

# BfR 2 GO

The Science Magazine  
of the German Federal Institute for Risk Assessment  
**Issue 2/2021**



Food and pesticides

## Fruits of fear



Cannabis additives

**The hype  
around hemp**

New trend

**Nicotine from  
a pouch**

'3Rs' guiding idea

**Mouse welfare  
principle**



# Dear Readers,

**The BfR is everywhere in our daily lives. You don't think so? Well, let's be a little more specific. The German Federal Institute for Risk Assessment (BfR) officially deals with a lot of the things we come across every day – on the basis of its legal mandate for risk assessment and risk communication. The BfR takes a close look at everyday life. And the results of its assessments not infrequently lead to changes in day-to-day life. For the better, we hope: safer, healthier, less risky.**

The topics covered in this latest edition of our Science Magazine are very clear evidence of that.

Let's start with this issue's main topic of plant protection products – a controversial topic in society on which opposing opinions clash. It is important to stick to the facts and stand up for consumer health protection with scientific arguments. Our aim is to provide objective and neutral information.

Flavouring substances are quite literally on everyone's lips: we ingest them every day with our food. Around 2,500 are permitted in the EU and are used in the manufacture of flavourings. Therefore, it is all the more important to test the safety of these 'flavour enhancers'. The BfR is involved. The same applies to current topics, such as the trend towards food containing hemp and the hemp ingredient cannabidiol, which is touted as 'calming'.

In the new BfR2GO, we also take a look at cleaning products, outdoor clothing, fast food packaging and cosmetics – specifically at per- and polyfluoroalkyl substances, or PFAS for short, which are found in a huge range of everyday products. Exceptionally long-lasting, they are absorbed by the body and are detectable in the blood. At present, the health impacts of PFAS have not yet been conclusively determined. However, there is reason for concern. The BfR is participating in research into the complicated relationship between PFAS and the human organism.

Last but not least, we look at a favourite among consumer health topics: vitamin D, which some consider as a cure-all. The BfR's assessment is rather reserved, although the benefits of the 'sun hormone' are undisputed. In any case, plenty of walks are recommended, even in the cold season. The winter sun not only raises vitamin D levels, it also lifts the spirit.

Have an enjoyable and not everyday read,

**Professor Dr. Tanja Schwerdtle**  
Vice President of the BfR







## On-trend – but be cautious!

Beeswax-coated cloths are all the rage. They are used to cover bowls, wrap bread, and are an alternative to aluminium foil and cling film. But be careful about them coming into contact with food: parts of these beeswax cloths can accidentally migrate into food. In the case of dyed textiles, so-called primary aromatic amines from printing inks are particularly critical. Some of them are classified as carcinogens. The wax residues can also harbour a health risk. If the beeswax does not meet the requirements as a food additive, it could be contaminated with mineral oil or pesticides. Similarly, the addition of jojoba oil into the cloth should be avoided – animal studies show toxic effects of jojoba oil in intestinal cells. Remember: fabrics and printing should be explicitly suitable for food contact and should never come into contact with fatty foods such as cakes, sausages or raw animal products. A hygienic boil wash is not possible since the wax would melt. Plus, the risk of transmission with plant-based products may be lower, but cannot be ruled out.

### More information:

[www.bfr.bund.de/en](http://www.bfr.bund.de/en)

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#### Editorial department address:

German Federal Institute for Risk Assessment (BfR)  
Max-Dohrn-Strasse 8–10  
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[www.bfr.bund.de/en](http://www.bfr.bund.de/en)  
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# Fruits



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# of fear

**Many people are suspicious of plant protection products. Is there cause for concern? Let's take stock.**

Plant protection products (PPP) hardly enjoy a good reputation. But it's not just that: many people fear they are harmful to health. They worry about 'chemicals' in food that is supposed to be as 'natural' as possible. This attitude is encouraged by, at times, unbalanced media reporting. In 2016, for example, the news that the PPP active substance glyphosate had been detected in the 14 best-selling types of beer caused quite a commotion. Yet the level of glyphosate was so low that you would have to drink 1,000 litres of beer every day to consume enough of the active substance for it to pose a health risk.

Reports such as these contribute to further unsettling the public. But what is the state doing to protect its citizens? What real health risks do people face? How are PPP authorised and how is their use monitored? Is there cause for concern?\*

## **Approval and authorisation: what's the difference?**

The authorisation of PPP and the approval of the active substances they contain are strictly regulated in the European Union (EU). Active substances are approved throughout the EU after prior assessment by one or more member states. Plant protection products on the other hand – they often contain several active substances and co-formulants – are authorised nationally by indi-

\* This article is partly based on presentations of the 21st BfR Consumer Protection Forum, held in Berlin on 9 and 10 June 2021 under the heading 'Plant Protection Products – a cause for concern?'.  
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© picture alliance/dpa/Oliver Berg

There is great uncertainty among the population. At protests like this, people call for a ban on glyphosate.



## A hazard is possible, a risk is real

A 'hazard' describes a potential harm to health, a theoretical possibility. 'Risk' on the other hand describes the probability of this hazard occurring – so the real situation in which we face the hazard (exposure). Here's an example: a tiger is a hazard. But what determines the risk is the extent to which we are at the tiger's mercy. A caged tiger is hazardous, but a low risk. Conversely, a hungry tiger running free ten metres away is an extremely high risk. Likewise, a PPP active substance can also pose a hazard as it is potentially toxic. No health risk is to be expected when PPP are used as intended, however, since they are investigated and evaluated prior to being authorised, and conditions for safe use are determined.

vidual member states. This is usually preceded by a zonal evaluation. For this purpose, the EU is divided into three zones – with Germany in the central zone. A national authority evaluates the application for authorisation on behalf of the other member states in the zone.

A key aspect during the approval of active substances is the assessment of their health risks. In Germany, this assessment is done independently by the German Federal Institute for Risk Assessment (BfR). Fundamental to this is the distinction between hazard and risk (see box).

"We comprehensively examine, from the farmer and wheat field resident to the consumer, what potential hazards an active substance poses to different groups of people," says Dr. Jens Schubert of the BfR. The focus is on the real risk, not the theoretical hazard.

### Thorough assessment

The BfR assesses how an active substance is absorbed and metabolised and what toxic (poisonous) effects may occur. The assessment also looks at whether a substance triggers genetic mutations (mutagenicity), whether it causes cancer (carcinogenicity) or damages genetic information (genotoxicity). A PPP active substance is approved, and a PPP authorised, only if no risk to health is to be expected when used as intended.

Based on the information on an active substance, the BfR together with experts from the other member states and the European Food Safety Authority (EFSA) estab-



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**The BfR comprehensively assesses the real risk posed by an active substance.**



lishes standard EU limit values that must be complied with. It is important to note that the dose of a substance determines its toxicity. PPP residues can be tolerated at low levels in food – far below a harmful dose. The limit of what is permitted is marked by the so-called maximum residue level of an active substance and its degradation products.

When determining (‘deriving’) the limit values, a safety margin is taken into account. A dose that produces an effect in animals is reduced by a factor of ten when transferred to humans, and then again by a factor of ten to take account of different people’s varying sensitivities.

### The limit value and the toxin

Limit values are like crash barriers on our roads. Just as they help to prevent traffic accidents, limit values are designed to guarantee the safe use of an active substance. However, it is a misconception that they represent a boundary between ‘harmful’ or ‘toxic’ and between ‘harmless’ or ‘non-toxic’.

Here’s an example: The ADI value (the acceptable daily intake) indicates the amount of a substance that can be ingested daily over a lifetime with no health risk. Occasionally exceeding the amount is not significant as it will be offset by lower intake on other days.

### Ensuring high quality food

While the BfR carries out the risk assessment as an independent authority, the German Federal Office of Consumer Protection and Food Safety (BVL) is tasked with the risk management further down the line. As well as granting authorisation, the BVL’s duties include determining the application areas and monitoring the use of plant protection products.

When authorising PPP, in addition to the health risks (assessed by the BfR), the BVL also considers the issue of efficacy (assessed by the Julius Kühn Institute) and environmental compatibility (assessed by the German Federal Environment Agency). The BVL sets out in detail how, where and by whom the PPP may be used.

“Plant protection products ensure the availability of high quality food for everyone,” says Dr. Martin Strelke, Head of Department at BVL. He sees plant protection confronted by some difficult problems. Strelke is concerned that the total number of PPP active substances has remained unchanged for years, even though around 20 per cent more PPP have been authorised since 2016. However, there was a shift between the areas of effectiveness at the expense of insecticides. As



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**Plant protection products are no cause for concern if they are used as intended.**



©Jonathan Kemper/unsplash

a result, around 20 per cent more emergency authorisations, which are available for only a short time, have had to be granted since 2016, and the trend is rising. “The loss of important PPP active substances is resulting in bigger gaps in protecting several crops,” he laments.

### Food: 20,000 controls per year

The food control office of each respective federal state in Germany is responsible for checking PPP residues. Every year, around 20,000 food samples are tested for pesticide residues by 19 investigation offices.

“Overall, no pesticide residues were found in about 40 per cent of food samples in 2019,” reports Anne Katrin Pietrzyk from the BVL. “Tolerable residues below the maximum residue level were found in just under 60 per cent, and in just over two per cent it was exceeded.”

If the maximum residue level in a product is exceeded, the first thing to look at is the uncertainty of the measurement. If this has been deducted and the measured value is still above the limit, the product is no longer considered ‘marketable’. This does not mean that it already poses a risk, however. As a rule, to reach the limit values that are significant in terms of health much higher concentrations are needed.

### ‘Organic’ with fewer synthetic traces

For anyone who still wants to eat as few ‘synthetic’ PPP residues as possible, organic food is an option. Such foods are almost 80 per cent free from traces of ‘synthetic’ pesticides. However, this does not take into account the ‘non-synthetic’ pesticides permitted (and not calculated) in organic agriculture.

Criticism of the existing PPP risk assessment comes from non-governmental organisations like the German Federation for the Environment and Nature Conservation (BUND). In the view of Corinna Hölzel from the Biodiversity Department of BUND, the risk assessment is outdated because it underestimates multiple exposures and hormonally active pesticides.

## Under debate: glyphosate

Glyphosate is the most commonly used active substance in weed killers (herbicides) in the world. The substance is highly effective – and highly controversial. Environmental organisations have been campaigning for a ban for decades due to ecological and health concerns. Glyphosate is approved in the EU for use in plant protection products until 15 December 2022. The renewal of approval is currently under discussion. The final decision will be made by the EU Commission together with the member states on the basis of a report by the European Food Safety Authority (EFSA). This is expected to come in the second half of 2022.

### Controls criticised as inadequate

Controls on PPP residues are inadequate as infringements are not sufficiently penalised, and pesticides no longer authorised in the EU enter the market via imported food. Furthermore, the precautionary principle needs to be applied consistently. The authorisation for a PPP active substance such as glyphosate should not be extended because, according to the International Agency for Research on Cancer, it is probably carcinogenic and as a total herbicide it has a highly damaging effect on biodiversity.

“Every substance is dangerous,” counters Dr. Tewes Tralau, Head of the ‘Pesticides Safety’ department at the BfR. The key aspect is always the dose you are exposed to. That’s true of every substance and every plant protection product, regardless of whether it’s ‘synthetic’ or ‘organic’.

Tralau doesn’t agree that the PPP risk assessment is ‘outdated’ and doesn’t take sufficient account of the hazards. Scientific studies are the basis for rational action. Mere suspicion or speculation are not a sufficient basis – not even for the precautionary principle. “As far as I am concerned, plant protection products are no cause for concern – as long as they are used as intended,” concludes Tralau as a scientist. ■

#### More information:

[www.bfr-akademie.de](http://www.bfr-akademie.de) > English > Archive: 2021 > 21st BfR Consumer Protection Forum “Plant protection products – a cause for concern?”

# “It won't work without chemistry”

## What matters is the dose: Dr. Tewes Tralau, pesticides expert at the German Federal Institute for Risk Assessment (BfR), on the risks of plant protection products and the search for alternatives.

### Mr. Tralau, most people prefer foods that are free from pesticides. Can you understand that?

That's based on the desire to eat foods the way nature has provided them. Personally I understand that, but from a scientific point of view this is virtually impossible. Unless you collect berries in the forest. But the vegetables we buy in the supermarket will often have come into contact with pesticides.

### How big is the risk from residues of plant protection products (PPP) on food?

There is no significant risk for the consumers posed by residues on food. If that were the case, a PPP would not be eligible for approval. During the authorisation, residues are assessed in terms of health impacts. A PPP is approved only if, according to the state of the art in science and technology, there is no health risk.

### But cannot excessive dosing of an agent lead to fruit or vegetables being heavily contaminated?

Of course it is conceivable that a PPP is not used as intended. However, if a farmer applied too much of a product he risks being detected during monitoring and would subsequently face legal consequences. Yet even in this case, there is no health risk to be expected for the consumer due to the large safety margins which serve as built-in buffers when derogating dosage levels and health-related limit values.

### How do you assess the results of the official food surveillance programmes?

They show that the majority of samples are either free of PPP or uncritical, meaning within a range that is harmless. Only a very small proportion of the samples ever come to our attention.

### The critics say: You don't need chemicals in the fields.

It won't work without chemistry, let's be clear about that. Even organic farming has to use spray agents. A classic example is copper sulphate, without which a large part of organic farming would not be possible. Incidentally, this is an agent that, due to its properties, would probably not be as easily approved anymore for conventional cultivation.

### Where is copper sulphate used?

Primarily in viticulture. Anyone who grows organic wine relies on copper sulphate as an agent to combat fungal infestation.

### How do you rate the health risk of 'organic' compared to 'chemical'?

Regarding risk, there is no difference. Chemical synthetic PPP are as safe as organic ones. Distinguishing between nature and chemistry is scientifically untenable. What we regard as nature is also chemistry. Let me give you an example from organic farming where pyrethroid extracts are used. Pyrethroids are insecticides produced from chrysanthemums. Such plant extracts have a fluctuating composition. If the same product is used in chemical plant protection, it is used as a pure substance. Apart from this distinction, a pyrethroid is a pyrethroid, whether 'organic' or 'chemical'.

”

**What we regard as nature is also chemistry.**

### The EU's farm-to-fork strategy aims to halve the use of synthetic pesticides by 2030. Is that feasible, and what consequences would it have?

Organic farming has lower yields than conventional farming. Today's food supply would not be possible without synthetic PPP. The alternatives used in organic farming, such as plant-strengthening products or microbiological PPP, in which bacteria or fungi act as pesticides, cannot fill the gap. Lower harvests are therefore inevitable. Accordingly, I have to buy in from elsewhere, thus depriving the respective local markets there. It will be difficult to achieve the targets.



Focusing on health risks:  
**Dr. Tewes Tralau** is head of the Pesticides Safety department at the BfR.

**The BfR assesses the specific risk posed by plant protection products. Yet, political objectives are in favour of an increasingly hazard-based assessment, in the EU for example. What is the difference?**

In a risk-based approach, you include exposure. This means I consider to what extent a person is subjected to a substance, or how much they are 'exposed' to. For the risk, this is crucial: the greater the exposure, the higher the dose and therefore the toxicity. Every substance is toxic at high doses.

**For example?**

Imagine I throw a small pebble at you. You would hardly feel it. But the bigger the pebble, the worse it will be. A large stone puts you in real danger. It's always the same material, yet the risk is quite different. It's just the same with chemicals: what matters is the dose.

**How does a hazard-based approach work?**

In this approach, a substance is banned because it is dangerous. That sounds convincing at first, but it isn't. Staying with our pebble example: I would ban all stones regardless of size, from grains of sand to a boulder.

**But no one wants to ban pebbles ...**

Much of what we consume on a daily basis or come into contact with is dangerous in terms of pure properties. Coffee would no longer be allowed today. Or let's take the smartphone with which you are currently recording this interview. You can use it with no danger, even though the chemicals and metals it is made of are a toxicological nightmare. Especially if you were to eat it.

**And plant protection products?**

PPP are dangerous per se, there's no question about that. But this danger is manageable. That is why they should not be banned flat out, as the hazard-based approach suggests. The world is full of dangerous chemicals that benefit us. Like smartphones. No one wants to ban those either. ■

# Big

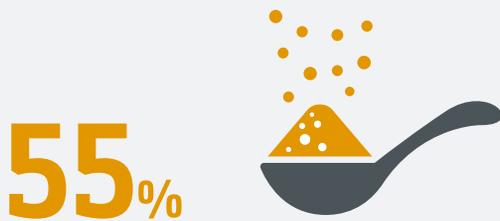


## – big scepticism?

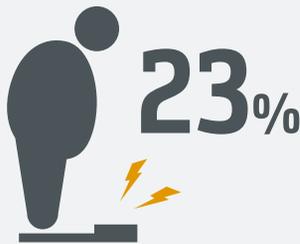
**Additives are found in numerous processed foods and usually appear in the list of ingredients as E-numbers. How important are the functions of additives to the population in Germany?  
A representative survey conducted by the German Federal Institute for Risk Assessment (BfR) yields new figures.**

**Underlying study:**  
Representative online survey of 1,015 people (German-speaking population aged 16 and above) in May 2021

48% see a **great benefit** in preservatives, while 44% also presume that they pose a **great health risk**. The respondents attributed the latter primarily to sweeteners (54%) and flavour enhancers (47%).



More than **half of the respondents** state that they avoid certain additives when buying food – most often **flavour enhancers** (84%) followed by **sweeteners** (69%).



**Intolerances** (27%) and **possible cancers** (26%) are the most commonly stated health risks associated with food additives. These are followed by the concern that food additives may promote **obesity** (23%).



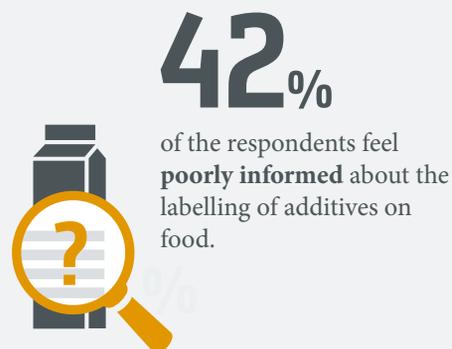
respondents (74%) consider it important for food to have a **nice texture**. An **appealing appearance** (70%) and **intense flavour** (66%) are also considered essential.

### Additives in Food

E 951, E 621, E 160a or E 270 ... This is how cryptically experts refer to food additives. Meant are sweeteners, flavour enhancers, dyes and preservatives. Approved in the EU, they carry E-numbers. According to the German Federal Office of Consumer Protection and Food Safety, there are currently around 320 of them. An additive does not constitute an ingredient of the food – it is added for technological purposes and affects, for example, the appearance, flavour, texture, and shelf life of the product. A food additive is approved in the EU only if it has been deemed harmless to health and as being technologically necessary. Moreover, consumers must not be misled by the use of an additive.

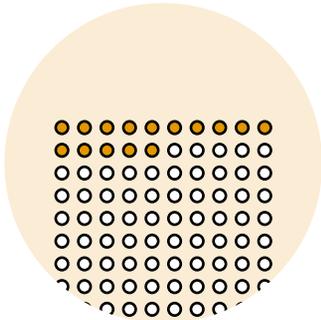


greatly value **natural ingredients** when buying food.



of the respondents feel **poorly informed** about the labelling of additives on food.

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > Publications > BfR Consumer Monitor > BfR Consumer Monitor 2021, Special Additives in Food



# Risks at a glance

**Visualisations can make risk information more understandable, particularly for people with low numeracy and reading skills.**

Every day, we make decisions that can affect our health. Ideally, scientific evidence can help us weigh the risks of different decision options – for instance, the benefits and harms of vaccination – and make good decisions for ourselves. A key prerequisite is that the risk information is packaged in comprehensible formats.

### Consequences of poor communication of risks

Poorly packaged risk information can affect how we understand and perceive risks and can negatively affect our decisions. It can lead us to under- or overestimate risks and, in turn, affect how we weigh the benefits and harms of decision alternatives. In terms of medical decisions, for example, we might end up making a decision that leads to unnecessary follow-up examinations or medical treatments, or that we regret later on.

Failing to communicate risk messages in an understandable way can increase health inequalities in societies. The reason is that some people have difficulties in reading texts and understanding numbers. As a result, their risk understanding is lower and they may perceive risks inaccurately. This makes them more vulnerable to poor health choices and can exacerbate existing inequalities in societies.

### How to improve risk communication?

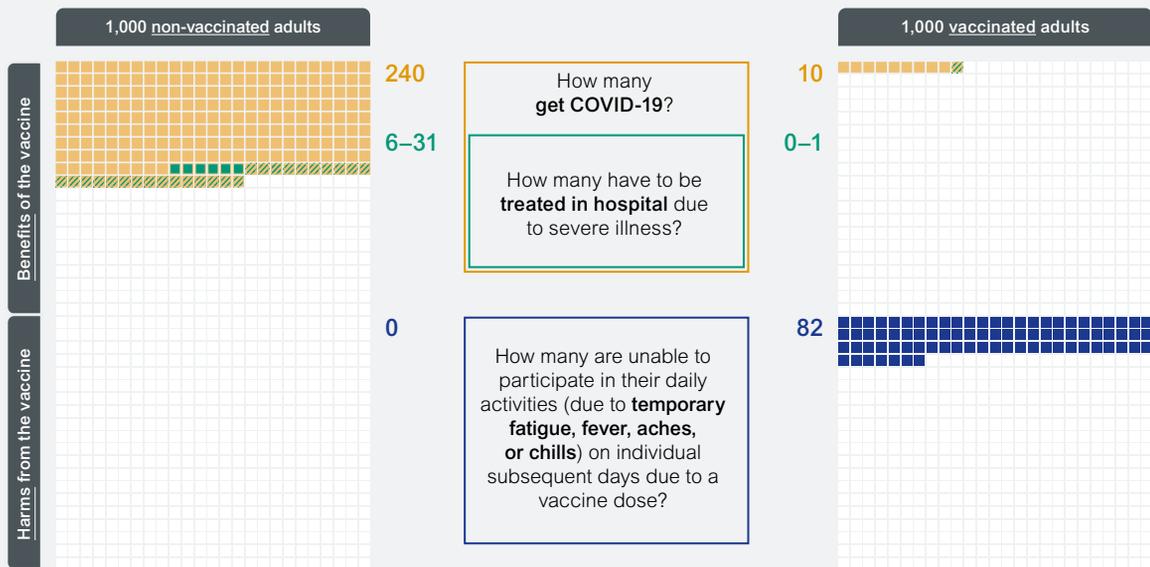
We can better understand risks when, for instance, risk probabilities are communicated numerically instead of verbally (for example, “5 in 100 people will experience a treatment side-effect” can be grasped more concretely than “The risk of treatment side-effects is low”). The reason is that people tend to interpret verbal probability statements differently. Simple frequencies or percentages (for example, 5 in 100 or 5%) are more comprehensible than probabilities or 1-in-x formats (for instance, 1 in 20). By communicating both numerator and denominator, it can be conveyed whether the risk is big or small. Moreover, when comparing risks, the denominator should be kept the same (for example always 100). Relative risk reductions are unclear (“The intervention reduced the number of infections by 20%”), instead, absolute risk reductions are recommended (“The intervention reduced the number of infections from 5 in 100 people without the treatment to 4 in 100 people with the treatment”). The latter illustrate the absolute size of a risk. If there is insufficient information to report numbers, the reason for this should be stated.

### The advantages of visual formats

Visual presentations can be a beneficial supplement or substitute for numerical or verbal information on

### Visualisation example: COVID-19 vaccination

This fact box compares adults under the age of 60 years without vaccination against COVID-19 (left side) with vaccinated adults (right side)



Excerpts from the Icon Array Fact box of the Harding Center for Risk Literacy and the Robert Koch Institute on the benefits and harms of the COVID-19 mRNA vaccines for adults under the age of 60 years.

risks. They can facilitate comprehension, especially for people with low numeracy or reading skills. Visual designs should convey proportions as part-to-whole representations (for example, via the proportional display of numerator and denominator). This allows us to build on our visual processing capacities to make size comparisons, even without the need to make numerical calculations. An example of a well-designed visual is the Icon Array Fact Box on the benefits and harms of COVID-19 mRNA vaccines by the Harding Center for Risk Literacy (see illustration). It was jointly developed with the Robert Koch Institute and translated into nine languages. The fact box results are presented here proportionally as icons in the shape of small boxes, showing the most relevant endpoints for benefits and harms listed for both 1,000 unvaccinated and 1,000 vaccinated adults each. This facilitates comparisons of the magnitude of potential risks both within and between decision options presented. ■

*A guest article by Christin Ellermann, Michelle McDowell, Clara Schirren, and Mirjam Jenny from the Harding Center for Risk Literacy at the University of Potsdam and the Robert Koch Institute in Berlin.*

**More information:**  
[www.hardingcentre.de/en](http://www.hardingcentre.de/en) > Transfer and Impact > Fact Boxes

#### Health risks in profile

Via the BfR risk profile, the German Federal Institute for Risk Assessment (BfR) visualises the results of its health risk assessments. Together with the Harding Center for Risk Literacy, the BfR is further developing the risk profile in the VisRisk research project. The aim is to create a numerical and visual presentation that summarises the most important facts of a risk assessment and thus strengthens consumers' understanding of risks and their decision-making competence. Possible courses of action for minimizing a health risk become apparent at a glance.

# “Coronavirus is showing that we need to understand data better”

Statistician Katharina Schüller is part of the team of the popular science campaign ‘Unstatistics of the Month’ - a group that critically scrutinises how figures are presented in public. In this interview, she explains why we often unconsciously classify data incorrectly.



**Ms. Schüller, for more than a year and a half we have been literally “bombarded” with projections on coronavirus. Particularly at the beginning, forecasts about the spread of the pandemic often proved to be inaccurate. Why was that?**

The assessment of a risk to support further decision-making is always based on data that already exists. But precisely these data are not particularly good for assessing the situation, especially at the beginning of a crisis because that is not why they were collated, and so may not be representative, for example. We cannot derive any precise recommended actions from them. As best, they can serve as a guideline for our actions.

**Were we too certain too soon?**

The forecasts often gave that impression. But there are two sources of uncertainty we need to consider. One lies in the nature of any data analysis: estimates are always inaccurate to some degree. These uncertainties

can be expressed as ranges of variation, or ‘confidence intervals’. Furthermore, there can always be influences on what is happening that are not foreseeable, such as virus mutations, fluctuations in the weather or reactions to the projection. This happened during the coronavirus pandemic.

**What lessons can you draw from this?**

Coronavirus is showing us the importance of solid information and a robust data infrastructure. What data is available is also crucial. There’s a saying that ‘You can’t manage what you can’t measure’. It means that where information is lacking, there are blind spots in the management of a crisis as well as problems you fail to see. There is also a cognitive bias.

**What does that mean?**

We overvalue incomplete data. Simply because they are there.

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**We overvalue incomplete data. Simply because they are there.**



**Katharina Schüller** encourages a conscious approach to statistics. She is on the board of the German Statistical Society and director of the Munich-based consultancy 'Stat-up'.

**Could you give us an example?**

If the current number of coronavirus cases reported in the headlines every day creeps up and down, then at some point it is about this one factor alone. At the same time, we ignore gaps in knowledge. Because what would happen if the 'Tagesschau' news programme were also to report every day on how many people have lost their job because of the pandemic? Or how many school lessons were cancelled? Or how often depression was diagnosed? That would give us a very different picture of the consequences of the pandemic.

**So it's wrong to concentrate solely on the infection figures?**

Yes, absolutely. You need to access the most diverse data sources to get a comprehensive picture of a crisis. These must be assessed and viewed in relation to each other. After all, millions of people with very different circumstances are affected by the coronavirus crisis. Single

mothers with children of school age, for example, who often have a hard time. We need to take this diversity of perspectives seriously. We will otherwise not recognise that there may be conflicting aims and measures that could have undesirable side-effects.

**How can we take better account of this diversity of perspectives?**

The question is: which aspects of reality do I want to include? We should understand a pandemic like coronavirus as a complex system: what points of view are relevant to navigate this system and to come out of the pandemic well? Which goals are important? Not all data are helpful. But expert analysis of these data is a key factor in drawing consequences from such a situation and controlling it – and making a lot of what we experienced in the past year more manageable.

**One focus of your work is Data Literacy – the expert handling of data. Can Data Literacy improve our ability to assess risks?**

For me, handling data is essential for risk competence. We need to learn to scrutinise data and information critically. We need to understand what is in the data, and what is only added as a result of our interpretation. Assessment is never purely objective, it also depends on the goals being pursued. With coronavirus, for example, the question is: are the measures that are taken solely about averting an immediate threat, or are we interested in medium and long-term consequences and issues around quality of life? Depending on our aims, we need to classify data according to specific criteria and assess them accordingly.

**What practical consequences should we draw from that?**

The decision-makers, politicians for example, need a better understanding of data: what are the strengths of data, where are the limitations and what are the opportunities? They need to know how to communicate data – including the unknowns, which we always have to think about too. We also need high quality public data and statistics based on a dependable infrastructure. That's one thing that is often forgotten when we talk about expertise in a crisis. Building a data infrastructure may not sound as hip and sexy as keywords like Big Data, Artificial Intelligence or Dashboards – but we need a quality-assured, professional system for data provision and analysis that policymakers and administrators can access reliably.

**How moral is it to collect data? The key term is data ethics.**

When it comes to collecting and processing information, the moral question is very often only asked in terms of what is not allowed. As if data ethics is only about not misusing data. But data ethics is also about what you should do: use data for a good purpose and to the benefit of society. Because not using data even though they could help to solve problems like the current pandemic better and faster is just as unethical as misuse. ■



# The hype around hemp

## **Foods and food supplements containing hemp: a must-have in a healthy diet or to be enjoyed with caution?**

**H**emp noodles, hemp tea, hemp chocolate – products with hemp are taking over the supermarket shelves, health stores and online shops, and are literally on everyone’s lips.

The hemp plant, also known by its Latin name cannabis, has been used in many ways for centuries, whether for the production of fibres for textiles or as a remedy, but also as narcotic drug. Now it’s making a comeback as a commercial crop. Numerous products containing hemp have made it onto the market in recent years. These mainly comprise foods and food supplements, but also include creams, e-cigarettes and even feed additives for pets. These products often contain hemp seeds, oil or protein powder obtained from these seeds as an ingredient. The seeds of the hemp plant are rich in valuable amino and fatty acids, similar to linseeds.

### **What causes the high?**

Unlike the seeds and roots of the plant, the other parts of the plant – for example the leaves and flowers – produce so-called cannabinoids. Among the best-known of these are tetrahydrocannabinol (THC) and cannabidiol (CBD). The legal situation governing products containing the leaves or flowers from cultivated hemp or extracts derived from them is complex. In individual cases, such products can be deemed by the competent authorities as being narcotic drugs.

THC is primarily held responsible for the intoxicating, psychoactive effect of cannabis products. THC has a perception-altering effect, and is listed as a narcotic drug in Germany. Therefore, in foods containing hemp, THC comes under the spotlight in respect of potential health risks.

In an assessment from 2015, the European Food Safety Authority (EFSA) concluded that an effect on the central nervous system and the cardiovascular system is to be expected after ingesting smaller amounts of THC. This may lead to mood swings and fatigue. As a consequence, the EFSA derived an ‘acute reference dose’ (ARfD) of 0.001 milligrams of THC per kilogram of body weight. This value indicates the estimated maximum intake of THC that can be consumed in the course of one day via food without a detectable health risk.

### **Excess THC from food containing hemp**

Current model calculations by the German Federal Institute for Risk Assessment (BfR) on the intake of THC via food consumption indicate that the consumption of hemp tea in particular could lead to an exceedance of the ARfD from EFSA. Hemp seeds and foods made from them such as hemp seed oil can also sometimes have a high THC content due to contaminations that occur during production and processing. “Children in particular are at increased risk of consuming too much of the



Products containing hemp are taking over the supermarket shelves: there are still a lot of unanswered questions concerning potential consequences for health.

substance because of their low body weight,” says Professor Dr. Bernd Schäfer, Head of the Food Toxicology unit at the BfR. Standardised maximum levels for THC in food do not yet exist. The introduction of maximum levels for hemp seeds and products made from them is currently being discussed at EU level, however.

The manufacturers of products that contain CBD claim in their marketing slogans that CBD has a calming and pain-relieving effect, and helps with sleep disorders. But what can research tell us about the effect of CBD on people? So far, there is an approved (and prescription-only) medicinal product in Germany with CBD as an active ingredient for the treatment of certain forms of epilepsy – where a positive effect has been proven. “Conversely, most of the effects advertised as being positive for health have not yet been scientifically proven,” emphasises Schäfer. There is also still limited understanding of the potential harmful effects of CBD in foodstuffs.

### **Adverse effects cannot be ruled out**

The EFSA is currently assessing the safety of CBD as part of several authorisation processes for novel foods. “However, it is already known from the medicinal use of CBD for certain forms of epilepsy that CBD can cause undesirable effects, at least at higher intake levels. These include a sedative, or sleep-inducing effect, and disturbances of liver function,” says Schäfer. “Based on current understanding, there can certainly also be interactions

with other medicinal products. However, according to current knowledge, there seems to be no intoxicating/narcotic effect in contrast to other cannabis ingredients.”

### **How are products containing CBD regulated in retail?**

Just now, products containing CBD are increasingly found on the market with a food supplement declaration. According to the German Federal Office of Consumer Protection and Food Safety (BVL), these products are currently not marketable, however, because they are considered to be novel foods which must be authorised by the European Commission before they are marketed. But no product containing CBD has yet been authorised as a novel food because the EFSA has not yet completed the necessary safety assessment.

What you need to know: The consumption of foodstuffs is generally not permitted to result in harm to health. Furthermore, the ingredients in foodstuffs, including food supplements, are not permitted to have any pharmacological effect. This means they are not allowed to have any properties for healing or alleviating illnesses – because as soon as they do, they are classified a medicinal products, not foods. ■

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > A-Z Index: Hemp

# A popular substance

## A current survey by the BfR collects data on the consumption of cannabidiol in Germany for the first time.

It is becoming apparent that there will be a global increase in the sale of products containing cannabidiol (CBD) in the coming years. Based on initial analyses, market researchers in the US, for example, predict that the market will grow around 20 percent annually over the next five years – a business worth billions. The latest data from the German Federal Institute for Risk Assessment (BfR) show that consumption will also continue to increase in Germany.

Until now, little was known about the consumption behaviour in Germany. In 2021, a team of experts from the BfR investigated the following topics for the first time using an online survey of 2,000 people who have already heard of CBD: Who consumes products with CBD – and why? How do people rate the health risk compared to the benefit?

Half of the respondents (50%) who had not yet consumed products with CBD say they would purchase or use such products in the future. 27 percent of respondents have already consumed or used the substance. Among them, the proportion of people under 30 is slightly higher than in the older age groups. “According to our survey, the reasons for consumption are diverse,” says Johanna Geppert, Communication Scientist at the BfR. “Among others, a potential pain-relief effect or the potential help for relaxation were mentioned, but also pure curiosity about the product.” CBD is also mostly consumed on a regular basis: 42 percent of people who have already consumed CBD say they use products at least once a week. By far the most popular are oils and tinctures. They are mainly purchased in online stores – with important buying criteria being the CBD content and the price.

According to Johanna Geppert, the fact that 50 percent of the respondents who have not yet tried CBD products could imagine doing so also fits in with the result that the health benefits of the products are rated much higher even by people who have not yet consumed



CBD: more than half of these respondents (51%) see a (very) high benefit. In comparison, only a good eighth (13%) suspect a (very) high risk.

The most likely perceived health risk is a possible habituation to CBD and dependency on CBD. 30 percent of the respondents believe that CBD products may contain THC. However, fewer respondents (24%) believe that the substance CBD may have an intoxicating effect. Before consuming the products, 29 percent of the 60-plus age group sought medical advice; this figure was 14 percent in the under-30 age group. Only 40 percent of the respondents believe that the effect of medicines can be influenced by CBD products. Five percent report side-effects following consumption. ■



# A matter of taste

**There is a vast variety of flavouring substances – but data gaps hinder their assessment regarding health effects.**

Flavouring substances turn foods into true taste sensations. These chemical compounds are added to many products such as beverages, confectionery, snacks, dairy products and convenience foods. Their role is to add or enhance a specific odour or taste. As foods can lose their inherent flavour during production, transport and storage, many of them would taste bland without flavourings. But these substances can do even more than that: they also ensure consistency of taste – after all, you want your favourite chips to taste the same after every potato harvest.

Around 2,500 chemically defined flavouring substances are permitted in the EU and are used in the manufacture of flavourings. Only complex mixtures of flavouring substances and other substances such as food additives, carriers and solvents form flavourings which then appear in solid or liquid form and can be used for food flavouring. A flavouring can consist of more than 100 components. Even small amounts, in the range of milligrams to grams, can be sufficient to add taste into a kilogram of food.

### Natural or nature-identical – which terms are currently applicable?

The previous German Flavouring Regulation made a distinction between natural, nature-identical and artificial flavouring substances. However, the terms 'nature-identical' and 'artificial' are no longer used in the EU Flavouring Regulation that now also applies in Germany. "Whether a substance is of natural origin or not is irrelevant for its hazard potential and the safety of consuming this substance. The chemical structure and the associated chemical and physical properties are decisive," explains Dr. Rainer Gürtler, Food Toxicologist at the German Federal Institute for Risk Assessment (BfR). The flavouring substances do not necessarily need to originate from the foods to which they lend their typical flavour. They can also originate from different plant-based or animal materials, be produced from microorganisms such as bacteria and yeasts, or be completely produced via chemical synthesis.

Their labelling is regulated in the EU Flavouring Regulation and the EU Food Information Regulations. For example, if strawberry fruit is indicated as a flavouring source on a product package, the claim 'natural' is permitted only if at least 95 per cent of the flavouring component originates from this source. Therefore, a yoghurt does not necessarily contain a fresh berry - its flavouring can also come from strawberries that have been freeze-dried, for example. If less than 95 per cent is from a consistent natural source, it must be called "natural strawberry flavouring with other natural flavourings" if the flavouring substance is only partly derived from strawberries but their flavour is easily recognisable.

One of the most popular fragrance and flavouring substance is vanillin: according to the German Association of the Flavour Industry (Deutscher Verband der



### What you need to know

It is often said that flavourings have an effect on eating habits and that we even eat more of the food than necessary because of them. Is that true? "We have no reliable data to support this assumption," says Food Toxicologist Dr. Rainer Gürtler. However, there are some indications that sensory experiences during infancy can influence the taste perception and have an effect on food preferences later in life. In the view of the BfR, flavouring substances should therefore not be used in the production of infant formula or in foods for special medical purposes for infants in the first 16 weeks of life.

More information:  
BfR Opinion No. 049/2020 of 3 November 2020

**99**  
**Several hundred flavouring substances have not yet been finally evaluated.**

## New Reference Laboratory

Is what's on the packaging really all that's in a product? Germany is the first EU member state that established a Reference Laboratory for Food Additives and Flavourings. In future, new analytical methods will be developed at the BfR to monitor, among other things, the use and intake of additives and flavourings. Tests will also be performed to determine whether flavourings are of natural or synthetic origin. Analytical methods will also be applied to provide evidence of a potential use of additives and flavouring substances that have not been approved.



Aromenindustrie), global annual demand amounts to 15,000 tons – whether for chocolate, ice cream, baked goods, beverages, cosmetics or pharmaceutical products. Demand thus considerably exceeds real vanilla bean resources, in addition the methods of extraction are relatively expensive. Vanillin is thus chemically produced on a large scale, including from fossil raw materials. According to the association, more than 90 per cent of the vanillin used worldwide today comes from synthetic production.

### There are still several data gaps

Apart from labelling, the EU Flavouring Regulation also governs the use of flavouring substances. According to this regulation, the vast majority of flavouring substances may be used without restriction, but some may be added only to certain food categories in specified maximum amounts. Although scientific evaluations are now available for almost all flavouring substances, there are several data gaps. “Several hundred flavouring substances have not yet been finally evaluated by the European Food Safety Authority (EFSA) – but despite this, they have been permitted for unrestricted use,” says Gürtler. The EFSA is calling for more reliable information con-

cerning the amounts used and then, depending on these data, additional toxicological studies where applicable, before the evaluations can be finalised.

The total number of around 2,500 flavouring substances, all of which have been on the market for decades and have had to be assessed at EU level since 2000, is simply huge: “Groups of chemically similar substances were therefore formed and assessed, and priority was given to the evaluation of the genotoxicity,” explains Gürtler. It took 20 years just to carry out these evaluations of groups of chemically similar flavouring substances. If the flavouring substances had all had to be toxicologically tested and assessed individually, it would have taken much more time.

So far, 45 flavouring substances have been deleted from the so-called Union list of the EU regulation, some of them due to health concerns and others because concerns could not be addressed and the flavour industry then did not submit additional toxicological data but refrained from further use of the substances concerned.

The data required to estimate intake have to-date been provided exclusively by the flavour industry. While production and import volumes are generally available, reliable information concerning the volumes used in food is lacking for a large number of flavourings. “The intake levels of around 1,300 flavouring substances could only be roughly estimated so far,” explains Gürtler. “Discussions are now taking place at the EU-level on how estimates of intake levels can be improved,” says the expert. Often, for example, there are also no suitable analytical methods available that are capable of detecting the often very low content of the individual substances in food. Developing and standardising methods for this is one of the tasks of the newly established Reference Laboratory for Food Additives and Flavourings at the BfR (see box). ■

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > A-Z Index: Flavourings



## Tracking down virus types

**A rotavirus infection can be life-threatening for young children in particular. Vaccines provide protection, but they are less effective in developing countries than in industrialised countries. Why is that? The German Federal Institute for Risk Assessment (BfR) and its partners set out to answer this question in sub-Saharan Africa specifically.**

Vaccines have been protecting against infection with rotavirus for 15 years. The number of cases with serious disease progression was reduced on the African continent too. But the experts noticed something: “Overall the vaccines perform worse in Africa than in Europe or North America,” says Professor Dr. Reimar Johne of the BfR. He is leading the ‘AfRota’ (Antigens and Reassortant Strains for Rotaviruses Circulating in Africa) project which kicked off in 2018. Together with three partners from Mozambique and South Africa, the BfR team investigated the reasons for this lower effectiveness. The finding: “The approved vaccines are produced on the basis of virus strains from Europe and North America. Different virus strains occur in Africa, so the vaccines could lose effectiveness there,” explains Johne.

To understand the rotavirus, its strains and the possibilities of adapted vaccines for this region, samples from humans and animals were characterised at the Instituto Nacional de Saúde in Maputo (Mozambique) and a diversity of strains was detected. It was found that the virus types that were not present in the vaccines were the ones that spread. A team at the University of the Free State in Bloemfontein (South Africa) took a closer look at selected strains: so-called whole genome analyses show that they are constantly evolving and exchanging genetic material. They thus form completely new types, known as reassortants.

Johne: “In the future, we need new vaccines that are tailored to the changed viruses.” The BfR is already developing systems for a generation of reassortants with parts of the rotavirus types identified in Africa, which might be used in specific vaccines for the region.

### Rotaviruses

Rotaviruses are prevalent worldwide, and can cause severe diarrhoea in young children in particular. The pathogens are highly infectious and transmitted via smear infection – from stools via the hands, objects, contaminated food and drinking water, and even via infected animals. There are hardly any deaths in Germany thanks to good medical care and high hygiene standards. In developing countries, the combination of poor hygiene and inadequate clinical treatment is fatal. According to one study, around 105,000 children under the age of five died of rotaviruses in 2016 in sub-Saharan Africa alone, out of 128,500 deaths globally.

In parallel, North-West University in Potchefstroom (South Africa) is working on producing rotavirus particles that cannot replicate. These could possibly be even safer to use as vaccines.

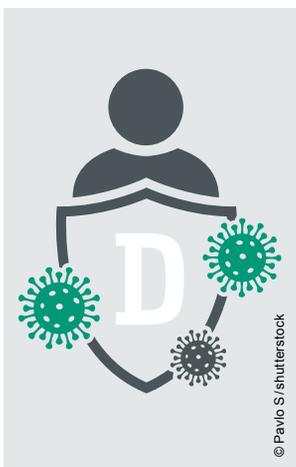
Many questions remain unanswered: Are the viruses and particles produced really suitable as vaccines? How can they be made highly effective, and at the same time safe? A further phase of the project plans to identify the necessary vaccine strains more precisely. ■

#### More information:

Falkenhagen, A. et al. 2020. Generation of Simian Rotavirus Reassortants with VP4- and VP7-Encoding Genome Segments from Human Strains Circulating in Africa Using Reverse Genetics. *Viruses*. 12, 201. DOI: 10.3390/v12020201

# A multi-talent with associated myths

**We need vitamin D above all for strong bones. In addition, it has been purported to protect against numerous diseases. What does science say? And what is important to consider?**



## Does vitamin D provide protection against coronavirus?

There is some evidence that insufficient vitamin D serum levels are associated with an increased risk of acute respiratory infections. However, the data for COVID-19, also a respiratory tract infection, are currently unclear. It has not yet been possible to demonstrate that individuals with a good supply of vitamin D are better protected against infection from coronavirus by taking additional vitamin D. In the view of the BfR, a general recommendation to use vitamin D supplements with the aim of preventing a SARS-CoV-2 infection or severe progression of COVID-19 can therefore not currently be substantiated. Individuals who nevertheless wish to supplement vitamin D as a precautionary measure can take 20 micrograms per day.

More information:  
BfR Communication No. 015/2021 of 14 May 2021

When the days become shorter and winter draws nearer, a quite specific micronutrient comes into focus: vitamin D. This so-called 'sunshine vitamin' occupies a special position among vitamins, because the body can produce it itself when the skin is exposed to sunlight. Intake of vitamin D via food is generally low because vitamin D is present in only a few foods. It is found in significant amounts for example in oily salt-water fish, eggs and mushrooms. Like all vitamins, vitamin D is involved in many central metabolic processes, and is therefore a vital multi-talent for humans. Among other things, it regulates calcium and phosphate metabolism and makes teeth and bones stronger. It also strengthens muscles and supports a well-functioning immune system.

### On everyone's lips

Food supplements containing vitamins are among the most frequently consumed nutritional supplements in Germany. During the COVID-19 pandemic, the hype surrounding nutritional supplements, including vitamin D supplements, increased with the fear of contagion. Reports on the internet have claimed that vitamin D could protect against infection by the coronavirus or reduce the severity of progression of COVID-19 (see box). There is also an ongoing discussion concerning a potential association between an insufficient supply of vitamin D and chronic diseases such as cancer, cardiovascular disease and diabetes. This has, however, not been scientifically proven to date.

### Boosting the body's own production

The amount of vitamin D that the body produces varies considerably from person to person and depends on numerous factors such as skin type, age and the time of the year. With sufficient sunlight, the body's own production contributes around 80 to 90 per cent of the supply. The Federal Office for Radiation Protection therefore recommends exposing the face, hands and arms to the sun uncovered and without sunscreen two to three times a week. Sunburn, however, should always be avoided. Regular outdoor activities provide one of the best ways to ensure a good vitamin D supply. During the lighter months, the body is able to build up reserves for the winter in fat and muscle tissue.

### For whom are vitamin D supplements useful?

Vitamin D supplements may be useful for people who seldom spend time outdoors or who, for example for cultural reasons, do not leave home unless they are fully covered up. Dark-skinned people are also included in this group since the higher content of the skin pigment melanin only allows a comparatively small fraction of UVB radiation to get through. Another risk group includes the elderly, because vitamin D formation decreases significantly with age. Older people also often have chronic diseases and are less mobile, which means



### Why 20 micrograms of Vitamin D?

Both at the national and the European level, there are currently no legally binding maximum quantities for vitamins and minerals in food supplements or added to fortified foods. For about the last two decades, the BfR has been involved in the assessment of health risks of vitamins and minerals, and has developed respective proposals for maximum amounts. These have been calculated such that no adverse health effects are to be expected with the additional amount of nutrients consumed, even if fortified foods are consumed in addition to nutritional supplements. The proposed maximum amounts are intended to serve risk management as a basis for discussion in the context of drawing up legal regulations at the EU level. The BfR's recommendation for adolescents and adults regarding a maximal amount of vitamin D in a nutritional supplement is: 20 micrograms per day

**More information:**  
BfR Opinion No. 009/2021 of 15 March 2021

they may spend less or no time outdoors. Older people living in nursing homes can thus be particularly vulnerable to a vitamin D deficiency. For this group, the German Federal Institute for Risk Assessment (BfR) therefore recommends considering supplementation with a general dose of up to 20 micrograms of vitamin D (800 International Units) per day.

### Things to consider

Persons wishing to supplement vitamin D can use food supplements with doses of up to 20 micrograms of vitamin D per day. This applies to adolescents and adults. This amount covers needs with no expected adverse health effects. Consumption of higher doses, and very high quantities in particular, should occur under medical supervision only, and taking into account the individual vitamin D status. Self-managed and uncontrolled intake of high-dose vitamin D supplements can be harmful to health. ■

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > A-Z Index: Vitamin D

# Nutritional treat or trick?

**Is young child formula a must? And how many children drink it? The BfR KiESEL study answers these questions and provides other facts concerning the nutrition of young children.**

## What do children eat today, and how much?

These results regarding the consumption of young child formula are provided by the BfR KiESEL study. KiESEL stands for "Kinder-Ernährungsstudie zur Erfassung des Lebensmittelverzehr" (The Children's Nutrition Survey to Record Food Consumption). The study examined the diet of children throughout Germany from the age of six months up to and including five years. The aim of the KiESEL study: to obtain the latest data on children's food consumption to be able to assess the health risks of dietary habits as accurately as possible. But why the focus on children in this age range? "Young children's food intake in relation to their body weight is higher than in adults", says nutritionist Nowak. "So it is particularly important for us to determine precise exposure data from children in this early phase of life, i.e. which foods they eat, and how much."

## Ready to eat with the BfR

Between 2014 and 2017, the study team visited a total of 1,104 families throughout Germany and interviewed them about their offspring's eating habits. Food diaries, in which the parents and childcare facilities documented exactly what the children ate and drank for four days, provided additional information. The data obtained allow us to perform realistic estimations on the quantities of nutrients and – of particular interest to the BfR – additives, pesticide residues and undesirable substances ingested by children through foods. By doing so, the BfR can examine whether the levels permitted are safe or should be further limited. The KiESEL study thus contributes to further improvement of food safety for children.

By the way: according to the BfR, young child formula is unnecessary in a balanced toddler diet. In Germany, with a few exceptions (vitamin D, iodine and in some cases iron), young children obtain sufficient amounts of micronutrients through the normal diet, including cow's milk. The consumption of young child formula can thus lead to an unnecessarily and even undesirably high intake of micronutrients. ■

"Formulated to meet the nutritional needs of young children" – claims such as this are frequently found on the packaging of drinks for young children. Often also labelled as "young child milk", these drinks generally contain less protein than cow's milk and are fortified with vitamins and nutrients. They are thus often promoted as being particularly suitable for children from 12 or 24 months.

## Used for one- and two-year-olds

A recent study by the German Federal Institute for Risk Assessment (BfR) shows that almost ten percent of children aged between 6 months and five years have ever had young child formula. BfR study director Nicole Nowak explains: "Children mostly started with these products at between 12 to 13 months or 18 to 24 months. The majority of children, 83 percent, receive young child formula in a feeding bottle. The products are thus used like infant formula."

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > A-Z Index: KiESEL study



## Refrigeration temperature

# 5.5

**degrees Celsius is the average temperature in domestic fridges in Germany.**

This is according to an online survey by the German Federal Institute for Risk Assessment (BfR) of 1,000 people aged 16 and above. The results showed that only half the respondents have an integrated display or a separate thermometer in their fridge – and so know the precise temperature they chill foods to at home. The BfR study is the first to provide indications of real temperature settings in household refrigerators in Germany. Meaningful data is expected to be collected from 2022 onwards by recording refrigerator temperatures over a period of over twelve months in selected households. By the way: to prevent food spoilage, refrigerators should be set to below 5 °C at best and maximum 7 °C. ■

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**More information:**

[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > Publications > Brochures > Protection against foodborne infections in private households



illustrations © Robert Samuel Hanson





# Danger on board?

**Say “dangerous goods” and most people think of heavy goods vehicles or tankers with warning signs. But everyday products in transport can also pose a danger.**

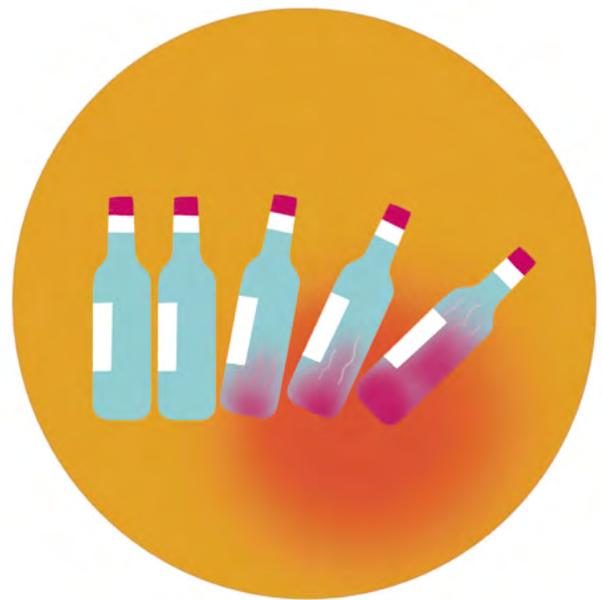
**E**gypt, 23 March 2021, 07.40 am local time: in the Suez Canal, the 400-metre-long container ship Ever Given runs aground right across the canal and blocks the sea route. 12 percent of the world’s maritime trade is paralysed. The world’s media runs constant articles on the incident, and it soon becomes clear: it could have been worse. Fortunately, the securing and stowage of the goods on the ship, which had been stuck for almost a week, were done properly.

Every day, millions upon millions of transport containers carrying a huge range of freight are moved around the world on giants of the sea like the Ever Given, as well as on goods trains and trucks. The range of products is as varied as the choice of goods on offer in world trade – from plastic bath animals to lawn fertiliser granules, every imaginable product is on board. The challenge of it: many goods harbour unexpected potential dangers on the often long journey to international retail shelves if they are not transported correctly. Science is on board here, because the potential hazards are chemical, biological and physical in nature.

## Hole-forming fruit juice

Carrying goods on their way to end consumers requires not just product and food safety, transport safety is also essential, and therefore the expertise of the German Federal Institute for Risk Assessment (BfR). Dr. Renate Krätke and her team deal with issues around the transport of dangerous goods within the BfR. In this field, which is monitored by several national and international authorities, comprehensive regulations govern a wide range of safety aspects during transport by road, rail, waterways and sea, including how cargo must be packed and positioned on a ship, for example. This is particularly important for liquid or solid mass goods that are transported unpackaged as loose 'bulk goods' in tankers or bulk carriers (also known as bulkers).

"For example, the citric acid in fruit juice can corrode metal containers," explains biologist and toxicologist Krätke. The same is true of vinegar, which has an acid content of over ten per cent, and undiluted cola syrup containing phosphoric acid. "If goods such as these are transported on ships for sometimes weeks at a time, and are not properly packed and stowed, there is an impact on the goods and on the containers," says Krätke. "For example, we are working on stipulating conditions of carriage that guarantee that acidic liquids are carried in non-corroding transport tanks."



## Risky spirits

The transport risks when it comes to alcoholic beverages seem perfectly apparent at first glance: the higher percentage of the drink, or the more ethanol it contains, the riskier its carriage becomes. The most important factors are the flash point temperatures (meaning the temperature at which flames will form on contact with an ignition source) and the boiling range (when there is a change from a liquid to a gaseous state). This results in strict specifications for the classification of dangerous goods. In practice, this means that spirits need to be stowed differently than beer, for example, which contains less alcohol and which means transport problems only at considerably higher temperatures.

## Anti-sliding rules

Some materials could easily slide during transport movements, shift their containers, and thus affect stability in the cargo area. There are 'angle of repose' rules for these loose goods, which determine how steeply and high they may be stacked. Such goods can include foodstuffs or animal feed, such as tapioca starch in powder form, or as pellets (tapioca pearls). The rules help to ensure that cargo does not move about on the mode of transport, and ships, trains and trucks do not become dangerously unbalanced.



**Gradual self-heating**

Additional regulations stipulate that foodstuffs and animal feed may not be stored next to goods such as crude oil and chemicals. That not only protects the foodstuff, it also protects the entire transport vehicle and the crew, according to Dr. Enikő Kámory. “Even supposedly harmless foodstuffs can harbour a risk in the wrong transport conditions,” explains the BfR scientist. For example, if solid foods that contain fat and oil are stored incorrectly and absorb moisture from the environment, natural degradation processes can cause the material itself to heat up. This occurs slowly at first, but can intensify over time and lead to spontaneous combustion. If a fire spreads in the container, neighbouring cargoes, such as chemicals, are no longer safe.

**Exploding flour**

Another example of the consequences that can result in extreme cases, in this case from incorrect storage, but also in principle from incorrect transport, is the destruction of a flour mill in Bremen – one of the most serious explosions in Germany since the end of the Second World War. In 1979, 14 people lost their lives in the accident and the physical damage ran to 100 million German Marks. The trigger was flour – or to be precise, a dust explosion caused by flour. The smaller the dust particles, the more susceptible they are to an explosion when they come into contact with an ignition source. A similar scenario could develop at any time during the transport of the everyday consumables we enjoy such as sugar, spices, coffee and cocoa if the rules prescribed for the transport of these goods are not adhered to, because these goods often make long journeys in containers.

The science-based transport regulations were evidently observed on the Ever Given. Thus, despite the extended waiting time, the goods were unloaded accident-free at their destination four months after the freighter had been freed. It goes to show that scientifically and empirically proven transport regulations are effective in reality. ■



# Nicotine from a pouch

**New nicotine products are entering the market. In addition to e-cigarettes, manufacturers are increasingly focusing on 'white' products, which contain nicotine alone, and no tobacco. A BfR study is examining the health risk of this new trend.**

Nicotine pouches or nicopods: suppliers also call them 'all white' products. Small pouches, like cushions, and filled with a white powder comprising nicotine salts, carriers, flavours and sweeteners. Whether mint, orange or hemp – there is a wide choice of flavours. The white pouches are supplied in tins, like sweets. They are placed firmly between the gums and lip for around 20 to 60 minutes to release nicotine which enters the bloodstream directly via the oral mucosa.

These 'all white' products are reminiscent of chewing or oral tobacco, such as traditional snuff or Scandinavian snus. They should not be confused, however, since they expressly contain no tobacco, but nicotine salts.

## Health effects

Since 2019, these novel products have also been spotted in Germany – despite the fact that their sale is so far prohibited in this market. In a study, the German Federal Institute for Risk Assessment (BfR) is investigating the health effects of consuming pouches. For the research team, it is initially important to know how much nicotine is absorbed through these products. "For this purpose, we randomly analysed various 'all white' products with different flavours and nicotine strengths," says scientist Nadine Dreiaek. The weight, plus the nicotine content and pH value, were determined in the laboratory. "The latter are important because nicotine is a basic alkaloid and is absorbed more quickly through the oral mucosa at high pH values," explains her colleague Sebastian Malke. Scientist Nadja Mallock adds: "The study results show that the weight and nicotine content of the products vary greatly. The weight-related nicotine contents show a wide range of between 4.48 and 75.5 milligrams per gram pouch." Dr. Thomas Schulz, who assesses the health effects of nicotine products at the BfR, explains: "This may present a health risk, because even 16.7 milligrams of nicotine have an acute toxic effect when taken orally."

## Not just straight to the heart

Studies have shown that consuming just one 6-milligram pouch of nicotine increases the heart rate by ten beats per minute. The pharmacological effects of nicotine on



- Taken orally, nicotine quickly enters the blood via the oral mucosa.
- Even in this form of delivery, nicotine can be addictive.
- Children, young people, pregnant and breast-feeding women, people with cardiovascular diseases such as high blood pressure or coronary heart disease and non-smokers are generally advised not to consume nicotine. They should therefore avoid 'all white' products.

the body are known to include not only an increase in heart rate, but also an increase in blood pressure and negative effects on sperm quality. Schulz estimates that consuming nicotine orally from 'all white' products results in nicotine levels in the blood that are similar to smoking cigarettes or vaping with e-cigarettes. Nicotine accumulates in saliva, gastric juice and breast milk and easily passes the placental barrier. ■

**More information:**  
BfR Opinion No. 027/2021 of 20 September 2021  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > A-Z index: Nicotine



## Health risk due to additives in tobacco and liquids

Scientific studies indicate the possibility of adverse health effects when certain components of tobacco for smoking are inhaled. This was the result of the German Federal Institute for Risk Assessment (BfR) health assessment for the substances diacetyl (2,3-butandione), 2,3-pentandione, 2,3-hexandione and 2,3-heptandione as well as for guar gum and sorbitol. Accordingly, the use of cannabidiol in cigarette tobacco and in liquids for e-cigarettes can also give the impression of a supposed health benefit. The European Tobacco Products Directive provides for a ban in such circumstances. The German Federal Ministry of Food and Agriculture had tasked the BfR with examining whether there are further scientific indications of substances with a health risk when inhaled. Under the German Tobacco Products Regulation, some substances with properties advertised in this way are already banned.

**More information:**  
BfR Opinion No. 021/2021 of 2 July 2021 (in German)

## 'UFI' can save lives in an emergency

Chemical products, such as detergents, often contain ingredients that are hazardous to health. The first point of contact in case of an accident is the emergency medical services or a poison centre. Often, however, the product in question cannot be clearly identified. The new 'UFI' is set to change that: UFI stands for 'Unique Formula Identifier'. The 16-character code comprising digits and letters links the hazardous product with information about its ingredients and properties which has been transmitted to the poisons centres. In case of emergency, the UFI facilitates rapid information to victims and medical staff about the risk of poisoning and the best medical care. Within the EU, many products that are classified as harmful to health already carry the UFI on the label. From 2025, it will be mandatory for almost all products classified as hazardous. The BfR had jointly proposed the UFI in 2011 and has been involved in its development ever since.

**More information:**  
<https://poisoncentres.echa.europa.eu> > English > Every second counts.  
[www.youtube.com](http://www.youtube.com) > Accidental poisoning - how the UFI code helps



## Research for safer tattoos

The 2nd International Conference on Tattoo Safety brought together experts from the fields of toxicology, analytics, legislation and manufacturing in Berlin in November 2021. The BfR event provided a platform for discussion of the toxicological assessment of tattoo inks and their manufacturing quality. Although many people consider tattoos to be harmless to health, little research has been done on tattoo inks and the long-term effects of pigments in the body. For example, the experts evaluated current research findings and identified data gaps. The new regulation through the European Chemicals Directive was also discussed. From January 2022, certain substances used in tattoo inks and permanent make-up will be gradually restricted in the EU, including the pigments Blue 15:3 and Green 7. The BfR has formulated minimum requirements for tattoo inks, and test methods for manufacturers and distributors. Among others, this opinion is intended to help identify tattoo pigments that are not suitable for tattoos. The BfR does not yet make any recommendations for use due to a lack of data.

**More information:**  
BfR Opinion No. 031/2021 of 14 October 2021



## Constant companions



**The chemicals known as PFAS are found in numerous everyday products, and are in the spotlight as a major problem for the environment and humans. New findings are available concerning the health risks, and a broad ban is coming closer.**

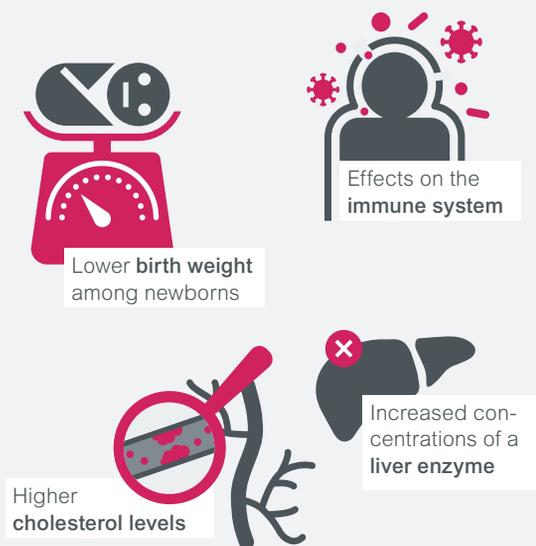
They are exceptionally stable, and are widely used in numerous everyday products, including non-stick pans, waterproofing agents, fire extinguishing foam, cleaning products, outdoor clothing, fast food packaging, drinks to-go containers, refrigerants and even cosmetics. They make them water, grease and dirt repellent. We are talking about so-called per- and poly-fluoroalkyl substances – in short: PFAS. But their blessing is also their curse: The molecular structure of the chemicals is so stable that they are difficult to break

down in the environment. PFAS spread around the world via air and water, are found in groundwater and soils, and accumulate in plants and animals. Humans mostly ingest them via drinking water and food. Research teams are detecting PFAS all over the world and everywhere – even in human blood and breast milk.

The list of possible health effects as the result of increased PFAS levels in the body is long: these include higher cholesterol levels, lower birth weight among

## PFAS – what's the problem?

### Potential impacts on health



The use of **PFOS** has been widely **prohibited** since 2009, and that of **PFOA** since July 2020. Further PFAS (C9 to C14) will be restricted in the EU from February 2023 onwards. Work is ongoing at the European level to restrict the production and use of all PFAS.

### Still unexplored

Do high PFAS concentrations in the blood really mean an increased risk of infection?

How exactly do PFAS enter the food chain from the environment?



### Further research needed

More sensitive analytical methods for PFAS in food samples need to be developed.

newborns, increased concentrations of a liver enzyme, and effects on the immune system. The latter was confirmed by the 'Risks of Subpopulations and Human Studies' unit at the German Federal Institute for Risk Assessment (BfR) with a study on PFAS in children, which was published in 2020. It shows that the post-vaccination concentration of antibodies in children is lower if they have a high level of PFAS in the blood. To determine this, private lecturer Dr. Klaus Abraham's team examined retained blood samples taken from infants at the Charité hospital in Berlin at the end of the 1990s.

### Guidance value is partially exceeded

The European Food Safety Authority (EFSA) used this work as a key study for a new assessment of the health risk from PFAS, and derived a new lower tolerable weekly intake of 4.4 nanograms per kilogram per week. The BfR based its own health assessment on this guidance value, and published it in summer 2021. The result: The long-term intake via food exceeds the health-based guidance value for certain PFAS in around 50 per cent of adults and adolescents in Germany. If mothers are affected, their infants may have a reduced concentration of vaccine antibodies in their blood during their first years of life in case they have been breastfed for a long time.

### Soon a widespread ban?

The good news: for the past 30 years or so, the levels of some PFAS frequently found in the blood of the

population have been decreasing significantly. Nevertheless, the latest figures from the BfR show that even the current levels are still too high. The institute is thus supporting the EU's intention to severely restrict the manufacture and use of all PFAS compounds. Five EU member states, including Germany, have published an announcement to this effect. In July 2022, the proposal for the restriction will then be submitted to the European Chemicals Agency. In concrete terms that means: any use of PFAS that is not considered socially indispensable, or for which equivalent alternatives are available, is to be banned in future.

### Better analytical methods, more research

Important questions are still unanswered. For example, it is not clear whether high PFAS concentrations in the blood are actually associated with an increased risk of infection. In addition, analytical techniques are in many cases not sensitive enough to measure the levels in many food samples, so improved methods need to be developed. Knowledge gaps also exist on the transfer of PFAS from the environment into the food chain. In this regard, the BfR is participating in research projects such as 'PROSPeCT'. The aim is to find out how PFAS get from the soil into plants in order to derive guidance values for soils in the future and ensure food safety in contaminated areas. ■

#### More information:

[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > FAQ: per- and polyfluoroalkyl substances (PFAS)  
BfR Opinion No. 020/2021 of 28 June 2021



Vigilant little creatures:  
The law stipulates compliance  
with the so-called '3Rs'.

# Mouse welfare principle

**Over 60 years ago, two British researchers drew up basic principles for working with laboratory animals. Their thinking has now become a key concept of research in the form of the '3Rs principles'.**

**M**ice can be mice here – would be a fitting inscription on the room-sized enclosure. In the semi-darkness, the rodents scurry through the area, squeeze curiously through narrow corridors and sniff each other with interest. The small mammals' spacious 'adventure playground' is located at the German Centre for the Protection of Laboratory Animals at the German Federal Institute for Risk Assessment (BfR) in Berlin-Marienfelde. Professor Dr. Lars Lewejohann and his team are researching how mice behave in different environments. A major aim of the work is to improve living conditions before, during and after experiments involving animals. The technical terms for this is 'Refinement'.

Together with the basic approaches of 'Replacement' and 'Reduction', 'Refinement' forms the basis of the ethically responsible treatment of laboratory animals. These '3R principles' were first formulated by the zoologist William Russell and the microbiologist Rex Burch in their 1959 paper 'The Principles of Humane Experimental Technique'.

It was the start of a quiet revolution in research using animals. Over 60 years later, it is bearing fruits: '3Rs' has gained worldwide recognition and must be considered in scientific projects. German law also requires these guiding principles to be taken into account in animal experiments. For example, if there is an animal-free method for the same research approach, this is to be adopted by preference.

## **Animal husbandry: room for improvement**

"For the public, the main focus is on reducing animal experiments or replacing them," says BfR scientist Lewejohann. "But despite considerable progress, we will not be able to banish them just yet, for example in the development of medicines and vaccines." Instead of an either-or, the biologist focuses on a pragmatic, step-by-step approach to improving the welfare of laboratory animals. "There is potential for further developments, for example in the housing conditions of the animals."

Lewejohann demonstrates this on the subject of keeping mice (they make up two-thirds of the laboratory animals in Germany). They enjoy the greatest possible freedom in their spacious enclosure and enjoy better conditions than in the wild because they have a constant supply of food. "The animals have ideal conditions here, they are not bored and even the older mice play", explains Lewejohann. "Of course, research facilities can't adopt something like this on a one-to-one for space reasons alone, but there are good compromise solutions."

## **The cages come to life at night**

One possibility is to connect several cages with tubes to give the animals greater opportunity to move around. "During the day, mice sleep," says the scientist. "That gives the wrong impression that they are inactive – but they come to life at night and are quite vigilant."



Professor Lars Lewejohann looks after the welfare of the animals in the laboratory and makes sure that they don't get bored in their cages.

To accommodate their urge to move, Lewejohann's team has installed running discs in the cages. The animals can exercise on them without having to bend their backs – as they would on a running wheel. Using smart trial and error, they can open 'puzzle boxes' and grab a small reward such as oat flakes or millet seeds. "Already with this form of 'enriched' husbandry, apathy and stereotypical behaviour in the mice declines considerably," Lewejohann has observed.

Prospects are also opening up for replacing animal experiments. These include organoids, the subject of intriguing discussions right now. These are three-dimensional microscopic 'miniature versions' of organs such as the liver, kidneys, brain or skin. In Berlin-Marienfelde, a BfR team is working on a bone organoid. "Advances in stem cell research have enabled this development," says Professor Dr. Gilbert Schönfelder, head of the German Centre for the Protection of Laboratory Animals at the BfR.

### Fruit flies and roundworms

Another approach that has been tested is research on invertebrates such as the fruit fly *Drosophila melanogaster* or the roundworm *C. elegans*. "Basic principles of biology apply to humans as well as to these organisms – therefore they can be studied and understood very well on them," explains Schönfelder.

The fact that the 3R principles and good science sit happily side by side is evidenced in the principle of 'reduce'. Put the other way: poor research is at the expense of

the animals. Because the results are meaningless, for example, and animals were used unnecessarily.

### Good animal welfare, good research

Scientific research should be meaningful and allow for statistically robust results, for example, but at the same time comply with the 3R principles. Many scientific journals now require compliance with these principles for publications submitted to them, and have also introduced common guidance known as the ARRIVE guidelines. "3R is part of the planning of an experiment from the very beginning," emphasises Schönfelder.

Another possibility is to enter the design of a study involving animals in the Animal Study Registry database at the Bf3R before it begins. "That is an important step in enabling scientific quality and transparency, and avoiding unnecessary animal experiments," explains Schönfelder.

But the most important thing is to remember that 3R is more than a bureaucratic body of rules. At its core is an idea. A guiding principle that was first introduced by William Russell and Rex Burch, and that continues to evolve today: in the minds of scientists who conduct research using animals. ■

**More information:**  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > German Centre for the Protection of Laboratory Animals (Bf3R)

# “A dialogue is useful”

## Putting the animal first: private lecturer Dr. Bettina Bert on the legal changes governing the approval of experiments.

### **Ms. Bert, since mid-2021, we have more stringent regulations concerning animal experiments. What is this all about?**

Even before the amendment to the Animal Welfare Act and the Regulation for the Protection of Animals Used for Experimental and Other Scientific Purposes, strict rules applied. Nevertheless, changes were necessary because the EU demanded improvements in the implementation of the Directive on the Protection of Laboratory Animals. This addresses the fact that animal welfare legislation in Germany has to be implemented in compliance with the Directive, and not only interpreted.

### **Does that mean the EU Directive was not fully adhered to until now?**

In principle, the EU Directive allows some leeway in terms of how the legal regulations are implemented in national legislation. Each Member State takes this leeway to adapt the regulations to existing legislation. From the EU Commission’s perspective, further amendment was needed because the implementation was not always in line with the Directive.

### **Does this mean more bureaucracy, or real progress?**

Certain things have been improved and clarified, such as legal uncertainties. For example, I think it is positive that scientists who carry out animal experiments have to check whether the methods they use can be improved in terms of animal welfare. The same applies to housing conditions. This was already mentioned in the previous Animal Welfare Act but has been made more explicit now, and will hopefully help to improve animal welfare. Inspections on animal experiments are more clearly regulated and the notification procedure has been replaced by a simplified approval procedure. Such changes always entail initial uncertainty regarding how everything is put into practice. A certain amount of bureaucracy is unfortunately unavoidable.

### **Animal testing facilities will be subject to stricter inspections in the future. Is the mistrust justified?**

While the media might paint a different picture, I believe that infringements are the exception. It is good that the procedure for inspections has been clarified. These will now be carried out following a risk analysis, and without advance notice. I believe a dialogue between the licensing authority and the scientific institution is useful. It should go beyond mere controls, and help to improve living conditions of animals.



In this interview: **Dr. Bettina Bert** is responsible for animal welfare and knowledge transfer at the German Federal Institute for Risk Assessment (BfR).

### **The BfR operates the [www.AnimalTestInfo.de](http://www.AnimalTestInfo.de) data-base, which provides easily understandable information about approved upcoming animal experimentation projects in Germany. There is now a database like this at the EU level (ALURES). Does that mean the German database is dispensable?**

Certainly not. ‘AnimalTestInfo’ is well-established and is very user-friendly. Even though we naturally forward our data to the EU, it is good to continue to keep this information available for the public.

### **What new tasks will the German Centre for the Protection of Laboratory Animals at the BfR have to deal with?**

The German Federal States now report the data on laboratory animals that have been used directly to the BfR. These data are then incorporated into the laboratory animal statistics that are published annually. This information was previously sent to the German Federal Ministry of Food and Agriculture. The BfR checks the data and forwards them to the Commission’s ALURES database. ■

#### **More information:**

[www.animaltestinfo.de](http://www.animaltestinfo.de) (in German)  
[https://ec.europa.eu/environment/index\\_en](https://ec.europa.eu/environment/index_en) > Chemicals  
 > Protection of laboratory animals > ALURES

## INTERNATIONAL NEWS

**A better understanding of food crises**

In 2021, the German Federal Institute for Risk Assessment (BfR) and its Belgian sister institution Sciensano signed a declaration of intent to collaborate. The research institutions will in the future cooperate more closely in the area of food safety and applied genomics. The focus is on the exchange of knowledge and on the further development of methods to provide information on the outbreak of food crises particularly those caused by micro-organisms.

**Working together to increase food safety in Latin and Central America**

In October, the BfR, together with the Chilean Food Safety and Quality Authority and international cooperation partners, organised the 2nd 'Latin American and Caribbean Risk Assessment Symposium' (LARAS). Some 500 experts from the fields of science, politics and industry came together virtually at each of four meetings and

shared views on the current topics of food safety at the regional and international level. The symposium also provided a forum for networking between key actors in the field of food safety and so made a major contribution to the developing structures of food safety in Latin and Central America.

**Perception of microplastics**

What do you think: Are microplastics harmful to human health? How can they get into food and drinks? Together with the European Food Safety Authority (EFSA) and the University of Vienna, the BfR is investigating the risk perception of microplastics in Germany and Italy. Using population-wide surveys – with regard to the environment and health – the risk perception and risk appraisal of microplastics are measured, along with general aspects of the topic. A comparative analysis of the data will subsequently be conducted. The results are expected in summer 2022

**Securing high-quality animal products**

As part of the EU-funded INTAQT project, the BfR together with the institutions from a total of ten European countries will investigate the quality of animal products from various production systems. Possibilities to improve these production systems will also be researched in order to improve product quality and the sustainability of production. All stakeholders in food production, including farms, consumers and certification bodies, are involved in the work. The project kicked off in the summer of 2021.

## INTERNAL AFFAIRS



### Award-winning

BfR scientist Dr. Anissa Scholtzek of the Biological Safety department has been awarded the sponsorship prize of the Wirtschaftsgenossenschaft Deutscher Tierärzte (WDT) for her dissertation on specific antibiotic resistances in *S. aureus*. With the award, the association recognises Scholtzek's research in the field of antibiotic resistance of bac-

terial pathogens. The results are evidence that new resistance mechanisms are constantly developing. These can impede correct diagnosis, and require particular attention.

### New members of the BfR Scientific Advisory Board

The Scientific Advisory Board of the BfR has been reconstituted for the 2021 to 2025 term of office. In addition to the 11 members of the previous advisory board, six new professors have been strengthening the scientific expertise of the board since October 2021. The board thus comprises a total of 17 experts from different fields and disciplines, including food chemistry, hygiene and analysis, nutrition, toxicology and epidemiology, as well as psychology, communication sciences, statistics and animal welfare. They advise the BfR on the strategic development of medium and long-term goals in the technical and scientific field as well as on setting priorities for its research and establishing collaborative partnerships.

More Information [www.bfr.bund.de/en](http://www.bfr.bund.de/en) > The Institute > Scientific Advisory Board

## PUBLICATIONS



### Who does what in Europe?

How is food and feed safety organised in Europe? What institutions are there in the various countries? The 5th edition of the BfR 'EU Food Safety Almanac' brochure has been published and provides an up-to-date overview of the responsibilities of the key players in 37 European countries. Each country chapter contains an overview of the responsible institutions as well as a detailed description of their legal bases, tasks and activities. The EU Almanac is published in English as a start, and can be ordered and downloaded free of charge on the BfR website.

More Information: [www.bfr.bund.de/en](http://www.bfr.bund.de/en) > Publications > Brochures



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