# BfR2G0

**ISSUE 1/2024** 



#### **MELATONIN**

SLEEP AID WITH RISKS

#### **PHTHALATES**

PLASTICISERS ON THE LOOSE

#### **THYROID**

DETECTING THE EFFECTS
OF CHEMICALS



# **MICRONUTRIENTS AND MORE**

Which foods contain vitamins and essential minerals? Will I get sick if I consume too much or too little of them? Should I take food supplements to meet my body's requirements, just in case?

These types of questions are answered on www.microco.info/ en/vitamine-homepage.html, the information portal of the German Federal Institute for Risk Assessment (BfR). It provides information about micronutrients - vitamins and minerals and explains their purpose in our bodies. There are also introductions to countless other substances which can be found in food supplements and enriched foods.



Check it out at: www.microco.info/en/vitamine-homepage.html

# "Look at life with the eyes of a child."

Children: a vulnerable group



# **Editorial**



#### Dear readers,

Children are not small adults. Their growing bodies have very specific needs as well as unique sensitivities. For example, children absorb more of a substance relative to their body weight due to their higher energy requirements. Just like the elderly or immunocompromised people, they belong to the most vulnerable members of society. That was enough for us to make "Risk Assessment for Children" our main topic. Children's lives should not get off to a false start – this, too, is a pillar of our work.

And now a note on our own behalf. For seven years, BfR2GO has been published twice a year and, we hope, consistently informs the public about the institute's scientific work in an easily understandable manner. Now the time has come for us to turn the table and ask you as our readers to provide us with some feedback. What do you think about BfR2GO? Does it reach the goals it has set for itself? What do you like and what would you do differently? We are eager to receive your opinions, praise, criticism, and suggestions. You can find more information about our survey on the last page of the magazine. And now, I wish you an exciting reading experience from the first page onwards.

Professor Dr Dr Dr h. c. Andreas Hensel BfR President

Assessment. Research. Communication.

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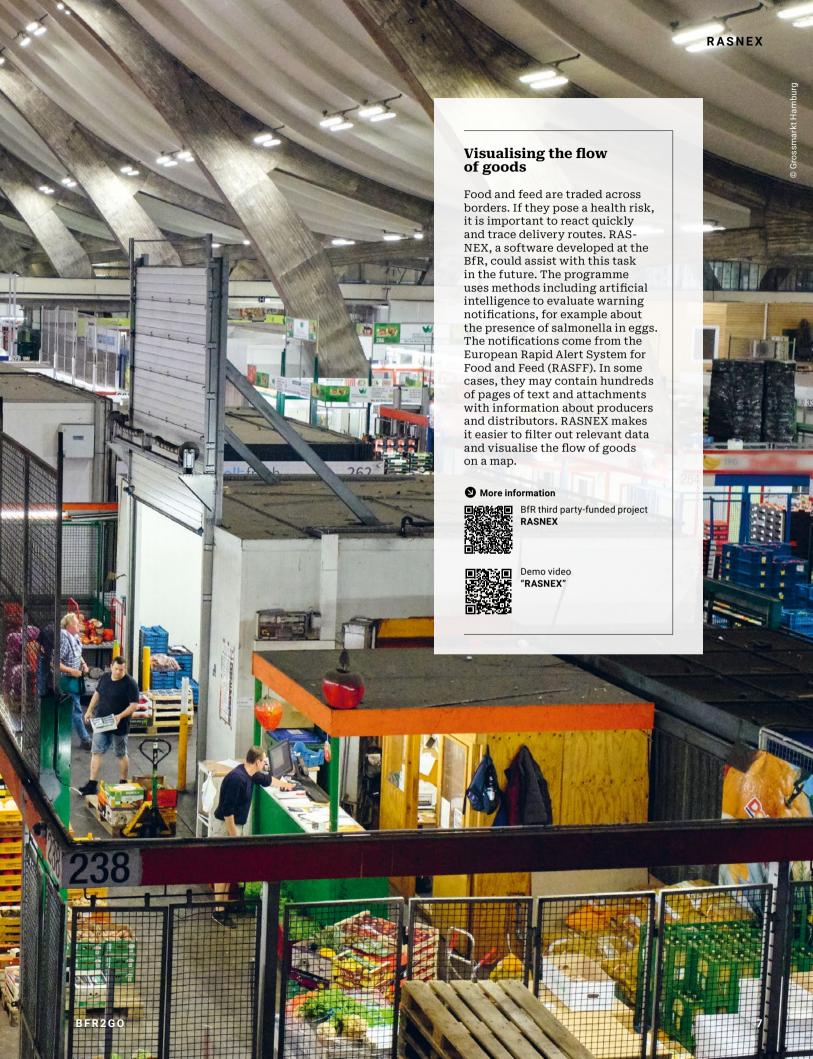
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# At I'ISK from a young age?

While children need our protection from many health risks, they are not as helpless as they may seem.

Illustrations: André Gottschalk

inimise risks - the guiding principle before a child is even born. So much so that the German Federal Institute for Risk Assessment (BfR) advises that women planning a pregnancy consume extra folic acid in their diet as well as through supplements beginning at the latest four weeks before conception. Until the end of the first trimester, a consistently higher intake of folate is required to prevent early stage developmental deformities of the embryo known as "neural tube defects" (e.g. "spina bifida").

#### **EVERYTHING FOR THE CHILD**

When children become more curious and mobile with time, more and more substances come into play – both intentionally and accidentally. Parents

constantly ask themselves new questions. Does the teething ring contain plasticisers? Are there carcinogens in the finger paint? Which seemingly harmless everyday items such as toilet cleaner or laundry detergent gel tabs can lead to accidental poisoning?

These examples show that parental responsibility is rarely child's play and requires parents to be on constant alert for countless health risks. But does it also mean that mum, dad and the rest of the family need to tread so carefully around their child to protect them from every perceived and real risk? While there is no way to eliminate worry entirely, science can offer support. Scientists at the BfR focus on many of these questions and deliver answers and assessments with their own research. For example, the BfR advises pregnant women to avoid

eating raw meat. This reduces the risk of an infection from toxoplasma pathogens that can harm children in the womb. And children under one year of age should not eat honey due to the risk of infant botulism, a severe bacterial disease.

#### **SMALL, BIG, DIFFERENT**

French painter Henri Matisse once said, "One must not forget to view the world through the eyes of a child." To a certain extent this also applies to scientific risk assessment because it is not sufficient to assess harmful effects of a substance on healthy middle-aged people alone. There are certain risk groups that also need to be considered, for example, the elderly, people with certain illnesses, pregnant women and children. The BfR pays close attention in particular to children's unique characteristics in its risk assessments.

Since children have higher energy requirements, they ingest higher amounts of a substance via food than an adult (exposure) in relation to their bodyweight. This is also true for intake via the skin and through inhalation. "This means that children have higher concentrations in their body which possibly can lead to a stronger effect," says BfR Vice President Professor Dr Tanja Schwerdtle.



Swallowed button cell batteries can cause chemical burns to the oesophagus. The BfR regularly counsels parents and caregivers on the risks.

How a substance is distributed, broken down, as well as excreted from the body is also important. When it comes to certain harmful substances, these processes are much slower in the first year of life. Older children, on the other hand, break down some substances even faster than adults (kinetics). "This too is related to high energy turnover and the high metabolic performance connected with it," says food chemist Schwerdtle, who also heads a department at the BfR assessing the risks for sensitive subpopulations.

As a child's body is still growing and maturing in all aspects, individual organs and tissues can be more



When playing with toys, children can be exposed to lead. Even the smallest amounts of lead negatively affects their health, which is why toy materials must comply with strict EU limits.



"Children have higher energy requirements and ingest higher amounts of a substance via food than an adult. This can lead to a stronger health effect."

Professor Dr Tanja Schwerdtle, BfR Vice President

sensitive or react differently to undesired substances. Children may be particularly sensitive in certain time periods, such as before birth or in the first year of life (dynamics). Lastly, behaviour is a decisive factor. "Due to their curiosity, young children are especially at risk of putting things in their mouth and choking," explains Schwerdtle. With increasing self-responsibility and a collected wealth of experiences and observations, this situation changes – although the teenage years reintroduce higher risk propensity.

#### **ALL IN THE SAME BOAT**

The annual statistics of the seven German Poison Centres (GIZ) show that roughly half of all inquiries involve children under four years of age. Toddlers try everything. This can lead to problems in the home if cleaning supplies or medicines are stored in reach of

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Spraying deodorant onto skin beyond the pain threshold — or even inhaling it on purpose: the "deodorant challenge" can lead to skin damage and circulatory collapse. children or if aesthetically pleasing plants are toxic.

It is primarily up to parents to know what happens within their own four walls. However, the responsibility is on manufacturers to make products such as toys and household chemicals as safe as possible. Depending on the product, this can relate to multiple aspects such as ingredients, materials used, or a child-proof design (e.g. of a battery compartment or screw top). Many of these measures are the result of legal requirements based on scientific research - which leads us back to risk assessment. Much is being done for children in this field (see box) to learn more about what substances in food and "everyday things" they are exposed to and in what amounts. The results are part of the BfR's risk assessments,

which serve as a basis for policymakers regarding laws and regulations.

A vital part of this is risk communication, a legal mandate for the BfR. It is aimed at multiple target groups including adolescents. Since 2013, the BfR has offered the free app "Poisoning accidents among children". The app, which is being continuously developed, features information about the ingredients in chemical products, plants and medicines. It also provides tips on what to do in a poisoning emergency as well as the phone numbers for the Poison Centres.

In 2026, the BfR will also launch a central poisoning register that collects information on cases of poisoning reported by all Poison Centres across Germany as well as by physicians directly to the BfR. Data

#### **BFR RESEARCHES RISKS TO CHILDREN**

Assessing health risks requires knowledge – on the one hand regarding which substances are harmful and how they impair health (hazard), and on the other hand about how we are exposed to potentially dangerous substances and in what amounts (exposure). Risk assessment takes into account both the potential hazard of a substance and the amount to which an organism is exposed. The BfR carries out its own research to fill knowledge gaps. For example, the EDKAR study investigates associations between teenage consumption of energy drinks as well as other lifestyle factors, and teenager's cardiovascular risks. The KiESEL study researches the food consumption of children between six months and five years of age. The BfR MEAL study analyses the ingredients of different meals typically prepared in Germany and clarifies what substances in what amounts children are exposed to on average. In the future, it is also planned for children to be involved in the COPLANT study, a long-term observation on plant-based nutritional habits in German-speaking regions.



Long-term excessive consumption of vitamin D supplements can increase blood calcium levels and even cause kidney damage in severe cases.

The BfR advises that vitamins and minerals from nutritional supplements are not needed for children that have a varied and balanced diet.

The social media dare to eat tortilla chips strongly spiced with capsaicin (active ingredient of chilli peppers) leads to medical emergencies in serious cases. It has been scientifically proven that children react very sensitively to spicy chili products.

Nervousness and excitability, sleeplessness, sweating attacks and racing hearts are to be expected when children ingest high doses of caffeine. The BfR recommends that children not consume energy drinks.

from the register will provide a national overview of poisoning risks for the first time and will be used to support both risk assessments and targeted risk communication.

## GROWING UP: THE BIGGEST CHALLENGE

It is especially crucial to reach teenagers and young adults when it comes to trends that pose risks to health, achieve fast popularity on social media and encourage others to copy. This includes dares that can be harmful to health such as the "hot chip challenge", in which extremely spicy tortilla chips are eaten, as well as the much riskier deodorant challenge where deodorant is sprayed or inhaled until the pain threshold is reached. There are also the trend-in-

dependent long-running issues of e-cigarette use and alcohol consumption, both of which are subject to age restrictions. In all of these cases, scientific reason in its role as a "buzzkill" battles with appearing cool in front of peers. None of this is easy. Children are only likely to understand later when the cycle begins again and the next generation has to be protected from everyday health risks. —

More information



BfR information "Children"



Professor Dr Tanja Schwerdtle, Vice President of the German Federal Institute for Risk Assessment (BfR), on the risks of undesirable substances for children – and new research approaches.



Ms Schwerdtle, why are children especially vulnerable in terms of health risks caused by undesirable substances for example?

In relation to their body weight, children have a significantly higher energy requirement than adults, due to growth and their urge to move. This means they have to eat more – and thus are at risk of consuming more problematic substances, too. Small children are especially at risk because their bodies' detoxification process does not function well yet. On top of this, their organs are still more sensitive and bone growth and pubertal development can be affected. Children's curiosity can also harm them because they can put things such as household chemicals, medicines or button cells in their mouths and choke.

Are there also examples of how the child's organism can better cope with certain risks? Children appear to get over infections faster than adults, for example.

Newborns and infants are still far more sensitive to pathogens. Ten to twelve infections a year are normal for toddlers! The immune system is not sufficiently trained until they reach school age. But this age-dependent development is not as relevant to risks from toxic substances – in this case there is unfortunately no "child bonus". With one exception: schoolchildren can detoxify some substances faster due to their faster

"We just do not know enough about the particular health risks for children. Many have been revealed by chance."

Professor Dr Tanja Schwerdtle, BfR Vice President

metabolism. An example for this is the fever and pain reliever paracetamol. Children need a higher dose in relation to their body weight due to this faster breakdown.

## How does the BfR research children's specific situation?

Important questions of risk assessment can only be answered by observational studies. They compare which effects different amounts of a substance can have on an organism. An example at the BfR is the EDKAR study with which we, together with the Charité in Berlin, are investigating the effect of energy drinks on the teenage circulatory system. And as part of the COPLANT study, a large investigation of plant-based foods, one module also focuses on the eating habits and health of children.

# Take food supplements, such as vitamins and minerals, as an example: What do parents need to be aware of when they are considering this for their children?

Such supplements are, with few exceptions, unnecessary for healthy children and adults. They are no replacement for a balanced and varied diet. One exception to this are micronutrients such as fluorine and vitamin D, which are important for young children. Overall, children in Germany get enough of most nutrients.

## Which deficits do you see regarding children and risk assessment?

Just not enough is known about the particular health risks for children. Many have been revealed by chance. There were cases of liver cirrhosis in small children up until the 1980s in Germany, Austria and elsewhere in Europe. At some point it was discovered that copper was the cause. It entered the child's system from copper water pipes and milk containers made of copper, and poisons it. Only then was it understood that the gall bladder regulates copper metabolism. Liver damage occurred because the excretion of toxic substances via the gall bladder is not yet fully functional in small children. —

# BITTER AFTERTASTE

Local, protein-rich sweet lupins are a popular feed alternative to imported soya. Unlike bitter lupins, sweet lupins have a lower concentration of toxic bitter substances that can negatively affect the health and capacity of animals. However, analyses by BfR researchers show that sweet lupins can also contain a higher concentration of these substances, quinolizidine alkaloids (QA). Feed experiments have also proven that QA can pass into cow's milk. The consumption of animal-based products can thus also entail health risks for humans. Therefore further investigations regarding QA in sweet lupins are planned in order to better assess their suitability as livestock feed.

#### More information



#ID BfR communication

"Alkaloids from sweet lupines pass into the milk in small quantities when fed to cows"

(pdf)





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# Tiny terrors?

93% of people in Germany know what microplastics are. 0.001 to 5 millimetres in size, these tiny plastic particles are a recurring topic in the media. The BfR has been researching them for 10 years. According to current scientific knowledge, these plastic particles in food do not pose any negative health risks. How they are absorbed by the body from the intestine, however, has not yet been sufficiently clarified. There is still not enough human and animal data available. In addition, there is a lack of reliable analysis methods for detecting these particles in humans or food. Demonstrating the presence of microplastics in vegetables or intestines is more difficult than in water or honey, for example. But analytics continues to develop.

#### More information



BfR information
"Microplastics"

# Ongoing investigation

At the BfR, standardised measurement procedures are continually being developed to detect chlorinated paraffins in food and feed. The substances are used as plasticisers in plastics, in textiles, paints, and in fire-proofing agents or lubricants, for example. The problem is that they can also be released into the environment. As they are largely non-degradable, they accumulate in the food chain and sometimes even end up on our plates. We know that chlorinated paraffins can damage organs such as the thyroid and kidneys. The use of certain chlorinated paraffins is now prohibited. To date, exact identification in a laboratory is difficult because chlorinated paraffins consist of many different individual substances that only minimally vary from one another in their chemical composition.



Plants produce substances as a defence against herbivorous animals and microorganisms. Some of these can be poisonous for humans. A well-known example is solanine in potatoes – green flesh or sprouted parts contain a lot of this. However, only just over a quarter of the population are worried about naturally occurring plant-based toxic substances, as revealed by a representative BfR survey. A possible reason for this could be that many of those surveyed know nothing about the substances. In addition: unlike the usually higher risk perception for synthetic substances, natural toxins in food are often given less thought.

#### More information



BfR Consumer Monitor
"Naturally occurring, plant-based toxins"
(pdf)

#### More information



"Hexahydrocannbinol (HHC) in foodstuffs" (pdf)

#### **HHC Fruit Gums:**

### Poisoning Possible

Hexahydrocannabinol (HHC) behaves similarly to its better-known relative, THC (tetrahydrocannabinol), the most significant psychoactive cannabinoid in the cannabis plant. Unlike THC, HHC is not yet listed under the Narcotic Drugs Act or the New Psychoactive Substances Act and is often sold as a "legal" alternative, despite significant legal concerns. The substance is used in various products, such as e-cigarette liquids and oils. There are also products containing HHC that resemble wine gums, which is especially dangerous for children. They could accidentally poison themselves severely by consuming what they believe to be a normal snack. Such cases have been documented in Germany. Currently, there is a significant lack of scientific research on the general health risks of HHC.

# Mysterious melatonin

Food supplements with melatonin promise a quick solution for insomnia. However, uncritical use of these products is ill-advised.



© vetre /adobestor

hen it gets darks in the evenings, the pineal gland begins to produce and release melatonin. The concentration of this hormone in the body then increases over the following hours and peaks at around three in the morning. As daylight increases, the melatonin production is inhibited and melatonin levels slowly decrease again. Through this light-dependent regulation, melatonin, together with other messenger substances, influences our circadian (day-night) rhythm, although melatonin concentrations and time-dependent fluctuations thereof can vary widely between individuals. Additionally, the hormone is involved in a number of other circadian processes, including the regulation of body temperature, blood pressure or the release of other hormones.

#### PILLS AND POWDERS AS "NIGHTCAPS"

Melatonin's role as a metronome for the body's internal clock provides an interesting basis for treating certain sleep problems. In fact, medications with melatonin as the active ingredient are approved for use in Germany for short-term treatment of sleep disturbances. Their use is intended for adults over 55 as well as for children with certain pre-existing medical conditions if other sleep-promoting measures and routines have proven unsuccessful.

Aside from these melatonin-containing prescription medications, melatonin-enriched foods may be found on the market, such as tea, as well as food supplements with melatonin, including capsules, sprays, powders, and even brightly-coloured fruit gummies. These typically contain between 0.5 and 1.5 milligrams (mg) of melatonin per daily dose, although some products have been

found to contain higher doses, e.g. up to 10 mg per dose. Their concentration thus roughly corresponds to that of certain prescription medications (typically around 2 mg per daily dose) and in some cases is actually higher. As of yet, there are no fixed maximum values for the concentration of melatonin in food supplements. Scientists from the German Federal Institute for Risk Assessment (BfR) are critical of the growing number of available food supplements of this type. One concern is that people with sleep issues can purchase these products without a prescription or prior medical consultation. Thus, there is no opportunity to control the duration of usage or potential undesired effects, or to medically investigate underlying reasons for the sleep disturbances. A further concern is that health risks, especially for longer-term use, remain to be studied in detail and well characterised.

#### **SLEEP AID WITH HEALTH RISKS**

In the few scientific studies performed with healthy adults, reported undesired effects of melatonin consumption most commonly included headache, lowered attention span, low blood pressure, nightmares, drowsiness in the mornings, and unsteadiness when



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## WHO SHOULD NOT CONSUME FOOD SUPPLEMENTS WITH MELATONIN?

- infants, children, and adolescents
- women attempting to become pregnant, pregnant and breastfeeding women
- people with autoimmune illnesses or epilepsy as well as people with compromised liver and/or kidney function
- only after consulting a doctor: people taking medications, people at risk for type 2 diabetes
- healthy adults: no unmonitored long-term intake

walking. Following melatonin intake, the ability to drive or perform tasks requiring a high degree of attention can be impaired. Some studies suggest that melatonin may influence the immune system, while others indicate that the hormone can change blood sugar levels. Since melatonin affects other hormones produced by the body, there is an ongoing discussion as to whether intake by children and

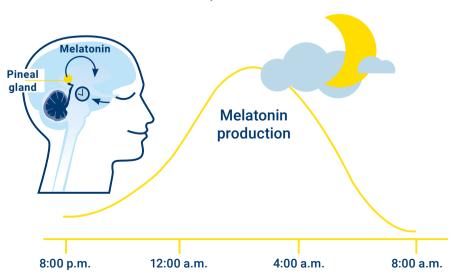
adolescents might impair childhood development, in particular hormonal development during puberty (see interview with Dr Valérie Trendelenburg on page 21).

The extent to which consumed melatonin affects the endogenous, or natural, levels of the hormone in the body varies widely between individuals. Studies have shown that even low doses can lead to melatonin levels in the body which vastly exceed natural levels and may thus potentially negatively impact the body's internal clock. Infants and small children, older people, and people with certain widespread genetic variants of particular enzymes metabolise melatonin more slowly. For these groups, there is a risk of melatonin accumulation, which may lead to higher health risks.

In the opinion of the BfR, for these reasons, adults should not consume food supplements with melatonin uncritically nor in unmonitored amounts, particularly not on a long-term basis. The BfR recommends that some groups of people, for example children or pregnant women, should generally avoid consumption of melatonin-containing food supplements, due to insufficiently studied health risks (see box).

#### **Melatonin and sleep**

Melatonin – together with other messenger substances – controls our circadian rhythm.





Melatonin-containing food supplements are also being advertised as sleeping aids for children. According to BfR scientist Dr Valérie Trendelenburg, this is a concerning trend.

## Ms Trendelenburg, why are you critical of giving melatonin to children?

Mainly because the health risks for healthy children and adolescents have not been well studied, especially when it comes to long-term use. In the available studies, the focus tends to be on children with pre-existing medical conditions, often serious ones, and the number of study participants is often very small.

#### Is there evidence of health risks?

Yes. For children and adolescents with sleep disorders who did not have other serious illnesses, undesirable effects were observed after several days of melatonin intake, including headaches, dizziness, and gastrointestinal problems. Moreover, even small amounts of consumed melatonin can influence other hormones produced in the body. This may have an impact on childhood development, for example on growth/height and pubertal development. We must not forget that melatonin is a hormone. It affects various processes in the body.

# And yet, there are products available which seem to be specifically made for children, for example melatonin fruit gummies.

This is concerning, because there is a risk of confusing the gummies with candy, meaning that children might easily consume these products by accident. Moreover, presentation of food supplements in such a form can contribute to an uncritical perception of such products.

## What does the BfR recommend?

Based on the current scientific evidence, we recommend not giving children and adolescents melatonin-containing food supplements. Concerned parents who assume that their children have sleep disorders should consult with paediatricians in order to determine the underlying cause.—

# DIY preservation

Do-it-yourself is in fashion – also when it comes to food. What needs to be considered when harvesting from your own garden and canning fruits and vegetables at home?

**FRESH AND CLEAN** 

Currant jam, kale crisps or pumpkin chutney – preserving fruit and vegetables is in demand. Preservation methods such as boiling water-bath canning, drying, and pickling not only help preserve perishable food, they also offer a great range of tasty recipes. From sweet to savoury to sour, there's something to suit every palate. However, it is important to follow certain rules so that culinary enjoyment does not end up leading to stomach ache or even a trip to the hospital.

As a basic rule, you should never use any fruit or vegetables that are overly ripe, mouldy, or spoilt in any other way. It is also important to wash them thoroughly, as pathogens can be transmitted to food during planting. harvesting, or transport. This also applies to freshly harvested (organic) products from one's own garden, a field, or a forest. Similarly, when preparing food, hands, surfaces, and utensils should be thoroughly cleaned, and only clean containers should be used for preservation. The safest method to remove possible germs from containers is to wash with boi-

ling water or at the highest possible temperature in the dishwasher.

#### **PRESERVING BY BOILING**

Boiling water-bath canning preserves fruit and vegetables through the use of heat and air-tight sealing in a container. However, the used food may be contaminated with pathogenic bacteria. Most of these bacteria are killed by heating food to a core temperature of over 70°C for at least two minutes. However, some types of bacteria are able to develop highly resistant forms, known as spores. When it comes to preserving food via heat, the spores of the bacterium Clostridium botulinum may pose health risks, as they are only inactivated at temperatures of above 100°C and the bacteria are able to multiply in the preserved food. If the spores survive the canning process, they can develop into the bacterial stage during storage and, while multiplying, form neurotoxins that can trigger botulism [see box].

#### **PICKLING IN VINEGAR OR OIL**

Vinegar can help prevent the growth of microorganisms. However, you should not rely on vinegar alone, as high acidity is required to kill pathogenic

## BOTULISM: RARE AND PREVENTABLE

Botulism is a very serious illness that is caused by neurotoxins from the bacteria Clostridium botulinum.
Only a handful of human botulism cases are registered in Germany each year. The neurotoxins can lead to nausea, blurred vision, trouble speaking or swallowing, and even death. How can you protect yourself from it? How can you recognise whether Clostridium botulinum has multiplied in canned food?

#### More information



BfR-FAQ "Botulism"



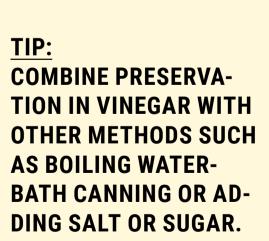
bacteria. Such acidity levels, however, are very unpleasant to human taste. Tip: combine vinegar with other preservation methods, such as boiling water-bath canning, or adding sugar or salt.

Pickling in oil is not a suitable method for homemade preserving. Self-made oils and vegetables or herbs in oil should not be prepared in large quantities and then stored. This is particularly the case if food is not sufficiently heated before it is consumed, but is rather intended as part of the preparation for salads or other raw dishes.

#### FREEZING AND DRYING

Freezing is a good method, for example to preserve whole berries for muesli or smoothies. It is important to wash the food thoroughly in advance, and freeze only in clean and tightly sealed containers or freezer bags. It is also worth freezing the food in small portions, so that it cools as quickly as possible and does not cause neighbouring frozen products to thaw.

People who enjoy snacks such as desiccated fruit, vegetable crisps or dried tomatoes should ensure that the water content in the selected fruit and vegetables is rapidly and strongly reduced during the drying process. Also, the dried food should ideally be stored in a dry place, as moisture can lead to mould growth and food spoiling.





The preparation of beans, chickpeas or lentils is often time-consuming due to long soaking and cooking times. This can be avoided by precooking and subsequent canning or freezing in portions. However, it is important to heat legumes sufficiently and cook them long enough. For example, the seeds and pods of garden beans contain phasin, a lectin protein. Just a few raw seeds are enough to cause stomach ache and nausea. In severe cases, it can even lead to bloody diarrhoea, fever, and low blood pressure. The good news is that heat destroys lectins.

As a rule of thumb, you should cook fresh legumes for at least 30 minutes. Dried legumes such as chickpeas, kidney beans, and lentils should be soaked for at least five hours. The water used for soaking should be discarded before cooking the legumes in fresh water. Less intensive cooking methods such as gentle stewing or steaming are not appropriate for most legumes. —

#### More information



BfR press release "Sick because of lectins in vegetables?" (in German)

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#### What should (not) be in a smoothie?

- Most fruits and vegetables available on the market, as well as herbs, nuts, and seeds can be used for smoothies.
- However, give consideration to variety, diversity, and tolerance. Large amounts of high-fibre vegetables and cabbages can cause digestive problems.
- Depending on its growing conditions, spinach can contain varying amounts of oxalic acid, which among other things binds to calcium. Prolonged intake of large amounts of oxalic acid can lead to calcium deficiency and the formation of kidney stones.
- Dried plant parts, such as wheat or barley grass powder, should only be added shortly before consuming. These dried ingredients may contain microorganisms that can rapidly multiply in smoothies.
- You should only put plant parts into the blender that are usually consumed raw. Pits, stems, and peels can contain undesirable ingredients in greatly varying quantities. In individual cases, for example, they contain higher amounts of pesticide residues. The maximum levels are often only set and monitored for plant parts that are commonly consumed.

Smoothies are considered healthy. They are rich in vitamins and can help boost the immune system. But preparation does involve some potential risks.

It sounds simple: put fruit and vegetables into a blender, add some fresh herbs, and your delicious smoothie is ready. However, you should pay attention to certain things when selecting the ingredients and preparing them to ensure that no unwanted ingredients creep in, such as harmful plant substances, contaminations, or pathogens.

#### Kitchen hygiene matters

- As protection against foodborne diseases, fruit, vegetables, and fresh herbs should always be thoroughly washed and, if possible, peeled.
- The following applies in particular to young children, pregnant women and the elderly: avoid ready-to-eat mixed salads and only use frozen ingredients, such as raspberries, after you have heated them thoroughly.
- Smoothies are not suitable for meal prepping, i.e. preparing meals ahead of schedule. They should be consumed as soon as possible after preparation. Until then, they can be stored in the fridge at up to 7°C on the day of preparation until consumption.

More information



BfR-FAO "(Green) smoothies" (pdf)

# The purée truth

How many undesirable substances do we take in with our food? And what impact does preparation have? For the BfR MEAL Study, the BfR cooked, puréed, and analysed.

For poked,

Not all foods are alike – at least not when it goes into the pot as a complete potato and is then processed into purée. Or when meat fillets are coated in breadcrumbs to create Wiener Schnitzel – in such cases, the original food changes significantly.

#### **NOTHING REMAINS AS IT WAS**

Several things happen to food during this transformational process. Its components may react with other ingredients during cooking, frying, or baking. Vitamins may be lost, while some substances that pose a health risk, such as acrylamide, may first arise due to intense heat.

The BfR MEAL Study, conducted by the German Federal Institute for Risk Assessment (BfR) with support from the Federal Ministry of Food and Agriculture, examines such issues. MEAL stands for "Mahlzeiten für die Expositionsschätzung und Analytik von Lebensmitteln" – "meals for exposure assessment and analysis of foods". Germany's first Total Diet Study is one of the world's most comprehensive studies of its

kind and represents over 90% of the population's dietary habits.

#### **ONE OF EVERYTHING, PLEASE**

"For the first time in Germany, we have conducted a systematic and representative analysis of ready-to-eat food," says Dr Irmela Sarvan, who leads the study. "We prepared 356 foodstuffs and meals as people in Germany usually do." To achieve this the BfR investigated where the average take-out pizza is bought, which websites are popular for recipes, how much juice or water is in a typical apple spritzer, and how brown fried potatoes are when they land on a plate.

"We bought the food from all over Germany and prepared it in our study kitchen," says BfR scientist

# TOTAL DIET STUDY (TDS)

TDS refers to a method recommended by the United Nations' Food and Agriculture Organisation (FAO), the World Health Organisation (WHO), and the European Food Safety Authority (EFSA), to identify the average levels of substances in a typical human diet for exposure assessment. Germany's first Total Diet Study, the BfR MEAL Study, began in 2015.

Dr Mandy Stadion. "This refers not just to cooking, frying or grilling, but also processing steps such as washing an apple or removing the apple core."

The meals were puréed before they entered the laboratory, where scientists investigated the average levels of more than 300 desirable and undesirable substances. Besides additives and substances from the production process (process contaminants), other substances were investigated as well such as nutrients, substances from the environment (environmental contaminants), mycotoxins, plant protection products, veterinary drugs, and substances that can enter food from packaging.

#### **VALUABLE RESULTS**

The final report of the BfR MEAL Study highlights key findings, for example for dioxins. Dioxins are undesirable substances from the environment that particularly accumulate in animal fat and can have a negative impact on fertility, as well on the immune and nervous system. "On the whole, the levels of dioxins were low, and often far lower than the maximum permitted levels," Stadion says.

Another substance investigated was methylmercury (MeHg). The organic mercury compound can damage the nervous system and kidneys and cause disorders of the cardiovascular system. The BfR MEAL Study confirmed that average intake is below the European Food Safety Authority's (EFSA) tolerated weekly intake (TWI) value. "However, 14-to-25-year-olds who eat more than an average amount of fish may exceed the guidance value," says Sarvan, head of the study. "Adults in Germany take in MeHg primarily by consuming Alaska pollock/pollock, as well as tuna, herring, and redfish."

#### **KEEPING AN EYE ON IODINE**

The BfR MEAL Study also showed that a large part of the population does not get enough iodine, despite the use of iodine salt in private households and industry. The trace element is essential for metabolic processes, bone formation, and brain development. The BfR MEAL Study identified the highest levels of iodine in salt, algae, cod, and molluscs (for example, mussels). Other good iodine sources include eggs, fish, seafood, meat, and milk, as well as their derived products.

The MEAL data allows recommendations to be drawn up for policymakers, for example correcting maximum permitted levels, more frequently monitoring certain foods, or making risk groups (children, the elderly, sick or pregnant women) aware of nutritional risks. Overall, the results show that Germany has a very high level of food safety. —

#### More information



bfr-meal-studie.de/en

# The BfR MEAL Study in numbers



149,499

kilometres were travelled while buying the food



#### 4 years & 8 months

is how long the kitchen team spent processing the food into ready-to-eat meals



# 75 individual ingredients

were bought and processed just to prepare the different recipes for the "Rinderrouladen" (a popular German meat dish) pool.



analysis results were received by the laboratories' study teams.

# LESS IS MORE



The use of antibiotics in animal husbandry has declined over recent years. This is important in the fight against resistant bacteria that may also enter humans through food.

Whether at the hospital or in the barn, antibiotics come into play when people and animals become ill from a bacterial infection. The extent to which antibacterial medicine is used in animal husbandry is also important for human health. In an annual report, the German Federal Institute for Risk Assessment (BfR) assesses the frequency of antibiotic treatment and the consumption quantity in animals raised for meat production.

#### **DOWNWARD TREND**

The development of antibiotic use in the meat production of calves, cattle, piglets and pigs, chickens, and turkeys is analysed and assessed in the BfR reports. Results for 2022 show that numbers are sinking particularly among the animal species with a high level of use in the past.

"This is good news," says Dr Matthias Flor, a biologist at the BfR. He describes his analysis of the data: "In comparison to the previous year the consumption quantity of antibiotics in the studied animal groups has declined by 12 percent." The decline was strongest in piglets and turkeys for meat production. Treatment frequency has also declined, again most significantly in piglets. How this continues to develop in 2023 will be revealed in the next report, due to be published in August 2024.

The downwards trend is an important step in the fight against resistant bacteria. "The use of antibiotics leads to bacteria 'arming'

themselves and becoming increasingly resistant," explains Flor. This is also an important issue for the general public: more than half of those asked in the BfR surveys regularly state that they are concerned about antibiotic resistance.

#### **SLOWING DOWN RESISTANCE**

We can encounter resistant pathogens in different places: MRSA germs (Methicillin-resistant Staphylococcus aureus) in hospitals, salmonella and campylobacter on food. They are especially found on raw poultry meat. While sufficient cooking and frying kills off the bacteria, they can still cause infections or transmit resistance to other bacteria in the human intestine if they come into contact with other food such as salad or bread. If the pathogens and their resistant genes spread, they become a problem, as it is possible antibiotics will no longer work.

The reduced use of antibiotics - in both animal husbandry and in medicine - can lower the long-term risk posed by resistant bacteria. They are a prime example of how closely human. animal, and environmental health are connected to each other in multiple ways. The "One Health" concept represents this. In practice, specialists in human and veterinary medicine as well as in environmental sciences are working closely together to counter global challenges such as antimicrobial resistance, new pathogens, and food-borne zoonoses. At the BfR, too, scientists do research on resistance development and participate in international One Health initiatives. —

#### More information



BfR information "Antibiotics"

#### KITCHEN HYGIENE AS A DEFENCE

ANTIBIOTIC-RESISTANT GERMS ARE ALSO TRANSMITTED THROUGH FOOD. 3 TIPS:

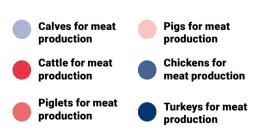
Always store raw meat, especially poultry, separately from ready-to-eat food

Thoroughly wash hands, kitchen utensils, and preparation surfaces after contact with raw animal food products and before preparing other food

Always thoroughly cook meat (70°C for at least two minutes at the centre)

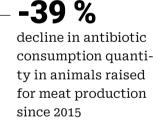
# Antibiotics in animals raised for meat production 2015 and 2022

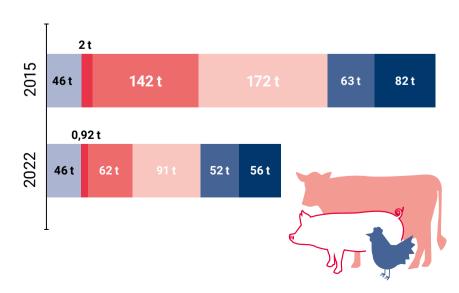
There has been a considerable decrease in the consumption quantity of antibiotics for almost all groups of animals (listed in tonnes (t))



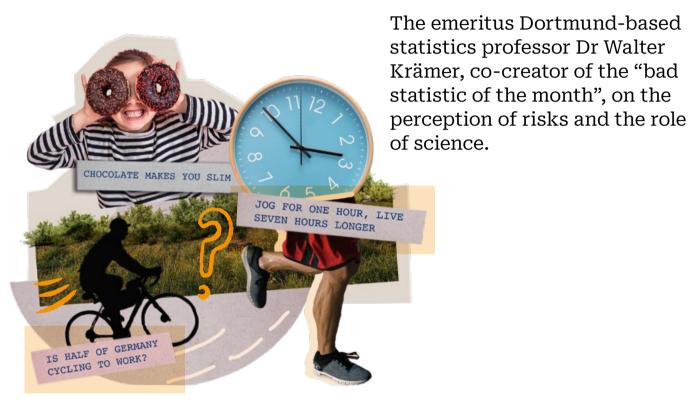
#### Consumption quantity:

2015: 507 tonnes 2022: 308 tonnes





# "The truth is only rarely properly conveyed"



Mr Krämer, at least since the COVID-19 pandemic, crises have been a constant topic of discussion. Viruses, war, terrorism, climate change: is this down to a distorted perception of risk?

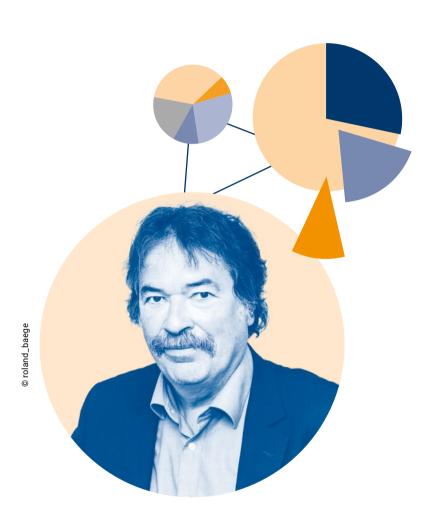
Yes, precisely. Give me one year since the Second World War in which there weren't myriad catastrophes. The difference is that our readiness to be hysterical has increased substantially, particularly when it comes to social media.

#### What can help keep us relaxed?

Whenever there's talk of the end of Western Civilisation, all I have to do is watch a couple of videos about life in Caesar's Ancient Rome. It calms me down to know how orderly and civilised things are for us now. So far, humanity has survived every predicted demise.

## You caution against perceiving small risks as big and big risks as small. Why?

If you wish to efficiently combat hazards to your health and safety, it makes most sense to start with the major risks, does it not? To do this, though, you have to know what really poses a risk to your money, your life or your health. And you have to know what are just trivialities. However, it might be difficult for a lot of people to differentiate between real risks and trivialities. We should be clear about which factors distort our risk perception: voluntarily willing versus involuntarily willing versus involuntary (voluntarily accepted risks are massively underestimated), known or unknown mechanics (mysterious risks such as death by cancer are overestimated in comparison to easily



"So far, humanity has survived every predicted demise."

> Dr Walter Krämer, statistics professor (emeritus)

understandable risks such as death by cardiovascular illnesses), manipulable or not (fear of flying versus fear of driving), and top of the list of course: natural versus artificial. Artificial risks are vastly overestimated around the world.

#### What are artificial risks?

Many examples are chemical, for example dihydrogen monoxide. Chemistry students frequently amuse themselves by collecting signatures outside of primary schools to call for a ban on the chemical. And they're successful. After all, this heinous stuff is the main component of acid rain, it contributes to soil erosion, and accelerates the corrosion of metal parts. Prolonged contact with it in its solid state harms tissue, and in its gas state it causes burns. Worldwide, thousands die every year due to dihydrogen monoxide. In actuality, dihydrogen monoxide, chemically denoted as H<sub>2</sub>O, is just water. But as soon as something has a chemical name, a whole lot of people get scared.

### How can science properly communicate risks?

With difficulty. Of course, lying is completely off limits. But unfortunately, the truth is only rarely properly conveyed. As long as many people don't understand the message – see above – the best risk communication is useless.

With your "bad statistic of the month", you take a critical look at scientific studies and the way they are presented in the media. "Science" is not infrequently somewhat inaccurate...

That's the unfortunate truth and is often a consequence of a poor grasp of certain basic statistical concepts. For example, the fact that correlation does not equal causation, meaning that a connection between two things does not necessarily mean that there is cause and effect. Or the fact that projections can be wildly inaccurate if they are based on studies with distorted sampling. —





# Using vineyards as an example: What happens before a plant protection product (PPP) enters the market?

ay we present: Uncinula necator, also known as powdery mildew. The fungus, which was unintentionally brought to Europe from North America in the mid-19th century, infests grapevines, weakens the plants, and destroys and rots the grapes. Uncinula necator is far from the only pest that affects vineyards. In order to prevent drastic reductions in crop yields, winemakers use PPP. In all likelihood, they have been doing so since antiquity. Sweet grapes have always required hard work.

Unlike in ancient times, however, PPP today are strictly assessed before they are used in fields or vineyards. The main focus is on the efficacy against the pest organism, the ecotoxicology, and the health risk assessment in terms of humans. The latter is the task of the German Federal Institute for Risk Assessment (BfR) in Berlin. Only when this comprehensive evaluation has been successfully completed, regulators give the green light for an active substance or a plant protection product.

It all starts with the regulators' approval of an active substance. This active substance is usually precisely

chemically defined and is the "active" substance which will later have the decisive impact – such as on a fungus – in the PPP. The approval of an active substance is carried out at the EU level and is thus valid across the EU. It is typically limited to seven, ten or 15 years and must therefore be regularly renewed. The responsible reviewer is in each case a rapporteur Member State of the EU; for extensive evaluations there are several rapporteur Member States.

#### **DETAILED DOSSIER**

First, the applicant submits a comprehensive dossier for evaluation. The document must contain all necessary information on the active substance. Detailed data on the effects of the active substance on the organism are included in the health risk assessment. How does it enter the body and how is it metabolised and excreted? What effects can be observed? What limits and thresholds need to be adhered to in order to exclude these effects so as not to expect risks to humans? Additionally, the metabolism in the plant, potential environmental effects, and the biodegradability of the active substances in the soil are examined.

As of yet, establishing these "guardrails" for active substances has required animal experiments from which conclusions regarding humans are extrapolated. Evidence suggesting mutagenic or carcinogenic effects or negative impacts on fertility or foetal

development (reproductive toxicity) for humans immediately preclude approval. The same is true for interference with hormonal (endocrine) balance.

By way of example, let us examine the tongue-twistingly termed active substance mefentrifluconazole, which is used in vineyards. The active substance blocks an enzyme which is essential for fungi such as Uncinula necator. In their comprehensive report, the scientific evaluators from the EU (the United Kingdom was the former rapporteur Member State) note the mode of action of mefentrifluconazole as well as possible mechanisms of fungal resistance and much more pertinent information. This includes practical uses, potential risks to human and animal health, residues on plants, animals and food, the retention in the environment and groundwater, and the (unintended) effect on nontarget organisms.

#### **WHAT ARE THE RISKS?**

In order to gain approval, the applicant was required to present studies regarding the active substance's toxicity. Using animal experiments, short-term and long-term toxicity were assessed. Liver damage can occur with high doses of mefentrifluconazole. This is not surprising, as the active substance is metabolised in the liver as the "target organ" and then excreted into the intestine via the bile. Mefentrifluconazole's genotoxicity, carcinogenicity, reproductive toxicity,

#### Products and chemicals

and potential negative effects on the nervous system were also assessed. There was no meaningful evidence to this effect.

Based on the toxicity evaluations, the scientific evaluators also determine ("derive") thresholds. These values serve as orientations for daily life and human safety (including in the production process) and are set to have a large "safety margin" in relation to an actually toxic amount of an active substance. After all, it is the dose that makes the poison.

#### ON THIS SIDE OF THE THRESHOLD

One of the thresholds is the acceptable daily intake (ADI). This value denotes the amount of an active substance a person can consume daily for an entire lifetime without expecting adverse effects. In the case of mefentrifluconazole, the ADI according to the current evidence is 0.035 milligrams per kilogram of body weight per day. This means that a person weighing 70 kilograms could consume up to 2.45 milligrams of the active substance without exceeding the ADI and therefore without risk to health.

"Residues of plant protection products in food, such as in grapes, are possible and are taken into account in the approval process," says BfR PPP expert Dr Jens Schubert. "But the deciding factor is not if, but rather how much. Has the ADI or another threshold been exceeded?" This can, for example, lead to a product no longer being marketable and being pulled from the shelves. Once the rapporteur Member State has received the draft assessment report for the

active substance, it is published for comments. After a final consultation, the European Food Safety Authority (EFSA) prepares the final version of the report, the EFSA conclusion. The final vote on the approval is then taken by a committee of the European Commission. The scientific assessment, including comments, is then followed by the regulatory decision.

#### **PLANT PROTECTION: TRIZONE EU**

Can the active substance approved by the EU now be used in the vineyard? The answer is no, because the corresponding PPP must first be authorised. In the case of mefentrifluconazole, the product is an agent having mefentrifluconazole as the active substance as well as additives which facilitate application. The authorisation of a PPP is similar to the approval of an active substance, but there are also a few differences. For example, the assessment and the authorisation is not EU-wide, but instead regionally decided in the northern, central, and southern "zones" of the EU.

One rapporteur Member State is responsible for the assessment in a given "zone". In the case of mefentrifluconazole, that state was Austria in the central zone. The focus is on the practical application of the product. The Member State responsible evaluates, for example, what pests the active substance is effective against, where it may be used, what dose is required, and what ecological consequences are likely to be expected. In Germany, PPP are authorised by the German Federal Office of Consumer Protection and Food Safety (BVL). The BVL also determines regulations for use, which include the necessary protective gear or waiting periods before harvest.

### "Residues of plant protection products in food are possible and are taken into account in the approval process."

Dr Jens Schubert, BfR PPP expert



#### FIGHTING FUNGI WITH COPPER **AND SULPHUR**

Organic farming does without artificially produced active substances. This means that mefentrifluconazole is off-limits. Instead, use is made of products with a plant or microbial basis or of naturally occurring chemical compounds. In the case of fungi on grapevines, the most commonly used solutions contain copper salts or sulphur. Copper and sulphur compounds have been used in agriculture for more than 200 years. These active substances also have undesirable toxicological effects on humans above a certain dose and must, just like "synthetic" products, be regularly approved and the corresponding PPP must subsequently be authorised. One example of such a product in organic winemaking contains copper sulphate, whose copper ions penetrate the fungal spores and then target proteins and enzymes. The second active component is ele-



"Natural" solutions also have pros and cons.

mental sulphur, which, inter alia, acts by breaking down the cell membranes of fungi to dry them out. The product works on both powdery and downy mildew. A drawback of copper, however, is that it accumulates in the soil. It turns out that "natural" solutions also have their pros and cons.—

More information



BfR information "Plant protection products"

**Approval process** 

(in the respective EU zone) (after active substance approva

## **Approval of PPP active substances**

(EU-wide)

1. pplication by applicant including further data and studies on the active substance

2. raft of an assessment report by a rapporteur **Member State** 

including further data from third parties (in Germany in collaboration with the BfR)

3. onclusion by the **EFSA** based on the assessment report by the rapporteur **Member State** 

commenting phase by Member States, applicants, the public

answering open questions during meetings between experts from Member States

4. A ecision in favour of or against an active substance by the relevant committee of the European Commission.

Epidemiological studies can provide useful information for health-related risk assessment, for example concerning contaminants in fish.

36

How healthy is fish nowadays? Many people are concerned as contaminants such as dioxins and per- and polyfluoroalkyl substances (PFAS) have been found in fish. The European Food Safety Authority (EFSA) has recently lowered the threshold for both substances. What does that mean for fish as food? An expert team from the Norwegian Scientific Committee for Food and Environment (VKM) took this question as the starting point for a risk-benefit assessment.

The assessment was based primarily on epidemiological research, as presented by the VKM at an international conference on epidemiological studies. The conference, held in Berlin, was organised by the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA). Such observational studies on humans involve the gene-

ral population or certain population groups, rather than focusing purely on individual cases. These studies help identify possible connections between "end points", such as disease (for example, heart problems or cancer) or death, and a specific cause (for example, contact with a chemical substance). In this way, it is possible to recognise health effects on the population under actual, real-life conditions.

#### THE DOSE MAKES THE POISON

In general, in order to establish how high a risk a potentially harmful substance poses to health, scientists in the field of toxicology – the science of poisons – conduct experiments on animals. These experiments allow scientists to clearly attribute a cause – for example, a chemical – to an effect, such as weakened organ function. Associations between various doses of a substance and certain effects can also be analysed. However, findings based on animals cannot be automatically transferred to humans.

Epidemiological studies, on the other hand, focus directly on humans. Their strength lies in the way they can support hints derived from animal experiments by showing health risks actually observed in the human population. These studies can also identify health risks that are not identified in animal experiments.

#### **OBSTACLES AND OPPORTUNITIES**

The conference in Berlin aimed to deepen the mutual understanding between epidemiology and risk assessment. The use of epidemiological data to assess health risks rarely occurs systematically. The supposed weakness of such studies, namely that they are only seldom able to prove a causal link between substance intake (exposure) and a disease, can even lead to such research being excluded from an assessment despite delivering valuable insights. However, despite the continued existence of barriers, mutual understanding and cooperation between the two fields is growing. "We need valuable epidemiological studies and a deeper understanding of epidemiology in the field of toxicology in order to develop common approaches," is how BfR scientist Professor Matthias Greiner summarises the situation. Pooling insights from various scientific disciplines remains a challenge. However, there are useful ideas to help achieve this, such as the weight-of-evidence approach, which incorporates, alongside both animal and animal-free experiments, valuable findings from epidemiological studies in assessments. In a sense, this represents a pincer attack from more than one side on risk. To return to fish and its benefits and risks. The comprehensive, approximately one-thousandpage assessment by the Norwegian research team reached the following clear conclusion: "The benefits clearly outweigh the negligible risk posed by the current concentration of contaminants and other undesirable substances in fish". So, eat and enjoy! —

#### More information



Video recordings of talks at the International Conference on Using Epidemiological Studies in Health Risk Assessment



W W

DOES IT CONTAIN NANOMATERIALS? –
CHECK THE LABEL! CONSUMERS BUYING
BODYCARE AND BEAUTY PRODUCTS IN THE
EU CAN CHECK THE INGREDIENTS. AN EU
PLATFORM PROVIDES INFORMATION
ABOUT THE PURPOSE OF USING
NANOMATERIALS.

Thick, gooey sun cream, runny shampoo or clumpy mascara are not much fun. This is why manufacturers try to optimise their formulas, with the use of nanomaterials being an option in this respect. As the nano-sized substances can have completely different and new properties than their larger equivalents, nanomaterials undergo a separate assessment to ensure they do not pose any health risks.

#### RISK ASSESSMENT OF TINY THINGS

The German Federal Institute for Risk Assessment (BfR) has been researching nanomaterials for years to better assess the associated health risks and to reinforce risk communication. Products containing easily released or unbound nanomaterials are given particular attention in a risk assessment. As many different product types contain nanomaterials, i.e. not only cosmetics, practically all exposure routes are relevant to an assessment. Exposure via the skin (dermal) is of key significance for cosmetics. Other exposure routes should also be considered for certain products, for example exposure via the airways (inhalation) when it comes to some spray products, or exposure via the digestive tract (oral) for toothpaste. Due to their small size, it is easier for the tiny nanomaterials to pass some of the body's barriers such as the intestinal wall or the alveoli in the lungs. Their distribution in the body can also differ from non-nano materials. Correctly estimating the intake amount in the body is one of the challenges faced in risk assessment. According to current scientific knowledge, healthy skin is a very good barrier.

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© Tube: Lumos sp, Icons: NicBrand @adobestock

While the BfR is not aware of any nanomaterial contained in cosmetics that enters the body in this way, unintentional but foreseeable exposure via other exposure routes must be taken into account in cosmetics risk assessment.

# EU COSMETIC PRODUCTS NOTIFICATION PORTAL

In Europe, manufacturers or those that make the product available in the EU for the first time, are responsible for the safety of bodycare and beauty products. A central reporting system for cosmetics has been introduced to ensure the population is protected. This helps the authorities with market monitoring and thus consumer protection. Dyes, preservatives and UV filters must be both registered with and approved by the European Commission before their use in cosmetics. All nano-sized ingredients must also be reported to the European Commission six months before they enter the market. Should the commission have any concerns regarding their use, the Scientific Committee on Consumer Safety is tasked with a health risk assessment. As there are different nanomaterials and new ones are always being developed, every single one is checked and considered for individual use.

All nanomaterials registered in the EU and their use in products is listed on the EUON platform of the European Chemicals Agency (ECHA). The page offers an overview of the diverse uses of nanomaterials, not only in cosmetics. A glance at the packaging of bodycare and beauty products helps consumers to decide for themselves whether or not to use nanomaterial-based cosmetics. Nanomaterial ingredients must be labelled with the word "nano" in brackets in the EU.—

#### More information



BfR information "Health assessment of Nanomaterials"



Online platform for registered chemicals and their use "European Union Observatory for Nanomaterials"

# WHAT PRODUCTS CONTAIN NANOMATERIALS AND WHY?

Nanoparticles or crystals have different functions



FACE MASKS: IMPROVED ABSORBENCY AND GEL-LIKE TEXTURE | NAIL VARNISH: OPAQUE, FULL COVERAGE COLOURS | EYESHADOW: MATTE FINISH | MAKE-UP: CO-LOUR AND ANTI-CLUMP PRODUCT FOR EVEN COVERAGE | SKIN PRIMER: COLOUR, UV FILTER, VITAMIN E CARRIER AND MOISTURE PROVIDER | MASCARA: COLOUR | LIPS-TICK: COLOUR, SMOOTHER AND MORE EVEN APPLICA-TION | LIP CARE: SUN PROTECTION | SUNTAN LOTION: TRANSPARENT SUN PROTECTION | SHAVING FOAM: LUBRICANT AND MOISTURISER| HAIR CONDITIONER: SLIPPERINESS FOR COMBING | SHAMPOO: EASY APPLI-CATION, ANTI-DANDRUFF | SHOWER GEL: COLOUR | HAIR GEL: COLOUR, BETTER HOLD | DEODORANTS: SMOOTH GLIDE AND SWEAT ABSORPTION | MOUTHWASH: RE-MINERALISATION OF TOOTH ENAMEL | TOOTHPAS-TE: EROSION PROTECTION FOR TOOTH ENAMEL

#### More information



ECHA campaign on use and purpose of (nanomaterials) in cosmetics #NanosINCosmeticsEU

# Plasticisers on the loose...

Phthalates make plastics more elastic. However, some phthalates can also have adverse health effects. Therefore, their use is now highly regulated.

They are meant to make plastics which are normally hard and brittle elastic and flexible: using phthalates, materials such as PVC can be processed to make products such as flooring, films, or hoses. For that reason, phthalates were produced in large quantities and put into many other products over the past decades. These included textiles, toys, lids for jars, as well as paints, glues, and solvents. Now, however, the use of many phthalates in consumer products has been banned or is at least highly regulated. This is because phthalates are not firmly bonded to plastics and other materials. They can be released from the materials and enter the environment or the food chain. In studies, phthalates and their degradation products are therefore frequently found in urine samples. In the body, some of them can have negative health impacts if ingested in sufficient quantities.

#### **EFFECTS IN ANIMAL STUDIES**

Adverse health effects due to phthalates have been shown in animal studies. In rats and mice, for example, researchers found that certain phthalates influence the formation of the male sex hormone testosterone. This suggests that the fertility of male animals can be impaired by phthalates. The damage was already noticeable while the reproductive organs were still developing in unborn animals. Because these phthalates impair the hormonal system, they are also termed "endocrine disruptors". Although results from

No need to worry about sharing bathwater with rubber duckies made in accordance with the legal requirements.

animal studies cannot be directly transferred to humans, it may be assumed that similar effects might occur in humans, too.

# TRACES OF PHTHALATES IN URINE SAMPLES

In early 2024, traces of phthalates found in urine samples made the headlines: the State Office for Nature, Environment and Consumer Protection in North Rhine-Westphalia as well as the UBA, Germany's Federal Environmental Agency, had discovered

traces of the substance mono-n-hexylphthalate – MnHexP for short – in urine samples from children and adults. This substance can result as a degradation product from the metabolisation of various phthalates. However, the use of these substances is highly restricted. In the meantime, traces of a phthalate that can be broken down in the body to MnHexP have been detected in sunscreen and other consumer products. At the time of going to press, the investigations into the background were still ongoing.

# EFFECTS ONLY ABOVE A CERTAIN CONCENTRATION

In general, though, adverse health effects from the various phthalates were only found when the animals in the studies were exposed to relatively high phthalate concentrations over a longer period of time. By comparison, the examined urine samples showed a far lower intake by consumers. Therefore, negative impacts on consumer health are not expected based on the current state of the research. Nevertheless, phthalates are undesirable substances in the body and their intake should there-

fore be kept to a minimum. In order to protect consumer health, the BfR is an active participant in various national and international committees on this issue. Also based on the BfR's assessments, the use of hazardous phthalates has been severely curtailed over the past years. Monitoring studies have since demonstrated far lower concentrations of phthalates and their degradation products in urine samples than 20 years ago. However, the cases from early 2024 show that the BfR's work regarding phthalates is far from over. —

#### More information

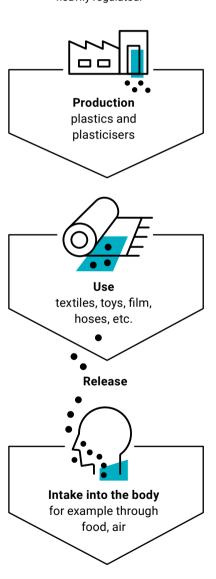


BfR information "Phthalates"

Because certain phthalates impair the hormonal system, they are also termed "endocrine disruptors".

## Phthalates escape into the environment and then enter the body

Now, their use in consumer products has been banned or is at least heavily regulated.



# Guard plate for the thyroid



© BfR

The biotechnologist Dr Kostja Renko and his team are using animal-free methods to study the effect of chemicals on the thyroid and its regulation in the body.

t all starts in the depths of the primordial ocean. Billions of years ago, single-cell organisms were already using a trace element from their oceanic environment: iodine. This, at least, is the assumption regarding the trace element's evolutionary significance. It helps cells detoxify aggressive compounds containing oxygen. Iodine and compounds containing iodine are the cells' "primordial vitamin". And iodine can do even more. Bound to the amino acid tyrosine it functions as a messenger substance or "primordial hormone". In addition, the binding of tyrosine and iodine forms the foundation of thyroid hormones. As far back as 800 million years ago, these appeared in simple sea creatures such as sponges and corals and have been part of the biological "inventory" ever since, particularly in the animal kingdom.

#### **DISRUPTORS IN THE SYSTEM**

Returning to the present: in a laboratory at the German Centre for the Protection of Laboratory Animals (Bf3R) in Berlin-Marienfelde, the biotechnologist Dr Kostja Renko is using microtiter plates – small rectangular plates made of transparent plastic with tiny "cavities" – to examine how chemicals in various doses impact thyroid cells and the thyroid hormone system. This system is made up of more than just the hormone-secreting thyroid from which the system derives its name. Very important transport and transformation processes for these hormones take place in almost every cell of the body. "We are working on new methods that allow potential endocrine disruptors to be detected," Kostja Renko says. "We are talking about chemical compounds that can disrupt the normal functioning of the hormone system and thus harm health."

Situated below the larynx, the thyroid's shape, with its two symmetrical lobes, is vaguely reminiscent of a butterfly. This suits its role, as it "gives wings" to metabolism. Thyroid hormones regulate energy metabolism, body temperature, and heart function.

Too much, and it can lead to a dangerously rapid heart rate and weight loss. On the other hand, lower thyroid function causes metabolism to slow greatly, a drop in heart rate, and tiredness and lethargy.

#### **DRIVING FORCE OF METABOLISM**

Thyroid hormones function not only as a driving force of metabolism. They are also important for the development of foetuses in the womb, in particular when it comes to brain development. If pregnant women are deficient in iodine, it may also lead to a hormone deficiency. In extreme cases this may result in the child suffering from congenital iodine deficiency syndrome (CIDS). This massive variant in innate hypothyroidism and the associated hormone deficiency is linked to stunted growth, abnormalities of the skeleton, a greatly enlarged thyroid, and reduced mental capacity. In recent decades, better nutrition including iodised salt has largely eradicated CIDS. However, innate thyroid abnormalities still occur that have no connection to iodine deficiency. "In order to identify it early on, you can take a small blood sample from newborn babies," Renko explains. "By administering thyroid hormones a deficiency can then be reliably compensated for and harm prevented." However, it is not yet clear to what degree minor changes in the thyroid hormone system,



Double dose: microtiter plates allow for the parallel testing of chemicals in varying concentrations.

for example due to unintended effects from chemicals, impact key phases in brain development. Endocrine disruptors can unbalance the thyroid at several levels. For example, they may disrupt the formation and secretion of the hormones T4 (thyroxine) and T3 (triiodothyronine), their distribution in the body, their metabolism, or the overarching regulation. The aim is to now develop and gain international recognition for reliable and animal-free methods for chemical tests relating to all these "sites of attack". Only in this way can they replace or at least reduce animal experiments in the long term. In any case, this is Kostja Renko's stated aim. Developing alternative methods is also a key task of the German Centre for the Protection of Laboratory Animals.

#### TRACING THE TRACE ELEMENT

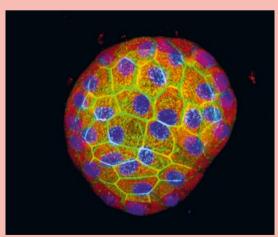
Renko's scientific path begins at the Institute of Experimental Endocrinology at Berlin's Charité Hospital. There his research involves, among other things, plant substances with possible side-effects on the thyroid hormone system. At this time, detection procedures are still often required that use radioactive iodine to trace disruptions to the formation, activation, or transport of the hormone.

"The tests make it necessary to work in an isotope laboratory," Renko recalls. "To put it bluntly: it's not much fun."

Obviously, the fun factor is not the (only) thing of importance to the scientist. Working with radioactive isotopes is time-consuming and expensive, entails health risks, and limits the number of tests that can be performed simultaneously. "Against this backdrop, an almost one-hundredyear-old method from analytical chemistry came to our aid," the researcher says. "We successfully used a 'classic' procedure for measuring iodine - he Sandell-Kolthoff reaction, first described in 1937 - in various tests to replace the radioactive iodine-containing tracer that we had been using up to that point." To put it simply, researchers use the Sandell-Kolthoff reaction to measure the iodine concentration in a liquid. The faster the yellow solution turns pale, the higher the iodine content.

#### **TEST FOR THE WHOLE WORLD**

Renko wants to help establish internationally recognised alternatives to animal experiments. These are published as test guidelines by the Organisation for Economic Cooperation and Development (OECD) facilitate the use for legally required testing of chemicals. "The path to obtaining such international recognition is long," the biotechnologist says. It requires formal proof that a method can be used globally in other laboratories with comparable results. "Together with our partners from academic research and industry, we are already making good progress with some of our methods." Each new method enlarges the tool box for risk assessment.



Living bioreactor: the thyroid consists of innumerable vesicles made up of follicles such as these.

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# "We are working on new methods that allow potential endocrine disruptors to be detected"

Dr Kostja Renko, biotechnologist

To finish, Kostja Renko allows the visitor to take a look through the microscope. Individual vesicles can be seen, transparent and surrounded by cells. These are thyroid follicles that make up the glandular tissue. The scientist and his doctoral student Lars Dahmen are working to make the follicles suitable for future use as "mini thyroids" in tests on endocrine disruptors. The material for this cell culture system are the thyroids of slaughtered pigs, normally a waste product of the meat industry.

"The fascinating thing about thyroid follicles is that they are microscopically small bioreactors," Renko says. "The 'final assembly' of the hormones does not take place in the cells themselves, but rather in the follicle vesicles." In other words, what nature does with the follicles "anticipates" a piece of biotechnology. Seen in this light, what actually is the primordial ocean but a huge bioreactor? With, of course, a decisive sprinkling of iodine. —



Taking due care with chemicals and cells: the safety workbench serves to protect the thyroid follicles and the researchers.

#### **INTERNATIONAL NEWS**

#### Leaders for strong food safety

30 Tunisian future decision makers are learning about national and global food safety as well as innovative leadership skills in a year-long part-time study programme. The programme is being conducted by the BfR and the Federal Office for Consumer Protection and Food Safety (BVL) together with the Tunisian Ministry of Health and the Tunisian National School of Administration.

It is part of a five-year project aimed at improving food safety and consumer health protection in Tunisia.

#### **EU Food Safety Forum**

At the first EU Food Safety Forum in Brussels, the BfR took part in panels and discussions about food safety and related future challenges in Europe. The forum was organised by the EU project "Food Safety for EU" (FS4EU) as

a new format for facilitating exchange between science, politics, and the general public. The BfR is a supporting partner of FS4EU.

#### **SOCIAL MEDIA**

#### The BfR is now also on Threads and Bluesky

Stay up to date: informative photo and video content about the BfR's main topics as well as information about current publications and events are now also available on the social media platforms Threads and Bluesky. It's worth a follow.



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#### **INTERNAL AFFAIRS**

#### Visiting the BfR

Professor Dr Daniela Morais Leme from the Universidade Federal do Paraná in Brazil is a guest researcher at the BfR for several months. The experienced toxicologist is a research fellow of the Humboldt Foundation and the Brazilian Federal Agency for Support and Evaluation of Gra-

duate Education (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior). At the BfR, she researches liver toxicity and animal-free methods (also called new approach methods) in the context of combination effects of pesticides.

#### **Award-winning**

In March 2024, Dr Denise
Bloch was awarded the "Young
Scientist Toxicology Award" by
the German Toxicology Society.
At the BfR, she leads a junior
research group investigating the
interactions between substances
using new approach methods.
Each year, the award is presented
to young scientists who have produced outstanding work in the
field of toxicology. Dr Bloch was



Denise Bloch

recognised for her work in the field of "new approach methods (NAM) and mixture toxicity."

#### SCIENCE COUNCIL

#### "Tasks excellently fulfilled"

- according to the conclusion of the Science Council which evaluated the BfR at the end of 2023. This council, Germany's highest scientific commission, had particular praise for the research quality, the development of animal-free methods, and the focus on young scientists. The focus on prescient issues and the relevance to everyday life in the BfR's publications were also well received.

More information



BfR press release 'Science Council"

#### **INTERNA**

#### **New EU partnerships**

The BfR is participating in the European Partnership on Animal Health and Welfare. Important topics covered by the seven-year project include prevention and control of infectious animal diseases, the use of antibiotics, and the wellbeing of livestock in sustainable production systems. The BfR is also part of the European Partnership for a Sustainable Future of Food Systems (FutureFoodS), which is planned for a ten-year period. The goal is to ensure environmentally friendly, socially acceptable, and economically feasible as well as healthy and safe food systems.

### **Consumer health**

# protection to go

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