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

Second 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. The aggregate exposures are included under the ‘Risk Characterisation’ section of the draft statement in Annex A (TOX/2016/14). For the purposes of assessing exposures from soil, a figure of 60% bioavailability relative to that from food and water has been applied. This figure is taken from the US EPA Integrated exposure uptake biokinetic (IEUBK) model (1999). The IEUBK model assumes that the relative bioavailability of lead in soil, relative to that of food and water, is 60 %.

4. At the February meeting Members also requested that consideration be given to exposures to lead from private water supplies, as the information considered to date by the Committee was for public water supplies. It has been established that representative data on the concentration of lead in private water supplies in the UK are not available. Private water supplies are not required to be tested in the same manner as public supplies, and where sampling of private supplies has been conducted, 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).

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

Secretariat
March 2016

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

First draft addendum to the 2013 COT statement on potential risks from 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 diet[1]. 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. 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"*[2]. There are currently no other Government dietary recommendations for infants and young children that relate to lead.

6. 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 a decrease of 1 Intelligence Quotient (IQ) point. (EFSA, 2010).

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

7. 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.

8. 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).

9. 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	97.5th percentile
England and Wales	12,000	< 1.0*	5.0
Northern Ireland	390	0.2	9.5
Scotland	1,500	0.2	4.2

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

10. 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).

11. 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 and 97.5th percentile concentration values of 8.7 and 63 ng/m^3, respectively were derived from these sites. No data were identified specifically relating to dust.

Exposure

12. 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

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 2).

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 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 1,200mL, respectively (COT, 2013).*
[b] *Consumption data from DYSIYC; high level is 97.5th percentile.*

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 3). Exposure estimates were derived using the occurrence data for first milk infant formula with default values for mean (800mL) and high level (1,200mL) consumption, in line with previous COT evaluations. The contribution to exposure arising from water used to reconstitute 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	**1,200 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 97.5th percentile level (9.5 µg/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 1,200mL 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.*

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 0.05 – 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

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[c] 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	97.5th percentile	Mean	97.5th percentile	Mean	97.5th 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[a]	0.08 – 0.13	0.18 – 0.27[a]	0.07 – 0.12	0.18 – 0.27[a]
Total including water where lead is present at the highest median level (1 µg/L)[b]	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 97.5th percentile level (9.5 µg/L)[b]	0.09 – 0.11	0.22 – 0.27	0.17 – 0.22	0.27 – 0.36	0.19 – 0.24	0.30 – 0.39

[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.*

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 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 0.06 - 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 to 15 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 2.4-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	**97.5th percentile**	**Mean**	**97.5th 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[a]	0.06 - 0.10	0.13 - 0.19[a]
Total including water where lead is present at highest median level (1 µg/L)[b]	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 97.5th percentile level (9.5 µg/L)[b]	0.18 - 0.23	0.27 - 0.35	0.20 - 0.24	0.27 - 0.33

[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.*

Exposure estimates based on the TDS

19. 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.

20. 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 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.

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 for the 12 to 14.99 month age range and dairy products = miscellaneous cereals > green vegetables = other vegetables for 15 to 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	**97.5th percentile**	**Mean**	**97.5th 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 97.5th 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

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 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.

24. 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 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.

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 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	97.5th percentile	Mean	97.5th 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 (1 µg/L)	0.17 - 0.32	0.28 - 0.48	0.16 - 0.27	0.27 - 0.44
TDS; using lead from water at highest 97.5th percentile (9.5 µg/L)	0.27 - 0.41	0.68 - 0.88	0.24 - 0.36	0.53 - 0.67

Soil/dust

26. 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.

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 BMDL01 dietary intake level of 0.5 µg/kg bw/day which EFSA estimated from

a BMDL01 blood lead concentration using the US EPA IEUBK model assuming negligible exposure from air, dust and soil.

28. 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 after adjusting for bioavailability relative to food[a].

Lead concentration	Age (months)				
	>9 to 12	12 to 15	15 to 18	18 to 24	24 to 60
Median (93 mg/kg)	0.58	0.53	0.50	0.47	0.35
97.5th percentile (310 mg/kg)	1.9	1.7	1.7	1.6	1.1

[a] *Exposure to lead from soil were adjusted by applying a factor of 0.6 to take account of bioavailability relative to food.*

Air

29. 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) using a range of published air ventilation rates for children in a similar age category (US EPA, 2008). The lead concentrations used for the estimation of exposure from air were the median value of 8.7 ng/m^3 and the 97.5th percentile value of 63 ng/m^3, respectively from the monitoring sites in the UK (paragraph 11).

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

Lead concentration	0 to 4[a]	4 to 6[b]	6 to 9[c]	9 to 12[c]	12 to 15[d]	15 to 18[d]	18 to 24[d]	24 to 60[e]
Median (8.7 ng/m^3)	0.0053	0.0046	0.0051	0.0051	0.0051	0.0051	0.0051	0.0048
97.5th percentile (63 ng/m^3)	0.022	0.033	0.038	0.038	0.038	0.038	0.038	0.036

[a] Based on a ventilation rate of 3.6 ng/m^3 and a bodyweight of 5.9 kg.
[b]Based on a ventilation rate of 4.1 ng/m^3 and a bodyweight of 7.8 kg.
[c]Based on a ventilation rate of 5.4 ng/m^3 and a bodyweight of 9.2 kg (for 6 to 12 month old infants).
[d] Based on a ventilation rate of 8.0 ng/m^3 and a bodyweight of 13.5 kg.(for 12 to 24 month old children).
[e] Based on a ventilation rate of 10.9 and a bodyweight of 16.1kg (for 24 to 60 month old children).

Risk Characterisation

30. 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*".

31. MOEs based on the estimated dietary exposures alone 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.

32. 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.

33. 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.

Table 10. 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 median lead level (1 µg/L)					Total diet including water with 97.5th percentile lead level (9.5 µg/L)				
			Ready to feed	Dry powder + water with lead at median (1 µg/L)	Dry powder + water with lead at 97.5th percentile (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 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[a] (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[b]	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

[a] *Values are the highest upper bound estimate for the age range.*
[b] *The MOE is calculated by dividing the $BMDL_{01}$ of 0.50 µg/kg bw/day by the respective dietary exposure.*

34. 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. Median concentration MOEs are all close to 1 and any risk would likely be considered to be small. However for high level concentration exposures, all MOEs are <1, and the lowest MOE is 0.26 indicating that risks cannot be ruled out. By comparison exposures from air are negligible (Table 9).

Table 11. Range of estimated exposures to lead from soil (adjusted for bioavailability) and corresponding MOEs compared to the $BMDL_{01}$ 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	0.58	0.53	0.50	0.47	0.35
	High level concentration	1.92	1.74	1.68	1.56	1.14
MOE[a]	Median concentration	0.86	0.95	1.00	1.07	1.44
	High level concentration	0.26	0.29	0.30	0.32	0.44

[a]The MOE is calculated by dividing the $BMDL_{01}$ of 0.50 µg/kg bw/day by the respective exposure.
These comparisons assume equivalent absorption from different sources.

35. 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.

36. 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.

Risk Characterisation for aggregate exposures

37. 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 12 to 14). 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 93 mg/kg and 97.5th percentile 310 mg/kg.

38. 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. Exposure from air was also minimal in this age group.

39. Table 12 shows the aggregate exposure estimates and MOEs for infants aged 4 to 6 and 6 to 9 months. The aggregate exposures for these age groups are based on the exposure estimates for breast milk, the total diet including water and air. Estimates from exposures via soil, were not calculated for this age group as infants <9 months are less able to move around and come into contact with soil. For 4 to 9 month olds, aggregate exposures correspond to MOEs ranging between 0.8 and 1.54, high level food sources may decrease the MOE by approximately a third, whilst high level exposures via water and air have around a 10 - 15% reduction on the MOEs.

Table 12. Aggregate exposures to lead for infants aged 4 to 9 months based on exposures from breast milk and the total diet including water and air, and the corresponding MOEs when these aggregate exposures are compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination[a]			**Age (months)**			
			4 to 6		**6 to 9**	
			Exposure (µg/kg bw/day)	**MOE**	**Exposure** (µg/kg bw/day)	**MOE**
Mean breast milk + mean air	+ mean total diet incl. water lead at	Median	0.325	1.54	0.345	1.45
		97.5th percentile	0.355	1.41	0.425	1.18
97.5th percentile breast milk + mean air	+ mean total diet incl. water lead at	Median	0.485	1.03	0.545	0.92
		97.5th percentile	0.515	0.97	0.625	0.80
Mean breast milk + mean air	+ **97.5th percentile total diet** incl. water lead at	Median	0.485	1.03	0.485	1.03
		97.5th percentile	0.515	0.97	0.565	0.88
Mean breast milk + **97.5th percentile air**	+ mean total diet incl. water lead at	Median	0.353	1.42	0.378	1.32
		97.5th percentile	0.383	1.31	0.458	1.09

[a] *Breast milk exposure from Table 2, air from Table 9 and water concentrations for total diet water are taken from Table 1.*

40. Table 13 shows aggregate exposure estimates and MOEs for infants aged 9 to 18 months. Exposures from soil have the greatest impact on MOEs reducing already low MOEs by about two thirds. High level exposures via food sources and water reduce MOEs by around 10 - 15% compared to median intakes. However as a whole infants in these age groups have MOEs <1. Such MOEs could be considered to be of toxicological concern, however the uncertainties in the exposure assessment make interpretation of any potential health effects difficult.

Table 13. Aggregate exposures to lead for infants aged 9 to 18 months based on exposures from breast milk, the total diet including water, soil (assuming 60% relative bioavailability), and air, and the corresponding MOEs when these aggregate exposures are compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination	Concentration of lead in TDS water	Age (months)					
		9 to 12		12 to 15		15 to 18	
		Exposure (µg/kg bw/day)	MOE	Exposure (µg/kg bw/day)	MOE	Exposure (µg/kg bw/day)	MOE
Mean breast milk + mean total diet (incl. water) + average soil + mean air	Median	0.817	0.61	0.903	0.55	0.8931	0.56
	97.5th percentile	0.927	0.54	0.983	0.51	0.9831	0.51
97.5th percentile breast milk + mean total diet (incl. water) + average soil + mean air	Median	1.017	0.49	1.003	0.50	0.893	0.56
	97.5th percentile	1.127	0.44	1.083	0.46	0.983	0.51
Mean breast milk + **97.5th percentile total diet (incl. water)** + average soil + mean air	Median	0.967	0.52	1.093	0.46	1.093	0.46
	97.5th percentile	1.077	0.46	1.303	0.38	1.363	0.37
Mean breast milk + mean total diet (incl. water) **+ high level soil** + mean air	Median	2.155	0.23	2.115	0.24	2.075	0.24
	97.5th percentile	2.265	0.22	2.195	0.23	2.165	0.23
Mean breast milk + mean total diet (incl. water) + average soil + **97.5th percentile** air	Median	0.817	0.59	0.936	0.53	0.926	0.54
	97.5th percentile	0.927	0.52	1.016	0.49	1.016	0.49

41. Aggregate exposure estimates and MOEs for young children aged 18 months to 5 years are provided in Table 14. As with infants aged 9 to 18 months, MOEs are all <1 with the main contributor to the reduction of MOEs being soil. The contribution to exposures from water are increased in those children with higher food consumptions, likely due to the increased shift towards an adult diet.

Table 14. Aggregate exposures to lead for young children aged 18 to 60 months based on exposures from the total diet including water, and soil (assuming 60% relative bioavailability), and the corresponding MOEs when these aggregate exposures are compared to the $BMDL_{01}$ of 0.5 µg/kg bw/day.

Exposure combination	**Concentration of lead in TDS water**	**Age (months)**			
		18 to 24		**24 to 60**	
		Exposure (µg/kg bw/day)	**MOE**	**Exposure** (µg/kg bw/day)	**MOE**
Mean total diet (incl. water) + average soil and air	Median	0.793	0.63	0.623	0.80
	97.5th percentile	0.883	0.57	0.713	0.70
97.5th percentile total diet (incl. water) + average soil + air	Median	0.953	0.52	0.793	0.63
	97.5th percentile	1.353	0.37	1.023	0.49
Mean total diet (incl. water) + **high level soil** + air	Median	1.885	0.27	1.415	0.35
	97.5th percentile	1.975	0.25	1.505	0.33
Mean total diet (incl. water) + average soil + **97.5th percentile air**	Median	0.826	0.61	0.654	0.76
	97.5th percentile	0.916	0.55	0.744	0.67

Overall Risk Characterisation

42. MOEs such as those aggregate estimates provide here for infants and young children aged 9 months to 5 years could be considered to be of

toxicological concern, however the uncertainties in the exposure assessment make interpretation of any potential health effects difficult. The MOEs for infants <9 months indicate risks are small or unlikely. Exposures via soil alone indicate risks cannot be ruled out for ages 9 months to 5 years. It is a source that is largely unavoidable in the early years when the neurodevelopmental effects are of most concern but unlikely to persist through childhood and into adulthood.

Conclusions

43. The risks associated with exposure to lead are assessed in this addendum 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. The same approach as used for the review of lead in the infant diet in 2013.

44. Exposures in infants 0 to 6 months old fed breast milk, ready to feed drinks and powder formula made with water at median lead concentrations are unlikely to be a cause for concern. However for a small group of high consuming infants risks cannot be ruled out where water with a high concentration of lead is present in water has been used to reconstitute powder formula.

45. In taking into account all sources of exposure (breast milk, air and the introduction of the adult diet) for the majority of infants aged 4 to 9 months old, the combined exposures have MOEs of >1 which can be taken to imply that at most, any risk is likely to be small. For a proportion of infants, MOEs < 1 indicate that a low level of risk cannot be ruled out. However this is based on an unusually high concentration of lead in breast milk and/or in water.

46. Exposures from the total diet alone (inclusive of water) are unlikely to be a cause for concern for the majority of infants and young children aged 9 months to 5 years.

47. When high levels of lead are present in the soil, MOEs calculated indicate a concern to children aged 9 months to 60 months. However due to possible confounders and uncertainties the majority of infant and young children are unlikely to be at material risk.

48. Conversely when considering aggregate exposures, soil may sufficiently contribute to the lowering of MOEs such that a risk to health cannot be ruled out even for those infants and young children not a risk from the diet alone.

49. Overall, MOEs associated with aggregate estimates provided here for the majority of infants (<9 months old) do not confer a cause for concern as risks are small or unlikely. However in young children aged 9 months to 60 months overall exposures indicate a potential risk, although due to

uncertainties in the risk assessment defining the magnitude of a potential risk to health is difficult.

Secretariat
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