## TOX/2025/14

# Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment

## **Risk Assessment of T-2 and HT-2 Mycotoxins in Food**

## Background

1. The mycotoxins T-2 and HT-2 were previously assessed by the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in 2018 (COT, 2018) and 2021 (COT, 2021), reviewing their presence in the diet of infants and young children and the potential implications of combined mycotoxin exposure, respectively.

2. In 2020, the European Commission (EC) proposed establishing maximum levels (ML) for the mycotoxins T-2 and HT-2 in foods, which were lower than the current indicative levels set out in the European Commission Recommendation 2013/165/EU. Following the proposal, maximum legislative levels came into force in the European Union (EU) on the 1st of July 2024. These maximum levels were established for the sum of T-2 and HT-2 toxins only. Maximum levels were not established for the modified forms of T-2 and HT-2 (such as neosolaniol (NEO) or 4,15-diacetoxyscirpenol (DAS)) due to limited occurrence data, and the absence of a suitable routine method available for their analysis.

3. In light of the new maximum levels proposed, the COT was asked by the Food Standards Agency (FSA) to assess the risk to UK consumers from T-2 and HT-2 in foods. As part of this work, the COT considered "the existing health-based guidance values (HBGVs) for T2 and HT2 mycotoxins set by the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA)" in February 2023 (TOX/2023/04). At that time, only the summary and conclusions of JECFA's 93rd meeting in 2022 were publicly available, and did not include the complete toxicological dataset used for their risk assessment. At this

meeting however, JECFA established a new group acute reference dose (ARfD) for T-2, HT-2 and DAS of 0.32  $\mu$ g/kg bw, and also a group Tolerable Daily Intake (TDI) of 0.025  $\mu$ g/kg bw for T-2, HT-2 and DAS, alone or in combination.

4. The COT noted that these HBGVs were broadly in line with EFSA's healthbased guidance values (HBGVs) which were established in 2017 (a group ARfD of 0.3  $\mu$ g/kg bw for T-2, HT-2 and NEO and a group TDI of 0.02  $\mu$ g/kg bw for T-2 (x 1), HT-2 (x 1) and NEO (x 0.3)). Overall, the COT was content to continue applying EFSA's HBGVs for future risk assessments.

5. To assist the COT with the assessment of the risk of T-2 and HT-2 from food, the FSA and Food Standards Scotland (FSS) undertook a call for evidence from July 2023 to October 2023. Following the call for evidence, a scoping paper was discussed at the COT meeting in July 2024 (TOX/2024/24). Due to the significant uncertainties in the preliminary exposure assessment, the Committee was unable to conclude on the possible risk of any exceedances of the HBGVs. This discussion paper provides an updated exposure assessment taking into consideration the comments and suggestions by the Committee.

6. In addition to the updated exposure assessment, annual time-trend analysis has been provided to visualise how levels of the sum of T-2 and HT-2 in cereal grains have varied across successive years.

## Introduction

## Type A trichothecenes

7. T-2 and HT-2 are type A trichothecenes which are produced by a variety of *Fusarium* and other fungal species. *Fusarium* species grow and invade crops and produce T-2 and HT-2 under cool, moist conditions prior to harvest. T-2 and HT-2 are found predominantly in cereal grains, and in particular oat grain, barley grain and wheat grain products (JECFA, 2016).

8. The chemical structures of T-2 and HT-2 are shown below in Figure 1.

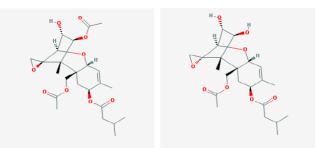


Figure 1. Chemical structures of T-2 (left) and HT-2 (right).

9. The toxicity of T2 and HT2 has been reviewed previously by EFSA (2011, 2017), JECFA (2002, 2016, 2022) and the SCF (2002). All the Committees agreed that these trichothecenes were haematotoxic, immunotoxic and caused reduced body weight, and emesis. These effects occurred at lower doses than other toxic effects such as dermal toxicity, developmental and reproductive toxicity, and neurotoxicity. Haematotoxicity was considered the critical chronic effect on which EFSA's group TDI was based; the underlying mode of action is the inhibition of protein synthesis, the induction of ribotoxic stress and apoptosis.

## Occurrence data

10. Occurrence data on T-2 and HT-2 in food were acquired through a nationwide call for evidence (FSA, 2023). This call was issued by the FSA and FSS in July 2023 and officially closed in October 2023. However, the FSA/FSS continued to receive data up until February 2024. The data call concerned cereals both pre and post cleaning/dehulling and finished products, including, where possible, data that spans multiple years to reflect any annual variability of T-2 and HT-2 levels. The data received cover the UK harvest seasons from 2004 to 2023. Sampling data at retail level were also submitted for 2024 (year tbc).

11. The FSA/FSS received occurrence data on T-2 and HT-2, either as a sum or as individual mycotoxins. The level of detail provided by the respondents and the

format varied, but the data included occurrence levels in processed and unprocessed cereal grains, cereal products and Ready to Eat (RTE) foods. The occurrence data submitted to the FSA/FSS were predominantly on unprocessed/raw materials, which were yet to undergo any cleaning. The processes of, for example, dehulling and scouring have been shown to decrease contamination levels substantially. Occurrence data on grains submitted by industry as 'already processed' refers to grains that have been dehulled and cleaned, but remain as a commodity, that is they have not been incorporated in any RTE foods. Submitted data on RTE foods included biscuits, rusks and cookies, extruded cereal seed or root-based products, cereal bars, infant formula milk-based powder, oat porridge, muesli, mixed breakfast cereals, bread and rolls.

12. The data were collated, cleaned and assured within the FSA Exposure Assessment and Trade (EAT) team. The quality assurance (QA) methodology aligned with the main principles outlined in the aqua book (UK HM Treasury, 2015) and the guidelines in the government data quality framework (UK Governement Data Quality Hub, 2020) on data quality rules.

13. Prior to the data cleaning, a verification exercise was undertaken by the FSA to account for missing limit of quantification (LOQ) and/or limit of detection (LOD) values and sample type categorisation. For these amendments, assumptions were made based on the descriptors and values included by the submitters, such as the descriptors provided for commodity types based on the sample identification codes. The following criteria were applied to include data without compromising scientific integrity. Data were included when all of the following criteria were met:

- a. Datapoints with reported LOQ > 0.
- b. Datapoints where the FoodEx (EFSA, 2025) code could be defined.
- c. Sample codes referring to products destined for human consumption (not feed).

14. Only data on the sum of T2 and HT2, which were analytically determined in samples, were considered in the exposure assessment to allow for a direct comparison with the group HBGV, which is for the sum of both mycotoxins.

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Occurrence levels for data submitted as the sum of T-2 and HT-2 ranged from "not detected" to 18,206 µg/kg (18 mg/kg), spanning all years. The highest levels were seen primarily in unprocessed oat grains. Table 1 shows the range of occurrences reported for the sum of T-2 and HT-2 in the different grains along with their respective LOQ ranges. For RTE products all reported values were considered, including individual T-2 or HT-2 occurrences, due to the limited data available.

Table 1: Occurrence levels reported in the whole dataset for the sum of T-2 and HT2 in all grains, including the range of LOQs. For Ready to Eat (RTE) products all reported values were considered, including individual T-2 or HT-2 occurrences. The minimum values reported were non-detects (nd).

Product	Minimum (µg/kg)	Maximum (µg/kg)	LOQ (µg/kg)
Processed oat	nd	2,936	10-40
grains			
Unprocessed oat	nd	18,206	10-30
grains			
Processed wheat	nd	49	2-20
grains			
Unprocessed	nd	51	2-20
wheat grains			
Processed barley	nd	24	10-20
grains			
Unprocessed	nd	302	10-20
barley grains			
RTE	nd	219	1-10

15. To estimate the median lower bound (LB) sum of T-2 and HT-2, values that were at or below the LOQ were assumed to be zero. To estimate the median upper bound (UB) occurrence levels, values that were at or below the LOQ were assumed to be at the LOQ, and values above the LOQ were used as reported. The LOQ ranged from 1-40  $\mu$ g/kg depending on the food types.

## Seasonal variability

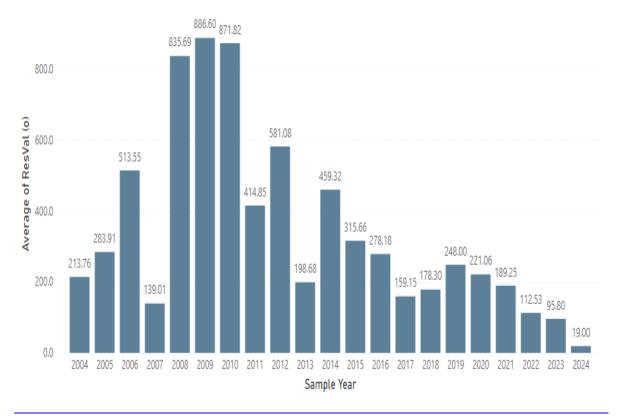
16. The presence of T-2 and HT-2 in crops is dependent on the weather at key growth stages such as flowering and can demonstrate large annual variability. While there are good agricultural practices deployed to manage the presence of

mycotoxins in general, they have not proven to be effective for T-2 and HT-2, given the large dependence on climate/weather. Similarly, reliable rapid testing is not currently available; recent assessments by industry see large variability between liquid chromatography mass spectrometry (LC-MS/MS) methods and Calibre/Charm Elisa semi-rapid methods. Moreover, rapid analytical methods for T-2 and HT-2 have not yet been validated, making it difficult to reliably detect and mitigate these toxins at the field level.

17. A recent review of current rapid screening methods for the mycotoxin T-2 and its metabolites in cereals for human consumption was published by Safefood (Safefood, 2024). Safefood is a body set up under the British-Irish Agreement Act of 1999 to promote awareness and knowledge of food safety and nutrition on the island of Ireland. Safefood note that: "The market is hugely competitive for commercially available rapid diagnostics kits delivering the simultaneous measurement of T-2 and HT-2 toxins, and most of the tests available are immunochemical methods including Enzyme-Linked Immunosorbent Assays (ELISA), Lateral Flow Devices (LFDs/Dipstick Assays) and Fluorescence Polarisation Immunoassays (FPIA)" (Safefood, 2024). However, Safefood also state that: "In the event of new regulatory limits under discussion being implemented, none of the kits in their current form would be 'fit for purpose'" (Safefood, 2024). This is because rapid tests must be accurate, reproducible and provide the required sensitivity for regulatory compliance.

18. Figures 2, 4 and 6 provide time-trend analyses for the sum of T-2 and HT-2 in all grains, and oat grains only, from data submitted via the call for evidence. The average values in these graphs are the averages of the median values per year. The year-on-year variability and seasonal trend provides an indication of the degree to which the presence of mycotoxins was impacted by climatic events at key stages of crop growth. Figures 3, 5 and 7 provide the corresponding number of samples analysed, with an increased in sample numbers since 2014. The increase is most likely due to the introduction of provisional maximum levels in the EU, as well as the subsequent availability of laboratory testing. The Figures provide data from 2014 to 2023.

6



Average T2 HT2 concentration per year for barley, oats and wheat

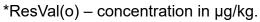


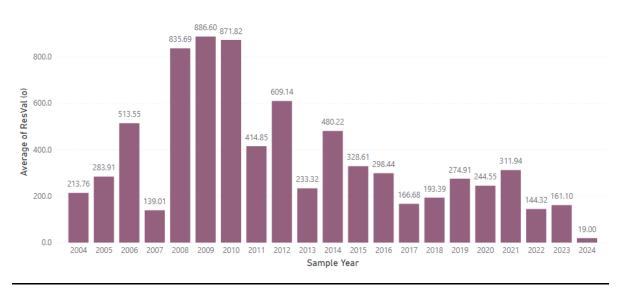
Figure 2: Average sum of T-2 and HT-2 concentration per year for 'all grains' (processed barley grains, unprocessed barley grains, processed oat grains, unprocessed oat grains, processed wheat grains and unprocessed wheat grains).

Number of samples per year



\*ResVal(o) – concentration in µg/kg.

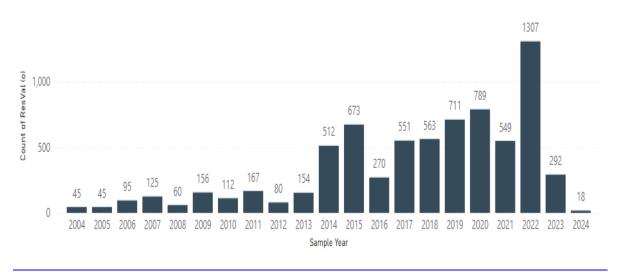
## Figure 3: Corresponding number of samples for Figure 2.



Average T2 HT2 concentration per year for processed and unprocessed oats

\*ResVal(o) – concentration in  $\mu$ g/kg.

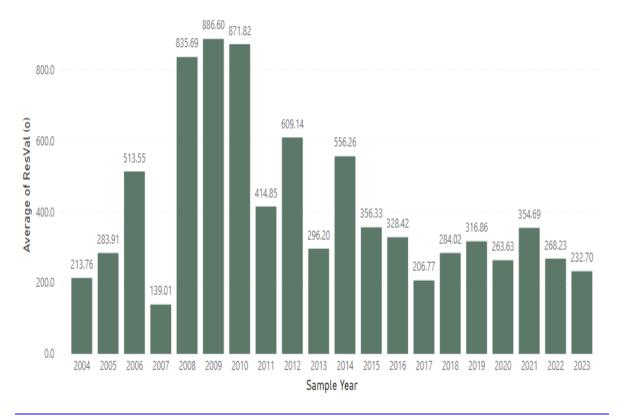
Figure 4: Average sum of T-2 and HT-2 concentration per year for oat grains only (processed oat grains and unprocessed oat grains).



Number of samples per year

\*ResVal(o) – concentration in  $\mu$ g/kg.

Figure 5: Corresponding number of samples for Figure 4.



Average T2 HT2 concentration per year for unprocessed oats

\*ResVal(o) – concentration in µg/kg.

Figure 6: Average sum of T-2 and HT-2 concentration per year for unprocessed oat grains only.

Count of ResVal (o) 2015 2016 2017 2018 2019 2020 2021 2022 Sample Year

\*ResVal(o) – concentration in µg/kg.

Number of samples per year

Figure 7: Corresponding number of samples for Figure 6.

#### Refinement of previous exposure assessment

19. In July 2024, the COT reviewed a scoping paper (<u>TOX/2024/24</u>) on potential consumer exposure to the sum of T-2 and HT-2. The assessment provided preliminary estimates of consumers' total exposure to the sum of T-2 and HT-2 from a typical diet comprising of i) processed food products and ii) unprocessed food products.

20. The exposure assessment included occurrence data supplied by industry following the call for evidence, and consumption data from the National Diet and Nutrition Survey (NDNS) (years 1-11). The 97.5<sup>th</sup> percentile consumption rate was used for each food group, as a worst-case scenario.

21. The majority of the occurrence data was from unprocessed foods rather than from foods as would be consumed adding uncertainty to the assessment and leading to an overestimation of the actual exposures. In addition, the occurrence data used

for the exposure assessments spanned from 2008 to 2023, with significant variability in the occurrence levels over this time period.

22. Due to the significant uncertainties in this preliminary exposure assessment, the Committee was unable to conclude on the possible risk of any exceedances of the HBGVs.

## Reduction factors for unprocessed cereal grains

23. Following the recommendations of the Committee on how the exposure assessment could be refined, a literature search was conducted to identify any information on the reduction of T-2 and HT-2 mycotoxins in cereal grains during processing. Applying reduction factors would allow for a more accurate representation of consumer exposure to T2 and HT2 and result in a more realistic exposure assessment.

24. Unprocessed oat grains intended for human consumption comprise of an outer hull which is the part of the grain which is often most contaminated. However, this outer hull is removed during processing and this so-called de-hulling therefore significantly reduces the level of contamination. Several reduction factors for the sum of T-2 and HT-2 for oat grains were identified in the scientific literature:

- Meyer et al. (2022) reported an average reduction of 85% for large oat kernels and 66% for thin oat kernels.
- Schwake-Anduschus et al. (2010) reported a mean reduction factor of 98% for unprocessed oat grains. However, this paper does not provide specific details about kernel size, as it focuses on different oat cultivars being studied (which accounts for the value of their reduction factor ranging from of 93.8 - 100%).
- EFSA (2011) references a slideshow (<u>Pettersson 2008</u>) which states that "normal cleaning and dehulling during mill processing can reduce levels by 80-95%, but the reduction is lower at lower initial toxin levels". However, this slideshow does not provide specific details about kernel size.

25. For this assessment, the reduction factor of 85% from Meyer et al (2022) was applied. While the paper references a range of reduction factors, the scientific basis for the factor of 85% was the most recent and was considered the most accurate. Although the reduction factor of 85% was specifically for large oat kernels, Meyer et al. (2023) note that "milling oats are traded to contain less than 10% of thin oats below 2 mm slotted hole sieve".

26. As some cultivars of oat and barley are hulless, Polišenská et al. (2020) noted that "special attention should be paid to the risk of their contamination by *Fusarium* mycotoxins, as the rate of mycotoxin reduction during processing could be much lower than that for hulled cereals". However, in the UK, naked oats are typically used for animal feed and not for human consumption.

27. No reduction factors were identified for wheat, maize or barley. The limited information available suggested that "starting levels and incidence of T-2 and HT-2 in wheat and maize and in the derived ingredients used in processing studies carried out for other *Fusarium* mycotoxins were very low so that little data could be collected on their fate"... "very little information on the change in mycotoxin concentrations in wheat, maize during manufacturing of retail products was obtained due to the low levels of mycotoxins found in the starting cereal ingredients" (Scudamore, 2009). It is therefore unclear whether or to which percentage processing reduced T2 and HT2 contamination in wheat, maize or barley.

#### Exposure assessment

#### **Methodology**

#### Grains

28. Exposure assessments were conducted on a survey population basis using consumption data and the corresponding LB and UB median occurrence values. Median occurrence levels were calculated for the sum of T-2 and HT-2 toxins (μg/kg) to avoid skewing the overall exposure, due to the wide concentration range of the

reported occurrence levels. This was applied to all grains and the exposure "scenarios" were as follows:

- Oat grains only,
- All grains; and,
- Ready To Eat (RTE).

29. A single food group was created, comprising of all the potential sources of oat consumption in NDNS food groups, for estimating exposure to the sum of T-2 and HT-2 from consumption of oat grains only (Tables 2-5). Exposure to the sum of T-2 and HT-2 from this food group was estimated from NDNS consumption data, using occurrence estimates under the following scenarios:

- Unprocessed oat grains,
- Unprocessed oat grains after application of a reduction factor of 85%,
- Processed oat grains (submitted by industry as 'already processed'); and,
- "Oats combined" (the amalgamation of the occurrence data described in the second and third bullet points above).

30. Additional food groups were created for estimating exposure to the sum of T-2 and HT-2 from consumption of cereal grains other than oat grains, no reduction factors were identified for these cereal grains. The following scenarios were applied:

- a) Unprocessed wheat grains,
- b) Processed wheat grains,
- c) Unprocessed barley grains; and,
- d) Processed barley grains.

31. Acute and chronic exposures for all grains (Tables 6-9) were estimated for the sum of T-2 and HT-2 (mean and 97.5<sup>th</sup> percentile).

## Ready To Eat (RTE) foods

32. For RTE foods, the exposure assessments were on a consumer basis using mean and maximum occurrence levels. The data was verified by applying the same inclusion criteria as for grains (described in paragraph 13).

33. Chronic and acute exposures to individual toxins (T-2 or HT-2) (mean and 97.5<sup>th</sup> percentile) were calculated using the mean and maximum concentration of either T-2 or HT-2 occurrence data. Estimated exposures to the sum of T-2 and HT-2 were only calculated for infant cereal, as this was the only food category for which data was available for the sum of T-2 and HT-2. Mean and maximum occurrence levels were used, as the datasets were not sufficient to calculate the median for the sum of the respective mycotoxin.

## **Consumption data**

34. Consumption data from the NDNS (Bates et al., 2014, 2016, 2020; Roberts et al., 2018), as well as the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (Department of Health, 2011) were used for the exposure assessments.

35. The grain food groups used for this assessment were derived by mapping FoodEx2 codes onto NDNS and DNSIYC food codes using an inhouse FSA recipes database. Consumption and subsequent exposures were calculated for the following population groups:

- Infants (4-18 months).
- Toddlers (1.5-3 years).
- Children (4-10 years).
- Older children (11-18 years).
- Adults (19-64 years).
- Older adults (≥ 65 years).
- Adult vegetarians/vegans (19-64 years); and,
- Women of childbearing age (16-49 years).

36. For the RTE food groups, each group was derived from FoodEx2 codes. These codes were searched in the FSA recipe database to identify and match NDNS and DNSIYC food codes. The consumption and subsequent estimated exposure for RTEs were calculated in the following population groups:

- Infants (4-18 months).
- Toddlers (1.5-3 years).
- Adults (19-64 years old); and,
- Adult vegetarians/vegans (19-64 years).

37. However, where infant RTE foods only were available, consumption and subsequent estimated exposures were calculated in infants and toddlers only.

## Results

38. Chronic and acute exposure estimates are presented in Tables 2-9 (cereal grains) and Tables 10-13 (RTE). These tables summarise the mean and 97.5<sup>th</sup> percentile exposure to the sum of T-2 and HT-2 for the different cereal grains or T-2 or HT-2 for RTE foods.

## Unprocessed oat grains

## Chronic exposure

39. Table 2 provides chronic exposure estimates resulting from the application of a reduction factor of 85% to unprocessed oat grains. After application of the reduction factor, the lowest exposures were in older children (11-18 years), with mean and 97.5<sup>th</sup> percentile exposures of 0.0014-0.0019 (LB-UB) and 0.0098-0.013 (LB-UB)  $\mu$ g/kg body weight (bw), respectively; the highest exposures were in infants and toddlers, where UB exposures at the 97.5<sup>th</sup> percentiles were up to 0.05  $\mu$ g/kg bw/day.

40. Estimated exposures from unprocessed oat grains have been included in Table 2 for comparison, with a UB 97.5<sup>th</sup> percentile exposure of up to 0.29  $\mu$ g/kg bw in infants (4-18 months) and toddlers (1.5-3 years; 0.28  $\mu$ g/kg bw).

**Table 1:** Chronic exposures to sum of T-2 and HT-2 from unprocessed oat grains and unprocessed oat grains with a reduction factor applied (μg/kg bw/day; LB-UB). Consumption data was based on DNSYIC and NDNS years 1-11, occurrence data was collected from the FSA's call for evidence.

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.047	0.29
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0061- 0.0083	0.038-0.051

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.044	0.28
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0058 – 0.0078	0.037 – 0.050

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.028	0.17
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0037 – 0.0050	0.023 – 0.031

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.011	0.076
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0014 – 0.0019	0.0098 – 0.013

Older Children (11-18 years) (n=2657)

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.014	0.095
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0018 – 0.0024	0.012 – 0.017

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.020	0.10
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0026 – 0.0035	0.013 – 0.018

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.024	0.14
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0031 – 0.0042	0.018 – 0.025

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.012	0.081
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0016 – 0.0022	0.011 – 0.014

Women of Childbearing age (16-49 years) (n=2556)

\*Estimates have been rounded to 2 significant figures.

\*\*Unprocessed oat grains- oat grains without processing (raw primary commodity (RPC)).

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

## Acute exposure

41. Table 3 provides acute exposure estimates resulting from the application of a reduction factor of 85% to the occurrence data for unprocessed oat grains. After application of the reduction factor, the lowest exposures were in women of childbearing age (16-49 years) with mean and 97.5<sup>th</sup> percentile exposures of 0.0032-0.0043 (LB-UB) and 0.019-0.026 (LB-UB) µg/kg bw, respectively. The highest exposures were in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile exposures of 0.013-0.018 (LB-UB) and 0.075-0.10 (LB-UB) µg/kg bw, respectively.

42. Without the application of a reduction factor to unprocessed oat grains, the highest acute exposures were seen in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile exposures of 0.10 and 0.58  $\mu$ g/kg bw, and toddlers with mean and 97.5<sup>th</sup> percentile exposures of 0.096 and 0.54  $\mu$ g/kg bw, respectively.

**Table 2:** Acute exposure to the sum of T-2 and HT-2 from unprocessed oat grains

 and unprocessed oat grains with applied reduction factor based on DNSYIC and

NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence (µg/kg bw/day; LB-UB).

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.10	0.58
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.013-0.018	0.075-0.10

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.096	0.54
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.013 – 0.017	0.070 – 0.094

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.063	0.33
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0081 – 0.011	0.043 – 0.059

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.025	0.16

Unprocessed	4083	22.20-30.00	0.0033 –	0.021 –
oats with			0.0045	0.028
reduction factor+				

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.026	0.15
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0034 – 0.0046	0.020 – 0.027

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.032	0.15
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0042 – 0.0057	0.019 – 0.026

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.047	0.24
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0061 – 0.0082	0.031 – 0.042

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.024	0.15

oats with 0.0043 0.026	Unprocessed	4083	22.20-30.00	0.0032 -	0.019 –
reduction factor+	oats with			0.0043	0.026
	reduction factor+				

\*Estimates have been rounded to 2 significant figures.

\*\*Unprocessed oat grains- oat grains without processing (raw primary commodity (RPC)).

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

#### Processed grains and oats combined

43. The data presented in Tables 4 and 5 provide exposures from processed oat grains, as provided via the call for evidence, unprocessed oat grains with a reduction factor applied (85%) and oats combined. Oats combined, which are unprocessed oats with a reduction factor applied plus processed oats (see paragraph 29) reflect a more realistic exposure scenario for the UK population, taking account of any occurrence data of processed oat grains submitted by industry (small overall number) and unprocessed oats to which a reduction factor has been applied (the majority of the data).

#### Chronic exposure

44. Table 4 shows chronic exposures from oat grains, i.e. processed oat grains, unprocessed oat grains with a reduction factor applied and oats combined.

45. The lowest chronic exposures for processed oat grains were for older children (11-18 years), with mean and P97.5<sup>th</sup> percentile exposures of 0.0016 and 0.011  $\mu$ g/kg bw, respectively while the highest chronic exposures were in infants (4-18 months) with mean and P97.5<sup>th</sup> percentile of 0.0069 and 0.043  $\mu$ g/kg bw, respectively.

46. For oats combined, the lowest chronic exposures were in older children (11-18 years) with mean and 97.5<sup>th</sup> percentile of 0.0015-0.0019 (LB-UB) and 0.010-0.013 (LB-UB)  $\mu$ g/kg bw, respectively, while the highest chronic exposures were in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile of 0.0063-0.0083 (LB-UB) and 0.039-0.051 (LB-UB)  $\mu$ g/kg bw, respectively. Toddlers (1.5-3 years) had similar exposures to infants.

47. The application of a reduction factor to unprocessed oat grains resulted in similar exposures to those reported for processed oat grains submitted by industry. This observation supports the choice of the reduction factor that was applied to unprocessed oat grains.

**Table 3:** Chronic exposure to the sum of T-2 and HT-2 from processed oat grains, unprocessed oat grains with applied reduction factor, and oats combined based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence (μg/kg bw/day; LB-UB).

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0069	0.043
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0061- 0.0083	0.038-0.051
Oats combined ++	4526	22.95 – 30.00	0.0063- 0.0083	0.039-0.051

Infants (4-18 months) (n=2683)

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0065	0.042

Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0058 – 0.0078	0.037 – 0.050
Oats combined	4526	22.95 – 30.00	0.0060 –	0.038 –
++			0.0078	0.050

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0042	0.025
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0037 – 0.0050	0.023 – 0.031
Oats combined ++	4526	22.95 – 30.00	0.0038 – 0.0050	0.023 – 0.031

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0016	0.011
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0014 – 0.0019	0.0098 – 0.013
Oats combined ++	4526	22.95 - 30.00	0.0015 – 0.0019	0.010 – 0.013

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0020	0.014
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0018 – 0.0024	0.012 – 0.017
Oats combined ++	4526	22.95 – 30.00	0.0019 – 0.0024	0.013 – 0.017

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0029	0.015
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0026 – 0.0035	0.013 – 0.018
Oats combined ++	4526	22.95 - 30.00	0.0027 – 0.0035	0.014 – 0.018

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0035	0.021
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0031 – 0.0042	0.018 – 0.025
Oats combined ++	4526	22.95 - 30.00	0.0032 – 0.0042	0.019 – 0.025

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0018	0.012
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0016 – 0.0022	0.011 – 0.014
Oats combined ++	4526	22.95 – 30.00	0.0017 – 0.0022	0.011 – 0.014

\*Estimates have been rounded to 2 significant figures.

+Oat grains with reduction factor - unprocessed oat grains with reduction factor applied.

\*\*Processed oat grains – RPC derivatives/ ingredients i.e. RPCs which have undergone basic processing such as grinding, milling or crushing.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

## Acute exposure

48. Table 5 shows the acute exposures from oat grains, i.e. processed oat grains, unprocessed oat grains with a reduction factor applied and oats combined.

49. For processed oat grains the lowest acute exposures were in women of childbearing age (16-49 years) with mean and P97.5<sup>th</sup> percentile exposures of 0.0036 and 0.021  $\mu$ g/kg bw, respectively, while the highest acute exposures were in infants (4-18 months) with mean and P97.5<sup>th</sup> percentile exposures of 0.015 and 0.085  $\mu$ g/kg bw, respectively.

50. For oats combined, the lowest chronic exposures were in women of childbearing age (16-49 years) with mean and  $97.5^{\text{th}}$  percentile exposures of 0.0033-0.0043 (LB-UB) and 0.020-0.026 (LB-UB) µg/kg bw, respectively, while the highest chronic exposures were in infants (4-18 months) with mean and  $97.5^{\text{th}}$  percentile exposures of 0.014-0.018 (LB-UB) and 0.078-0.10 (LB-UB) µg/kg bw, respectively. Toddlers has similar exposures to infants.

51. Application of a reduction factor of 85% to the levels obtained for unprocessed oat grains resulted in similar exposures to data submitted for processed oat grains (LB) for all population groups.

**Table 4:** Acute exposure to sum of T-2 and HT-2 from processed oat grains,

 unprocessed oat grains with applied reduction factor, and oats combined based on

DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence ( $\mu$ g/kg bw/day; LB-UB).

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.015	0.085
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.013-0.018	0.075-0.10
Oats combined++	4526	22.95 – 30.00	0.014-0.018	0.078-0.10

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.014	0.079
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.013 – 0.017	0.070 – 0.094
Oats combined++	4526	22.95 – 30.00	0.013 – 0.017	0.072 – 0.094

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0092	0.049
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0081 – 0.011	0.043 – 0.059
Oats combined++	4526	22.95 – 30.00	0.0084 – 0.011	0.045 – 0.059

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0037	0.023
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0033 – 0.0045	0.021 – 0.028
Oats combined++	4526	22.95 - 30.00	0.0034 - 0.0045	0.021 – 0.028

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0038	0.022
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0034 – 0.0046	0.020 – 0.027
Oats combined++	4526	22.95 – 30.00	0.0035 – 0.0046	0.021 – 0.027

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0047	0.022
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0042 – 0.0057	0.019 – 0.026
Oats combined++	4526	22.95 - 30.00	0.0043– 0.0057	0.020 – 0.026

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
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Processed oats**	443	25	0.0069	0.035
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0061 – 0.0082	0.031 – 0.042
Oats combined++	4526	22.95 – 30.00	0.0063 – 0.0082	0.032 – 0.042

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Processed oats**	443	25	0.0036	0.021
Unprocessed oats with reduction factor+	4083	22.20-30.00	0.0032 – 0.0043	0.019 – 0.026
Oats combined++	4526	22.95 - 30.00	0.0033 – 0.0043	0.020 – 0.026

\*Estimates have been rounded to 2 significant figures.

+Oats with reduction factor - unprocessed oat grains with reduction factor applied.

\*\*Processed oat grains – RPC derivatives/ ingredients i.e. RPCs which have undergone basic processing such as grinding, milling or crushing.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

## Total exposure from all grains

52. The total exposure from all grains was considered under two different scenarios and the data are presented in Tables 6-9, i.e. exposures from (i) the sum of processed barley grains, wheat grains and oat grains (Tables 6-7), and (ii) the sum of unprocessed barley grains, wheat grains, and oat grains (Tables 8-9).

53. The exposure from the sum of unprocessed grains was included for completeness, taking into account the cleaning and further suitability checks the data underwent. However, this is as a worst-case scenario and an overestimation of real-life exposures.

## Processed grains

54. Tables 6 and 7 show the estimated exposures from processed barley grains, processed wheat grains, and oats combined (the sum of processed oat grains submitted by industry and unprocessed oat grains to which a reduction factor has been applied). Tables 6 and 7 also include the estimated exposures to the sum of all grains.

#### Chronic exposure

55. Table 6 shows that oats combined was the main contributor to the overall chronic exposure from all three grain types, in all population groups. Exposures from barley made the lowest contribution to the overall exposure.

56. The highest chronic estimated exposures to the sum of all processed grains were in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile exposures of 0.0063-0.010 (LB- UB), and 0.039-0.052 (LB-UB)  $\mu$ g/kg bw, respectively, with toddlers having similar exposure estimates. The lowest chronic exposures were seen in older children with mean and 97.5<sup>th</sup> percentile exposures of 0.0015-0.0039 (LB-UB), and 0.010-0.017 (LB-UB)  $\mu$ g/kg bw, respectively.

**Table 5:** Chronic exposure to sum of T-2 and HT-2 from processed barley, oats combined (combination of processed oat grains and unprocessed oat grains with reduction factor) (RPC) and processed wheat based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence ( $\mu$ g/kg bw/day; LB-UB).

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.0063- 0.0083	0.039-0.051
Processed wheat grains	454	0 -2.00	0-0.0018	0-0.0062
Processed barley grains	25	0 -10.00	0-0.00010	0-0.00055
All grains sum	NA	NA	0.0063-0.010	0.039-0.052

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.0060 – 0.0078	0.038 – 0.050
Processed wheat grains	454	0 -2.00	0-0.0032	0-0.0080
Processed barley grains	25	0 -10.00	0- 0.00013	0- 0.0011
All grains sum	NA	NA	0.0060-0.011	0.038-0.053

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0038 – 0.0050	0.023 – 0.031
Processed wheat grains	454	0 -2.00	0-0.0031	0- 0.0073
Processed barley grains	25	0 -10.00	0- 0.00010	0- 0.00082
All grains sum	NA	NA	0.0038- 0.0082	0.023-0.035

Older Children (11-18 years) (n=2657)

Food groups		Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
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Oats combined	4526	22.95 - 30.00	0.0015 –	0.010 –
++			0.0019	0.013
Processed wheat grains	454	0 -2.00	0-0.0018	0-0.0043
Processed barley grains	25	0 -10.00	0- 0.00017	0- 0.00052
All grains sum	NA	NA	0.0015- 0.0039	0.010-0.017

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0019 – 0.0024	0.013 – 0.017
Processed wheat grains	454	0 -2.00	0-0.0011	0-0.0029
Processed barley grains	25	0 -10.00	0-0.0039	0- 0.052
All grains sum	NA	NA	0.0019- 0.0075	0.013-0.059

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0027 – 0.0035	0.014 – 0.018
Processed wheat grains	454	0 -2.00	0-0.00097	0-0.0024
Processed barley grains	25	0 -10.00	0-0.0054	0-0.071
All grains sum	NA	NA	0.0027- 0.0099	0.014-0.075

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.0032 - 0.0042	0.019 – 0.025

Processed wheat grains	454	0 -2.00	0-0.0013	0-0.0031
Processed barley grains	25	0 -10.00	0-0.0036	0-0.035
All grains sum	NA	NA	0.0032- 0.0091	0.019-0.047

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0017 – 0.0022	0.011 – 0.014
Processed wheat grains	454	0 -2.00	0-0.0011	0-0.0028
Processed barley grains	25	0 -10.00	0- 0.00061	0-0.0010
All grains sum	NA	NA	0.0017- 0.0039	0.011-0.019

\*Estimates have been rounded to 2 significant figures.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (identical to "Oats combined" from Table 4 above).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

## Acute exposure

57. Table 7 shows that as for chronic exposures, for acute exposures, oats combined was the main contributor to the overall exposure derived for all three grain types, in all population groups. Exposures from barley made the lowest contribution to the overall exposure.

58. For the sum of all processed grains the highest acute exposure estimates were in infants (4-18 months) with mean and  $97.5^{\text{th}}$  percentile exposures of 0.014-0.021 (LB-UB), and 0.078-0.10 (LB-UB) µg/kg bw, respectively, exposures in toddlers (1.5-3 years) were similar. The lowest acute exposure estimates were in women of childbearing age (16-49 years) with mean and 97.5<sup>th</sup> percentile exposures of 0.0033-0.0082 (LB-UB), and 0.020-0.034 (LB-UB) µg/kg bw, respectively.

**Table 6:** Acute exposure to sum of T-2 and HT-2 from processed barley, oats combined (combination of processed oat grains and unprocessed oat grains with reduction factor), and processed wheat based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence ( $\mu$ g/kg bw/day; LB-UB).

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.014-0.018	0.078-0.10
Processed wheat	454	0 -2.00	0-0.0035	0-0.011
Processed barley grains	25	0 -10.00	0-0.00031	0-0.0016
All grains	NA	NA	0.014-0.021	0.078-0.10

Infants (4-18 months) (n=2683)

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data	Median T-2/HT-2 concentration	Mean*	P97.5*
		µg/kg LB-UB		

	call samples (n)			
Oats combined ++	4526	22.95 – 30.00	0.013 – 0.017	0.072 – 0.094
Processed wheat	454	0 -2.00	0-0.0058	0-0.014
Processed barley grains	25	0 -10.00	0- 0.00038	0- 0.0036
All grains	NA	NA	0.013-0.022	0.072-0.097

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0084 – 0.011	0.045 – 0.059
Processed wheat	454	0 -2.00	0-0.0054	0- 0.012
Processed barley grains	25	0 -10.00	0- 0.00027	0- 0.0022
All grains	NA	NA	0.0084-0.016	0.045-0.062

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.0034 – 0.0045	0.021 – 0.028
Processed wheat	454	0 -2.00	0-0.0033	0-0.0081
Processed barley grains	25	0 -10.00	0- 0.00058	0- 0.0013
All grains	NA	NA	0.0034- 0.0077	0.021-0.032

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 - 30.00	0.0035 – 0.0046	0.021 – 0.027

Processed wheat	454	0 -2.00	0-0.0022	0-0.0055
Processed	25	0 -10.00	0-0.011	0- 0.16
barley grains				
All grains	NA	NA	0.0035-0.017	0.021-0.16

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined	4526	22.95 - 30.00	0.0043–	0.020 –
++			0.0057	0.026
Processed wheat	454	0 -2.00	0-0.0017	0-0.0040
Processed	25	0 -10.00	0-0.013	0-0.18
barley grains				
All grains	NA	NA	0.0043-0.020	0.020-0.19

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0063 – 0.0082	0.032 – 0.042
Processed wheat	454	0 -2.00	0-0.0025	0-0.0053
Processed barley grains	25	0 -10.00	0-0.014	0-0.11
All grains	NA	NA	0.0063-0.024	0.032-0.12

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Oats combined ++	4526	22.95 – 30.00	0.0033 – 0.0043	0.020 – 0.026
Processed wheat	454	0 -2.00	0-0.0022	0-0.0057
Processed barley grains	25	0 -10.00	0- 0.0021	0-0.0023

All grains	NA	NA	0.0033-	0.020-0.034
			0.0082	

\*Estimates have been rounded to 2 significant figures.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (identical to "Oats combined" from Table 5 above).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

#### All unprocessed grains

59. Table 8 and Table 9 provide the estimated exposures to the sum off all three grain types, unprocessed.

#### Chronic exposure

60. Table 8 provides an estimate of the worst-case scenario as it shows the estimated chronic exposures of the sum of T-2 and HT-2 from all three grain types in their unprocessed form. The data shows that across all age groups, the lowest contribution to the overall exposure was from unprocessed barley. Unprocessed oat grains made the highest contribution to the overall.

61. The highest chronic exposure estimates for the sum of all three grain types were in infants (4-18 months) and toddlers (1.5-3 years), with a mean and 97.5<sup>th</sup> percentile exposure of 0-0.056/0.061 (LB-UB) and 0-0.29 (LB-UB)  $\mu$ g/kg bw, respectively. The lowest chronic exposure estimates were in older children (11-18 years), with a mean and 97.5<sup>th</sup> percentile exposure of 0-0.020 (LB-UB) and 0-0.089 (LB-UB)  $\mu$ g/kg bw, respectively.

**Table 7:** Chronic exposure to sum of T-2 and HT-2 from unprocessed oat grains, unprocessed wheat grains, and unprocessed barley grains based on DNSYIC and

NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence (µg/kg bw/day; LB-UB).

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.047	0.29
Unprocessed wheat grains	192	0 -10.00	0-0.0091	0-0.031
Unprocessed barley grains	105	0 -10.00	0-0.00010	0-0.00055
All grains sum	NA	NA	0-0.056	0-0.29

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.044	0.28
Unprocessed wheat grains	192	0 -10.00	0-0.016	0-0.040
Unprocessed barley grains	105	0 -10.00	0- 0.00013	0- 0.0011
All grains sum	NA	NA	0-0.061	0-0.29

Children (4-10 years) (n=2537)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.028	0.17
Unprocessed wheat grains	192	0 -10.00	0-0.015	0- 0.036
Unprocessed barley grains	105	0 -10.00	0- 0.00010	0- 0.00082
All grains sum	NA	NA	0-0.044	0-0.20

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.011	0.076
Unprocessed wheat grains	192	0 -10.00	0-0.0089	0-0.022
Unprocessed barley grains	105	0 -10.00	0- 0.00017	0- 0.00052
All grains sum	NA	NA	0-0.020	0-0.089

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.014	0.095
Unprocessed wheat grains	192	0 -10.00	0-0.0056	0-0.015
Unprocessed barley grains	105	0 -10.00	0-0.0039	0- 0.052
All grains sum	NA	NA	0-0.023	0-0.12

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.020	0.10
Unprocessed wheat grains	192	0 -10.00	0-0.0048	0-0.012
Unprocessed barley grains	105	0 -10.00	0-0.0054	0-0.071
All grains sum	NA	NA	0-0.030	0-0.15

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
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Unprocessed oats**	4083	170.44	0.024	0.14
Unprocessed wheat grains	192	0 -10.00	0-0.0063	0-0.015
Unprocessed barley grains	105	0 -10.00	0-0.0036	0-0.035
All grains sum	NA	NA	0-0.034	0-0.15

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.012	0.081
Unprocessed wheat grains	192	0 -10.00	0-0.0057	0-0.014
Unprocessed barley grains	105	0 -10.00	0- 0.00061	0-0.0010
All grains sum	NA	NA	0-0.019	0-0.093

\*Estimates have been rounded to 2 significant figures.

\*\*Unprocessed oat grains – oat grains without processing (raw primary commodity (RPC)).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

#### Acute exposure

62. Table 9 provides a worst-case scenario with estimated acute exposures of the sum of all unprocessed grains. As with chronic exposure estimates, the data shows that across all age groups, the lowest contribution to the exposure was from unprocessed barley while the highest contribution was from unprocessed oat grains.

63. The highest acute exposure estimates to the sum of all three grain types were in infants (4-18 months) and toddlers (1.5-3 years) with mean and 97.5<sup>th</sup> percentile exposures of 0-0.12 (LB-UB) and 0-0.59/0.055 (LB-UB)  $\mu$ g/kg bw, respectively, while

the lowest acute exposure was in women of childbearing age (19-64 years) with mean and  $97.5^{th}$  percentile exposures of 0-0.035 (LB-UB) and 0-0.17 (LB-UB) µg/kg bw, respectively.

**Table 8:** Acute exposure to sum of T-2 and HT-2 from unprocessed oat grains, unprocessed wheat grains, and unprocessed barley grains based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call for evidence (µg/kg bw/day; LB-UB).

Infants (4-18	months)	(n=2683)
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Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.10	0.58
Unprocessed wheat grains	192	0 -10.00	0-0.018	0-0.056
Unprocessed barley grains	105	0 -10.00	0-0.00031	0-0.0016
All grains	NA	NA	0-0.12	0-0.59

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.096	0.54
Unprocessed wheat grains	192	0 -10.00	0-0.029	0-0.069
Unprocessed barley grains	105	0 -10.00	0- 0.00038	0- 0.0036
All grains	NA	NA	0-0.12	0-0.55

Children (4-10 years) (n=2537)

Food groups Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
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Unprocessed oats**	4083	170.44	0.063	0.33
Unprocessed wheat grains	192	0 -10.00	0-0.027	0- 0.062
Unprocessed barley grains	105	0 -10.00	0- 0.00027	0- 0.0022
All grains	NA	NA	0-0.084	0-0.35

Older Children (11-18 years) (n=2657)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.025	0.16
Unprocessed wheat grains	192	0 -10.00	0-0.016	0-0.040
Unprocessed barley grains	105	0 -10.00	0- 0.00058	0- 0.0013
All grains	NA	NA	0-0.040	0-0.17

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.026	0.15
Unprocessed wheat grains	192	0 -10.00	0-0.011	0-0.028
Unprocessed barley grains	105	0 -10.00	0-0.011	0- 0.16
All grains	NA	NA	0-0.045	0-0.24

Elderly (65+ years) (n=1538)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.032	0.15
Unprocessed wheat grains	192	0 -10.00	0-0.0084	0-0.020

Unprocessed barley grains	105	0 -10.00	0-0.013	0-0.18
All grains	NA	NA	0-0.051	0-0.24

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.047	0.24
Unprocessed wheat grains	192	0 -10.00	0-0.012	0-0.027
Unprocessed barley grains	105	0 -10.00	0-0.014	0-0.11
All grains	NA	NA	0-0.069	0-0.34

Women of Childbearing age (16-49 years) (n=2556)

Food groups	Count of T-2 HT-2 data call samples (n)	Median T-2/HT-2 concentration µg/kg LB-UB	Mean*	P97.5*
Unprocessed oats**	4083	170.44	0.024	0.15
Unprocessed wheat grains	192	0 -10.00	0-0.011	0-0.028
Unprocessed barley grains	105	0 -10.00	0- 0.0021	0-0.0023
All grains	NA	NA	0-0.035	0-0.17

\*Estimates have been rounded to 2 significant figures.

\*\*Unprocessed oat grains – oat grains without processing (raw primary commodity (RPC)).

LB - Lower bound: values below the limit of quantification (LOQ) are treated as zero; UB - Upper bound: values below the LOQ are treated as at the LOQ.

\*\* If single value is shown, it indicates that the exposures are based on detected values above the LOQ.

Exposure from ready to eat (RTE) foods

64. Consumer-based exposure estimates were caried out for infants (4-18 months), toddlers (1.5-3 years), adults (19-64 years), and adult vegetarians/vegans (19-64 years) from RTE foods. The chronic and acute exposure estimates are presented in Annex 1 and Annex 2, brief summaries of the exposures are provided here.

65. The estimated exposures are the mean and 97.5<sup>th</sup> percentile exposures based on the mean and maximum concentration (mean-max concentration) of T-2 or HT-2 or the sum of both, where available. Exposures to T-2 or HT-2 only were predominantly used as very few datapoints were available overall for RTE foods and even fewer on the sum of T-2 and HT-2.

Sum of T-2 and HT-2 exposure estimates

66. Data for the sum of T-2 and HT-2 were only available for infant cereals. Exposure to the sum of T-2 and HT-2 in this group are presented in Annex 1A and Annex 1B for chronic and acute exposure, respectively.

67. In brief, the highest mean and 97.5<sup>th</sup> percentile exposures, both for chronic and acute were in infants (4-18 months). Mean and 97.5<sup>th</sup> percentile chronic exposures were 0.36-0.71  $\mu$ g/kg bw (mean-max concentration), and 1.5-2.9  $\mu$ g/kg bw (mean-max concentration)  $\mu$ g/kg bw, respectively, while mean and 97.5<sup>th</sup> percentile acute exposure were 0.71-1.4  $\mu$ g/kg bw (mean-max concentration), and 2.6-5.2  $\mu$ g/kg bw (mean-max concentration)  $\mu$ g/kg bw respectively. However, chronic exposures in toddlers (1.5-3 years) still ranged from 0.22  $\mu$ g/kg bw (mean) to 1.4  $\mu$ g/kg bw (97.5<sup>th</sup> percentile and from 0.52  $\mu$ g/kg bw (mean) to 2.6  $\mu$ g/kg bw (97.5<sup>th</sup>

T-2 or HT2 exposure estimates only

68. Where there were limited data on the sum of T-2 and HT-2 from RTE foods for an exposure assessment, the data on individually reported levels of T-2 or HT-2 were used.

#### Chronic exposure estimates to T-2

69. The highest chronic exposure estimates to T-2 from RTE foods were from oat porridge in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile exposures of 0.033-0.10 (mean-max concentration), and 0.17-0.51 (mean-max concentration)  $\mu$ g/kg bw, respectively. The lowest chronic exposure estimates to T-2 from RTE foods were from plain muesli in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile exposures of 0.0030-0.0043 (mean-max concentration), and 0.001-0.0015 (mean-max concentration) ng/kg bw, respectively (Annex 2A).

#### Acute exposure estimates to T-2

70. The highest acute exposure estimates for T-2 from RTE foods were from oat porridge in infants (4-18 months), with mean and 97.5<sup>th</sup> percentile exposures of 0.074-0.23 (mean-max concentration), and 0.27-0.83 (mean-max concentration)  $\mu$ g/kg bw, respectively. The lowest acute exposure estimates to T-2 from RTE foods were from plain muesli in infants (4-18 months) with mean and 97.5<sup>th</sup> percentile of 0.00073-0.0011 (mean-max concentration), and 0.0025-0.0036 (mean-max concentration)  $\mu$ g/kg bw, respectively (Annex 2B).

#### Chronic exposure estimates to HT-2

71. The highest chronic exposure estimates for HT-2 from RTE foods were from infant cereals, in infants (4-18 months), with mean and 97.5<sup>th</sup> percentile exposures of 0.70-0.71 (mean-max concentration), and 2.9-2.9 (mean-max concentration)  $\mu$ g/kg bw, respectively. The lowest chronic exposure estimates for HT-2 from RTE foods were from puffs/curls and extruded snacks in adults (19-64 years) with mean and

97.5<sup>th</sup> percentile exposures of 0.00064-0.00064 (mean-max concentration), and 0.0020-0.0020 (mean-max concentration) µg/kg bw, respectively (Annex 2C).

Acute exposure estimates to HT-2

72. The highest acute exposure estimates to HT-2 from RTE foods were from infant cereals, in infants (4-18 months), with mean and 97.5<sup>th</sup> percentile exposures of 1.4-1.4 (mean-max concentration), and 5.2-5.2 (mean-max concentration)  $\mu$ g/kg bw, respectively. The lowest acute exposure estimates from HT-2 from RTE foods were from puffs/curls and extruded snacks in adults (19-64 years) with mean and 97.5<sup>th</sup> percentile exposures of 0.0018-0.0018 (mean-max concentration), and 0.0050-0.0050 (mean-max concentration)  $\mu$ g/kg bw, respectively (Annex 2D).

#### **Risk characterisation**

73. Trichothecenes, such as T-2 and HT-2 can cause chronic and acute adverse effects, with haematotoxicity and emesis being the critical effects, respectively. The COT confirmed in 2023 that they continued to be content with the HBGVs established by EFSA, a group ARfD of 0.3  $\mu$ g/kg bw for T-2, HT-2 and NEO and a group TDI of 0.02  $\mu$ g/kg bw for T-2, HT-2 and NEO.

74. Following the EU's decision to establish maximum levels for T-2 and HT-2, the COT was asked by the FSA/FSS to perform an assessment to determine the risk to human health in the UK from T-2 and HT-2 exposure. To assist with the assessment the FSA/FSS undertook a call for evidence. NEO was not included in the call for evidence and has not been further considered here. The current paper provided an updated exposure assessment, following further data cleanup and the application of a reduction factor for oat grains, to attempt a more realistic exposure of UK consumers from oat grains, barley grains and wheat grains. The estimated exposures were compared to their respective HBGVs to assess acute (Table 15) and chronic (Table 14) health risks of UK consumers.

#### **Chronic exposure**

75. The majority of the mean estimated chronic exposures for unprocessed oat grains (unprocessed/raw materials, which were yet to undergo any cleaning) were at or below the TDI, with infants and toddlers exceeding the TDI 2-fold. High consumption (97.5th percentile) resulted in exceedances ranging from 4-fold (older children) to 15/14-fold (infants/toddlers) the TDI. In comparison, exposures for unprocessed oat grains to which a reduction factor (85%) has been applied, to account for dehulling and processing of oat grains, the exposures were below the TDI, with a few exceptions, i.e. infants (2-3-fold), toddlers (2-3-fold) and children 1-2-fold), high consumer vegetarians were at the TDI. The same applied to oats combined, assessing risks for all oat grains submitted, processed oat grains and unprocessed oat grains with a reduction factor applied.

76. Consumption of the sum of all unprocessed grains (oat, barley, wheat) would result in (UB) exceedances of the TDI for mean and high consumers, across all age groups, with mean exposures for older children, adults and women of childbearing age being at the TDI. Considering exposures for processed grains, i.e. processed barley and wheat grains and oats combined (processed oat grains submitted by industry plus unprocessed oat grains to which a reduction factor has been applied) those exceedances are substantially reduced. Infants and toddlers, who had exceedances of 15- and 14-fold the TDI, respectively, under a more realistic exposure scenario are below the TDI for mean consumption and exceed the TDI only 2-3-fold for high consumption, reducing their overall risk substantially. Under the more realistic scenario of processed grains, the elderly would exceed the TDI up to 4-fold rather than 8-fold at the 97.5<sup>th</sup> percentile, while children, vegetarians and women of childbearing age would be exceeding up to 2-fold or be at the TDI.

77. Oat grains are unlikely to be eaten unprocessed, hence the application of a reduction factor (85%) to unprocessed oats which has resulted in a more realistic exposure scenario. The resulting exposures are also in line with the small data set of processed oat grain submitted by industry. As with oat grains, wheat grains and barley grains are unlikely to be eaten unprocessed hence overall exposure to all

processed grains was the more realistic exposure scenario for UK consumers. Oat grains were the major contributor to the sum of all three grains in this assessment.

78. While for the majority of age groups, especially for mean consumers, exposures to all grains are at or below the TDI, exposures for infants and toddlers, as well as the elderly continue to be of toxicological concern. Exceedances of up to 3-fold in adults and up to 2-fold in children and vegetarians are undesirable but unlikely to result in health concerns.

Table 14: Chronic risk to sum of T-2 and HT-2 from some cereal grains based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call, expressed as x-fold of estimated chronic exposure as a percentage of the TDI of 0.02 µg/kg bw/day.

	Infants (4-18 months) (n=2683)	Infant s (4- 18 mont hs) (n=26 83)	Toddl ers (1.5-3 years) (n=11 57)	To ddl ers (1. 5-3 yea rs) (n= 115 7)	Chil dren (4- 10 year s) (n=2 537)	Chil dren (4- 10 year s) (n=2 537)	Old er Chil dren (11- 18 year s) (n=2 657)	Older Child ren (11- 18 years ) (n=26 57)	Adu Its (19- 64 year s) (n=5 094)	Adu Its (19- 64 year s) (n=5 094)	Elde rly (65+ year s) (n=1 538)	Elde rly (65+ year s) (n=1 538)	Adult Veget arian s / Vega ns (19- 64 years ) (n=17 0)	Ad ult Ve get ari an s / Ve ga ns (19 -64 yea rs) (n= 170 )	Wo men of Chil dbe arin g age (16- 49 year s) (n=2 556)	Wo men of Chil dbe arin g age (16- 49 year s) (n=2 556)
Food groups	Mean*	P97.5 *	Mean *	P9 7.5 *	Mea n*	P97. 5*	Mea n*	P97.5 *	Mea n*	P97. 5*	Mea n*	P97. 5*	Mean *	P9 7.5 *	Mea n*	P97. 5*
Unprocessed oats	2	15	2	14	1	9	0.5	4	0.7	5	1	5	1	7	0.6	4
Unprocessed oats with reduction factor+	0.3-0.4	2-3	0.3- 0.4	2-3	0.2- 0.3	1-2	0.1	0.5- 0.7	0.1	0.6- 0.9	0.1- 0.2	0.9	0.2	0.9 -1	0.1	0.6- 0.7
Oats combined++	0.3-0.4	2-3	0.3- 0.4	2-3	0.2- 0.3	1-2	0.1	0.5- 0.7	0.1	0.7- 0.9	0.1- 0.2	0.7- 0.9	0.2	1	0.1	0.6- 0.7

All grains sum	0-3	0-15	0-3	0-	0-2	0-10	0-1	0-5	0-1	0-6	0-2	0-8	0-2	0-8	0-1	0-5
(unprocessed)				15												
All grains sum	0.3-0.5	2-3	0.3-	2-3	0.2-	1-2	0.1-	0.5-	0.1-	0.7-	0.1-	0.7-	0.2-	1-2	0.1-	0.6-
(processed)			0.6		0.4		0.2	0.9	0.4	3	0.5	4	0.5		0.2	1

\*Estimates have been rounded to 1 significant figure; except in cases where the exceedance was <1.

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%) applied.

If single value is shown, this indicates that the exposures were based on detected values above the LOQ or exceedances at the LB and UP value were the same.

'All grains sum' refers to oat grains, wheat grain, and barley grain.

## Acute exposure

79. Acute mean and 97.5th percentile exposures of unprocessed oat grains (unprocessed/raw materials, which were yet to undergo any cleaning) were below the ARfD, with the exception of infants and toddler which exceeded the ARfD 2-fold, and children (97.5th percentile) which were at the ARfD. While below the ARfD, high consumption of unprocessed oats could lead to exposures close to the ARfD in vegetarians. Application of a reduction factor (85%) to unprocessed oat grains resulted in exposures being well below the ARfD in all age groups. The same applies to exposures to oats combined, not surprising as the oats combined groups is predominantly driven by unprocessed oats. However, the limited data on processed oat grains submitted by industry showed similar exposures as the exposures to unprocessed oat grains to which a reduction factor was applied, further supporting the selection of a reduction factor of 85%.

80. Mean and 97.5th percentile consumption estimates of the sum of all unprocessed grains (oat, barley, wheat) were below the ARfD, except for infants and toddlers with 2-fold exceedances, and high consumption (97.5th percentile) in children and vegetarians, which were at the ARfD. While consumption in the elderly (97.5th percentile) was below the ARfD, it was close to the ARfD. In contrast, exposures for the sum of all processed grains were below the ARfD.

81. Considering it is unlikely that individuals would consume unprocessed grains, the acute exposures here are not of concern. However, it should be noted that the database for processed wheat and barley was relatively small and that processed oat grains here would be oats combined, i.e. unprocessed oat grains to which a reduction factor has been applied. The reduction factor of 85% was selected from the literature and while supported by the limited data submitted by industry for processed oat grains, could significantly vary, potentially leading to an underestimation of risk, especially in hot spots of T-2 and HT-2 occurrence.

Table 15: Acute risk to sum of T-2 and HT-2 from some cereal grains based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call, expressed as estimated x-fold of chronic exposure as a percentage of the ARfD of 0.3 µg/kg bw/day.

	Infants (4-18 months) (n=2683)	Infant s (4- 18 mont hs) (n=26 83)	Toddl ers (1.5-3 years) (n=11 57)	To ddl ers (1. 5-3 yea rs) (n= 115 7)	Chil dren (4- 10 year s) (n=2 537)	Chil dren (4- 10 year s) (n=2 537)	Old er Chil dren (11- 18 year s) (n=2 657)	Older Child ren (11- 18 years ) (n=26 57)	Adu Its (19- 64 year s) (n=5 094)	Adu Its (19- 64 year s) (n=5 094)	Elde rly (65+ year s) (n=1 538)	Elde rly (65+ year s) (n=1 538)	Adult Veget arian s / Vega ns (19- 64 years ) (n=17 0)	Ad ult Ve get ari an s / Ve ga ns (19 -64 yea rs) (n= 170 )	Wo men of Chil dbe arin g age (16- 49 year s) (n=2 556)	Wo men of Chil dbe arin g age (16- 49 year s) (n=2 556)
Food groups	Mean*	P97.5 *	Mean *	P9 7.5 *	Mea n*	P97. 5*	Mea n*	P97.5 *	Mea n*	P97. 5*	Mea n*	P97. 5*	Mean *	P9 7.5 *	Mea n*	P97. 5*
Unprocessed oats	0.3	2	0.3	2	0.2	1	0.1	0.5	0.1	0.5	0.1	0.5	0.2	0.8	0.1	0.5
Unprocessed oats with reduction factor	0-0.1	0.3	0-0.1	0.2 - 0.3	0	0.1- 0.2	0	0.1	0	0.1	0	0.1	0	0.1	0	0.1

Oats combined***	0-0.1	0.3	0-0.1	0.2	0	0.2	0	0.1	0	0.1	0	0.1	0	0.1	0	0.1
				-												
				0.3												
All grains sum	0-0.4	0-2	0-0.4	0-2	0-	0-1	0-	0-0.6	0-	0-	0-	0-	0-0.2	0-1	0-	0-
(unprocessed)					0.3		0.1		0.2	0.8	0.2	0.8			0.1	0.6
All grains sum	0.1	0.3	0-0.1	0.2	0.1	0.2	0	0.1	0-	0.1-	0-	0.1-	0-0.1	0.1	0	0.1
(processed)				-					0.1	0.5	0.1	0.6		-		
				0.3										0.4		

\*Estimates have been rounded to 1 significant figure; except in cases where the exceedance is <1.

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%) applied.

If single value was shown, this indicates that the exposures were based on detected values above the LOQ or exceedances at the LB and UP value were the same.

'All grains sum' refers to oat grains, wheat grain, and barley grain.

# Ready to Eat (RTE) foods

# Chronic

82. Data for the sum of T-2 and HT-2 in RTE foods were only available for infant cereals (Annex 1A). Hence, exposure estimates were only calculated for infants (4-18 months) and toddlers 1.5-3 years). All exposures exceeded the TDI, the lowest exceedance being 11-22-fold in toddlers for mean exposures (mean-max concentration) and the highest being at 75-145-fold (mean max concentration) at the 97.5th percentile in infants.

83. Chronic exposures to T-2 (only; Annex 2A) were at the TDI in infants and toddlers with high intakes (97.5<sup>th</sup> percentile) for biscuits (oatmeal), wheat bread rolls and dried pasta, while mixed breakfast cereals resulted in exceedances up to 3-fold the TDI. Oat porridge exceeded the TDI in all groups and exposure scenarios, ranging from 1.8-8-fold in adults and vegetarians, and 2-26-fold in infants and toddlers.

84. Chronic exposures (97.5<sup>th</sup> percentile) to HT-2 (only, Annex 2C) resulted in exceedances of the TDI in most RTE foods for infants and toddlers and plain muesli and oat porridge in adults and vegetarians. Overall, exceedances in oat porridge were highest, with exceedances being 3-22-fold in adults and vegetarians and 3-70-fold in infants and toddlers.

85. Exposures from RTE foods suggest a significant concern to consumer health, especially in infants and toddlers, however also for some foods in adults and vegetarians, mainly oat porridge. However, the submitted data on RTE foods is very limited; on average, sample numbers were <5, in the case of oat porridge <25. While the estimated exposures may be an indication of potential foods of concern, they were subject to a high degree of uncertainty. Hence, the exposures may not be representative. It is furthermore unlikely, that individuals would consumer these foods at these levels throughout their life, every day.

## Acute exposure

86. Exposures to the sum of T-2 and HT-2 from RTE foods exceeded the ARfD, ranging from 2-17-fold in infants and 2-9-fold in toddlers; data were only available for infant cereals, hence only these two age groups have been considered (Annex 1B).

87. Exposures to T-2 (only; Annex 2B) and HT-2 (only; Annex 2D) from RTE foods were all below the ARfD, with the exception of oat porridge in infants and toddlers, exceedances of the ARfD ranged from 2-7-fold. For HT-2 (only) adults were at the TDI at the 97.5<sup>th</sup> percentile (max occurrence), while vegetarians exceeded the ARfD 3-fold.

88. While exceedances of the ARfD for adults, especially vegetarians are undesirable, it is unlikely that an occasional exceedance would result in a concern for health. Exceedances in infants and toddlers could potentially be of concern, if exposures were to occur at this level (in potential hotspots), however, the sample number for oat porridge was < 25 and may not be representative.

#### **Uncertainties and assumptions**

89. The risk assessment for T-2 and HT-2 in food included a number of assumptions and uncertainties, which relate to the preparation of the occurrence data, the calculation of the consumption data and exposure assessment, as well as the risk assessment itself. These uncertainties are listed below in further detail.

90. Uncertainties associated with the preparation of the occurrence data:a. When an LOD was not reported these data were included assuming all other acceptance criteria were met.

b. When a result value was not reported it was assumed to be equal to the LOQ (when LOQ > 0).

c. When a sample code description was not reported, the code was researched, and the description was filled in. Any changes to the codes over the years that the data covered would not be captured.

d. Food codes were grouped in food groups for the purpose of the assessment on the basis of the FoodEx descriptions of the codes. When in doubt assumptions were made as to which group the codes fitted best.

e. In the UK and Ireland, it is common for grain to be delivered to the mill 'as harvested' i.e. uncleaned and unprocessed with the husk still intact. Where mycotoxin contamination is associated with the outer layers of the grain this may exhibit higher levels of contamination. A large proportion of data submitted as part of the data call were from such unprocessed grains which therefore may exhibit higher levels of contamination compared to cleaned, processed grains. Thus, a processing reduction factor of 85% was applied to the sum of T-2 and HT-2 in unprocessed oat grains. It was assumed that this constitutes a realistic reduction, although different reduction factors have been reported in the literature, potentially over or underestimating the reduction and subsequent exposure.

f. It was assumed that no reduction is achieved by processing of wheat or barley grains, due to the lack of data suggesting otherwise.

91. Uncertainties associated with the calculations of the consumption and exposure assessment estimates:

a. The description of food categories within the Foodex food code system were not always aligned with the names given to similar foods in NDNS and DNSIYC. Therefore, some assumptions were made during the mapping of these foods to identify the closest match when searching the inhouse FSA recipes database for the most relevant food.

b. For the RTE food groups, in some cases, there are a limited number of consumers (<60) as well as a limited number of samples. This may lead to unreliable exposure estimates. Consumer numbers less than 60 (<60)

should be treated with caution as they may not be true representation of the entire population.

c. For RTE food groups, there is uncertainty on whether concentrations were provided on a wet weight or dry weight basis, hence conversion factors were not applied while building the food groups. These include foods such as dried infant cereals and other dried food groups.

d. NDNS does not include pregnant or lactating women, therefore data for women of childbearing age (16-49 years) were used as a proxy and therefore may not be representative of the maternal diet.

e. Exposure assessments based on the consumption of unprocessed grains are highly conservative, as they do not reflect a realistic pattern of intake.

92. Uncertainties associated with the risk assessment:

a. The exposure assessment only includes T-2 and HT-2 mycotoxins, however the group TDI and group ARfD established by EFSA also includes NEO. Uncertainty regarding the occurrence of NEO in cereal grains, as well as its exclusion from the exposure assessment might lead to an underestimation of total exposure and thus a possible underestimation of the corresponding health risk.

b. For RTE foods we are comparing T2 or HT2 only to a HBGV based on the sum of both mycotoxins (plus NEO) and while doing so may give an indication of exposure, this might not provide a realistic assessment since the exposure estimate may under-estimate exposure.

#### Conclusions

93. Following discussions by the COT the exposure assessment for T-2 and HT-2, following an FSA/FSS call for evidence, has been refined, and a reduction factor has been applied to unprocessed oat grains, i.e. oat grains that have not yet been cleaned/dehulled. The application of a reduction factor (85%) has significantly reduced the acute and chronic exposures to T-2 and HT-2. While the reduction factor

was selected from the literature it is supported by exposures based on the limited data on processed grains submitted by industry.

94. Chronic exposures of unprocessed oat grains in infants and toddlers exceed the TDI by up to 15-fold and in children up to 4-fold. After application of the reduction factor, exposures for infants and toddlers continue to exceed the TDI but to a lesser extent (up to 3-fold). While infant and toddlers and to a lesser extent children and vegetarians exceeded the ARfD of 0.3  $\mu$ g/kg bw for unprocessed oat grains and the sum of all unprocessed grains (oat, barley, wheat), application of the reduction factor (85%) resulted in all acute exposures being below the ARfD. It is implausible that individuals would consume unprocessed grains, this is a worst-case and unlikely to be a real-life exposure scenario.

95. Overall, chronic exposures to oats combined and the sum of all processed grains (oat, wheat, barley) were of toxicological concern in infants, toddlers and the elderly, while exposures in children and vegetarians were undesirable but unlikely to result in serious health concerns. Acute exposures were not of toxicological concern.

96. This is in line with the COT's conclusion on the risk of T-2 and HT-2 in the infant diet (COT, 2018). Based on a 2015 mycotoxin survey of oat-based products (FSA, 2015), acute exposures were all below the EFSA group ARfD and therefore not of toxicological concern, while for chronic exposures the EFSA group TDI was exceeded. Hence, an effect on health could not be entirely excluded.

97. T-2 and HT-2 occurrence is significantly influenced by climate and levels can vary significantly from year to year, as indicated in Figures 1,3 and 5. Year to year variability may mean that individuals could be exposed to high levels of T-2 and HT-2 in one year compared to other years. While this may potentially affect acute exposures due to hot spots or a particularly bad year leading to occasional high exposures, exposures to the sum of T-2 and HT-2 from grains were calculated on a commodity basis. Consumption was modelled based on all foods containing the grains and occurrence was calculated at the LB and UB median. Therefore, these were the most representative estimates of chronic exposure.

98. Chronic exposures from RTE foods suggest a significant concern to consumer health, especially in infants and toddlers, however also for some foods in adults and vegetarians, mainly oat porridge. While acute exposures in adults, especially vegetarians were undesirable, exceedances of the ARfD for infants and toddlers are of potential concern, if they were to occur at the levels reported. However, the estimated exposures based on RTE foods were based on very limited data and are subject to a high degree of uncertainty. In addition, samples on T-2 and HT-2 were only available for infant foods, for all other foods samples were available for either T-2 (only) or HT-2 (only).

99. The exposures from RTE foods are furthermore of significantly higher concern than exposures from processed oat grains or all processed grains (oat, wheat, barley). It is unclear why this is the case, especially given that grains incorporated into RTE foods would have undergone further processing. Year-to-year variability may have played a role, however, it was difficult to link the submitted data on RTE foods to an identifiably bad year for T-2 and HT-2 levels. Some of the reported RTE foods, especially oat grains were from 2013 and 2014, reportedly years with high mycotoxin levels, while other RTE foods were from 2022-2024, years with overall lower occurrence data on T-2 and HT-2.

100. Exposures to processed grains were based on a commodity approach and calculated by using the median across the occurrence data, while exposures to RTE foods, due to the limited number of samples, were calculated on a food-by-food basis and mean and maximum occurrence level. RTE foods only provide a very limited snapshot of exposures to final food products and direct comparison to exposures from all grains was therefore not possible. The analytical method used may further add to the uncertainties in the exposures from RTE foods, where a low level/non-detect was determined to be at the LOQ, the LOQ was used as the level to estimate exposures. As some methods may not have been sensitive enough this would have resulted in relatively high "occurrence levels".

101. Overall, based on the occurrence data provided via the call for evidence for processed grains (oat, barley and wheat) and the limited number of RTE foods, a

health concern arising from chronic exposures, especially for infants and toddlers cannot be excluded. However, given all the uncertainties, the estimated exposures for RTE foods may not reliable and not representative of RTE foods.

### Questions on which the views of the Committee are sought:

102. Members are invited to consider the following questions:

- Given the uncertainties associated with the occurrence data, consumption data and exposure assessment, do the Committee consider there to be a health risk from exposures to T-2 and HT-2?
- ii) If so, are there any age groups, exposure scenarios or commodities of particular concern?
- iii) If Members are unable to conclude, is there any further information or data analysis that would assist the Committee in reaching a conclusion?
- iv) Do the Committee have any other questions?

#### Secretariat

March 2025

# Abbreviations

ARfD	Acute reference dose
DAS	4,15- diacetoxyscirpenol
DNSIYC	Diet and Nutrition Survey of Infants and Young Children
ELISA	Enzyme-Linked Immunosorbent Assays
FPIA	Fluorescence Polarisation Immunoassays
HBGV	Health-based guidance value
HT-2	HT-2 toxin
LB	Lower bound
LC-MS	Liquid chromatography mass spectrometry
LFDs	Lateral Flow Devices
LOD	Limit of detection
LOQ	Limit of quantification
Max	Maximum
ML	Maximum levels
NDNS	National Diet and Nutrition Survey
NEO	Neosolaniol
QA	Quality assurance
RTE	Ready to eat
RPC	Raw primary commodity
T-2	T-2 toxin
TDI	Tolerable daily intake
UB	Upper bound
СОТ	Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment
EAT	FSA's Exposure assessment team
EC	European Commission
EFSA	European Food Safety Authority

EU	European Union
FSA	Food Standards Agency
FSS	Food Standards Scotland
JECFA	Joint FAO/WHO Expert Committee on Food Additives

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# Annex 1 to TOX/2025/14

# Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment

# **Risk assessment of T-2 and HT-2 Mycotoxins in Food**

#### Annex 1 (Sum of T2 and HT2)

Data for the sum of T-2 and HT-2 were only available for infant cereals.

Annex 1A. Chronic exposure to sum of T-2 and HT-2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call.

Infants (4-18 months) (n=2683)

Food Groups	Count of T2 HT2 Data Call Samples (n)	Mean T2 Concentration (µg/kg)	Max T2 Concentration (µg/kg)	Consumers (n)	Mean	P97.5	Mean	P97.5
Infants' cereals	2	110.6	219	1128	0.36	1.5	0.71	2.9

Toddlers (1.5-3 years) (n=1157)

Food Groups	Count of T2	Mean T2	Max T2	Consumers (n)	Mean	P97.5	Mean	P97.5
	HT2 Data Call	Concentration	Concentration					
	Samples (n)	(µg/kg)	(µg/kg)					

Infants'	2	110.6	219	34	0.22	0.70	0.44	1.4
cereals								

Exposure estimates have been rounded to 2 significant figures; concentrations have been rounded to one decimal place.

\*Mean/Max concentration.

**Annex 1B.** Acute exposure to sum of T-2 and HT 2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call.

Infants (4-18 months) (n=2683)

Food Groups	Count of T2 HT2 data call samples (n)	Mean T2 Concentration (µg/kg)	Consumers (n)	Mean	P97.5	Mean	P97.5
Infants' cereals	2	219	1128	0.71	2.6	1.4	5.2

Toddlers (1.5-3 years) (n=1157)

Food Groups	Count of T2 HT2 data call samples (n)	Mean T2 Concentration (µg/kg)	Consumers (n)	Mean	P97.5	Mean	P97.5
Infants' cereals	2	219	1128	0.52	1.3	1.0	2.6

Exposure estimates have been rounded to 2 significant figures; concentrations have been rounded to one decimal place.

\*Mean/Max concentration.

# Annex 2 to TOX/2025/14

# Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment

# **Risk assessment of T-2 and HT-2 Mycotoxins in Food**

Annex 2 (Exposure to T-2 or HT-2, only, from RTE products)

**Table 2A**: Chronic exposure to T-2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call.

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	91	0.00030	0.0010	0.00043	0.0015
Biscuits, oatmeal	4	8.4	12.5	1441	0.0059	0.020	0.0088	0.030
Multigrain bread rolls	2	3.1	3.1	98	0.0027	0.0081	0.0027	0.0081
Wheat bread rolls	2	3.1	3.1	435	0.0050	0.018	0.0050	0.018

Dried pasta	4	3.1	3.1	1140	0.0056	0.020	0.0056	0.020
Mixed breakfast cereals	3	5.0	8.9	1691	0.0095	0.036	0.017	0.064
Extruded breakfast cereals	4	5.0	10	338	0.0029	0.010	0.0057	0.020
Oat porridge	24	11.7	36.1	389	0.033	0.17	0.10	0.51
Plain cereal bars	2	5.9	8.7	5	0.0038	0.0056	0.0056	0.0082

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	14	0.0043	0.0076	0.0062	0.011
Biscuits, oatmeal	4	8.4	12.5	566	0.0058	0.018	0.0086	0.027
Multigrain bread rolls	2	3.1	3.1	75	0.0053	0.019	0.0053	0.019
Wheat bread rolls	2	3.1	3.1	125	0.0063	0.021	0.0063	0.021

Dried pasta	4	3.1	3.1	602	0.0055	0.016	0.0055	0.016
Mixed breakfast cereals	3	5.0	8.9	983	0.0077	0.033	0.014	0.058
Extruded breakfast cereals	4	5.0	10	379	0.0032	0.010	0.0064	0.020
Oat porridge	24	11.7	36.1	70	0.038	0.14	0.12	0.42
Plain cereal bars	2	5.9	8.7	24	0.0032	0.0066	0.0046	0.0097

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	211	0.0015	0.0049	0.0022	0.0072
Biscuits, oatmeal	4	8.4	12.5	1472	0.0017	0.0059	0.0025	0.0088
Multigrain bread rolls	2	3.1	3.1	530	0.0018	0.0051	0.0018	0.0051
Wheat bread rolls	2	3.1	3.1	293	0.0017	0.0055	0.0017	0.0055

Dried pasta	4	3.1	3.1	1677	0.0027	0.0075	0.0027	0.0075
Mixed breakfast cereals	3	5.0	8.9	2935	0.0021	0.0078	0.0037	0.014
Extruded breakfast cereals	4	5.0	10	278	0.0011	0.0031	0.0022	0.0062
Oat porridge	24	11.7	36.1	222	0.012	0.036	0.038	0.11
Plain cereal bars	2	5.9	8.7	135	0.00098	0.0031	0.0014	0.0046

# Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	11	0.0016	0.0032	0.0023	0.0047
Biscuits, oatmeal	4	8.4	12.5	55	0.0018	0.0041	0.0026	0.0060
Multigrain bread rolls	2	3.1	3.1	33	0.0020	0.0046	0.0020	0.0046
Wheat bread rolls	2	3.1	3.1	10	0.0013	0.0033	0.0013	0.0033

Dried pasta	4	3.1	3.1	64	0.0035	0.010	0.0035	0.010
Mixed breakfast cereals	3	5.0	8.9	98	0.0023	0.0058	0.0041	0.010
Extruded breakfast cereals	4	5.0	10	14	0.0010	0.0021	0.0020	0.0042
Oat porridge	24	11.7	36.1	6	0.016	0.052	0.050	0.16
Plain cereal bars	2	5.9	8.7	2	0.0015	0.0016	0.0022	0.0024

Exposure estimates have been rounded to 2 significant figures; concentrations have been rounded to one decimal place.

\*Mean/Max concentration.

**Table 2B:** Acute exposure to T-2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence datacollected from the FSA call.

Infants (4-18 months) (n=2683)

Food groups	Count of T-2 data call samples (n)		T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	91	0.00073	0.0025	0.0011	0.0036

Biscuits, oatmeal	4	8.4	12.5	1441	0.014	0.037	0.020	0.055
Multigrain bread rolls	2	3.1	3.1	98	0.0075	0.019	0.0075	0.019
Wheat bread rolls	2	3.1	3.1	435	0.011	0.032	0.011	0.032
Dried pasta	4	3.1	3.1	1140	0.018	0.056	0.018	0.056
Mixed breakfast cereals	3	5.0	8.9	1691	0.017	0.084	0.030	0.15
Extruded breakfast cereals	4	5.0	10	338	0.0069	0.022	0.014	0.043
Oat porridge	24	11.7	36.1	389	0.074	0.27	0.23	0.83
Plain cereal bars	2	5.9	8.7	5	0.011	0.021	0.017	0.031

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	14	0.0093	0.019	0.014	0.028

Biscuits, oatmeal	4	8.4	12.5	566	0.016	0.039	0.023	0.057
Multigrain bread rolls	2	3.1	3.1	75	0.012	0.032	0.012	0.032
Wheat bread rolls	2	3.1	3.1	125	0.014	0.035	0.014	0.035
Dried pasta	4	3.1	3.1	602	0.017	0.046	0.017	0.046
Mixed breakfast cereals	3	5.0	8.9	983	0.014	0.057	0.025	0.10
Extruded breakfast cereals	4	5.0	10	379	0.0072	0.020	0.014	0.040
Oat porridge	24	11.7	36.1	70	0.11	0.27	0.34	0.85
Plain cereal bars	2	5.9	8.7	24	0.011	0.023	0.016	0.034

Adults (19-64 years) (n=5094)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	211	0.0028	0.0070	0.0041	0.010

Biscuits, oatmeal	4	8.4	12.5	1472	0.0046	0.014	0.0068	0.021
Multigrain bread rolls	2	3.1	3.1	530	0.0040	0.010	0.0040	0.010
Wheat bread rolls	2	3.1	3.1	293	0.0040	0.0093	0.0040	0.0093
Dried pasta	4	3.1	3.1	1677	0.0087	0.019	0.0087	0.019
Mixed breakfast cereals	3	5.0	8.9	2935	0.0038	0.013	0.0067	0.024
Extruded breakfast cereals	4	5.0	10	278	0.0025	0.0052	0.0051	0.010
Oat porridge	24	11.7	36.1	222	0.026	0.050	0.081	0.16
Plain cereal bars	2	5.9	8.7	135	0.0025	0.0080	0.0037	0.012

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of T-2 data call samples (n)	T-2 concentration μg/kg (mean)	T-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	4.0	5.9	11	0.0034	0.0057	0.0050	0.0083

Biscuits, oatmeal	4	8.4	12.5	55	0.0052	0.011	0.0077	0.016
Multigrain bread rolls	2	3.1	3.1	33	0.0040	0.0068	0.0040	0.0068
Wheat bread rolls	2	3.1	3.1	10	0.0039	0.0092	0.0039	0.0092
Dried pasta	4	3.1	3.1	64	0.010	0.020	0.010	0.020
Mixed breakfast cereals	3	5.0	8.9	98	0.0045	0.015	0.0079	0.026
Extruded breakfast cereals	4	5.0	10	14	0.0025	0.0045	0.0050	0.0089
Oat porridge	24	11.7	36.1	6	0.039	0.10	0.12	0.32
Plain cereal bars	2	5.9	8.7	2	0.0040	0.0053	0.0060	0.0078

Exposure estimates have been rounded to 2 significant figures; concentrations have been rounded to one decimal place. \*Mean/Max concentration.

**Table 2C:** Chronic exposure to HT-2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call.

Infants (4-18 months) (n=2683)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	91	0.0013	0.0044	0.0029	0.0099
Biscuits, oatmeal	4	14.6	24.3	1441	0.010	0.034	0.017	0.058
Multigrain bread rolls	2	6.9	7	98	0.0059	0.018	0.0060	0.018
Wheat bread rolls	2	6.3	6.3	435	0.010	0.036	0.010	0.036
Dried pasta	4	6.3	6.3	1140	0.011	0.040	0.011	0.040
Mixed breakfast cereals	3	8.6	11.2	1691	0.016	0.062	0.021	0.081
Oat porridge	23	20.1	95.7	389	0.057	0.28	0.27	1.4
Infants' cereals	2	217.5	219	1128	0.70	2.9	0.71	2.9
Plain cereal bars	2	14.5	18.2	5	0.0093	0.014	0.012	0.017
Puffs/ curls type extruded snack	1	5.2	5.2	630	0.0023	0.0072	0.0023	0.0072

Toddlers (1.5-3 years) (n=1157)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	14	0.018	0.033	0.041	0.074
Biscuits, oatmeal	4	14.6	24.3	566	0.010	0.032	0.017	0.053
Multigrain bread rolls	2	6.9	7	75	0.012	0.041	0.012	0.042
Wheat bread rolls	2	6.3	6.3	125	0.013	0.044	0.013	0.044
Dried pasta	4	6.3	6.3	602	0.011	0.033	0.011	0.033
Mixed breakfast cereals	3	8.6	11.2	983	0.013	0.056	0.017	0.072
Oat porridge	23	20.1	95.7	70	0.065	0.24	0.31	1.1
Infants' cereals	2	217.5	219	34	0.44	1.4	0.44	1.4
Plain cereal bars	2	14.5	18.2	24	0.0077	0.016	0.0097	0.020
Puffs/ curls type	1	5.2	5.2	387	0.0023	0.0057	0.0023	0.0057

extruded				
snack				

## Adults (19-64 years) (n=5094)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	211	0.0065	0.021	0.015	0.047
Biscuits, oatmeal	4	14.6	24.3	1472	0.0030	0.010	0.0049	0.017
Multigrain bread rolls	2	6.9	7	530	0.0041	0.011	0.0041	0.012
Wheat bread rolls	2	6.3	6.3	293	0.0034	0.011	0.0034	0.011
Dried pasta	4	6.3	6.3	1677	0.0055	0.015	0.0055	0.015
Mixed breakfast cereals	3	8.6	11.2	2935	0.0036	0.013	0.0047	0.017
Oat porridge	23	20.1	95.7	222	0.021	0.061	0.10	0.29
Infants' cereals	2	217.5	219	2	0.032	0.042	0.032	0.042

Plain cereal bars	2	14.5	18.2	135	0.0024	0.0077	0.0030	0.0097
Puffs/ curls type extruded snack	1	5.2	5.2	673	0.00064	0.0020	0.00064	0.0020

## Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	11	0.0067	0.014	0.015	0.031
Biscuits, oatmeal	4	14.6	24.3	55	0.0030	0.0070	0.0051	0.012
Multigrain bread rolls	2	6.9	7	33	0.0044	0.010	0.0045	0.010
Wheat bread rolls	2	6.3	6.3	10	0.0026	0.0067	0.0026	0.0067
Dried pasta	4	6.3	6.3	64	0.0071	0.021	0.0071	0.021
Mixed breakfast cereals	3	8.6	11.2	98	0.0039	0.010	0.0051	0.013

Oat porridge	23	20.1	95.7	6	0.028	0.090	0.13	0.43
Infants' cereals	2	217.5	219	0	0	0	0	0
Plain cereal bars	2	14.5	18.2	2	0.0037	0.0039	0.0047	0.0050
Puffs/ curls type extruded snack	1	5.2	5.2	22	0.00073	0.0011	0.00073	0.0011

Exposure estimates have been rounded to 2 significant figures, concentrations have been rounded to one decimal place.

\*Mean/Max concentration.

**Table 2D:** Acute exposure to HT-2 from RTE products from DNSIYC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call.

## Infants (4-18 months) (n=2683)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration µg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	91	0.0031	0.011	0.0070	0.024
Biscuits, oatmeal	4	14.6	24.3	1441	0.023	0.064	0.039	0.11

Multigrain bread rolls	2	6.9	7	98	0.017	0.041	0.017	0.042
Wheat bread rolls	2	6.3	6.3	435	0.023	0.066	0.023	0.066
Dried pasta	4	6.3	6.3	1140	0.036	0.11	0.036	0.11
Mixed breakfast cereals	3	8.6	11.2	1691	0.029	0.14	0.038	0.19
Oat porridge	23	20.1	95.7	389	0.13	0.46	0.61	2.2
Infants' cereals	2	217.5	219	1128	1.4	5.2	1.4	5.2
Plain cereal bars	2	14.5	18.2	5	0.028	0.052	0.035	0.066
Puffs/ curls type extruded snack	1	5.2	5.2	630	0.0060	0.015	0.0060	0.015

Toddlers (1.5-3 years) (n=1157)

Food groups		HT-2 concentration µg/kg (mean)		Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
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Plain muesli	3	17.3	39	14	0.040	0.082	0.090	0.19
Biscuits, oatmeal	4	14.6	24.3	566	0.027	0.067	0.045	0.11
Multigrain bread rolls	2	6.9	7	75	0.027	0.071	0.028	0.072
Wheat bread rolls	2	6.3	6.3	125	0.029	0.071	0.029	0.071
Dried pasta	4	6.3	6.3	602	0.035	0.094	0.035	0.094
Mixed breakfast cereals	3	8.6	11.2	983	0.024	0.098	0.031	0.13
Oat porridge	23	20.1	95.7	70	0.19	0.47	0.91	2.2
Infants' cereals	2	217.5	219	34	1.0	2.6	1.0	2.6
Plain cereal bars	2	14.5	18.2	24	0.026	0.057	0.033	0.071
Puffs/ curls type extruded snack	1	5.2	5.2	387	0.0061	0.014	0.0061	0.014

Adults (19-64 years) (n=5094)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	211	0.012	0.030	0.027	0.068
Biscuits, oatmeal	4	14.6	24.3	1472	0.0079	0.024	0.013	0.040
Multigrain bread rolls	2	6.9	7	530	0.0088	0.022	0.0090	0.022
Wheat bread rolls	2	6.3	6.3	293	0.0081	0.019	0.0081	0.019
Dried pasta	4	6.3	6.3	1677	0.018	0.038	0.018	0.038
Mixed breakfast cereals	3	8.6	11.2	2935	0.0065	0.023	0.0085	0.030
Oat porridge	23	20.1	95.7	222	0.045	0.087	0.21	0.41
Infants' cereals	2	217.5	219	2	0.13	0.17	0.13	0.17
Plain cereal bars	2	14.5	18.2	135	0.0062	0.020	0.0078	0.025
Puffs/ curls type extruded snack	1	5.2	5.2	673	0.0018	0.0050	0.0018	0.0050

Adult Vegetarians / Vegans (19-64 years) (n=170)

Food groups	Count of HT-2 data call samples (n)	HT-2 concentration μg/kg (mean)	HT-2 concentration μg/kg (max)	Consumers (n)	*Mean; Mean	*Mean; P97.5	*Max; Mean	*Max; P97.5
Plain muesli	3	17.3	39	11	0.015	0.024	0.033	0.055
Biscuits, oatmeal	4	14.6	24.3	55	0.0089	0.019	0.014	0.031
Multigrain bread rolls	2	6.9	7	33	0.0087	0.015	0.0089	0.015
Wheat bread rolls	2	6.3	6.3	10	0.0079	0.019	0.0079	0.019
Dried pasta	4	6.3	6.3	64	0.020	0.042	0.020	0.042
Mixed breakfast cereals	3	8.6	11.2	98	0.0077	0.026	0.010	0.033
Oat porridge	23	20.1	95.7	6	0.067	0.18	0.32	0.85
Infants' cereals	2	217.5	219	0	0	0	0	0
Plain cereal bars	2	14.5	18.2	2	0.0099	0.013	0.012	0.016
Puffs/ curls type	1	5.2	5.2	22	0.0021	0.0040	0.0021	0.0040

extruded				
snack				

Exposure estimates have been rounded to 2 significant figures; concentrations have been rounded to one decimal place.

\*Mean/Max concentration.