FEDERAL INSTITUTE
FOR RISK ASSESSMENT

# Science in the Service of Humanity

BfR

Risiken erkennen – Gesundheit schützen

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Science in the Service of Humanity

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# Focus on Precaution

Food hall, perfumes, household goods, children's clothes – a stroll around a department store reveals just how many products consumers come into contact with or eat every day.

## Protecting consumers from health risks

The Federal Institute for Risk Assessment (BfR) is responsible for assessing the risks associated with these products and for issuing recommendations on how to minimise them. In this way it makes a major contribution to the safety of foods, substances and products and, by extension, to consumer health protection.

**The Federal Institute for Risk Assessment makes a major contribution to rendering foods, substances and consumer products safer. Human beings as consumers are the focal point of its work.**

**BfR endeavours to be a pioneer in science-based risk assessment for the purposes of consumer health protection.**

**The Institute identifies potential risks, assesses them using scientific criteria and makes an active contribution to minimising them.**

*More than 600 members of staff, including around 250 scientists, are involved in consumer health protection at three BfR locations in Berlin.*

## Taking action upstream of concrete hazards!

According to BfR the precautionary principle is centre stage of consumer health protection. Consumers expect public authorities to take action well in advance of concrete health hazards and to introduce protective measures.

The main tasks of BfR are scientific risk assessment, the proposal of measures designed to minimise these risks and the communication of this process to its target groups. At three locations in Berlin around 250 scientists from different disciplines assess the risks from foods, substances and products which could impair consumer health. These risks may stem from substances but also from micro-organisms.

**Food constituents, food additives, residues of pesticides and contaminants in food must be safe!**

In order to implement the concept of precautionary consumer protection, BfR assesses for instance the constituents and additives in foods, residues of pesticides and veterinary drugs as well as other undesirable substances which may constitute a risk to health. In this work it draws on the latest scientific findings. Materials which come into contact with food must also be safe.

Within the framework of the marketing authorisation procedure, BfR is responsible for the health assessment of novel foods and products made from genetically modified organisms. In the case of these foods, a nutritional-medical assessment is necessary in addition to the toxicological assessment.

The latter is also undertaken, when required, within the framework of the notification procedure for foods for special dietary purposes.

*Today, many foods are pre-packaged when they reach the hands of consumers. No substances that could constitute a risk to health may migrate from the packaging to the food.*

Food additives like preservatives and antioxidants prolong the shelf life of foods. They give the products the appearance which consumers expect. Additives of this kind must also be safe when they are consumed daily throughout a lifetime. The health assessment of food additives is an important task for BfR.

Pesticides contribute to the production of foods of plant origin of a higher standard, at cheaper prices and in sufficient amounts. The maximum levels laid down for residues ensure that the treated fruit, vegetables or cereals do not constitute a threat to health and that they are cultivated under the conditions of "good agricultural practice".

**How much mercury can be tolerated in fish?**

Mercury is a heavy metal which can cause damage to health if high amounts are ingested. Mercury is widespread in the environment and also occurs as a natural constituent in all inland waterways and world oceans. As a consequence of industrial activity, the levels may vary considerably from region to region.

Mercury also accumulates in the food chain via fish. There it mainly occurs in its more toxic form as methyl mercury. Methyl mercury can lead to developmental disorders in the unborn child. BfR, therefore, advises pregnant women and breastfeeding mothers to restrict their consumption of types of fish known to have high levels of mercury that may contain up to 1.0 mg mercury per kg according to the Maximum Levels Regulation. This group mainly encompasses large and old predatory fish like sharks, halibut or certain types of tuna. Common fish like rock salmon, herring, salmon, carp or trout are not included in this group.

**Fish which may contain up to 1 mg mercury per kilogram and whose consumption should be restricted during pregnancy and whilst breastfeeding:**

Anglerfish
Atlantic catfish
Bonito (Sarda sarda)
Eel
Emporor, orangy roughy, rosy soldierfish
Grenadier
Halibut
Marlin
Megrim
Mullet
Pike
Plain bonito (Orcynopsis unicolor)
Poor cod
Rays
Redfish
Sail fish
Scabbard fish
Seabream, pandora
Shark (all species)
Snake mackerel, butterfish
Sturgeon
Swordfish
Tuna (Thunnus species, Euthynnus spec)

**The BSE crisis:**
**Risk assessment despite open questions**

The BSE problem presents a special challenge to consumer health protection. It is true that research has made considerable progress since the first occurrence of the disease in England but it is still not possible to detect the infection in live animals.

Scientists at today's BfR already pointed out at the beginning of the 1990s that a transmission of the disease to man could not be ruled out and had recommended measures in order to prevent transmission of this kind.

In 2000 uniform regulations were issued throughout Europe in order to protect consumers and agricultural livestock from infection. Some of these measures followed the recommendations of the then BgVV, today BfR. Since then, they have been gradually adapted to emerging scientific findings.

When it became clear towards the end of 2000 that BSE also occurred in German cattle herds, scientists in today's BfR recommended more extensive measures to protect consumers in Germany. The lowering of the age limit for the BSE rapid test in cattle from 30 to 24 months was one such measure as were the recommendations on how to make the slaughter process and the slaughter chain safer. Some of the recommendations have been taken over into European law like the modified techniques used during the slaughter process.

The assessment of the risks to consumers from BSE highlights the challenge facing scientists again and again: without sufficiently reliable risk assessment data, they are called on to comment on the scale of a potential hazard. Even if far more knowledge is available today about the infection and course of the BSE disease than was the case 10-15 years ago, many questions are still unanswered and there is a need for considerable research.

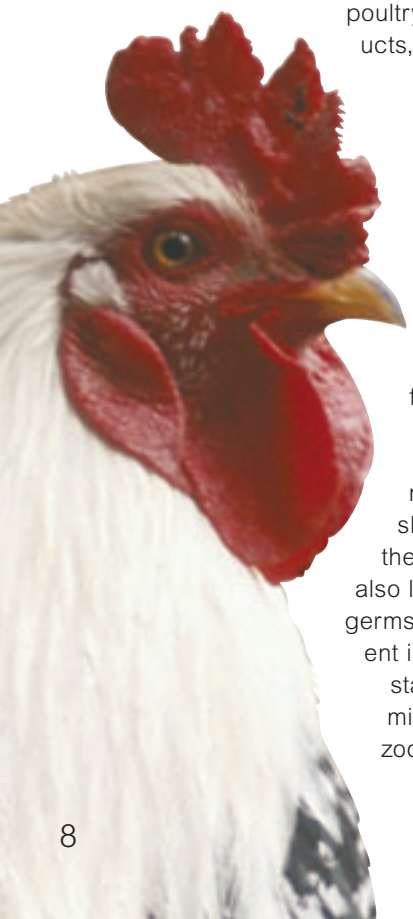
*Safe foods from animals can only be guaranteed if the highest level of hygiene is upheld from breeding right down to the consumer's plate. This is the only way of preventing or at least reducing food infections.*

## Safe food can only be obtained from healthy animals!

Veterinary medicine initially plays an important role in the case of foods of animal origin. After all, the goal is to already prevent the spread of and control any pathogens, that can cross over from animals to human beings, in the animal sheds. During food production, processing and treatment there is also a need for food technologists and molecular biologists who can make valuable contributions on questions to do with methods and the diagnosis of pathogens. Only with safety concepts extending from the animal shed to the consumer's plate, is it possible to prevent and reduce food infections and intoxications.

## Food safety from the stable to the plate!

Salmonella in pork and eggs, Campylobacter in poultry, Listeria in meat, dairy and meat products, novoviruses in drinking water – these are just a few of the pathogens in foods which frequently lead to disease in man. Each year around 200,000 cases of food infections are notified to the health authorities in Germany. The real number of cases is probably far higher (more than 2 million) since many are not reported. One extremely important area of food safety is, therefore, minimising health risks from micro-organisms or parasites which may have contaminated foods of plant or animal origin. Pathogens of this kind may have already reached animals in the sheds and then the foods made from them. Poor hygiene during processing can also lead to the contamination of foods with germs. What's more, any germs already present in foods may multiply and form toxic substances. BfR endeavours to reduce these microbial risks through research into zoonoses, by developing diagnostic methods suitable for daily use and corresponding hygiene concepts both in the animal sheds and during processing. Safe foods can only be obtained from healthy animals. The identification of diseases in animal stocks and wildlife populations is, therefore, one of the tasks of BfR as is assessing the resulting risks for human beings.



*Foods from animals will only be safe if the highest level of hygiene is upheld from breeding right down to the consumer's plate. This is the only way of preventing or at least reducing food infections.*

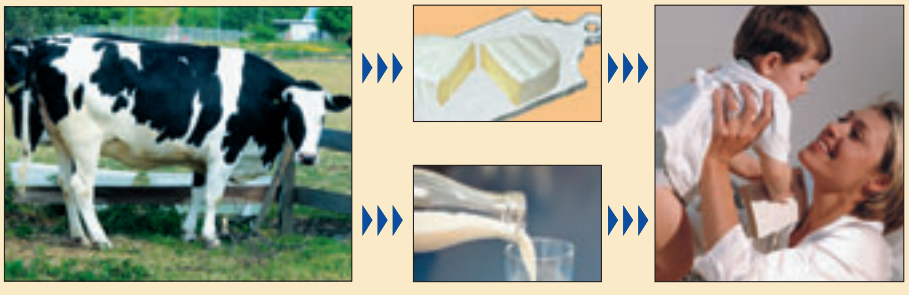
*The Trichinella infestation of pigs has become very rare thanks to good shed hygiene, intensive examination of the meat after slaughter and corresponding hygiene provisions during the processing of pork. From time to time, there are however cases of transmission of trichina to man. At BfR research is done into diseases (zoonoses) which can be transmitted from animals via food to human beings. Together with experts in Germany and abroad, scientists in BfR endeavour to determine the cause of these infections and to estimate the health risks for man.*

*With state-of-the-art molecular biological methods, BfR searches for the causes of foodborne infections*

**Lower exposure to germs reduces the risk of Listeria infections**

Again and again there are reports of cases of disease which are quite obviously linked to the consumption of specific foods like, for instance, vacuum-packed products. The causes of these infections are bacteria of the species Listeria monocytogenes. They are very widespread and may be transmitted during milking or slaughter from animals to milk or meat and from there to human beings. Frequently, contamination does not take place until processing or treatment of the food, for instance when cheese is cut. Listeria are frequently detected in poultry meat, pâté, cold meats, smoked fish and raw milk cheese, and sometimes even in pasta and ready-to-eat salads. Vacuum packaging but also refrigeration over longer periods promotes the growth of Listeria more than that of other bacteria.

Aside from individual sensitivity, the risk of someone becoming ill depends on the number of bacteria ingested. The level of 100 germs per gram or millilitre food recommended by BfR years ago, which may not be exceeded up to the end of the shelf life of the food, is now being discussed on the international level as a guidance value for the safety of ready-to-eat foods.



*Bacterial pathogens like Listeria are a particular problem in foods of animal origin. However, they may also occur in raw plant products like salads and soya beans.*


Controlling disease in animals which supply foods is a special challenge for consumer health protection. Veterinary drugs used here should not only restore the health of the animals. Their residues after treatment and their metabolites in foods must also be safe for human beings. Hence BfR is responsible for assessing the risks from residues of pharmacological substances. The same applies to the health assessment of feed additives where there must be a guarantee that the foods obtained from food-producing animals are safe.

## Protection for animals without this involving any risk for human beings

The tasks of BfR also include documenting the resistance of zoonosis pathogens to antibiotics that are used both in veterinary and in human medicine.

The assessment of substances which consumers come into contact with is a key task of consumer health protection. Here it is not important whether the substances are of natural origin or are synthetically produced substances. The latter are generally called chemicals. BfR is the central Institution for the health assessment of substances in Germany. The range of substances extends from industrial chemicals to natural food ingredients like THC (tetrahydrocannabinolic acid), known as a narcotic in hemp-containing foods, or glycerine in liquorice. The scientific assessment of the substance properties and the potential risks is also the basis for classification and labelling, for safety measures like the laying down of limit values, for constraints on application and also bans issued by the authorities responsible for management.

**No consumer protection without an assessment of substances and products**

BfR has also been assigned the special task in accordance with the Chemicals Act of undertaking the basic toxicological assessment and the preparation of scientifically backed proposals for the classification of chemicals. This assessment serves to develop and lay down rules for the safe handling of the chemical substances. The assessment of new industrially manufactured substances is of particular importance since every year a few hundred substances are developed in the laboratories of the chemical industry. Furthermore, there are around one hundred thousand chemical compounds which were already on the market prior to the entry into force of the Chemicals Act. They now have to be reviewed or even assessed for the first time within the framework of the existing substance programme of the European Union. Chemical assessment is a task which requires that the scientists of BfR are familiar with the available toxicological data on a substance. But not only that, they must also assess whether the studies and experiments conducted by industry in conjunction with toxicological tests are or were reliable, which is particularly problematic in the case of existing substances. By means of its own experimental research, BfR examines the reliability of individual test methods. It has the statutory task of taking part in the further development of toxicological test methods.

**Practical consumer health protection: The assessment of dyes in textiles**

For textiles there are around 600 different auxiliaries and treatment agents. Furthermore, there are more than 1,000 dyes, most of which are azo dyes. A few hundred substances in this dye group are produced from carcinogenic parent substances, specific aromatic amines. Under certain circumstances dyes of this kind may pass through the skin and then be broken down during metabolism into their parent substances, the aromatic amines. Splitting on the skin by skin bacteria is another possibility.

Of the group of azo dyes, which can split potentially carcinogenic aromatic amines, around 150 are still commercially available. German industry stopped using them several years ago. BfR made a major contribution to these dyes being banned throughout Europe today. The supervisory authorities still detect dyes of this kind in individual cases particularly in textiles from third world countries.

Overall BfR has a positive track record: contact allergies have only been observed in conjunction with poorly dyed, non-colour fast textiles. It is assumed that allergies triggered in this way account for 1-2% of contact allergy cases. Chemical substances in clothing only have worrying effects in exceptional cases.

Once BfR has concluded the basic toxicological tests of a substance based on documents supplied by industry and submitted a proposal for classification based on toxicity, other institutions like the Federal Environmental Agency or the Federal Institute for Occupational Safety and Health use these data for the risk assessment and classification for which they are, in turn, responsible. BfR itself uses the assessment in order to estimate the health risk from chemicals and products for consumers. As the statutory notification office, BfR collects information on health impairments which can be attributed to consumer products and chemicals.

*Chemical safety involves assessing the harmfulness of chemical substances and products as well as providing information on any related health hazards. By collecting and processing data of this kind, BfR contributes to the safe handling of these substances and products.*

*Safe handling by the consumer of household chemicals, dyes and other products is a goal of chemical assessment.*

**Cosmetics:**
**Safe even when used lifelong!**

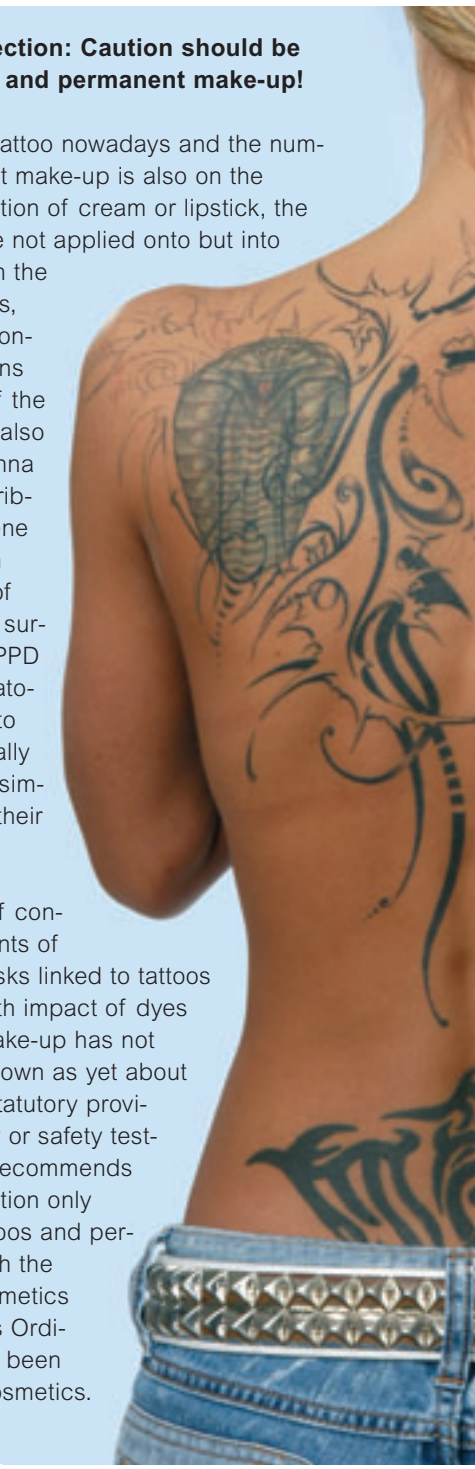
Cosmetics are frequently used by consumers throughout their lives. The term cosmetics encompasses not only decorative cosmetics like eye shadow or foundation but also skin creams, soaps and toothpaste. Any ingredients used in cosmetics may not, therefore, harm health even when used throughout an entire lifetime. BfR collects data and also obtains knowledge about the toxicity of ingredients of this kind from its own studies. When assessing substances in cosmetics it must also be borne in mind how the individual substances interact with other ingredients in cosmetics and whether their impact is altered by environmental factors.

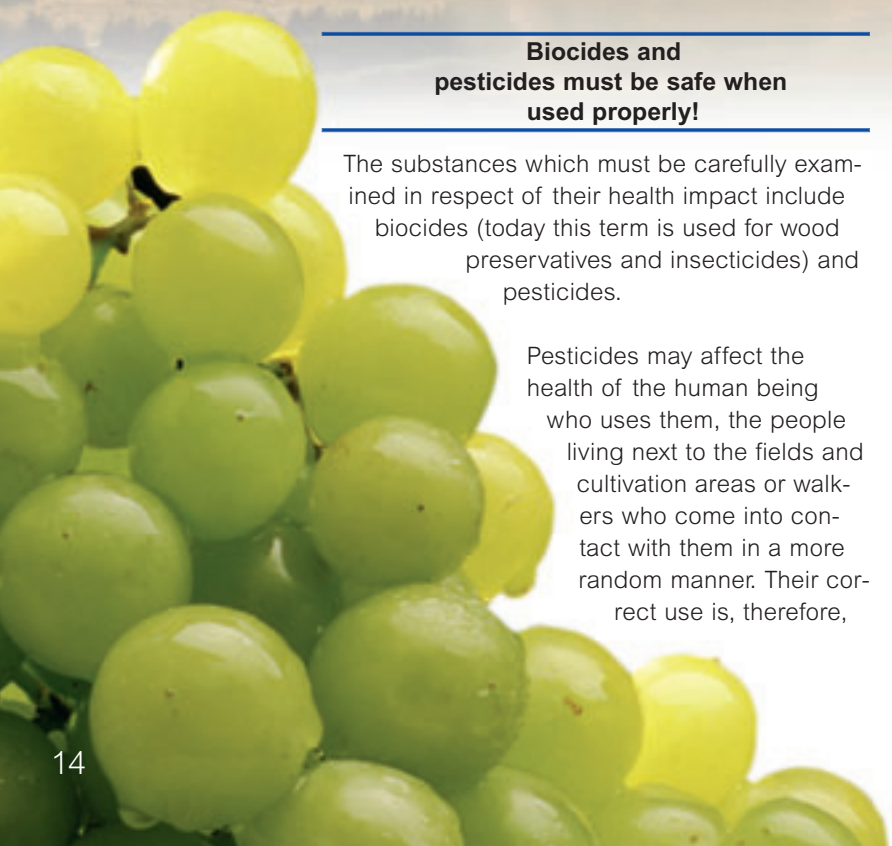
*Sun cream remains on the skin whilst swimming. It must, therefore, be examined whether and, if so, how the substances change when exposed to chlorine, water or light and whether harmless substances possibly turn into harmful ones.*

**Practical consumer health protection: Caution should be exercised in the case of tattoos and permanent make-up!**

Almost one in ten Germans has a tattoo nowadays and the number of people opting for permanent make-up is also on the increase. In contrast to the application of cream or lipstick, the colour pigments in these cases are not applied onto but into the skin. From there they can reach the blood stream via deeper skin layers, spread through the body and be converted. Severe allergic skin reactions and inflammations are just some of the adverse effects. Allergic reactions also occur in the case of temporary henna tattoos. In many cases they are attributed to the substance paraphenylene diamine (PPD). It is used to darken henna and during the application of black henna tattoos, it reaches the surface or even penetrates the skin. PPD can trigger serious cases of dermatosis. People who become sensitive to PPD can continue to react allergically to the substance or to dyes with a similar chemical structure throughout their lives.

BfR explicitly draws the attention of consumers, more particularly the parents of adolescents and children, to the risks linked to tattoos and permanent make-up. The health impact of dyes used for tattoos and permanent make-up has not been examined. Nor is anything known as yet about their lifelong effect. There are no statutory provisions concerning the purity, quality or safety testing of tattoo dyes. BfR, therefore, recommends that until there is a statutory regulation only those dyes should be used for tattoos and permanent make-up which comply with the requirements of the European Cosmetics Directive or the German Cosmetics Ordinance. This ensures that they have been tested and authorised for use in cosmetics.





## Biocides and pesticides must be safe when used properly!

The substances which must be carefully examined in respect of their health impact include biocides (today this term is used for wood preservatives and insecticides) and pesticides.

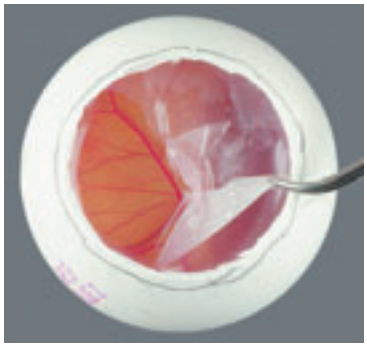
Pesticides may affect the health of the human being who uses them, the people living next to the fields and cultivation areas or walkers who come into contact with them in a more random manner. Their correct use is, therefore, an important contribution to health protection. Residues of pesticides in foods must not harm consumers either. Hence, it is important to know which levels are safe. BfR is responsible for undertaking health assessments of this kind. They are an important foundation for the laying down of maximum levels for pesticides that a food may contain.

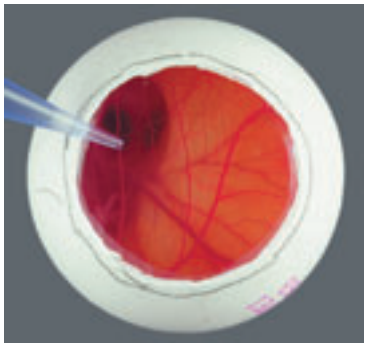
In the case of wood preservatives and insecticides, it is important that when used correctly and properly these biocidal products do not impair the health either of the residents of a building treated with them or the users.

The health assessment of the products used in this area, therefore, also encompasses aspects like their long-term impact and disposal (decontamination), for instance once an insecticide application has been completed.

## Improved animal welfare: An important goal of BfR

For regulatory testing, national and international guidelines are based on animal experiments. At the same time, the EU regulations stipulate that an experiment may not be performed if a practicable and scientifically sound method is available that does not entail the use of an animal. The assessment and development of alternatives to animal experiments is, therefore, a task of BfR. At ZEBET (Centre for Documentation and Evaluation of Alternatives to Animal Experiments) alternative methods are documented, collected and also assessed. Another focus is on BfR's own experimental research on alternatives and the promotion of research in this area. Furthermore, the Institute has endeavoured for several years to improve animal husbandry, particularly of experimental animals.





*Chicken egg instead of rabbit eye – replacement of the Draize test with the HETCAM test to examine the irritant and corrosive effect of substances. This is just one of many alternative methods to animal experiments currently available. In the ZEBET database scientists and public authorities can find out about the current level of knowledge in this area. This database can also be accessed via the Internet.*

**The legal status of BfR**

BfR is a scientifically-oriented, legally responsible federal authority in the portfolio of the Federal Ministry of Consumer Protection, Food and Agriculture. The Institute mainly plays an advisory role. It assesses health risks on the basis of the latest available scientific findings. BfR is the only institution of this kind on the federal level.

In order to ensure that its work cannot be influenced by political, economic or social interests, the expert independence of the Institute has been anchored in law. With its health risk assessments BfR makes a major contribution to the safety of foods, substances and products and, by extension, a direct contribution to consumer health protection. BfR does not assume any monitoring duties. However, it is involved in a series of marketing authorisation and notification procedures.

**Not monitoring but scientific advice!**

First and foremost, the Institute advises the Federal Ministry to which it reports. Its specialist scientists do, however, also work for other ministries on the federal level like the Federal Ministry of Health, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Ministry of Transport. Frequently, other public authorities in the Federal States ask BfR for advisory expert opinions on questions of consumer health protection.

**Shared burden: The system of consumer health protection in Germany**

In a country like Germany with a federal structure, responsibility for consumer health protection falls to the Federal Government and the Federal States.

Laws and ordinances, which serve the purposes of consumer health protection, are enacted by the Federal Government and Parliament. BfR advises the Federal Ministries on the elaboration of statutory provisions. It undertakes the scientific assessment of health risks and identifies action options for risk minimisation. These are implemented on the federal level by management as protection measures for consumers. Many statutory provisions for consumer protection are now laid down on the European level. Regulations of the European Union immediately apply directly in all Member States; directives of the European Union, by contrast, must first be taken over into each member state's national law. BfR is also involved in the elaboration of European provisions for consumer protection. Its experts sit on numerous scientific advisory bodies of the EU.

In Germany the public authorities of the Federal States are responsible for monitoring compliance with national and European statutory provisions of consumer health protection. BfR supports the Federal States in this task by developing and establishing, for instance, analytical methods for monitoring purposes or by issuing expert opinions on topical issues of consumer health protection.

BfR holds a dialogue with different target groups interested in the results of its work. In this way it complies with its statutory remit for risk communication. This is how the Institute contributes to more transparency and to improving consumer health protection in Germany.


## Consumer protection moves beyond national borders

In the course of European unification and globalisation, consumer health protection cannot and should not stop at national borders. As the national peer agency to the European Food Safety Authority (EFSA), BfR sees itself as part of an international network and as a strong partner on the highest scientific level. BfR inputs its expertise into the work of EFSA, into the bodies of the European Union, into the Organisation for Economic Co-operation and Development (OECD) and into other national and international bodies.

BfR is also involved in the work of the Codex Alimentarius System of the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The task of the Codex Alimentarius Commission is to draw up standards for food (for instance maximum levels for harmful substances) which, within the framework of the World Trade Organisation, should promote unimpeded and fair world trade.

In the field of food safety BfR is active as the FAO/WHO Collaborating Centre. It runs the programme for the control of foodborne infections and intoxications in Europe and co-ordinates further training measures for experts and managers from developing and Eastern European countries. Every six years BfR stages a World Congress on Foodborne Infections and Intoxications.

**Risk management:**
**Research, assessment, communication**

What is a risk? 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. BfR's task is to provide the people responsible with a solid scientific basis for risk management. The identification and evaluation of a risk – these two elements are described as "risk assessment" – is the first step in consumer health protection. Ideally, this step is taken in a dialogue with all the stakeholders and leads to a consensus on the degree of acceptance of a risk. Once this agreement has been achieved, risk management can orient itself towards this and corresponding measures can be taken.

**Lamp oils in children's hands**

Cases of poisoning with coloured lamp oils affecting above all small children prompted scientists in today's BfR to take a look at the data. The results: coloured and perfumed lamp oil is the most dangerous household chemical for children aged between 1 and 3 years. Their lemonade-like colour and special aroma make lamp oils particularly attractive to children. They are tempted into tasting them. In just one gulp children take in 8-15 millilitre lamp oil. In individual cases the mere sucking of the lamp wick was enough to allow 1 millilitre to enter the child's body. Already 0.1 millilitre lamp oil per kilogram body weight is sufficient to trigger severe lung damage.

Scientists at BfR then issued a series of recommendations for risk-reduction measures which were implemented in the space of a few years: child-resistant closures, warnings (on refill packs and burners), new labelling ("harmful: may cause lung damage if swallowed"), standardised proposals for safe lamp construction and the restriction of the sale and the use of coloured and perfumed lamp oils to those on a paraffin or petroleum basis. This led to the development of replacement substances. In 2000 the sale of these lamp oils was banned in containers with a capacity of less than 15 litres throughout Europe.

Risk communication has accompanied this process since 1990 starting with the identification of the risk down to the implementation of the individual measures. The dialogue with different target groups was supported in publications, press releases and numerous interviews on the radio, TV and in the daily press.

Cases of severe damage to lungs in children caused by lamp oils have become a rare event. The less serious cases which have occurred can either be attributed to residues of old products or to the, as yet non-prohibited, dangerous clear lamp oils or grill lighters. In order to effectively ward off these dangers too, the Federal Government, based on the BfR data and risk assessment, has formulated and submitted an application for a ban on all dangerous lamp oils and grill lighters to the EU.

## Research in BfR

The expertise of the Federal Institute results from scientific exchange and, to a large degree, from its research. Its own experimental research enables BfR to carry out its statutory tasks without being influenced by external interests. BfR scientists are mostly engaged in applied research. Some experimental studies are particularly important in areas in which other institutions are not active. One example is a comparative study on the allergenic potential of organically and conventionally cultivated types of vegetables. The project aims to answer the question whether monocultures, as a stress factor, promote the formation of allergens in plants. Under defined conditions plants of the same species are cultivated under organic and conventional conditions. With the help of immunological and molecular-biological methods, the allergenic potential of both is then compared.

In order to identify and assess risks, suitable analytical methods are needed by means of which the harmful substances or micro-organisms can be identified and quantified in routine tests. One important task is, therefore, the development of standard analytical methods which is done within BfR. Methods of this kind are needed, for instance, by the public authorities of the Federal States in order to monitor compliance with statutory provisions and prevent risks for consumers. For the purposes of standardisation, the analytical methods are examined jointly by the Federal States and the industry concerned. They are then taken over into the official collection of test methods. One example is methods for the identification of genetically modified organisms (GMO) and food products made from them. They are first developed in BfR, then standardised and used by the supervisory authorities in order to monitor compliance with labelling obligations.

The BSE crisis revealed just how important it can be for consumer protection to reliably know whether a sausage contains constituents of pig or cattle, too. Proof of origin is also of importance when it comes to protecting consumers from misleading information. This ensures that the Bordeaux wine does indeed come from the region of that name. When it comes to developing methods to determine the origin of products down to the specification of animal species, BfR is the leading authority in Europe.

## Pollutants in foods: The problem of furan

Foods, which undergo heating during production, may contain the harmful substance, furan. The colourless, highly volatile liquid has proved to be carcinogenic and mutagenic in animal experiments. This substance has been detected, for instance, in canned vegetables and meat, bottled food, coffee and bread. It has not yet been clarified what conditions and mechanisms lead to the formation of furan during the production of these foods. The available data are not sufficient in order to estimate the overall exposure of consumers to furan from foods and other sources and the resulting health risk. There is, therefore, a need for clarification of the effect of the substance in the low dose range and of the mechanism of action. BfR is the leading authority when it comes to developing improved methods for the detection of furan levels in foods. After their standardisation they can, for instance, be used by the official food control bodies. These standardised methods can then be used in the Federal States to collect data which permit better assessment of the health risk to consumers from furan and provide a basis for risk-reducing measures.

## Does the Bordeaux bottle really contain wine from Bordeaux?

Consumer protection increasingly encompasses protection from misleading advertising. The consumer would like to be sure that the bottle of Bordeaux which he has bought does indeed contain wine from the Bordeaux region and not a wine from any other region. Today, thanks to modern analytical methods like nuclear magnetic resonance spectroscopy and isotope ratio mass spectrometer (IRMS), it is possible to determine the ratio of various stable isotopes, i.e. the same elements with different atomic weights. For instance, the ratio of the oxygen isotopes $^{18}O$ to $^{16}O$ in foods and food ingredients is an important indication of the origin of a product. Stable isotope ratios of this kind are dependent on the earth's rotation and on climatic and biological factors. This ratio is, therefore, also expressed in plants which grow at different latitudes. Scientists in the "Senior expert office for the control of foreign wines" based at BfR have succeeded in developing a detection method for the origin of wines which is based on the different ratios of the oxygen isotopes.

## Innovative research and basic research

Besides applied research BfR also engages in innovative research and basic research. These projects are mainly conducted under the European framework programme.

In recent years a new, efficient technology has been developed which makes it possible to simultaneously examine the different properties of biological material. Microarrays or "DNA chips", as they are called, are miniaturised carriers on which a high number of nucleic acid molecules (so-called probes) are densely bound in a defined order. The microarrays are used, for instance, to develop new medicines and alternatives to animal experiments. BfR uses this technology to develop rapid methods for the detection and characterisation of pathogenic germs in a food in order to rapidly identify a risk to the population. These new methods are validated, standardised and then made available for widespread use.

## The use of gene expression analyses in the risk assessment of chemicals

For the marketing authorisation of new chemicals and the health assessment of so-called "existing substances", reliable toxicological data are needed. If the annual production of the substance in question exceeds a certain volume, long-term animal experiments must be conducted in laboratory rodents in order to collect these data. The sub-acute toxicity test in rats, also called the "28-day test", is an important basic test for chemical substances which is followed by further tests. Thanks to the use of gene expression analysis, it was already possible on the level of a sub-acute toxicity test to rapidly obtain reliable information on the toxicity mechanisms of substances. In this way, the number of stressful long-term animal studies may be reduced. BfR tests biotechnological methods of this kind, toxicogenomics, in order to be able to identify potentially hazardous substances far more quickly.

Once the mechanism of action of a substance is known, this permits conclusions about its toxic properties. Whenever there is contact with a substance, genes and proteins or metabolites "react" in a certain form, the specific "fingerprint". Vice versa, this fingerprint permits conclusions about the mechanism of action, the path of the toxic effect. Knowledge of the mechanism of action is of great importance for the assessment of the toxic potential and risk, which the substance may constitute to man.

For toxicogenomic analysis, tissue samples are examined, for instance, from the 28-day test in laboratory rodents. Using toxicogenomics, thousands of sequences of the hereditary substance and cellular proteins can be investigated at the same time. In this way changes in the complex activity pattern when exposed to an admixed substance can be observed. By means of this analysis of complex cellular responses, reactions to as yet non-toxic levels can already be registered.

Insight into molecular mechanisms of action constitutes major progress in respect of transferring results obtained from animal studies to human beings. It is expected that this development will revolutionise the risk assessment of substances.

# Communication as an important part of risk prevention


BfR is the only Federal Institute in Germany with a statutory remit for risk communication. This means the ongoing and interactive process of opening up communication to the public at large, science, other stakeholders in the process and interested groups. Information is to be provided as early as possible about potential health risks and access given to assessments and work results. Within the framework of risk communication, information is to be collected, the expectations of consumers and interest groups are to be identified and, wherever it is scientifically defensible, they are to be involved in the risk assessment process.

Risk communication accompanies the overall process of risk analysis and, therefore, encompasses the question in hand, the laying down of protection targets, scientific assessment and any relevant explanations, risk management, control and evaluation of measures. In this process BfR's statutory task includes the sub-aspect of the communication of aspects of risk assessment and the evaluation of measures.

The Institute sees risk communication as a participative dialogue involving qualitative and quantitative factors. The primary target group is risk-conscious citizens. They are to be supported in their decision-making efforts by giving them the available information in order to allow them to assess for themselves the risks in full awareness of the various uncertainties.

**Only a clearly and comprehensively informed consumer can decide whether he wishes to consciously accept a risk or not.**

Besides the classical paths of press and public relations work, the Federal Institute also embarks on new paths. It actively involves consumers and other "stakeholders" (all those who make use of the risk assessments of BfR) in its work. This can be done for example by means of hearings or consumer surveys. In this way the Institute guarantees transparent and confidence-building communication in the interests of health protection.

The Institute also undertakes scientific work on risk communication issues. The focus is on methods to quantify risk perception and the elaboration of scientifically backed strategies for early risk identification. The Institute examines, within the framework of the assessment of risks and consequences, how effective its communication is, what messages reach consumers and other stakeholders and whether they influence their behaviour.

By means of its understanding of risk communication, BfR would like to contribute to

- disseminating perception competence and raising awareness of the problem,
- improving understanding and knowledge,
- improving judgement skills and supporting decision-making abilities,
- changing attitudes, acceptance and behaviour,
- managing conflicts and risks of crisis,
- strengthening the credibility of and trust in regulatory bodies.

# www.bfr.bund.de

The Internet has developed into an important medium for providing information to the public at large and for the dialogue with the various target groups. This is where BfR provides comprehensive information on its work. Every month more than 65,000 people visit the Institute's homepage and there are more than 1.5 million hits on the information stored there. BfR sees this as convincing proof of the interest in the Institute's work.

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