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Assessment of health risks from ergot alkaloids in selected cereal products

Opinion No. 041/2023 of the BfR of 25 September 2023

Ergot alkaloids are constituents of ergot which can occur more frequently on grain ears and grasses in wet years. Ergot is a solid dark fungal growth - so-called sclerotia (*Secale cornutum*) - which is formed by the parasitic fungus *Claviceps spp.* Ergot alkaloids can enter flour via ergot if dark sclerotia are milled with grain. However, ergot alkaloids are undesirable in the food chain and their entry into food should therefore be kept as low as possible, as intake can lead to both short-term and long-term health effects. Short-term (acute) health effects include, for example, headaches, sensory disturbances in the limbs, hallucinations or convulsions. Possible long-term (chronic) effects are tissue damage, persistent muscle spasms and damage to the central nervous system with nausea, persistent headaches and psychosis.

As of January 1st in 2022, maximum levels for ergot alkaloids in milled products from cereals with a high or low degree of milling as well as in cereal grains, wheat gluten and processed cereal based food for infants and young children apply throughout Europe for the first time in accordance with Regulation (EU) 2021/1399. For two out of a total of five maximum level categories (rye and rye milling products as well as "light" milling products of wheat, spelt, oats and barley i.e. those with a low degree of milling), it is planned to reduce the currently applied maximum levels as of July 1st in 2024. In the present report, the German Federal Institute for Risk Assessment (BfR) has assessed to what extent the currently applied maximum levels and those that will be lowered in the future are suitable to prevent adverse health effects caused by ergot alkaloids for consumers in Germany.

Therefore, the hypothetical short-term intake of ergot alkaloids by children aged six months up to under six years via the consumption of various foods containing cereals was calculated first. Children of this age consume the highest amounts of cereals in relation to their comparatively low body weight and thus represent the most sensitive consumer group. For the calculation of the short-term intake, it was assumed that all foods consumed that can be assigned to the five maximum level categories have contents in the amount of the respective currently applied maximum levels. In a second step, BfR calculated to which extent the planned reduction of the regulatory maximum levels of ergot alkaloids in individual cereal milling products would affect these hypothetical intake levels. In addition, the intake resulting from available occurrence data on ergot alkaloids in food from official control laboratories was calculated.

An acute reference dose (ARfD) of 1 microgram per kilogram body weight and day (1 µg/kg b.w. and day) which was derived in 2012 as part of an opinion by the European Food Safety Authority (EFSA) was used for the assessment of short-term intake. The ARfD indicates the estimated maximum amount of ergot alkaloids that can be ingested daily without an identifiable health risk.

As a result, the BfR concluded that - on the basis of the hypothetical short-term intake of ergot alkaloids via rye products described above - adverse health effects may occur for children of all age groups considered if the respective foodstuffs contain ergot alkaloid levels at the

currently applicable or discussed maximum levels. Furthermore, adverse health effects due to ergot alkaloids uptake can occur in children aged one to under six years through the short-term consumption of products made from "light" flours and in children aged one to under three years through that of "dark" flours and wholemeal products, each based on wheat, spelt, barley or oats. Accordingly, BfR welcomes the planned reduction of the ergot alkaloid maximum levels for low-milled ("light") products made from barley, wheat, spelt and oats as well as for rye milling products. In addition, BfR recommends to investigate whether a reduction of the maximum levels for highly milled products ("dark flours" and "wholemeal") from barley, wheat, spelt and oats is possible.

In a supplement to the present report, BfR has calculated the empirical ("actual") ergot alkaloid intake of children aged six months to under six years instead of a hypothetical intake. For this purpose, the measured ergot alkaloid occurrence data from the laboratories of the official monitoring of the federal states from the years 2013-2021 were used instead of the currently applicable or planned lowered maximum levels to estimate the short-term intake. For the assessment of short-term intake, the ARfD was again used, and for the assessment of the probability of health effects after long-term intake of ergot alkaloids, the Tolerable Daily Intake (TDI) was used. This was also derived by EFSA in the 2012 opinion. The TDI indicates the amount of a substance that can be ingested daily over a lifetime without a recognisable health risk.

As a result, BfR concluded that, based on the empirical short-term intake of ergot alkaloids via rye products described above, adverse health effects may occur in children of all age groups considered. On the basis of the available ergot alkaloid content data, the BfR classifies the probability of the occurrence of health effects due to the long-term intake of ergot alkaloids via the consumption of rye products as low. For the other four product groups, the BfR is currently unable to conclusively assess whether short- and/or long-term health effects can occur in children through the consumption of the respective products due to an insufficient database on ergot alkaloid levels in oats, processed cereal based food for infants and young children and wheat gluten.

1 Subject of the assessment

The German Federal Institute for Risk Assessment (BfR) has updated the risk assessment on ergot alkaloids in food and also assessed to which extent the maximum permissible levels envisaged from 1 July 2024 are suitable for avoiding health risks for the population in Germany.

2 Results

The present opinion refers to the currently applied as well as the planned lowered maximum levels for ergot alkaloids (EAs) according to the Annex of Regulation (EU) 2021/1399.

The hypothetical short-term exposure of children aged between 0.5 and < 6 years to EAs through consumption of the products was calculated in accordance with the Annex of Regulation (EU) 2021/1399 in order to assess to which extent the maximum permissible levels envisaged from 1 July 2024 are suitable for minimising health risks for the population

in Germany. The short-term approach is shown to be suitable for the assessment of the maximum levels as more realistic estimates are achieved by using the maximum levels in the short-term exposure scenario and the conservative estimate in the long-term scenario is also covered.

The acute reference dose (ARfD) of 1 µg/kg body weight and day which was derived in 2012 in an opinion of the European Food Safety Authority (EFSA, 2012) was used for the assessment of acute effects from EAs after a single or short-term intake. This specifies the estimated maximum quantity of a substance that can be consumed with food in the course of one day either during one meal or during several meals - without a detectable risk to health.

To answer the present question, only data for 0.5 to <6-year-old children were used, as this consumer group usually consumes more in relation to their body weight than older children, adolescents and adults. Therefore, they represent the most sensitive group.

Rye and milled rye products as well as wheat (incl. spelt) and oats represent the largest contributors to exposure due to consumption of the products listed in the Annex of Regulation (EU) 2021/1399 by 0.5 to < 6-year-old children.

The exposure of all age groups considered is 7 to 15% of the ARfD looking at the product groups wheat gluten (2.9.2.4) and processed cereal based food for infants and young children (2.9.2.5).

In addition, the ARfD is not exceeded in the product group milled products of barley, wheat, spelt and oats (with an ash content of at least 900mg/100g) and barley, wheat, spelt and oat grains placed on the market for the final consumer (2.9.2.2) by children aged 0.5 to < 1 year and 3 to < 6 years, and in the product group milled barley, wheat, spelt and oat grains (with an ash content of less than 900mg/100g) (2.9.2.1) by 0.5 to < 1-year-old children.

Therefore, BfR concludes that the probability of occurrence of adverse health effects is to be classified as low in these hypothetical short-term exposure scenarios using the currently applied maximum levels.

In contrast, children of all age groups exceed the ARfD (between 193 and 334% of the ARfD) through the consumption of rye and rye milling products, if the products have EA levels at the level of the currently applied maximum level.

Also, when considering the product group of milling products with a low degree of milling (2.9.2.1), the exposure of 1 to < 3-year-old and 3 to < 6-year-old children exceed the ARfD (153 and 142% of the ARfD, respectively).

When considering the product group of milling products with a high degree of milling (2.9.2.2), for which no reduction of the currently applied maximum level is planned, the ARfD is exceeded by the exposure of the age group of 1 to < 3-year-olds (159% of the ARfD).

Therefore, BfR concludes that for these hypothetical short-term exposure scenarios with the currently applied maximum levels impairments to health can occur for the respective age groups with medium likelihood.

BfR welcomes the planned reduction of the maximum levels for EAs in milling products with a low degree of milling (2.9.2.1) as well as for rye and rye milling products (2.9.2.3) as the planned halving of the maximum level for the first-mentioned product group would result in a reduction of the EA exposure below the ARfD for all age groups considered. BfR recommends to support initiatives to further reduce maximum levels within the EU.

However, BfR points out that the exposure of the age groups of 0.5 to < 1-year-olds and of 1 to < 3-year-old children continues to exceed the ARfD (159 and 167% of the ARfD, respectively) even after the planned reduction of the currently applied maximum level for rye and rye milling products (2.9.2.3). Thus, there would still be a medium likelihood with regard to the occurrence of adverse health effects for these age groups in this exposure scenario.

Furthermore, BfR recommends examining whether a reduction of the maximum level for the product group of milling products with a high degree of milling (2.9.2.2) is possible. For these, no reduction of the currently applied maximum level of 150 µg/kg is planned at present, but the exposure exceeds the ARfD in the age group of 1 to < 3-year-olds (159% of the ARfD).

3 Rationale

3.1 Risk assessment

3.1.1 Hazard identification

Description of agent and food matrix

Ergot alkaloids (EAs) are formed by all fungal species of the genus *Claviceps*. These are tubular fungi belonging to the order *Hypocreales*, although tubular fungi of the order *Eurotiales* also form EAs. Dark, sickle-shaped sclerotia characteristic of infection with fungi of the genus *Claviceps* become visible in the ears about three to four weeks after infection of the plant, where they appear instead of grains (EFSA, 2012). Sclerotia, also known as ergot sclerotia, are the overwintering structure of the fungi, whose composition and content of different EAs depends on both the host plant and the fungus strain predominant in the region concerned (EFSA, 2005).

In Europe, the fungal species *Claviceps purpurea* is the most widespread and infects mainly grasses (*Poaceae*) including nutritionally important cereals such as rye, wheat, barley and oats (EFSA, 2012). Compared to other cereals, rye has the highest EA levels (EFSA, 2017). Therefore, rye products have been subject of several BfR opinions.^{1,2} EAs mainly formed by *Claviceps purpurea* are ergometrin, ergotamine, ergocornine, ergosine, ergocristine, ergocryptine (α- and β-form) and corresponding epimers ergometrinine, ergotaminine,

¹ https://www.bfr.bund.de/cm/343/mutterkornalkaloide_in Roggenmehl.pdf (in German)

² <https://www.bfr.bund.de/cm/343/einzelfall-bewertung-von-ergotalkaloid-gehalten-in-roggenmehl-und-roggenbrot.pdf> (in German)

ergocorninine, ergosinine, ergocristinine, α -ergocryptinine and β -ergocryptinine (EFSA, 2012).

Within the European Union, only maximum levels for ergot sclerotia in unprocessed cereals other than maize and rice applied until the end of 2021 according to Regulation (EC) No 1881/2006 (EC, 2006). Since 1 January 2022, in accordance with Regulation (EU) 2021/1399, additional maximum levels apply for the sum of the twelve above-mentioned EAs in milled products from cereals and in cereal grains placed on the market for the final consumer. The maximum levels for the sum of EAs are justified by the fact that the presence of EAs in food cannot be ruled out due to the absence of sclerotia, as they can also enter the food chain via fragments or dusts of sclerotia produced during transport, storage and processing of the cereals (EFSA, 2017). The required data basis is based on the Commission Recommendation of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food (EU, 2012).

As of 1 July 2024, a reduction of the maximum level for EAs in milling products from barley, wheat, spelt and oats (with an ash content of less than 900mg/100g) from 100 μ g/kg to 50 μ g/kg is planned according to Regulation (EU) 2021/1399. By the same date, the maximum level for EAs in rye milling products as well as in rye grains placed on the market for the final consumer is also to be reduced from 500 μ g/kg to 250 μ g/kg. For EAs in milling products made from barley, wheat, spelt and oats (with an ash content of at least 900mg/100g) as well as in barley, wheat, spelt and oat grains placed on the market for the final consumer, a maximum level of 150 μ g/kg was set, which is also to apply unchanged beyond 1 July 2024 (EU, 2021).

3.1.2 Hazard characterisation

The aim of this opinion is to assess to what extent the permissible maximum levels envisaged from 1 July 2024 are suitable for avoiding health risks for the population in Germany.

The toxicity mediated by EAs is based on their tetracyclic ergoline ring structure. Thus, EAs function as ligands for adrenergic, serotonergic and dopaminergic receptors in particular and, depending on their structure, can act agonistically and partially agonistically as well as antagonistically. Further influencing factors with regard to the toxicity of EAs are the respective receptor types present in the target tissue as well as the receptor distribution. Due to the rapid epimerisation, both the *8S*-epimers (suffix: "-inine") and the *8R*-epimers (suffix: "-ine") have a relevant toxicological potential, although only the *8R*-epimers are biologically active (EFSA, 2012).

The influence of EAs on mentioned neurotransmitter receptors can lead to both short-term and long-term neurotoxic effects. An animal study observed signs of neurotoxicity such as muscle weakness, mydriasis and tremor after a single administration of sublethal doses of EAs. Repeated administration of ergotamine, ergometrine or α -ergocryptine to rats resulted in weight gain, altered hormonal status and ischaemia, predominantly in the extremities.

Thereby, the respective toxins hardly differed with regard to their toxic potential. Furthermore, it was shown that at higher doses reproductive toxic effects occurred in rodents. There is no evidence that EAs induce genotoxic or mutagenic effects (EFSA, 2012).

In 2012, the European Food Safety Authority (EFSA) published an opinion on EAs in food and feed. In this opinion, the Scientific Panel on Contaminants in the Food Chain (CONTAM) applied a threshold-based approach to risk assessment as there was no evidence of carcinogenicity and considered both acute and chronic effects of exposure to EAs.

For this purpose, a 13-week feeding study with ergotamine in rats was identified as critical study (Speijers *et al.*, 1993) and a BMDL₁₀ (benchmark dose lower confidence limit 10%) of 0.33 mg/kg body weight (b.w.) and day was derived as a reference point for the occurrence of tail muscle atrophy due to vasoconstriction as the most sensitive endpoint.

For the assessment of acute effects, an acute reference dose (ARfD) of 1 µg/kg b.w. and day was derived using an uncertainty factor of 300, which takes into account interspecific and intraspecific differences as well as uncertainties due to incomplete toxicological data. With regard to the assessment of chronic toxicity, an additional uncertainty factor of 2 was applied to account for the fact that the underlying reference point was derived from a subchronic rather than a chronic study. This results in a tolerable daily intake (TDI) for the sum of the 12 EAs mentioned above of 0.6 µg/kg b.w. and day.

3.1.3 Exposure assessment

3.1.3.1 Data basis for food consumption

In order to update the VELS study (Food consumption survey to determine food intake by infants and small children for the estimation of the acute toxicity risk from pesticide residues, „*Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln*“), the BfR conducted the KiESEL study („Children's Nutrition Survey to Record Food Consumption“, „*Kinder-Ernährungsstudie zur Erfassung des Lebensmittelverzehrs*“). The study was linked as a module to the "Study on the Health of Children and Adolescents in Germany" ("KiGGS Wave 2") of the Robert-Koch Institute (Mauz *et al.*, 2017).

A total of 1,104 children between the ages of six months and including five years participated in KiESEL. The survey was performed between 2014 and 2017. Based on an interview, the legal 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 also participated in the dietary survey in which food consumption was recorded by a weighing or estimation record on three consecutive days plus one independent day. In addition, out-of-home consumption (e.g. in day care facilities) was recorded using a reduced estimation record (Nowak *et al.*, 2022). The results from the weighing records were used for the evaluation.

For answering the present question, data from the disaggregation food consumption of the consumption model for exposure estimation for plant protection products could be used, which disaggregated all consumed food items into its raw agricultural commodities (RAC) based on the recipes. In order to take into account all sources of the products named in Regulation (EU) 2021/1399, an additional grouping into the products named therein was made, as described below:

- The product group "2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)" was assigned to all consumption items of the cereals mentioned, provided the flour type <900 was indicated or the products were semolina or pearl barley.
- The product group "2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) and barley, wheat, spelt and oat grains placed on the market for the final consumer" was assigned to grains, groats, meal, bran, flour type >900, wholemeal flour and flakes.
- The product group "2.9.2.3 Rye milling products and rye placed on the market for the final consumer" includes all rye consumed.
- All items containing wheat gluten as an ingredient (e.g. as an ingredient in meat substitutes or in soups and sauces) were assigned to the product group "2.9.2.4 Wheat gluten".
- According to Directive 2006/125/EC, the product group "2.9.2.5 Processed cereal-based food for infants and young children" included cereal porridges, milk porridges, mueslis, pasta, rusks and biscuits with a cereal content of at least 25%. All products labelled for children (e.g. "children's muesli"), with an age indication (e.g. "from the 8th month") or which were directly targeting children due to their presentation were included. The selection referred only to products containing the cereals regulated in Regulation (EU) 2021/1399. Cereal and milk porridges that were documented in the food records as reconstituted food were converted back to the powder using standard factors.

Basically, there is uncertainty about the definition of "milling products" and whether they include all products up to "grains placed on the market for final consumers" (e.g. puffed cereals in mueslis). For the present question, all products were included in order to avoid underestimation. As the RAC data refers to the quantity of the original agricultural product used (e.g. 1.24 g of wheat grains are used to produce 1 g of wheat flour type 812), the consumption of the product groups mentioned in Regulation (EU) 2021/1399 would be overestimated. Therefore, factors were applied to minimise this overestimation. In a conservative approach, the lowest conversion factor from each product group was identified and applied to the consumption. This approach applies to the product groups "milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)" (factor 1.24) and "wheat gluten" (factor 10.53). The other cereal groups include cereal grains, which is why the conversion factor 1 was applied. "Cereal based foods" are not affected, as no evaluation was carried out for them at RAC level.

For the present question, only data for children were used. The reason for this is that children usually consume more than adults in relation to their b.w. and therefore represent the most sensitive group with regard to the occurrence of possible health effects. It can therefore be assumed that consumption and exposure cover the values of adults.

Table 1 shows this based on the consumption of barley, oats, rye and wheat (incl. spelt). RAC consumption data from the KiESEL study for children (0.5 to < 6 years) (incl. disaggregation of cereal porridges) are compared with RAC data from the National Nutrition Survey II (NVS II) for adolescents and adults (14 - 80 years). For the latter, RAC data from the "BfR model for pesticide residue intake calculations" were used for comparison ("pesticide model") (BfR, 2011).

With the exception of barley, children consume larger amounts of the respective products compared to adults. The higher consumption of barley by adults is mainly due to beer, which is not a relevant source of ergot alkaloids (EFSA, 2017).

Table 1: Long-term consumption [g/kg b.w. and day] of cereals by children (non-breastfed) from 0.5 to < 6 years of age according to the KiESEL study and by adolescents and adults from 14 - 80 years of age according to the NVS II ("pesticide model") (consumers only).

Product	KiESEL	NVS II
Barley	0.1	0.5
Oats	0.5	0.1
Rye	0.8	0.6
Wheat (incl. spelt)	6.3	1.9*

*excl. green spelt and spelt (0.01 g/kg b.w. and day)

3.1.3.2 Data on the short-term consumption by children of the products listed in the Annex of Regulation (EU) 2021/1399

The calculation of short-term consumption was based on the 95th percentile (P95) of the individual highest quantity consumed on a single day over the entire survey period. The consumption is given in g per kg b.w. and day. The reference to the b.w. is based on the individual b.w. of the children.

(Partially) breastfed children were excluded from the evaluation, leaving a total of 952 children in the evaluation. These were divided into three age groups and evaluated accordingly: 0.5 to < 1 year, 1 to < 3 years and 3 to < 6 years.

Table 2 shows the short-term consumption by children of products listed in the Annex of Regulation (EU) 2021/1399. In principle, all children consume at least one of the regulated products. In all product groups, the proportion of consumers increases with age. One exception is processed cereal based food for infants and young children which - as expected - are consumed to a lesser extent with increasing age. This fact, as well as partly significant

age-dependent differences in the consumption quantities, illustrate the necessity of differentiating between age groups when assessing consumption and exposure.

Children between 1 and < 3 years have the highest short-term consumption for the groups of milling products with a low degree of milling (ash content <900mg/100g) (2.9.2.1), ground products with a high degree of milling (ash content >900mg/100g) (2.9.2.2) and wheat gluten (2.9.2.4). As expected, children between 0.5 and < 1 year have the highest short-term consumption in the group processed cereal based food for infants and young children (2.9.2.5). This age group also has a slightly higher consumption for rye and rye milling products (2.9.2.3) than the age group of 1 to < 3 years.

For all age groups, the highest consumption is found in the group of milling products with a low degree of milling (ash content <900mg/100g). After that, the order of the products with the next highest consumption is distributed differently among the age groups. Thus, for 0.5 to < 1-year-olds, processed cereal based food for infants and young children follow, for 1 to < 3-year-olds, milling products with a high degree of milling (ash content >900mg/100g) and for 3 to < 6-year-olds, rye and rye milling products.

Table 2: Short-term consumption [g/kg b.w. and day] by children from 0.5 to < 6 years of age according to the KiESEL study for products listed in the Annex to Regulation (EU) 2021/1399 (only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumers	Short-term consumption
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	48 (84%)	9,9
	1 to < 3	308 (100%)	15.3
	3 to < 6	588 (100%)	14.2
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	40 (70%)	4.6
	1 to < 3	261 (85%)	10.6
	3 to < 6	510 (87%)	6.1
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	37 (64%)	6.7
	1 to < 3	256 (83%)	6.4
	3 to < 6	515 (88%)	3.9
2.9.2.4 Wheat gluten	0.5 to < 1	8 (14%)	0.2
	1 to < 3	133 (43%)	0.3
	3 to < 6	269 (46%)	0.2
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	38 (67%)	7.3
	1 to < 3	91 (30%)	4.8
	3 to < 6	32 (5%)	3.6

* N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

3.1.3.3 Data on long-term consumption by children of the products listed in the Annex of Regulation (EU) 2021/1399

For the derivation of long-term consumption, the mean individual consumption over the survey period was calculated. The median (P50) represents average consumers. The P95

represents high consumers. The consumption is given in g per kg b.w. and day. The reference to the b.w. is based on the individual b.w. of the children.

(Partially) breastfed children were excluded from the evaluation, so that a total of 952 children were included in the evaluation. These were divided into three age groups and evaluated accordingly: 0.5 to < 1 year, 1 to < 3 years and 3 to < 6 years.

Table 3 shows the long-term consumption by children of the products listed in the Annex of Regulation (EU) 2021/1399. Also in the long-term, 1 to < 3-year-old children consume the highest amounts of the listed products compared to the other age groups. In contrast to short-term consumption, this is also true for rye and milled rye products (2.9.2.3). An exception is processed cereal based food for infants and young children (2.9.2.5), which - as expected - is consumed most by the 0.5 to < 1-year-old children.

The product group with by far the highest long-term consumption is milling products with a low degree of milling (ash content <900mg/100g). Remarkably, the difference between average and high consumers in this product group is much less pronounced compared to the other product groups: For example, the consumption of products of group 2.9.2.2 by 1 to < 3-year-old high consumers is seven times higher than that of average consumers in this age group. This suggests a degree of brand or sort loyalty among consumers of rye and wholemeal products. This means that there are particular consumer groups who regularly consume larger quantities of these products, which can potentially have higher EA levels. This difference between average and high consumers can also be observed in the group of processed cereal based food for infants and young children. This can be explained in the older children by a preference for biscuits and rusks. In the 0.5 to < 1-year-old age group, the children who almost exclusively eat cereal and milk porridge probably may cause these high consumption amounts.

Table 3: Long-term consumption [g/kg b.w. and day] by children from 0.5 to < 6 years of age according to the KiESEL study for products listed in the Annex of Regulation (EU) 2021/1399 (only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumers	Long-term consumption	
			P50*	P95*
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	48 (84%)	2.0	5.1
	1 to < 3	308 (100%)	4.2	9.6
	3 to < 6	588 (100%)	4.4	7.9
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	40 (70%)	0.5	2.9
	1 to < 3	261 (85%)	0.8	5.6
	3 to < 6	510 (87%)	0.5	3.8
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	37 (64%)	0.6	3.1
	1 to < 3	256 (83%)	0.7	3.7
	3 to < 6	515 (88%)	0.6	2.1
2.9.2.4 Wheat gluten	0.5 to < 1	8 (14%)	<0.1	0.1
	1 to < 3	133 (43%)	<0.1	0.1
	3 to < 6	269 (46%)	<0.1	0.1

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumers	Long-term consumption	
			P50*	P95*
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	38 (67%)	2.9	6.9
	1 to < 3	91 (30%)	0.8	4.2
	3 to < 6	32 (5%)	0.6	2.2

* P50 (median): Average consumers; P95: High consumers

** N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

3.1.3.4 Hypothetical assessment of the short-term exposure of EAs via the consumption of the products listed in the Annex of Regulation (EU) 2021/1399

For the hypothetical estimation of short-term exposure, the currently applied maximum levels and the lowered maximum levels envisaged from 1 July 2024 were linked at individual level to the consumption of the respective products within a maximum level category in two scenarios. Subsequently the day of maximum exposure per individual was determined. The P95 over the days of maximum exposure represents the short-term intake of EAs. The exposure is given in μg per kg b.w. and day.

Since the total intake of a substance is the sum of all contributions via the diet, the hypothetical exposure over all considered product groups ("total exposure") was considered in an additional scenario. First, the exposure per individual and day was determined for each product and then summed up. The hypothetical short-term total exposure results from the P95 of the individual days with the maximum exposure.

Table 4 shows the hypothetical short-term exposure for children based on the consumption levels for foods regulated in the Annex of Regulation (EU) 2021/1399 and using levels of these foods at currently applied or planned maximum levels. "Current maximum levels" represents the scenario based on the currently applied maximum levels. "Maximum levels from 2024" represents the exposure based on the planned maximum levels from 1 July 2024. If the currently applied maximum levels are used as a basis, children's intake range between $2.9 \mu\text{g}/\text{kg}$ b.w. and $3.9 \mu\text{g}/\text{kg}$ b.w. of EAs in the short-term, when calculating the intake across all products ("total exposure"). Corresponding to the comparatively high short-term intake, children aged 1 to < 3 years have the highest short-term exposure, with the exception of rye and rye milling products (2.9.2.3) and processed cereal based food for infants and young children (2.9.2.5). In all age groups, rye products have the highest contribution to exposure, followed by milling products with a low degree of milling (ash content

<900mg/100g). In line with the planned halving of the respective maximum levels for milling products with a low degree of milling (ash content <900mg/100g) and rye and rye milling products (2.9.2.3), the exposure for these products would also be reduced by 50%. Calculated over all products (“total exposure”), the reduction in the maximum level reduces the short-term exposure by approx. 38% (3 to < 6-year-olds) to 49% (0.5 to < 1-year-olds).

Table 4: Hypothetical short-term exposure [µg/kg b.w. and day] of children aged 0.5 to < 6 years to EAs via products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KIESEL study, consumers only, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Short-term exposure	
		Current maximum levels	Maximum levels from 2024
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	1.0	0.5
	1 to < 3	1.5	0.8
	3 to < 6	1.4	0.7
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	0.7	
	1 to < 3	1.6	
	3 to < 6	0.9	
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	3.3	1.7
	1 to < 3	3.2	1.6
	3 to < 6	1.9	1.0
2.9.2.4	0.5 to < 1	0.1	

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Short-term exposure	
		Current maximum levels	Maximum levels from 2024
Wheat gluten	1 to < 3	0.1	
	3 to < 6	0.1	
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	0.1	
	1 to < 3	0.1	
	3 to < 6	0.1	
Total exposure**	0.5 to < 1	3.5	1.8
	1 to < 3	3.9	2.4
	3 to < 6	2.9	1.8

* N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

** Scenario where exposure has been estimated over all categories listed in the Annex of Regulation (EU) 2021/1399.

It should be noted that due to the joint grouping of oats and barley with wheat in product groups 2.9.2.1 and 2.9.2.2, the comparatively high consumption of oats as well as the comparatively lower consumption of barley are also included with the same maximum levels in the hypothetical exposure estimate. Accordingly, Table 5 shows the short-term consumption and short-term exposure of 0.5 to < 6-year-old children for the product groups 2.9.2.1 and 2.9.2.2 separately for the respective cereal types.

The short-term consumption of oats in the product group 2.9.2.2, milling products with a high degree of milling (ash content >900mg/100g) is 11.0 g/kg b.w. for 1 to < 3-year-olds. Wheat (incl. spelt) is consumed by the same age group only in an amount of 7.4 g/kg b.w. Barley,

on the other hand, is only consumed by 1 to < 3-year-olds in the short-term in an amount of 1.0 g/kg b.w.

In product group 2.9.2.1 Milling products with a low degree of milling (ash content <900mg/100g), wheat (incl. spelt) is consumed most in all age groups considered and thus contributes most to the exposure in the maximum level scenarios. In the product group 2.9.2.2 Milling products with high degree of milling (ash content >900mg/100g), on the other hand, oats make the largest contribution to exposure in accordance with the higher consumption (with the exception of the 3 to < 6-year-olds, who ingest EAs mostly via wheat (incl. spelt)).

Table 5: Short-term consumption [g/kg b.w. and day] and hypothetical short-term exposure [µg/kg b.w. and day] of children aged 0.5 to < 6 years to EAs via products from product groups 2.9.2.1 and 2.9.2.2 according to the Annex of Regulation (EU) 2021/1399 separated by cereal type (consumption data: KiESEL study, only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumer	Short-term Consumption	Short-term exposure	
				Current maximum levels	Maximum levels from 2024
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)					
Barley	0.5 to < 1	10 (18%)	0.6	0.06	0.03
Barley	1 to < 3	170 (55%)	0.1	0.01	0.01
Barley	3 to < 6	331 (56%)	0.6	0.06	0.03

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumer	Short-term Consumption	Short-term exposure	
				Current maximum levels	Maximum levels from 2024
Oats	0.5 to < 1	0.3 ** (1%)	1.7	0.17	0.09
Oats	1 to < 3	8 (3%)	2.4	0.24	0.12
Oats	3 to < 6	18 (3%)	1.9	0.19	0.10
Wheat (incl. spelt)	0.5 to < 1	48 (84%)	9.9	0.99	0.49
Wheat (incl. spelt)	1 to < 3	308 (100%)	15.3	1.53	0.76
Wheat (incl. spelt)	3 to < 6	588 (100%)	14.2	1.42	0.71
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer					

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Number (percentage) consumer	Short-term Consumption	Short-term exposure	
				Current maximum levels	Maximum levels from 2024
Barley	0.5 to < 1	0.4 ** (1%)	0.6	0.09	
Barley	1 to < 3	81 (26%)	1.0	0.15	
Barley	3 to < 6	132 (22%)	0.8	0.12	
Oats	0.5 to < 1	25 (43%)	4.2	0.63	
Oats	1 to < 3	189 (61%)	11.0	1.65	
Oats	3 to < 6	324 (55%)	4.5	0.68	
Wheat (incl. spelt)	0.5 to < 1	38 (67%)	4.1	0.62	
Wheat (incl. spelt)	1 to < 3	233 (75%)	7.4	1.11	
Wheat (incl. spelt)	3 to < 6	466 (79%)	6.0	0.90	

* N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

** Decimal places in the number of individuals results from the application of weighing factors

3.1.3.5 Hypothetical assessment of the long-term exposure of EAs via consumption of the products listed in the Annex of Regulation (EU) 2021/1399

For the hypothetical estimation of long-term exposure, the currently applied maximum levels as well as the lowered maximum levels foreseen from 1 July 2024 were linked in two scenarios at the individual level with the consumption of the foods of the respective maximum level categories. The resulting exposure was averaged over the survey period per individual. The exposure for average consumers is represented by the median (P50). The P95 represents the exposure for high consumers. The exposure is given in μg per kg b.w. and day.

Since the total intake of a substance is the sum of all contributions via the diet, the hypothetical exposure over all considered product groups ("total exposure") was considered in an additional scenario. For the long-term total exposure, the exposure per individual was averaged over the survey period. The median and the P95 of the average individual exposure result in the total exposure over all products for average and high consumers.

Table 6 shows the long-term exposure for children after linking the maximum levels set in the Annex of Regulation (EU) 2021/1399 to consumption. Analogous to the short-term exposure, one scenario based on the currently applied maximum levels ("Current maximum levels") and one showing exposure based on the maximum levels planned from 1 July 2024 ("Maximum levels from 2024") are shown. If the exposure is considered by age group, the age group of 1 to < 3-years-old shows the highest exposure according to consumption. Again, processed cereal based food for infants and young children (2.9.2.5) is an exception, as 0.5 to < 1-year-olds have a higher exposure due to the higher consumption. Considered by product group, average and high consumers show the highest EA intake in both maximum level scenarios via rye and rye milling products (2.9.2.3) and milling products with a low degree of milling (ash content <900mg/100g). If the exposure to EAs is determined for all regulated products in total ("total exposure"), average consumers consume between 0.5 μg and 0.9 μg EAs per kg b.w. per day based on the currently applied maximum levels. High consumers are exposed to between 1.8 $\mu\text{g}/\text{kg}$ b.w. and 2.9 $\mu\text{g}/\text{kg}$ b.w. per day. If the maximum levels are reduced, the exposure for average consumers is reduced by about 20% to 44% and for high consumers by about 39% to 41%.

Table 6: Hypothetical long-term exposure [$\mu\text{g}/\text{kg}$ b.w. and day] of children aged 0.5 to < 6 years to EAs via products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study, consumers only, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Long-term exposure			
		Current maximum levels		Maximum levels from 2024	
		P50*	P95*	P50*	P95*
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	0.2	0.5	0.1	0,3
	1 to < 3	0.4	1.0	0.2	0,5
	3 to < 6	0.4	0.8	0.2	0,4
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	0.1	0.4	0.1	0,4
	1 to < 3	0.1	0.8	0.1	0,8
	3 to < 6	0.1	0.6	0,1	0,6
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	0.3	1.5	0,2	0,8
	1 to < 3	0.4	1.9	0,2	0,9
	3 to < 6	0.3	1.1	0,2	0,5
2.9.2.4 Wheat gluten	0.5 to < 1	<0.1	<0.1	<0,1	<0,1
	1 to < 3	<0.1	0.1	<0,1	0,1
	3 to < 6	<0.1	<0.1	<0.1	<0.1

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Long-term exposure			
		Current maximum levels		Maximum levels from 2024	
		P50*	P95*	P50*	P95*
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	0.1	0.1	0.1	0.1
	1 to < 3	<0.1	0.1	<0.1	0.1
	3 to < 6	<0.1	<0.1	<0.1	<0.1
Total exposure**	0.5 to < 1	0.5	1.8	0.4	1.0
	1 to < 3	0.9	2.9	0.6	1.7
	3 to < 6	0.9	1.8	0.5	1.1

* P50 (median): Average consumers; P95: High consumers

** N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

*** Scenario where exposure has been estimated over all categories listed in the Annex to of Regulation (EU) 2021/1399. Annex of Regulation

As already described for the short-term exposure (cf. section 3.1.3.4), the joint grouping of potentially less contaminated cereals can also lead to an overestimation in this case. Table 7 shows, for example, that besides wheat, oats in particular are contributing to high amounts to long-term consumption and thus to exposure. In contrast, barley has a very small contribution to the total exposure due to its comparatively low consumption by children.

Table 7: Long-term consumption [g/kg b.w. and day] and hypothetical long-term exposure [$\mu\text{g}/\text{kg}$ b.w. per day] of children aged 0.5 to < 6 years to EAs via products from product groups 2.9.2.1 and 2.9.2.2 according to the Annex of Regulation (EU) 2021/1399 separated by cereal type (consumption data: KiESEL study, only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Number (percentage) consumers	Long-term consumption		Long-term exposure			
					Current maximum levels		Maximum levels from 2024	
			P50*	P95*	P50*	P95*	P50*	P95*
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)								
Barley	0.5 to < 1	10 (18%)	<0,01	0,14	<0,01	0,01	<0,01	0,01
Barley	1 to < 3	170 (55%)	<0,01	0,04	<0,01	<0,01	<0,01	<0,01
Barley	3 to < 6	331 (56%)	0,01	0,27	<0,01	0,03	<0,01	0,01
Oats	0.5 to < 1	0.3 *** (1%)	0,44	0,44	0,04	0,04	0,02	0,02
Oats	1 to < 3	8 (3%)	0,96	1,39	0,10	0,14	0,05	0,07

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Number (percentage) consumers	Long-term consumption		Long-term exposure			
					Current maximum levels		Maximum levels from 2024	
			P50*	P95*	P50*	P95*	P50*	P95*
Oats	3 to < 6	18 (3%)	0.62	1.54	0.06	0.15	0.03	0.08
Wheat (incl. spelt)	0.5 to < 1	48 (84%)	1.97	5.11	0.20	0.51	0.10	0.26
Wheat (incl. spelt)	1 to < 3	308 (100%)	4.16	9.43	0.42	0.94	0.21	0.47
Wheat (incl. spelt)	3 to < 6	588 (100%)	4.31	7.76	0.43	0.78	0.22	0.39
2.9.2.2								
Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer								
Barley	0.5 to < 1	0.4 *** (1%)	0.14	0.14	0.02	0.02	0.02	0.02
Barley	1 to < 3	81 (26%)	0.07	0.81	0.01	0.12	0.01	0.12

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Number (percentage) consumers	Long-term consumption		Long-term exposure			
					Current maximum levels		Maximum levels from 2024	
			P50*	P95*	P50*	P95*	P50*	P95*
Barley	3 to < 6	132 (22%)	0.04	0.39	0.01	0.06	0.01	0.06
Oats	0.5 to < 1	25 (43%)	0.30	2.03	0.04	0.30	0.04	0.30
Oats	1 to < 3	189 (61%)	0.33	3.74	0.05	0.56	0.05	0.56
Oats	3 to < 6	324 (55%)	0.22	2.85	0.03	0.43	0.03	0.43
Wheat (incl. spelt)	0.5 to < 1	38 (67%)	0.39	1.51	0.06	0.23	0.06	0.23
Wheat (incl. spelt)	1 to < 3	233 (75%)	0.49	2.94	0.07	0.44	0.07	0.44
Wheat (incl. spelt)	3 to < 6	466 (79%)	0.36	2.54	0.05	0.38	0.05	0.38

* P50 (median): Average consumers; P95: High consumers

** N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

*** Decimal places in the number of individuals results from the application of weighing factors

3.1.3.6 Uncertainties in exposure assessment

Due to the availability of consumption data on several single days, the KiESEL data are suitable for exposure assessment for acute as well as chronic health risks. Nevertheless, the use of a few single-day measurements for the calculation of a lifetime intake is associated with uncertainties. These are assumed to be small in this case, due to the comparatively high proportion of individuals consuming the foods in question here.

The disaggregation of the foodstuffs into their individual components was partly carried out by means of standardised recipes (if the recipe was not noted in the dietary records or no manufacturer's details were available). Thus, the details of these recipes may differ from the recipes actually applied by the study population. In this context, this mainly applies to the classification of the types of flour. However, due to the large number of consumers, this uncertainty is classified as low.

By using conversion factors from RAC level to product level according to the product groups listed in the Annex of Regulation (EU) 2021/1399, a gross overestimation regarding consumption was minimised. However, due to the conservative selection of the factors, there is still an overestimation of consumption and the resulting short-term or long-term exposure.

Standard factors have been used for the disaggregation of the cereal and milk porridges given as a reconstituted food. The conversion factor of liquid to powder may differ from the actual mixing ratio used by the consumers. However, as the manufacturers of these products provide precise information on the preparation of the powders, this uncertainty is considered to be low.

In principle, there is uncertainty about the definition of "milling products" and whether these include all products including "grains placed on the market for the final consumer"³ (e.g. puffed cereal wafers or grains that are processed into muesli). For this opinion, all products were included in order to avoid underestimation.

The determination of the short-term EA intake across all products ("total exposure") represents a conservative approach, as it is assumed that all cereals consumed on one day simultaneously have concentrations in the range of the maximum levels. More realistic is the situation in which an individual consumes a single large portion of a product that has high levels. Since inputs from other foods also contribute to the total exposure, considering only one product could lead to an underestimation of the short-term exposure. On the other hand, the assumption that all products simultaneously have contents in the range of the maximum levels ("total exposure") is an overestimation. Moreover, EA concentrations are also measured far above the currently applied maximum level (BVL, 2017), which is why the hypothetical estimate based on maximum levels can also underestimate the short-term exposure.

³ Final consumer: the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity (Regulation (EC) No 178/2002).

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Also in the hypothetical estimate of long-term exposure to EAs, it should be noted that when considering the total exposure across all products, it is assumed that all food consumed is contaminated with the maximum level, which is unlikely, especially in the long-term, and therefore results in a large overestimation. However, the TDI exceedances are in a similar range as the ARfD exceedances in the short-term approach. In any case, it must be taken into account that the sole consideration of only one group can again lead to an underestimation, since the total exposure is always a sum of the contributions from all foods.

By grouping different cereals into one product group, the consumption of cereals that may not contain such high concentrations of EAs in reality was also included in the exposure. The contribution of EAs to the total exposure via the consumption of other foods potentially containing EAs, such as buckwheat or soy, was not considered. This is of particular importance when considering long-term exposure.

3.1.4 Risk characterisation

Table 8 shows the proportion of the short-term exposure to the ARfD and the amount and percent of children exceeding the ARfD (1 µg/kg b.w. and day). This is derived from the calculated hypothetical short-term exposure resulting from the consumption of foodstuffs that are assigned to the product groups listed in the Annex of Regulation (EU) 2021/1399 and that have EA contents at the maximum levels specified therein (cf. Table 4).

Even after the planned reduction of the maximum levels for two of the product groups listed in the Annex of Regulation (EU) 2021/1399, the exposure is 175% to 240% of the ARfD when considering the hypothetical short-term exposure across all products (“total exposure”) by children. The intake of EAs via rye and rye milling products is the decisive factor. It should be noted that even after lowering the maximum levels, 12% of 1 to < 3-year-olds still exceed the ARfD through the intake of rye alone.

None of the observed individuals exceeds the ARfD by the consumption of wheat gluten or processed cereal based food for infants and young children

Table 8: Short-term exposure to EAs expressed as percentage of the ARfD (1 µg/kg b.w. and day) in children aged 0.5 to < 6 years via consumption of products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study, only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Percentage of ARfD [%]		Number of children (percentage) > ARfD	
		Current maximum levels	Maximum levels from 2024	Current maximum levels	Maximum levels from 2024
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	99	49	3 (5%)	-
	1 to < 3	153	76	84 (27%)	7 (2%)
	3 to < 6	142	71	107 (18%)	12 (2%)
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	69		1 (1%)	
	1 to < 3	159		31 (10%)	
	3 to < 6	92		20 (3%)	
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	334	167	18 (31%)	3 (6%)
	1 to < 3	318	159	107 (35%)	36 (12%)

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Percentage of ARfD [%]		Number of children (percentage) > ARfD	
		Current maximum levels	Maximum levels from 2024	Current maximum levels	Maximum levels from 2024
	3 to < 6	193	97	171 (29%)	22 (4%)
2.9.2.4 Wheat gluten	0.5 to < 1	10		-	
	1 to < 3	12		-	
	3 to < 6	9		-	
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	15		-	
	1 to < 3	10		-	
	3 to < 6	7		-	
Total exposure	0.5 to < 1	345	183	25 (44%)	13 (23%)
	1 to < 3	387	240	228 (74%)	124 (40%)
	3 to < 6	291	175	437 (74%)	163 (28%)

* N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

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Table 9 shows the short-term exposure expressed as percentage of the ARfD of 0.5 to < 6-year-old children for product group 2.9.2.1 and 2.9.2.2 separately according to the respective cereal types. Due to the comparatively low consumption in these product groups, barley only contributes to a small extent to the exposure.

Of the listed cereals, wheat (incl. spelt) contributes most to the exposure and the potential exceedance of the ARfD in the product group milling products from barley, wheat, spelt and oats with a low degree of milling (ash content <900mg/100g) for all age groups considered.

In the product group of milling products from barley, wheat, spelt and oats with a high degree of milling (ash content >900mg/100g), both oats and wheat (incl. spelt) contribute to a large extent to the potential exceedance of the ARfD due to the exposure of the age groups considered (between 62% and 165% of the ARfD). It is particularly noteworthy that exposure based on the maximum level of 150 µg/kg for this product group exceeds the ARfD in 1 to < 3-year-old children by the consumption of both oats and wheat (incl. spelt) alone.

Table 9: Short-term exposure to EAs expressed as percentage of the ARfD (1 µg/kg b.w. and day) by children aged 0.5 to < 6 years via products from product groups 2.9.2.1 and 2.9.2.2 according to the Annex of Regulation (EU) 2021/1399 separated by cereal type (consumption data: KIESEL study; only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Percentage of ARfD [%]		Number of children (percentage) > ARfD	
		Current maximum levels	Maximum levels from 2024	Current maximum levels	Maximum levels from 2024
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)					
Barley	0.5 to < 1	6	3	-	-
Barley	1 to < 3	1	1	-	-
Barley	3 to < 6	6	3	-	-
Oats	0.5 to < 1	17	9	-	-
Oats	1 to < 3	24	12	-	-
Oats	3 to < 6	19	10	-	-
Wheat (incl. spelt)	0.5 to < 1	99	49	3 (5%)	-

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Percentage of ARfD [%]		Number of children (percentage) > ARfD	
		Current maximum levels	Maximum levels from 2024	Current maximum levels	Maximum levels from 2024
Wheat (incl. spelt)	1 to < 3	153	76	84 (27%)	7 (2%)
Wheat (incl. spelt)	3 to < 6	142	71	107 (18%)	12 (2%)
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer					
Barley	0.5 to < 1	9		-	
Barley	1 to < 3	15		-	
Barley	3 to < 6	12		-	
Oats	0.5 to < 1	63		0.3** (1%)	
Oats	1 to < 3	165		19 (6%)	
Oats	3 to < 6	68		4 (1%)	

Product according to the Annex of Regulation (EU) 2021/1399	Age* (years)	Percentage of ARfD [%]		Number of children (percentage) > ARfD	
		Current maximum levels	Maximum levels from 2024	Current maximum levels	Maximum levels from 2024
Wheat (incl. spelt)	0.5 to < 1	62		0.2** (0%)	
Wheat (incl. spelt)	1 to < 3	111		13 (4%)	
Wheat (incl. spelt)	3 to < 6	90		17 (3%)	

* N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

** Decimal places in the number of individuals results from the application of weighing factors

Table 10 shows the long-term exposure expressed as percentage of the TDI (0.6 µg/kg b.w. and day) by 0.5 to < 6-year-old children and the amount and percentage of children exceeding the TDI. This is derived from the calculated hypothetical long-term exposure resulting from the consumption of foodstuffs belonging to the product groups listed in the Annex of Regulation (EU) 2021/1399 and containing EAs at the maximum levels specified therein (cf. Table 6).

Even after lowering the maximum levels for two of the product groups listed in the Annex of Regulation (EU) 2021/1399, the hypothetical total exposure of high consumers is between 161% and 283% of the TDI.

If the product groups are considered separately, the planned reduction of the maximum level has the effect that the hypothetical exposure of the high consumers of all age groups considered only exceeds the TDI in the group of rye product consumers and in the 1 to < 3-year-old high consumers of the group of milling products with a high degree of milling (ash content >900mg/100g).

Table 10: Long-term exposure to EAs expressed as percentage of the TDI (0.6 µg/kg b.w. and day) by children aged 0.5 to < 6 years via consumption of products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study; only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*	P50*	P95*
2.9.2.1 Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	0.5 to < 1	33	85	16	43	2 (3%)	-
	1 to < 3	69	159	35	80	80 (26%)	6 (2%)
	3 to < 6	74	132	37	66	116 (20%)	1 (0%)
2.9.2.2 Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer	0.5 to < 1	14	72	14	72	0,5*** (1%)	
	1 to < 3	19	139	19	139	27 (9%)	
	3 to < 6	13	96	13	96	24 (4%)	

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*	P50*	P95*
2.9.2.3 Rye milling products Rye placed on the market for the final consumer	0.5 to < 1	54	258	27	129	15 (27%)	4 (8%)
	1 to < 3	59	310	29	155	78 (25%)	28 (9%)
	3 to < 6	50	178	25	89	107 (18%)	17 (3%)
2.9.2.4 Wheat gluten	0.5 to < 1	1	6	1	6	-	-
	1 to < 3	1	9	1	9	-	-
	3 to < 6	1	6	1	6	-	-
2.9.2.5 Processed cereal based food for infants and young children	0.5 to < 1	10	23	10	23	-	-
	1 to < 3	3	14	3	14	-	-
	3 to < 6	2	7	2	7	-	-

Product according to the Annex of Regulation (EU) 2021/1399	Age** (years)	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*	P50*	P95*
Total exposure	0.5 to < 1	91	305	65	161	24 (42%)	15 (27%)
	1 to < 3	158	482	94	283	251 (82%)	140 (45%)
	3 to < 6	148	299	84	190	457 (78%)	194 (33%)

* P50 (median): Average consumers; P95: High consumers

** N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

*** Decimal places in the number of individuals results from the application of weighing factors

Table 11 shows the long-term exposure expressed as percentage of the TDI for the 0.5 to < 6-year-old children for product group 2.9.2.1 and 2.9.2.2 separately for the respective cereal types.

Also in the long-term, barley hardly contributes to the exposure for all age groups considered. Analogous to the short-term scenario, wheat (incl. spelt) in the product group of milling products from barley, wheat, spelt and oats with a low degree of milling (ash content <900mg/100g) contributes most to the exposure for all age groups considered (average and high consumers). In the product group of milling products from barley, wheat, spelt and oats with a high degree of milling (ash content >900mg/100g), wheat (incl. spelt) contributes most to the exposure for average consumers (all age groups) and oats for high consumers (all age groups). For high consumers aged 1 to < 3 years, the consumption of oats alone contributes to 93% of the TDI.

Table 11: Long-term exposure to EAs expressed as percentage of the TDI (0.6 µg/kg b.w. and day) by children from 0.5 to < 6 years of age via products from product groups 2.9.2.1 and 2.9.2.2 according to the Annex of Regulation (EU) 2021/1399 separated by cereal type (only consumers, non-breastfed).

Product according to the Annex of Regulation (EU) 2021/1399	Age** [years]	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*		
2.9.2.1 Ground products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g)							
Barley	0.5 to < 1	<1	2	<1	1	-	-
Barley	1 to < 3	<1	1	<1	<1	-	-
Barley	3 to < 6	<1	4	<1	2	-	-
Oats	0.5 to < 1	7	7	4	4	-	-
Oats	1 to < 3	16	23	8	12	-	-
Oats	3 to < 6	10	26	5	13	-	-
Wheat (incl. spelt)	0.5 to < 1	33	85	16	43	2 (3%)	-

Product according to the Annex of Regulation (EU) 2021/1399	Age** [years]	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*		
Wheat (incl. spelt)	1 to < 3	69	157	35	79	80 (26%)	6 (2%)
Wheat (incl. spelt)	3 to < 6	72	129	36	65	115 (20%)	1 (0%)
2.9.2.2 Ground products of barley, wheat, spelt and oats (with an ash content of at least 900mg/100g) Barley, wheat, spelt and oat grains placed on the market for the final consumer							
Barley	0.5 to < 1	4	4	4	4	-	-
Barley	1 to < 3	2	20	2	20	-	-
Barley	3 to < 6	1	10	1	10	-	-
Oats	0.5 to < 1	7	51	7	51	0.2*** (0,4%)	

Product according to the Annex of Regulation (EU) 2021/1399	Age** [years]	Percentage of TDI [%]				Number of children (percentage) > TDI	
		Current maximum levels		Maximum levels from 2024		Current maximum levels	Maximum levels from 2024
		P50*	P95*	P50*	P95*		
Oats	1 to < 3	8	93	8	93	8 (3%)	
Oats	3 to < 6	5	71	5	71	5 (1%)	
Wheat (incl. spelt)	0.5 to < 1	10	38	10	38	-	
Wheat (incl. spelt)	1 to < 3	12	74	12	74	6 (2%)	
Wheat (incl. spelt)	3 to < 6	9	64	9	64	6 (1%)	

* P50 (median): Average consumers; P95: High consumers

** N total (0.5 to < 1): 57; N total (1 to < 3): 308; N total (3 to < 6): 588

*** Decimal places in the number of individuals results from the application of weighing factorsDecimal

Conclusion:

The present opinion refers to the currently applied as well as the planned lowered maximum levels for ergot alkaloids (EAs) according to the Annex of Regulation (EU) 2021/1399.

The hypothetical short-term exposure of children aged between 0.5 and < 6 years to EAs through consumption of the products was calculated in accordance with the Annex of Regulation (EU) 2021/1399 in order to assess to which extent the maximum permissible levels

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envisaged from 1 July 2024 are suitable for minimising health risks for the population in Germany. The short-term approach is shown to be suitable for the assessment of the maximum levels as more realistic estimates are achieved by using the maximum levels in the short-term scenario and the conservative estimate in the long-term scenario is also covered.

The acute reference dose (ARfD) of 1 µg/kg body weight and day which was derived in 2012 in an opinion of the European Food Safety Authority (EFSA, 2012) was used for the assessment of acute effects from EAs after a single or short-term intake. This specifies the estimated maximum quantity of a substance that can be consumed with food in the course of one day either during one meal or during several meals - without a detectable risk to health.

To answer the present question, only data for 0.5 to <6-year-old children were used, as this consumer group usually consumes more in relation to their body weight than older children, adolescents and adults. Therefore, they represent the most sensitive group.

Rye and milled rye products as well as wheat (incl. spelt) and oats represent the largest contributors to exposure due to consumption of the products listed in the Annex of Regulation (EU) 2021/1399 by 0.5 to < 6-year year-old children.

The exposure by the consumption of wheat gluten (2.9.2.4) and processed cereal based food for infants and young children (2.9.2.5) contributes to 7 to 15% of the ARfD over all age groups.

In addition, the ARfD is not exceeded in the product group milled products of barley, wheat, spelt and oats (with an ash content of at least 900mg/100g) and barley, wheat, spelt and oat grains placed on the market for final consumers (2.9.2.2) by children aged 0.5 to < 1 year and 3 to < 6 years, and in the product group milled barley, wheat, spelt and oat grains (with an ash content of less than 900mg/100g) (2.9.2.1) by 0.5 to < 1-year-old children.

Therefore, BfR concludes that the probability of occurrence of adverse health effects is to be classified as low in these hypothetical short-term exposure scenarios using the currently applied maximum levels.

In contrast, children of all age groups considered exceed the ARfD (between 193 and 334% of the ARfD) through the consumption of rye and rye milling products, if the products have EA levels at the level of the currently applied maximum level.

Also, when considering the product group of milling products with a low degree of milling (2.9.2.1), the ARfD is exceeded by 1 to < 3-year-old and 3 to < 6-year-old children (153 and 142%, respectively).

When considering the product group of milling products with a high degree of milling (2.9.2.2), for which no reduction of the currently applied maximum level is planned, the ARfD is exceeded by the exposure of the age group of 1 to < 3-year-olds (159% of the ARfD).

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Therefore, BfR concludes that for these hypothetical short-term exposure scenarios with the currently applied maximum levels impairments to health can occur for the respective age groups with medium likelihood.

3.2 Annex of RegulationAnnex of RegulationAnnex of RegulationRisk management options, recommended measures

BfR welcomes the planned reduction of the maximum levels for EAs in milling products with a low degree of milling (2.9.2.1) and for rye and rye milling products (2.9.2.3) and recommends supporting projects to further reduce the maximum levels in the EU. A halving of the maximum level for the first mentioned product group would result in a lower deviation of the ARfD for all age groups considered.

However, the BfR points out that even after the planned reduction of the currently applied maximum level for rye and rye milling products (2.9.2.3), the age groups of 0.5 to < 1-year-olds and 1 to < 3-year-old children continue to fully exhaust the ARfD (exhaustion rates 159 and 167%, respectively). Thus, there would still be a medium likelihood with regard to the occurrence of adverse health effects for these age groups in this exposure scenario

In addition, BfR recommends examining whether a reduction of the maximum levels for the product group of milling products with a high degree of milling (2.9.2.2) is possible. For these, no reduction of the currently applied maximum level of 150 µg/kg is planned at present, but the ARfD is exceeded by the age group of 1 to < 3-year-olds (159% exhaustion).

3.3 Other aspects

3.3.1 Comparison of the short-term consumption of rye by children according to VELS study and KiESEL study

Opinion No. 024/2013 of 7 November 2012, updated on 28 August 2013: "Case-by-case assessment of EA levels in rye flour and rye breads" contains a case-by-case assessment of four high levels of EAs in rye flour and rye breads measured by a monitoring authority. The short-term consumption of children from the VELS study of rye containing breads and total rye (sum of all contents for rye in food) was evaluated. The data of the VELS study were collected in 2001/2002 (Banasiak *et al.*, 2005, Heseke *et al.*, 2003) and have since been replaced by the data of the KiESEL study. Since BfR has updated the risk assessment on EAs in food in the present document, the consumption data for the considered foods of the VELS study used as a basis at that time are compared with the updated data of the KiESEL study. The short-term consumption of rye was considered in total, as this is comparable to the rye consumption of the KiESEL evaluation (cf. Table 12).

Compared to the VELS study, 0.5 to < 1-year-old children in the KiESEL study consume almost twice as much rye at 6.7 g/kg b.w. While 1 to < 3-year-olds also consume more rye according to the KiESEL data compared to VELS, the 3 to < 6-year-olds consume slightly lower amounts compared to VELS. The age classifications of the latter two age groups of the two studies are not directly comparable.

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The difference in the consumption of the 0.5 to < 1-year-olds is due to the fact that among 37 consumers in the KiESEL study, two children are at the level of the P95 or higher. The P90 of consumption in KiESEL is 3.94 g/kg b.w. and thus at the level of the P95 of VELs consumption.

Table 12: Short-term intake (g/kg b.w. and day) of children aged 0.5 to < 5 years according to the VELs study and of children aged 0.5 to < 6 years according to the KiESEL study for rye (sum of all proportions for rye in food) (only consumers; non-breastfed)

VELs			KiESEL		
Age (years)	Number consumers	Short-term consumption	Age (years)	Number consumers	Short-term consumption
0.5 to < 1	96 (61%)	3.9	0.5 to < 1	37 (64%)	6.68
1 to < 2	164 (96%)	4.3	1 to < 3	256 (83%)	6.37
2 to < 5	463 (97%)	4.1	3 to < 6	515 (88%)	3.87

Supplement to the report

Assessment of health risks from ergot alkaloids in selected cereal products

4 Subject of the assessment

The present supplement to the report aims to classify the currently applied maximum levels as well as the maximum levels planned from 1 July 2024 based on current occurrence data submitted to BfR by the Federal Office of Consumer Protection and Food Safety (BVL). Furthermore, in the course of this opinion, an exposure assessment based on short-term and long-term consumption was carried out using actual levels of EAs in food submitted by BVL in order to assess whether health risks for the population in Germany may arise from the consumption of the products listed in the Annex of Regulation (EU) 2021/1399.

5 Results

The comparison of the occurrence data provided by BVL from the years 2013-2021 with the currently applied maximum levels or the maximum levels planned from 2024 shows that the 95th percentile of EA level of product group 2.9.2.1 (milling products from barley, wheat, spelt and oats; ash content < 900mg/100g) is above the currently applied maximum level (100 µg/kg) only in the Upper Bound (UB) scenario. In product group 2.9.2.2 (milling products from barley, wheat, spelt and oats; ash content ≥ 900mg/100g), EA levels are below the currently applied maximum level in all scenarios considered. However, it should be noted for both product groups that the levels originate almost exclusively from wheat samples and EA contents of the product groups can therefore be both overestimated or underestimated due to missing or insufficient occurrence data for oats and barley.

The mean levels of product group 2.9.2.3 (rye milling products and rye) are below the currently applied and planned maximum levels in all scenarios (lower bound (LB), modified lower bound (mLB) and UB). In P95, however, the levels in all scenarios (LB, mLB and UB) exceed the currently applied maximum level of 500 µg/kg.

For the product groups wheat gluten (product group 2.9.2.4) and processed cereal based foods for infants and young children (product group 2.9.2.5) no comparison in relation to the currently applied maximum levels could be made due to insufficient data.

In order to assess whether health risks to the population in Germany may arise from the consumption of the products listed in the Annex of Regulation (EU) 2021/1399, the short-term and long-term exposure of children aged 0.5 to < 6 years to EAs was determined. This consumer group usually consumes more than older children, adolescents and adults in relation to their body weight (b.w.) and therefore represents the highest exposed age group. For the exposure calculation, the consumption of the products listed in the Annex of Regulation (EU) 2021/1399 was linked to EA levels reported by BVL. Due to insufficient data, no or no meaningful estimation was possible for the product groups 2.9.2.4 or 2.9.2.5.

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For the assessment of acute exposure to EAs, the acute reference dose (ARfD) of 1 µg/kg b.w. and day was used. For the assessment of chronic effects from EAs after long-term intake, the tolerable daily intake (TDI) of 0.6 µg/kg b.w. and day was used. The health-based guidance values were derived in 2012 in an opinion of the European Food Safety Authority (EFSA, 2012). The ARfD specifies the estimated maximum quantity of a substance that can be consumed with food in the course of one day during one meal or during several meals without a detectable risk to health. The TDI specifies the quantity of a substance that can be consumed on a daily basis over an entire lifetime without a detectable risk to health.

The empirical short-term exposure showed an exceedance of the ARfD by children (202% to 350% of the ARfD) through the consumption of rye milling products and rye (product group 2.9.2.3) in the mLB scenario.

In the UB scenario, the ARfD is exceeded in all product groups considered by at least one of the age groups. In addition to rye products, the ARfD is also exceeded in children aged 0.5 to < 6 years by the consumption of milling products made from barley, wheat, spelt and oats (with an ash content of less than 900mg/100g).

Therefore, BfR concludes that acute adverse health effects may occur with a medium likelihood due to the consumption of rye products. Due to the insufficient data available on the occurrence of EAs in oats, it is not possible to conclusively assess the health risk from the consumption of these products, which may make a relevant contribution to exposure due to the comparatively high consumption by children (see section 3.1.3.4), of product groups 2.9.2.1 and 2.9.2.2.

Empirical long-term exposure has shown that in the mLB the TDI is not exceeded by either average or high-consuming children.

Only in the conservative UB approach for high consumers of rye products and when considering the exposure of high consumers across all products listed in the Annex of Regulation (EU) 2021/1399 ("total exposure") the TDI was exceeded. Accordingly, the likelihood of chronic adverse health effects from the consumption of the products listed in the Annex of Regulation (EU) 2021/1399 is to be regarded as low, since the exposure in the UB scenario is overestimated due to the influence of left-censored data. However, it has to be taken into account that the occurrence data on oats, processed cereal foods and wheat gluten are insufficient to make representative statements with regard to exposure. In addition, other sources of input from products that may contribute to the total exposure but are not listed in the Annex of Regulation (EU) 2021/1299, such as buckwheat or soy (see section 6.3), are not taken into account.

6 Rationale

6.1 Risk assessment

This opinion is a supplement to the report "Assessment of health risks from ergot alkaloids in selected cereal products". Consequently, the information on hazard identification (see section

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3.1.1) and characterisation (see section 3.1.2) already available in the above-mentioned risk assessment has not been submitted again in the context of the present health assessment. The same applies to the data on consumption (see section 3.1.3.1) as well as to the data on short-term and long-term consumption (see sections 3.1.3.2 and 3.1.3.3), which were used for the subsequent empirical exposure estimation of 0.5 to < 6-year-old children to ergot alkaloids (EAs) via products listed in the Annex of Regulation (EU) 2021/1399. Accordingly, the following deviates from the usual structure of the health risk assessment prepared by BfR⁴ and deals exclusively with the additional results of the exposure assessment and risk characterisation.

6.1.1 Exposure assessment

6.1.1.1 Current occurrence data on EAs used for exposure assessment and classification of current and planned lowered maximum EAs levels according to the Annex of Regulation (EU) 2021/1399

The exposure assessment was based on current occurrence data from the National Monitoring and other survey programmes of the federal states in Germany, which were requested from the federal states by the Federal Office of Consumer Protection and Food Safety (BVL) in the course of the underlying request. The transmitted data set comprised 6,008 samples with 65,766 individual data on ergot sclerotia, sum contents of EAs and individual parameters in cereals and cereal products. For the exposure estimation, the following were used:

- Matrices which can be assigned to the product groups according to the Annex of Regulation (EU) 2021/1399 (grains and milling products)
- Individual parameters: Ergocornin(in)e, ergocristin(in)e, ergometrin(in)e, ergosin(in)e, ergotamin(in)e, α -ergocryptin(in)e, β -ergocryptin(in)e and the sum of α - and β -ergocryptin(in)e if no information was available on the two individual parameters.
- Samples comprising at least the above-mentioned individual parameters for summation⁵
- Samples from non-risk-oriented sampling (i.e., planned samples, monitoring samples, project samples)
- Samples with clear assignment of matrix and subsample
- for samples with more than one subsample, the subsample with the higher total content
- in the case of cereal grains (e.g., rye grains), only those samples whose sampling was carried out in the retail trade, i.e., grains intended for final consumers

⁴ <https://www.bfr.bund.de/cm/364/guideline-for-the-assessment-of-health-risks.pdf>

⁵ For 1,153 samples, no measurement results are available for at least one of the β -forms of ergocryptin(in)e. This is due to the analytical development of the measurement methods and was accepted in order not to further reduce the number of samples.

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In 203 individual measurements, the measurement result was reported below the specified limit of detection (LOD) or limit of quantification (LOQ). In this case, the measurement result was set to <LOD or <LOQ, as the analytical uncertainties in this range do not allow quantification.

After data cleaning and summation, the final data set included total EA levels for 1,549 samples. In addition, 157 samples on soy and buckwheat were taken into account for the classification of further dietary sources of EAs. The sum of EAs per sample was determined according to the lower bound (LB), modified lower bound (mLB) and upper bound (UB) approach.

The LB approach is based on the requirements of the Regulation (EU) 2021/1399, according to which the maximum level for EAs refers to the lower limit (LB of the sum). In the LB approach, measurements <LOD or <LOQ are set equal to zero. The use of this approach leads to an underestimation of the levels and thus the resulting exposure, as the left-censored values may lie between zero and the respective LOD or LOQ.

The mLB approach reduces this underestimation by distinguishing between <LOD and <LOQ. If a value is below the LOD, it is set to zero. If the value is below the LOQ, it is assigned the value of the respective LOD.

Since this approach may still result in an underestimation, the UB approach is additionally calculated. Values <LOD are equated with the respective LOD and values <LOQ with the respective LOQ. In this approach, the levels and thus the resulting exposure tend to be overestimated. The joint presentation of LB, mLB and UB reflects the range in which the actual levels lie.

The data were analysed according to the allocation to the product groups in accordance with the Annex of Regulation (EU) 2021/1399, and additionally according to the different cereal types.

Levels are reported in micrograms per kilogram ($\mu\text{g}/\text{kg}$). Reported parameters include the minimum, 5th percentile (P5), median (P50), mean, 95th percentile (P95) and maximum.

The occurrence data were transmitted by the BVL to the BfR and discussed. Data processing and software settings for statistical evaluation were coordinated with the BVL.

Table shows the sum of EAs for the different product groups according to the Annex of Regulation (EU) 2021/1399, which were used for the empirical exposure estimation.

For product group 2.9.2.4 (wheat gluten) no occurrence data were available for evaluation. Furthermore, for processed cereal based food for infants and young children (product group 2.9.2.5) only occurrence data from nine samples were submitted. These were exclusively "rusks or biscuits for infants and young children". Consequently, no representative statement can be made for this product group.

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Based on the LB and mLB approach, the mean and P95 of the occurrence data of product groups 2.9.2.1 and 2.9.2.2 are below the currently applied and planned maximum levels. In the UB approach, the P95 is in the range of the currently applied maximum level of 100 µg/kg for products of group 2.9.2.1. Since EA levels used for this purpose originate exclusively from wheat samples (see Table 14), the statistical parameters may represent both an overestimation or an underestimation.

The mean levels of product group 2.9.2.3 (rye milling products and rye) are below the currently applied and planned maximum levels in all scenarios (LB, mLB and UB). In P95, however, the levels exceed the currently applied maximum level of 500 µg/kg in all scenarios (LB, mLB and UB).

Table 13: Sum of EAs [µg/kg] by product group according to the Annex of Regulation (EU) 2021/1399. Data collection of the federal states between the years 2013 and 2021.

Product group according to the Annex of Regulation (EU) 2021/1399*.		2.9.2.1	2.9.2.2	2.9.2.3	2.9.2.4	2.9.2.5
Current maximum level / maximum level from 2024** [µg/kg]		100 / 50	150	500 / 250	400	20
N Samples		174	336	1030	0	9****
N (percentage) Detects***		18 (10%)	66 (20%)	586 (57%)	-	0 (0%)
LB	Min	0.0	0.0	0.0	-	0.0
	P5	0.0	0.0	0.0	-	0.0
	P50	0.0	0.0	12.8	-	0.0
	Mean	1.5	9.2	113.5	-	0.0
	P95	8.8	56.9	509.1	-	0.0
	Max	84.5	440.8	2556.6	-	0.0

Product group according to the Annex of Regulation (EU) 2021/1399*		2.9.2.1	2.9.2.2	2.9.2.3	2.9.2.4	2.9.2.5
mLB	Min	0.0	0.0	0.0	-	0.0
	P5	0.0	0.0	0.0	-	0.0
	P50	0.0	0.0	21.6	-	0.0
	Mean	4.2	11.4	120.4	-	0.1
	P95	13.8	66.0	523.5	-	0.7
	Max	84.5	440.8	2556.6	-	0.7
UB	Min	6.5	4.8	9.8	-	9.8
	P5	6.5	6.5	11.1	-	9.8
	P50	34.8	38.5	78.5	-	9.8
	Mean	42.2	45.7	161.6	-	9.9
	P95	100.0	120.0	528.5	-	11.1
	Max	137.6	465.8	2556.6	-	11.1

* 2.9.2.1: Milling products from barley, wheat, spelt and oat products (with an ash content of less than 900mg/100g), 2.9.2.2: Milling products from barley, wheat, spelt and oat products (with an ash content of 900mg/100g or more) and barley, wheat, spelt and oat grains placed on the market for the final consumer, 2.9.2.3: Rye milling products and rye placed on the market for the final consumer, 2.9.2.4: Wheat gluten, 2.9.2.5: Processed cereal based food for infants and young children.

**Currently applied maximum level or planned maximum level (µg/kg) from 1 July 2024 in accordance with the Annex of Regulation (EU) 2021/1399.

***A sample was determined as a detect as soon as a single parameter was quantified

****No representative statement possible due to low sample size

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Table shows the sum of EAs according to the product groups 2.9.2.1 and 2.9.2.2 separately by cereal type.

For product group 2.9.2.1, only occurrence data on EAs in wheat (incl. spelt) were submitted.

The comparison of the cereal types within the product group 2.9.2.2 shows that barley has comparatively the lowest EA levels in all scenarios. For oats, only occurrence data from twelve samples were available. Therefore, no representative statement can be made for oats, and the contents are to be interpreted as a tendency. The EA levels for all cereal species of product group 2.9.2.2 are below the currently applied maximum level in P95 in all scenarios (LB, mLB and UB).

Overall, the occurrence data for the cereals barley and oats, which were combined with wheat (incl. spelt) in product groups 2.9.2.1 and 2.9.2.2 to form a maximum level category, is insufficient. Accordingly, the maximum levels applied for barley and oats cannot be classified (product group 2.9.2.1) or can only be classified insufficiently (product group 2.9.2.2) on the basis of the occurrence data available here. Furthermore, it cannot be conclusively assessed whether the joint grouping of the cereal species wheat (incl. spelt), oats and barley leads to an overestimation or underestimation of the hypothetical exposure based on the currently applied or planned maximum levels (see sections 3.1.3.4 and 3.1.3.5) due to the different consumption amounts of the respective cereals (see sections 3.1.3.2 and 3.1.3.3). Only the occurrence data from 34 samples of barley, which are to be assigned to product group 2.9.2.2, indicate that these are below the levels of wheat (incl. spelt). Using the maximum levels for the exposure estimation would therefore result in a gross overestimation for this product group. In the case of 0.5 to < 6-year-old children, however, this is negligible due to the low consumption.

Table 14: Sum of EAs [µg/kg] by product groups 2.9.2.1 and 2.9.2.2 according to the Annex of Regulation (EU) 2021/1399 separated by cereal type. Data collection of the federal states between the years 2013 and 2021.

Product according to the Annex of Regulation (EU) 2021/1399*.		2.9.2.1			2.9.2.2		
		Wheat (incl. spelt)	Barley	Oats	Wheat (incl. spelt)	Barley	Oats
Current maximum level / maximum level from 2024** [µg/kg]		100 / 50			150		
N Samples		174	0	0	290	34	12****
N (percentage) Detects***		18 (10%)	-	-	61 (21%)	4 (12%)	1 (8%)
LB	Min	0.0	-	-	0.0	0.0	0.0
	P5	0.0	-	-	0.0	0.0	0.0
	P50	0.0	-	-	0.0	0.0	0.0
	Mean	1.5	-	-	10.1	1.0	9.2
	P95	8.8	-	-	64.0	12.2	109.8
	Max	84.5	-	-	440.8	17.5	109.8
mLB	Min	0.0	-	-	0.0	0.0	0.0
	P5	0.0	-	-	0.0	0.0	0.0
	P50	0.0	-	-	0.0	0.0	0.0
	Mean	4.2	-	-	12.7	1.2	9.3

	P95	13.8	-	-	68.5	12.9	111.9
	Max	84.5	-	-	440.8	20.3	111.9
UB	Min	6.5	-	-	4.8	9.8	9.8
	P5	6.5	-	-	6.5	9.8	9.8
	P50	34.8	-	-	51.0	9.8	9.8
	Mean	42.2	-	-	50.9	10.9	18.8
	P95	100.0	-	-	120.0	21.2	117.2
	Max	137.6	-	-	465.8	30.4	117.2

* 2.9.2.1: milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g), 2.9.2.2: milling products of barley, wheat, spelt and oats (with an ash content of 900mg/100g or more) and grains of barley, wheat, spelt and oats placed on the market for the final consumer

**Currently applied maximum level or planned maximum level (µg/kg) from 1 July 2024 in accordance with the Annex of Regulation (EU) 2021/1399.

***A sample was determined as a detect as soon as a single parameter was quantified

**** no representative statement possible due to low sample size

6.1.1.2 Assessment of the short-term exposure of EAs via the consumption of the products listed in the Annex of Regulation (EU) 2021/1399

For the estimation of short-term exposure, the P95 of the EA levels per product group or cereal variety was linked to the respective consumption at the individual level and the day of maximum exposure per individual was determined. The P95 of the resulting exposure distribution represents the short-term exposure of EAs for consumers of the respective product group. Only the consumption of the respective product group was taken into account.

However, since the total intake of a substance or substance group is the sum of all contributions via the diet, the hypothetical exposure over all considered product groups ("total exposure") was considered in an additional scenario. For the short-term exposure per individual and day, the exposure per product group was determined and then summed up. The P95 of the individual days with the maximum exposure results in the short-term total exposure.

The exposure is determined for the mLB and UB approach. The exposure is given in µg per kg body weight (b.w.) and day.

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An additional exposure estimation separately for the cereal types summarised in the product groups 2.9.2.1 and 2.9.2.2 was not carried out, as the submitted occurrence data do not provide a sufficient data basis for this. Table 15 shows the short-term exposure for children from 0.5 to < 6 years to EAs through the consumption of the products listed in the Annex of Regulation (EU) 2021/1399 based on the occurrence data submitted by BVL. Product group 2.9.2.4 (wheat gluten) is not listed due to lacking occurrence data. Product group 2.9.2.5 (processed cereal-based food for infants and young children) is listed, but it should be noted that due to the limited sample size, no representative statement can be made with regard to exposure.

In product groups 2.9.2.1 (milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g)) and 2.9.2.2 (milling products of barley, wheat, spelt and oats (with an ash content of 900mg/100g or more) and barley, wheat, spelt and oat grains placed on the market for the final consumer), children between 1 to < 3 years have the highest short-term exposure. In group 2.9.2.3 (rye milling products and rye), children aged 0.5 to < 1 year have a slightly higher short-term exposure than those aged 1 to < 3 years.

For all age groups, the highest short-term exposure is found in product group 2.9.2.3 with 2.0 to 3.5 µg/kg b.w. and day in both the mLB and the UB approach. Depending on the respective scenario, this is followed by the short-term exposure due to the consumption of products from product group 2.9.2.2 with 0.3 to 0.7 µg/kg b.w. and day in the mLB approach and from product group 2.9.2.1 with 1.0 to 1.5 µg/kg b.w. and day in the UB scenario. The level of short-term exposure is thus in the same range as the hypothetical estimation based on the currently applied maximum level (see section 3.1.3.4). The envisaged halving of the respective maximum level for product groups 2.9.2.1 and 2.9.2.3 thus has the potential to significantly reduce the actual exposure.

Since the total intake of EAs is the sum of all contributions via the diet, the consideration of "total exposure" represents the short-term exposure considering all product groups. For all age groups considered, this lies in a range of 2.3 to 3.4 µg/kg b.w. and day (mLB) or 2.8 to 4.1 µg/kg b.w. and day (UB).

Table 15: Short-term exposure of children aged 0.5 to < 6 years to EAs via products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study, consumers only, non-breastfed).

Product group according to the annex of the Regulation (EU) 2021/1399*	Age (years)	N total	Number (percentage) consumers	Short-term exposure [µg/kg b.w. and day]	
				mLB	UB
2.9.2.1	0.5 to < 1	57	48 (84%)	0.1	1.0

Product group according to the annex of the Regulation (EU) 2021/1399*	Age (years)	N total	Number (percentage) consumers	Short-term exposure [µg/kg b.w. and day]	
				mLB	UB
	1 to <3	308	308 (100%)	0.2	1.5
	3 to <6	588	588 (100%)	0.2	1.4
2.9.2.2	0,5-<1	57	40 (70%)	0.3	0.5
	1-<3	308	261 (85%)	0.7	1.3
	3-<6	588	510 (87%)	0.4	0.7
2.9.2.3	0.5 to <1	57	37 (64%)	3.5	3.5
	1 to <3	308	256 (83%)	3.3	3.4
	3 to <6	588	515 (88%)	2.0	2.0
2.9.2.5**	0.5 to <1	57	38 (67%)	<0.1	0.1
	1 to <3	308	91 (30%)	<0.1	0.1
	3 to <6	588	32 (5%)	<0.1	<0.1
Total exposure	0.5 to <1	57	51 (90%)	3.1	3.5
	1 to <3	308	308 (100%)	3.4	4.1
	3 to <6	588	588 (100%)	2.3	2.8

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* 2.9.2.1: milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g), 2.9.2.2: milling products of barley, wheat, spelt and oats (with an ash content of 900mg/100g or more) and barley, wheat, spelt and oat grains placed on the market for the final consumer, 2.9.2.3: rye milling products and rye placed on the market for final consumer, 2.9.2.5: processed cereal based food for infants and young children. Product group 2.9.2.4 (wheat gluten) not shown as no occurrence data are available

**Exposure assessment is based on N=9 samples of "rusks or biscuits for infants and young children". No representative statement for this product group possible.

The short-term exposure estimation across all products ("total exposure") according to the Annex of Regulation (EU) 2021/1399 is - based on the occurrence data provided by BVL - in the same range as the hypothetical exposure estimate based on the currently applied maximum levels (see section 3.1.3.4). Rye milling products and rye (product group 2.9.2.3) as well as Milling products of barley, wheat, spelt and oat products (with an ash content of at least 900mg/100g) and barley, wheat, spelt and oat grains placed on the market for the final consumer (product group 2.9.2.2) provide the largest contributions to the exposure via consumption of the products considered according to the Annex of Regulation (EU) 2021/1399.

6.1.1.3 Assessment of the long-term exposure of EAs via consumption of the products listed in the Annex of Regulation (EU) 2021/1399

For the estimation of the average long-term exposure, the mean EA levels per product group were linked to the respective consumption at the individual level. This approach corresponds to the assumption that 0.5 to < 6-year-old children consume products with sometimes higher and sometimes lower levels of EAs in the long-term. The resulting exposure was averaged over the survey period per individual. The exposure for average consumers is represented by the median (P50) of all consumers. The P95 represents the exposure for high consumers. Only the consumption of the product group considered was taken into account.

A scenario in which only products with high EA levels (P95) are consumed in the long-term was not considered, since a continuous intake of high EA levels was rated as unrealistic even when assuming brand-loyalty, due to the inhomogeneous occurrence of EAs.

Since the total intake of a substance or substance group is the sum of all contributions via the diet, the hypothetical exposure over all considered product groups ("total exposure") was considered in an additional scenario. For the long-term total exposure, the exposure per individual was summed up for all products over all days and then averaged over the survey period. The median and the P95 of the average individual exposure result in the long-term total exposure over all products for average and high consumers. Individuals who consumed at least one product from the product groups were considered as consumers.

Exposure for consumers of a single product group may be underestimated for some product groups because the proportion of consumers varies between groups. Accordingly, non-consumers of certain groups with lower exposure would bias the total intake value. The expected underestimation is small in this case, as the proportion of consumers is high in all groups. In the short-term scenario, despite this possible underestimation, the health-based guidance value was already exceeded (see Section 6.1.2), so that refinement was not

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necessary. This was not the case in the long-term scenario. Therefore, in an additional approach, the consumers of the product group with the highest intake values (here rye) were selected as the population, to which the intakes via the other product groups was added (see section 6.1.1.4).

The exposure is determined for the mLB and UB approach. The exposure is given in μg per kg b.w. and day.

An additional exposure estimation separately for the cereal types summarised in the product groups 2.9.2.1 and 2.9.2.2 was not carried out, as the submitted occurrence data do not provide a sufficient data basis for this.

Table shows the long-term exposure of children aged 0.5 to < 6 years to EAs via the consumption of the products listed in the Annex of Regulation (EU) 2021/1399 based on the occurrence data provided by BVL. Product group 2.9.2.4 (wheat gluten) is not listed as no exposure estimate could be made due to missing content data. Product group 2.9.2.5 (processed cereal-based food for infants and young children) is listed, but it should be noted that due to the limited availability of content data for this product group, no representative statement can be made with regard to exposure.

Also in the long-term scenario, 1 to < 3-year-old children consume the highest amounts of EAs in almost all product groups in relation to their b.w. The highest exposure to EAs in all age groups considered results from the consumption of rye milling products and rye. Average consumers of this product group consume about $0.1 \mu\text{g}/\text{kg}$ b.w. and day (mLB, UB). High consumers of rye and rye milling products consume between 0.3 and $0.4 \mu\text{g}/\text{kg}$ b.w. and day (mLB) or between 0.3 and $0.6 \mu\text{g}/\text{kg}$ b.w. and day (UB).

Considering the total exposure, average consumers are exposed to between $<0.1 \mu\text{g}/\text{kg}$ b.w. (mLB) and $0.3 \mu\text{g}/\text{kg}$ b.w. (UB) per day, and high consumers between $0.3 \mu\text{g}/\text{kg}$ b.w. (mLB) and $1.0 \mu\text{g}/\text{kg}$ b.w. (UB) per day. These intake values are below the values from the hypothetical assessments based on the currently applied maximum levels (0.5 to $0.9 \mu\text{g}/\text{kg}$ b.w. and day for average consumers and 1.8 to $2.9 \mu\text{g}/\text{kg}$ b.w. and day for high consumers) or on the planned maximum levels (0.4 to $0.6 \mu\text{g}/\text{kg}$ b.w. and day (average consumers) and 1.0 to $1.7 \mu\text{g}/\text{kg}$ b.w. and day (high consumers)) (see Section 3.1.3.5).

The long-term exposure based on the measured levels is below the hypothetical exposure assessment based on the maximum levels (see section 3.1.3.5).

Table 16: Long-term exposure of children aged 0.5 to < 6 years to EAs via products listed in the Annex of Regulation (EU) 2021/1399 (consumption data: KIESEL study, consumers only, non-breastfed).

Product group according to the Annex of Regulation (EU) 2021/1399*	Age (years)	N total	Number (percentage) consumers	Long-term exposure [µg/kg b.w. and day]			
				P50**		P95**	
				mLB	UB	mLB	UB
2.9.2.1	0.5 to < 1	57	48 (84%)	<0.1	0.1	<0.1	0.2
	1 to <3	308	308 (100%)	<0.1	0.2	<0.1	0.4
	3 to < 6	588	588 (100%)	<0.1	0.2	<0.1	0.3
2.9.2.2	0.5 to < 1	57	40 (70%)	<0.1	<0.1	<0.1	0.1
	1 to <3	308	261 (85%)	<0.1	<0.1	0.1	0.3
	3 to < 6	588	510 (87%)	<0.1	<0.1	<0.1	0.2
2.9.2.3	0.5 to < 1	57	37 (64%)	0.1	0.1	0.4	0.5
	1 to <3	308	256 (83%)	0.1	0.1	0.4	0.6
	3 to < 6	588	515 (88%)	0.1	0.1	0.3	0.3

Product group according to the Annex of Regulation (EU) 2021/1399*.	Age (years)	N total	Number (percentage) consumers	Long-term exposure [µg/kg b.w. and day]			
				P50**		P95**	
				mLB	UB	mLB	UB
2.9.2.5***	0.5 to < 1	57	38 (67%)	<0.1	<0.1	<0.1	0.1
	1 to <3	308	91 (30%)	<0.1	<0.1	<0.1	<0.1
	3 to < 6	588	32 (5%)	<0.1	<0.1	<0.1	<0.1
Total exposure	0.5 to < 1	57	51 (90%)	<0.1	0.2	0.4	0.6
	1 to <3	308	308 (100%)	0.1	0.3	0.4	1.0
	3 to < 6	588	588 (100%)	0.1	0.3	0.3	0.6

* 2.9.2.1: milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g), 2.9.2.2: milling products of barley, wheat, spelt and oats (with an ash content of 900mg/100g or more) and barley, wheat, spelt and oat grains placed on the market for the final consumer, 2.9.2.3: rye milling products and rye placed on the market for the final consumer, 2.9.2.5: processed cereal based food for infants and young children. Product group 2.9.2.4 (wheat gluten) not shown as no occurrence data are available

** P50 (median): Average consumers; P95: high consumers; mLB: modified Lower Bound; UB: Upper Bound

*** Exposure assessment is based on N=9 samples of "rusks or biscuits for infants and young children". No representative statement for this product group possible.

6.1.1.4 Assessment of the long-term exposure of EAs for rye consumers via the consumption of products listed in the Annex of Regulation (EU) 2021/1399

In the long-term exposure scenario on "total exposure" described in section 6.1.1.3, children who have consumed at least one product from a product group are considered as consumers. Consequently, non-consumers of individual product groups can lower the total exposure estimate. For example, 83% of 1 to <3-year-olds consume rye products, so the total exposure is underestimated for rye consumers if the total population of 100% is used (100% of children consume at least one product from a product group). By selecting only consumers of rye, the 17% non-consumers are excluded.

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This step serves as an additional refinement of the exposure estimation to avoid underestimation. The calculation is performed for the group with the highest contribution to exposure (rye).

Table shows the intake of EAs only for consumers of rye whose exposure was calculated over all product groups ("total exposure"). The combination of the consumption with mean EA levels results in a daily exposure that is approximately 0.1 µg/kg b.w. higher compared to the scenario for all consumers (see Table 16). Table.

Table 17: Total long-term exposure for rye-consuming children aged 0.5 to < 6 years to EAs across all products according to the Annex of Regulation (EU) 2021/1399 (consumption data: KIESEL study, rye-consuming children only, non-breastfed).

	Age (years)	Long-term exposure [µg/kg b.w. and day]			
		P50*		P95*	
		mLB	UB	mLB	UB
Total exposure	0.5 to < 1	0,1	0,3	0,4	0,6
	1 to <3	0,1	0,4	0,5	1,0
	3 to < 6	0,1	0,3	0,3	0,6

* P50 (median): Average consumers; P95: High consumers; mLB: modified Lower Bound; UB: Upper Bound

6.1.1.5 Uncertainties in exposure assessment

The uncertainties mentioned in the report supplement "Assessment of health risks from ergot alkaloids in selected cereal products ", which refer to the data basis on consumption as well as to the calculation for short- and long-term consumption (see section 3.1.3.6), also have to be considered for the uncertainty analysis of the present opinion. Furthermore, the following additional uncertainties arise for the present empirical exposure assessment:

In some samples of product groups 2.9.2.1, 2.9.2.2 and 2.9.2.3 the EA levels were underestimated because no measurements on the β-form of ergocryptine and/or ergocryptinine were available.

The sample sizes for processed cereal based foods for infants and young children and oats are too small to be representative.

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The data collection of the dataset submitted by BVL refers to the years 2013 to 2021. Thus, data collected before the introduction of maximum levels for EAs are also taken into account. However, the data evaluations of the BVL can provide information on whether the levels have decreased in the course of the introduction of the maximum levels and thus whether the long-term exposure of 0.5 to < 6-year-old children reported in the present health assessment has been overestimated.

The sum of EAs was determined using the LB, mLB and UB approaches. These approaches are subject to various uncertainties: The LB approach leads to an underestimation of the actual contents and thus the resulting exposure, since values <LOD or <LOQ are set equal to zero, but the actual contents may lie between zero and the respective LOD or LOQ. In the mLB approach, this underestimation is less pronounced, as only values <LOD are set equal to zero. If the measured value is below the LOQ, it is assigned the value of the respective LOD. Since the actual contents can still be underestimated even in the mLB, the UB approach was calculated as a supplement in the present statement. In this approach, contents <LOD are equated with the respective LOD and values <LOQ with the respective LOQ. Consequently, the real contents and thus the resulting exposure are probably overestimated. The joint presentation of LB, mLB and UB reflects the range in which the actual EA levels lie.

The assumption used for the short-term exposure assessment that all products consumed on one day ("total exposure") have contents in the P95 range results in an overestimation of exposure. However, this effect is rated to be small, especially in the mLB, because the main contribution to EA exposure is due to the consumption of rye milling products and rye, and the contribution from other foods is of minor importance.

The P95 of the entire product group (2.9.2.1 and 2.9.2.2) was assigned to the consumption of barley and oats for the short-term intake, which is, however, mainly based on EA levels from wheat (incl. spelt). For barley, this probably results in an overestimation, but the influence is negligible due to the low consumption of barley by children (see sections 3.1.3.2 and 3.1.3.3). For oats, it is unclear due to insufficient data whether this results in an overestimation or underestimation of exposure.

Both short-term and long-term exposure across all products is underestimated as the contribution from the consumption of wheat gluten (product group 2.9.2.4) was not considered due to missing occurrence data. This underestimation is classified as low because the hypothetical exposure estimation using the maximum levels has shown that a comparatively low additional exposure of max. 0.1 µg/kg b.w. and day is to be expected from the consumption of wheat gluten with EA levels at the currently valid maximum level (see sections 3.1.3.4 and 3.1.4.5). Whether EA levels in wheat gluten are actually in the same range or below the currently valid maximum level cannot be conclusively clarified due to a lack of occurrence data.

Short- and long-term exposure may be both underestimated or overestimated due to insufficient data on oats and processed cereal based foods for infants and young children. This applies both to the total exposure and to the exposure by the corresponding product groups.

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In addition, both short-term and long-term exposure are underestimated due to the fact that other dietary sources that may contribute to the total exposure and are not listed in the Annex of Regulation (EU) 2021/1299, such as buckwheat or soybean (see Section 6.3), were not considered.

6.1.2 Risk characterisation

Table 18 shows the short-term exposure expressed as percentage of the acute reference dose (ARfD) of 1 µg/kg b.w. and day by 0.5 to < 6-year-old children and the amount and percentage of children exceeding the ARfD. This results from the calculated empirical short-term exposure derived from the consumption of foodstuffs which are assigned to the product groups listed in the Annex of Regulation (EU) 2021/1399 and which have EA levels according to the data submitted by BVL (see Table 13).

In the mLB scenario, the exposure is 202% to 350% of the ARfD by children's consumption of rye milling products and rye alone (product group 2.9.2.3). In the group of 1 to < 3-year-olds, 38% of the children exceed the health-based guidance value solely through the consumption of rye-containing products.

In the UB scenario, the ARfD is exceeded in all product groups by at least one of the age groups. Within the age groups considered, especially the 1 to < 3-year-old children exceed the ARfD through the consumption of products according to the Annex of Regulation (EU) 2021/1399. In addition to rye products, 27% of the 1 to < 3-year-old children also exceed the ARfD through the consumption of milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g).

Table 18: Short-term exposure to EAs expressed as percentage of the ARfD (1 µg/kg b.w. and day) of 0.5 to < 6-year-old children via consumption of products according to the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study, only consumers, non-breastfed).

Product group according to the Annex of Regulation (EU) 2021/1399*.	Age (years)	N total	Number (percentage) consumer	Percentage ofARfD [%]		Number (percentage) > ARfD	
				mLB	UB	mLB	UB
2.9.2.1	0.5 to < 1	57	48 (84%)	14	99	-	3 (5%)
	1 to <3	308	308 (100%)	21	153	-	84 (27%)
	3 to < 6	588	588 (100%)	20	142	-	107 (18%)
2.9.2.2	0.5 to < 1	57	40 (70%)	30	55	-	1 (1%)
	1 to <3	308	261 (85%)	70	128	4 (1%)	21 (7%)
	3 to < 6	588	510 (87%)	41	74	-	15 (3%)
2.9.2.3	0.5 to < 1	57	37 (64%)	350	353	18 (31%)	18 (31%)
	1 to <3	308	256 (83%)	333	336	116 (38%)	116 (38%)
	3 to < 6	588	515 (88%)	202	204	178 (30%)	179 (30%)
2.9.2.5**	0.5 to < 1	57	38 (67%)	1	8	-	-
	1 to <3	308	91 (30%)	0	5	-	-

Product group according to the Annex of Regulation (EU) 2021/1399*.	Age (years)	N total	Number (percentage) consumer	Percentage ofARfD [%]		Number (percentage) > ARfD	
				mLB	UB	mLB	UB
	3 to < 6	588	32 (5%)	0	4	-	-
Total exposure	0.5 to < 1	57	51 (90%)	305	355	20 (35%)	23 (40%)
	1 to <3	308	308 (100%)	342	406	131 (43%)	219 (71%)
	3 to < 6	588	588 (100%)	226	283	223 (38%)	431 (73%)

* 2.9.2.1: milling products of barley, wheat, spelt and oats (with an ash content of less than 900mg/100g), 2.9.2.2: milling products of barley, wheat, spelt and oats (with an ash content of 900mg/100g or more) and barley, wheat, spelt and oat grains placed on the market for the final consumer, 2.9.2.3: rye milling products and rye placed on the market for the final consumer, 2.9.2.5: processed cereal based food for infants and young children. Product group 2.9.2.4 (wheat gluten) not shown because no content data were available.

** Exposure assessment is based on N=9 samples of "rusks or biscuits for infants and young children". No representative statement for this product group possible.

Table 19 shows the long-term exposure expressed as percentage of the tolerable daily intake (TDI) of 0.6 µg/kg b.w. and day by the long-term exposure of 0.5 to < 6-year-old children and the amount and percentage of children exceeding the TDI. This is derived from the long-term exposure resulting from the consumption of foods that are assigned to the product groups listed in the Annex of Regulation (EU) 2021/1399 and that have EA contents according to the data submitted by BVL (see Table 13).

In the mLB scenario, the TDI is not exceeded in any of the age groups considered with average or high consumption of the products listed in the Annex of Regulation (EU) 2021/1399. In total, four of the 1 to < 3-years-old (1%) and one of the 0.5 to < 1-years-old (2%) children exceed the TDI due to the consumption of rye milling products and rye (2.9.2.3). When considering the intake across all products ("total exposure"), it can be seen that eleven of the 1 to < 3-year-olds (4%) and one of the 0.5 to < 1-year-olds (2%) exceed the health-based guidance value.

In the UB scenario, the TDI is only exceeded by the consumption of milled rye products and rye (product group 2.9.2.3) by 1 to < 3-year-old high consumers. Within this age group, 4% of the children exceed the TDI by consuming these products. In the UB approach, all age groups exceed the TDI in the total exposure scenario.

Table 19: Long-term exposure to EAs expressed as percentage of the TDI (0.6 µg/kg b.w. and day) of 0.5 to < 6-year-old children via consumption of products according to the Annex of Regulation (EU) 2021/1399 (consumption data: KiESEL study, only consumers, non-breastfed).

Product group according to the Annex of Regulation (EU) 2021/1399*	Age (years)	N total	Number (percentage) consumers	Percentage of TDI [%]				Number (percentage) > TDI	
				P50*		P95*		mLB	UB
				mLB	UB	mLB	UB		
2.9.2.1	0.5 to < 1	57	48 (84%)	1	14	4	36	-	-
	1 to <3	308	308 (100%)	3	29	7	67	-	1 (0.4%)
	3 to < 6	588	588 (100%)	3	31	6	56	-	-
2.9.2.2	0.5 to < 1	57	40 (70%)	1	4	5	22	-	-
	1 to <3	308	261 (85%)	1	6	11	42	-	2 (1%)
	3 to < 6	588	510 (87%)	1	4	7	29	-	-
2.9.2.3	0.5 to < 1	57	37 (64%)	13	17	62	83	1 (2%)	1 (2%)
	1 to <3	308	256 (83%)	14	19	75	100	4 (1%)	13 (4%)
	3 to < 6	588	515 (88%)	12	16	43	58	-	-

Product group according to the Annex of Regulation (EU) 2021/1399*.	Age (years)	N total	Number (percentage) consumers	Percentage of TDI [%]				Number (percentage) > TDI	
				P50*		P95*		mLB	UB
				mLB	UB	mLB	UB		
2.9.2.5**	0.5 to < 1	57	38 (67%)	0	5	0	11	-	-
	1 to <3	308	91 (30%)	0	1	0	7	-	-
	3 to < 6	588	32 (5%)	0	1	0	4	-	-
Total exposure	0.5 to < 1	57	51 (90%)	8	35	62	104	1 (2%)	4 (6%)
	1 to <3	308	308 (100%)	17	58	72	169	11 (4%)	50 (16%)
	3 to < 6	588	588 (100%)	15	55	47	104	-	38 (6%)

* P50 (median): Average consumers; P95: High consumers; mLB: modified Lower Bound; UB: Upper Bound

** Exposure assessment is based on N=9 samples of "rusks or biscuits for infants and young children". No representative statement for this product group possible.

Table 20 shows the long-term total exposure expressed as percentage of the TDI of 0.6 µg/kg b.w. and day by 0.5 to < 6-year-old rye consuming children via the consumption of the products listed in the Annex of Regulation (EU) 2021/1399. This results from the long-term exposure of the rye-consuming children derived from the consumption of foodstuffs that are to be assigned to the product groups listed in the Annex of Regulation (EU) 2021/1399 and that have EA levels according to the data submitted by BVL (see Table 13).

In the conservative UB approach, the TDI is exceeded by high consumers of rye products. However, an exceedance of the TDI for rye consumers cannot be ruled out even in the mLB approach, as contributions from other foods (such as soy) are not taken into account.

Table 20: Total long-term exposure to EAs expressed as percentage of the TDI (0.6 µg/kg b.w. per day) of 0.5 to < 6-year-old rye-consuming children via consumption of products listed in the Annex to Regulation (EU) 2021/1399 (“total exposure”) (consumption data: KIESEL study, rye-consuming children only, non-breastfed).

Age (years)	Percentage of TDI [%]				Number (percentage) > TDI	
	P50*		P95*		mLB	UB
	mLB	UB	mLB	UB		
0.5 to < 1	16	43	64	105	1 (2%)	4 (6%)
1 to <3	20	62	81	173	11 (4%)	50 (16%)
3 to < 6	18	57	49	107	0 (0%)	37 (6%)

* P50 (median): Average consumers; P95: High consumers; mLB: modified Lower Bound; UB: Upper Bound

6.2 Risk management options, recommended measures

As described in section 6.1, the dataset submitted by BVL on EA levels in the products listed in the Annex of Regulation (EU) 2021/1399 did not contain data on the occurrence of EAs in wheat gluten. In addition, the sample sizes included for processed cereal based foods for infants and young children, oats and barley were too small for representative statements with regard to exposure. Therefore, BfR recommends collecting further occurrence data on the matrices mentioned. In addition, the data basis should be expanded to include other potential sources that can contribute to total exposure but are not listed in the Annex of Regulation (EU) 2021/1299, such as soy and buckwheat (see Section 6.3).

6.3 Other aspects

6.3.1 Occurrence data of other foods potentially containing EAs

In the present opinion, only the EA levels of regulated products according to the Annex of Regulation (EU) 2021/1399 were considered for the short-term and long-term exposure of 0.5

to < 6-year-old children. However, the dataset provided by BVL indicates that other foods, such as soy and buckwheat, may be relevant contributors to exposure.

Table 21 shows the sum of EAs in soy and buckwheat which could contribute significantly to the total exposure, especially against the background of the increasing consumption of soy products and pseudo cereals. The contents of soy and buckwheat are above those of wheat products and below those of whole wheat products.

Table 21: Sum of EAs [µg/kg] in soy and buckwheat. Data collection of the federal states between the years 2013 and 2021.

		Soy	Buckwheat
N Samples		65	92
N (%) Detects*		16 (25%)	10 (11%)
LB	Min	0.0	0.0
	P5	0.0	0.0
	P50	0.0	0.0
	Mean	5.8	6.6
	P95	32.2	51.0
	Max	45.0	156.0
mLB	Min	0.0	0.0
	P5	0.0	0.0
	P50	0.0	0.0
	Mean	7.1	8.9
	P95	32.5	51.,0

		Soy	Buckwheat
	Max	49.0	156.0
UB	Min	6.5	9.8
	P5	6.5	9.8
	P50	9.8	30.0
	Mean	35.6	48.6
	P95	91.8	120.0
	Max	106.2	201.0

*A sample was determined as a detect as soon as a single parameter could be quantified.

Further information on the BfR website on the subject of ergot alkaloids

Questions and answers on ergot alkaloids in cereal products:

<https://www.bfr.bund.de/cm/349/frequently-asked-questions-on-ergot-alkaloids-in-cereal-products.pdf>

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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, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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