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 inform 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 a reference point for dietary intake 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\textsubscript{01}) blood level associated with 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 from breast milk in children aged 0 to 18 months.

6. Levels of lead have recently been measured in an FSA survey of metals in infant formulae and food (FSA, 2016a) and in the composite food samples of the 2014 Total Diet Study (TDS) (FSA, 2016b).

7. Median and 97.5\textsuperscript{th} percentile values for 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 97.5\textsuperscript{th} 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         |
| England and Wales          | 12,000            | <1.0\*          |
| Northern Ireland           | 390               | 0.2             |
| Scotland                   | 1,500             | 0.2             |

*Reported by DWI as <1.0 µg/L based on limits of quantitation (LOQs). A median value of 1.0 µg/L and a 97.5\textsuperscript{th} 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. It
was therefore not possible to estimate likely exposure in those relying on private water supply with any confidence.

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., 2011) 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 97.5$^{th}$ percentile concentration values of 8.7 and 63 ng/m$^3$, respectively were derived from these sites (Defra, 2015).

**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 estimates.

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.

<table>
<thead>
<tr>
<th>Age bands (months)</th>
<th>Bodyweight</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - &lt;4</td>
<td>5.9 kg$^a$</td>
</tr>
<tr>
<td>≥4 - &lt;6</td>
<td>7.8 kg$^b$</td>
</tr>
<tr>
<td>≥6 - &lt;9</td>
<td>8.7 kg$^b$</td>
</tr>
<tr>
<td>≥9 - &lt;12</td>
<td>9.6 kg$^b$</td>
</tr>
<tr>
<td>≥12 - &lt;15</td>
<td>10.6 kg$^b$</td>
</tr>
<tr>
<td>≥15 - &lt;18</td>
<td>11.2 kg$^b$</td>
</tr>
<tr>
<td>≥18 - &lt;24</td>
<td>12.0 kg$^b$</td>
</tr>
<tr>
<td>≥24 - &lt;60</td>
<td>16.1 kg$^c$</td>
</tr>
</tbody>
</table>

$^a$ 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 (800 mL) and high level (1,200 mL) 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 to lead exposure in this age group.

Table 3. Lead exposure (μg/kg bw/day) from breastfeeding estimated for consumption of breast milk containing lead at 2.6 μg/L.

<table>
<thead>
<tr>
<th>Age group (months)</th>
<th>0 to 4&lt;sup&gt;a&lt;/sup&gt;</th>
<th>&gt;4 to 6&lt;sup&gt;a&lt;/sup&gt;</th>
<th>&gt;6 to 9&lt;sup&gt;b&lt;/sup&gt;</th>
<th>&gt;9 to 12&lt;sup&gt;b&lt;/sup&gt;</th>
<th>12 to 15&lt;sup&gt;b&lt;/sup&gt;</th>
<th>15 to 18&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of consumers</td>
<td>N/A</td>
<td>N/A</td>
<td>140</td>
<td>124</td>
<td>66</td>
<td>32</td>
</tr>
<tr>
<td>Mean</td>
<td>0.35</td>
<td>0.27</td>
<td>0.17</td>
<td>0.099</td>
<td>0.076</td>
<td>0.066</td>
</tr>
<tr>
<td>High level</td>
<td>0.53</td>
<td>0.40</td>
<td>0.41</td>
<td>0.30</td>
<td>0.19</td>
<td>0.13</td>
</tr>
</tbody>
</table>

<sup>a</sup> Mean and high level lead exposures were based on exclusive breastfeeding and consumption of 800 and 1,200mL, respectively (COT, 2013).

<sup>b</sup> Consumption data from DNSIYC; high level is 97.5<sup>th</sup> percentile. Values rounded to 2 significant figures (SF).

Infant formulae and complementary food

15. Potential 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 from the infant metals survey (FSA 2016a) with default values for mean (800 mL) and high level (1,200 mL) 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 97.5<sup>th</sup> percentile value (from Table 1). It should be noted that the median value was based on measurements below the limit of quantification.
Table 4. Estimated lead exposures from exclusive first milk infant formula for 0 to 4 months.

<table>
<thead>
<tr>
<th>Infant Formula Types</th>
<th>LB - UB exposure (µg/kg bw/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>800 mL</td>
</tr>
<tr>
<td>Ready to Feeda</td>
<td>0.00 - 0.049</td>
</tr>
<tr>
<td>Dry Powderb,c</td>
<td>0.020 - 0.081</td>
</tr>
<tr>
<td>Dry Powderb + water with lead at 1 µg/L</td>
<td>0.14 - 0.20</td>
</tr>
<tr>
<td>Dry Powderb + water with lead at 9.5 µg/L</td>
<td>1.1 - 1.2</td>
</tr>
</tbody>
</table>

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 and occurrence data from the infant metals survey (FSA 2016a). The overall potential mean and 97.5th percentile lead exposures (excluding water) in 4 to 12 month old infants ranged from 0.0049 – 0.11 and 0.18 – 0.25 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. When lead was assumed to be present in drinking water at the highest median level (from Table 1), exposure from this source had a minimal impact on total dietary exposure 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 would be lower than the conservative values in Table 5. When the lead level in water was assumed to be 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.

<table>
<thead>
<tr>
<th>Food Groups</th>
<th>LB - UB exposure (µg/kg bw/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 to 6 months (n=116)</td>
</tr>
<tr>
<td></td>
<td>Mean 97.5th percentile</td>
</tr>
<tr>
<td>Infant formula</td>
<td>0.000 – 0.0027 0.0011 – 0.057</td>
</tr>
<tr>
<td>Commercial infant foods</td>
<td>0.024 – 0.042 0.12 – 0.16</td>
</tr>
<tr>
<td>Other foods</td>
<td>0.020 – 0.025 0.12 – 0.14</td>
</tr>
<tr>
<td>Total (excluding water)</td>
<td>0.049 – 0.064 0.19 – 0.23&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Total including water with lead at 1 µg/L&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.059 - 0.074 0.20 - 0.24</td>
</tr>
<tr>
<td>Total including water with lead at 9.5 µg/L&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.089 – 0.10 0.23 – 0.27</td>
</tr>
</tbody>
</table>

<sup>a</sup> Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5<sup>th</sup> percentile consumption values for each of the three food categories.

<sup>b</sup> 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 (FSA, 2016a) and the 2014 TDS (FSA, 2016b). The infant metals 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 approach.

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 0.067 - 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, when lead was assumed to be present in drinking water at the highest median level (Table 1) exposure from this source 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, when lead in drinking water was assumed to be present at the highest 97.5th percentile, exposure was increased by up to 2.6-fold.

Table 6. Estimated lead exposures from infant formulae, commercial infant foods and other foods in children aged 12 to 18 months.

<table>
<thead>
<tr>
<th>Food Groups</th>
<th>LB - UB exposure (µg/kg bw/day)</th>
<th>12 to 15 months (n=670)</th>
<th>15 to 18 months (n=605)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>97.5th percentile</td>
<td>Mean</td>
</tr>
<tr>
<td>Infant formula</td>
<td>0.000-0.0076</td>
<td>0.000 - 0.034</td>
<td>0.000-0.0040</td>
</tr>
<tr>
<td>Commercial infant foods</td>
<td>0.019 - 0.027</td>
<td>0.10 - 0.15</td>
<td>0.011 - 0.015</td>
</tr>
<tr>
<td>Other foods</td>
<td>0.045 - 0.078</td>
<td>0.12 - 0.17</td>
<td>0.047 - 0.082</td>
</tr>
<tr>
<td>Total (excluding water)</td>
<td>0.067 - 0.10</td>
<td>0.15 - 0.22a</td>
<td>0.061 - 0.084</td>
</tr>
<tr>
<td>Total including water with lead at 1 µg/L</td>
<td>0.076 - 0.11</td>
<td>0.16 - 0.23</td>
<td>0.071 - 0.094</td>
</tr>
<tr>
<td>Total including water with lead at 9.5 µg/L</td>
<td>0.19 - 0.22</td>
<td>0.27 - 0.34</td>
<td>0.20 - 0.22</td>
</tr>
</tbody>
</table>

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 potential 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 using data from the infant metals survey. This is due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the infant metals survey.

20. The lead concentration in tap water was recorded as <0.8 µg/L in the TDS, which is similar to the median concentrations in tap water in England and Wales (Table 1). Therefore the exposures in table 7 have been estimated using the highest 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, assuming lead was present in water at the median concentration. Assuming a lead concentration of 9.5 µg/L (highest 97.5th percentile), in place of the concentration identified for tap water, increased estimates of lead exposure 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 making 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 (FSA, 2016b).

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

<table>
<thead>
<tr>
<th>Lead concentration in water</th>
<th>LB - UB exposure (µg/kg bw/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12 to 15 months (n=670)</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>1 µg/L</td>
<td>0.15 - 0.27</td>
</tr>
<tr>
<td>9.5 µg/L</td>
<td>0.23 - 0.35</td>
</tr>
</tbody>
</table>

Values rounded to 2 SF.
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 lead exposures that were estimated using TDS data for children aged 18 to 60 months. Again, the exposure estimates derived using data from the TDS are higher than those estimated using data from the infant metals survey, due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the infant metals survey. As described in paragraph 20, the exposures have been estimated using the median and 97.5th percentile concentrations of lead in water 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 assuming lead present in water at the median concentration. Assuming 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 making 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 (FSA, 2016b).

Table 8. Estimated lead exposures in children aged 18 to 60 months.

<table>
<thead>
<tr>
<th>Lead concentration in water</th>
<th>LB - UB exposure (µg/kg bw/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18 to 24 months (n=70)</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>1 µg/L</td>
<td>0.17 - 0.32</td>
</tr>
<tr>
<td>9.5 µg/L</td>
<td>0.27 - 0.41</td>
</tr>
</tbody>
</table>

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, for 6 – 12 month olds and 1 to 5 years, respectively (US EPA, 2011a). 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). Data specific to dust were not available and therefore for the purposes of this evaluation, it is assumed that they are the same as soil, although this is likely to be an overestimate (Table 9).

27. The bioavailability of lead in soil is likely to be highly variable, depending on the source. In this assessment, a conversion factor of 0.6 was applied to the soil data to account for the bioavailability. 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 reference point for dietary intake 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.

Table 9. Potential lead exposures (µg/kg bw/day) from soil and dust in infants and young children aged 6 to 60 months after adjusting for bioavailability relative to food.

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

Exposures to lead from soil/dust 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 (table 10) were estimated using the body weights shown in Table 2, assuming the mean ventilation rates derived from the US EPA exposure factors handbook (US EPA, 2011b) and the median (8.7 ng/m³) and 97.5th percentile value (63 ng/m³) concentrations of lead in air from the monitoring sites in the UK (paragraph 10).
### Table 10. Estimated exposure to lead from air

<table>
<thead>
<tr>
<th>Lead concentration</th>
<th>Exposure by age group (months) (µg/kg bw/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.7 ng/m³</td>
<td>0 to 4 (3.6 m³/d)&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0.0053</td>
</tr>
<tr>
<td>63 ng/m³</td>
<td>0.038</td>
</tr>
</tbody>
</table>

<sup>a</sup> Ventilation rate  
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<sub>01</sub> 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. A decrement of 1 IQ point is unlikely to have an impact on an individual, but if there is a decrease of 1 IQ point at the population level, there will be some individuals for whom the decrement is much larger, together with an increase in the proportion of individuals with low IQ such that they are not capable of independent living and a decrease in the proportion of individuals with a high IQ who are likely to be innovators, with potential socio-economic impacts (FAO/WHO, 2011).

31. MOEs based on the estimated dietary exposures alone are shown in Table 11. For lead exposure estimates for infants aged 0 to 4 months who were high level, exclusive consumers of breast milk, a marginally low MOE of 0.9 was obtained. However, although a low level of risk cannot be ruled out, the COT does not consider that this is cause for undue 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 to a cumulative toxicant over a relatively short time.

32. The MOE values for lead exposure estimates for exclusive feeding with infant formulae were >1 for ready to feed formulae. For powder formula reconstituted with water assumed to contain 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 assumed to contain 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.

33. Estimates of total dietary exposure when drinking water is taken into account, assuming 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<sub>01</sub> for neurodevelopmental effects of lead.

<table>
<thead>
<tr>
<th>Survey/Consumption data</th>
<th>Exclusive breast milk</th>
<th>Exclusive infant formula</th>
<th>Total diet including water with lead at 1 µg/L</th>
<th>Total diet including water with lead at 9.5 µg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (months)</td>
<td>0 to 4</td>
<td>0 to 4</td>
<td>0 to 4</td>
<td>1 µg/L</td>
</tr>
<tr>
<td></td>
<td>0 to 4</td>
<td>0 to 4</td>
<td>0 to 4</td>
<td>9.5 µg/L</td>
</tr>
<tr>
<td>Estimated dietary exposures&lt;sup&gt;a&lt;/sup&gt; (µg/kg bw/day)</td>
<td>Average consumers 0.35</td>
<td>0.049 0.14 - 0.20 1.1 - 1.2</td>
<td>0.059 - 0.12 0.071 - 0.11 0.15 - 0.29</td>
<td>0.089 - 0.23 0.19 - 0.22</td>
</tr>
<tr>
<td></td>
<td>High level consumers 0.53</td>
<td>0.073 0.20 - 0.29 1.7 - 1.8</td>
<td>0.19 - 0.26 0.14 - 0.23 0.30 - 0.49</td>
<td>0.23 - 0.37 0.27 - 0.34</td>
</tr>
<tr>
<td>MOE&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Average consumers 1.0 10 3 - 4 4.5</td>
<td>0.4 - 0.5 4.9 5 - 7 2 - 3 2 - 3 2 - 3 2 - 3</td>
<td>2 - 6 2 - 3 1 - 2 1 - 2</td>
<td>1 - 2 1 - 2</td>
</tr>
<tr>
<td></td>
<td>High level consumers 0.9 7 2 - 3 0.3 - 0.3</td>
<td>2 - 3 2 - 4 1 - 2 1 - 2 1 - 2</td>
<td>1 - 2 2 - 2 0.7 - 0.9 0.6 - 0.7 0.7 - 0.9</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Values are the lowest LB to highest UB estimate for the age range, expressed as 2 SF.

<sup>b</sup> The MOE is calculated by dividing the BMDL<sub>01</sub> of 0.50 µg/kg bw/day by the respective UB - LB dietary exposure, expressed as 1 SF.
34. Table 12 summarises MOEs for estimates of exposure from soil and dust, 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 and dust (adjusted for bioavailability) and corresponding MOEs compared to the BMDL01 for neurodevelopmental effects of lead.

<table>
<thead>
<tr>
<th>Age (months)</th>
<th>6 to 9</th>
<th>9 to 12</th>
<th>12 to 15</th>
<th>15 to 18</th>
<th>18 to 24</th>
<th>24 to 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated exposures (µg/kg bw/day)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (170 mg/kg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.70</td>
<td>0.63</td>
<td>0.96</td>
<td>0.91</td>
<td>0.85</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>97.5th percentile (820 mg/kg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>3.1</td>
<td>4.7</td>
<td>4.4</td>
<td>4.1</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>MOEa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (170 mg/kg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.7</td>
<td>0.8</td>
<td>0.5</td>
<td>0.5</td>
<td>0.6</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>97.5th percentile (820 mg/kg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

a The MOE is calculated by dividing the BMDL01 of 0.50 µg/kg bw/day by the respective exposure, expressed as 1 SF.

Risk Characterisation for aggregate exposures

35. 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 and dust of median 170 mg/kg and 95th percentile 820 mg/kg.

36. 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 dust and minimal lead exposure from air.

37. 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 and dust were not calculated for this age group as infants <6 months are less able to move around and come into contact with soil and dust. 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.

<table>
<thead>
<tr>
<th>Exposure combination$^a$</th>
<th>Exposure (μg/kg bw/day)$^b$</th>
<th>MOE $^c$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean breast milk + mean air + mean total diet incl. water lead at 1 μg/L</td>
<td>0.33-0.35</td>
<td>1-2</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>0.36-0.38</td>
<td>1</td>
</tr>
<tr>
<td>Mean breast milk + 97.5th percentile air + mean air + mean total diet incl. water lead at 1 μg/L</td>
<td>0.46-0.48</td>
<td>1</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>0.49-0.51</td>
<td>1</td>
</tr>
<tr>
<td>Mean breast milk + mean air + mean total diet incl. water lead at 1 μg/L</td>
<td>0.48-0.52</td>
<td>1</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>0.51-0.55</td>
<td>0.9-1</td>
</tr>
<tr>
<td>Mean breast milk + 97.5th percentile air + mean total diet incl. water lead at 1 μg/L</td>
<td>0.36-0.37</td>
<td>1</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>0.39-0.41</td>
<td>1</td>
</tr>
</tbody>
</table>

$^a$ 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 ILB to 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.

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

39. Aggregate exposure estimates and MOEs for young children aged 18 months to 5 years are provided in Table 15. Similar to the 6 to 18 months age groups, MOEs are all <1 with the major impact from soil and dust. In addition to the uncertainties in the MOEs noted above, further uncertainty relates to the variability of bioavailability of lead in soil, and the assumption that the levels of lead in dust are the same as those in soil.
Table 14. Exposures to lead at ages 6 to 18 months aggregated from breast milk, total diet, water, soil/dust (assuming 60% relative bioavailability) and air, and the corresponding MOEs when compared to the BMDL$_{01}$ of 0.5 μg/kg bw/day.

<table>
<thead>
<tr>
<th>Exposure combination</th>
<th>Age (months)</th>
<th>6 to 9</th>
<th>9 to 12</th>
<th>12 to 15</th>
<th>15 to 18</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure$^a$ (μg/kg bw/day)</td>
<td>MOE$^b$</td>
<td>Exposure$^a$ (μg/kg bw/day)</td>
<td>MOE$^b$</td>
<td>Exposure$^a$ (μg/kg bw/day)</td>
</tr>
<tr>
<td>Mean breast milk + mean air</td>
<td>1 μg/L</td>
<td>0.99-1.0</td>
<td>0.5</td>
<td>0.83-0.86</td>
<td>0.6</td>
</tr>
<tr>
<td>+ mean total diet incl. water lead at</td>
<td>9.5 μg/L</td>
<td>1.0-1.1</td>
<td>0.5</td>
<td>0.92-0.97</td>
<td>0.5</td>
</tr>
<tr>
<td>97.5$^{th}$ percentile breast milk + average soil + mean air</td>
<td>1 μg/L</td>
<td>1.2</td>
<td>0.4</td>
<td>1.0-1.1</td>
<td>0.5</td>
</tr>
<tr>
<td>+ mean total diet incl. water lead at</td>
<td>9.5 μg/L</td>
<td>1.3</td>
<td>0.4</td>
<td>1.1-1.2</td>
<td>0.4-0.5</td>
</tr>
<tr>
<td>Mean breast milk + average soil + mean air</td>
<td>+ 97.5th percentile total diet incl. water lead at</td>
<td>1 μg/L</td>
<td>1.1</td>
<td>0.5</td>
<td>0.94-1.1</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>1.1-1.2</td>
<td>0.4-0.5</td>
<td>1.0-1.1</td>
<td>0.5</td>
<td>1.6-1.7</td>
</tr>
<tr>
<td>Mean breast milk + high level soil + mean air</td>
<td>+ mean total diet incl. water lead at</td>
<td>1 μg/L</td>
<td>3.7</td>
<td>0.1</td>
<td>3.3</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>3.7-3.8</td>
<td>0.1</td>
<td>3.4</td>
<td>0.1</td>
<td>5.0-5.1</td>
</tr>
<tr>
<td>Mean breast milk + average soil + 97.5$^{th}$ percentile air</td>
<td>+ mean total diet incl. water lead at</td>
<td>1 μg/L</td>
<td>0.99-1.0</td>
<td>0.5</td>
<td>0.85-0.89</td>
</tr>
<tr>
<td>9.5 μg/L</td>
<td>1.1</td>
<td>0.5</td>
<td>0.95-1.0</td>
<td>0.5</td>
<td>1.3-1.5</td>
</tr>
</tbody>
</table>

$^a$ Exposures rounded to 2 SF, expressed as LB to UB range where appropriate.

$^b$ 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/dust (assuming 60% relative bioavailability) and air, and the corresponding MOEs when compared to the BMDL$_{0.1}$ of 0.5 μg/kg bw/day.

<table>
<thead>
<tr>
<th>Exposure combination</th>
<th>Age (months)</th>
<th>18 to 24</th>
<th>24 to 60</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure</td>
<td>MOE$^b$</td>
<td>Exposure</td>
</tr>
<tr>
<td></td>
<td>(μg/kg bw/day)$^a$</td>
<td></td>
<td>(μg/kg bw/day)$^a$</td>
</tr>
<tr>
<td>Average soil + air</td>
<td>+ mean total diet incl. water lead at 1 μg/L</td>
<td>1.0-1.2</td>
<td>0.4-0.5</td>
</tr>
<tr>
<td></td>
<td>9.5 μg/L</td>
<td>1.1-1.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Average soil + air</td>
<td>+ 97.5th percentile total diet incl. water lead at 1 μg/L</td>
<td>1.1-1.3</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>9.5 μg/L</td>
<td>1.5-1.7</td>
<td>0.3</td>
</tr>
<tr>
<td>High level soil + air</td>
<td>+ mean total diet incl. water lead at 1 μg/L</td>
<td>4.3-4.4</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>9.5 μg/L</td>
<td>4.4-4.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Average soil + 97.5th percentile air</td>
<td>+ mean total diet incl. water lead at 1 μg/L</td>
<td>1.1-1.2</td>
<td>0.4-0.5</td>
</tr>
<tr>
<td></td>
<td>9.5 μg/L</td>
<td>1.2-1.3</td>
<td>0.40</td>
</tr>
</tbody>
</table>

$^a$ Exposures rounded to 2 SF, expressed as LB to UB range where appropriate.

$^b$ 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**

40. 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 and dust contains lead at the upper end of the typical concentration range found in urban soil.

41. 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 have been 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 cannot be excluded. This is particularly the case if soil/dust, and to a lesser extent water, contains lead at the higher end of reported concentrations.

42. The COT noted that the potential impact of soil on total lead exposure of children has been recognised for some time and is not a new finding of this assessment. Well-recognised major sources of lead in soil include mining and smelting activities, sewage sludge usage in agriculture; and aerial contamination from vehicle exhausts. Fresh input from these sources has reduced to low levels in recent years but much of the historical lead burden remains. It has been estimated that in Britain there has been in excess of 4000 km² of land affected by lead as a result of mining activity dating from Roman times or earlier (EA, 2002; Defra, 2014).

Conclusions

43. 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.

44. Lead can adversely affect neurodevelopment. The risks associated with exposure to lead are assessed by comparison of the calculated exposures to the reference point for dietary intake estimated by the EFSA to correspond to the BMDL₀₁ blood level associated with a decrease of one IQ point. The consequence of a downward shift in the distribution of IQs in the population is to increase the number of individuals with learning difficulties and to decrease those with an exceptionally high level of intellectual ability.

45. For infants aged 0 to 6 months old fed breast milk, ready to feed drinks and powder formula made with water containing typical lead concentrations, any risk would 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 of lead in public water supplies. It was not possible to estimate likely exposure in those relying on private water supply.

46. For older infants, and for young children, any risk from diet alone will also be small. However the effects of lead will be due to total lead exposure and not just from lead in the diet. When the possible contribution from soil and dust is taken into account, a risk at the population level and to some infants and young children cannot be ruled out. The potential adverse contribution from soil has been recognised for some time. There are a number of
uncertainties in both the $\text{BMDL}_{01}$ and the exposure assessments and, in general, conservative approaches have been taken.

47. The COT previously noted the decreasing trends in dietary exposure to lead and blood lead levels in recent decades. Nevertheless, the absence of an identified threshold for neurodevelopmental effects of lead and the relatively small MOEs identified in this assessment emphasise the need for continued efforts to control lead in the environment.

48. This assessment does not indicate a need for specific advice on lead relating to the diet of infants and young children

COT Statement 2016/03
August 2016
References


FSA (2016a). Survey of metals and other elements in infant foods (to be published)

FSA (2016b). Metals and other elements in the 2014 Total Diet Study (to be published)


