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SCIENCE IN THE SERVICE OF HUMANITY

BfR

Bundesinstitut für Risikobewertung

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Laboratory work is just one of the many tasks performed by the employees of the BfR. Every day, they help to ensure that food, substances and products are safe.

Foreword

Prof. Dr. Dr. Andreas Hensel, President

Prof. Dr. Reiner Wittkowski, Vice-President

Dear Readers,
"Avoiding crises before they occur" – this is the slogan BfR has used to describe the goal of its scientific work since it was founded. To the extent that we can measure these things, 2013 was yet another year in which not many crises occurred, whether genuine or crises as portrayed in the media. This is a strong indication for the high standard of food safety in Germany as well as an attestation of the effective work of the BfR. The institute has succeeded in facilitating the transfer of knowledge to all relevant stakeholders – in politics, industry and to the population at large. This is done based on high scientific standards but also in a way that is understandable for specific target groups. This is proof that transparency and independence which are standard criteria laid down by the BfR founding law are valuable and key factors in building trust among all stakeholders.

Both nationally and internationally, the BfR plays an increasingly leading role as a scientific reference institute. This involves the progressive increase of BfR's international contacts. One example is the cooperation with food safety authorities in Iceland. Together with the Lower Saxony State Office for Consumer Protection and Food Safety, the BfR is helping the Icelandic authorities – the Icelandic Agency for Food Safety and Veterinary Medicine (MAST) and the Icelandic Institute for Food and Biotechnology (MATIS) – to create new capacities for official monitoring and laboratory testing. The main focus of this cooperation is: pesticide residues, chemical contamination and genetically modified organisms in food and feed.

Irrespective of this, the BfR also faces new internal challenges that necessitate a continuous process of structural change. New legal tasks, annual budget cuts and the expansion of our remit in existing areas of responsibility have made it necessary to reorganise the expert groups within the BfR and adapt these groups in terms of personnel. The objectives included meeting the extended requirements in the field of the European REACH legislation on chemicals or fulfilling the new responsibilities created by the amendment of the German Animal Welfare Act. The structural adjustment measures were initiated in 2013 and implemented at the beginning of 2014 – and are already having their first effects.

The BfR attaches major importance to supporting the advancement of scientists. Currently, over 40 PhD candidates have the opportunity to work on their scientific qualifications at the BfR, in developing methods, collecting data or conducting applied research. This is an important contribution to improving risk assessment practices. In 2013, the BfR decided to go a step further and will break new ground in 2014 by establishing its own PhD programme. This will include in addition to a content-based scientific supervision, measures to promote the development of soft skills.

Laying the foundations for major innovative projects

2013 was also a year when the foundations were laid for major innovative projects which will shape the future activities of the institute and be of paramount importance for risk assessment. One example is the planned creation of a central register for cases of poisoning in order to create a national monitoring system. In consideration of the existence of real and perceived risks, cases of poisoning are of major significance for public health, for risk assessment in legally stipulated procedures and for the timely identification, prevention and communication of health risks. In addition, a national poisoning register allows early identification and realistic assessment of toxicological health impairments and creates a solid basis for evidence-based risk estimation, particularly in the event of a crisis. The systematic and harmonised documentation of cases of suspected and actual poisoning at poison information centres and at the BfR as well as the centralised collection and assessment of this data is designed to substantially improve BfR's effectivity in early detection and the health assessment of cases of poisoning. This is also beneficial for national and regional authorities, the industry and the poison information centres.

The BfR is also laying the groundwork for a national "Total Diet Study" in Germany in order to prevent the loss of key data on substances in food products. With this project the BfR works in close cooperation with its French sister authority ANSES and complies with stipulations of the European Food Safety Authority (EFSA), the World Health Organisation (WHO) and the Food and Agriculture Organisation of the United Nations (FAO). Together with the results from consumption studies, the data of the Total Diet Study will for the first time permit the calculation of intake estimates for several substances such as additives and process contaminants across the full range of relevant foods. For many other substances like dioxins or heavy metals, uncertainties in existing intake estimates can be reduced and the risk assessments of the BfR improved. This wide-ranging project enjoys high priority at the BfR. The first outcomes are expected in the year 2019.

On the following pages, this Annual Report will provide insights into the diverse issues in which the BfR was involved during the course of 2013. The report, however, can only be seen as an excerpt. For more in-depth, easy-to-understand and transparent information on current topics we also refer you to our website.

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

Prof. Dr. Dr. Andreas Hensel,
President

Prof. Dr. Reiner Wittkowski,
Vice-President

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About the BfR

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

Objectives and Mission

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

The Federal Institute for Risk Assessment, or BfR for short, is an independent scientific research institution which prepares around one hundred reports and opinions every day outlining the health risks of food and feed, consumer products and chemicals. The institute communicates its findings and recommendations to the policy makers and the public at large. The federal government uses the opinions of the BfR as a basis for ensuring consumer health protection. Set up in 2002, the BfR today employs a staff of about 770 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, for instance 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 an important decision-making aid for taking the necessary measures. With its scientifically based risk assessment activities, the BfR provides important stimuli for consumer health protection both in Germany and abroad.

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

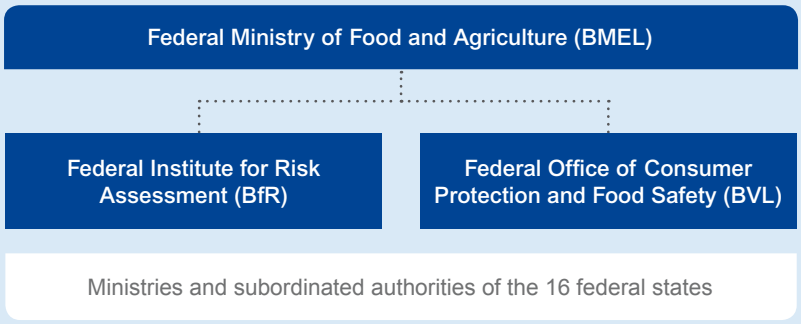
Position in the field of consumer health protection

The BfR was founded as a federal agency with legal capacity within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). Its tasks result, amongst other things, from the Act establishing the BfR which was enacted in conjunction with the reorganisation of consumer health protection and food safety in Germany in 2002. The legislative has also defined the work activities of the institute in ten further laws – including the German Plant Protection Act, the German Genetic Engineering Act, the German Food and Feed Code, and the Chemicals Act.

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

In a federal system like in Germany, the responsibility for consumer health protection falls to the Federal Government and the federal states. Laws and ordinances designed to promote consumer health protection are enacted by the German Government and the 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 national level.

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



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

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

The BfR assesses the health risks of food and feed, chemicals and consumer products. The ingredients of products are also a focal point of the institute's work.

Principles and Working Procedures

The BfR is committed to certain principles that ensure the high quality of its opinions. When the institute was founded in 2002, the strategic focus was on the consolidation of the science-based approach to risk assessment. Various measures have since been taken that have played a key role in consolidating this approach and thereby underpinning the high quality of the work of the BfR.

Independence

The independence of experts is a fundamental precondition for independent risk assessment. For this reason, the separation of scientific risk assessment from subsequent risk management has been standard practice in Europe for more than ten years now.

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

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

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

It is of decisive importance that, in order to ensure independence, no funding may be obtained from industry.

Transparency, scientific excellence and independence are the most important principles employed by the BfR in order to strenghten the trust of all involved parties in the process of risk assessment.

Assessment of risks

In science a risk is described as the probability that an event will occur which is detrimental to health and the expected scale of health impairment. A health risk can never be completely ruled out. By means of a package of suitable measures, which are described as risk management, efforts are however made to minimise the risk as far as possible and to prevent any threat to health.

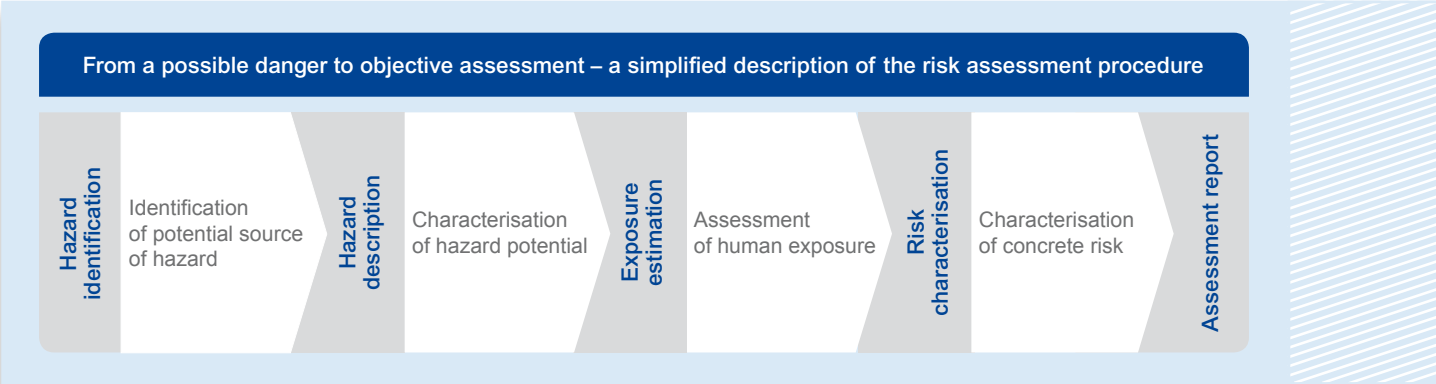
The job of the BfR is to provide the policy decision-makers with the solid scientific basis for risk management they need. Identifying a risk and evaluating this risk – the two together are described as "risk assessment" – is the first step in the area of health consumer protection. Ideally, this step is taken in dialogue with all relevant parties and culminates in a consensus on the degree of acceptance of a risk. 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 schema 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 assessment. The latter is based at least partly on calculations or mathematical models, and the risks are described using mathematical or statistical methods.

The risk assessments of the BfR are also always the subject of the institute's risk communication activities. The BfR has the legal mandate to inform the public about potential, identified and assessed risks. The assessments should be presented in a transparent and easy-to-understand manner. The findings are made publicly accessible on the Internet website of the BfR while maintaining the confidentiality of protected data. At expert hearings, scientific conferences and consumer forums, the institute enters into dialogue with representatives from the world of politics, science, associations, industry and non-governmental organisations.

The BfR has published a guideline for health assessments in the field of consumer protection outlining the basic principles for all BfR assessments:
www.bfr.bund.de/en > Publications > Brochures



The BfR has the statutory task of undertaking scientific research that is closely linked to its activities.

Research

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

Alongside its mandate to assess and communicate health risks for consumers, the BfR also conducts experimental and non-experimental research:

- within the framework of reference laboratory activities with the aim of developing and establishing new detection methods
- on risk assessment within the framework of the biological and chemical safety of food and feed, chemicals and consumer products
- on risk communication and risk perception
- on supplementary and alternative methods to animal experiments

The BfR defines its main areas of research every two years in form of a research programme. In order to implement this programme, the BfR not only funds its own research but also acquires public third-party funding. The most important instrument for internal research promotion are the special research projects that are subject to an annual application and review procedure. Every year, around 60 projects are supported with funding for consumables and in some cases staffing. In addition, the BfR also has funds at its disposal that it can award to third parties. In this way, the BfR regularly invites grants for research projects geared towards the development and validation of alternative methods to animal experiments as well as projects in the area of risk research and risk communication. The externally funded national and international projects are to be seen as supplementary to the BfR's in-house research activities. In 2013, the BfR acquired funding for new projects focusing on issues such as the safety of nanomaterials as well as in the fields of antimicrobial resistance, innovative toxicology and the safety of global supply chains. The BfR has continuously increased the funding for research activities in recent years, underlining the particular importance of research for the work of the institute.

First status report on the nanotechnology research strategy

In order to deal with open questions regarding nanomaterials and to weigh up the risks and opportunities involved, the BfR, the Federal Institute for Occupational Safety and Health and the Federal Environment Agency developed a joint research strategy in 2007. In 2013, the three institutions collaborated with the Federal Physical-Technical Institute and the Federal Institute for Materials Research and Testing to submit an initial assessment detailing the status and main findings of over 80 research projects on the subject of nanomaterials. Areas where progress has been made include the development of characterisation and test procedures, the monitoring of the burden affecting humans and the environment, and risk assessment. Furthermore, the assessment also lists several focus areas and issues for the future direction of German safety research in the field of nanotechnology.

Detailed status report:
www.bfr.bund.de/en > Research

Committees

A total of 15 scientific expert committees advise the BfR in questions relating to the safety of food and feed, chemicals and products, nutrition, risk research and risk perception. These networks pool the expertise available in Germany at the highest scientific level and also form an external quality assurance system. The approximately 200 committee members are external, independent experts who support the work of the BfR in an advisory capacity and on an honorary basis. They come from universities and other research institutions, national and regional authorities, trade and consumer associations, private laboratories and industry.

The BfR committees each have at least ten members, who elect a chairperson from among their ranks. The BfR provides support by taking over management tasks. Meetings are normally held twice a year. The minutes of these meetings containing the scientific views and resolutions of the committees are made available to the general public on the BfR website. The resolutions of the committees have the character of advice. They are examined by the BfR and, where applicable, they flow into assessments and opinions issued by the BfR as reference points. This is very different from other institutions in the EU like the European Food Safety Authority (EFSA), where expert reports and opinions are not prepared by in-house scientific personnel but by external members of the relevant EFSA bodies. The advisory role of the BfR committees is laid down in the joint rules of procedure.

Three appointment procedures have been carried out since the BfR committees were established – in 2007, 2010, and most recently in 2013, when the public invitation for applications was issued for the third appointment period from 2014 to 2017. Several hundred qualified scientists submitted applications, and the appointments commission selected a total of 187 suitable experts from among the ranks of these applicants to serve on the various BfR committees. The committees have meanwhile begun their work.

Apart from the 15 BfR committees, the National Breastfeeding Committee and the Committee of the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET) are also attached to the BfR.

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

The BfR is advised by 15 scientific expert committees. Meetings generally take place twice a year.

Quality management

Authorities, and in particular scientific institutes like the BfR, must be able to prove that they work in accordance with internationally recognised standards, and they must ensure this by operating a functioning quality management system, QM system for short.

The criteria for quality-assured work activities are laid down in international standards. The standard DIN EN ISO/IEC 9001:2008 stipulates how business processes and responsibilities have to be organised in order to guarantee high-quality work and products. The standard DIN EN ISO/IEC 17025 lays down the rules for the management of test and calibration laboratories as well as the technical requirements. Test laboratories which satisfy the standard prove by doing so that they have the technical competence and capability to achieve substantiated results. Since 2010, all work areas of the BfR – science, assessment, communication and administration – have been certified in line with the quality standard DIN EN ISO 9001:2008. The BfR's scientific laboratories have been accredited in line with DIN EN ISO/IEC 17025 since back in 2002.

The two quality certificates have to be renewed regularly. On 9 August 2013, the independent TÜV Nord Cert GmbH certification company once again issued a certificate confirming that the quality-assured operations at the BfR comply with DIN EN ISO 9001:2008. Compliance with the standard DIN EN ISO/IEC 17025 was most recently confirmed at the BfR in the autumn of 2012 by Germany's "DAkkS" National Accreditation Body. The DAkkS certificate issued on 26 April 2013 confirms the successful re-accreditation of the three organisational units Analytics, Microbiology and Toxicology together with their laboratories. Their work is performed with a high level of competence, is of an internationally comparable standard, and meets the statutory and normative requirements.

Food safety is an international issue – and the BfR therefore cooperates with various global partners.

Internationalisation

The increasing transboundary movements of goods in the food sector clearly illustrates that food safety is an international issue. The BfR collaborates with various global partners in order to raise awareness for health risks beyond the borders of Germany. On a European level, the BfR is linked up with various sister authorities through its national focal point (EFSA Focal Point) and jointly with the European Food Safety Authority (EFSA) through its involvement in expert panels and the Advisory Board. Cooperation with partner authorities outside Europe is also gaining in importance as it helps to reduce "imported" risks in the medium term from countries of origin with lower safety standards. The goal is to help these countries to establish scientific standards so that potential problems can be locally averted and as a result local consumers as well as those in other countries can be protected.

Scientists from international institutions visit the BfR on a regular basis to talk about such things as analytical techniques.

The BfR follows various approaches in order to target experts and multipliers in other countries. In 2013, the BfR offered a summer school for foreign experts in the field of risk assessment and risk communication for the second time. The institute is also entering into more and more cooperation agreements with European and non-European institutions. The main focus here is on exchange visits, collaboration in research projects and the organisation of cooperation events.

In 2013, for example, the BfR welcomed high-ranking representatives of government ministries and authorities from a wide range of countries including China, Uruguay, Thailand, Iceland, Argentina and Belarus. Moreover, the existing cooperation agreement with the Lithuanian "National Food and Veterinary Risk Assessment Institute" was renewed, a bilateral project signed with the Icelandic "Food and Veterinary Authority" and a declaration of intent submitted on closer cooperation with the "China Animal Health and Epidemiological Center".

The EU Almanac of the BfR outlining food safety structures and institutions in 35 European countries and on European level. The brochure has been published in different languages.
www.bfr.bund.de/en > Publications > Brochures

Methods are developed and validated in the BfR reference laboratories for tasks such as the analysis of mineral oil residues in food products.

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. The laboratories are divided into two groups: national reference laboratories in accordance with Regulation (EC) 882/2004 and other BfR laboratories with reference function.

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

Due to the nature of their task, the national reference laboratories act as watchdogs for the timely identification of occurring risks. Their work forms the basis for national and, increasingly, international exposure assessments.

The main job of reference laboratories is to develop and validate methods and to perform laboratory comparison tests (Interlaboratory Tests) for the purpose of quality assurance. The creation of national reference laboratories ensures 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 generally covered by the principle of the free movement of goods within the European Union. The national reference laboratories also act as a national link between the community reference laboratories of the EU and the food surveillance authorities 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 connections. 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.

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

President
Professor Dr. Dr. Andreas Hensel

Vice-President
Professor Dr. Reiner Wittkowski

Department Administration
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 income 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 for compliance with legal regulations.

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

The Risk Communication Department conducts research projects on the perception of risks in the public sphere and on the early identification and impact assessment of risks. A further focus of its work is crisis prevention and coordination. The department also comprises press and PR activities, the BfR committees and the BfR-Akademie. To this end, BfR enters into an active dialogue with various stakeholders from science, trade and industry, political circles, the media, associations, non-governmental organisations and consumers.

Department Exposure
Head: Professor Dr. Matthias Greiner

The Exposure Department assesses the exposure of the consumer in the areas of food, chemicals and product safety, and offers interdisciplinary scientific cooperation services in fields such as mathematical modelling. The department performs statutory tasks in the areas of chemicals safety, dangerous goods transport, poison and product documentation, and good laboratory practice. It also conducts research projects and is an IT service provider for the BfR.

Department Biological Safety
Head: Professor Dr. Bernd Appel

The work of the department is focused on 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 materials and tableware) as well as cosmetics – including the processes involved in their extraction, production, processing and distribution – as vehicles of biological risks.

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

The department assesses foods with regard to the risks of the substances they contain. These substances may occur naturally in foods, may take the form of additives or flavourings, or may be undesired substances which end up in the food via production, storage or treatment processes. It also assesses food risks as well as the risks of specific population groups. Experimental projects on the effect mechanisms of the oral intake (bioavailability), internal exposure (biomarkers) and molecular effect mechanisms (toxicogenomics) of relevant substances are an integral part of the assessment activities.

Department Safety of Pesticides
Head: Dr. Roland Solecki

The main remit of the department's work is the health assessment of active ingredients and formulations of pesticides and biocides. Assessment comprises evaluation of toxicological properties with the aim of classification and labelling as well as the derivation of limit values. Based on anticipated exposure levels, the department carries out risk assessments 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.

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

The department assesses chemical substances governed by the laws on chemicals and identifies measures to mitigate risks. A further aim is to identify, research, assess and prevent the health risks of cosmetics, tobacco products and other products with which the consumer comes into contact (such as food packaging, toys, clothing etc.). Experimental projects on the migration of, exposure to and toxicity of chemical substances are an integral part of these assessment activities.

Department Safety in the Food Chain
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 the Monitoring of Marine Biotoxins and for Additives for Use in Animal Nutrition as well as the Senior Expert Office for the Import Control of Wine. Other focal points of the department's work are product identity and the traceability of food products.

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

The department carries out the tasks laid down in the German Animal Welfare Act and the Animal Protection Experiment Regulation. The activities of the department also form the basis for advice to political decision-makers. Its main tasks are developing and evaluating alternatives to animal experiments based on the “3R” concept. The department is also involved in the (further) development of toxicological testing methods, and on a regulatory level this includes the Chemicals Programme of the Organisation for Economic Cooperation and Development (OECD).

Personnel and Training

A staff of 768 was employed at the BfR at the end of 2013. This means that there was a further increase in the number of employees compared to the previous year. The main tasks of the personnel section in 2013 were the recruitment of qualified staff, training, personnel development and the promotion of the compatibility of career and family at the BfR.

Personnel recruitment

In order to recruit qualified personnel, the BfR again participated in trade fairs and events specifically for the field of natural sciences in 2013, as in previous years. The personnel section had its own stand at two job fairs in Berlin, for example, and at the Biotechnica fair in Hannover. The aim was to supplement the classic print and online employment ads by positioning the BfR as an attractive employer at various events and thereby to expand the group of potential applicants. The BfR published a total of 101 job announcements in 2013, received 3,213 applications and signed 266 new employment contracts.

A guideline document was prepared for management personnel to make it easier for new employees to familiarise themselves with their work and procure the information they need. In addition, introductory events with tours of the premises regularly take place at the various locations. The central service units, staff representatives and gender equality officers also introduce themselves to new staff at these events.

Training

The BfR provides training in six different professions. In 2013, a total of 33 young people were involved in apprenticeships. While eleven apprentices successfully completed their training – most of them with the grade "good" or better, eleven new trainees began a three or three and a half year apprenticeship at the BfR in September 2013.

At the start of their training period, the new apprentices meet up with their specialist supervisors and the institute management so that everyone can get to know each other.

The BfR offers apprenticeships in the occupations: office communication specialist, animal carer, chemical/biology lab assistant, systems mechanic for sanitary, heating and air-conditioning, media and information service clerk.

As the BfR would like to increase the number of employees with a migration background among trainees as well, job announcements for apprenticeships are also sent to various clubs and associations who systematically address people with this kind of background. In addition, the announcements are also sent out to schools in the surrounding area, helping to raise the profile of the BfR as a local employer.

Furthermore, the BfR gave roughly 166 pupils and students an insight into day-to-day routine at the institute through internships; we also supervised dissertations and looked after ten external PhD candidates and two junior lawyers within the scope of their legal preparatory service.

Personnel development

To ensure that the many different tasks of the institute can be performed in the best possible quality, the continuous further training of the workforce is an essential factor at the BfR. 319 external further training measures were approved in 2013, including 52 courses within the framework of training for specialised toxicologists at the German Society for Experimental and Clinical Pharmacology and Toxicology. Moreover, the BfR designed and staged 13 in-house courses on specialised and methodological subjects.

Personnel development activities in 2013 focused on management development and language training. Building on the requirement profile for management personnel at the BfR, a programme was created for the systematic development of executive-level employees, incorporating not only deputising functions but also the different experience levels of management personnel. In addition, multi-week English courses were staged for employees with different levels of proficiency, and there was also a course on “Presenting in English”.

Compatibility of family and career

The BfR was awarded the “audit berufundfamilie” certificate in 2009, and the certificate was confirmed in a re-audit in 2012. With the promotion of the compatibility of family and career, the BfR is pursuing the goal of bonding employees more strongly to the institute and gaining a higher profile in the competition for qualified personnel. The measures taken to promote compatibility in recent years include extensive expansion of flexible working hours, the creation of guest offices and parent-child rooms, and the introduction of alternating telework.

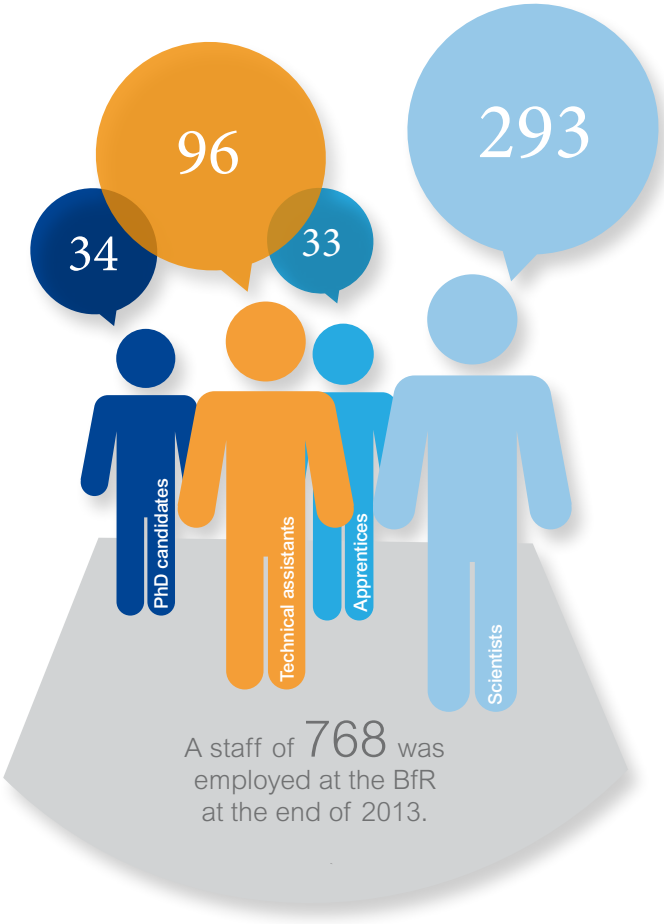
When it comes to the compatibility of family and working life, the emphasis is increasingly also on employees who provide care for family members, and the personnel unit is therefore devoting more time and resources to this issue. In 2013, for example, the BfR prepared a position paper on the German Family Care Leave Act, voicing its support for employees who wish to take advantage of care leave arrangements.

In 2013, there was also a workshop on the evaluation of telework at the BfR. All employees who were taking advantage of the alternating telework concept at the time were invited to attend. Following this evaluation workshop, a plan was drawn up to further improve the telework conditions at the BfR.

Key Data for 2013

How many scientists does the Federal Institute for Risk Assessment employ? Which bodies and committees do they serve on? How does the institute finance itself? The answers to these questions are provided in the following section on the key data of the BfR. The figures all refer to the reporting year 2013.

Personnel

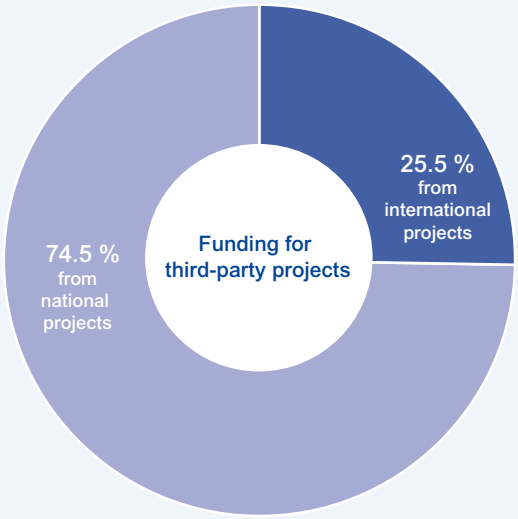


Participation in bodies

National	Number
Federal bodies	60
Federal government federal state bodies	45
BVL bodies	22
Bodies of other institutions	97
European Level	**Number**
Bodies of the European Commission	41
Bodies of the European Food Safety Authority	46
Bodies of the European Chemicals Agency	5
Bodies of other European institutions	20
Worldwide	**Number**
WHO/FAO: Bodies of Codex Alimentarius	12
WHO/FAO: other bodies	4
Bodies of other United Nations specialised Agencies	6
OECD bodies	37
Other bodies involved in global standardisation activities	9

On behalf of the institute, BfR employees conduct research, provide advice and perform assessments in 404 bodies.

Research

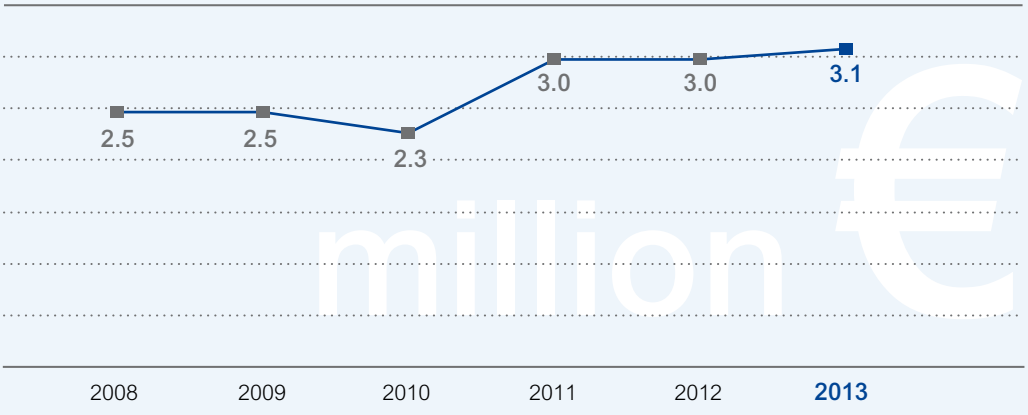


Funding for third-party projects in 2013 amounted to **3.1 million euros,** with international projects accounting for 25 % of this figure.

Third-party projects	Number	Funds
International (EU, EFSA etc.)	21	786,367 €
National (BMBF, DFG, BLE etc.)	26	2,296,972 €
total	**47**	**3,083,339 €**

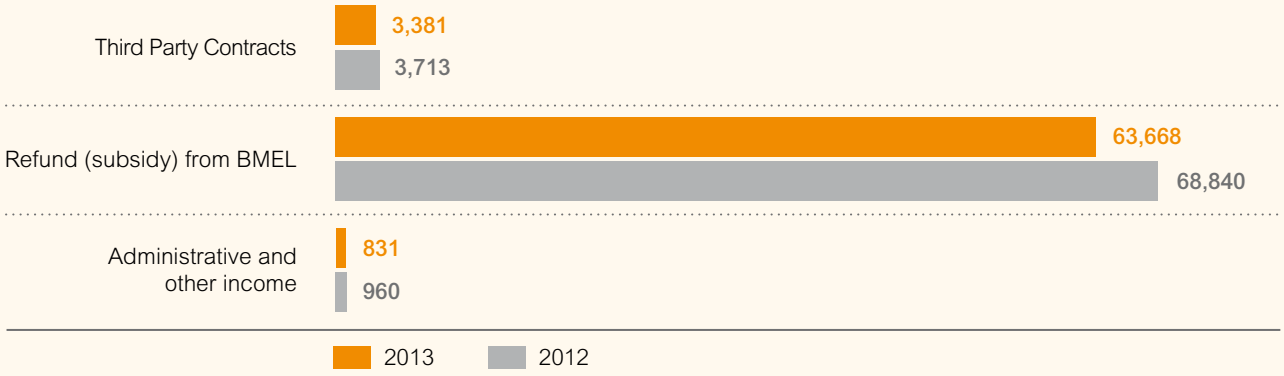
During the past six years, the BfR has increased its third-party projects funds by **24 %**.

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



Procurement/Finances

Income (in thousands of euros)



68 million euros is how much the BfR received in total revenues in 2013.

Expenditures (in thousands of euros)

Investment costs were lower in 2013 than in the two previous years, as the move from the Dahlem location to Jungfernheide was completed in 2013.

Selected Expenses

Scientific collections and libraries	355,000 €
Initial and further training	266,000 €
Press and public relations, publications and professional information	631,000 €
Conferences, trade fairs and exhibitions	193,000 €

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)	2,370
Expert opinions for supervisory federal ministries (BMEL, BMUB, BMVI)	290
Expert opinions in conjunction with international procedures (EU, OECD, WHO) for the assessment of chemical substances and testing methods, e. g. on alternatives to animal experiments	100
Expert opinions for the European Food Safety Authority (EFSA) and EFSA Focal Points of other Member States	40
Other expert opinions for public authorities and courts outside prescribed procedures	240
Other opinions, mainly for associations, individuals, NGOs	340
Total	**3,380**

The 2,370 assessments in prescribed procedures include:	**Number**
Assessments pursuant to pesticides legislation	770
Assessments of intoxication cases pursuant to § 16 e Chemicals Act (ChemG)	530
Opinions on chemicals pursuant to chemicals legislation (REACH)	510
Assessments pursuant to biocides legislation	410
Opinions on feed procedures stipulated in feed legislation	60
Opinions on exemptions from consumer protection provisions in food legislation, §§ 54, 68 Food and Feed Code (LFGB)	50
Other risk assessments in prescribed procedures	40

Note: The figures provide some insight into the type and scale of expert opinions prepared by the BfR in 2013. 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	12
Contributions to compilations	19
Articles in journals	193
Contributions to proceedings	115
Poster contributions	154
Presentations	490
Dissertations/habilitations/ diplomas/masters/bachelors	48

The BfR published around 200 articles in scientific journals in 2013.

Selected Events in 2013

Every year, the BfR organises many internal and external events highlighting various themes covered by the institute as part of its risk communication activities. These events include non-public events as well as events open to specialists and public events which are designed to appeal to different target and interest groups. The BfR staged a total of 124 events in 2013, including a high number of large-scale events. The institute also set new trends with innovative event formats like the local “action weekends”.

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

18–27 January 2013

The BfR at the International Green Week in Berlin

In line with the motto “Vitamins and minerals are essential but: getting the dose right is crucial”, around 10,000 people visited the BfR stand to find out which and how many micronutrients are contained in meat, dairy products, fruit and vegetables. Among other things, the BfR experts explained when taking food supplements is a good idea and when vitamins and co. pose a health risk.

The BfR welcomed around 10,000 visitors to its stand at the International Green Week, and the BfR mascot attracted a great deal of interest.

18–19 March 2013

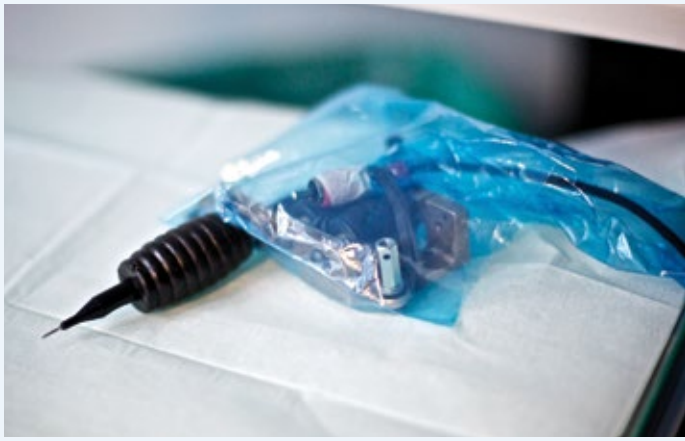
BMEL-BfR Symposium "Alle(s) Wild?"

At the symposium, the Federal Ministry of Food and Agriculture and the BfR joined forces to outline the current status of scientific knowledge on the use of lead-free ammunition in the hunting season. The topics of discussion included scientific findings from various research projects into this issue such as the impact behaviour of hunting ammunition, the killing effect of lead-free bullets and the food safety of wild game killed during hunting. The aim of the event with over 300 participants was to outline the conclusions of the research reports. Discussions also addressed the required composition of the ammunition and the influence of bullets made from alternative materials on the ballistic and physiological hazard potential compared to bullets made of lead.

The symposium on "Alle(s) Wild? – research reports concerning wild game" provided a wide range of opportunities for discussion and the exchange of ideas.

6–7 June 2013

BfR Symposium "First International Conference on Tattoo Safety"



Hygiene during tattooing was one of the themes of the "First International Conference on Tattoo Safety".

In cooperation with Freie Universität Berlin, the BfR staged an international symposium on the safety of tattooing inks in the university's Henry Ford Building which was attended by respected experts in the field. In five theme tracks, the experts outlined current knowledge and questions in the field of analysis, exposure, toxicology, hygiene, technology, and risk assessment. On day two of the event, stakeholders had the opportunity to voice their opinions of the health risks of tattoos.

12–23 August 2013

Second BfR Summer School on the topic of food safety

At the second BfR Summer School, 33 scientists from Germany and abroad discussed the topics of risk assessment and risk communication in the field of food safety. The programme included workshops on issues such as the assessment of residues, contaminants and microbiological agents. The idea of the BfR Summer School is to enable the participants to conduct their own risk assessments and to pass on this expertise in their home towns and countries.

Scientists from various countries attended the BfR Summer School to learn about risk assessment and risk communication. The programme comprised presentations and exercises as well as sightseeing tours of Berlin.

7–8 September 2013

BfR info weekend "Berlin Alexanderplatz – Introducing BfR"

The BfR staged a public event in an "infocube" on the famous Alexanderplatz square complete with interactive games, surveys, a wheel of fortune and a wide range of information, providing around 8,000 visitors with an opportunity to talk directly to the BfR about issues in the field of consumer health protection. There were themes for all age groups, such as recommendations on breastfeeding or on the potential health risks of food supplements. Well-known criminal biologist Mark Benecke answered questions on the safety of tattoos and tattooing products.

Footage of the info weekend (commentary in German): ***www.bfr.bund.de > Presse > Mediathek***

At the heart of things: the BfR with its info stand on Berlin's Alexanderplatz square

22 September 2013

The BfR at Universal Children's Day on the Potsdamer Platz square

Smaller visitors had lots of questions – how to recognise poisonous mushrooms, for example.

The BfR had a stand on the Potsdamer Platz square to mark Universal Children's Day with a poison garden, a mushroom station, a smell labyrinth, an art event and games with a "poisoning theme". During the festival, the BfR showed the children how they can detect and avert danger at home. The BfR also presented its app "Poisoning Accidents Among Children".

Footage of the event (commentary in German): ***www.bfr.bund.de > Presse > Mediathek***

11–12 November 2013

BfR Symposium "Antimicrobial Resistance in the Food Chain"

The resistance of pathogens to antibiotics is on the increase, and experts agree that the use of antibiotics must be limited to cases in which it is absolutely necessary from a therapeutic point of view. The BfR therefore invited 250 representatives from science, politics and industry from different federal states to discuss the current situation and the necessary strategies with regard to antimicrobial resistance in the food chain. The symposium was also the first event at which data were presented on the use of antibiotics and the resistance situation in livestock for Germany as a whole.

How many antibiotics are used in livestock management? Presentations and poster sessions explained the connection between therapeutic use and resistance to pathogens.

New "BfR-Akademie" launched in 2014: under the new name "BfR-Akademie", the BfR has been planning events with its accustomed professional approach since the beginning of 2014 and is currently in the process of staging these events. The academy is also responsible for optimising existing – and developing new – further training modules on the issues of risk assessment and risk communication for different target groups.

30

Bacteria that are resistant to antimicrobials are being detected in livestock animals with increasing frequency. The microorganisms can also migrate to humans through food, making it more difficult to treat infections.

Main Topics 2013

The safety assessment, analysis and regulation of tattooing agents are still in the nascent phase, but there are more and more people with tattoos. Allergies and infected wounds are two of the potential risks. 36

Pyrrolizidine alkaloids are substances that occur naturally in plants. They have carcinogenic and mutagenic effects. A research project conducted by the BfR found high concentrations in herbal teas and teas. 42

Antibiotic-resistant bacteria in the food chain

Resistances to antibiotics are a central topic in the debate surrounding food safety, as resistance rates in bacteria from livestock animals have risen sharply in recent decades. The frequent use of antibiotics in animal production is also being blamed in the public arena for the occurrence of multiple-resistance germs in hospitals and for problems in the treatment of infections. The exact interrelation, however, remain unclear. With its research and evaluation, the BfR is helping both to improve the understanding of the factors that lead to the development and spread of antimicrobial resistance and to evaluate the resulting risks. For example, the institute presented data for the first time in 2013 on how often and in what quantities antibiotics were used in livestock animals.

Resistance rates in bacteria from fattening animals have risen sharply in recent decades. The exact relationships between the use of antibiotics on the farm, the resistance levels among the animals and the impact on human health are still unclear, however.

It was recently proved using data on the resistance situation from 2012 that the incidence of resistant bacteria in the various species of animals varies greatly. Results from the annual resistance monitoring of *E. coli* from 2009 to 2012 show that resistance rates in isolates from fattening animals such as broilers, fattening turkeys, fattening pigs and fattening calves during these years were significantly higher than in isolates from laying hens and dairy cows. Isolates from fattening cattle show a significantly lower resistance rate as compared to other fattening animals. Resistance monitoring examines both zoonotic pathogens as well as harmless intestinal bacteria (“commensals”) that do not cause any disease.

Higher resistance rates to important antibiotics

Resistance monitoring in 2012 showed no significant change in the resistance situation in most areas compared to the period from 2009 to 2011. Of concern, however, is the continuing rise in the resistance rates of *E. coli* to third generation cephalosporins and the fluoroquinolone ciprofloxacin. These are two types of antibiotics that are of particular importance in the treatment of humans. In particular, infections with multiple-resistance bacteria are becoming increasingly problematic in the treatment of humans. →

At the National Reference Laboratory for Antimicrobial Resistance, the BfR analyses several thousand pathogen isolates for their resistance characteristics every year. For testing purposes, the pathogens are first cultivated in nutrient agar.

Of all the species examined, *E-coli* bacteria resistant to antibiotics were found most frequently in broilers and fattening turkeys. The cause is probably the frequent use of antibiotics.

Resistance monitoring examines both zoonotic pathogens as well as harmless intestinal bacteria that do not cause any disease.

Fattening pigs are treated with an antimicrobial agent on an average 4.2 days during each fattening period.

The resistance situation for commensal *E. coli* from animals serves as an indicator of the exposure of the relevant animal population to antimicrobial substances. The associated selection pressure makes clear that each application of antibiotics promotes the survival and spread of resistant bacteria. The resistance results show that specific consideration of the animal species and its production type and age group is necessary if meaningful steps are to be taken towards a reduction in antibiotics use and in antibiotics resistance in livestock farming.

Antibiotics: use on the farm = resistance in the animal?

In May 2013 the "Veterinary Consumption of Antibiotics (VetCAb)" pilot study commissioned and supervised by the BfR presented the first ever representative data on antibiotics use in livestock animals in Germany. This was done using the volumes of antibiotics administered in 2011 on more than 2,000 livestock farms for cattle, pigs and broilers. Data was gathered on the type, frequency and quantity of antibiotics used, as well as on the species of animal or type of livestock production in question. For the presentation of the results, in addition to the volume data, the number of treatments, the number of individual applications and the frequency of treatment were defined as standardised measurements. Quantity and frequency-related measurements are required since the dosages for the different antibiotics vary greatly.

The largest administered volumes were documented for the two antimicrobial classes beta-lactams and tetracyclines. In the livestock populations covered, the frequency of treatment varied greatly between the animal species under observation. Fattening pigs were treated with an antimicrobial agent on an average (median) of 4.2 days during each fattening period, while broilers were treated on 10.1 days. Antibiotics were used more frequently on animal species where frequently antibiotic resistances are observed.

The VetCAb project was launched in order to better assess the use of antibiotics in agricultural livestock. The representative data show the largest administered volumes for the two active substance groups beta-lactams and tetracyclines.

The methodology established in the VetCAb project formed the basis of the 16th amendment to the German Medicines Act passed in 2013, which came into force on 1 April 2014. The law provides for the collection of data on the treatment frequency for different groups of livestock animals throughout Germany based upon notification of usage by farmers. Gathering this information in a centralised database will contribute towards data on the use of antibiotics in animal production being collected in standardised electronic form.

Knowledge of the frequency of treatment makes it possible to identify farms with particularly frequent antibiotics usage which therefore play a potentially key role in the selection and spread of resistance. Farms with above-average frequency of treatment are required to take countermeasures. Any farm that exceeds a certain frequency threshold must develop an action plan in conjunction with its veterinarian and present this to the relevant veterinary supervisory authority. →

Information on VetCAb (in German):
www.vetcab.de

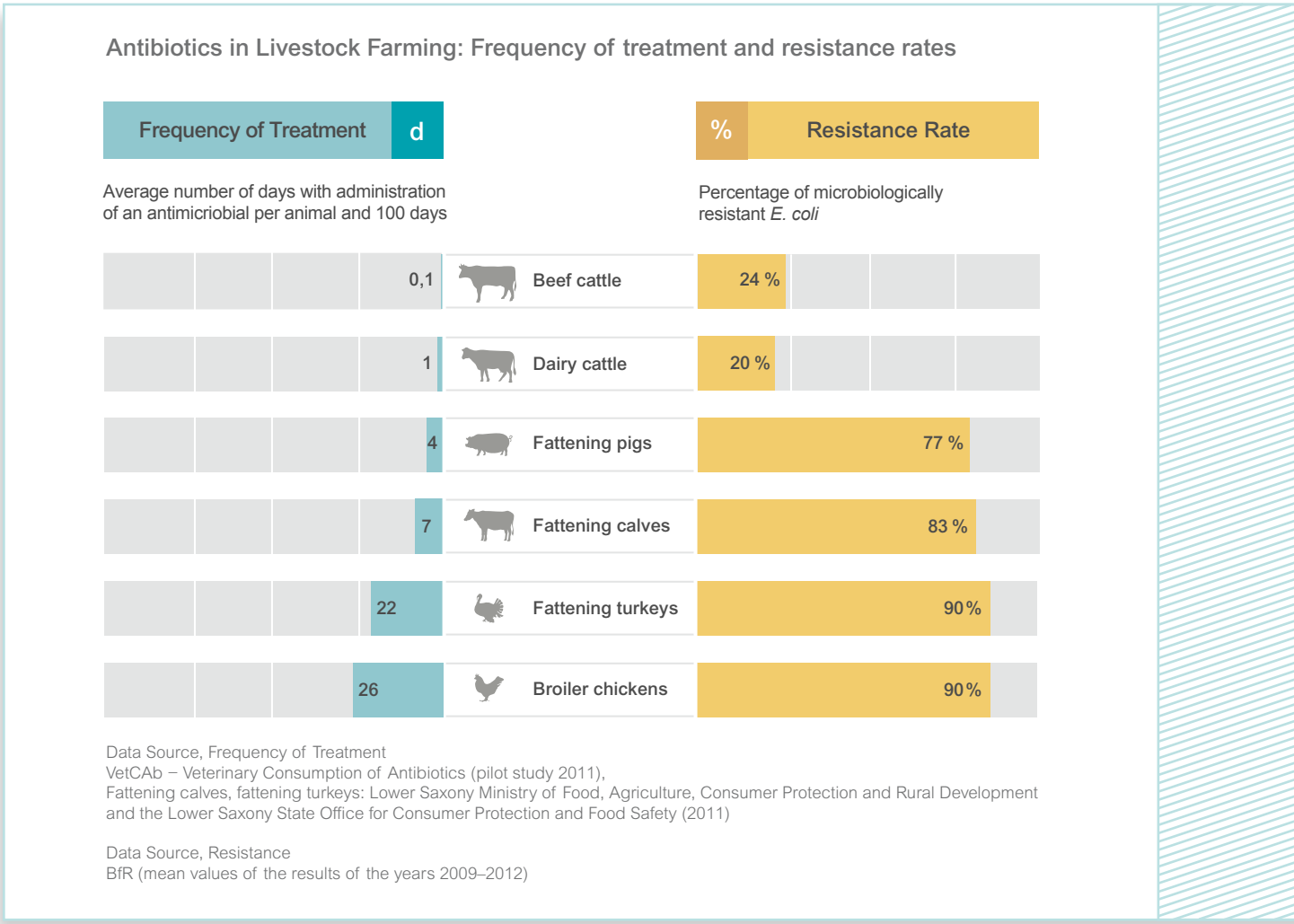
The BfR conducts scientific studies to outline suitable courses of action to minimise the entry of resistant bacteria into the food chain and assesses their effect.

Evaluation of the transmission of resistant bacteria to humans

Besides the possibility of a reduced ability to treat animals, the significance of resistant bacteria originating from livestock farming lies above all in the possible transmission of resistant bacteria to humans by direct contact, but also via food. In another collaborative research project, "MedVetStaph", sponsored by the Federal Ministry of Research, the BfR is therefore primarily examining the transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) along the food chain. Evaluation shows that while a significant reduction in bacterial contamination can be achieved in the slaughtering of pigs, in poultry slaughtering bacteria that have been brought in are transferred to the animal carcasses to a significant extent and therefore to fresh meat.

Studies with sensitive detection methods that the BfR supervised within the framework of the similarly sponsored RESET collaborative project showed furthermore that ESBL and AmpC-producing *E. coli* are found not only in livestock animals, but also on raw meat and other foods. The results from molecular characterisation of the bacteria indicate that humans and animals in some cases have the same or similar ESBL types. There are, however, also bacteria types among humans that have never been observed in any of the animal reservoirs examined. Moreover, these studies have led to the sporadic detection of carbapenemase-producing *Salmonella* spp. and *E. coli*. Since carbapenems are often the last line of defence in the treatment of serious infections in humans, the spread of resistances against this class of antimicrobial must be prevented. The use of carbapenems is generally not permitted for animals. Any detected occurrence of such resistances must therefore be closely monitored.

BfR studies on the transferability of resistant bacteria to humans show that it is above all during poultry slaughtering that bacteria are transferred to the carcasses and therefore to fresh meat.



Data Source, Frequency of Treatment
VetCAb – Veterinary Consumption of Antibiotics (pilot study 2011),
Fattening calves, fattening turkeys: Lower Saxony Ministry of Food, Agriculture, Consumer Protection and Rural Development and the Lower Saxony State Office for Consumer Protection and Food Safety (2011)

Data Source, Resistance
BfR (mean values of the results of the years 2009–2012)

Measures demanded to minimise the use of antibiotics

There is a broad consensus in science, politics and industry regarding the need to minimise the use of antimicrobial substances in livestock farming in order to help reduce antibiotic resistances. A number of measures have been set out for the various areas of the industry, some of which are already being implemented. These are intended, for example, to prevent newly housed animals from bringing resistant bacteria with them. In addition, improved management conditions, modified feeding and intensified hygiene measures, which in some cases are coupled with extended vaccination programmes, are designed to keep the animals as healthy as possible and thus to avoid the need for treatment with antibiotics. All additional knowledge of farming, hygiene and management measures will be of great value in determining further, specific reduction strategies.

The BfR will also conduct further scientific studies, for instance on the link between antibiotics usage and the development of resistance, in order to help to identify suitable courses of action to minimise the entry of resistant bacteria from the food chain into the population and to evaluate the effect that these bacteria will have. ||

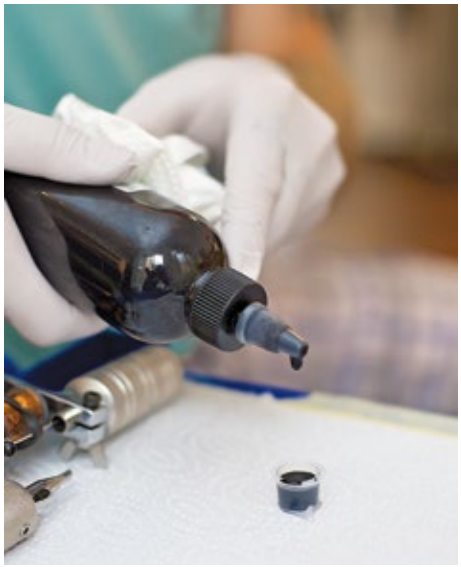
The skin's natural barrier function is impaired during the tattooing process, which makes hygiene during tattooing all the more important. Moreover, further research is needed into the substances used in tattooing inks in order to rule out health risks.

Tattooing agents: risks that get under the skin

Approximately nine percent of the German population is tattooed, and this number continues to grow. However, tattoos involve health risks and can, for example, cause allergic reactions and infections. The substances contained in tattooing agents have not been subjected to a health assessment for insertion in the skin or been approved, and their long-term effects on the human body are unknown. Much data is still lacking for an assessment of the risk associated with tattooing agents – including data on how the inks are dispersed in the body and the effect they have. To gain more knowledge in this area, the BfR is conducting research into the identity of cleavage products from tattoo inks and is developing new analytical methods for enforcement laboratories. In addition, the BfR is assessing the hygienic risks associated with tattooing.

Tattoos are linked with health risks. Undesired side effects include non-infectious and infectious reactions. The most common non-infectious reactions are intolerances (allergies) to one of the pigments applied or to the preservatives or metals, such as chrome or nickel, that are frequently contained in tattoo inks. During tattooing colour pigments are inserted into the skin using needles, thus causing tiny lesions. These are entry portals for bacteria which can lead to infectious reactions. The lesion itself can become infected or the body can become systemically infected if pathogens enter the bloodstream. Persons with immune deficiencies have an increased risk of infection or a decelerated wound healing.

Since the skin's natural barrier function is impaired when injecting a tattoo, there is additionally a risk that the substances contained in tattoo inks disperse in the body and lead to undesired side effects. There is virtually no information available on the long-term health consequences of these processes.



The focal point of research and regulations: tattoo inks and their ingredients.

Substances contained in tattooing agents barely regulated

While the Tattooing Agent Ordinance has been in force in Germany since May 2009, the chemical requirements stipulated therein are based on requirements for cosmetics. Since cosmetics – in contrast to tattoos – are applied to the surface of the skin, the requirements are not comparable. Furthermore, the Ordinance only lists limitations and prohibitions regarding certain substances and does not yet contain any explicitly permitted substances. This means that even if tattooing inks comply with the Tattooing Agent Ordinance, they are not necessarily free of substances that endanger health. The reason for this is the lack of scientific data that currently precludes a complete risk assessment. →

Visit to a tattoo studio: at the "First International Conference on Tattoo Safety", the emphasis was on the exchange of information between practitioners and scientists.

The basis for every tattoo: a blueprint of the desired motif.

BfR conference on risks and problems with tattooing agents

In order to assess the current state of the science and regulation of tattooing agents, the BfR, in conjunction with Freie Universität Berlin, held a symposium in June 2013 titled the "First International Conference on Tattoo Safety". At this conference in Berlin, internationally renowned experts presented current knowledge on the topics of analytics and exposure, toxicology, hygiene and microbiology, technology, and regulation of tattooing agents. Also taking part at the conference were professional associations of tattoo artists, manufacturers of tattoo inks and pigments, and specialist medical representatives. As a result of the conference it was concluded that due to lack of data it is currently not feasible to make a complete and reliable risk assessment of tattooing agents. There is a great need for research, in particular with respect to the possible transport of substances from tattoo inks out of the human skin and subsequent accumulation in lymphatic organs such as the lymph nodes, for example. Only when data is available for this, as well as on the possible effects of individual substances on the human organism, will it be possible to compile so-called positive lists. These would record the substances for which, up to a certain dosage, no negative effects on health are to be expected. The collection of the missing data will take some time; the positive list is therefore more of a long-term perspective. During the conference, it also became clear that the requirements of the Tattooing Agent Ordinance are frequently not observed, particularly with respect to the chemical quality of tattoo inks. The BfR therefore regards increased inspection of compliance with the legal requirements as absolutely essential.

> Based on the current status of scientific knowledge, it is not yet possible to make a complete risk assessment of tattooing inks.

Tattoo removal by laser: the BfR identifies cleavage products

There is currently a lack of data for a risk assessment, in particular with regard to the dispersion of substances contained in tattoo inks in the human body and to the cleavage products from these that can arise when exposed to energy such as, for example, in UV irradiation or lasering. The BfR is therefore currently investigating the identity of cleavage products from tattoo inks in particular within the framework of a research project. This involves thermal cleaving of the tattoo inks in experimental tests by means of pyrolysis and subsequent mass spectrometry analysis (pyrolysis GC/MS). Thermal cleaving occurs at 800 degrees Celsius. This corresponds to the temperature that can be expected in the human skin during laser removal of tattoos.

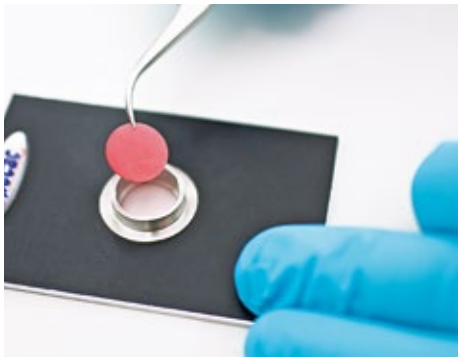
Initial comparisons of samples treated with laser exposure or experimentally with pyrolysis confirm that both scenarios lead to the same cleavage products. Conclusive confirmation of this is not yet forthcoming and is the aim of current testing. To identify the resulting fragments, the BfR is using a so-called reference library. This details the characteristics of certain known cleavage products. Researchers are establishing whether the fragments created via pyrolysis match the substances listed in the reference library. So far a total of 14 organic pigments have been analysed using this technique. One result is that the pyrolysis of the yellow azo pigment Yellow 74 releases a possibly carcinogenic substance, o-anisidine.

Besides identification of cleavage products from pigments, this method is also suitable for determining the cleavage products from other tattooing agent ingredients like preservatives and formulation additives. The latter are often polymers, which are hard to analyse with other techniques. The application of these methods in the analysis of tattoo inks and their cleavage products is to be further developed at the BfR, and a spectrum library is to be compiled for the identification of substances frequently contained in tattoo inks. →

Cleavage products resulting from pyrolysis of pigment Yellow 74

Cleavage products	Health risks
o-anisidine	Toxic, possibly carcinogenic
2-methoxyphenyl isocyanate	Harmful to health, irritant
2-methoxy-4-nitroaniline	Harmful to health, irritant

Yellow tattoo inks contain the azo pigment Yellow 74. During lasering, it degrades into a potentially carcinogenic substance.



For analysis using Fourier transform infrared spectrometry, a pellet is made from the inks to be tested and then analysed.

Faster analysis method being tested

Besides the further development of the regulation of tattoo inks, checking compliance with the current Tattooing Agent Ordinance is also a challenging objective. On the one hand, elaborate sample preparation procedures have to be conducted in order to perform the analysis of organic pigments that are primarily responsible for the colour. On the other hand, objections about questionable products can only be raised after a certain time delay. A method of rapidly identifying tattoo inks that do not comply with the Tattooing Agent Ordinance is therefore the objective of continuing research efforts at the BfR. The new and quicker technique is designed to support the regional state agencies for consumer and health protection in implementing the provisions of the German Food and Feed Code.

While the majority of the currently routine techniques used in the quantitative analysis of inorganic pigments require microwave-supported acid hydrolysis of the samples, the BfR is concentrating on the Fourier transform infrared spectrometry method (FTIR). This technique permits quick qualitative identification of the organic pigments contained in tattooing agents. By this method, the sample is exposed to a beam of infrared light. Certain wavelengths of the infrared light are absorbed by the sample and the remaining light passing through the sample forms a spectrum. This is characteristic for certain chemical bonds and, through the comparision with the reference library, it can be used in the identification of pigments. Initial measurements of 18 commercially available tattoo inks and seven organic pigments show that it is possible in principle to identify organic pigments in tattoo inks using the FTIR technique.

The limitations of this method are current being systematically analysed by the BfR. Inorganic constituents for example, such as the inorganic titanium dioxide frequently found in tattooing agents, influence the spectrum and can complicate the interpretation of the results. If several pigments are present in one tattooing agent, the unambiguous identification is also decreased. Furthermore, it has been observed that certain organic pigments exist in several variant forms that have differing FTIR spectra. ||

The BfR is researching methods for the rapid identification of tattoo inks. The new methods are designed to determine whether tattooing agents comply with the legal regulations.

Organic pigments with high colour brilliance are generally used for tattoos.

Substances contained in tattoo inks and their risks

Tattooing agents can be composed of many different individual substances that have not been subjected to a health assessment for this application. Tattoos are mostly made with organic pigments that exhibit high colour brilliance. Problematic substances in tattooing agents include, for example, carcinogenic aromatic amines as cleavage products from organic pigments or as contamination, as well as heavy metals, preservatives and a large number of substances whose function is only partially understood, such as local anaesthetics, promoter for wound healing or essential oils. Furthermore, there are tattooing agents with special effects such as “glow in the dark”, whose composition is largely unknown. Undesired, acute reactions associated with tattoos include infections, foreign body reactions, scarring and allergic reactions. Little is known about the long-term effects of tattooing agents.

FAQ on tattooing agents (in German) at:
www.bfr.bund.de > A-Z-Index > Tätowierungen

Pyrrolizidine alkaloids in herbal teas and teas

Pyrrolizidine alkaloids are secondary plant substances produced by plants as protection against predators. Due to their health-damaging potential, 1,2-unsaturated pyrrolizidine alkaloids in particular are undesirable in foods. The BfR is pursuing various research approaches to this issue: in a project to measure pyrrolizidine alkaloids in food and feed, the BfR analysed different herbal tea and tea samples to determine the concentration of 1,2-unsaturated pyrrolizidine alkaloids. These findings were evaluated in a preliminary risk assessment, which the BfR published in July 2013. Alongside analytical aspects, investigations into the absorption and the molecular effect mechanisms of pyrrolizidine alkaloids are a further core area of research.

Pyrrolizidine alkaloids are secondary plant substances produced by a large number of plant varieties all over the world. Over 500 different pyrrolizidine alkaloids are known, and their occurrence is expected in more than 6,000 plant species. Plants containing pyrrolizidine alkaloids primarily belong to the aster family, roof leaf plants or legumes.

Due to their health-damaging potential, 1,2-unsaturated pyrrolizidine alkaloids (PAs) in particular are undesirable in foods and feeds. As food contaminants, they have primarily been found to date in the European food sector in honey and lettuce mixtures containing wild herbs that form PAs. The BfR has published risk assessments on these topics.

Pyrrolizidine alkaloids: carcinogenic and mutagenic

Knowledge regarding the toxicology of PAs is based on the observation of health impairments in humans and livestock worldwide due to the intake of plant varieties containing PAs (country-specific intake as food or medication, contamination of food or feed) as well as on data from relevant feeding trials.

Acute toxic effects were observed when PAs were ingested in larger doses within a short space of time. In humans, these effects are mainly seen in the liver in the form of veno-occlusive changes (veno-occlusive disease, VOD). Enlarged hepatocytes are typical for the chronic liver toxicity of unsaturated PAs in animals. In a study to determine the chronic effects of PAs, rats were given the 1,2-unsaturated pyrrolizidine alkaloid riddelline via gavage. The substance induced the formation of tumours, and a No-Observed-Adverse-Effect-Level (NOAEL) of 0.01 milligrams PAs per kilogram bodyweight and day (mg/kg BW/day) was measured for non-neoplastic changes. →

In a research project, the BfR found unexpectedly high concentrations of potentially health-threatening pyrrolizidine alkaloids in individual tea samples. In the case of short-term consumption, however, an acute health risk for adults and children is unlikely.

To better assess the potential health risks, the BfR carried out a research project to measure the concentrations of unsaturated pyrrolizidine alkaloids in herbal teas and teas.

Based on animal experiments, the carcinogenic effect of certain unsaturated PAs like lasiocarpine, monocrotaline and riddelline can be seen as validated and a corresponding risk considered to exist for humans. For other PAs like isatidine, jacobine, retrorsine, seneciphylline, senkirkine and petasitenine, animal studies using the compound itself or its active metabolites also indicate a carcinogenic effect, but in these cases the data are incomplete. PAs that showed to be carcinogenic in animal experiments also exhibited mutagenic effects in genotoxicity testing. The estimated value for the lowest dose that causes a cancer incidence of not more than 10 % with 95-percent certainty (benchmark dose lower confidence limit 10 %, BMDL 10) is 0.073 mg/kg BW/day. This figure was derived from a carcinogenicity study using lasiocarpin based on the findings for male rats.

PA research I: bioavailability and molecular effect mechanisms
A number of PAs showed carcinogenic and mutagenic effects in animal experiments, but the molecular mechanisms of PA effects on the human organism are not yet fully understood. The BfR is conducting molecular biology analyses (transcriptomics) to determine the effect mechanisms of PA toxicity in humans. These analyses are designed to show how PAs effect the gene expression of xenobiotic-metabolising enzymes in primary human hepatocytes and human cell lines. So-called transport analyses with selected PAs supply information on oral bioavailability. The findings point to structure-dependent transport via the intestinal barrier. The suspected cause is seen as being interactions of the individual PAs with transport proteins (MDR1 for example). The research project can help to identify biomarkers that can be used to develop an hepatic *in-vitro* test system for the sensitive detection of PAs.

Some pyrrolizidine alkaloids showed carcinogenic and mutagenic properties in animal experiments, but the effect mechanisms on the human organism are not yet fully understood.

Analytical determination of pyrrolizidine alkaloids in herbal tea and tea samples

To better assess the potential health risks, the BfR carried out a research project to measure the concentrations of unsaturated pyrrolizidine alkaloids in food and feed – including herbal teas and teas. The tested tea varieties were baby fennel tea, fennel tea, chamomile tea, herbal tea, peppermint tea, nettle tea, melissa tea, rooibos tea, black tea and green tea. A total of 184 herbal tea and tea samples from retail outlets and 37 medicinal teas from pharmacies were analysed by means of solid phase extraction followed by liquid chromatography tandem mass spectrometry. The determination of total PA concentration in the herbal tea and tea samples was based on the concentrations of seventeen individually measured PAs. The first results measured in the non-representative tests were total PA concentrations from 0 to 3.4 milligrams PA per kilogram of dry product in the tested herbal tea and tea samples.

Potential health risks for high consumers, children, pregnant women and breastfeeding women

The total PA concentrations in herbal tea and tea samples from the research project subsequently were evaluated in a risk assessment by the BfR. Estimation of exposure was based on the measured concentration data and the consumption data for herbal tea and tea for adults from the NVS II National Food Consumption Study and for children from the VELS study (food consumption survey to determine food intake by infants and small children for the estimation of the acute toxicity risk from pesticide residues). The BfR used the MOE (Margin of Exposure) method, which is an internationally recognised approach to estimate the potential health risks of substances with genotoxic and carcinogenic effects. The MOE is calculated from the ratio of two factors: human exposure as a measure of the extent of oral intake of a substance and the effective oral dose established or calculated in animal tests for a given tumour incidence. It is assumed here that a MOE of 10,000 or higher for genotoxic carcinogens poses little danger to health.

In its risk assessment, the BfR came to the conclusion that, despite the fact that unexpectedly high PA concentrations were measured in the samples, it is unlikely that short-term intake poses an acute health risk to adults and children. A short-term intake is considered to be an intake lasting up to 14 days. With longer-term intake, an impairment to health is also unlikely in average consumers (adults and children) who do not prefer any specific variety of herbal tea. Here, the MOE values are above the relevant health-related margin of 10,000. →

PA research II: PAs in dry tea product and their migration into tea infusions

The BfR is a partner in an EFSA project aimed at investigating food products in Europe for potential PA content. The job of the BfR is to analyse herbal teas, teas and food supplements. In addition, the institute is looking into the migration of PAs from tea leaves into tea beverages. For this purpose, PA profiles and concentrations are measured in the dry tea product and the tea infusion and compared with one another. Moreover, consumer habits with regard to tea preparation are being simulated and the influence of these habits on migration of PAs into the beverage investigated. These findings make a key contribution to assessing the risk of PAs in herbal tea and tea.

Among other things, the BfR measures the concentrations of pyrrolizidine alkaloids that migrate into the beverage when people make tea infusions.

Consumers should choose a varied and diverse range of food and drinks. This prevents one-sided burdens with potentially health-threatening substances like pyrrolizidine alkaloids.

However, the MOE values for the intake of PAs are well below 10,000 in people who drink large quantities of herbal tea and tea over a longer period of time. In the event of the consumption of products with high PA concentrations in particular, there is a risk of health impairment, particularly in the case of children, pregnant women and nursing mothers. Any statements on the probability of impairment to health due to the regular consumption of highly contaminated tea infusions is subject to major uncertainty, as there are considerable fluctuations in concentration data between the different tea varieties, and sometimes also for the same tea variety.

The potential risk for the consumer can be mitigated by following the general recommendation for variety and alternatives in the choice of foods. This can prevent one-sided burdens of various potentially health-threatening substances that must be expected to sporadically occur in low amounts in food. Parents in particular are advised not to exclusively offer their children herbal teas and tea. Pregnant and breastfeeding women should vary their consumption of herbal teas and tea with other beverages.

FAQ on pyrrolizidine alkaloids in food: ***www.bfr.bund.de/en > Food Safety > Substance risks***

A potential health risk exists for people who consume large amounts of herbal tea and tea with high pyrrolizidine alkaloid concentrations over long periods of time.

The BfR recommends that herbal tea and tea batches be checked for PA concentrations prior to marketing and that the causes of high PA concentrations in the products in question be investigated.

Pyrrolizidine concentrations in teas should be reduced

In view of the genotoxic and carcinogenic effects of PAs, the BfR is of the opinion that efforts must be made to minimise the PA concentrations in herbal teas and teas. This measure is also deemed necessary in view of the fact that possible additional exposure to PAs may occur due to other foods like honey.

The BfR recommends that herbal tea and tea batches are checked for PA concentrations prior to marketing and that the industrial parties concerned investigate the causes of high PA concentrations in the products in question. The institute also recommends checks with regard to potential PA concentrations in herbal tea and tea samples as part of the food monitoring process. ||

Opinions of the BfR on the topic of pyrrolizidine alkaloids:
www.bfr.bund.de/en > Publications > Opinions
- *salad mixes: Opinion 028/2007*
- *honey: Opinion 038/2011*
- *herbal teas and teas: Opinion 018/2013*

Food Safety

The safety of food is one of the foremost tasks of consumer protection. Safe feed is one of the preconditions for safe food. Be it ingredients, additives, residues and contaminants or bacteria and parasites, the BfR assesses food and feed products and prepares expert opinions on issues connected to their safety. Food safety activities involve the toxicological, nutritional-physiological or nutritional-medical assessment of foods.

Food Safety

The Federal Institute for Risk Assessment (BfR) works on the principle of “From Farm to Fork”, according to which the entire food chain must be accounted for by safety concepts if the end product is to be healthy food. In addition to the Food Safety Department, the Biological Safety Department and the Safety in the Food Chain Department are also dedicated to food safety. Results from toxicological, microbiological and nutritional-physiological assessments of food and feed provide the scientific basis for the setting of maximum levels or limit values. External, independent experts from nine different committees also advise the BfR on an honorary basis on questions of food safety.

Toddler milk: popular, but not necessary

For several years there has been a variety of products on the market in Germany which are labelled as children's milk or toddler milk. Rather than conventional milk, these are milk substitute drinks based on cow milk protein which contain lactose and other sugars as well as vegetable fats. These products are enriched with vitamins and minerals and in some cases with other, non-essential substances such as prebiotics, probiotics, taurine or inositol. To improve their taste, some products contain flavouring agents such as vanillin. Manufacturers promote them as being particularly suitable for young children, i. e. children aged from one to three.

Toddler milk drinks are subject to the provisions of the German Dietetic Food Ordinance. Therefore they must have a composition that is suitable to meet the special dietary requirements of young children. In 2011, the BfR, however, stated that healthy young children can meet all their dietary needs by consuming conventional foods. The BfR also shares the opinion of paediatricians and nutritional scientists that cow's milk is a nutritionally valuable food. Thus it is recommended that, as part of a balanced diet, young children consume 300 grams of milk and milk products with 1.5 percent fat per day.

To find out why parents purchase toddler milk rather than conventional milk, the BfR conducted an online consumer survey in which participated over 800 people. As well as establishing the reasons for and against buying toddler milk, the survey also investigated possible differences in drinking behaviour and in other aspects of diet among children who drink toddler milk or cow milk. The results show that above all health reasons, but also the presence of certain ingredients and purportedly better tolerance, were crucial factors for the purchase of those products. The survey respondents' children drank toddler milk in greater quantities than cow milk and more frequently from a feeding bottle. Toddler milk was not only drunk as a substitute for conventional milk, but also in addition to or alternating with it. Furthermore, children who were given toddler milk did not have a less varied diet than children who drank cow milk.

Is toddler milk more suitable for the nutrition of small children than conventional drinking milk?

Mould fungi that can form toxic ergot alkaloids are found particularly frequently in rye.

Since the nutrient contents of toddler milk and cow milk are markedly different and since young children in Germany generally have a sufficient intake of energy and nutrients, except for iodine and vitamin D, a further BfR project investigated how the consumption of toddler milk would affect the nutrient intake of young children. To do this, the BfR carried out model calculations in which cow milk consumption was completely replaced by toddler milk. The results indicate that children who drink toddler milk would have higher intakes of polyunsaturated fatty acids, iron, iodine and vitamin D, but also of zinc, copper and vitamins A, E, B1, folate equivalents and pantothenic acid. The intake of vitamin C would also be markedly increased. Some products contain less calcium than cow milk, so the consumption of those products could lead to a reduced calcium intake.

Toddler milk products therefore represent one method of improving the intake of iodine and vitamin D for young children. However, beyond that these products are no more suitable than other enriched foods or the early introduction of meat and fish into childrens' diets. Families should be better informed that, with a balanced diet, toddler milk is unnecessary from a nutritional point of view and, particularly when consumed in large quantities, can lead to an undesirably high intake of several micronutrients.

The results from the consumer survey and the model calculations are available in the BfR Wissenschaft brochure 01/2014 (in German):
www.bfr.bund.de > Publications > BfR-Wissenschaft

Ergot alkaloids in rye products

Food products made of grain can contain toxic ergot alkaloids. These substances are metabolites of specific fungal species which occur more frequently on ears of wheat in moist harvest years. In Germany, ergot alkaloids are found particularly frequently in rye.

Due to the toxic effect of ergot alkaloids (see box page 52), the European Food Safety Authority (EFSA) defined health-based guidance values in 2012 for the first time. Against this backdrop, the Federal Ministry of Food and Agriculture (BMEL) then commissioned the BfR to conduct a health assessment of individual ergot alkaloid concentrations in rye flour and rye bread that had been reported by the food surveillance authorities. The latter had measured ergot alkaloid concentrations in rye bread of 59 and 585 micrograms per kilogram (µg/kg) and in rye flour of 1,000 and 2,300 µg/kg.

The BfR carried out the health assessment based on an estimation of the exposure of 2 to 4-year-olds, who represent the consumer group with the highest burden due to their lower body weight relative to the amount consumed. In consideration of the health-based guidance values published by EFSA, the BfR arrived at the following results based on the aforementioned data: five percent of the 2 to 4-year-old children included in a dietary study consume 250 grams or more of bread or bread rolls containing rye per day. This consumption amount is equivalent to up to six slices of bread. Based on these intake amounts and short-term consumption of rye bread with an ergot alkaloid concentration of 59 µg/kg, health

impairments are improbable. Short-term consumption of only medium amounts of rye bread with an ergot alkaloid concentration of 585 µg/kg may possibly lead to undesirable health effects. This also applies to short-term consumption of products made of rye flour with ergot alkaloid concentrations of 1,000 and 2,300 µg/kg. Due to the known uterus-contracting effect of certain ergot alkaloids, the BfR also considers pregnant women as a highly sensitive risk group with regard to the consumption of highly contaminated grain products.

In order to minimise the ergot alkaloid concentrations in rye products, the BfR recommends strict application of agricultural and technological good manufacturing practice. The focus should be on the efforts of all actors in the industry along the entire value added chain in the choice of seeds, the cultivation technique and the selection of raw materials through to the technological processing of the rye. The BMEL has had suitable recommendations for action drawn up by experts from associations, institutions and companies, and these recommendations have been published on the website of the BMEL.

BfR Opinion No. 024/2013 on the case-based assessment of ergot alkaloid concentrations (in German):
www.bfr.bund.de > Publications > Opinions

Health effects of ergot alkaloids

Today, assessment of the health risk focuses on effects that may occur after consumption of only small amounts of ergot alkaloids: these are gastrointestinal diseases, cardiovascular problems, headaches, central nervous system dysfunctions and muscle contractions. Human data also shows that contractions of the uterus are also possible following the intake of only small amounts of certain ergot alkaloids. Under certain circumstances, these contractions can result in uterine bleeding and miscarriage. The effects of the intake of high amounts of ergot alkaloids on human health are well established. They include circulatory disorders, hallucinations, cramps and sensation disorders as well as paralysis, which may occur within a short space of time and can result in death in the event of respiratory failure or cardiac arrest. However, these kinds of epidemic no longer occur today in the countries of the European Union.

The ergot alkaloids contained in rye can also be contained in flour and bakery products. Health-based guidance values were introduced for these substances in 2012.

Under control: unusual harm scenarios in the feed and food sector

What if terrorists contaminated feed or food with dangerous microorganisms or toxins? What information, verification systems and tools or methods would the authorities and companies need in the event of such an attack? The BfR-coordinated research project “Ensuring the safety of the food and feed supply chain in case of damage resulting from bio or agro terrorism attacks (SiLeBAT)” has been addressing these questions since the project was launched in October 2010 and has developed a number of solutions. The project was financed with contributions from the Federal Ministry of Education and Research within the framework of German security research.

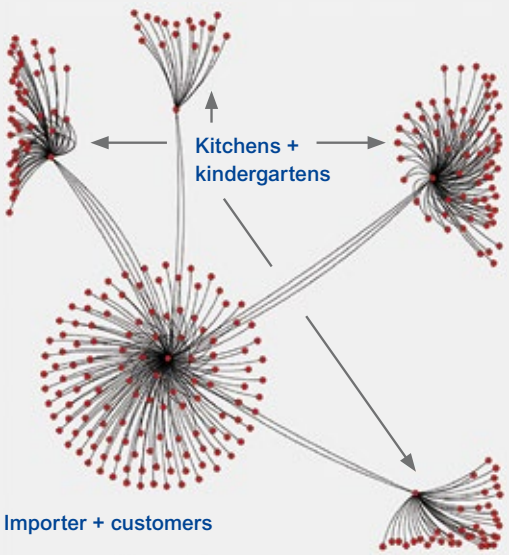
Even if feed and food in Germany are more secure than ever before, existing legal requirements and diverse checks of manufacturers, traders and authorities cannot provide total protection from criminal or even terrorist activities. Solutions have therefore been developed in the SiLeBAT project that can be used both preventatively and in the event of an attack. The spectrum of new developments ranges from methods of sample preparation, laboratory procedures for identifying bioterrorist pathogens and software tools to a knowledge database and

concepts for effective information exchange in case of crisis situations. Among other things, the BfR has developed special software for evaluating food supply chains as well as a product protection checklist for feed or food business that will help them prevent any deliberate contamination of their products (see boxes below).

The SiLeBAT project shows how food safety in the age of global flows of goods can be further improved by all parties involved cooperating with each other. One central conclusion is that scientific analyses, technologies and action plans must be continually adapted to the changing general conditions.

Example 1: "FoodChain Lab" Software

For the risk assessment of damage scenarios, it is important to be able to evaluate specialised information quickly and correctly. The "FoodChain Lab" software developed by the BfR can provide an important contribution here. For example it is possible with this software to make interactive evaluations of the relevant data from food tracing in case of a crisis and to graphically depict the food supply chains. The BfR has already used the software in the resolution of several food-related outbreaks of illness. For example, in the investigation into the norovirus epidemic in the autumn of 2012, "FoodChain Lab" helped to identify the epidemiological correlation between deep-frozen strawberries imported from China and the observed pattern of the outbreak (see illustration).



Visualisation of the frozen strawberry goods chain in the norovirus epidemic of 2012 using the BfR "FoodChain Lab" software. The institutions included in the outbreak data are shown here as red dots. The lines represent goods deliveries that contained frozen strawberries.

Example 2: Product protection checklist

The product protection checklist may help to reduce the probability of future bio or agro terrorist attacks. The checklist consists of a catalogue of questions in the form of an Excel file that asks, for example, whether access points to production facilities in feed and food plants are secure and whether employees are trained to spot suspicious activities or unauthorised persons. It is therefore possible to identify non-secure areas where products could be contaminated. It also lists steps that make production facilities and processes more secure. Companies are thereby provided with support in estimating the security of their own facilities and processes, in identifying existing weaknesses and in taking protective measures. Small and medium-sized companies in particular are interested in the checklist, since their financial means and staffing levels are generally insufficient for the development of these kinds of analysis.

The SiLeBAT project shows how food safety can be further improved in the age of global flows of goods through the cooperation of all involved parties.

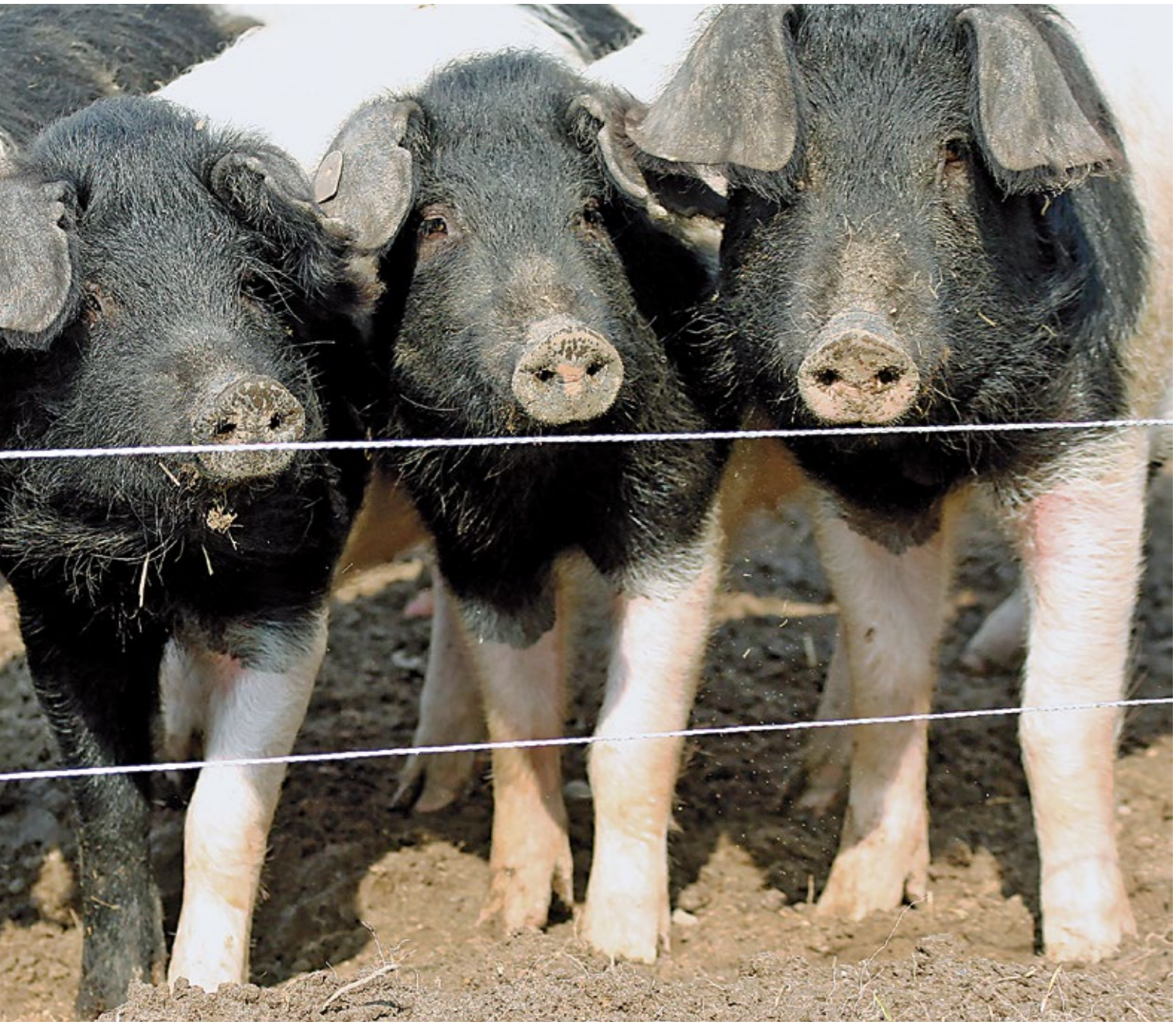
Heavy metals in offal of cattle and pigs

The liver and kidney of slaughtered animals contain a higher concentration of heavy metals such as cadmium, lead and mercury than is found in muscle meat. Although livers and kidneys from cattle and pigs are eaten infrequently and in small quantities, it is still important to know their heavy metal content for food safety purposes. As there are currently only limited data available regarding heavy metal contamination in older slaughtered animals, the BfR carried out a pilot project in collaboration with the German federal states and the Federal Office of Consumer Protection and Food Safety. In this study, cattle and pigs up to the age of two and older animals aged two and above were examined. The aim was to find out whether a higher concentration of heavy metals can be found in the internal organs liver and kidneys of older animals.

The average content of lead, cadmium and mercury was significantly higher in the organs of older slaughtered animals than in the organs of younger pigs and cattle. The maximum permissible levels in internal organs were also exceeded more frequently in older animals than in younger animals. While for lead 0.4 percent (%) of kidneys from older cattle exceeded the maximum levels, for cadmium this was the case in 13 % of cattle kidneys and 8.9 % of pig kidneys. In contrast, the maximum cadmium levels were exceeded in only 0.4 % of younger animals. The maximum levels for mercury were exceeded in 18 % of kidneys in older cattle and in 41 % of kidneys in older pigs, whereas younger animals generally contained lower levels of mercury, with only 3 % measuring above the maximum admissible level. In older animals, the levels of the three heavy metals increased, with kidneys in particular exceeding the maximum levels.

Organs from animals which are over two years old can generally be declared unfit for human consumption if the animals come from regions contaminated by heavy metals. To find out whether heavy metal content in liver and kidney differs from region to region, the BfR compared their contamination in animals from three of the federal states involved in the study. During the evaluation, new statistical procedures were employed which also took into account data below the limit of quantification and the limit of detection. The results show that there are regional differences concerning both average heavy metal content and the number of times the maximum level was exceeded. However, the data do not allow a uniform conclusion, suggesting that the federal states are too big geographical entities for characterising different levels of heavy metal contamination. The regions should be differentiated into smaller administrative units for future investigations.

What do these heavy metal levels mean for consumers? An average consumption of liver and kidney from older animals would result in a very low exposure corresponding to less than 1 % of the tolerable weekly intake (TWI) even if – as in this study – maximum levels of heavy metal



What are the concentrations of cadmium, lead and mercury in the offal of pigs? Is the offal of older animals more highly contaminated than that of younger animals? A research project of the BfR conducted in cooperation with the federal states provides initial information.

concentrations are assumed. Average consumption of kidneys with maximum cadmium concentrations from older cattle and pigs would result in a moderate exposure for cadmium, corresponding to 17 % and 14 % of the TWI, respectively. The exposure of frequent consumers of cattle and pig kidney corresponds to 72 % and 55 % of the TWI for cadmium, respectively. For frequent consumers the total exposure via different food products (liver and kidney and other contaminated food types incl. non-animal origin) must be taken into account. The calculations above use a worst case assumption of consumption of organs from only older animals contaminated at maximum levels analysed. In many cases the exposure will be lower since older animals constitute only a proportion of the total slaughters. Detailed results are given elsewhere (see "information").

The results show that livers and kidneys from animals aged two and over contain higher quantities of heavy metals than those from younger animals. The results also indicate that efforts should be made to further reduce heavy metal contamination.

Martin A., C. Müller-Graf, I. More, H. Schafft, L. Ellerbroek, M. Spolders und M. Greiner. 2013. Beurteilung der Gehalte von Blei, Cadmium und Quecksilber in Lebern und Nieren von ab zwei Jahre alten Schlachtschweinen und -rindern in Deutschland. J Verbrauch Lebensm. (in German) Online article: doi:10.1007/s00003-013-0851-y

Product Safety

Consumers come into contact with products like cosmetics, food packagings or toys on a daily basis. The job of the BfR is to assess the health risks of these products and to promote product safety with its recommendations. The “product safety” working field comprises a wide range of different products: cosmetics and hygiene products, packagings and containers for food, toys, clothing, detergents and cleaning products, tobacco products and other consumer products like furniture, mattresses, carpets and hobby products. The findings of the BfR risk assessments are incorporated in recommendations for the legislative as well as for manufacturers and consumers.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PG 60

Product Safety

Product safety is an important part of consumer protection and looks at questions like: how can a toy or a cosmetic product pose a risk to consumer health? The Chemicals and Product Safety Department not only investigates the substances used in these products but also how the substances are released. Because whether any of the many different products presents a health risk primarily depends on how consumers come into contact with the substances it contains. The committee for consumer products, the committee for cosmetics and the National Reference Laboratory for substances that come into contact with food are attached to the department.

German "GS" seal of approval: further development of test criteria for PAHs

Polycyclic aromatic hydrocarbons (PAHs) are regularly detected in consumer products. This is typically the case in materials like rubber or elastic plastics, but products like tattooing inks or textiles may also contain PAHs. Black materials are often affected if they are dyed using carbon black contained PAHs. Numerous PAH compounds have carcinogenic effects. The BfR therefore advocates the minimisation of consumer exposure and calls for a reduction in the PAH concentrations in consumer products – to the extent that this is possible based on the current state of the art in science and technology.

The proposals of the BfR have already been incorporated in the European chemicals regulation REACH. While there are currently no stipulations under REACH for maximum PAH concentrations in consumer products, regulations will be introduced at the end of 2015 that for the first time define limit values for eight PAH compounds classified as carcinogenic: from this date, consumer products will generally only be able to contain a maximum 1 milligram per kilogram (mg/kg) of each individual PAH compound, with a limit of 0.5 mg/kg of each individual compound for toys and products for small children. This applies to the PAH compounds that are classified as carcinogenic, namely benzo[*a*]pyrene, benzo[*e*]pyrene, benzo[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, chrysene and dibenzo[*a,h*]anthracene.

In addition to its involvement in the ongoing development of the legal provisions of the REACH Regulation, the BfR also provides advice on the definition of the test criteria for the "GS" (Geprüfte Sicherheit – certified safety) seal of approval. The GS seal of approval confirms that a product meets the requirements of the German product safety act and therefore complies with specific standards and stipulations for the protection of the consumer. The test criteria are more extensive than the requirements outlined in the REACH Regulation: toys that are in contact with the skin for longer periods of time or which are designed to come into contact with the skin may in future only contain a maximum 0.2 mg/kg of the eight mentioned PAH compounds that are classified as carcinogenic. This figure is based on the detection limit for these compounds currently achieved by the testing laboratories. In future, the restriction is also to apply to two further PAHs in these products, namely benzo[*g,h,i*]perylene and indeno[1,2,3-*cd*]pyrene. These PAH compounds are currently not legally classified as carcinogens, but there are clear indications that they have a carcinogenic effect. The new limit values are scheduled for introduction in 2015.

Toys made of rubber may contain health-threatening polycyclic aromatic hydrocarbons (PAHs). The test criteria for PAHs in toys bearing the "GS" seal of approval have now been extended.

In order to further improve the level of protection for the consumer, the BfR has proposed the further development of PAH testing methods and the inclusion of higher molecular PAHs in the GS testing criteria. For this reason, the institute is working together with the GS testing laboratories and the ZLS – the central office of the federal states for safety technology and the authority responsible for the product safety act. Moreover, taking additional individual toxicologically relevant PAH substances into consideration and lowering the maximum admissible concentrations, the BfR also advocates the further development of sample processing in order to ensure the higher reliability of the measured test results.

Polycyclic aromatic hydrocarbons (PAHs) are organic compounds that are formed during incomplete combustion processes from coal, fuel and tobacco as well as during barbecuing. Numerous PAHs are also natural components of crude oil. As toxic environmental chemicals, these substances are ubiquitous and are ingested by consumers in the air they breathe and the food they eat. In consumer products, these substances mainly occur due to the use of extender oils containing PAHs in the production of rubber and plastics, which means they can be absorbed via the skin.

PAH restriction in products with "GS" seal of approval

The GS seal of approval confirms that a product meets specific legal standards and regulations on the protection of consumers. The basis for the GS seal is the German Product Safety Act, which governs the safety requirements for consumer products. Since back in 2008, consumer products for which a GS seal application has been filed have been tested for polycyclic aromatic hydrocarbons. Up to the present, however, an individual limit value has only been in place for one PAH compound, namely benzo[*a*]pyrene. All other analysed PAHs are only taken into account in testing in the form of a total limit value. Based on the recommendation of the BfR, nine additional carcinogenic PAHs alongside benzo[*a*]pyrene should be included in future in the form of individual limit values. This would mean that the criteria used for GS testing extend beyond those outlined in the REACH Regulation.

The BfR regularly evaluates the current state of analytics, toxicology and the regulation of nanomaterials.

Research into nanoparticles in textiles and plastics

Nanomaterials are very small materials which have particular characteristics due to their small size. Because of this, they are used in many consumer products. Nanosilver and nanoclay in particular are nanoparticles which are frequently used in industry. Nanosilver, for example, has an antimicrobial effect and therefore prevents unpleasant smells in used sports gear. Nanoclay platelets cause plastics to become more rigid and, as plastic additives function as a barrier against gases and liquids. Thus, nanoclay is often used in food packaging. In order to anchor the nanoclay platelets in the polymeric material, quaternary ammonium compounds, which function as a biocide, are added.

The BfR regularly evaluates the current state of analytics, toxicology and the regulation of nanomaterials, and is also involved in a range of research projects in these areas. Examples include the EU projects NANoREG and NanoDefine, which aim to develop methods for the regulatory testing of nanomaterials and find suitable detection methods for the implementation of the EU definition. Both projects started in 2013 and a further project, nanoGEM, was completed in the same year (see info box).

The BfR also regularly conducts health assessments on the concrete use of nanoparticles in textiles and plastics. In its opinion from 2009, for example, the institute refers to findings indicating adverse effects of nanosilver on living cells and the risk of increasing resistance. At the moment, the BfR is investigating whether the consumer comes into any contact at all with nanosilver from textiles and nanoclay from food contact materials. Such exposure is not inevitable; it rather depends on whether nanoparticles are released from the products and are transferred to the human body. In order to find out whether particles have a migration potential, the BfR uses synthetic perspiration solutions or food simulants. For a comprehensive analysis, the nanomaterials are first characterised. Electron microscopes, which can detect nanomaterials up to around 100 nanometres and accurately determine the exact size of the particle, are used for textiles. Plastics are further identified using infrared spectroscopy. Inductively coupled mass spectrometry then determines which concentrations of relevant elements are present in the product and how much is released into the artificial simulants at various time intervals.

For textiles, it appears that the type of production technology used has a significant influence on the consumer's exposure to nanosilver. Nanoparticles which are applied onto the fibres (fibre coating) are released more easily than those which are worked into the fibre. With polymeric materials, the release can be controlled through the skilful use of quaternary ammonium compounds which are fine-tuned to the material and the food to be packaged.

As part of the "**nanoGEM**: nanostructured materials – health, exposure and material properties" project funded by the Federal Ministry of Education and Research, the BfR and 19 partner organisations investigated the potential health risks posed by nanomaterials. The BfR's task was to systematically examine several test substances in various biological settings for their size and interaction with proteins. In addition, the BfR established methods for examining modes of action and assessed consumer exposure to nanomaterials using computer modelling. The results showed that only a few of the 16 nanomaterials exhibited damaging effects. If the surfaces of the particles were modified, then harmful effects could be reduced. Furthermore, the use of nanomaterials in consumer products generally causes no serious contamination for the consumer. Instead, the risk posed by specific materials should be investigated on an individual basis.

Release of lead from coffee and espresso machines

As part of a current research project, the BfR is investigating the release of metals from various metallic materials and articles with food contact and their transfer to food or food simulants. Various analytical procedures are being established and applied during the course of the project. In 2013, the BfR published its first results on the release of lead from coffee machines.

For the research project, the BfR used exemplarily eight brand-new coffee machines designed for household use. These comprised three portafilter, three coffee pad and two capsule espresso machines. On several days, five samples of artificial tap water were taken from each machine without the use of coffee powder, pads or capsules. This simulated the release process during intended use. In accordance with the manufacturers' guidelines, each machine was also decalcified using the recommended products and subsequently re-tested. The outcome was that the artificial tap watersamples from the coffee machines used in the test showed differences in their release of lead, for example, and that there was a downward trend in the amount of lead released both during the sampling process over the course of a day as well as across the various days of the project. In some cases, the strong increase in lead release after decalcifying was particularly conspicuous.

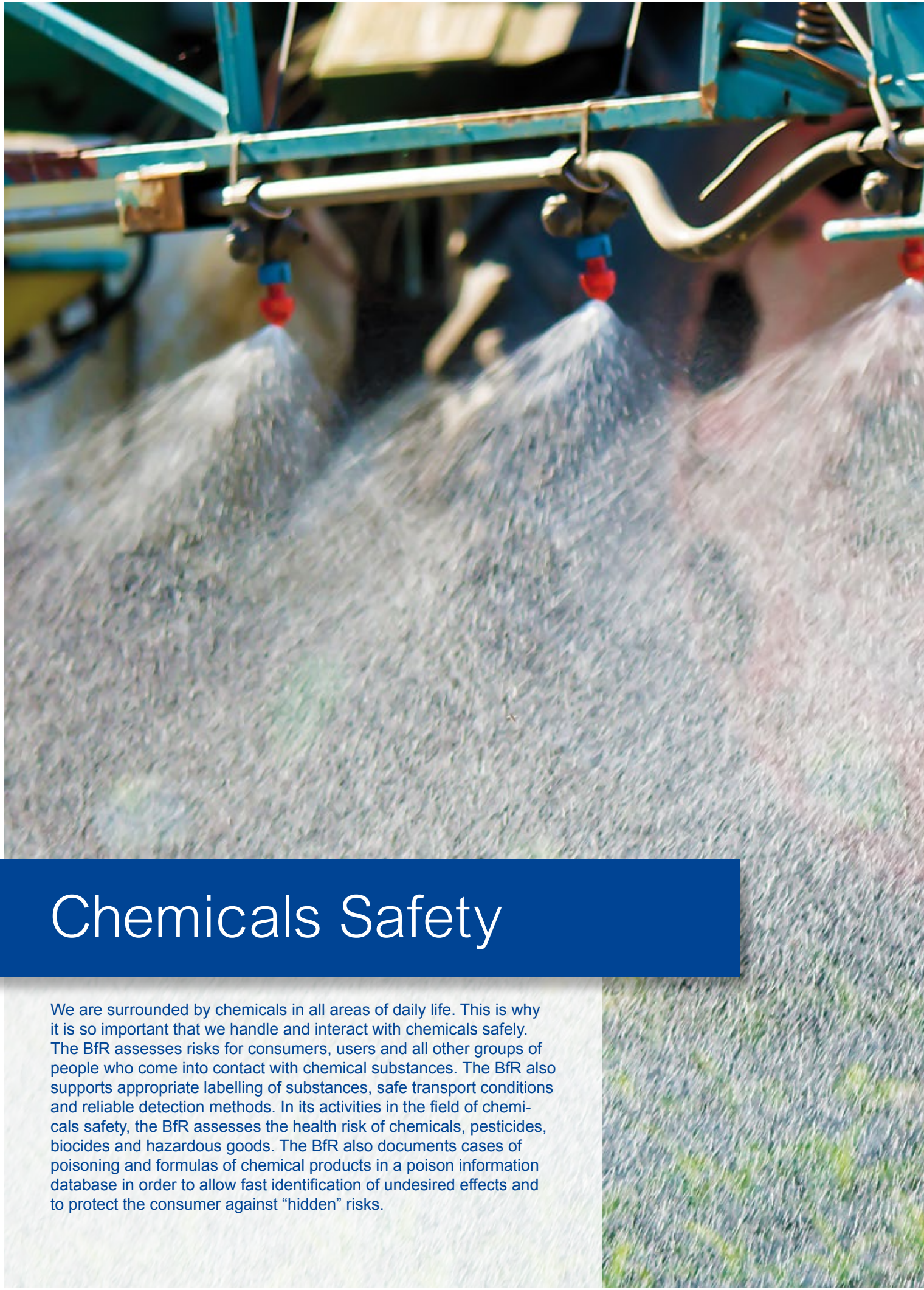
In the EU, there is currently no legal limit for the release of metals from metallic food contact materials. In its resolution on “metals and alloys used in food contact materials and articles”, the European Council recommends a specific release limit for lead based on the permissible lead content in drinking water of 10 micrograms lead per kilogram (µg/kg) food. However, for a transitional period the European Council considers a specific release limit for lead of up to 40 µg/kg of food to be acceptable.

In the samples tested, the BfR found that two of the portafilter espresso machines exceeded the recommended level of 10 µg/kg. The release of lead from one of the two portafilter espresso machines following decalcifying was within the temporarily acceptable limit. The other portafilter espresso machine exceeded the temporarily accepted limit following decalcifying, with levels ranging from 2 to 1,600 µg/kg. For all other machines, lead concentration following decalcifying was below the European Council's recommended limit of 10 µg/kg. The BfR points out that the data collected from these samples and measurements are not representative. The findings were nevertheless reported to the competent food surveillance authorities.

In the BfR's investigation, the amount of metal released from the portafilter espresso machines decreased during the course of the day from the first sample to the fifth sample. The results show that, on top of the daily rinsing process suggested by the manufacturer, rinsing before consumption of the first cup of espresso or coffee can reduce exposure to lead.

Dietary intake of lead lies within the range of the healthy tolerable amount. Additional release from food contact materials made from metal and alloys into food, should therefore be avoided as much as possible. For the use of portafilter espresso machines, the BfR recommends that the rinsing procedures suggested by the manufacturer are carried out thoroughly both during daily use and after decalcifying.

In a research project, the BfR measured release levels of lead from different types of coffee and espresso machines clearly exceeding the current release limit for lead.



Chemicals Safety

We are surrounded by chemicals in all areas of daily life. This is why it is so important that we handle and interact with chemicals safely. The BfR assesses risks for consumers, users and all other groups of people who come into contact with chemical substances. The BfR also supports appropriate labelling of substances, safe transport conditions and reliable detection methods. In its activities in the field of chemicals safety, the BfR assesses the health risk of chemicals, pesticides, biocides and hazardous goods. The BfR also documents cases of poisoning and formulas of chemical products in a poison information database in order to allow fast identification of undesired effects and to protect the consumer against “hidden” risks.

Chemicals Safety

The field of chemicals safety touches on many areas of consumer health protection. In Germany, the BfR is the central institution for the health-related assessment of substances. Several departments at the BfR, such as the Departments for Exposure, Chemicals and Product Safety, and Safety of Pesticides, are concerned with this issue.

In agriculture, glyphosate is used as, among other things, a weed control substance in the horticultural sector, in stubble fields on cropland, as a pre-harvest treatment agent and for grassland regeneration.

Risk assessment of the pesticide glyphosate

The BfR is responsible for the health risk assessment of plant protection products and their active substances. The objective of the institute is to protect the health of operators and uninvolved third parties during the appropriate application of plant protection products and to avoid a health risk to consumers resulting from subsequent residues in food products. The products assessed by the BfR also include products containing glyphosate.

Glyphosate is one of the most widely used active substances in plant protection products worldwide. In agriculture, glyphosate is mainly used as a weed control substance in the garden area, in stubble fields on cropland, as a pre-harvest treatment (desiccation) and for grassland regeneration. The widespread and frequent use of plant protection products containing glyphosate, also in genetically modified crops outside Germany, is the subject of critical public debate.

With regard to potential health risks, glyphosate is to be viewed less critically than is generally assumed, but certain co-formulants are worthy of closer investigation.

Within the framework of the re-assessment of the health risks of glyphosate in the EU evaluation of active substances, the BfR staged a scientific symposium in January 2014.

In 2013, a routine re-assessment of glyphosate was carried out within the framework of the EU evaluation of active substances. In this European process, each approved active substance is re-assessed together with a sample formulation to determine its risks to health and the environment as well as its efficacy. The report on the health assessment was prepared by the BfR – as had been the case when the active substance was tested in 2003. For this purpose, the BfR described and evaluated more than 150 new original toxicological studies in addition to the documents that had already been evaluated in 2003. In addition, over 900 studies published in scientific journals were also taken into consideration.

Analysis of these numerous new documents did not provide any indication that glyphosate is either carcinogenic or toxic for reproduction. Furthermore, there were no signs of developmental toxicity of glyphosate; nor were there indications that any major changes to the health-based limit values needed to be made. In addition, the BfR still considers the maximum residue concentrations for glyphosate in food and feed to be safe. When the European Commission defined the maximum residue concentrations, it took account of the use of glyphosate as both a weed killer and a desiccation agent. It is known from past studies that humans and animals can ingest small quantities of glyphosate via food and feed that contain residues at admissible levels. The re-assessment of the BfR scientifically demonstrated that the intake of residues via plant-based foods amounts to a maximum of 1.5 percent of the acceptable daily lifelong intake without having any harm to health. The migration of glyphosate into animal food products is low and also poses no health risk.

Glyphosate is used in plant protection products as an aqueous formulation or in combination with various co-formulants. The herbicidal effect of glyphosate is systematically reinforced by the addition of so-called surfactants, which are designed to promote the penetration of glyphosate into the plants. Certain surfactants like POE tallow amines have higher toxicity than the active substance glyphosate. The higher toxicity of some preparations compared to the toxicity of the active substance has also been proven in several animal experiments. Therefore, the BfR supplemented this process by conducting an in-depth toxicological assessment of the POE tallow amines and integrated the results in the report on the re-assessment of glyphosate.

In November 2013, the BfR submitted the partial report of the overall assessment to the lead-managing institution, the Federal Office of Consumer Protection and Food Safety (BVL), who then forwarded the overall report to the European Food Safety Authority. After the public comments of the EU member states and all other interested parties have been documented, a more extensive expert meeting will, if necessary, take place on EU level in order to discuss this active substance. The procedure for the renewed approval of glyphosate is expected to be completed at the end of 2014.

From the point of view of BfR, the findings on the toxicity of the POE tallow amines prove the need for research regarding the interactions of active substances with co-formulants. The need for research in this area extends far beyond glyphosate. Innovative approaches are called for in order to achieve long-term improvement of risk assessment methods. In particular, the assessment of residues of multiple substances in plant protection products and possible interactions with other components of these products (cumulative risk assessment) are under consideration. For this reason, BfR is to initiate a research project to investigate the interactions of different active substances and co-formulants in plant protection products. Research projects of this kind will help to improve the methods used for cumulative risk assessment in the long-term.

FAQ on the health assessment of glyphosate:
www.bfr.bund.de/en > Chemicals > Pesticides

Multiple residues of plant protection products in food

"Poisonous cocktail in fruit and vegetables", "Pesticides are poisoning our food" – headlines concerning residues of pesticides cause public worry time and time again, whether due to the residues of individual substances or multiple substances.

In principle, the permitted residue quantities may not harm the health of consumers, even if multiple active substances are ingested at once. In its pesticide and biocide legislation, the EU therefore stipulates that multiple residues are to be given particular consideration. Developing suitable methods for this is currently a great challenge for chemical risk assessment. Since 2008, the European Food Safety Authority EFSA has released numerous publications on various issues in the area of so-called cumulative risk assessment. The themes of these publications include estimating exposure using distribution-based methods and the grouping of chemicals in cumulative assessment groups.

Cumulative risk assessment should be carried out according to the current state of scientific knowledge. But it should also be simple and transparent so that it can be used in routine procedures of regulatory practice. To help achieve this goal, the BfR organised an international workshop in March 2013. At this workshop, current scientific knowledge on multiple residues was tested for its applicability in regulatory practice. More than 50 representatives from science, research, public authorities, NGOs and industry discussed their experiences to date and identified unresolved issues. The discussions showed that only assessment methods which are easy to implement are suitable for a standard application when setting maximum residue levels and authorising plant protection products or biocidal products. The official food surveillance authorities must also be able to judge quickly and safely whether a food sample with residues from several chemicals represents a health risk for consumers. Models which demand extensive toxicological information, the handling of large databases and complex calculation procedures are not suitable.

In 2014, the BfR is developing a concept on how it is going to conduct cumulative risk assessment in legislative procedures for plant protection products and biocidal products and will test this on selected examples.

Residues of different plant protection products can occur simultaneously in food, but their interaction must not impair the health of consumers.

Recommendations for action on the assessment of multiple residues of plant protection products:

1. The cumulative risk should first be assessed by adding up the hazard quotients (HQ) of each active substance, resulting in the hazard index (HI). This method sufficiently protects consumers and can be gradually refined if necessary with additional toxicological information. The hazard quotient is a suitable measure of the extent to which the residue of an active substance ingested via food reaches its toxicological limit values (ADI, ARfD).
2. The cumulative assessment groups, in which individual substances are currently classified based on their toxicological effect, should be further subdivided based on additional information regarding their mechanism of action.
3. To estimate cumulative exposure in a regulatory context, it would be preferable to use deterministic methods.
4. The actual cumulative exposure of consumers by pesticide residues should be regularly investigated using data from food monitoring.

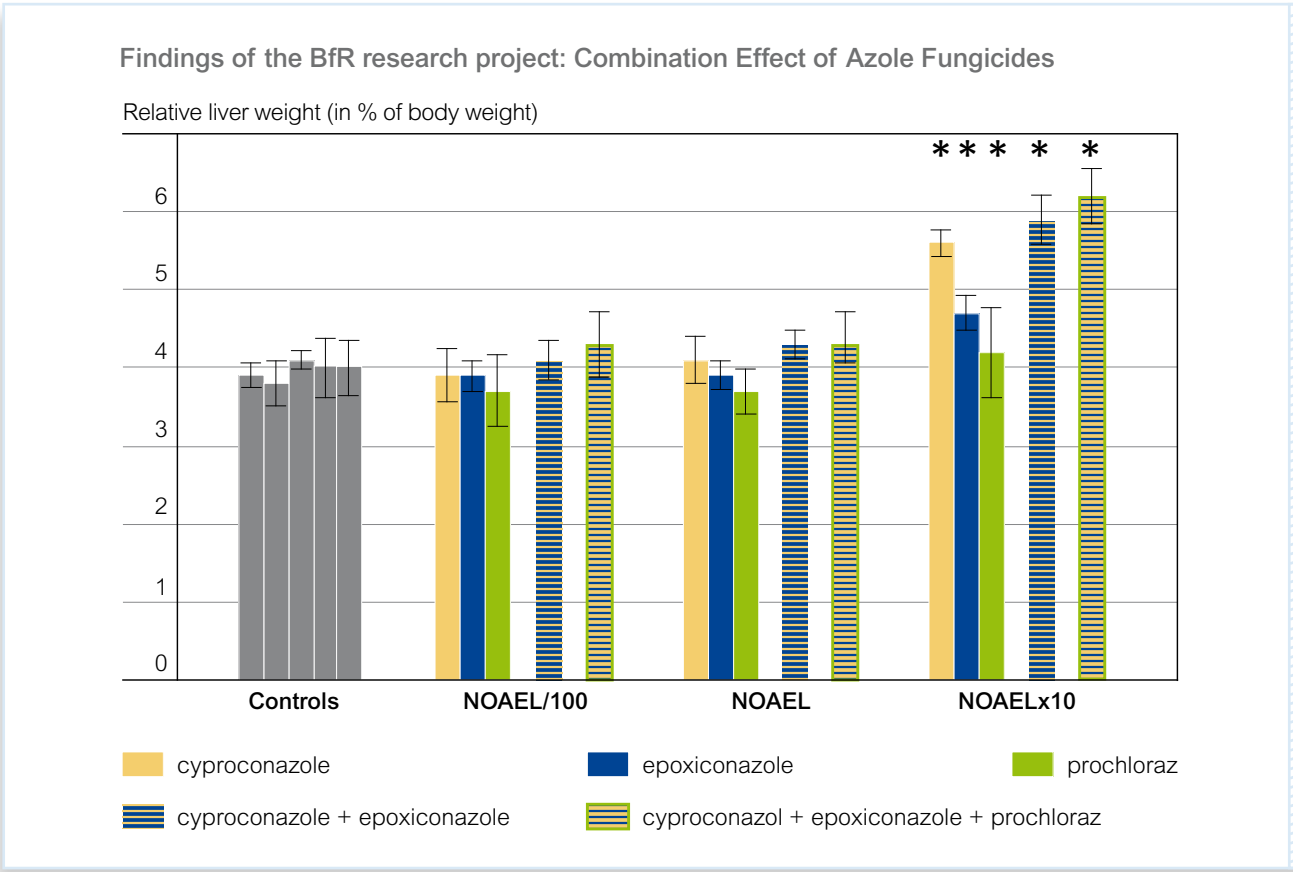
Combination effects of multiple residues as exemplified by azole fungicides

Assessing the health risks of multiple residues of pesticides presents a challenge as, although sufficient toxicological data are present for the individual active substances, there have been relatively few experimental studies into possible combination effects.

To contribute to the experimental studies into this subject, a research project was carried out in the BfR with a frequently used group of active substances, the azole fungicides. The tested substances were first examined individually and then in different combinations, in a wide dose range, on both rats and specific cell lines. The main focus of the test was the liver, the main target organ of these fungicides. In the rat feeding studies, the results show that combination effects were present only in dosages where the individual substances also had an effect. They were merely more pronounced in some cases.

As an example, the figure below shows a result from the aforementioned 28-day study of rats. The weight of the rats' livers only changed significantly compared to the control group when they received high doses of the fungicides. Liver weight following the administration of multiple substances was only marginally more elevated than it was following treatment with individual active substances.

For the assessment of combination effects, the data prove that a simple additivity of the effects of various substances on the same organ provides sufficient protection. The EFSA, among others, also argues in favour of this so-called dose additivity assessment principle.



Change in relative liver weight of rats following administration of the azole fungicides cyproconazole, epoxiconazole and prochloraz individually and in two different combinations, over a wide dose range, compared to control groups. NOAEL stands for "no observed adverse effect level". It is based on corresponding observations made by regulatory studies into the relevant substances. The dose range varied from the NOAEL divided by 100 to the NOAEL multiplied by 10. Changes were only observed for the highest dose (statistically significant with $p < 0.01$ in Mann Whitney U Test).*

Risk Communication

One of the key tasks of the Federal Institute for Risk Assessment is the risk communication. This is defined as a continuous and interactive process characterised by participatory dialogue with various target groups. Risk communication is therefore far more than informing all concerned parties and interested groups about the assessment work of the institute and its findings. The provision of early information to the public on potential health risks, research findings and work results forms the basis for this dialogue. In its risk communication, the BfR adheres to three principles in order to strengthen the trust of all parties involved in the process of risk assessment: transparency, reliability and the greatest possible openness.


Thunfisch
Rapsöl
Butter
Margarine
Schwarze Johannisbeere
Zitrone
BfR
Bundesinstitut für Risikobewertung
Margarine

Risk Communication

There is a specific Department for Risk Communication at the BfR whose job is to inform the public about potential health risks as well as the underlying research findings connected with these risks. In this process, the BfR enters into dialogue with the various interest groups via measures in the field of classic press and public relations activities as well as through events like expert discussions, consumer protection forums, conferences and public symposiums. This interdisciplinary department also conducts research projects on risk perception, early risk identification and the prediction of the consequences of these risks. Prevention and coordination of crises is also part of the remit of the Risk Communication Department. The department can draw on external know-how in the form of the risk research and perception committee.

Communication that works: press and public relations at the BfR

Why does food contain aluminium? Can residues of plant protection products be found in fruit and vegetables? How dangerous is nail modelling? These were just some of the questions received by the BfR in 2013. Over 500 interviews and background discussions took place, resulting in a strong media presence. The BfR was represented in around 70 TV reports and cited around 4,000 times on a national and international level in newspaper and magazine articles. The majority of the articles written by the BfR in 2013 dealt with the issues of mycotoxines in food, pyrrolizidine alkaloids in tea, hormonally active substances in cosmetic products, food hygiene and antimicrobial resistance.

With over three million visitors in 2013, the BfR website is one of the institute's most important information resources. As part of this web presence, more than one hundred texts were written and updated in 2013, with additional new formats also created such as online surveys and films. Alongside downloads from the website, demand for the BfR printed brochures remained high. More than 120,000 publications were sent out, consisting mainly of the BfR Annual Report, the BfR EU Food Safety Almanac – which presents a clear overview of how the European food safety authorities are structured – and the BfR leaflets on hygiene. The leaflet on hygiene rules in the catering sector, published by the BfR and “aid infodienst”, was particularly well received and translated into nine languages.

In 2013, the BfR conducted over 500 interviews and background discussions; the institute was represented in around 70 TV reports and cited around 4,000 times in national and international newspaper and magazine articles.

The BfR enters into dialogue with the public through its press and PR activities as well as the events it organises. At the BfR "Science Slam", for example, the scientists from the institute outlined their work in short presentations.

The BfR is developing new formats with the aim of offering a wider range of services to existing users and reaching new target groups. One highlight of the BfR public relations work was the release of the app "Poisoning Accidents Among Children" in August 2013 with the Federal Minister at that time, Ilse Aigner. Within four months, more than 90,000 users had installed the application on their smartphones. The new twitter account and YouTube channel are other notable examples of the BfR's work in public relations.

As part of a workshop held in January 2013, around 20 journalists were informed on food safety issues dealt with by the BfR. A wide range of issues was covered, spanning the entire production chain all the way from the farm to the plate. At the BfR's Alt-Marienfelde site, the so-called "carry-over" tests – tests for the transfer of undesired substances and microorganisms from feed to food-producing animals – were discussed. Press conferences were held as part of the international symposia "Safety of Tattoo Inks" and "Antimicrobial Resistance in the Food Chain".

Facts and figures on press activities

3,065,560	Visits to the BfR website
120,074	Dispatched publications (brochures etc.)
93,000	Downloads of the BfR app "Poisoning Accidents Among Children"
16,011	Views on the BfR YouTube channel
7,098	Subscribers to the BfR Newsletter
4,272	Mentions of the BfR in newspaper articles
1,184	Queries from the public (in writing)
68	TV interviews
60	Radio interviews

Risks at a glance: the BfR "Risk Profile"

In order to be able to take measures to protect their own health, consumers expect understandable information and recommendations for action that they can implement in their daily lives. To cater to these expectations, the scientific opinions published by the BfR have also included a so-called "Risk Profile" since April 2013. This takes the form of a chart showing the risk characterisation, the quality of the data and options for action at a glance. The readers of an opinion can therefore easily identify the facts of the matter at hand and the central characteristics of the risk assessed in the opinion.

The BfR risk profile contains the five following elements. The valid characteristics of the risk elements are graphically highlighted:

- Affected group of persons
- Probability of health impairment due to exposure
- Severity of health impairment due to exposure
- Validity of available data
- Ability of the consumer to control the risk – by avoidance or taking extra care

The characteristic "Controllability" plays a particularly important role in the perception of risks. Consumers often perceive risks as being more significant, for example, if they as individuals have no means of controlling a risk.

When developing the BfR risk profile, a deliberate decision was made not to state risk information solely based on quantitative values. For laypeople in particular, quantitative data on the probability of occurrence of a health hazard has only limited information value and often results in errors of judgement.

The BfR risk profile using the example of an opinion on perchlorate in food

BfR Risk Profile:
Perchlorate finds in foods
Opinion no. 022/2013

A	**Affected group**	**General population, children, people with thyroid disease or iodine deficiency**			
B	**Probability of health impairment due to one-time consumption of large portions of products with high concentrations**	Practically impossible	Improbable	**Possible**	Probable	Certain
C	**Severity of health impairment due to one-time consumption of large portions of products with high concentrations**	No impairment	**Slight impairment [reversible]**	Moderate impairment [reversible/irreversible]	Serious impairment [reversible/irreversible]
D	**Validity of available data**	High: the most important data is available and there are no contradictions	**Medium: some important data is missing**	Low: much important data is missing or contradictory	
E	**Controllability by the consumer [1]**	Control not necessary	Controllable through precautionary measures	Controllable through avoidance	**Not controllable**

Text fields with dark blue background highlighting characterise the properties of the risk assessed in this Opinion.
(for more detailed information, please refer to the text in BfR Opinion no. 022/2013 dated 28 June 2013).

Notes

The Risk Profile is designed to visualise the risk described in the BfR Opinion. It is not designed to permit risk comparisons. The Risk Profile should only be read together with the Opinion.

Line E - Controllability by the consumer
[1] – Efforts are needed on all levels to reduce the entry of perchlorate into the food chain and therefore to minimise the burden for consumers.
The details in the line "Controllability by the consumer" are not designed to serve as a recommendation by the BfR but are of descriptive character.

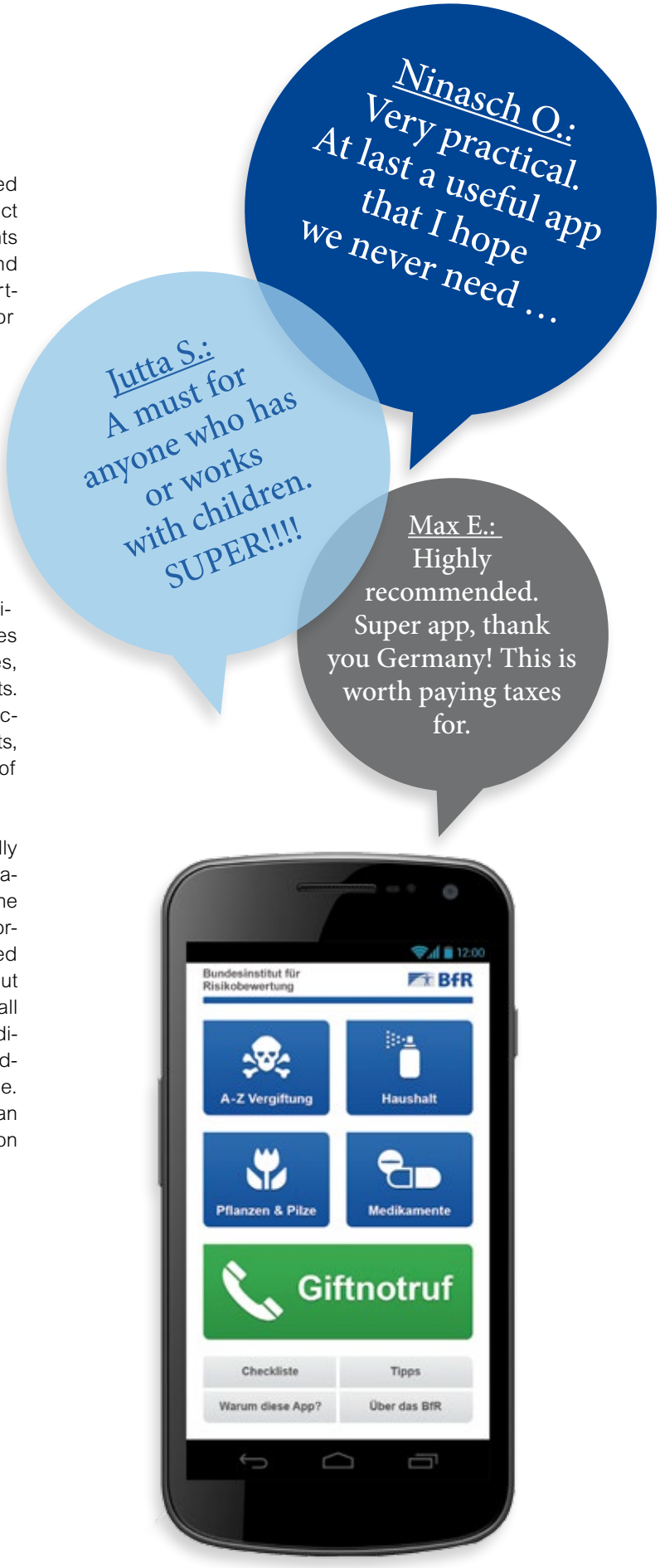
BfR app “Poisoning Accidents Among Children”

In August 2013, the BfR released its first app entitled “Poisoning Accidents Among Children”. This new product aims to help reduce the number of poisoning accidents among children. Within five months of launch, around 90,000 users installed the application on their smartphones. The BfR app received the German Award for Online Communication in 2014.

Around 200,000 calls are received each year at poison information centres in Germany, with half of these cases involving children. Questions include such things as: what to do if a child accidentally drinks a corrosive detergent or a grill lighter fluid? The new app cannot replace a phone call to a poison information centre or the emergency service. It does, however, provide valuable support to parents, helping them to keep calm and make the correct decision in a difficult situation. The BfR app also provides background information on the chemicals, medicines, plants and fungi which can cause poisoning accidents. In addition, the app contains tips for how to prevent accidents, as many incidents could be avoided if parents, grandparents, childminders and carers were aware of the risks and stored dangerous products safely.

The BfR app is easy to use. It has a clear, user-friendly design and directs users intuitively to important information such as first aid measures. Whether travelling, in the playground or visiting the grandparents, all of the information is available anytime, anywhere. Once installed on the smartphone, the app can also be used without Internet access. In an emergency, it is possible to call one of the nine poison information centres in Germany directly from the app. This way, professional advice regarding treatment can be obtained as quickly as possible. When the smartphone's location function is activated, an automatic connection to the relevant poison information centre in the federal state is established.

The free app is available for smartphones with Android and iOS operating systems from the relevant app stores (in German).
www.bfr.bund.de > Presse > BfR-App



The BfR has commissioned two wide-ranging media analyses on nanotechnology and residues of pesticides in food in order to determine how the media communicate selected topics addressed by the BfR to the public at large.

Nanotechnology and pesticides as mirrored by the media

Even in the age of the internet, classical media are still a central source of information for consumers when it comes to health risks. At the same time it is well known from research into risk perception that media coverage of a subject can significantly influence its public perception. Because risk topics often are interpreted differently by the media from the way science interprets them, the BfR regularly carries out media analyses to find out how the media report on selected topics addressed by the institute. Most recently, the BfR commissioned two comprehensive media analyses, on nanotechnology and pesticide residues in food. Both topics are of central importance to the BfR and frequently present in the media.

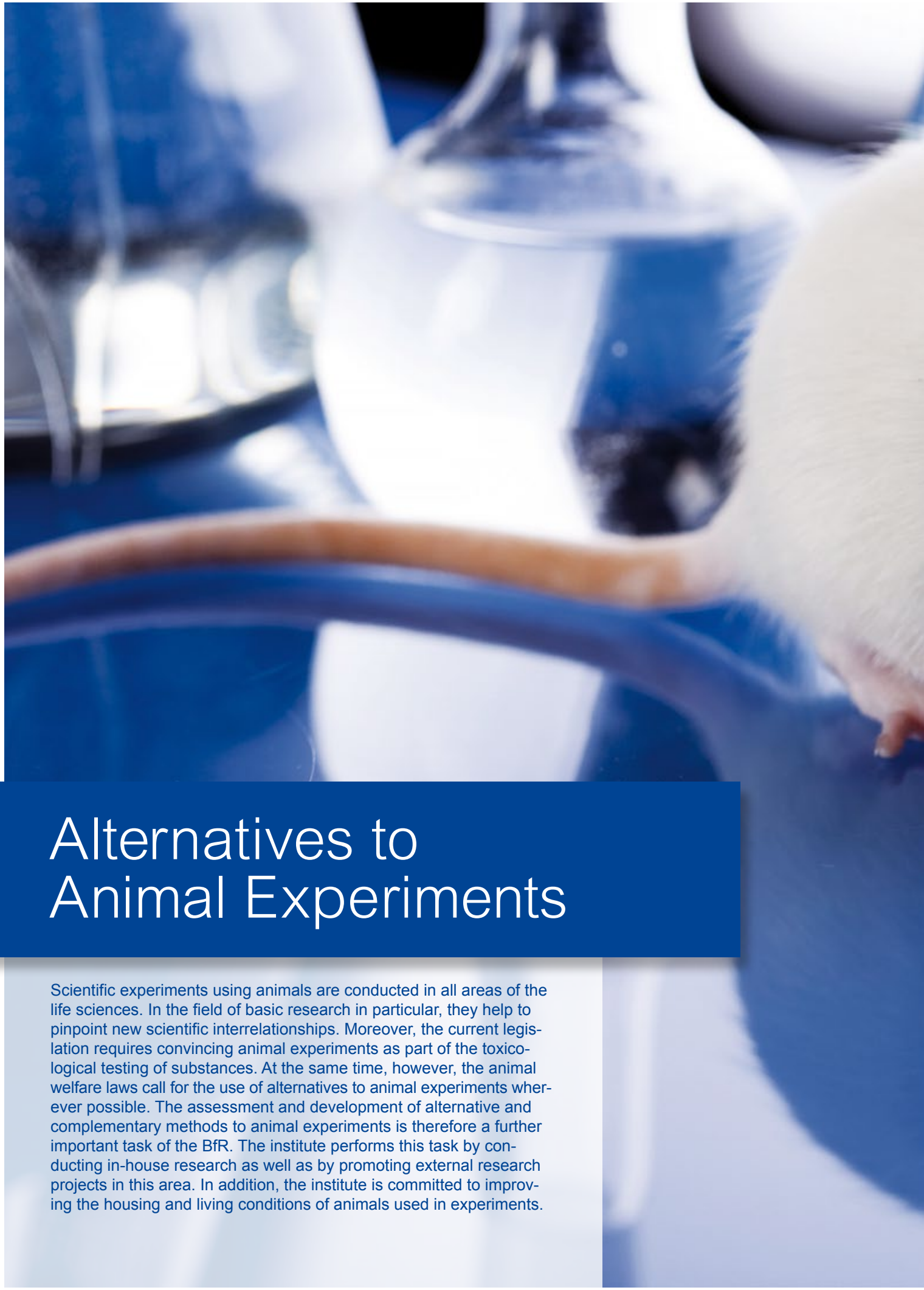
German print media from 2008 to 2012 were analysed with regard to their reporting on the subject of nanotechnology. This study is the continuation of an earlier media analysis by the BfR that examined the reporting of this subject from 2000 to 2007. The basis for both analyses comprised articles in leading German media. Analysis of these articles showed that the importance of the topic of nanotechnology in the media has decreased in spite of a large number of public activities. This is evidenced by the constantly sinking number of relevant articles. As a comparison, 155 relevant articles were identified in 2008, while in 2012 there were only 89. At the same time, articles have become longer. This is presumably to be viewed as being closely related to the fact that the topic is becoming increasingly specialised. Thus the majority of the articles identified were published in the science section, with a proportion of 83.1 percent in 2012. However, hardly any of the media coverage was controversial. The focus was more on the benefits of nanotechnology. One or more benefits were cited in more than 80 percent of all the articles from 2008 to 2012. Nanotechnology is therefore presented in German media as a primarily scientific subject with a high benefit value.

The topic of pesticide residues in food, on the other hand, was taken up far more critically by the selected leading media. For the period of examination from 2003 to 2010, reporting reached its zenith in 2007 and 2008, after which the number of relevant articles fell again. The amended Pesticide Regulation came into effect in 2008, and it may be presumed that the increased level of reporting took place in the run-up to these legislation. The most important topic in 2008 was "Politics and Regulation", while in other years "Consumer Protection" was the main issue. The third most frequent topic was "Application in Farming". Most articles were published in the economics section, followed by the science section. This means that the topic is placed more in an economic context that has little to do with consumers' real lives. From the point of view of risk communication, there is the additional complicating factor that while the reporting did discuss a range of health risks, it mentioned virtually no possible benefits.

In view of the results of two surveys conducted by the BfR on the subjects of nanotechnology and pesticide residues, it is fair to assume that the tendencies observed in the media coverage of these subjects have (partly) influenced consumers' perception of them. The critical, risk-oriented reporting on pesticides in foods corresponds with the highly critical attitude of the population. The population rates the benefit of nanotechnology as high. Thus the argumentation patterns identified in the media coverage are reflected in the public's perception.

The two media surveys have been published as the "BfR-Wissenschaftshefte" brochures 09/2013 and 11/2013 (in German):
www.bfr.bund.de > Publications > BfR-Wissenschaft

The BfR media analyses show that the media generally reported on nanotechnology in scientific terms, focusing on the benefits of products. Reporting on the topic of residues of plant protection products mostly adopted a critical tone.



Alternatives to Animal Experiments

Scientific experiments using animals are conducted in all areas of the life sciences. In the field of basic research in particular, they help to pinpoint new scientific interrelationships. Moreover, the current legislation requires convincing animal experiments as part of the toxicological testing of substances. At the same time, however, the animal welfare laws call for the use of alternatives to animal experiments wherever possible. The assessment and development of alternative and complementary methods to animal experiments is therefore a further important task of the BfR. The institute performs this task by conducting in-house research as well as by promoting external research projects in this area. In addition, the institute is committed to improving the housing and living conditions of animals used in experiments.

Alternatives to Animal Experiments

At the BfR, the department Experimental Toxicology and ZEBET develops and evaluates various alternatives and complementary methods to animal experiments that are based on the 3R concept. It draws up new toxicological assessment strategies and looks into innovative online-based technologies with the aim of identifying and assessing internationally developed alternatives and complementary methods to animal experiments. The department also develops new concepts to reduce the overall number of animals used in experiments. The new German Animal Welfare Act places the BfR under obligation to address the goal of reducing the pain and suffering of laboratory animals. The department therefore also houses the experimental animal management section, which can draw on high-level expertise in the field of laboratory animal science.

Toxicological *in-vitro* test methods for nanomaterials

Nanotechnology is considered worldwide to be a technology with huge potential. However, the safety of engineered nanomaterials has not been sufficiently proven for many applications. This new technology can only be successful in the long term if nanomaterials do not pose a risk both to human health and the environment. This also involves the detection of genotoxic or mutagenic effects.

To identify such risks, screenings are first of all carried out on bacteria and cell cultures in addition to tests on mice and rats. The initial findings of these so called genotoxicity-test-batteries require verification using more developed and more complex model organisms, since cell systems sometimes produce irrelevant results for mammalian organisms (“false-positives”). As a consequence, many research projects focus on improving, optimising and developing novel *in vitro* tests in order to identify (geno-)toxic effects. The BfR has gained a longstanding expertise in the field of alternatives to animal testing. This know-how was applied to establish “animal-free” test systems for nanomaterials, as in the EU-funded Nanogenotox project.

From April 2010 to March 2013, 16 laboratories and institutions from eleven European countries took part in a wide-ranging European joint action coordinated by French food authority ANSES. The objective of the Nanogenotox project was to develop operating procedures to assess the genotoxic and mutagenic potential of manufactured nanomaterials which are relevant to the current market. After the suitability of the methods was confirmed, they were applied to a selected subset of nanomaterials. The extensive project plan consisted of two phases: phase one encompassed the physiochemical characterisation of the material followed by the determination of the genotoxic potential employing a variety of cell-based assays. Due to their sensitivity in detecting genotoxic properties of nanomaterials *in vitro* systems mimicking the intestine and the lung were used in inter-laboratory studies which formed phase two of the project.

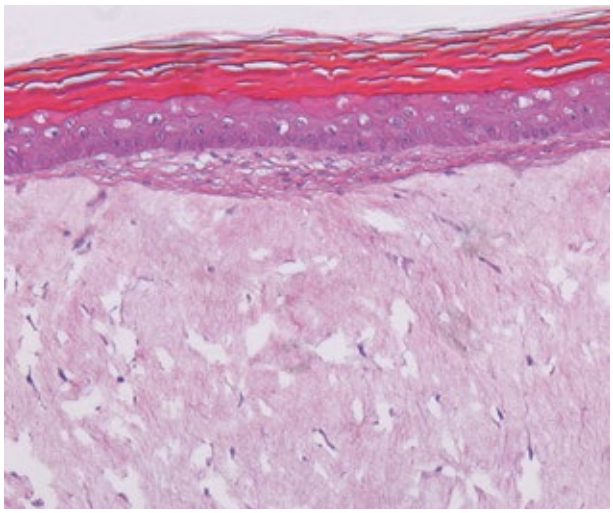
The BfR contributed to the Nanogenotox work packages on two levels. First, the BfR led the “evaluation” work package, assessing all of the consortium's work and results. In support of this the BfR organised an international meeting of evaluators to establish the relevance of the findings for regulatory acceptance. The BfR also developed *in vitro* methods for testing the genotoxicity of nanomaterials using human lung cells and three-dimensionally reconstructed human skin models. In both test systems,

the BfR did not identify directly genotoxic or mutagenic properties of nano-titanium dioxide, if tested at exposure levels which could be expected under normal conditions. Finally, the BfR also took part in the inter-laboratory test involving the intestinal cells which were identified as sensitive cell systems for *in vitro* genotoxicity testing during the first phase of the project.

Future work will focus on the establishment of appropriate methods which allow quantifying the intracellular amount/dose of nanoparticles in cells which can come into contact with nanomaterials, after a "real-life" exposure treatment. With respect to this, the BfR participates in a Franco-German follow-up project.

All results of the research projects:
www.nanogenotox.eu

When investigating the genotoxicity of nanomaterials in vitro, the BfR works with three-dimensionally reconstructed human skin models that are grown in so-called 6-well plates during the test.



Histology of skin model shows epidermis consisting of stratum corneum and basal, spinous and granular keratinocytes (from top to bottom). Dermis contains numerous viable fibroblasts.

Application guideline for tests for skin irritants and corrosives

The determination of skin-irritant or skin-corrosive properties is legally required for the toxicological assessment of cosmetic ingredients and industrial chemicals. The main method of testing for these properties to date has involved animal experiments on rabbits. As the new Cosmetics Regulation contains a European marketing ban from July 2013 on cosmetics containing ingredients that have been tested on animals, this testing method can no longer be used, at least in the case of these products.

In the last ten years, artificial human skin models have been developed which closely imitate the texture and properties of human skin. These so-called Reconstructed Human Epidermis (RHE) models are based on the *in vitro* differentiation of human skin cells into three-dimensional tissue structures. On the basis of these skin models, the BfR worked with international partners to develop and validate tests for corrosive and irritant properties of various substances and products. These tests are recognised for official purposes around the world as OECD test guideline 431 (*in vitro* skin corrosion) and OECD test guideline 439 (*in vitro* skin irritation). By combining these two test methods, harmful tests on rabbits which were previously used can be replaced completely. →

However, experience shows that users and evaluating authorities sometimes have difficulty determining the right course of action or employing suitable methods. For example concerning the combined use of *in vitro* models and the limitations which must be considered, particularly with regard to additional *in vitro* or *ex vivo* test systems. Furthermore, there are still test guidelines which do not take the developments of recent years into account.

On the initiative of the BfR, an OECD expert working group was therefore established to develop a guidance document which will help evaluating authorities and users to use animal-free methods correctly. The instructions set out in the guidance document can make an important contribution towards reducing the use of animal experiments in research to determine skin corrosion and skin irritation. The advantages and limitations of test methods for skin-corrosive or skin-irritant properties, for example, are presented in detail. Other *in vitro*, *ex vivo*, and *in silico* methods are also considered in the document. A testing and assessment strategy (Integrated Approach for Testing and Assessment, IATA) aims to help the relevant authorities and applicants to evaluate existing data and assess the need for additional tests, with *in vitro* and *ex vivo* methods given high priority. Most of the work on the guidance document took place in 2013; it is to be published by the OECD in 2014.

Before work on the guidance document could be completed, the OECD expert working group also revised the test guidelines in 2013 to facilitate their application and, in certain fields, to allow them to be applied for the first time. This was the case for OECD test guideline 431 on skin corrosion *in vitro*, for example. Following a study by the working group, this guideline can now also be used for the testing of substances in the field of transportation. In this case, additional differentiation into three hazard groups (1A, 1B and 1C) is required.

Assessing pain and suffering in genetically altered laboratory animals

For the breeding of genetically altered animal lines, new legal regulations have been in place since the German Animal Welfare Act was amended in July 2013. The Animal Welfare Act and its associated ordinance regulate all details that must be considered when using animals for scientific purposes in Germany. One of the provisions of the new law is that not only the creation of genetically altered animals but also maintenance and breeding of these animals have to be authorised by competent authorities. The key factor in this obligation for approval is whether the animals are subjected to pain, suffering, fear or permanent damage due to their genetic alteration.

Mice are the most frequently genetically altered species of laboratory animals. However, as traditional prey animals, they exhibit very few directly observable signs of pain or suffering – if they do, it is only when they are subjected to a high level of suffering. It is for this reason that scientists and competent authorities require useful criteria for the detection and assessment of pain and for the creation of suitable counter-measures. Signs of general stress, such as a change in fertility or increased mortality, as well as indicators of each particular genetic alteration, such as tumour frequency or muscle alterations, must be taken into account.

For the practical implementation of the new animal welfare guidelines, the BfR held a workshop in June 2013 on classifying pain and suffering in genetically altered laboratory animals. Various research institutions and competent authorities for animal testing projects from the German federal states took part in the workshop. The workshop dealt with signs of general pain and suffering which can be applied for all breeds of mice. The participants compared what they considered to be the most sensible approaches based on their own experiences with suggestions published by the EU Commission in January 2013.

The workshop's recommendations first explain the cases in which pain assessment is necessary. Particular emphasis is placed on the importance of cooperation between animal care personnel, scientists and animal welfare officers to correctly identify pain and suffering and to take measures to reduce or avoid it as quickly as possible. It is also recommended that for the assessment of pain and suffering no further animals are bred and that they are not subjected to additional pain. This means that blood samples, for example, should only be taken from animals whose blood count is likely to change. Furthermore, for the classification of pain and suffering, the minimum number of animals, the most important time points during the life cycle and the key criteria (e. g. litter size, occurrences of developmental disorders) were described and recorded in form drafts. If signs of pain and suffering are observed, or when a particular type of pain is possible due to the nature of the genetic alteration, both additional time points as well as specific examinations must be defined and documented by the responsible scientific personnel.

These recommendations are helpful for scientists and competent authorities in the assessment of mouse breeds with genetic alterations and are the basis for nationwide standardised administrative procedures. Additional workshops will further develop and improve the criteria.

All findings of the workshop about assessing pain and suffering in genetically altered laboratory animals:
www.nature.com/nature/journal/v512/n7512/full/512028c.html

< *Mice and rats are the most frequently used genetically altered animals in experiments. Both scientists and competent authorities need useful criteria for these animals, both in terms of assessing the burden imposed on them and to stipulate suitable measures to mitigate the suffering of the animals.*

Third-party funded projects of the BfR in 2013

Research for exposure assessment and for the assessment of biological risks

Period	Acronyme	Topic
01/2010–12/2013	SFB 852	Nutrition and intestinal microbiota – host interaction in the pig Influence of nutritional factors on the prevalence of viruses, including viruses with zoonotic potential, in faeces of clinically healthy pigs
11/2010–12/2013	MedVet-Staph	*Staphylococcus aureus* as zoonotic pathogen: Epidemiology of human colonisation and infection by LA-MRSA
11/2010–12/2013	RESET	Resistance in animals and humans: ESBL and (fluoro)quinolone resistance in enterobacteriaceae, risk assessment of the resistance to beta lactam antibiotics with extended spectrum (ESBLs) and (fluoro)quinolones
10/2011–12/2013	EMIDA LA-MRSA	Methicillin-resistant *Staphylococcus aureus* lineages in primary productions: multi-host pathogen, spill-over and spill-back between animals and humans
12/2011–08/2013	CFP/EFSA/ BIOMO/2011/01	Implementation and testing of electronic submission in XML format of zoonoses, zoonotic agents, animal population, antimicrobial resistance and food-borne outbreaks data in the European Union
02/2011–04/2014	FBI Zoo 2	Food-Borne Zoonotic Infections of Humans – *Salmonella* in the poultry food chain: outbreak potential, evolution, and pathogenicity
11/2010–12/2014	VibrioNet	VibrioNet: Climate warming and the emergence of seafood- and waterborne vibriosis
10/2011–10/2014	Gene transfer	Molecular mechanism of horizontal gene transfer in pathogenic epsilon-proteobacteria
01/2012–12/2014	PROMISE	Consumer: PROtection by microbial risk MItigation through combatting SEgregation of expertise
10/2012–06/2015	e-H@C HUPAction	Developing a system to improve information exchange within the organisational infrastructure in the interest of the more rapid detection, monitoring, and control of EHEC and other human pathogenic bacteria in the value chain, vegetables in the Euregio Rhine Waal.
07/2012–08/2015	InnoStep	Development of innovative production integrated microbiological levels control systems in meat production to reduce *Campylobacter* spp. and *Salmonella* spp.

	Further information
	DFG (FKZ 109100242003) www.sfb852.de
	BMBF (FKZ 01KI1014C) www.medvetstaph.net
	BMBF (FKZ 01KI131A) www.reset-verbund.de
	BMBF (FKZ 0315868A) www.kooperation-international.de/detail/info/emida-era-net-la-mrsa-methicillin-resistente-staphylococcus-aureus-linien-in-der-primaerproduktio.html
	EFSA
	BMBF (FKZ 01KI1012I) http://fbi-zoo.net
	BMBF (FKZ 01KI1015A) www.vibrionet.de
	DFG (FKZ STI 201/3-1) http://gepris.dfg.de/gepris/projekt/175974972
	EU (FP7-KBBE-2010-4-265877) http://promisenet.wordpress.com
	EU (II-2-03=201) http://giqs.org/projekte/hupaction
	BLE (FKZ 2816801511)

Abbreviations

BMBF: Federal Ministry for Education and Research
BMUB: Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety
BMWi: Federal Ministry for Economic Affairs and Energy
BLE: Federal Office for Agriculture and Food
DFG: German Research Foundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

Research for the safety of national and international production chains

Period	Acronyme	Topic
10/2010–09/2013	AniBioThreat	Bio-Preparedness on measures concerning prevention, detection and response to animal bio-terrorism threats
10/2010–09/2014	SiLeBAT	Securing the feed and food chain in the event of biological and agri-terrorist (BAT) damage scenarios
07/2013–06/2016	ZooGloW	Zoonoses and food safety along global supply chains
07/2013–06/2016	SPICED	Securing the spices and herbs commodity chains in Europe against deliberate, accidental or natural biological and chemical contamination
12/2013–11/2018	EFFORT	Ecology from Farm to Fork Of microbial drug Resistance and Transmission

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

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

Research for modern methods in toxicology

Period	Acronyme	Topic
10/2009–09/2013	CFT/EFSA/CEF/2009/02	Examination and drafting of summary data sheets on toxicity data related to the evaluation of substances to be used in consumer products
11/2010–09/2014	Gastrointestinal Barrier	Interaction between metabolism and transport of toxicologically relevant compounds in the gastrointestinal barrier
11/2013–10/2015	Combiomics	Combiomics – Investigation of mixture effects of pesticides *in vitro*
12/2013–11/2015	LivSys	Modelling of the toxome of cultivated human hepatocytes

	Further information
	EU (Home/2009/ISEC/AG/191) **www.anibiothreat.com**
	BMBF (FKZ 13N11202) **www.silebat.de**
	BMBF (FKZ 13N12697) **www.bmbf.de/pubRD/Projektumriss_ZooGloW.pdf**
	EU (FP7-SEC-2012 – 312631) **http://spiced.eu**
	EU (FP7-KBBE-2013-7-613754) **www.effort-against-amr.eu**

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

	Further information
	EU **www.efsa.europa.eu/de/tendersawarded/tender/cft_toxicitydata_tender_specifications.pdf**
	DFG (FKZ LA 1177/6-1) **http://gepris.dfg.de/gepris/projekt/156632571**
	BMBF (FKZ 031A267A)
	BMBF (FKZ 3R-474-007)

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DFG: German Research Foundation
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FKZ: Project reference number

Research for harmonisation and standardisation of exposure assessments

Period	Acronyme	Topic
12/2010–06/2013	PILOT-PANEU	Pilot study in the view of a Pan-European dietary survey – adolescents, adults and elderly
02/2012–01/2016	TDS_Exposure	Total Diet Study Exposure

Research for alternatives to animal experiments

Period	Acronyme	Topic
04/2008–09/2013	ESNATS	Embryonic Stem cell-based Novel Alternative Testing Strategies
09/2010–12/2013	HET-MN	Pre-validation of HET-MN (Hen's Egg Test – Micronucleus Induction) as alternative method to the *in vivo* micronucleus test in rodents
02/2013–03/2013	PCLS Pre-validation	Pre-validation of the *ex vivo* model Precision Cut Lung Slices (PCLS) for the prediction of acute inhalation toxicity
10/2011–09/2014	3D skin models	Verification of the metabolic competence and pre-validation of the comet assay in human 3D skin models

Allergy research: effect-based analytics and early risk detection

Period	Acronyme	Topic
09/2009–02/2013	food-borne allergens	Development of innovative rapid test and screening methods for on-site detection of food-borne allergens in product development and control
07/2010–06/2013	Contact Allergen	Development of a contact allergen activated T cell (CAATC) assay using dendritic cells from skin: characterisation of the sensitising potency of chemicals via dendritic cell-induced expression of lineage specific T cell transcription
01/2011–12/2014	MIRABEL	Model Integrated Risk for Allergy, Bayesian Estimation for Life quality (MIRABEL)

Research for feed safety

Period	Acronyme	Topic
07/2008–06/2013	SafeGuard	Sound Animals and healthy Food within the Euregio Guaranteed by an United Approach
03/2011–08/2014	QSAFFE	Quality and Safety of Feeds and Foods for Europe
06/2013–06/2016	Tannisil	Improving protein quality of roughages in ruminant nutrition by using silage additives on the basis of condensated tannins

	Further information
	EFSA (CFP/EFSA/DATEX/2010/02) **www.efsa.europa.eu/de/supportingpub/508e.htm**
	EU (FP7-KBBE-2011-5-289108) **www.tds-exposure.eu**

	Further information
	EU (HEALTH-F5-2008-201619) **www.esnats.eu**
	BMBF (FKZ 0315803B)
	BMBF (FKZ 0315720A)
	BMBF (FKZ 0316008A)

	Further information
	BLE (FKZ 2816400508)
	BMBF (FKZ 0315724)
	EU

	Further information
	EU (INTERREG IVa III-2-03=025) **http://giqs.org/projekte/safeguard**
	EU (FP7-KBBE-2010-4-265702) **www.qsaffe.eu**
	BLE (FKZ 2813804310)

Abbreviations

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BLE: Federal Office for Agriculture and Food
DFG: German Research Foundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

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

Period	Acronyme	Topic
03/2010–02/2013	Nanogenotox	Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard
08/2010–10/2013	NanoGEM	Nanostructured materials – health, exposure and material properties
07/2013–12/2013	Nanoscale	Regulation of cellular adhesion and uptake of synthetic polymeric nanoparticles by specific functionalisation with biological target molecules
04/2012–01/2014	Migration Nanoton	Migration analyses for food contact with nanoclay doped plastic
04/2012–08/2014	Oxid Stress Nano	Classification of nanomaterials for potential oxidative stress at the level of oxidative protein modifications
05/2012–10/2014	Nanopinion	Monitoring public opinion on Nanotechnology in Europe
02/2011–01/2015	QNano	A pan-European infrastructure for quality in nanomaterials safety testing
03/2013–08/2016	NANoREG	A common European approach to the regulatory testing of nano-materials
11/2013–10/2017	NanoDefine	Development of methods and standards supporting the implementation of the Commission recommendation for a definition of a nanomaterial

Scientific cooperation

Period	Acronyme	Topic
05/2008–12/2013	EFSA focal point	Germany's national focal point on technical and scientific matters

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

	Further information
	EU www.nanogenotox.eu
	BMBF (FKZ 03X0105F) www.nanogem.de/cms/nanogem/front_content.php
	Free University Berlin
	government Rhineland-Palatinate
	government Rhineland-Palatinate
	EU http://nanopinion.eu/de
	EU www.qualitynano.eu
	EU www.nanoreg.eu
	EU www.nanodefine.eu

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

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BLE: Federal Office for Agriculture and Food
DFG: German Research Foundation
EU: European Union
EFSA: European Food Safety Authority
FKZ: Project reference number

Publications in scientific journals 2013

A

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Al Dahouk, S., V. Jubier-Maurin, H. Neubauer, S. Kohler. 2013. Quantitative analysis of the *Brucella suis* proteome reveals metabolic adaptation to long-term nutrient starvation. BMC Microbiol **13:** 199.

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Bechlars, S., D. A. Wustenhagen, K. Dragert, R. Dieckmann, E. Strauch, S. Kubick. 2013. Cell-free synthesis of functional thermostable direct hemolysins of *Vibrio parahaemolyticus*. Toxicon **76:** 132–142.

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C

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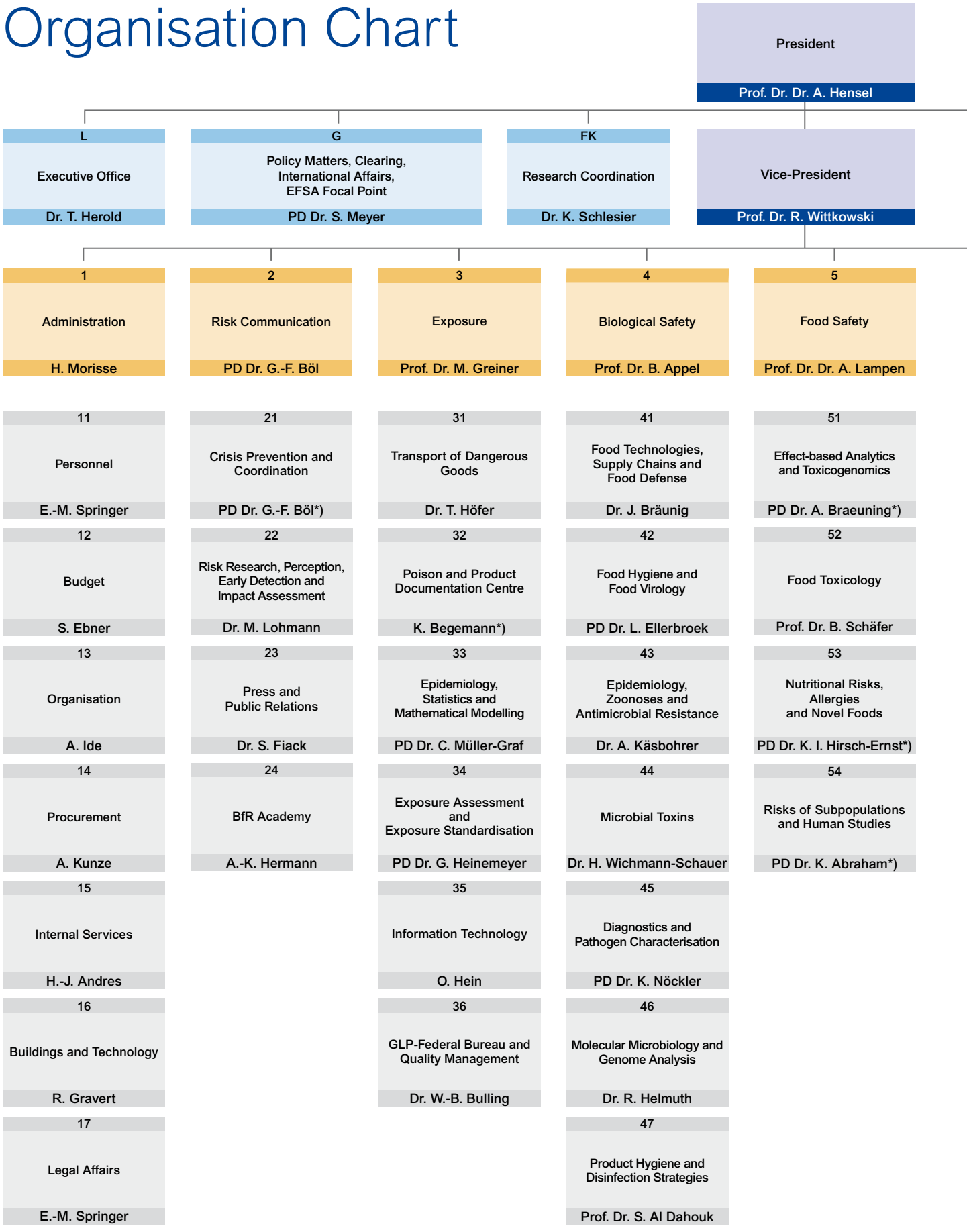
Organisation Chart



Status: September 2014

Short Portrait of the BfR

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

The BfR was established in November 2002 to strengthen consumer health protection. It is the scientific body of the Federal Republic of Germany that prepares expert reports and opinions on questions of food and feed safety and the safety of substances and products. In doing so, the Institute assumes an important task in improving consumer health protection and food safety. The activities of the BfR are conducted under the responsibility of the Federal Ministry of Food and Agriculture. At the three BfR locations in Berlin, a staff of about 770, among them 300 scientists, is being employed to work in the field of consumer health protection.The scientific expertise needed for its assessment and research activities is provided on a nonpartisan basis.

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

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

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

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