

Committee on Toxicity of Chemicals in Food, Consumer products and the Environment

Discussion paper on vitamin D exposure levels in formula fed infants and children aged up to four years

Background

1. Dietary sources of vitamin D include oily fish and eggs. Some fat spreads and breakfast cereals are also fortified with vitamin D. However, since not many foods are rich in vitamin D, the main source of vitamin D for infants and children aged up to 4 years, is through exposure to sunlight, ingestion of supplements and feeding formulas that are fortified with vitamin D.
2. Current UK government advice on vitamin D supplementation is based on recommendations made by the Scientific Advisory Committee on Nutrition (SACN) in its report entitled 'Vitamin D and health' (SACN, 2016).
3. Infant formula is suitable from birth, whilst follow-on formula is suitable for infants from 6 months of age, as communicated via the [NHS.uk website](https://www.nhs.uk).
4. In the UK, it is currently advised via the [NHS](https://www.nhs.uk) 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 having 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

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5. The original Directive 2006/141/EC set out minimum levels for infant and follow-on formula of 1 µg per 100 kcal and maximum levels of 2.5 and 3 µg per 100 kcal for infant and follow-on formula, respectively.

Tolerable upper limits for vitamin D

6. In 2012, the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) established tolerable upper levels (TULs) for vitamin D (EFSA, 2012), based on a risk assessment conducted in 2003 by the Scientific Committee on Food (SCF, 2003). The SCF risk assessment used hypercalcaemia as the adverse effect induced by excessive vitamin D exposure. The TULs established by EFSA in 2012 were as follows:

- For infants (birth to 1 year of age), the TUL is 25 µg per person, per day.
- For children aged 1 to 4 years, the TUL is 50 µg per person, per day.

7. In 2014, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) published a statement on the adverse effects of high levels of vitamin D, in which the COT agreed with the TULs set by EFSA in 2012 (COT, 2014).

8. However, in 2018, based on the overall evidence, the EFSA NDA Panel kept the TUL of 25 µg/day for infants up to 6 months old, and set a new UL of 35 µg /day for infants aged 6-12 months (EFSA, 2018).

Limits for vitamin D content in infant and follow-on formulae

9. In 2006, the European Commission (Directive 2006/141/EC) established a minimum vitamin D content in infant formula of 1 µg per 100 kcal, and a maximum of 2.5 µg per 100 kcal (EC, 2006). For follow-on formula, the minimum was 1 µg per 100 kcal, and a maximum of 3 µg per 100 kcal.

10. Subsequently in 2016, under Commission Delegated Regulation (EU) 2016/127 on the specific compositional and information requirements for infant

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formula and follow-on formula, the minimum levels for vitamin D content in both infant and follow-on formulae were doubled from 1 to 2 µg per 100 kcal. These new limits, which came into force in February 2020, are shown in Table 1. This regulation is applicable in Great Britain as from 1 January 2021; all regulations and tertiary legislation on nutrition were retained. EU legislation on nutrition continues to be directly applicable in Northern Ireland.

11. 'Toddlers' milks' and 'growing up milks' are not regulated as infant or follow-on formulae and do not fall under the remit of Commission Delegated Regulation (EU) 2016/128 (the legislation that has the specified maximum and minimum levels of vitamin D content) (EC, 2019). There are no specific regulations for milks for children over 12 months of age ('toddler milks' are considered to be 'general food' which just need to comply with general food law, for example in terms of allergen labelling).

12. Although the legislation is for infants, the Nutrition labelling, composition and standards (NLCS) team have asked the FSA to include up to 4 years of age in the assessment, as toddler milks are produced and advertised for the second and third year of life, therefore the first 4 years captures this.

Table 1: Present limits for vitamin D content in infant and follow-on formulae.

	Minimum (per 100 kcal)	Maximum (per 100 kcal)
Infant formula	2 µg*	2.5 µg
Follow-on formula	2 µg*	3 µg

*Previously 1 µg

Risk management goals

13. The Scottish Government is liaising with the FSA to ensure that their current advice on universal vitamin D supplementation is appropriate following the change in the minimum vitamin D content of infant and follow-on formulae. The potential impact this might have on the current UK government advice on vitamin D supplementation is also considered.

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14. As such, the FSA would like the Committee's view on the potential risk of vitamin D toxicity in infants consuming infant and follow-on formulae as a result of the increase in the minimum vitamin D content. This will inform further discussion across the four nations on whether existing advice around vitamin D supplements remains appropriate or needs updating.

15. Although not regulated under this new legislation, and because the NLCS have requested that exposures up to 4 years be considered, exposure assessments have also been undertaken for children aged 1 to 4 years. These exposure assessments include vitamin D levels and consumption figures for 'toddlers' milks' and 'growing up milks'.

Exposure assessment

16. The FSA has conducted an exposure assessment to assess whether the increased minimum vitamin D content in infant and follow-on formulae causes infants (and vitamin D content in 'toddlers' milks' and 'growing up milks' causes children aged 1 to 4 years) to exceed the TUL (with and without additional exposure from supplements).

Exposure assessment (infant formula only)

17. Table 2 below shows consumption data for infant formula which are taken from the 2011 Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and the rolling National Dietary and Nutrition surveys (NDNS) years 1-11 (Bates *et al.*, 2014, 2016, 2020; Roberts *et al.*, 2018).

Table 2: Chronic consumption rates of infant formulae for 4- to 48-month-olds of the UK population (g/person/day).

Age group	Number of consumers	Mean*	97.5th %ile*	Max*	Mean *	97.5th %ile*	Max*
4-<6 months	92	630	1000	1100	81	140	160
6-<12 months	874	490	890	1500	54	110	140

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12-<18 months	260	360	770	900	34	70	90
18-<48 months	32#	330	750	810	25	46	60
4-<12 months	966	500	920	1500	56	110	160

*Rounded to 2 significant figures

#Consumption or exposure estimates made with a small number of consumers may not be accurate. As the number of consumers is less than 60, this data should be treated with caution and may not be representative for a large number of consumers. Estimates are consumption-based and includes toddlers consuming infant formula, follow-on milk and growing-up milk.

18. Table 3 below shows several representative infant formula products available on the UK market. The vitamin D content of these products (expressed as µg/100 kcal) was calculated from the products' label information (*i.e.*, µg/100 ml and kcal/100 ml).

Table 3: Common infant formula products available on the UK market and their vitamin D concentrations.

Formula type	Vitamin D/ 100 ml (µg)	Kcal/ 100 ml	Vitamin D/ 100 kcal (µg)
SMA PRO First Infant Milk Powder Formula Milk	1.5	67	2.24
SMA PRO Follow-on Milk Powder Formula Milk	1.7	67	2.54
SMA PRO Growing Up Milk Powder Formula Milk	1.1	67	1.64
Aptamil® First Infant Milk - 200ml Bottle	1.65	66	2.5
Aptamil® Follow On Milk - 700g Tin	1.7	68	2.5
Aptamil® Toddler Milk	3.4	68	5

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- 800g EaZypack			
Aptamil® Toddler Baby Milk 200ml (1-2 years)	3.1	51	6.08
Aptamil® Toddler Milk - 800g EaZypack (2-3 years)	3.7	59	6.27
New Cow & Gate First Infant Formula Milk 800g	1.45	66	2.20
New Cow & Gate Follow on Formula Milk 800g	1.7	68	2.5
Toddler Milk 800g Powder 1-2 Years Cow & Gate	3.4	67	5.07
Toddler Milk 800g Powder 2-3 Years Cow & Gate	2.6	55	4.73

Exposure estimates based on the new regulation

19. Using an average calorie content of 67 kcal/100 ml of infant formula (from values in Table 3), and the minimum and maximum vitamin D concentrations stated in the new regulations (Table 1), the following vitamin D concentrations in infant and follow-on formulae were derived:

- minimum and maximum vitamin D concentrations of 1.34 µg/100 ml and 1.68 µg/100 ml in infant formula, respectively; and,
- minimum and maximum vitamin D concentrations of 1.34 and 2.01 µg/100 ml in follow-on formula, respectively.

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20. Table 4 below shows the estimated chronic exposures to vitamin D for 4- to 12-month-olds from consumption of infant formula. These estimates make use of the new minimum vitamin D content of 2 µg/100 kcal in infant formulae.

Table 1: Estimates of chronic exposure to vitamin D for 4- to 12-month-olds from consumption of infant formula (based on the new regulation for infant formula; without supplements) (µg/person/day).

Age group (months)	Number of consumers	Mean	97.5th percentile	Maximum
4 - <6	92	8.5 -11	13-17	15-19
6 - <12	874	6.5 – 9.8	12-18	20-29
4 - <12 ^a	966	6.7- 10	12-18	20-29

^a Uses minimum and maximum vitamin D concentrations of 1.34 µg/100 ml and 2.01 µg/100 ml, respectively.

Exposure estimates based on infant formula products currently available on the UK market

21. Chronic exposures to vitamin D were also estimated using concentrations of vitamin D in infant and follow-on formula products and ‘toddlers’ milks’ and ‘growing up milks’ currently available on the UK market. These exposure estimates are shown below in Table 5.

Table 5: Estimates of chronic exposure to vitamin D from consumption of infant formulae products currently available on the UK market (without supplements) (µg/person/day).

Age group	Concentration used (µg/100kcal)	Number of consumers	Mean*	97.5th Percentile*	Maximum*
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4-<6 months	2.20 - 2.5	92	9.2 - 10	15 - 17	17 - 19
6-<12 months	2.54	874	8.3	15	25
12-<18 months	1.64 - 5.0	260	4.0 - 12	8.4 - 26	9.9 - 31
18-<48 months	1.64 - 6.27	32 [#]	3.6 - 12	8.2 - 28	8.9 - 30
4-<12 months	2.20 - 2.54	966	7.3 – 8.5	13 - 16	21 - 25

*Rounded to 2 significant figures

[#]Consumption or exposure estimates made with a small number of consumers may not be accurate. As the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers.

Exposure assessment (supplements only)

22. As noted in paragraph 4, it is currently advised 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. Therefore, an exposure assessment was conducted to show levels of vitamin D exposure in infants through consumption of vitamin D supplements (without infant formulae) (Table 6). These estimates make use of the vitamin D content of some supplements currently available on the UK market, as shown in Table 7 below.

Table 6: Summary of infants' and toddlers' estimated exposure to vitamin D through consumption of supplements (alone).

Age group	Recommended intake/ daily exposure (µg)
4-<6 months	3.5 - 10
6-<12 months	3.5 - 10
12-<18 months	3.5 - 10

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18-<48 months	3.5 - 10
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Table 7: Vitamin D supplements available on the UK market for infants and toddlers.

Age group	Supplement	Vitamin D form	Recommended intake (as per label) (µg)
4-<6 months	Baby Drops Vitamin D 10ug 1.7ml Boots	D3	10
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Healthy Start Children's Vitamin Drops 10ml Health Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30ML (2 Months Supply) Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	5
6-<12 months	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Baby Ddrops Vitamin D 10ug 1.7ml Boots	D3	10
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D	D3	8.5

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	Drops 30ml - Boots		
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Healthy Start Children's Vitamin Drops 10ml Health Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	5
12-<18 months	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Abidec Advanced Multivitamin Syrup Plus Omega 6 & 9 150ml - Boots	D3	7.5
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Ddrops One Liquid Vitamin D3 10µg - 60 drops - Boots	D3	10
	Healthy Start Children's Vitamin Drops 10ml Health Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) Superdrug	D3	10

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	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	10
18-<48 months	Bassetts multivitamins + omega 3 3-6 Years LloydsPharmacy	Not stated	5
	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Abidec Advanced Multivitamin Syrup Plus Omega 6 & 9 150ml - Boots	D3	7.5
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Ddrops One Liquid Vitamin D3 10µg - 60 drops - Boots	D3	10
	Healthy Start Children's Vitamin Drops 10ml Health Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30ML (2 Months Supply) Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	10

Scenario-based combined exposure to vitamin D from infant formula and supplements

23. Table 2 shows the chronic consumption rates that were used for the exposure

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assessment for infants. According to the current guidance on vitamin D (see paragraph 4), infants consuming less than 500 ml of infant formula per day may have additional exposure through consumption of vitamin D supplements. Therefore, estimates of their combined exposure to vitamin D from supplements and infant formula (Table 8) or follow-on formula (Table 9) are shown below. These estimates show amount of daily exposure per person, given the amount of infant formula consumed.

Table 8: Scenario-based combined exposure to vitamin D from ingestion of infant formula and supplements.

Daily consumption (ml)	Daily kcal consumed*	Vitamin D exposure µg/day*	Exposure from supplements (µg/day)*	Minimum combined exposure (µg/day)*	Maximum combined exposure (µg/day)*
100	67	1.3 – 1.7	3.5	4.8	5.2
100	67	1.3 – 1.7	8.5	9.8	10
100	67	1.3 – 1.7	10	11	12
200	130	2.7 – 3.4	3.5	6.2	6.9
200	130	2.7 – 3.4	8.5	11	12
200	130	2.7 – 3.4	10	13	14
300	200	4.0 – 5.0	3.5	7.5	8.5
300	200	4.0 – 5.0	8.5	13	14
300	200	4.0 – 5.0	10	14	15
400	270	5.4 – 6.7	3.5	8.9	10
400	270	5.4 – 6.7	8.5	14	15
400	270	5.4 – 6.7	10	15	17
500	340	6.70 – 8.4	3.5	10	12
500	340	6.7 – 8.4	8.5	15	17
500	340	6.7 – 8.4	10	17	18
1000	670	13 – 17	3.5	17	20
1000	670	13 - 17	8.5	22	26
1000	670	13 - 17	10	23	27

Values are to 2 significant figures

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*Using an average of 67 kcal /100 ml, the concentration of vitamin D in infant formula were derived, given the minimum and maximum vitamin D concentrations of 2 and 2.5 µg/100 kcal permitted in infant formula.

Table 9: Scenario-based combined exposure to vitamin D from ingestion of follow-on formula and supplements.

Exposure from follow-on formula	Exposure from follow-on formula	Exposure from follow-on formula			
Daily consumption (ml)	Daily kcal consumed*	Vitamin D exposure µg/day*	Exposure from supplements (µg/day)	Minimum combined exposure (µg/day)	Maximum combined exposure (µg/day)
100	67	1.34 - 2.01	3.5	4.84	5.51
100	67	1.34 - 2.01	8.5	9.84	10.5
100	67	1.34 - 2.01	10	11.3	12.0
200	134	2.68 - 4.02	3.5	6.18	7.52
200	134	2.68 - 4.02	8.5	11.2	12.5
200	134	2.68 - 4.02	10	12.7	14.0
300	201	4.02 - 6.03	3.5	7.52	9.53
300	201	4.02 - 6.03	8.5	12.5	14.5
300	201	4.02 - 6.03	10	14.0	16.0
400	268	5.36 - 8.04	3.5	8.86	11.5
400	268	5.36 - 8.04	8.5	13.9	16.5
400	268	5.36 - 8.04	10	15.4	18.0
500	335	6.70 - 10.05	3.5	10.2	13.6
500	335	6.70 - 10.05	8.5	15.2	18.6
500	335	6.70 - 10.05	10	16.7	20.1
1000	670	13.4 - 20.1	3.5	16.9	23.6
1000	670	13.4 - 20.1	8.5	21.9	28.6
1000	670	13.4 - 20.1	10	23.4	30.1

*Using an average of 67 kcal /100 ml, the amount of vitamin D in follow-on formula were derived, given the minimum and maximum vitamin D concentrations of 2 and 3 µg/100 kcal permitted in follow-on formula.

24. Table 10 shows estimates of combined exposure to vitamin D in children aged 1 to 4 years (i.e. exposure from ingestion of growing up/toddler milks, and from vitamin D supplements). As noted above, the TUL for children aged 1 to 4 years is 50 µg per person, per day. This TUL is not exceeded.

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Table 10: Scenario-based combined exposure to vitamin D in toddler milks and supplements

Exposure from growing up/toddler milk	Exposure from growing up/toddler milk	Exposure from growing up/toddler milk			
Daily consumption (ml)	Daily kcal consumed*	Vitamin D exposure µg/day*	Exposure from supplements (µg/day)	Minimum combined exposure (µg/day)	Maximum combined exposure (µg/day)
100	67	1.1 - 3.7	3.5	4.6	7.2
100	67	1.1 - 3.7	8.5	9.6	12.2
100	67	1.1 - 3.7	10	11.1	13.7
200	134	2.2 - 7.4	3.5	5.7	10.9
200	134	2.2 - 7.4	8.5	10.7	15.9
200	134	2.2 - 7.4	10	12.2	17.4
300	201	3.3 - 11.1	3.5	6.8	14.6
300	201	3.3 - 11.1	8.5	11.8	19.6
300	201	3.3 - 11.1	10	13.3	21.1
400	268	4.4 - 14.8	3.5	7.9	18.3
400	268	4.4 - 14.8	8.5	12.9	23.3
400	268	4.4 - 14.8	10	14.4	24.8
500	335	5.5 - 18.5	3.5	9.0	22.0
500	335	5.5 - 18.5	8.5	14.0	27.0
500	335	5.5 - 18.5	10	15.5	28.5
1000	670	11 - 37	3.5	14.5	40.5
1000	670	11 - 37	8.5	19.5	45.5
1000	670	11 - 37	10	21.0	47.0

*Using an average of 67 kcal /100 ml, exposures to vitamin D from selected growing up and toddler milk available on the UK market were combined with exposures from vitamin D supplements. The exposure estimates employed minimum and maximum vitamin D concentrations of 1.64 and 6.27 µg/100 kcal of growing up/toddler milks.

Risk characterisation

25. **Infants (<6 months old):** Chronic exposures to vitamin D from consumption of infant formulae (alone) have been estimated for 4 – 6-month-olds (Table 5). Here, there are no exceedances of the TUL of 25 µg per person per day at the mean, 97.5th percentile, or maximum levels of exposure. However, infants may have additional exposure to vitamin D through consumption of supplements. Table 8

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shows the estimates of combined exposure from infant formula and supplements. There are only slight exceedances of the TUL of 25 µg/day for infants up to 6 months old, and only when 1000 ml or more of infant formulae are consumed daily at the maximum vitamin D limits of 2.5 µg/100 kcal (values shown in bold).

26. **Infants (6 to 12 months old):** Chronic exposures to vitamin D from consumption of infant formulae (alone) have been estimated for 6 – 12-month-olds (Table 5). Here, there are no exceedances of the TUL of 35 µg per person per day at the mean, 97.5th percentile, or maximum levels of exposure. However, infants may have additional exposure to vitamin D through consumption of supplements. As shown in Table 9, which shows estimates of combined exposure from ingestion of follow-on formula and supplements, there are no exceedances of the TUL of 35 µg/day.

27. **Children aged 1 to 4 years (12 to <18 months and 18 to <48 months old):** An exposure assessment for toddlers was included in this discussion paper (Table 10) which was based on the range of vitamin D concentrations in toddler milks available on the UK market (derived from label information). A number of these products contain much higher levels of vitamin D per 100 kcal compared with infant and follow-on milks (Table 3). Table 2 indicates that children aged 1 to 4 years generally consume less than 500 ml of fortified milk per day; as such, they are likely to ingest vitamin D supplements as well. However, as shown in Table 10, estimates of combined exposure from ingestion of supplements and toddler milk do not lead to any exceedances of the TUL of 50 µg/day.

Summary & conclusions

28. In this discussion paper, exposures of infants and children aged 1 to 4, to vitamin D have been estimated from their consumption of infant formulae and vitamin D supplements (alone and combination). Across these exposure assessments, exceedances of the TULs only occur in infants, and only when they consume 1000 ml or more of infant formula per day (at the maximum permitted vitamin D concentration (2.5 µg/100 kcal)) and vitamin D supplements (Table 8; values shown

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in bold). However, there is some uncertainty on the contribution of vitamin D from other food sources not considered in this discussion paper which might lead to underestimation of total vitamin D exposures in infants and toddlers.

29. Current UK government advice is that infants should not be given vitamin D supplements if they consume 500 ml or more of infant formula per day. Therefore, as long as the advice is followed, it is expected that infants will not exceed the TULs (given the new minimum vitamin D content used in infant formulae products).

Questions on which the views of the Committee are sought:

1. Does the Committee consider that the new minimum vitamin D content in infant formulae leads to excessive vitamin D exposure in infants?
2. If so, does the Committee consider that the current UK government guidance on vitamin D supplementation for infants needs updating?

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Abbreviations

DNSIYC	diet and nutrition survey of infants and young Children
EFSA	European Food Safety Authority
Kcal	kilocalories
NDNS	national Dietary and Nutrition survey
NHS	UK National Health Service
NLCS	nutrition labelling, composition and standards
SACN	Scientific Advisory Committee on Nutrition
SCF	Scientific Committee on Food
TUL	tolerable upper level

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