Risk characterisation

In this guide

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64. 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 continue to apply the HBGVs established by EFSA: a group ARfD of 0.3 µg/kg bw for T-2, HT-2 and NEO and a group TDI of 0.02 µg/kg bw for T-2, HT-2 and NEO.

65. Following the EU’s decision to establish maximum levels for T-2 and HT-2 in specific foods, the COT was asked by the FSA and FSS to provide an assessment to determine the risk to human health in the UK from T-2 and HT-2 exposure from grains and grain products. To assist with the assessment the FSA and FSS undertook a call for evidence in 2024. NEO was not included in the call for evidence and has not been further considered here.

66. The statement provides an updated exposure assessment for UK consumers, following the call for evidence, data cleanup and the application of a

reduction factor for unprocessed oat grains, to provide a more relevant exposure of UK consumers from oat grains, barley grains and wheat grains. The estimated exposures were compared to their respective HBGVs to assess acute and chronic health risks of UK consumers. The limited data on RTE foods were also included in the assessment.

67. 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 plus the limited data on processed oats industry submitted. 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.

Oats combined and all processed grains

68. All chronic exposure estimates for oats combined were below the TDI of 0.02 µg/ kg bw/ day, with a few exceptions: high (97.5^{th} percentile) exposure estimates for infants and toddlers (exceedance 2- to 3-fold; LB-UB), children aged 4-10 years (exceedance 2-fold; UB), whilst high (97.5^{th} percentile) consumer vegetarians had exposures approximately equal to the TDI.

69. For all processed grains (i.e. oats combined, processed barley and processed wheat), mean exposures are below the TDI for all population groups assessed, indicating no health concern. However, 97.5^{th} percentile exposure estimates for infants, toddlers and adults (exceedances of up to 3-fold of TDI; UB), and the elderly (exceedance of up to 4-fold of the TDI; UB) are of potential toxicological concern, while 97.5^{th} percentile exposure estimates for children 4-10 years old and adult vegetarians (up to 2-fold; UB) are undesirable but unlikely to result in health concerns.

70. Acute exposure estimates for both oats combined, and all processed grains are below the ARfD across all population groups assessed, both at mean and high consumption, and are therefore not of toxicological concern.

Ready to Eat (RTE) foods

71. Data for the sum of T-2 and HT-2 in RTE foods were only available for infants' cereals. Hence, exposure estimates were only calculated for infants (4-18 months) and toddlers (1.5-3 years). All chronic exposures exceeded the TDI, the lowest exceedance was 11-fold (mean occurrence with mean consumption rate) in toddlers, while the highest exceedance was 145-fold (max occurrence with 97.5 th percentile consumption rate) in infants.

72. Chronic exposures to T-2 (only) were at the TDI in toddlers for high intakes (97.5th percentile) for wheat bread rolls, 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 2-fold (mean occurrence with 97.5th percentile consumption rate) to 8-fold (max occurrence with 97.5th percentile consumption rate) in adults and vegetarians, and 2-fold (mean occurrence with mean consumption rate) to 26-fold (max occurrence with 97.5th percentile consumption rate) in infants and toddlers.

73. Chronic exposures (97.5th percentile) to HT-2 (only) 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 2-fold (mean occurrence with 97.5th percentile consumption rate) to 22-fold in adults and vegetarians (max occurrence with 97.5th percentile consumption rate), and 3-fold (mean occurrence with mean consumption rate) to 70-fold (max occurrence with 97.5th percentile consumption rate) in infants and toddlers.

74. Chronic exposures from RTE foods suggest a 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. In addition, exposure estimates also depend on whether they were calculated using the sum of T-2 and HT-2 or individual mycotoxins. 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. The large exceedances of the TDI that have been derived from RTE foods (22-, 26-, and 70-fold) only occur when using the maximum occurrence with the 97.5th percentile consumption rate. It is unlikely, that individuals would be exposed to foods at these levels continuously throughout their life, given the seasonable variability in T-2 and HT-2 occurrence levels. The mean occurrence level combined with the mean consumption rate may therefore be more appropriate for assessing a realistic chronic exposure; these exposure estimates are much

lower, indicating a lower risk.

75. Acute exposures to the sum of T-2 and HT-2 from RTE foods exceeded the ARfD, ranging from 2-fold (mean occurrence with mean consumption rate) to 17-fold (max occurrence with 97.5th percentile consumption rate) in infants, and 2-fold (mean occurrence with mean consumption rate) to 9-fold (max occurrence with 97.5th percentile consumption rate) in toddlers. Data were only available for infants' cereals, hence only these two age groups have been considered.

76. Acute exposures to T-2 (only) from RTE foods were all below the ARfD, except for oat porridge in infants and toddlers with exceedances of up to 3-fold the ARfD (max occurrence with 97.5th percentile consumption rate). For HT-2 (only), 97.5th percentile adult consumers (max occurrence) had exposures equal to the ARfD, whilst exposures of vegetarians exceeded the ARfD 3-fold (maximum occurrence with 97.5th percentile consumption rate). For HT-2 (only), infants and toddlers exceeded the ARfD by 2-fold (mean occurrence with 97.5th percentile consumption rate) to -7-fold (max occurrence with 97.5th percentile consumption rate) from oat porridge, whilst exceedances ranging from 3-fold (mean occurrence with mean consumption rate) to 17-fold (max occurrence with 97.5th percentile consumption rate) of the ARfD occurred from infants' cereals.

77. 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.

78. Comparing the exposure estimates from grains and RTE foods, RTE foods result in higher exposures to T-2 and HT-2, compared to processed oats or even unprocessed oats. However, given the small data set for RTE foods, the use of individual mycotoxins and mean and maximum occurrence levels adds significant uncertainty to these exposures. This stresses the need for a sufficiently large dataset to provide a reliable exposure assessment from RTE foods. The COT highlighted that the dataset for RTE foods here might not accurately reflect general exposure levels due to the limited number of data points and potential bias from targeted sampling where, for example, contamination was known or suspected.