

Risk characterisation

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69. Trichothecenes such as T-2 and HT-2 can cause chronic and acute adverse effects, haematotoxicity and emesis being the critical effects, respectively. After considering the scientific evidence underpinning the EFSA and JECFA assessments, the COT agreed in 2023 to continue applying the HBGVs established by EFSA in any future assessments, 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.

70. This statement provides an updated risk assessment on T-2 and HT-2 mycotoxins only, including an exposure assessment for UK consumers following the FSA and FSS call for evidence. It should be noted that the data received for processed wheat and barley were limited and exposures are dominated by oat data. Processed oat grains in this assessment were “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; while this was supported by the limited data submitted by industry for processed oat grains, it could vary, potentially leading to an underestimation of risk, especially in instances where T-2 and HT-2 occurred in 'hot spots'. Hot spots refer to specific geographic areas or locations where the levels of T-2 and HT-2 toxins in cereal grains are significantly higher than average.

71. All estimates of mean chronic exposure to the sum of T-2 and HT-2 from "oats combined" (Annex A; Table 9) and all processed grains (Annex A; Table 9) were below the TDI of 0.02 µg/ kg bw/day and were therefore not of toxicological concern. While the majority of 97.5th percentile chronic exposure estimates for "oats combined" and all processed grains were also not of toxicological concern, exposures in infants and toddlers ("oats combined") and infants, toddlers, adults, and older adults (all processed grains) exceeded the TDI up to 4-fold. A toxicological concern cannot, therefore, be excluded. Exposures in vegetarians/vegans ("oats combined"; all processed grains) and older children (4-10 years; all processed grains) were at or close to the TDI but were unlikely to result in health concerns.

72. Acute exposure estimates for "oats combined" and for all processed grains were below the ARfD across all population groups assessed, both at mean and high consumption, and are therefore not of toxicological concern (Annex A; table 10).

73. Results on grains from this assessment were in line with the COT's assessment 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 97.5th percentile chronic exposures, the EFSA group TDI was exceeded in infants and young children aged 4-60 months. Hence, the COT concluded in 2018 that an effect on infant and toddler health could not be entirely excluded.

74. Chronic exposures from RTE foods (Annex A; Tables 13-15) suggest a potential concern for consumer health, especially in infants and toddlers, and for some foods in adults and vegetarians/vegans, mainly oat porridge. Estimated chronic exposures to the sum of T-2 and HT-2, which was only available for 'infant cereals', exceeded the TDI 11-fold (toddlers) and 145-fold (infants) (Annex A; Table 11). Chronic estimated exposures for 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. Estimated exposures from oat porridge exceeded the TDI in all age groups and exposure scenarios, ranging

from 2- to 8-fold in adults and vegetarians/vegans, and 2-fold to 26-fold in infants and toddlers, respectively. Chronic exposure estimates to HT-2 only exceeded the TDI in most RTE foods for infants and toddlers with exceedances ranging from 3- to 70-fold, respectively, and plain muesli and oat porridge in adults and vegetarians/vegans (exceedance 2- to 22-fold, respectively).

75. When considering the exceedances from RTE foods and the potential concerns for human health it is important to note that the submitted data on RTE foods was very limited; on average, sample numbers were 5, and even in the case of oat porridge the number of samples analysed was 25. Furthermore, exposure estimates were calculated either on the sum of T-2 and HT-2 or in most instances on individual mycotoxins only. Hence, while the estimated exposures calculated from RTE foods may be an indication of potential foods of concern, they are subject to a high degree of uncertainty. In addition, the large exceedances of the TDI that have been derived from RTE foods (22-, 26-, and 70-fold) were based on the maximum occurrence when the 97.5th percentile consumption rate was applied (Annex A; Tables 13 and 15). It is unlikely that high consuming individuals would be exposed to foods at the highest occurrence levels continuously throughout their life, given the known seasonal variability of T-2 and HT-2 occurrence levels and differences in consumption between life stages and across the year. The mean occurrence level combined with the mean consumption rate may therefore provide a more appropriate indication of realistic chronic exposure; exposures estimated in this manner were much lower, indicating a lower risk.

76. Acute exposures to the sum of T-2 and HT-2 from RTE foods ('infant cereals') exceeded the ARfD 2-fold to 17-fold in infants and 2-fold to 9-fold in toddlers (Annex A; Table 12). 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 of the ARfD (Annex A; Table 14). For HT-2 (only), in infants and toddlers, exposures exceeded the ARfD by 2-fold to 7-fold from oat porridge, and by 3-fold to 17-fold from infants' cereals (Annex A; Table 16). Exceedances at this level in infants and toddlers might be of concern due to their lower bodyweight and consequent susceptibility to lower absolute exposures. The sample number for oat porridge was, however, small (25) and the levels reported may not be representative, especially given that no information was provided regarding sampling strategies; it is unclear whether random samples were analysed or whether sampling had occurred after a known incident or suspected contamination.

77. For HT-2 (only), high level (97.5th percentile) adult consumers had exposures equal to the ARfD, whilst exposures in vegetarians/vegans exceeded the ARfD 3-fold from oat porridge. While exceedances of the ARfD for adults, especially vegetarians/vegans, were of potential toxicological concern, it is unlikely that this level of exceedance would result in a significant concern for health.

78. Exposure estimates from grains and RTE foods indicated that RTE foods result in higher exposures to T-2 and HT-2 compared to either processed or unprocessed oats. However, exposures to processed grains were calculated on a commodity basis 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 using mean and maximum occurrence levels. RTE foods provided a very limited snapshot of exposures to final food products and direct comparison to exposures from grains was therefore not possible. The analytical method used may further add to uncertainty in estimating exposures from RTE foods. Use of the LOQ as the occurrence level to estimate exposures where a low level/non-detect was determined to be below the LOQ will, especially where methods are relatively insensitive and have high LOQs, result in relatively high “occurrence levels”. Using the mean and maximum for individual mycotoxins, rather than the sum of T-2 and HT-2, added further uncertainties.

79. Year-to-year variability in the occurrence of T-2 and HT-2 in cereal grains (Figures 2a-c) can lead to occasional high acute exposures, particularly during “bad years” or in localised hot spots. In contrast, chronic 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. These, therefore, were the most representative estimates of chronic exposure.