

Risk assessment at the BfR: independent and transparent

Questions and answers on safeguarding the independence of the German Federal Institute for Risk Assessment

BfR FAQ, updated on 11 September 2023

The independence of experts from economic, political and social interests is a fundamental requirement for an objective risk assessment based purely on scientific facts. For more than 20 years, the separation of scientific risk assessment from its associated management has proven itself in Germany and at the European level. In keeping with this, the German Federal Institute for Risk Assessment (BfR) is an independent scientific institution within the portfolio of the German Federal Ministry of Food and Agriculture (BMEL). It conducts its own research on the basis of its Establishment Act and advises the German federal government and federal states ("Länder") on issues regarding food, feed, chemical and product safety. The BfR is independent in its scientific assessment, research and communication.

The BfR exchanges information with all relevant stakeholders (NGOs, consumer associations, industry, government, science, media) to fulfil its legal mandate. If there are conflicting scientific positions on an issue, it is important to involve the various stakeholders in the health assessment discussion process using scientific forums and stakeholder conferences. For reasons of independence, the BfR does not accept funding from industry, nor does it financially in such research projects.

The following rules ensure the independence of the German Federal Institute for Risk Assessment.

How does the German Federal Institute for Risk Assessment perform risk assessments?

The risk assessments are carried out by BfR employees. External experts provide the BfR with advice, when necessary, but they do not make risk assessment decisions. The work results and recommendations made by the BfR are used by all interested parties as an important source of information and decision-making tool. Statements made by the BfR follow internationally recognised scientific principles and are presented in a manner that is also transparent for outsiders. To prepare these statements the BfR conducts its own research and evaluates existing scientific studies. It also takes into account previously unpublished reports and data, for example, from authorisation procedures. Relevant opposing scientific views are stated.

Transparency is required at all levels of risk assessment. An opinion must be clear, understandable and reproducible from start to finish, beginning with the its objectives and scope and continuing on with the source, nature and evidence of its underlying data. The same qualities must also hold for the methods and assumption used in the opinion, the uncertainty and variability contained in the opinion and, finally, with the opinion's result and conclusion. For this reason, the BfR has been advocating for transparency in risk assessment procedures and for the disclosure of industry studies in numerous forums around the world for many years.

The individual steps of risk assessment are described in detail in our “Guidelines for health risk assessments in consumer protection” (BfR 2020: Guidelines for health risk assessments¹). The BfR guidelines set out how the assessment of possible health risks from food, feed, chemical substances and consumer products is to be performed. The guidelines serve as a reference for the BfR and are, therefore, part of its quality management system.

How is the independence of BfR employees ensured?

All BfR employees must comply with federal legislation in their work and decisions. Each employee expressly undertakes to do so by signing their employment contract or receiving the status of civil servant. The legal norms of the public service apply to them, for example, with regard to objectivity, effectiveness, expertise as well as impartiality, incorruptibility and corruption prevention. The relevant regulations are the result of laws and implementing provisions from the Federal Ministry of the Interior (see e.g. the Federal Civil Servants Act, Section 10 Administrative Procedures Act and other regulations).

Which regulations specifically ensure that BfR employees carry out assessments solely on a scientific basis, uninfluenced by other interests?

As set out in the relevant legal provisions, BfR employees are generally required to declare secondary employment or to obtain permission for secondary employment, depending on the type of employment contract they have with the BfR (employee covered by a collective wage agreement or civil servant). The BfR checks any planned secondary employment for conflicts of interest. If there are indications that a BfR employee's secondary employment might impair their legally intended independence, then the secondary employment is strictly prohibited by the BfR. In this way, BfR employees cannot have an inadmissible conflict of interest due to a parallel activity in industry. Through these rules and procedures, the legislator ensures that the federal government receives objective advice from its scientific institutions.

Are BfR employees allowed to work for foundations, institutions, networks or associations funded by industry on a voluntary basis or in addition to their primary work?

Generally, it is one of the tasks of BfR employees to communicate with stakeholders as part of their duties. To this end, they are involved in working groups and bodies of foundations or institutions as well as in interest groups in industry or consumer protection associations. This is then part of their main job. BfR employees perform their duties impartially and independently in accordance with their legal or collective agreement obligations. They are expressly obliged to do so when they are hired or appointed and are regularly made aware of this.

What ensures that the participation of BfR employees in industry-funded bodies and institutions does not jeopardise the BfR's independence?

Employees are obliged to report secondary employment. The secondary employment of a BfR employee is to be prohibited as soon as this employment could have an impact on the professional interests of the employee.

¹ <https://www.bfr.bund.de/cm/350/leitfaden-fuer-gesundheitliche-bewertungen-bf.pdf>

Furthermore, employees are generally obliged to maintain secrecy about matters that they have become aware of as part of their work in public service, even after the termination of their civil servant or employment contract.

Which rules apply to the participation of BfR employees in conferences and scientific events?

The participation of BfR staff in conferences and other scientific events is part of the BfR's scientific work. Any participation on behalf of the BfR must be approved by BfR management. As part of the approval procedure, an assessment is made as to whether participation in the event in question would create a conflict of interest with regard to the Institute's tasks and independence. Scientific events may also be organised by stakeholders with whom the BfR communicates regularly. A list of these stakeholders can be found in BfR background information no. 033/2014 "BfR Risk Communication in Practice" on the BfR website².

Which rules apply when selecting experts?

Members of BfR committees and of the Scientific Advisory Board are selected using objective and transparent criteria. They are chosen solely on the basis of their scientific excellence, competence and expertise.

The concept of the BfR committees intends for scientific excellence to be the decisive criterion, not the affiliation or non-affiliation with certain social groups. Volunteer positions are awarded following a public tender procedure in which every expert around the world is free to apply on the basis of their professional self-assessment. The procedure is open and explicitly addresses not only experts from universities and research institutions, but also representatives from consumer and environmental protection organisations, industry and authorities, in order to cover the BfR's scientific advisory needs in terms of technical breadth and depth. The procedure is as follows: first, all experts interested in participating in a BfR committee are asked in a public invitation to apply. The specially established Appointment Board then selects suitable experts from among the applicant pool. The Appointment Board is composed of the members of the BfR's Scientific Advisory Board, one representative each from the Federal Ministry of Food and Agriculture (BMEL) and the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV), a representative from the "Senate Commissions on Food Safety" and a representative from one of the BMEL's departmental research institutions.

Which rules apply to committee work?

The BfR committees all work according to binding rules of procedure³. The committees advise the BfR on open scientific specialist issues and are asked specifically to adopt a critical approach, to bring the current state of science and technology to bear on the latest assessment work of the BfR and also to identify future fields of activity for risk assessment. The advice resulting from the committees' work is addressed to the BfR and is only intended to be understood as a recommendation. The BfR takes note of these opinions and makes decisions independent of the committees. Committee members come from universities and other research institutions, federal and state authorities, business and consumer associations, private laboratories and industry.

² <https://www.bfr.bund.de/cm/350/die-risikokommunikation-des-bfr-in-der-praxis.pdf>

³ <https://www.bfr.bund.de/cm/343/geschaeftsordnung-der-bfr-kommissionen.pdf>

How are possible conflicts of interest of BfR committee members documented?

Potential conflicts of interest of committee members are already recorded and documented in writing during the appointment process.

In addition, members are prompted verbally at the beginning of each meeting to state any conflicts of interest in relation to the topics discussed within the committee. If a conflict of interest is identified, the committee member in question is excluded from the deliberations on the relevant topics. This is noted in the minutes of the meeting. All BfR committee meeting minutes can be viewed on the BfR website. BfR employees explicitly have no voting rights in the committees, so that the committees' advisory work is completely separated from the official assessment processes.

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