Exposure assessment

In this guide

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

Methodology

47. 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 data submitted in response to the FSA call for evidence. The concentration range of the reported occurrence levels was very wide, so median occurrence levels were calculated for the sum of T-2 and HT-2 toxins (µg/kg) to avoid skewing the overall exposure. This was applied to “all grains” and exposure scenarios for i) oat grains only, and ii) “all

grains” (oats, wheat, and barley).

48. 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).

49. 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. Median occurrence values in these food categories were below the LOQ so 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.

50. Acute and chronic exposures for “all grains” were estimated for the sum of T-2 and HT-2 (mean and 97.5^{th} percentile).

51. None of the datasets for RTE foods were sufficient to calculate median exposure, so the exposure assessments were conducted on a consumer basis using mean and maximum occurrence levels. In most cases occurrence data were only available for individual mycotoxins (T-2 or HT-2) but not for their sum. For the majority of RTE foods, therefore, chronic and acute exposures to individual toxins were calculated, the exception being infant cereal, for which usable data were available for the sum of T-2 and HT-2.

52. 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),
- Older adults (65+ year-olds),
- Adult vegetarians/vegans (19-64 year-olds), and
- Women of childbearing age (16-49 year-olds).

Results

53. Exposures from unprocessed oats only (which constituted the majority of the data received from industry) were very high but were considered unlikely to reflect a real-life scenario. When a reduction factor (85 %) was applied to the values for unprocessed oats the resulting levels were similar to the (very limited) data for processed oats submitted by industry. This supported the use of the selected reduction factor of 85 % to adjust exposures from unprocessed oats; it also supported the use of “oats combined”, processed oats plus unprocessed oats adjusted using the reduction factor, as being the most realistic exposure scenario with the data currently available for oats.

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

55. 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), and RTE foods are summarised in the following paragraphs. Full results of the exposure assessment can be found in Annex A (supplementary information).

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

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

Chronic exposure

57. For “oats combined”, i.e. unprocessed oats corrected using a reduction factor of 85 % and processed oats as submitted by industry (Annex A; 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/day (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/day (LB-UB) and 0.039-0.051 µg/kg bw/day (LB-UB), respectively. Toddlers (1.5-3 years) had similar exposures to infants.

58. For all processed grains, i.e. “oats combined”, processed wheat and processed barley as submitted by industry (Annex A; 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/day and 0.010-0.017 µg/kg bw/day, 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/day and 0.039-0.052 µg/kg bw/day, respectively.

Acute exposure

59. For “oats combined”, i.e. unprocessed oats corrected using a reduction factor of 85 % and processed oats as submitted by industry (Annex A; 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 had similar exposures to infants.

60. For all processed grains, i.e. “oats combined”, processed wheat and processed barley as submitted by industry (Annex A; 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 foods

61. Limited occurrence data was submitted in response to the call for evidence, so consumer-based exposure estimates from RTE foods were only calculated for specific population groups that may have high relative intakes of oat products, i.e. infants (4-18 months), toddlers (1.5-3 years), adults (19-64 years), and adult vegetarians/vegans (19-64 years).

62. Mean and 97.5th percentile exposures were calculated 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 A; Tables 11-16). Very few datapoints for either T-2 or HT-2, and even fewer on the sum of T-2 and HT-2, were available for RTE foods. Exposures to T-2 or HT-2 (separately) were therefore included in this assessment in order to extract as much information as possible from the data submitted by industry.

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

63. The only RTE food category for which occurrence data for the sum of T-2 and HT-2 were available was infants’ cereals, so the only population groups for which exposure via this food category was considered was infants and toddlers (Annex A; 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/day (mean-max concentration), and 1.5-2.9 µg/kg bw/day (mean-max concentration), respectively.

- In toddlers (1.5-3 years), mean and 97.5th percentile chronic exposure estimates ranged from 0.22 µg/kg bw (mean) to 1.4 µg/kg bw/day (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

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

65. Chronic exposure estimates to T-2 only (Annex A; 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/day (mean-max concentration), and 0.001-0.0015 µg/kg bw/day (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/day (mean-max concentration), and 0.17-0.51 µg/kg bw/day (mean-max concentration), respectively.

66. Acute exposure estimates to T-2 only (Annex A; 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.

67. Chronic exposure estimates to HT-2 only (Annex A; 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/day (mean-max concentration), and

0.002-0.002 µg/kg bw/day (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/day (mean-max concentration), and 2.9-2.9 µg/kg bw/day (mean-max concentration), respectively.

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

- The lowest acute exposure estimates to HT-2 from RTE foods was from puffs/curls 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.