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antibiotic resistance / risk communication / pesticides
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tests / residue / poisonings / alternative
consumer health protection / food hygiene



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10th Anniversary

of the Federal Institute for Risk Assessment

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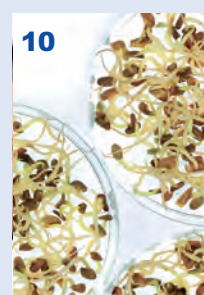
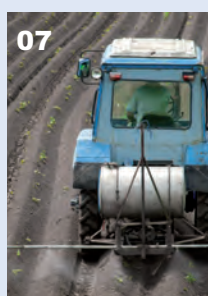
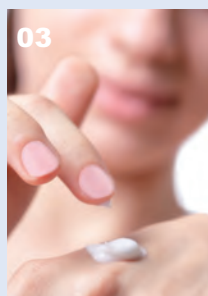
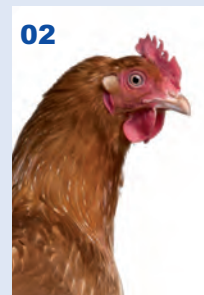


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Preface



When the Federal Institute for Risk Assessment (BfR) was founded in 2002, nobody anticipated such health issues as coumarin in cinnamon cookies or EHEC pathogens on sprout seeds. But even then it was foreseeable that the constantly growing number of newly developed foods and consumer products would raise more and more questions regarding their potential health risk in future as well – and that therefore consumer protection must be improved further.

Today, ten years after the foundation of the BfR, we can look back on a range of both large and small incidents in the area of food, feed and consumer products. In almost all cases, the BfR made a significant contribution to uncovering actual or alleged risks and to presenting expert assessments that are easy to understand for consumers. Setting up an institute that makes scientific assessments independent of government and business has turned out to be the right step at the right time to ensure up-to-date consumer protection. The BfR's work is carried out by a staff which incorporates a wide range of expertise and scientific knowledge.

The high competence of the BfR in the area of consumer protection is based on a long tradition that goes back far beyond the ten-year existence of the institute. Consumer health protection in Germany began as far back as 1876 with the historic inauguration of the Imperial Health Office. After the Second World War, the Federal Health Office was set up from which the Federal Institute for Consumer Health Protection and Veterinary Medicine emerged in 1994. The reorganisation of consumer protection as a result of the BSE crisis eventually led to the foundation of the BfR in 2002.

Apart from the core competence of the BfR, i.e. assessment and communication of the health risks of substances or microorganisms in food and products intended for consumers, there is an increasing call for other services by the institute – especially at the international level. For example, the BfR is now involved in numerous significant consumer protection tasks EU-wide, such as approving pesticides and biocides. In addition, the tasks carried out by the BfR also include recognition and validation of alternative and supplementary methods for animal experiments as well as the area of chemicals safety where the institute has, as part of the REACH process, been involved in the classification, labelling, registration and restriction of industrial chemicals.

On the occasion of our anniversary, I would like to offer you the opportunity to take a look back over the last ten years from the perspective of consumer protection and get fascinating insights into the work of our specialised departments. I would be delighted if, apart from edifying information, you will also be left with the assurance that consumer health protection in Germany and Europe is something you can count on.

Yours

Andreas Hensel

President

Federal Institute for Risk Assessment

Words of welcome



In the year 2011, dioxin and EHEC showed quite plainly: the most urgent consumer protection task is to protect citizens from health risks. This challenge grows with increasing globalisation: long and complex trade routes, state-of-the-art production technologies and ever new products in a commercial world in which national boundaries have all but disappeared all increase vulnerability.

However, the federal government is aware that with the Federal Institute for Risk Assessment, it is supported by experts whose scientific expertise is completely dependable. The Federal Institute has given ample proof of its abilities in the course of the last ten years. It has built up a reputation and is held in high esteem not only by politicians but even by the population at large. People trust the BfR. Due to its international network, esteem for the BfR does not stop at Germany's borders. It goes far beyond the frontiers of our country: the recommendations of the Federal Institute even influence decisions within the European Union.

My thanks go to the staff who give life to the Federal Institute. Their excellent qualifications and great commitment have turned the BfR's ten years into a success story which is to be continued.

The BfR is the most important pillar on which the roof of consumer health protection rests. We will continue to depend on the bearing capacity of that pillar in future!

Ilse Aigner

Federal Minister

Federal Ministry of Food, Agriculture and Consumer Protection

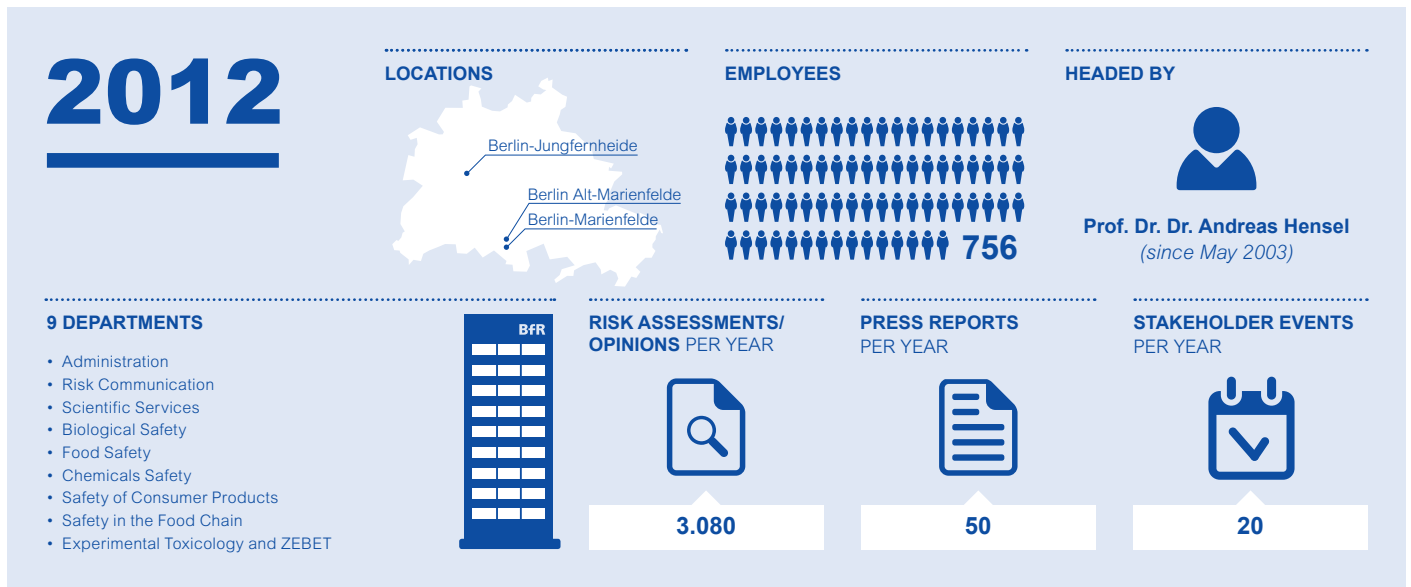
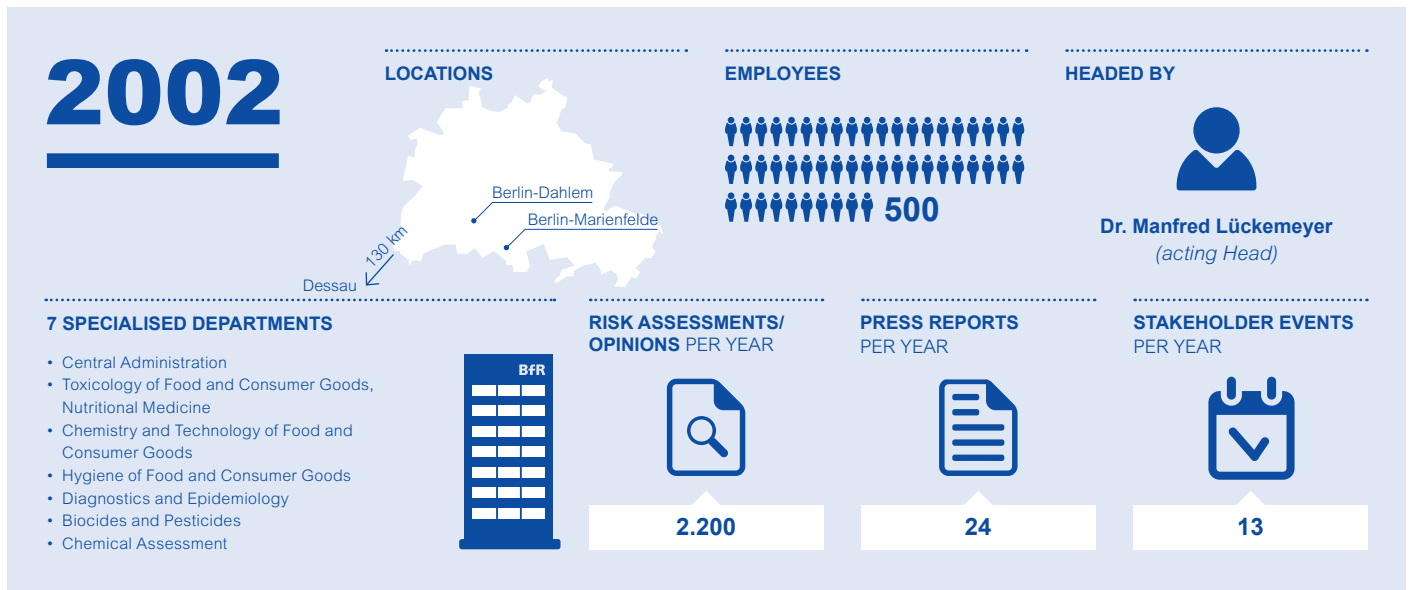


2012 is an important year for the BfR and for EFSA, as, like the BfR, EFSA is also marking the tenth anniversary of its creation. Following a series of food crises in the late 1990s, our organisations were created in 2002 as part of a commitment to ensuring a high level of food and feed safety and consumer protection. Our organisations' activities mirror each other in many respects and the recent years were engraved by an excellent scientific cooperation. Given the continuously increasing workload, EFSA has to work closely with and rely on its partners in the Member States, which, like the BfR, are knowledgeable and competent, and committed to keep the food in Europe safe for all of its citizens. EFSA appreciates the contributions from the highly qualified scientific experts of the BfR – and this not only as members of EFSA's scientific panels and networks, but also when it comes to crises. A good example of excellent cooperation in an emergency case is the EHEC incident in summer 2011, when EFSA and the BfR worked closely together to protect the health of the consumers. In bridging the gap between science and the consumer, it is important to know and understand consumer and public perception of risk and for organisations like the BfR and EFSA, to understand better consumers' attitudes to food and foodrelated risks. We share the view that speaking with one voice to the public is crucial; thus a lot of efforts are made aiming for consistent and harmonised messages on risk assessments. EFSA and the BfR will continue its fruitful cooperation, exchange information and views, and work together for the benefit of all European consumers. EFSA looks forward to working with the colleagues from the BfR over the coming years and wishes the BfR every success for the next ten years.

Catherine Geslain-Lanéelle

Executive Director
European Food Safety Authority (EFSA)

The BfR – then and now



Heike Morisse
Head of Department
Administration

The requirements on consumer health protection have changed over the years. The BfR has adjusted to the legal specifications resulting from these developments by significantly changing its human resources, especially in the area of temporary employees. The assessment and research tasks are now carried out by up to 300 scientists. In the early years of the BfR, that number was much lower.

Consumer health protection in Germany – the BfR as the key element



In Germany, consumer protection rests on several pillars. At the heart is the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) with the task of developing political measures and prepare legal regulations. The BfR is an institution within the portfolio of the BMELV since 2002. BfR scientists and experts advise the federal government, the federal states and their surveillance authorities. Recommendations are based on the scientific opinion which the BfR issues for food and feed as well as products and chemicals intended for consumers. Through its work, the BfR protects consumers by averting health hazards through food and feed. In many cases, the BfR was active long before a risk had the opportunity to turn into a possible danger for the consumer.

Focal Point at the European level

The BfR also plays a central role in Europe-wide consumer protection. The institute acts as the German Focal Point for the European Food Safety Authority (EFSA). Each of the 27 EU member state has an own national Focal Point. Their function is to coordinate the exchange of information between the EFSA and the authorities responsible for food and feed safety at the national level as well as representatives from business, politics, science and consumer association sectors.



Prof. Dr. Reiner Wittkowski
Vice President
Federal Institute for Risk Assessment

Why is it so important to separate risk assessment and risk management?

In the course of the reorganisation of consumer health protection in 2002, it was legally enforced that risk assessment and risk management be institutionally separated. That was an important step. This functional and structural separation enables us to assess existing risks on a purely scientific basis, independently of business and socio-political influences. As a result of this independence, we are perceived as a scientific point of reference by the scientific, political, business and media communities.

Federal Ministry of Food, Agriculture and
Consumer Protection (BMELV)

Federal Institute for Risk Assessment (BfR)

Federal Office of Consumer Protection and Food Safety (BVL)

Ministries and subordinated authorities of the 16 federal states

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.



01

A Christmas gift with a difference – high coumarin levels in cinnamon cookies

Not all cinnamons are alike!

Just as is the case with potatoes, there are many different types of cinnamon. These types are categorised into two main groups: Cassia cinnamon and Ceylon cinnamon. As regards coumarin contents, there are major differences: whereas for Cassia cinnamon, an average of 3,000 mg coumarin per kilogramme of cinnamon was detected, the content for Ceylon cinnamon is usually well below 100 mg of coumarin per kilogramme of cinnamon. Consumers frequently using large quantities of cinnamon as a condiment should therefore opt for the low-coumarin Ceylon cinnamon.



Is the intake of coumarin from drugs comparable to that from cinnamon?

The value for the tolerable daily intake for coumarin was determined from the therapeutic application of coumarin-containing medicines. This is a legitimate approach, since the BfR found out on the basis of a human bioavailability study that coumarin is absorbed to a similar extent from the “natural product” cinnamon as it is from drugs. The notion that coumarin from cinnamon is less harmful, because it is not absorbed to the same degree from the plant matrix, is therefore erroneous.

In the Christmas season of 2005, a laboratory in Münster found surprisingly high coumarin levels, far exceeding the maximum permissible value, in 13 samples of cinnamon cookies of different manufacturers. Coumarin is an aromatic compound which is found in a number of plants such as woodruff, melilot and cinnamon and which can cause liver damage, especially in sensitive persons. While consumers were worried, experts had a major discussion on how serious the health risks posed by the consumption of cinnamon-containing products really is.

The BfR recommended limited consumption

In order to provide clarity, the BfR published a risk assessment of coumarin. As part of the assessment, BfR scientists confirmed the tolerable daily intake (TDI) for coumarin of 0.1 mg per kilogramme of body weight, a value which had already been derived by the European Food

Safety Authority. The BfR based its derivation on experience from the use of coumarin as a drug which had led to liver damage. Given the high coumarin contents measured in cinnamon biscuits, the BfR advised consumers to eat cinnamon-containing food in moderation.

New coumarin maximum values

Due to these toxicological insights, the BfR at the same time made a stand for a continued limitation of coumarin in cinnamon-containing food in the new European law on flavourings. Before the high concentrations in Cassia cinnamon became known, it was planned to cancel the maximum values for coumarin. Since January 2011, new maximum values have been in place which are different for different foods. The BfR is of the opinion that if these specifications are observed, the tolerable daily intake is not exceeded as a result of consuming cinnamon-containing foods.



Prof. Dr. Dr. Alfonso Lampen
Head of Department Food Safety



02



Small but dangerous – combating zoonotic pathogens

In 2002, the result of a study of broiler meat from Berlin-based retail businesses caused a stir: on average, 58 % of all samples were contaminated with *Campylobacter*, a bacterium that can cause severe diarrhoea in humans. The BfR had noted previously on the basis of routine surveillance that the pathogen may be spread through broiler meat. To estimate the risk for consumers, the BfR conducted a risk assessment. The main focus of this assessment was the possibility of spreading the bacteria from raw broiler meat to the prepared meal. Using a simulation model, the scientists inferred that roughly 47 % of all human *Campylobacter* infections in Germany can be attributed to broiler meat.

The BfR recommends internationally coordinated measures

The most common cause for the transmission of *Campylobacter* to the prepared meal is, in the estimation of the BfR, a lack of hygiene during the preparation of meals. It therefore recommends to consumers to roast broiler meat thoroughly and to observe basic hygiene when preparing meals. Moreover, it is important already to keep contamination with the pathogen low during animal production and at slaughter. Especially for broiler meat there is

an intensive European and even worldwide trade. Less than a third of the quantities consumed originate from Germany. For this reason, the BfR strongly recommends that the strategy for combating *Campylobacter* is coordinated internationally.

Successful battle against *Salmonella*

Apart from *Campylobacter*, *Salmonella* are among the most common causes of zoonoses. However, the number of cases of illness is decreasing rapidly. Whereas in 1990 almost 200,000 human infections were reported in Germany, that number was down to just under 25,000 cases of salmonellosis in 2010. This success was possible through a strict EU-wide control programme and through the work of the BfR which conducts analyses on the pathogen and studies on the spread of zoonoses, and prepares and supervises control measures. In contrast, *Campylobacter* bacteria are still common, as a national monitoring into broilers conducted by the BfR in 2008 showed. Over 62 % of broilers tested in slaughterhouses were contaminated with the pathogen. The scientists found the *Salmonella* bacterium in 18 % of of the slaughtered animals.



Prof. Dr. Bernd Appel
Head of Department
Biological Safety

What makes zoonoses so dangerous?

A serious problem with zoonoses is the increased development of antimicrobial resistances which more and more frequently make the use of antimicrobials in the treatment of diseases inefficient. For this reason, the BfR not only monitors the occurrence of the pathogens but also their resistance properties on the basis of a standardised monitoring programme. Another problem is that pathogens such as *Salmonella* and *Campylobacter* generally do not harm production animals. This means that without a laboratory analysis, they cannot be detected by either farmers or veterinarians. In addition, modern animal keeping offers a host of different entry path for the pathogens, for example the purchase of animals and feed from external sources or from the stable environment. This makes control for farmers correspondingly difficult.

What are zoonoses?

Zoonoses are infectious diseases which can be transmitted from animals to humans and, conversely, from humans to animals. They can be caused by bacteria, viruses, fungi and other types of pathogens. Well known examples of zoonoses include rabies, *Salmonella* infections and bird flu.



Dr. Margareta Büning-Fesel
Executive Chairperson of the "aid
info-service consumer protection,
food, agriculture"

"The BfR provides us with sound background information and scientific facts, which we translate into concrete recommendations for everyday nutrition as part of our communication. We received excellent support with our communication, for example, in the summer of 2011 for our online question forum on EHEC."



Dr. Helmut Tschiersky-Schöneburg
President of the Federal Office of
Consumer Protection and Food
Safety (BVL)

"The BfR and the BVL share their origins, i.e. they emerged from the same predecessor institution. Even though the two authorities have gone their separate ways for ten years now, the BfR continues to be our most important partner organisation. The success of one depends on the other. This is apparent both in everyday work and in times of dioxin and EHEC."



Kai Kupferschmidt
Biomolecular Scientist
Education and Science Editor
Tagesspiegel

"As a science journalist, it is my responsibility to rationally rank risks and adequately communicate them to the reader. That is one of the hardest parts of my job. No wonder that the federal government has entrusted this task to an entire agency."



Dr. Klaus Engel
President of the German Chemical
Industry Association (VCI)

"The BfR has become a widely recognised neutral authority with a high scientific reputation in the area of risk assessment. The continual improvement of the safety of their products is extremely important to chemical companies. With its independent scientific assessments, the BfR makes an important contribution to ensuring this safety."



Prof. Dr. Volker Moennig
Chairperson of the German
Veterinary Medicine Society

"The BfR is one of the key establishments within the network of veterinary science in Germany. Risk assessment is an indispensable discipline in our increasingly complex and interconnected world, and the development of scientifically based insights into actual or perceived risks is becoming more and more important for political decision makers as well as the public. We wish the BfR all the best and much success for the coming years."



Prof. Dr. Matthias Horst
General Manager of the German
Federation for Food Law and Food
Science (BLL)

"Food safety is a major concern for the public and the economy and is therefore given high priority both in politics and the media. Two essential preconditions for food safety are a risk assessment, at the highest scientific level, that is free of political, economic or even ideological influences as well as objective and easy-to-understand risk communication. The BfR stands for both these preconditions. In the course of its existence, it has earned great recognition. In as much as it provides long-term support for the work of the EFSA in the interest of a high safety level in the entire European community, the BfR is also an important pillar of the European food safety system."



Hubertus Primus
Executive Director of
Stiftung Warentest

"What poses the more severe health risks for consumers – the cleaning cloth in the kitchen or dioxin contamination in eggs? The Federal Institute for Risk Assessment has not always given the seemingly obvious answers and has thus contributed to changing the direction of many a debate. This has only been possible because trust, which is based on the competence and transparency of the institute's work, has been built up within the (specialist) public. The Federal Institute for Risk Assessment not only advocates these properties but actively lives them. Thus, it has made considerable contributions and provided major impulses for consumer health protection in Germany in general and the work of Stiftung Warentest in particular."



Prof. Dr. Roland Körber

Director of the Federal State
Laboratory Berlin-Brandenburg

“The competence of the BfR in all areas of consumer health protection is indispensable in our daily work. Through the wide range of personal contacts of our experts and study directors with BfR scientists, current problems in the assessment of concrete issues of food safety can be processed quickly and efficiently.”



Minister Gert Lindemann

Lower Saxony Ministry of Food,
Agriculture, Consumer Protection
and Regional Development

“When I look back on the past ten years, during which I was closely involved with the issues of food safety, I am pleasantly surprised to see how quickly after its foundation the BfR identified with its new tasks and – with the help of its experts – developed into an excellent partner. Apart from sound risk assessments which are necessary for proper administrative actions on the part of state authorities with regard to critical issues, I particularly appreciate the BfR’s far-sightedness with regard to future concerns. Time and again, you have succeeded in identifying the topics of the future and to create a platform where experts can discuss them, thereby ensuring that these subjects are dealt with early on. My wish for the future is that the BfR will continue to be available for sometimes critical but invariably constructive discussions and dialogue.”



Dr. Gibrfried Schenk

Managing Director of the Association for the Promotion of Sustainable Agriculture (FNL)

“Apart from the high level of scientific expertise of its staff, I especially appreciate the BfR’s exemplary commitment to public relations work. Thus a wide range of specialist events and publications are supplemented with a generally strong media presence as well as consumer events. In particular, I would like to emphasise the plant mazes for consumers that have been organised since 2009 and the participation of the BfR – which is especially important to us and is by now a tradition – in the Farm Experience of the International Green Week in Berlin.”



Dr. Bernhard Url

Managing Director of AGES – Austrian Agency for Health and Food Safety (AGES)

“Over the last ten years, you have become a European quality brand for scientific risk assessment, transparency and communication. As a ‘major player’, you have had a decisive influence on the harmonisation of risk assessment in Europe. Despite local particularities we have made significant progress in the area of consumer protection and thus contributed substantially to the European integration process. From an Austrian viewpoint, I would like to say a special thank-you to the BfR for its constant support and the open exchange in the course of our cooperation.”



Prof. Dr. Reinhard Burger

President of the Robert Koch Institute (RKI)

“The example of EHEC underscored the importance of the cooperation between the RKI and the BfR as the federal institute which acts as the centre for risk assessment of foods and the safety of consumers in Germany. Whenever such outbreaks occur which are caused by food, the BfR is our first point of contact. The shared goal of both institutes is to identify health risk for the population in good time and to prevent them.”



Dr. Hans-Joachim Götz

President of the German Association of Veterinary Practitioners (bpt)

“Whether it is avian influenza, the dioxin scandal or, most recently, resistance to antimicrobials: the BfR is one of the most important legislative advisors. At the same time, through its opinions, it ensures that critical public debates are based on facts. By keeping production animals healthy, veterinarians play an important part in the production of healthy food and make a vital contribution to human health by combating zoonoses on site. With its evaluations of the significance of real risks, the BfR provides important support to veterinarians in their daily work.”

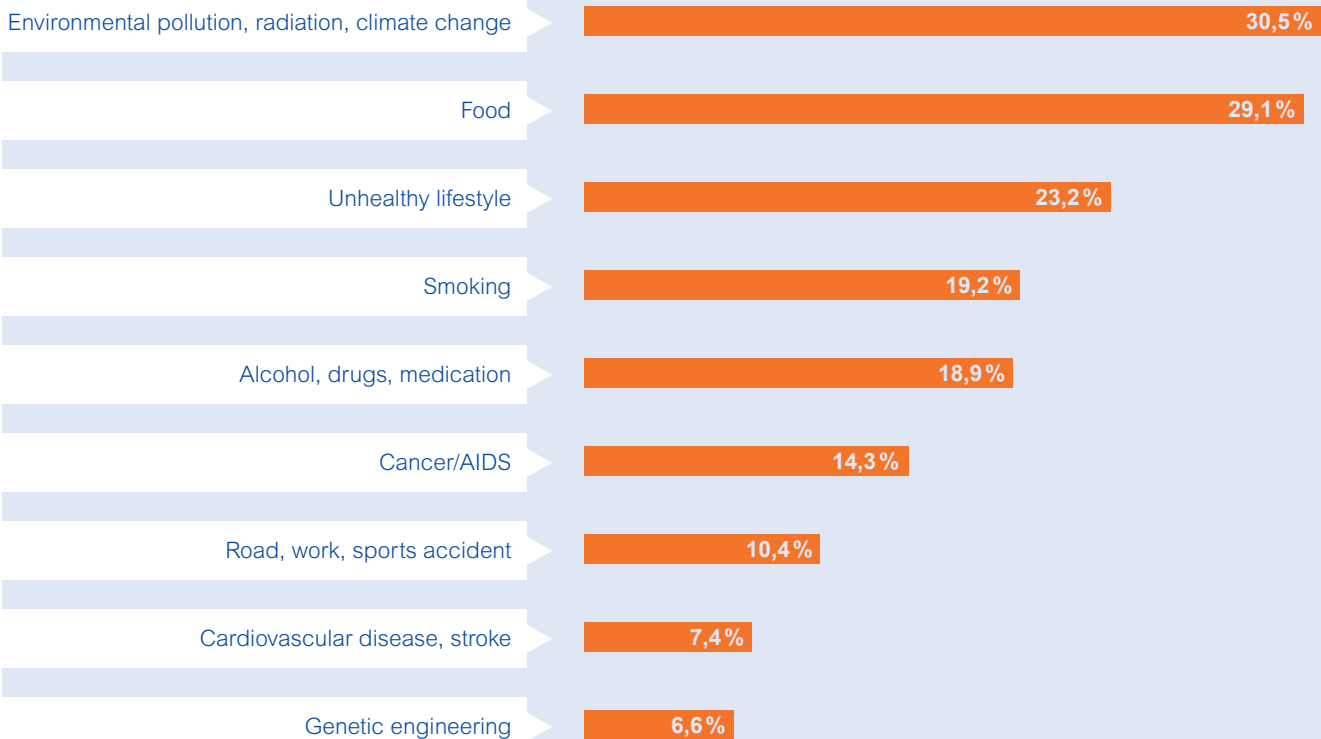
Risk communication – a demanding balancing act

Dioxin in eggs, EHEC germs in sprouts or plasticisers in toys – there is no shortage of warnings of problematic substances in food and consumer goods. Even the permanent presence in the media of a possible risk frightens many people. But what health risk is really posed by an egg that exceeds the limit value of three trillionth of a gramme of dioxin per gramme of egg fat? And how can you communicate to the public that a perceived risk in most cases has nothing to do with the effective risk? With its risk communication, the BfR has accomplished these difficult tasks for the last ten years.

Apart from the consumers, science, business, politics, the media, associations and non-governmental organisations are important points of contact in the dialogue with the public. In its risk communication, the BfR takes into account the often differing risk perception of its target groups. Thus for each risk assessment, all mentioned figures are contextualised in such a way that they remain meaningful to the public and hence also for non-scientists. All recommendations of the BfR are based on objective estimates which in turn invariably draw on the results of scientific investigations.

The risk perception of consumers

What issues pose the most serious health risks to consumers?
(open question, up to three selections possible)



■ consumer (n=779)

Source: Second evaluation on consumer awareness of the BfR, 2008 (www.bfr.bund.de)



*Modern analytics:
Blessing or curse?*

Why consumers often make incorrect assumptions about risks

Blessing and curse of modern analytics:

Through extremely sensitive analytical measurement methods, substances detrimental to health can now be detected in extremely small quantities. Modern analytics makes it possible to find unwanted substances in foods which in the past would have been declared as contaminant-free. Although such substances, due to their exceedingly low concentrations, hardly ever pose a harmfulness to human health, consumers often perceive their mere detection as a risk.

Limited portrayal of risks:

Many media are imprecise in their portrayal of risks. For example, if a headline reads “one hundred people ill from food poisoning”, this sounds very alarming at a first glance. However, such absolute numbers say nothing about the real extent of risk for consumers. To make a rational assessment, additional figures are needed, for example how many people ate the food concerned over what period of time. Even the statement “cancer risk has doubled” does not say much without supplementary information. After all, there is a big difference between the risk “only” going up from 0.001 to 0.002 and an increase from 5 to 10 per cent.

Elusive figures:

A limit value of 10^{-6} grammes for a critical substance means that a given product quantity must not contain more than 0.000001 grammes of it. This quantity is so small that it is hardly comprehensible for consumers. Illustrative comparisons facilitate comprehension of such data and should therefore always be provided along with such figures.

Everything technical causes fear:

Technically or industrially produced substances and products (especially chemicals) are almost always seen by consumers as more dangerous than natural substances. This despite the fact that many natural products too contain substances that are injurious to health. Such substances include hydrocyanic acid in bitter almonds and myristicin in nutmeg.



PD Dr. Gaby-Fleur Böhl

Head of Department Risk Communication

Why are risks perceived in so many different ways?

How big the risk seems depends on a number of factors. These factors include, for example, to what extent we are personally affected and whether the risk is also associated with a benefit. The controllability of a risk and the question whether or not the risk is taken voluntarily too play a role. Thus a smoker who makes a conscious decision to light a cigarette perceives his or her personal risk to be lower than a non-smoker who is involuntarily exposed to cigarette smoke.

Why is perception assessment so important for the work of the BfR?

The BfR has the task of informing the public about possible risks in foods and products. To make sure that the BfR neither causes panic nor indifference with regard to a substance that is possibly problematic in terms of its health effects, we must know what effects our messages have, so that we can choose the right “language”. For this reason, the BfR always makes a clear distinction between “risk” and “danger”, for example. Danger denotes the harmfulness of a substance in general – for example if it is caustic or carcinogenic. But a risk only arises when a person comes into contact with this substance.

The media play an important role in communicating BfR findings. How do journalists convey the often complex subject matter?

Our opinions provided with a completed risk assessment are very detailed. For this reason, they are always preceded by an easy-to-understand summary – our “grey box”. Additional press releases and FAQs facilitate communication of the issues. In addition, we are constantly in contact with journalists even outside crisis periods. That is when we can convey complex information calmly and in more detail in the course of background discussions.

Can consumers exclude their risk completely, if they follow the recommendations of the BfR?

Even if our recommendations are observed, risks can only be minimised but never entirely excluded. There is no such thing as zero risk for an individual. What matters is the daily personal risk balance. Those who smoke a lot, do not get much exercise and have a tendency to speed when driving are at a higher risk of an early death than a sporty non-smoker who uses public transport. Generally we would like to see a more thoughtful and especially a more relaxed attitude towards risks.



03



Useful dwarfs? – Nanotechnology conquers everyday life

Nanomaterials

The term “nanos” is of ancient Greek origin and means “dwarf”. One nanometre is one billionth of a metre. Nanomaterials with at least one dimension under 100 nanometres are called nano-objects. They can consist of particle, fibre or plate-shaped structures and, for example, be processed into extremely thin layers. In contrast, nanostructured materials usually consist of nano-objects which are connected to each other. Examples for nanomaterials are nano-silver, carbon nanotubes, titanium dioxide in nanoform and so-called nanoclay. Depending on how they are processed, nanomaterials can, for example, make car paint scratch-resistant, ties stain-resistant, or they protect against UV light in sunscreens.

How do the media and consumers view nanotechnology?

In 2007, the BfR published the results of a study on the portrayal of nanotechnology in the media. The evaluation of almost 1,700 articles shows that it is mainly the advantages of the technology that are covered. 70 % of the articles emphasise the positive sides of the products and processes. This picture also emerged from a representative BfR survey of consumers. Two thirds of all respondents see the opportunities of nanotechnology as more important than its risks and from such products expect improvements in many areas of life. However, this acceptance level strongly depends on the extent to which consumers come into contact with products containing nanoparticles. Whereas 86 % of participants are in favour of the use of nanoparticles in paints and varnishes, 84 % of respondents are against their use in food. The BfR is planning to analyse the portrayal of nanotechnology in the media and consumers' views to this topic again in 2012.

Nanotechnology is a generic term for a wide variety of different technologies for researching, processing and producing materials in the nanometre scale. With their help, structures, technologies and systems can be developed with entirely new properties and functions. Currently, nanotechnologies are used, for example, in paint and varnish, building materials, clothing and cosmetic products. According to the German industry, technologically manufactured nanomaterials are not used in food yet, however. Due to the advancing development of nanotechnology, increasing production quantities and hence a rise in the release of nanomaterials is to be expected.

Mandatory labelling for cosmetics and food

Even though nanoparticles are used in more and more products, little is known about whether their ingestion carries health risks. The BfR has been providing support with the developments in this area since 2007. In theory, free inorganic nanoparticles in particular could, due to their small size and high mobility, pose a risk. The BfR is not aware of a single case so far in which nanomaterials were shown to have caused damage to health. Nevertheless, cosmetics containing nanomaterials will, as of

2013, have to be labelled accordingly. In addition, the list of ingredients in food will have to include nanomaterials from the end of 2014.

Titanium dioxide – critical substance?

The BfR has conducted preliminary risk assessments for various nanomaterials including titanium dioxide which is used in nano form in sunscreens, for example. The decisive criterion for the assessment is whether and in what quantity particles enter the body and accumulate in certain organs. The studies consulted show that nanoparticle penetration of at least healthy skin is virtually non-existent. In experiments with mice, oral ingestion via drinking water led to changes in their genetic material. Titanium dioxide particles absorbed through breathing caused inflammation in the lungs of rats and in a long-time study even led to tumours. However, the doses used in these tests were very high. It is unclear whether these findings apply to humans. Overall, there are currently not enough meaningful studies about the behaviour of titanium dioxide nanoparticles in the body. At this stage it is not possible, therefore, to make a conclusive assessment of the possible adverse health effects of titanium dioxide in humans.



04

Plasticisers and Co. take the fun out of playing



PD Dr. Dr. Andreas Luch
Head of Department
Safety of Consumer Products

What sort of problematic substances can be present in toys?

The BfR for the most part addresses three substance classes. Firstly, there are allergenic fragrances used in dolls, cuddly toy animals and puzzles. Secondly, there are CMR substances, i.e. substances with carcinogenic (causing cancer), mutagenic (causing gene mutation) and toxic to reproduction (causing damage to embryos) effects which can be contained, for example, in rubber parts of toys. The third substance class are heavy metals such as lead and cadmium which are components used in some inks.

Every year, the European Rapid Alert System RAPEX receives about 2,000 messages pointing out a danger posed by consumer products. In the years 2008 to 2011, almost a third of all reports were related to toys. This means that toys have been the most frequently reported product category in recent years.

Children are especially at risk

Many plastic toys are characterised by their high contents of phthalates (plasticisers), which are toxic to reproduction, lead and banned azo colourants. While playing, such substances can be released from the material and absorbed by children, for example when they hold the toy in their hand or take it in their mouth.

BfR criticises new Directive

To protect children better, the European Parliament passed a new Directive on toys with stricter limit values in 2009. It notably refers to problematic compounds such as CMR substances (see interview), heavy metals and allergenic fragrances. The BfR criticises the standards as not being sufficient. The risk assessment of a host of critical substances shows that the defined limit values, especially for carcinogenic substances and some heavy metals, can still pose a health risk to children. From the viewpoint of the BfR, it is particularly important that the regulations for CMR substances

are not based on the contents but instead on the released quantities. Essentially, only this value is relevant for absorption into the body. The EU Commission is currently deliberating whether the limit values, for example for lead, cadmium and various CMR substances, should be lowered.

55 fragrances to be banned in toys in the future

Some fragrances in toys can cause allergies and are therefore especially problematic. Roughly two per cent of all children suffer from contact allergy due to such fragrances. Their skin reacts with redness and blistering and even inflammation. As of July 2013, 55 fragrances will be banned in toys due to their possible health effects, although trace amounts of up to 100 mg per kilogramme of toy will be permitted. The BfR was the first institution to develop, between 2008 and 2010, a special analytical method with which the release of 24 allergenic fragrances can be determined. Using this method, the BfR subsequently examined 49 scented toys. Findings: Almost three quarters of all analysed products contained allergenic fragrances. Some of them contained up to ten times the future limit values. The BfR criticises that the limit values laid down in the Directive on toys are too high and recommends to parents not to buy scented toys.





**Prof. Dr. Dr. h.c.
Thomas C. Mettenleiter**
President of the Friedrich Loeffler
Institute (FLI)

“We have been successfully working together with the BfR since its foundation; in relation to a number of different subjects, our fields of activity ideally complement each other. In the area of food, the BfR closes a previously existing gap, especially when it comes to risk assessment through certain substances. It thereby makes an important contribution to consumer protection.”



Prof. Dr.-Ing. Matthias Kleiner
President of the German Research
Foundation (DFG)

“The DFG pursues goals very similar to those of the BfR, most notably through a number of its Senate Commissions: for the benefit of human health, scientific assessments are conducted which primarily serve the purpose of providing information and advice to Parliament and relevant authorities. This is done in conjunction with the BfR, representatives of which serve on the Commissions. This interaction ensures that exchange takes place on all the important questions of consumer health protection and risk assessment of substances, enriching both institutions.”



Dirk Radermacher
General Manager of the German
Association of the Spice Industry

“Our image of the BfR is ambivalent: we often do not agree with the BfR’s health assessments of ingredients of spices. In our opinion, the view is too much limited to the active substance without taking into account the overall matrix. In the case of coumarin, this led to a situation where a traditional German Christmas biscuit, i.e. cinnamon cookies, were reduced to trivial sugar biscuits. But in the scientific debate with NGOs who, in their own campaign interest exaggerate the spectacular results – for example of pesticide residue studies and make them into dubious press releases – we greatly appreciate the strictly scientific and factual BfR opinions. – This is our subjective view of the objective work of the BfR.”



Prof. Eberhard Haunhorst
President of the Office of Consumer
Protection and Food Safety
of Lower Saxony (LAVES)

“In the BfR, the LAVES has, over the last ten years, been able to count on a reliable partner authority in the capital city. With its sound assessments, this partner authority supports our daily supervisory work and has thus made a decisive contribution to overcoming crises in the federal states. This was most impressively demonstrated in the course of the dioxin issue and the EHEC outbreak in 2011. We would like to take this opportunity to thank the BfR for the fruitful cooperation based on trust and loyalty and look forward to continuing our joint efforts.”



Dr. Hanns-Christoph Eiden
President of the Federal Office for
Agriculture and Food (BLE)

“Consumer health protection is a subject which will always be topical. For this reason, it is all the more important that scientifically sound analyses are carried out and that universally valid, official risk assessments are deducted therefrom. They provide the basis for efficient and essential coordination at the federal level when it comes to consumer health protection in Germany. The BfR has made an important and indispensable contribution here. The latest occasion on which we made this positive experience was the joint management of the EHEC crisis. I wish our kindred spirit all the best for the future.”



Univ.-Prof. Dr. Günter Klein
Director of the University of Veterinary
Medicine Hannover, Institute
for Food Quality and Safety

“The BfR is the most important neutral authority on risk assessment of zoonoses in the food chain. Expert discussions at the BfR with all involved circles in particular contribute to finding solutions to difficult questions. I have worked with the BfR as part of diverse scientific cooperation projects since it was founded. The scientific exchange with BfR staff specialising in the same field has been very intensive and invariably pleasant from a social viewpoint.”


Marc Mortureux

General Director of the French agency for food, environmental and occupational health safety (ANSES)

“BfR represents one of the most complete and efficient institutes within the European framework. In order to protect the consumer’s health, it deals with risk assessments, health assessments, research and reference either with food or non-food products. For the ANSES, BfR is one of the main European partner through its action in protecting and informing the consumer, identifying new health risks and its deep willingness of cooperation with institutions involved in consumer health protection.”


Dr. Gisela Runge

Scientific Manager of the Association of the German Dairy Industry (MIV)

“Our association has appreciated the strong scientific competence of the BfR for the last ten years. In a way that is unique in Germany, the institute combines all the key points of consumer health protection, i.e. research, assessment and communication of potential risks. As such it is a success story. One aspect worth mentioning is the active dialogue between the dairy industry and BfR representatives at all levels. The BfR is thus a model for the whole EU.”



Prof. Dr. Monika Schäfer-Korting
Chairperson of the Scientific Board of the BfR

“The BfR fulfils important tasks in consumer health protection in Germany and Europe. Because of the scientific work done at the institute, the BfR is both a nationally and internationally sought after cooperation partner for tertiary and non-tertiary research institutions as well as sister institutes within the European Union. In addition, providing advice to politicians, the BfR needs a strong scientific foundation. The Scientific Board gives assistance in building up this foundation. We wish the BfR continued success in coping with its diverse tasks at the top science level.”


Renate Künast

Chairperson of Bündnis 90/Die Grünen
Former Minister for Consumer Protection

“Setting up the BfR was the logical consequence after the BSE crises and other incidents at the time. The new idea was: scientific expertise is strengthened – free from implementation worries and costs. ‘Safety has priority.’ The safety checks for food, consumer health protection and toys are more than just expertise – I appreciate them, because they provide helpful and concrete information to consumers.”


Dr. Thomas Janning

Managing Director of the German Poultry Association (ZDG)

“The BfR has, in the ten years of its existence, proved to be an extremely competent point of contact for the ZDG. Both, the umbrella organisation and the member companies of the German poultry industry perceive the exchange on questions about food products, food safety and consumer protection as valuable and constructive. In numerous cases, the scientific results produced by BfR researchers resulted in relevant and practical benefits for the poultry industry.”

photo: Frank Ossenbrink


Dr. Helmut Born

General Secretary of the German Farmers' Association

“I was privileged to play a small part in the emergence of the BfR in the Von Wedel Committee on the occasion of the BSE crisis. After some initial difficulties that were only to be expected, the BfR is now well on track to blaze the way into the public sphere for scientifically sound risk analyses. The BfR should never lose sight of this goal. For example, farming families have experienced first hand how alleged and actual risks of pesticide residues are often confused in public perception. In addition, our wish for better coordination of activities at state and federal level under the roof of the BfR has not been granted yet. However, risk communication can only work really well, if it is focused and noticeable.”



05



Risk assessment without animal experiments – the ZEBET

In German laboratories, about 2.9 million animals are used for experiments and other scientific purposes per year, mainly in the research on diseases. But even for toxicological studies of new drugs and chemical substances, animal experiments are conducted. These tests are legally required as part of the approval procedure for new products. However, the law stipulates to replace animal experiments to the greatest extent possible by alternative methods. To boost the development of alternative methods, the Center for Documentation and Evaluation of Alternative Methods to Animal Experiments (ZEBET) was founded as early as 1989. Since 2002, the ZEBET has been part of the BfR.

Skin models instead of rabbits

For this purpose, ZEBET employees document and assess alternative methods developed worldwide, ensure the progress of validation studies, and conduct their own experimental investigations – with great success. Thus between 2004 and 2007, the ZEBET coordinated a study for the EU Commission in

which a model of human skin was developed which permits testing the skin-irritation properties of products. Before that, this test had to be conducted using rabbits, often implying suffering. Since 2010, this procedure has been adopted by the Organisation for Economic Co-operation and Development (OECD).

Further alternative procedures developed and coordinated by the ZEBET

- To test eye irritation properties of chemical substances the EU has accepted four testing methods not using animals as alternatives to the rabbit test by now. Two of these are now used by the OECD member states as standard tests.
- Possible phototoxic reactions provoked by cosmetics and drugs on the skin (swelling, blistering etc.) were formerly used to be tested on mice and guinea pigs. Together with manufacturers, the ZEBET developed a cell culture test which has replaced animal experiments completely in this area since 2004.

Three questions to ZEBET

Why are animal experiments conducted at all?

Especially in mammals, many metabolic processes and organ functions are similar to those of the human body. For this reason, it is possible to transfer, up to a point, certain toxicological effects of a given substance, for example. Such experiments enable scientists to make statements on the risk potential of new drugs, products or specific substances.

How long does the development of an alternative procedure take and how is this done?

Whether or not a new method completely replaces an animal experiment is tested through an internationally recognised and standardised procedure. The ZEBET played an important part in the development of this concept. The first step is to conduct preliminary studies which are then gradually refined. This process ends with recognition by the OECD member states. The process can take several years. But still: before 1989, there was no recognised toxicological testing method which could do without animals. We have come a long way since then.

Has the work done by the ZEBET led to a reduction in the number of test animals?

The Ministry of Consumer Protection every year compiles the data to establish how many test animal applications were lodged for research projects in Germany. Both within Germany and the EU, the trend is to increasingly dispense with experimental animals in toxicological tests. At the same time, however, more test animals, particularly mice, are needed for research on diseases. To counteract this trend, there are institutions such as the ZEBET as well as specific research funding programmes and animal welfare awards.



The results of the BfR on environmental contaminants in foods are summarised in the BfR brochures "Cadmium in Food" and "Absorption of Environmental Contaminants through Food" at www.bfr.bund.de (in German only).

06



Small quantities, big challenge – environmental contaminants in food

One important task of the BfR consists in evaluating the health risks posed by substances from the environment which can be taken in from food. Heavy metals, dioxins and solvents are examples of these so-called environmental contaminants. They naturally occur in the environment or get into the air, water and soil as a result of industrial processes – and hence into the food chain. Since environmental conditions, industrial production processes, and people's consumption habits are all subject to constant change, it is necessary to regularly adjust statements made on the intake quantity of these substances.

Eating habits and contamination data determine exposure

In 2008, the BfR-coordinated project LExUKon (a German acronym that stands for "Lebensmittelbedingte Exposition gegenüber Umweltkontaminanten", i.e. Food-related Exposure to Environmental Contaminants) was launched. Its goal was to evaluate the actual dietary exposure of environmental contaminants from food and the resultant health risk for

consumers. This exposure evaluation was based on the data of the National Nutrition Survey II provided by the Max Rubner-Institute. It summarises the results of a countrywide survey of approximately 20,000 persons who, among other things, provided information on their eating habits. These data were combined with the concentrations of environmental contaminants in foods obtained from food monitoring, a programme of the competent state authorities coordinated by the Federal Office of Consumer Protection and Food Safety as well as data from the literature. In this way, it was possible to determine the exposure quantities for all types of food and environmental contaminants which provide the basis for the risk assessment.



Dr. Monika Lahrssen-Wiederholt Head of Department Safety in the Food Chain

Why are environmental contaminants problematic in the first place?

Heavy metals such as lead and cadmium accumulate in the body. In higher concentrations, lead can cause damage to the nervous system and long time exposure leads to osteoporosis. In addition, dioxins and PCB can have unwanted effects on the immune system, hormonal balance and reproductive functions. Cadmium damages the kidneys.

What are the most important insights yielded by the LExUKon project?

Vegetables and cereals, especially wheat, i.e. bread and muesli etc. appear to represent the main sources of cadmium occurrence. Lead predominantly originates from beverages and cereal products. Fish is an important source of methyl mercury, whereas dairy products and meat are representing main sources of dioxins and PCB. Altogether, the daily consumption of food significantly contributes to a person's overall exposure – even if individual foods contain relatively small amounts of environmental contaminants.

How serious is the health risk posed by environmental contaminants? Are there special risk groups?

The ascertained average intake quantities are below the currently applicable TWI values, i.e. the tolerable weekly intake values for substances hazardous to health. Frequent eaters of certain foods may have a higher risk. Thus a nutrition study showed that the elderly eat more fish on average and as a result take in more mercury. Vegetarians too are considered to be high users, since they eat above-average amounts of vegetables and cereals. The quantities of cadmium and lead that they take in are correspondingly higher.

Five steps towards more transparency: Illustration of the risk assessment procedure using the example of dioxin



BfR has published the principles of its assessment work in the brochure "Guideline on Health Assessments" at www.bfr.bund.de



At the end of 2010, contamination of plant-based feed fat containing dioxin was discovered in Schleswig-Holstein. The fat was used in mixed feed products for fattening pigs and chickens. In some samples, the dioxin contents established in the meat of pigs and laying hens as well as eggs were above the defined maximum contents. The BfR then conducted a risk assessment, i.e. an estimation of the potential risk to consumer health. The procedure consists of five individual steps and in principle can be applied to any substance.

From a possible danger to objective assessment –

Simplified description of the risk assessment procedure using the example of dioxin in eggs and pork

Step 1: Hazard identification

What are dioxins?

- Dioxins (and dioxin-like polychlorinated biphenyls, dl-PCB) are chlorinated hydrocarbons which accumulate in the fatty tissue of animals and humans.
- They are unwanted by-products which can be formed as part of certain industrial processes as well as during combustion (e.g. when domestic or special waste is burned).

Step 2: Hazard description

What concrete hazard is posed by dioxins?

- Long-term inflammatory skin changes (chloracne) and changes in fat metabolism in case of exposure in high (single) doses.
- Chronic effects observed in animal experiments included disorders of the reproductive, immune and nervous system as well as hormonal imbalance. Various dioxins are considered to be tumour promoters.
- The tolerable daily intake for dioxins is 2 pg per kilogramme of body weight.

Step 3: Exposure estimation

What is the extend of dietary intake of dioxin from eggs and pork consumption?

- Based on the number of eggs that consumers eat on average, they only ingest about 4 % of the tolerable daily intake from the eggs contaminated with dioxin in December 2010. For contaminated pork, it is approximately 1 % of the tolerable daily intake.
- In case of high consumption, about 10 % of the tolerable daily intake is reached for eggs and 2 % for pork.

Step 4: Risk characterisation

What is the likelihood of health effects and how severe is the expected health hazard?

Given the calculated extent to which the tolerable daily intake is reached for medium and high consumption of eggs and pork, no health risks are to be expected for adults and children.

Step 5: Assessment report

Representation of the four assessment steps, possible uncertainties, conclusions and recommendations on how to handle the risk.

The BfR comes to the conclusion that neither an immediate nor a long-term health risk is to be expected for the consumer.



07

More harmony in Europe – developing standardised criteria for pesticide and biocide authorisation



Are hormonally active substances permitted in pesticides?

There are substances in pesticides and biocides which can also have an impact on the hormonal system of mammals. If they have an adverse effect, they are called endocrine disruptors. In accordance with the Plant Protection Act, the effects on the hormonal balance of humans and animals of active substances with suspected endocrine disrupting properties had to be assessed as part of the German authorisation procedure from as early as 1998. According to the new EU regulation from 2009, endocrine disrupting properties are from the outset an exclusion criterion for the approval of active substances. The European Commission is to suggest measures to establish concrete scientific criteria for determining properties with endocrine disrupting effects by 2013.



Dr. Ursula Banasiak
Head of Department
Chemicals Safety

Up until ten years ago, the assessment of the health risks of pesticides and biocides was predominantly the task of national authorities and institutes. Authorisation procedures and testing criteria were generally the responsibility of the individual member states of the EU, and there were significant differences in terms of their regulations. As a result of the harmonisation of legal specifications for chemicals safety, assessments of the active substances in pesticides and biocides are meanwhile exclusively conducted at the European level. An important requirement for this change was the development, jointly between the EU member states and the European institutions, of standardised concepts for the health risk assessment of chemicals. Especially in the area of endocrine disrupting properties of active substances in pesticides and biocides, the BfR has made a significant contribution to drawing up a scientific concept. For a long time, the BfR has been committed to a high EU-wide uniform standard for the assessment and approval of these active ingredients. It is a central and legally assigned task of the BfR to assess the health risks of pesticides and biocides.

Suggestions for the assessment of substances with endocrine disrupting effects within the EU

It is one of the central requirements for the authorisation of pesticides and biocides that they must not have any harmful effects on human health. This is a mandatory requirement of the chemicals legislation at EU level. This means that all active substances must be comprehensively tested for their toxicological properties. Active substances deemed to be harmful to health include substances with hormone-like effects, among others. If it is proven that they have an adverse effect on the human hormone system, they can not be approved and authorised. Since 2008, BfR scientists have been intensively engaged in the issue of such “endocrine disruptors” for human health. Their aim was to develop scientifically sound criteria for the assessment of the health effects of such substances at European level. The tiered approach drawn up is currently being tested using different chemicals and is discussed with other EU states and the Commission.



08

Recognising, assessing and preventing poisonings – the Documentation and Assessment Centre for Poisonings



Prof. Dr. Matthias Greiner
Head of Department
Scientific Services

How are poisonings documented and assessed by the BfR?

The basis for the unique documentation and assessment system for health impairments through chemical products and substances is provided by the BfR poison information database. It contains the product formulas of dangerous preparations as well as report data on cases of poisoning which the BfR assesses on the basis of recognised criteria of clinical toxicology. Once a month, product formula updates are sent to the nine Poison Information Centres in Germany which use the data for around-the-clock emergency advice in the event of poisonings. Since it became compulsory to report such cases in 1990, over 250,000 documents have been filed, and every year tens of thousands more are added. Due to the positive experiences, other European states too are planning to compile a database following the German model developed at the BfR.

Paints, detergents and other chemical substances again and again lead to poisoning, especially in infants. Physicians in Germany, when treating such a poisoning incident, have a legal obligation to pass on important information connected to the case to the BfR. This report must include a description of how the accident happened, the quantities ingested, symptoms presented and development of the illness. In addition, manufacturers of detergents, washing and pesticide products are legally required to inform the BfR of the type of substances contained in their products. All information is centrally collected in the BfR's Documentation and Assessment Centre for Poisonings. In the centre, staff notify information of poisonings and product formulations for medical emergency advice, assess the associated human health impairment, document the data in a poison information database and finally inform the public of any consumer risks.

Investigating poisoning risks

With this task, the BfR plays an important role in consumer protection. Scientists collect and document the medical reports according to standardised criteria, thereby evaluating the frequency and severity of all poisonings reported in Germany. The BfR investigates especially striking cases or series of cases and assesses possible health risks. Important observations are published as press releases,

publications or – in case of identified risks – in the form of rapid communications to manufacturers, ministries and industrial associations. Having evaluated more than 65,000 cases, the BfR succeeded in identifying products and chemical substances whose risk potential has hitherto been underestimated. The information helps to assess possible poisonings in humans correctly and to infer preventive measures.

Example: lamp oils

Over several years, there was an increase in the number of incidents observed in children of poisoning with paraffin-containing lamp oils. The BfR investigated these cases and conducted various risk assessments. Findings: For one- to three-year-old children, lamp oils are among the most dangerous of all household chemicals. Already a small sip of lamp oil – or even just sucking on a lamp wick – can lead to life threatening lung damage. Through child-proof caps, warnings on the packaging and an EU ban on coloured or scented lamp oils in 2000, the number of poisoning incidents went down considerably. Nevertheless, even after this regulation came into effect, the BfR still recorded serious cases of poisoning and deaths from the non-banned clear lamp oils. For this reason, Germany, on the advice of the BfR, pushed for further tightening of the regulations which have been in force EU-wide since the end of 2010.

Further cases of poisoning from consumer chemicals

- 2006:** Lung damage through nano-sealing sprays: 150 cases, of which 6 pulmonary oedemas
- 2010:** Inner chemical burns through the detergent PorCöz: 130 cases
- 2009/2010:** Accumulation of carbon dioxide poisoning as a result of indoor grilling: 16 cases, of which 13 pulmonary oedemas
- 2001–2010:** Chemical burns of the eye through accidents involving car batteries: 1,118 cases in total, out of which 56 with moderate severe to severe health damage



Hans-Michael Goldmann (FDP)
Chairperson of the Committee on Food, Agriculture and Consumer Protection by the German Bundestag

“I am still enthusiastic about the high professionalism of the BfR which is coupled with adroit handling and presentation in relation to the public and politicians. In the course of my work as Committee Chairperson, I have frequently been in contact with the BfR. During public hearings and expert discussions, the specialists of the institute answered all questions on current and often contentious issues. In addition, I have been able to observe the work done on site on the occasion of numerous visits and was impressed with the complex and demanding standards that the institute sets for itself and especially its employees. I can only encourage the bright minds within the institute to keep up their committed, self-motivated and flexible approach to work.”



Thilo Bode
Managing Director of foodwatch

“The BfR is most valuable for consumers, if its actions and communications are entirely independent of political and economic influences – there should not be any doubt about that in the future.”



Michael Miersch
FOCUS, Head of Department Research, Technology and Medicine

“Public perception of risks often degenerates into hysteria in Germany. The BfR offers factual orientation within the chaotic voices of alarmists and warns consumers if necessary.”



Josef Sanktjohanser
President of the German Retail Federation (HDE)

“For us, the BfR is the most credible authority when it comes to the facts. Our customers and companies trust the BfR.”



Hans-Christoph Erling
Chairperson of the German Milling Organisation

“Ultimately, food safety can only be provided by food manufacturers. The mills do everything required and sensible to ensure that their products are safe. However, all these efforts are in vain, if consumers do not trust the work of a company and the supervisory authorities. We trust the BfR as a neutral authority that assesses risks at the top scientific level and communicates them in a way that is easy to understand. It is to be hoped that the BfR will further enhance its reputation – even among unusually critical people – and can thereby continue to provide orientation in the area of food safety.”



Manfred Nüssel
President of the German Raiffeisen Association (DRV)

“Apart from scientific analysis and assessment, the risk communication provided by the BfR is of central importance to us. The companies of the DRV have used the valuable information of the BfR for years to provide advanced training for their employees and to educate customers. We hope that in future politics and the media will make more use of your valuable work – not only after the successful management of crisis situations.”



Dr. Hermann-Josef Nienhoff
Managing Director of QS Qualität und Sicherheit GmbH

“During crises, uncertainties and risks become apparent. Thus they often provide the fertile soil for new developments. For example, the mandate to the BfR to objectively and independently assess health risks to consumers emerged from the BSE crisis. QS was asked to reduce risks across all stages by means of consistent quality assurance along the entire value-added chain. The assessments of the BfR enable the economy, administration and politics, and notably us as well, to realistically evaluate the risk situation. This applies to acute incidents and forward-looking measures taken in quality assurance.”



Geert Dancet

Executive Director of the European Chemicals Agency (ECHA)

“As the Executive Director of ECHA, I would like to acknowledge the extremely useful contributions of BfR to the work of the Agency, and in particular to the Committee for Risk Assessment (RAC). The contributions of the RAC Member Dr. Agnes Schulte, a BfR staff, have been essential in achieving the top scientific quality of the RAC opinions; an essential achievement for the Agency. This cooperation has been reinforced during 2011, as BfR hosted in Berlin the Joint Workshop with the European Commission, EFSA and ECHA on the classification and labelling of active substances in Plant Protection Products. The workshop report has been recently published by the Commission and, in close cooperation with the EFSA, we are already in the implementation phase. The leadership of BfR in the Organising Committee was essential for the workshop outcome. I am sure it will continue, facilitating the coordination and mutual understanding among the MSCAs with the European Agencies and the Commission.”



Prof. Dr. Hubert Weiger

Chairman of Friends of the Earth Germany (BUND)

“We all benefit from the competence and scientific expertise of the BfR, for it is important to the BUND as well to draw attention to shortcomings in consumer health protection. Even if our own conclusions are not always identical to those of the BfR, our differing assessments should constructively complement each other, in the interest of the consumer.”



Dr. Adolf Kler

Chairperson of the German Herbal and Fruit Infusions Association

“The opinions of the BfR meet with great acceptance among consumers and also offer our member companies a valuable basis in the assessment of the safety of the relevant products. The great competence of the BfR is the result of open exchange with experts from all involved disciplines. We hope that the BfR succeeds in pursuing this comprehensive approach in future too, despite the steady increase in contamination.”



Brigitte Behrens

Managing Director of Greenpeace

“Greenpeace and the BfR have a very changeable relationship – we certainly never get bored with the BfR. At the heart of our debate is the consistent implementation of the precautionary principle about which in some respects we have very different and in others very similar opinions. It is good to see that opinions can change at times and that some of our demands are heard.”



Gerd Billen

Executive Director of the Federation of German Consumer Organisations (vzbv)

“The foundation of the BfR ensured that scientific insights are the basis for risk communication with consumers and decision makers. The BfR is the main support pillar of consumer protection. I wish the institute the confidence to tackle politically sensitive subjects and to put them on the agenda. In so doing, the BfR should in future also make use of the innovative possibilities of consumer dialogue.”



Klaus Reingen

General Manager of the Association of the German Confectionery Industry (BDSI)



Prof. Dr. Reinhard Matissek

Director of the Food Chemistry Institute of the BDSI (LCI)

“For the BDSI and all its member companies, food safety and quality is a central concern which, within the association's own food chemistry institute, has been dealt with successfully for over 60 years. We appreciate the BfR as our competent point of contact at the level of scientific risk assessments and wish the institute a 'steady hand' in all its assessments and decisions.”



09



Ensuring a healthy start in life – the National Breastfeeding Committee

Questions to the Breastfeeding Committee

What are the obstacles that lead to women discontinuing breastfeeding prematurely?

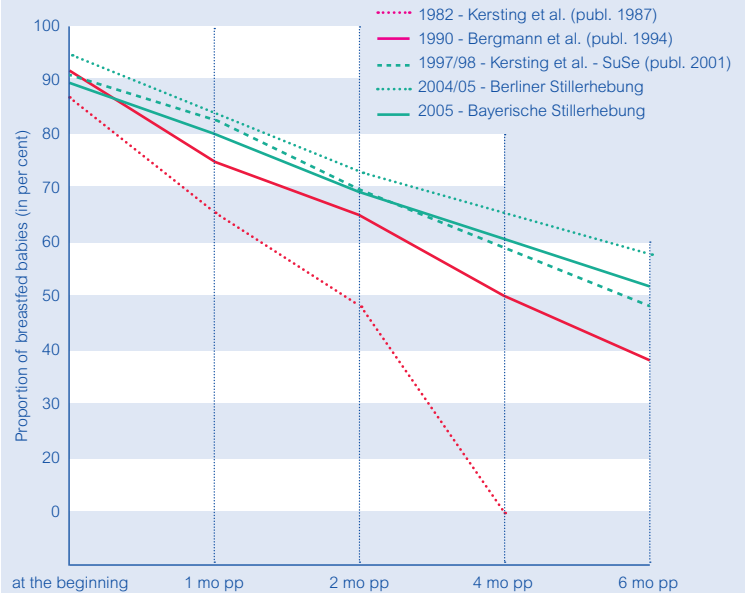
Often it is problems with the breastfeeding technique leading to blocked milk ducts, pain or inflammation of the breast. This makes it hard for mother and child to persevere, if it does not seem to work right away. Only in rare cases are these problems caused by anatomical particularities, for example if the palate of the baby has an unusual shape. Something many people do not know: if as a mother I go back to work, the Maternity Protection Act grants me breaks during working hours for breastfeeding.

What is the German breastfeeding rate compared to other European countries?

Scandinavian countries, especially Norway and Sweden are still a great role model, since the breastfeeding rates there are significantly higher than in Germany. Since the 1970s, the breastfeeding rates have clearly increased in Germany, however – cause for optimism for future developments.

The breastfeeding situation in Germany: a great deal remains to be done, but the trend is an upward one!

Since 1982, a number of studies on the breastfeeding situation in Germany have been conducted. Although these show that more than half of the mothers wean their children at the end of the sixth month, at least many more children are now breastfed for between four and six months than 20 years ago.



Breastfeeding is the best option for both mother and child. Nevertheless, many mothers breastfeed their babies for a period shorter than that recommended. For this reason, the National Breastfeeding Committee was founded back in 1994; it became part of the BfR in 2002. Its goal is to promote breastfeeding in Germany. For this purpose, it provides comprehensive information to medical professionals such as doctors, midwives and nurses but also directly to young mothers and their partners.

Hand in hand with BfR scientists

The National Breastfeeding Committee gives also advice to policy makers. It advises the federal government and actively develops political courses of action. It also implements and coordinates measures for promoting breastfeeding and for overcoming existing impediments to breastfeeding. On the other hand, BfR scientists also supervise the activities of the Breastfeeding

Committee by conducting risk assessments on possible residue and contaminants in breast milk on a regular basis.

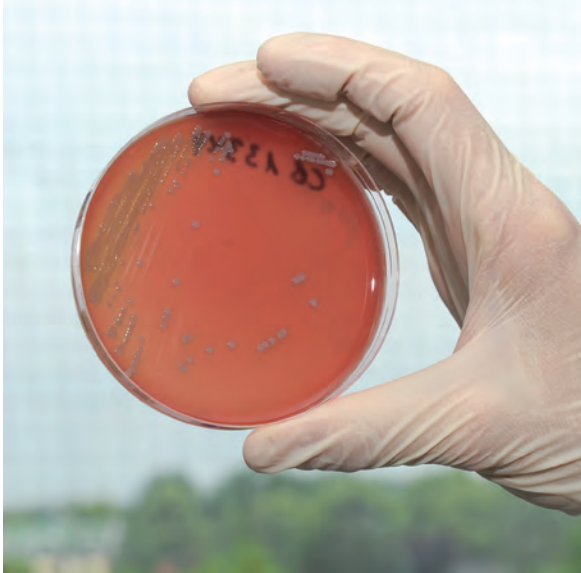
Standardised monitoring for Germany

In 2004, the National Breastfeeding Committee was significantly involved with the development of the EU action plan for protection, promotion and support of breastfeeding in Europe. In addition, the Committee supports the project “Young Family Network” initiated by the federal government in 2010. Another focal point of the work of the Committee is drawing up a concept for a national system for monitoring of breastfeeding in Germany. Standardised monitoring is necessary to objectively assess the effectiveness of measures to promote breastfeeding. The results of studies conducted so far (see graph) are difficult to compare, since they used different methodologies.



10

10



EHEC outbreak 2011 – detective work in very busy times

In May 2011, Germany saw an above-average number of cases of severe intestinal infections caused by EHEC pathogens. Within one week, 900 cases were reported – as many as usually in one year. In contrast to the normal pattern, the main group affected this time was adults, with more women coming down with the symptoms than men. There was a great deal of uncertainty among consumers, all the more, as the quest for the cause of the infection proved difficult. Together with national and international health and consumer protection authorities, the BfR investigated the cause of the outbreak. At the end of July, Germany's largest food-borne disease outbreak was solved. **Chronology of events:**

Beginning of May 2011

An increased number of people fall ill with EHEC infections in Germany.

20 May 2011

The Robert Koch Institute (RKI) informs the BfR about an increase in the incidence of EHEC cases.

25 May 2011

Patient interviews indicate that infections are connected with the consumption of tomatoes, cucumbers and green salads. The BfR and the RKI therefore recommend not to eat these foods raw.

30 May 2011

The National Reference Laboratory for *E. coli* at the BfR discovers that the EHEC pathogen type on Spanish cucumbers differs from the EHEC type of infected patients. Cucumbers from Spain were initially considered as the possible trigger, since EHEC pathogens had been found on them.

3 June 2011

An EHEC task force composed of representatives of the BfR, the RKI, the Federal Office of Consumer Protection and Food Safety (BVL), the German federal states and the European Food Safety Authority (EFSA) is set up.

5 June 2011

An analysis of flows of goods leads to a sprout producer in Lower Saxony. The BfR provides support to the federal state in investigating the leads.

10 June 2011

The BfR, the BVL and the RKI recommend that consumers refrain from consuming sprouts and rescind the earlier consumption recommendation for cucumbers, tomatoes and green salads.

24 June 2011

In France too, there is an increase in EHEC infections following the consumption of raw sprouts.

26 June 2011

The EU Commission instructs the EFSA, with the involvement of the BfR, to combine the results from Germany and France. Findings: in both cases, it is highly likely that the cause was fenugreek seeds imported from Egypt.

30 June 2011

The BfR publishes provisional results on the significance of these sprouts relating to the outbreak in Germany. Due to the results, the competent Germany supervisory authorities order the withdrawal of the affected fenugreek seed batches.

5 July 2011

The BfR publishes a risk assessment of the EHEC outbreak and confirms: it is highly probable that the outbreak was caused by fenugreek seeds imported from Egypt and sprouts cultivated from these seeds.

6 July 2011

The European Commission orders the withdrawal and non-harmful destruction of three batches of fenugreek seeds. In addition, it imposes an import ban on certain types of seeds from Egypt.

21 July 2011

The BfR assesses the risk potential through possible cross-contamination with other batch charges. The BfR, the BVL and the RKI thereafter issue a more specific statement: consumers should continue to refrain from eating raw fenugreek seeds imported from Egypt as well as raw sprouts and shoots produced from them.

End of July 2011

There have been no new cases of illness in connection with the current outbreak for three weeks. The EHEC outbreak is deemed to be over and solved.

Professor Dr. Dr. Andreas Hensel,
President of the Federal Institute for
Risk Assessment



Risk assessment by the BfR – what will the key issues be in the future?

In the course of its ten-year existence, the BfR has collected innumerable facts and insights, which are indispensable for the assessment of health risks. However, every good scientist knows: knowledge is dynamic. What appears as irrefutable today may turn out to be wrong tomorrow. This awareness has always played a fundamental role in the work of the BfR – and this will continue to be the case in the future. What this means in concrete terms is that our scientists will always base their risk assessments on the latest available scientific knowledge. If new insights are gained, these will automatically be incorporated in the assessment work, and this can certainly lead to a fundamental change for a given recommendation. The top priority of the BfR is, now and in future, the adoption of an objective and independent view of science.

Taking perceived risks seriously

Risks perceived by consumers are occasionally derided by experts. Nevertheless, the BfR will continue to take them very seriously. For in the last analysis, the measure

of uncertainty of the population not least reflects the quality of the work done by the BfR. If a risk negligible from an expert's point of view nonetheless causes fear, this is a challenge for us to put the perceived risk into its proper context by means of clear and easy-to-understand information. In other words: the BfR will continue to gear its communication to the level of existing knowledge of its target audiences.

Risk communication as a continuous and interactive process

The dialogue with the various target groups of the BfR will continue to be an important factor in realising this goal. These target groups include national and international ministries and authorities, scientific institutions and consumer associations as well as the world of business and the media. In communicating risks, we often go far beyond pure information. The aim is to talk to the public in good time about possible health risks and about our insights and research findings. That way we can, where appropriate, detect any perceived risks and either refute or corroborate them with scientific facts. Close cooperation with the media will continue to have top priority in this process.

Further strengthening cooperation

Smooth cooperation between politicians, authorities and institutions of consumer health protection is the key to finding quick solutions to acute crises. The EHEC outbreak in 2011 was a prime example of this. A quick investigation depends on the cooperation of the employees of the districts, the German federal states, the federal government and the EU who, when it comes to establishing the cause of a given phenomenon, must all work together closely. This cooperation must be strengthened further – also within the European Union.

There is no such thing as absolute safety

The EHEC outbreak also shows, however, that a great deal of educational work remains to be done in the area of protection from food-borne infections. For even by observing simple rules of hygiene when preparing food, consumers can protect themselves from numerous pathogens. More research is needed, in addition, to develop quick detection methods for pathogenic germs and chemical substances in plant-based foods, for example pesticide residue. But despite all scientifically ascertained limit values, recommendations and safety factors, one thing will continue to apply in the future: an element of risk will always remain.

Chronology table: History of the BfR

1876

Founding of the Imperial Health Office



1906

Some sections of the Imperial Health Office moved into new premises on the "Dahlem Triangle" which continued as one of the locations of the BfR up until the end of 2011.



1919

The system change from the Empire to the Republic gives rise in 1919 to the new name of "Reich Health Office".

1933–1945

In the Reich Health Office, a "racial hygiene and human biology research department" was set up. It officially paved the way for the killing and forced sterilisation of thousands of Sinti and Roma. An exhibition on the subject "The Reich Health Office in National Socialism" is dedicated to this dark chapter in the history of the institution. It is currently on loan to the memorial and educational centre "House of the Wannsee Conference".

1945

Renaming as Central Institute for Hygiene and Health Care which initially reported to the City Council and then the Senate of Berlin.

1952

Establishment of the Federal Health Office within the portfolio of the Federal Ministry of Health.



1994

Founding of the Federal Institute for Consumer Health Protection and Veterinary Medicine within the portfolio of the Federal Ministry of Health.

2002

Founding of the Federal Institute for Risk Assessment within the portfolio of the Federal Ministry of Food, Agriculture and Consumer Protection



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, Agriculture and Consumer Protection. At the three BfR locations in Berlin, a staff of about 750, 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 globalized 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 recognized 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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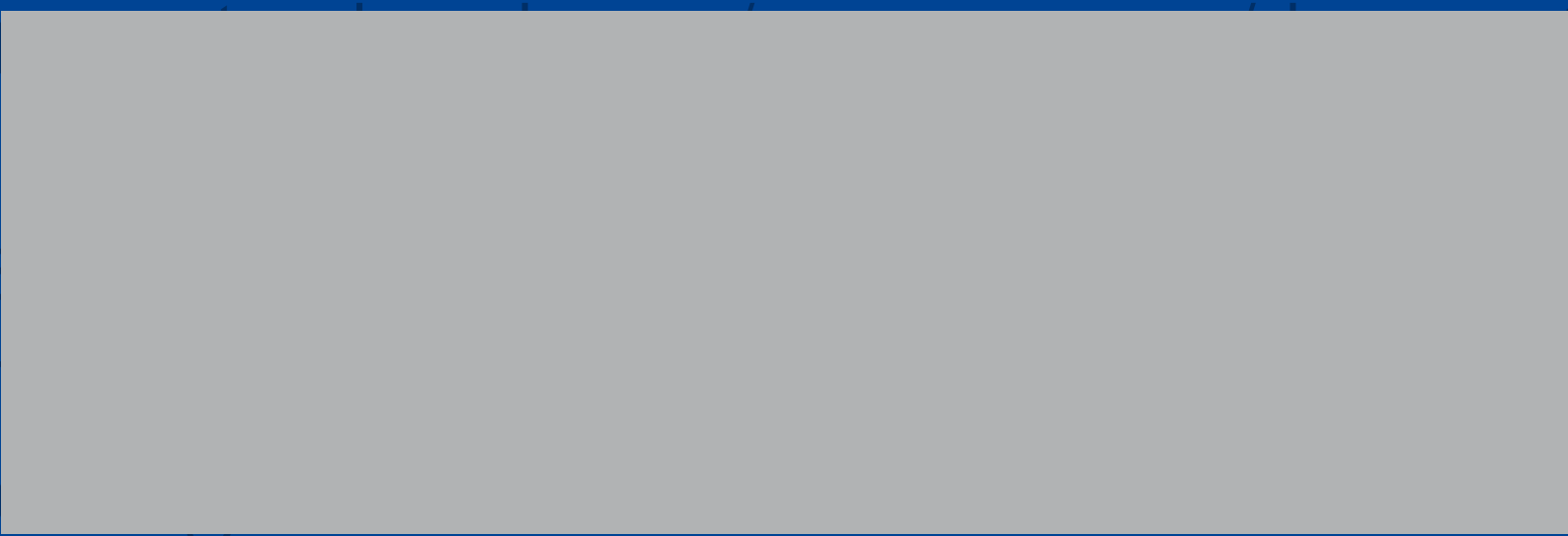
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