Hunting for risks

The BfR combines practice-oriented science with health assessment.

Listeria are adaptable and widespread bacteria. They are mostly harmless, but *Listeria monocytogenes* is extremely undesirable. This species is the cause of listeriosis, an infectious disease associated with diarrhoea and abdominal pain, which can be severe. It is caused by contaminated food. Long-lasting outbreaks of listeriosis are a regular occurrence, and invariably the question arises: which product is the source of the epidemic? Solving the problem requires not only scientific tools but also a detective's intuition.

This was the case from 2012 to 2016, for example, when a listeriosis outbreak in southern Germany puzzled scientists. 78 people fell ill, eight of them died. The search for the origin remained unsuccessful – until the method of genome sequencing, which deciphers the entire genetic material of the bacterium, led to a breakthrough in March 2016. A sample from smoked pork belly revealed exactly the same genetic information as that of the pathogen found in those infected with the disease. The sale of meat products from the producer was halted and the cause eliminated.

This episode is not an isolated case. Since 2016, more than 60 listeriosis outbreaks have been traced in this way in Germany. It's an example of how successful consumer protection works: with modern scientific methods and through close cooperation between state and federal authorities, in this case with the National Reference Laboratory for Listeria at the German Federal Institute for Risk Assessment (BfR) in Berlin.

Detecting everyday health risks, assessing them and pointing out ways to reduce the risk – these tasks have been the focus of the BfR since its foundation 20 years ago. Whether it's food-borne pathogens, cosmetics and toys or cleaning agents, plant protection products and kitchen appliances: the Institute's approximately 1,200 employees deal with it all.

Identifying risks to protect health

The legal mandate of the BfR is to "assess and evaluate risks of food and feed, substances, microorganisms and products (...) to human health". This is stated in the Institute's "Guideline for the Assessment of Health Risks". Furthermore, one of its central tasks is to provide information about health risks and to recommend countermeasures. "Identify Risks – Protect Health": the Institute's motto sums it up. The BfR comes is part of the portfolio of the German Federal Ministry of Food and Agriculture (BMEL).

At the same time, the practice of the BfR has changed profoundly in some domains over the past 20 years. This concerns both health risk assessment (see box on page 11) and other key areas of the Institute's work. For example, new regulations for the assessment of plant protection products and pesticides (biocides) have made the Institute's assessments much more detailed. "To put it bluntly: 20 years ago, an assessment fit on a sheet of paper," says Head of Department Dr Tewes Tralau, who is responsible for the safety of pesticides at the BfR. "Today, we prepare assessment reports that can be 1,000 pages long per active ingredient." This enables a comprehensive classification of the hazard potential and is one reason why plant protection products have become considerably safer.

How safe are cosmetics?

Product safety was established as a new field at the BfR about a decade and a half ago. It focuses on the health risk assessment of products such as toys, clothing, cosmetics, packaging material, e-cigarettes and tattoo ink. In short: pretty much everything we deal with in everyday life.

Consumer and media interest is high. Yet it's not always possible to find simple answers to all questions. Often, the test objects contain several different substances, not just one single suspicious chemical. In addition, there needs to be investigation into how much of a substance is actually absorbed on contact. "Both the material properties and the chemical safety have to be tested," says Head of Department Professor Dr Dr Andreas Luch. "That's why we are collaborating in a multidisciplinary way here at the BfR."

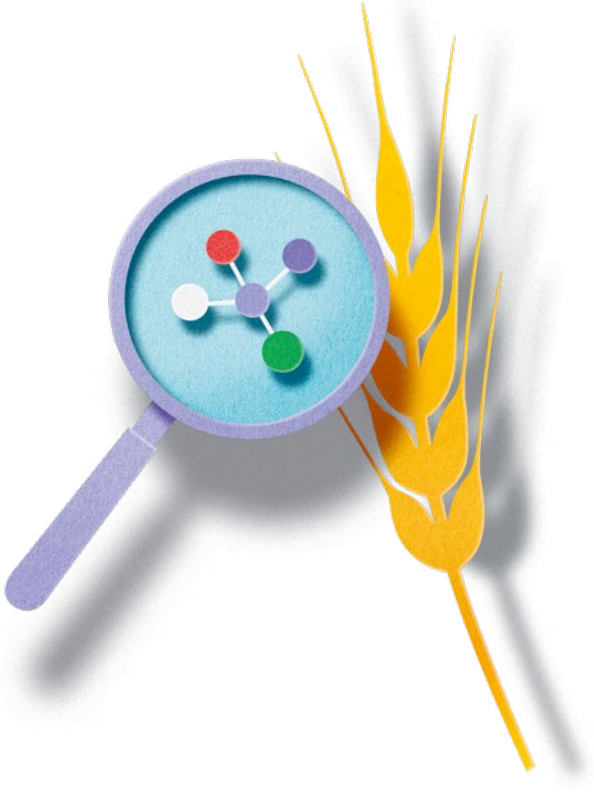
Analytics: measuring what's inside

As the example of listeriosis shows, detection methods – known as analytics in the technical language – have become extremely refined. This applies to pathogens as well as chemical substances or impurities (contaminants). These days, one can detect the equivalent of a single drop of an undesirable substance in Lake Constance.

The further development of analytical procedures is one of the important scientific tasks of the BfR. Especially the National Reference Laboratories located at the Institute are entrusted with this. "These facilities help to increase food safety and to locate outbreaks better and faster," explains Professor Dr Karsten Nöckler, whose department (Biological Safety) includes the Reference Laboratory for Listeria.

Perceived and actual risks are sometimes worlds apart

"Good analytics is the basis of any good risk assessment," says Dr Carsten Fauhl-Hassek, Head of the Department Safety in the Food Chain. Despite all the accuracy, it's always necessary to become even more accurate, as his colleague, private lecturer Dr Robert Pieper, points out. "An example of this is the group of PFAS chemicals, for which the health-based guidance values have been greatly lowered in the EU," says Pieper.



PFAS stands for per- and polyfluorinated alkyl substances. As stable compounds, they are found in such things as non-stick pans and outdoor clothing, making them water, grease and dirt-repellent. The chemicals accumulate in the environment and end up in our food. This is where detection methods need to be significantly refined, for example to be able to accurately determine the PFAS concentration in food. Analytics is the basis for answering the question of how extensive the PFAS contamination actually is.

Major goal: having data at hand even faster

Whether it's listeria, tattoo inks or PFASs: access to reliable data, such as that generated by high-quality analytics, is crucial for the Institute's work. (Almost) everything at the BfR revolves around good data. They are the main foundation for any serious risk assessment. This always revolves around the question of how high the exposure is, i.e. how much a person is exposed to a substance. The basic rule behind this is that the dose determines the toxicity of a substance. A weak toxin in a high dose can be more dangerous than a strong one that's only ingested in small amounts.

Especially in the event of a crisis, it's crucial to be able to quickly access important data, be it the detection of germs or the concentration of an unwanted chemical. This information makes it possible to assess exposure and determine the risk. In most cases, such measurements take place outside the BfR (for example, by authorities of the federal states), so they're often not immediately at hand. "We're working on making data available even faster," says BfR President Professor Dr Dr Andreas Hensel. "That is one of our most important goals in scientific risk assessment."

What's really in our food

Reliable data are also important when it comes to the question of what's really in our food. The BfR's MEAL study provides a comprehensive and realistic picture of which substances are consumed in Germany in what quantities. For this purpose, ingredients are purchased nationwide, prepared in a specially equipped kitchen and then analysed – it doesn't get much closer to reality than that.

On the one hand, the food itself is analysed for nutrients, mycotoxins (fungal toxins) or residues of plant protection products. On the other hand, impurities that occur during preparation (such as acrylamide produced during roasting), substances that have migrated into the food from the packaging and authorised additives are also examined. "The MEAL study is an example of how the BfR generates its own scientific data and uses these for health risk assessments," explains Head of Department Professor Dr Matthias Greiner.

Cause and effect – a complicated relationship

Even now, animal experiments remain an important basis for assessing the safety of a substance. New perspectives for toxicology (the science of toxins) and risk assessment also arise from substitute methods for animal experiments. Great progress has been made in this area in recent years, for example in the development of organoids or "mini-organs". These provide a link between animal experiments and cell culture. "Organoids enable us to study the influence of chemical substances on human tissue and to detect potential risks," says Professor Dr Gilbert Schönfelder, head of the German Centre for the Protection of Laboratory Animals (Bf3R) at the BfR.

In addition, information from studies with human study participants is increasingly being used for risk assessment at the BfR. Such "human data" often come from epidemiological studies. They have the advantage of being literally closer to humans. Yet human studies do not only have advantages. For example, it's often difficult to clearly assign cause and effect. Is a connection between a health disorder and a harmful substance really causal, or is it coincidental instead? "Such questions are a challenge for risk assessment," says BfR Vice President Professor Dr Tanja Schwerdtle. "We need to develop new guidelines to get clarity about and for the future handling of human data."

Complete safety remains out of reach

The health risk posed by a substance is determined by relating its inherent hazard potential to exposure. In other words, to the question of how much a person is exposed to the substance, how high the "toxic dose" is. If the dose is large enough, any substance becomes a poison. However, this assessment framework of toxicology is increasingly being called into question.

One current trend is to focus on hazard potential instead of exposure. According to this approach, a chemical can be withdrawn from the market even if it's safe when

Examined hazard – this is how risks are assessed

Generally speaking, a health risk assessment consists of five steps.

First, a health hazard must be identified. This can be a micro-organism or a chemical, for example.

Afterwards, the harmful effect must be characterised and assessed. Is there a relationship between dose and effect?

Following this, reliable data and methods are used to estimate how much a person is exposed to the hazard. Only once it has been established how much of the hazardous substance a person absorbs, for example through food, skin or the respiratory tract, can the risk be determined.

Based on this information, the risk characterisation is carried out: how likely are health impairments from a potential hazard?

The final result is the assessment report, which summarises the steps and may include recommendations on how to reduce the risk.

used as intended. The idea of making the potential hazard posed by a substance the main criterion for its assessment is met with scepticism at the BfR. The whole world is chemistry – the decisive factor is whether and to what extent humans come into contact with a substance. There's no such thing as zero risk, but there are acceptable and unacceptable risks.

Risk from the consumer's perspective

Weight the risks, don't play them up or down: The scientific approach of the BfR is also the guiding principle for the Institute's communication. This is extremely important, since educating the public about health risks is a central part of the Institute's mandate. "We inform the general public in a factual but clear way," explains private lecturer Dr Gaby-Fleur Böl, Head of the Risk Communication Department. In extensive social science studies, her research team also investigates how consumers perceive health risks in everyday life. "Perceived and actual risks are sometimes worlds apart – we bring these together."

Communication, be it of research findings or of recommendations, is a major challenge in the age of social media. Messages need to be concise and visual while remaining accurate. This can also be tricky because when focusing on health risks, the benefits are sometimes not sufficiently taken into account. Fish, for example, contains undesirable substances such as mercury compounds, but it's also a valuable food with healthy ingredients. And then there are those substances that some interest groups believe should be banned, but for which there are no equivalent substitutes.

Risk and benefit are sometimes closely intertwined. Can and should we weigh the pros and cons here? There's no shortage of challenges for the BfR in the future. ◘

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