

Exposure assessment

In this guide

[In this guide](#)

1. [Background - Annex A to TOX/2025/40](#)
2. [Introduction - Annex A to TOX/2025/40](#)
3. [Toxicity - Annex A to TOX/2025/40](#)
4. [Health Based Guidance Values \(HBGVs\) - Annex A to TOX/2025/40](#)
5. [Exposure assessment - Annex A to TOX/2025/40](#)
6. [Risk characterisation - Annex A to TOX/2025/40](#)
7. [Uncertainties and assumptions - Annex A to TOX/2025/40](#)
8. [Conclusions - Annex A to TOX/2025/40](#)
9. [Abbreviations - Annex A to TOX/2025/40](#)
10. [References - Annex A to TOX/2025/40](#)

This is a draft statement for discussion. It does not reflect the final views of the Committee and should not be cited.

45. Dietary exposures to T-2 and HT-2 in the population were estimated from consumption of cereal grains in the diet. However, as the occurrence data were predominantly from unprocessed grains, the approach to assessing exposure in foods as consumed is described below.

Methodology

46. Exposure assessments were conducted on a survey population basis using food consumption data (mean and 97.5th percentile) and the corresponding LB and UB median occurrence values calculated from the FSA call for information. 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” for i) oat grains only, and ii) all grains (oats, wheat, and barley).

47. A single food group was created in the National Diet and Nutrition Survey (NDNS) for estimating exposure to the sum of T-2 and HT-2 from consumption of oat grains only. 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).

48. 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: however, no scientifically robust reduction factors were identified for these cereal grains. In addition, median occurrence values from the data here were below the LOQ, hence the application of a reduction factor would not be expected to affect exposure estimates. The following scenarios were applied:

- Unprocessed wheat grains,
- Processed wheat grains,
- Unprocessed barley grains; and,
- Processed barley grains.

49. Acute and chronic exposures for all grains were estimated for the sum of T-2 and HT-2 (mean and 97.5th percentile).

50. For all RTE foods, the exposure assessments were on a consumer basis using mean and maximum occurrence levels as the datasets were not sufficient to calculate the median. Furthermore, for the majority of RTE foods, chronic and acute exposures to individual toxins (T-2 or HT-2 only) were calculated, as due to the data submitted by industry, occurrence data were only available for individual mycotoxins, but not their sum. The exception being infant cereal for which usable data were available for the sum of T-2 and HT-2 and hence estimated exposures to the sum of T-2 and HT-2 were calculated for this food group.

51. All exposures were estimated for the following age and population groups; the information was based on data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and NDNS (Bates et al., 2014, 2016, 2020; Roberts et al., 2018):

- Infants (4-18 month-olds),
- Toddlers (1.5-3 year-olds),
- Children (4-10 year-olds),
- Older children (11-18 year-olds),
- Adults (19-64 year-olds),
- Elderly (65+ year-olds),
- Adult vegetarians/vegans (19-64 year-olds), and
- Women of childbearing age (16-49 year-olds).

Results

52. Exposures from unprocessed oats only (which constituted the majority of the data received from industry) were very high, however these exposure estimates were unlikely to reflect a real-life scenario. Applying a reduction factor (85 %) to unprocessed oats significantly reduced the levels, and the resulting levels were similar to the very limited data for processed oats, as submitted by industry. This supported the use of the selected reduction factor of 85 %, but it also supported combined oats (unprocessed oats plus reduction factor, and processed oats) as being the most realistic exposure scenarios, for oats.

53. No reduction factors for unprocessed wheat or barley could be identified, and hence all grain exposure was based on the limited data available from processed wheat and barley, as submitted by industry, as well as oats combined. The data showed that the overall exposure from all grains, here, was driven primarily by exposures from oats.

54. Brief summaries, highlighting the most important estimated exposures to the sum of T-2 and HT-2 from oats combined, all processed cereal grains (oats combined, wheat and barley), as well as RTE foods are presented in the following paragraphs. Full results of the exposure assessment can be found in Annex B (supplementary information).

55. Exposure estimates for T-2 and HT-2 in cereal grains were based on a commodity approach and calculated by using the median across the occurrence data. Exposure estimates for T-2 and HT-2 in RTE foods were calculated by using the mean and maximum occurrence level on a food-by-food basis, due to the limited number of samples. All exposure estimates used both the mean and 97.5th percentile consumption rates (across all age and food groups). To note, the exposure estimates from grains (commodity approach) were not added to

exposure estimates from RTE foods to avoid double counting.

Estimated exposures to the sum of T-2 and HT-2 for oats combined and all processed grains

Chronic exposure

56. Oats combined, i.e. unprocessed oats corrected using a reduction factor of 85 % and processed oats as submitted by industry (Annex B; Table 5):

- The lowest chronic exposures to the sum of T-2 and HT-2 were in older children (11-18 years) with mean and 97.5th percentile exposures of 0.0015-0.0019 µg/kg bw (LB-UB) and 0.010-0.013 µg/kg bw (LB-UB), respectively.
- The highest chronic exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.0063-0.0083 µg/kg bw (LB-UB) and 0.039-0.051 µg/kg bw (LB-UB), respectively. Toddlers (1.5-3 years) had similar exposures to infants.

57. All processed grains, i.e. oats combined, processed wheat and processed barley as submitted by industry (Annex B; Table 5):

- The lowest chronic exposures to the sum of T-2 and HT-2 from all processed cereal grains occurred in older children (11-18 years), with mean and 97.5th percentile exposures of 0.0015-0.0039 µg/kg bw and 0.010-0.017 µg/kg bw, respectively.
- The highest chronic exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.0063-0.010 µg/kg bw and 0.039-0.052 µg/kg bw, respectively.

Acute exposure

58. Oats combined, i.e. unprocessed oats corrected using a reduction factor of 85% and processed oats as submitted by industry (Annex B; Table 6):

- The lowest acute exposures to the sum of T-2 and HT-2 were in women of childbearing age (16-49 years) with mean and 97.5th percentile exposures of 0.0033-0.0043 µg/kg bw (LB-UB) and 0.020-0.026 µg/kg bw (LB-UB), respectively.
- The highest acute exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.014-0.018 µg/kg bw (LB-UB) and 0.078-0.10 µg/kg bw (LB-UB), respectively. Toddlers have similar exposures to infants.

59. All processed grains, i.e. oats combined, processed wheat and processed barley as submitted by industry (Annex B; Table 6):

- The lowest acute exposures to the sum of T-2 and HT-2 were in women of childbearing age (16-49 years) with mean and 97.5th percentile exposures of 0.0033-0.0082 µg/kg bw and 0.020-0.034 µg/kg bw, respectively.
- The highest acute exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.014-0.021 µg/kg bw and 0.078-0.10 µg/kg bw, respectively.

Estimated exposures from ready to eat (RTE) foods

60. Due to the limited occurrence data from the call for evidence, consumer-based exposure estimates from RTE foods were only calculated for specific populations groups, i.e. infants (4-18 months), toddlers (1.5-3 years), adults (19-64 years), and adult vegetarians/vegans (19-64 years). These population groups cover the most vulnerable (infants and toddlers) and highest consumption (adults and vegetarians/vegans, due to the foods being oat based).

61. The estimated exposures are the mean and 97.5th percentile exposures based on the mean and maximum concentration (mean-max concentration) of T-2 or HT-2 (separately) or the sum of both, where available (Annex B; Tables 11-16). Exposures to T-2 or HT-2 (separately) were included in this assessment as very few datapoints were available for RTE foods overall and even fewer on the sum of T-2 and HT-2.

Chronic and acute exposure estimates for the sum of T-2 and HT-2

62. Chronic and acute exposure estimates for the sum of T-2 and HT-2, were only available for infants' cereals, and hence only infants and toddlers have been considered (Annex B; Tables 11-12):

- The highest mean and 97.5th percentile exposures, both for chronic and acute, were in infants (4-18 months).
- In infants, mean and 97.5th percentile chronic exposure estimates were 0.36-0.71 µg/kg bw (mean-max concentration), and 1.5-2.9 µg/kg bw (mean-max concentration), respectively.
- In toddlers, mean and 97.5th percentile chronic exposure estimates ranged from 0.22 µg/kg bw (mean) to 1.4 µg/kg bw (97.5th percentile).
- Acute mean and 97.5th percentile exposure estimates in infants were 0.71-1.4 µg/kg bw (mean-max concentration), and 2.6-5.2 µg/kg bw (mean-max

concentration), respectively.

- Acute mean and 97.5th percentile exposure estimates in toddlers ranged from 0.52 µg/kg bw to 2.6 µg/kg bw, respectively).

Chronic and acute exposure estimates for T-2 or HT-2

63. Where data on the sum of T-2 and HT-2 in RTE foods were either not available, too limited and/or did not meet the inclusion criteria, the data on individually reported levels of T-2 or HT-2 were used to provide exposure estimates.

64. Chronic exposure estimates to T-2 only (Annex B; Table 13):

- The lowest chronic exposure estimates to T-2 from RTE foods were from plain muesli in infants with mean and 97.5th percentile exposures of 0.00030-0.00043 µg/kg bw (mean-max concentration), and 0.001-0.0015 µg/kg bw (mean-max concentration), respectively).
- The highest chronic exposure estimates to T-2 from RTE foods were from oat porridge in infants with mean and 97.5th percentile exposures of 0.033-0.10 µg/kg bw (mean-max concentration), and 0.17-0.51 µg/kg bw (mean-max concentration), respectively.

65. Acute exposure estimates to T2 only (Annex B; Table 14):

- The lowest acute exposure estimates to T-2 from RTE foods were from plain muesli in infants with mean and 97.5th percentile exposures of 0.00073-0.0011 µg/kg bw (mean-max concentration), and 0.0025-0.0036 µg/kg bw (mean-max concentration), respectively.
- The highest acute exposure estimates for T-2 from RTE foods were from oat porridge in toddlers, with mean and 97.5th percentile exposures of 0.11-0.34 µg/kg bw (mean-max concentration), and 0.27-0.85 µg/kg bw (mean-max concentration) respectively.

66. Chronic exposure estimates to HT-2 only (Annex B; Table 15):

- The lowest chronic exposure estimates for HT-2 from RTE foods was from puffs/curls type extruded snack, in adults, with mean and 97.5th percentile exposures of 0.00064-0.00064 µg/kg bw (mean-max concentration), and 0.002-0.002 µg/kg bw (mean-max concentration), respectively.
- The highest chronic exposure estimates for HT-2 from RTE foods was from infants' cereals, in infants, with mean and 97.5th percentile exposures of 0.70-0.71 µg/kg bw (mean-max concentration), and 2.9-2.9 µg/kg bw (mean-

max concentration), respectively.

67. Acute exposure estimates to HT-2 only (Annex B; Table 16):

- The lowest acute exposure estimates to HT-2 from RTE foods as from puffs/curly type extruded snack, in adults, with mean and 97.5th percentile exposures of 0.0018-0.0018 µg/kg bw (mean-max concentration), and 0.0050-0.0050 µg/kg bw (mean-max concentration), respectively.
- The highest acute exposure estimates to HT-2 from RTE foods was from infants' cereals, in infants, with mean and 97.5th percentile exposures of 1.4-1.4 µg/kg bw (mean-max concentration), and 5.2-5.2 µg/kg bw (mean-max concentration), respectively.