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

Third 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.

2. A first draft addendum on lead (TOX/2016/07) was presented to Members in February 2016. At this meeting Members requested that a more holistic approach to modelling be used for the exposure scenarios. The bioavailability of lead from soil, air, food and water would need to be taken into account to provide more accurate exposures. It was also requested that lead exposures from water from private wells be considered assuming that it was possible to obtain occurrence data. In addition the Committee requested that a paragraph be included on lead exposure from game, reflecting its previous conclusions on this.

3. A second draft addendum (TOX/2016/14) was prepared taking into account the Committee's comments, including the application of a 60% relative bioavailability factor for lead in soil, and was presented at the April meeting. Members requested further consideration of soil and private water supply data as per their comments on arsenic. The Committee, in considering the MOEs presented in the addendum, requested a range of MOEs to be provided that would allow improved interpretation of the risk assessment, and also requested a clearer description of the uncertainties.

4. The third draft statement addendum presented in Annex A of this document has been revised incorporating the additional information requested by the Committee, and includes minor amendments to the text and formatting to improve the clarity of the risk assessment.

New information

Water

5. In 2014 Local Authorities held records for approximately 38,700 private water supplies in England, ~14,400 in Wales, ~20,200 in Scotland and ~1,300 in Northern Ireland. Of the private supplies in England and Wales, 67% and 85% served single dwellings respectively. The DWI estimated that in England approximately 570,000 people lived or worked on premises that relied on a private water supply, this figure was ~80,000 for Wales (DWI, 2015a,b).

6. Representative data on lead concentrations in UK private water supplies were not available. According to legislation private water supplies are not required to be tested in the same manner as public supplies, and those supplies serving single dwellings are exempt from monitoring unless specifically requested by the owner. Where sampling of private supplies occurs, especially those serving single dwellings, it is usually as the result of a risk assessment that has identified the supply as potentially high risk and therefore the results are highly likely to be skewed (personal communication from DWI, February 2016). Reports published by the DWI in 2014 indicated that for the period 2011 – 2014, of the 712 samples taken from private water supplies that served single dwellings in England, 7.7% exceeded the maximum limit for lead of 10 µg/L. In Wales, for the same period, 6.2% of the 225 samples tested from supplies serving single dwellings exceeded the maximum limit (DWI, 2015a,b).

7. A study by Ander *et al* (2016) reported concentrations of lead in samples taken from private water supplies serving single domestic dwellings in Cornwall. A total of 497 samples were tested from different properties across Cornwall between spring 2011 to spring 2013. This was a targeted survey that focussed on Cornwall as it is an area known to have high concentrations of lead and other elements in the surface environment, and which also has a large number of private water supplies (approximately 3,800 in 2014) (Ander *et al*, 2016). Ander *et al* (2016) reported a median lead concentration in drinking water of 0.33 µg/L and a 95th percentile concentration of 2.9 µg/L; the LOD was 0.02 µg/L and the minimum and maximum concentrations were <0.02 and 44.5 µg/L respectively. However the data and discussion of the lead concentrations seems to focus on lead in relation to household plumbing. The supplementary data indicate that median and 75th percentile filtered ground water levels are 0.8 and 1.65 µg/L in high pH drinking water respectively, and 0.85 and 1.75 µg/L in low pH drinking water respectively.

Soil

8. The estimated exposures to lead via soil have been recalculated using data from the Department for Environment, Food and Rural Affairs (Defra) and the British Geological Survey (BGS). Defra reported normal background concentrations (NBCs) for lead in soil in England and Wales (Defra, 2012 and 2013). An NBC is the 95th percentile upper confidence interval of the available data; it is defined as a contaminant concentration that is seen as typical and

widespread in topsoils (depth 0 – 15 cm). In order to establish meaningful NBCs, Defra grouped the available soil data in domains (e.g. principal, urban and mineralisation) that were defined by the most significant controls on a contaminant's high concentrations and distribution.

9. The median and the upper 95% confidence limit of the 95th percentile concentrations reported for the urban area of England (regarded as the normal background concentration) were 170 mg/kg and 820 mg/kg respectively (n =7529 samples) (Defra, 2012 and Ander *et al*., 2013). Corresponding upper 95% confidence limit of the 95th percentile concentrations reported for the urban area for Wales was up to 1300 mg/kg (n=342 samples) (DEFRA, 2013). Fewer soil samples were taken for Wales compared to England, so the corresponding concentrations are associated with much greater uncertainty than those for England. Welsh soils have developed on a diverse range of parent materials, including those hosting metalliferous mineralization, and therefore are inherently variable in their chemical composition. The most significant domain in terms of percentage area within a country was the principal domain (areas which do not contain significantly elevated levels), constituting approximately 94 for England and 86% for Wales. However, whilst the urban domains only cover between 2 and 6% of the area of England and Wales, in 2011 over 80% of the population of England and Wales resided in urban areas (ONS, 2013).Therefore, the median and upper 95% confidence limit of the 95th percentile concentrations developed for urban areas in England were used in the exposure assessments. No data were identified specifically relating to dust.

10. In addition to the data for soil, the use of a single default soil and dust ingestion value has been revised. The soil exposure assessment now starts at 6 months old and uses default combined soil and dust ingestion values of 60 mg/day for 6 to 12 month olds and 100 mg/day for 1 to 5 year olds. These default values have been taken from a United States Environmental Protection Agency (US EPA) exposure factors handbook published in 2011 (US EPA, 2011a).

Air

11. The exposure assessments for air have been revised, using the default ventilation rates available in the 2011 US EPA exposure factors handbook (US EPA, 2011b) in order to be consistent with other papers in this series of COT evaluations. This has not caused any significant changes in the exposure assessment.

Questions to the Committee

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

Secretariat
May 2016

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

Third 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. For lead shot game the FSA (2012) advises that in order to minimise the risk of lead intake *"people who frequently eat lead-shot game, particularly small game, should cut down their consumption. This is especially important for vulnerable groups such as toddlers and children, pregnant women and women trying for a baby, as exposure to lead can harm the developing brain and nervous system"*[1]. There are currently no other Government dietary recommendations for infants and young children that relate to lead.

3. In 2013 the COT issued a statement on potential risks from lead in the infant diet[2]. 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.

4. 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 ($BMDL_{01}$) blood level associated with

[1] https://www.food.gov.uk/science/advice-to-frequent-eaters-of-game-shot-with-lead
[2] http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2013/lead

a decrease of 1 Intelligence Quotient (IQ) point, which was considered to be relevant at the population level. (EFSA, 2010).

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

New data on sources of lead exposure

5. 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 as the highest concentration in an individual sample from the SUREmilk study (Woolridge *et al*., 2004), is used for exposure estimates of lead in children aged 12 to 18 months.

6. 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).

7. Median and 97.5th percentile values concentrations of lead in drinking water in 2014 were provided by the Drinking Water Inspectorate (DWI), 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	97.5th percentile
England and Wales	12,000	< 1.0*	5.0
Northern Ireland	390	0.2	9.5
Scotland	1,500	0.2	4.2

** Reported by DWI as <1.0 µg/L based on limits of quantitation (LOQs). A median value of 1.0 µg/L and a 97.5th percentile value of 9.5 µg/L were used in the exposure assessment.*

8. The DWI estimated that in England approximately 570,000 people lived or worked on premises that relied on a private water supply, this figure was ~80,000 for Wales (DWI, 2015a,b). Representative data on lead concentrations in UK private water supplies were not available. Where sampling of private supplies occurs, especially those serving single dwellings, it is usually as the result of a risk assessment that has identified the supply as potentially high risk and therefore the results are likely to be highly skewed.

9. The median and the upper 95% confidence limit of the 95th percentile "normal background concentrations" of lead in soil reported for the urban area of England of 170 mg/kg and 820 mg/kg respectively (Defra, 2012 and Ander et al., 2013) have been used in estimating exposure from this source. The corresponding concentrations reported for Wales were up to 1300 mg/kg (DEFRA, 2013), but the relevance of these concentrations for the majority of the UK population is uncertain.

10. Lead concentrations were measured in 554 air samples in particulate matter less than 10 µm (PM_{10}) and as metal deposition at 23 and 5 sites, respectively, across the UK in 2014. Median and 97.5th percentile concentration values of 8.7 and 63 ng/m^3, respectively were derived from these sites.

Exposure

11. Detailed assessments have been performed for the dietary sources of exposure to lead. Exposure assessments of potential non-dietary sources (i.e. soil and air) have been provided and incorporated into overall exposure.

12. Consumption data (for food and water) 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. Body weight data are summarised in Table 2.

Table 2: Average body weights used in exposure assessments.

Age bands (months)	Weighted bodyweight
0 - <4	5.9 kg[a]
≥4 - <6	7.8 kg[b]
≥6 - <9	8.7 kg[b]
≥9 - <12	9.6 kg[b]
≥12 - <15	10.6 kg[b]
≥15 - <18	11.2 kg[b]
≥18 - <24	12.0 kg[c]
≥24 - <60	16.1 kg[c]

[a] *DH, 1994, COT 2013.*
[b] *DH, 2013.*
[c] *Bates et al., 2014.*

Infants

Breast milk

13. Since no new data were available for breast milk, the estimated exposures of exclusively breastfed infants, aged 0 to 6 months were calculated using default values for mean (800mL) and high level (1,200mL) consumption, in line with previous COT evaluations (Table 3).

14. Data on breast milk consumption have now become available from DNSIYC 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 3). 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 3. 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	0.17	0.099	0.076	0.066
High level	0.53	0.40	0.41	0.30	0.19	0.13

[a] *Mean and high level lead exposures were based on exclusive breastfeeding and consumption of 800 and 1,200mL, respectively (COT, 2013).*
[b] *Consumption data from DNSIYC; high level is 97.5th percentile.*
Values rounded to 2 significant figures (SF).

Infant formulae and complementary food

15. Possible lead exposure levels from infant formulae were calculated for infants up to 4 months of age assuming exclusive feeding on formula (Table 4). 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 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 4. Estimated lead exposures from exclusive first milk infant formula for 0 to 4 months.

Infant Formula Types	LB - UB exposure (µg/kg bw/day)	
	800 mL	1,200 mL
Ready to Feed[a]	0.00 - 0.049	0.00 - 0.073
Dry Powder[b,c]	0.020 - 0.081	0.030 - 0.12
Dry Powder[b] + water with lead at 1 µg/L[d]	0.14 - 0.20	0.20 - 0.29
Dry Powder[b] + water with lead at 9.5 µg/L[d]	1.1 - 1.2	1.7 - 1.8

[a] *Exposure based on first milk infant formula using lower (LB) and upper bound (UB) concentrations of 0 and 0.36 µg/L, respectively.*
[b] *Exposure based on first milk infant formula using LB and UB concentrations of 1 and 4 µg/L, respectively.*
[c] *Exposure does not include the contribution from water.*
[d] *Determined by applying a factor of 0.85 to default formula consumption of 800mL and 1,200mL per day for estimating water consumption.*
Values rounded to 2 SF

16. 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, were 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 0.0045 – 0.12 and 0.18 – 0.24 µg/kg bw/day, respectively (Table 5).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 estimated for the combination of the three food categories (Table 5). The highest median value was below the limit of quantitation (LOQ) therefore lead exposures are likely to be lower than the conservative values in Table 5. 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 5. Estimated lead exposures from infant formulae, commercial infant foods, and other foods in infants aged 4 to 12 months.

Food Groups	LB - UB exposure (µg/kg bw/day)					
	4 to 6 months (n=116)		6 to 9 months (n=606)		9 to 12 months (n=686)	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile
Infant formula	0.000 – 0.0046	0.0011 – 0.039	0.000 – 0.015	0.000 – 0.053	0.000 – 0.017	0.000 – 0.046
Commercial infant foods	0.024 – 0.042	0.12 – 0.16	0.036 – 0.052	0.15 – 0.21	0.034 – 0.054	0.14 – 0.19
Other foods	0.020 – 0.025	0.12 – 0.14	0.037 – 0.049	0.12 – 0.15	0.044 – 0.064	0.12 – 0.16
Total (excluding water)	0.045 – 0.061	0.18 – 0.21[a]	0.075 – 0.10	0.18 – 0.24[a]	0.079 – 0.12	0.18 – 0.24[a]
Total including water with lead at 1 µg/L[b]	0.055 – 0.071	0.19 – 0.22	0.085 – 0.11	0.19 – 0.25	0.089 – 0.13	0.19 – 0.25
Total including water with lead at 9.5 µg/L[b]	0.085 – 0.10	0.22 – 0.25	0.17 – 0.19	0.27 – 0.33	0.19 – 0.24	0.30 – 0.36

[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.*
[b] *Exposure from water was determined using mean water consumption for the age band.*
Values rounded to 2 SF.

Children aged 12 to 18 months

17. 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 and NDNS were used for the estimation of exposure for each study.

Infant Metals Survey

18. The lower to upper bound ranges of total dietary mean and 97.5th percentile exposures (excluding drinking water) from infant formula, commercial infant foods and other foods were 0.066 - 0.10 and 0.13 - 0.22 µg/kg bw/day, respectively (Table 6). 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 to 18 months age range (Table 5). However in young children aged 15 to 18 months drinking water present at the highest 97.5th percentile increased lead exposures by up to 2.6-fold.

Table 6. 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	**LB - UB exposure (µg/kg bw/day)**			
	12 to 15 months (n=670)		**15 to 18 months (n=605)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
Infant formula	0.000-0.0069	0.000 - 0.034	0.000-0.0040	0.000 - 0.025
Commercial infant foods	0.019 - 0.027	0.10 - 0.15	0.011 - 0.015	0.065 - 0.083
Other foods	0.045 - 0.078	0.12 - 0.17	0.047 - 0.082	0.10 - 0.15
Total (excluding water)	0.066 - 0.10	0.15 - 0.22 [a]	0.061 - 0.084	0.13 - 0.17 [a]
Total including water with lead at 1 µg/L [b]	0.076 - 0.11	0.16 - 0.23	0.071 - 0.094	0.14 - 0.18
Total including water with lead at 9.5 µg/L [b]	0.19 - 0.22	0.27 - 0.34	0.20 - 0.22	0.27 - 0.31

[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.*
[b] *Determined using mean water consumption for the age band.*
Values rounded to 2 SF.

Exposure estimates based on the TDS

19. Table 7 shows the possible lead exposures that were calculated using TDS data for children aged 12 to 18 months using NDNS 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.

20. The lead concentration in tap water was recorded as <0.8 µg/L in the TDS, which is similar to the median concentration in tap water in England and Wales (Table 1). Therefore the exposures in table 7 have been estimated using the median and 97.5th percentile concentrations as described in Table 1). Total mean and 97.5th percentile lead exposures from a combination of all food groups ranged from 0.15 – 0.29 and 0.32 – 0.49 µg/kg bw/day, respectively at the median water concentration. 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 LOQ (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.

21. 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 (e.g. rice, pasta and bakery products) for the 12 to 15 month age range and dairy products = miscellaneous cereals > green vegetables = other vegetables for 15 to 18 month old children.

Table 7. Estimated lead exposures from the TDS in children aged 12 to 18 months.

Lead concentration in water in the TDS	**LB - UB exposure (µg/kg bw/day)**			
	12 to 15 months (n=670)		**15 to 18 months (n=605)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
1 µg/L	0.15 - 0.27	0.32 - 0.46	0.16 - 0.29	0.30 - 0.49
9.5 µg/L	0.23 - 0.35	0.53 - 0.67	0.25 - 0.38	0.60 - 0.76

Values rounded to 2 SF.

Children aged 18 months to 60 months

22. 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

23. Table 8, 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. As described in paragraph 20, the exposures have been estimated using the median and 97.5th percentile concentrations as described in Table 1)

24. Total dietary mean and 97.5th percentile lead exposures from a combination of all food groups ranged from 0.17 – 0.32 and 0.27 – 0.44 µg/kg bw/day, respectively at the median water concentration. 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.

25. 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 8. Estimated lead exposures from the TDS in children aged 18 to 60 months.

Lead concentration in water in the TDS	**LB - UB exposure (µg/kg bw/day)**			
	18 to 24 months (n=70)		**24 to 60 months (n=429)**	
	Mean	**97.5th percentile**	**Mean**	**97.5th percentile**
1 µg/L	0.17 - 0.32	0.28 - 0.48	0.16 - 0.27	0.27 - 0.44
9.5 µg/L	0.27 - 0.41	0.68 - 0.88	0.24 - 0.36	0.53 - 0.67

Values rounded to 2 SF.

Soil/dust

26. Potential exposures to lead in soil were calculated assuming combined soil and dust ingestion of 60 or 100 mg/day respectively (US EPA, 2011). 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. Median and the upper 95% confidence limit of the 95th percentile lead concentrations in urban soil of 170 and 820 mg/kg respectively were used in these exposure estimations (see paragraph 9) (Table 9).

27. A conversion factor of 0.6 was applied to the soil data to account for the bioavailability of lead from soil. This figure is relative to lead available from food and water, and is taken from the US EPA IEUBK model (1999). This

adjustment has been made so that exposures can be compared with the $BMDL_{01}$ dietary intake level of 0.5 µg/kg bw/day which EFSA estimated from a $BMDL_{01}$ blood lead concentration using the US EPA IEUBK model assuming negligible exposure from air, dust and soil.

Table 9 Possible lead exposures from soil in infants and young children aged 6 to 60 months after adjusting for bioavailability relative to food.

Lead concentration	Age (months)					
	6 to 9	9 to 12	12 to 15	15 to 18	18 to 24	24 to 60
Median (170 mg/kg)	0.70	0.63	0.96	0.91	0.85	0.64
97.5th percentile (820 mg/kg)	3.4	3.1	4.7	4.4	4.1	3.1

Exposure to lead from soil were adjusted by applying a factor of 0.6 to take account of bioavailability relative to food.
Values rounded to 2 SF.

Air

28. Potential exposures to lead in air were calculated (Table 10) using a range of air ventilation rates for children in a similar age category (US EPA, 2011), and the median (8.7 ng/m^3) and 97.5th percentile value (63 ng/m^3) concentrations of lead in air from the monitoring sites in the UK (paragraph 10).

Table 10. Estimated exposure to lead from air

Lead concentration	Exposure by age group (months) (µg/kg bw/day)							
	0 to 4[a]	4 to 6[b]	6 to 9[c]	9 to 12[d]	12 to 15[e]	15 to 18[f]	18 to 24[g]	24 to 60[h]
Median (8.7 ng/m^3)	0.0053	0.0046	0.0054	0.0049	0.0065	0.0062	0.0058	0.0055
97.5th percentile (63 ng/m^3)	0.038	0.033	0.039	0.035	0.048	0.045	0.042	0.040

[a] *Based on a ventilation rate of 3.6 m^3/day and a bodyweight of 5.9 kg.*
[b] *Based on a ventilation rate of 4.1 m^3/day and a bodyweight of 7.8 kg.*
[c] *Based on a ventilation rate of 5.4 m^3/day and a bodyweight of 8.7 kg.*
[d] *Based on a ventilation rate of 5.4 m^3/day and a bodyweight of 9.6 kg.*
[e] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 10.6 kg.*
[f] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 11.2 kg.*
[g] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 12 kg.*
[h] *Based on a ventilation rate of 10.1 m^3/day and a bodyweight of 16.1kg*
Values rounded to 2 SF.

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 alone are shown in Table 11. For lead exposure estimates of high level consumers for exclusive breastfeeding for infants aged 0 to 4 months, a marginally low MOE of 0.9 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.

31. 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 >2. 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. For formula reconstituted with water containing lead at the 97.5th percentile concentration MOEs are in the range of 0.3 to 0.5, however it is unclear as to how common such exposures are.

32. 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 0.6. However, as noted above, it is not clear whether such exposures commonly occur.

Table 11. Estimated dietary exposures and MOEs compared to the $BMDL_{01}$ for neurodevelopmental effects of lead.

		Exclusive breast milk	Exclusive infant formula			Total diet including water with lead 1 µg/L					Total diet including water with lead 9.5 µg/L				
			Ready to feed	Dry powder + water with lead at											
				1 µg/L	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/ DNSIYC	TDS/ NDNS	TDS/ NDNS	Infant metals survey/ DNSIYC	Infant metals survey/ DNSIYC	TDS/ DNSIYC	TDS/ NDNS	TDS/ NDNS
Age (months)		0 to 4	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[a] (µg/kg bw/day)	Average consumers	0.35	0.049	0.14 - 0.20	1.1 - 1.2	0.055 - 0.13	0.071 - 0.11	0.15 - 0.29	0.17 - 0.32	0.16 - 0.27	0.085 - 0.24	0.19 - 0.22	0.23 - 0.38	0.27 - 0.41	0.24 - 0.36
	High level consumers	0. 53	0.073	0.20 - 0.29	1.7 - 1.8	0.19 - 0.25	0.14 - 0.23	0.30 - 0.49	0.28 - 0.48	0.27 - 0.44	0.22 - 0.36	0.27 - 0.34	0.53 - 0.76	0.68 - 0.88	0.53 - 0.67
MOE[b]	Average consumers	1	10	3 - 4	0.4 - 0.5	4 - 9	5 - 7	2 - 3	2 - 3	2 – 3	2 - 6	2 - 3	1 - 2	1 - 2	1 - 2
	High level consumers	0.9	7	2 - 3	0.3 - 0.3	2 - 3	2 - 4	1 - 2	1 - 2	1 – 2	1 - 2	2 - 2	0.7 - 0.9	0.6 - 0.7	0.7 - 0.9

[a] *Values are the lowest LB to highest UB estimate for the age range, expressed as 2 SF.*
[b] *The MOE is calculated by dividing the $BMDL_{01}$ of 0.50 µg/kg bw/day by the respective UB - LB dietary exposure, expressed as 1 SF.*

33. Table 12 summarises MOEs for estimates of exposure from soil, assuming concentrations of lead at the median and 95th percentile of reported ranges. For median and high level concentrations all MOEs are <1, with the lowest MOE of 0.1 indicating that risks cannot be ruled out. By comparison exposures from air are negligible (Table 10).

Table 12. Estimated exposures to lead from soil (adjusted for bioavailability) and corresponding MOEs compared to the $BMDL_{01}$ for neurodevelopmental effects of lead.

		Age (months)					
		6 to 9	**9 to 12**	**12 to 15**	**15 to 18**	**18 to 24**	**24 to 60**
Estimated exposures (µg/kg bw/day)	Median concentration	0.70	0.63	0.96	0.91	0.85	0.64
	High level concentration	3.4	3.1	4.7	4.4	4.1	3.1
MOE[a]	Median concentration	0.7	0.8	0.5	0.5	0.6	0.8
	High level concentration	0.1	0.2	0.1	0.1	0.1	0.2

[a] *The MOE is calculated by dividing the $BMDL_{01}$ of 0.50 µg/kg bw/day by the respective exposure, expressed as 1 SF.*

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 high level exposure estimate for the remaining source (Tables 13 to 15). Calculation of these exposures assumed lead concentrations for water of median 1 µg/L and 97.5th percentile 9.5 µg/L, and for soil of median 170 mg/kg and 95th percentile 820 mg/kg.

35. Aggregate exposures have not been calculated for 0 to 4 month olds as this age group were considered to be exclusively breast- or formula-fed, with no exposure to other foods or to soil and minimal exposure from air .

36. Table 13 shows the aggregate exposure estimates and MOEs for infants aged 4 to 6 months. The aggregate exposures for these age groups are based on the exposure estimates for breast milk, the total diet including water, and air. Estimates from exposures via soil, were not calculated for this age group as infants <6 months are less able to move around and come into contact with soil. For 4 to 6 month olds, aggregate exposures correspond to MOEs ranging between 0.9 and 2.0, with high level sources having a minimal impact on the MOEs.

Table 13. Exposures to lead for infants aged 4 to 6 months aggregated from breast milk, the total diet, water and air, and the corresponding MOEs when compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination[a]			**Exposure (µg/kg bw/day)**[b]	**MOE** [c]
Mean breast milk + mean air	+ mean total diet incl. water lead at	1 µg/L	0.33-0.35	1-2
		9.5 µg/L	0.36-0.38	1
97.5th percentile breast milk + mean air	+ mean total diet incl. water lead at	1 µg/L	0.46-0.48	1
		9.5 µg/L	0.49-0.51	1
Mean breast milk + mean air	+ **97.5th percentile total diet** incl. water lead at	1 µg/L	0.47-0.50	1
		9.5 µg/L	0.50-0.53	0.9-1
Mean breast milk + **97.5th percentile air**	+ mean total diet incl. water lead at	1 µg/L	0.36-0.37	1
		9.5 µg/L	0.39-0.41	1

[a] *Breast milk exposure from Table 3, diet from Table 5, air from Table 10 and water concentrations for total diet water are taken from Table 1.*
[b] *Exposures are lowest LB to highest UB, rounded to 2 SF.*
[c] *MOEs are calculated from UB-LB exposures, rounded to 1 SF. Only one MOE is shown when the estimated aggregate exposures generated the same value.*

37. Table 14 shows aggregate exposure estimates and MOEs at ages 6 to 18 months. Exposures from soil have the greatest impact on MOEs reducing them by 4 to 5 fold at high lead concentrations. However, as a whole, infants in these age groups have MOEs of 0.6 or below.

38. Aggregate exposure estimates and MOEs for young children aged 18 months to 5 years are provided in Table 15. Similarly to the 6 to 18 months age groups, MOEs are all <1 with the major impact from soil.

Table 14. Exposures to lead at ages 6 to 18 months aggregated from breast milk, total diet, water, soil (assuming 60% relative bioavailability) and air, and the corresponding MOEs when compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination			Age (months)							
			6 to 9		9 to 12		12 to 15		15 to 18	
			Exposure[a] (µg/kg bw/day)	**MOE[b]**	**Exposure[a] (µg/kg bw/day)**	**MOE[b]**	**Exposure[a] (µg/kg bw/day)**	**MOE[b]**	**Exposure[a] (µg/kg bw/day)**	**MOE[b]**
Mean breast milk + average soil + mean air	+ mean total diet incl. water lead at	1 µg/L	0.96-0.99	0.5	0.82-0.86	0.6	1.2-1.3	0.4	1.2-1.3	0.4
		9.5 µg/L	1.0-1.1	0.5	0.92-0.97	0.5	1.3-1.4	0.4	1.3-1.4	0.4
97.5th percentile breast milk + average soil + mean air	+ mean total diet incl. water lead at	1 µg/L	1.2-1.2	0.4	1.0-1.1	0.5	1.3-1.4	0.4	1.2-1.3	0.4
		9.5 µg/L	1.3-1.3	0.4	1.1-1.2	0.4-0.5	1.4-1.5	0.3-0.4	1.3-1.4	0.4
Mean breast milk + average soil + mean air	+ **97.5th percentile total diet** incl. water lead at	1 µg/L	1.1-1.1	0.5	0.92-0.98	0.5	1.4-1.5	0.3-0.4	1.3-1.5	0.3-0.4
		9.5 µg/L	1.1-1.2	0.4-0.5	1.0-1.1	0.5	1.6-1.7	0.3	1.6-1.8	0.3
Mean breast milk **+ high level soil** + mean air	+ mean total diet incl. water lead at	1 µg/L	3.7-3.7	0.1	3.3-3.3	0.2	4.9-5.0	0.1	4.7-4.8	0.1
		9.5 µg/L	3.7-3.8	0.1	3.4-3.4	0.1	5.0-5.1	0.1	4.7-4.9	0.1
Mean breast milk + average soil + **97.5th percentile air**	+ mean total diet incl. water lead at	1 µg/L	0.99-1.0	0.5	0.85-0.89	0.6	1.3-1.4	0.4	1.3-1.4	0.4
		9.5 µg/L	1.1-1.1	0.5	0.95-1.0	0.5	1.3-1.5	0.3-0.4	1.3-1.4	0.4

[a] *Exposures are lowest LB to highest UB rounded to 2 SF.*
[b] *MOEs are calculated from UB-LB exposures rounded to 1 SF. Only one MOE is shown when the estimated aggregate exposures generated the same value.*

Table 15. Exposures to lead for young children aged 18 to 60 months aggregated from the total diet, water, soil (assuming 60% relative bioavailability) and air, and the corresponding MOEs when compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination			Age (months)			
			18 to 24		24 to 60	
			Exposure (µg/kg bw/day)[a]	MOE[b]	Exposure (µg/kg bw/day)[a]	MOE[b]
Average soil + air	+ mean total diet incl. water lead at	1 µg/L	1.0-1.2	0.4-0.5	0.77-0.88	0.6-0.7
		9.5 µg/L	1.1-1.3	0.4	0.85-0.97	0.5-0.6
Average soil + air	+ **97.5th percentile total diet** incl. water lead at	1 µg/L	1.1-1.3	0.4	0.88-1.0	0.5-0.6
		9.5 µg/L	1.5-1.7	0.3	1.1-1.3	0.4-0.5
High level soil + air	+ mean total diet incl. water lead at	1 µg/L	4.3-4.4	0.1	3.2-3.3	0.2
		9.5 µg/L	4.4-4.5	0.1	3.3-3.4	0.2
Average soil + **97.5th percentile air**	+ mean total diet incl. water lead at	1 µg/L	1.1-1.2	0.4-0.5	0.80-0.91	0.6
		9.5 µg/L	1.2-1.3	0.40	0.88-1.0	0.5-0.6

[a] *Exposures are lowest LB to highest UB, rounded to 2 SF.*
[b] *MOEs are calculated from UB-LB exposures , rounded to 1 SF. Only one MOE is shown when the estimated aggregate exposures generated the same value.*

Overall Risk Characterisation

39. MOEs for infants of 0-6 months are in the region of 1 or greater, unless exclusively fed on infant formula prepared with water containing lead at the upper end of the reported concentration range. For older infants and young children, the MOEs for aggregate exposures are in the region of 0.5, and lower if soil contains lead at the upper end of the normal concentration range found in urban soil.

40. The COT has previously concluded that an MOE > 1 can be taken to imply that, at most, any risk is likely to be small. Smaller MOEs do not necessarily indicate a problem due to uncertainties in the assessment. The BMDL was for a small effect in a pooled analysis of multiple cohorts of young children, and uncertainties relate to possible failure to control completely for confounding factors, and the possibility that the samples of children studied have been unrepresentative simply by chance. There are also uncertainties in

the exposure assessments, particularly with respect to the aggregate exposure estimates, and the number of children that could be exposed at the levels identified. In general, conservative approaches are taken. However, the MOEs calculated for infants of 6-12 months and for young children aged 1-5 years are such that a risk at the population level (rather than the individual infant/child) cannot be ruled out, This is particularly the case if soil, and to a lesser extent water, contains lead at the higher end of reported concentrations.

Conclusions

41. The COT has previously assessed the potential risks from lead in the infant diet, and has now updated its assessment taking into account more recent data on lead from different sources of exposure, both for infants and for children aged 1-5 years.

42. Lead can adversely affect neurodevelopment. The risks associated with exposure to lead are assessed by comparison of the calculated exposures to the dietary exposure level estimated by the EFSA to correspond to the $BMDL_{01}$ blood level associated with a decrease of 1IQ point. This effect could be relevant at the population level but not for the individual infant or child..

43. For infants aged 0 to 6 months old fed breast milk, ready to feed drinks and powder formula made with water at typical lead concentrations, any risk is likely to be small. This similarly applies if complementary food is introduced to the diet. However a small risk cannot be ruled out for infants of this age exclusively fed on infant formula prepared with water containing lead at the upper end of the concentration range .

44. For older infants, and for young children, any risk from diet alone is also likely to be small. However the effects of lead will be due to total lead exposure and not just to the diet. When the possible contribution from soil is taken into account a risk at the population level cannot be ruled out. There are a number of uncertainties in both the $BMDL_{01}$ and the exposure assessments and, in general, conservative approaches are taken.

45. This assessment does not indicate a need for specific advice relating to the diet of infants and young children, but emphasises the need for continued efforts to control lead in the broader environment.

Secretariat
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