

## **10 years of scientific assessment of health risks from food, chemicals and consumer products at the Federal Institute for Risk Assessment (BfR)**

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The Federal Institute for Risk Assessment (BfR) is a scientific institution within the portfolio of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV). The main remit of the BfR comprises the assessment of existing and the identification of new health risks in the area of food, chemical and product safety, the drawing up of recommendations on risk reduction and the communication of this process. This work culminates in the provision of scientific policy advice by the BfR. The institute advises various federal ministries including BMELV, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Ministry of Transport, Building and Urban Development (BMVBS), and other authorities such as the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Occupational Safety and Health (BAuA). The BfR conducts its own research on topics that are closely linked to its assessment tasks. The results of all research activities are used accordingly in the BfR's risk assessments and opinions. All findings are made available to the public in a transparent and intelligible manner.

Transparency, scientific excellence and independence are the three central principles pursued by the BfR in order to strengthen the trust of everyone involved in the process of risk assessment. When the BfR was set up in 2002, the strategic emphasis was on perpetuating the scientifically based approach to risk assessment. Since then, various measures have been taken that make a key contribution to this goal and therefore towards ensuring the high quality of work performed by the BfR.

### **1 Independent assessments, recommendations and research**

The central task of the BfR is the independent scientific risk assessment of food and feed as well as substances and products as the basis for the consumer health protection activities of Germany's federal government. The institute does not perform a monitoring function but is involved in a number of registration and approval procedures. In the implementation of the REACH Regulation (EC) 1907/2006, for example, the BfR focuses on substances posing potential risks for consumers, identifies and names substances as potential SVHCs (substances of very high concern) and proposes risk reduction measures in the form of restriction and approval procedures for substances of particular relevance for the consumer. The independence of the BfR in its specialist fields was laid down by law when the institute was founded, ensuring that its health risk assessments are not influenced by political, economic or social interests. The BfR is also independent in its research, which is why research projects financed by external funding sources have to be exclusively from public third-parties..

### **2 Standardisation and harmonisation of opinions and assessments**

The BfR published over 3,000 opinions in 2011, primarily within the framework of legally stipulated procedures. One of the main jobs of the BfR is to assess the health risks of pesticides, biocides and industrial chemicals within the context of approval procedures based on the plant protection and biocide laws, EU active substance evaluation and the REACH procedure. A guideline was drawn up for the compilation of health assessments and opinions to ensure the preparation and publication of standardised, harmonised, substantiated and intelligible statements that are also highly regarded on international level. To also make the assessments intelligible for non-experts, a BfR risk indexing procedure was developed for the standardisation and graphic presentation of the central risk characteristics of the published

risk assessments. This BfR risk profile is in future to be compiled for all suitable BfR opinions.

### **3 Accreditation of laboratories and certification of all work areas (assessment, science and administration)**

The scientific laboratories of the BfR have been DIN EN ISO/IEC 17025 accredited since 2002, which means all organisational and technical criteria for quality verification are met and that all findings and results are painstakingly documented. In addition, the science, assessment and administration work areas were certified by the TÜV Nord auditing company in line with DIN EN ISO 9001:2008 in 2010. A procedural guideline was developed for crisis management, for example, and has greatly helped the BfR to manage food crises in recent years. The BfR is the first federal authority that employs a certified quality management system in all areas. This underlines the importance the BfR attaches to the job of consumer health protection and is a further area in which the institute sets an international benchmark.

### **4 Cooperation with international organisations and institutions in the area of consumer health protection**

The BfR attaches particular importance to closer national cooperation and international networking, above all with the official consumer protection institutions in Germany and European competent agencies (like the Austrian Agency for Health and Food Safety (AGES), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Technical University of Denmark (DTU)). Joint research strategies are developed and also proposed to the European Food Safety Authority (EFSA). For this purpose the naming of BfR as EFSA Focal Point in Germany in 2008 was favourable. German expertise in the field of food safety is pooled at the BfR and used in the exchange of information with EFSA and the European member states. The long-term objective is to harmonise risk assessment methodology in order to permit greater use of arising synergies for assessment work and the communication of risks. This also includes the mutual recognition of the findings of risk assessments. One of the current focal points of the international activities of the BfR is the cooperation with international competent agencies in South Korea and China. The goal of this cooperation is to exchange information on standards in the area of food safety – particularly with a view to globalisation – and risk assessment in Europe and Asia. In order to improve the worldwide standards in the field of food and product safety and pool the numerous enquiries from institutions and authorities regarding food safety to promote the transfer of know-how, the BfR staged an internationally attended two-week summer school in the summer of 2012 as part of a pilot project. The themes covered at this summer school were risk assessment and risk communication.

### **5 Establishment of National Reference Laboratories (17 NRLs)**

National Reference Laboratories are involved in the definition of standards for food monitoring in order to ensure the safety of food throughout the EU. To this end, 17 reference laboratories in the fields of food safety, food hygiene and feed safety are attached to the BfR. The remit of the National Reference Laboratories means that they play a watchdog role in the early detection of emerging risks. They are the basis for national, and increasingly international, exposure assessments. The National Reference Laboratories also act as a national link between the Community Reference Laboratories of the EU and the food monitoring authorities in the member states.

## **6 Support from a Scientific Advisory Board and external expert committees (15 BfR Committees)**

In 2005, a Scientific Advisory Board was set up at the BfR comprising twelve scientists from various university-based and non-university research establishments. The primary task of the Scientific Advisory Board is to advise the institute on the definition of its core fields of research. It also facilitates contacts and cooperation between the BfR and other research establishments in Germany and abroad and advises the institute on the appointment of respected scientists to the BfR Committees.

In 2008, the BfR set up 14 scientific BfR Committees to advise the institute on food and feed, chemical safety and product safety. Following a public call for applications and a selection process conducted by the external appointment committee set up specifically for this purpose, at least ten experts were appointed to each committee for the period up to 2010. During the course of the new selection process for the committees for the period from 2011 to 2013, the newly created BfR Committee for Risk Research and Risk Perception also began its work. The 15 advisory BfR Committees enhance the scientific quality of the BfR opinions and also act as a form of external quality assurance.

## **7 Expansion of the research-based approach through intensified research activities and establishing the BfR as a national and international cooperation partner**

The BfR has the statutory task of undertaking scientific research that is closely linked to its activities. It conducts application-focused, targeted research and scientific investigations in order to perform its assigned remit. In this way, the BfR secures and promotes the scientific expertise that is needed to ensure a level of competence in the field of risk assessment, risk communication and risk perception that is internationally recognised and independent of economic interests. The externally funded projects (financed by bodies such as the EU, the German Research Foundation (DFG) and federal ministries) close knowledge gaps within existing areas of key research, promote the expertise and integration of the BfR on national and international level and have been granted significantly increased funding in recent years. In 2011, for example, 3.32 million euros were obtained in funding (compared to an average 2.65 million per year in the period from 2004 to 2010). In 2009, the German Science Council emphasised the impressive scientific orientation of the BfR and recommended that its research operations be expanded. This was one of the factors in the decision of BMELV to extend the research activities of the BfR. This development is reflected by the increased funding scope of BfR research projects in recent years.

## **8 Research activities in the area of risk perception and early risk detection**

With the help of representative consumer surveys, Delphi expert surveys and media analyses, the BfR investigates the mechanisms that play a role in the subjective perception of risks. By using standardised survey methods (e.g. Delphi studies, population surveys and media and Internet forum analysis), the BfR has succeeded in documenting the status of knowledge, the information needs and the information requirements of consumers with regard to both known risks on a regular basis over longer periods and with regard to new risks within a relatively short space of time. In this way, the BfR has succeeded in integrating the subjective aspect of risk perception in the communication process. The expertise of the BfR in the field of early risk detection is being extended further by, among other things, the creation of a practicable cross-departmental system for the systematic early identification of risks with the support of an internal group of experts as well as by the involvement of the BfR in the early risk detection network of EFSA.

## **9 Transparent, open and intelligible risk communication**

The BfR is the only public institution in Germany with a risk communication department that publishes the findings of its scientific assessment work in an easy-to-understand format and incorporates these findings in a participative communication process in the form of expert discussions, status seminars, consumer protection forums, stakeholder conferences and public symposiums. The aim is to ensure that the entire assessment process is transparent for all members of the public. By pursuing a strategy of comprehensive, complete and understandable risk communication, the BfR renders science visible and usable for the consumer.

A permanent Internet presence providing fast, up-to-date, easy-to-understand information, the ever-growing range of modern, interactive media formats for both the classic website (videos, "users ask, BfR answers" format) and mobile services via smartphones or tablets (mobile website, apps) and the activities of the BfR in the social networks (Twitter, Youtube) are designed to continue to increase awareness levels and therefore also underpin the standing and importance of the BfR in the field of consumer health protection.

## **10 Expansion of the Department of Experimental Toxicology and ZEBET**

The BfR has extended its expertise in the field of toxicology by setting up the Department of Experimental Toxicology and ZEBET and creating a university chair together with the Charité University Clinic in Berlin. This secures the long-term future of the BfR's USP as the German institution that pools by far the broadest and highest level of expertise on toxicology issues. The BfR also shares its knowledge and experience in this field in lectures and courses within the framework of the "Toxicology" Masters programme of Charité - Universitätsmedizin Berlin.