TOX/2016/05

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

Review of potential risks from arsenic in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

Introduction

1. The Scientific Advisory Committee on Nutrition (SACN) is undertaking a review of scientific evidence that will influence the Government's dietary recommendations for infants and young children. The SACN is examining the nutritional basis of the advice. The Committee on Toxicity in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from chemicals in the diet of infants, most of which has been completed, and young children. The reviews will identify new evidence that has emerged since the Government's recommendations were formulated, and will appraise that evidence to determine whether the advice should be revised. The recommendations cover diet from birth to age five years.

2. There is currently only one Government dietary recommendation for infants and young children which relates to arsenic. This recommendation is that toddlers and young children (aged 1 to 4.5 years) should not be given rice drinks as a *substitute* for breast milk, infant formula or cows' milk. This is due to the potential for rice drinks to contain high levels of arsenic, and because of this age group's proportionally higher milk consumption and lower bodyweights compared to other consumers (DH, 2009; FSA, 2009a). In addition, the Department of Health (DH) advises that cows' milk or alternatives are not suitable as drinks for infants under 12 months old. Rice drinks are not suitable alternatives for breast milk or formula at any stage of infancy or early childhood as they are considered to be nutritionally inadequate (FSA, 2009b). The advice regarding rice drink consumption provided on NHS choices is more precautionary and states that "*children under five shouldn't have rice drinks as they may contain unsafe levels of arsenic*" (NHS Choices, 2015).

3. On 25th June 2015, the European Commission (EC) set maximum levels (MLs) for inorganic arsenic in rice and rice-based products; these MLs are presented in Table 1. The EC stated that the MLs were set specifically for rice and rice-based products because the analysis of inorganic arsenic in these foods is reliable. Different MLs were proposed in view of the differing arsenic contents of these foods. The EC also noted that rice is an important ingredient in a broad variety of foods intended for infants and young children, and that a separate ML had been established for this commodity when used as an ingredient for the production of such food. The application of the MLs

was deferred until 1st January 2016 to allow Member States and food business operators to adapt to them.

Table 1. Maximum levels of inorganic arsenic (as the sum of As (III) and As (V)) permitted in rice and rice-based products (Commission Regulation (EU) 2015/1006)

Food Group	Maximum Level (µg/kg)
Non-parboiled milled rice (polished or white rice)	200
Parboiled rice and husked rice	250
Rice waffles, rice wafers, rice crackers and rice cakes	300
Rice destined for the production of foods for infants and young children[a]	100

[a] Foodstuffs listed in this category as defined in Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33).

4. This discussion paper provides estimated arsenic exposures for infants and young children in the UK aged 0 to 12 months and 1 to 5 years, respectively. Where information on the concentration or proportion of inorganic arsenic that is present in a source of exposure has been available, estimates of exposure to inorganic arsenic have also been provided. Where such information has not been available, a worst case scenario approach has been taken and it has been assumed that all of the arsenic measured in that source of exposure is inorganic.

Background

5. Arsenic is a metalloid that occurs in the environment in a variety of forms as the result of both natural and anthropogenic activity. 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 (arsenobetaine, arsenosugars, and arsenolipids) (EFSA, 2009). The inorganic arsenic present in the environment comprises mainly of species in the trivalent or pentavalent oxidative states, present primarily as the oxoanions arsenite (As(III)) and arsenate (As(V)), but also present as thio complexes. In food samples, inorganic arsenic is often reported as arsenite and arsenate, or as the sum of these, even though it is likely bound to thio groups in peptides or proteins in the food itself (EFSA, 2009).

6. Absorption of arsenic compounds varies depending on the chemical species, its solubility, and the matrix in which it is present; soluble arsenicals in water are highly bioavailable. In humans, inorganic arsenic is rapidly cleared from the blood (FAO/WHO, 2011), and is widely distributed to almost

all organs (EFSA, 2009). Inorganic arsenic is metabolised primarily by stepwise reduction of arsenate to arsenite, this is followed by oxidative addition of methyl groups, although alternative pathways have also been proposed that include methylated arsenical glutathione metabolites. Ingested inorganic arsenic is excreted as arsenate and arsenite, and as the pentavalent metabolites methylarsonic acid (MMA^V) and dimethylarsinic acid (DMA^V), with lesser amounts of the trivalent metabolites methylarsonous acid (MMA^{III}) and dimethylarsinous acid (DMA^{III}), and thioarsenical metabolites. Previously it has been assumed that methylation of inorganic arsenic was a detoxification route, it is no longer clear whether this is correct or not as, based on limited data, the simple organic arsenic species MMA^{III} and DMA^{III} appear to be more toxic than inorganic arsenic (arsenite and arsenate), and have high affinity for thiols and cellular proteins (FAO/WHO, 2011).

7. The results of toxicity studies in animals are not considered to provide a suitable basis for risk characterisation due to the high level of inter-species variability in arsenic metabolism and toxicokinetics. The main adverse effects associated with long-term ingestion of inorganic arsenic in humans are skin lesions, cancer, developmental toxicity, neurotoxicity[1], cardiovascular diseases[2], abnormal glucose metabolism, and diabetes[2] (EFSA, 2009).

8. There is some evidence for neurobehavioural effects of inorganic arsenic exposure during childhood, at exposure levels occurring in areas with elevated concentrations in drinking water. Most of the available studies have been performed on relatively small numbers of children, and often lack information on early life exposures to arsenic. Furthermore, neurobehavioural outcomes can be influenced by multiple other factors including age at time of examination, nutrition, and stimulation. There is a need for more longitudinal studies to evaluate the type of effects, the critical windows of exposure, and the dose-response relationship (EFSA, 2009; FAO/WHO, 2011).

9. Although few data are available regarding the toxicity of organic arsenic compounds in humans, exposure to such compounds is not generally considered to be of toxicological concern (EFSA, 2009).

10. 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), due to the fact that it is genotoxic and a known human carcinogen (COT, 2008).

Expert opinions

[1] Mainly associated with acute exposure from deliberate poisoning/suicide, or drinking water with high concentrations (EFSA, 2009).
[2] Evidence in areas with relatively low levels of inorganic arsenic exposure is inconclusive for these adverse effects (EFSA, 2009).

11. Expert opinions on exposure to arsenic in food have been published by the European Food Safety Authority's (EFSA) Panel on Contaminants in the Food Chain (CONTAM) (EFSA, 2009), and the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (FAO/WHO, 2011). The World Health Organization (WHO) has also reviewed exposures to arsenic via drinking water as part of the development of their 'Guidelines for Drinking Water Quality' (WHO, 2012). The International Agency for Research on Cancer (IARC) has published an evaluation of the carcinogenicity of arsenic and arsenic compounds (IARC, 2012).

EFSA

12. In their 2009 opinion (Annex A), the EFSA CONTAM Panel estimated that mean dietary exposures to inorganic arsenic in infants (<6 months) ranged from 0.04 to 1.76 µg/kg bw/day for average consumers[3]. The Panel also estimated that mean dietary exposures to inorganic arsenic in children <3 years old ranged from 0.5 to 1.39 µg/kg bw/day for average consumers, and from 0.84 to 2.66 µg/kg bw/day for high level consumers. The Panel stated that dietary exposure to inorganic arsenic in children under 3 years of age was 2 to 3-fold that of adults, due to their greater food consumption relative to their body weight (EFSA, 2009).

13. By modelling the available dose-response data from key epidemiological studies, and selecting a benchmark response of 1% extra risk, the CONTAM Panel established 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 of $BMDL_{01}$ values was identified for cancers of the lung, skin and urinary bladder, as well as skin lesions (EFSA, 2009).

14. As the estimated exposures fell within the range of $BMDL_{01}$ values, then this meant that there was little or no margin of exposure and that the possibility of a risk to some consumers could not be excluded. However, although children had higher estimated dietary exposures to inorganic arsenic than adults, this did not necessarily indicate that children were at greater risk because the adverse effects are due to long-term exposure (EFSA, 2009).

15. Overall, the CONTAM Panel recommended that dietary exposure to inorganic arsenic should be reduced. In order to refine the risk assessment for inorganic arsenic, the Panel recommended that speciation data be produced for different food commodities to support dietary exposure assessment and dose-response data for the possible health effects (EFSA, 2009).

16. In 2014, EFSA published a technical report on dietary exposures to inorganic arsenic in the European population based on new occurrence data for inorganic arsenic in food received since the 2009 opinion, together with

[3] These exposures were based on 3 categories: breast-fed infants (where the Panel assumed all of the arsenic present in breast milk was inorganic), infants fed with infant formula, and infants fed rice-based food with/without the water used in preparation (EFSA, 2009).

refined consumption data. Although the new data resulted in lower exposure estimates, EFSA concluded that, amongst other things, this could have been due to the way the occurrence data were evaluated and used, and that more analytical data were needed in order to reduce the uncertainty in the exposure estimates for inorganic arsenic (EFSA, 2014).

JECFA

17. In 1988 the JECFA confirmed their previous evaluation of arsenic by assigning it a provisional tolerable weekly intake (PTWI) of 15 µg/kg bw, but stated that "*the margin between the PTWI and intakes reported to have toxic effects in epidemiological studies was narrow*". In 2011, the JECFA confirmed that this PTWI was no longer appropriate[4] and withdrew it (FAO/WHO, 2011).

18. Both the COT and the EFSA also concluded that this PTWI was no longer appropriate. The COT concluded that the approach used to establish the PTWI could no longer be considered appropriate, in view of the evidence of genotoxicity and carcinogenicity (COT, 2008). The CONTAM Panel stated that the PTWI was no longer appropriate as data had shown that inorganic arsenic was a human carcinogen, and that a range of adverse effects had been reported at exposures lower than those that had been reviewed by the JECFA when they established the PTWI (EFSA, 2009).

19. In place of the PTWI, the JECFA determined a single BMDL for a 0.5% increased incidence of lung cancer above background; the value calculated for the 95% lower confidence limit of the $BMDL_{0.5}$ was 3.0 µg/kg bw/day. This was the lowest of the BMDLs calculated by the JECFA. Sensitivity analysis that was undertaken to investigate the impact of uncertainty in the exposure estimates in the study upon which this value was based indicated that this $BMDL_{0.5}$ could be in the range of 2.0 to 7.0 µg/kg bw/day (FAO/WHO, 2011).

20. The Committee noted that, in order to improve assessments of dietary exposures to inorganic arsenic, there was a need for improved data on the occurrence of different species of arsenic in, and their bioavailability from, different foods as they are consumed. The Committee also noted that further information on the toxicity of the arsenic species that are found in food is required (FAO/WHO, 2011).

21. The Committee recommended that future epidemiological studies of the health impacts of arsenic should incorporate appropriate measures of total exposure to inorganic arsenic, including from food and from water used in the cooking and processing of food (FAO/WHO, 2011).

Notes on the EFSA and JECFA BMDLs

22. It should be noted that a majority of the epidemiological studies from which the EFSA and JECFA BMDLs have been derived have focused on

[4] As it was within the region of a $BMDL_{0.5}$ that they had established (JECFA, 2011).

exposures to inorganic arsenic via drinking water, and have not measured or reported total dietary exposure to inorganic arsenic. In order to use the data generated by these epidemiological studies in their BMDL modelling, both Committees had to estimate dietary exposures for the study populations.

23. The EFSA and JECFA Committees established different BMDL values as they used different approaches in some aspects of their modelling; in particular, when modelling the dose-response data, and in their approaches to assessing dietary exposure to arsenic of the populations in the epidemiological studies. Furthermore, the JECFA included newer studies in their modelling that had been published after the 2009 EFSA opinion. The dose response section of the JECFA monograph has been included in Annex B.

24. The risks associated with exposure to inorganic arsenic are assessed in this discussion paper by comparing the estimated exposures with the lowest of the available BMDLs, the $BMDL_{01}$ of 0.3 µg/kg bw/day established by the EFSA. The exposures upon which this BMDL was based were associated with lung cancer (EFSA, 2009). There are currently no health-based guidance values against which exposures to total arsenic or organic arsenic can be compared.

WHO

25. Along with food, drinking water is considered to be one of the most important sources of oral exposure to arsenic. A provisional guideline value of 10 µg of arsenic per litre of drinking water was established by the WHO in 1993 (WHO, 2008), and was previously supported by the JECFA PTWI (15 µg/kg bw/day) assuming an allocation of 20% to drinking water. Although this PTWI was withdrawn by the JECFA in 2011 (paragraph 17), the WHO retained the guidance value of 10µg/L as a goal for arsenic in drinking water, and designated that the guideline was provisional. This was in view of the practical difficulties in removing arsenic from drinking-water, particularly from small supplies, the practical quantification limit for arsenic, and the fact that in many countries even the provisional guideline would not be attainable. The WHO stated that this guideline was retained "*on the basis of treatment performance and analytical achievability with the proviso that every effort should be made to keep concentrations as low as reasonably possible*" (WHO, 2012).

IARC

26. Arsenic and arsenic compounds have been considered by the IARC in 1979, 1987 and 2002. In 1979, the IARC concluded, based on evidence of skin and lung cancer, that 'arsenic and certain arsenic compounds' were carcinogenic to humans (Group 1); they considered that the information that was available on the carcinogenicity of arsenic compounds in experimental animals was inadequate for evaluation (IARC, 1979). In 1987, they concluded that the evidence for the carcinogenicity of arsenic and arsenic compounds to humans was *sufficient*, but that the evidence for carcinogenicity to animals

was *limited*. The majority of the studies that were reviewed focussed on the increased incidence of skin and/or lung cancers, with some additional reports of bladder, liver, gastrointestinal, and renal cancers (IARC, 1988). At the 2002 evaluation, the IARC concluded that arsenic in drinking water was carcinogenic to humans (Group 1) on the basis that there was *sufficient evidence* in humans that arsenic in drinking-water causes cancers of the urinary bladder, lung and skin. In 2002 they also concluded that when taken together, the studies on inorganic arsenic provided *limited evidence* for carcinogenicity in experimental animals (IARC, 2004).

27. In 2011, the IARC evaluated the carcinogenicity of arsenic and arsenic compounds again, as new data had become available since the previous evaluations. In their new evaluation, the IARC stated that there was "*sufficient evidence* in humans for the carcinogenicity of mixed exposure to inorganic arsenic compounds, including arsenic trioxide, arsenite, and arsenate. Inorganic arsenic compounds, including arsenic trioxide, arsenite, and arsenate, cause cancer of the lung, urinary bladder, and skin. Also, a positive association has been observed between exposure to arsenic and inorganic arsenic compounds and cancer of the kidney, liver, and prostate". The IARC also stated that there was "*sufficient evidence* in experimental animals for the carcinogenicity of inorganic arsenic compounds" (IARC, 2012).

28. Overall, the IARC has classified arsenic and inorganic arsenic compounds as *carcinogenic to humans* (Group 1 agents) (IARC, 2012).

Arsenic exposures in infants aged 0 to 12 months and young children aged 1 to 5 years

Sources of arsenic exposure

Human breast milk

29. There are limited data available on the concentration of arsenic in breast milk. Those data which are available often relate to women with high exposures to arsenic (e.g. due to the region they live in) (EFSA, 2014), and rarely determine the species of arsenic present in samples.

30. A literature search has not identified any data for arsenic concentrations in breast milk in the UK. Therefore a value of 0.33 µg/L, derived from a study by Björklund *et al*. (2012), has been used to estimate exposures to arsenic via breast milk in infants aged 0 to 18 months. This value was the median concentration of 60 samples of breast milk collected in 2002-2009 from Swedish first-time mothers at 2-3 weeks postpartum. The limit of detection was 0.007 µg/L, and the minimum and maximum reported concentrations were 0.041 and 4.6 µg/L respectively. Björklund *et al*. performed speciation on the samples of breast milk with the highest arsenic concentrations (3 samples with a range of 2-4 µg/L) according to a protocol described by Fängström *et al*. (2008); this protocol states an LOD of 0.2 µg/L for arsenate (As(V)) and of 0.1 µg/L for arsenite (As(III)), methylarsonic acid,

and dimethylarsinic acid. Björklund *et al*. reported that the speciation showed no content of inorganic arsenic or its methylated metabolites in the 3 samples; this provides a basis for assuming that <10% of the arsenic present in the samples was inorganic.

31. Furthermore, using the Spearman correlation test, Björklund *et al*. assessed the association between the elemental concentrations in breast milk and certain dietary components, and reported that the arsenic concentrations were significantly correlated with fish consumption ($r_s = 0.37$, $p = 0.005$, $n = 54$).

Infant formulae and food

32. Concentrations of total and inorganic arsenic (as the sum of As(III) and As(V), and also MMA if present) have recently been measured in an FSA survey of metals and other elements in infant formulae and foods (e.g. commercial infant foods) (referred to as the Infant Metals Survey), and in the composite food samples of the 2014 Total Diet Study (TDS).

33. With the introduction of MLs for inorganic arsenic in rice and rice-based products, it is possible that some of the exposures from these food products will decrease in time.

34. It is well established that rice can be a significant source of exposure to inorganic arsenic (EFSA, 2009). The FSA has previously issued advice against the use of rice drinks as a substitute for breast milk, infant formula, or cows' milk, when feeding 1 to 4.5 year olds (paragraph 2). Substitution with rice drinks is expected to occur when a child cannot tolerate other forms of milk, although it is not generally recommended by health practitioners and dieticians[5]. The exposures via rice drinks have been assessed so that this recommendation may be reviewed, and revised if necessary. The mean and 97.5th percentile concentrations of inorganic arsenic in 60 samples of rice drinks tested by the FSA were 12 and 20 µg/kg, respectively (FSA, 2009c). This testing was performed as part of an FSA survey of total and inorganic arsenic in rice drinks, and its results were used in the exposure assessments upon which the recommendations regarding consumption of rice drinks were based. As no new UK data are available, these concentrations have been used in the current exposure assessments for rice drinks.

35. Rice cakes are a common snack food for infants and young children, with some brands specifically marketed for consumption by this age group (these may fall under the 'commercial infant foods' category). With the introduction of different MLs for inorganic arsenic in rice intended for the production of infant foods, and for inorganic arsenic in rice cakes (i.e. not those intended for infants or young children), concern has been raised about

[5] This is due to both the arsenic content, and because rice drink is considered a nutritionally inadequate substitute for breast milk or formula at any stage of infancy or early childhood (FSA, 2009b).

the consumption of rice cakes not specifically marketed for infants (referred to herein as 'adult' rice cakes) by those aged 0 to 5 years. For these reasons, it has been deemed necessary to perform separate exposure assessments to estimate the level of exposure to inorganic arsenic in infants and young children from the consumption of 'adult' rice cakes; exposure assessments have also been completed for infant rice cakes so that the two sources of exposure can be compared.

36. Concentrations of inorganic arsenic in infant rice cakes have been measured in the Infant Metals Survey. A mean concentration of 150 µg/kg has been derived from the analytical results for 6 types of infant rice cakes (median = 147 µg/kg, range = 74 to 256 µg/kg). Each type of infant rice cake that was tested had a total sample size of 700 g (i.e. multiple samples of each type were homogenised into one large sample). It has not been possible to determine a concentration for 'adult' rice cakes from the TDS as the samples that may have contained rice cakes would have been bulked with other foods for analysis (i.e. there is no 'rice cakes' sub-group).

37. A recent study by Signes-Pastor *et al*. (2016) measured the concentration of inorganic arsenic in several rice-based products commonly consumed by infants including baby rice, rice cereals and rice crackers (i.e. rice cakes (confirmed by personal communication with lead author, January 2016)). The researchers tested 36 samples of infant rice cakes and 61 samples of 'adult' rice cakes that were purchased from 36 food shops (15 local shops and 25 big supermarkets) in the UK in 2014. Mean and 97.5th percentile concentrations of 127 and 187 µg/kg, respectively (median = 127 µg/kg), were determined for the infant rice cakes. For the 'adult' rice cakes, mean and 97.5th percentile concentrations of 96 and 197 µg/kg, respectively (median = 98 µg/kg) were determined (personal communication with Dr A. Signes-Pastor, January 2016). It is noted that these data do not support the concern that arsenic levels in 'adult' rice cakes would be higher than in infant rice cakes.

38. The mean inorganic arsenic concentration reported in the Infant Metals Survey has been used in the exposure assessment for infant rice cakes (150 µg/kg). This concentration was used as it was relatively consistent with that reported by Signes-Pastor *et al.*, albeit slightly higher. For the assessment of exposures from non-infant specific/'adult' rice cakes, the mean concentration reported by Signes-Pastor *et al*. has been used (96 µg/kg) as it was not possible to derive a value from the TDS. The exposure assessments have not been performed using the new MLs for inorganic arsenic in rice-based products (paragraph 3), as not all rice-based products would contain inorganic arsenic at the ML.

Drinking water

39. In water, arsenic is most likely to be present as arsenate (As(V)) if the water is oxygenated, and arsenite (As(III)) under reducing conditions (WHO, 2011). Drinking water can therefore be a major contributor to inorganic arsenic exposure, especially in areas with high natural levels, and when

factoring in its use in the preparation of other beverages and food (EFSA, 2009; WHO, 2011)).

40. EU legislation sets a maximum limit of 10 µg/L for arsenic in water (Directive 98/83/EC).

41. Levels of arsenic in drinking water in 2014 from England and Wales, Northern Ireland and Scotland were provided by the Drinking Water Inspectorate, Northern Ireland Water and the Drinking Water Quality Regulator for Scotland, respectively. Median and 97.5th percentile values calculated from this data are shown in Table 2. These values have been used to calculate exposures to arsenic from drinking water in combination with exposures from food.

42. As specific data for inorganic arsenic concentrations were not available, and as it is well established that essentially all of the arsenic in drinking water is inorganic (EFSA, 2009), all of the exposure estimates that take water into account have been performed assuming that all of the arsenic measured in water was inorganic.

Table 2. Median and 97.5th percentile concentrations (µg/L) of inorganic arsenic in water across the UK for 2014, all arsenic in water is assumed to be inorganic.

Country	Number of samples	Median concentration (µg/L)	97.5th Percentile concentration (µg/L)
England and Wales	12479	0.22	2.10
Northern Ireland	392	0.40	0.70
Scotland	1500	0.20	0.90

Environmental

Dust and soil

43. Arsenic can be present in soil both naturally (depending on the type of bedrock etc.), and as the result of anthropogenic activity (e.g. mining or the use of phosphate fertilisers) (Rawlings *et* al., 2012; EFSA, 2009).

44. Concentrations of arsenic in soil were measured in 5,670 topsoil[6] samples collected between 1978 and 1982 in England and Wales, avoiding large urban areas. Samples were analysed 30 years later (Rawlings *et al.*, 2012). The median and 90th percentile concentrations were 15 and 30 mg/kg, respectively.

[6] From a depth of 0 to 15 cm

45. Concentrations of arsenic in soil were also measured in 453 soil samples collected as part of the Environment Agency's Soil and Herbage Pollutant Survey (EA, 2007). The soil samples were collected from a variety of urban and rural sites across England, Scotland, Wales and Northern Ireland between 2001 and 2002 (SHS, 2007). Samples were also collected from industrial sites (e.g. power stations and incinerators); these samples have not been included as exposure to soil at such sites is unlikely to occur in infants and young children. The median and 97.5th percentile concentrations of arsenic in the urban and rural soil samples were 7.5 and 32.1 mg/kg, respectively. Given the similarity in these results, the more recent SHS data have been used in the current exposure assessment.

46. No relevant data were available for arsenic concentrations in dust. As the proportion of inorganic arsenic in soil varies depending on local geology and anthropogenic sources, a worst case scenario approach has been taken for the exposure assessment and it has been assumed that all of the arsenic present in soil is inorganic.

Air

47. Both natural (e.g. volcanic eruptions or microbial reduction) and anthropogenic (e.g. coal-fired power generation and smelting) activities release arsenic into the atmosphere, mainly as As_2O_3 particles or bound to particulate matter (EFSA, 2009).

48. EU legislation sets a maximum limit of 6 ng/m^3 for arsenic in air (Directive 2004/107/EC).

49. Arsenic in particulate matter less than 10 µm (PM_{10}) was measured at 23 sites and as metal deposition was measured at 4 sites across the UK in 2014. Median values from these sites ranged from 0.12 to 1.09 ng/m^3 and 99th percentile values ranged from 0.12 to 4.92 ng/m^3. No data were available for inorganic arsenic.

50. As data on the proportion of inorganic arsenic in air was not available, a worst case scenario approach has been taken for the exposure assessment and it has been assumed that all of the arsenic present in air is inorganic.

Exposure assessment

51. Consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013), and from years 1-4 of the National Diet and Nutrition Survey Rolling Programme (NDNS) (Bates *et al.*, 2014) have been used for the estimation of dietary exposures. Bodyweight data used in the estimation of arsenic exposures are shown in Table 3 below.

Table 3. Average bodyweights used in the estimation of arsenic exposures (DH, 2013; Bates *et al*., 2014)

Age group (months)	Bodyweight (kg)
0 to <4	5.9
>4 to <6	7.8
>6 to <9	8.7
>9 to <12	9.6
>12 to <15	10.6
>15 to <18	11.2
>18 to <24	12.0
>24 to <60	16.1

Infants (0 to 12 months)

Breast milk

52. As no consumption data were available for exclusive breastfeeding in infants aged 0 to 6 months, the default consumption values used by COT in its evaluations of the infant diet, of 800 and 1200 mL for average and high level consumption (EFSA, 2009) have been used to estimate exposures to arsenic from breastmilk based on a median total arsenic concentration of 0.33 µg/L (paragraph 30). The ranges of exposure to total arsenic in exclusively breastfed 0 to 6 month olds were 0.034 to 0.045 and 0.051 to 0.067 µg/kg bw/day in average and high level consumers respectively (Table 4).

Table 4. **Total arsenic** exposure from exclusive breastfeeding in 0 to 6 month old infants, estimated for average and high level consumption of breast milk containing total arsenic at 0.33 µg/L.

Arsenic concentration (µg/L)	Exposure (µg/kg bw/day)			
	Average consumer (800 mL/day)		High consumer (1200 mL/day)	
	0 to <4 months	>4 to <6 months	0 to <4 months	>4 to <6 months
0.33	0.045	0.034	0.067	0.051

53. For this assessment, it has been assumed that <10% of the arsenic that is present is inorganic (paragraph 30). This would result in exposure ranges in exclusively breastfed 0 to 6 month olds of <0.0034 to <0.0045 and <0.0051 to <0.0067 µg/kg bw/day in average and high level consumers respectively (Table 5).

Table 5. Estimated **inorganic arsenic** exposure from exclusive breastfeeding in 0 to 6 month old infants, estimated for average and high level consumption of breast milk containing inorganic arsenic at < 0.033 µg/L.

Arsenic concentration (µg/L)	Exposure (µg/kg bw/day)			
	Average consumer (800 mL/day)		High consumer (1200 mL/day)	
	0 to <4 months	>4 to <6 months	0 to <4 months	>4 to <6 months
0.33	<0.0045	<0.0034	<0.0067	<0.0051

54. Data on breast milk consumption were available from the DNSIYC and the NDNS, and have been used to estimate exposures for infants aged 4 to 18 months (Tables 6 and 7) based on the same median total arsenic concentration of 0.33 µg/L. There were too few records of breast milk consumption for children older than 18 months in the NDNS to allow a reliable exposure assessment, and breast milk is expected to contribute minimally in this age group.

55. Mean exposures to total arsenic for 4 to 18 month olds were 0.008 to 0.030 µg/kg bw/day, and 97.5th percentile exposures were 0.017 to 0.053 µg/kg bw/day (Table 6). Assuming that <10% of the arsenic is inorganic, this would result in mean exposures to inorganic arsenic for the same age group of <0.0008 to <0.0030 µg/kg bw/day, and 97.5th percentile exposures of <0.0017 to <0.0053µg/kg bw/day (Table 7).

Table 6. **Total arsenic** exposure in 4 to 18 month old infants from breast milk, estimated for mean and 97.5th percentile level consumption of breast milk containing total arsenic at 0.33 µg/L.

Age group (months)	Exposure (µg/kg bw/day)	
	Mean	97.5th percentile
>4 to <6	0.030	0.051
>6 to <9	0.022	0.053
>9 to <12	0.013	0.038
>12 to <15	0.010	0.025
>15 to <18	0.008	0.017

Table 7. Estimated **inorganic arsenic** exposure in 4 to 18 month old infants from breast milk, estimated for mean and 97.5th percentile level consumption of breast milk containing inorganic arsenic at < 0.033 µg/L.

Age group	Exposure (µg/kg bw/day)

(months)	Mean	97.5th percentile
>4 to <6	<0.0030	<0.0051
>6 to <9	<0.0022	<0.0053
>9 to <12	<0.0013	<0.0038
>12 to <15	<0.0010	<0.0025
>15 to <18	<0.0008	<0.0017

Infant formulae and commercial infant foods

56. Exposure estimates for this category were derived using occurrence data from the FSA's survey of metals and other elements in infant formulae and food, which measured both total and inorganic arsenic (paragraph 32). Exposure estimates based on both lower bound (LB) and upper bound (UB) concentrations are provided. As no consumption data were available for 0 to 4 month old infants, and as this age group would not be expected to be consuming solid foods, exposure estimates were calculated for infant formulae only, using the EFSA default values of 800 and 1200 mL (EFSA, 2009) (Tables 8 and 9). Consumption data from the DNSIYC were used to estimate exposures for 4 to 12 month olds (DH, 2013) (Tables 10 and 11).

57. In 0 to 4 month olds, exposures to total arsenic from ready-to-feed infant formula were 0.000 to 0.041 µg/kg bw/day in average consumers, and 0.000 to 0.061 µg/kg bw/day in high level consumers (Table 8). When exposures to total arsenic are calculated for reconstituted dry formula using the highest median (0.4 µg/L) and 97.5th percentile (2.1 µg/L) concentrations for arsenic reported in Table 2, this results in total exposures of 0.070 to 0.301 µg/kg bw/day in average consumers, and of 0.101 to 0.452 µg/kg bw/day in high level consumers.

Table 8. Estimated average and high level exposures (µg/kg bw/day) to **total arsenic** from infant formulae for 0 to 4 month olds.

Infant Formula	Total As Exposure (LB-UB Range) (µg/kg bw/d)	
	Average consumer (800 mL/day)	High level consumer (1200 mL/day)
Ready-to-Feed	0.000-0.041	0.000-0.061
Dry Powder [a]	0.020-0.061	0.031-0.092
Dry Powder + median water of 0.4 µg/L [b]	0.070-0.111	0.101-0.162
Dry Powder + 97.5th percentile water of 2.1 µg/L [b]	0.260-0.301	0.391-0.452

[a] Exposure does not include the contribution from water

[b] Calculated assuming reconstituted formula comprises 85% water

58. Exposures to inorganic arsenic from ready-to-feed formula were 0.000 to 0.027 µg/kg bw/day in average consumers, and 0.000 to 0.041 µg/kg bw/day in high level consumers (Table 9). When exposures to inorganic arsenic are calculated for reconstituted formula based on the highest median and 97.5th percentile concentrations for arsenic reported in Table 2, this results in exposures of 0.064 to 0.277 µg/kg bw/day in average consumers, and of 0.091 to 0.415 µg/kg bw/day in high level consumers.

Table 9. Estimated average and high level exposures (µg/kg bw/day) to **inorganic arsenic** from infant formulae for 0 to 4 month olds.

Infant Formula	Inorganic As Exposure (LB-UB Range) (µg/kg bw/d)	
	Average consumer (800 mL/day)	High level consumer (1200 mL/day)
Ready-to-Feed	0.000-0.027	0.000-0.041
Dry Powder [a]	0.014-0.037	0.021-0.055
Dry Powder + median water of 0.4 µg/L [b]	0.064-0.087	0.091-0.125
Dry Powder + 97.5th percentile water of 2.1 µg/L [b]	0.254-0.277	0.381-0.415

[a] Exposure does not include the contribution from water
[b] Calculated assuming reconstituted formula comprises 85% water

59. Total mean exposures (excluding water) to total arsenic from infant formulae, commercial infant foods, and complementary foods, for 4 to 12 month olds were 0.186 to 0.979 µg/kg bw/day, and 97.5th percentile exposures were 0.824 to 4.771 µg/kg bw/day. Total mean and 97.5th percentile exposures have also been calculated using the highest median and 97.5th percentile concentrations for arsenic in water reported in Table 2. The total mean exposures including water were 0.186 to 1.009 µg/kg bw/day, while the 97.5th percentile exposures including water were 0.834 to 4.881 µg/kg bw/day (Table 10). Total arsenic levels in commercial infant foods and complementary foods include a contribution from organic arsenic which is likely to be due to the presence of fish in the foods analysed.

Table 10. Estimated mean and 97.5th percentile exposures (µg/kg bw/day) to **total arsenic** from infant formulae, commercial infant foods and other foods (excluding water) for 4 to 12 month olds.

Food	Total As Exposure (LB-UB Range) (µg/kg bw/day)					
	4 -5.99 Months (n=116)		6-8.99 Months (n=606)		9-11.99 Months (n=686)	
	Mean	97.5th	Mean	97.5th	Mean	97.5th
Infant Formula	0.000-0.003	0.002-0.032	0.000-0.012	0.001-0.042	0.001-0.012	0.009-0.037
Commercial Infant Foods	0.132	0.467	0.189	0.63	0.175	0.662
Complementary Foods	0.054-0.057	0.334-0.339	0.404-0.409	3.121-3.126	0.805-0.813	4.714-4.720
Total (excl. water)	0.186-0.187	0.824-0.827	0.594-0.598	3.246-3.247	0.945-0.979	4.767-4.771
Total (incl. median water of 0.4 µg/L)	0.186-0.187	0.834-0.837	0.594-0.598	3.256-3.257	0.945-0.979	4.787-4.791
Total (incl. 97.5th percentile water of 2.1 µg/L)	0.196-0.197	0.864-0.867	0.614-0.618	3.316-3.317	0.975-1.009	4.877-4.881

* Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories

60. Total mean exposures (excluding water) to inorganic arsenic for the same age group were 0.054 to 0.178 µg/kg bw/day and 97.5th percentile exposures were 0.226 to 0.451 µg/kg bw/day. The total mean exposures including water were 0.056 to 0.203 µg/kg bw/day, while the 97.5th percentile exposures including water were 0.232 to 0.536 µg/kg bw/day (Table 11).

Table 11. Estimated mean and 97.5th percentile exposures (µg/kg bw/day) to **inorganic arsenic** from infant formulae, commercial infant foods and other foods (excluding water) for 4 to 12 month olds.

Food	Inorganic As Exposure (LB-UB Range) (µg/kg bw/d)					
	4 -5.99 Months (n=116)		6-8.99 Months (n=606)		9-11.99 Months (n=686)	
	Mean	97.5th	Mean	97.5th	Mean	97.5th
Infant Formula	0.000-0.014	0.001-0.031	0.000-0.014	0.001-0.031	0.000-0.011	0.006-0.027
Commercial Infant Foods	0.044-0.064	0.214-0.264	0.061-0.089	0.201-0.287	0.057-0.082	0.216-0.306
Complementary Foods	0.009-0.011	0.057-0.063	0.058-0.064	0.284-0.293	0.086-0.096	0.333-0.345
Total (excl. water)	0.054-0.077	0.226-0.279	0.122-0.156	0.352-0.411	0.144-0.178	0.395-0.451

Total (incl. median water of 0.4 µg/L)	0.056-0.079	0.232-0.285	0.126-0.160	0.365-0.424	0.149-0.183	0.411-0.467
Total (incl. 97.5th percentile water of 2.1 µg/L)	0.064-0.087	0.257-0.310	0.142-0.176	0.423-0.482	0.169-0.203	0.480-0.536

* Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories

Children aged 12 to 18 months

61. Estimated exposures to total and inorganic arsenic from food for children aged 12 to 18 months were calculated using occurrence data from both the FSA's survey of metals and other elements in infant formulae and food, and the 2014 TDS. The basis for each study is explained in Annex C, but in brief, the exposure data derived from the infant survey allow estimation of total and inorganic arsenic exposure in infant formula and foods as sold, whereas the results from the TDS are based on analysis of food that is prepared as for consumption. In addition, the infant metal survey included analysis of infant formulae and commercial infant foods which are not included in the TDS. Both studies measured total and inorganic arsenic; exposure estimates based on both lower bound (LB) and upper bound (UB) concentrations are provided.

62. The consumption data from the DNSIYC were used for the estimation of exposure for each study for children aged 12 to 18 months (DH, 2013).

Exposure estimates based on the 'Infant Metals Survey'

63. For total arsenic, the ranges of total mean and 97.5th percentile exposures (excluding water) from infant formula, commercial infant foods and complementary foods were 1.029 to 1.152 and 4.418 to 4.462 µg/kg bw/day, respectively. The total mean exposures including water (calculated using the highest median and 97.5th percentile values in Table 2) were 1.039 to 1.182 µg/kg bw/day, while the 97.5th percentile exposures including water were 4.438 to 4.552 µg/kg bw/day (Table 12).

Table 12. Estimated mean and 97.5th percentile exposures (µg/kg bw/day) to **total arsenic** from infant formulae, commercial infant foods and other foods (excluding water) for 12 to 18 month olds.

Food	**Total As Exposure (LB-UB Range) (µg/kg bw/day)**			
	12-14.99 Months (n=670)		**15-17.99 Months (n=605)**	
	Mean	**97.5th**	**Mean**	**97.5th**

Infant Formula	0.002-0.008	0.017-0.039	0.001-0.005	0.013-0.030
Commercial Infant Foods	0.101	0.462	0.055	0.303
Complementary Foods	1.039-1.052	4.387-4.402	0.974-0.987	4.362-4.371
Total (excl. water)	1.140-1.152	4.457-4.462	1.029-1.038	4.418-4.420
Total (incl. median water of 0.4 µg/L)	1.150-1.162	4.477-4.482	1.039-1.048	4.438-4.440
Total (incl. 97.5th percentile water of 2.1 µg/L)	1.170-1.182	4.547-4.552	1.059-1.068	4.518-4.520

* Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories

64. For inorganic arsenic, the ranges of total mean and 97.5th percentile exposures (excluding water) were 0.139 to 0.166 and 0.416 to 0.466 µg/kg bw/day, respectively. The total mean exposures including water were 0.144 to 0.196 µg/kg bw/day, while the 97.5th percentile exposures including water were 0.435 to 0.555 µg/kg bw/day (Table 13).

Table 13. Estimated mean and 97.5th percentile exposures (µg/kg bw/day) to **inorganic arsenic** from infant formulae, commercial infant foods and other foods (excluding water) for 12 to 18 month olds.

Food	**Inorganic As Exposure (LB-UB Range) (µg/kg bw/d)**			
	12-14.99 Months (n=670)		**15-17.99 Months (n=605)**	
	Mean	**97.5th**	**Mean**	**97.5th**
Infant Formula	0.001-0.006	0.011-0.028	0.001-0.003	0.009-0.022
Commercial Infant Foods	0.033-0.047	0.162-0.219	0.019-0.026	0.089-0.132
Complementary Foods	0.106-0.121	0.372-0.387	0.128-0.143	0.385-0.413
Total (excl. water)	0.139-0.165	0.428-0.466	0.147-0.166	0.416-0.432
Total (incl. median water of 0.4 µg/L)	0.144-0.170	0.445-0.483	0.153-0.172	0.435-0.449

Total (incl. 97.5th percentile water of 2.1 µg/L)	0.166-0.192	0.517-0.555	0.177-0.196	0.513-0.546

* Determined from a distribution of consumption of any combination of categories rather than by summation of the respective individual 97.5th percentile consumption value for each of the three food categories

Exposure estimates based on the TDS

65. Tables 14 and 15 show the estimated total and inorganic arsenic exposures that were calculated using the TDS data for children aged 12 to 18 months. A more detailed breakdown of individual food groups for the TDS can be found in Annex C. The exposure data derived from the TDS are higher than those estimated from the infant metal survey due to the inclusion of a larger number of foods in the exposure estimate for the TDS relative to the infant metal survey.

66. Using the TDS data (which includes tap water and bottled water), total mean and 97.5th percentile exposures to total arsenic from a combination of all food groups ranged from 1.820 to 2.196 and 8.712 to 9.207 µg/kg bw/day, respectively. The total arsenic concentration for tap water in the TDS was <1.2 µg/L. In order to determine the possible impact of arsenic concentrations in water from different regions, this has been replaced by the highest median (0.4 µg/L) and 97.5th percentile (2.1 µg/L) for arsenic levels in water reported in Table 2. This results in total mean and 97.5th percentile exposures to total arsenic from a combination of all food groups of 1.824 to 2.204 and 8.712 to 9.214 µg/kg bw/day, respectively (Table 14), demonstrating that the arsenic content of water has a negligible impact on total dietary exposure to total arsenic.

Table 14. Estimated **total arsenic** exposures from the total diet for the TDS in children aged 12 to 18 months.

Food Group	**Total As Exposure (LB-UB Range) (µg/kg bw/day)**			
	12-14.99 Months (n=670)		**15-17.99 Months (n=605)**	
	Mean	**97.5th**	**Mean**	**97.5th**
TDS (incl. TDS water at <1.2 µg/L)	1.922-2.196	8.712-9.207	1.820-2.111	8.940-9.202
TDS (incl. median water of 0.4 µg/L)	1.926-2.188	8.712-9.207	1.824-2.102	8.948-9.191
TDS (incl. 97.5th percentile water of 2.1 µg/L)	1.943-2.204	8.713-9.208	1.843-2.121	8.979-9.214

67. Total mean and 97.5th percentile exposures to inorganic arsenic from the combination of all food groups in the TDS ranged from 0.126 to 0.702 and 0.316 to 1.243 µg/kg bw/day, respectively. The inorganic arsenic concentration identified for tap water in the TDS was <1 µg/L. As for total arsenic, this has been replaced by the highest median (0.4 µg/L) and 97.5th percentile (2.1 µg/L) reported in Table 2. This results in total mean and 97.5th percentile exposures to inorganic arsenic from a combination of all food groups of 0.129 to 0.692 and 0.323 to 1.195 µg/kg bw/day, respectively (Table 15), demonstrating that the arsenic content of water has a negligible impact on total dietary exposure to inorganic arsenic.

Table 15. Estimated **inorganic arsenic** exposures from the total diet for the TDS in children aged 12 to 18 months.

Food Group	Inorganic As Exposure (LB-UB Range) (µg/kg bw/day)			
	12-14.99 Months (n=670)		15-17.99 Months (n=605)	
	Mean	97.5th	Mean	97.5th
TDS (incl. TDS water at <1 µg/L)	0.126-0.659	0.316-1.243	0.137-0.702	0.327-1.162
TDS (incl. median water of 0.4 µg/L)	0.129-0.634	0.323-1.169	0.142-0.673	0.332-1.130
TDS (incl. 97.5th percentile water of 2.1 µg/L)	0.146-0.651	0.349-1.195	0.161-0.692	0.350-1.141

68. In general, the food groups with the highest contribution to total arsenic exposure in the TDS were fish (which is not likely to contain inorganic arsenic), and miscellaneous cereals (see Annex C).

69. In general, the food groups with the highest contribution to inorganic arsenic exposure in the TDS were miscellaneous cereals and potatoes (see Annex C).

Children aged 18 months to 5 years

70. Exposure estimates for these age groups were derived using occurrence data from the 2014 TDS; and consumption data from the NDNS (Bates *et al*., 2014).

71. Tables 16 and 17 show the possible total and inorganic arsenic exposures that were calculated using the TDS data for children aged 18 months to 5 years. A more detailed breakdown of individual food groups for the TDS can be found in Annex D.

72. Using the TDS data, total mean and 97.5th percentile exposures to total arsenic from a combination of all food groups were 1.837 to 2.704 and 6.835 to 9.587 µg/kg bw/day, respectively. The total arsenic concentration for tap water in the TDS was <1.2 µg/L. In order to determine the possible impact of arsenic concentrations in water from different regions, this has been replaced by the highest median (0.4 µg/L) and 97.5th percentile (2.1 µg/L) for arsenic levels in water reported in Table 2. This results in total mean and 97.5th percentile exposures to total arsenic from a combination of all food groups of 1.841 to 2.714 and 6.839 to 9.597 µg/kg bw/day, respectively (Table 16), demonstrating that the arsenic content of water has a negligible impact on total dietary exposure to total arsenic.

Table 16. Estimated **total arsenic** exposures from the total diet for the TDS in children aged 18 months to 5 years.

Food Group	Total As Exposure (LB-UB Range) (µg/kg bw/day)			
	18 to 24 Months (n=70)		24 to 60 Months (n=429)	
	Mean	97.5th	Mean	97.5th
TDS (incl. TDS water at <1.2 µg/L)	2.385-2.704	9.216-9.587	1.837-2.100	6.835-7.123
TDS (incl. median water of 0.4 µg/L)	2.389-2.695	9.221-9.578	1.841-2.092	6.839-7.119
TDS (incl. 97.5th percentile water of 2.1 µg/L)	2.409-2.714	9.239-9.597	1.858-2.109	6.774-7.128

73. Total mean and 97.5th percentile exposures to inorganic arsenic from the combination of all food groups in the TDS ranged from 0.123 to 0.786 and 0.256 to 1.182 µg/kg bw/day, respectively. The inorganic arsenic concentration identified for tap water in the TDS <1 µg/L. As for total arsenic, this has been replaced by the highest median (0.4 µg/L) and 97.5th percentile (2.1 µg/L) reported in Table 2. This results in total mean and 97.5th percentile exposures to inorganic arsenic from a combination of all food groups of 0.127 to 0.776 and 0.259 to 1.175 µg/kg bw/day, respectively (Table 17), demonstrating that the arsenic content of water has a negligible impact on total dietary exposure to inorganic arsenic.

Table 17. Estimated **inorganic arsenic** exposures from the total diet for the TDS in children aged 18 months to 5 years.

Food Group	Total As Exposure (LB-UB Range) (µg/kg bw/day)	
	18 to 24 Months (n=70)	24 to 60 Months (n=429)

	Mean	97.5th	Mean	97.5th
TDS (incl. TDS water at <1 µg/L)	0.144-0.786	0.291-1.182	0.123-0.650	0.256-1.021
TDS (incl. median water of 0.4 µg/L)	0.149-0.757	0.291-1.161	0.127-0.624	0.259-0.992
TDS (incl. 97.5th percentile water of 2.1 µg/L)	0.168-0.776	0.316-1.175	0.144-0.641	0.282-1.001

74. As with the younger children, the food groups with the highest contribution to total arsenic exposure in the TDS were fish (which is not likely to be inorganic), and miscellaneous cereals. The latter group (and potatoes) made the biggest contribution to total inorganic arsenic levels (see Annex D).

Exposures from the consumption of rice drinks

75. In order to review previous FSA advice about the consumption of rice drinks, a separate exposure assessment has been performed. This assessment has considered exposures in infants and young children aged 1 to 5 years only as the DH advise that cows' milk and alternatives (i.e. rice drinks) are not suitable for infants under 12 months old (paragraph 2). There are very few consumers of rice drinks recorded in the DNSIYC and the NDNS (5 in total for 1 to 5 year olds). As the data for consumption of rice drinks are very limited, the exposure estimates have been based on the consumption of cows' milk, assuming that, in a worst case scenario, there is complete replacement of cows' milk with rice drinks. Mean and 97.5th percentile inorganic arsenic concentrations of 12 and 20 µg/kg in rice drinks (FSA, 2009b), have also been used (Table 18).

76. For infants and young children aged 1 to 5 years, mean and 97.5th percentile exposures range from 0.218 to 0.604 and 0.600 to 1.516 µg/kg bw/day, respectively. The highest value for the 97.5th percentile range of exposures from rice drinks (for >12 to <15 month olds, 1.516 µg/kg bw/day) is more than double the upper bound mean exposure value estimated from the TDS data for this age range (Table 15). The highest values for the 97.5th percentile range of exposures for the remaining age groups (15 to 60 month olds) were between 1.5 and 2 times higher than the upper bound mean exposure values estimated from the TDS data for the same age groups (Tables 15 and 17).

Table 18. Estimated inorganic arsenic exposures from rice drinks for infants and young children aged 1 to 5 years, using consumption data for cows' milk as a proxy.

Age group	Mean inorganic arsenic concentration (12 µg/L)	97.5th percentile inorganic arsenic concentration (20 µg/L)

(months)	Average consumer[a] (µg/kg bw/day)	High level consumer[b] (µg/kg bw/day)	Average consumer[a] (µg/kg bw/day)	High level consumer[b] (µg/kg bw/day)
>12 to <15	0.362	0.910	0.604	1.516
>15 to <18	0.344	0.774	0.573	1.290
>18 to <24	0.316	0.863	0.526	1.438
>24 to <60	0.218	0.600	0.363	1.000

[a] Based on mean consumption from the DNSIYC and the NDNS
[b] Based on 97.5th percentile consumption from the DNSIYC and the NDNS

77. Based on upper bound mean exposures for the total diet (calculated with the highest median water concentration), and on the median occurrence value for inorganic arsenic in rice drinks (12 µg/L), consumption of up to about 50 mL of rice drink per day would not be expected to cause an appreciable increase in exposures to inorganic arsenic in infants and young children aged 1 to 5 years. This level of consumption would cause less than a 10% increase in background exposure from the total diet for this age group.

Exposures from the consumption of rice cakes

78. Due to the popularity of rice cakes as a snack food for infants and young children, separate exposure assessments have also been performed for this food product. Exposures have been estimated using consumption data from the DNSIYC (DH, 2013) and the NDNS (Bates *et al*., 2014); separate consumption data were available for infant and 'adult' rice cakes. A mean inorganic arsenic concentration of 150 µg/kg has been used in the assessment of infant rice cake consumption (Table 19), while a mean concentration of 96 µg/kg has been used for the assessment of 'adult' rice cakes (Table 20) (paragraph 38). Consumption data have been provided to allow the consumption estimates to be put into context given the approximate weights of the different types of rice cakes (rice cakes marketed for infants have an approximate weight of 2 g per cake while the weight of one 'adult' rice cake is ~10 g).

79. For infants aged <6 months, mean and 97.5th percentile exposures to inorganic arsenic from the consumption of infant rice cakes were 0.006 and 0.011 µg/kg bw/day, respectively, although these values are based on a very limited number of consumers. For infants aged 6 to 12 months mean and 97.5th percentile exposures to inorganic arsenic from the consumption of infant rice cakes range from 0.023 to 0.031 and 0.068 to 0.109 µg/kg bw/day, while those from the consumption of 'adult' rice cakes range from 0.018 to 0.025 and from 0.035 to 0.057 µg/kg bw/day, respectively. There were no consumers of 'adult' rice cakes aged < 6 months.

80. For young children aged 1 to 5 years, mean and 97.5th percentile exposures from the consumption of infant rice cakes range from 0.026 to 0.035 and 0.070 to 0.122 µg/kg bw/day, while those from the consumption of

'adult' rice cakes range from 0.025 to 0.066 and from 0.058 to 0.113 µg/kg bw/day, respectively. The highest value of the 97.5th percentile range of exposures from infant rice cakes (for >12 to <15 month olds, 122 µg/kg bw/day) is ~20% of the upper-bound mean exposures estimated from the TDS data for this age group (Table 15).

Table 19. Estimated inorganic arsenic exposures from infant rice cakes for infants and young children aged 4 months to 5 years.

Age group (months)	Consumption (g/day)		Consumption (g/kg bw/day)		Exposure (µg/kg bw/day)	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile
>4 to <6	0.30	0.47	0.04	0.07	0.006	0.011
>6 to <9	1.38	4.00	0.16	0.45	0.023	0.068
>9 to <12	1.97	6.59	0.21	0.73	0.031	0.109
>12 to <15	2.45	8.01	0.23	0.81	0.035	0.122
>15 to <18	2.59	6.00	0.23	0.52	0.035	0.078
>18 to <24	2.05	5.50	0.18	0.47	0.026	0.070
>24 to <60	3.20	6.44	0.20	0.47	0.029	0.071

Table 20. Estimated inorganic arsenic exposures from 'adult' rice cakes for infants and young children aged 4 months to 5 years.

Age group (months)	Consumption (g/day)		Consumption (g/kg bw/day)		Exposure (µg/kg bw/day)	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile
>4 to <6	n/a	n/a	n/a	n/a	n/a	n/a
>6 to <9	1.81	3.34	0.19	0.36	0.018	0.035
>9 to <12	2.40	5.29	0.26	0.59	0.025	0.057
>12 to <15	2.68	8.75	0.26	0.80	0.025	0.077
>15 to <18	2.81	7.83	0.26	0.73	0.025	0.070
>18 to <24	7.22	12.25	0.69	1.18	0.066	0.113
>24 to <60	4.56	7.50	0.31	0.61	0.030	0.058

Soil/dust

81. Potential exposures of UK infants aged >9 to 12 months and young children aged 1 to 5 years to arsenic in soil were calculated assuming ingestion of 100 mg/day (US EPA, 2008; WHO, 2007). Children of these age groups are likely to consume more soil and dust than younger infants who are less able to move around and come into contact with soil and dust. Median and 97.5th percentile soil arsenic concentrations of 7.5 and 32.1 mg/kg

respectively were used in these exposure estimations (paragraph 45, EA, 2007) (Table 21). Due to a lack of data on the proportion of inorganic arsenic in soil, a worst case scenario approach has been taken and it has been assumed that all of the arsenic present in soil is inorganic.

82. Data specific to dust were not available, however this is not considered an issue as the EPA's default ingestion value is for combined soil and dust ingestion; using only the arsenic concentrations determined for soil would therefore result in a relatively conservative exposure estimate.

Table 21. Possible inorganic arsenic exposures (µg/kg bw/day) from soil in infants and young children aged >9 months to 5 years.

Arsenic concentration (mg/kg)	**Exposure (µg/kg bw/day)**				
	Age (months)				
	>9 to 12	**12 to 15**	**15 to 18**	**18 to 24**	**24 to 60**
7.5 (Median)	0.078	0.071	0.067	0.063	0.047
32.1 (97.5th)	0.334	0.303	0.287	0.268	0.199

Air

83. Potential exposures of UK infants aged 0 to 12 months and young children aged 1 to 5 years to arsenic in air were estimated (Table 22) assuming mean ventilation rates of 3.6, 4.1, 5.4, 8.0, 9.5 and 10.9 m^3/day, respectively for infants and children aged 0 to <3, 3 to <6 and 6 to <12 months and 1 to <2, 2 to <3 and 3 to <6 years (US EPA, 2008). To assess the exposures in these age groups, average bodyweights of 5.9, 7.8, 9.2, 13.5, 15.1 and 19.7 kg, respectively, were used (Bates *et al*., 2014; DH, 2013).

84. The arsenic concentrations used in the exposure calculations were the lowest and highest median values and lowest and highest 99th percentile values of 0.12, 1.09, 0.12 and 4.92 ng/m^3, respectively, from monitoring sites in the UK (paragraph 49). As data on the proportion of inorganic arsenic in air was not available, a worst case scenario approach has been taken and it has been assumed that all of the arsenic present in air is inorganic.

Table 22. Possible exposures to inorganic arsenic (µg/kg bw/day) in infants and young children from the air.

Arsenic concentration (ng/m^3)	Exposure (µg/kg bw/day)					
	Ages (months)					
	0 to <3	3 to <6	6 to <12	12 to <24	24 to <36	36 to <72
0.12 (lowest median)	0.00007	0.00006	0.00007	0.00007	0.00008	0.00007
1.09 (highest median)	0.00067	0.00057	0.00064	0.00065	0.00069	0.00060
0.12 (lowest 99th percentile)	0.00007	0.00006	0.00007	0.00007	0.00008	0.00007
4.92 (highest 99th percentile)	0.00300	0.00259	0.00289	0.00292	0.00310	0.00272

Risk Characterisation

85. Potential risks from the exposure of infants and young children to inorganic arsenic were characterised by margins of exposure (MOEs), calculated as the ratio of the $BMDL_{01}$ value of 0.3 µg/kg bw/day, to estimated exposures from dietary and non-dietary sources. This BMDL was the lowest of the range of $BMDL_{01}$ values identified by the EFSA CONTAM Panel for cancers of the lung, skin and urinary bladder, and for skin lesions (EFSA, 2009). This BMDL has been used as it is the lowest of all the BMDL values that are currently available. There are no health-based guidance values against which exposures to total or organic arsenic can be compared.

86. The MOEs based on the estimated dietary exposures are shown in Table 23. For the total diet, only the exposures calculated using the 97.5th percentile water concentration have been used, as it has been demonstrated that the arsenic content of water has a negligible impact on total dietary exposure to inorganic arsenic. The MOEs for exclusively breastfed 0 to 4 month old infants are considerably greater than 1; this is in line with the view that breastfeeding protects against arsenic exposure (EFSA, 2009). The MOEs for exclusively formula-fed 0 to 4 month olds are greater than 1 at median water concentrations of arsenic, but are in the region of or less than 1 at 97.5th percentile water concentrations. The remaining MOEs for infants aged 4 to 12 months, and young children aged 1 to 5 years, are generally equal to or less than 0.6.

Table 23. Estimated dietary exposures to inorganic arsenic and the corresponding MOEs when they are compared to the lowest $BMDL_{01}$ for inorganic arsenic (0.3 µg/kg bw/day).

Food	Age (months)	Estimated dietary exposures (µg/kg bw/day)	MOE[a]

		Average consumers	High level consumers	Average consumers	High level consumers
Exclusive breast milk	0 to 4	<0.0045[b]	<0.0067[b]	>66.7	>44.8
Exclusive infant formula (median water of 0.4 µg/L)	0 to 4	0.087[c]	0.125[c]	3.4	2.4
Exclusive infant formula (97.5th percentile water of 2.1 µg/L)	0 to 4	0.277[c]	0.415[c]	1.1	0.7
Total diet (incl. 97.5th percentile water of 2.1 µg/L)	4 to 12	0.203[d]	0.536[d]	1.5	0.6
	12 to 18	0.692[e]	1.195[e]	0.4	0.3
	18 to 24	0.776[e]	1.175[e]	0.4	0.3
	24 to 60	0.641[e]	1.001[e]	0.5	0.3

[a] The MOE is calculated by dividing the $BMDL_{01}$ of 0.3 µg/kg bw/day by the respective dietary exposure
[b] Based on the assumption that <10% of the arsenic in breast milk is inorganic
[c] Based on the assumption that reconstituted infant formula comprises 85% water
[d] These are the highest upper bound exposure estimates for this age range
[e] These are the highest upper bound exposure estimates for this age range, from the TDS

Risk characterisation for specific food products

87. The risks from exposure to inorganic arsenic from the consumption of rice drinks or rice cakes have also been characterised using the MOE approach. Special focus was paid to these foods due to the need to review current Government recommendations on consumption of rice drinks by infants and young children, and due to the popularity of rice cakes as a snack food for this age group, and their relatively high concentrations of inorganic arsenic.

Rice drinks

88. Table 24 summarises the MOEs for the estimated exposures calculated for rice drinks using the mean concentration of inorganic arsenic (12 µg/L). These exposures have been performed using consumption data for

cows' milk, as there were very limited data available on the consumption of rice drinks, and as, in a worst case scenario, there could be complete replacement of cows' milk with rice drinks (paragraph 75). The MOEs for average consumers from all age groups are greater than or in the region of 1, while the MOEs for all high level consumers are equal to or less than 0.5.

Table 24. Range of possible exposures to inorganic arsenic from rice drinks, and the corresponding MOEs when they are compared to the lowest $BMDL_{01}$ for inorganic arsenic (0.3 µg/kg bw/day).

Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE[a]	
	Average consumers	High level consumers	Average consumers	High level consumers
12 to 18	0.362[b]	0.910[b]	0.8	0.3
18 to 24	0.316	0.863	1.0	0.3
24 to 60	0.218	0.600	1.4	0.5

[a] The MOE is calculated by dividing the $BMDL_{01}$ of 0.3 µg/kg bw/day by the respective exposure
[b] Based on highest estimate for this age range

89. It has been estimated that, for those aged 1 to 5 years, consumption of 50mL of rice drink per day would not cause an appreciable increase in background exposure to inorganic arsenic (paragraph 77).

Rice cakes

90. Tables 25 and 26 summarise the MOEs for the estimated exposures from the consumption of infant and 'adult' rice cakes. All of the MOEs from rice cake consumption are greater than 1. The MOEs for infants aged 4 to 18 months from infant rice cake consumption are lower than those from 'adult' rice cake consumption. For 18 to 24 month olds, the MOEs from 'adult' rice cake consumption are considerably lower than those from infant rice cake consumption. The MOEs from the consumption of infant rice cakes and of 'adult' rice cakes for young children aged 24 to 60 months are relatively similar.

91. The exposures from the consumption of rice cakes can be considered in addition to those from the total diet, bearing in mind that this would result in a degree of double-counting due to the inclusion of rice cakes in the total diet exposure assessments. Adding the highest of the 97.5th percentile exposures for infants < 12 month olds (0.109 µg/kg bw/day from consumption of infant rice cakes) to the highest mean exposure from the total diet[7] for the same age

[7] Total diet including the median water concentration

group (0.183 µg/kg bw/day) would result in an increase of approximately 40% above the mean total diet exposure. Adding the highest of the 97.5th percentile exposures for 1 to 5 year olds (0.122 µg/kg bw/day from 18 to 24 month olds consuming infant rice cakes) to the highest mean exposure from the total diet for the same age group (0.673 µg/kg bw/day) would result in an increase of ~15% above the mean total diet exposure.

Table 25. Range of possible exposures to inorganic arsenic from infant rice cakes, and the corresponding MOEs when they are compared to the lowest $BMDL_{01}$ for inorganic arsenic (0.3 µg/kg bw/day).

Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE[a]	
	Average consumers	High level consumers	Average consumers	High level consumers
4 to 12	0.031[b]	0.109[b]	9.7	2.8
12 to 18	0.035[b]	0.122[b]	8.6	2.5
18 to 24	0.026	0.070	11.5	4.3
24 to 60	0.029	0.071	10.3	4.2

[a] The MOE is calculated by dividing the $BMDL_{01}$ of 0.3 µg/kg bw/day by the respective exposure
[b] Based on highest estimate for this age range

Table 26. Range of possible exposures to inorganic arsenic from 'adult' rice cakes, and the corresponding MOEs when they are compared to the lowest $BMDL_{01}$ for inorganic arsenic (0.3 µg/kg bw/day).

Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE[a]	
	Average consumers	High level consumers	Average consumers	High level consumers
4 to 12	0.025[b]	0.057[b]	12.0	5.3
12 to 18	0.025[b]	0.077[b]	12.0	3.9
18 to 24	0.066	0.113	4.5	2.7
24 to 60	0.030	0.058	10.0	5.2

[a] The MOE is calculated by dividing the $BMDL_{01}$ of 0.3 µg/kg bw/day by the respective exposure
[b] Based on highest estimate for this age range

92. As toxicity will depend on total exposure to inorganic arsenic from all sources, it is important to consider combined exposures from food, water, and non-dietary sources. Table 27 summarises the MOEs for the estimated exposures from soil, assuming concentrations of inorganic arsenic at the median and 97.5th percentile of reported ranges (paragraph 81). The MOEs are in the region of or greater than 1. By comparison exposures to inorganic

arsenic from air are negligible (the MOEs across all groups range from 100 up to 5000).

Table 27. Range of possible exposures to inorganic arsenic from soil, and the corresponding MOEs when they are compared to the lowest $BMDL_{01}$ for inorganic arsenic (0.3 µg/kg bw/day).

Age (months)	Estimated dietary exposures (µg/kg bw/day)		MOE[a,b]	
	Median concentration	97.5th percentile concentration	Median concentration	97.5th percentile concentration
9 to 12	0.078	0.334	3.8	0.9
12 to 15	0.071	0.303	4.2	1.0
15 to 18	0.067	0.287	4.5	1.0
18 to 24	0.063	0.268	4.8	1.1
24 to 60	0.047	0.199	6.4	1.5

[a] The MOE is calculated by dividing the $BMDL_{01}$ of 0.3 µg/kg bw/day by the respective exposure
[b] These comparisons assume equivalent absorption from different sources

93. There are uncertainties in the assessment of risks to infants and young children from exposure to inorganic arsenic because, for some sources of exposure (e.g. soil), it has been necessary to assume that all of the arsenic present in that source is inorganic. This has occurred for sources where inorganic arsenic has not been measured, and information about the proportion of inorganic arsenic likely to be present in that source of exposure has not been available.

94. In addition to this, where specific consumption or ingestion data have not been available for a specific age group or source of exposure, then default values have been used in their place (e.g. breast milk/formula consumption by 0 to 4 month old infants). Furthermore, some exposure estimates have been based on a limited number of consumers.

Questions on which the views of the Committee are sought

95. Members are invited to comment on the exposure calculations and to answer the following questions.

i. Do Members consider that the exposure assessment should focus on total arsenic, inorganic arsenic or both?

ii. Do Members agree with the assumption about the inorganic arsenic content of breast milk made in paragraph 53?

iii. How should the inorganic arsenic content of water be taken into account in the exposure calculations?

iv. Do Members agree with the use of the lowest BMDL, 0.3 µg/kg bw/day, in the risk characterisation?

v. Do Members consider that the estimated exposure from rice drinks support the current FSA/DH recommendation that toddlers and young children should not be given rice drinks as a *substitute* for breast milk, infant formula or cows' milk, or the NHS Choices recommendation that they should not have rice drinks?

vi. Do Members consider that there is a need for recommendations regarding rice cake consumption in order to protect the health of infants and young children?

vii. Do Members require any further information to come to a conclusion?

viii. Do Members have any further comments?

Secretariat
January 2016

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

Review of potential risks from arsenic in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

The EFSA CONTAM Panel's 'Scientific opinion on Arsenic in Food' *EFSA Journal* 7 (10) pp.1351 is available from the EFSA website at http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1351.pdf

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

Review of potential risks from arsenic in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

Annex B contains Chapter 8 (Dose-respone analysis and estimation of carcinogenic risk) of the Arsenic (addendum) in FAO JECFA Monograph 8. This is available at:
http://www.inchem.org/documents/jecfa/jecmono/v63je01.pdf

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

Review of potential risks from arsenic in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

Possible arsenic exposure from dietary sources in children aged 12 to 18 months

Two surveys were conducted during 2014 which measured the concentrations of elements in food consumed by infants (4 to 18 months) and young children (18 months to 5 years). The first survey was a survey on types of foods eaten by infants (referred to as the Infant Metals Survey), the other was a total diet study (TDS) which focused on sampling foods eaten by young children. Both studies measured the concentrations of total and inorganic arsenic (as the sum of As(III) and As(V), and also MMA if present).

The Infant Metals Survey measured the concentrations of metals and other elements in food 'as sold', in the following categories: infant formula commercial infant foods, and groups of food comprising the top 50 most commonly consumed varieties of foods not specifically marketed for infants (Tables C1-C3). The results from this survey were used together with food consumption data from the Diet and Nutrition Survey for Infants and Young Children (DNSIYC) (DH, 2013) to estimate dietary exposures for infants aged 12 to 18 months.

The TDS consisted of: (i) selecting foods based on food consumption data, to represent as best as possible a typical diet; (ii) their preparation to food as consumed and (iii) the subsequent pooling of related foods before analysing the composite samples for elements. The concentrations of 26 elements, including total and inorganic arsenic, were measured in the 2014 TDS. The composite samples for 27 food groups (Table C4) were collected from 24 UK towns and analysed for their levels of arsenic and other elements. Where appropriate, tap water was used in the preparation and cooking of food samples. The results from this survey were also used together with food consumption data from the DNSIYC (DH, 2013) to estimate dietary exposures for infants aged 12 to 18 months.

Table C1. Infant formula

Infant Formula	
Dry Powder	**Made Up Formula**
First and Hungrier Milk	First Milk and Hungrier Milk
Follow On Milk	Follow On milk

Growing Up Milk	Growing up Milk
Soy Milk	
Goat Milk	
Organic Milk	
Comfort Milk	

Table C2. Commercial infant foods

Commercial Infant Foods
Cereal Based Foods and Dishes
Dairy Based Foods and Dishes
Fruit Based Foods and Dishes
Meat and Fish Based Foods and Dishes
Snacks (Sweet and Savoury)
Other Savoury Based Foods and Dishes (excluding Meat)
Drinks

Table C3. Other foods commonly eaten by infants.

Other Foods	
Beverages	Fruit Products
Bread	Green Vegetables
Canned Vegetables	Meat Products
Cereals	Milk
Dairy Products	Other Vegetables
Eggs	Potatoes
Fish	Poultry/Chicken
Fresh Fruit	

Table C4. The 27 food groups used for analysis of 26 elements in the 2014 TDS

TDS Food Groups*	
Bread	Fresh Fruit
Miscellaneous Cereals	Fruit Products
Carcase Meat	Non Alcoholic Beverages
Offal	Milk
Meat Products	Dairy Products
Poultry	Nuts

Fish	Alcoholic Drinks
Fats and Oils	Meat Substitutes
Eggs	Snacks
Sugars	Desserts
Green Vegetables	Condiments
Potatoes	Tap Water
Other Vegetables	Bottled Water
Canned Vegetables	

*Food samples representative of the UK diet are purchased throughout the year in 24 towns covering the UK and 137 categories of foods are combined into 27 groups of similar foods for analysis

Exposure Assessments

Infant Metals Survey

Tables containing the results of the exposure assessments for 12 to 18 month olds that were based on the Infant Metals Survey have been included in the main body of the discussion paper.

Total Diet Study

Tables C5 and C6 summarise lower- and upper-bound total dietary exposures to total arsenic and inorganic arsenic calculated using the 2014 TDS for ages 12 to 18 months. The data for each food category is reported separately so that the contribution to exposure from each class could be assessed more transparently for the most relevant infant age group. In addition the total exposure from the diet has also been provided.

Table C5. Estimated total arsenic exposures from food eaten by infants aged 12 to 18 months using data from the TDS Groups.

Food Groups	**Total As Exposure (LB-UB Range) (µg/kg bw/day)**			
	12-14.99 Months (n=670)		**15-17.99 Months (n=605)**	
	Mean	**97.5th**	**Mean**	**97.5th**
Alcoholic drinks	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Bottled water	0.000-0.001	0.000-0.005	0.000-0.001	0.000-0.012
Bread	0.000-0.015	0.000-0.041	0.000-0.017	0.000-0.046
Canned vegetables	0.000-0.005	0.000-0.026	0.000-0.005	0.000-0.023
Carcase meat	0.000-0.006	0.000-0.030	0.000-0.007	0.000-0.036
Condiments	0.005-0.005	0.030-0.030	0.006-0.006	0.029-0.029
Dairy products	0.000-0.030	0.000-0.159	0.000-0.025	0.000-0.111
Desserts	0.001-0.001	0.010-0.010	0.002-0.002	0.011-0.011
Eggs	0.000-0.002	0.000-0.011	0.000-0.002	0.000-0.011

Fats and oils	0.000-0.001	0.000-0.003	0.000-0.001	0.000-0.003
Fish	1.855-1.855	8.607-8.607	1.739-1.739	8.816-8.816
Fresh fruit	0.000-0.034	0.000-0.117	0.000-0.042	0.000-0.120
Fruit products	0.000-0.006	0.000-0.040	0.000-0.006	0.000-0.042
Green vegetables	0.000-0.003	0.000-0.014	0.000-0.003	0.000-0.013
Meat products	0.000-0.003	0.000-0.015	0.000-0.004	0.000-0.016
Meat substitutes	0.000-0.000	0.000-0.000	0.000-0.000	0.003-0.003
Milk	0.000-0.079	0.000-0.224	0.000-0.079	0.000-0.191
Miscellaneous cereals	0.051-0.051	0.159-0.159	0.061-0.061	0.180-0.180
Non-alcoholic beverages	0.000-0.036	0.000-0.172	0.000-0.044	0.000-0.207
Nuts	0.000-0.000	0.002-0.002	0.000-0.000	0.002-0.002
Offal	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Other vegetables	0.000-0.020	0.000-0.072	0.000-0.020	0.000-0.066
Potatoes	0.000-0.021	0.000-0.077	0.000-0.020	0.000-0.064
Poultry	0.008-0.008	0.036-0.036	0.009-0.009	0.040-0.040
Snacks	0.002-0.002	0.011-0.011	0.003-0.003	0.018-0.018
Sugars	0.000-0.001	0.000-0.007	0.000-0.002	0.000-0.009
Tap water	0.000-0.012	0.000-0.045	0.000-0.013	0.000-0.054
Total	1.922-2.196	8.712-9.207	1.820-2.111	8.940-9.202

Table C6. Estimated inorganic arsenic exposures from food eaten by infants aged 12 to 18 months using data from the TDS Groups.

Food Groups	**Inorganic As Exposure (LB-UB Range) (µg/kg bw/day)**			
	12-14.99 Months (n=670)		**15-17.99 Months (n=605)**	
	Mean	**97.5th**	**Mean**	**97.5th**
Alcoholic drinks	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Bottled water	0.000-0.002	0.000-0.013	0.000-0.002	0.000-0.031
Bread	0.000-0.030	0.000-0.083	0.000-0.034	0.000-0.092
Canned vegetables	0.000-0.021	0.000-0.105	0.000-0.020	0.000-0.093
Carcase meat	0.000-0.012	0.000-0.059	0.000-0.014	0.000-0.071
Condiments	0.000-0.006	0.000-0.033	0.000-0.006	0.000-0.032
Dairy products	0.000-0.119	0.000-0.637	0.000-0.101	0.000-0.444
Desserts	0.000-0.005	0.000-0.039	0.000-0.006	0.000-0.046
Eggs	0.000-0.008	0.000-0.043	0.000-0.008	0.000-0.044
Fats and oils	0.000-0.003	0.000-0.013	0.000-0.004	0.000-0.014
Fish	0.000-0.011	0.000-0.052	0.000-0.010	0.000-0.053
Fresh fruit	0.000-0.068	0.000-0.233	0.000-0.084	0.000-0.240
Fruit products	0.000-0.022	0.000-0.159	0.000-0.025	0.000-0.168
Green vegetables	0.000-0.012	0.000-0.054	0.000-0.013	0.000-0.050

Meat products	0.000-0.011	0.000-0.061	0.000-0.014	0.000-0.065
Meat substitutes	0.000-0.000	0.000-0.000	0.000-0.001	0.000-0.008
Milk	0.000-0.079	0.000-0.224	0.000-0.079	0.000-0.191
Miscellaneous cereals	0.073-0.073	0.229-0.229	0.088-0.088	0.260-0.260
Non-alcoholic beverages	0.000-0.036	0.000-0.172	0.000-0.044	0.000-0.207
Nuts	0.000-0.001	0.000-0.004	0.000-0.000	0.000-0.004
Offal	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Other vegetables	0.000-0.039	0.000-0.144	0.000-0.040	0.000-0.131
Potatoes	0.053-0.053	0.193-0.193	0.049-0.049	0.160-0.160
Poultry	0.000-0.012	0.000-0.054	0.000-0.014	0.000-0.060
Snacks	0.000-0.002	0.000-0.012	0.000-0.003	0.000-0.019
Sugars	0.000-0.005	0.000-0.028	0.000-0.007	0.000-0.034
Tap water	0.000-0.030	0.000-0.113	0.000-0.034	0.000-0.135
Total	0.126-0.659	0.316-1.243	0.137-0.702	0.327-1.162

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References

DH (Department of Health) (2013). Diet and Nutrition Survey of Infants and Young Children (DNSIYC), 2011. Available at: http://transparency.dh.gov.uk/2013/03/13/dnsiyc-2011/

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

Review of potential risks from arsenic in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

Possible arsenic exposure from dietary sources in young children aged 18 to 60 months

A Total Diet Study (TDS) was conducted during 2014 which measured the concentrations of total and inorganic arsenic (as the sum of As(III) and As(V), and also MMA if present) in food consumed by young children (18 months and older).

The TDS consisted of: (i) selecting foods based on food consumption data, to represent as best as possible a typical diet; (ii) their preparation to food as consumed and (iii) the subsequent pooling of related foods before analysing the composite samples for elements. The concentrations of 26 elements, including total and inorganic arsenic, were measured in the 2014 TDS. The composite samples for 27 food groups (Table D1) were collected from 24 UK towns and analysed for their levels of arsenic and other elements. Where appropriate, tap water was used in the preparation and cooking of food samples. The results from this survey were also used together with food consumption data from years 1 to 4 of the National Diet and Nutrition Survey Rolling Programme (NDNS) (Bates *et al.,* 2014) to estimate dietary exposures for young children aged 18 months to 5 years.

Table D1. Food groups used for analysis of 26 elements in the 2014 TDS

TDS Food Groups*	
Bread	Fresh Fruit
Miscellaneous Cereals	Fruit Products
Carcase Meat	Non Alcoholic Beverages
Offal	Milk
Meat Products	Dairy Products
Poultry	Nuts
Fish	Alcoholic Drinks
Fats and Oils	Meat Substitutes
Eggs	Snacks
Sugars	Desserts
Green Vegetables	Condiments
Potatoes	Tap Water
Other Vegetables	Bottled Water
Canned Vegetables	

*Food samples representative of the UK diet are purchased throughout the year in 24 towns covering the UK and 137 categories of foods are combined into 27 groups of similar foods for analysis

Exposure Assessment

Tables D2 and D3 summarise lower- and upper-bound total dietary exposures to total arsenic and inorganic arsenic calculated using the 2014 TDS for young children aged 18 months to 5 years. The data for each food category is reported separately so that the contribution to exposure from each class could be assessed more transparently for the most relevant infant age group. In addition the total exposure from the diet has also been provided.

Table D2. Estimated total arsenic exposures from food eaten by young children aged 18 months to 5 years using data from the TDS Groups.

Food Groups	Total As Exposure (LB-UB Range) (µg/kg bw/day)			
	18-24 Months (n=70)		2-5 years (n=429)	
	Mean	97.5th	Mean	97.5th
Alcoholic drinks	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Bottled water	0.000-0.000	0.000-0.004	0.000-0.001	0.000-0.011
Bread	0.000-0.018	0.000-0.041	0.000-0.021	0.000-0.048
Canned vegetables	0.000-0.009	0.000-0.033	0.000-0.005	0.000-0.020
Carcase meat	0.000-0.008	0.000-0.041	0.000-0.005	0.000-0.026
Condiments	0.004-0.004	0.020-0.020	0.006-0.006	0.033-0.033
Dairy products	0.000-0.027	0.000-0.130	0.000-0.015	0.000-0.061
Desserts	0.002-0.002	0.013-0.013	0.003-0.003	0.013-0.013
Eggs	0.000-0.002	0.000-0.009	0.000-0.002	0.000-0.009
Fats and oils	0.000-0.001	0.000-0.004	0.000-0.001	0.000-0.004
Fish	2.300-2.300	9.185-9.185	1.762-1.762	6.762-6.762
Fresh fruit	0.000-0.051	0.000-0.134	0.000-0.037	0.000-0.097
Fruit products	0.000-0.014	0.000-0.055	0.000-0.013	0.000-0.062
Green vegetables	0.000-0.003	0.000-0.017	0.000-0.003	0.000-0.012
Meat products	0.000-0.004	0.000-0.019	0.000-0.005	0.000-0.017
Meat substitutes	0.000-0.000	0.001-0.001	0.000-0.000	0.004-0.004
Milk	0.000-0.074	0.000-0.232	0.000-0.052	0.000-0.150
Miscellaneous cereals	0.065-0.065	0.137-0.137	0.053-0.053	0.135-0.135
Non-alcoholic beverages	0.000-0.060	0.000-0.246	0.000-0.057	0.000-0.166
Nuts	0.000-0.000	0.000-0.000	0.000-0.000	0.004-0.004
Offal	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Other vegetables	0.000-0.012	0.000-0.040	0.000-0.013	0.000-0.045
Potatoes	0.000-0.020	0.000-0.042	0.000-0.018	0.000-0.053
Poultry	0.011-0.011	0.031-0.031	0.009-0.009	0.039-0.039

Snacks	0.003-0.003	0.018-0.018	0.003-0.003	0.018-0.018
Sugars	0.000-0.002	0.000-0.010	0.000-0.003	0.000-0.012
Tap water	0.000-0.013	0.000-0.070	0.000-0.012	0.000-0.046
Total	2.385-2.704	9.216-9.587	1.837-2.100	6.835-7.123

Table D3. Estimated inorganic arsenic exposures from food eaten by young children aged 18 months to 5 years using data from the TDS Groups.

Food Groups	**Inorganic As Exposure (LB-UB Range) (µg/kg bw/day)**			
	18-24 Months (n=70)		**2-5 years (n=429)**	
	Mean	**97.5th**	**Mean**	**97.5th**
Alcoholic drinks	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Bottled water	0.000-0.001	0.000-0.011	0.000-0.003	0.000-0.029
Bread	0.000-0.036	0.000-0.081	0.000-0.041	0.000-0.095
Canned vegetables	0.000-0.034	0.000-0.131	0.000-0.021	0.000-0.082
Carcase meat	0.000-0.016	0.000-0.081	0.000-0.010	0.000-0.051
Condiments	0.000-0.004	0.000-0.022	0.000-0.007	0.000-0.036
Dairy products	0.000-0.109	0.000-0.520	0.000-0.061	0.000-0.244
Desserts	0.000-0.010	0.000-0.052	0.000-0.011	0.000-0.051
Eggs	0.000-0.006	0.000-0.035	0.000-0.006	0.000-0.037
Fats and oils	0.000-0.005	0.000-0.016	0.000-0.005	0.000-0.015
Fish	0.000-0.014	0.000-0.055	0.000-0.011	0.000-0.041
Fresh fruit	0.000-0.102	0.000-0.267	0.000-0.074	0.000-0.194
Fruit products	0.000-0.057	0.000-0.220	0.000-0.052	0.000-0.250
Green vegetables	0.000-0.011	0.000-0.069	0.000-0.012	0.000-0.048
Meat products	0.000-0.017	0.000-0.078	0.000-0.020	0.000-0.068
Meat substitutes	0.000-0.000	0.000-0.003	0.000-0.001	0.000-0.011
Milk	0.000-0.074	0.000-0.232	0.000-0.052	0.000-0.150
Miscellaneous cereals	0.094-0.094	0.198-0.198	0.077-0.077	0.195-0.195
Non-alcoholic beverages	0.000-0.060	0.000-0.246	0.000-0.057	0.000-0.166
Nuts	0.000-0.000	0.000-0.000	0.000-0.001	0.000-0.010
Offal	0.000-0.000	0.000-0.000	0.000-0.000	0.000-0.000
Other vegetables	0.000-0.024	0.000-0.081	0.000-0.025	0.000-0.090
Potatoes	0.050-0.050	0.105-0.105	0.045-0.045	0.133-0.133
Poultry	0.000-0.016	0.000-0.046	0.000-0.014	0.000-0.059
Snacks	0.000-0.003	0.000-0.020	0.000-0.004	0.000-0.020
Sugars	0.000-0.008	0.000-0.038	0.000-0.012	0.000-0.049
Tap water	0.000-0.033	0.000-0.176	0.000-0.030	0.000-0.114
Total	0.144-0.786	0.291-1.182	0.123-0.650	0.256-1.021

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References

Bates, B.; Lennox, A.; Prentice, A.; Bates, C.; Page, P.; Nicholson, S.; Swan, G. (2014) National Diet and Nutrition Survey Results from Years 1, 2, 3 and 4 (combined) of the Rolling Programme (2008/2009 – 2011/2012) Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/310995/NDNS_Y1_to_4_UK_report.pdf