Meeting

Minutes for item 9 - these were previously reserved

Item 9: Discussion paper on vitamin D exposure levels in formula fed infants (reserved) (TOX/2021/62)

1. No interests were declared.

2. In 2006, the European Commission established a minimum vitamin D content for infant- and follow-on formulae of 1 µg per 100 kcal. Subsequently in 2016, this was doubled to 2 µg per 100 kcal. This regulation became applicable in Great Britain as from 1 January 2021. EU legislation on nutrition continues to be directly applicable in Northern Ireland.

3. In the UK, it is currently advised via the NHS that:

- babies from birth to 1 year of age who are being breastfed should be given a daily supplement containing 8.5 to 10 µg of vitamin D (regardless of whether the mother is taking a vitamin D supplement);
- babies should not be given a vitamin D supplement if they are receiving more than 500 ml of infant formula per day, because infant formula is fortified with vitamin D and other nutrients; and
- children aged 1 to 4 years old should be given a daily supplement of 10 µg of vitamin D.

4. In order to inform discussion across the four nations on whether existing advice around vitamin D supplements remained appropriate or needed updating, in light of the increase in the minimum vitamin D content of infant- and follow-on formulae, the FSA conducted an exposure assessment to determine whether this increase could result in infants (0-12 month-olds) exceeding the tolerable upper level (TUL) (with and without additional exposure from vitamin D supplements).

5. Although the legislation is relevant just for infants, the Nutrition Labelling, Composition and Standards (NLCS) group have asked the FSA to include children up to 4 years of age in the assessment, to determine whether existing advice around vitamin D supplements remains appropriate or needs updating. Therefore, the FSA has also conducted an exposure assessment of vitamin D exposure levels in children (aged 1 to 4 years) from consumption of ‘toddlers’ milks’ and ‘growing up milks’, with and without additional exposure from vitamin D supplements.

6. The revised tolerable upper levels (TULs) set for vitamin D by EFSA in 2018 were 25, 35 and 50 µg/day for infants aged 0-6, 6-12 and >12 months resp ectively. The Committee noted that the TUL for toddlers above 1 year of age was not changed in EFSA’s 2018 assessment following its original establishment in 2003 and confirmation in 2012.

7. The Committee noted that in the conclusions section of the paper, in which it was estimated that there could be slight exceedances of the TUL in infants consuming maximum intakes of infant formula along with additional intake from vitamin D supplements, it should be clarified that use of supplements would not be recommended by the NHS in such children, as the maximum consumption value used (1000 ml) is above 500 ml. The Committee was further reassured that in this exposure scenario, where the NHS advice was not followed, exposure estimates only marginally exceed the TUL.

8. Overall, the Committee agreed that the increase in the minimum vitamin D content of infant formula was not a safety concern. On the basis of the information presented to the Committee, the estimated exposures were not considered to be excessive, and the estimates of maximum combined exposure only marginally exceed the TUL and only when NHS advice on supplement use in high consumers of formula.

9. However, it was noted that the exposure assessment considered vitamin D intake only from infant formula and supplements; other dietary sources had not been assessed. This was important for infants over the age of 4 months, a proportion of whom would be eating solid foods. Some of these foods, such as spreads, would be fortified with vitamin D.

10. In terms of risk/benefit, the rationale for increasing the minimum vitamin D content in infant formula was not clear in this discussion paper.

11. One Member noted that there is some public interest in taking vitamin D for covid. In respect of this, the Committee's advice was to follow the guidance provided by the NHS on maximum vitamin D levels, and not to exceed them. If vitamin D supplements were taken for covid, then this should be balanced against other sources of vitamin D.

12. One Member questioned whether the vitamin D content in toddlers' drinks needs to be better regulated, since toddlers will be exposed to vitamin D from other dietary sources as well. The Secretariat noted that the Department of Health and Social Care had the policy lead on this. However, generally manufacturers do not tend to fortify products above nutritional reference levels.

13. Several editorial changes were requested. Firstly, it should be clarified in Table 2 that the first set of three columns are in units of g/person/day, whilst the second set (to the right) are in g/kg bw/day. Secondly, 'Kcal' should be renamed to 'kcal' in both Table 3 and in the list of abbreviations. Lastly, 'Table 1' on page 7 should be renamed to 'Table 4'.

14. In the assessment of vitamin D exposure, it should be emphasised = that in both infants and children, exceedances of the TULs occurred only when they consumed ≥1000 ml of infant formula per day in addition to vitamin D supplements.