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

Overarching Statement on consumption of plant-based drinks in children aged 6 months to 5 years of age: Lay summary

Introduction

1. The Department of Health and Social Care (DHSC), Public Health England (PHE) and the Food Standards Agency (FSA) are receiving an increasing number of enquiries regarding the use of plant-based drinks in the diets of infants and young children. Therefore, the COT was asked to consider the potential risks posed by soya, almond and oat drinks consumed in the diets of these age groups.

2. The UK government advises that first infant formula (which is usually based on cows' milk) is the only suitable alternative to breast milk in the first 12 months of a baby's life. Whole cows' milk can be given as a main drink from the age of 1 year. From this age, unsweetened calcium-fortified plant-based drinks, such as soya, almond and oat drinks can also be given to children, as part of a healthy, balanced diet.

3. The main challenge in the assessment of the safety of these drinks is the lack of information regarding dietary intakes for infants and young children following dairy-free or plant-based diets.

4. Organisations providing recommendations for ensuring a balanced diet for vegan children under 5 were used to identify appropriate portion sizes and consumption frequency to develop representative intake scenarios for children following dairy-free or plant-based diets. These were then used to calculate daily intake figures for different age groups in order to calculate exposure to the chemicals of concern in the different drinks.

5. Although the exposure estimates made the best use of the available data, there was a high degree of uncertainty with regards to actual intakes. This was because these figures were based on recommendations to ensure that dietary requirements for infants and children of these ages were met. Actual intakes may be different.

6. The Committee agreed to use the previously-adopted approach of assuming that a child's consumption was exclusively of a single plant-based drink as it is

possible that young children may develop a preference for one drink. This was regarded as the most cautious approach because it assumes the highest intakes.

7. The need for real-world consumption information for people following plant-based diets in all age groups was highlighted by the Committee, as the popularity of these diets is increasing and information on realistic dietary intakes would help inform future risk assessments.

Soya

8. Soya drinks are a popular alternative to dairy products and their use is becoming more widespread. Soya products contain phytoestrogens (in the form of isoflavones). Concerns about adverse effects from isoflavones in the diet of infants and young children relate principally to their ability to mimic the female hormone, oestrogen, and therefore their potential impact on development and reproduction.

9. The safety of phytoestrogens was considered by the COT in 2003 and 2013. In 2003, the Scientific Advisory Committee on Nutrition (SACN) considered the COT outputs and concluded that there was no scientific basis for changing the current government advice – namely, that there is no substantive medical need for, nor health benefit arising from the use of soya-based infant formula, and that it should be used only in exceptional circumstances to ensure adequate nutrition, such as for babies who have cows' milk allergy. In 2013 this was reconfirmed by the COT. Currently, soya formula should be used only if it has been recommended or prescribed by a health visitor or GP.

10. For this evaluation, the Committee reviewed data published since the 2013 evaluation. The Committee concluded that new animal studies did not add significantly to the overall database.

11. As with previous evaluations, although there was some indication of possible adverse effects in human studies, it was not possible to determine from the available data, whether sensitivity to phytoestrogens varies among different age groups.

12. The Committee concluded that the intakes of phytoestrogens from consumption of soya drinks in children aged 6 months to five years was no greater than the estimated maximum intake by infants aged 0 – 6 months consuming soya formula where medically necessary (see paragraph 9 above). This maximum level of phytoestrogen intake was estimated to be 9.5 mg/kg bw per day.

13. The Committee agreed that, based on the available information, exposure to phytoestrogens from other soya-based products in the diets of children aged 6 months to 5 years of age was lower than that from soya drinks, and therefore of less concern. It was, however, noted that when exposure to phytoestrogens from all sources of soya in the diet was considered, the exposure came much closer to the maximum level of 9.5 mg/kg bw per day.

14. Members agreed that, in addition to potential toxicological concerns, consideration of nutritional issues would also be required to assess whether it was necessary to issue additional advice on the consumption of soya-based drinks in children aged 6 months to 5 years of age.

Oats

15. Oat drinks can be given to children following plant based or dairy- free diets, as an alternative to cows' milk. Oats can be contaminated with mycotoxins, notably the trichothecene mycotoxins T-2 and HT-2, deoxynivalenol (DON), and Ochratoxin A (OTA). Mycotoxins are naturally occurring toxins produced by certain moulds. As such, they are unavoidable contaminants in certain foods, like oats. International standards are in place to limit exposures to mycotoxins to the lowest possible levels. The COT evaluated the available data and considered the estimated exposures to the above contaminants.

T2 and HT-2

16. The European Food Safety Authority (EFSA) considered the safety of T-2 and HT-2 in 2017. Health-based guidance values were established for emetic effects (causing vomiting) following acute (short term or single) exposure, and for immune- and hepatotoxicity effects (toxic effects on the liver) following long-term exposure. After reviewing UK intake data, COT concluded that in terms of acute exposure to the sum of HT-2 and T-2, consumption of a large quantity of oat drink (minimum of 5.4L/ day) was required to exceed the Acute Reference Doses (ARfD). Thus, acute exposure to HT-2 & T-2 from the consumption of oat drink was considered to be of low risk.

17. Generally, all long term exposures for T-2, HT-2 were below the respective TDI, with the exception of minor exceedances observed in children aged 1-2 years old for T-2 and HT-2. The assessment of total exposure from oat drinks combined with the general diet was considered conservative (i.e. high compared with likely reality) and as the exceedances were minor and transient in nature, it was concluded that there would be no chronic health effects in respect to T-2 and HT-2.

DON

18. For DON, a group Tolerable Daily Intake (TDI) was established for the sum of DON, and its related compounds, 3-Ac-DON, 15-Ac-DON and DON-3-glucoside based on animal studies in which body weight gain was reduced. Vomiting was identified as the critical effect following acute exposure in humans.

19. COT concluded that in terms of acute exposure to DON, consumption of a large quantity of oat drink (minimum 28L/d) was required to exceed the Acute Reference Dose (ARfD). Thus, acute exposure to DON was considered to be of low risk.

20. Generally, all long term exposures for T-2 and HT-2 were below the TDI, with the exception of minor exceedances observed in children aged 1-5 years old. The assessment of total exposure from oat drinks combined with that from the general diet was considered conservative and as the exceedances were minor and transient in nature, it was concluded that there would be no chronic health effects in respect to DON.

OTA

21. For OTA, EFSA in 2020 established a Margin of Exposure (MOE) approach for neoplastic and non- neoplastic effects (kidney tumours and microscopic kidney lesions, respectively) to assess the risk posed by OTA. The MOE is a measure that is used to determine the level of exposure at which there starts to be a safety concern. For genotoxic carcinogens, MOEs ≥10, 000 indicate low concern. For other effects, an MOE ≥100 indicates low concern. It is not clear whether OTA can cause kidney tumours by directly interacting with the DNA (genotoxic carcinogen), or via a different mechanism.

22. It was noted that there were many uncertainties in the cancer endpoint used for risk characterisation, and furthermore, it was unclear whether or not OTA was a genotoxic carcinogen and thus which MOE threshold value would be applicable. The Committee noted that the MOE of ≥10,000 for substances that are directly genotoxic and carcinogenic may not be appropriate in this case because there is some evidence that OTA does not interact directly with DNA. Some age groups had MOEs lower than desirable for non-neoplastic changes while all age groups had MOEs lower than 10,000 for cancer effects. The uncertainty in the assessment was considered to be high, especially considering the lack of analytical information on the presence of these contaminants in oat drinks and the assumptions used in the exposure assessment. It was noted that it is likely that the risk was being overestimated.

23. In respect of OTA, the Committee was unable to conclude whether the exposure estimates indicated a potential health concern. It was agreed that assessments of actual exposure are needed for adults as well as young children, to establish whether there were potential health concerns for the general population.

24. Overall it was concluded that for the sum of DON and T-2 and HT-2, based on the available data there was no risk to health. However due to the uncertainties in the available dataset, the risk from exposure to OTA could not be determined.

Almonds

25. Almond drinks have a lower nutritional value than soya or oat drinks, however they can be given to children as an alternative to cows' milk. The mycotoxin, aflatoxin B1 was identified as a possible chemical contaminant in almonds, which could be potentially transferred to almond drinks. Aflatoxin B1 is a genotoxic carcinogen, so the EU sets a legal limit for the amount of aflatoxin which can be present; this is called the maximum level and uses the 'as low as reasonably achievable' (ALARA) principle. This is to ensure that exposure to such compounds is at the lowest possible level. As no more reliable data on aflatoxin levels were available, it was assumed that the almonds contained aflatoxin at the legal maximum level.

26. The lack of analytical information on the effect that processing of almonds during almond drink manufacture has on the levels of aflatoxins, as well as the lack of information on the levels in almond drinks themselves, was considered the main limitation in assessing the risk to health. Considering the above limitations, it was concluded that undertaking a risk assessment based on the Maximum Levels set by EFSA was highly uncertain and was likely to lead to an overestimation of risk and therefore was not appropriate. The risk to health from exposure to AFB1 could not be determined.

27. Almonds also contain cyanogenic glycosides, which can be released when the almond is physically broken down by chewing or processing. When this happens, they may interact with the enzyme ß-glucosidase, also present in almonds. This enzyme breaks down the cyanogenic glycosides and can yield hydrogen cyanide. Exposure to large amounts of hydrogen cyanide can lead to convulsions, loss of consciousness, dizziness, weakness, mental confusion and heart failure.

28. High levels of glycosides are present in bitter almond varieties, whereas there is very little present in sweet varieties. The quantity of cyanogenic glycosides present in almond drinks is uncertain, but only low levels of cyanide have been detected on analysis. Available information indicates that bitter almond varieties are not grown in commercial almond orchards and although the inadvertent use of bitter almonds in almond milk drinks cannot be completely ruled out, bitter almonds would not be deliberately used as they would be unpalatable, imparting a strong 'marzipan' flavour to the drink. Overall, Members agreed that there were no specific concerns for acute toxicity from cyanogenic compounds in almond drinks.