TOX/2016/29

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

Discussion paper on the results of the 2014 survey of metals and other elements in infant foods

Background

1. The Food Standards Agency (FSA) has completed a survey of 15 elements in the 2014 survey of metals and other elements in infant formula, commercial infant foods, and other foods (non-infant specific foods[1]) (FSA, 2016). The results of the survey provide information on the concentrations of aluminium, antimony, arsenic (including inorganic arsenic), cadmium, chromium, copper, iodine, iron, lead, manganese, mercury, nickel, selenium, tin and zinc in these foods. Estimates of dietary exposures have been calculated for each element for UK infants and young children aged 4 to 18 months using food consumption data taken from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013).

2. The Committee is invited to comment on the concentration data derived from this survey (attached in Annex A), and the subsequent exposure assessments (Table 1 and Tables 1 to 6 in Annex B). To aid the discussions, brief summaries of toxicology including the most recent health-based guidance values for each of the elements surveyed, have been included in this discussion paper. A Food Surveillance Information Sheet (FSIS) will be drafted, incorporating the comments of the Committee, with a view to publishing later this year.

3. The Committee has provided comment on similar surveys in the past, with the most recent being a 2003 multi-element survey of infant foods[2] (COT, 2003a; FSA, 2003). The FSA has also completed a survey of metals in weaning foods and formulae for infants (FSA, 2006); however the COT did not provide comment on this survey. Although these surveys could provide a useful comparison of concentrations of different elements in specific foods, they cannot be directly compared to the current survey due to differences in the methodology of the survey itself (e.g. the grouping of certain foods) and in the exposure assessments.

[1] Those which are not specifically manufactured or intended for infants, but are known to be or may be consumed by infants (e.g. bread, fruit and vegetables).
[2] COT (2003) 'Statement on a survey of metals in infant food' Available at: http://cot.food.gov.uk/sites/default/files/cot/statement.pdf

The survey

4. Surveys such as this are carried out on a regular basis and are an important part of the UK Government's surveillance programme for chemicals in food. Survey results are used to estimate dietary exposures of the general UK population or specific sub-populations (e.g. infants) to chemicals in food, such as nutrients and contaminants, to identify changes or trends in exposure and make assessments on the safety and quality of the food supply.

5. A total of 47 samples of powdered and ready-to-feed infant formula (including follow-on formula and growing up milks), 200 samples of commercial infant foods, and 50 other foods were purchased from retail outlets throughout the UK during 2013 and 2014. All samples were analysed as sold (i.e. dry powdered infant formula and dried cereal products such as baby rice were not reconstituted prior to analyses), using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) at the Food and Environment Agency for 15 metals and other elements.

6. The samples of formula-based products were representative of those on sale in the UK at the time of marketing. Samples of specific brands of commercial infant foods were collected in proportion to their market share. Selection of other foods were based on those that made the largest contribution to the infant diet, as recorded in the DNSIYC along with the Department of Health (DH) recommended first foods, next foods and foods from 8-9 months and 12 months (DH, 2015). Each of these 50 foods was a composite of 10 samples from different manufacturers and retailers.

Dietary exposure assessment

7. The concentration data in Tables 1 to 4 of Annex A formed the basis of the exposure assessments. The concentration data from individual products were used to derive the overall mean concentration for each food group (e.g. a mean concentration for follow-on formula was calculated based on the results for each type of follow-on formula analysed). Table 1 below summarises the results of the exposure assessments carried out for each element in the three overarching food categories: infant formula, commercial infant foods and other foods. More detailed exposure assessments are presented in Annex B (Tables 1 to 6).

Table 1. Summary of estimated dietary exposures in UK infants aged 4 to 18 months to a selection of metals and other elements analysed in infant formula, commercial infant foods and other foods

Food Category	**Consumer**	**Dietary exposures in UK infants aged 4 to 18 months (µg/kg bw/day)**															
		Al	**Sb**	**As**	**iAs**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Infant Formula	Mean	0.64-1.1	0-0.030	0-0.013	0-0.010	0-0.010	0.0029-0.10	11	4.0	240	0-0.015	2.2	0-0.0061	0.010-0.25	0.020-0.53	0-0.090	180
	High level	2.0-3.6	0-0.10	0.012-0.040	0.010-0.030	0-0.022	0-0.32	37	14	760	0-0.046	6.9	0-0.020	0-0.90	0.060-1.8	0-0.31	600
Commercial Foods	Mean	12	0.010-0.020	0.13	0.04-0.062	0.06	0.30-0.39	5.7	0.28-0.33	81	0.030-0.040	19	0.0012-0.010	0.60-0.80	0.14	0.36-0.41	51
	High level	54-55	0.040-0.10	0.58	0.19-0.26	0.27	1.4-1.8	26	1.6-1.7	370	0.13-0.17	78	0.010-0.030	2.6-3.6	0.67-0.70	1.9-2.1	250
Other Foods	Mean	19-20	0-0.050	0.78-0.79	0.090-0.10	0.19-0.20	0.26-0.48	16	5.3	160-170	0.040-0.070	63	0.020-0.030	0.92-1.5	0.8	38	160
	High level	50-51	0-0.12	4.2	0.35-0.37	0.52	0.81-1.2	39	19	450-460	0.12-0.16	170	0.13-0.15	2.8-3.8	2.1	250	370
Total	Mean	33-34	0.0040-0.11	0.91-0.94	0.14-0.18	0.25-0.27	0.59-1.0	37	11	550	0.071-0.12	85	0.022-0.046	1.6-2.6	1.1-1.6	38	440
	High level	74-76	0.029-0.21	4.3-4.4	0.41-0.47	0.57-0.59	1.7-2.5	69	23	1300	0.17-0.26	190	0.13-0.16	3.9-5.6	2.6-3.0	250	860

* Values are rounded to 2SF. Values are presented as estimates based on lower-bound (LB) to upper-bound (UB) concentration data. The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all concentration data were above the LOD.

Evaluation

8. Below are brief summaries of the toxicology of each of the elements analysed in this survey. Where possible, published health-base guidance values have been noted, and compared with the results of the current exposure assessments.

Aluminium

9. In 2011, the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) revised their provisional tolerable weekly intake (PTWI) for aluminium. Based on new data that had addressed some of the research needs that they had identified in previous assessments, the JECFA withdrew their PTWI of 1 mg/kg bodyweight (bw)/day, and established a new PTWI of 2 mg/kg bw/day. This new PTWI was derived using a no observed adverse effect level (NOAEL) of 30mg/kg bw/day taken from a developmental and chronic neurotoxicity study in rats, and an uncertainty factor of 100 for inter-species and intra-species differences. The JECFA also converted the NOAEL to a weekly exposure, as this was considered more appropriate in view of the cumulative retention of aluminium (FAO/WHO, 2012).

10. For aluminium, the total mean and high level exposures were 33-34 µg/kg bw/day and 74-76 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with total mean exposures ranging from 19-20 µg/kg bw/day. Overall, the current estimates of dietary exposure to aluminium were well below the JECFA PTWI (equivalent to 286 µg/kg bw/day) at both mean and high level exposure.

11. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to aluminium were not of toxicological concern.

Antimony

12. The World Health Organization (WHO) has set a tolerable daily intake (TDI) of 6 µg/kg bw (WHO, 2003). This was based on a NOAEL of 6 mg/kg bw for decreased body weight gain and reduced food and water intake in a 90-day drinking water study in rats; and an uncertainty factor of 1000 (10 for inter-species, 10 for intra-species and 10 for the use of a sub-chronic study). The toxicity of antimony is a function of the water solubility and the oxidation state of the species, with antimony (III) being more toxic than antimony (V), and inorganic compounds being more toxic than organic compounds. No information was provided regarding how the TDI was established in relation to the speciation, although, the WHO noted that antimony leached from antimony-containing materials would be in the form of the antimony (V) oxo-anion, which is the less toxic form (WHO, 2003).

13. For antimony, the total mean and high level exposures were 0.0040-0.11 µg/kg bw/day and 0.029-0.21 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with total mean exposures ranging from 0-0.050 µg/kg bw/day. Overall, the current estimates of dietary exposure to aluminium were well below the WHO TDI at both mean and high level exposure.

14. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to antimony were not of toxicological concern.

Arsenic

15. The toxicity of arsenic is dependent on the form, organic or inorganic, and the oxidation state of arsenical compounds. It is generally accepted that inorganic arsenic compounds are more toxic than the organic arsenic compounds that are commonly found in fish, seafood and other marine organisms (EFSA, 2009a). For this reason, the Committee has previously recommended that surveys such as this one should measure both total and inorganic arsenic (COT, 2003b).

16. The COT has commented on arsenic in food a number of times in the past. In general the conclusions have been that dietary exposure to organic arsenic was unlikely to constitute a risk to health, but that dietary exposure to inorganic arsenic should be as low as reasonably practicable (ALARP), because it is genotoxic and a known human carcinogen (COT, 2008).

17. For total arsenic, the total mean and high level exposures were 0.91-0.94 µg/kg bw/day and 4.3-4.4 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with total mean exposures ranging from 0.78-0.79 µg/kg bw/day. There is currently no health-based guidance value with which exposures to total arsenic can be compared.

Inorganic arsenic

18. The main adverse effects associated with long-term ingestion of inorganic arsenic in humans are skin lesions, cancer, developmental toxicity, neurotoxicity, cardiovascular diseases, abnormal glucose metabolism, and diabetes (EFSA, 2009a). The International Agency for Research on Cancer (IARC) has reviewed arsenic on a number of occasions, concluding that it is a group 1 carcinogen that causes cancer of the lung, urinary bladder, and skin in humans (IARC, 2012). There are a number of proposed mechanisms of carcinogenicity of inorganic arsenic, including oxidative damage, epigenetic effects and interference with DNA damage repair, but not direct reaction with DNA (EFSA, 2009a; FAO/WHO, 2011a; IARC, 2012).

19. The European Food Safety Authority (EFSA), and the JECFA have published risk assessments on exposure to inorganic arsenic in food. Based

on the available epidemiological studies, the EFSA calculated a range of values for the 95% lower confidence limit of the benchmark dose ($BMDL_{01}$) of 0.3 to 8 µg/kg bw/day, this range was identified for cancers of the lung, skin and urinary bladder, as well as skin lesions (EFSA, 2009a). Using a different approach to modelling the dose-response data, and studies that had been published after the EFSA assessment, the JECFA calculated a BMDL of 3.0 µg/kg bw/day for a 0.5% increased incidence of lung cancer (FAO/WHO, 2011a).

20. At a recent meeting, the COT concluded that the JECFA $BMDL_{0.5}$ of 3.0 µg/kg bw/day identified for lung cancer should be used in the characterisation of the potential risks from exposure to inorganic arsenic. This was because the JECFA risk assessment was based on more robust and recent evidence than that available to the EFSA (COT, 2016). A margin of exposure (MOE) approach should be used to compare exposure estimates to the BMDL.

21. The COT also noted that as there was no precedent for interpreting MOEs that have been calculated based on a BMDL derived from an epidemiological study and relating to a low cancer incidence, such interpretation must be done on a case-by-case basis. As the JECFA BMDL used in this case was based on human data and a 0.5% increased incidence of lung cancer in a well-conducted prospective cohort study, and as inorganic arsenic does not appear to be directly genotoxic, the COT concluded that an MOE of 10 or above could be considered a low concern (COT, 2016).

22. The total mean exposures to inorganic arsenic were 0.14-0.18 µg/kg bw/day. This range of exposures generates an MOE of 20 (rounded to 1 significant figure (SF)), as this is greater than 10, these exposures would be considered a low concern. The total high level exposures were 0.41-0.47 µg/kg bw/day and generate MOEs of 6-7 (rounded to 1 SF). As these MOEs are marginally less than 10 there could be a small risk to high level consumers. The highest contributing food category to total mean exposure was the ‘other foods’ category, with total mean exposures ranging from 0.090-0.10 µg/kg bw/day.

23. The COT is invited to consider the following draft conclusion:

> *Although the current average dietary exposures to inorganic arsenic would be considered a low concern, the high level exposures could present a small risk to consumers; the Committee therefore reiterated that efforts to reduce the levels of inorganic arsenic in food should continue.*

Cadmium

24. Cadmium is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. Cadmium can also cause bone demineralisation, either through direct bone damage or indirectly as a result of renal dysfunction. Using benchmark dose

modelling the EFSA derived a critical urinary cadmium concentration of 1 µg/g creatinine after 50 years of exposure, and estimated that in order to remain below this level in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 µg/kg bw, corresponding to a weekly dietary intake of 2.52 µg/kg bw. The EFSA noted that because of the long half-life of cadmium in the human body, a health-based guidance value should be set on weekly rather than daily basis, and hence established a tolerable weekly intake (TWI) of 2.5 µg/kg bw. The EFSA also noted that some subgroups such as children may exceed the TWI by about two-fold, and stated that although on an individual basis exceeding the TWI by about two-fold is unlikely to lead to adverse effects on the kidney, it clearly demonstrates the need to reduce exposure to Cd at the population level (EFSA, 2009b).

25. In contrast to the EFSA TWI, the JECFA has established a provisional tolerable monthly intake (PTMI) for cadmium of 25 µg/kg bw (equivalent to ~6 µg/kg bw/week or 0.8 µg/kg bw/day). This PTMI was based on data on urinary cadmium levels in humans and a point of departure of 5.24 µg/g creatinine which corresponded to a dietary intake of 0.8 µg/kg bw/day; the JECFA considered that a monthly guidance value was more appropriate than a daily or weekly value due to cadmium's exceptionally long half-life (FAO/WHO, 2011b). As the EFSA TWI is the lower of the health-based guidance values, it has been used to assess the current exposures.

26. For cadmium, the total mean and high level exposures were 0.25-0.27 µg/kg bw/day and 0.57-0.59 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with total mean exposures ranging from 0.19-0.20 µg/kg bw/day. Overall, the total mean exposure estimates were approximately 70% of the TWI and would thus not be of toxicological concern. The total high level estimates were approximately 60% above the EFSA TWI but within the JECFA PTMI. Such exposures are unlikely to lead to adverse effects on the kidney, although it is important to consider whether the potential vulnerability of the infant kidney would be increased due to its immaturity.

27. The COT is invited to consider the following draft conclusion:

> *The Committee concluded that the current average dietary exposure estimates to cadmium would not be of toxicological concern and that although the high level exposure estimates were greater than the EFSA tolerable weekly intake, they would be unlikely to lead to adverse effects. However efforts to reduce the levels of cadmium in food should continue.*

Chromium

28. The toxicity of chromium varies depending on the valency state, with hexavalent chromium (Cr (VI)) being more toxic than trivalent chromium (Cr (III)), which is an essential trace element. Most of the ingested Cr (VI) is considered to be reduced in the stomach to Cr (III), which is poorly bioavailable and presents low ability to enter cells. In contrast to Cr (III), Cr

(VI) is able to cross cellular membranes. Ingested Cr (III) has a low level of toxicity, due partly to its poor absorption, while Cr (VI) and its compounds are oxidizing agents capable of directly inducing tissue damage, and epidemiological studies have found an association between exposure to Cr (VI) and lung cancer (EFSA, 2014a).

29. In 2014 the EFSA established a TDI for Cr (III) of 0.3 mg/kg bw based on the lowest NOAEL identified in a chronic oral toxicity study in rats. In their assessment, the EFSA assumed that all chromium in food was present as Cr (III); the EFSA noted that there was a lack of data on Cr (VI) in food and stated that this assumption was based on the outcome of recent speciation work, the fact that food is by-and-large a reducing medium, and that oxidation of Cr (III) to Cr (VI) would not be favoured in such a medium. The EFSA also assumed that all of the chromium present in drinking water was Cr (VI) (EFSA, 2014a), however as drinking water was not included in this survey, the TDI for Cr (III) has been used to assess the current dietary exposure estimates.

30. For chromium, the total mean and high level exposures were 0.59-1.0 µg/kg bw/day and 1.7-2.5 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘commercial infant foods’ category, with total mean exposures ranging from 0.30-0.39 µg/kg bw/day. Overall, the current estimates of dietary exposure to chromium were well below the EFSA TDI at both mean and high level exposure.

31. The COT is invited to consider the following draft conclusion:

> *The Committee concluded that the current estimated dietary exposures to chromium were not of toxicological concern.*

Copper

32. Although copper is an essential trace element, high levels can cause acute gastrointestinal effects. This may be a direct irritant effect of copper in water and is not so apparent when copper is present in the food matrix (EVM, 2003). The JECFA has derived a provisional maximum tolerable daily intake (PMTDI) of 50-500 µg/kg bw on the basis of human epidemiological and nutritional data related to background exposure to copper (originally proposed in 1973) (FAO/WHO, 1982a). The Expert Group on Vitamins and Minerals (EVM) has set a safe upper level (SUL) for copper of 160 µg/kg bw/day based on a NOAEL of 16 mg/kg bw/day from a 13-week feeding study of copper sulphate in rats in which effects on the liver, kidney and forestomach were seen at higher doses (EVM, 2003). The Scientific Committee on Food (SCF) has set an upper level (UL) for copper of 1 mg/day for 1-3 year olds; if applied to the age group assessed in this survey, this is equivalent to approximately 100 µg/kg bw/day based on an average body weight of 10 kg for infants aged 4 to 18 months (DH, 2013). This UL was extrapolated from an UL for adults of 5 mg/day which was based on a NOAEL of 10 mg/day from a 12 week supplementation study in 7 healthy adults for which the critical endpoint was

adverse effects on liver function, an uncertainty factor of 2 was applied to account for potential variability within the normal population (SCF, 2003a).

33. Regarding copper, the total mean and high level exposures were 37 µg/kg bw/day and 69 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with a total mean exposure of 16 µg/kg bw/day. Overall, the current estimates of dietary exposure to copper were below all of the available health-based guidance values at both mean and high level exposure.

34. The COT is invited to consider the following draft conclusion:

> *The Committee concluded that the current estimated dietary exposures to copper were not of toxicological concern.*

Iodine

35. Iodine is essential for the synthesis of thyroid hormones; through these hormones iodine has an important role in energy-yielding metabolism and many other physiological processes. Iodine deficiency is of particular concern in infants because of the risk of developmental brain damage, which can lead to physical and mental retardation and lower cognitive and motor performance in later life. In addition to this, chronic iodine deficiency may lead to compensatory thyroid hypertrophy/hyperplasia with goitre. The EFSA has recently proposed adequate intakes for iodine of 70 and 90 µg/day for 7 to 11 month olds and 1 to 3 year olds, respectively (EFSA, 2014b).

36. Chronic excessive iodine intake can also lead to goitre, and may accelerate the development of sub-clinical thyroid disorders to overt hypothyroidism or hyperthyroidism, increase the incidence of autoimmune thyroiditis, and increase the risk of thyroid cancer (EFSA, 2014b). The SCF has set an UL for iodine of 200 µg/day for 1-3 year olds. This UL was derived by adjustment of the adult UL of 600 µg/day on the basis of body surface area (defined as body weight$^{0.75}$) since there was no evidence of increased susceptibility in children. The adult UL was based on a study covering a 5-year exposure at iodide intake levels of 30 mg/kg bw/day (equivalent to approximately 1800 mg iodide/day) in which no clinical thyroid pathology occurred, an uncertainty factor of 3 was applied to this (SCF, 2002). If the UL is applied to the age group assessed in this survey, then it is equivalent to approximately 20 µg/kg bw/day based on an average body weight of 10 kg for infants aged 4 to 18 months (DH, 2013).

37. For iodine, the total mean and high level exposures were 11 µg/kg bw/day and 23 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with a total mean exposure of 5.3 µg/kg bw/day. Overall, the current estimates of dietary exposure to iodine were below or marginally greater than (~15%) the SCF UL at both mean and high level exposure, and would thus not be of toxicological concern.

38. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to iodine were not of toxicological concern.

Iron

39. Iron in foods occurs in two main forms: haem and non-haem. The major sources of haem iron in the diet are haemoglobin and myoglobin from meat, poultry and fish, while the major sources of non-haem iron consist mainly of iron salts, derived from plant and dairy products. Most of the non-haem iron present in foods is in the ferric form. Fortification of food with iron is common in developing countries, where deficiency of the element is widespread. The EVM has stated that overall there are insufficient appropriate data to establish a SUL for iron. Although many supplementation studies have been conducted, they have generally been in iron-deficient groups and none of them are applicable to the population as a whole. For iron-replete individuals in non-developing countries, the most common side effects reported are gastrointestinal in nature, and include constipation, nausea, vomiting, and epigastric pain. These effects are reported to follow supplemental doses of between 50 and 220 mg/day, the frequency increasing at higher dose levels. For guidance purposes, a supplemental intake of approximately 17 mg/day (equivalent to 1.7 mg/kg bw/day for a 10 kg infant) would not be expected to produce adverse effects in the majority of people. This was derived by dividing the lower end of the range found to have an effect by an uncertainty factor of 3 to allow for extrapolation from a LOAEL to a NOAEL. This was based on data referring to ferrous iron (Fe II), which is the form of iron generally used in supplements. No additional uncertainty factor was needed for inter-individual variation because the assessment was based on studies on large numbers of people. The EVM did not estimate a SUL for total iron as gastrointestinal effects are associated with iron in supplements rather than in foods (EVM, 2003).

40. The United States Institute of Medicine (US IOM) has established a tolerable upper intake level (TUL) for supplemental non-haem iron of 40 mg/day for infants and children. This TUL is based on a NOAEL of 40 mg/day from epidemiological studies of supplementation with non-haem iron in infants and young children; an uncertainty factor of 1 was applied as there was little uncertainty regarding the range of intakes that is likely to induce gastrointestinal effects in infants and young children (IOM, 2001). If this TUL is applied to the age group assessed in this survey, then it is equivalent to approximately 4 mg/kg bw/day based on an average body weight of 10 kg for infants aged 4 to 18 months (DH, 2013).

41. Regarding iron, the total mean and high level exposures were 550 µg/kg bw/day and 1300 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘infant formula’ category, with a total mean exposure of 240 µg/kg bw/day. Overall, the current estimates of

dietary exposure to iron were below EVM's guidance value for supplemental iron and the US IOM's UL at both mean and high level exposure.

42. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to iron were not of toxicological concern.

Lead

43. Exposure to lead is associated with developmental neurotoxicity in infants and young children, a sub-group of the population who are particularly vulnerable to its adverse effects because they absorb a higher percentage of ingested lead (COT, 2013). To assess the potential risks of exposure to lead, the EFSA has derived a $BMDL_{01}$ of 12 µg/L from blood lead levels associated with a decrease of 1 Intelligence Quotient (IQ) point; this decrease is considered to be relevant at the population level. The BMDL corresponds to a dietary intake value of 0.5 µg/kg bw/day (EFSA, 2010); this value can be used in an MOE approach to assess exposures to lead.

44. The COT has 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*" (COT, 2013).

45. For lead, the total mean and high level exposures were 0.071-0.12 µg/kg bw/day and 0.17-0.26 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with total mean exposures ranging from 0.040-0.070 µg/kg bw/day. Overall, the current estimates of dietary exposure to lead generated ranges of MOEs of 4-7 and 2-3 (rounded to 1 SF) for mean and high level exposures, respectively.

46. The COT is invited to consider the following draft conclusion:

The Committee concluded that any risk posed by the current estimated dietary exposures to lead were small.

Manganese

47. Manganese is an essential trace element that can exist in a variety of oxidation states. It is neurotoxic at high levels of occupational inhalation exposure, but there is limited evidence of neurological effects at lower doses. The extent of neurotoxicity is determined by the oxidation state, with Mn (III)

being more toxic than Mn (II) (WHO, 2006). The dose response relationship in experimental animals has not been adequately clarified and the effects observed in animals may not reflect the subtle neurological effects reported in humans (EVM, 2003). Children might be particularly susceptible to the neurotoxicity of manganese. There is insufficient information to determine whether there are risks associated with dietary exposure to manganese and no available health-based guidance value.

48. The EVM considered that, based on the results of epidemiological studies of neurological effects associated with concentrations of manganese in drinking water, total manganese intakes of 12.2 mg/day for the general population (equivalent to 1.22 mg/kg bw/day for infants aged 4 to 18 months) would not result in adverse health effects (EVM, 2003). This conclusion was based on a number of assumptions since neither of the two studies used to establish these guidance values recorded water consumption or dietary manganese intake. The WHO derived a TDI of 60 µg/kg body weight/day in the Guidelines for Drinking Water Quality (WHO, 2004). This was based on the upper range value of manganese intake of 11 mg/day, identified using dietary surveys, at which there were considered to be no observed adverse effects. An uncertainty factor of 3 was applied to take into consideration the possible increased bioavailability of manganese from water. No information was provided on how these reference doses were set in relation to speciation.

49. For manganese, the total mean and high level exposures were 85 µg/kg bw/day and 190 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with a total mean exposure of 63 µg/kg bw/day. Overall, the current estimates of dietary exposure to manganese were well below the EVMs suggested safe intake value at both mean and high level exposure.

50. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to manganese were not of toxicological concern.

Mercury

51. Mercury exists in multiple forms and in three oxidation states (elemental mercury, mercurous mercury, and mercuric mercury). The properties and chemical behaviour of mercury strongly depend on its oxidation state and its chemical form. Mercurous and mercuric mercury form numerous inorganic and organic chemical compounds. Organic forms of mercury, such as methylmercury, are the most toxic following ingestion as they are absorbed more effectively in the gastrointestinal tract than elemental mercury or inorganic mercury compounds (WHO, 2006).

52. Food is the major source of exposure to mercury in the general population, particularly methylmercury in fish. The EFSA has established TWIs of 4 µg/kg bw and 1.3 µg/kg bw for inorganic mercury and methylmercury, respectively. The EFSA TWI for inorganic mercury was in line

with that established by the JECFA, which was based on the lowest $BMDL_{10}$ of 0.112 mg/kg bw/day, expressed as mercuric chloride, for an increase in relative kidney weight in rats. After correcting this value for the amount of mercury in mercuric chloride (73.9 %), and adjusting to account for 5 days per week dosing, rather than 7 days per week dosing, this value resulted in a $BMDL_{10}$ of 0.06 mg/kg b.w. per day, expressed as mercury. After application of a 100-fold uncertainty factor, and conversion to a weekly basis, this gave a TWI of 4 µg/kg bw (EFSA, 2012).

53. The TWI for methylmercury was based on a methylmercury concentration in maternal hair of 11.5 mg/kg, this was the mean of the apparent no observed effect level (NOEL) from a Seychelles nutrition cohort at 9 and 30 months (11 mg/kg maternal hair), and the $BMDL_{05}$ from a Faroese cohort at age seven years (12 mg/kg in maternal hair). By application of a maternal hair to maternal blood ratio of 250, the mean maternal hair concentration was converted into a maternal blood concentration (46 µg/L); this concentration was converted to a daily dietary mercury intake of 1.2 µg/kg bw by using a one-compartment toxicokinetic model. A factor of 2 was applied to account for variation in hair to blood ratio, and when converting the steady state concentration of mercury in blood to an estimated daily intake, a factor of 3.2 was applied, resulting in a TWI of 1.3 µg/kg bw. In their assessment, the EFSA regarded total mercury as inorganic mercury for all food categories apart from 'Fish and other seafood', and stated that because this approach was chosen, total mercury dietary exposure could not be derived by adding inorganic and methylmercury dietary exposure together (EFSA, 2012). For the purposes of this assessment, total dietary exposures will be compared to the TWI of 4 µg/kg bw for inorganic mercury (equivalent to ~0.57 µg/kg bw/day).

54. Regarding mercury, the total mean and high level exposures were 0.022-0.046 µg/kg bw/day and 0.13-0.16 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the 'other foods' category, with total mean exposures ranging from 0.020-0.030 µg/kg bw/day. Overall, the current estimates of dietary exposure to mercury were well below the EFSA TWI for inorganic mercury at both mean and high level exposure. The mean and high level exposure estimates for the fish-based groups of the 'commercial infant foods' ('*meat and fish based foods and dishes*') and 'other foods' ('*fish*') categories were also below the TWI for methylmercury (equivalent to 0.19 µg/kg bw/day) (see Tables 3 to 6 in Annex B).

55. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to mercury were not of toxicological concern.

Nickel

56. The EFSA has recently published an opinion on nickel in food (EFSA, 2015). Although the IARC has classified nickel and nickel compounds as human carcinogens, the EFSA considered it unlikely that dietary exposure to

nickel results in cancer in humans, and concluded that dietary exposure likely represents the most important contribution to the overall exposure to nickel in the general population. The non-carcinogenic adverse effects of oral exposure to nickel in humans include effects on the gastrointestinal, haematological, neurological and immune systems. Following acute exposure, the most reported effects were on the gastrointestinal and neurological systems. Exposure through skin or by inhalation may lead to nickel sensitization, and, although oral exposure is not known to lead to sensitization, oral absorption of nickel is able to elicit eczematous flare-up reactions in the skin of nickel-sensitized individuals. The EFSA has derived a TDI for nickel of 2.8 µg/kg bw/day from a $BMDL_{10}$ of 0.28 mg/kg bw as calculated from the dose response analysis of the incidence of litters with post-implantation loss in rats, and by applying the default uncertainty factor of 100 to account for inter-species differences and human variability. The EFSA noted that mean chronic dietary exposure to nickel for all age groups was close to or above the TDI, and that high level exposures (95th percentile) were above the TDI. On this basis, the EFSA concluded that current chronic dietary exposure to nickel is of concern for the general population. The EFSA also noted that the TDI may not be sufficiently protective of individuals sensitized to nickel (EFSA, 2015).

57. For nickel, the total mean and high level exposures were 1.6-2.6 µg/kg bw/day and 3.9-5.6 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with total mean exposures ranging from 0.92-1.5 µg/kg bw/day. Overall, the total mean exposure estimates to nickel were below but nearing the EFSA TDI. The total high level estimates were approximately 40 to 100% greater than the TDI.

58. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current average and high level dietary exposure estimates to nickel could be of concern for UK infants.

Selenium

59. Selenium is an abundant element that can exist in 4 oxidation states (-2, +1, +2, and +6). Selenium is also an essential trace element and, in food, is generally present as the amino acid derivatives selenomethionine and selenocysteine. The toxicity of selenium depends on the nature of the selenium compound, particularly its solubility; selenium sulphide is much less toxic than selenite, selenate and selenomethionine. Selenium toxicity is cumulative. In humans, the first signs of chronic toxicity appear to be pathological changes to the hair and nails, followed by adverse effects on the nervous system (EVM, 2003).

60. The EVM has derived a SUL of 7.5 µg/kg bw/day for selenium based on a lowest observed adverse effect level (LOAEL) of 0.91 mg/day, derived from an epidemiological dietary study in which signs of selenosis (prolonged prothombin time, morphological changes in the nails, and increased white blood cell count) were observed in individuals with selenium blood levels of 1.054 to 1.854 mg/L. These blood levels were calculated to represent a

selenium intake of 0.91 mg/day, and an uncertainty factor of 2 was applied to extrapolate from the LOAEL to a NOAEL. A larger uncertainty factor was not considered necessary because the intake of 0.91 mg/day produced only slight effects and was close to a NOAEL (EVM, 2003).

61. The SCF has also set an UL for selenium of 60 µg/day for 1-3 year olds (SCF, 2000). If the UL is applied to the age group assessed in this survey, then it is equivalent to approximately 6 µg/kg bw/day based on an average body weight of 10 kg for infants aged 4 to 18 months (DH, 2013). The SCF UL was derived from an adult UL of 300 µg/day on a body weight basis as there were no reports of increased susceptibility in children. The adult UL was established using a NOAEL of 850 mg/day for clinical selenosis in a study on 349 subjects. A follow-up study supported this NOAEL as 5 individuals recovered from selenosis when their selenium intake had been reduced to a mean of 819 mg/day. The NOAEL used was derived from a study on a large number of subjects and was expected to include sensitive individuals. An uncertainty factor of 3 was used to allow for the remaining uncertainties in the studies used in deriving the UL (SCF, 2000).

62. Regarding selenium, the total mean and high level exposures were 1.1-1.6 µg/kg bw/day and 2.6-3.0µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with a total mean exposure of 0.8 µg/kg bw/day. Overall, the current estimates of dietary exposure to selenium were below the EVM and SCF’s upper levels at both mean and high level exposure.

63. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to selenium were not of toxicological concern.

Tin

64. Tin is rarely found as the metallic element in nature but is more usually found combined with other substances, most commonly as the dioxide (EVM, 2003). It has oxidation states of II and IV. Inorganic tin is of low toxicity, whereas some organotin compounds are potent neurotoxicants, though these are not normally present in food, beverages or food supplements (EVM, 2003; WHO, 2006). Gastrointestinal effects are the main manifestation of toxicity associated with ingestion of foods or drinks contaminated with tin. These are caused by the irritant action of soluble inorganic tin compounds; recovery from the effects is rapid. Some sub chronic feeding studies have observed haematological changes in rats, but other chronic carcinogenicity studies and one multi generation reproduction study did not record any such effects, or noted that the observed changes were transient. Pancreatic atrophy has also been observed in sub chronic studies in rats (EVM, 2003).

65. The JECFA established a PTWI of 14 mg/kg bw for tin in 1988 but later stated that the basis for this PTWI was unclear and that it may have been derived from intakes associated with acute effects (FAO/WHO, 2006). The

EVM has established a guidance level of 220 µg/kg bw/day based on sub-chronic toxicity studies in rats that showed pancreatic atrophy occurring at doses of about 240 mg/kg bw/day. In addition, changes to liver cells and anaemia were observed in a study in which a NOAEL of 22-33 mg/kg bw/day could be derived. Applying uncertainty factors of 10 for inter-species variation and 10 for inter-individual variability to this NOAEL, gave a daily intake of about 0.2-0.3 mg/kg bw/day. The EVM suggested that the lower end of this range, 0.22 mg/kg bw/day, could be used for guidance purposes only and would be expected not to produce adverse effects in humans (EVM, 2003).

66. For tin, the total mean and high level exposures were 38 µg/kg bw/day and 250 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘other foods’ category, with total mean exposures ranging from 38 µg/kg bw/day. Overall, the total mean exposure estimates to tin were well below EVM guidance level, and would therefore not be of toxicological concern. Although the total high level estimate was approximately 10% above the EVM guidance level, this is only a minor exceedance and would be unlikely to result in adverse effects.

67. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to tin were not of toxicological concern.

Zinc

68. Zinc is an essential trace element, occurring in nature as the sulphide, the silicate, and the oxide. Excessive zinc intake interferes with the gastrointestinal absorption of copper, potentially leading to secondary copper deficiency, which can result in conditions such as anaemia and bone abnormalities (EVM, 2003). The JECFA has established a PMTDI for zinc of 0.3-1.0 mg/kg bw; clinical studies in which up to 600 mg of zinc sulphate (equivalent to 200 mg elemental zinc) had been administered daily in divided doses for a period of several months were used as the basis for deriving the PMTDI (FAO/WHO, 1982b). The EVM has derived a SUL of 25 mg/day (equivalent to 2.5 mg/kg bw/day for a 10 kg infant) based on a LOAEL of 50 mg/day from epidemiological studies assessing the impact of zinc supplementation, and an uncertainty factor of 2 (to extrapolate from the LOAEL to a NOAEL) (EVM, 2003). The SCF has extrapolated an UL of 7 mg/day for 1 to 3 year olds from an adult UL of 25 mg/day on the basis of body surface area (defined as body weight$^{0.75}$) since there was no evidence of increased susceptibility in children. The adult UL was based on a NOAEL of 50 mg/day from epidemiological studies assessing the impact of zinc supplementation; an uncertainty factor of 2 was applied owing to the small number of subjects included in relatively short-term studies but acknowledging the rigidly controlled metabolic experimental conditions that had been employed (SCF, 2003b). If the SCF UL is applied to the age group assessed in this survey then, based on an average body weight of 10 kg for infants aged 4 to 18 months, it would be equivalent to approximately 700 µg/kg bw/day, respectively (DH, 2013).

69. Regarding zinc, the total mean and high level exposures were 440 µg/kg bw/day and 860 µg/kg bw/day, respectively. The highest contributing food category to total mean exposure was the ‘infant formula’ category, with total mean exposures ranging from 180 µg/kg bw/day. Overall, the current estimates of mean dietary exposure to zinc were below all of the available health-based guidance values. The current estimates of high level dietary exposure were marginally greater than the SCF guidance values (~20%) but below the JECFA and EVM values.

70. The COT is invited to consider the following draft conclusion:

The Committee concluded that the current estimated dietary exposures to zinc were not of toxicological concern.

Questions on which the views of the Committee are sought:

71. Members are invited to consider the following questions and to raise any other matters that arise from the newly submitted data.

i) The Committee is asked to comment on the information provided and consider the draft conclusions for each element, set out in paragraphs 11, 14, 23, 27, 31, 34, 38, 42, 46, 50, 55, 58, 63, 67, and 70.

ii) The Committee is also invited to comment on priorities for future surveys and research, based on the outcome of this survey of metals and other elements in infant foods.

Secretariat
June 2016

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

Discussion paper on the results of the 2014 survey of metals and other elements in infant foods

Concentration data used to estimate exposures to the foods surveyed in the 2014 survey of metals and other elements in infant foods (FSA, 2016). This data is based on the original concentration data reported in the survey, but was manipulated to allow exposure assessments to be performed.

Secretariat
June 2016

Table 1. Concentration data used to assess exposures to elements in ready-to-feed infant formulas

Ready-To-Feed Formula	Concentrations (µg/l)*															
	Al	Sb	As	iAs^	Cd	Cr	Cu	I	Fe	Pb	Mn	Hg	Ni	Se	Sn	Zn
First milk & hungrier milk (from birth)	18-34	0-1	0-0.3	0-0.2	0-0.2	0-3	376	143	5136	0-0.4	63	0-0.2	0-9	18	0-3	5974
Follow on milk (6 months +)	15-31	0-0.8	0-0.4	0-0.3	0-0.2	0-3	329	115	8785	0-0.5	71	0-0.2	0-7	17	0-3	5608
Growing up milk (12 months +)	15-29	0-0.8	0.3-0.7	0.2-0.5	0-0.3	0-3	346	140	10223	0-0.5	65	0-0.2	0-9	14	0-3	7615

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

Table 2. Concentration data used to assess exposures to elements in dry infant formulas (samples of dry formula were analysed 'as sold' and not reconstituted prior to analyses)

Dry Powder Formula	Concentrations (µg/kg)*															
	Al	Sb	As	iAs^	Cd	Cr	Cu	I	Fe	Pb	Mn	Hg	Ni	Se	Sn	Zn
First milk & hungrier milk (from birth)	388-488	0-5	1-3	0.7-1.8	3-4	15-35	2970	948	42363	1-4	593	0-1	18-54	107	0-23	40388
Comfort (from birth)	767	0-5	1-3	0.9-1.9	0-2	37-73	2967	753	46600	0-5	603	0-1	0-40	173	0-24	42800
Follow on milk (from 6 months)	400-450	0-5	1-3	0.9-2	3	0-25	2855	913	72475	0-3	615	0-1	0-40	93	0-22	44500
Growing up milk (12 months +)	650	5-9	2-3	1.4-2.3	3-4	0-40	3195	1150	83950	0-4	580	0-1	0-40	105	0-22	60300
Soy based (from birth)	2550	0-6	7	4.6	11	35-55	2905	855	65250	0-5	2785	0-1	200	147	0-23	46000
Goat based (from birth and growing up)	950	0-5	9	6-6.3	0-2	40-45	4220	960	71900	6.5	800	0-1	0-45	137	0-35	47000
Organic milk†	1000	<5	14	~7	8	~30	3740	1030	47500	~3	2470	<1	<40	79	~40	49400

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.
† Contained milk and cereals

Table 3. Concentration data used to assess exposures to elements in commercial infant foods

Commercial Infant Foods	Concentrations (µg/kg)*															
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Cereal based foods and dishes	183-229	0-2	10	5-6	3	14-19	422	74-76	10813	0-1	2778	0	124-127	26	14-18	6460
Dairy based foods and dishes	861-878	0-3	11	3-7	2	24-34	347	85-87	8934-8984	1-2	871	0-1	23-44	15	80-86	8644
Fruit based foods and dishes	1125	0-3	9	1-4	2-3	43-54	862	22-27	7543	1-3	2436	0-1	92-117	6-7	43-50	4993-5002
Baby drinks	453	0-1	2	1	0	0-7	24	0-5	757	3	218	0-0	0-9	0	0	103
Other savoury based foods and dishes (no meat)	1995-1999	0-3	15	7-9	10	47-57	774	61-63	14821	3-5	1603	0-1	66-97	17	61-68	8640
Snacks (sweet and savoury)	5185	0-0	98	58-62	24	75	2202	4	28750	10	18125	0	292	45	0	12180
Meat and fish based foods and dishes (All†)	1425-1427	0-3	15	2-4	9	35-49	595	14-22	7454	4-5	944	0-1	43-72	17	47-52	5190

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.
† Meat and fish based foods and dishes included beef, chicken, fish, ham, lamb, pork and turkey

Table 4. Concentration data used to assess exposures to elements in other foods

Food Group	Concentrations (µg/kg)*														
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Beverages	0-40	0-1	1	1	0	0-3	0-4	0-4	0-50	0	9-11	0	0-7	0	0-3	0-27
Bread	4300	0-5	6	4	26	47-73	1797	23-30	21133	2-5	11677	0-1	0-80	46	0-16	12700
Canned vegetables	1780	0-3	1-2	1	7	23-40	1107	0-5	11100	5-7	1917	0-1	143-177	12	35767	2627
Cereal	1966-2760	0-3	59-60	37-38	26-29	42-83	1353-1683	14-23	35454-37788	5-6	10611-11639	0-1	78-127	14-30	12-19	8556-10038
Dairy products	100-150	0-3	0-1	0-1	0-1	0-11	155	269	590-628	2	188-196	0-1	0-23	43	8-16	11890
Eggs	0-50	0-3	5	1-3	0-1	0-10	560	469	22700	0-1	360	0-1	0-20	245	0-8	12800
Fish	697-717	0-4	1730	0-10	11-12	17-33	537	515	7133	0-2	777	56	0-27	353	17-23	5660
Fresh fruit	328-363	0-1	1	1	0-1	0-5	578	0-3	1667	1	2739	0	22-32	1	0-4	1002
Fruit products	327	0-1	1	0-1	0	0-5	149	3-4	647	1	280	0	0-9	0	0-3	143-153
Green vegetables	1990	0-1	2	1	5	0-11	1084	11-12	11565	2	2585	0	210	9	0-4	6390
Meat products	1920	0-3	3	2	4	50	690	0-11	8500	0-3	1650	0-1	0-50	61	0-8	10900
Milk	0-17	0-1	0	0	0	0-3	36	271	0-90	0	16	0	0-7	14	0-3	3055
Other vegetables	847-865	0-1	2	2	17	4-8	1288	0-3	5632	7-8	2244	0	163-171	18	10-14	3996
Potatoes	90	0-1	0	0	21	0-5	769	0-3	3160	0-1	1400	0	0-30	3	0-4	2450
Poultry	0-50	0-3	4	3	0-1	0-10	270	28	2900	0-1	90	0-1	0-20	83	0-8	5960

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.

^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

References:

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

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

Discussion paper on the results of the 2014 survey of metals and other elements in infant foods

Detailed exposure assessment tables for UK infants aged 4 to 18 months based on concentration data from the 2014 survey of metals and other elements in infant foods (FSA, 2016), and consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013).

Secretariat
June 2016

Table 1. Breakdown of mean exposure estimates for infants aged 4 to 18 months to elements in infant formulas

Food Groups	**Mean exposure estimates (µg/kg bw/day)***															
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Comfort milk	0.018	0	0	0	0	0.0010 - 0.0020	0.069	0.018	1.1	0	0.014	0	0-0.0010	0.0040	0-0.0010	1.0
First milk from birth (dry powder)	0.011-0.013	0	0	0	0	0-0.0010	0.081	0.026	1.2	0	0.016	0	0-0.0010	0.0030	0-0.0010	1.1
Follow on milk (6 months+) (dry powder)	0.014-0.016	0	0	0	0	0-0.0010	0.1	0.033	2.6	0	0.022	0	0-0.0010	0.0030	0-0.0010	1.6
Growing up milk (12 months+) (dry powder)	0.006	0	0	0	0	0	0.03	0.011	0.78	0	0.005	0	0	0.0010	0	0.56
Goat milk	0.007	0	0	0	0	0	0.03	0.007	0.51	0	0.006	0	0	0.0010	0	0.34
Organic milk	0.002	0	0	0	0	0	0.008	0.002	0.11	0	0.005	0	0	0	0	0.11
Soy milk	0.098	0	0	0	0	0.0010 - 0.0020	0.11	0.033	2.5	0	0.11	0	0.008	0.0060	0-0.0010	1.8
First milk from birth (ready to feed)	0.20-0.37	0-0.011	0-0.0030	0-0.0020	0-0.0020	0-0.033	4.1	1.6	56	0-0.0040	0.68	0-0.0020	0-0.098	0-0.20	0-0.033	65
Follow on milk (6 months+) (ready to feed)	0.24-0.50	0-0.013	0-0.0060	0-0.0050	0-0.0030	0-0.049	5.3	1.9	140	0-0.0080	1.15	0-0.0030	0-0.11	0-0.27	0-0.049	91
Growing up milk (12 months+) (ready to feed)	0.044-0.084	0-0.0020	0.0010 - 0.0020	0.001	0-0.0010	0-0.0090	1	0.41	30	0-0.0010	0.19	0-0.0010	0-0.026	0-0.041	0-0.009	22
Total	0.64-1.1	0-0.030	0.0010-0.013	0-0.010	0-0.010	0.0029-0.10	11	4	240	0-0.015	2.2	0-0.0061	0.010-0.25	0.020-0.53	0-0.090	180

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower

bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

Table 2. Breakdown of 97.5th percentile exposure estimates for infants aged 4 to 18 months to elements in infant formulas

Food Groups	97.5th percentile exposure estimates (µg/kg bw/day)*															
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Comfort milk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First milk from birth (dry powder)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Follow on milk (6 months+) (dry powder)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Growing up milk (12 months+) (dry powder)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Goat milk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Organic milk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Soy milk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First milk from birth (ready to feed)	1.7-3.2	0-0.093	0-0.028	0-0.019	0-0.019	0-0.28	35	13	480	0-0.037	5.9	0-0.019	0-0.84	0-1.7	0-0.28	550
Follow on milk (6 months+) (ready to feed)	1.2-2.6	0-0.066	0-0.033	0-0.025	0-0.017	0-0.25	27	9.5	730	0-0.041	5.9	0-0.017	0-0.58	0-1.4	0-0.25	460
Growing up milk (12 months+) (ready to feed)	0.60-1.17	0-0.032	0.012-0.028	0.0080-0.020	0-0.012	0-0.12	14	5.6	410	0-0.020	2.6	0-0.0080	0-0.36	0-0.6	0-0.12	300
Total	2.0-3.6	0-0.10	0.012-0.040	0.010-0.030	0-0.022	0-0.32	37	14	760	0-0.046	6.9	0-0.020	0-0.90	0.060-1.8	0-0.31	600

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

Table 3. Breakdown of mean exposure estimates for infants aged 4 to 18 months to elements in commercial infant foods

Food Groups	Mean exposure estimates (μg/kg bw/day)*															
	Al	Sb	As	iAs^	Cd	Cr	Cu	I	Fe	Pb	Mn	Hg	Ni	Se	Sn	Zn
Cereal based foods and dishes	0.17-0.20	0-0.0020	0.0090	0.005	0.0030	0.013-0.017	0.39	0.068-0.070	9.9	0-0.0010	2.5	0	0.11-0.11	0.024	0.012-0.016	5.9
Dairy based foods and dishes	0.56-0.57	0-0.0020	0.007	0.002-0.005	0.0010	0.015-0.022	0.22	0.055-0.056	5.8	0.0010	0.56	0-0.0010	0.015-0.028	0.010	0.052-0.056	5.6
Fruit based foods and dishes	2.1	0-0.0060	0.017	0.002-0.008	0.0040-0.0060	0.081-0.10	1.6	0.042-0.051	14	0.0020-0.0060	4.6	0-0.0020	0.17-0.22	0.011-0.013	0.081-0.095	9.5
Meat and fish based foods and dishes (All†)	4.4	0-0.0090	0.046	0.006-0.012	0.027	0.11-0.15	1.8	0.043-0.067	23	0.012-0.015	2.9	0-0.0030	0.13-0.22	0.052	0.14-0.16	16
Baby drinks	0.56	0-0.0010	0.0020	0.001	0	0-0.0090	0.029	0-0.0060	0.93	0.0040	0.27	0	0-0.011	0	0	0.13
Other savoury based foods and dishes (no meat)	2.4	0-0.0040	0.018	0.009-0.011	0.012	0.057-0.069	0.94	0.074-0.077	18	0.0040-0.0060	2.0	0-.0010	0.080-0.12	0.021	0.074-0.083	10
Snacks (sweet and savoury)	1.7	0	0.032	0.019-0.02	0.0080	0.024	0.71	0.0010	9.3	0.0030	5.8	0	0.094	0.014	0	3.9
Total	12	0.010-0.020	0.13	0.043-0.062	0.06	0.30-0.39	5.7	0.28-0.33	81	0.030-0.040	19	0.0012-0.010	0.60-0.80	0.14	0.36-0.41	51

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10μg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

Table 4. Breakdown of 97.5th percentile exposure estimates for infants aged 4 to 18 months to elements in commercial infant foods

Food Groups	97.5th percentile exposure estimates (µg/kg bw/day)*															
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Cereal based foods and dishes	1.3-1.6	0-0.014	0.071	0.035-0.042	0.021	0.099-0.13	3.0	0.52-0.54	76	0-0.0070	20	0	0.84-0.86	0.18	0.092-0.12	46
Dairy based foods and dishes	6.1-6.2	0-0.021	0.077	0.021-0.049	0.014	0.17-0.24	2.4	0.60-0.61	63	0.0070-0.014	6.1	0-0.0070	0.16-0.31	0.11	0.56-0.61	61
Fruit based foods and dishes	14	0-0.037	0.11	0.012-0.05	0.025-0.037	0.53-0.67	11	0.27-0.34	94	0.012-0.037	30	0-0.012	1.1-1.5	0.074-0.087	0.53-0.62	62
Meat and fish based foods and dishes (All†)	28	0-0.059	0.30	0.039-0.079	0.18	0.69-0.96	12	0.28-0.43	150	0.079-0.098	19	0-0.020	0.85-1.4	0.34	0.93-1.0	100
Baby drinks	6.8	0-0.015	0.030	0.015	0	0-0.11	0.36	0-0.075	11	0.045	3.3	0	0-0.14	0	0	1.5
Other savoury based foods and dishes (no meat)	19	0-0.028	0.14	0.065-0.083	0.093	0.44-0.53	7.2	0.57-0.58	140	0.028-0.046	15	0-0.010	0.61-0.90	0.16	0.57-0.63	80
Snacks (sweet and savoury)	10	0	0.19	0.112-0.12	0.046	0.15	4.3	0.0080	56	0.019	35	0	0.56	0.087	0	34
Total	54-55	0.040-0.10	0.58	0.187-0.265	0.27	1.4-1.8	26	1.6-1.7	370	0.13-0.17	78	0.010-0.030	2.6-3.6	0.67-0.70	1.9-2.1	250

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.
† Meat and fish based foods and dishes included beef, chicken, fish, ham, lamb, pork and turkey

Table 5. Breakdown of mean exposure estimates for infants aged 4 to 18 months to elements in other foods

Food Groups	97.5th percentile exposure estimates (µg/kg bw/day)*															
	Al	Sb	As	iAs^	Cd	Cr	Cu	I	Fe	Pb	Mn	Hg	Ni	Se	Sn	Zn
Beverages	0-0.036	0-0.0010	0.0010	0.0010	0	0-0.0030	0-0.0040	0-0.0040	0-0.045	0	0.0080-0.0090	0	0-0.0060	0	0-0.0030	0-0.024
Bread	5.8	0-0.0070	0.0080	0.0050	0.034	0.062-0.098	2.4	0.031-0.040	28	0.0030-0.0070	16	0-0.0010	0-0.1070	0.062	0-0.021	17
Canned vegetables	1.9	0-0.0030	0.0010-0.0020	0.0010	0.008	0.024-0.042	1.2	0-0.0050	12	0.0050-0.0070	2.0	0-0.0010	0.15-0.19	0.013	37	2.8
Cereal	5.3	0-0.0060	0.115	0.074	0.055	0.15-0.16	3.2	0.036-0.043	73	0.0080-0.010	22	0-0.0020	0.17-0.24	0.057	0.023-0.037	19
Dairy products	0.32-0.48	0-0.0090	0-0.0030	0-0.0020	0-0.0020	0-0.036	0.50	0.86	1.9-2.0	0.0060-0.0080	0.61-0.63	0-0.0020	0-0.072	0.14	0.026-0.051	38
Eggs	0-0.019	0-0.0010	0.0020	0-0.0010	0	0-0.0040	0.21	0.18	8.6	0	0.14	0	0-0.0080	0.092	0-0.0030	4.8
Fish	0.26-0.26	0-0.0010	0.635	0-0.0040	0.0040	0.0060-0.012	0.20	0.19	2.6	0-0.0010	0.29	0.020	0-0.010	0.13	0.0060-0.0080	2.1
Fresh fruit	1.3-1.5	0-0.0050	0.0050-0.0060	0.0030-0.0040	0.0020-0.0030	0-0.020	2.4	0-0.013	6.8	0.0030-0.0050	11	0-0.0010	0.089-0.13	0.0040-0.0060	0-0.016	4.1
Fruit products	0.37	0-0.0010	0.0010	0-0.0010	0	0-0.0060	0.17	0.0030-0.0050	0.73	0.0010	0.32	0	0-0.011	0	0-0.0030	0.16-0.17
Green vegetables	1.3	0-0.0010	0.0010	0.0010	0.0040	0-0.0070	0.72	0.0070-0.0080	7.7	0.0010-0.0020	1.7	0	0.14	0.0060	0-0.0030	4.2
Meat products	0.57	0-0.0010	0.0010	0.0010	0.0010	0.015	0.21	0-0.0030	2.5	0-0.0010	0.49	0	0-0.015	0.018	0-0.0020	3.2
Milk	0-0.25	0-0.012	0-0.0030	0-0.0020	0-0.0030	0-0.044	0.52	3.9	0-1.3	0-0.0060	0.23	0-0.0030	0-0.10	0.21	0-0.044	44
Other vegetables	1.9	0-0.0030	0.0050-0.0060	0.0040	0.037	0.0080-0.019	2.9	0-0.0060	13	0.016-0.018	5.0	0-0.0010	0.37-0.38	0.039-0.040	0.023-0.031	8.9
Potato	0.20	0-0.0030	0-0.0010	0-0.0010	0.047	0-0.011	1.7	0-0.0060	7.1	0-0.0010	3.1	0-0.0010	0-0.067	0.0070	0-0.0090	5.5
Poultry	0-0.016	0-0.0010	0.0010	0.0010	0	0-0.0030	0.087	0.0090	0.94	0	0.029	0	0-0.0060	0.027	0-0.0030	1.9
Total	19-20	0-0.050	0.78-0.79	0.090-0.10	0.19-0.20	0.26-0.48	16	5.3	160-170	0.040-0.070	63	0.020-0.030	0.92-1.5	0.8	38	160

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.
^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

Table 6. Breakdown of 97.5th percentile exposure estimates for infants aged 4 to 18 months to elements in other foods

Food Groups	**97.5th percentile exposure estimates (µg/kg bw/day)***															
	Al	**Sb**	**As**	**iAs^**	**Cd**	**Cr**	**Cu**	**I**	**Fe**	**Pb**	**Mn**	**Hg**	**Ni**	**Se**	**Sn**	**Zn**
Beverages	0-0.43	0-0.0090	0.014	0.010	0-0.0020	0-0.032	0-0.043	0-0.043	0-0.54	0-0.0030	0.097-0.11	0-0.0020	0-0.075	0-0.0050	0-0.032	0-0.29
Bread	24	0-0.028	0.032	0.022	0.14	0.26-0.42	10	0.13-0.17	120	0.013-0.030	66	0-0.0060	0-0.45	0.26	0-0.090	72
Canned vegetables	12	0-0.017	0.0070-0.014	0.0050-0.010	0.051	0.16-0.28	7.6	0-0.035	77	0.035-0.046	13	0-0.0030	0.99-1.2	0.085	250	18
Cereal	24	0-0.029	0.52	0.33	0.25	0.67-0.71	15	0.16-0.20	330	0.035-0.043	100	0-0.0080	0.78-1.1	0.26	0.10-0.17	87
Dairy products	1.2-1.8	0-0.035	0-0.012	0-0.0080	0-0.0070	0-0.14	1.9	3.3	7.2-7.7	0.021-0.029	2.3-2.4	0-0.0070	0-0.28	0.53	0.098-0.20	150
Eggs	0-0.14	0-0.0070	0.013	0.0020-0.0090	0-0.0010	0-0.028	1.6	1.3	63	0-0.0030	1.0	0-0.0030	0-0.055	0.68	0-0.022	35
Fish	1.6-1.7	0-0.0090	4.1	0-0.023	0.027	0.039-0.078	1.3	1.2	17	0-0.0050	1.8	0.13	0-0.063	0.83	0.041-0.053	13
Fresh fruit	5.0-5.5	0-0.020	0.017-0.021	0.012-0.014	0.0070-0.012	0-0.075	8.7	0-0.050	25	0.010-0.018	41	0-0.0050	0.33-0.48	0.013-0.021	0-0.060	15
Fruit products	3.4	0-0.0090	0.0070-0.011	0.0050-0.0070	0-0.0020	0-0.060	1.7	0.030-0.045	7.3	0.010-0.013	3.2	0-0.0020	0-0.11	0-0.0030	0-0.034	1.62-1.73
Green vegetables	7.2	0-0.0050	0.0070	0.0050	0.019	0-0.038	3.9	0.038-0.042	42	0.0060-0.0090	9.3	0-0.0010	0.76	0.032	0-0.014	23
Meat products	5.1	0-0.0080	0.0090	0.0060	0.011	0.13	1.8	0-0.029	23	0-0.0080	4.4	0-0.0010	0-0.13	0.16	0-0.021	29
Milk	0-1.1	0-0.051	0-0.013	0-0.0090	0-0.013	0-0.19	2.3	17	0-5.8	0-0.026	1.0	0-0.0130	0-0.45	0.91	0-0.19	200
Other vegetables	9.0-9.2	0-0.014	0.024-0.026	0.017-0.018	0.18	0.039-0.088	14	0-0.030	60	0.078-0.084	24	0-0.0040	1.7-1.8	0.19	0.11-0.15	42
Potato	0.86	0-0.012	0-0.0040	0-0.0030	0.20	0-0.048	7.4	0-0.024	30	0-0.0060	13	0-0.0030	0-0.29	0.030	0-0.038	23
Poultry	0-0.11	0-0.0060	0.0090	0.0060	0-0.0010	0-0.022	0.61	0.063	6.5	0-0.0020	0.2	0-0.0010	0-0.045	0.19	0-0.018	13
Total	50-51	0-0.12	4.2	0.35-0.37	0.52	0.81-1.2	39	19	450-460	0.12-0.16	170	0.13-0.15	2.8-3.8	2.1	250	370

* Values are presented as lower-bound (LB) to upper-bound (UB). The LB was calculated by treating concentration data < LOD as 0, while the UB was determined by treating values <LOD as equal to the LOD. If there is only one figure shown then all data were above the LOD.

^ As samples were only tested for inorganic arsenic (iAs) where total arsenic (tAs) results were >10µg/kg, a factor of 70 % was applied to reported tAs to estimate iAs, for those samples not tested for iAs. The corresponding iAs estimates were then combined with the reported iAs results to calculate the lower bound and upper bound means for the exposure assessments, in accordance with the approach taken by EFSA in their 2009 opinion and 2014 report. Range reported as <LOD for those samples not tested for inorganic arsenic.

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