COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Statement of T2-toxin (T2), HT2-toxin (HT2) and neosolaniol (NEO) in the diet of infants aged 0 to 12 months and children aged 1 to 5 years: Lay summary

1. T2 and HT2 toxins are type A trichothecene fungal toxins and are produced by a variety of *Fusarium* and other fungal species. *Fusarium* species grow and invade crops and produce T2 and HT2 under cool, moist conditions prior to harvest. T2 and HT2 are found predominantly in cereal grains (particularly oats) and their products. NEO is a hydrolytic phase I metabolite of T2 and may be formed in fungi and mammals. NEO has been found in some brewed coffee samples, in a sample of cereal-containing baby food and at trace level in some barley field malt samples.

2. T2 and HT2 have been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2001, the Scientific Committee on Food (SCF) in 2002 and the European Food Safety Authority (EFSA) in 2011 and 2017. NEO was included in the EFSA 2017 evaluation of T2 and HT2.

3. There is very little information on the *in vivo* absorption of T2 and HT2 in animals after oral administration. T2 is rapidly absorbed after direct administration into the small intestine and is extensively hydrolysed to HT2 and other metabolites. It is rapidly distributed to the liver, kidney and other organs without accumulation. Excretion is also rapid. The metabolism of T2 and HT2 in humans and other species is complex and a number of phase I and phase II metabolites are produced. No data have been identified for the toxicokinetics of NEO.

4. Several acute and subacute toxicity studies had been published since the European Food Safety Authority (EFSA) 2011 evaluation, focussing predominantly on the anorectic effects of T2 and HT2 at low doses (mink, pig and mouse). Subchronic toxicity studies published since 2011 had investigated similar endpoints to those used by EFSA in its 2011 evaluation for establishing a health-based guidance value (HBGV). They tended to be of longer duration than the pig studies used but confirmed the immunotoxicity and haematotoxicity of T2 and HT2.

5. Prior to 2017, chronic HBGVs had been established for T2 and HT2 by JECFA, SCF and EFSA. In their 2017 Opinion, EFSA established a group acute reference dose (ARfD) of 0.3 µg/kg bw for T2, HT2 and NEO and a group TDI of 0.02 µg/kg bw for T2 (x1), HT2 (x1) and NEO (x0.3) [values in parentheses are correction factors for potency].

6. As levels of NEO were below the LOD in all samples of wheat, maize, oat and rye-based products analysed in two UK surveys, no exposure assessment was performed for this metabolite.

7. Acute and chronic exposures were calculated for the sum of T2 and HT2 using occurrence data from a retail survey of oat-based products commissioned by the FSA in 2015 and consumption data from NDNS and DNSIYC. Exposures in 0 to 4-month old infants are negligible as infants in this age range are unlikely to consume solid foods, including oat based products. Mean and 97.5th percentile acute exposures ranged from 0.022 – 0.032 and 0.056 – 0.11 µg/kg bw, respectively. These were all below the ARfD of 0.3 µg/kg bw and are therefore not of toxicological concern.

8. Mean and 97.5th percentile chronic exposures were calculated and ranged from 0.0099 – 0.014 and 0.029 – 0.063 µg/kg bw/day, respectively. All the mean exposures were below the TDI of 0.02 µg/kg bw and were therefore not of toxicological concern. The chronic 97.5th percentile exposures ranged from 145 – 315% of the EFSA TDI. Whilst an effect on health cannot be entirely excluded it is doubtful that children would be regularly exposed to these levels, which were measured in a year in which levels of T2/HT2 in oat grains were particularly high, over a prolonged period. In most years, levels of T2 and HT2 will be much lower than those observed in this harvest. It is therefore unlikely that dietary exposure levels of T2, HT2 or NEO would be of any toxicological concern in infants and young children.

The full COT statement can be found at:
https://cot.food.gov.uk/sites/default/files/cotstatement-t2ht2andneosolaniol.pdf

Lay Summary to COT Statement 2018/07