Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Zearalenone exposure from breakfast cereals in Norwegian children

Opinion of the Panel on Contaminants of the Norwegian Scientific Committee for Food Safety

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Contributors

Persons working for VKM, either as appointed members of the Committee or as ad hoc experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Assessed by

The report has been evaluated and approved by Panel of Contaminants of VKM:
Janneche Utne Skåre (Chair), Heidi Amlund, Augustine Arukwe, Anne Lise Brantsæter, Gunnar Sundstøl Eriksen, Christiane Kruse Fæste, Helle Katrine Knutsen, and Anders Ruus.

Scientific coordinators from the secretariat

Edel Holene and Inger Therese Lillegaard

Summary

Zearalenone is a mycotoxin produced by *Fusarium* species, which may invade crops in the field. Zearalenone can, after crop harvesting, be detected both in grain and products thereof. In EU, the current maximum level (ML) of 50 µg zearalenone/kg breakfast cereals, except maize-based, is under discussion for a potential increase.

The toxicity of zearalenone has recently been reviewed by the European Food Safety Authority (EFSA) and a tolerable daily intake (TDI) of 0.25 µg/kg body weight was established. EFSA concluded that chronic dietary exposure to zearalenone based on the available occurrence data are below or in the region of the TDI for all age groups and therefore, not of a health concern. However, due to a possible higher consumption of high-fibre breakfast cereals among Norwegian children than other European children, the Norwegian Food Safety Authority requested the Scientific Committee for Food Safety (VKM) to assess the exposure to zearalenone from food, especially from breakfast cereals, in Norwegian children (2-, 4-, 9- and 13-year-olds). On the basis of Norwegian consumption data different exposure scenarios of zearalenone maximum levels in breakfast cereals (i.e. 50, 100 and 150 µg/kg) were also requested to be included in the evaluation.

Consumption of high-fibre breakfast cereals among children in Norway is within the same order of magnitude as reported for children's consumption of all sorts of breakfast cereals from other European countries. It is not known whether Norwegian children consume more high-fibre breakfast cereals than other European children. The consumption of low-fibre breakfast cereals is lower than that of high-fibre ones for all age groups between 4-13 years among Norwegian children.

The evaluation of zearalenone exposure, based on the consumption of high-fibre breakfast cereals among Norwegian 2-, 4-, 9- and 13-year olds and the same zearalenone occurrence data as used by EFSA, indicates that the current zearalenone exposure among mean and high consumers is well below the TDI for all age groups.

A short-term exposure scenario among Norwegian children based on the presumption that the zearalenone concentration is 50 µg/kg in breakfast cereals (current maximum level) indicated that at this concentration, exposure from breakfast cereals will slightly exceed the TDI only among 4-year old high consumers (i.e. the 95-percentile of consumers only). Short-term exposure scenarios based on zearalenone concentrations of 100 and 150 µg/kg breakfast cereals indicated that all high consumers among Norwegian children would exceed the TDI. In case that a child consumes the same batch of breakfast cereals containing zearalenone at an increased maximal level daily for some weeks, the TDI could be exceeded during this period. However, the TDI has been set for long-term exposure and does not apply directly for short-term exposure.

The long-term exposure scenario considering a 3-fold increase in the mean zearalenone concentration as a result of increasing the ML 3-fold to 150 µg/kg in breakfast cereals indicates that the exposure will probably be well below the TDI for all age groups of Norwegian children, including high consumers of breakfast cereals.

Norwegian summary

Zearalenon er en muggsoppgift som arter *Fusarium* lager. Denne muggsoppen kan invadere korn på åkre. Etter kornhøsting kan zearalenon bli påvist både i kornet og i kornprodukter. I EU diskuteres det å øke grenseverdien for zearalenon i frokostblandinger som ikke er basert på mais. Den nåværende grenseverdien er på 50 µg zearalenon per kilo frokostblandinger.

Det europeiske risikovurderingsorganet EFSA (European Food Safety Authority) har nylig gjennomgått toksisiteten av zearalenon og satt det tolerable daglige inntaket (TDI) til 0,25 µg/kg kroppsvekt. EFSA konkluderte også med at ut i fra tilgjengelige forekomstdata av zearalenon er langvarig eksponering for zearalenon fra mat under eller i området for TDI for alle aldersgrupper og utgjør ikke noen helsefare. Det kan imidlertid være mulig at norske barn har et høyere konsum av grove frokostblandinger enn andre europeiske barn. Mattilsynet ba derfor Vitenskapskomiteen for mattrygghet (VKM) om å vurdere norske barns (2-, 4-, 9- og 13-åringer) eksponering for zearalenon fra mat, særlig fra frokostblandinger. Videre skulle det inkluderes eksponeringsscenarioer for ulike grenseverdier av zearalenon i frokostblandinger (50, 100 og 150 µg/kg) basert på norske kostholdsundersøkelser.

Norske barns konsum av grove frokostblandinger er i samme størrelsesorden som konsumet for alle typer frokostblandinger hos barn fra andre europeiske land. Det er ukjent hvorvidt norske barn spiser mer av grove frokostblandinger enn andre europeiske barn. Norske barn mellom 4 og 13 år spiser mindre av fine enn av grove frokostblandinger.

Vurderingen av zearalenoneksponering er utført på grunnlag av konsum av grove frokostblandinger hos norske 2-, 4-, 9- and 13-åringer og de samme forekomstdataene av zearalenon som EFSA brukte i sin vurdering. Både hos gjennomsnittskonsumentene og høykonsumentene er nåværende eksponering for zearalenon godt under TDI for alle aldersgruppene.

Et scenario for kortvarig eksponering, som forutsetter at zearalenonkonsentrasjonen er tilsvarende dagens grenseverdi på 50 µg/kg frokostblanding, indikerer at eksponering fra frokostblandinger bare vil medføre en lav overskridelse av TDI hos norske 4-år gamle høykonsumenter (dvs. 95-percentilen av ”consumers only”). De scenarioene for kortvarig eksponering som forutsetter at zearalenonkonsentrasjonen er på henholdsvis 100 og 150 µg/kg frokostblanding, tyder på at høykonsumentene blant norske barn vil kunne overskride TDI. Det er derfor mulig at hvis et barn daglig i noen uker konsumerer samme produksjonsparti av en frokostblanding som har zerealenonkonsentrasjon som tilsvarer et økt maksimumsnivå, kan TDI overskrides i denne perioden. TDI er imidlertid satt for langtidseksponering, og gjelder ikke direkte for kortvarig eksponering.

I scenarioet for langvarig eksponering er det forutsatt at den gjennomsnittlige zearalenonkonsentrasjonen tredobles dersom grenseverdien tredobles til 150 µg/kg frokostblanding. Beregningene tyder på at langtidseksponeringen sannsynligvis vil være godt under TDI for alle aldersgrupper av norske barn, også for høykonsumentene av frokostblandinger.

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Background

Upon request from the European Commission (Question No EFSA-Q-2010-00958, adopted on 31 May 2011), the European Food Safety Authority (EFSA) has recently published a Scientific Opinion on the risks for public health related to the presence of zearalenone in food (EFSA, 2011). The European Commission requested EFSA to assess the potential increase of consumer health risk by a possible increase of the currently existing maximum level (ML) of 50 microgram per kilo (µg/kg) to 75, 100, 125 or 150 µg/kg for breakfast cereals by taking into account the exposure to zearalenone from other food sources considering occurrence data, specific consumption patterns of breakfast cereals in the different Member States and specific vulnerable groups of the population, including children, and high level consumers.

Commission Regulation (EC) No 1881/2006 set MLs for cereals and cereal products, as well as for maize and maize products. No ML has been set for wheat bran used as an ingredient, but wheat bran used in high-fibre breakfast cereals should not have a level higher than 75 µg/kg in order to enable high-fibre breakfast cereal producers to comply with the existing ML of 50 µg/kg for breakfast cereals other than maize-based. After a difficult harvest in 2008, a temporary increase of the concentration of zearalenone to 100 µg/kg high-fibre breakfast cereals (other than maize-based) was given for production date before October 31st, 2009. A possible permanent increase of this level is being discussed in the EU.

The EFSA report of 2011 concluded that a potential increase in the ML for zearalenone in breakfast cereals from 50 µg/kg to 75, 100, 125 or 150 µg/kg is unlikely to result in a chronic dietary exposure exceeding the TDI. In a worst case scenario, it is possible that an individual could consume the same batch of breakfast cereal containing zearalenone at the ML every day for 2 to 4 weeks, in which case exposures may exceed the TDI.

Due to lower body weight in children, the risk for exceeding the TDI is greater for children than adults. High-fibre breakfast cereals often contain wheat bran, where zearalenone concentration tends to be the highest. Based on the discussions in the EU Expert Committee on Agricultural Contaminants at the meeting of November 10th 2011, The Norwegian Food Safety Authority required more data about Norwegian children and their exposure to zearalenone. Based on published consumption surveys in Norway, Norwegian children appear to have higher consumption of high-fibre breakfast cereals than what reported for other European children in the EFSA Opinion (2011).

Terms of reference

The Norwegian Food Safety Authority requests the Scientific Committee for Food Safety (VKM) to assess the exposure to zearalenone from food in Norwegian children (2-, 4-, 9- and 13-year-olds). We are both interested in knowing the children's total exposure to zearalenone from major food sources and the contribution from breakfast cereals alone. What kinds of breakfast cereals are consumed by children in Norway (maize, whole grain with a high content of fibre, other)?

EFSA has assessed the potential health risk for different scenarios of zearalenone maximum levels in breakfast cereals. These are 50 (current value), 75, 100, 125 and 150 µg/kg food. We would like these scenarios to be included on the basis of Norwegian consumption data.

Limitation

At a meeting held on December 2nd, 2011, the Norwegian Food Safety Authority asked VKM to prioritize assessment of Norwegian children's exposure to zearalenone from breakfast cereals alone, due to restricted time schedule for the request. For the same reason, the short-time scenarios were limited to 50, 100 and 150 µg zearalenone/kg breakfast cereals and the long-term scenario was limited to only consider a maximum limit of 150 µg zearalenone/kg breakfast cereals.

1 Introduction

1.1 The mycotoxin zearalenone

Fungi that readily colonize crops may produce mycotoxins, which are potentially toxic when ingested by humans or animals. The mycotoxin, zearalenone, is produced by several *Fusarium* species, which grow and invade crops in moist and cold field conditions. After crop harvesting, zearalenone may be detected in the grain and products thereof. According to European data, maize and wheat bran contain the highest concentrations of zearalenone (EFSA, 2011).

Table 1 The maximum levels (MLs) for zearalenone as laid down in Commission Regulation (EC) No 1881/2006.

Category	Food*	Maximum level (µg/kg)
1	Unprocessed cereals other than maize	100
2	Unprocessed maize with the exception of those intended for processing by wet milling	350
3	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed below in 6, 7, 8, 9 and 10	75
4	Refined maize oil	400
5	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals, excluding maize snacks and maize based breakfast cereals	50
6	Maize intended for direct human consumption, maize-based snacks and maize-based breakfast cereals	100
7	Processed cereal-based foods (excluding processed maize-based foods) and baby foods for infants and young children [a]	20[b]
8	Processed maize-based foods for infants and young children [a]	20[b]
9	Milling fractions of maize with particle size >500 µm falling within CN (Combined Nomenclature) code 1103 13 or 1103 20 40 and other maize milling products with particle size >500 µm not used for direct human consumption falling within CN code 1904 10 10	200
10	Milling fractions of maize with particles size ≤500 µm falling within CN code 1102 20 and other maize milling products with particle size ≤500 µm not used for direct human consumption falling within CN code 1904 10 10	300

* For further definitions and explanations of individual food commodities, see the original regulations.
[a] The food in this category is as defined in Commission Directive 96/5/EC of 16 February 1996 on processed cereal based foods and baby foods for infants and young children as last amended by Directive 2003/13/EC.
[b] The maximum level refers to the dry matter, which is defined according to Regulation (EC) No 401/2006.

Grains and grain-based food such as breakfast cereals, bread and bakery were the largest contributors to the estimated dietary exposure to zearalenone in Europe due to high consumption (EFSA, 2011).

Within the EU regulations, the maximum levels (MLs) for zearalenone in some types of grain and grain products, especially for maize and products thereof, are given in Table 1. Currently, the ML for zearalenone in breakfast cereals, except those based on maize, is under discussion for possible increase.

1.2 Unwanted health effects of zearalenone and tolerable daily intake (TDI)

Zearalenone has been shown to produce unwanted health effects, particularly on the reproductive system of animals by eliciting estrogenic activities (EFSA, 2011). However, adverse effects due to zearalenone exposure from food have so far not been documented in humans.

The toxicity of zearalenone was recently reviewed by EFSA (2011) and a tolerable daily intake (TDI) for zearalenone of 0.25 µg/kg body weight was established.

2 Exposure characterisation in children

2.1 Background for calculations of zearalenone exposure through food

2.1.1 Norwegian dietary surveys

Data from two different dietary surveys were used in this assessment of zearalenone exposure from breakfast cereals among children in Norway.

Småbarnskost 2007 was based on a semi-quantitative 14-day food frequency questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. The study was conducted in 2007, and a total of 1674 2-year-olds participated (Kristiansen et al., 2009).

Ungkost 2000 was based on a 4-day food consumption registration with a precoded food diary. Food amounts were presented in predefined household units or as portions estimated from photographs (Øverby and Andersen, 2002, Pollestad et al., 2002). A total of 391 4-year-olds, 810 9-year-olds and 1005 13-year-olds participated in the survey. The study was conducted in 2000 among the 9- and 13-year-old children, and in 2001 among the 4-year-old children.

2.1.2 Definition of breakfast cereals

In order to calculate the children's exposure to zearalenone from breakfast cereals, food items and dishes containing high-fibre breakfast cereals were identified and consumption calculated in grams per day. Concerning porridges, only the cereal part was included in the consumption calculation. High-fibre breakfast cereals were defined as having at least 6g of fibre per 100g or at least 3g of fibre per 100 kcal (Regulation (EC) No 1924/2006).

2.1.3 Occurrence data of zearalenone

The concentrations of zearalenone in the foods grouped into "oat, porridge and flakes", "muesli" and "high-fibre cereals" are retrieved from the "Scientific Opinion on the risks for public health related to the presence of zearalenone in food" (EFSA, 2011) (see Table 2). For "oat, porridge and flakes" the concentration for oat flakes was used, for "muesli" the

concentration from muesli was used, and for "high-fibre cereals" the combined value for breakfast cereals was used (Table 2).

Table 2 Zearalenone concentrations in the food groups "oat flakes", "muesli" and "breakfast cereals".

Food group		Mean (µg/kg) [a]
Oat flakes	Lower bound (LB) Upper bound (UB)	0.5 3.1
Muesli	Lower bound (LB) Upper bound (UB)	1.2 5.5
Breakfast cereals	Lower bound (LB) Upper bound (UB)	1.2 5.7

[a] Data retrieved from EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks for public health related to the presence of zearalenone in food. EFSA Journal 2011; 9(6):2197. [page 32.] doi:10.2903/j.efsa.2011.2197. Available online: www.efsa.europa.eu/efsajournal

2.1.4 The terms "all participants" and "consumers only"

For each age group calculations were performed for all participants in the study and for a subgroup of consumers only. The consumers only had consumed high-fibre breakfast cereals during the last 14 days among the 2-year-olds, and during the 4-day registration period among the 4-, 9- and 13-year-olds.

2.2 Consumption of breakfast cereals among 2-year-old Norwegian children

The consumptions of high-fibre breakfast cereals among all participants and consumers only (i.e. those who reportedly consumed high-fibre cereals during the study period) in Småbarnskost 2007 are shown in Tables 3 and 4, respectively. The consumptions of oat, muesli and porridge grains other than oat are shown in both Tables 3 and 4. In addition, the combined consumption of all these high-fibre breakfast cereals is shown in the column named "Total consumption of high-fibre cereals".

Table 3 All participants: Consumption (g/day) of high-fibre cereals among 2-year-old Norwegian children (n=1674).

	Oat, porridge and flakes [a] g/day	Muesli [b] g/day	Porridge grains [c] g/day	Total consumption of high-fibre cereals [d] g/day
Mean (SD)	8 (12)	1 (4)	1 (12)	8 (14)
Median (95 percentile)	4 (30)	0 (9)	0 (0)	4 (32)

[a] Oat flakes used in porridge and as dry flakes (not in bread, or mixed breakfast cereals), [b] Muesli include sweetened and unsweetened mixed breakfast cereals, [c] Include high-fibre baby porridge and homemade porridge other than oat, [d] Combined consumption of oat and muesli and other porridge grains.

Table 4 Consumers only: Consumption (g/day) of high-fibre cereals among the 2-year-old Norwegian children (n=875).

	Oat, porridge and flakes [a] g/day	Muesli [b] g/day	Porridge grains [c] g/day	Total consumption of high-fibre cereals [d] g/day
Mean (SD)	15 (13)	2 (4)	1 (4)	16 (16)
Median (95-percentile)	10 (42)	0 (9)	0 (5)	10 (42)

[a] Oat flakes used in porridge and as dry flakes (not in bread, or mixed breakfast cereals). [b] Muesli include sweetened and unsweetened mixed breakfast cereals. [c] Includes high-fibre baby porridge and homemade porridge other than oat. [d] Combined consumption of oat and muesli and other porridge grains.

2.3 Consumption of breakfast cereals among 4-, 9- and 13-year-old Norwegian children

The consumptions of high-fibre breakfast cereals among all participants and consumers only (i.e. those who reported to consume high-fibre cereals during the study period) in Ungkost 2000 are shown in Tables 5 and 6, respectively. The consumption of oat and muesli is shown in both Tables 5 and 6. In addition, the combined consumption of these high-fibre cereals is shown in the column named "Total consumption of high-fibre cereals". The consumption of low-fibre breakfast cereals including Cornflakes and rice/wheat/oat puffs is shown in the right column. This low-fibre consumption is not included in the total consumption of high-fibre cereals.

Table 5 All participants: Consumption (g/day) of breakfast cereals among 4-, 9- and 13-year-old Norwegian children.

	Oat, porridge and flakes [a] g/day	Muesli [b] g/day	Total consumption of high-fibre cereals [c] g/day	Consumption of low-fibre cereals [d] g/day
4-year-olds (n= 391)				
Mean (SD)	**6 (19)**	**3 (13)**	**9 (23)**	**4 (9)**
Median (95-percentile)	**0 (26)**	**0 (15)**	**0 (41)**	**0 (23)**
9-year-olds (n= 810)				
Mean (SD)	**6 (26)**	**5 (17)**	**11 (31)**	**7 (15)**
Median (95-percentile)	**0 (44)**	**0 (29)**	**0 (72)**	**0 (33)**
13-year-olds (n= 1005)				
Mean (SD)	**4 (16)**	**5 (22)**	**8 (27)**	**6 (15)**
Median (95-percentile)	**0 (23)**	**0 (23)**	**0 (45)**	**0 (35)**

[a] Oat flakes used in porridge and as dry flakes (not in bread, or mixed breakfast cereals). [b] Muesli include sweetened and unsweetened mixed breakfast cereals. [c] Combined consumption of oat and muesli. [d] Low-fibre cereals include Cornflakes and rice/wheat/oat puffs. **Note that** these are **not** included in the high-fibre cereal consumption.

Table 6 **Consumers only:** Consumption (g/day) of breakfast cereals among 4-, 9- and 13-year-old Norwegian children.

	Oat, porridge and flakes [a] g/day	Muesli [b] g/day	Total consumption of high-fibre cereals [c] g/day	Consume of low-fibre cereals [d] g/day
4-year-olds (n= 137)				
Mean (SD)	**16 (29)**	**9 (20)**	**25 (33)**	**3 (7)**
Median (95-percentile) [e]	**8 (90)**	**0 (34)**	**11 (100)**	**0 (17)**
9-year-olds (n= 248)				
Mean (SD)	**21 (43)**	**16 (29)**	**37 (46)**	**5 (11)**
Median (95-percentile) [e]	**0 (134)**	**8 (84)**	**16 (146)**	**0 (28)**
13-year-olds (n= 273)				
Mean (SD)	**14 (28)**	**17 (40)**	**31 (45)**	**6 (14)**
Median (95-percentile) [e]	**0 (70)**	**8 (70)**	**15 (110)**	**0 (33)**

[a] Oat flakes used in porridge and as dry flakes (not in bread, or mixed breakfast cereals), [b] Muesli include sweetened and unsweetened mixed breakfast cereals, [c] Combined consumption of oat and muesli, [d] Low-fibre cereals include Cornflakes and rice/wheat/oat puffs. **Note that** these are **not** included in the high-fibre cereal consume, [e] **Note that** since n is low, there is high uncertainty associated with the 95-percentile

2.4 Exposure to zearalenone from breakfast cereals among Norwegian children

The daily exposure to zearalenone among Norwegian children, both among all participants and among those who reported to consume high-fibre cereals during the study period (i.e. consumers only) is shown in Tables 7 and 8, respectively. The calculations were based on the reported consumption of high-fibre cereals among Norwegian children, and on zearalenone concentrations (upper bound, UB, and lower bound, LB) in breakfast cereals as reported in "Scientific Opinion on the risks for public health related to the presence of zearalenone in food" (EFSA, 2011) (see Table 2).

Table 7 All participants: Zearalenone exposure from breakfast cereals among 4-, 9- and 13-year-old Norwegian children. Calculations are based on Norwegian consumption of high-fibre breakfast cereals and zearalenone concentrations from EFSA (2011)[a].

	Consumption g/day Mean (95-percentile)	EFSA – LB[a] µg zearalenone/kg	EFSA – UB[a] µg zearalenone/kg	EFSA – LB µg zearalenone/kg b.w./day[b] Mean (95-percentile)	EFSA – UB µg zearalenone/kg b.w./day[b] Mean (95-percentile)
2-year-olds (n=1674)					
Oat, porridge and flakes	8 (30)	0.5	3.1	0.0003 (0.0012)	0.0020 (0.0073)
Muesli	1 (9)	1.2	5.5	0.0001 (0.0008)	0.0004 (0.0039)
Total consumption of high-fibre cereals [c]	**8 (32)**	**1.2**	**5.7**	**0.0007 (0.0030)**	**0.0036 (0.0143)**
4-year-olds (n=391)					
Oat, porridge and flakes	6 (26)	0.5	3.1	0.0002 (0.0007)	0.0010 (0.0045)
Muesli	3 (15)	1.2	5.5	0.0002 (0.0010)	0.0009 (0.0046)
Total consumption of high-fibre cereals [d]	**9 (41)**	**1.2**	**5.7**	**0.0006 (0.0027)**	**0.0029 (0.0130)**
9-year-olds (n=810)					
Oat, porridge and flakes	6 (44)	0.5	3.1	0.0001 (0.0007)	0.0006 (0.0043)
Muesli	5 (29)	1.2	5.5	0.0002 (0.0011)	0.0009 (0.0050)
Total consumption of high-fibre cereals [d]	**11 (72)**	**1.2**	**5.7**	**0.0004 (0.0027)**	**0.0020 (0.0128)**
13-year-olds (n=1005)					
Oat, porridge and flakes	4 (23)	0.5	3.1	0.00004 (0.0002)	0.0003 (0.0014)
Muesli	5 (23)	1.2	5.5	0.0001 (0.0006)	0.0006 (0.0026)
Total consumption of high-fibre cereals [d]	**8 (45)**	**1.2**	**5.7**	**0.0002 (0.0011)**	**0.0009 (0.0052)**

[a] See Table 2 in this document for zearalenone concentrations, lower bound (LB) and upper bound (UB). [b] Mean body weights (b.w.) from Småbarnskost 2007 and Ungkost 2000 are 12.8 kg, 18 kg, 32 kg and 49.5 kg for 2-, 4-, 9- and 13-year olds, respectively. [c] Total consumption of high-fibre cereals is combined consumption of oat, muesli and porridge other than oat (see also Table 3). [d] Total consumption of high-fibre cereals is combined consumption of oat and muesli.

Table 8 Consumers only: Zearalenone exposure from breakfast cereals among 4-, 9- and 13-year-old Norwegian children. Calculations are based on Norwegian consumption of high-fibre breakfast cereals and zearalenone concentrations from EFSA (2011)[a].

	Consumption g/day Mean (95-percentile)	EFSA – LB[a] µg zearalenone/kg	EFSA – UB[a] µg zearalenone/kg	EFSA – LB µg zearalenone/kg b.w./day[b] Mean (95-percentile)	EFSA – UB µg zearalenone/kg b.w./day[b] Mean (95-percentile)
2-year-olds (n=875)					
Oat, porridge and flakes	15 (42)	0.5	3.1	0.0006 (0.0016)	0.0036 (0.0102)
Muesli	2 (9)	1.2	5.5	0.0002 (0.0008)	0.0009 (0.0039)
Total consumption of high-fibre cereals [c]	**16 (42)**	**1.2**	**5.7**	**0.0015 (0.0039)**	**0.0071 (0.0187)**
4-year-olds (n=137)					
Oat, porridge and flakes	16 (90)	0.5	3.1	0.0004 (0.0025)	0.0028 (0.0155)
Muesli	9 (34)	1.2	5.5	0.0006 (0.0023)	0.0028 (0.0104)
Total consumption of high-fibre cereals[d]	**25 (100)**	**1.2**	**5.7**	**0.0017 (0.0067)**	**0.0079 (0.0317)**
9-year-olds (n=248)					
Oat, porridge and flakes	21 (134)	0.5	3.1	0.0003 (0.0021)	0.0020 (0.0130)
Muesli	16 (84)	1.2	5.5	0.0006 (0.0032)	0.0028 (0.0144)
Total consumption of high-fibre cereals[d]	**37 (146)**	**1.2**	**5.7**	**0.0014 (0.0055)**	**0.0066 (0.0260)**
13-year-olds (n=273)					
Oat, porridge and flakes	14 (70)	0.5	3.1	0.0001 (0.0007)	0.0009 (0.0044)
Muesli	17 (70)	1.2	5.5	0.0004 (0.0017)	0.0019 (0.0078)
Total consumption of high-fibre cereals[d]	**31 (110)**	**1.2**	**5.7**	**0.0008 (0.0027)**	**0.0036 (0.0127)**

[a] See Table 2 in this document for zearalenone concentrations, lower bound (LB) and upper bound (UB). [b] Mean body weights (b.w.) from Småbarnskost 2007 and Ungkost 2000 are 12.8 kg, 18 kg, 32 kg and 49.5 kg for 2-, 4-, 9- and 13-year olds, respectively. [c] Total consumption of high-fibre cereals is combined consumption of oat, muesli and porridge other than oat (see also Table 3). [d] Total consumption of high-fibre cereals is combined consumption of oat and muesli.

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2.5 Estimated exposure to zearalenone from the total diet

In a draft risk assessment of mycotoxin, VKM has estimated zearalenone exposure from the total diet based on Norwegian occurrence data in cereals and food consumption data from Ungkost 2000 and Småbarnskost 2007 (draft Mycotoxin risk assessment, VKM 2012). In the total diet consumption, only cereals including high-fibre breakfast cereals, were taken into account for zearalenone exposure. Non-cereal food items were assumed not to have any significant contribution to the total daily intake. The mean concentrations of zearalenone in various cereals from the Norwegian market and the concentrations used by EFSA (2011) were comparable.

The range of zearalenone concentration used in the risk assessment is based on the year with the lowest zearalenone concentration versus the year with the highest zearalenone concentration between 2008 and 2010. The exposure range is given as the lowest and highest mean exposure and as the lowest and highest 95-percentile of exposure.

Depending on the variations in concentrations between years, the zearalenone exposure among 4-year-olds is in the range of 0.01-0.10 µg zearalenone/kg b.w./day based on mean consumption, and in the range of 0.02-0.20 µg zearalenone/kg b.w./day for the 95-percentile consumers. Among the 9-year-olds, the zearalenone exposure was in the range of 0.01-0.08 µg zearalenone/kg b.w./day based on mean consumption, and for the 95-percentile consumers the range was 0.01-0.10 µg zearalenone/kg b.w./day. Among the 13-year-olds, the zearalenone exposure was lower than for the 4- and 9-year-olds and in the range of 0.004-0.05 µg zearalenone/kg b.w./day based on mean consumption, and for the 95-percentile consumption the range was 0.008-0.10 µg zearalenone/kg b.w./day.

2.6 Exposure scenarios after increased maximum levels of zearalenone in high-fibre breakfast cereals

2.6.1 Short-term dietary exposure

Short-term exposure scenarios based on the presumption that all high-fibre breakfast cereals have a zearalenone concentration equal to 50, 100 and 150 µg zearalenone/kg, respectively, have been estimated by VKM.

In the 50 µg/kg exposure scenario, the mean zearalenone exposure from high-fibre breakfast cereals in all participants for all age groups is in the range 0.008-0.031 µg zearalenone/kg b.w./day, and for the 95-percentile consumption in the range 0.045-0.125 µg zearalenone/kg b.w./day (Table 9). For consumers only in all age groups (Table 10), the mean consumption is in the range 0.031-0.069 and for the 95-percentile (i.e. high consumers) the range is 0.111-0.278 µg zearalenone/kg b.w./day.

Scenario 100 µg/kg gives mean exposures that are below the TDI for all participants in all age groups (Table 9). However, for the 95-percentile, the exposure is close to the TDI for all age groups except for 13-year-olds. The 95-percentile exposures among the 4- and 9-year-old consumers only are nearly 2 times the TDI (Table 10).

Scenario 150 gives a considerably higher exposure to zearalenone for all participants in all age groups with regard to both the mean consumption and the 95-percentile (Table 9). The mean exposure from zearalenone is close to the TDI among consumers only for all ages except the 13-year-olds (Table 10). The 95-percentiles for all age groups exceed the TDI up to 3 times.

A child could consume the same batch of breakfast cereals containing zearalenone at an increased maximal level (e.g. 100 or 150 µg/kg) every day for some weeks. In this case, exposure can increase up to 1 µg zearalenone/kg b.w./day (Table 10).

2.6.2 Long-term dietary exposure

For long-term exposure, EFSA (2011) suggested that a doubling or tripling of the ML in cereals could shift the distribution of zearalenone concentrations equally, and used the concentration 17.1 µg/kg (3-fold the mean UB occurrence in breakfast cereals of 5.7µg/kg) in their scenario for long-term exposure, when ML is increased to 150 µg/kg. VKM has used the same zearalenone concentration (17.1 µg/kg) in the exposure scenarios in this evaluation, combined with breakfast cereal consumption among Norwegian children. The results (Table 11) indicate that long-term high exposure (i.e. 95-percentile of consumers only) would increase to 0.095 µg/kg b.w. This was seen among 4-year olds, which was the age group with the highest exposure.

Table 9 All participants: Short-term exposure scenarios for zearalenone from high-fibre breakfast cereals at concentrations equal to 50 (today's maximum level), 100 and 150 µg/kg breakfast cereals among 2-, 4-, 9- and 13-year-old children.

	Consumption g/day Mean (95-percentile)	**Scenario 50 (todays level) µg zearalenone/kg b.w./day [a] Mean (95-percentile)**	**Scenario 100 µg zearalenone/kg b.w./day[a] Mean (95-percentile)**	**Scenario 150 µg zearalenone/kg b.w./day[a] Mean (95-percentile)**
2-year-olds (n=1674)				
Oat, porridge and flakes	8 (30)	0.031 (0.117)	0.063 (0.234)	0.094 (0.352)
Muesli	1 (9)	0.004 (0.035)	0.008 (0.070)	0.012 (0.105)
Total consumption of high-fibre cereals[b]	**8 (32)**	**0.031 (0.125)**	**0.063 (0.250)**	**0.094 (0.375)**
4-year-olds (n=391)				
Oat, porridge and flakes	6 (26)	0.017 (0.072)	0.033 (0.144)	0.050 (0.217)
Muesli	3 (15)	0.008 (0.042)	0.017 (0.083)	0.025 (0.125)
Total consumption of high-fibre cereals[c]	**9 (41)**	**0.025 (0.114)**	**0.050 (0.228)**	**0.075 (0.342)**
9-year-olds (n=810)				
Oat, porridge and flakes	6 (44)	0.009 (0.069)	0.019 (0.137)	0.028 (0.206)
Muesli	5 (29)	0.008 (0.045)	0.016 (0.091)	0.023 (0.136)
Total consumption of high-fibre cereals[c]	**11 (72)**	**0.017 (0.112)**	**0.034 (0.225)**	**0.052 (0.337)**
13-year-olds (n=1005)				
Oat, porridge and flakes	4 (23)	0.004 (0.023)	0.008 (0.046)	0.012 (0.070)
Muesli	5 (23)	0.005 (0.023)	0.010 (0.046)	0.015 (0.070)
Total consumption of high-fibre cereals[c]	**8 (45)**	**0.008 (0.045)**	**0.016 (0.091)**	**0.024 (0.136)**

[a] Mean body weights (b.w.) from Småbarnskost 2007 and Ungkost 2000 are 12.8 kg, 18 kg, 32 kg and 49.5 kg for 2-, 4-, 9- and 13-year olds, respectively. [b] Total consumption of high-fibre cereals is combined consumption of oat, muesli and porridge other than oat (see also Table 3). [c] Total consumption of high-fibre cereals is combined consumption of oat and muesli.

Table 10 **Consumers only:** Short-term exposure scenarios for zearalenone from high-fibre breakfast cereals at concentrations equal to 50 (today's maximum level), 100 and 150 µg/kg breakfast cereals among 2-, 4-, 9- and 13-year-old Norwegian children.

	Consumption g/day Mean (95-percentile)	**Scenario 50 (todays level) µg zearalenone/kg b.w./day [a] Mean (95-percentile)**	**Scenario 100 µg zearalenone/kg b.w./day[a] Mean (95-percentile)**	**Scenario 150 µg zearalenone/kg b.w./day[a] Mean (95-percentile)**
2-year-olds (n=875)				
Oat, porridge and flakes	15 42)	0.059 (0.164)	0.117 (0.328)	0.176 (0.492)
Muesli	2 (9)	0.008 (0.035)	0.016 (0.070)	0.023 (0.105)
Total consumption of high-fibre cereals[b]	**16 (42)**	**0.063 (0.164)**	**0.125 (0.328)**	**0.187 (0.492)**
4-year-olds (n=137)				
Oat, porridge and flakes	16 (90)	0.044 (0.250)	0.089 (0.500)	0.133 (0.750)
Muesli	9 (34)	0.025 (0.094)	0.050 (0.189)	0.075 (0.283)
Total consumption of high-fibre cereals[c]	**25 (100)**	**0.069 (0.278)**	**0.139 (0.556)**	**0.208 (0.833)**
9-year-olds (n=248)				
Oat, porridge and flakes	21 (134)	0.033 (0.209)	0.066 (0.419)	0.098 (0.628)
Muesli	16 (84)	0.025 (0.131)	0.050 (0.263)	0.075 (0.394)
Total consumption of high-fibre cereals[c]	**37 (146)**	**0.058 (0.228)**	**0.116 (0.456)**	**0.173 (0.684)**
13-year-olds (n=273)				
Oat, porridge and flakes	14 (70)	0.014 (0.071)	0.028 (0.141)	0.042 (0.212)
Muesli	17 (70)	0.017 (0.071)	0.034 (0.141)	0.052 (0.212)
Total consumption of high-fibre cereals[c]	**31 (110)**	**0.031 (0.111)**	**0.063 (0.222)**	**0.094 (0.333)**

[a] Mean body weights (b.w.) from Småbarnskost 2007 and Ungkost 2000 are 12.8 kg, 18 kg, 32 kg and 49.5 kg for 2-, 4-, 9- and 13-year olds, respectively. [b] Total consumption of high-fibre cereals is combined consumption of oat, muesli and porridge other than oat (see also Table 3). [c] Total consumption of high-fibre cereals is combined consumption of oat and muesli.

Table 11 **All participants and consumers only:** Long-term exposure scenarios for zearalenone from high-fibre breakfast cereals at concentrations equal to 17.1 µg/kg breakfast cereals among 2-, 4-, 9- and 13-year-old Norwegian children.

	Consumption g/day Mean (95 percentile)	Exposure scenario 150 µg zearalenone/kg b.w./day [a]	
		All participants Mean (95 percentile)	Consumers only Mean (95 percentile)
2-year-olds (n=1674)			
Oat, porridge and flakes	8 (30)	0.011 (0.041)	0.021 (0.057)
Muesli	1 (9)	0.001 (0.012)	0.003 (0.012)
Total consumption of high-fibre cereals[b]	**8 (32)**	**0.011 (0.044)**	**0.022 (0.057)**
4-year-olds (n=391)			
Oat, porridge and flakes	6 (26)	0.006 (0.025)	0.015 (0.086)
Muesli	3 (15)	0.003 (0.014)	0.009 (0.032)
Total consumption of high-fibre cereals[c]	**9 (41)**	**0.009 (0.039)**	**0.024 (0.095)**
9-year-olds (n=810)			
Oat, porridge and flakes	6 (44)	0.003 (0.024)	0.011 (0.072)
Muesli	5 (29)	0.003 (0.015)	0.009 (0.045)
Total consumption of high-fibre cereals[c]	**11 (72)**	**0.006 (0.038)**	**0.020 (0.078)**
13-year-olds (n=1005)			
Oat, porridge and flakes	4 (23)	0.001 (0.008)	0.005 (0.024)
Muesli	5 (23)	0.002 (0.008)	0.006 (0.024)
Total consumption of high-fibre cereals[c]	**8 (45)**	**0.003 (0.016)**	**0.011 (0.038)**

[a] Mean body weights (b.w.) from Småbarnskost 2007 and Ungkost 2000 are 12.8 kg, 18 kg, 32 kg and 49.5 kg for 2-, 4-, 9- and 13-year olds, respectively. [b] Total consumption of high-fibre cereals is combined consumption of oat, muesli and porridge other than oat (see also Table 3). [c] Total consumption of high-fibre cereals is combined consumption of oat and muesli.

3 Risk characterisation

The reported consumption of high-fibre breakfast cereals among children in Norway (Tables 3 to 6) is within the same order of magnitude as reported for children's consumption of all sorts of breakfast cereals from other European countries (EFSA, 2011; Table 10). However, since the relative contributions of high- and low-fibre breakfast cereals were not reported by EFSA (2011), it is not known whether Norwegian children consume more high-fibre breakfast cereals than other European children. Among Norwegian children, the consumption of low-fibre breakfast cereals is lower than that of high-fibre ones for all age groups between 4-13 years (Tables 5-6). This pattern is especially noticeable among those who consume high-fibre breakfast cereals (Table 6).

There is, however, a decrease in the percentage of high-fibre breakfast cereals consumers with age (Tables 3-6). Among the 2-year-olds, 52% eat high-fibre breakfast cereals during a 14-day period while 35% of the 4-year-olds, 31% of the 9-year-olds and 27% of the 13-year-olds eat high-fibre breakfast cereals during a 4-day registration period.

It is important to note that this opinion only takes zearalenone-exposure resulting from consumption of high-fibre breakfast cereals among Norwegian children into consideration. Neither the consumption of high-fibre cereals from other sources, such as bread, whole meal pizza, pasta and cakes, nor the contribution from low-fibre breakfast cereals to zearalenone exposure is included. Notably, whole meal bread is an important source of cereals in the Norwegian diet.

The estimated mean exposure to zearalenone from breakfast cereals based on the Norwegian dietary survey data and zearalenone concentrations from the EFSA Opinion (2011) is below the TDI of 0.25 µg zearalenone/kg b.w./day for all participants in all age groups (Table 7), and also below the TDI among the consumers only (Table 8). Although the Norwegian children consume high-fibre breakfast cereals, the zearalenone exposure is lower than the TDI also for the high consumers (i.e. the 95-percentile of consumers only).

Exposure assessments of zearalenone from the total diet among Norwegian children based on Norwegian analysed zearalenone values, indicate that the total exposure among Norwegian children is below the TDI (draft Mycotoxin risk assessment, VKM 2012). The total exposures of zearalenone in Norwegian children are in the same range as those reported by EFSA (2011).

The short-term exposure scenarios in the present opinion are based on the presumption that breakfast cereals contain 50, 100 or 150 µg/kg of zearalenone (Tables 9 and 10). With the exposure scenario 50, only 4-year old high consumers (i.e. the 95-percentile of consumers only) slightly exceeded the TDI. Short-term exposure scenarios based on zearalenone concentrations of 100 and 150 µg/kg breakfast cereals indicated that all high consumers among Norwegian children would exceed the TDI. In case that a child consumes the same batch of breakfast cereals containing zearalenone at an increased maximal level daily for some weeks, the TDI could be exceeded during this period. However, the TDI has been set for long-term exposure and does not apply directly for short-term exposure.

The long-term exposure scenario for a 3-fold higher ML (resulting in 3-fold higher mean zearalenone concentration, i.e. 17.1 µg zearalenone/kg breakfast cereals) indicates that long-term exposure among Norwegian children will probably be well below the TDI for all age groups, including high consumers of breakfast cereals (Table 11).

4 Conclusion

Consumption of high-fibre breakfast cereals among children in Norway is within the same order of magnitude as reported for children's consumption of all sorts of breakfast cereals from other European countries. It is not known whether Norwegian children consume more high-fibre breakfast cereals than other European children. The consumption of low-fibre breakfast cereals is lower than that of high-fibre ones for all age groups between 4-13 years among Norwegian children.

The estimated zearalenone exposures based on the consumption of high-fibre breakfast cereals among Norwegian 2-, 4-, 9- and 13-year olds and the occurrence data reported in the EU (EFSA, 2011) indicate that the current zearalenone exposure among mean and high consumers is well below the TDI of 0.25 µg/kg body weights for all age groups.

In addition, exposure calculations based on the total diet consumption and zearalenone occurrence found in cereals on the Norwegian market (draft Mycotoxin risk assessment, VKM 2012) indicate that the current exposure is below the TDI and in the same range as exposures estimated by EFSA in their zearalenone risk assessment (EFSA, 2011).

The short-term exposure scenario based on the presumption that zearalenone concentration is 50 µg/kg in breakfast cereals (current ML), indicates that at this concentration the short-term exposure from breakfast cereals will not exceed the TDI among Norwegian children except for 4-year old high consumers (i.e. the 95-percentile of consumers only) who slightly exceeded TDI. Short-term exposure scenarios based on the zearalenone concentrations of 100 and 150 µg/kg breakfast cereals, indicated that all high consumers would exceed the TDI. In case that a child consumes the same batch of breakfast cereals containing zearalenone at an increased maximal level daily for some weeks, the TDI could be exceeded during this period. However, the TDI has been set for long-term exposure and does not apply directly for short-term exposure.

The long-term exposure scenario considering a 3-fold increase in the mean zearalenone concentration as a result of increasing the maximum level 3-fold to 150 µg/kg in breakfast cereals indicates that the exposure will probably be well below the TDI for all age groups of Norwegian children, including high consumers of breakfast cereals.

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