Risk characterisation

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73. 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 continued to be content with 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.

74. Following the EU's decision to establish maximum levels for T-2 and HT-2, the COT was asked by the FSA/FSS to perform an assessment to determine the risk to human health in the UK from T-2 and HT-2 exposure. To assist with the assessment the FSA/FSS undertook a call for evidence. NEO was not included in the call for evidence and has not been further considered here. The current paper provided an updated exposure assessment, following further data cleanup and the application of a reduction factor for oat grains, to attempt a more realistic exposure of UK consumers from oat grains, barley grains and wheat grains. The

estimated exposures were compared to their respective HBGVs to assess acute (Table 15) and chronic (Table 14) health risks of UK consumers.

Chronic exposure

75. The majority of the mean estimated chronic exposures for unprocessed oat grains (unprocessed/raw materials, which were yet to undergo any cleaning) were at or below the TDI, with infants and toddlers exceeding the TDI 2-fold. High consumption (97.5th percentile) resulted in exceedances ranging from 4-fold (older children) to 15/14-fold (infants/toddlers) the TDI. In comparison, exposures for unprocessed oat grains to which a reduction factor (85%) has been applied, to account for dehulling and processing of oat grains, the exposures were below the TDI, with a few exceptions, i.e. infants (2-3-fold), toddlers (2-3-fold) and children 1-2-fold), high consumer vegetarians were at the TDI. The same applied to oats combined, assessing risks for all oat grains submitted, processed oat grains and unprocessed oat grains with a reduction factor applied.

76. Consumption of the sum of all unprocessed grains (oat, barley, wheat) would result in (UB) exceedances of the TDI for mean and high consumers, across all age groups, with mean exposures for older children, adults and women of childbearing age being at the TDI. Considering exposures for processed grains, i.e. processed barley and wheat grains and oats combined (processed oat grains submitted by industry plus unprocessed oat grains to which a reduction factor has been applied) those exceedances are substantially reduced. Infants and toddlers, who had exceedances of 15- and 14-fold the TDI, respectively, under a more realistic exposure scenario are below the TDI for mean consumption and exceed the TDI only 2-3-fold for high consumption, reducing their overall risk substantially. Under the more realistic scenario of processed grains, the elderly would exceed the TDI up to 4-fold rather than 8-fold at the 97.5^{th} percentile, while children, vegetarians and women of childbearing age would be exceeding up to 2-fold or be at the TDI.

77. Oat grains are unlikely to be eaten unprocessed, hence the application of a reduction factor (85%) to unprocessed oats which has resulted in a more realistic exposure scenario. The resulting exposures are also in line with the small data set of processed oat grain submitted by industry. As with oat grains, wheat grains and barley grains are unlikely to be eaten unprocessed hence overall exposure to all processed grains was the more realistic exposure scenario for UK consumers. Oat grains were the major contributor to the sum of all three grains in this assessment.

78. While for the majority of age groups, especially for mean consumers, exposures to all grains are at or below the TDI, exposures for infants and toddlers, as well as the elderly continue to be of toxicological concern. Exceedances of up to 3-fold in adults and up to 2-fold in children and vegetarians are undesirable but unlikely to result in health concerns.

Table 14: Chronic risk to sum of T-2 and HT-2 from some cereal grains based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call, expressed as x-fold of estimated chronic exposure as a percentage of the TDI of 0.02 µg/kg bw/day.

	Infants (4-18 months) (n=2683)	**Infants (4-18 months) (n=2683)**	**Toddlers (1.5-3 years) (n=1157)**	**Toddlers (1.5-3 years) (n=1157)**	**Children (4-10 years) (n=2537)**	**Children (4-10 years) (n=2537)**	**Older Children (11-18 years) (n=2657)**
Food groups	Mean*	P97.5*	Mean *	P97.5*	Mean*	P97.5*	Mean*
Unprocessed oats	2	15	2	14	1	9	0.5
Unprocessed oats with reduction factor+	0.3-0.4	2-3	0.3-0.4	2-3	0.2-0.3	1-2	0.1
Oats combined++	0.3-0.4	2-3	0.3-0.4	2-3	0.2-0.3	1-2	0.1
All grains sum (unprocessed)	0-3	0-15	0-3	0-15	0-2	0-10	0-1

All grains sum (processed)	0.3-0.5	2-3	0.3-0.6	2-3	0.2-0.4	1-2	0.1-0.2

*Estimates have been rounded to 1 significant figure; except in cases where the exceedance was 1.

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%) applied.

If single value is shown, this indicates that the exposures were based on detected values above the LOQ or exceedances at the LB and UP value were the same.

'All grains sum' refers to oat grains, wheat grain, and barley grain.

Acute exposure

79. Acute mean and 97.5th percentile exposures of unprocessed oat grains (unprocessed/raw materials, which were yet to undergo any cleaning) were below the ARfD, with the exception of infants and toddler which exceeded the ARfD 2-fold, and children (97.5th percentile) which were at the ARfD. While below the ARfD, high consumption of unprocessed oats could lead to exposures close to the ARfD in vegetarians. Application of a reduction factor (85%) to unprocessed oat grains resulted in exposures being well below the ARfD in all age groups. The same applies to exposures to oats combined, not surprising as the oats combined groups is predominantly driven by unprocessed oats. However, the limited data on processed oat grains submitted by industry showed similar exposures as the exposures to unprocessed oat grains to which a reduction factor was applied, further supporting the selection of a reduction factor of 85%.

80. Mean and 97.5th percentile consumption estimates of the sum of all unprocessed grains (oat, barley, wheat) were below the ARfD, except for infants and toddlers with 2-fold exceedances, and high consumption (97.5th percentile) in children and vegetarians, which were at the ARfD. While consumption in the elderly (97.5th percentile) was below the ARfD, it was close to the ARfD. In contrast, exposures for the sum of all processed grains were below the ARfD.

81. Considering it is unlikely that individuals would consume unprocessed grains, the acute exposures here are not of concern. However, 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. 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.

Table 15: Acute risk to sum of T-2 and HT-2 from some cereal grains based on DNSYIC and NDNS years 1-11 consumption data and occurrence data collected from the FSA call, expressed as estimated x-fold of chronic exposure as a percentage of the ARfD of 0.3 µg/kg bw/day.

	Infants (4-18 months) (n=2683)	Infants (4-18 months) (n=2683)	Toddlers (1.5-3 years) (n=1157)	Toddlers (1.5-3 years) (n=1157)	Children (4-10 years) (n=2537)	Children (4-10 years) (n=2537)	Older Children (11-18 years) (n=2657)	Older Child (11-1 years (n=2
Food groups	Mean*	P97.5*	Mean *	P97.5*	Mean*	P97.5*	Mean*	P97.5
Unprocessed oats	0.3	2	0.3	2	0.2	1	0.1	0.5
Unprocessed oats with reduction factor	0-0.1	0.3	0-0.1	0.2-0.3	0	0.1-0.2	0	0.1
Oats combined***	0-0.1	0.3	0-0.1	0.2-0.3	0	0.2	0	0.1
All grains sum (unprocessed)	0-0.4	0-2	0-0.4	0-2	0-0.3	0-1	0-0.1	0-0.6

All grains sum (processed)	0.1	0.3	0-0.1	0.2-0.3	0.1	0.2	0	0.1

*Estimates have been rounded to 1 significant figure; except in cases where the exceedance is 1.

+ Oat grains with reduction factor - unprocessed oat grains with reduction factor (85%) applied.

++ Oats combined - combination of processed oat grains and unprocessed oat grains with reduction factor (85%) applied.

If single value was shown, this indicates that the exposures were based on detected values above the LOQ or exceedances at the LB and UP value were the same.

'All grains sum' refers to oat grains, wheat grain, and barley grain.

Ready to Eat (RTE) foods

Chronic

82. Data for the sum of T-2 and HT-2 in RTE foods were only available for infant cereals (Annex 1A). Hence, exposure estimates were only calculated for infants (4-18 months) and toddlers 1.5-3 years). All exposures exceeded the TDI, the lowest exceedance being 11-22-fold in toddlers for mean exposures (mean-max concentration) and the highest being at 75-145-fold (mean max concentration) at the 97.5th percentile in infants.

83. Chronic exposures to T-2 (only; Annex 2A) were at the TDI in infants and toddlers with high intakes (97.5th percentile) for biscuits (oatmeal), wheat bread rolls and dried pasta, 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 1.8-8-fold in adults and vegetarians, and 2-26-fold in infants and toddlers.

84. Chronic exposures (97.5th percentile) to HT-2 (only, Annex 2C) 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 3-22-fold in adults and

vegetarians and 3-70-fold in infants and toddlers.

85. 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. However, the submitted data on RTE foods is very limited; on average, sample numbers were 5, in the case of oat porridge 25. 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. It is furthermore unlikely, that individuals would consumer these foods at these levels throughout their life, every day.

Acute exposure

86. Exposures to the sum of T-2 and HT-2 from RTE foods exceeded the ARfD, ranging from 2-17-fold in infants and 2-9-fold in toddlers; data were only available for infant cereals, hence only these two age groups have been considered (Annex 1B).

87. Exposures to T-2 (only; Annex 2B) and HT-2 (only; Annex 2D) from RTE foods were all below the ARfD, with the exception of oat porridge in infants and toddlers, exceedances of the ARfD ranged from 2-7-fold. For HT-2 (only) adults were at the TDI at the 97.5th percentile (max occurrence), while vegetarians exceeded the ARfD 3-fold.

88. 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.