how much the BfR received in total in 2015.

Expenditures (in thousands of euros)

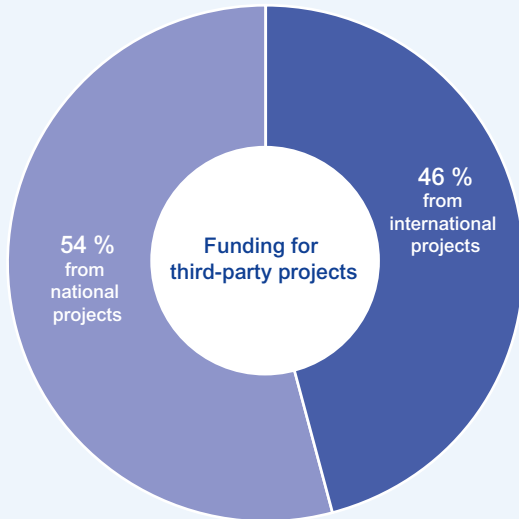


The increase in expenditure over 2014 was due mainly to increased investment in construction measures and the foundation of the German Centre for the Protection of Laboratory Animals (Bf3R). The BfR also made use of its budget flexibility options, which were established per federal legislation, to create jobs in areas with a particularly heavy workload in order to be able to process the increased quantitative as well as qualitative demands in a more efficient and timely manner in the best interests of consumer protection.

Selected Expenses

Scientific collections and libraries	429,014.30 €
Initial and further training	324,004.04 €
Public relations work and risk perception research	661,167.93 €
Conferences, trade fairs and exhibitions	186,671.84 €

Research

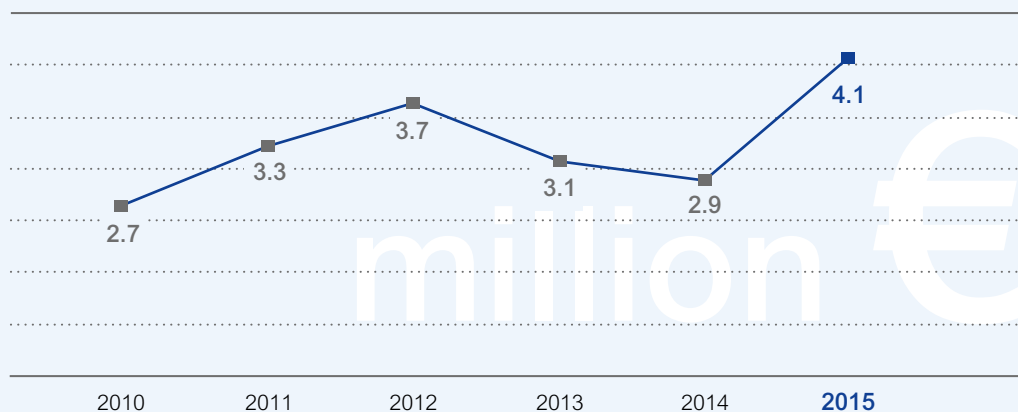


Funding for third-party projects in 2015 amounted to **4.1 million euros**. Almost half of it went to international research projects.

Third-party projects	Number	Funds
international (EU, EFSA etc.)	20	1,858,753 €
national (BMBF, DFG, BLE etc.)	25	2,202,832 €
total	45	4,061,585 €

Compared to 2014, the BfR increased its third party revenue by **41 percent**.

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



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)	2,050
Expert opinions for supervisory federal ministries (BMEL, BMUB, BMVI)	350
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	90
Expert opinions for the European Food Safety Authority (EFSA) and EFSA Focal Points of other Member States	30
Other expert opinions for public authorities and courts outside prescribed procedures	190
Other opinions, mainly for associations, individuals, NGOs	290
Total	3,000

The 2,050 assessments in prescribed procedures include:

	Number
Assessments pursuant to pesticides legislation	830
Assessments of intoxication cases pursuant to § 16 e Chemicals Act (ChemG)	390
Opinions on chemicals pursuant to chemicals legislation (REACH)	350
Assessments pursuant to biocides legislation	280
Opinions on feed procedures stipulated in feed legislation	70
Opinions on exemptions from consumer protection provisions in food legislation, §§ 54, 68 Food and Feed Code (LFGB)	40
Other risk assessments in prescribed procedures	90

Note: The figures provide some insight into the type and scale of expert opinions prepared by the BfR in 2015. 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.

Publications

	Number
Books	2
Contributions to compilations	14
Articles in journals	209
Contributions to proceedings	114
Poster contributions	203
Presentations	716
Dissertations/habilitations/diplomas/ masters/bachelors	52
Reports/EFSA	24



Around **700 presentations** were given in 2015.

Selected events in 2015

The BfR Academy conducts a large number of events every year on various topics from the BfR's range of tasks. The goal of these events is to promote an exchange with various target groups and to inform about the BfR's assessments and research results. Approximately 180 internal and external events were staged in 2015, the majority of them serving the purpose of scientific dialogue followed by information events. Several further training events were also organised.

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

16–25 January 2015

BfR at International Green Week in Berlin

The BfR presented itself at Green Week under the heading “Safe foods from the farm to the fork”. BfR experts provided information on plant diseases and how they can endanger human health. The benefits and possible health risks of plant protection products were also presented. On the one hand, they protect the health of plants and thereby that of consumers too but on the other, they can have damaging effects if not used in the proper manner. For this reason, information was also given on maximum residue levels of plant protection products in foods and how to control them.



On a stroll along the educational trail at the BfR stand, visitors had the opportunity to walk through a wheat field to have a look at wheat plants that had been cultivated in different ways, some of which had also been infected with plant diseases such as ergot.

3–4 March 2015



Methodical limitations and future challenges were discussed in presentations during the training school on nanotechnologies.

1st BfR Academy Training School on Nanotechnologies for Risk Assessors

The first BfR Academy Training School on the subject of nanotechnology took place at the beginning of March. Together with experts in the risk assessment and regulation of nanomaterials, the current status of research was established on topics such as characterisation and the toxicity testing of nanomaterials.

4th BfR-Summer Academy

Increased international standardisation and communication between national bodies of various countries is necessary to ensure the safety of food and consumer products in globalised markets. With this goal in mind, participants from 18 countries from China to Uruguay studied the principles of risk assessment and risk communication at the fourth BfR-Summer Academy. To deepen the knowledge previously conveyed in presentations, the participants got involved in workshops in which they were able to apply individual case examples from their own countries.

25–27 March 2015

Further training event for the public health service

The further training event for the public health service was conducted once again in 2015 in cooperation with the Robert Koch Institute (RKI) and Federal Environment Agency (UBA) at the BfR location in Marienfelde. As in previous years, public health service staff were able to catch up with current topics from the work areas of the three institutes. There were presentations on tobacco products and e-cigarettes, for example, as well as on drinking water hygiene. In addition to this, the German Commission for Hospital Hygiene and Infection Prevention at the RKI presented its new and revised recommendations.



The further training event for the public health service was conducted once again in 2015 in cooperation with the RKI and UBA.

17–28 August 2015



Scientists of different nationalities exchanged information and experiences on the principles of risk assessment and communication at the BfR-Summer Academy.

Information Events

Further Training Events

Scientific Dialogue

20 September 2015

BfR at World Children's Day Festival at Potsdamer Platz in Berlin

For the second time, the BfR had a stand at World Children's Day at Potsdamer Platz. Under the motto "Diversity instead of monotony – safe through variety", visitors were able to gather information on topics such as pyrrolizidine alkaloids (PA) in teas. PA are plant ingredients which have proven to be carcinogenic in tests with animals. BfR staff members explained how to prevent possible damage through health hazardous substances by maintaining a varied diet. Children were encouraged to paint pictures of what they had eaten in the last few days. In this playful way, the kids and their parents were able to get acquainted with the BfR's KIESEL study, in which the eating habits of children aged from six months up to and including five years are being examined.

At World Children's Day, our little visitors were encouraged to paint pictures of what they had eaten in the last few days.



25 September 2015

Opening of the German Centre for the Protection of Laboratory Animals (Bf3R)

The German Centre for the Protection of Laboratory Animals (Bf3R) was opened at the end of September 2015 by Christian Schmidt, Federal Minister of Food and Agriculture. Attached to the BfR, the centre coordinates activities to protect laboratory animals and lower their number in Germany to an absolute minimum. These tasks and the research funding of alternative methods to experiments with animals were presented at the opening.

During the opening, the Animal Welfare Research Prize put up by the Federal Ministry of Food and Agriculture was awarded to Professor Dr. Marcel Leist and his research group at the University of Konstanz. They were awarded the prize for developing a model on the basis of cell cultures which can be used instead of animal experiments when conducting research on neurodegenerative diseases such as Alzheimer's and Parkinson's.

You will find more information on the German Centre for the Protection of Laboratory Animals (Bf3R) on p. 84.





2–3 November 2015

BfR Symposium on Antimicrobial Resistance in the Food Chain

The significance of livestock farming and food production for the occurrence of resistant bacteria in humans is a subject of intensive public discussion. The BfR has issued invitations several times in the last few years to symposiums on this topic with experts from various fields. The latest developments with regard to the occurrence of resistant germs in the food chain were discussed at the symposium Antimicrobial Resistance in the Food Chain 2015. Measures planned and already in use to reduce consumer exposure to resistant bacteria from livestock farming were also discussed. Human and veterinary medicine should work together to minimise antimicrobial resistance (“One Health” approach).



3–4 December 2015



Numerous questions were answered at the consumer protection forum on pyrrolizidine alkaloids, which met with great public interest.

16th BfR Consumer Protection Forum “Pyrrolizidine alkaloids – Challenges to agriculture and consumer protection”

The occurrence and health risks of pyrrolizidine alkaloids (PA) were discussed with scientists at the 16th BfR Consumer Protection Forum. PA are secondary metabolites produced by several plants, such as ragwort, as protection against herbivores. It has been shown in animal experiments that PA can cause cancer and they are undesired in foods and feeds for this reason. Representatives of consumer protection organisations and trade and industry associations had the opportunity on the second day of the forum to present and discuss their points of view. The event was broadcast live on the internet in German and English per livestream.

Information Events

Further Training Events

Scientific Dialogue



36

The active substance glyphosate was examined with regards to its suitability for continued use in plant protection products according to EU specifications.



Main Topics 2015



The BfR develops, validates and assesses analytical strategies and methods for testing the authenticity of foods and feeds.

44



For the first time in Germany, foods are being analysed systematically and representatively in ready-to-eat condition in the BfR MEAL Study, which means they are prepared in the manner in which they are normally eaten.

50



The active substance evaluation procedure within the EU stipulates that the Rapporteur Member State for the European approval process prepares the first assessment report for the scientific discussion with the other EU Member States, as well as the applicants and the general public.

Health risk assessment of glyphosate

Just like every other active substance in plant protection products, glyphosate is also reassessed for the European market at regular intervals within the scope of EU evaluation of active substances with regard to the risks it poses to health and the environment, as well as its efficacy. The approval of glyphosate expires at the end of 2016. If the active substance is not reapproved or if the current approval is not extended, glyphosate and plant protection products that contain it may not remain on the European market.

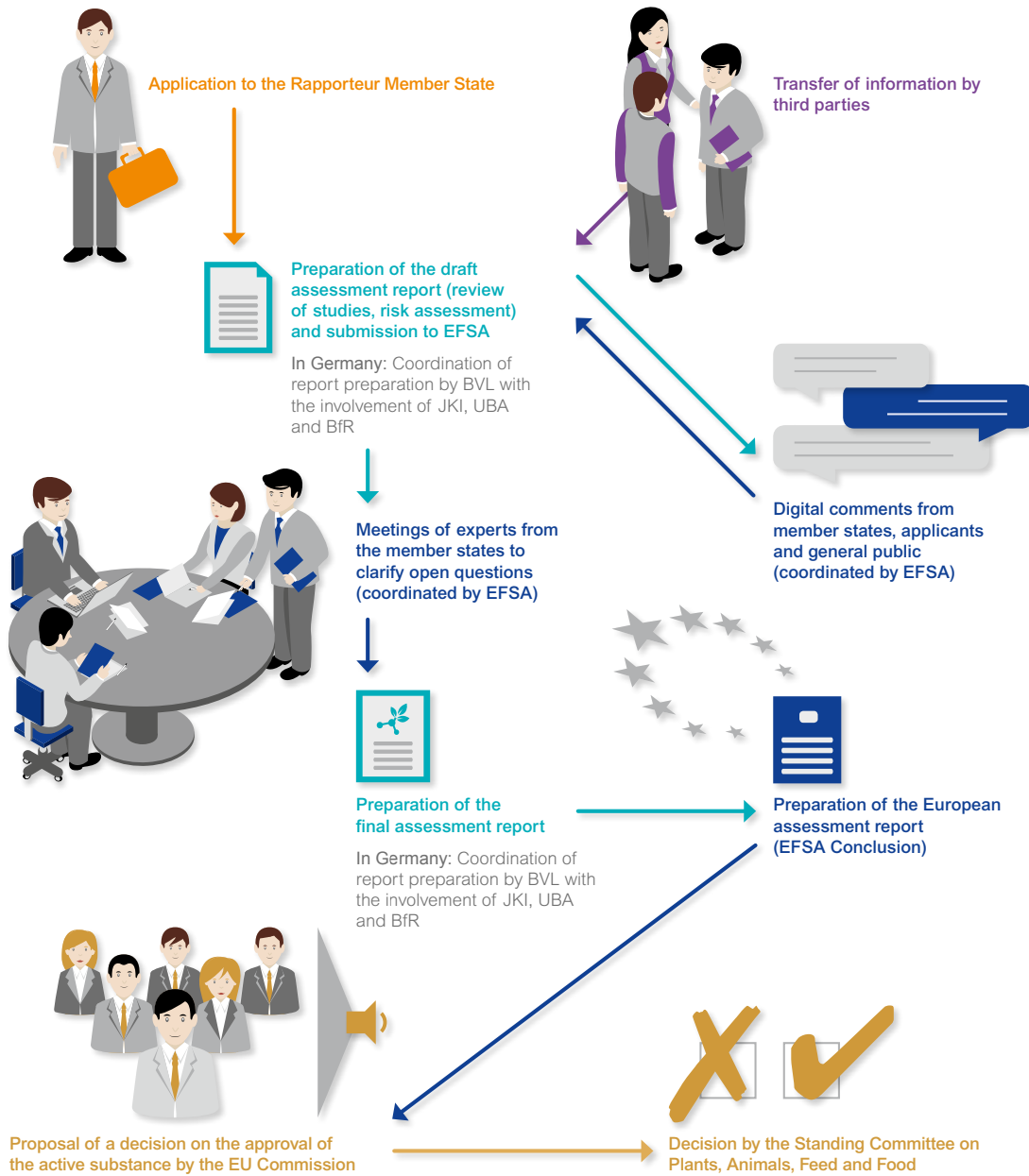
The procedure for the EU evaluation of active substances stipulates that the Rapporteur Member State for the European approval process prepares the first assessment report for the European Food Safety Authority (EFSA) so that it can then be reviewed by all EU Member States, revised, jointly discussed and finally adopted by EFSA. The report serves as the scientific basis for the decision of the EU Commission, which can include other considerations in its decision such as the precautionary principle.

The EU Commission appointed Germany as the Rapporteur Member State for the Community evaluation and assessment of glyphosate. The authorities involved in the authorisation process for plant protection products in Germany in accordance with legal provisions acted here on behalf of the German national government as Rapporteur Member State for the European approval procedure. In addition to the toxicological assessment of the active substance glyphosate and a sample formulation, the BfR was obliged to perform a risk assessment for consumers, users, workers, bystanders and local residents as well as an examination of the analytical methods for monitoring glyphosate residues. The Julius Kühn Institute (JKI) assessed the efficacy of the substance and its effects on bee health and the Federal Environment Agency (UBA) the effects on the environment. →



The BfR evaluated the active substance glyphosate and a sample formulation with regard to both the hazards as well as the risks to human health.

EU Approval Process of Active Substances in Plant Protection Products



Applicant **Third parties** **EU member state** **EFSA** **EU Commission**

BVL: Federal Office of Consumer Protection and Food Safety; EFSA: European Food Safety Authority; JKI: Julius Kühn Institute, Federal Research Centre for Cultivated Plants; UBA: Federal Environment Agency

This text version is a translation of the original German text which is the only legally binding version.

Consultation phase

The Federal Office of Consumer Protection and Food Safety (BVL) conveyed the application for the renewal of approval of glyphosate to the BfR, JKI and UBA in August 2012. The applicant is the Glyphosate Task Force (GTF), which comprises 26 firms. In line with legal provisions for the approval process, the applicants must submit comprehensive data which prove that the active substances can be used safely. To this end, the applicants must also conduct literature research and report on the status of studies. In addition to the GTF documentation, the BVL provided the BfR with additional documentation which had been submitted by third parties for review. In line with these legal provisions, the active substance glyphosate was then tested for its suitability for continued use in plant protection products in compliance with legal stipulations by the German authorities.

The BVL handed over the entire assessment report to EFSA at the end of 2013. EFSA then invited the applicants, the other EU Member States and the general public to comment on the report at the beginning of 2014. In this way, all interested persons, organisations, associations and other interest groups were able to participate in the process. The submitted comments, 350 of which concerned the health assessment, were validated by rapporteur Germany with the involvement of the BfR and worked into a new version of the Renewal Assessment Report (RAR) in which the staff reviewed more than 250 experimental studies with animals which the applicants had submitted and evaluated more than 1,000 sources. Unresolved assessment issues and questions raised in the comments were discussed at a meeting of experts organised by EFSA in February 2015 with the participation of all 28 member states. Rapporteur Germany, with the involvement of the BfR, incorporated all of the results of the scientific discussion into the final version of the RAR of April 2015.

At almost the same time that the EFSA Renewal Assessment Report was completed, the International Agency for Research on Cancer (IARC), an institute of the World Health Organisation (WHO) which evaluates epidemiological studies on cancer all over the world to investigate the causes of cancer and also prepares prevention strategies, announced in a booklet published in March 2015 that they had assessed the active substance glyphosate as “probably carcinogenic to humans” along with the active substances contained in other pesticides. The IARC did not present a complete assessment at this point in time. →

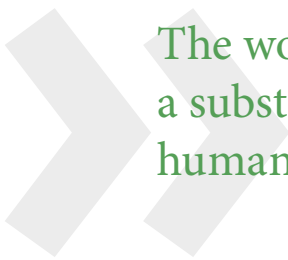


BfR staff reviewed over 250 new experimental studies with animals that had been submitted by applicants and assessed more than 1,000 sources from published scientific literature.

Hazard identification by IARC and risk assessment by the BfR

The “hazard identification” conducted by IARC constitutes the first step in the process of “risk assessment”. The classification of a substance as a carcinogenic hazard can be an important indication that a certain level of exposure through a particular job, the environment or through food, for example, could lead to a higher risk of developing cancer. With the risk assessment of pesticide residues in foods as conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), a safe intake quantity is established after the degree of risk has been determined. As the IARC hazard identification can also form an additional basis for risk assessment in the EU approval process, the BfR recommended that the European approval process be extended, whereupon the European Commission postponed the deadline for the submission of the RAR. Once the IARC monograph was published in July 2015, the BfR reviewed it and presented its assessment in an addendum to the Renewal Assessment Report in September 2015.

Both IARC and BfR assessed the epidemiological studies on glyphosate as providing “limited evidence” with regard to the carcinogenic properties of glyphosate. The assessment of IARC deviates in places from that of the BfR regarding the industry studies involving animal experiments. This can be explained by, among other things, the fact that the BfR assessment is based on the original studies of the applicants' laboratories which conducted them. The IARC assessment, on the other hand, is not based on the original studies but rather on the published evaluations of third parties, such as the American Environmental Protection Agency (EPA) and Joint FAO/WHO Meeting on Pesticide Residues (JMPR). The original data of the unpublished manufacturers' studies were not available to IARC. That is why IARC arrives at some conclusions in its secondary evaluations which contradict the primary evaluations of bodies such as EPA and JMPR. The BfR assessed a much more comprehensive data basis of a total of eleven long-term studies on rats and mice regarding the carcinogenic properties of glyphosate using the “weight of evidence” approach recommended in the European guidelines. This approach is not based solely on a post-



The word hazard is used to describe the properties of a substance itself. A risk only occurs, however, when humans come into contact with a hazardous substance.




A distinction between effects caused by the active substance and observations with plant protection products containing glyphosate is not only necessary where users are concerned but also non-involved third parties, including children.

hoc statistical test, it includes all of the findings on the dose-dependent effect, biological significance, reproducibility and consistency of the toxic effects, the plausibility of the key events, the tumour frequency among untreated test animals and the significance of various statistical methods.

Special significance of the mixture toxicity

In its glyphosate assessment, IARC also took into consideration studies conducted on plant protection products containing glyphosate, the results of which cannot be causally attributed to the active substance glyphosate. The BfR took this circumstance into account by making a clear distinction between effects caused by the active substance and observations made with plant protection products containing glyphosate. This distinction is essential as, due to co-formulants or interactions between co-formulants and active substances, plant protection products can be more toxic than would be assumed on the basis of the active substance concentration. The two-stage EU process for the approval of active substances and authorisation of plant protection products takes these circumstances into account by taking a separate look at the mixture toxicity. In this context, the BfR also recommended on the basis of its own research that, as has already been the case in Germany for some time, certain co-formulants (tallow amines) should no longer be approved in other European countries as well. →



The EFSA report forms the basis for the preparation of a recommendation to help the European Commission to reach a decision on the renewal of approval for glyphosate.

EFSA Conclusion

The RAR addendum of August 2015 was verified and commented upon by experts from the member states and discussed on 29 September 2015 at a meeting organised by EFSA. In addition to representatives of the EU Member States, observers from the European Chemicals Agency (ECHA), WHO, JMPR, IARC and EPA participated in the meeting. EFSA took the results into account when preparing its final assessment report. After evaluating the public and expert consultations, EFSA published the report including all related supplements and the BfR addendum on the assessment of the IARC monograph on their website (www.efsa.europa.eu).

i EFSA has published the background documents related to its peer review of glyphosate. The documents can be viewed at: www.efsa.europa.eu/en/press/news/151119a

This EFSA report forms the basis for the preparation of a decision proposal by the European Commission on the renewal of approval for glyphosate. This decision will be reached in a voting process in the Standing Committee on Plants, Animals, Feed and Food (SCoPAFF) before being announced with binding effect in the Official Journal of the European Union.



Accompanying discussions on active substance approval

In June 2015, the media reported on findings of glyphosate in 16 breast milk samples and described these test results as “very worrying”, whereupon concerned mothers in particular asked the BfR if breast-feeding could still be recommended without any reservations. The BfR expressed scientific doubt about the reliability of the results, since the ELISA test that had been used is not suitable for the detection of substances in breast milk and the alleged findings were roughly 200 times lower than the determination limit that the manufacturer of the test stated to be reliable. For this reason, the BfR commissioned renowned European research laboratories to develop two independent analytical methods with high sensitivity in order to test 114 breast milk samples from the states of Lower Saxony and Bavaria. Both methods were newly developed and can precisely determine glyphosate residues in breast milk from quantities of one nanogram (ng = one billionth of a gram) per millilitre (mL) (determination limit). This means that these analytical methods are more than ten times more sensitive than the methods normally used to analyse plant protection product residues in foods and 75 times more sensitive than the ELISA method (according to the information provided by the manufacturer). As anticipated by the BfR on the basis of the physical-chemical properties of glyphosate, no residues of the active substance glyphosate contained in plant protection product were measured above the detection limit in any of the examined breast milk samples. This confirms the results of the BfR study which conclude that mothers have no cause for concern and should continue to breast-feed as before. ||

i More information on glyphosate:
www.bfr.bund.de/en > A-Z Index
 > glyphosate

More information from the WHO and JMPR:
www.who.int/foodsafety/faq/en/
www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

Hazard classification of glyphosate

As a consequence of the current discussions, the BfR initiated a regular examination of the legal classification of the carcinogenic properties of glyphosate in line with the CLP regulation (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) on a European level. Decisions made in compliance with this regulation are to be used as the only binding legal regulation for the classification and labelling of substances and mixtures.

As the responsible authority in Germany, the Federal Institute for Occupational Safety and Health (BAuA) prepared a recommendation to change the legal classification of glyphosate in consultation with the other responsible German authorities (UBA, BVL and BAuA) and submitted it to the European Chemicals Agency (ECHA). The recommendation for the harmonisation of classification and labelling is as follows:

- > Serious eye damage Category 1,
H318: “Causes serious eye damage”.
- > Specific target organ toxicity with repeated exposure Category 2,
H373: “May cause damage to organs through prolonged or repeated exposure”.
- > Hazard to aquatic environment long-term Category Chronic 2,
H411: “Toxic to aquatic life with long-lasting effects”.

Authenticity testing

Cases of food adulteration are being discovered over and over again. Some adulterations, such as the extension of milk powder with melamine or the colouring of spices with Sudan dyes, do not only amount to deception and fraud, they can also result in health risks for consumers. The authenticity testing of food and feed is therefore a fundamental aspect of consumer health protection. The BfR develops, validates and assesses analytical strategies and methods for authenticity testing. This involves the examination of the composition and origin of food and feed to ensure that the products actually comply with the labelling information of the manufacturer or distributor. The increasing globalisation of commodity chains is posing a special challenge to authenticity testing and document-based traceability. In the event of an incident or crisis, only when seamless documentation on all production, processing and distribution stages is on hand specific goods can be identified and withdrawn from the market quickly and effectively.

SPICED: Improved safety of spices and dried herbs

Spices, including dried culinary herbs, refine the quality and appearance of food dishes and give them a characteristic taste. Due to the often high value of these commodities, there were repeated instances of deliberate, unauthorised adulteration in international spice trading in order to stretch the product with cheaper materials or to feign better quality. In the past, for example, there have been cases where potentially health-damaging substances such as Sudan dye or lead oxide have been added to paprika powder to produce the desired intensive red colour. In addition to this, unintentional or natural contamination with chemical and/or biological agents can take place during the production, processing, storage and marketing of the goods. Despite the relatively small quantities of spices consumed, contamination of this kind can pose a health risk to consumers. →



In international spice trading, there have been repeated instances in the past of deliberate, unauthorised adulterations in order to stretch products with cheaper materials or to fake better quality.





Using a non-targeted method, the spectroscopic characteristics of the ingredients of a sample, i.e. its physico-chemical fingerprint, are determined using a combination of spectroscopy and multivariate data analysis.

Due to their many different uses, spices have a great potential for carrying over adulterations and contamination in a wide range of products with a wide distribution area. They belong to one of the most frequently reported product groups in the European Rapid Alert System for Food and Feed (RASFF). Against this background, the EU project “SPICED” was initiated in July 2013. The objective of SPICED is to improve the safety of spices and dried culinary herbs towards biological and chemical contamination along the entire food chain. The consortium involved in the project, which is coordinated by the BfR, is made up of eleven institutions from seven European countries. It comprises partners from trade and industry, science and food authorities. Over and above this, additional representatives of industry are available to the project partners in an advisory capacity as integrated stakeholders.

The elements of the spice supply chains are examined more closely in the SPICED project in order to identify possible points of contamination and characterise them more thoroughly. Parallel to this, control and warning systems are analysed and assessed with regard to their usability and effectiveness for these special commodity chains. In addition to this, existing analytical methods are being optimised and/or further developed to enable the successful identification of possible contamination in spices and herbs.

Staff at the BfR's Biological Safety and Safety in the Food Chain departments are conducting research on important aspects of the SPICED project. For example, various bacterial microorganisms including pathogens are being examined with regard to their ability to survive in spices and dried herbs during storage. In addition to classical cultivation on growth media, molecular biological methods which enable relatively quick and above all very specific and sensitive detection are being established.

- > Spices and herbs are among the oldest trading goods in the world.
- > They caused wars and were more valuable than gold. More than 400 different herbs and spices are commercially available all over the world.
- > The EU is one of the world's biggest markets for spices and herbs.
- > Pepper, paprika and chili are the top European export hits among the spices.

The SPICED project has the goal of improving the safety of spices including dried culinary herbs with regard to biological and chemical contamination along the entire food chain.

Another important area of research is the authenticity testing of spices and dried herbs with main focus on the detection of substances that were added to stretch the product or feign better quality. The difficulty in the classical detection of adulteration lies in the fact that only the substance that is being looked for can normally be found. This means that a spice/herb sample can be examined more closely for adulterants which are already known (e.g. foreign plant material, starch or sand), while unknown substances can be overlooked. The goal of the research was therefore to develop so-called non-targeted methods which enable the discovery of previously unknown adulterations such as the addition of unexpected substances. Using a non-targeted method, the spectroscopic characteristics of the ingredients of a sample, i.e. its physico-chemical fingerprint, are determined by the combination of spectroscopy and multivariate data analysis. A new sample can be tested against a reference database, which is built up by recording the natural variation on basis of the examination of non-adulterated, authentic samples. By comparison with the authentic data, it is possible to identify many different deviations from the anticipated result, such as products containing deliberate or accidental contaminants/adulterants.

The project ends in June 2016 with an international symposium at the BfR at which the most important project results will be presented and discussed with other stakeholders. In addition to this, the research results have been and will continue to be published in internationally renowned journals and in a special issue of the peer-reviewed scientific journal "Food Control". The cooperation with partners at various institutions that has been brought about and intensified through SPICED will also be used for subsequent collaboration. →



SPICED – “Securing the spices and herbs commodity chains in Europe against deliberate, accidental or natural biological and chemical contamination”

Duration:
3 years (1 July 2013 – 30 June 2016)

Total budget:
approx. € 4.6 m

Funding:
approx. € 3.5 m

Coordinator:
Department Biological Safety (BfR)

The project has received funding from the European Union's 7th Framework programme for research, technological development and demonstration under grant agreement No. 312631.

i Detailed information on the SPICED project at:
www.spiced.eu



Throughout the EU it is fundamentally prohibited by law to feed processed animal proteins to domestic animals, but there are exceptions to this.



Protein spots in poultry meal extracts in a 2-D electrophoresis gel. Individual spots are "picked" out of the gel, examined per mass spectrometer and the proteins identified on the basis of databases. Only poultry-specific proteins are of benefit to a specific detection system.

Animal protein in foods and feeds

Around three million tonnes of animal byproducts from the slaughter and production processes accrue every year in Germany. The German meat industry generates annual sales of 30 billion euros. Animal waste must be disposed of properly. Throughout the EU it is fundamentally forbidden to feed processed animal proteins (PAP) to all domestic animals, from cattle to fish. In addition to this, the "anti-cannibalism" rule stipulates that no animal species may be fed to another animal of the same species. These rules have made a considerable contribution towards gaining effective control of the lethal cattle disease BSE (bovine spongiform encephalopathy) and minimising the number of cases.

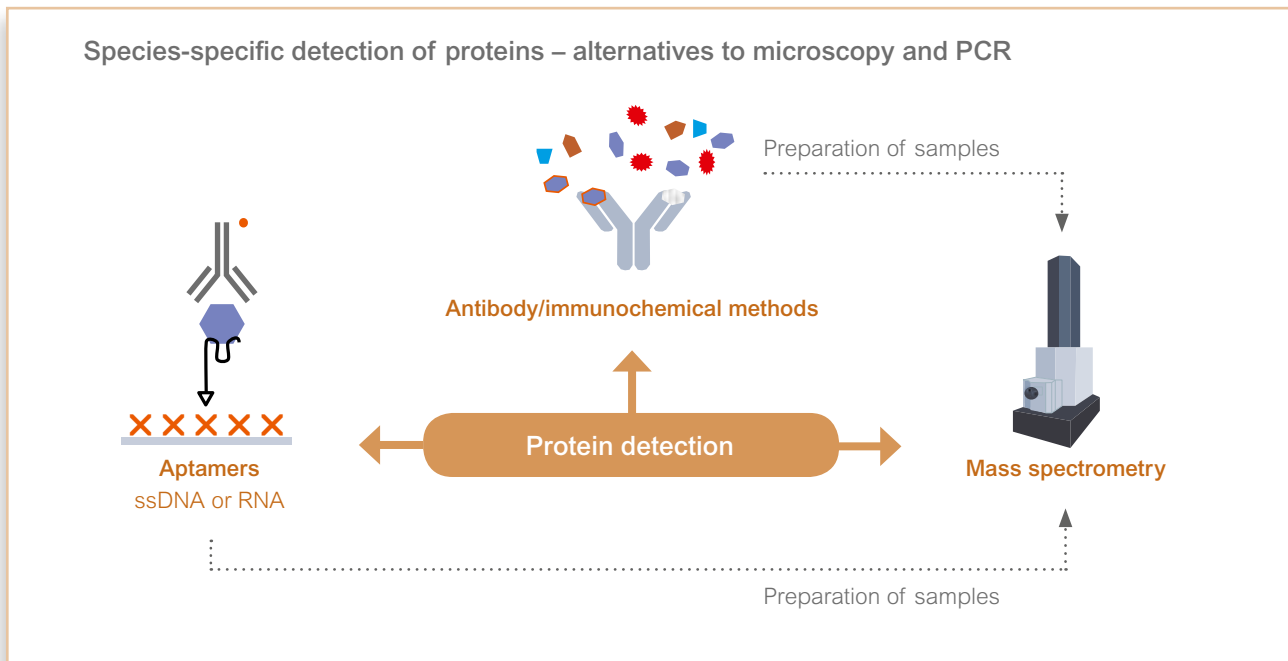
There are exceptions to the strict feeding ban, however. Proteins from milk and eggs that cannot be contaminated with prions, the pathogens of BSE, as well as fish, blood and animal meals from non-ruminants are authorised as animal feed under certain circumstances. The list of banned products and exceptions is extremely complex and depends on the animal species or group and the intended use.

The processing of animal proteins for feeding purposes is also strictly regulated. The heat and pressure conditions in the prescribed processes severely alter the protein structure. The standard processing of animal processing requires a core temperature of 133°C and a pressure of 3 bar for at least 20 minutes. The resultant changes in the proteins pose great analytical challenges: is it still determinable with such highly processed products from which animal species they originated? And is it possible to distinguish banned PAP from approved milk powder?

Two analytical methods are currently prescribed by law in the European Union. By using a simple light-microscopic method, it is determined on the basis of heat-resistant particles such as hair, bone splinters or scales, whether a feed contains any PAP at all. However, this method cannot make a precise distinction between closely related animal species, so that a DNA analytical method is used to detect banned ruminant constituents. This involves the detection of a ruminant-specific gene sequence in the polymerase chain reaction (PCR). Still it is impossible to distinguish between banned and authorised ruminant protein, e.g. derived from milk or animal meal by means of PCR analysis, because ruminant DNA will be detected in both.

In the feed area, protein-based methods with which both, the animal species as well as the tissue type can be identified, are being considered as analytical alternatives.

In the food area, the "horse meat scandal" made clear that fast in-place methods to uncover adulterations are lacking. Antibody-based strip tests are ideal for this purpose as they deliver a valid test result within minutes and are very easy to handle.



Research is being conducted in two directions in the BfR Food Safety Department: the development of antibody-based quick test methods for animal species differentiation in cooperation with a partner institute and the development of suitable mass spectrometric methods in the National Reference Laboratory for Animal Protein in Feed (NRL-TP). New enrichment and filtration methods have to be developed in order to obtain sufficient protein or protein fragments for further analysis. The specific use of antibodies or aptamers (DNA or RNA molecules which can bind with high affinity to certain protein sections, just like antibodies) in combination with special extraction and molecule size exclusion methods is opening up promising new perspectives in this area.

Against the background of an increase in the number of cases of fraud, validated detection methods for species-specific protein would make a valuable contribution towards traceability and the discovery of adulterations in foods and feeds. ||



Total Diet Studies – TDS for short – determine in which concentrations substances are contained in ready-to-eat foods on average.

What's in your food – the BfR MEAL Study

In what quantities do we ingest undesired substances on average through our food? Are certain foods more contaminated than others? And what health effects does the preparation method have on the food?

Total Diet Studies – TDS for short – help to answer these and other questions. TDS is the name given to an international method which determines in which concentrations substances are contained in ready-to-eat foods. These can comprise beneficial as well as harmful substances. Developed in the USA in the mid-20th century, more than 50 countries have conducted their own total diet studies in the meantime. The first total diet study for Germany was launched in 2015. The BfR was commissioned to do so by the Federal Ministry of Food and Agriculture (BMEL).

The first German total diet study is called the BfR MEAL Study and is scheduled to run for a total of seven years. For the first time in Germany, foods are being analysed systematically and representatively in ready-to-eat condition, i.e. prepared in the manner in which they are normally eaten. A separate kitchen is being built for this purpose at the BfR location in Alt-Marienfelde. Five scientists and a documentation assistant have been working on the study up to now and additional jobs are planned. The BMEL funded the study in 2015 to the tune of almost a million euros. Over the entire duration of the study, the BMEL will probably spend a total of approx. 10 million euros for our partners involved in the project. →



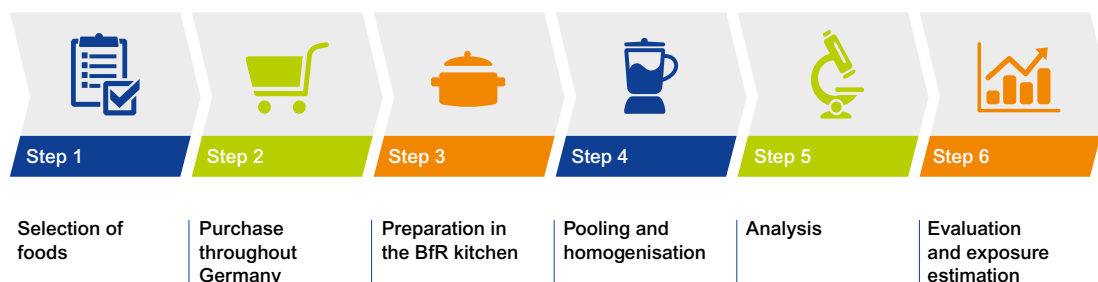
The BfR MEAL Study is the most comprehensive total diet study worldwide with regard to both the number of foods examined as well as the number of substances.



Foods of the same type are homogenised in the lab for the analysis.

Compared to other TDS, the BfR MEAL Study is the most comprehensive worldwide with regard to both the number of foods examined as well as the number of substances. The BfR MEAL Study provides a representative reflection of German eating habits by covering at least 90 % of the foods consumed in Germany plus some rarely eaten foods if they are known to contain high levels of undesired substances. The examined substances include environmental contaminants, mycotoxins, process contaminants, food additives, nutrients, pharmacologically effective substances and substances that migrate from packaging. In this way, the study closes data gaps for which there have been no systematic studies in Germany up to now.

Sequence of the BfR MEAL Study



One of the main aims of the BfR MEAL Study is to generate content data that is representative of German eating habits. To this end, the foods consumed in Germany are aggregated into groups for each of which the scientists establish a representative pool from samples of the prepared foods. The pools can also be differentiated by certain criteria depending on the food and substance group examined, e.g. by regional and seasonal differences or by ecological or conventional cultivation. In this way, roughly 4,000 pooled samples will emerge from around 60,000 sub-samples over the coming years. In the basis module, the pools are examined for certain substance groups, including heavy metals and dioxins. Some of these pools and additional foods are further analysed in substance-specific modules for process contaminants or food additives, for example. The modular structure of the BfR MEAL Study makes it possible to deal with the specific peculiarities of each substance group and address a large variety of issues.

The goal of the BfR MEAL Study is to better identify possible food risks for the German population. The first results will likely be available in late 2018/early 2019 in the form of recommendations for risk management and consumption recommendations. ||

i More information (in German) on the BfR MEAL Study at: www.bfr-meal-studie.de



Food Safety

The safety of foods is one of the most pressing tasks of consumer protection. One of the prerequisites is safe animal feed. No matter whether it may be ingredients, additives, residues and contaminants or germs and parasites, the BfR assesses foods and feeds and prepares opinions on questions concerning their safety. In the field of food safety, the BfR is involved with the toxicological and nutrition-physiological and/or medical assessment of food.




Food Safety

The BfR works according to the principle “From the field to the plate”. 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. The knowledge gained from the toxicological, microbiological and nutritional evaluation of feed and food provides the scientific basis for deriving maximum levels or limits. The Exposure department helps to characterise the relevant risks by drawing up estimates for intake quantities based on consumption studies and statistical evaluations. Furthermore, external, independent experts from nine BfR committees advise the BfR on issues of food safety on a voluntary basis.

Oral intake of metallic nanoparticles

Nanoparticles are used with increasing frequency due to special properties that can enhance certain products (such as antimicrobial effect, UV protection, solubility of vitamins). A BfR consumer survey showed that acceptance levels for these kinds of products are lower the closer the product in question comes to the body of the user. The willingness to purchase sealing products containing nanoparticles – car polish, for example – is very high, while acceptance levels for nanoproducts in the food segment are very low.

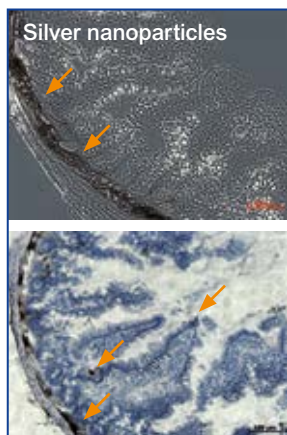
The extent to which consumers intentionally or unintentionally come into contact with these products is not always known. They certainly come into contact with silver nanoparticles in packaging materials that prolong the shelf life of food products, as the producers refer to the use of these nanoparticles on the packaging itself. Food supplements containing nanosilver are available on the internet, accompanied by unproven claims that they have a curative effect on a wide range of complaints. As nanoscale materials might be particularly toxic, the BfR investigates whether uptake occurs and the intake of these particles is associated with health risks.



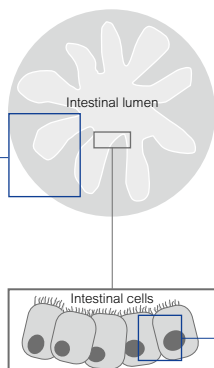
Regular intake of larger amounts of nanosilver via products such as food supplements can damage the barrier function of the intestinal mucosa.

Cellular intake of silver nanoparticles

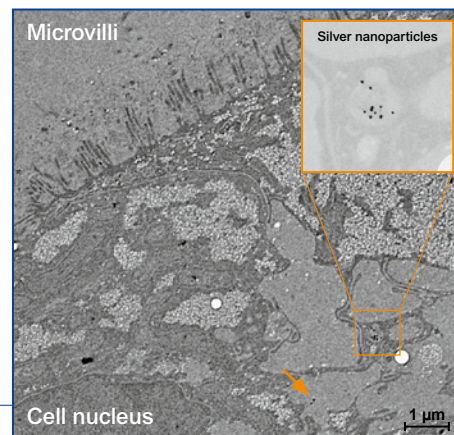
In the rat



Small intestine cross-section



In cell culture



One of the questions addressed by BfR researchers was how nanoparticles behave in the gastrointestinal tract during the digestion process. It has not been clear up to now whether nanoparticles dissolve here, for example, or whether they clump together to form larger particles, thus losing their specific toxicological properties and small size.

In order to answer this question silver nanoparticles were artificially digested in a purpose-modified system. The conditions that exist in the oral cavity, the stomach and the intestines were simulated, and the size of the particles in the digestive juices then examined. It was found that the size of the nanoparticles hardly changes at all during passage through the gastrointestinal tract. The next step was to investigate the effect of the particles on model cells of the mucous membrane of the small intestine. The mucous membrane of the intestine is the largest

resorption area for nutrients and, where applicable, also for nanoparticles. This membrane also acts as an effective barrier to substances that should not enter the blood stream and other organs. The investigation showed that the transport of these particles is mostly prevented by an intact intestinal mucous membrane and that only a small quantity of the particles therefore pass the intestinal barrier and enter the blood stream. However, regular intake of larger quantities of nanosilver in food supplements can result in an overdose and therefore in damage to the barrier function of the intestinal mucosa. The consequences of this kind of long-term intake on the human body and in particular on the organs are still unclear. It is also for this reason that the BfR advises against the use of nanosilver in consumer products.

The study findings were published in the journal Biological Chemistry. (DOI: 10.1515/hsz-2015-0145)



Hormonally active substances in foods

Hormonally active substances may occur as natural ingredients in various foods. Examples include hormones in milk or meat as well as phyto-oestrogens. The phyto-hormones include 8-prenylnaringenin, which is formed in hops and found in beer, certain polyphenols in wine and isoflavones in soy. Occasionally, such ingredients are added in isolated form to dietary supplements.

In 2015, the BfR was also tasked with the assessment of health risks of hormones and hormonally active substances in foods. Hormones are produced in animals as endogenous messenger substances to regulate metabolic processes. Accordingly, they also occur naturally in meat and milk. Cow's milk contains higher natural concentrations of oestrogens and progesterone than the muscle meat of slaughtered animals, fish or eggs. Natural hormone levels in meat can vary considerably. The meat of intact (non-castrated) young boars, for example, has significantly higher concentrations of the female sex hormone 17 β -oestradiol and the male steroid hormone nandrolone than the meat of castrated animals. Only a small portion of the hormones ingested with food is absorbed by the body and further metabolised. Compared to the endogenous synthesis of hormones in humans, the anticipated absorbed amount of hormones is considered to be low. The available data regarding natural hormone sources in foods like meat and milk currently do not point to any health risks.

Isoflavones are secondary plant compounds occurring, for example, in soy or red clover. Due to potential (weak) oestrogenic effects in the body, they are also called phyto-oestrogens. Dietary supplements and dietetic foods with isolated or enriched isoflavones are offered on the German market for the alleviation of menopausal ailments. The European Food Safety Authority (EFSA) has so far rejected the health claims made for isoflavones. In 2007, the BfR already concluded that in particular the long-term intake of high isoflavone amounts is not without risk for perimenopausal and postmenopausal women. In 2015, EFSA released a risk assessment of isolated isoflavones for the aforementioned target groups. Thereupon, the BfR explained the main findings of the scientific opinion of EFSA in a communication intended for consumers: Based on the evaluated human studies and the applied preparations, doses and treatment durations in these studies, there are no indications of adverse effects of isolated isoflavones on the female mammary gland, uterus and thyroid in postmenopausal women. Based on the relevant studies, EFSA proposed guidance values for an adequate safe use of isoflavone enriched



Isoflavones are secondary plant compounds and occur, for example, in soy.

products (for example: a maximum supplemental intake of 100 mg per day for a maximal duration of 10 months for soy isoflavones and soy extracts, and a maximum supplemental intake of 43.5 mg per day for a maximal duration of 3 months for red clover). The BfR supports these guidance values which should not be exceeded in the case of postmenopausal women and proposes that the guidance values should be also used for perimenopausal women until sufficient data are available for this consumer group to complete the risk assessment. The intake of isoflavone-rich preparations is not recommended for women with a history or current diagnosis of oestrogen-dependent (cancer) disease of the mammary gland or the uterus. Since it may not be known whether such diseases are present, it could be necessary to obtain medical advice before using dietary supplements with isolated isoflavones.

Isolated endogenous steroids are sometimes added to dietary supplements, such as the anabolic prohormone dehydroepiandrosterone (DHEA). In the human body, this substance can be converted into both male sex hormones like testosterone and female sex hormones like 17 β -oestradiol. Studies show that an intake of 25 mg DHEA per day can change endogenous hormone levels, particularly in postmenopausal women. Moreover, the intake of this substance can result in clinically apparent hormonal effects like acne in certain population groups. In addition, it is unclear whether DHEA may influence the growth of hormone-dependent breast or prostate tumours. Therefore, the BfR does not recommend the use of steroidal hormones – like DHEA with its prohormonal effect – without medical supervision and a medical indication.

i More information (in German) on isoflavones at: www.bfr.bund.de > A-Z Index > Isoflavone

Assessment of the health risks of certain “sports foods”

“Fit and slim”: “Sports foods” – a collective term used to describe a group comprising a wide range of foods – are designed to appeal to sportspeople or people who lead a physically active lifestyle. EU food legislation does not provide a definition for sports food. However, sports food products are available on the market in widely varying forms and compositions: From sports drinks and carbohydrate or protein concentrates to various micronutrient products marketed as food supplements. One commercially important group of sports products are food supplements with substances that are intended to influence metabolic processes – by increasing “fat burning” and rapid weight loss, for example. In many cases, slimming products, particularly those sold via the internet, can contain substances that present a health risk or that have not been adequately assessed.

Hydroxycitric acid (HCA), for example, is obtained from the rind of an Indian spice plant called *Garcinia cambogia*. It is sold – above all via the internet – as *Garcinia cambogia* extract or, with the emphasis on the HCA content, as a product that promotes weight loss and increased “fat burning”. No binding specifications exist for the HCA products currently available in Germany or via the internet. In 2015, the BfR conducted a risk assessment of products containing HCA. Animal studies have shown toxic effects on the testicles of male rats following oral intake of certain *Garcinia cambogia* extracts con-

Garcinia cambogia is a medium-sized flowering evergreen tree with orange-sized, pumpkin-like fruits found in South Asia. The hydroxycitric acid contained in extracts obtained from the fruit rind is said to promote weight loss. No consensus exists on these properties in the scientific community, however. A valid assessment by the European Food Safety Authority (EFSA) is not yet available.



taining HCA at high doses. Animal studies using other products, however, have not found such effects at the doses tested in these latter studies. It is unclear to what extent the findings from trials with one extract are applicable to other extracts. However, the effects observed in the animal studies using certain products containing HCA are to be regarded as severe. Human studies using lower doses than in the animal studies have not reported any signs of testicular damage to date. Against the backdrop of suspected adverse effects based on the animal studies, however, the aspect of testicular toxicity has not been adequately investigated in human studies to date. This means that there are still unanswered questions concerning the safety of slimming products containing HCA, depending on the *Garcinia cambogia* extracts with HCA that are used and the dose at which they are used.

2,4-Dinitrophenol (DNP) is an industrial chemical that promotes “fat burning” by disrupting normal energy metabolism: As a result, the macronutrients absorbed from food are not converted into energy that can be used by the human body but into heat. In the 1930s, DNP was mainly used in the USA as a medication that boosted metabolism and thereby induced weight loss, but it was taken off the market shortly thereafter due to serious undesirable side effects. Products containing DNP are nevertheless illegally marketed as slimming aids (“fat burners”) for sportspeople, particularly via the internet. DNP is praised as being highly effective by the bodybuilding community, but its use can result in severe, life-threatening toxic effects. In recent years, there have even been fatalities as a result of the consumption of DNP. It was for this reason that the BfR published a communication in 2015 outlining the health risks of food supplements containing DNP. Possible symptoms of acute poisoning with DNP range from nausea, vomiting, sweating attacks, agitation, dizziness, yellow colouring of the skin, skin redness, overheating of the body, respiratory distress, a drop in blood pressure, cardiac arrhythmia, to coma and death. In the medical literature, the lethal oral dose is given as 1–3 g of DNP taken as a single dose. Consumption of smaller quantities of the substance over a longer period of time can lead to a yellowish opacity of the lens of the eye (cataract), skin lesions and effects on the blood as well as the cardiovascular and nervous system. As the substance accumulates in the body, the repeated intake of smaller doses over several days may also lead to lethal levels of poisoning. The BfR therefore urgently advises against the intake of DNP.

i The BfR has published detailed information on dinitrophenol (DNP) in the updated Communication No. 046/2015 (in German), which can be found at: www.bfr.bund.de > A-Z Index > Dinitrophenol (DNP)

BfR study on 3-MCPD and 3-MCPD fatty acid esters

Undesirable substances can occur when foods are heated during the production process. These substances include 3-monochloropropane-1,2-diol (3-MCPD), which can be formed when foods that contain both fat and salt are exposed to high temperatures. This affects numerous food products, such as bakery and smoked goods, coffee, preserves, baby food or potato products. Findings of animal studies show that 3-MCPD causes infertility in male rats and has a carcinogenic effect on kidneys and testicles. For this reason, EFSA derived an accepted tolerable daily intake quantity of 0.8 µg/kg body weight for this substance, which should not be exceeded in the longer term.

In 2007, 3-MCPD fatty acid esters were detected in a number of foods for the first time, including margarine, oils, infant formula and soy sauce. These substances are created above all in the industrial purification of fats and oils. As little or no information was available on the toxicology of 3-MCPD fatty acid esters at this time, the BfR and the European Food Safety Authority (EFSA) commissioned a series of studies in order to assess whether these substances may pose an additional risk to consumers alongside the parent compound 3-MCPD. The effects of 3-MCPD were compared with those of a 3-MCPD fatty acid ester in a 90-day feeding study using rats conducted by the University of Parma. It was proven that the dipalmitate ester of 3-MCPD triggered changes in the tissue of the target organs of kidneys and testicles that were similar to but weaker than the changes caused by 3-MCPD itself. Various in-vitro and in-vivo studies initiated by the BfR found that most of the 3-MCPD bound to fatty acids in the form of esters is released in the intestine and that this additional amount of 3-MCPD must also be taken into consideration for the purpose of risk assessment.

In a 28-day feeding study on rats, a proteomics method was used to investigate comparative complex protein pattern changes in different organs in order to gain insights into the biochemical effects and mechanisms of the early-stage changes in the organs caused by these substances and the associated metabolic changes in the liver, kidneys and testicles. It was found that, as in the previous 90-day study, 3-MCPD and its dipalmitate caused similar molecular biological changes to liver, kidneys and testicles. The main effect was on carbohydrate and fat metabolism. As the data obtained on molecular and biochemical level confirm the findings of classic ani-

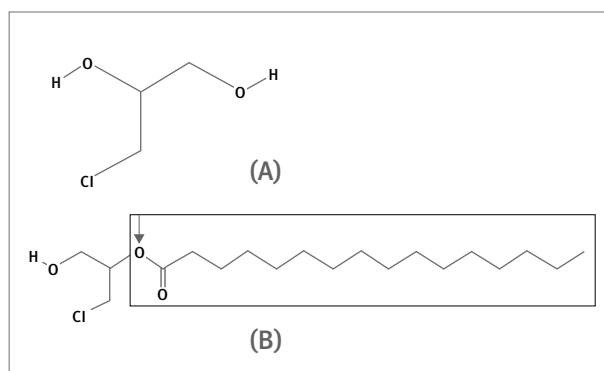


Undesired substances can occur through heating during the production of foods.

mal studies, we can be all the more certain that the harmful effect of the 3-MCPD fatty acid esters is mainly determined by the release of the base substance 3-MCPD during the digestion process. The recorded results were published in special-interest journals and are taken into account in the risk assessment for 3-MCPD of EFSA.

i More information on 3-MCPD fatty acid esters in foods: www.bfr.bund.de/en > A-Z Index > monochloropropanediol (3-MCPD)

Information on research into the use of gene and protein expression analysis in risk assessment: www.bfr.bund.de/en > Research > Main research > Research on risk identification, early risk detection and risk reduction



Chemical structure of 3-monochloropropane-1,2-diol (3-MCPD, A) and 3-MCPD-2-palmitate (B). The rectangle marks the fatty acid residue bound to 3-MCPD via an ester bond (oxygen molecule O).



*Trichinellosis is caused by roundworms of the genus *Trichinella*.*



More than 120 scientists participated in the International Trichinellosis Conference.

Infections due to roundworms common throughout the world

Over 120 attendees from 35 countries came together at the 14th International Trichinellosis Conference in Berlin in September 2015 to discuss their research findings. Trichinellosis (synonym trichinosis) is a dangerous food-borne infectious disease which affects several thousand people worldwide every year. During the conference, which was staged in cooperation with the Freie Universität Berlin (FUB), the German Society of Veterinary Medicine (DVG) and the Federal Ministry of Food and Agriculture (BMEL), the participants presented comprehensive sequencing data on all *Trichinella* species known to date and engaged in an in-depth discussion of the results of genome and proteome research. This will pave the way for a more detailed understanding of the links between the genetic, structural and functional properties of these parasites and the optimisation of diagnostic methods, and will also shed more light on the epidemiological relationships.

Trichinellosis is caused by roundworms of the genus *Trichinella*. Although testing for *Trichinella* in pigs, horses and wild boars is compulsory in the European Union, trichinellosis outbreaks in Germany, while rare, do occur at regular intervals of several years. These are mostly caused by the consumption of insufficiently cooked game meat, raw wild boar products or imported raw sausage and ham.

Trichinella larvae are predominantly found in the meat of pigs and wild boars, although they can also be present in horses and bears. The animals are typically infected when they eat rotten carcasses. Through the consumption of raw or insufficiently heated meat or products made from the meat of affected animals, the larvae contained in the muscle meat of these animals can be ingested by humans and cause illness.

i More information on trichinellosis:
www.bfr.bund.de/en > A-Z Index > trichinellosis

Despite testing for *Trichinella* in pigs, horses and wild boars by the European Union, trichinellosis outbreaks in Germany, while rare, do occur at regular intervals of several years.

The transmissibility of colistin resistance underscores the necessity to restrict the use of antibiotics to the extent required for treatment.

Resistance to colistin is transferrable

Resistance to antibiotics has been a central working area for the BfR for many years. What is of particular importance for consumer health protection is the investigation of mechanisms and factors that are responsible for the transfer of resistant bacteria from animals via food to humans – because antimicrobial resistance can lead to limitations in the treatment of infections in humans. If resistant bacteria trigger a disease, then this disease may possibly be more difficult to treat. In principle, resistant bacteria are no more harmful to humans than pathogens without this resistance. However, some of the resistant bacteria can transfer their resistance genes to other pathogens or to the bacteria in the human microflora.

One of the main tasks of the BfR is research on the spread of resistance to those antibiotics that are of particular importance in the treatment of humans. One new focal point was resistance to colistin, a polypeptide antibiotic in the class of polymyxins. Colistin is rarely used in human medicine because it is not well tolerated. Its significance for human medicine lies in the treatment of severe infections with gram-negative pathogens which are resistant to most of the commonly used antimicrobials including carbapenems. This form of treatment is only rarely necessary, since the number of infections with such pathogens is still low in Germany. Colistin is of considerable importance in veterinary medicine, especially in the treatment of infections of the gastrointestinal tract in livestock.

Resistance to colistin is nothing new per se and has been described in the bacterial isolates of animals for a number of years. It was previously assumed this was a non-transferrable form of resistance which is firmly anchored in the chromosome of individual bacteria. Then, in 2015, a team of Chinese researchers published a report on a gene for colistin resistance which is located on a plasmid and can therefore be transferred between bacteria. This gene bears the name *mcr-1*.

Studies conducted by the BfR showed that the gene has been present in bacteria of livestock and foods for a number of years. The occurrence of colistin resistance has been systematically observed since 2011. The highest proportion of colistin-resistant pathogens was detected in *E. coli* in poultry but is also found less frequently in *E. coli* isolates of cattle and pigs. The majority of these colistin-resistant isolates had the resistance gene *mcr-1*. Targeted investigations in other countries have shown that this resistance gene is widespread in animals and foods but is rarely detected in humans.

As bacteria can pass on the resistance to colistin to other species of bacteria, it is theoretically possible for consumers to ingest bacteria that possess this resistance via food or acquire it through direct contact with animals. It is therefore now necessary to investigate by means of detailed additional studies how frequently this gene is actually transferred, to which pathogens it is transmitted, and how resistance can spread.

This new development once again underlines the need to restrict the use of antibiotics to the level that is absolutely therapeutically necessary.

 The BfR has put together a FAQ on the antibiotic colistin and on transferrable colistin resistance at: www.bfr.bund.de/en > FAQ > food safety

Safety of dietetic feed

The more correct term for “dietetic feed” is “feed for particular nutritional purposes”: the use of these kinds of feed extends far beyond dietetic purposes.

“Feed for particular nutritional purposes” is designed to meet the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired. Feed products of this type are characterised by a specific composition or a special production method. In Europe, feed for particular nutritional purposes is regulated by Regulation (EC) No. 767/2009 on the labelling of feed. All recognised feed for particular nutritional purposes is contained in the list in Directive 2008/38/EC.

The BfR is responsible for the assessment of the safety of these feed products as part of the procedure for their approval. Its task is to examine the safety of feed for animals, humans and the environment when the feed is used in the correct manner. However, there are very few guidelines regarding the documents the producer has to submit to provide sufficient evidence of the safety and efficacy of these kinds of feed product. This makes assessment of these feed products considerably more difficult.

In its assessment, the BfR first reviews whether a particular nutritional purpose exists at all – in other words, whether the “special feed” can positively influence deficient digestion, absorption or metabolic processes. The BfR also investigates whether the composition and production process of the special feed differ from those of conventional feed products.

Feed products of specific composition (such as reduced protein content) can reduce the prevalence of renal dysfunction in older cats, for example. Feed for particular nutritional purposes is primarily used for cats and dogs, and increasingly horses as well. It has only been used for livestock in individual cases to date.

In the view of the BfR, therefore, feed that makes reference to diseases that are not or not only food-related (such as joint disease) does not constitute feed for “particular nutritional purposes” as defined by Regulation (EC) No. 767/2009.



“Feed for particular nutritional purposes” is designed to meet the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired.



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 Federal Institute for Risk Assessment (BfR) to contribute to product safety through recommendations. The field of product safety comprises a great variety of different products: cosmetics and hygiene products, food packaging and containers, toys, clothing, detergents and cleaning agents, tobacco products and other consumer products such as furniture, mattresses, carpets and DIY products. The results of the BfR risk assessment flow into recommendations made to political bodies, trade and industry and the general public.



Product Safety

Product safety is an important aim of consumer protection and involves questions such as: can a toy or cosmetic product pose a health risk? In answering these questions, the Chemical 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 department includes the BfR-Committees for Commodities and Cosmetics as well as the National Reference Laboratory for Food Contact Materials.

Tattoo removal using laser treatment: release of benzene and hydrogen cyanide

Tattoos largely consist of mainly insoluble pigments that are permanently inserted into the lower layer of the skin (dermis). These pigments consist predominantly of coloured inorganic substances like chromium or iron oxides, carbon black or white titanium dioxide. However, modern tattoos with particularly intensive colours generally consist of organic pigments with hugely varying colour tones. Human health risk assessment of tattoo inks and their ingredients is a great challenge, as unlike cosmetic agents tattoo inks are not applied topically but penetrate the skin barrier directly and therefore enter the body straight away.



When removing tattoos with a laser, heat-induced gases are produced in the skin which become visible as the so-called “whitening” effect.

Laser removal of tattoos represents a source of hazard that has not been adequately researched up-to-date. Parallel to the increased popularity of tattoos, more and more people want to remove their tattoos due to various reasons. Lasers with nanosecond or picosecond pulses are generally used for tattoo removal. Hereby, light pulses are absorbed by the tattoo pigment based on their wavelengths and lead to heat-driven fragmentation directly within the skin. Additionally, the formation of gases creates cavities, which in turn leads to light refraction – a phenomenon that is visible for several minutes due to the white coloration of the skin (so-called “whitening”). Also the incorrect use of the laser can result in scarring, pigmentation abnormalities and damage to the eyes. Very often a complete removal of the tattoo is not possible, especially when white, yellow, red or orange colours were used. A further unpleasant symptom is the darkening of brighter tattoos. Finally, reports in the literature cite allergies occurring in the aftermath of laser removal.

Another significant potential problem is the decomposition of the organic pigments occurring during the laser removal treatment. Short-term heating of a pigment particle to a temperature of several hundred degrees Celsius causes the pigment molecule to break down into smaller chemical sub-structures, by breaking up one or several chemical bonds. It was demonstrated in the literature that carcinogenic primary aromatic amines are released from some red and yellow azo pigments as well as from a violet quinacridone pigment during the breakdown process. Scientists at the BfR have now proved for the first time that the only blue pigments currently used in tattoo inks – copper phthalocyanine, which is also known as phthalocyanine blue or pigment B15:3 – can release

highly toxic hydrogen cyanide (HCN) and the human carcinogen benzene during the laser removal procedure. Other breakdown products in aqueous suspensions include 1,2-benzodicyanide and benzonitrile. Due to the fact that HCN is a colourless, fast-acting and toxic gas, it is classified as harmful to health. The detected maximum values of 30 µg/ml HCN with pigment concentrations of above 1 mg/ml significantly reduced the survival rate of human skin cells in *in vitro* studies.

The individual risks associated with laser tattoo removal vary depending on size, puncture depth, with the pigment and concentration used, as well as with irradiation intensity and wavelength of the laser. More scientific experiments are needed to permit a realistic simulation for the creation of toxic breakdown products in skin samples after laser removal. Laser removal breakdown products should be identified and toxicologically assessed for the most common pigments used in tattooing inks. To this end, experiments are currently conducted at the BfR with pig skin that was tattooed *post mortem*. The data obtained on the breakdown products of colourants during these experiments will be taken into account in future human health risk assessments for tattooing inks.



The colour plays a role: the complete removal of white, yellow, red and orange-coloured tattoos is often not possible.

i The findings of research into tattoo removal were published in the journal *Scientific Reports*. (DOI: 10.1038/srep12915)

More information on tattoos:

www.bfr.bund.de/en > A-Z Index > tattoo

The individual risks of tattoo removal using lasers vary depending on size, puncture depth, the pigment used and the pigment concentration as well as the irradiation intensity and wavelength of the laser.

New techniques for identifying and characterising microplastics

Be it toothpaste, peeling products or shower gel – the use of plastics containing products in our daily lives is steadily increasing. Consequences are the growing accumulation of so-called microplastics, tiny plastic particles, in aquatic as well as terrestrial ecosystems. This is not only due to the decomposition of large plastic products but also due to the polymer particles that are used in cosmetic products, for example. There are a number of tasks that need to be performed in the area of consumer health protection: suitable detection methods need to be developed, the entry pathways into the human food chain must be identified, and the potential effects on human health must be determined. Water-repellent particles in particular can prove to be “Trojan horses”: it is probable that these particles take up harmful substances from the environment via adsorption and then gradually release these substances in the human body.

Together with the Lower Saxony State Office for Consumer Protection and Food Safety, the BfR is working on new procedures for the identification and characterisation of microplastics. Besides Fourier transform infrared spectroscopy (FTIR), which identifies polymers based on their specific vibrations of chemical bonds, the other focal point of this work is the development of mass spectrometry analysis methods. Using pyrolysis gas chromatography coupled to mass spectrometry, microplastic samples are

thermally fragmented and the resulting gases are characterised by means of mass spectrometry, thereby allowing identification of the respective polymer. Of particular importance in this context is the imaging process of time-of-flight secondary ion mass spectrometry (ToF-SIMS). This technology permits analysis of microplastic particles in the same form as they occur in the environment. For this purpose, the polymer surface is “bombarded” with an ion beam in order to separate the secondary ions, and these ions are then analysed based on their time of flight. This process permits imaging of the entire ion spectrum and hence the determination of particle size and composition.

First ToF-SIMS analyses showed that a high percentage of the larger polyethylene pellets with a diameter of approx. five millimetres break down into microplastic particles with diameters of less than ten micrometres after 14 days. This process was reinforced during the following 14 days: the share of the smallest microplastic fraction (particles between one and 1.5 micrometres in size) increased by 50 %, the second smallest fraction (1.5 to 2.5 micrometres) showed a remarkable increase of 350 %. It was possible to clearly distinguish the individual microplastic particles from the sample background. This was the first time an imaging mass spectrometry method had been used to identify and characterise secondary microplastic particles. The method that was developed for this purpose is now to be used for the analysis of real samples.

*The research results were published in the journal Science of the Total Environment.
(DOI: 10.1016/j.scitotenv.2016.04.025)*



So-called microplastics, tiny plastic particles, are accumulating more and more in aquatic as well as terrestrial ecosystems.

Risk of poisoning from washing detergent capsules

Household products must be safe if used for their intended purpose – but also in the event of foreseeable misuse, when children are playing, for example, and tasting products with their mouth. Poisoning due to cleaning products and detergents has been a rare occurrence in the past, but there has been a new trend in recent years that gives rise to concern from the view of BfR and the European Commission: many laundry detergents now come in the form of soft plastic pods filled with coloured fluid that dissolve during the washing cycle. These “liquid caps” are easy to dose – one cap per cycle – and are particularly popular in France and Italy. There are still very few of these detergent capsule products marketed in Germany, and it is unclear whether this situation will change in future. As gel capsules appear to be more appealing to children than traditional detergents, accidents are more

frequent with these products: the comparatively highly concentrated washing agent is released from the capsule as a jet, often causing severe irritation in the mouth or eyes. The percentage of accidents that require hospital treatment is far higher with liquid cap products than with traditional laundry detergents. After oral contact with the liquid caps content children often vomit multiple times.

When the first scientific studies and media reports had described the increased risk of poisoning, laundry detergent manufacturers launched measures to improve product safety (A.I.S.E. Product Stewardship Programme): these measures included the use of opaque outer packaging, better seals and additional warning information. However, implementation of these measures did not achieve the desired effects. For this reason, the European Commission introduced far stricter legal requirements for laundry detergent capsules: since mid-2015 the capsule film must contain a bittering agent that is designed to dissuade children from licking them. In addition, the pods must withstand higher pressures and the outer packaging has to be equipped with a safer seal and has to be opaque in order to make the coloured caps invisible when the seal is closed.

Together with Public Health England, the National Health Institute in Italy and eight European poisons centres, the BfR is investigating whether these new measures actually do reduce the risks: in a study on behalf of the European Commission, all calls to the participating poisons centres related to exposures to liquid cap products are being registered and the callers provided medical advice. The next day, a poisons centre staff member calls back and enquires about the circumstances of the accident in detail. It is particularly important to determine what makes a product attractive to children: According to Article 35 of the European CLP Regulation (EC No 1272/2008), consumer products that are classified as hazardous should not be designed in such a way that they can attract the active curiosity of children or mislead consumers – due to the fact that the packaging makes them think of food or drinks, for example.

The collection of case data began in August 2015 and will continue until the spring of 2016. Up to the end of the year, there was no discernible trend in poisoning frequency in Europe. Preliminary analysis indicates that the number of reported accidents in Germany is at least not showing further increase. The final report to the European Commission in summer 2016 will outline the findings of the study and assess all current and potential future safety measures for liquid cap products geared towards reducing the risk of poisoning.



Tobacco additives may not further increase the already considerable health risks associated with tobacco.

Risk assessment of tobacco additives

The new European tobacco directive came into force in 2014 and had to be transferred into national law by the member states by 20 May 2016. In Germany, a new Tobacco Products Act and a tobacco directive have been introduced. Among other things, the European directive introduces combined text-image warnings, the percentage of space on the packaging for warnings is higher than before, and – for the first time – regulations have been agreed upon at European level regarding electronic cigarettes and novel tobacco products.

One of the tasks of the BfR is to assess tobacco additives, which should not further increase the already considerable health risks associated with tobacco. This relates not only toxicity but also product properties and compounds that might increase addiction potential or make it easier to inhale tobacco smoke, such as for example menthol. The new regulations are also designed to restrict the options for the development and market launch of more attractive products for smokers. It is for this reason that aroma capsules and characteristic flavours are to be banned for cigarettes and other tobacco products. Also prohibited for tobacco products in future is the suggestion of supposed health benefits, vitality or an active “lifestyle”.

In terms of consumer protection, the new European stipulations improve the way in which tobacco is regulated in a number of important ways. At the same time, the enactment of the new Tobacco Products Act means that the previous approval obligation for tobacco additives in Germany no longer applies – with the result that additives that used to be inadmissible during the production process may now be used unless they are explicitly prohibited. It is therefore to be expected that the range of additives and the range of products will increase markedly in the coming years. This will also create new tasks and new challenges for risk assessment activities.

i The BfR Opinion no. 045/2015 (in German) contains detailed information on the health assessment of additives for tobacco products and electronic cigarettes and can be found at:
www.bfr.bund.de > Publikationen > BfR-Stellungnahmen > 2015



Chemicals Safety

Chemicals surround us in all areas of our daily life. This means that safety when dealing with chemicals is very important. The BfR assesses risks for all groups of people who may 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 chemical safety, the BfR assesses the health risk of chemicals, plant protection products, biocidal products and hazardous substances. 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 chemical and pesticide safety affects many areas of consumer and user health protection. In Germany, the BfR is one of the central institutions for health-related substance evaluations. Multiple departments within the BfR, such as the departments for exposure, chemical and product safety, and pesticide safety, deal with this issue.

Guidance for the safe use of plant protection products

Plant protection products must not have any harmful effects on human health. The same plant protection product can have different effects in different doses, depending on the amount of the product to which a person is exposed. The exposure pathway also plays a role – whether the substance is inhaled or absorbed via the skin, for example. This is why the approval of plant protection products in Germany is conditional on a comprehensive assessment of health risks by the BfR. After a toxicologically defined health-related limit level has been set (this is called an AOEL – acceptable operator exposure level), this risk assessment serves to determine a safe exposure level for the active substance based on direct use of the plant protection product. Above all users of the plant protection product can be exposed, but so can workers performing other tasks in the treated cultures, as well as non-involved bystanders and local residents. If the health risk resulting from proper use of the substance is

too high, protective clothing must be worn, for example, or safety distances must be complied with when using the substance. If risk reduction measures of this kind are not sufficient to exclude damaging effects to health, the plant protection product may not be approved.

In order to determine the health risk for the various groups who might be affected due to the use of plant protection products, the BfR first estimates their exposure levels and compares them to the AOEL. As no specifically determined data are generally available for the plant protection product in question, models are used that are based on measurement data for comparable applications. Until recently, different models and outdated concepts were still being used in Europe for the assessment of plant protection products. In accordance with the EU regulation on plant protection products, one member state performs the assessment of a plant protection product for all requested applications for one zone of the EU on behalf of the other states. To improve and harmonise the exposure assessment in all member states, the European



The EFSA guidance document is an important milestone for the harmonised risk assessment of plant protection products in Europe.



The prerequisite for the authorisation of plant protection products in Germany is a comprehensive assessment of the health risks by the BfR.

Food Safety Authority (EFSA) was commissioned to draw up a technical guidance document for the assessment of exposure levels of users, workers, local residents and bystanders. A working group in which BfR experts also played a lead role then assessed all existing models in terms of their quality and the availability of the underlying data. The idea behind the guidance document is to identify the most suitable model for the exposure scenario in question, to define basic principles for exposure assessment and to stipulate relevant standard parameters.

Following a public consultation phase, the guidance document was adopted in May 2015 by the Standing Committee on Plants, Animals, Food and Feed. The Committee also stipulated that the document applies to all approval applications for plant protection products from 1 January 2016 onwards.

The EFSA guidance document introduces many fundamentally new rules, including the use of two new exposure models. The AOEM (agricultural operator exposure model) developed at the BfR uses statistical methods for the first time in order to identify parameters that influence exposure and to model the measurement data. In addition, the EFSA guidance document incorporates further relevant exposure pathways and application scenarios for bystanders and local residents. The guidance document is an important milestone for the harmonised risk assessment of plant protection products in Europe.

i The EFSA guidance document is available at:
www.efsa.europa.eu

Plant protection products residues: processing factors must be taken into account

Even when authorised plant protection products are used in a proper manner and for the intended purpose to protect plants against harmful organisms, it is still possible that residues may be present in the harvested crops and in the food and feed therefrom. To ensure that these residues do not pose a risk to the health of consumers, the BfR draws up proposals for maximum residue levels. In the European Union, maximum admissible residue levels of pesticides are only established for raw agricultural products (Annexes to Regulation (EC) No. 396/2005). However, many of these products are not eaten raw but after having been processed, and some of the processing operations – such as milling of wheat grain or the production of apple juice – can alter the chemical nature and level of residues. Both increases and reductions in residue levels may be observed in the various processed fractions; for example, in bran and flour from wheat grain or in pomace and juice in the case of apple fruit. The ratio of residue concentration in the processed product relative to that in the starting material is called “processing factor”. The magnitude of this factor depends not only on the type of processing method but also on the physico-chemical properties of the active substance. Processing factors are not only of importance for assessment of health risks that can result from pesticide residues in processed food but also serve as an important source of information for official food control activities. Even if the statutory maximum residue levels are only stipulated for raw products, they nevertheless apply to the processed products made from these raw products – by taking into account the processing factors. Only this information allows for judgement of whether a sampled processed product complies with the legal requirements. The EU Regulation 396/2005 foresees the provision of processing factors in a separate annex, but this annex has not yet been established.

In the framework of the approval of pesticidal active substances and the authorisation of plant protection products, applicants are required to submit processing studies to the regulatory authorities. In these studies, processing factors are derived from processes simulated in the laboratory. In order to make the information in these studies available also to interested public, the BfR has evaluated the reliability of all available studies based on strict criteria and published ca. 6,300 derived factors for 193 active substances in a database on the BfR website. Alongside the derived factors, the website also provides transparent information on how the BfR performed

its “quality check” for every individual study by outlining all the key study parameters that determine the reliability of the findings. These quality criteria include i. a. the suitability of the analytical method used and the proved storage stability of the samples. Dependent on the reliability of the recorded results, the studies are divided into three categories. In addition, some contents of the testing guidelines used for the studies are critically reviewed in the light of the experience gained, and suggestions are made for improvements. One of these suggestions is that the simulated processing methods should be standardised to a greater extent and that the terminology used for processing fractions should be harmonised. A total of 34 of such standard process diagrams have already been proposed.

i More information (in German) on processing factors: www.bfr.bund.de > A-Z Index > Verarbeitungsfaktoren

Container fumigation and residues of volatile toxins in products

In the international freight transport sector, gaseous pesticides are used to protect vulnerable goods. The transported goods are mostly treated directly in the container and exposed against the fumigants between 24 and 72 hours in general. However, illegal fumigation and inadequate ventilation can lead to far longer exposure. The gaseous biocides used for this purpose include substances such as methyl bromide, hydrogen phosphide (“phosphine”), sulphuryl fluoride or 1,2-dichloroethane, all of which own an extremely high toxicity for both, harmful organisms (so-called “pests”) and humans. There are reports of occasional poisoning accidents due to insufficient ventilation, involving employees in ports or import companies. As the outgassing characteristics of the fumigants have not been



Gaseous pesticides are often used in containers to protect vulnerable goods.

investigated to date, a reliable assessment of the hazard potential for consumers is currently not possible. For this reason, experimental fumigation of products like socks, packing paper and sunflower seeds was performed by the BfR in cooperation with the Central Institute for Occupational Medicine and the Julius Kühn Institute. The out-gassing characteristics were shown to depend on both, the applied agent and the fumigated product. In general, the amounts observed after a few days were below the limit values defined by the US Office of Environmental Health Hazard Assessment for a chronic exposure to the respective fumigants. As different fumigants have recently been identified simultaneously in the same transport container, further experiments are being carried out to assess potential combination effects.

i More information (in German) on fumigated containers: www.bfr.bund.de > A-Z Index > Begaste Container

Health hazards in the event of maritime accidents

27 May 2015: the cargo ship “Purple Beach” was involved in an accident to the south west of Helgoland. When serious accidents of this kind occur, the German Central Command for Maritime Emergencies is the agency of the federal government and the federal states (“Laender”) that heads the response by the emergency services on federal, regional and municipal level. The expertise of the BfR is also requested in these cases, and BfR scientists were on the scene within hours.

Highly irritant and harmful smoke rose from the ship and drifted many kilometres across the sea. This was caused by the incipient chemical decomposition of 6,000 tonnes of a fertiliser containing ammonium nitrate in one of the holds. The crew had already left the “Purple Beach”, and a specialised firefighting unit had also been forced to withdraw. When the BfR got involved, 25 measuring teams had begun to determine potentially health-damaging substances in the air along the coast. The BfR was then involved in the assessment of the health risk posed by the smoke. The accident team had to assess both the situation on board with the ongoing chemical reactions in the hold as well as the potential further scenario. A precautionary hazard warning was issued for a region encompassing the area from Friesland to Wesermarsch and Jade, Cuxhaven, Bremerhaven and Wilhelmshaven. A decision had to be made as to how to continue to inform the population in the coastal communities via the media and via the hotline number that had been set up. Once the pollutant measurements had been completed, it was possible to cancel the

warning. In the follow-up to the “Purple Beach” incident, the BfR drew up proposals for the German Transport Ministry on the safe transport of these kinds of cargo. The amendment of transport requirements was on the agenda of the International Maritime Organisation of the United Nations in the autumn of 2015.

The BfR is responsible for health assessments for the maritime transport of hazardous goods. This means the institute is involved not only in hazards resulting from maritime vessels in the event of accidents but also and among other things in cases where cargo residues are washed ashore. For the last two years, the focus has been on clumps of industrial hydrocarbon wax that have washed ashore on beaches. This is believed to be due to tank cleaning of chemical tankers.

The specialist expertise of the BfR in the field of health risk assessment is underpinned by its continuous involvement in national and international consultations on the transport of hazardous goods. In the case of maritime accidents, this expertise plays a key role in managing damage scenarios and ensures assessment of health risks in line with state of the art practices in the scientific field.

i You can find assessments of the health risks of cargo residues from tanker vessels that have been washed ashore (in German) at: www.bfr.bund.de > Chemikaliensicherheit > Transport gefährlicher Güter > Seeverkehr: Havarien

The BfR is responsible
for health assessments for
the maritime transport of
hazardous goods.



Risk Communication

Another important task of the Federal Institute of Risk Assessment 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, insights gained 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 separate department for risk communication which informs the general public about possible health risks and the research results which form the basis for this assessment. The BfR enters into the dialogue with the various target groups through measures involving classical press and PR work, 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 recognition of risks and estimation of their consequences are conducted in the department with its interdisciplinary structure. The 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. In this interview, department head PD Dr. Gaby-Fleur Böhl talks about the day-to-day work of the department.

**Interview with
head of department
PD Dr. Gaby-Fleur Böhl**



Dr. Böhl, how can complex scientific issues be communicated in an appropriate way?

The BfR strategy for risk communication generally focuses on transparency, dependability and the greatest possible degree of openness. We explain scientific matters using simple words and tools to make sure people can understand them. One example of this is our “Risk Profile” – a chart-like illustration we use in our opinions. The reader can see right away whether a risk exists for a specific group of people, such as children or pregnant women.

And our communication is not a one-way street: we stage a range of events and enter into dialogue with our stakeholders. Our video series “Consumers ask – the BfR answers” is also an interactive format: people can ask questions via our website, and the scientists then respond in the form of a short video.

What is the professional background of the employees in your department?

The Risk Communication department is probably the most interdisciplinary department of all at the BfR. We have a staff of 50 employees who have studied widely varying subjects, such as Biology, Chemistry, Medicine, but also Psychology, Politics or Social Science. We need to be able to call on both natural science expertise as well as know-how in the social sciences, because our mission is to explain natural science to someone so that he or she understands it. This is something our staff should enjoy doing; then risk communication is the perfect job for them. Recommendations for daily life in the form of slogans are particularly important for our work, and some of these slogans are still remembered by people many years later.

What new features and formats have recently been added on the communication front?

The BfR provides information via its own Twitter account, which is also available in English, and via a YouTube channel. One new format is the film series entitled “100 seconds of BfR”, the first edition of which was about pyrrolizidine alkaloids in tea and honey. It explains whether these substances may pose a risk to the population and tells people what they themselves can do to avoid the problem. We have also launched a “BfR Poisoning App”, and we’re quite proud it won the German Award for Online Communication in 2014, as well as the “BfR Opinion App” which presents our opinions in a compact format.

Our mission is to explain natural science to someone so that he or she understands it.

During the second half of the year, many media picked up on the controversy surrounding the imminent re-approval of glyphosate, an active substance in plant protection products. How did the department respond to this special situation?

We communicated the methods we used to reach our assessment findings in a transparent way and explained the assessment in a comprehensible manner for consumers – in a FAQ on our website, for example. There were several reports in the media that were simply incorrect and that led to uncertainty, such as false information on the supposed detection of glyphosate in breast milk. We provided information by phone to many mothers and advised them to continue breastfeeding. The simple comparisons in our communication were positively received: when the news spread regarding glyphosate residues in beer, for example, we explained that someone would have to drink 1,000 litres of beer a day to achieve a level that might possibly be unsafe – quite apart from the health risk posed by alcohol in the first place. Even in the case of a substance that is hazardous per se, the decisive factor is the level of exposure to this substance and the amount ingested. Properly conducted scientific studies and factual communication of findings are essential if we are to avoid uncertainty.

How important is dealing with the fears of the population in your work?

Let me answer this with an example: if you ask the population whether residues of plant protection products are allowed in food, two in three people will say “no”. This means we repeatedly have to explain that residues of plant protection products are permitted in food products, but that they have to be at such a low level that there is no risk whatsoever that they are harmful to health. Or when it comes to red wine, consumers should worry less about remains of plant protection products and more about the alcohol in the wine. We have long since known from risk perception research that the fear of chemical substances is far greater than the fear of biological substances – or, to put it simply, things we're familiar with.

Who decides which issues are researched by the Risk Perception Research Unit?

On the one hand, we focus on topics that already attract a great deal of attention, such as residues of plant protection products or antimicrobial resistance. At the same time, we also deal with issues that are not so much in the public eye but that are nevertheless of major relevance; one current example of this is veganism. In focus group interviews, we ask people who have adopted a vegan lifestyle why they decided in favour of this diet and whether they take care to supplement certain vitamins etc. This kind of analysis is extremely exciting. It's important to us that we not only look at the “hard” natural science facts but also study data collected by the social scientists, as this helps us to identify what interests and motivates the population and why it does so. The resulting insights then form the basis for our choice of communication measures.

When was the new “Crisis Prevention and Coordination” unit called into being, and why was it necessary to create it?

The new unit was set up in April 2015 and is not least a consequence of the EHEC crisis. For us to do our work effectively, all the threads have to come together in a single organisational unit in the event of a crisis. The unit is not only tasked with coordinating activities during a crisis, however, but has the job of promoting prevention and collecting relevant knowledge. One key role is liaising with our stakeholder contacts. We hold talks at regular intervals not just with industry associations but also with consumer associations, NGOs and other organisations with the aim of avoiding crises before they occur wherever possible. ||

A vegan diet is associated with possible health risks – above all in the case of infants, small children and children, who have high-level requirements for nutrient supply during their growth phase.

Vegan diet – a case for risk communication?

A growing number of people are making the choice to adopt a vegan diet and therefore to refrain from consuming all foods of animal origin. The results of representative surveys conducted in 2014 and 2015 indicate that some 950,000 people in Germany are vegans. Some studies state that a vegan diet has positive effects on overall health: it is said to keep cholesterol levels low and reduce the risk of cardiovascular diseases as well as cancer.

Nevertheless, a vegan diet is associated with possible health risks – above all in the case of infants, small children and children, who have high-level requirements for nutrient supply during their growth phase. One of the main problems with a vegan diet is a lack of vitamin B₁₂, iron, calcium, iodine and zinc as well as long-chain Omega 3 fatty acids.



It was in response to the prevailing scientific uncertainty regarding the pros and cons of a vegan diet that the risk perception experts at the BfR decided to address this issue. Target-group specific risk communication strategies were developed based on the individual and social influencing factors that play a key role in the motivation to adopt and maintain a vegan diet. To this end, focus group interviews were conducted with a total of 42 vegans in different age groups. This qualitative survey method documented underlying or latent attitudes, values and opinions that only come to the surface if an individual is encouraged to talk about them in a group environment.

Although the recorded survey data are not representative due to the limited number of cases, they allow some general conclusions based on the, in some cases very pronounced deviations from the population overall.

Vegans have above-average educational qualifications and a sound knowledge of nutrition. 40 of the 42 participants in the focus groups were aware that a vegan diet can lead to a deficiency of vitamin B₁₂, and the overwhelming majority of them therefore supplement this vitamin on a regular basis. Two in three of the vegans previously already followed vegetarian diets. This means that vegetarianism promotes the decision to adopt a vegan diet – by virtue of the fact that vegetarians have already fundamentally changed their diet and have the role of a “food outsider”. It is generally the case that reporting in the media is a major factor in the decision to switch to a diet free of animal products. For the majority of respondents, films on the inhumane rearing of animals were the most important trigger for the change of diet. The majority of vegans are convinced that humans do not have the right to kill animals or cause them to suffer without necessity. As the production of animal products can entail suffering on the part of the animal, they reject this practice on principle. Human rights such as freedom and inviolability are “transferred” to the animals. The published categorisation of vegans into ethical, health and eco vegans was not confirmed. Health-related motives are rarely mentioned and are generally more of a welcome side-effect. This means that it is not possible to determine standardised attitude patterns with regard to the decision in favour of a vegan diet.

Even a pregnancy does not generally cause vegans to (temporarily) consume animal products once again. On the contrary: some participants decided to adopt a vegan diet precisely because they became pregnant. Children are also given a vegan diet.

The findings show that there is a need for risk communication to become active, and that there is a particular need for wide-ranging information about possible nutrient deficiency due to a vegan diet during pregnancy and in the case of infants and small children. Risk communication is always more successful if it picks up on the convictions that already exist in the target group. Nearly all vegans have already looked into how to ensure their

body is supplied with all required nutrients. This can take the form of both a deliberate decision to consume certain foods and through supplementation. This is why communication referring to vegan diet alternatives or supplementation is fundamentally promising. The aim of risk communication should be to provide concrete guidelines on how to counteract the risk of nutrient deficiency for oneself or one's children without giving up a vegan diet. The BfR study also reveals possible risk potentials in other areas: every vaccine comes into contact with animal protein during the production process, for example, and this can result in decision-making conflicts for those following a vegan diet.

BfR Consumer Monitor

Consumers are a central target group of the BfR, which is why it is important for the institute to know how the themes it addresses are perceived by the public at large. One question of particular importance concerns the things that consumers are afraid of and the health risks that they believe exist. How do they assess the safety of foods, as well as of toys, cosmetics and textiles they can buy in Germany? A further relevant factor is the level of trust in the structures of consumer health protection, as this in turn influences the perception of risks. Opinions, perceptions and attitudes can change rapidly, however. The topics that are of interest to the general public today may already have been forgotten tomorrow or pushed out of the public sphere by different issues.



Representative population surveys on selected topics at the BfR are published as BfR Consumer Monitor.

This is why the BfR launched the Consumer Monitor in 2014. The Consumer Monitor is a representative population survey conducted at regular intervals to ascertain the assessments of the public regarding selected issues addressed by the BfR. This survey is supplemented by representative surveys conducted by the BfR on individual issues that are of topical interest and that are published as BfR Consumer Monitor Specials.

In the Consumer Monitor, the BfR has established a tool that enables it to respond to the information and communication needs of consumers faster than was previously the case and therefore to further underpin the confidence of the public in consumer health protection. Two issues of the Consumer Monitor were published in 2015, including one "Special" on the topic of resistance to antibiotics.

i All BfR Consumer Monitors published to date are available at:
www.bfr.bund.de/en > Publications > Brochures > BfR Consumer Monitor

Facts and figures on press activities

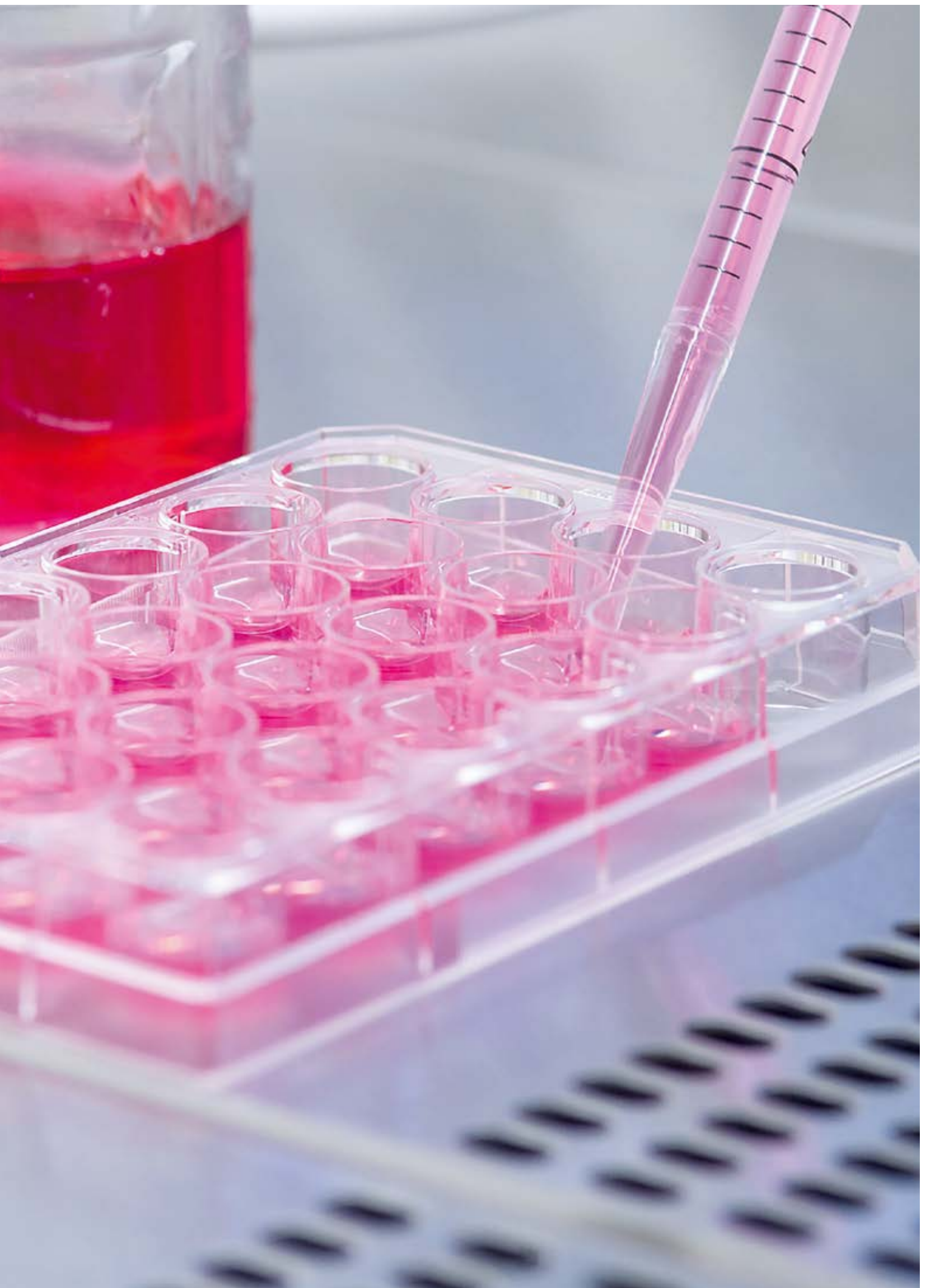
4,019,185	visits to the BfR website
169,709	downloads of the BfR apps "Poisoning Accidents Among Children" and "Opinions"
86,718	delivered publications (brochures etc.)
22,013	views on the BfR YouTube channel and BfR media library
7,639	subscribers to the BfR newsletter
4,523	mentions of the BfR in newspaper articles
1,318	inquiries from private citizens (in writing)
49	television interviews



A close-up photograph of laboratory glassware on a grey surface. In the foreground, a clear plastic multi-well plate is partially visible, containing several wells with a pinkish-red liquid. To the right, a glass beaker is filled with a vibrant red liquid. On the left, an orange plastic cap is visible. The background is slightly blurred, showing a white surface with some faint markings.

Alternatives to Animal Experiments

Scientific experiments with animals are conducted in all areas of life sciences. In basic research in particular, they promote scientific progress. For the toxicological testing of drugs and chemicals, for example, German legislation requires that animal tests be substituted by equally conclusive alternative methods wherever possible. The requirement to replace animal experiments when and wherever possible is firmly anchored in the German Animal Welfare Act. The assessment and development of these alternative methods which replace and supplement animal experiments constitute another important task of the BfR. In addition to meeting the legal requirements, this also includes our own research work as well as supporting external research projects in this field. Alongside this, the institute is committed to improving the living and housing conditions of laboratory animals.



Alternatives to Animal Experiments

The Department of Experimental Toxicology and ZEBET at the BfR has already been working on alternative methods to animal experiments for many years. The founding of the German Centre for the Protection of Laboratory Animals (Bf3R) in 2015 signalled even more intensive research into alternative methods. The Centre coordinates all activities in Germany aimed at reducing animal experiments to an absolute minimum and offering the best possible protection to laboratory animals. The Bf3R was created within the framework of the initiative entitled “A Question of Attitude – New Ways to Improve Animal Welfare” and launched by the Federal Ministry of Food and Agriculture. The work of the Centre inspires research activities all over the world and facilitates scientific dialogue. In this interview, department head Professor Dr. Gilbert Schönfelder talks about the remit and goals of the Bf3R and what it has achieved to date.

**Interview with
head of department
Professor Dr.
Gilbert Schönfelder**



Professor Schönfelder, what does the work of the “German Centre for the Protection of Laboratory Animals” (Bf3R) involve?

The Bf3R is the only governmental institution of its kind in the world and is entrusted with stepping up research into alternative methods as well as advising authorities and scientific institutions on this issue. It promotes research projects to advance the development of alternative methods on both national and international level, and informs both the public and the scientific community about topics in the area of animal welfare relating to laboratory animals. ZEBET and the National Committee for the Protection of Laboratory Animals are now areas of competence at the Bf3R.

Why was it necessary to create the Bf3R?

There is widespread interest in society in limiting animal experiments. Some people are even calling for the complete banning of these experiments. Despite this, the

number of laboratory animals used in basic research has still not fallen to any great degree. A further argument in support of more intensive research into alternative methods is the current debate as to which animal experiments enable us to draw conclusions regarding certain processes in humans, thereby paving the way for the development of medical therapy concepts. Then there are the efforts to develop models which possibly supply more robust results, such as 3D models of organs made from human cells. All these aspects together outline the need to ensure better protection of laboratory animals. This does not mean that animal experiments should be completely prohibited. Wherever they are indispensable, it will still be necessary to conduct these experiments until suitable alternative methods have been developed.

Why is this further development only taking place now?

ZEBET was set up back at the end of the 1980s, and the situation then was totally different. We shouldn't forget that the review of safety has only been stipulated in the German Medicines Act since the early 1970s – in response to the “thalidomide scandal”. In the endeavour to ensure the safety of medicines and other products, the focus was initially on animal experiments as the most suitable method. Even back then, some organisations were demanding that animal experiments be restricted and laboratory animals be protected as effectively as possible. At that time, however, science was not sufficiently advanced to provide answers to the pressing questions. The Centre we now have is the only entity of its kind in Europe: Germany is the only country with an official centre for the protection of laboratory animals

Every single animal that doesn't have to be used in an experiment is an animal that experiences less suffering and less pain.

that can comprehensively demonstrate expertise in the relevant areas and that is independent in its activities; in other words, the work of the Bf3R is not influenced by political, economic or social interests.

What does the abbreviation “Bf3R” stand for?

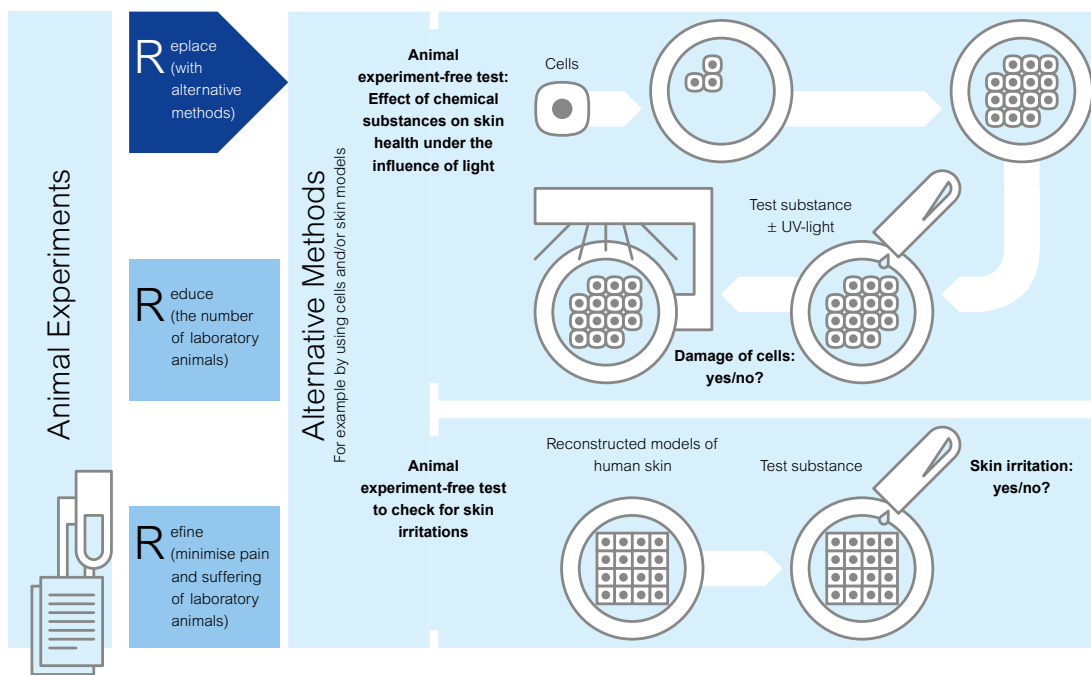
The abbreviation expresses the affiliation with the BfR and also makes reference to the “3R principle” according to Russell and Burch. These three Rs stand for “Replace”, “Reduce” and “Refine” – “Replace” is geared towards completely replacing animal experiments, “Reduce” towards reduction in overall the number of experiments, and “Refine” at the mitigation of the pain or suffering of animals used in experiments.

The number of animal experiments can be reduced with the help of alternative methods, but also through the painstaking biometric planning of animal experiments and through systematic analysis of literature before conducting any experiments. If it is still necessary to expose animals to pain and suffering in an experiment that is absolutely essential, then all measures must be taken to reduce this pain and suffering to a minimum.

What is the background of the employees of the Bf3R?

The Bf3R makes the BfR even more interdisciplinary, with representatives of the natural sciences, veterinary medicine, human medicine, engineering and law all working closely together. →

3R Principle for Alternative Methods



Why do you need legal experts?

The practical implementation of legal requirements is not always defined in detail. The concept of harm is a good example: pain, suffering and harm are basic elements used in the definition of an animal experiment. While the legal interpretation of the concepts of pain and suffering are relatively clear-cut, it is unclear how to apply the concept of harm in relation to laboratory animals. This is where interdisciplinary cooperation incorporating legal expertise is of particular importance.

On what issues does the Bf3R advise authorities and research institutions?

The amendment of the German Animal Welfare Act in 2013 outlined the legal requirements. If someone wants to conduct an animal experiment, they have to submit an application for the experiment to the approval authorities. We are often consulted to carry out a review to determine whether there isn't an alternative to the animal experiment after all. The task of the National Committee, on the other hand, is to advise authorities and animal welfare bodies on the acquisition, breeding, accommodation, care and use of laboratory animals. The issues are therefore not confined to alternative methods but also extend to questions relating to interpretation of the law. The recommendations of the National Committee are particularly important when it comes to complex legal matters.

Will there come a day when animals are no longer used for experiments?

I don't think this will happen in the foreseeable future. Of course, our long-term goal is to replace animal experiments altogether, but we haven't yet reached the level of science that would make this possible. It's important to emphasise that every single animal experiment that doesn't have to be conducted makes a difference. Every single animal that doesn't have to be used in an experiment is an animal that experiences less suffering and less pain.

How can the public obtain information on animal experiments?

In Europe, it has been mandatory to publicly document every animal experiment since 2013. The "non-technical project summary" required for this purpose supplies information on the purpose for which an application was approved, which animal species is to be used and how many animals are to be used. We already developed the internet-based AnimalTestInfo database in 2014. All interested parties can access the database to view all non-technical project summaries from Germany. The database is unique throughout the world and guarantees a high level of transparency.



The development of OECD test methods for the toxicological assessment of substances is coordinated by the BfR in Germany.

The BfR developed the "AnimalTestInfo" database in close cooperation with the authorities of the federal states ("Laender") responsible for the approval of animal experiment projects and published it on the internet in December 2014. It is the first Web-based database solution for the publication of project summaries on animal experiments in Europe. AnimalTestInfo contains information on all approved animal experiment projects of scientific research institutes of the universities, industry and the government in Germany.

i The BfR reported on AnimalTestInfo in the special-interest journal "Nature":
www.nature.com/nature/journal/v519/n7541/full/519033d.html?WT.ec_id=NATURE-20150305

More information (in German) at: www.animaltestinfo.de

What financial resources are available to the Bf3R?

We have received around six million euros for the purchase of research equipment. We also receive continuous research funding of just under one million euros a year and have been assigned additional staff.

The Bf3R has already bought new research equipment. What will this equipment enable you to do?

One of our research goals is to obtain information on the optical level, in order to better understand the ultrastructure of cells and tissue. It's easy to imagine a room the size of an office – perhaps with a desk, a chair and a computer. But if you try to imagine this room in a size as small as a thousandth of a pinhead, it's impossible. Human beings are heavily dependent on their spatial perception skills. But information on rooms as tiny as the one I mentioned can help us to understand how complex organs work, something that is particularly beneficial in the field of research into alternative methods. Nowadays, areas of this kind can be depicted spatially with the help of high resolution imaging methods. We bought the relevant equipment so that we can use this gigantic technical advance for our purposes. In this way, we can investigate processes on a cellular level in organs and develop cell and tissue culture methods with which animal experiments can be substituted or reduced.

Does the Bf3R award research funds to projects for the development of alternative methods?

ZEBET has been inviting bids for project funding for more than 20 years. Promoting research in this way is of major importance in Germany, as it provides start-up finance in the field of alternative method research. Funding is available to scientists who have promising ideas but cannot point to the kind of scientific findings that would pique the interest of the big funders of research. Our start-up finance concept enables the scientists to generate data for two to three years so that they can subsequently apply for larger-scale funding.

What alternatives exist; what has already been achieved?

A wide range of different technologies (cell culture models, omics technologies, imaging techniques etc.) are already being used in the many biomedical research laboratories around the world that do without animal experiments and generate new knowledge and insights in the field of basic research.

In the field of application-focused science, there are already several OECD-audited and validated methods which can be used, for example, to test the irritant potential of chemicals on skin models. As a result, the number of animal experiments in this field is lower than it otherwise would be. There are also cases in which an animal experiment is funded – in cases where there is uncertainty regarding the results obtained by other means, for example.

Why is the number of animal experiments on the rise?

The implementation of the EU Directive on the protection of laboratory animals into national law in 2013 also necessitated a new version of the regulation on the statistical reporting of laboratory animals with an extension of the obligation to report the use of laboratory animals. Accordingly, the use of cephalopods (e.g. squid, octopus), the larvae of vertebrates and the breeding of genetically modified animals have to be reported.

Has the Bf3R already achieved any success?

In my opinion, absolutely. During the short time since it was founded, the Bf3R has drawn up the first ever international proposal for the assessment of the severity of genetically altered fish (bony fish, teleostei), thereby creating a common basis for the categorisation of severity of fish by the authorities, researchers and legal experts. There are still a few gaps that need to be closed by biological research, but this kind of consensus is necessary, even if it is only of a preliminary nature.

The AnimalTestInfo database is a further success story, because it is the only database of its kind in the world. It is unique because it provides the public with transparent information on animal experiments, and because it supplies new and detailed information on animal experiments in Germany that enables us to more effectively identify research fields for the development of new alternative methods. The database not only supports our own research, but also helps us to provide scientific advice on promotion measures in the field of alternative method research in Germany and Europe.

Last but not least, there is the scientific article entitled "The 'reasonable cause', for killing excess animals, a classic question of animal welfare law in the context of biomedical research". The concept of the "reasonable cause" is one of the most difficult and most frequently discussed problems in the German animal welfare law. This article illustrated the potential conflict between modern biomedical research and the concerns of animal welfare, and outlined solution approaches. ||

 Publications of the Bf3R

The animal experimentation quandary: stuck between legislation and scientific freedom.

In: EMBO reports (DOI: 10.15252/embr.201642354)

Considerations for a European animal welfare standard to evaluate adverse phenotypes in teleost fish.

In: The EMBO Journal (DOI: 10.15252/embj.201694448)

Laboratory animals: German initiative opens up animal data.

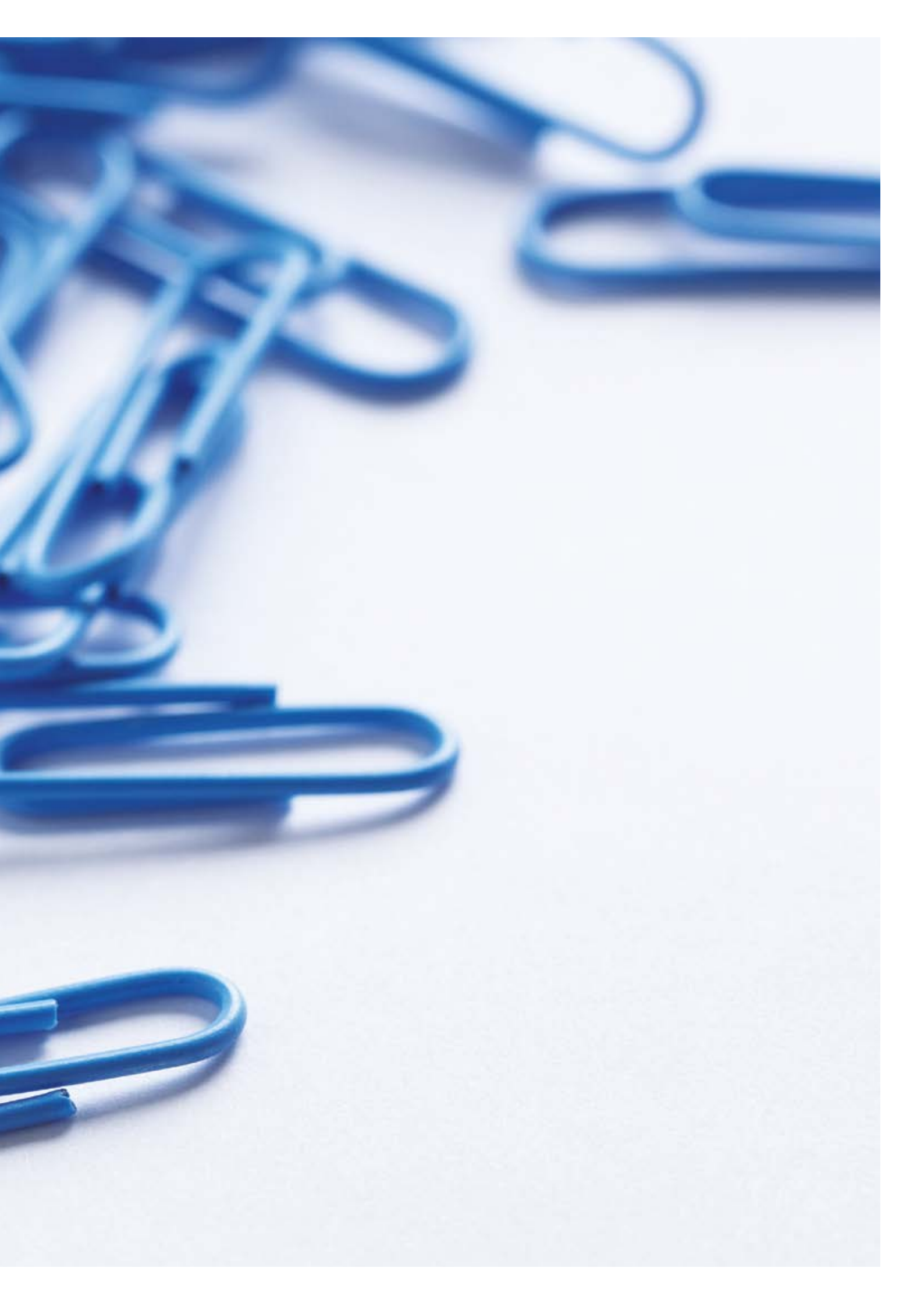
In: Nature (DOI: 10.1038/519033d)

Der "vernünftige Grund" zur Tötung von überzähligen Tieren (The "reasonable cause" for killing excess animals).

In: Natur und Recht (DOI: 10.1007/s10357-015-2903-9)



Annexes



Third-party funded projects of BfR in 2015

Research for exposure assessment and for the assessment of biological risks

Period	Acronyme	Topic
11/2010–08/2015	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
10/2012–06/2015	e-H@C HUPAction	Developing a system to improve information exchange within the organizational 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
11/2015–11/2018	EsRAM	Development of measures for reduction of antibiotic resistant bacteria along the entire poultry production chain
01/2015–12/2015	Leptospirose	Consiliary Laboratory for Leptospirosis – Diagnostics and Epidemiology
06/2015–05/2018	NutriAct	Nutritional Intervention for Healthy Aging: Food Patterns, Behavior, and Products

Further Information
BMBF (FKZ: 01KI1015A) www.vibrionet.de
DFG (FKZ: STI 201/3-1) http://gepris.dfg.de/gepris/projekt/175974972
EU (II-2-03=201) http://giqs.org/projekte/hupaction
BLE (FKZ: 2816801511)
BMBF (FKZ: 01KI1301C)
BMBF (FKZ: 01KI1313B)
BLE (FKZ: 2817701614)
RKI (FKZ: 1369-365)
BMBF www.nutriact.de

Abbreviations

BLE:	Federal Office for Agriculture and Food
BMBF:	Federal Ministry of Education and Research
BMEL:	Federal Ministry of Food and Agriculture
BMUB:	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety
BMWi:	Federal Ministry for Economic Affairs and Energy
DFG:	German Research Foundation
EFSA:	European Food Safety Authority
EU:	European Union
FKZ:	Project reference number
GZ:	Reference number
LANUV:	State Office for Nature, Environment and Consumer protection North Rhine-Westphalia
NRW:	North Rhine-Westphalia
RKI:	Robert Koch-Institute
UBA:	Federal Environment Agency

Research for the safety of national and international production chains

Period	Acronyme	Topic
07/2013–12/2016	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
12/2015–08/2016	Traceability of products	Project cooperation between BfR and LANUV NRW for the continuously traceability of products

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

Period	Acronyme	Topic
12/2012–02/2016	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
05/2015–05/2019	EuroMix	European Test and Risk Assessment Strategies for Mixtures

Research for modern methods in toxicology

Period	Acronyme	Topic
11/2010–11/2015	Gastrointestinale Barrier	Interaction between metabolism and transport of toxicologically relevant compounds in the gastrointestinal barrier
11/2013–04/2016	Combiomics	Combiomics – Investigation of mixture effects of <i>in vitro</i>
12/2013–06/2016	LivSys	Modelling of the toxome of cultivated human hepatocytes
07/2015–06/2018	Okadasäure	Molecular characterization of toxicological properties of the marine biotoxin okadaic acid in <i>in vitro</i> models for the human intestinal barrier and liver
12/2015–11/2017	PFOA	Molecular mechanisms of the toxicity of perfluorooctanoic acid
12/2014–09/2015	Nahrungsmittel- kanzerogene	Metabolic activation and inactivation of food carcinogens 5-hydroxymethylfurfural and furfuryl alcohol in humans, mice and rats

	Further Information
	BMBF (FKZ: 13N12697)
	EU (FP7-SEC-2012 – 312631) www.spiced.eu
	EU (FP7-KBBE-2013-7-613754) www.effort-against-amr.eu
	EU (FP7-KBBE-2013-7-613688) https://secure.fera.defra.gov.uk/foodintegrity/index.cfm
	NRW-Projekt

	Further Information
	BMUB (FKZ: 3712 62 204)
	EFSA
	BMWi (FKZ: 01FS12034)
	EU (H2020-SFS-2014-2-633172) www.euromixproject.eu

	Further Information
	DFG (FKZ: LA 1177/6-1) http://gepris.dfg.de/gepris/projekt/156632571
	BMBF (FKZ: 031A267A)
	BMBF (FKZ: 031A270C)
	DFG (GZ: LA 1177/11-1)
	DFG (GZ: LA 1177/10-1) DFG (GZ: BU 3060/1-1)
	DFG (FKZ: MO 2520/1-1)

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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
04/2015–03/2016	REACH-Compliance Check – Phase II	Data Availability of High Tonnage Chemicals under REACH, Phase II: In-depth Examination
07/2014–06/2016	National monitoring of intoxication	Research project “National monitoring of intoxication”
04/2015–10/2016	LiquiTabs	Study on hazardous detergents mixtures contained in soluble packaging for single use

Research for alternatives to animal experiments

Period	Acronyme	Topic
04/2014–03/2017	BB3R-Forschung	Berlin-Brandenburg research platform BB3R with integrated graduate education

Research for feed safety

Period	Acronyme	Topic
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
06/2015–12/2018	Tender Mycotoxine	Provision of technical services to NEN

Further Information
EU (FP7-KBBE-2011-5-289108) www.tds-exposure.eu
UBA (FKZ: 3714 67 420 0)
UBA (FKZ: 3715 67 422 0)
BMU (FKZ: UM14654010)
EU (30-CE-0702569/00-44-SI2.705912)

Further Information
BMBF (FKZ: 031A262D) www.bb3r.de/projekt/index.html

Further Information
BLE (FKZ: 2813804310)
EU (SA/CEN/ENTR/522/2013-11 Contract item: 2013-11.11)
EU (SA/CEN/ENTR/520/2013-17)

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

Period	Acronyme	Topic
02/2011–07/2015	QNano	A pan-European infrastructure for quality in nanomaterials safety testing
10/2012–10/2016	MODENA	Modelling Nanomaterial Toxicity
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 Visualisation Tools and Guidance for “Seeing at the Nanoscale”
12/2015–11/2018	NanoToxClass	Establishing nanomaterial grouping/ classification strategies according to toxicity and biological effects for supporting risk assessment
05/2015–04/2018	nanoGRAVUR	Nanostructured materials – Grouping for occupational health and consumer and environmental protection and risk mitigation
09/2015–08/2018	NANoREG 2	Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks

Scientific cooperation

Period	Acronyme	Topic
01/2014–12/2016	EFSA focal point	Germany's national focal point on technical and scientific matters

i Additional information on 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.bmel-forschung.de

	Further Information
	EU (FP7-INFRASTRUCTURES-2010-1-262163) www.qualitynano.eu
	EU COST-Action (TD 1204)
	EU (FP7-NMP-2012-Large-6-310584) www.nanoreg.eu
	EU (FP7-NMP-2013-LARGE-7-604347) 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)
	BMBF (FKZ: 03XP0008A)
	BMBF (FKZ: 03XP0002D)
	EU (H2020-NMP-2014-two-stage-646221) www.nanoreg2.eu

	Further Information
	EFSA www.efsa.europa.eu/en/about/partnersnetworks

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Publications in scientific journals 2015

A

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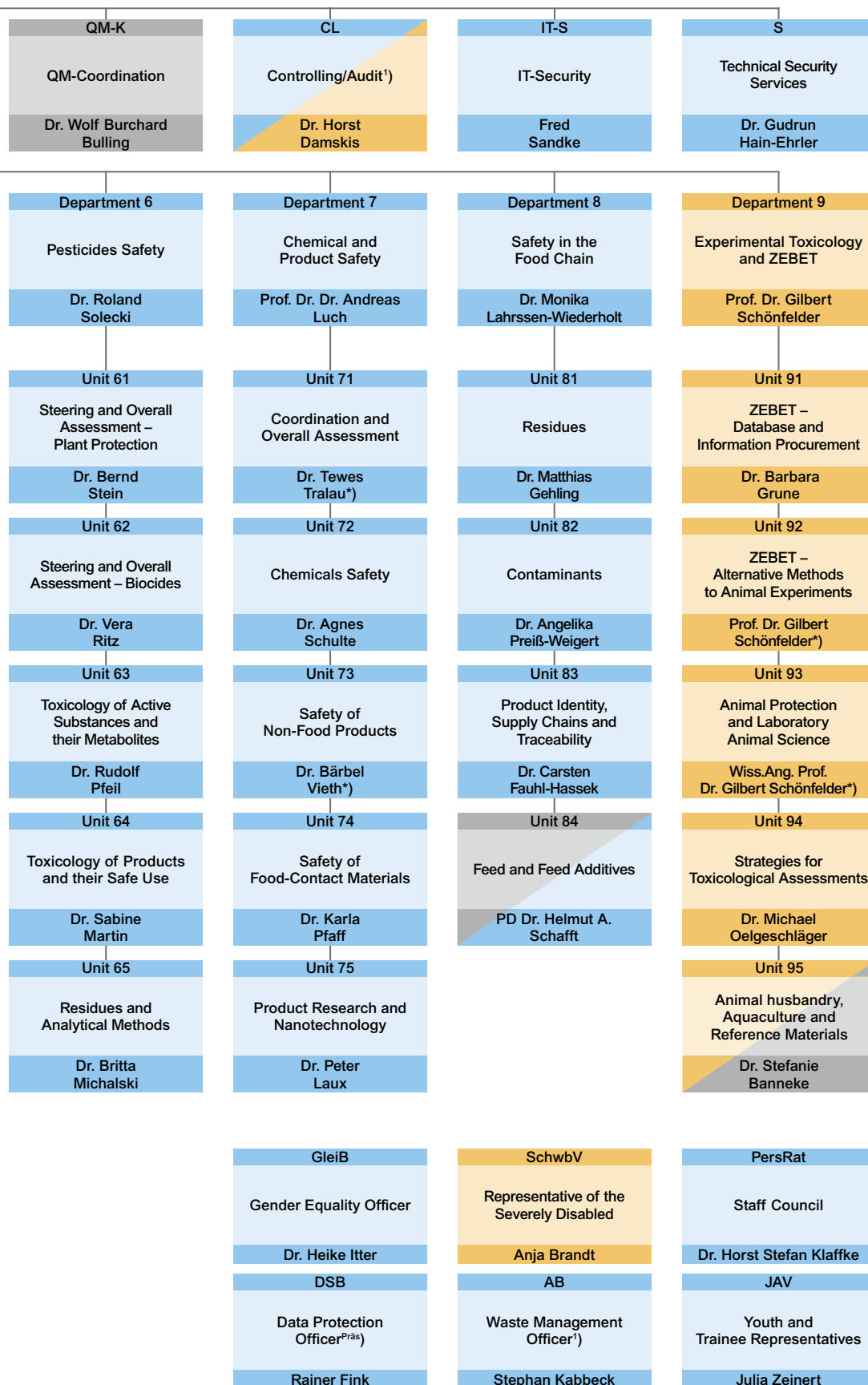
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^{*)} Temporary appointment/
entrusted with the
performance of tasks

) 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 and feed, consumer products and chemicals. Through its work, it makes an important contribution to rendering food, products and the use of chemicals safer in Germany.

The Federal Institute for Risk Assessment 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 as well as on the safety of substances and products. In doing so, the institute assumes an important task in improving consumer 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 800, including around 300 scientists, work in the field of consumer health protection. The institute is independent with regard to both its scientific assessments and its research activities.

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 numerous 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 participates in national and international panels, advises policymakers and provides information to the public at large. Staging events and organising projects are just two of the ways in which the BfR passes on information on potential risks. Due to the high standard of its work, its scientific independence and its transparent assessments, the institute has become a recognised actor and important driver of consumer health protection on both national and international level – and consumers know they can trust its judgements.

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