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

## **Uncertainties and assumptions**

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79. The risk assessment for T-2 and HT-2 in food included a number of assumptions and uncertainties, which relate to the preparation of the occurrence data, the calculation of the consumption data and exposure assessment, as well as the risk assessment itself. These uncertainties are listed below in further detail.

80. Uncertainties associated with the preparation of the occurrence data:

a. When an LOD was not reported these data were included assuming all other acceptance criteria were met.

b. When a result value was not reported it was assumed to be equal to the LOQ (when LOQ > 0).

c. When a sample code description was not reported, the code was researched, and the description was filled in. Any changes to the codes over the years that

the data covered would not be captured.

d. Food codes were grouped in food groups for the purpose of the assessment on the basis of the FoodEx descriptions of the codes. When in doubt assumptions were made as to which group the codes fitted best.

e. In the UK and Ireland, it is common for grain to be delivered to the mill 'as harvested' i.e. uncleaned and unprocessed with the husk still intact. Where mycotoxin contamination is associated with the outer layers of the grain this may exhibit higher levels of contamination. A large proportion of data submitted as part of the data call were from such unprocessed grains which therefore may exhibit higher levels of contamination compared to cleaned, processed grains. Thus, a reduction factor of 85% was applied to the sum of T-2 and HT-2 in unprocessed oat grains. It was assumed that this constitutes a realistic reduction, although different reduction factors have been reported in the literature, potentially over or underestimating the reduction and subsequent exposure.

f. No reduction factor was applied to unprocessed wheat and barley grains. The COT did not identify a scientifically robust reduction factor, however the occurrence data here for both unprocessed and processed forms also fell below LOQ. Hence the application of a reduction factor would not be expected to affect exposure estimates.

81. Uncertainties associated with the calculations of the consumption and exposure assessment estimates:

a. The description of food categories within the FoodEx food code system were not always aligned with the names given to similar foods in NDNS and DNSIYC. Therefore, some assumptions were made during the mapping of these foods to identify the closest match when searching the inhouse FSA recipes database for the most relevant food.

b. For the RTE food groups, in some cases, there are a limited number of consumers (60) as well as a limited number of samples. This may lead to unreliable exposure estimates. Consumer numbers less than 60 (60) should be treated with caution as they may not be true representation of the entire population.

c. Samples on sum of T-2 and HT-2 were only available for infant foods, for all other foods samples either T-2 (only) or HT-2 (only) were available.

d. For RTE food groups, there is uncertainty on whether concentrations were provided on a wet weight or dry weight basis, hence conversion factors were not applied while building the food groups. These include foods such as dried infant cereals and other dried food groups.

e. NDNS does not include pregnant or lactating women, therefore data for women of childbearing age (16-49 years) were used as a proxy and therefore may not be representative of the maternal diet.

f. The summation of exposures from individual grains, especially for acute exposures, is likely to overestimate actual exposure, particularly at the 97.5<sup>th</sup> percentile, as it is unlikely an individual would eat all grain foods in one single day, at that level.

82. Uncertainties associated with the risk assessment:

a. The exposure assessment only includes T-2 and HT-2 mycotoxins, however the group TDI and group ARfD established by EFSA also includes NEO. Uncertainty regarding the occurrence of NEO in cereal grains, as well as its exclusion from the exposure assessment might lead to an underestimation of total exposure and thus a possible underestimation of the corresponding health risk.

b. Exposure to T-2 and HT-2 were based on grains or products thereof only. Other potential sources of T-2 and HT-2, such as POAO were not considered.

c. For RTE foods T-2 or HT-2 only were compared to a HBGV based on the sum of both mycotoxins (plus NEO). While this may give an indication of exposure, it might not provide a realistic assessment may under-estimate the actual exposure.

d. T-2 and HT-2 occurrence in cereal grains is significantly influenced by climate and levels can vary significantly from year to year (as indicated in Figure 2). 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.