

Conclusions

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93. Following discussions by the COT the exposure assessment for T-2 and HT-2, following an FSA/FSS call for evidence, has been refined, and a reduction factor has been applied to unprocessed oat grains, i.e. oat grains that have not yet been cleaned/dehulled. The application of a reduction factor (85%) has significantly reduced the acute and chronic exposures to T-2 and HT-2. While the reduction factor was selected from the literature it is supported by exposures based on the limited data on processed grains submitted by industry.

94. Chronic exposures of unprocessed oat grains in infants and toddlers exceed the TDI by up to 15-fold and in children up to 4-fold. After application of the reduction factor, exposures for infants and toddlers continue to exceed the TDI but to a lesser extent (up to 3-fold). While infant and toddlers and to a lesser extent children and vegetarians exceeded the ARfD of 0.3 µg/kg bw for unprocessed oat grains and the sum of all unprocessed grains (oat, barley,

wheat), application of the reduction factor (85%) resulted in all acute exposures being below the ARfD. It is implausible that individuals would consume unprocessed grains, this is a worst-case and unlikely to be a real-life exposure scenario.

95. Overall, chronic exposures to oats combined and the sum of all processed grains (oat, wheat, barley) were of toxicological concern in infants, toddlers and the elderly, while exposures in children and vegetarians were undesirable but unlikely to result in serious health concerns. Acute exposures were not of toxicological concern.

96. This is in line with the COT's conclusion 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 chronic exposures the EFSA group TDI was exceeded. Hence, an effect on health could not be entirely excluded.

97. T-2 and HT-2 occurrence is significantly influenced by climate and levels can vary significantly from year to year, as indicated in Figures 1,3 and 5. Year to year variability may mean that individuals could be exposed to high levels of T-2 and HT-2 in one year compared to other years. While this may potentially affect acute exposures due to hot spots or a particularly bad year leading to occasional high exposures, 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. Therefore, these were the most representative estimates of chronic exposure.

98. Chronic exposures from RTE foods suggest a significant concern to consumer health, especially in infants and toddlers, however also for some foods in adults and vegetarians, mainly oat porridge. While acute exposures in adults, especially vegetarians were undesirable, exceedances of the ARfD for infants and toddlers are of potential concern, if they were to occur at the levels reported. However, the estimated exposures based on RTE foods were based on very limited data and are subject to a high degree of uncertainty. In addition, samples on T-2 and HT-2 were only available for infant foods, for all other foods samples were available for either T-2 (only) or HT-2 (only).

99. The exposures from RTE foods are furthermore of significantly higher concern than exposures from processed oat grains or all processed grains (oat, wheat, barley). It is unclear why this is the case, especially given that grains

incorporated into RTE foods would have undergone further processing. Year-to-year variability may have played a role, however, it was difficult to link the submitted data on RTE foods to an identifiably bad year for T-2 and HT-2 levels. Some of the reported RTE foods, especially oat grains were from 2013 and 2014, reportedly years with high mycotoxin levels, while other RTE foods were from 2022-2024, years with overall lower occurrence data on T-2 and HT-2.

100. Exposures to processed grains were based on a commodity approach and calculated 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 and mean and maximum occurrence level. RTE foods only provide a very limited snapshot of exposures to final food products and direct comparison to exposures from all grains was therefore not possible. The analytical method used may further add to the uncertainties in the exposures from RTE foods, where a low level/non-detect was determined to be at the LOQ, the LOQ was used as the level to estimate exposures. As some methods may not have been sensitive enough this would have resulted in relatively high “occurrence levels”.

101. Overall, based on the occurrence data provided via the call for evidence for processed grains (oat, barley and wheat) and the limited number of RTE foods, a health concern arising from chronic exposures, especially for infants and toddlers cannot be excluded. However, given all the uncertainties, the estimated exposures for RTE foods may not be reliable and not representative of RTE foods.