Risk characterisation - Statement on the effects of lead on maternal health

In this guide

47. Potential risks from maternal 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. 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 (see paragraph 26-27), EFSA therefore concluded that a margin of exposure of 10 or greater should be sufficient to ensure that there was no appreciable risk of a clinically significant effect on IQ. At lower MOEs, but greater than 1.0, the risk is likely to be low, but not such that it could be dismissed as of no potential concern. (EFSA, 2010).

48. In 2013, the COT further concluded that 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 concern, 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 (COT, 2013).

Food

49. Using the estimated dietary exposure of 0.5 µg/kg bw day, equivalent to the BMDL01 of 12 µg/L blood Pb concentration, for effects of Pb on developmental neurotoxicity (EFSA, 2010), the MOEs for women of childbearing age from the highest-lead-containing food groups in the total diet study are given in Tables 3 and 4 for the highest measured mean and 97.5th percentile lead levels, respectively.

Table 3. Calculated MOEs for lead in the food groups with the highest measured mean lead concentrations (upper bound) for the total diet in women aged 16 to 49 years of age.

Commodity	**Mean lead exposure (µg/kg bw/day)***	**MOE for 0.5 µg/kg bw/day**
Green vegetables	0.0088	57
Misc. cereals	0.0080	63
Other vegetables	0.0063	79
Total in all food	0.12	4.2

The calculated exposures were compared to the dietary intake value of 0.5 µg/kg b.w. per day which corresponds to the blood BMDL01 of 12 µg/L for developmental neurotoxicity. “Total” was obtained by summing the individual upper bound estimates for all foods assessed (see Table 1, Appendix 1).

* Average body weight for women of childbearing age used for exposure = 70.3 kg, value provided by the FSA Exposure Assessment Team from years 1 – 11 of the rolling National Diet and Nutrition Survey, NDNS (Bates *et al*., 2014, Bates *et al*., 2016, Roberts *et al*., 2018).

Table 4. MOEs for lead in the dietary commodities with the highest measured 97.5th percentile lead concentrations (upper bound) and for the total diet in women aged 16 to 49 years of age.

Commodity	**97.5th percentile lead exposure (µg/kg bw/day)***	**MOE for 0.5 µg/kg bw/day**
Green vegetables	0.034	15
Misc. cereals	0.023	22
Other vegetables	0.019	26
Total in all food	0.23	2.2

The calculated exposures were compared to the dietary intake value of 0.5 µg/kg b.w. per day which corresponds to the blood BMDL01 of 12 µg/L for developmental neurotoxicity. “Total” was obtained by summing the individual upper bound estimates for all foods assessed (see Table 1, Appendix 1).

*Average body weight for women of childbearing age used for exposure = 70.3 kg, value provided by the FSA Exposure Assessment Team from years 1 – 11 of the rolling National Diet and Nutrition Survey, NDNS (Bates et al., 2014, Bates et al., 2016, Roberts et al., 2018).

50. Neither the mean nor the 97.5th percentile exposure MOEs for the foods with the highest measure of lead, nor for the total amount of lead in food as a whole as reported by the NDNS, has a value of 1 or lower, indicating that any risk of toxicity from lead in food is likely to be small.

Drinking water

51. The MOEs for lead in drinking water are shown in Table 5.

Table 5. MOEs for lead in drinking water using the concentration data provided by the water regulators for England and Wales, Scotland and Northern Ireland and consumption data provided by the FSA Exposure Assessment Team.

Region	**97.5th percentile lead exposure (µg/kg bw/day) ****	**MOE for 0.5 µg/kg bw/day**
England and Wales *	0.00098	510
Scotland	0.00021	2400
Northern Ireland	0.00050	1000

The calculated exposures were compared to the dietary intake value of 0.5 µg/kg b.w. per day which corresponds to the blood BMDL01 of 12 µg/L for developmental neurotoxicity MOEs rounded to 2 s.f.

*Using 99th percentile lead concentration.

**Average body weight for women of childbearing age used for exposure = 70.3 kg, value provided by the FSA Exposure Assessment Team from years 1 – 11 of the rolling National Diet and Nutrition Survey, NDNS (Bates *et al*., 2014, Bates *et al*., 2016, Roberts *et al*., 2018).

52. The MOEs for intake of lead from drinking water from Scotland and Northern Ireland are above 10, indicating that there was no appreciable risk from lead in drinking water. The MOE for intake of lead from drinking water in England and Wales is greater than 1, therefore indicating that any risk of toxicity from lead in drinking water is likely to be small.

Air

53. The inhaled exposure level would have minimal impact upon total lead exposure. Relative to the BMDL01 corresponding dietary intake value derived by EFSA, a conservative intake from air gives an MOE of 36 for developmental neurotoxicity.

Soil and Dust

54. The MOEs for exposures from lead in soil are shown in Table 6 and Table 7.

Table 6. MOEs for lead in soil from regions in England using the mean concentrations of lead. Soil lead concentration data are taken from Defra (Ander et al. 2011) and a soil ingestion rate from the Environment Agency (2009).

Region	**Mean lead exposure (µg/kg bw/day) ***	**MOE for 0.5 µg/kg bw/day**
Rural	0.025	20
Semi-Urban	0.041	12
Urban	0.118	4

The calculated exposures were compared to the dietary intake value of 0.5 µg/kg b.w. per day which corresponds to the blood BMDL01 of 12 µg/L for developmental neurotoxicity.

* Average body weight for women of childbearing age used for ingestion rate = 70.3 kg, value provided by the FSA Exposure Assessment Team from years 1 – 11 of the rolling National Diet and Nutrition Survey, NDNS (Bates *et al*., 2014, Bates *et al*., 2016, Roberts *et al*., 2018).

Table 7. MOEs for lead in soil from regions in England using the highest measured (75^{th} percentile) lead concentrations. Soil lead concentration data taken from Defra (Ander et al. 2011) and a soil ingestion rate from the Environment Agency (2009).

Region	**75^{th} Percentile lead exposure (µg/kg bw/day) ***	**MOE for 0.5 µg/kg bw/day**
Rural	0.033	15

Semi-Urban	0.071	7
Urban	0.229	2

The calculated exposures were compared to the dietary intake value of 0.5 µg/kg bw/day which corresponds to the blood BMDL01 of 12 µg/L for developmental neurotoxicity.

* Average body weight for women of childbearing age used for ingestion rate = 70.3 kg, value provided by the FSA Exposure Assessment Team from years 1 – 11 of the rolling National Diet and Nutrition Survey, NDNS) (Bates *et al*., 2014, Bates *et al*., 2016, Roberts *et al*., 2018).

55. The MOEs for soil ingestion from regions across England are all greater than 1, therefore, any risk of toxicity from lead in soil is likely to be small. Furthermore, the soil ingestion rate could be an overestimate, particularly as it is a combined value for soil and dust. The ingestion rate is also highly uncertain as it is based upon a small and variable evidence base. Consequently, as the assumptions in the exposure estimates are conservative, the actual soil ingestion rate and lead exposure through this route could be much lower.

Aggregate Characterisation

56. A combined exposure assessment, considering exposure to lead from all sources, relative to the estimated dietary exposure of 0.5 µg/kg bw day, equivalent to the BMDL01 of 12 µg/L blood Pb concentration, for effects of Pb on developmental neurotoxicity (EFSA, 2010), gives a MOE in the range of 0.9-2 depending on the individual contribution to the total from each source (food, drinking water, soil/dust). In a scenario where there are high exposures to lead from all sources (food, drinking water, soil/dust) the MOE is 0.9, and in a scenario where there are average levels of exposure to each source, the MOE is 2. In all aggregate scenarios, any risk of toxicity from lead is likely to be small.