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Mycotoxins in plant-based drinks (soy, almond and oat): the BfR updates its assessment of their health risks based on newly collected data

Plant toxins were also investigated

→ Update and supplement to opinion 029/2024 of 25 June 2024.

In brief

- Mycotoxins (mould toxins) are secondary metabolites of moulds. They are natural toxins whose occurrence in food and feed is undesirable but cannot be completely avoided. Mycotoxins may occur as contaminants in plant products and raw materials such as grains, nuts and almonds if they are infested with mould during cultivation, storage or processing, and subsequently also transfer to processed products such as plant-based drinks made of oat, soy or almond.
- In this opinion, the German Federal Institute for Risk Assessment (BfR) has collected new data on the occurrence of mycotoxins in commercially available plant-based drinks. Specifically, 162 samples of soy drinks, almond drinks and oat drinks, which are often consumed as alternatives to cow's milk, were examined. Taking into account the assumed intake levels, possible health risks associated with the intake of mycotoxins such as aflatoxin B1 (AFB1), ochratoxin A (OTA), deoxynivalenol (DON) and T-2 and HT-2 toxins (T2/HT2) in children between the ages of six months and six years were then assessed. Children generally consume larger amounts of food in relation to their body weight than adults. This is associated with a higher intake of substances – including undesirable substances – in relation to their body weight. Children in this age group are therefore considered to be particularly sensitive to possible health impairments.
- **Aflatoxin B1** Long-term intake of aflatoxin B1 is known to cause kidney damage, liver damage such as cirrhosis, and the occurrence of kidney and liver cancer. Due to its genotoxic carcinogenic effect, no safe intake level can be derived for AFB1. AFB1 was detected in 31 of 39 samples of almond drinks. Taking into account the levels detected, the BfR concludes that the consumption of these almond drinks may pose a

health risk to particularly sensitive consumer groups such as children and that health impairments can occur with a medium likelihood.

- **Ochratoxin A** damages the kidneys and liver and is considered a possible human carcinogen due to its carcinogenic effect in laboratory animals. It was detected at very low amounts in 33 of 39 samples of almond drinks and in 23 of 29 samples of soy drinks. The consumption of these plant-based drinks by children aged six months to six years is considered to be of little concern.
- **Deoxynivalenol** impairs the development of children in the long term at low doses. In addition, at high doses it causes acute stomach and intestinal complaints such as vomiting and diarrhoea, as well as headaches and fever. It was detected in 67 of 86 samples of oat drinks. The BfR considers the occurrence of health impairments after consumption of these oat drinks to be unlikely.
- **T-2 and HT-2 toxins** have haematotoxic and myelotoxic effects and interfere with blood formation. T2/HT2 was detected in all 86 samples of oat drinks tested. The BfR considers the likelihood of health impairments after consumption of these oat drinks by children as low. However, other oat products, such as oat flakes, may also contain these toxins. Consuming several oat-containing products increases the total intake and thus the health risk.
- In this risk assessment, the researchers examined not only mycotoxins but also **plant toxins** – substances produced by plants, usually to defend themselves against predators. Depending on the dose, some of these substances can be harmful to human health. The researchers found no evidence of health risks associated with **tropane alkaloids** (TA) – with the exception of one soy drink product. In this product, the tropane alkaloids atropine and scopolamine were repeatedly found in such high concentrations that the occurrence of health impairments must be considered. For **lupanine**, which was examined as representative of the **quinolizidine alkaloid** group, no evidence of possible health impairments was found, even in cases of high intake of oat drinks. **Pyrrolizidine alkaloids**, a large group of compounds, were detected in plant-based drinks at amounts below the limit of quantification (LOQ).
- As there is currently insufficient information on the consumption of plant-based drinks by children, the calculations were based on data on cow's milk consumption. This is basically plausible because many consumers use plant-based drinks as an alternative to cow's milk. However, the calculations are based on the assumption that only one type of plant-based drink replaces cow's milk. The intake of certain mycotoxins and plant toxins for a specific type of plant-based drink is overestimated if different types of plant-based drinks are consumed instead.
- On the other hand, the intake of undesirable substances may be underestimated if the focus is solely on plant-based drinks, as consumers also ingest these substances from other foods. Mycotoxins can also occur in grains, fruit, vegetables, tree nuts, peanuts, cocoa, coffee and spices, for example.
- In general, the following applies to healthy nutrition: a diverse, varied and broad selection of foods not only ensures a balanced nutrient intake, but also helps to keep

the intake of undesirable substances, which cannot always be avoided due to the natural origin of our food, as low as possible.

1 Subject of the assessment

In its opinion 029/2024, the German Federal Institute for Risk Assessment (BfR) conducted a health risk assessment of the results on the occurrence of mycotoxins in plant-based drinks from the study "Initial characterisation of selected plant-based drinks with regard to their quality and to their microbiological and chemical safety " conducted by the Max Rubner Institute (MRI) (MRI 2023). The results were contextualised with regard to their relevance for consumer exposure and an assessment was made as to whether the concentrations determined could pose a health risk to vulnerable groups. The BfR was unable to assess the extent to which the data collected by the MRI was representative of the German market and therefore recommended generating further data on the occurrence of mycotoxins in plant-based drinks.

The BfR collected the relevant data in 2024 and 2025 and, based on this data, prepared an updated risk assessment.

2 Result

In its opinion 029/2024, the BfR conducted an assessment of the health risks posed by the intake of mycotoxins from the consumption of plant-based drinks for aflatoxin B1 (AFB1) in almond drinks, deoxynivalenol (DON) in oat drinks and T-2 and HT-2 toxins (T2/HT2) in oat drinks. The BfR collected further data in 2024 and 2025 and used this data to perform an updated risk assessment. A total of 162 plant-based drinks were tested for mycotoxins and plant toxins. The products tested were selected with the aim of obtaining a representative survey of the plant-based drinks available on the German market. Based on market research data, the products with the highest market shares were examined in order to achieve the highest possible market coverage for three types of plant-based drinks (oat drink, almond drink and soy drink). The plant-based drinks were analysed using a multi-analyte method, which, in addition to the mycotoxins already examined in the MRI study, enabled the determination of numerous other substances from the area of mycotoxins and plant toxins.

Based on the new data from the BfR, the health risk assessment of ochratoxin A (OTA) in soy drinks and almond drinks, for which no meaningful data was available in the MRI report, was supplemented for this opinion. The health risk assessment will thereby be limited to those substance-matrix combinations that have been detected most frequently and for which sufficient toxicological data are available as a basis for a proper risk assessment.

In addition, the health risk assessment is limited to children aged 0.5 to <6 years as a vulnerable consumer group. Compared to adults, and due to their lower body weight, children have a higher consumption and thus a higher exposure in relation to their body weight.

The most recent data on consumption for children is available from the KiESEL study (The Children's Nutrition Survey to Record Food Consumption). As only a small number of children consumed plant-based drinks in the KiESEL study (n=38), cow's milk consumption is primarily used for the exposure assessment. This is based on the assumption that the corresponding plant-based drinks are used as an alternative to cow's milk and thus result in comparable consumption amounts.

A comparison with the actual consumption of plant-based drinks recorded in the KiESEL study suggests that using data on cow's milk consumption as a substitute for plant-based drink consumption could result in an overestimation. However, the differences in consumption levels are not significant. It should also be noted that sales of plant-based drinks are increasing, so it can be assumed that consumption of plant-based drinks has also increased since the field phase of the KiESEL study (2014-2017). However, the BfR does not have more recent consumption data to support this assumption.

The BfR has applied the margin of exposure (MOE) concept to assess the health risks of AFB1 intake in almond drinks, as aflatoxins are genotoxic carcinogens for which no safe intake level can be derived. In its assessment of the health risks associated with the intake of AFB1 from the consumption of almond drinks based on realistic scenarios, the BfR concludes that in the case of long-term consumption of almond drinks containing AFB1 at concentrations determined by the BfR, the likelihood of health impairments in children aged 0.5 to <6 years is medium. If aflatoxins B2, G1 and G2 are also taken into account in the assessment of health risks, the BfR reaches the same conclusion.

Given the very low OTA concentrations determined by the BfR, realistic scenarios for the intake of OTA from the consumption of almond drinks or soy drinks by children aged 0.5 to <6 years result in margins of exposure (MOE) that are considered to be of low concern for public health with regard to both the neoplastic and non-neoplastic effects of OTA.

In its assessment of the health risks associated with the intake of DON from the consumption of oat drinks based on realistic scenarios, the BfR concludes that in the case of both long-term and short-term consumption of oat drinks with DON at concentrations determined by the BfR, health impairments in children aged 0.5 to <6 years are unlikely. When the modified forms 3-acetyl-DON (3-Ac-DON), 15-Ac-DON and DON-3-glucoside (DON-3-Glu) are also taken into account in the assessment of health risks, the BfR reaches the same conclusion.

When conducting the health risk assessment of the intake of T2/HT2 alone through the consumption of oat drinks, the BfR concludes, based on realistic scenarios, that in the case of both short-term and long-term consumption of oat drinks containing T2/HT2 at concentrations determined by the BfR, the likelihood of health impairments in children aged 0.5 to <6 years is low.

However, it should be noted that, based on the average concentrations of T2/HT2 determined by the BfR, long-term high consumption of oat drinks by children aged 0.5 to <6 years already results in 82 % of the TDI. It should be further noted that oat drinks are not the only source of T2/HT2 intake, but that T2/HT2 is also ingested through the consumption of other foods, in particular other oat products. In this opinion, the BfR assumes that plant-based drinks are used as an alternative to cow's milk. Accordingly, a scenario in which children aged 0.5 to < 6 years consume oat flakes together with oat drinks can be considered

realistic. The consumption of oat drinks as an alternative to cow's milk would therefore represent an additional source of T2/HT2 intake, thereby increasing both the overall exposure to T2/HT2 and the likelihood of health impairments.

In addition, the BfR examined the plant-based drinks for plant toxins. In one soy drink product, the tropane alkaloids (TAs) atropine and scopolamine were repeatedly found at such high concentrations that the occurrence of health impairments must be considered. To this end, the BfR carried out individual case studies on the short-term intake of TAs from the consumption of the soy drink product with the highest TAs contamination and the soy drink product with the second-highest TAs contamination. Using the data for short-term consumption and the maximum TA content in soy drinks of 1,274 ng/kg as determined by the BfR, this results in percentages of 100 % (average consumption) and 330 % (high consumption) of the ARfD. Exceeding the ARfD can generally lead to health impairments. In contrast, an analogous calculation using a TA concentration of 57 ng/kg, which was the maximum determined by the BfR in the other soy drink samples, results in percentages of 4.5 % (average consumption) and 15 % (high consumption). Thus, the plant-based drinks examined (with the exception of the soy drink product mentioned above) do not indicate that the occurrence of TAs in plant-based drinks could pose a health risk to consumers.

The BfR also tested the plant-based drinks for lupanine (representative for a contamination with quinolizidine alkaloids – QAs). For classification purposes, the BfR carried out an exemplary worst-case scenario for the short-term intake of lupanine through high consumption (P95) of oat drinks. This resulted in a MOE value of 16 when using the maximum lupanine concentration of 240 µg/kg determined by the BfR, and a correspondingly higher MOE value of 1,300 when using a lupanine concentration at the 95th percentile (3 µg/kg). This means that even for these exemplary worst case scenarios, the MOE values are well above 1 and thus within a range that, according to the EFSA's assessment, does not pose any health concerns.

3 Rationale

The BfR has generated a comprehensive data set on the occurrence of mycotoxins in the three best-selling plant-based drinks (oat, almond and soy). The results of this data collection will be used to update the BfR opinion 029/2024 ("Mycotoxins in plant-based drinks: more data required") of 25 June 2024.

For the update, the BfR will not conduct a health risk assessment for all substance-matrix combinations examined, but will limit itself to those cases that have been detected most frequently and for which sufficient toxicological data are available as a basis for a proper risk assessment. The risk assessment covers the following substance-matrix combinations:

In almond drinks

- Aflatoxin B1 (AFB1) and the sum of aflatoxins B1, B2, G1 and G2 (AFT)
- Ochratoxin A (OTA)

In soy drinks

- Ochratoxin A (OTA)

In oat drinks

- Deoxynivalenol (DON) and the sum of DON and its modified forms (3-Ac-DON, 15-Ac-DON and DON-3-Glu)
- The sum of toxins T-2 and HT-2 (T2/HT2)

In addition, the BfR also surveyed the concentrations of selected plant toxins (pyrrolizidine alkaloids, tropane alkaloids and lupanine, representative for quinolizidine alkaloids) in the plant-based drinks mentioned above. The classification of these concentrations can be found under point 3.6 of the opinion.

3.1 Hazard identification

3.1.1 Hazard identification for AFB1 and the sum of aflatoxins B1, B2, G1 and G2

Aflatoxins belong to the group of mycotoxins and are mainly produced by the two fungal species *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins can be detected in various foods, such as tree nuts, peanuts, maize, spices and dried fruit (EFSA 2020a).

Regulation (EU) 2023/915 sets maximum levels for aflatoxins (differentiated for aflatoxin B1 and the sum of aflatoxins B1, B2, G1 and G2) in various foods. Current maximum levels of 8.0 µg/kg (for AFB1) and of 10.0 µg/kg (for the sum of the aflatoxins B1, B2, G1 and G2) apply to almonds, placed on the market for the final consumer or for use as an ingredient in food, but there is no specific maximum level for aflatoxins in almond drinks. Regulation (EU) 2023/915 does, however, set a maximum level of 0.05 µg/kg for the main metabolite aflatoxin M1 in raw milk, heat-treated milk, and milk for the manufacture of milk-based products.

3.1.2 Hazard identification for OTA

OTA is the most prevalent mycotoxin within the ochratoxin group and has the highest toxic potential. OTA is mainly produced by fungi of the genera *Aspergillus* and *Penicillium*, in particular by the fungal species *A. ochraceus*, *A. carbonarius* and *P. verrucosum*. OTA can be detected in plant-based foods such as grains and grain products, spices, dried fruit and coffee, as well as in animal food products such as mature ham and hard cheese (EFSA 2020b).

Regulation (EU) 2023/915 sets maximum levels for OTA in various foods. For example, a maximum level of 5 µg/kg applies to soybeans. There are no specific maximum levels for OTA in soy drinks and almond drinks according to Regulation (EU) 2023/915.

3.1.3 Hazard identification for DON and for the sum of DON and its modified forms

DON is one of the mycotoxins primarily produced by fungal species of the genus *Fusarium*. Human exposure occurs mainly through grains and grain products, in which DON can be detected almost ubiquitously (EFSA 2017c).

Regulation (EU) 2023/915 sets maximum levels for DON in various foods. For example, a maximum level of 750 µg/kg applies to oats placed on the market for the final consumer. Regulation (EU) 2023/915 sets no specific maximum level for DON in oat drinks. Furthermore, modified forms of DON are not (yet) taken into account when setting maximum levels.

3.1.4 Hazard identification for T2/HT2

T-2 toxin and its main metabolite HT-2 toxin are mycotoxins that are primarily formed by *Fusarium langsethiae*, but also by some other Fusarium species. Human exposure occurs mainly through grains and grain products, with oats and oat products having the highest concentrations (EFSA 2017b).

Regulation (EU) 2024/1038, which entered into force on 1 July 2024, established maximum levels for T2/HT2 in food for the first time. For example, a maximum level of 100 µg/kg applies to oats placed on the market for the final consumer and to oat flakes. There is no specific maximum level for T2/HT2 in oat drinks.

3.1.5 Plant-based drinks

Plant-based drinks are products that are advertised as plant-based milk alternatives and are further differentiated according to their ingredients. The BfR has examined almond drinks, oat drinks and soy drinks. Colloquially, plant-based drinks are also referred to as plant milk because they resemble milk in appearance and consistency and are commonly used by consumers as an alternative to milk. However, in the European Union, the term "milk" may only be used for products obtained by milking an udder (cow's, sheep's and goat's milk).

3.2 Hazard characterisation

3.2.1 Hazard characterisation for AFB1 and the sum of aflatoxins B1, B2, G1 and G2

The International Agency for Research on Cancer (IARC) has classified aflatoxins in Group 1 (*carcinogenic to humans*) and last confirmed this classification in 2012 (IARC 2012). The carcinogenic potential of aflatoxins B1 and G1 was detected, while the results for the other two aflatoxins, B2 and G2, were less clear. The health risk assessment cites the potential to cause liver cancer as a critical effect, which is higher for aflatoxin B1 than for aflatoxin G1.

Aflatoxins have genotoxic and mutagenic properties. The European Food Safety Authority (EFSA) therefore concluded that no dose without effect can be determined and that, accordingly, no health-based guidance values (HBGVs) can be established.

EFSA therefore recommends using the margin of exposure (MOE) concept for the health risk assessment of aflatoxins. The MOE is the quotient of a suitable toxicological reference value and human exposure to the substance. For carcinogenic compounds, the benchmark dose lower confidence limit (BMDL) is often used as a reference value. The $BMDL_{10}$ is determined by modelling appropriate dose-effect relationship data and corresponds to the lower limit of the confidence interval of the dose that, in the case of a carcinogenic effect, is associated with an additional cancer risk of 10 % (benchmark dose response 10 %, BMR_{10}) compared to the control group. From a public health perspective, a margin of exposure (MOE) of 10,000 and above is generally considered to be of low concern – but not harmless – for genotoxic carcinogens and is therefore given low priority for risk management measures.

EFSA has identified a two-year carcinogenicity study in rats (Wogan et al. 1974) with AFB1 as the critical study for the toxicity of aflatoxins. Based on the data on the induction of liver cell carcinomas in male rats, a benchmark dose lower confidence limit $BMDL_{10}$ of 0.4 µg/kg bw per day was determined using benchmark modelling (EFSA 2020a).

EFSA also analysed the data on the potency of aflatoxins B1, B2, G1 and G2, but was unable to identify any clear quantitative differences. EFSA therefore recommends that the same

relative potency be assumed for aflatoxins B1, B2, G1 and G2 in a risk assessment (EFSA 2020a).

The BfR has tested plant-based drinks for AFB1 as well as aflatoxins B2, G1 and G2, so that the health risk for both AFB1 alone and the sum of aflatoxins B1, B2, G1 and G2 is assessed below.

3.2.2 Hazard characterisation for OTA

Animal studies in rodents have shown that oral administration of OTA leads to hepatocellular and renal carcinomas. Furthermore, OTA has induced nephrotoxic and immunosuppressive effects in in vivo studies. It could not be concluded with certainty whether the effects observed in animal studies also lead to carcinogenicity in humans, so the IARC has classified OTA in Group 2B (possibly carcinogenic to humans) (IARC 1993).

OTA has a high binding affinity to plasma proteins, which leads to reduced excretion and, consequently, to comparatively long half-lives (5-6 days in pigs and up to 35 days in humans) and, in the case of chronic exposure, to an accumulation of OTA in humans and animals (EFSA 2020b).

In 2020, EFSA conducted a re-evaluation of the health risks associated with exposure to OTA through the consumption of food and concluded that there are significant uncertainties regarding the genotoxic mechanisms that lead to kidney tumours in animal studies. As it could not be conclusively clarified whether OTA induces direct or indirect genotoxic effects, EFSA considered that the application of a threshold-based approach was no longer appropriate. As a result, the health-based guidance value (tolerable weekly intake, TWI) of 120 ng/kg bw per week established by EFSA in 2006 was suspended and the MOE approach (see Section 3.2.1) was used instead for the assessment of the health risks.

For the neoplastic effects of OTA, EFSA identified a two-year carcinogenicity study in rats (NTP 1989) as the critical study. Based on the data on the induction of kidney tumours in male rats, a benchmark dose lower confidence limit $BMDL_{10}$ of 14.5 µg/kg bw per day was determined using benchmark modelling (EFSA 2020b).

In addition, EFSA has also established a toxicological reference value for the health risk assessment of the non-neoplastic effects of OTA. EFSA has identified a 90-day study on sows as the most sensitive species as the critical study for this purpose (Krogh et al. 1974). Based on the toxicologically most sensitive endpoint (early signs of renal toxicity such as microscopic changes in the renal tubules), a benchmark dose lower confidence limit $BMDL_{10}$ of 4.73 µg/kg bw per day was determined (EFSA 2020b).

With regard to public health, the EFSA considers MOE values of 10,000 and above for the neoplastic effects of OTA and MOE values of 200 and above for the non-neoplastic effects of OTA to be of low concern – but not harmless (EFSA 2020b).

3.2.3 Hazard characterisation for DON and for the sum of DON and its modified forms

After oral intake of DON, both acute and chronic effects can occur, which can lead in particular to immunotoxic and developmental toxic effects. The mechanism of action involves binding to ribosomes, which leads to inhibition of protein biosynthesis. Pigs are particularly sensitive to DON and, depending on the level of oral exposure, show symptoms

such as refusal to eat and vomiting, which is why DON is colloquially referred to as "vomitoxin".

The EFSA has identified a two-year carcinogenicity study in mice (Iverson et al. 1995) as the critical study for chronic DON intake. This study did not demonstrate a carcinogenic effect of DON, but did show reduced weight gain in the mice. Based on this effect as a critical endpoint, the EFSA established a tolerable daily intake (TDI) of 1 µg/kg bw per day (EFSA 2017c).

In humans, primarily acute toxic effects have been described which manifest in nonspecific symptoms such as vomiting, diarrhoea, lower abdominal pain, headaches, and fever. As already described by Luo et al. in 1987 in a study on an acute outbreak in China, these symptoms often occur just 30 minutes after consuming contaminated food. On the basis of this study, EFSA has established an acute reference dose (ARfD) of 8 µg/kg bw per day (EFSA 2017c).

The BfR points out that the two health-based guidance values do not refer to DON alone, but were established as group values for the sum of DON and its modified forms (3-acetyl-DON, 15-acetyl-DON, DON-3-glucoside) (EFSA 2017c). This means that, in principle, the modified forms must also be taken into account in the health risk assessment.

The BfR also tested, in addition to DON, the plant-based drinks for 3-Ac-DON, 15-Ac-DON and DON-3-Glu, so that the health risk for both DON alone and the sum of DON and its modified forms is assessed below.

3.2.4 Hazard characterisation for T2/HT2

In in vivo studies, haematotoxic and myelotoxic effects and disrupted haematopoiesis were observed after administration of T-2 toxin. This is attributable to the T-2 toxin-mediated inhibition of protein biosynthesis (EFSA 2017a). Because T-2 toxin is rapidly metabolised to HT-2 toxin, it is not possible to differentiate between the toxic effects of T-2 and HT-2 toxin and therefore the health-based guidance values were established for the sum of the toxins T-2 and HT-2.

In 2017, EFSA reassessed the TDI for T2/HT2, referring to a study by Rahman et al. from 2014 as a critical study. In this subchronic 90-day study on rats, a reduction in total leukocyte count was observed and a correlation with haematotoxic effects from in vivo studies on other species was established. On the basis of the results of the study by Rahman et al. (2014), a group TDI of 0.02 µg/kg bw per day was established for the sum of T2/HT2 and their modified forms. The TDI was established on the basis of a 10 % reduction in total leukocyte count, which is within the range of individual physiological variation and is not yet considered adverse (EFSA 2017a).

In addition, EFSA considered in its reassessment also the derivation of an ARfD for short-term exposure to T2/HT2. Acute in vivo studies on mink revealed that, on oral or intraperitoneal exposure, both T-2 and HT-2 toxin had emetic effects which were considered to be the most sensitive endpoint for acute exposure to T2/HT2. On the basis of the results of a study by Wu et al. (2016), a group ARfD of 0.3 µg/kg bw per day was established for the sum of T2/HT2 and their modified forms. The ARfD is not established directly on the basis of emesis, but on a 10 % increase in the plasma level of the hormone 5-hydroxytryptamine (5

HT) and the peptide hormone PYY3-36, which are involved in the induction of vomiting (EFSA 2017a).

The BfR points out that the two HBGVs are not limited to T2/HT2, but were established as group values for the sum of T2/HT2 and their modified forms (EFSA 2017a). This means that, in principle, the modified forms must also be taken into account in the health risk assessment. Since the MRI's investigations are limited to T2/HT2, the health risk below will also only be assessed for these two substances.

3.3 Exposure assessment

3.3.1 Data on the consumption of plant-based drinks and cow's milk as a substitute

3.3.1.1 Data basis for consumption

As an update to the VELS study, the BfR carried out a representative study throughout Germany, "KiESEL" ("The Children's Nutrition Survey to Record Food Consumption"). The study was linked as a module to the Robert Koch Institute's "German Health Interview and Examination Survey for Children and Adolescents" ("KiGGS Wave 2").

A total of 1,104 children aged from six months up to and including five years participated in KiESEL over the period from 2014 to 2017. On the basis of an interview, the parents/guardians completed a questionnaire on general nutrition, nutrition in the first year of life and a Food Propensity Questionnaire on rarely consumed foods. Of these, 1,008 children or their parents also took part in the nutrition survey using a weighing/estimation record. The children's food consumption was documented in a weighing record for three successive days and in a one-day weighing record on an independent day. In addition, out-of-home consumption (e.g. in a care setting) was acquired using a reduced estimation record (Nowak et al. 2022).

In order to determine long-term consumption, all participants who had consumed cow's milk (or plant-based drinks) on at least one day of the study had their consumption of the corresponding food group summed for the individual days of consumption and then the mean of all the days of the study was calculated. When determining short-term consumption, the maximum over all days of consumption was calculated instead. Children who were still partially breastfed were excluded from the evaluation. Consumption is presented in various age and gender groups. In addition, confidence intervals were determined non-parametrically using a bootstrap method.

3.3.1.2 Data on long-term consumption of **cow's milk**

The KiESEL study is the most recent representative consumption study for children in Germany. With a recording period up to 2017, it may not fully reflect current consumption trends, such as the consumption of plant-based drinks. For example, the KiESEL study documents only a small number of children who consumed plant-based drinks (n=38). The exposure assessment is therefore based primarily on the consumption of cow's milk. This is based on the assumption that the corresponding plant-based drinks are used as an alternative to cow's milk and therefore result in comparable consumption amounts. This assumption is particularly relevant for the increasing number of consumers who follow a vegan diet. The consumption of plant-based drinks and cow's milk is compared in Section 3.3.1.4 to assess the assumption.

The results of long-term cow's milk consumption are presented in**Fehler! Verweisquelle konnte nicht gefunden werden.** . Children who did not consume cow's milk on at least one of the observation days were excluded from the evaluation. For this reason, the age group of 0.5 to under 1 year olds consists of only a small number of children who consume milk (n=15). In contrast, the proportion of children who had consumed cow's milk on at least one of the days was 85 % (n=811) across all age groups. Younger children consumed slightly more than older children, while there were no significant differences between boys and girls.

Across all age groups, children consumed a median of 7.1 grams (g) per kilogram (kg) of body weight (bw) per day (d). The high level of consumption, represented by the 95th percentile, amounts to 25.3 g/(kg bw*d).

Table1: Long-term consumption of cow's milk by children aged 0.5 to <6 years according to the KiESEL study. The confidence intervals (CI) were determined using a non-parametric bootstrap method.

Age/gender group	Number of consumers	Mean (95 % CI) [g/(kg bw*d)]	Median (95 % CI) [g/(kg bw*d)]	95th percentile (95 % CI) [g/(kg bw*d)]
All	811	9.6 (8.9-10.2)	7.1 (6.3-7.8)	25.3 (23.2-29.9)
0.5 - <1 year	15	10.8 (7.7-14.4)	8.7 (2.7–16.4)	27.2 (19.3-32.3)
1 - <3 years	263	12.5 (11.2-14.0)	8.7 (7.4-10.9)	38.9 (30.3-42.6)
>=3 years	533	8.1 (7.5-8.7)	6.3 (5.6-7.5)	20.2 (17.2-22.9)
Male	411	9.2 (8.5-10.1)	7.1 (6.4-7.8)	24.5 (22.0-28.7)
Female	400	10 (9.0-10.9)	7.1 (5.7-8.4)	27.2 (23.4-30.6)

3.3.1.3 Data on short-term consumption of **cow's milk**

The short-term consumption of cow's milk by children aged 0.5 to <6 years is shown in**Fehler! Verweisquelle konnte nicht gefunden werden.**. Across all age groups, the median was 12.8 g/(kg bw*d) and the 95th percentile was 41.5 g/(kg bw*d). Here, too, no significant differences between milk consumption in boys and girls could be demonstrated, while a reduction in consumption amounts with increasing age was observed when looking at the medians.

Table2: Short-term consumption of cow's milk by children aged 0.5 to 6 years according to the KiESEL study. The confidence intervals were determined using a non-parametric bootstrap method.

Age/gender group	Number of consumers	Mean (95 % CI) [g/(kg bw*d)]	Median (95 % CI) [g/(kg bw*d)]	95th percentile (95 % CI) [g/(kg bw*d)]
All	811	16.3 (15.5-17.1)	12.8 (12.0-13.6)	41.5 (35.1-45.2)
0.5 - <1 year	15	16.3 (12.7-19.8)	17.3 (8.2–23.2)	32.1 (27.1-33.0)
1 - <3 years	263	20.1 (18.3-22.0)	16.7 (14.4-17.9)	53.8 (46.9-59.2)
>=3 years	533	14.4 (13.6-15.3)	11.9 (11.4-12.7)	32.4 (29.6-33.8)
Male	411	15.9 (14.7-17.0)	12.9 (12.0-14.1)	40.2 (32.9-42.1)
Female	400	16.7 (15.5-18.1)	12.5 (11.6-14.3)	46.9 (33.9-48.7)

3.3.1.4 Comparison of data on cow's milk consumption with data on **plant-based drink** consumption

In order to be able to estimate the extent to which the use of data on cow's milk reflects the consumption of plant-based drinks, a comparison was made with children's consumption data available from the KiESEL study. The median long-term consumption of plant-based drinks across all age groups (n=38) was 5.5 g/(kg bw*d) (95 % CI 3.6–7.6 g/(kg bw*d)) and thus below the consumption of cow's milk of 7.1 g/(kg bw*d) (95 % CI 6.3–7.8 g/(kg bw*d)). However, since the confidence intervals for the consumption of cow's milk and of plant-based drinks overlap, this difference was not significant. The same applies when considering the 95th percentile of long-term consumption, which was 13.2 g/(kg bw*d) (95 % CI 11.7¬30.0 g/(kg bw*d)) for the consumption of plant-based drinks compared to 25.3 g/(kg bw*d) (95 % CI 23.2-29.9 g/(kg bw*d)) for the consumption of cow's milk.

The median short-term consumption of plant-based drinks was 11.9 g/(kg bw*d) (95 % CI 8.7–15.2 g/(kg bw*d)) and the 95th percentile was 20.6 g/(kg bw*d) (95 % CI 18.2¬44.8 g/(kg bw*d)). Comparison with the consumption of cow's milk, for which median consumption amounts to 12.8 g/(kg bw*d) (95 % CI 12.0-13.6 g/(kg bw*d)) and the 95th percentile to 41.5 g/(kg bw*d) (95 % CI 35.1-45.2 g/(kg bw*d)), reveals differences that are likewise not significant.

The comparison of consumption data indicates that using cow's milk consumption data as substitute for the consumption of plant-based drinks might be an overestimation. However, the differences between the consumption amounts are not significant. It should furthermore be taken into account that sales of plant-based drinks are rising and it can therefore be assumed that the consumption of plant-based drinks has also increased since the field phase of the KiESEL study (2014-2017). However, more recent consumption data to support this assumption are not available.

3.3.2 Data on the occurrence of mycotoxins in plant-based drinks

3.3.2.1 Sample planning

The aim of the sample planning was to obtain as representative a picture as possible of plant-based drinks on the German market. To this end, market data was purchased from the household panel of the company YouGov (formerly GfK). This panel represents a representative sample of consumers in Germany. The results contain the ten most important brands and products for different groups of plant-based drinks (e.g. oat drinks or almond drinks) together with their respective market share in litres.

The market data shows that the market for plant-based drinks is very heterogeneous. For oat drinks, the ten products with the highest market share cover only about 37 % of the total market. The products at the bottom of the ranking each have market shares of only 2 to 3 %, which suggests a very high number of different products. In the case of almond drinks, the 10 products with the highest market share cover around 70 % of the market, and in the case of soy drinks, the figure is 69 %. The products at the bottom of the rankings have market shares of approximately 3 % (almond drinks) and 4 % (soy drinks).

The high heterogeneity of the market was also confirmed by parallel research conducted in Mintel's Global New Products Database (GNPD) (MINTEL 2025). This database continuously incorporates new products entering the market. For the years 2020 to 2025 alone, 229 new products were listed here in the categories of oat drinks, soy drinks and almond drinks.

Based on the results, it was decided to aim for the highest possible market coverage, taking into account the available laboratory capacity. To this end, the ten products with the highest market share were selected for drinks made of oat, almond and soy. Furthermore, additional oat drinks from the three manufacturers with the largest market share were selected, as these combined have a market share of around 65 % according to market data, in order to increase market coverage as much as possible. Overall, however, it is unclear how large the total market coverage is.

In order to obtain an overview of the variability in concentrations, at least three batches from 2024 should be purchased from each selected product and, in a second phase at the beginning of 2025, two further batches from each. Furthermore, a list of plant-based drinks already tested at the MRI in 2022 was consulted for sampling (MRI 2023). Additional batches of each of the products listed there were purchased, provided the products were still available.

3.3.2.2 Sample purchase

Commercially available plant-based drinks based on oats, soy and almonds were purchased on the market and examined. The plant-based drinks were purchased in two periods: from October to November 2024 and from March to April 2025. The plant-based drinks were purchased at various retail outlets in Berlin, with the brand and variety of the product being taken into account in a manner representative of market data.

The purchasing team received lists containing information such as product name, brand, minimum purchase quantity and transport temperature. For each product, three packages from the same batch and a total minimum quantity of 1,000 ml were purchased and assigned an internal code for tracking purposes. After receipt and registration at the BfR, the samples were stored unrefrigerated until they were handed over to the testing laboratory.

For quality assurance and documentation of all information on the packaging, each product was photographed upon receipt and the product names, corresponding batch numbers and "best before" dates were checked. A total of 162 plant-based drinks were purchased, of which 92 in 2024 and 70 in 2025 were obtained.**Fehler! Verweisquelle konnte nicht gefunden werden.** shows the number of samples per year and type.

Table3: Number of samples taken, itemised by product category and year of sampling

	Number of samples per year		
Product category	**2024**	**2025**	**Total**
Almond drink	29	10	39
Oat drink	37	49	86
Soy drink	21	8	29
Chocolate soy drink	3	2	5
Oat and almond drink	2	-	2
Chocolate oat drink	-	1	1
Total	92	70	162

3.3.2.3 Further data sources

The BfR does not have any occurrence data on mycotoxin levels in plant-based drinks from the monitoring programmes of the German federal states ("Laender"). Plant-based drinks were examined in 2021 as part of a monitoring project, but only for the occurrence of elements.

3.3.2.4 Analysis of samples by the Federal Institute for Risk Assessment

A multi-analyte method for testing plant-based drinks was developed and fully validated at the National Reference Laboratory for Mycotoxins and Plant Toxins. Compared to previous methods, sensitivity has been significantly improved to achieve LOQs of well below 1 µg/kg in most cases.

In addition to the mycotoxins already investigated in the MRI study, the substances analysed (analytes) include numerous other substances from the area of mycotoxins and plant toxins. Validation was carried out in accordance with the requirements of Regulation (EU) 2023/2782 on sampling and analysis methods for the control of mycotoxin levels in food.

Overall, the method was validated for 92 mycotoxins and plant toxins. For two analytes (phomopsin A and nivalenol), validation for soy drinks was not possible, thus 90 analytes were validated in this matrix. A detailed overview of the substances examined with the validated detection and limits of quantification (LOQ) can be found inTable19 in the appendix.

After analysis of all 162 samples, a data set with 14,836 individual results was compiled. The assessment of health risks will be limited to those substance-matrix combinations that were detected most frequently and for which a toxicological assessment basis is available. In

addition to the substance-matrix combinations subject to health risk assessment shown below, numerous other mycotoxins were detected in the plant-based drinks examined, for example enniatins in oat drinks or sterigmatocystin in all three types of plant-based drinks examined. A statistical evaluation of the entire data set can be found in the tables in Appendix 6.4 .

3.3.2.5 Comparison with the occurrence data from the Max Rubner Institute

Fehler! Verweisquelle konnte nicht gefunden werden. shows a comparison of the occurrence data collected by the BfR with the corresponding occurrence data from the MRI study (MRI 2023). Only those substance-matrix combinations that were used for the following exposure assessments are listed. Since the 95th percentile of the MRI data was not reported, it cannot be used for comparison. Furthermore, the MRI did not analyse aflatoxins B2, G1 and G2 or the modified forms of DON (3-acetyl-DON, 15-acetyl-DON, DON-3-glucoside), meaning that no comparative values from the MRI study are available for these total levels either.

Also, the MRI was evaluated using the modified lower bound approach, while the BfR applied both the modified lower bound approach and the upper bound approach. The difference between the two approaches lies in how values below the limit of detection and the limit of quantification (LOQ) are handled. In the modified lower bound approach, values below the LOD are replaced with zero and values between the LOD and the limit of quantification (LOQ) are replaced with the value for the LOD. In terms of statistical evaluation, the modified lower bound approach represents the best case, i.e. the reported statistical parameters represent the lower limit of the concentrations that are at least present in the collected data set. In contrast, in the upper bound approach, values below the limit of detection (LOD) are replaced with the LOD value and values between the limit of detection and the limit of quantification (LOQ) are replaced with the LOQ value. In terms of statistical evaluation, the upper bound approach thus represents the worst case, i.e. the reported statistical parameters represent the upper limit of the maximum concentrations present in the collected data set.

The data from the modified lower bound approach is used to compare the occurrence data collected by the BfR with that of the MRI. The MRI has stated its values in ng/l, the BfR in ng/kg. Since the density of commercially available plant-based drinks is very close to that of water, the units are equated for the purposes of this opinion. As can be seen from **Fehler! Verweisquelle konnte nicht gefunden werden.** , the concentrations determined by the BfR for AFB1 in almond drinks, at 8 ng/kg (MW) and 55 ng/kg (maximum concentration) respectively, are slightly lower than those determined by the MRI (MW = 18.1 ng/l and maximum value = 130.0 ng/l). In contrast, the data collected by the BfR for DON in oat drinks, with a mean value of 2,900 ng/kg and a maximum value of 35,000 ng/kg, show significantly higher concentrations than those determined by the MRI (MW = 691.8 ng/l and maximum value = 5,457.5 ng/l). For T2/HT2 in oat drinks, the data collected by the BfR and the MRI are at a comparable level, showing mean values of 470 ng/kg (BfR) and 397.2 ng/l (MRI) and maximum values of 2,300 ng/kg (BfR) and 2,146.5 ng/l (MRI).

Furthermore, with respect to oat drinks, it was investigated whether the concentrations in the samples taken in 2024 differed from those in the samples taken in 2025 against the background of the newly introduced maximum levels for the sum of T-2 and HT-2 toxins. The mean value for 2024 was 600 ng/kg in the modified lower bound and 740 in the upper

bound. For the samples from 2025, the values are 360 ng/kg (modified lower bound) and 570 ng/kg (upper bound). To decide whether these lower values for 2025 are significant, the Peto-Peto test (Peto&Peto, 1927) was used on the basis of the censored values. This revealed a significant difference between the two years. However, the values for both years are below the values collected by the MRI for samples from 2023 (see **Fehler! Verweisquelle konnte nicht gefunden werden.**), which suggests that the introduction of maximum levels is not the cause of this difference. Regular testing of oats has shown that mycotoxin concentrations are subject to annual fluctuations, mostly due to weather conditions. For this reason, the values from both years have been summarised below.

Table4: Comparison of mycotoxin concentrations from the MRI and the BfR studies; only the concentrations for those substance-matrix combinations used for the following exposure assessment are shown. The 95th percentile was not reported in the MRI study, so it could not be used for comparison. Modified lower bound: concentrations < LOD = 0, concentrations between LOD and LOQ = LOD; upper bound: concentrations < LOD = LOD, concentrations between LOD and LOQ = LOQ.

Mycotoxin	Product category	MRI				BfR							
		Number of samples	Number of samples with detectable concentrations	Concentration [ng/l] (modified lower bound)		Number of samples	Number of samples with detectable concentrations	Concentration [ng/kg] (modified lower bound)			Concentration [ng/kg] (upper bound)		
				Mean value	Maximum value			Mean value	95th percentile	Maximum value	Mean value	95th percentile	Maximum value
AFB1	Almond drinks	24	23	18.1	130.3	39	31	8	35	55	13	36	55
Total aflatoxins B1, B2, G1, G2	Almond drinks	-*	-	-	-	39	31	8.5	37	58	21	55	77
OTA	Almond drinks	24	0	0	0	39	33	11	43	110	31	43	110
OTA	Soy drinks	12	0	0	0	29	23	19	180	290	55	180	290
DON	Oat drinks	37	33	691.8	5,457.5	86	56	2,900	9,100	35,000	3,000	9,100	35,000
Total DON and modified forms	Oat drinks	-*	-	-	-	86	67	4,600	13,000	64,000	5,900	13,000	64,000
T2/HT2	Oat drinks	37	29	397.2	2,146.5	86	86	470	1,500	2,300	650	1,500	2,300

For the exposure assessments, the BfR equated the concentrations in ng/l with ng/kg. No conversion factor was applied.

*The MRI did not analyse aflatoxins B2, G1 and G2 or the modified forms of DON (3-acetyl-DON, 15-acetyl-DON, DON-3-glucoside), thus no comparative values from the MRI study are available for these total levels.

** The apparent discrepancy between the results of the MRI and the BfR can be explained by the different sensitivity of the two methods used. While the MRI used a method with a limit of detection (LOD) of 288 ng/l and a limit of quantification (LOQ) of 950 ng/l, the detection and quantification limits for soy drinks using the method applied by the BfR were 4 ng/kg (LOD) and 11 ng/kg (LOQ) respectively.

3.3.3 Exposure assessment

3.3.3.1 Methodological approach

Long-term exposure was determined by multiplying the data for long-term consumption (median/50th percentile and 95th percentile) by the mean and 95th percentile of the concentrations, respectively. The use of the mean of the concentrations represents the exposure of children who are exposed to random concentrations over a longer period of time. In addition, the use of the 95th percentile of the concentrations represents a worst-case calculation for long-term intake. In this scenario, it is assumed that only plant-based drinks with mycotoxin concentrations in the range of the 95th percentile are consumed over a long period of time. In the previous opinion, the maximum concentration was used, deviating from the usual procedure of the BfR, as the 95th percentile of the concentrations was not reported in the MRI report. Accordingly, only the 95th percentile of the concentrations is listed for the BfR data in**Fehler! Verweisquelle konnte nicht gefunden werden.**.

To determine short-term exposure, the data for short-term consumption (median/50th percentile and 95th percentile) were multiplied exclusively by the 95th percentile of the concentrations, as in this case the assumption of short-term consumption of a plant-based drink with a high mycotoxin concentration represents a realistic scenario.

As can be seen from**Fehler! Verweisquelle konnte nicht gefunden werden.** , the statistical evaluation shows only minor differences between the upper bound approach and the modified lower bound approach. This is due to the low proportion of left-censored data (concentrations below the detection and LOQ limits) in the substance-matrix combinations considered. Due to these minor differences between the upper bound approach and the modified lower bound approach, only the occurrence data from the upper bound approach was used for the exposure assessments and the subsequent risk characterisations in accordance with the precautionary principle. For comparison, the exposure assessments using the occurrence data from the modified lower bound approach can be found in the tables in the appendix.

As already stated at the beginning of this opinion, the exposure assessment below will be limited to the substance-matrix combinations AFB1 and OTA in almond drinks, OTA in soy drinks, and DON and T2/HT2 in oat drinks.

3.3.3.2 Estimation of exposure to **AFB1** and the sum of **aflatoxins B1, B2, G1 and G2** from the consumption of **almond drinks**

Fehler! Verweisquelle konnte nicht gefunden werden. shows long-term exposure to AFB1 and the sum of aflatoxins B1, B2, G1 and G2 from the consumption of almond drinks. At average consumption and mean AFB1 concentrations, the exposure of children aged 0.5 to <6 years is 0.09 ng/(kg bw[1] *d). If, on the other hand, high consumption is assumed, the intake increases to 0.33 ng/(kg bw*d). Assuming the 95th percentile of AFB1 concentrations, the intake is 0.25 ng/(kg bw*d) for average consumption and 0.90 ng/(kg BW*d) for high consumption. If aflatoxins B2, G1 and G2 are also taken into account in the exposure assessment, the long-term exposure to the sum of aflatoxins increases to 0.15 ng/(kg bw*d) (average consumption) or 0.52 ng/(kg bw*d) (high consumption) and, when using the 95th

[1] body weight

percentile of the concentrations, to 0.39 ng/(kg bw*d) (average consumption) or 1.40 ng/(kg bw*d) (high consumption).

Table5: Long-term exposure to aflatoxin B1 (AFB1) and the sum of aflatoxins B1, B2, G1 and G2 from the consumption of almond drinks by children aged 0.5 to <6 years according to the KiESEL study. Concentrations used: AFB1: mean = 13 ng/kg, 95th percentile = 36 ng/kg; sum of aflatoxins B1, B2, G1, G2: mean = 21 ng/kg, 95th percentile = 55 ng/kg.

		Long-term exposure [ng/(kg BW*d)]			
	Concentration	**Mean concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	AFB1	0.09	0.33	0.25	0.90
	Total aflatoxins B1, B2, G1, G2	0.15	0.52	0.39	1.40

3.3.3.3 Estimated exposure to **OTA** from the consumption of **almond and soy drinks**

Fehler! Verweisquelle konnte nicht gefunden werden. shows the long-term exposure to OTA from the consumption of almond drinks and soy drinks. For almond drinks, the exposure of children aged 0.5 to <6 years at average consumption and mean levels is 0.22 ng/(kg bw*d). If, on the other hand, high consumption is assumed, the intake increases to 0.77 ng/(kg bw*d). Assuming the 95th percentile of concentrations, the intake is 0.31 ng/(kg bw*d) for average consumption and 1.10 ng/(kg bw*d) for high consumption.

In comparison, the exposure of children aged 0.5 to <6 years with average consumption of soy drinks with mean concentrations is 0.40 ng/(kg bw*d). If, on the other hand, high consumption is assumed, the intake increases to 1.40 ng/(kg bw*d). If the 95th percentile of concentrations is assumed, the intake is 1.30 ng/(kg bw*d) for average consumption and 4.60 ng/(kg bw*d) for high consumption.

Table6: Long-term exposure to ochratoxin A (OTA) from the consumption of almond and soy drinks by children aged 0.5 to <6 years according to the KiESEL study. Concentrations used: Almond drinks: mean = 31 ng/kg, 95th percentile = 43 ng/kg; soy drinks: mean = 55 ng/kg, 95th percentile = 180 ng/kg.

		Long-term exposure [ng/(kg bw*d)]			
	Concentration	**Mean concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	OTA	0.22	0.77	0.31	1.10
Soy drinks	OTA	0.40	1.40	1.30	4.60

3.3.3.4 Estimated exposure to **DON** and the sum of **DON and its modified forms** from the consumption of **oat drinks**

The results for short- and long-term exposure to DON and the sum of DON and its modified forms (3-Ac-DON, 15-Ac-DON, DON-3-Glu) from the consumption of oat drinks are presented in**Fehler! Verweisquelle konnte nicht gefunden werden.**. The long-term exposure of children aged 0.5 to <6 years is 21 ng/(kg bw*d) (average consumption) or 76 ng/(kg bw*d) (high concentration) at mean DON concentrations. In the case of the 95th percentile of DON concentrations, long-term exposure is 65 ng/(kg bw*d) (average consumption) or 231 ng/(kg bw*d) (high consumption). If the modified forms 3-Ac-DON, 15-Ac-DON, DON-3-Glu are also taken into account in the exposure assessment, the long-term exposure to the sum of DON and its modified forms increases to 42 ng/(kg bw*d) (average consumption) or 150 ng/(kg bw*d) (high consumption) when using the mean concentrations, and to 95 ng/(kg bw*d) (average consumption) or 340 ng/(kg bw*d) (high consumption) when using the 95th percentile of the concentrations.

When considering short-term consumption, the exposure of children aged 0.5 to <6 years to DON is 120 ng/(kg bw*d) (average consumption) or 380 ng/(kg bw*d) (high consumption). When modified forms of DON are also taken into account, short-term exposure increases to 170 ng/(kg bw*d) (average consumption) and 550 ng/(kg bw*d) (high consumption).

Table7: Long-term and short-term exposure to deoxynivalenol (DON) and the sum of DON and its modified forms (3-Ac-DON, 15-Ac-DON, DON-3-Glu) from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study.
Concentrations used: DON: mean = 3,000 ng/kg, 95th percentile = 9,100 ng/kg;
Total DON and its modified forms: mean = 5,900 ng/kg, 95th percentile = 13,000 ng/kg.

		Long-term exposure [ng/(kg bw*d)]				**Short-term exposure [ng/(kg bw*d)]**	
	Concentration	**Mean concentration**		**95th percentile concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Oat drinks	DON	21	76	65	231	120	380
	Total DON and modified forms	42	150	95	340	170	550

3.3.3.5 Estimated exposure to **T2/HT2** from the consumption of **oat drinks**

Fehler! Verweisquelle konnte nicht gefunden werden. shows the results of long-term and short-term exposure assessments for the intake of T2/HT2 from the consumption of oat drinks. The long-term exposure of children aged 0.5 to <6 years is 4.6 ng/(kg bw*d) (average consumption) or 16 ng/(kg bw*d) (high consumption), with an assumption of mean concentrations. Using the 95th percentile of concentrations, the intake levels for long-term exposure are 11 ng/(kg bw*d) (average consumption) and 37 ng/(kg bw*d) (high consumption).

When considering short-term consumption, the exposure of children aged 0.5 to <6 years is 19 ng/(kg bw*d) (average consumption) or 61 ng/(kg bw*d) (high consumption).

Table8: Long-term and short-term exposure to the sum of the toxins T-2 and HT-2 (T2/HT2) from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study. Concentrations used: mean = 650 ng/kg, 95th percentile = 1,500 ng/kg.

		Long-term exposure [ng/(kg bw*d)]				**Short-term exposure [ng/(kg bw*d)]**	
	Concentration	**Mean concentrations**		**95th percentile concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Oat drinks	T2/HT2	4.6	16	11	37	19	61

3.4 Risk characterisation

The percentages of health-based guidance values and the calculation of the margin of exposure (MOE) refer to the exposure assessments in Chapter 3.3 and are summarised inFehler! Verweisquelle konnte nicht gefunden werden. to**Fehler! Verweisquelle konnte nicht gefunden werden.** .

3.4.1 Risk characterisation for AFB1 and for the sum of aflatoxins B1, B2, G1 and G2 in almond drinks

As already explained in Chapter 3.2.1 , the margin of exposure (MOE) concept must be applied to assess the health risks posed by the intake of AFB1 and the sum of aflatoxins B1, B2, G1 and G2, as aflatoxins are genotoxic carcinogens for which no safe intake level can be established. For this purpose, a benchmark dose lower confidence limit (BMDL) of 400 ng/(kg bw*d) is used as the toxicological reference value, which was established from a two-year carcinogenicity study in rats.

The BfR emphasises that this toxicological reference value does not represent a health-based guidance value (HBGV), but merely serves to prioritise risk management measures. From a public health perspective, a margin of exposure (MOE) of 10,000 and above is generally considered to be of low concern – but not harmless – for genotoxic carcinogens and is therefore given low priority for risk management measures.

Using the data on long-term exposure to AFB1 according to**Fehler! Verweisquelle konnte nicht gefunden werden.** in Chapter 3.3.3.2 , MOE values of between 450 and 4,400 are obtained, depending on the scenario under consideration, which are thus well below an MOE value of 10,000 for all the scenarios under consideration (**Fehler! Verweisquelle konnte nicht gefunden werden.**). If aflatoxins B2, G1 and G2 are also taken into account in the exposure assessment, the MOE values are even lower, ranging between 290 and 2,800 (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Table9: Margin of exposure for long-term intake of AFB1 and the sum of aflatoxins B1, B2, G1 and G2 from the consumption of almond drinks by children aged 0.5 to <6 years according to the KiESEL study and using a $BMDL_{10}$ of 400 ng/(kg bw*d) as the toxicological reference value.
Concentrations used: AFB1: mean = 13 ng/kg, 95th percentile = 36 ng/kg;
Total aflatoxins B1, B2, G1, G2: mean = 21 ng/kg, 95th percentile = 55 ng/kg.

		Long-term exposure – margin of exposure			
	Concentration	**Mean concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	AFB1	4400	1200	1600	450
	Total aflatoxins B1, B2, G1, G2	2800	780	100	290

In its assessment of the health risks associated with the intake of AFB1 from the consumption of almond drinks based on realistic scenarios, the BfR concludes that long-term consumption of almond drinks containing AFB1 at concentrations determined by the BfR may result in a medium likelihood of health impairments in children aged 0.5 to <6 years. When aflatoxins B2, G1 and G2 are also taken into account in the assessment of health risks, the BfR reaches the same conclusion.

When conducting an assessment of the health risks posed by chronic intake of AFB1 and the sum of aflatoxins B1, B2, G1 and G2, it must also be taken into account that almond drinks are not the only source of aflatoxins, but that aflatoxins are also ingested when consuming other foods. In this assessment, it is assumed that almond drinks are consumed as an alternative to cow's milk. When aflatoxins are transferred from feed to milk, they are metabolised, which results in cow's milk mainly containing the metabolite aflatoxin M1 (AFM1), which has about ten times less toxic potential than AFB1. In contrast, aflatoxins that may be present in almonds used for the production of almond drinks are not metabolised to AFM1 during the manufacturing process. The BfR was able to detect AFB1 in the vast majority of the almond drinks examined (31 out of 39 samples). The average concentrations detected were 13 ng/kg, with a maximum concentration of 55 ng/kg. For AFM1 in raw milk, heat-treated milk and milk for the manufacture of milk-based products, a maximum concentration of 50 ng/kg is set according to Regulation (EU) 2023/915. With the assumption that the concentrations of AFB1 in plant-based drinks and AFM1 in cow's milk are comparable, consuming plant-based drinks as an alternative to cow's milk would increase the proportion of AFB1 in the overall exposure and at the same time reduce the proportion of AFM1. As AFB1 has a higher toxic potential than AFM1, this would increase the likelihood of health impairments.

The present risk characterisations based on representative data thus support the conclusions of the previous opinion that the intake of AFB1 and the sum of aflatoxins B1, B2, G1 and G2 from the consumption of almond drinks may pose a health risk to vulnerable consumer groups.

3.4.2 Risk characterisation for OTA in almond drinks and soy drinks

As already described in Section 3.2.2, EFSA recommends applying the margin of exposure (MOE) concept as a precautionary measure for the assessment of health risks from OTA intake, as it could not be conclusively clarified whether OTA induces direct or indirect genotoxic effects. A $BMDL_{10}$ of 14.5 µg/(kg bw*d) is used as the toxicological reference value for the neoplastic effects of OTA, which was established from a two-year carcinogenicity study of rats (EFSA 2020b).

The BfR once again emphasises that this toxicological reference value does not represent a health-based guidance value (HBGV), but merely serves to prioritise risk management measures. From a public health perspective, a margin of exposure (MOE) of 10,000 and above is generally considered to be of low concern – but not harmless – for genotoxic carcinogens and is therefore given low priority for risk management measures.

Using the data on long-term exposure to OTA according to**Fehler! Verweisquelle konnte nicht gefunden werden.** in Chapter 3.3.3.3 results for the consumption of almond drinks in margin of exposure (MOE) values in the range of 13,000 to 67,000 – depending on the scenario considered –and, for intake from the consumption of soy drinks, MOE values in the range of 3,100 to 37,000 (**Fehler! Verweisquelle konnte nicht gefunden werden.**). This means that, with one exception (worst-case scenario for long-term high intake of soy drinks with exclusively high OTA concentrations), the MOE values for all scenarios considered are above an MOE value of 10,000 and thus within a range that EFSA considers to be of low concern with regard to the neoplastic effects of OTA.

Table10*:* Margin of exposure for the long-term intake of OTA from the consumption of almond drinks and soy drinks by children aged 0.5 to <6 years according to the KiESEL study and using a $BMDL_{10}$ of 14.5 µg/(kg bw*d) as the toxicological reference value for the neoplastic effects of OTA.
Concentrations used: Almond drinks: mean = 31 ng/kg, 95th percentile = 43 ng/kg;
Soy drinks: mean = 55 ng/kg, 95th percentile = 180 ng/kg.

		Long-term exposure – margin of exposure – neoplastic effects			
	Concentration	**Mean concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	OTA	67,000	19,000	48,000	13,000
Soy drinks	OTA	37,000	10,000	11,000	3,100

However, as the mechanism of the genotoxic effect of OTA could not be conclusively clarified, EFSA recommends additionally conducting a health risk assessment of the non-neoplastic effects of OTA and also applying the margin of exposure (MOE) concept for this purpose. A $BMDL_{10}$ of 4.73 µg/(kg bw*d) was established from a 90-day study in sows as a toxicological reference value for this purpose. For the risk characterisation of the non-neoplastic effects of long-term exposure to OTA, EFSA considers MOE values of 200 and above to be of low concern for public health (EFSA 2020b).

Using the data on long-term exposure to OTA according to**Fehler! Verweisquelle konnte nicht gefunden werden.** Table 6 in Chapter 3.3.3.3, MoE values in the range of 4,400 to 22,000 are obtained for the non-neoplastic effects of OTA from the consumption of almond drinks, depending on the scenario considered, and MOE values in the range of 1,000 to 12,000 for intake from the consumption of soy drinks (**Fehler! Verweisquelle konnte nicht gefunden werden.**). Thus the MOE values for all scenarios considered are well above an MOE value of 200 and thus within a range that EFSA considers to be of low concern with regard to the non-neoplastic effects of OTA.

Table11: Margin of exposure for long-term intake of OTA from the consumption of almond drinks and soy drinks by children aged 0.5 to <6 years according to the KiESEL study and using a $BMDL_{10}$ of 4.73 µg/(kg bw*d) as the toxicological reference value for the non-neoplastic effects of OTA.
Concentrations used: Almond drinks: mean = 31 ng/kg, 95th percentile = 43 ng/kg;
Soy drinks: mean = 55 ng/kg, 95th percentile = 180 ng/kg.

		Long-term exposure – margin of exposure – non-neoplastic effects			
	Concentration	Mean concentrations		95th percentile concentrations	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	OTA	22,000	6,200	16,000	4,400
Soy drinks	OTA	12,000	3,400	3,700	1,000

The BfR detected OTA in the majority of almond drinks (33 out of 39 samples) and soy drinks (23 out of 29 samples). These high detection rates (especially when compared to the MRI studies) are mainly due to the high sensitivity of the method used by the BfR. The mean concentrations for almond drinks were 31 ng/kg with a maximum concentration of 110 ng/kg, and for soy drinks they were 55 ng/kg with a maximum concentration of 290 ng/kg. Given the very low OTA concentrations determined by the BfR, realistic scenarios for the intake of OTA from the consumption of almond drinks or soy drinks by children aged 0.5 to <6 years result in margins of exposure that are considered to be of low concern for public health in terms of both the neoplastic and non-neoplastic effects of OTA.

When assessing the health risks posed by chronic OTA intake, it should also be taken into account that OTA is one of the mycotoxins that can enter the food chain via a variety of sources. Plant-based drinks thus represent an additional source of OTA intake from food consumption that has not been taken into account in exposure assessment to date and may contribute to overall exposure to OTA.

3.4.3 Risk characterisation for DON and for the sum of DON and its modified forms in oat drinks

For the assessment of the health risks from the intake of DON and for the sum of DON and its modified forms from the consumption of oat drinks, the TDI of 1,000 ng/(kg bw*d) was used as the health-based guideline value for long-term exposure and the ARfD of 8,000 ng/(kg bw*d) was used for short-term exposure.

Using the data on long-term exposure to DON according to**Fehler! Verweisquelle konnte nicht gefunden werden.** in Chapter 3.3.3.4 results in percentages in the range of 2.1 % to 23.1 % of the TDI depending on the scenario considered (**Fehler! Verweisquelle konnte nicht gefunden werden.**). If the modified forms 3-Ac-DON, 15-Ac-DON and DON-3-Glu are also taken into account in the exposure assessment, the percentages of the TDI increase to between 4.2 % and 34 % (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Using a similar approach results in percentages for short-term DON intake of 1.5 % (average consumption) and 4.7 % (high consumption) of the ARfD (**Fehler! Verweisquelle konnte nicht gefunden werden.**). When the modified forms 3-Ac-DON, 15-Ac-DON and DON-3-Glu are also taken into account in the exposure assessment, the percentages increase to 2.1 % (average consumption) and 6.9 % (high consumption) (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Table12: Percentage of health-based guidance values for long-term intake (TDI = 1,000 ng/(kg bw*d)) and short-term intake (ARfD = 8,000 ng/(kg bw*d)) of DON and the sum of DON and its modified forms (3-Ac-DON, 15-Ac-DON, DON-3-Glu) from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study.
Concentrations used: DON: mean = 3,000 ng/kg, 95th percentile = 9,100 ng/kg;
Total DON and its modified forms: mean = 5,900 ng/kg, 95th percentile = 13,000 ng/kg.

		Long-term exposure – percentage of TDI				**Short-term exposure – percentage of ARfD**	
	Concentration	**Mean concentration**		**95th percentile concentration**		**95th percentile concentration**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Oat drinks	DON	2.1 %	7.6 %	6.5 %	23.1 %	1.5 %	4.7 %
	Total DON and modified forms	4.2 %	15.0 %	9.5 %	34.0 %	2.1 %	6.9 %

In its assessment of the health risks associated with the intake of DON from the consumption of oat drinks based on realistic scenarios, the BfR concludes that both long-term and short-term consumption of oat drinks containing DON at the concentrations determined by the BfR are unlikely to cause health impairments in children aged 0.5 to <6 years. The BfR reaches the same conclusion when the modified forms 3-Ac-DON, 15-Ac-DON and DON-3-Glu are also taken into account in the assessment of health risks.

The present risk characterisations based on representative data thus support the conclusions of the previous opinion.

3.4.4 Risk characterisation for T2/HT2 in oat drinks

For the assessment of health risks from the intake of T2/HT2 from the consumption of oat drinks, the TDI of 20 ng/(kg bw*d) was used as the health-based guidance value for long-term exposure and the ARfD of 300 ng/(kg bw*d) for short-term exposure.

Using the data on long-term exposure to T2/HT2 according to**Fehler! Verweisquelle konnte nicht gefunden werden.** in Chapter 3.3.3.5 results in percentages in the range of 23 % to 190 % of the TDI depending on the scenario considered (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Using a similar approach for short-term intake results in percentages of 6 % (average consumption) and 20 % (high consumption) of the ARfD (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Table13: Percentage of health-based guidance values for long-term intake (TDI = 20 ng/(kg bw*d)) and short-term intake (ARfD = 300 ng/(kg bw*d)) of T2/HT2 from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study.
Concentrations used: Mean = 650 ng/kg, 95th percentile = 1,500 ng/kg.

		Long-term exposure – percentage of TDI				**Short-term exposure – percentage of ARfD**	
	Concentration	**Mean concentrations**		**95th percentile concentrations**		**95th percentile concentrations**	
Product category	mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Oat drinks	T2/HT2	23 %	82 %	53 %	190 %	6 %	20 %

In its assessment of the health risks associated with the **short-term intake** of T2/HT2 from the consumption of oat drinks based on realistic scenarios, the BfR concludes that short-term consumption of oat drinks containing T2/HT2 concentrations determined by the BfR results in a low likelihood of health impairments in children aged 0.5 to <6 years.

However, when conducting an assessment of the health risks associated with the intake of T2/HT2, it must also be taken into account that oat drinks are not the only source of T2/HT2, but that T2/HT2 can also be ingested from the consumption of other oat products, such as oat flakes. In a scenario where all oat products consumed have T2/HT2 concentrations equal to the maximum level of 100 µg/kg applicable since 1 July 2024, the ARfD for children aged 1 to <6 years could be exceeded in the case of short-term consumption (154–371 % of the ARfD). A possible additional intake of T2/HT2 from the consumption of oat drinks was not taken into account in this scenario.

In its assessment of the health risks associated with **long-term intake** of T2/HT2 from the consumption of oat drinks based on realistic scenarios, the BfR concludes that in the case of long-term **average consumption** of oat drinks with T2/HT2 concentrations equal to the **mean concentrations** determined by the BfR, the likelihood of health impairments in children aged 0.5 to <6 years is low.

In contrast, **long-term high consumption** solely of oat drinks with T2/HT2 concentrations equal to the **mean concentrations** determined by the BfR by children aged 0.5 to <6 years already results in 82 % of the TDI. It should also be noted that oat drinks are not the only source of T2/HT2 intake, but that T2/HT2 is also ingested from the consumption of other foods, in particular other oat products. In this opinion, the BfR assumes that plant-based drinks are used as an alternative to cow's milk. Accordingly, a scenario in which children aged 0.5 to < 6 years consume oat flakes together with oat drinks can be considered

realistic. The consumption of oat drinks as an alternative to cow's milk would therefore represent an additional source of T2/HT2 intake, thereby increasing both the overall exposure to T2/HT2 and the likelihood of health impairments.

The BfR was able to detect T2/HT2 in all oat drinks tested (86 out of 86 samples). The average concentration was 650 ng/kg, with a maximum concentration of 2,300 ng/kg. The present risk characterisations based on representative data thus support the conclusions of the previous opinion that, for children aged 0.5 to <6 years as a vulnerable consumer group, the consumption of oat drinks as an alternative to cow's milk may represent an additional source of intake of T2/HT2.

3.5 Uncertainties

With a survey period from 2014 to 2017, the KiESEL study is the most up-to-date representative consumption study for children in this age group in Germany. However, changes in consumption behaviour since the survey period cannot be ruled out. This applies in particular to the consumption quantities for plant-based drinks (not used for the exposure assessment), as the market has changed significantly since the survey period. However, it is not possible on the basis of this data to conclusively assess the assumption that the consumption of plant-based drinks can be adequately described by cow's milk consumption data. The BfR assumes that the uncertainties regarding the consumption of plant-based drinks have only a minor impact on the result of the exposure assessment, as it is plausible to assume that the consumption behaviour for cow's milk and plant-based drinks is similar. However, the calculations performed here are based on the indirect assumption that the entire consumption of cow's milk is replaced by only one type of plant-based drink. For consumers who divide their consumption between different plant-based drinks, the scenarios presented here overestimate the intake from individual plant-based drinks.

Compared to adults, children, due to their lower body weight, have a higher consumption and thus a higher exposure in relation to their body weight. A self-determined vegetarian/vegan diet typically only develops in adolescence and puberty, so the proportion of consumers and perhaps also the quantity of plant-based drinks consumed could be higher in this age group than in younger children. However, since the calculations were based on cow's milk as a substitute rather than the actual consumption of plant-based drinks, the intake calculations can be considered sufficiently conservative for all age groups.

It should also be noted that the exposure assessments and the associated risk characterisations are limited to mycotoxin intake from the consumption of the respective plant-based drinks, meaning that the total exposure through food consumption (as already explained in Chapters 3.4.1 and 3.4.4) may be significantly higher.

The occurrence data used for the risk assessment are subject to measurement uncertainty. A relative expanded measurement uncertainty of 50 % was estimated for the results collected by the BfR (expansion factor k=2).

3.6 Classification of the concentrations of selected plant toxins in plant-based drinks

As described under 3.3.2.4 , the plant-based drinks were analysed using an LC-MS/MS-based multi-method that covered selected plant toxins in addition to mycotoxins. The results on the occurrence of these plant toxins are classified below.

3.6.1 Tropane alkaloids

Tropane alkaloids (TA) are secondary plant compounds with a high occurrence in certain plants such as henbane, thorn apple and belladonna. More than 200 different TA have been identified to date (BfR 2013). Data on the occurrence of TA in food and feed and on the toxicity of TA are only available to a limited extent and primarily for atropine and scopolamine, which are also used medicinally. These compounds are known to affect the heart rate and central nervous system even at low doses (BfR 2013). Atropine is a racemate consisting of equal parts of the two enantiomers (-)-hyoscyamine and (+)-hyoscyamine, whereby only (-)-hyoscyamine is toxicologically relevant. The same ultimately applies to the (-)-enantiomer of scopolamine. However, since only the (-)-enantiomers are selectively formed in the plant anyway (EFSA 2013), differentiation is not necessary when testing plant-based foods, as it can be assumed that "atropine" and "scopolamine" are exclusively the toxicologically relevant (-)-enantiomers.

When conducting an assessment of the health risks of TAs, the focus is on acute toxic effects. Based on a human study of healthy young adults, in whom higher doses resulted in the occurrence of a reduction in heart rate and effects on the central nervous system, such as dizziness, headaches and nausea, EFSA has derived a NOAEL of 0.16 µg/kg bw per day. Applying an additional safety factor of 10 for interindividual variability in the population, this results in an acute reference dose (ARfD) of 0.016 µg/kg bw per day. The ARfD applies to the sum of (-)-hyoscyamine and (-)-scopolamine (BfR 2013).

The BfR tested the plant-based drinks for TAs. One soy drink product stood out as having a higher TA concentration than the other products. This product was sampled a total of four times at different points during the investigation and, with TA concentrations of 271, 705, 856 and 1,274 ng/kg, had the four highest TA concentrations of all the plant-based drinks tested. In comparison, the TA concentrations in the other 25 soy drink samples examined ranged from below the limit of detection to a maximum of 57 ng/kg.

In order to classify these findings, the BfR conducted individual case studies on the short-term intake of TAs from the consumption of the soy drink product with the highest TAs contamination and the soy drink product with the second-highest TAs contamination. Using the data for short-term consumption according to**Fehler! Verweisquelle konnte nicht gefunden werden.** and the maximum TA content in soy drinks determined by the BfR of 1,274 ng/kg, this results in percentages of 100 % (average consumption) and 330 % (high consumption) of the ARfD. Exceeding the ARfD can, in principle, lead to the occurrence of health impairments. In contrast, an analogous calculation using a TA concentration of 57 ng/kg, which was the maximum determined by the BfR in the other soy drink samples, results in percentages of 4.5 % (average consumption) and 15 % (high consumption). Thus, the plant-based drinks examined (with the exception of the one reported soy drink product) do not indicate that the occurrence of TAs in plant-based drinks could pose a health risk to consumers.

3.6.2 Chinolizidine alkaloids

Chinolizidine alkaloids (QAs) are bitter-tasting secondary plant compounds that occur naturally in lupin seeds (Khan et al. 2015; Wink 2019). In total, more than 170 structurally different QAs are known, with lupanine, hydroxylupanine, albin, sparteine, lupinine and

angustifoline being the main representatives in food production, depending on the variety used (BfR 2025).

When conducting an assessment of the health risks associated with QAs, the focus is on acute toxic effects such as pupil dilation, dizziness, nausea, dry mouth, stomach pain, vomiting, diarrhoea or heart problems. Based on human data on sparteine, EFSA has derived a toxicological reference value of 0.16 mg/kg bw per day for considerations relating to the margin of exposure (MOE). This corresponds to the lowest effective dose of sparteine in pharmaceutical applications. For the other QAs, a comparable effect and potency to sparteine is assumed, so that a group assessment is carried out for QAs under the assumption of dose additivity. If a comparison with the estimated short-term intake of QAs results in MOE values of 1 and above, EFSA considers that there are no health concerns (EFSA 2019).

The BfR has tested plant-based drinks for lupanine (representative for contamination with QAs). Lupanine was only quantified in oat drinks, and in that case in 16 of 86 samples (19 %). For classification purposes, the BfR conducted an exemplary worst-case analysis for the short-term intake of lupanine from high consumption (P95) of oat drinks. This resulted in a MOE value of 16 when using the maximum lupanine concentration of 240 µg/kg determined by the BfR, and a correspondingly higher MOE value of 1,300 when using a lupanine concentration equal to the 95th percentile of the concentrations (3 µg/kg). This means that even for these exemplary "worst case" scenarios, the MOE values are well above 1 and thus within a range that, according to EFSA, does not pose any health concerns.

3.6.3 Pyrrolizidine alkaloids

Pyrrolizidine alkaloids (PAs) are a large group of compounds produced mainly by plants, but also by fungi and bacteria (Robertson & Stevens 2017). Several hundred PAs and their N-oxides are known to date (Wiedenfeld et al. 2008). The primary target organ for toxic effects in humans is the liver. The genotoxic-carcinogenic effects of 1,2-unsaturated PAs are considered the most sensitive endpoint (EFSA 2017d). Regulation (EU) 2023/915 sets maximum levels for the sum of 21 PAs and 14 other co-eluting PAs in various foods.

The BfR tested plant-based drinks for the legally regulated PAs, but was unable to quantify them in any sample (all samples <LOQ). Based on the concentrations determined by the BfR, the occurrence of PAs in plant-based drinks can therefore be considered of little concern to public health.

4 Other aspects

For some substance-matrix combinations that were also frequently detected but for which there is currently insufficient toxicological data, it was not possible to make a meaningful assessment of the health risks. This applies, for example, to enniatins in oat drinks and sterigmatocystin in all three types of plant-based drinks examined.

Toxicological studies specifically for enniatins are currently being conducted as part of the PARC project (European Partnership for the Assessment of Risks from Chemicals), which was explicitly designed to close data gaps in risk assessment. In parallel, EFSA has already been mandated to conduct an assessment of the risks to animal and human health from the

occurrence of enniatins in feed and food (M-2024-00047). The deadline for the EFSA opinion is 30 September 2026.

Further information on mycotoxins on the BfR website

Topic page on the health risk assessment of mycotoxins and plant toxins in food
https://www.bfr.bund.de/en/food-safety/assessment-of-substance-risks-in-foods/health-assessment-of-contaminants-in-food/health-risk-assessment-of-mycotoxins-and-plant-toxins-in-food/

BfR opinion: Mycotoxins in plant-based drinks: more data required
https://www.bfr.bund.de/cm/349/mycotoxins-in-plant-based-drinks-more-data-required.pdf

Questions and answers on aflatoxins in food and feed (in German)
https://www.bfr.bund.de/fragen-und-antworten/thema/fragen-und-antworten-zu-aflatoxinen-in-food-and feeds/

Questions and answers: Mould in food – health risks and how to avoid them
https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/mould-in-foods-health-risks-and-how-to-avoid-them/

Flyer: Mould toxins in food – How you can protect yourself
https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/mould-in-foods-health-risks-and-how-to-avoid-them/

5 References

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BfR (2024) opinion 029/2024 "Mycotoxins in plant-based drinks: more data required" dated 25 June 2024

BfR (2025) opinion 035/2025 "Alkaloids and allergies: Current data on health risks from lupin seeds in food" dated 17 September 2025

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6 Appendix

6.1 Exposure assessments using mycotoxin concentrations according to the BfR's modified lower bound approach

Table14: Long-term exposure to mycotoxins from the consumption of plant-based drinks by children aged 0.5 to <6 years according to the KiESEL study and using the mycotoxin concentrations according to the BfR's modified lower bound approach from Table 3.

		Long-term exposure [ng/(kg bw*d)]			
	Concentration	**Mean concentrations**		**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	Aflatoxin B1 (AFB1)	0.06	0.20	0.25	0.9
Almond drinks	Total aflatoxins B1, B2, G1 G2	0.06	0.21	0.26	0.93
Almond drinks	Ochratoxin A (OTA)	0.08	0.28	0.31	1.10
Soy drinks	OTA	0.38	1.40	1.30	4.60
Oat drinks	Deoxynivalenol (DON)	21	73	65	230
Oat drinks	Total DON and modified forms	33	120	95	340
Oat drinks	Total T-2 and HT-2 toxin (T2/HT2)	3.3	12	11	37

Table15: Short-term exposure to mycotoxins from the consumption of plant-based drinks by children aged 0.5 to <6 years according to the KiESEL study and using the mycotoxin concentrations according to the BfR's modified lower bound approach from Table 3.

		Short-term exposure [ng/(kg bw*d)]	
	Concentration	**95th percentile concentrations**	
Product category	Mycotoxin	P50 consumption	P95 consumption
Oat drinks	DON	120	380
Oat drinks	Total DON and modified forms	170	550
Oat drinks	T2/HT2	19	61

6.2 Risk characterisations using mycotoxin concentrations in accordance with the BfR's modified lower bound approach

Table16: Margin of exposure for long-term intake of mycotoxins from the consumption of plant-based drinks by children aged 0.5 to <6 years according to the KiESEL study and using the mycotoxin concentrations according to the BfR's modified lower bound approach from Table 3.

		Long-term exposure – margin of exposure			
	Concentration	Mean concentrations		95th percentile concentrations	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Almond drinks	AFB1	7,100	2,000	1,600	450
Almond drinks	Total aflatoxins B1, B2, G1 G2	6,700	1,900	1,500	430
Almond drinks	OTA (neoplastic)	180,000	51,000	48,000	13,000
Almond drinks	OTA (non-neoplastic)	60,000	17,000	16,000	4,400
Soy drinks	OTA (neoplastic)	38,000	11,000	11,000	3,200
Soy drinks	OTA (non-neoplastic)	12,000	3,500	3,700	1,000

Table17: Percentage of health-based guidance values for long-term intake (TDI) of mycotoxins from the consumption of plant-based drinks by children aged 0.5 to <6 years according to the KiESEL study and using the mycotoxin concentrations according to the BfR's modified lower bound approach from Table 3.

		Long-term exposure – percentage of TDI			
	Concentration	Mean concentrations		95th percentile concentrations	
Product category	Mycotoxin	P50 consumption	P95 consumption	P50 consumption	P95 consumption
Oat drinks	DON	2.1 %	7.3 %	6.5 %	23 %
Oat drinks	Total DON and modified forms	3.3 %	12.0 %	9.5 %	34 %
Oat drinks	T2/HT2	17 %	59 %	53 %	190 %

Table18 : Percentage of health-based guidance values for short-term intake (ARfD) of mycotoxins from the consumption of plant-based drinks by children aged 0.5 to <6 years according to the KiESEL study and using the mycotoxin concentrations according to the BfR's modified lower bound approach from Table 3.

		Short-term exposure – percentage of ARfD	
	Concentration	95th percentile concentrations	
Product category	**Mycotoxin**	**P50 consumption**	**P95 consumption**
Oat drinks	**DON**	1.5 %	4.7 %
Oat drinks	**Total DON and modified forms**	2.1 %	6.9 %
Oat drinks	**T2/HT2**	6.3 %	20 %

6.3 Limit of detection and limit of quantification of the analytical method

Table19 : Limit of detection (LOD) and limit of quantification (LOQ) in ng/kg for the analytes examined, itemised by plant-based drink type; LOD was only determined for almond drink as representative of all plant-based drink types; abbreviations: AOH: alternariol; AME: alternariol monomethyl ether; NO – N-oxide; ZEN – zearalenone; HFB1 – hydrolysed fumonisin B1

Analyte	LOD	LOQ oats	LOQ almond	LOQ soy	Analyte	LOD	LOQ oats	LOQ almond	LOQ soy
3-Acetyl-DON	37.6	102	102	305	**Erucifolin-NO**	1.56	30.4	30.4	30.4
15-Acetoxyscirpenol	10.7	102	305	102	**Europin-NO**	1.23	10.1	10.1	10.1
15-Acetyl-DON	37.8	102	305	2040	**Fumonisin B1**	30.3	508	508	508
Aflatoxin B1	1.12	10.2	30.5	10.2	**Fumonisin B2**	7.5	62.9	62.9	62.9
Aflatoxin B2	1.04	10.1	10.1	10.1	**Fumonisin B3**	12	101	101	101
Aflatoxin G1	1.68	10.1	30.4	10.1	**Fusarenone X**	117	507	10100	1520
Aflatoxin G2	1.7	10.2	10.2	10.2	**Heliotrine**	0.778	10.1	10.1	10.1
Aflatoxin M1	0.462	2.03	2.03	2.03	**Heliotrine-NO**	0.693	10.1	10.1	10.1
α-Zearalanol	22.4	107	107	107	**HT-2 toxin**	28.2	102	305	102
α-Zearalenol	22.6	101	101	101	**HFB 1**	7.53	20.3	20.3	20.3
α-Zearalenol sulfate	10.6	102	102	102	**Intermedin**	1.67	10.1	10.1	10.1
Altenuene	25	304	304	304	**Intermedin-NO**	1.42	10.1	10.1	10.1
AOH	14	101	101	101	**Jacobin**	3.4	10.1	203	30.4
AOH-3-glucoside	16.3	102	102	306	**Jacobin-NO**	1.41	10.1	10.1	10.1
AOH-3 sulfate	21.6	101	101	101	**Lasiocarpin**	1.02	10.1	10.1	10.1
AME	20.1	101	101	101	**Lasiocarpin-NO**	1.17	10.1	10.1	10.1
AME-3-glucoside	31	101	101	304	**Lupanine**	10.5	0.201	0.201	0.201
AME-3 sulfate	10.5	101	101	101	**Monocrotaline-NO**	2.48	30.4	10.1	10.1
Altertoxin I	25.4	304	101	101	**Neosolaniol**	25.8	102	305	102
Atropine	1.56	30.4	10.1	10.1	**Nivalenol**	66.1	3050	3050	
Beauvericin	4.48	40.6	40.6	40.6	**Ochratoxin A**	3.7	31.8	10.6	10.6
β-Zearalanol	27.6	102	102	305	**Ochratoxin alpha**	28.2	60.8	60.8	60.8
β-Zearalenol	24.9	102	102	102	**Ochratoxin B**	9.5	102	102	102
β-Zearalenol sulfate	13.3	101	101	101	**Phomopsin A**	26.7	102	102	
Citrinin	28.5	305	102	102	**Retrorsin**	2.76	10.1	203	10.1
Deepoxy-DON	34	101	2030	2030	**Retrorsin-NO**	1.31	10.1	10.1	30.4
DON	71.4	507	507	507	**Roquefortin C**	12.7	102	102	102
DON-3-glucoside	63	2030	2030	2030	**Roridin A**	10.6	106	2110	106
Diacetoxyscirpenol	9.88	97.8	97.8	97.8	**Roridin E**	1.15	10.2	30.5	30.5
Echimidine group	1.14	10.1	10.1	10.1	**Scopolamine**	1.17	10.1	10.1	30.4
Echimidine-NO + Heliosupine-NO	1.48	20.3	20.3	20.3	**Senecionin**	1.27	10.1	10.1	10.1
Enniatin A	3.56	40.6	40.6	40.6	**Senecionin-NO**	2.42	10.1	30.4	203
Enniatin A1	2.78	40.6	40.6	40.6	**Seneciphylline**	2.94	10.1	10.1	10.1
Enniatin B	3.6	40.6	40.6	40.6	**Seneciphylline-NO**	1.48	10.1	10.1	10.1
Enniatin B1	3.73	40.6	40.6	40.6	**Senkirkin**	1.01	10.1	10.1	10.1
Ergocornine	5.29	40.6	40.6	40.6	**Stachybotrylactam**	1.58	203	10.2	203
Ergocorninine	8.83	41.4	41.4	41.4	**Sterigmatocystin**	1.27	10.2	10.2	10.2
Ergocristine	8.16	40.6	40.6	40.6	**T-2 toxin**	13.3	102	102	102
Ergocristinine	7.84	41	41	41	**T2 triol**	89.7	606	606	202
Ergocryptine	6.45	40.6	40.6	40.6	**Tentoxin**	8.24	101	101	101
Ergocryptinine	6.93	43	43	43	**Verrucarin A**	9.82	98	98	294
Ergometrine	2.95	40.6	40.6	40.6	**Verrucarol**	167	3040	1010	3040
Ergometrine	5.05	40.6	40.6	40.6	**Zearalanone**	22.9	102	102	102
Ergosine	6.22	40.6	40.6	40.6	**ZEN**	10.6	102	102	102
Ergosinine	6.99	41.7	41.7	41.7	**ZEN-14-glucoside**	15	101	101	101
Ergotamine + Ergotamine	9.78	82.8	82.8	82.8	**ZEN-14 sulfate**	9.19	101	101	101

6.4 Statistical characteristics of the test results

Table20 : Statistical characteristics for all plant-based drinks; only analytes with at least one result above the limit of quantification (LOQ); all occurrence data in ng/kg; abbreviations: n: number of results; n > LOQ: number of results above the LOQ; LOD: limit of detection; LB: lower bound; UB: upper bound; MV: mean value; P95: 95th percentile; Max: maximum

Analyte	n	n > LOQ	LOD	LOQ	LB MV	LB P95	LB Max	UB MV	UB P95	UB Max
Enniatin B	162	95	3.6	41	470	2000	3600	480	2000	3600
Beauvericin	162	90	4.5	41	110	370	590	120	370	590
Enniatin B1	162	90	3.7	41	190	810	1300	200	810	1300
Sterigmatocystin	162	74	1.3	10	20	90	170	24	90	170
Enniatin A1	162	59	2.8	41	66	310	620	77	310	620
T-2 toxin	162	56	13	100	88	360	720	120	360	720
Tentoxin	162	56	8.2	100	71	250	930	100	250	930
Deoxynivalenol	162	47	71	510	1600	6900	35,000	1700	6900	35,000
HT-2 toxin	162	43	28	310	170	780	1600	270	780	1600
Ochratoxin A	162	43	3.7	11	18	110	290	25	110	290
Deoxynivalenol-3-glucoside	162	22	63	2000	850	3500	27,000	1500	3500	27,000
Lupanine	162	17	11	200	1900	590	240,000	1900	590	240,000
Atropine	162	16	1.6	10	19	29	1100	21	30	1100
Ergocorninine	162	15	8.8	41	14	98	330	25	98	330
Ergocryptinine	162	15	6.9	43	11	80	250	20	80	250
Aflatoxin B1	162	13	1.1	31	2.2	16	55	4.5	16	55
Enniatin A	162	11	3.6	41	6.9	44	160	23	44	160
Ergosine	162	10	6.2	41	5.1	48	110	14	48	110
Ergocornine	162	9	5.3	41	4.7	39	97	15	41	97
Zearalenone	162	9	11	100	38	100	4500	76	110	4500
3-Acetyl-deoxynivalenol	162	8	38	310	55	38	2100	120	310	2100
Scopolamine	162	8	1.2	10	4.2	1.2	200	8.3	30	200
Alternariol	162	7	14	100	9.6	14	190	41	100	190
Ergocristinine	162	7	7.8	41	3.1	7.8	90	12	41	90
Ergocryptine	162	6	6.5	41	3.3	6.5	89	12	41	89
Ergosinine	162	6	7	42	3.5	7	120	12	42	120
Citrinin	162	5	29	100	8.9	29	400	40	100	400
Alternariol methyl ether	162	2	20	100	6.5	20	230	39	100	230
15-Acetoxyscirpenol	162	1	11	310	7	11	860	61	310	860
Alpha-zearalenol	162	1	23	300	4.3	23	470	43	300	470
Alpha-zearalenol sulfate	162	1	11	100	3.2	0	520	14	11	520
Beta-zearalenol	162	1	25	310	3.6	0	520	33	25	520
Beta-zearalenol sulfate	162	1	13	100	3.7	0	600	17	13	600
Ergocristine	162	1	8.2	41	0.5	0	56	9.1	8.2	56
Ochratoxin B	162	1	9.5	100	2.3	9.5	180	21	100	180
Zearalenone-14-glucoside	162	1	15	100	0.84	0	140	16	15	140
Zearalenone-14-sulfate	162	1	9.2	100	23	9.2	3600	40	100	3600

Table21: Statistical characteristics for oat drinks; only analytes with at least one result above the limit of quantification (LOQ); all occurrence data in ng/kg; abbreviations: n: number of results; n > LOQ: number of results above the LOQ; LOD: limit of detection; LB: lower bound; UB: upper bound; MV: mean value; P95: 95th percentile; Max: maximum

Analyte	n	n > LOQ	LOD	LOQ	LB MV	LB P95	LB Max	UB MV	UB P95	UB Max
Enniatin B	86	84	3.6	41	860	2400	3600	860	2400	3600
Beauvericin	86	82	4.5	41	190	460	590	190	460	590
Enniatin B1	86	82	3.7	41	340	980	1300	350	980	1300
Enniatin A1	86	57	2.8	41	120	350	620	130	350	620
T-2 toxin	86	53	13	100	160	470	720	190	470	720
Tentoxin	86	46	8.2	100	100	270	380	140	270	380
Deoxynivalenol	86	45	71	510	2900	9100	35,000	3000	9100	35000
Sterigmatocystin	86	42	1.3	10	22	86	150	25	86	150
HT-2 toxin	86	39	28	310	300	1000	1600	460	1000	1600
Deoxynivalenol-3-glucoside	86	21	63	2000	1600	3800	27,000	2700	3800	27,000
Lupanine	86	16	11	200	3500	3100	240,000	3600	3100	240,000
Ergocorninine	86	15	8.8	41	27	190	330	38	190	330
Ergocryptinine	86	15	6.9	43	21	130	250	31	130	250
Ochratoxin A	86	12	3.7	11	5.8	37	96	9.4	37	96

Enniatin A	86	11	3.6	41	13	75	160	38	75	160
Ergosine	86	10	6.2	41	9.6	78	110	20	78	110
Ergocornine	86	9	5.3	41	8.6	71	97	22	71	97
3-Acetyl-deoxynivalenol	86	8	38	310	100	790	2100	190	790	2100
Ergocristinine	86	7	7.8	41	5.9	46	90	17	46	90
Alternariol	86	6	14	100	14	110	190	50	110	190
Ergocryptine	86	6	6.5	41	6.3	52	89	18	52	89
Ergosinine	86	6	7	42	6.6	66	120	17	66	120
Zearalenone	86	4	11	100	11	11	130	59	100	130
Atropine	86	3	1.6	10	0.8	1.6	22	2.5	10	22
Alternariol methyl ether	86	2	20	100	11	20	230	49	100	230
Ergocristine	86	1	8.2	41	0.94	0	56	9.9	8.2	56
Scopolamine	86	1	1.2	10	0.23	0	16	1.8	7.9	16

Table22: Statistical characteristics for soy drinks; only analytes with at least one result above the limit of quantification (LOQ); all occurrence data in ng/kg; abbreviations: n: number of results; n > LOQ: number of results above the LOQ; LOD: limit of detection; LB: lower bound; UB: upper bound; MV: mean value; P95: 95th percentile; Max: maximum

Analyte	n	n > LOQ	LOD	LOQ	LB MV	LB P95	LB Max	UB MV	UB P95	UB Max
Ochratoxin A	29	22	3.7	11	54	180	290	55	180	290
Sterigmatocystin	29	11	1.3	10	20	80	170	24	80	170
Atropine	29	10	1.6	10	95	660	1100	98	660	1100
Tentoxin	29	7	8.2	100	75	280	930	96	280	930
Enniatin B	29	6	3.6	41	40	190	600	66	190	600
Citrinin	29	5	29	100	45	220	400	78	220	400
Scopolamine	29	4	1.2	30	19	140	200	32	140	200

Enniatin B1	29	3	3.7	41	20	81	380	37	81	380
HT-2 toxin	29	2	28	100	13	94	210	39	100	210
Enniatin A1	29	1	2.8	41	5.1	2.8	120	19	41	120
Ochratoxin B	29	1	9.5	100	9.3	9.5	180	44	100	180

Table23: Statistical characteristics for almond drinks; only analytes with at least one result above the limit of quantification (LOQ); all occurrence data in ng/kg; abbreviations: n: number of results; n > LOQ: number of results above the LOQ; LOD: limit of detection; LB: lower bound; UB: upper bound; MV: mean value; P95: 95th percentile; Max: maximum

Analyte	n	n > LOQ	LOD	LOQ	LB MV	LB P95	LB Max	UB MV	UB P95	UB Max
Sterigmatocystin	39	13	1.3	10	10	35	110	15	35	110
Aflatoxin B1	39	11	1.1	10	8	35	55	13	35	55
Ochratoxin A	39	7	3.7	32	11	43	110	31	43	110
Scopolamine	39	3	1.2	10	2.6	12	73	4.1	12	73
Atropine	39	1	1.6	30	2	1.6	71	7	30	71
Tentoxin	39	1	8.2	100	5.7	8.2	170	27	100	170

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