

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

### **Review of potential risks from lead in the diet of 1 to 5 year old children and updated exposures for infants aged 0 to 12 months**

#### **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, most of which has been completed, 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. The recommendations cover diet from birth to age five years, but are being considered in two stages, focussing first on infants aged 0 to 12 months, and now on advice for children aged 1 to 5 years.
2. There are currently no Government dietary recommendations for infants and young children which relate to lead.
3. The 2013 COT statement on potential risks from lead in the infant diet is included in Annex A<sup>1</sup>. This discussion paper provides estimated lead exposures for children in the UK aged 1 to 5 years and also provides an updated exposure assessment for infants because new data have become available since the COT statement.
4. The risks associated with exposure to lead are assessed in this discussion paper using the same approach as was taken for the infant diet in 2013, i.e. comparison with the dietary exposure level of 0.5 µg/kg bw/day. This exposure level was estimated by the European Food Safety Authority (EFSA) to correspond to the benchmark dose lower confidence limit (BMDL<sub>01</sub>) blood level associated with a decrease of 1 Intelligence Quotient (IQ) point (see Annex A).

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<sup>1</sup> <http://cot.food.gov.uk/sites/default/files/cot/cotstatlead.pdf>

5. There are no new reviews on lead from international bodies to consider updating or revising the toxicology section from the infant statement. When considering the risk assessment for the updated exposures the toxicology section and human health based guidance value explained in the 2013 COT statement are used.

## **Lead exposures in infants aged 0 to 12 months and young children aged 1 to 5 years**

### ***New data on sources of lead exposure***

#### *Human breast milk*

6. A literature search identified no new data for lead levels in breast milk in the UK since those in the 2013 COT statement on the potential risks of lead in the infant diet. Therefore the value of 2.6 µg/L, identified from the SUREmilk study (Woodridge *et al.*, 2004), is used for exposure estimates of lead in children aged 12 to 18 months. This was the highest concentration in an individual sample. The COT<sup>2</sup> had previously noted that the SUREmilk samples were collected primarily to explore the viability of breast milk collection methods, and not as part of a rigorous survey.

#### *Infant formulae and foods*

7. Levels of lead 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).

#### *Drinking water*

8. The Drinking Water Inspectorate publishes 1<sup>st</sup> and 99<sup>th</sup> percentile data from the water companies, which undertake water testing in England and Wales. The range of 99<sup>th</sup> percentiles across England and Wales in 2014 was <0.29 to 11.6 µg/L.

#### *Environmental*

##### Dust and soil

9. Concentrations of lead in soil were measured in 5,670 topsoil<sup>3</sup> samples collected between 1978 and 1982 in England and Wales, avoiding large urban areas. Samples were analysed 30 years later. (Rawlings *et al.*, 2012). The median and 90<sup>th</sup> percentile concentrations were 49 and 134 mg/kg, respectively. Concentrations of lead in soil were measured in 453 soil

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<sup>2</sup> <http://cot.food.gov.uk/sites/default/files/cot/cotsuremilk.pdf>

<sup>3</sup> From a depth of 0 to 15 cm

samples collected as part of the Environment Agency's Soil and Herbage Pollutant Survey (EA, 2007). The soil samples were collected from a variety of urban and rural sites across England, Scotland, Wales and Northern Ireland between 2001 and 2002 (SHS, 2007). Samples were also collected from industrial sites (e.g. power stations and incinerators); these samples have not been considered as exposure to soil at such sites is unlikely to occur in infants and young children. The median and 97.5<sup>th</sup> percentile concentrations of lead in the urban and rural soil samples were 41 and 250 mg/kg, respectively. Given the similarity in these results, the more recent SHS data from are used in the current exposure assessment.

## Air

10. Lead in particulate matter less than 10 µm (PM<sub>10</sub>) was measured at 23 sites and as metal deposition was measured at 5 sites across the UK in 2014. Median values from these sites ranged from 1.2 to 31.2 ng/m<sup>3</sup> and 99<sup>th</sup> percentile values ranged from 2.3 to 642 ng/m<sup>3</sup>. This high 99<sup>th</sup> percentile value is skewed by one data point of 1067 ng/m<sup>3</sup>.

## Exposure

11. 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 lead 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

12. Since no new data were available on breastmilk, the estimated exposures of exclusively breastfed infants, aged 0-6 months, are as in the 2013 COT statement. Data on breast milk consumption have now become available from DNSIYC and NDNS and these were used in estimating exposure from breastmilk in the 6-18 months age groups based on the maximum lead level of 2.6 µg/L (Table 1). 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 1. Lead exposure from breastfeeding estimated for mean and 97.5<sup>th</sup> percentile level consumption of breast milk containing lead at 2.6 µg/L.

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It does not reflect the views of the Committee and should not be cited.

Age group (months)	Number of consumers	Exposure ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	
		Mean	97.5 <sup>th</sup> percentile
>6 to 9	140	0.2	0.4
>9 to 12	124	0.1	0.3
12 to 15	66	0.1	0.2
15 to 18	32	0.1	0.1

### Infant formulae

13. Exposure estimates for this age category were derived using occurrence data from the FSA's survey of metals in infant formulae and food and consumption data from DNSIYC.

14. Possible lead exposure levels from infant formulae were calculated for infants up to 4 months of age assuming exclusive feeding on formula, and for infants and children aged 4.0 to <18.0 months using DNSIYC consumption data. Mean exposures for 4.0 to <12 months ranged from 0.00-0.02  $\mu\text{g}/\text{kg bw}/\text{day}$  and 97.5<sup>th</sup> percentile exposures ranged from 0.00-0.05  $\mu\text{g}/\text{kg bw}/\text{day}$ , respectively (Table 2).

Table 2: Estimated lead exposures ( $\mu\text{g}/\text{kg bw}/\text{day}$ ) from infant formulae, commercial infant foods and other foods (excluding water) in infants aged 12 to 18 months

Food	Lead – LB - UB Range ( $\mu\text{g}/\text{kg bw}/\text{day}$ )							
	0 to 3.99 Months <sup>a</sup>		4 to 5.99 Months (n=116)		6 to 8.99 Months (n=606)		9 to 11.99 Months (n=686)	
	800 mL	1200 mL	Mean	97.5th	Mean	97.5th	Mean	97.5th
<b>Infant Formula</b>	0.02-0.08	0.03-0.12	0.00-0.01	0.00-0.05	0.00-0.02	0.00-0.05	0.00-0.02	0.00-0.05
<b>Commercial Infant Foods</b>	N/A		0.02-0.04	0.12-0.16	0.04-0.05	0.15-0.21	0.03-0.05	0.14-0.19
<b>Other Foods</b>	N/A		0.02-0.03	0.12-0.14	0.04-0.05	0.12-0.15	0.04-0.06	0.12-0.16
<b>Total (excluding water)</b>	N/A		0.05-0.07	0.18-0.23	0.08-0.13	0.18-0.27	0.07-0.12	0.18-0.27

<sup>a</sup> 0 to 3.99 months is not recorded in DNSIYC. Exposure estimates were derived using the occurrence data for First Milk Infant Formula with default values for mean (800mL) and high level (1200mL) consumption, assuming exclusive feeding on infant formula

## Food

15. Table 2 also shows lead exposures from infant formula, commercial infant foods, and other foods commonly consumed as complementary foods, calculated for children aged 4 to 12 months. The overall possible mean and 97.5<sup>th</sup> percentile lead exposures ranged from 0.05-0.13 and 0.18-0.27 µg/kg bw/day, respectively.

### *Children aged 12 to 18 months*

16. Exposure estimates for these age groups were derived using occurrence data from the infant metals survey and the 2014 TDS; the basis for each survey is explained in Annex B. In brief, the exposure data derived from the infant survey allow estimation of lead exposure in infant formula and foods as sold, whereas the results for the TDS are based on analysis of food that is prepared as for consumption. In addition, 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

17. The ranges of mean and 97.5<sup>th</sup> percentile exposures from infant formula, commercial infant foods and other foods were 0.06-0.11 and 0.13-0.23 µg/kg bw/day, respectively (Table 3).

Table 3. Estimated lead exposures from infant formulae, commercial infant foods and other foods in infants aged 12 to 18 months using data from the FSA infant foods survey

Food	Lead - LB-UB Range (µg/kg bw/day)			
	12 to 14.99 Months (n=670)		15 to 17.99 Months (n=605)	
	Mean	97.5th	Mean	97.5th
<b>Infant Formulae</b>	0.00-0.01	0.00-0.03	0.00-0.01	0.00-0.03
<b>Commercial Infant Foods</b>	0.02-0.03	0.10-0.15	0.01-0.02	0.07-0.08
<b>Other Foods</b>	0.05-0.08	0.12-0.17	0.05-0.08	0.10-0.15
<b>Total (excluding water used in reconstitution)</b>	0.06-0.11	0.15-0.23	0.06-0.10	0.13-0.19

Exposure estimates based on the TDS

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18. Table 4 shows the possible lead exposures that were calculated using the 27 and 25 Group TDS data for children aged 12 to 18 months. A more detailed breakdown of individual food groups for the 27 and 25 TDS can be found in Annex B. This approach was taken in order to allow the potential impact of lead levels in water to be assessed. The exposure data derived from the TDS are higher than those estimated from the infant metal survey. This is due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the infant metal survey

19. In the 27 Group TDS (which includes tap water and bottled water), total mean and 97.5<sup>th</sup> percentile lead exposures from a combination of all food groups ranged from 0.14-0.29 and 0.29-0.49, respectively. In the 25 Group TDS (excluding tap water and bottled water), total mean and 97.5<sup>th</sup> percentile lead exposures from a combination of all food groups ranged from 0.14-0.28 and 0.29-0.48 µg/kg bw/day, respectively. Thus in the TDS samples, the concentration of lead in drinking water (< 0.8 µg/L) had a negligible impact on total dietary exposure. Adding the upper end of the range of high-level exposure to lead from drinking water (0.54 µg/kg bw/day from Table 6 below) to upper bound mean and high-level exposure to lead from the 25 group TDS for 15 to 17.99 months old infants results in a combined mean and high-level exposure of 0.82 and 1.02 µg/kg be/day. The latter estimate is particularly conservative as it would be unlikely that a high-level consumer of drinking water containing a lead concentration at the upper range of the 99<sup>th</sup> percentile (11.6 µg/L) to also be a high-level consumer of the foods in the 25 group TDS. The combined estimate for exposure to lead from the 25 group TDS in addition to drinking water does not take account of the contribution from water used by the research laboratory (0.14 µg/L which is below the LOQ of 0.29 µg/l) for the cooking of food samples.

20. The food group with the highest contribution to lead exposure in the TDS was milk, followed by the dairy products, fresh fruit, miscellaneous cereals and non-alcoholic beverages food groups (see Annex B).

Table 4. Estimated lead exposures from the total diet for the 27 and 25 group TDS in infants aged 12 to 18 months

Food Group	Lead - LB - UB Range (µg/kg bw/day)			
	12 to 14.99 Months (n=670)		15 to 17.99 Months (n=605)	
	Mean	97.5th	Mean	97.5th
<b>27 Groups</b>	0.14-0.26	0.29-0.46	0.15-0.29	0.29-0.49
<b>25 Groups</b>	0.14-0.26	0.29-0.45	0.15-0.28	0.29-0.48

*Children aged 18 months to 5 years*

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

## TDS

22. Table 5, shows the possible lead exposures that were calculated using the 27 and 25 group TDS data for children aged 18 months to 5 years. A more detailed breakdown of individual food groups for the 27 and 25 TDS can be found in Annex C. Again, the exposure data derived from the TDS are higher than those estimated from the infant metal survey, due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the infant metal survey.

23. In the 27 Group TDS, total mean and 97.5<sup>th</sup> percentile lead exposures from a combination of all food groups ranged from 0.15-0.32 and 0.25-0.48 µg/kg bw/day, respectively. In the 25 Group TDS, total mean and 97.5<sup>th</sup> percentile lead exposures from a combination of all food groups ranged from 0.15-0.31 and 0.25-0.47 µg/kg bw/day, respectively. Thus again, the concentration of lead in tap water in the TDS samples (< 0.8 µg/L) had a negligible impact on total dietary exposure. Adding the upper end of the range of high-level exposure to lead from drinking water (0.73 µg/kg bw/day from Table 6 below) to upper bound mean and high-level exposure to lead from the 25 group TDS for 18 to 24 months old infants results in a combined mean and high-level exposure of 1.04 and 1.20 µg/kg be/day. The latter estimate is particularly conservative as it would be unlikely that a high-level consumer of drinking water containing a lead concentration at the upper range of the 99<sup>th</sup> percentile (11.6 µg/L) to also be a high-level consumer of the foods in the 25 group TDS. The combined estimate for exposure to lead from the 25 group TDS in addition to drinking water does not take account of the contribution from water used by the research laboratory (0.14 µg/L which is below the LOQ of 0.29 µg/L) for the cooking of food samples.

24. As for the 12-18 month age group, the food groups with the highest contribution to lead exposure were milk, followed by the dairy fresh fruit, miscellaneous cereals and non-alcoholic beverages food groups (see Annex C).

Table 5. Estimated lead exposures from the total diet for the 27 and 25 group TDS in infants aged 18 months to 5 years

Food Groups	Lead – LB - UB Range (µg/kg bw/day)			
	18 to 24 Months (n=70)		24 to 60 months (n=429)	
	Mean	97.5th	Mean	97.5th
<b>27 Groups</b>	0.16-0.32	0.25-0.48	0.15-0.27	0.25-0.44
<b>25 Groups</b>	0.16-0.31	0.25-0.47	0.15-0.26	0.25-0.43

## Drinking water

25. Lead exposures from drinking water and water used in preparation of beverages for infants aged 4 to 12 months and young children aged 1 to 5



years have been calculated using the range of 99<sup>th</sup> percentile values of <0.29 µg/L to 11.6 µg/L (paragraph 8). The consumption data for infants aged 4 to 12 months were consumer only data from DNSIYC. The possible exposures in Table 6 show a very wide range depending on the source of tap water. At the lower end of the ranges, the possible exposures are much lower than from food. At the upper end of the range of 99<sup>th</sup> percentile values, exposure could exceed that from food, but the extent to which consumers are routinely exposed at this level is unclear. For example, tap water could have been sampled without allowing the water to flush through.

Table 6. Possible lead exposures from drinking water in infants and children aged 0 to 5 years

Age group (months)	Number of consumers	Exposure range (µg/kg bw/day)	
		Mean	97.5 <sup>th</sup> percentile range
4 to 6	77	<0.001 - 0.053	<0.004 - 0.173
6 to 9	490	<0.003 - 0.110	<0.010 - 0.391
9 to 12	597	<0.004 - 0.140	<0.012 - 0.473
12 to 15	558	<0.004 - 0.15	<0.012 - 0.491
15 to 18	503	<0.004 - 0.168	<0.013 - 0.538
18 to 24	198	<0.005 - 0.182	<0.018 - 0.733
24 to 60	364	<0.004 - 0.154	<0.013 - 0.524

26. Water used to reconstitute dry formula provides another source of lead exposure from drinking water. Consumption estimates of this source of drinking water (used to reconstitute dry formula) were derived using a reconstitution factor of 6.67; with 85 percent of the reconstituted formula being water. Exposure to lead from this source has been estimated in table 7 below. Since DNSIYC does not cover infants aged 0 to 4 months, a scenario was assumed in which infants are exclusively fed on infant formula, consisting of 85 per cent water, at the default values for milk consumption used by EFSA (2012): 800 mL (mean) and 1200 mL (high level). This approach is consistent with that used by COT in its 2013 statement. There is likely to be double counting of the values in tables 6 and 7, and therefore the total exposure from these sources should not be summed. The highest of the values is used in the risk characterisation in this discussion paper.

Table 7: Possible lead exposures from drinking water used to make up dry infant formula by infants and children aged 0 to 5 years

Age group (months)	Number of consumers	Exposure range (µg/kg bw/day)	
		Mean	97.5 <sup>th</sup> percentile



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0 to 4	N/A	<0.033 – 1.339*	<0.050 – 2.007*
4 to 6	3	<0.003 – 0.115	<0.003 – 0.127
6 to 9	18	<0.007 - 0.288	<0.023 - 0.938
9 to 12	35	<0.005 – 0.187	<0.015 – 0.590
12 to 15	8	<0.004 – 0.170	<0.012 – 0.486
15 to 18	2	<0.010 – 0.408	<0.011 – 0.459
18 to 24	6	<0.004 – 0.149	<0.005 – 0.218
24 to 60	4	<0.008 – 0.302	<0.013 – 0.528

- Assumed average and high level consumption of 800 and 1200 mL

### Soil/dust

27. Potential exposures of UK infants aged >9 to 12 months and young children aged 1 to 5 years to lead in soil and/or dust were calculated assuming ingestion of 100 mg/day (US EPA, 2008; WHO, 2007) and median and 97.5th percentile lead concentrations of 41 and 250 mg/kg reported for soil (EA, 2007) (Table 8). 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 8. Possible lead exposures ( $\mu\text{g}/\text{kg bw}/\text{day}$ ) from soil and/or dust in infants and young children aged > 9 months to 5 years

Lead concentration (mg/kg)	Ages (months)				
	>9 to 12	12 to 15	15 to 18	18 to 24	24 to 60
41 (median)	0.43	0.39	0.37	0.34	0.25
250 (97.5 <sup>th</sup> percentile)	2.6	2.4	2.2	2.1	1.6

### Air

28. Potential exposures of UK infants aged 0 to 12 months and young children aged 1 to 5 years to lead in air were calculated (Table 9) assuming mean ventilation rates of 3.6, 4.1, 5.4, 8.0, 9.5 and 10.9 m<sup>3</sup>/day, respectively for infants and children aged 0 to <1, 3 to <6 and 6 to <12 months and 1 to <2, 2 to <3 and 3 to <6 years (US EPA, 2008). The lead concentrations used in the exposure calculations were the lowest and highest median values and lowest and highest 99<sup>th</sup> percentile values of 1.2, 31.3, 2.3 and 642 ng/m<sup>3</sup>, respectively from the monitoring sites in the UK (paragraph 10).

Table 9. Estimated UK exposure to lead ( $\mu\text{g}/\text{kg bw}/\text{day}$ ) in infants and young children from the air

Lead concentration	Ages (months)
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(ng/m <sup>3</sup> )	0 to <3	3 to <6	6 to <12	12 to <24*	24 to <36*	36 to <72*
1.2 (lowest median value)	0.0007	0.0006	0.0007	0.0007	0.0008	0.0007
31.2 (highest median value)	0.019	0.016	0.018	0.019	0.020	0.017
2.3 (lowest 99 <sup>th</sup> percentile value)	0.0014	0.001	0.0014	0.0014	0.0015	0.0013
642 (highest 99 <sup>th</sup> percentile value)	0.392	0.337	0.376	0.380	0.404	0.350

\*Based on average bodyweights of 13.5, 15.1 and 19.7 kg at these ages.

### Risk Characterisation

29. Potential risks from infants' exposures to lead were characterised by margins of exposure (MOEs), calculated as the ratio of the BMDL of 0.5 µg/kg bw/day to estimated exposures from diet, soil and air. The COT previously concluded that *“as the BMDL was for a small effect (a one-point difference in IQ), derived from pooled analysis of multiple cohort studies of exposures in infants and children, and is likely to be conservative, an MOE of >1 can be taken to imply that at most, any risk is likely to be small. MOEs <1 do not necessarily indicate a problem, but scientific uncertainties (e.g. because of potential inaccuracies in the assessment of exposures, failure to control completely for confounding factors, and the possibility that the samples of children studied have been unrepresentative simply by chance) mean that a material risk cannot be ruled out. This applies particularly when MOEs are substantially <1”*.

30. MOEs based on the estimated dietary exposures are shown in Table 10 and, with the exception of breast milk as noted in the 2013 statement, are in the region of or greater than 1. Estimates of exposure from drinking water range from very low to 0.7 µg/kg bw/day and from water used in reconstituting infant formula range from very low to 2 µg/kg bw/day. Thus in some instances the MOE could be down to 0.25. However, as noted above, it is not clear whether such exposures commonly occur.

Table 10. Estimated dietary exposures and MOEs compared to the BMDL<sub>01</sub> for neurodevelopmental effects of lead.

Food	Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE	
		Average consumers	High level consumers	Average consumers	High level consumers
Exclusive breast milk	0 to 4	0.35	0.53	2.9	0.9

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Exclusive infant formula	0 to 4	< 0.08 <sup>a</sup>	< 0.12 <sup>a</sup>	> 6	> 4
Total diet (excluding water)	4 to 12	< 0.13 <sup>b</sup>	< 0.27 <sup>b</sup>	> 3	> 1.9
	12 to 18	< 0.28 <sup>b</sup>	< 0.48 <sup>b</sup>	> 1.8	> 1
	18 to 24	< 0.31 <sup>b</sup>	< 0.47 <sup>b</sup>	> 1.5	> 1.1
	24 to 60	< 0.26 <sup>b</sup>	< 0.43 <sup>b</sup>	> 1.9	> 1.2

<sup>a</sup> Based on highest upper bound estimate for the age range

<sup>b</sup> Based on highest upper bound estimate for the age range, which is from the TDS. The MOE is calculated by dividing the BMDL<sub>01</sub> of 0.50 µg/kg bw/day by the respective dietary exposure

31. Because toxicity will depend on total exposure to lead from all sources, it is important to consider combined exposures from food, water, and also non-dietary sources. Table 11 summarises MOEs for estimates of exposure from soil and/or dust, assuming concentrations of lead at the median and p7.5<sup>th</sup> percentile of reported ranges. By comparison exposures from air are negligible.

32. Table 11. Range of estimated exposures to lead from soil/dust and corresponding MOEs compared to the BMDL<sub>01</sub> for neurodevelopmental effects of lead.

Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE	
	Median concentration	High level concentration	Median concentration	High level concentration
9 to 12	0.43	2.6	1.2	0.2
12 to 15	0.39	2.4	1.3	0.4
15 to 18	0.37	2.2	1.4	0.4
18 to 24	0.34	2.1	1.5	0.3
24 to 60	0.25	1.6	2	0.25

The MOE is calculated by dividing the BMDL<sub>01</sub> of 0.50 µg/kg bw/day by the respective exposure

These comparisons assume equivalent absorption from different sources.

33. There are uncertainties in the assessment of risks to infants and young children from exposure to lead because quantification of exposures may not always have been accurate in the epidemiological studies used to characterise hazard, confounding factors may not have been fully taken into

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account, and the samples of children studied may have been unrepresentative by chance.

34. When allowance is made for these uncertainties, it appears that total exposure to lead is unlikely to pose a material risk to health in the large majority of UK infants and young children. However, there remains a concern that adverse effects could occur where concentrations of lead in water or soil are unusually high.

### **Questions on which the views of the Committee are sought**

35. Members are invited to comment on the exposure calculations and to answer the following questions.

- i. How should the lead content of water be taken into account in the exposure calculations?
- ii. Should the new information be formulated as an addendum to the 2013 statement or would members prefer a complete statement?
- iii. Do Members agree with the approach to exposure assessment?
- iv. Should additional information, for example on concentrations of lead in food, be included?
- v. Do Members agree with the draft conclusions in paragraphs 33 and 34, which are the key conclusions from the 2013 statement extended to include children aged 1 to 5 years?

**Secretariat**  
**November 2015**

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## References

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This is a background paper for discussion.  
It does not reflect the views of the Committee and should not be cited.

**TOX/2015/37 ANNEX A**

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

**Review of potential risks from lead in the diet of 1 to 5 year old children  
and updated exposures for infants aged 0 to 12 months**

**Statement on the potential risks from lead in the infant diet**

<http://cot.food.gov.uk/sites/default/files/cot/cotstatlead.pdf>

**Secretariat  
November 2015**

TOX/2015/37 ANNEX B

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

**Review of potential risks from lead in the diet of 1 to 5 year old children  
and updated exposures for infants aged 0 to 12 months**

*Possible lead exposure from dietary sources in children aged 12 to 18 months*

Two surveys were conducted during 2014 to measure the concentrations of elements in food consumed by infants and young children. The first survey was a total diet study (TDS) which focused on sampling foods eaten by young children (18 months and older) and the other was a survey on types of foods eaten by infants younger than 18 months (referred to as the Infant Survey).

The TDS consist of: (i) selecting foods based on food consumption data, to represent as best as possible a typical diet; (ii) their preparation to food as consumed and (iii) the subsequent pooling of related foods before analysing the composite samples for elements.

The Infant Survey on the other hand measured the concentrations of metals and other elements in food 'as sold', in the following categories: , infant formula commercial infant foods and groups of food comprising the top 50 most commonly consumed varieties of foods not specifically marketed for infants (see tables B1-B3).

Table B1. Infant formula

<b>Infant Formula</b>	
<b>Dry Powder</b>	<b>Made Up Formula</b>
First and Hungrier Milk	First Milk and Hungrier Milk
Follow On Milk	Follow On milk
Growing Up Milk	Growing up Milk
Soy Milk	
Goat Milk	
Organic Milk	
Comfort Milk	

Table B2. Commercial infant foods



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<b>Commercial Infant Foods</b>
Cereal Based Foods and Dishes
Dairy Based Foods and Dishes
Fruit Based Foods and Dishes
Meat and Fish Based Foods and Dishes
Snacks (Sweet and Savoury)
Other Savoury Based Foods and Dishes (excluding Meat)
Drinks

Table B3. Other foods commonly eaten by infants.

<b>Other Foods</b>	
Beverages	Fruit Products
Bread	Green Vegetables
Canned Vegetables	Meat Products
Cereals	Milk
Dairy Products	Other Vegetables
Eggs	Potatoes
Fish	Poultry/Chicken
Fresh Fruit	

### ***Exposure Assessments***

Tables B4 and B5 summarise lower- and upper-bound total dietary exposures to lead using the 27 groups of the 2014 TDS for ages 12 to 18 months. The data for each food category is reported separately so that the contribution to exposure from each class could be assessed more transparently for the most relevant infant age group. In addition the total exposure from the diet has also been provided.

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It does not reflect the views of the Committee and should not be cited.

Table B4. Estimated lead exposures from food eaten by infants aged 12 to 18 months using data from 27 TDS Groups

Food Group	Lead - LB - UB Range ( $\mu\text{g}/\text{kg bw}/\text{day}$ )			
	12 to 14.99 Months (n=670)		15 to 17.99 Months (n=605)	
	Mean	97.5th	Mean	97.5th
Alcoholic drinks	0	0	0	0
Bottled water	0	0	0	0.00-0.01
Bread	0.02	0.04	0.02	0.05
Canned vegetables	0.01	0.04	0.01	0.04
Carcase meat	0	0.00-0.02	0	0.00-0.02
Condiments	0	0.02	0	0.02
Dairy products	0.03	0.16	0.03	0.11
Desserts	0	0.01	0	0.01
Eggs	0	0.00-0.01	0	0.00-0.01
Fats and oils	0	0	0	0
Fish	0	0.02	0	0.02
Fresh fruit	0.00-0.02	0.00-0.08	0.00-0.03	0.00-0.08
Fruit products	0.01	0.07	0.01	0.07
Green vegetables	0.02	0.08	0.02	0.07
Meat products	0	0.02	0	0.02
Meat substitutes	0	0	0	0
Milk	0.00-0.05	0.00-0.15	0.00-0.05	0.00-0.13
Miscellaneous cereals	0.02	0.07	0.03	0.08
Non Alcoholic beverages	0.00-0.02	0.00-0.11	0.00-0.03	0.00-0.14
Nuts	0	0	0	0
Offal	0	0	0	0
Other vegetables	0.02	0.06	0.02	0.05
Potatoes	0.00-0.01	0.00-0.05	0.00-0.01	0.00-0.04
Poultry	0	0.01	0	0.01
Snacks	0	0.01	0	0.01
Sugars	0	0.01	0	0.02
Tap water	0.00-0.01	0.00-0.03	0.00-0.01	0.00-0.04
<b>Total</b>	<b>0.14-0.26</b>	<b>0.29-0.46</b>	<b>0.15-0.29</b>	<b>0.29-0.49</b>

### **Possible lead exposures from other foods**

The food groups “bottled water” and “tap water” (drinking water) were removed from the 27-group TDS in order to create a 25-group TDS. The exposures from drinking water were estimated separately and discussed in the main body of the paper. This was to account for the variability in occurrence levels of lead found in various locations across the UK.

Table B5. Estimated lead exposures from foods eaten by infants aged 12 to 18 months using data from 25 TDS Groups.

Food Groups	Lead – LB - UB Range ( $\mu\text{g}/\text{kg bw}/\text{day}$ )			
	12 to 14.99 Months (n=670)		15 to 17.99 Months (n=605)	
	Mean	97.5th	Mean	97.5th
Alcoholic drinks	0	0	0	0
Bread	0.02	0.04	0.02	0.05
Canned vegetables	0.01	0.04	0.01	0.04
Carcase meat	0	0.00-0.02	0	0.00-0.02
Condiments	0	0.02	0	0.02
Dairy products	0.03	0.16	0.03	0.11
Desserts	0	0.01	0	0.01
Eggs	0	0.00-0.01	0	0.00-0.01
Fats and oils	0	0	0	0
Fish	0	0.02	0	0.02
Fresh fruit	0.00-0.02	0.00-0.08	0.00-0.03	0.00-0.08
Fruit products	0.01	0.07	0.01	0.07
Green vegetables	0.02	0.08	0.02	0.07
Meat products	0	0.02	0	0.02
Meat substitutes	0	0	0	0
Milk	0.00-0.05	0.00-0.15	0.00-0.05	0.00-0.13
Miscellaneous cereals	0.02	0.07	0.03	0.08
Non-alcoholic beverages	0.00-0.02	0.00-0.11	0.00-0.03	0.00-0.14
Nuts	0	0	0	0
Offal	0	0	0	0
Other vegetables	0.02	0.06	0.02	0.05
Potatoes	0.00-0.01	0.00-0.05	0.00-0.01	0.00-0.04
Poultry	0	0.01	0	0.01
Snacks	0	0.01	0	0.01
Sugars	0	0.01	0	0.02
<b>Total</b>	<b>0.14-0.26</b>	<b>0.29-0.45</b>	<b>0.15-0.28</b>	<b>0.29-0.48</b>

**Secretariat  
November 2015**

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

### Review of potential risks from lead in the diet of 1 to 5 year old children and updated exposures for infants aged 0 to 12 months

*Possible lead exposure from dietary sources in young children aged 18 to 60 months*

Possible lead exposures from adult foods

#### TDS

The concentrations of 26 elements, including metals were measured in the 2014 UK TDS. Composite samples for 27 TDS food groups (Table 1) were collected from 24 UK towns and analysed for their levels of lead and other elements. Where appropriate, tap water was used in the preparation and cooking of food samples. The results from this survey were used together with food consumption data from the Diet and Nutrition Survey for Infants and Young Children (DNSIYC) (DH, 2013) for ages 12 to 18 months and the National Diet and Nutrition Survey Rolling Programme years 1-4 (NDNS) (Bates *et al.*, 2014) for age 18 months to 5 years, to estimate dietary exposures.

Table C1. Food groups used for analysis of 26 elements in the 2014 TDS

<b>TDS Food Groups*</b>	
Bread	Fresh Fruit
Miscellaneous Cereals	Fruit Products
Carcase Meat	Non Alcoholic Beverages
Offal	Milk
Meat Products	Dairy Products
Poultry	Nuts
Fish	Alcoholic Drinks
Fats and Oils	Meat Substitutes
Eggs	Snacks
Sugars	Desserts
Green Vegetables	Condiments
Potatoes	Tap Water
Other Vegetables	Bottled Water
Canned Vegetables	

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\*Food samples representative of the UK diet are purchased throughout the year in 24 towns covering the UK and 137 categories of foods are combined into 27 groups of similar foods for analysis

### ***Exposure Assessment***

Tables C2 and C3 summarise lower- and upper-bound total dietary exposures to lead using the 27 groups of the 2014 TDS for ages 18 months to 5 years. The data for each food category is reported separately so that the contribution to exposure from each class could be assessed more transparently for the most relevant infant age group. In addition the total exposure from the total diet has been provided.

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It does not reflect the views of the Committee and should not be cited.

Table C2. Estimated lead exposures from food eaten by infants aged 18 to 60 months using data from 27 groups of the 2014 Total Diet Study

Food Groups	Lead – LB - UB Range ( $\mu\text{g}/\text{kg bw}/\text{day}$ )			
	18 to 24 Months (n=70)		24 to 60 months (n=429)	
	Mean	97.5th	Mean	97.5th
Alcoholic drinks	0	0	0	0
Bottled water	0	0	0	0.00-0.01
Bread	0.02	0.04	0.02	0.05
Canned vegetables	0.01	0.05	0.01	0.03
Carcase meat	0.00-0.01	0.00-0.03	0	0.00-0.02
Condiments	0	0.02	0.01	0.03
Dairy products	0.03	0.13	0.02	0.06
Desserts	0	0.01	0	0.01
Eggs	0	0.00-0.01	0	0.00-0.01
Fats and oils	0	0	0	0
Fish	0	0.02	0	0.01
Fresh fruit	0.00-0.03	0.00-0.09	0.00-0.02	0.00-0.06
Fruit products	0.02	0.09	0.02-0.02	0.1
Green vegetables	0.02	0.1	0.02	0.07
Meat products	0.01	0.03	0.01	0.02
Meat substitutes	0	0	0	0
Milk	0.00-0.05	0.00-0.15	0.00-0.03	0.00-0.10
Miscellaneous cereals	0.03	0.06	0.02	0.06
Non-alcoholic beverages	0.00-0.04	0.00-0.16	0.00-0.04	0.00-0.11
Nuts	0	0	0	0
Offal	0	0	0	0
Other vegetables	0.01	0.03	0.01	0.04
Potatoes	0	0.00-0.03	0.00-0.01	0.00-0.04
Poultry	0	0.01	0	0.01
Snacks	0	0.01	0	0.01
Sugars	0	0.02	0.01	0.02
Tap water	0.00-0.01	0.00-0.05	0.00-0.01	0.00-0.03
<b>Total</b>	<b>0.16-0.32</b>	<b>0.25-0.48</b>	<b>0.15-0.27</b>	<b>0.25-0.44</b>

### **Possible lead exposures from other foods**

The food groups “bottled water” and “tap water” (drinking water) were removed from the 27-group TDS in order to create a 25-group TDS. The exposures from drinking water were estimated separately and discussed in the main body of the paper. This was to account for the variability in occurrence levels of lead found in various locations across the UK.

Table C3. Estimated lead exposures from foods eaten by infants aged 18 to 60 months using data from 25 TDS Groups

Food Groups	Lead – LB - UB Range ( $\mu\text{g}/\text{kg bw}/\text{day}$ )			
	18 to 24 Months (n=70)		24 to 60 months (n=429)	
	Mean	97.5th	Mean	97.5th
Alcoholic drinks	0	0	0	0
Bread	0.02	0.04	0.02	0.05
Canned vegetables	0.01	0.05	0.01	0.03
Carcase meat	0.00-0.01	0.00-0.03	0	0.00-0.02
Condiments	0	0.02	0.01	0.03
Dairy products	0.03-0.03	0.13	0.02	0.06
Desserts	0	0.01	0	0.01
Eggs	0	0.00-0.01	0	0.00-0.01
Fats and oils	0	0	0	0
Fish	0	0.02	0	0.01
Fresh fruit	0.00-0.03	0.00-0.09	0.00-0.02	0.00-0.06
Fruit products	0.02	0.09	0.02	0.1
Green vegetables	0.02	0.1	0.02	0.07
Meat products	0.01	0.03	0.01	0.02
Meat substitutes	0	0	0	0
Milk	0.00-0.05	0.00-0.15	0.00-0.03	0.00-0.10
Miscellaneous cereals	0.03	0.06	0.02	0.06
Non-alcoholic beverages	0.00-0.04	0.00-0.16	0.00-0.04	0.00-0.11
Nuts	0	0	0	0
Offal	0	0	0	0
Other veg	0.01	0.03	0.01	0.04
Potatoes	0.00-0.01	0.00-0.03	0.00-0.01	0.00-0.04
Poultry	0	0.01	0	0.01
Snacks	0	0.01	0	0.01
Sugars	0	0.02	0.01	0.02
<b>Total</b>	<b>0.16-0.31</b>	<b>0.25-0.47</b>	<b>0.15-0.26</b>	<b>0.25-0.43</b>

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