German Federal Institute for Risk Assessment

**Opinion** 029/2024

doi https://doi.org/10.17590/20241004-092933-0

25 June 2024

# Mycotoxins in plant-based drinks: more data required

## Results of a study by the Max Rubner Institute and their relevance for risk assessment

Mycotoxins are secondary metabolites of moulds. They may occur as contaminants in plant products and raw materials such as grains, nuts, and almonds if they are infested by moulds during cultivation, storage or further processing. These metabolites can also be transferred into processed products such as oat, soy, or almond drinks. The Max Rubner Institute (MRI) investigated these plant-based drinks for their levels of various mycotoxins such as aflatoxin B1, deoxynivalenol (DON) and the toxins T-2 and HT-2. Aflatoxin B1 is classified as genotoxic and carcinogenic. This means that no safe threshold for the carcinogenic effect can be established. Low doses of deoxynivalenol (DON) have a long-term adverse effect on child development. In addition, high doses cause acute gastrointestinal disorders such as vomiting and diarrhoea as well as headaches and fever. The toxins T-2 and HT-2 have a haematotoxic and myelotoxic effect and disrupt haematopoiesis.

The German Federal Institute for Risk Assessment (BfR) carried out a health assessment of the mycotoxin levels detected in plant-based drinks. The assessment is limited to the particularly vulnerable group of children aged 0.5 to <6 years. In relation to their body weight, children generally consume larger amounts of food than adults. This is associated with a higher intake of substances, including undesirable ones, per kilogram of body weight. As a result, the health risk to adults is generally lower.

As only few data are available on children's consumption of plant-based drinks, cow's milk intake in this age group was used based on the assumption that plant-based drinks are consumed as an alternative to cow's milk.

In the case of soy drinks, it has been found that mycotoxins were only detectable in a very small number of samples. The levels found were very low, meaning that

any additional intake of mycotoxins from the consumption of soy drinks by children up to six years of age can provisionally be considered negligible.

The MRI detected the presence of aflatoxin B1 in 23 out of 24 samples of almond drinks. In its assessment of health risks, the BfR concludes that regular consumption of almond drinks with such aflatoxin levels may cause health impairments in children in the age group from 0.5 to <6 years with a medium likelihood.

The MRI also investigated 37 samples of oat drinks. The *Fusarium* toxins Deoxynivalenol and T-2 and HT-2 toxins were detected in 33 and 29 samples, respectively.

Regarding DON levels in oat drinks, the BfR concludes that short- and long-term consumption of these oat drinks is unlikely to cause health impairments in children aged 0.5–6 years as the consumption results only in a very small percentage of the derived health-based guidance values – both the tolerable daily intake (TDI) for long-term intake over a lifetime and the acute reference dose (ARfD) for short-term intake over a single day.

For the assessment of the short-term intake of the toxins T-2 and HT-2 solely from the consumption of oat drinks containing the levels detected by the MRI, the BfR concludes that the likelihood of health impairments in children of the above-stated age group is low. Other oat products such as oat flakes may likewise contain these *Fusarium* toxins. Therefore, the total intake and thus also the likelihood of health impairments increase if multiple oat products are consumed.

The BfR notes that the data were not generated on a representative basis and therefore only provide an initial insight into the mycotoxin levels in plant-based drinks. Further studies covering the market are required to generate representative data on mycotoxins in plant-based drinks in order to be able to provide a better assessment of health risks to the population.

## 1 Subject of the assessment

The Max Rubner Institute (MRI) carried out an interdisciplinary project entitled “Initial characterisation of selected plant-based drinks with regard to their quality and to their microbiological and chemical safety” and published the results in the form of a final report on the MRI website (https://www.mri.bund.de/de/pflanzendrink-bericht). In addition to the results from nutritional and microbiological investigations, this final report also contains occurrence data of contaminants, including various mycotoxins, in the investigated plant-based drinks. The German Federal Institute for Risk Assessment (BfR) assessed the results of this study with regard to health risks. The mycotoxin results were contextualised with regard to their relevance to consumer exposure and an assessment was made of the extent to which the determined mycotoxin levels may pose a health risk to vulnerable groups.

## 2 Results

The assessment of the health risks from consuming plant-based drinks having the mycotoxin levels determined by the MRI is limited to an assessment of aflatoxin B1 (AFB1) in almond drinks, deoxynivalenol (DON) in oat drinks and T-2 and HT-2 toxin (T-2/HT-2) in oat drinks. The other mycotoxins listed in the MRI report were either not detected in almond and oat drinks (ochratoxin A and zearalenone) or cannot (yet) be assessed (sterigmatocystin).

In soy drinks, the investigated mycotoxins could only be quantified in one or two samples at very low levels despite very low detection and quantification limits. The BfR therefore concludes that, on the basis of the available data, the additional exposure to mycotoxins through the consumption of soy drinks could be considered negligible and therefore no detailed assessment of health risks is provided. It should, however, be noted that the number of samples (n=12) is too low to permit a conclusive estimation of the contribution of soy drinks to the particular overall exposure.

The assessment of health risks is furthermore limited to children aged 0.5 to <6 years as a vulnerable group of consumers. Due to their lower body weight, children have a higher consumption and thus higher exposure in relation to their body weight compared to adults.

The most recent data on children's consumption is available from the KiESEL study (The Children's Nutrition Survey to Record Food Consumption). Since only a small number of children in the KiESEL study consumed plant-based drinks (n=38), cow's milk consumption is primarily used as the basis for 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 that comparable amounts are consumed.

A comparison with the consumption of plant-based drinks actually recorded in the course of the KiESEL study indicates that using cow's milk consumption data as a substitute for the consumption of plant-based drinks might be an overestimation. However, the differences in 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.

Exposure was assessed based on the data generated by the MRI on the occurrence of mycotoxins in plant-based drinks. Moreover, the BfR does not currently have any further data, for example comparative data from monitoring programmes of the German Federal States ("Laender").

The BfR has applied the "margin of exposure (MoE)" approach to assess health risks arising from the consumption of AFB1 in almond drinks since aflatoxins are genotoxic carcinogens for which no safe intake level can be established. A BMDL10[1] of 400 ng/(kg bw*d), which was derived from a two-year carcinogenicity study in rats, was used as toxicological reference value. With regard to public health, for genotoxic carcinogens an MoE value of

[1] In this case, the BDML10 indicates the dose at which the number of additional cancer cases in the animal experiment increases by 10%.

10,000 and above is generally considered to be of low concern, although not harmless, and therefore a low priority for risk management measures.

The MRI was able to quantify AFB1 in almost all the investigated almond drinks (23 out of 24 samples). The BfR has thus determined MoE values of between 79 and 3496 depending on the particular age group and the scenario under consideration. For the assessment of the health risks of AFB1 intake from the consumption of almond drinks based on realistic scenarios, the BfR therefore concludes that, for long-term consumption of almond drinks containing AFB1 at the levels determined by the MRI, likelihood of health impairments in children aged 0.5 to <6 years is medium.

The TDI of 1000 ng/(kg bw*d) for long-term exposure and the ARfD of 8000 ng/(kg bw*d) for short-term exposure were used as health-based guidance values for assessing the health risks of DON intake from the consumption of oat drinks. For the assessment of the health risks of DON exposure through the consumption of oat drinks based on conservative scenarios, the BfR concludes that health impairments in children aged 0.5 to <6 years are unlikely in the case of both long-term and short-term consumption of oat drinks containing DON at the levels determined by the MRI.

The TDI of 20 ng/(kg bw*d) for long-term exposure and the ARfD of 300 ng/(kg bw*d) for short-term exposure were used as health-based guidance values for assessing the health risks of T-2/HT-2 intake from the consumption of oat drinks. For the assessment of the health risks of short-term intake of T-2/HT-2 from the consumption of oat drinks based on realistic scenarios, the BfR concludes that, for (solely) short-term consumption of oat drinks containing T-2/HT-2 at the levels determined by the MRI, the likelihood of health impairments in children aged 0.5 to <6 years is low.

It should, however, be taken into account that T-2 and HT-2 toxins may be ingested not only from the consumption of oat drinks, but also from the consumption of other oat products, such as oat flakes. In a scenario in which all consumed oat products contain T-2/HT-2 at the maximum level of 100 µg/kg applicable from 1 July 2024, short-term consumption may result in an exceedance of the ARfD for children aged 1 to <6 years (154–371% of the ARfD). Possible additional intake of T-2/HT-2 from the consumption of oat drinks was not considered in this scenario.

For the assessment of the health risks of long-term intake of T-2/HT-2 from the consumption of oat drinks, it should be considered that the BfR assumes in the present opinion 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 should be considered realistic. The MRI was able to quantify T-2/HT-2 in the majority of the investigated oat drinks (29 out of 37 samples). The consumption of oat drinks as an alternative to cow's milk would therefore represent an additional source for T-2/HT-2 intake and thus increase both the overall exposure to T-2/HT-2 and the likelihood of health impairments.

The data generated by the MRI in the course of the present project provide an initial indication of the occurrence of mycotoxins in plant-based drinks. Due to the small number of samples and the lack of comparative data from other monitoring programmes, the BfR is currently unable to assess the extent to which the data generated by the MRI are representative of the German market and thus of German consumers' exposure. The BfR's

risk characterisations indicate that mycotoxin intake from the consumption of plant-based drinks can pose a health risk to vulnerable consumer groups. The BfR therefore recommends that further data on the occurrence of mycotoxins in plant-based drinks, in particular of aflatoxins in almond drinks and of T-2 and HT-2 toxins in oat drinks, are generated. Sufficiently sensitive analytical methods should be used for this purpose in order to obtain the highest possible percentage of quantifiable levels and thus achieve a representative data basis for a more realistic exposure assessment.

# 3 Rationale

## 3.1 Risk assessment

In the course of the project "Initial characterisation of selected plant-based drinks with regard to their quality and to their microbiological and chemical safety", the MRI generated data on the occurrence of mycotoxins in plant-based drinks using highly sensitive analytical methods. The investigations include the three matrices oat, almond, and soy drinks, in each of which the mycotoxins aflatoxin B1 (AFB1), deoxynivalenol (DON), ochratoxin A (OTA), sterigmatocystin (STC), T-2 and HT-2 toxin (T-2/HT-2) as well as zearalenone (ZEN) were analysed. The results (with the exception of OTA, which could not be detected in any sample) are summarised in Table 3 of the MRI's final report (https://www.mri.bund.de/de/pflanzendrink-bericht). Firstly, the BfR comments to this as follows:

Oat drinks

The MRI investigated 37 samples of oat drinks for mycotoxins and was able to detect DON in 33 samples, STC in 25 samples and T-2/HT-2 in 29 samples, while the mycotoxins AFB1 and ZEN were not detected in any sample. With regard to STC, the European Food Safety Authority (EFSA) concluded in a scientific opinion from 2013 that it is not currently possible to carry out a health risk assessment of STC due to insufficient data (EFSA 2013). Consequently, the following assessment of the health risks arising from the consumption of oat drinks will be limited to DON and T-2/HT-2 intake.

Almond drinks

The MRI investigated 24 samples of almond drinks for mycotoxins and was able to detect AFB1 in 23 samples and STC in 16 samples, while the mycotoxins DON, T-2/HT-2 and ZEN were not detected in any sample. In line with the above explanations regarding STC, the following assessment of the health risks from the consumption of almond drinks will be limited to AFB1 intake.

Soy drinks

The MRI investigated twelve samples of soy drinks for mycotoxins and was able to quantify the various mycotoxins at low levels in only one or two samples despite very sensitive methods with low detection and quantification limits. The BfR therefore concludes that, on the basis of the available data, the additional intake of mycotoxins from consuming soy drinks could be considered negligible. It should, however, be noted that the number of twelve samples is too low to permit a conclusive estimation of the contribution of soy drinks

to the particular overall exposure. Due to these uncertainties, no detailed assessment of the health risks from consuming soy drinks is provided below.

### 3.1.1 Hazard identification

AFB1

Aflatoxins are mycotoxins mainly formed by the two fungal species *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins can be detected in various foods, such as tree nuts, peanuts, maize, spices, or dried fruits (EFSA 2020).

Regulation (EU) 2023/915 sets maximum levels for aflatoxins (differentiated for aflatoxin B1 and the sum of the aflatoxins B1, B2, G1, 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.

DON

DON is one of the mycotoxins primarily formed by fungal species of the genus *Fusarium*. Human exposure mainly arises from cereals and cereal products, in which DON can be detected almost ubiquitously (EFSA 2017c).

Regulation (EU) 2023/915 sets maximum levels for DON in various foods. For instance, a maximum level of 750 µg/kg applies to oats, placed on the market for the final consumer. For DON in oat drinks, no specific maximum level is laid down in Regulation (EU) 2023/915.

T-2/HT-2

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 mainly arises from cereals and cereal products, with the highest levels detected in oats and oat products (EFSA 2017b).

Regulation (EU) 2024/1038 has for the first time set maximum levels for T-2/HT-2 in various foods entering into force on 1 July 2024. Accordingly, a maximum level of 100 µg/kg will apply, for example, to oats, placed on the market for the final consumer, and to oat flakes. For T-2/HT-2 in oat drinks, no specific maximum level is laid down in Regulation (EU) 2024/1038.

### 3.1.2 Hazard characterisation

3.1.2.1 Hazard characterisation for AFB1

The International Agency for Research on Cancer (IARC) has classified aflatoxins in group 1 (carcinogenic to humans) and most recently confirmed this classification in 2012 (IARC 2012). Carcinogenic potential has been proven for the two aflatoxins B1 and G1, while the

results for the other two aflatoxins B2 and G2 were less clear. The critical effect in the health risk assessment is the potential for the development of liver cancer, which is higher for aflatoxin B1 than for aflatoxin G1.

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

EFSA therefore recommends applying the "margin of exposure (MoE)" approach to the health risk assessment of aflatoxins. The MoE is the ratio of a suitable toxicological reference point and human exposure to the substance. The benchmark dose lower confidence limit (BMDL) is often used as a reference point for carcinogenic compounds. The BMDL10 is determined by modelling suitable data on the dose-response relationship and corresponds to the lower limit of the confidence interval of the dose which, in the case of a carcinogenic effect, is associated with an additional cancer risk of 10% (benchmark dose response 10%, BMR10) compared to the control group.

EFSA has identified a two-year carcinogenicity study in rats (Wogan et al. 1974) with AFB1 as a critical study for the toxicology of aflatoxins. On the basis of data on the induction of hepatocellular carcinomas in male rats, a BMDL10 of 0.4 µg/kg bw per day was determined using benchmark modelling (EFSA 2020).

EFSA, moreover, analysed data on the potency of aflatoxins B1, B2, G1 and G2, but was unable to identify any clear quantitative differences. EFSA therefore recommends assuming the same relative potency for aflatoxins B1, B2, G1 and G2 for risk assessment purposes (EFSA 2020).

#### 3.1.2.2 Hazard characterisation for DON

Both acute and chronic effects can occur after oral intake of DON which can lead in particular to immunotoxic and developmentally toxic effects. The mechanism of action involves binding to ribosomes leading to an inhibition of protein biosynthesis. Pigs respond particularly sensitively to DON and, depending on the level of oral exposure, exhibit symptoms such as feed refusal and vomiting, which is why DON is also known colloquially as "vomitoxin".

EFSA has identified a two-year carcinogenicity study in mice (Iverson et al. 1995) as a critical study for chronic DON intake. Although DON carcinogenicity could not be shown in this study, reduced weight gain of the mice was detected. On the basis of this effect as a critical endpoint, EFSA has 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 pointed out that the two health-based guidance values relate not only to DON but were established as group values for the sum of DON and its modified forms (3-Ac-DON, 15-Ac-DON, DON-3-Glu) (EFSA 2017c). This means that, in principle, the modified forms must

also be considered in the health assessment. Since the MRI's investigations are limited to DON, the health risk below will also be assessed for DON alone.

3.1.2.3 Hazard characterisation for T-2/HT-2

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 T-2/HT-2, 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 T-2/HT-2 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 T-2/HT-2. 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 T-2/HT-2. 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 T-2/HT-2 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 pointed out that the two HBGVs are not limited solely to T-2/HT-2, but were established as group values for the sum of T-2/HT-2 and their modified forms (EFSA 2017a). This means that, in principle, the modified forms must also be considered in the health assessment. Since the MRI's investigations are limited to T-2/HT-2, the health risk below will also only be assessed for these two substances.

### 3.1.3 Exposure assessment

Children have a higher consumption due to their lower body weight and thus higher exposure in relation to their body weight compared to adults. For this reason, the following exposure assessments and subsequent risk characterisations will be limited to children aged 0.5 to under 6 years as a more vulnerable consumer group.

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

3.1.3.1.1 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 6 months up to and including 5 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.

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

Since only a small number of children in the KiESEL study consumed plant-based drinks (n=38), cow's milk consumption was primarily used as the basis for exposure assessment and compared in 3.3.1.1 with the consumption of plant-based drinks for contextualisation purposes. This is based on the assumption that the corresponding plant-based drinks are used as an alternative to cow's milk and thus that comparable amounts are consumed. This assumption is particularly plausible for the increasing number of consumers who follow a vegan diet.

The results for the long-term consumption of cow's milk are presented in **Table 1**. The children's median consumption was 7.1 grams (g) per kilogram (kg) body weight (bw) per day (d). The high level of consumption, represented by the 95th percentile, amounts to 25.3 g/(kg bw*d). Younger children consumed somewhat more than older children. There were no significant differences between boys and girls and therefore the further estimations only differentiate by age. Children from both age groups 0.5 to under 1 year and from 1 to under 3 years had the highest median consumption of 8.7 g/(kg bw*d). In the 95th percentile, it was the age group of 1 to under 3-year-olds with 38.9 g/(kg bw*d). Children who had not consumed cow's milk on at least one of the observation days were excluded from the estimation. Consequently, the age group of 0.5 to under 1-year-olds consists of just a small number of children having consumed milk (n=15). In contrast, the percentage of children who had consumed cow's milk on at least one of the days was 85% across all age groups (n=811).

**Table 1: 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 | 10.0 (9.0-10.9) | 7.1 (5.7-8.4) | 27.2 (23.4-30.6) |

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

The short-term consumption of cow's milk by children is presented in **Table 2** which was 12.8 g/(kg bw*d) in the median, and 41.5 g/(kg bw*d) in the 95th percentile. Here, too, no significant differences were found between the milk consumption of boys and girls. Focusing on the medians revealed a reduction in consumption amounts with increasing age, with the highest consumption of 17.3 g/(kg bw*d) occurring among 0.5 to under 1-year-olds. For the 95th percentile, it was again the age group of 1 to under 3-year-olds that had the highest consumption of 53.8 g/(kg bw*d).

**Table 2: 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) |

3.1.3.1.4 Comparison of data on the consumption of cow's milk with data on the consumption of **plant-based drinks**

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.

3.1.3.2 Data on mycotoxin levels in plant-based drinks

In the course of the BfR MEAL Study, the two matrices "rice drinks" and "soy drinks" from the "plant-based drinks" food group were investigated but only soy drinks were included in the "mycotoxins" module, where the levels in the investigated pooled samples for all the toxins of relevance here were below the limit of quantification and thus at a comparable level to the MRI data.

The BfR has no data on mycotoxin levels in plant-based drinks from monitoring programmes of the Federal States' ("Laender"). While plant-based drinks were indeed investigated in the course of a monitoring project in 2021, this was only for the occurrence of elements.

**Table 3** is an extract from Table 3 of the MRI's final report (https://www.mri.bund.de/de/pflanzendrink-bericht). Only those analyte-matrix-combinations and those occurrence data which were used for the following exposure assessment are shown.

**Table 3: Extract from Table 3 on page 25 of the MRI's final report; only the levels for those analyte-matrix-combinations which were used for the following exposure assessments are shown.**

| Mycotoxin | Product category | Number of samples | Number of samples with quantifiable levels | Mycotoxin levels | |
|---|---|---|---|---|---|
| | | | | Mean [ng/l]* | Maximum value [ng/l]* |
| **AFB1** | **Almond drinks** | 24 | 23 | 18.1 | 130.3 |
| **DON** | **Oat drinks** | 37 | 33 | 691.8 | 5457.5 |
| **T-2/HT-2** | **Oat drinks** | 37 | 29 | 397.2 | 2146.5 |

* The MRI provided mycotoxin levels in ng/l. For the exposure assessment, the BfR has equated the stated levels with ng/kg. No conversion factor was applied here.

#### 3.1.3.3 Methodological approach

Long-term exposure was determined by multiplying the data for long-term consumption (median/50th percentile and 95th percentile) by the mean of the mycotoxin levels and by the maximum level. Using the mean of the levels represents the exposure of children who are exposed to random levels over an extended period of time.

The BfR usually uses the 95th percentile of levels for worst-case calculations on long-term intake, but this was not specified in the MRI report. Accordingly, the BfR has used the respective maximum level in this case. This scenario assumes that only plant-based drinks with mycotoxin levels of the order of the maximum level are consumed over a long time period, even if this leads to an overestimation due to the heterogeneous distribution of mycotoxins in food.

Only the maximum level was used to estimate short-term exposure, since in this case assuming short-term consumption of a plant-based drink with a high mycotoxin level is a realistic scenario.

As already explained at the beginning of the opinion at hand, the exposure assessment below will be limited to the analyte-matrix combinations AFB1 in almond drinks and DON and T-2/HT-2 in oat drinks.

##### 3.1.3.3.1 Assessment of the exposure to **AFB1** from the consumption of **almond drinks**

**Table 4** presents the long-term exposure to AFB1 from the consumption of almond drinks. At average consumption and mean levels, exposure across all the children considered amounts to 0.1 ng/(kg bw*d). If, on the other hand, high consumption is assumed, intake increases to 0.5 ng/(kg bw*d). Assuming the maximum level, exposure is 0.9 ng/(kg bw*d) with average consumption and 3.3 ng/(kg bw*d) with high consumption. According to the underlying consumption data, children aged 1 to under 3 years have the highest exposure, ranging from 0.2 ng/(kg bw*d) (average consumption, mean levels) to 5.1 ng/(kg bw*d) (high consumption, maximum level).

**Table 4: Long-term exposure to aflatoxin B1 (AFB1) from the consumption of almond drinks by children aged 0.5 to <6 years according to the KiESEL study. Levels used: Mean: 18.1 ng/kg, maximum 130.3 ng/kg.**

| | | Long-term exposure [ng/(kg bw*d)] | | | |
|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Almond drinks | All | 0.1 | 0.5 | 0.9 | 3.3 |
| | 0.5-<1 | 0.2 | 0.5 | 1.1 | 3.5 |
| | 1-<3 | 0.2 | 0.7 | 1.1 | 5.1 |
| | 3-<6 | 0.1 | 0.4 | 0.8 | 2.6 |

3.1.3.1 Assessment of the exposure to **DON** from the consumption of **oat drinks**

The results for short- and long-term exposure to DON from the consumption of oat drinks are presented in **Table 5**. At mean levels, long-term exposure across all age groups amounts to 4.9 ng/(kg bw*d) (average consumption) or 17.5 ng/(kg bw*d) (high consumption). In the case of maximum levels, long-term exposure is 38.9 ng/(kg bw*d) (average consumption) or 138.0 ng/(kg bw*d) (high consumption). Due to the higher consumption amounts, the 1 to under 3-year-olds have the highest exposure, reaching a maximum intake of 212.4 ng/(kg bw*d) (high consumption, maximum level).

**Table 5: Long- and short-term exposure to deoxynivalenol (DON) from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study. Levels used: Mean: 691.8 ng/kg, maximum 5457.5 ng/kg.**

| | | Long-term exposure [ng/(kg bw*d)] | | | | Short-term exposure [ng/(kg bw*d)] | |
|---|---|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Oat drinks | All | 4.9 | 17.5 | 38.9 | 138.0 | 70.1 | 226.2 |
| | 0.5-<1 | 6.0 | 18.8 | 47.7 | 148.3 | 94.2 | 175.3 |
| | 1-<3 | 6.0 | 26.9 | 47.5 | 212.4 | 91.0 | 293.6 |
| | 3-<6 | 4.4 | 14.0 | 34.5 | 110.2 | 65.1 | 176.7 |

When considering short-term consumption, exposure across all children is 70.1 ng/(kg bw*d) (average consumption) or 226.2 ng/(kg bw*d) (high consumption). For the highest exposed age group of 1 to under 3-year-olds, intake levels are 91.0 ng/(kg bw*d) (average consumption) or 293.6 ng/(kg bw*d) (high consumption).

3.1.3.2 Assessment of the exposure to **T-2/HT-2** from the consumption of **oat drinks**

**Table 6** shows the results of the long- and short-term exposure assessments for intake of T-2/HT-2 from the consumption of oat drinks. Assuming mean levels, long-term exposure across all age groups is 2.8 ng/(kg bw*d) (average consumption) or 10.0 ng/(kg bw*d) (high consumption). Applying the maximum level results in intake levels for long-term exposure of 15.3 ng/(kg bw*d) (average consumption) or of 54.3 ng/(kg bw*d) (high consumption). 1 to under 3-year-olds show the highest exposure of 83.6 ng/(kg bw*d) (high consumption, maximum level).

When considering short-term consumption, exposure across all children is 27.6 ng/(kg bw*d) (average consumption) or 89.0 ng/(kg bw*d) (high consumption). For the highest exposed age group of 1 to under 3-year-olds, intake levels are 35.8 ng/(kg bw*d) (average consumption) or 115.5 ng/(kg bw*d) (high consumption).

**Table 6: Long- and short-term exposure to the sum of T-2/HT-2 from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study. Levels used: Mean: 397.2 ng/kg, maximum 2146.5 ng/kg.**

| | | Long-term exposure [ng/(kg bw*d)] | | | | Short-term exposure [ng/(kg bw*d)] | |
|---|---|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Oat drinks | All | 2.8 | 10.0 | 15.3 | 54.3 | 27.6 | 89.0 |
| | 0.5-<1 | 3.5 | 10.8 | 18.8 | 58.3 | 37.0 | 69.0 |
| | 1-<3 | 3.5 | 15.5 | 18.7 | 83.6 | 35.8 | 115.5 |
| | 3-<6 | 2.5 | 8.0 | 13.6 | 43.4 | 25.6 | 69.5 |

## 3.2 Risk characterisation

Percentage of the health-based guidance values or calculation of the *margin of exposure* (MoE) refer to the exposure assessments in section 3.3 and are summarised in the **Tables 7 to 9**.

### 3.2.1 Risk characterisation for AFB1 in almond drinks

As already explained in section 3.2.1, the MoE approach should be applied to the assessment of the health risks of AFB1 intake since aflatoxins are genotoxic carcinogens for which no safe intake level can be derived. The toxicological reference value used for this purpose is a $BMDL_{10}$ of 400 ng/(kg bw*d) which was derived from a two-year carcinogenicity study in rats.

The BfR explicitly points out that this toxicological reference value is **not a health-based guidance value**[2] but merely serves to prioritise risk management measures. With regard to

[2] The MoE approach is used in risk assessment to provide guidance for risk management with regard to the urgency of measures.

public health, for genotoxic carcinogens an MoE value of 10,000 and above is generally considered to be of low concern, although not harmless, and therefore a low priority for risk management measures.

Using the data for long-term exposure according to Table 4 in section 3.3.3.2 results in MoE values of between 79 and 3496 depending on the particular age group and scenario, which are thus well below an MoE value of 10,000 for all the scenarios under consideration (**Table 7**).

**Table 7: *Margin of exposure* for long-term intake of AFB1 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 toxicological reference value. Levels used: Mean: 18.1 ng/kg, maximum 130.3 ng/kg.**

| | | Long-term exposure – *margin of exposure* | | | |
|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Almond drinks | All | 3093 | 873 | 430 | 121 |
| | 0.5-<1 | 2526 | 813 | 351 | 113 |
| | 1-<3 | 2539 | 567 | 353 | 79 |
| | 3-<6 | 3496 | 1093 | 486 | 152 |

For the assessment of the health risks of AFB1 exposure through the consumption of almond drinks based on realistic scenarios, the BfR concludes that, for long-term consumption of almond drinks containing AFB1 at the levels determined by the MRI, the likelihood of health impairments in children aged 0.5 to <6 years is medium.

For the assessment of the health risks from chronic exposure to AFB1, it should also be taken into account that almond drinks are not the only source for aflatoxin intake, but that aflatoxins are also ingested from the consumption of other foods. The assessment at hand assumes that almond drinks are consumed as an alternative to cow's milk. During the transfer of aflatoxins from feed into the milk metabolisation takes place which means that mainly the metabolite aflatoxin M1 (AFM1) is present in cow's milk, which has a lower toxic potential compared to AFB1. In contrast, aflatoxins that may be present in almonds used for producing almond drinks are not metabolised to AFM1 during the manufacturing process. The MRI was able to quantify AFB1 in almost all almond drinks investigated (23 out of 24 samples). The levels determined were on average 18.1 ng/kg with a maximum level of 130.3 ng/kg. For AFM1 a maximum level of 50 ng/kg in raw milk, heat-treated milk, and milk for the manufacture of milk-based products is set according to Regulation (EU) 2023/915. Assuming that the levels of AFB1 in plant-based drinks and of AFM1 in cow's milk are comparable, the consumption of plant-based drinks as an alternative to cow's milk would increase the proportion of AFB1 in the overall exposure and simultaneously reduce the proportion of AFM1. Since AFB1 has a higher toxic potential than AFM1, this would increase the likelihood of health impairments.

Due to the small number of samples analysed and the lack of comparative data from other monitoring programmes, the BfR is currently unable to assess the extent to which the data generated by the MRI on the occurrence of AFB1 in almond drinks are representative of the German market and thus of German consumers' exposure. The present risk characterisation indicates that the intake of AFB1 from the consumption of almond drinks may pose a health risk to vulnerable consumer groups. The BfR therefore recommends that further data on the occurrence of AFB1 in almond drinks are generated.

### 3.2.2 Risk characterisation for DON in oat drinks

The TDI of 1000 ng/(kg bw*d) for long-term exposure and the ARfD of 8000 ng/(kg bw*d) for short-term exposure were used as health-based guidance values for assessing the health risks of DON intake from the consumption of oat drinks.

Using the data for long-term exposure according to Table 5 in section 3.3.3.3 results in percentages of 0.4% to 21.2% of the TDI depending on the particular age group and scenario under consideration (**Table 8**).

A similar procedure results in percentages of 0.8% to 3.7% of the ARfD for short-term intake (**Table 8**).

For the assessment of the health risks of DON exposure through the consumption of oat drinks based on conservative scenarios, the BfR concludes that health impairments in children aged 0.5 to <6 years are unlikely in the case of both long-term and short-term consumption of oat drinks containing DON at the levels determined by the MRI.

**Table 8: Percentage of health-based guidance values for long-term intake (TDI=1000 ng/(kg bw*d)) and for short-term intake (ARfD=8000 ng/(kg bw*d)) of DON from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study. Levels used: Mean: 691.8 ng/kg, maximum 5457.5 ng/kg.**

| | | Long-term exposure – Percentage of TDI | | | | Short-term exposure – Percentage of ARfD | |
|---|---|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Oat drinks | All | 0.5% | 1.7% | 3.9% | 13.8% | 0.9% | 2.8% |
| | 0.5-<1 | 0.6% | 1.9% | 4.8% | 14.8% | 1.2% | 2.2% |
| | 1-<3 | 0.6% | 2.7% | 4.7% | 21.2% | 1.1% | 3.7% |
| | 3-<6 | 0.4% | 1.4% | 3.4% | 11.0% | 0.8% | 2.2% |

### 3.2.3 Risk characterisation for T-2/HT-2 in oat drinks

The TDI of 20 ng/(kg bw*d) for long-term exposure and the ARfD of 300 ng/(kg bw*d) for short-term exposure were used as health-based guidance values for assessing the health risks of T-2/HT-2 intake from the consumption of oat drinks.

Using the data for long-term exposure according to Table 6 in section 3.3.3.4 results in percentages of 13% to 418% of the TDI depending on the particular age group and scenario under consideration (**Table 9**).

A similar procedure results in percentages of 9% to 38% of the ARfD for short-term intake (**Table 9**).

**Table 9: Percentage of health-based guidance values for long-term intake (TDI=20 ng/(kg bw*d)) and for short-term intake (ARfD=300 ng/(kg bw*d)) of T-2/HT-2 from the consumption of oat drinks by children aged 0.5 to <6 years according to the KiESEL study. Levels used: Mean: 397.2 ng/kg, maximum 2146.5 ng/kg.**

| | | Long-term exposure – Percentage of TDI | | | | Short-term exposure – Percentage of ARfD | |
|---|---|---|---|---|---|---|---|
| | Levels | Mean level | | Maximum level | | Maximum level | |
| Basis | Age group (years) | P50 consumption | P95 consumption | P50 consumption | P95 consumption | P50 consumption | P95 consumption |
| Oat drinks | All | 14% | 50% | 77% | 271% | 9% | 30% |
| | 0.5-<1 | 17% | 54% | 94% | 292% | 12% | 23% |
| | 1-<3 | 17% | 77% | 93% | 418% | 12% | 38% |
| | 3-<6 | 13% | 40% | 68% | 217% | 9% | 23% |

For the assessment of the health risks of **short-term exposure** to T-2/HT-2 from the consumption of oat drinks based on realistic scenarios, the BfR concludes that, for short-term consumption of oat drinks containing T-2/HT-2 at the levels determined by the MRI, the likelihood of health impairments in children aged 0.5 to <6 years is low.

However, for the assessment of the health risks from the intake of T-2/HT-2, it should furthermore be taken into account that oat drinks are not the only source for T-2/HT-2 intake, but that T-2/HT-2 can also be ingested from the consumption of other oat products, such as oat flakes. In a scenario in which all consumed oat products contain T-2/HT-2 at the maximum level of 100 µg/kg applicable from 1 July 2024, short-term consumption may result in an exceedance of the ARfD for children aged 1 to <6 years (154–371% of the ARfD). Possible additional intake of T-2/HT-2 from the consumption of oat drinks was not considered in this scenario.

Furthermore, for the assessment of the health risks of **long-term exposure** to T-2/HT-2 solely from the consumption of oat drinks based on realistic scenarios, the BfR concludes that, for long-term **average consumption** of oat drinks containing T-2/HT-2 at the **mean levels** determined by the MRI, the likelihood of health impairments in children aged 0.5 to <6 years is low.

In contrast, the percentage of the TDI solely by **long-term high consumption** of oat drinks containing T-2/HT-2 at the **mean levels** determined by the MRI is already 50% for children across all age groups (for children in the age group from 1 up to <3 years even 77% of the TDI). Also in this context, it should likewise be taken into account that oat drinks are not the

only source for T-2/HT-2, but that T-2/HT-2 can also be ingested from the consumption of other foods, in particular from the consumption of other oat products. In the opinion at hand, 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 could be considered realistic. The consumption of oat drinks as an alternative to cow's milk would therefore represent an additional source for T-2/HT-2 intake and thus increase both the overall exposure to T-2/HT-2 and the likelihood of health impairments.

The MRI was able to quantify T-2/HT-2 in the majority of the investigated oat drinks (29 out of 37 samples). The levels were on average 397.2 ng/kg with a maximum level of 2146.5 ng/kg. Due to the small number of samples analysed and the lack of comparative data from other monitoring programmes, the BfR is currently unable to assess the extent to which the data generated by the MRI on the occurrence of T-2/HT-2 in oat drinks are representative of the German market and thus of German consumers' exposure. The present risk characterisation indicates that, for children aged 1 to <6 years as a vulnerable consumer group, consuming oat drinks as an alternative to cow's milk may represent an additional source for T-2/HT-2 intake. The BfR therefore recommends that further data on the occurrence of T-2/HT-2 in oat drinks are generated.

### 3.3 Uncertainties

With its survey period from 2014 to 2017, the KiESEL study is the most up-to-date representative consumption study for children of this age group in Germany. However, changes in consumption behaviour since the survey period cannot be ruled out. This is particularly the case for the consumption amounts (not used for estimating) of plant-based drinks, as there have been significant changes to the market 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 with regard to the consumption of plant-based drinks have only a minor impact on the results of the exposure assessment, since it is plausible to assume that the consumption behaviour for cow's milk and for plant-based drinks will be similar.

It should additionally be taken into account that the exposure assessments and thus the subsequent risk characterisations are solely limited to mycotoxin intake from the consumption of the respective plant-based drinks and therefore overall exposure levels from the consumption of foods (as already explained in sections 3.4.1 and 3.4.3) could prove to be significantly higher.

It should moreover be noted that the toxicological reference values and health-based guidance values used for risk characterisation were not only derived for the mycotoxins AFB1, DON and T-2/HT-2 under consideration in the opinion at hand, but that they are each group values for the sum of mycotoxins (sum of aflatoxins B1, B2, G1 and G2; sum of DON and its modified forms 3-Ac-DON, 15-Ac-DON and DON-3-Glu; sum of the toxins T-2 and HT-2 and their modified forms). Exposure is thus underestimated, which in this case, however, should in the BfR's view have only a minor impact on the risk characterisation, since, according to the current state of knowledge, the mycotoxins not analysed by the MRI firstly

occur less frequently and at lower levels and secondly have a lower toxic potential than the analysed mycotoxins.

The data generated by the MRI in the course of the present project provide an initial indication of the occurrence of mycotoxins in plant-based drinks. The number of samples investigated is, however, too low for a representative data basis. Further data on the occurrence of mycotoxins in plant-based drinks from other monitoring programmes are not available and it is therefore not possible to contextualise the data generated by the MRI. The extent to which the data generated by the MRI are representative of the German market and thus of German consumers' exposure cannot currently be assessed by the BfR (due to the small number of samples analysed and the lack of comparative data from other monitoring programmes).

### 3.4 Risk management options, recommended measures

The BfR recommends that further data on the occurrence of mycotoxins in plant-based drinks are generated, in particular of aflatoxins in almond drinks and of T-2 and HT-2 toxins in oat drinks, in order to enable better assessment of German consumers' exposure from the consumption of plant-based drinks. Sufficiently sensitive analytical methods should be used for this purpose in order to obtain the highest possible percentage of quantifiable levels and so achieve a representative data basis for a more realistic exposure assessment.

## 4 References


EFSA (European Food Safety Authority) (2013) Scientific opinion on the risk for public and animal health related to the presence of sterigmatocystin in food and feed. EFSA Journal 2013; 11(6):3254; 81 pp.

EFSA (European Food Safety Authority) (2017a) Appropriateness to set a group health-based guidance value for T-2 and HT-2 toxin and its modified forms. EFSA Journal 2017; 15(1):4655; 53 pp.

EFSA (European Food Safety Authority) (2017b) Human and animal dietary exposure to T-2- and HT-2 toxin. EFSA Journal 2017; 15(8):4972; 57 pp.

EFSA (European Food Safety Authority) (2017c) Risks to human and animal health related to the presence of DON and its acetylated and modified forms in food and feed. EFSA Journal 2017; 15(9):4718; 345pp.

EFSA (European Food Safety Authority) (2020) Risk assessment of aflatoxins in food. EFSA Journal 2020; 18(3):6040; 112pp.

IARC (International Agency for Research on Cancer) (2012) Aflatoxins. Chemical Agents and Related Occupations. A review of Human Carcinogens. IARC monographs on the evaluation of carcinogenic risks to humans, 100F, 225-248.

Iverson F, Armstrong C, Nera E, Truelove J, Fernie S, Scott P, Stapley R, Hayward S and Gunner S (1995) Chronic feeding study of deoxynivalenol in B6C3F1 male and female mice. Teratogenesis, Carcinogenesis and Mutagenesis, 15, 283-306.

MRI (Max Rubner Institute) (2024) Initial characterisation of selected plant-based drinks with regard to their quality and to their microbiological and chemical safety [in German]. https://www.mri.bund.de/de/pflanzendrink-bericht

Luo XY, Li YW, Wen SF and Hu X (1987) Food poisoning caused by scabby wheat and the detection of Fusarium mycotoxins. Journal of Hygiene Research, 16, 33–37.

Nowak N, Diouf F, Golsong N, Höpfner T, Lindtner O (2022) KiESEL – The Children's Nutrition Survey to Record Food Consumption for the youngest in Germany. BMC Nutrition, 8 (1), 64. https://doi.org/10.1186/s40795-022-00527-6

Rahman S, Sharma AK, Singh ND, Telang AG, Azmi S, Prawez S (2014) Clinico-haematological changes in T-2 toxicosis in Wistar rats. Indian Journal of Veterinary Pathology, 38:22-28.

Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006. OJ L 119 of 5/5/2023, p. 103

Commission Regulation (EU) 2024/1038 of 9 April 2024 amending Regulation (EU) 2023/915 as regards maximum levels of T-2 and HT-2 toxins in food. OJ L of 10/4/2024

Wogan GN, Paglialunga S, Newberne PM (1974) Carcinogenic effects of low dietary levels of aflatoxin B1 in rats. Food and Cosmetics Toxicology, 12:681-685

Wu W, Zhou H, Bursian SJ, Link JE, Pestka JJ (2016) Emetic responses to T-2 toxin, HT-2 toxin and emetine correspond to plasma elevations of peptide YY3-36 and 5-hydroxytryptamine. Archives of Toxicology, 90:997-1007.

**About the BfR**

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety.
The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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

**Legal notice**

Publisher:
**German Federal Institute for Risk Assessment**
Max-Dohrn-Straße 8-10
10589 Berlin, Germany
T +49 30 18412-0
F +49 30 18412-99099
bfr@bfr.bund.de
bfr.bund.de/en

Institution under public law
Represented by the president Professor Dr Dr Dr h.c. Andreas Hensel
Supervisory Authority: Federal Ministry of Food and Agriculture
VAT ID No. DE 165 893 448
Responsible according to the German Press Law: Dr Suzan Fiack



**BfR** | Identifying Risks –
Protecting Health