

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

**First draft addendum to the 2013 COT statement on potential
risks from lead 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 lead occurrence data required an update of the exposures in the statement on the potential risks from lead 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 lead (TOX/2015/37) was presented to Members in December 2015.

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

**Secretariat
January 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 lead 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, 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. In 2013 the COT issued a statement on potential risks from lead in the infant diet¹. This addendum to the 2013 statement updates the lead exposures for infants because new data have become available, and provides exposure assessments for children aged 1 to 5 years. There are currently no Government dietary recommendations for infants and young children that relate to lead.

3. The risks associated with exposure to lead are assessed in this addendum using the same approach as was taken for the infant diet in 2013, i.e. calculated exposures from a variety of sources are compared to 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 (BMDL₀₁) blood level associated with a decrease of 1 Intelligence Quotient (IQ) point. (EFSA, 2010).

¹ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2013/lead>

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

New data on sources of lead exposure

4. 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 (Woolridge *et al.*, 2004), is used for exposure estimates of lead in children aged 12 to 18 months.
5. 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).
6. Median and 97.5th percentile values concentrations of lead 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 < 1.0 and 9.5 µg/L, respectively.

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

	Number of samples	Median	97.5 th percentile
England and Wales	12,000	< 1.0*	5.0
Northern Ireland	390	0.2	9.5
Scotland	1500	0.2	4.2

* The calculated value was <1.0. However a value of 1.0 will be used in the exposure assessment.

7. Concentrations of lead in soil were measured in 453 UK urban and rural soil samples collected between 2001 and 2002. The median and 97.5th percentile concentrations of lead in the urban soil samples were 93 and 310 mg/kg, respectively and in rural soil samples were 37 and 180 mg/kg, respectively (EA, 2007).
8. Lead concentrations were measured in 554 air samples in particulate matter less than 10 µm (PM10) and as metal deposition at 23 and 5 sites, respectively, across the UK in 2014. Median values from these sites ranged from 1.2 to 31 ng/m³ and 97.5th percentile values ranged from 2.3 to 230 ng/m³. However, this high 97.5th percentile value is skewed by one data point of 1100 ng/m³. No data were identified specifically relating to dust.

Exposure

9. 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

10. Since no new data were available for breast milk, the estimated exposures of exclusively breastfed infants, aged 0-6 months, are as in the 2013 COT statement (Table 2).

11. Data on breast milk consumption have now become available from DNSIYC and NDNS and these were used in estimating exposure from breast milk in the 6-18 months age groups based on the maximum lead level of 2.6 µg/L (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. Lead exposure (µg/kg bw/day) from breastfeeding estimated for mean and 97.5th percentile level consumption of breast milk containing lead at 2.6 µg/L.

	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	124	66	32
Mean	0.35	0.27	0.2	0.1	0.1	0.1
High level	0.53	0.40	0.4	0.3	0.2	0.1

^a Mean and high level lead exposures were based on exclusive breastfeeding and consumption of 800 and 1200mL, respectively (COT, 2013).

^b High level is 97.5th percentile

Infant formulae and complementary food

12. Exposure estimates were derived using occurrence data from the FSA's survey of metals in infant formulae and food, and consumption data from DNSIYC.

13. Possible lead 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 (1200mL) consumption, in line with previous COT evaluations. The contribution to exposure arising from water used to reconstitute powdered infant formulae was calculated using a value of 1.0 µg/L to represent the highest median value and 9.5 µg/L as the highest 97.5th percentile value (from Table 1).

Table 3: Estimated lead exposures (µg/kg bw/day) from exclusive first-milk infant formula for 0 to 3.99 months

Infant Formula Types	Lead – LB - UB Range (µg/kg bw/day)	
	800 mL	1200 mL
Ready to Feed	0.00-0.05 ^c	0.00-0.07 ^c
Dry Powder ^a	0.02-0.08 ^d	0.03-0.12 ^d
Dry Powder + water with lead at median level (1 µg/L) ^b	0.14-0.20	0.20-0.29
Dry Powder + water with lead at 97.5 th percentile level (9.5µg/L) ^b	1.1-1.2	1.7-1.8

^a Exposure does not include the contribution from water

^b Determined by applying a factor of 0.85 to default formula consumption of 800mL and 1200mL per day for estimating water consumption

^c Exposure based on First Milk infant formula using lower and upper bound concentrations of 0 and 0.36 µg/L, respectively

^d Exposure based on First Milk infant formula using lower and upper bound concentrations of 1 and 4 µg/L, respectively

14. Exposures of infants and children aged 4.0 to <12.0 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 lead exposures (excluding water) in 4 to 12 month old infants ranged from 0.05 – 0.13 and 0.18 – 0.27 µg/kg bw/day, respectively (Table 4). These values are largely towards the lower end of the range of values reported in the 2013 COT statement for which mean values ranged from 0.08 to 0.52 µg/kg bw/day. Exposure to lead from drinking water when present at the highest median level (from table 1) had a minimal impact on total dietary exposure that was

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estimated for the combination of the three food categories (Table 4). The highest median value was below the limit of detection therefore lead exposures are likely to be lower than the conservative values in Table 4. When lead level in water was present at the highest 97.5th percentile, drinking water increased lead exposures by up to 2-fold compared to exposures excluding water.

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

Food Groups	Lead – LB - UB Range (µg/kg bw/day)					
	4 to 5.99 months (n=116)		6 to 8.99 months (n=606)		9 to 11.99 months (n=686)	
	Mean	97.5 th percentile	Mean	97.5 th percentile	Mean	97.5 th percentile
Infant formula	0.00 – 0.01	0.00 – 0.05	0.00 – 0.02	0.00 – 0.05	0.00 – 0.02	0.00 – 0.05
Commercial infant foods	0.02 – 0.04	0.12 – 0.16	0.04 – 0.05	0.15 – 0.21	0.03 – 0.05	0.14 – 0.19
Other foods	0.02 – 0.03	0.12 – 0.14	0.04 – 0.05	0.12 – 0.15	0.04 – 0.06	0.12 – 0.16
Total (excluding water)	0.05 – 0.07	0.18 – 0.23*	0.08 – 0.13	0.18 – 0.27*	0.07 – 0.12	0.18 – 0.27*
Total including water where lead is present at the highest median level (1 µg/L) ^a	0.06-0.08	0.19-0.24	0.09-0.14	0.19-0.28	0.08-0.13	0.19-0.28
Total including water where lead is present at the highest 97.5 th percentile level (9.5 µg/L) ^a	0.09-0.11	0.22-0.27	0.17-0.22	0.27-0.36	0.19-0.24	0.30-0.39

* 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.

^a Exposure from water was determined using mean water consumption for the age band

Children aged 12 to 18 months

15. Exposure estimates for children aged 12 to 18 months 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

16. The lower to upper bound ranges of total dietary mean and 97.5th percentile exposures (excluding drinking water) from infant formula,

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commercial infant foods and other foods were 0.06-0.11 and 0.13-0.23 µg/kg bw/day, respectively (Table 5). As observed for children aged 4.0 to <12.0 months, exposure to lead from drinking water, present at the highest median (table 1) had a minimal impact on total exposure from all food categories in the 12-15 months age range (Table 5). However in young children aged 15-18 months drinking water present at the highest 97.5th percentile increased lead exposures by up to 2.4-fold.

Table 5. 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 Groups	Lead exposure LB - UB Range (µg/kg bw/day)			
	12 to 14.99 months (n=670)		15 to 17.99 months (n=605)	
	Mean	97.5 th percentile	Mean	97.5 th percentile
Infant formula	0.00-0.01	0.00-0.03	0.00-0.01	0.00-0.03
Commercial infant foods	0.02-0.03	0.10-0.15	0.01-0.02	0.07-0.08
Other foods	0.05-0.08	0.12-0.17	0.05-0.08	0.10-0.15
Total (excluding water)	0.06-0.11	0.15-0.23*	0.06-0.10	0.13-0.19*
Total including water where lead is present at highest median level (1 µg/L) ^a	0.07-0.12	0.16-0.24	0.07-0.11	0.14-0.20
Total Including water where lead is present at highest 97.5 th percentile level (9.5 µg/L) ^a	0.18-0.23	0.27-0.35	0.20-0.24	0.27-0.33

* 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.

^a Exposure from water was determined using mean water consumption for the age band

Exposure estimates based on the TDS

17. Table 6 shows the possible lead 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 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

18. From the TDS (which includes tap water and bottled water), total mean and 97.5th percentile lead exposures from a combination of all food groups ranged from 0.14 – 0.29 and 0.29 – 0.49 µg/kg bw/day, respectively. Replacing the lead concentration identified for tap water in the TDS (<0.8

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µg/L) with the highest median (<1 µg/L, Table 1) had a negligible impact on total exposure. Use of the lead concentration of 9.5 µg/L (highest 97.5th percentile), in place of the concentration identified for tap water, increased lead exposures by up to 1.6-fold. The TDS samples were prepared using water at the research laboratory, for which the level of lead was below the limit of quantitation (0.29 µg/L). If water containing a higher lead 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.

19. The food groups with the highest contribution to total dietary lead exposure based on the TDS were dairy products > green vegetable = other vegetables = miscellaneous cereals for the 12-14.99 month age range and dairy products = miscellaneous cereals > green vegetables = other vegetables for 15-17.99 month old children.

Table 6. Estimated lead exposures from the 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	97.5 th percentile	Mean	97.5 th percentile
TDS	0.14-0.26	0.29-0.46	0.15-0.29	0.29-0.49
TDS; using lead from water at highest median level (1 µg/L)	0.15-0.27	0.32-0.46	0.16-0.29	0.30-0.49
TDS; using lead from water at highest 97.5 th percentile (9.5 µg/L)	0.23-0.35	0.53-0.67	0.25-0.38	0.60-0.76

Children aged 18 months to 60 months

20. Exposure estimates for young children aged 18 to 60 months were derived using occurrence data from the 2014 TDS, and consumption data from the NDNS.

Exposure estimates based on the TDS

21. Table 7, shows the possible lead exposures that were calculated using TDS data for children aged 18 to 60 months. 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.

22. Total dietary mean and 97.5th 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. Replacing the lead concentration identified for tap water

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in the TDS (<0.8 µg/L) with the highest median (1 µg/L) reported in Table 1 had a negligible impact on total exposure in 18 to 60 month old children. However, using the highest 97.5th percentile lead value for drinking water (9.5 µg/L) in place of the lead concentration identified for tap water in the TDS increased lead exposures by up to 1.8-fold.

23. The food groups with the highest contribution to lead exposure were in the order dairy products > green vegetables > other vegetables for 18 to 24 month old children; the latter food groups contributed equally in 24 to 60 month old children.

Table 7. Estimated lead exposures from the total diet for the TDS in infants aged 18 to 60 months

Food Group	Lead – LB - UB Range (µg/kg bw/day)			
	18 to 24 months (n=70)		24 to 60 months (n=429)	
	Mean	97.5 th percentile	Mean	97.5 th percentile
TDS	0.16-0.32	0.25-0.48	0.15-0.27	0.25-0.44
TDS; using lead from water highest at median level (1µg/L)	0.17-0.32	0.28-0.48	0.16-0.27	0.27-0.44
TDS; using lead from water at highest 97.5 th percentile (9.5 µg/L)	0.27-0.41	0.68-0.88	0.24-0.36	0.53-0.67

Soil/dust

24. Potential exposures of UK infants, aged >9 to 12 months and young children aged 12 to 60 months, from lead in soil were calculated assuming ingestion of 100 mg/day (US EPA, 2008; WHO, 2007) and median and 97.5th percentile lead concentrations of 93 and 310 mg/kg reported for urban soils (EA, 2007) (Table 8). Urban soil data were selected as these are likely to be representative for a greater proportion of the population. 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 them.

Table 8. Possible lead exposures (µg/kg bw/day) from soil in infants and young children aged > 9 to 60 months

Lead concentration (mg/kg)	Age (months)				
	>9 to 12	12 to 15	15 to 18	18 to 24	24 to 60
93 (median)	0.97	0.88	0.83	0.78	0.58
310 (97.5 th percentile)	3.2	2.9	2.8	2.6	1.9

Air

25. Potential exposures of UK infants aged 0 to 12 months and young children aged 12 to 60 months 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 m³/day, respectively for infants and children aged 0 to <1, 3 to <6, 6 to <12, 12 to <24, 24 to <36 and 36 to <72 months (US EPA, 2008). The lead concentrations used in the exposure calculations were the lowest and highest median values of 1.2 and 31 ng/m³ and lowest and highest 97.5th percentile values of 2.3 and 230 ng/m³, respectively from the monitoring sites in the UK (paragraph 8).

Table 9. Estimated UK exposure to lead (µg/kg bw/day) in infants and young children from the air

Lead concentration (ng/m ³)	Ages (months)					
	0 to <3 ^b	3 to <6	6 to <12	12 to <24 ^a	24 to <36 ^a	36 to <72 ^a
1.2 (lowest median value)	0.00073	0.00063	0.00070	0.00071	0.00075	0.00066
31 (highest median value)	0.019	0.016	0.018	0.018	0.020	0.017
2.3 (lowest 97.5 th percentile value)	0.0014	0.0012	0.0014	0.0014	0.0014	0.0013
230 (highest 97.5 th percentile value)	0.14	0.12	0.14	0.14	0.14	0.13

^a Based on average bodyweights of 13.5, 15.1 and 19.7 kg for children aged 12 to <24, 24 to <36 and 36 to <72 months.

^b The ventilation rate of 3.6 was applied to infants aged 0 to <3 months in this exposure assessment as there was no available data on ventilation rates for infants aged 1 to <3 months.

Risk Characterisation

26. 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*

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material risk cannot be ruled out. This applies particularly when MOEs are substantially <1".

27. MOEs based on the estimated dietary exposures are shown in Table 10. For lead exposure estimates of high level consumers for exclusive breastfeeding for infants aged 0 to 6 months, a marginally low MOE of 0.94 was obtained. However the COT does not consider that this is a cause for concern since the MOE is only a little less than one, the estimate was based on a maximum level in the study and is for exposure of a cumulative toxicant over a relatively short time.

28. The MOE values for exposure estimates for exclusive feeding with infant formulae were >1 for ready to feed formulae. For powder formula reconstituted with water containing lead at the highest median concentration, the MOEs were >1.7, however these are worst case values as they were calculated using a value of 1 µg/L and the median concentrations were actually < 1 µg/L.

29. Estimates of total dietary exposure when drinking water is taken into account, using the highest median and highest 97.5th percentile drinking water concentrations for lead, range from very low to <0.88 µg/kg bw/day. Thus in young children aged 12 to 60 months, in some instances, the MOE could be as low as 0.57. However, as noted above, it is not clear whether such exposures commonly occur.

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Table 10. Estimated dietary exposures and MOEs compared to the BMDL₀₁ for neurodevelopmental effects of lead.

		Exclusive breast milk	Exclusive infant formula			Total diet including water with median Pb level (1 µg/L)					Total diet including water with 97.5th percentile Pb level (9.5 µg/L)				
			Ready to feed	Dry powder + water with lead at median level (1 µg/L)	Dry powder + water with lead at 97.5 th percentile level (9.5 µg/L)										
Survey/Consumption data		N/A	Infant metals survey	Infant metals survey	Infant metals survey	Infant metals survey/ DNSIYC	Infant metals survey/ DNSIYC	TDS/ NDNS	TDS/ NDNS	TDS/ NDNS	Infant metals survey/ DNSIYC	Infant metals survey/ DNSIYC	TDS/ NDNS	TDS/ NDNS	TDS/ NDNS
Age (months)		0 to 6	0 to 4	0 to 4	0 to 4	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/day)	Average consumers	0.35	0.05	0.20	1.2	0.14	0.12	0.29	0.32	0.27	0.24	0.24	0.38	0.41	0.36
	High level consumers	0.53	0.07	0.29	1.8	0.28	0.24	0.49	0.48	0.44	0.39	0.35	0.76	0.88	0.67
MOE	Average consumers	1.4	10	2.5	0.42	3.6	4.2	1.7	1.6	1.9	2.1	2.1	1.2	1.2	1.4
	High level consumers	0.94	7.1	1.7	0.28	1.8	2.1	1.0	1.0	1.0	1.3	1.4	0.66	0.57	0.75

*Values are the highest upper bound estimate for the age range

The MOE is calculated by dividing the BMDL₀₁ of 0.50 µg/kg bw/day by the respective dietary exposure

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30. 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, assuming concentrations of lead at the median and 97.5th percentile of reported ranges. All MOEs are <1 and the lowest MOE is 0.16. By comparison exposures from air are negligible.

31. Table 11. Range of estimated exposures to lead from soil and corresponding MOEs compared to the BMDL₀₁ for neurodevelopmental effects of lead.

		Age (months)				
		>9 to 12	12 to 15	15 to 18	18 to 24	24 to 60
Estimated exposures (µg/kg bw/day)	Median concentration	0.97	0.88	0.83	0.78	0.58
	High level concentration	3.2	2.9	2.8	2.6	1.9
MOE	Median concentration	0.51	0.56	0.60	0.64	0.86
	High level concentration	0.16	0.17	0.18	0.19	0.26

The MOE is calculated by dividing the BMDL₀₁ of 0.50 µg/kg bw/day by the respective exposure

These comparisons assume equivalent absorption from different sources.

32. There are uncertainties in the assessment of risks to infants and young children from exposure to lead because confounding factors may not have been fully taken into account, and the samples of children studied may have been unrepresentative by chance.

33. 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.

Secretariat

January 2016

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