Annex A to TOX/2025/26 - First draft statement on the risk for T-2 and HT-2 mycotoxins in food

Exposure Assessment

In this guide

In this guide

- 1. Background Annex A to TOX/2025/26
- 2. Introduction Annex A to TOX/2025/26
- 3. Toxicity Annex A to TOX/2025/26
- 4. HBGVs Annex A to TOX/2025/26
- 5. Exposure Assessment Annex A to TOX/2025/26
- 6. <u>Risk characterisation Annex A to TOX/2025/26</u>
- 7. Uncertainties and assumptions Annex A to TOX/2025/26
- 8. Conclusions Annex A to TOX/2025/26
- 9. Abbreviations Annex A to TOX/2025/26
- 10. References Annex A to TOX/2025/26

This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

41. Exposures of 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

42. Exposure assessments were conducted on a survey population basis using food 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 (μ g/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, ii) all grains (oats, wheat, and barley), and iii) RTE foods.

43. 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).

44. 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 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:

a) unprocessed wheat grains,

b) processed wheat grains,

c) unprocessed barley grains; and,

d) processed barley grains.

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

46. 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.

Results

47. While exposures from unprocessed oats only were very high, these exposure estimates are unlikely to reflect a real-life scenario. The very limited data from processed oats, as submitted by industry, showed significantly lower levels of T-2 and HT-2 than in unprocessed oats. Applying a reduction factor (85%) to unprocessed oats (which constituted the majority of the data received from industry) significantly reduced the levels, and levels after application were similar to those from industry for processed oats. While this supported the use of the reduction factor of 85%, it also supported combined oats (unprocessed oats plus reduction factor, and processed oats) as the most realistic exposure scenarios, for oats, besides RTE foods.

48. No reduction factors for unprocessed wheat or barley could be applied, 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 available showed that the overall exposure from grains, here, was driven primarily by exposures from oats.

49. 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 the previous discussion paper (TOX/2025/14). 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).

50. Exposures from i) all processed cereal grains (oats combined, wheat and barley) and ii) oats combined (only) were estimated for the following population groups: 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 (19-64 year-olds), and women of childbearing age (16-49 year-olds).

Oats combined and all processed grains

Chronic exposure

51. Across all population groups evaluated, the lowest chronic exposures for all processed cereal grains (oats combined, wheat and barley) occurred in older children (11-18 years), with mean and 97.5th percentile exposures of 0.0015-0.0039 μ g/kg bw and 0.010-0.017 μ g/kg bw, respectively while the highest chronic exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.0063-0.010 μ g/kg bw and 0.039-0.052 μ g/kg bw, respectively.

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

Acute exposure

53. For all processed cereal grains (oats combined, wheat and barley), the lowest acute exposures were in women of childbearing age (16-49 years) with mean and 97.5th percentile exposures of 0.0033-0.0082 μ g/kg bw and 0.020-0.034 μ g/kg bw, respectively, while the highest acute exposures were in infants (4-18 months) with mean and 97.5th percentile exposures of 0.014-0.021 μ g/kg bw and 0.078-0.10 μ g/kg bw, respectively.

54. For oats combined, the lowest acute exposures were in women of childbearing age (16-49 years) with mean and 97.5th percentile exposures of 0.0033-0.0043 μ g/kg bw (LB-UB) and 0.020-0.026 μ g/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 μ g/kg bw (LB-UB) and 0.078-0.10 μ g/kg bw (LB-UB), respectively. Toddlers have similar exposures to infants.

Exposure from ready to eat (RTE) foods

55. Consumer-based exposure estimates from RTE foods were generated for the following population groups: infants (4-18 months), toddlers (1.5-3 years), adults (19-64 years), and adult vegetarians/vegans (19-64 years).

56. 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. Exposures to T-2 or HT-2 (separately) 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

57. Data for the sum of T-2 and HT-2 were only available for infants' cereals. In brief, 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 exposures were 0.36-0.71 μ g/kg bw (mean-max concentration), and 1.5-2.9 μ g/kg bw (mean-max concentration), respectively. Chronic exposure estimates in toddlers (1.5-3 years) ranged from 0.22 μ g/kg bw (mean) to 1.4 μ g/kg bw (97.5th percentile).

58. For acute exposure in infants, mean and 97.5th percentile estimates were 0.71-1.4 μ g/kg bw (mean-max concentration), and 2.6-5.2 μ g/kg bw (mean-max concentration), respectively. Acute exposure estimates in toddlers ranged from 0.52 μ g/kg bw (mean) to 2.6 μ g/kg bw (97.5th percentile).

T-2 or HT-2 exposure estimates (separately)

59. Where data on the sum of T-2 and HT-2 in RTE foods were too limited and did not meet the inclusion criteria, the data on individually reported levels of T-2 or HT-2 were used.

Chronic exposure estimates to T-2

60. The highest chronic exposure estimates to T-2 from RTE foods were from oat porridge in infants (4-18 months) with mean and 97.5th percentile exposures of 0.033-0.10 μ g/kg bw (mean-max concentration), and 0.17-0.51 μ g/kg bw (mean-max concentration), respectively. The lowest chronic exposure estimates to T-2 from RTE foods were from plain muesli in infants (4-18 months) with mean and 97.5th percentile exposures (of 0.00030-0.00043 μ g/kg bw; mean-max concentration, and 0.001-0.0015 μ g/kg bw; mean-max concentration, respectively).

Acute exposure estimates to T-2

61. The highest acute exposure estimates for T-2 from RTE foods were from oat porridge in toddlers (1.5-3 years), with mean and 97.5th percentile exposures of 0.11-0.34 μ g/kg bw (mean-max concentration), and 0.27-0.85 μ g/kg bw (mean-max concentration) respectively. The lowest acute exposure estimates to T-2 from RTE foods were from plain muesli in infants (4-18 months) with mean and

97.5th percentile exposures (of 0.00073-0.0011 μ g/kg bw; mean-max concentration, and 0.0025-0.0036 μ g/kg bw; mean-max concentration, respectively).

Chronic exposure estimates to HT-2

62. The highest chronic exposure estimates for HT-2 from RTE foods was from infants' cereals, in infants (4-18 months), with mean and 97.5th percentile exposures of 0.70-0.71 μ g/kg bw (mean-max concentration), and 2.9-2.9 μ g/kg bw (mean-max concentration), respectively. The second highest chronic exposure estimates for HT-2 from RTE foods were from oat porridge, in infants (4-18 months), with mean and 97.5th percentile exposures of 0.057-0.27 μ g/kg bw (mean-max concentration), and 0.28-1.4 μ g/kg bw (mean-max concentration), respectively.

Acute exposure estimates to HT-2

63. The highest acute exposure estimates to HT-2 from RTE foods was from infants' cereals, in infants (4-18 months), with mean and 97.5th percentile exposures of 1.4-1.4 μ g/kg bw (mean-max concentration), and 5.2-5.2 μ g/kg bw (mean-max concentration), respectively. The second highest chronic exposure estimates for HT-2 from RTE foods were from oat porridge, in infants (4-18 months), with mean and 97.5th percentile exposures of 0.13-0.61 μ g/kg bw (mean-max concentration), and 0.46-2.2 μ g/kg bw (mean-max concentration), respectively.