



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

COT STATEMENT ON A SURVEY OF METALS IN INFANT FOOD

Introduction

1. The Food Standards Agency (FSA) has recently completed a survey of metals in infant food. This survey was carried out to establish the concentrations of 12 metals in a representative range of commercial infant foods and formulae. The Committee was asked to comment on the survey and assess if the levels of each element in the diet posed a risk to human health.

2. This survey follows on from a previous survey of metals in infant foods, which the Committee considered in 1999¹, concluding:

- “We *note* that the estimates of intake by infants rely on assumptions about feeding patterns (infants aged 0-6 months) or on survey data that may now be outdated (infants aged 6-12 months). We would welcome new studies to determine the patterns of consumption of foodstuffs in infants.
- However, we *consider* that the consumption of the infant foods sampled in the survey will not result in the intake of such quantities of any of the analysed elements such as would give concern for the health of infants.”

Current Survey of Metals in Infant Foods

3. This survey was carried out between March 2001 and July 2002 to establish the concentrations of 12 metals in a representative range of commercial infant foods and formulae. It was designed to provide a picture of the elemental concentrations of the main types and brands of infant foods on sale in the UK and to allow an assessment of infants’ exposures from these elements in these foods.

4. To assess the levels of each element in infant foods, 189 samples of commercial baby foods (infant formulae, manufactured baby foods, desserts, rusks and infant drinks) were analysed using Inductively Coupled Plasma–Mass Spectrometry (ICP-MS), which does not determine the individual species of each metal.

5. In the absence of a more recent NDNS survey for 6-12 month olds three different approaches were used to provide consumption data for estimation of the dietary exposure of infants to each metal. Details of these

methods, and descriptions of their limitations are available in COT paper TOX 2003-05 at:

http://www.food.gov.uk/science/ouradvisors/toxicity/cotmeets/cot_2003/115049/.

6. The first approach used the same source of consumption data as the previous survey of infant foods ¹, i.e. the 1986 survey of British Infants ² for age 6-12 months, thereby allowing direct comparison of the data. Dietary exposures were calculated using the mean concentration of metal in each food category allowing a dilution factor for dried/concentrated foods. This method provides mean and high level dietary exposure of infants consuming a combination of one or more of any of the foods studied (formulae, manufactured baby foods, drinks and rusks), which is not possible from feeding instructions alone.

7. The second approach used a food consumption figure of 48 g/kg body weight/day for a high level infant consumer which was identified by the Scientific Committee on Food (SCF) when deriving maximum residue levels for pesticides in infant foods ³. The basis for this consumption value is not clear. Estimates for formulae consumption were based on a volume of 500-600 ml which is recommended by the Committee on the Medical Aspects of food and nutrition policy (COMA) for infants up to 12 months old ⁴. The average weight of powder in 600 ml of made-up formula was calculated for use in exposure estimates. This approach did not allow for a contribution to dietary exposure from juices or other drinks.

8. The third approach used manufacturers' feeding guidelines, as detailed on each product label, as the source of consumption data for formula. An average consumption level of food and drinks for each age range from weaning at 4 months of age was calculated from three different manufacturers' feeding guidelines ^{5, 6, 7}. The mean concentration of each element was calculated from the concentration of that element in every eligible food for a particular age group (using a dilution factor for samples of dried food). Average weights of 5.9, 7.7, 8.9 and 9.9 kg were assumed for infants of 0-3, 4-6, 7-9 and 10-12 months respectively ⁴. Because the selection of infant foods surveyed was based on market share, the resulting mean concentration is assumed to reflect greater weight to more frequently consumed foods (such as ready-to-feed jar meals). Drinks, including juices, were taken into account in this approach. Due to the higher levels of some elements in soya based formula, separate exposure estimates were calculated, one based on soya formulae and infant foods (excluding dairy) and the other based on cows' milk-based formulae (from birth and follow on formulae) and foods. However only three samples of soya based formula were taken, so these data may not be representative.

9. The exposure estimates do not include the metal content of water used to reconstitute formula or dried food, or offered as a drink. They also do not include any contribution from foods not manufactured specifically for infants (e.g. normal 'adult' foods or home-prepared baby meals) or from breast milk. Nor do they consider wastage of food.

10. The Committee considered that the first approach using the 1986 NDNS consumption data was probably an under-estimation, but was useful in providing a comparison with the results of the previous survey. The third approach based on manufacturers' feeding guidelines generated the highest intakes, and could be considered a worst case scenario. Using the data derived from these two approaches provided a range in which the actual exposures are likely to be found. The Committee considered that there were a number of uncertainties and assumptions made in approach 2 and noted that the intakes calculated using this approach always fell within the range created by approaches 1 and 3. Therefore approach 2 was considered superfluous.

11. The survey results are reported in a food surveillance information sheet⁸ and are summarised below.

Concentrations of elements in the products surveyed.

12. The levels of arsenic, cadmium, lead, mercury and tin were below the relevant regulatory levels for all foods surveyed^{9, 10, 11}. Regulatory levels have not been set for the other metals surveyed. Copper and zinc are added to infant formula to ensure that infants receive adequate intakes of these essential elements. The levels of copper and zinc in all formulae surveyed fell within the acceptable range of fortification set by The Infant Formulae and Follow-on Formulae Regulations 1995¹².

13. With the exception of mercury, the mean concentrations of all elements in the products surveyed were in the region of, or lower than in the previous survey. Antimony, arsenic, cadmium and lead concentrations were above the limit of detection (LOD) in most samples. Zinc was detected in all samples and copper in all but one.

14. Mercury was detected at concentrations at or above the LOD in approximately one quarter of the samples, but the majority of those samples exceeding the LOD were very close to it. The mean concentration and the upper end of the range of mercury in infant foods appeared to be twice those seen in the previous survey (3 µg/kg, range <0.5 – 20, compared to 1.4 µg/kg, range <0.3 – 10). About 50% of this increase is likely to be due to the higher LOD for mercury in this survey (due to a decrease in the sensitivity of the equipment used in the analysis). In the current survey there were more foods containing fish than in the previous survey (7 out of 189 compared to 2 out of 97), however the fish containing meals only provided a minor contribution to the overall mean mercury concentration. Overall, it is apparent that the average mercury concentrations in infant foods have increased since the last survey.

15. With the exception of mercury, the average metal concentrations were higher in soya formula than in cows' milk formula, the most notable differences being seen with nickel and aluminium where concentrations were 2 to 3 times higher in soya formula. The concentrations in soya formula were similar to those reported in the previous survey.

Dietary exposure

16. The estimated dietary exposures for each metal are shown in Table 1, together with the comparable results from the previous survey. These were compared with available tolerable intakes, such as Provisional Tolerable Weekly intakes (PTWIs) set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), taking into account previous COT evaluations. The COT evaluation was also informed by a summary of the toxicological data on these metals, which is available at:

<http://www.food.gov.uk/multimedia/pdfs/TOX-2003-05.PDF>.

17. The term Provisional Tolerable Weekly Intake (PTWI) is used by JECFA in identifying tolerable intakes of food contaminants with cumulative properties. Within this statement, the PTWI has been divided by 7 to provide a tolerable daily intake for comparison with the estimated daily dietary exposures. Like the Acceptable Daily Intake (ADI) set for food additives, the PTWI is considered to be applicable to all age groups above 12 weeks of age. Evaluation of dietary exposure of younger infants requires case-by-case consideration of the toxicological database.

COT evaluation

18. Water used to reconstitute infant formula and dried foods could make an important contribution to the metal concentration in the food as consumed. This is particularly important in the case of arsenic, where water is a significant source of dietary exposure to inorganic arsenic. The Committee recommended that future surveys of this type should allow for water used in reconstituting foods and formula.

19. The methods used to analyse the concentration of each metal have not determined which metal species are present, only the total concentration. Therefore risk assessment must allow for the possibility that where one form of a metal is more toxic (for example organic or inorganic) and where there is no information on the speciation of that metal in food, it is the more toxic form that is present predominantly in the food. However, this is a worst case scenario. Information on the speciation of each metal would allow for a more robust risk assessment.

Aluminium

20. The maximum estimated intake was lower than for the previous survey and approximately 18% of the JECFA PTWI¹³ which is equivalent to 1000µg/kg bw/day. Aluminium intakes resulting from a soya based diet were higher than those from a normal diet, probably due to the higher levels of aluminium in soya formulae with a maximum intake of 24% of the PTWI. There is no information available on whether infants are more susceptible to the effects of aluminium. However taking into account the additional margin of safety compared with the PTWI and that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case

scenario consumption data, the intake of aluminium from infant foods and formulae is unlikely to be of concern.

Antimony

21. The maximum estimated intake was lower than for the previous survey and approximately 29% of the WHO TDI^{14, 15} of 0.86 µg/kg bw/day. There is no information available on whether infants are more susceptible to the effects of antimony. However taking into account the additional margin of safety compared with the PTWI and that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case scenario consumption data, the intake of antimony from infant foods and formulae is unlikely to be of concern.

Arsenic

22. All dietary exposures were within the JECFA PTWI for inorganic arsenic¹⁶. However, in its latest consideration of arsenic in the diet, the COT concluded that there are no appropriate safety guidelines for inorganic or organic arsenic and that exposure to inorganic arsenic should be As Low As Reasonably Practicable (ALARP)¹⁷. Where comparable data are available, the estimated mean dietary exposure resulting from this survey is similar to that derived from the 1999 survey. The highest arsenic levels were found in fish-containing dishes, which are likely to contain predominantly organic arsenic¹⁸. Overall, these data suggest that dietary exposure of infants to inorganic arsenic have not increased

23. Based on the current permitted level of inorganic arsenic in drinking water (50 µg/L), the contribution to the daily inorganic arsenic intake from water used to reconstitute formula could potentially be 3 to 5 µg/kg bw/day[§]. This is approximately twice the contribution from infant foods. The maximum permitted level of inorganic arsenic in water is due to be reduced from 50 to 10 µg/L in December 2003. However the vast majority of water companies are already complying with the lower level at which the potential inorganic arsenic intake from water used to reconstitute infant formulae could be 0.6 to 1 µg/kg bw/day.

Cadmium

24. The maximum estimated intake was lower than for the previous survey and approximately 72% of the JECFA PTWI for cadmium¹⁹ which is equivalent to 1 µg/kg bw/day. There is no information available on whether infants are more susceptible to the effects of cadmium. However taking into account that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case scenario consumption data, the intake of cadmium from infant foods and formulae is unlikely to be of concern.

[§]Based on a water consumption of 600ml used to reconstitute formulae and a body weight of between 5.9 to 9.8 kg.

Chromium^{*}

25. The maximum estimated intake was lower than for the previous survey and approximately 3% of the guidance level for trivalent chromium of 150 µg/kg bw/day recommended by the Expert Group on Vitamins and Minerals (EVM)²⁰. Trivalent chromium is considered to be an essential trace element, whereas hexavalent chromium has been classified as carcinogenic²¹. The vast majority of chromium found in food is in the trivalent form²² and so comparison of the total chromium levels in food with guidance levels for trivalent chromium is appropriate. There is no information available on whether infants are more susceptible to the effects of chromium. However taking into account the additional margin of safety compared with the PTWI and that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case scenario consumption data, the intake of chromium from infant foods and formulae is unlikely to be of concern

Copper^{*}

26. The maximum estimated intake was lower than for the previous survey and approximately 20% of the JECFA Provisional Maximal Tolerable Daily Intake (PMTDI)²³ of 500 µg/kg bw/day and 61% of the Safe Upper Level (SUL) of 160 µg/kg bw/day recommended by the EVM²⁰. Infants may be less able to absorb copper, but may also be less efficient at excreting copper than adults and so it is uncertain if infants would be more susceptible to copper toxicity than adults. However taking into account the additional margin of safety compared with the PMTDI/SUL and the fact that this is likely to be an over estimate of exposure, the intake of copper from infant foods and formulae is unlikely to be of concern.

Lead

27. The maximum estimated intake was lower than for the previous survey and approximately 17% of the PTWI for lead²⁴ which is equivalent to 3.6 µg/kg bw/day. The COT has previously concluded that it is not possible to establish a threshold for lead²⁵. Infants absorb a higher percentage of lead than adults following oral ingestion and are more susceptible to the neurotoxic effects of lead, particularly those leading to deficits in Intelligence Quotient (IQ). However the JECFA PTWI is a level of exposure that is not expected to increase the blood lead concentration of children. The decrease in exposure compared with the previous survey is consistent with the COT view that efforts should continue to reduce lead exposure from all sources.

Mercury

28. In 2002 when the COT considered methylmercury in fish²⁶ it concluded that the then current JECFA PTWI²⁷ may not be sufficiently protective for breast-feeding women because of the potential risk to the neonate. The EPA

^{*}Essential element

reference dose²⁸, which was derived from subtle neurobehavioural effects seen in children exposed prenatally, was used in assessing fish consumption by breastfeeding women in order to protect the young infant. However the COT noted inconsistencies in the evidence and agreed to review this conclusion following the JECFA evaluation of methylmercury in June 2003. JECFA has now revised its PTWI to 1.6 µg/kg bw/week²⁹. The new lower JECFA PTWI is intended to be protective of both the general population and the high-risk groups, and therefore it can be used in assessing the dietary exposure of infants to mercury.

29. The estimated intakes of mercury were higher than those from the previous survey. The maximum estimated intake (0.2 µg/kg bw/day for infants of 9-12 months) was approximately 87% of the JECFA PTWI for methylmercury which is equivalent to 0.23 µg/kg bw/day. Estimated intakes for infants aged 0-3 months, who are at greatest risk from methylmercury, was 30% of the PTWI. It is probable that mercury absorption would be lower in older infants due to concomitant intake of food and formula. In addition, these are likely to be overestimates of exposure estimates due to the use of upper bound concentrations and worst case scenario consumption data, and it is likely that not all of the mercury in infant foods is in the organic form. Overall, the Committee concluded that the estimated mercury intakes did not give cause for concern, but concentrations of mercury in infant foods should continue to be monitored.

Nickel

30. The estimated intakes were lower than for the previous survey. The worst case intakes (based on manufacturers' feeding guidelines) for 7-12 month old infants (normal diet) and for 4-12 month old infants (soya diet) exceeded the WHO TDI¹⁴ of 5 µg/kg bw/day by up to 68%. Taking into account that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case scenario consumption, this exceedance of the TDI was considered unlikely to be of significance. Ingestion of nickel may exacerbate contact dermatitis/eczema in pre-sensitised individuals. Infants are less likely than adults to be sensitised to nickel and are therefore not to be considered a susceptible sub group. Overall, the dietary exposures were not considered to be of concern.

*Selenium **

31. The maximum estimate intake was similar to the previous survey. The estimated intakes for all ages were within the upper limit of the safe range recommended for adults by the WHO³⁰ (400 µg/day) and the SUL of 450 µg/day recommended for adults by the EVM²⁰. This comparison assumes that it is appropriate to use bodyweight in scaling from the adult safe upper levels to levels applicable to infants since it is not clear whether this would produce an apparent safe upper level below an infant's nutritional requirement for selenium.

Tin

32. The maximum estimated intake was lower than for the previous survey and approximately 1% of the JECFA PTWI³¹ which is equivalent to 2000 µg/kg bw/day and 9% of the EVM²⁰ guidance level of 220 µg/kg bw/day. There is no information available on whether infants are more susceptible to the effects of tin. However taking into account the additional margin of safety compared with the PTWI and that this is likely to be an over estimate of exposure due to the use of upper bound concentrations and worst case scenario consumption data, the intake of tin from infant foods and formulae is unlikely to be of concern.

Zinc^{*}

33. The maximum estimated intake was similar to the previous survey. Most of the estimated intakes of zinc exceeded the SUL recommended by the EVM²⁰, and some exceed the JECFA PMTDI³². However the SUL and PMTDI may not be applicable to infants due to their high nutritional requirements for zinc; 4 mg/day 0-6 months (690 µg/kg bw/day), and 5 mg/day 7-12 months (510 µg/kg bw/day). For this reason infant foods are often fortified with zinc (0.5-1.5mg/100 kcal for formulae and 2 mg/100 kcal for infant foods).

34. The intakes calculated using the 1986 NDNS data suggest that the average infant diet does not provide enough zinc, despite fortification (an infant of 7-12 months, with an average weight of 9.8 kg would require approximately 510 µg/kg bw day to achieve 5 mg/day). However, this approach may not reflect current intakes due to the age of the consumption data. Whilst the estimated intakes of zinc were higher for those infants consuming a soya based diet, soya is known to inhibit absorption of zinc in the gut²⁰ and so it is possible that the actual amount absorbed could be lower than those infants on a normal diet.

Essential elements

35. For most of the metals, estimated intakes have decreased since the previous survey. Whilst this is desirable for contaminants such as lead, cadmium, antimony, nickel and tin, decreasing intakes of essential elements (chromium, copper, selenium and zinc) may have the potential to lead to nutritional deficiency. However, consideration of nutritional deficiency is not within the remit of the COT.

* Essential element

Conclusions

36. We *note* that, with the exception of mercury, the concentrations of each metal in infant foods do not appear to have increased since the previous survey in 1999. Whilst some of the apparent increase in the concentration of mercury in infant foods may be attributable to methodological differences between the surveys we *consider* that the levels of mercury should continue to be monitored. Information on the forms of mercury in infant foods would help to demonstrate an adequate margin of safety for methylmercury.

37. We *note* that the estimates of intake by infants rely on survey data that may now be outdated or on assumptions about feeding patterns that may represent an overestimate of food consumption. Whilst these approaches permit an assessment of the results of this survey we would *welcome* new studies to determine the patterns of consumption of foodstuffs in infants.

38. We *consider* that there are no relevant tolerable intakes or reference doses by which to assess dietary exposure to either inorganic or organic arsenic. Inorganic arsenic is genotoxic and a known human carcinogen. We therefore *conclude* that exposure to inorganic arsenic should be as low as reasonably practicable (ALARP). However we are *reassured* that since the previous survey arsenic intakes do not appear to have increased.

39. We *welcome* the apparent decline in lead exposure since the previous survey. However since it is not possible to identify a threshold for the association between lead exposure and decrements in intelligence quotient, efforts should continue to reduce lead exposure from all sources.

40. We *consider* that the consumption of the infant foods sampled in the survey will not result in the intake of such quantities of any of the analysed elements such as would give concern for the health of infants.

41. We *consider* that future assessments of metals in infant foods would be more robust if information was made available on the actual species of metal present in the food and on the contribution of the metal concentrations in water used to reconstitute formula and dried foods.

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Table 1: Estimated dietary exposure of infants to metals from infant foods (excluding water)

		Mean intakes calculated using manufacturers' consumption guidelines - mg/kg bw/day				Mean (and 97.5percentile) intakes calculated using 1986 NDNS - mg/kg bw/day		Safety guideline
		2002 survey				2002 survey	1999 survey	
		0-3 ^a	4-6 ^a	7-9 ^a	10-12 ^a	7-12 ^{a,b}	7-12 ^{a,b}	
Aluminium^c	Normal Diet	14	142	175	177	22 (76)	39 (98)	JECFA PTWI equivalent to 1000 µg/kg bw/day ¹³
	Soya Diet	82	242	222	218	-	-	
Antimony^c	Normal Diet	0.02	0.08	0.15	0.15	0.03 (0.10)	0.092 (0.29)	WHO TDI of 0.86 µg/kg bw/day (New TDI of 6 µg/kg bw/day proposed) ^{14, 15}
	Soya Diet	0.18	0.25	0.21	0.20	-	-	
Arsenic^c	Normal Diet	0.09	1.3	1.8	1.8	0.25 (0.87)	0.24 (0.61)	JECFA PTWI for inorganic arsenic equivalent to 2.14 µg/kg bw/day ¹⁶ COT has concluded there are no appropriate safety guidelines. ¹⁷
	Soya Diet	0.18	1.6	2.0	1.9	-	-	
Cadmium^c	Normal Diet	0.04	0.35	0.61	0.64	0.09 (0.31)	0.16 (0.41)	JECFA PTWI equivalent to 1 µg/kg bw/day ¹⁹
	Soya Diet	0.22	0.57	0.68	0.72	-	-	
Chromium^c	Normal Diet	1.2	2.9	3.6	3.6	0.65 (1.91)	1.8 (4.2)	EVM Guidance Level = of 150 µg/kg bw/day for total dietary intake of trivalent chromium ²⁰
	Soya Diet	1.5	3.3	3.7	3.7	-	-	
Copper^c	Normal Diet	41	72	78	76	13 (40)	21 (52)	JECFA PMTDI = 500 µg/kg bw/day ²³ EVM Safe Upper Level = 160 µg/kg bw/day for total dietary intake ²⁰
	Soya Diet	62	98	82	81	-	-	
Lead^c	Normal Diet	0.08	0.37	0.51	0.52	0.08 (0.22)	0.21 (0.52)	JECFA PTWI equivalent to 3.6 µg/kg bw/day. ²⁴ COT considered it is not possible to establish a threshold for lead ²⁵
	Soya Diet	0.22	0.56	0.59	0.61	-	-	
Mercury^c	Normal Diet	0.07	0.18	0.18	0.19	0.04 (0.11)	0.023 (0.046)	JECFA PTWI for methylmercury equivalent to 0.23 µg/kg bw/day ²⁹
	Soya Diet	0.07	0.19	0.19	0.20	-	-	
Nickel^c	Normal Diet	0.7	4.2	5.8	5.9	0.96 (3.0)	2.0 (5.1)	WHO TDI = 5 µg/kg bw/day ¹⁴
	Soya Diet	4.2	8.4	7.6	7.9	-	-	

Selenium ^c	Normal Diet	1.3	2.2	2.2	2.1	0.43 (1.42)	0.54 (1.4)	The upper limit of the safe range proposed by the WHO was 400 µg/day determined for adults only based on epidemiological data ³⁰ EVM Safe Upper Level = 450 µg/day for total dietary intake, equivalent to 7.5 µg/kg bw/day for a 60 kg adult ²⁰
	Soya Diet	2.5	3.5	2.6	2.6	-	-	
Tin ^c	Normal Diet	0.57	4.6	18.6	18.5	2.6 (8.9)	8.1 (32)	JECFA PTWI is equivalent to 2000 µg/kg bw/day ³¹ EVM Guidance Level = 220 µg/kg bw/day for total dietary intake ²⁰
	Soya Diet	0.62	4.7	19.7	20.1	-	-	
Zinc	Normal Diet	756	1262	1089	1062	198 (687)	220 (690)	JECFA PMTDI = 1000 µg/kg bw/day. ³² EVM Safe Upper Level = 42 mg/day (equivalent to 700 µg/kg bw/day in a 60 kg adult) for total dietary intake. ²⁰
	Soya Diet	946	1503	1148	1128	-	-	

Notes:

^a Age range in months

^b Dietary exposure in brackets are for the 97.5th percentile consumers

^c For all metals except zinc, data are upper bound means calculated using the limit of detection (LOD) when an element is not detected in a sample. The LOD was defined as 3 times the standard deviation of measured values for reagent blanks after correction for typical sample weight and dilution.