

FSIS Multi-element survey of infant foods

Summary

The Food Standards Agency has conducted a survey to establish the concentrations of 12 metals and other elements in a wide range of commercial infant foods and formulae.

The aim of this survey was to provide a picture of the concentrations of metals and other elements in 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.

The key facts are:

- Aluminium, antimony, arsenic, cadmium, chromium, copper, lead, mercury, nickel, selenium, tin and zinc were measured in 189 samples of commercial infant foods (infant formulae, manufactured baby foods, desserts, rusks and infant drinks)
- Levels of these elements in infant foods and formulae were generally similar to those measured in a MAFF survey of infant foods published in 1999¹ and within legal limits where they exist.
- The independent Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) considered estimated exposures for infant consumers of these formulae/foods. It concluded that the consumption of infant foods sampled in this survey will not result in the intake of such quantities of any of the analysed elements as would give concern for the health of infants.

Background

Metals and other elements can be present in foods naturally, as a result of human activities (such as farming practices and industrial emissions), from storage or processing of foods (such as tin dissolution from cans into canned food), or added intentionally (such as aluminium-containing additives in bakery products). The main route of intake for most of these elements is from our diet. Some of these elements are essential nutrients which we need to get from food for healthy functioning. Others have no known beneficial health effects, but all may be harmful if eaten in excessive amounts.

The FSA regularly monitors the concentrations of metals and other elements in food. Previous multi-element surveys of the Total Diet Study (which is representative of the average UK diet) have shown that concentrations of metals and other elements in food do not present significant risks to the general UK population². However, estimates of dietary intakes for the general population cannot be easily or accurately extended to infants, as infants consume a diet that is different in many ways from that of adults and of children old enough to eat conventional adult foods. As infants grow and develop very rapidly in their first year of life, their energy requirements and so their food consumption is on average much higher relative to their body weight than that of adults and older children. This means that infants can have relatively much higher dietary exposures to some metals and other elements present in food than other age groups, when expressed on a body weight basis.

In addition, infants' diets are made up of a more restricted range of foods, particularly before and in the early stages of weaning when the diet is made up entirely or largely of breast milk and/or commercial infant formulae. On weaning, solids are given, a large proportion of which may be commercially available baby foods. The composition of commercial infant formulae and baby foods can be very different from the foods that make up the diet of the general population and therefore information is needed on the levels of metals and other elements in these food groups. The range of infant foods is constantly growing and changing, so it is important that the Agency regularly up-dates its information on infant foods.

This survey was carried out by the Central Science Laboratory (CSL) between March 2001 and July 2002. It follows on from a multi-element survey of infant foods in 1999 and provides the Food Standards Agency with more extensive and up-to-date information on the concentrations of these elements in infant foods. This information allows trends in element levels to be identified and estimates of dietary exposure to be made.

Brand Names

In accordance with the Food Standards Agency policy for the release of brand names when reporting the results of food chemical surveillance,³ details about the individual samples are given in full in Annex 1. It should be noted that the absence of any particular brand from this survey means only that the brand was not included in the survey. No further meaning should be read into the absence of any brand from this Food Survey Information Sheet.

Methodology

Sampling and analyses

The 189 samples of infant foods and formulae were purchased from retail outlets in the UK between March 2001 and January 2002. The sample plan was intended to reflect the main products and brands within the major categories of commercial infant foods on sale, taking into account available market share data. Five categories of commercial infant foods were sampled: infant formulae (24 samples, including 'from birth' and 'follow-on' formulae, products made from cows' milk and soya-based products), manufactured baby foods (129 samples, including canned, bottled and packet foods), baby drinks (11 samples), desserts (15 samples) and rusks (10 samples). Three samples from the same lot/batch were purchased for each individual product. Two samples were analysed separately and the mean reported, and the third was retained.

Samples were analysed for aluminium, antimony, arsenic, cadmium, chromium, copper, lead, mercury, nickel, selenium, tin and zinc. CSL are accredited by the United Kingdom Accreditation Service for the analysis of these elements in food and have received

satisfactory scores in relevant FAPAS (Food Analysis Performance Assessment Scheme) rounds.

Multi-element analyses were carried out using Inductively Coupled Plasma-Mass Spectrometry (ICP-MS). All samples were analysed 'as sold' (i.e., formulae and dried meals were not reconstituted prior to analyses). Samples were digested in concentrated nitric acid and multi-element analyses were performed by direct nebulization ICP-MS. Arsenic and selenium were measured by hydride generation-ICP-MS (HG-ICP-MS) because of the better limits of detection achievable for these elements using this method. Arsenic in products containing fish and poultry was determined by direct ICP-MS because this method is more reliable for determining the total arsenic levels arising from the forms present in these foods (HG-ICP-MS cannot accurately quantify some of the organoarsenic compounds known to be present in fish and poultry). Further details of analyses are given in the contractor's final report of the project⁴ which is available from the FSA library (see Further Information section).

Quality Control

The approach used for quality control in multi-element analyses at CSL has been discussed elsewhere.⁵ Every multi-element analysis in this study included the following quality control checks:

- Three National Institute of Standards and Technology (NIST) Certified Reference Materials (CRMs) were analysed with every batch of samples [i.e. NIST 1547 (Peach Leaves), NIST 1548a (typical diet) and NIST 8436 (Durum wheat flour)]. Batches were rejected if results for 2 of the 3 CRMs were not within the certified range or 40 percent of the quoted value, whichever was greater.
- A calibration standard was analysed at the start and end of each run. Batches were rejected if the re-measured standard was outside of the original value by 20 percent or more.
- Replicate values for a given sample had to have a Relative Standard Deviation (RSD) of less than or equal to 20 percent or a standard deviation of less than or equal to the Limit of Quantification (LOQ), whichever was greater. In addition, 10 percent of all samples were analysed in duplicate.
- Limits of Detection (LODs) were defined as 3 times the standard deviation of measured

values for reagent blanks after correction for typical sample weight and dilution. The LODs obtained in this work are given in Table 1.

Results

A summary of the mean concentration of elements in each broad food type is given in Table 2. Soya-based formulae are listed separately from cows milk-based formulae. However, the number of soya-based infant formulae analysed was limited (3 samples), so the data may not be representative. Results are expressed as upper bound, that is, where individual sample analyses were less than the limit of detection, the result is expressed as equal to the limit of detection. Details of individual results are detailed in Annex 1.

The results are discussed below and compared with data from previous studies and relevant legal limits. There are no EC or UK regulatory limits that specifically apply to contaminants in infant foods, with the exception of an EC limit for lead in infant formulae (EC Regulation 466/2001 as amended^{6,7}). The European Commission has undertaken to establish limits for infant foods by 2004, but in the interim, in the absence of any specific limits, those set for individual foodstuffs may be applied. These limits were, in almost all cases, designed to apply to a single food commodity when it is placed on the market. However, when a food is composed of more than one ingredient, as most commercial infant foods will be, then the limit would only apply to the relevant component and not to the whole product. There are Regulations that control the essential composition of infant formulae and cover essential elements such as copper and zinc, and these are referred to below where appropriate. Estimates of infants' dietary exposures from eating foods in the present study are described in the subsequent section.

Aluminium

Aluminium was detected in most samples with a mean concentration of 2.1 milligrams per kilogram, and a range of less than 0.01 to 39.8 milligrams per kilogram. These results are consistent with the previous survey of infant foods in which the mean concentration of aluminium was 3 milligrams per kilogram. Aluminium concentrations were, on average, six times higher in soya-based formulae than in other dried formulae (4.5 milligrams per kilogram compared to 0.73 milligrams per kilogram). The concentrations measured are similar to the results for the 2 soya-based formulae (mean of 4.6 milligrams per kilogram) reported in the previous survey¹ and are to be expected as soya beans can naturally

accumulate aluminium.

Antimony

Antimony was detected in most samples but generally at very low concentrations, with the mean for all foods of 0.0017 milligrams per kilogram, and range of less than 0.0001 to 0.0211 milligrams per kilogram. These values are similar and slightly lower than those reported in the 1999 infant food survey¹ (mean of 0.004 milligrams per kilogram, range of 0.0001 – 0.036 milligrams per kilogram).

Arsenic

Arsenic was detected in most samples but generally at very low concentrations (mean 0.023 milligrams per kilogram, range of less than 0.0002 to 0.78 milligrams per kilogram), with the highest concentrations found in products containing fish. Higher levels were also seen in manufactured meals containing poultry and rice, although these were lower than the levels measured in fish-containing dishes. These results are consistent with results obtained for the foods making up the adult diet and with other scientific literature^{2,8}. The mean value for all foods is similar to the mean of 0.016 milligrams per kilogram found in the previous survey of infant foods¹.

Arsenic concentrations found in all of the samples analysed in this survey are within the general limit of 1 milligrams per kilogram for foods, and for those drinks sampled, within the specific limits of 0.1 milligrams per kilogram for ready-to-drink non-alcoholic beverages and 0.5 milligrams per kilogram for concentrates and undiluted fruit juices as set by the UK Arsenic in Food Regulations, 1959, as amended.⁹

Cadmium

Cadmium was present in most samples with a mean concentration of 0.009 milligrams per kilogram and a range of less than 0.0001 to 0.1 milligrams per kilogram. Concentrations found are consistent with the mean level reported in the previous survey of infant foods of 0.011 milligrams per kilogram¹ and those found in the foods making up the normal adult diet.²

EC Regulation 466/2001 Setting Maximum levels for Certain Contaminants in Foodstuffs, as amended by EC Regulation 221/2002^{6,7}, sets limits for cadmium for those foods which

contribute significantly to population dietary exposures to cadmium. The limits set for foods which are likely to be present in infant foods vary from 0.05 milligrams per kilogram to 0.2 milligrams per kilogram. The highest cadmium concentration of 0.1 milligrams per kilogram was seen in a sample of rice cakes. The limit for cadmium in rice is 0.2 milligrams per kilogram.

Chromium

Chromium was present in about 90 percent of the samples, with a mean concentration of 0.06 milligrams per kilogram, which is half the average concentration found in the MAFF survey of infant foods of 0.12 milligrams per kilogram.¹ Chromium levels ranged from less than 0.004 milligrams per kilogram to 0.6 milligrams per kilogram and were within the range of chromium concentrations found in the normal adult diet.²

Copper

Copper was detected in all but one sample, with a mean concentration of 1.2 milligrams per kilogram and a range of less than 0.0025 to 4.5 milligrams per kilogram. These values are similar to those reported for the 1999 survey of infant foods¹ (mean concentration of 1.4 milligrams per kilogram and range of less than 0.003 milligrams per kilogram to 5.3 milligrams per kilogram).

The levels of some nutrients in infant formulae are subject to statutory control by the Infant Formulae and Follow-on Formulae Regulations 1995 as amended.¹⁰ These Regulations set a range between which copper levels in 'from birth' formulae should fall. The minimum and maximum levels are expressed on a calorific rather than weight basis and are 20 to 80 µg/ 100 kcal. The formulae analysed in this survey which are covered by these Regulations fall within the specified range.

Lead

Lead was detected in most samples at relatively low concentrations (mean 0.008 milligrams per kilogram, range less than 0.0003 milligrams per kilogram to 0.045 milligrams per kilogram), with the highest concentrations found in dried, dehydrated and concentrated foods and in rusks. These results are slightly lower than the 1999 MAFF

survey of infant foods¹ (mean 0.015 milligrams per kilogram, range <0.001 milligrams per kilogram to 0.1 milligrams per kilogram).

A specific limit for lead in infant formulae of 0.02 milligrams per kilogram is set in EC Regulation 466/2001 as amended.^{6,7} All of the samples of formulae analysed in this survey are below this limit. For other foods used as ingredients in infant foods, limits range from 0.05 milligrams per kilogram to 0.3 milligrams per kilogram. None of the infant foods exceed the lowest limit.

Mercury

Mercury was detected at concentrations at or above the LOD in only about one quarter of the samples in this survey, most of which are dried foods. The mean mercury concentration was 0.003 milligrams per kilogram, with a range of less than 0.0005 milligrams per kilogram to 0.02 milligrams per kilogram. Both the mean and maximum mercury concentrations are twice that of the last infant foods survey (mean of 0.0014 milligrams per kilogram, range <0.0003 milligrams per kilogram to 0.01 milligrams per kilogram)¹. Approximately 50 percent of this increase is attributable to the higher limit of detection for mercury in ready-to-feed foods in this survey (0.001 milligrams per kilogram) compared to the previous survey (0.0003 milligrams per kilogram). This was due to decreased sensitivity of the method used by the contractor, although the limit of detection is still low.

Regulatory limits for mercury are only set for fish, which can contain much higher levels of mercury than other foods. There are two limits for mercury in fish set in EC legislation, a limit of 0.5 milligrams per kilogram that applies to most species, and a higher limit of 1 milligram per kilogram for those species that naturally accumulate higher levels of mercury, such as the larger, longer lived predatory fish^{6,7}. All of the samples of infant foods analysed for this survey are well within the lower limit.

Nickel

Nickel was detected in almost all samples, with a mean concentration of 0.1 milligrams per kilogram and a range of less than 0.002 milligrams per kilogram to 1.4 milligrams per kilogram). These results are consistent with the 1999 MAFF survey of infant foods¹ (mean

concentration of 0.16 milligrams per kilogram and a range of less than 0.003 milligrams per kilogram to 1.34 milligrams per kilogram). Nickel concentrations in soya-based formulae were on average almost six times higher (up to 0.23 milligrams per kilogram) than those for the other dried formulae (0.04 milligrams per kilogram). This is consistent with the levels of nickel detected in the two soya-based formulae analysed in the previous survey¹ (mean 0.2 milligrams per kilogram) and is to be expected as soya beans naturally accumulate certain elements including nickel.

Selenium

Selenium was detected in most samples, with a mean concentration of 0.04 milligrams per kilogram in all foods, and a range of less than 0.0001 milligrams per kilogram to 0.19 milligrams per kilogram. These results are consistent with those found in the last survey of infant foods¹ (mean concentration of 0.034 milligrams per kilogram and a range of less than 0.0004 milligrams per kilogram to 0.143 milligrams per kilogram) and for the foods making up the general diet.²

Tin

Tin was present in 60 percent of the samples at generally low concentrations with a mean of 0.3 milligrams per kilogram, and a range of less than 0.001 milligrams per kilogram to 15.8 milligrams per kilogram. Only twelve samples contained tin concentrations in excess of 1 milligram per kilogram. These were either in ready-to-eat meals that predominantly contained fruit or were tomato sauce based, or in fruit-containing dry meals. The acidity of tomatoes and other fruits is known to increase the dissolution of tin from cans or from contact materials during processing, which can be seen from the results of previous FSA and MAFF surveys on canned foods.¹¹ These levels are on average lower than those found in the previous survey of infant foods¹ (mean of 0.9 milligrams per kilogram and range of less than 0.003 milligrams per kilogram to 33 milligrams per kilogram).

Tin concentrations in all samples were well within the limit of 200 milligrams per kilogram set by the UK Tin in Food Regulations 1992.¹² They are also well within the proposed EC limit for tin in infant foods of 50 milligrams per kilogram.

Zinc

Zinc was detected in all samples tested, with a mean concentration of 18.9 milligrams per kilogram and a range 0.02 milligrams per kilogram to 65.9 milligrams per kilogram. These results are similar to the 1999 survey of infant foods¹ in which a mean concentration of 16.4 milligrams per kilogram and range of less than 0.06 milligrams per kilogram to 68.1 milligrams per kilogram was reported. These concentrations are higher than those found in the general diet.² This is because many infant foods are fortified with zinc to ensure they satisfy nutritional requirements for this essential element for infants.

The Infant Formulae and Follow-on Formulae Regulations 1995, as amended¹⁰, set a minimum and maximum concentration for zinc in both from birth and soya-containing formulae, and a minimum concentration for follow-on formulae. All are expressed on an energy basis. The acceptable range for from birth formulae is 0.5 to 1.5 mg/ 100 kcal and for soy protein containing formulae 0.75 to 2.4 mg/ 100 kcal. All the formulae samples in this survey which are covered by these Regulations fall within the specified range.

Assessment of dietary exposures

Method

Two approaches were used to provide consumption data for the estimation of dietary exposures.

Typically, the FSA uses consumption data from the National Diet and Nutrition Surveys (NDNS) to estimate dietary exposure to contaminants in food. The NDNS provide detailed and robust information on the diets of individuals and are carried out on a representative cross section of the UK population. However, because the most recent survey of British infants (6-12 months old)¹³ was carried out in 1986, and therefore may not be representative of the current situation, two additional approaches for estimating infant dietary exposures were considered. One approach was based on manufacturers' feeding recommendations, the other on a risk assessment by the Scientific Committee on Foods

(SCF) and the Committee on Medical Aspects of food and nutrition policy (COMA) recommendations for infant formulae consumption. These approaches and their limitations are described at:

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

The independent Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), which gives Government independent expert advice on food safety, reviewed these three approaches, and two were viewed as providing a range of exposures in which the actual exposures were likely to be found. The 1986 National Diet and Nutrition Survey (NDNS) of British Infants (6-12 months old) was considered likely to underestimate consumption, but useful in providing a comparison with the previous infant food survey. The other approach, using manufacturers' feeding recommendations, was considered to provide worst-case consumption data. Both approaches are briefly described below together with the limitations of each.

The NDNS of British Infants provides detailed data on the amounts and patterns of consumption of different foods by infants from 6-12 months old. These data allow estimates to be made of the overall 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. Dietary exposures were calculated using the mean concentration of metal in each food category allowing a dilution factor for dried/concentrated foods. Mean and high level dietary exposure of infants are reported in Table 3.

The approach using manufacturer's feeding recommendations was based on the feeding guidelines on the product label for infant formulae, and for foods after weaning, average recommended amounts and types of food from three manufacturer's example menus¹⁴⁻¹⁶. No meaning should be read into the selection of these particular menus. Dietary exposures were calculated using the mean concentration of metal in each food category allowing a dilution factor for dried/concentrated foods. Dietary exposure of infants using this approach are reported in Table 3.

Both approaches have some limitations that should be borne in mind. For the NDNS, this survey, as outlined above, is not current, and so is unlikely to reflect the range of foods now available or current weaning practices, for instance, feeding cows' milk is no longer

recommended for infants under 12 months. Data for this survey were also collected from a limited number (488) of participants. The uncertainty regarding the actual amounts of formula and food presented to an infant that is actually consumed is particularly relevant for the approach using manufacturers' feeding recommendations. This approach is based on example menus, which indicate a particular type of food to be fed, such as a jar of a wet meal containing meat and vegetables, but this is unlikely to represent the actual amount of the food that is eaten and retained by the infant.

Neither of these approaches 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. No account is made of the possible contribution from water used to reconstitute dried or concentrated infant foods and formulae to the total concentration of an element in an infant's diet.

It must be noted that due to the different grouping of age intervals, dietary estimates using NDNS data cannot be directly compared to those using manufacturers' instructions.

What estimated exposures mean for infant health

The COT considered the estimated dietary intakes from consumption of the foods sampled in this survey. Dietary exposures from cows' milk based infant formulae and commercially available infant foods are listed in Table 3a. Dietary exposures for those infants consuming soya-based formulae have been estimated separately as soya-based formulae can contain higher levels of some elements such as aluminium and nickel. For estimated total exposures, contributions from foods with an obvious dairy component have been excluded. These are listed in Table 3b. However, these exposures should be treated with caution as only three samples of soya formulae were included in this survey.

Dietary exposures for aluminium¹⁷, arsenic¹⁸, (inorganic only), cadmium²⁰, copper²¹, lead²², mercury²⁴, tin²⁵ and zinc²⁶ are compared to the Joint Expert Committee on Additives of the Food and Agriculture Organisation of the United Nations and the World Health Organisation International Programme on Chemical Safety (JECFA) Provisional Tolerable Weekly Intakes (PTWI) or Provisional Maximum Tolerable Daily Intakes (PMTDI). The

PTWI or PMTDI is an estimate of the amount of a substance that can be ingested over a lifetime without appreciable risk.

The World Health Organisation (WHO) have set Tolerable Daily Intakes (TDI) for antimony^{27,28} and nickel²⁷, and recommended an upper limit of the safe range of population intake for selenium. Chromium, copper, nickel, selenium, tin and zinc are also compared to the Safe Upper Levels (SUL)/Guidance Levels recommended by the Expert Group on Vitamins and Minerals (EVM)^{29,30}.

For arsenic, the COT considers there are no relevant tolerable intakes or reference doses by which to assess dietary exposure to either inorganic or organic arsenic¹⁹. Inorganic arsenic is genotoxic and a known human carcinogen. They have therefore concluded that exposure to inorganic arsenic should be as low as reasonably practicable. However they were reassured that arsenic intakes do not appear to have increased since the previous survey.

Overall, the COT considered that the **consumption of infant foods and formulae sampled in this 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.**

They welcomed the apparent decline in lead exposure since the previous survey but considered efforts should continue to reduce lead exposure from all sources. Although it was not concerned about the infant exposures to mercury from the foods in the survey, the COT noted that concentrations of mercury had increased since the last survey of infant foods and recommended that mercury should continue to be monitored.

The COT added that it would welcome new studies to determine the patterns of consumption of foodstuffs in infants.

The COT's full statement can be accessed from the Agency's website at:

<http://www.food.gov.uk/science/ouradvisors/toxicity/statements/cotstatements2003/>

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Further Information

Further information on this survey can be obtained from:

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A copy of the final report of this survey has been placed in the FSA Library - address detailed above. If you wish to consult a copy please contact the library for an appointment giving at least 24 hours notice or alternatively, copies can be obtained from the library: a charge will be made to cover photocopying and postage.