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

First draft addendum to the 2013 COT statement on potential risks from aluminium in the infant diet

Introduction

1. The Committee on Toxicity (COT) has been asked to consider the toxicity of chemicals in the infant diet and the diet of young children aged 1-5 years, in support of a review by the Scientific Advisory Committee on Nutrition (SACN) of Government recommendations on complementary and young child feeding. A scoping paper (TOX/2015/32), highlighting some of the chemicals for possible consideration for the diet of young children aged 1-5 years was discussed by the COT in October 2015. Members concluded that the availability of new aluminium occurrence data required an update of the exposures in the statement on the potential risks from aluminium in the infant diet (COT, 2013) and an exposure assessment for the diet of young children aged 1-5 years. This would be in the form of an addendum to the statement. A discussion paper on aluminium (TOX/2015/38) was presented to Members in December 2015.

2. A first draft addendum on aluminium (TOX/2015/38) was presented to Members in December 2015. At this meeting Members requested that information be provided on the uptake of aluminium by soya plants and whether there were other species of plant that showed similar uptake of aluminium.

3. The Committee requested comments be included regarding aluminium nano-particles especially with regards to inhalation and any associated risks, and aluminium in soil, especially with regards to aluminosilicates and their bioavailability. Members also requested that bioavailability of soluble/insoluble aluminium species be considered in more detail and whether the diet or soil is the major route of aluminium exposure.

4. As per the Committee’s request exposures from diet were estimated using both median and 97.5th percentile aluminium levels in drinking water.

5. Since the December 2015 meeting, reviews of lead and arsenic have been considered by COT leading to the inclusion of aggregate exposure scenarios. To keep this addendum consistent with these other reviews within the 1-5 years feeding review, the Secretariat has included aggregate exposure scenarios for Members to consider.

6. Members are asked to comment on the draft statement addendum, attached as Annex A.

Secretariat
March 2016

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

First draft addendum to the 2013 COT statement on potential risks from aluminium in the infant diet

Background

1. The Scientific Advisory Committee on Nutrition (SACN) is undertaking a review of scientific evidence that will influence the Government's dietary recommendations for infants and young children. SACN is examining the nutritional basis of the advice. The Committee on Toxicity in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from chemicals in the diet of infants and young children. The reviews will identify new evidence that has emerged since the Government's recommendations were formulated, and will appraise that evidence to determine whether the advice should be revised.

2. In 2013 the COT issued a statement on potential risks from aluminium in the infant diet[1]. This addendum to the 2013 statement updates the aluminium exposures for infants because new data have become available for children in the UK, and provides exposure assessments for children aged 1 to 5 years. There are currently no Government dietary recommendations for infants and young children which relate to aluminium.

7. With respect to soya-based drinks Government advice, based on the conclusions of a 2003 COT report[2], is: "You should only give your baby soya formula if a health professional advises you to. However, you can give your child unsweetened calcium-fortified milk alternatives, such as soya, almond and oat drinks, from the age of one as part of a healthy balanced diet" (NHS Choices, 2016).

8. The risks associated with exposure to aluminium are assessed in this addendum using the same approach as was taken for the infant diet in 2013, using the provisional tolerable weekly intake (PTWI) of 2,000 µg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO, 2012).

[1] http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2013/aluminium
[2] http://cot.food.gov.uk/cotreports/cotwgreports/phytoestrogensandhealthcot

Aluminium exposures in infants aged 0 to 12 months and young children aged 1 to 5 years

New data on sources of aluminium exposure

9. A literature search identified no new data on levels of aluminium in breast milk in the UK since the 2013 COT statement on the potential risks of aluminium in the infant diet. Therefore the mean and maximum measured values of 27 and 79 µg/L (Baxter *et al.*, 1991) were used for exposure estimates of aluminium in children aged 6 to 18 months.

10. Levels of aluminium have recently been measured in an FSA survey of metals in infant formulae and food, and in the composite food samples of the 2014 Total Diet Study (TDS).

11. Median and 97.5th percentile concentrations of aluminium in drinking water in 2014 were provided by the Drinking Water Inspectorate, Northern Ireland Water and the Drinking Water Quality Regulator for Scotland (Table 1). The highest median and 97.5th percentile values were 24 and 100 µg/L, respectively.

Table 1. Aluminium concentrations (µg/L) in tap water from public water supplies.

	Number of samples	Median	97.5th percentile
England and Wales	43,000	5.1	34
Northern Ireland	1,900	24	100
Scotland	5,100	23	62

12. Aluminium concentrations were measured in 5,670 topsoil[3] samples collected between 1978 and 1982 in England and Wales, avoiding large urban areas. Samples were analysed 30 years later. (Rawlins *et al.*, 2012). The median and 97.5th percentile concentrations were 58,000 and 82,000 mg/kg. No specific data were identified on aluminium levels in dust.

13. Aluminium in nano form has a wide range of uses including catalyst supports in manufacturing processes, flame retardants, adsorbents, biomedical applications, drug carriers, imaging agents and drug or vaccine delivery (Adamcakova-Dodd et al., 2012; Sharma, 2012). Any aluminium entering the food chain from these sources will be measured as aluminium in the surveys, but cannot be specifically identified as nanomaterial.

[3] From a depth of 0 to 15 cm

Exposure

14. Consumption data from the Diet and Nutrition Survey in Infants and Young Children (DNSIYC) (DH, 2013) and recent data from the National Diet and Nutrition Survey Rolling Programme years 1-4 (NDNS) (Bates *et al.*, 2014) have been used for the estimation of dietary exposure. Bodyweight data used in the estimation of aluminium exposures were average bodyweights of 5.9, 7.8, 8.7 and 9.6 kg for infants aged 0 to 4.0, >4.0 to 6.0, >6.0 to 9.0 and >9.0 to 12.0 months old, respectively (COT, 2013). Average bodyweights of 9.2, 10.6, 11.2, 12 and 16.1 kg were used for infants and young children aged 6.0 to <12.0, 12.0 to <15.0, 15 to <18, 18 to 24 and 24 to 60 months, respectively (DH, 2013; Bates *et al.*, 2014).

Infants

Breast milk

15. Since no new data were available on breast milk, the estimated exposures of exclusively breastfed infants aged 0-6 months are identical to the 2013 COT statement (Table 2).

16. Data on breast milk consumption from DNSIYC and NDNS were used in estimating exposure from breast milk in the 6 to18 months age groups as complementary feeding is introduced (Table 2). There were too few records of breast milk consumption for children older than 18 months in NDNS to allow a reliable exposure assessment, and breast milk is expected to contribute minimally in this age group.

Table 2. Aluminium exposure (µg/kg bw/week) from breastfeeding estimated for mean and 97.5th percentile level consumption of breast milk

		Age group (months)					
		0 to 4[a]	**>4 to 6[a]**	**>6 to 9[b]**	**>9 to 12[b]**	**12 to 15[b]**	**15 to 18[b]**
Number of consumers		N/A	N/A	140	120	66	32
Exposure from 27 µg aluminium/L breast milk (µg/kg bw/week)	Mean	26	19	13	7	5.6	4.9
	High level	38	29	30	22	14	9.8
Exposure from 79 µg aluminium/L breast milk (µg/kg bw/week)	Mean	75	57	15	21	16	14
	High level	110	85	88	64	41	29

[a] *Mean and high level aluminium exposures were based on exclusive breastfeeding and consumption of 800 and 1,200mLof formula for mean and high level, respectively (COT, 2013).*
[b] *Consumption data from DYSIYC; high level is 97.5th percentile.*

Infant formulae and complementary food

17. Exposure estimates for infants were derived using occurrence data from the FSA survey of metals in infant formulae (referred to as the Infant Metals Survey) and food consumption data from DNSIYC.

18. Possible aluminium exposure levels from infant formulae were calculated for infants up to 4 months of age assuming exclusive feeding on formula (Table 3). Exposure estimates were derived using the occurrence data for first milk infant formula with default values for mean (800mL) and high level (1,200mL) consumption, in line with previous COT evaluations. The contribution to exposure arising from water used to reconstitute powder infant formulae was calculated using the highest median and the highest 97.5th percentile concentration value for water (Table 1).

Table 3. Estimated aluminium exposures (µg/kg bw/week) from exclusive first-milk infant formula for 0 to 3.99 months.

Infant Formula	Aluminium – LB - UB Range (µg/kg bw/week)	
	800 mL	1,200 mL
Ready to Feed	17 - 32[d]	26 - 48[d]
Dry Powder[a]	55 - 70[e]	83 - 100[e]
Dry Powder + water at 24 µg/L[b]	74 - 89	110 - 130
Dry Powder + water at 100µg/L[c]	140 - 150	200 - 220

[a] *Exposure does not include the contribution from water.*
[b] *Determined from applying a factor of 0.85 to default formula consumption of 800mL and 1,200mL per day for estimating water consumption.*
[c] *Determined from applying a factor of 0.85 to default formula consumption of 800mL and 1,200mL per day for estimating water consumption.*
[d] *Exposures based on first milk infant formula using lower and upper bound concentrations of 18-34 µg/L, respectively.*
[e] *Exposures based on first milk infant formula using lower and upper bound concentrations of 388-488 µg/L, respectively.*

19. Aluminium exposure of infants aged 4 to <12 months, from infant formulae, commercial infant foods and other foods commonly consumed by this age group, was estimated using DNSIYC consumption data. The overall possible mean and 97.5th percentile aluminium exposures (excluding water) in 4 to 12 month old infants ranged from 120-260 and 360-550 µg/kg bw/week,

respectively (Table 4). These values are within the range of estimates reported in the 2013 COT statement in which mean values ranged from 98 to 1,200 µg/kg bw/week. Exposure to aluminium from drinking water when present at the highest median or the highest 97.5th percentile level (Table 1) had a minimal impact on total exposure that was estimated for the combination of the three food categories (Table 4).

Table 4. Estimated aluminium exposures (µg/kg bw/week) from infant formulae, commercial infant foods, and other foods in infants aged 4 to 12 months.

	Aluminium LB-UB[a] Range (µg/kg bw/week)					
	4 to 5.99 months (n=116)		**6 to 8.99 months (n=606)**		**9 to 11.99 months (n=686)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**	**Mean**	**97.5th percentile**
Infant formula	8.5 – 16	18 – 33	6.8 - 13	17 – 28	5.1 – 9.4	12 – 22
Commercial infant foods	81 – 82	320 – 320	120 – 120	460 – 460	110 – 110	440 – 440
Complementary foods	26 – 28	130 – 130	80 – 82	260 – 270	130 – 130	350 – 360
Total (excluding water)	120 – 130	360 – 380[b]	210 – 220	540 – 550[b]	250 – 260	540 – 550[b]
Total aluminium using water at median level (24 µg/L)	120 – 130	360 – 380	210 – 220	550 – 560	250 – 260	550 – 560
Total aluminium using water at 97.5th percentile level (100 µg/L)	120 – 130	370 – 390	220 – 230	560 – 570	260 - 270	570 – 580

[a] *Values are LB to UB ranges.*
[b] *Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories.*

Children aged 12 to 18 months

20. Exposure estimates for these age groups were derived using occurrence data from the Infant Metals Survey and the 2014 TDS. The infant metal survey included analysis of infant formulae and commercial infant foods which are not included in the TDS. Consumption data from DNSIYC were used for the estimation of exposure for each study.

Infant Metals Survey

21. The ranges of total mean and 97.5th percentile exposures from infant formula, commercial infant foods and other foods were 220 - 238 and 423 - 499 µg/kg bw/week, respectively (Table 5). As observed in younger age groups, exposure to aluminium from drinking water, whether present at the highest median or the highest 97.5th percentile level (Table 1) had a minimal impact on total exposure from all food categories in the 12-18 months age range (Table 5).

Table 5. Estimated aluminium exposures (µg/kg bw/week) from infant formulae, commercial infant foods, and other foods in infants aged 12 to 18 months using data from the FSA infant foods survey.

	Aluminium LB - UB Range (µg/kg bw/week)			
	12 to 14.99 months (n=670)		**15 to 17.99 months (n=605)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
Infant formula	1.8 – 3.4	8.1 – 15.1	1.0 – 4.3	5.5 – 11
Commercial infant foods	63 – 63	320 – 320	35 – 35	190 – 200
Complementary foods	170 – 200	360 – 370	180 – 190	360 – 370
Total (excluding water used in reconstitution)	230 – 240	490 – 500[a]	220 – 230	430 – 440[a]
Total aluminium from water at median level (24 µg/L)[a]	230 – 240	500 – 510	220 – 230	430 – 440
Total + aluminium from water at 97.5th percentile level (100 µg/L)	240 – 250	520 – 530	230 – 240	460 – 470

[a] *Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories.*

Exposure estimates based on the TDS

22. Table 6 shows the possible aluminium exposures that were calculated using TDS data for children aged 12 to 18 months using DNSIYC consumption data. The exposure data derived from the TDS are higher than

those estimated from the Infant Metals Survey. This is due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the Infant Metals Survey.

23. From the TDS (which includes tap water and bottled water), total mean and 97.5th percentile aluminium exposures from a combination of all food groups ranged from 550 - 650 and 1,200 – 1,300 µg/kg bw/week, respectively. Concentration of aluminium in drinking water had a negligible impact on total dietary exposure. Replacing the aluminium concentration identified for drinking water in the TDS (<20 µg/L) with the highest median (24 µg/L) or the highest 97.5th percentile value (100 µg/L) reported in Table 1 had a negligible impact on total dietary exposure. The TDS samples were prepared using water at the research laboratory, for which the level of aluminium was below the LOD of 3 µg/L. If water containing a higher aluminium concentration is used in food preparation, then the total dietary exposure might be higher but it is not possible to assess what the impact would be.

24. The food groups with the highest contribution to total dietary aluminium exposure were in the order: miscellaneous cereals > non-alcoholic beverages > bread.

Table 6. Estimated aluminium exposures (µg/kg bw/week) from the TDS in infants aged 12 to 18 months.

	Aluminium LB - UB Range (µg/kg bw/week)			
	12 to 14.99 months (n=670)		**15 to 17.99 months (n=605)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
TDS	550 – 570	1,200 – 1,300	640 – 650	1,300
TDS using Al concentration in water at median level (24 µg/L)	560 – 570	1,200 – 1,300	640 – 650	1,300
TDS using Al concentration in water at 97.5th percentile (100 µg/L)	560 – 570	1,300	660	1,300

Children aged 18 months to 5 years

25. Exposure estimates for these age groups were derived using occurrence data from the 2014 TDS and consumption data from the NDNS.

26. Total mean aluminium exposures from a combination of all food groups ranged from 710 - 760. The 97.5th percentile exposure was estimated at 1,200 µg/kg bw/week for the age range 18-60 months. As with younger children, concentration of aluminium in drinking water had a negligible impact on total dietary exposure. Replacing the aluminium concentration identified for tap water in the TDS (<20 µg/L) with the highest median (24 µg/L) or the highest 97.5th percentile value (100 µg/L) reported in Table 1 also had negligible impact on total exposure in 18-60 month old children.

27. The food groups with the highest contribution to total dietary aluminium exposure were miscellaneous cereals > non-alcoholic beverages > bread for 18-24 month old children and non-alcoholic beverages > miscellaneous cereals > bread for 24 to 60 month old children.

Table 7. Estimated aluminium exposures (µg/kg bw/week) from the TDS in infants aged 18 to 60 months.

	Aluminium LB-UB Range (µg/kg bw/week)			
	18 to 24 months (n=70)		**24 to 60 months (n=429)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
TDS	740 - 760	1,200	710	1,200
TDS + Al from water at median level (24 µg/L[a])	750 - 760	1,200	710 - 720	1,200
TDS + Al from water at 97.5th percentile level (100 µg/L[b])	750 - 760	1,200	710 - 720	1,200

Exposure from soya-based formula and drink

28. Aluminium is naturally present in varying amounts in most foodstuffs and levels in food crops are influenced by geographical region (EFSA, 2008). Most aluminium in soils is in the form of oxides or aluminosilicates, however in acidic soils (pH < 5.5) aluminium may also exist as the trivalent cation Al^{3+} (Ma, 2005). Soybean plants grown in acidic soils may contain high levels of aluminium as Al^{3+} is absorbable by the soybean roots (Fanni et al., 2014). Therefore exposure from soya was considered separately. Aluminium was reported in powdered soya formula at a level of 2,550 µg/kg. Using the consumption values of regular infant formula for the 4 to 6 month age group,

exposure estimates for aluminium in soya formula would be 212 and 377 µg/kg bw/week for mean and 97.5th percentile consumers, respectively before taking into account water used in reconstitution, i.e. at least an order of magnitude above the exposure for non-soya formula (Table 4).

29. Consumption data of soya drink from DNSIYC for the age range 6 to 12 months and young children was used for estimating additional exposure to aluminium from this potential complementary source in the diet (there were no soya drink consumption data for 4 to 6 month old infants). A very limited number of studies had measured aluminium levels in soya drink. A median value of 188 µg/L (slightly higher than the mean value of 160 µg/L) reported by Baxter *et al.* (1991) for UK samples, was used to estimate the possible exposure reported in Table 8. For infants aged 6 to 12 months, mean and 97.5th percentile exposures to aluminium from the consumption of soya drink ranged from 38 - 51 and 90 - 112 µg/kg bw/week respectively. For young children aged 12 to 60 months, mean and 97.5th percentile exposures range from 15 to 27 and 29 to 75 µg/kg bw/week, respectively. The upper end of the 97.5th percentile exposure range in children aged 12 to 60 months is less than 15% of the lowest overall dietary mean exposure to aluminium estimated from the TDS (Table 6). However, expressing the exposure from this source in terms of the values determined from the TDS results in some double counting, due to the presence of soya drink in the TDS.

Table 8. Chronic exposure (µg/kg bw/week) to aluminium from soya drink in UK infants and young children.

		Aluminium (µg/kg bw/week)					
		Age group (months)					
		6 to 9	**9 to 12**	**12 to 15**	**15 to 18**	**18 to 24**	**24 to 60**
Number of consumers		4	8	7	12	4	11
Consumption (g/person /week)	Mean	2,204	1,889	1,434	1,590	1,152	1,328
	97.5th percentile	3,886	5,687	4,066	3,858	3,327	2,617
Consumption (g/kg bw/week)	Mean	271	200	143	143	110	82
	97.5th percentile	481	596	400	348	333	153
Exposure (µg/kg	Mean	51	38	27	27	21	15

bw/week)	97.5th percentile	90	112	75	65	63	29

Soil/dust

30. Potential exposures of UK infants aged >9 to 12 months and young children aged 12 to 60 months to aluminium in soil were calculated assuming ingestion of 100 mg/day (US EPA, 2008; WHO, 2007) and median and 97.5th percentile aluminium concentrations of 58,000 and 80,000 mg/kg reported for soil (Rawlins et al., 2012) (Table 9). Data specific to dust were not available. Children of these age groups are likely to consume more soil and dust than younger infants who are less able to move around and come into contact with soil and dust.

Table 9. Possible aluminium exposures (µg/kg bw/week) from soil in infants and young children aged > 9 to 60 months.

	Aluminium (µg/kg bw/week)				
Aluminium concentration in soil	**Age (months)**				
	>9 to 12	**12 to 15**	**15 to 18**	**18 to 24**	**24 to 60**
Median (93 mg/kg)	4,200	3,800	3,600	3,400	2,500
97.5th percentile (310 mg/kg)	5,800	5,300	5,000	4,700	3,500

31. Exposure from air is not considered in this addendum as it is likely to be a minor source compared with diet.

Risk Characterisation

32. Potential risks from infants' exposures to aluminium were characterised by comparison with the PTWI of 2,000 µg/kg bw. Use of the TDS data, which involves preparation of food as for consumption, will allow for migration of aluminium from food contact materials, although there could be some additional exposure from this route in the home, depending on food preparation and storage. Drinking water seems to be a minor source of aluminium exposure compared to food.

33. The estimates of dietary exposure to aluminium are below the PTWI and do not indicate a toxicological concern (Table 10). An exception to this

would be infants fed exclusively on soya-based formula, who could have much higher dietary exposures. Furthermore, these estimated exposures in Table 10 do not account for the aluminium content of the water used to reconstitute the soya formula and thus the figures provided are not wholly representative. Current UK government advice is that infants should not be fed soya formula unless it has been prescribed or recommended by a medical practitioner. Although foods based on soya were included in TDS samples, these are composited with other similar (non-soya) foods prior to analysis. Thus, the specific contribution of soya-based foods to exposure assessments for aluminium in older children (12 to 60 months) cannot be determined from TDS data. However, exposure to aluminium from soya drinks used as a potential complementary source in the diet of older infants and young children was estimated separately (Table 8). In comparison with the total dietary exposures provided in Table 10, exposures from soya drinks are unlikely to be a significant; as they make relatively small contributions to exposures that are already considerably below the PTWI, and furthermore decline with increasing age.

Table 10. Estimated dietary exposures (µg/kg bw/week) to aluminium and comparison to the PTWI.

		Exclusive breast milk[a]	Exclusive infant formula[ab]	Soya-based infant formula[ad]	Total diet including water with median Al level (24 µg/L)[a]					Total diet including water with P97.5 Al level (100 µg/L)[a]				
Survey/ Consumption Data		N/A	Infant metals survey	N/A	Infant metals survey/ DNSIYC	Infant metals survey/ DNSIYC	TDS/ DNSIYC	TDS/ NDNS	TDS/ NDNS	Infant metals survey/ DNSIYC	Infant metals survey/ DNSIYC	TDS/ DNSIYC	TDS/ NDNS	TDS/ NDNS
Age (months)		0 to 6	0 to 4	4 to 6	4 to 12	12 to 18	12 to 18	18 to 24	24 to 60	4 to 12	12 to 18	12 to 18	18 to 24	24 to 60
Estimated dietary exposures (µg/kg bw/week)	Average consumers	19 – 75	17 – 150[c]	210	120 – 260	220 – 240	560 – 650	750 – 760	710 – 720	120 – 270	230 – 250	560 – 660	750 – 760	710 – 720
	High level consumers	29 – 110	26 – 220[a]	380	360 – 560	430 – 510	1,200 – 1,300	1,200	1,200	370 – 580	460 – 530	1,300	1,200	1,200
% PTWI	Average consumers	1.0 – 3.8	0.9 – 7.5	11	6 – 13	11 – 12	28 – 33	38 – 38	36 – 36	6 – 14	12-13	28 – 33	38 – 38	36 – 36
	High level consumers	1.5 – 5.5	1.3 – 11	19	18 – 28	22 – 26	60 – 65	60	60	19 – 29	23 – 27	65	60	60

[a] Values are LB to UB ranges.
[b] Exclusive infant formula is only considered here for 0 to 4 months because from the DNSIYC and NDNS consumption data other foods are included in the diet of infants and children older than 4 months.
[c] Includes ready to feed formulae and dry formulae. These values also include the aluminium present in the water used to make up the formulae, considering both the highest median or highest 97.5th percentile aluminium concentrations in water.
[d] A scenario based approach using powdered formula with levels of aluminium reported at 2,550 µg/kg and consumption values of regular infant formula for the 4 to 6 month age group without taking into account the aluminium concentration in water used to reconstitute the dry formula.

Risk Characterisation for aggregate exposures

34. The aggregate exposures have been calculated by adding the mean/average exposure estimates from all but one source to the 97.5th percentile/high level exposure estimate for the remaining source. Aggregate exposures have not been calculated for infants 0 to 4 months old, as this age group were considered to be exclusively breast- or formula-fed, with no exposure to other foods or to soil.

35. Table 11 shows the aggregate exposure estimates and percent contribution to the PTWI for infants aged 4 to 6 and 6 to 9 months. The aggregate exposures for these age groups are based on the exposure estimates for breast milk and the total diet including water. Estimates from exposures via soil were not calculated for this age group as infants <9 months are less able to move around and come into contact with soil. For infants 4 to 9 months old, aggregate exposures are 9 to 29% of the PTWI and thus are not of toxicological concern.

Table 11. Aggregate exposures to aluminium for infants aged 4 to 9 months based on exposures from breast milk and the total diet including water, and the percent contribution to the PTWI (2,000 µg/kg bw/week).

Exposure combination	**Concentration of aluminium in water**	**Age (months)**			
		4 to 6		**6 to 9**	
		Exposure (µg/kg bw/week)	**% PTWI**	**Exposure (µg/kg bw/week)**	**% PTWI**
Mean breast milk plus mean total diet (incl. water)	Median (24 µg/L)	187	9	235	12
	97.5th percentile (100 µg/L)	187	9	245	12
97.5th percentile breast milk plus mean total diet (incl. water)	Median (24 µg/L)	215	11	308	15
	97.5th percentile (100 µg/L)	215	11	318	16
Mean breast milk plus **97.5th percentile total diet (incl. water)**	Median (24 µg/L)	437	22	575	29
	97.5th percentile (100 µg/L)	447	22	585	29

36. Table 12 shows the aggregate exposure estimates and contribution to the PTWI for infants aged 9 to 12, 12 to 15, and 15 to 18 months. The aggregate exposures for these age groups are based on the exposure estimates for breast milk, the total diet including water, and soil. The COT (2013) previously noted that absorption of various aluminium compounds is generally between 0.01 and 0.3%, with the more water-soluble compounds tending to be more bioavailable. The presence of some dietary constituents such as citrate, can enhance uptake by forming absorbable soluble complexes. It is likely that the forms of aluminium predominant in soil are the less water soluble forms such as alumina silicates. The solubility and mobility of aluminium in soil is greatest when the soil is rich in organic matter capable of forming aluminum-organic complexes and when the pH is low (ATSDR, 2008). A bioavailability factor relative to food has not been proposed.

37. For infants aged 9 to 12, 12 to 15, and 15 to 18 months, all of the aggregate exposures result in exceedances of the PTWI in the range of 2 to 3 times the PTWI.

Table 12. Aggregate exposures to aluminium for infants aged 9 to 18 months based on exposures from breast milk, the total diet including water, and soil, and the percent contribution to the PTWI (2,000 µg/kg bw/week).

Exposure combination	**Concentration of aluminium in water**	**Age (months)**					
		9 to 12		**12 to 15**		**15 to 18**	
		Exposure (µg/kg bw/week)	**% PTWI**	**Exposure (µg/kg bw/week)**	**% PTWI**	**Exposure (µg/kg bw/week)**	**% PTWI**
Mean breast milk plus mean total diet (incl. water) plus average soil	Median (24 µg/L)	4,481	224	4,386	219	4,264	213
	97.5th percentile (100 µg/L)	4,491	225	4,386	219	4,274	214
97.5th percentile breast milk plus mean total diet (incl. water) plus average soil	Median (24 µg/L)	4,524	226	4,411	221	4,279	214
	97.5th percentile (100 µg/L)	4,801	227	4,411	221	4,289	214
Mean breast milk plus **97.5th percentile total diet (incl. water)** plus average soil	Median (24 µg/L)	4,781	239	5,116	256	4,914	246
	97.5th percentile (100 µg/L)	4,801	240	5,116	256	4,914	246
Mean breast milk plus mean total diet (incl. water) **plus high level soil**	Median (24 µg/L)	6,081	304	5,876	294	5,664	283
	97.5th percentile (100 µg/L)	6,091	305	5,876	294	5,674	284

38. Table 13 shows the aggregate exposure estimates and the contribution to the PTWI for young children aged 18 to 24 and 24 to 60 months. The aggregate exposures for these age groups are based on the exposure estimates for the total diet including water, and soil, as breast milk is expected to contribute minimally in children older than 18 months. For children18 to 60 months old, all of the aggregate exposures result in exceedances of the PTWI, ranging between 161 and 273% of the PTWI.

Table 13. Aggregate exposures to aluminium for young children aged 18 to 60 months based on exposures from the total diet including water, and soil, and the percent contribution to the PTWI (2,000 µg/kg bw/week).

Exposure combination	**Concentration of aluminium in water**	**Age (months)**			
		18 to 24		**24 to 60**	
		Exposure (µg/kg bw/week)	**% PTWI**	**Exposure (µg/kg bw/week)**	**% PTWI**
Mean total diet (incl. water) plus average soil	Median (24 µg/L)	4,160	208	3,220	161
	97.5^{th} percentile (100 µg/L)	4,160	208	3,220	161
97.5^{th} percentile total diet (incl. water) plus average soil	Median (24 µg/L)	4,600	230	3,700	185
	97.5^{th} percentile (100 µg/L)	4,600	230	3,700	185
Mean total diet (incl. water) plus **high level soil**	Median (24 µg/L)	5,460	273	4,220	211
	97.5^{th} percentile (100 µg/L)	5,460	273	4,220	211

Table 14. Range of estimated exposures (µg/kg bw/week) to aluminium from ingested soil and comparison to the PTWI.

		Age (Months)				
		9 to 12	**12 to 15**	**15 to 18**	**18 to 24**	**24 to 60**
Estimated exposures (µg/kg bw/week)	Median concentration	4,200	3,800	3,600	3,400	2,500
	High level concentration	5,500	5,300	5,000	4,700	3,500
% PTWI	Median concentration	210	190	180	170	125
	High level concentration	275	265	250	235	175

39. These exceedances of the PTWI are due to the possible contribution from soil. Taking into account that much of the aluminium in soil is likely to be less bioavailable than that in food, and that the PTWI was derived from a study on aluminium citrate, which is one of the more bioavailable forms of aluminium, these exceedances of the PTWI are not clearly adverse, but there is uncertainty in this conclusion.

40. Because toxicity will depend on total exposure to aluminium from all sources, it is important to consider combined exposures from food, water, and also non-dietary sources. Drinking water seems to be a minor source of aluminium exposure compared to food. However exposure to aluminium present in soil/dust has the potential to exceed the PTWI (Table 14), and be the majority contributor to overall aggregate exposures. However, it should be noted that all measurements of aluminium do not distinguish between specific aluminium compounds, and the relative bioavailability of the species naturally present in soil or dust is unknown.

Conclusions

41. Aluminium is naturally present in the environment and is found in varying amounts in most foodstuffs. Levels in food are influenced by geographical region, and aluminium in soils is often in the form of oxides or aluminosilicates. In more acidic soils (pH < 5.5), aluminium may also exist as the trivalent cation Al3+ which is absorbable by soybean plants which prefer acidic soil.

42. In 2013, COT noted that the absorption of aluminium is dependent on a range of factors including other dietary constituents and the mineral status of the individual.

43. Estimated exposures have been compared to the PTWI of 2,000 µg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO, 2012).

44. In children aged up to 6 months, soya-based formula contributed approximately 10 times the aluminium compared to infant formula or breast milk; however exposures were still considerably below the PTWI. In infants aged 4 to 9 months, when the introduction of the adult diet occurs, combined dietary and breast milk exposures are only 30% of the PTWI based on a worst case high level exposure and are not considered of concern. Total exposures inclusive of infant formula for the age range 4 to 9 months were below the worst case aggregate exposure estimate for breast milk, and thus not considered to be of concern.

45. For infants and young children aged 9 to 18 months old combined exposures taking into account diet (inclusive of water), breast milk and soil exceed the PTWI by 2 to 3 fold. Aggregate exposures including diet (inclusive of water) and soil exceed the PTWI by 2/3 to almost 3 fold for young children aged 18 to 60 months old. Whilst normally such exceedances would be of concern to health, these exceedances are principally due to the contribution from soil, from which aluminium is likely to be less bioavailable. Furthermore, the PTWI was derived from a study on a more bioavailable form of aluminium, aluminium citrate. Therefore these exceedances of the PTWI are not clearly adverse, however there is uncertainty in this conclusion.

46. Overall, the estimated exposures of infants and young children to aluminium from the dietary sources that have been considered do not indicate toxicological concerns or a need for modified Government advice. The consumption of soya drink by infants and young children aged 6 to 60 months does not appreciably increase dietary aluminium exposure.

Secretariat
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