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Contaminants and minerals in foods for infants and young children

Part 3: Risk- and benefit management

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Definitions of terms and abbreviations

AI – adequate intake

ALARA – As Low As Reasonably Achievable, Maximum levels are set as low as possible based on what can be achieved through effective agricultural, fishery and production methods and taking into consideration the risks associated with consumption.

Baby food – food, other than processed cereal-based foods, that is used as part of a varied diet and that does not constitute the sole source of nutrition for infants and young children (SLVFS [*Statens livsmedelsverks författningssamling* – Swedish National Food Agency Statutes] 1997:27), for example: Meals and fruit purées.

BMDL – Lower confidence limit on the benchmark dose, Benchmark modelling is used to estimate the exposure that causes a higher cancer incidence compared to the background incidence

EC – European Commission

EFSA – European Food Safety Authority

ESPGHAN – The European Society of Paediatric Gastroenterology, Hepatology and Nutrition

EU – European Union

Contaminants – refers to arsenic, lead and cadmium in this report.

FSMP – foods for special medical purposes

Jecfa – Joint FAO/WHO Expert Committee on Food Additives

IARC – International Agency for Research on Cancer

IOM – Institute of Medicine, USA

IQ – intelligence quotient

Minerals – refers to iron, copper and manganese in this report

Infant formula – In accordance with LIVFS [*Livsmedelsverkets föreskrifter* – Swedish National Food Agency Regulations] 2008:2, foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding

PCBF (Processed cereal-based foods) – cereal-based foods for infants and young children

RI – Recommended intake

RP – Reference Point

SCF – Scientific Committee on Food

SNR – Swedish Nutrition Recommendations

Young children – children aged 1-3 years

Infants – children below the age of 12 months

TDI – Tolerable Daily Intake, i.e. the quantity of a substance that a person can ingest every day throughout their life without any risk to their health

Follow-on formula – foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the

principal liquid element in a progressively diversified diet of such infants (LIVFS 2008:2).

TWI – Tolerable Weekly Intake

Gruel – A kind of cereal-based food for infants and young children that consists of cereal of some kind boiled in water, milk or other liquid.

WHO – World Health Organization

UL – (Upper Level) – according to EFSA, the maximum chronic daily amount of a nutrient (from all sources) considered not to give rise to any adverse effects to health

Foreword

This risk management report is based on the Swedish National Food Agency's (Livsmedelsverket) study on certain heavy metals (arsenic, lead, cadmium) and minerals (iron, copper, manganese) in food for infants and young children – infant formulae, cereal-based porridges and gruels, foods for special medical purposes and certain foods for normal consumption that children are likely to consume. The results of the analyses carried out are summarised in the report entitled Contaminants and minerals in foods for infants and young children – analytical results, Livsmedelsverkets rapport 1/2013 part 1 (3).

The results of the chemical analysis of the products have subsequently been used to carry out intake calculations and risk/benefit assessments for these products and to draw conclusions regarding the risks and benefits of the foreign substances and minerals in question. These results are summarised in the report entitled Contaminants and minerals in foods for infants and young children – risk and benefit assessment, Livsmedelsverkets rapport 1/2013 part 2 (3).

The results of the analysis report have also been used to examine whether the results of the analysis agree with the declared contents on packaging and whether the results of the analysis agree with current maximum levels. The results of this inspection are set out in a report.

This report describes Livsmedelsverket's conclusions from the study and the adjustments that have been made, in which other relevant factors have also been taken into consideration to determine whether action needs to be taken and can be taken and what form that action may take. These factors may, for example, include whether or not a product remains on the market, what control options are available, whether the consequences of an action are proportionate to the potential risks or benefits that are considered to be associated with a product or whether an action is practicable and considered to be effective.

The purpose of the report is to clearly set out Livsmedelsverket's reasons for the actions decided on.

The project team working on risk management consisted of Rickard Bjerselius, toxicologist and project leader, Emma Halldin Ankarberg, toxicologist, Anders Jansson, Government Inspector, Ingrid Lindeberg, Government Inspector, Jorun Sanner Färnstrand, information officer and Cecilia Wanhainen, Principal Regulatory Officer.

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Summary

During the 2011-12 period, Livsmedelsverket has conducted analyses on the minerals iron, copper and manganese and the heavy metals arsenic, lead and cadmium in 92 different foods specially intended for children: infant formula follow-on formula porridge, gruel and foods for special medical purposes (primarily infant formula, enteral formula and supplementary foods intended for sick children). Even some foods for normal consumption that children are likely to consume have been included in the study, mainly rice,- oat,- and soya drinks as they are used as an alternative for children who do not drink milk.

The results show that arsenic, lead and cadmium is present in many of the food products included in the study, which may pose a health problem. High levels of the mineral element manganese may also pose a potential health problem. The results show deficiencies in some of the companies' internal controls, particularly regarding foods for special medical purposes. The study also revealed remarkable deficiencies in the legislation governing the content of minerals and heavy metals in products intended for infants and young children.

Heavy metals

All rice products studied – porridge, gruel and rice-based drinks – contained arsenic. This may pose a potential health risk for young children who eat a lot of these products. Rice-based drinks are considered to pose the greatest risk. These are used as a replacement for milk for children who are allergic to milk or children who are on a vegan diet, for example, and may therefore be consumed every day for many years. *Livsmedelsverket therefore recommends that children under the age of six should not drink rice-based drinks. Livsmedelsverket also advises parents to not give their children only rice-based porridge or gruel, but to vary what they give their children and include products made from other raw materials.*

36 per cent of infant formula for healthy children and 67 per cent of infant formula and enteral formula/supplementary foods for children with special medical needs contained lead in levels that led to an intake that is not health-wise acceptable. This gives rise to concern since young children are particularly sensitive to the effects of lead. Livsmedelsverket therefore informs the companies concerned of these results and of the importance of reducing the lead content of foods for infants and young children. One product contained significant levels of lead that could pose a health risk for children. Livsmedelsverket is referring the case to the responsible control authority for further processing.

Among the 40 porridge and gruel products studied, the levels of lead were generally low. Although, two of these contained significant levels of lead. Even though the levels were below the current maximum levels, they are not acceptable

from a health point of view. Five cereal-based porridge and gruel products contained elevated levels of cadmium, as did two soya drinks. Even though the lead and cadmium levels in these products do not pose any immediate health risk for children, the study shows that harmful substances can be present in food products for infants and young children. *Parents can reduce the risk of adverse health effects by varying between different brands of porridge, gruel and plant-based drinks.*

The fact that baby food contains such high levels of heavy metals such as arsenic, lead and cadmium is unacceptable considering that children who are growing and developing are particularly sensitive to the effects of such substances. The results indicate deficiencies in internal controls at the companies in question, which could reduce the levels of these substances through more careful selection and control of raw materials. Livsmedelsverket is informing these companies and the responsible control authorities of the results.

Minerals

The study carried out analyses for the minerals iron, copper and manganese. The results show that the foods for special medical purposes contained manganese at levels that could pose a health risk when the products are given in the recommended quantity. However, these levels do not exceed the EU maximum levels for manganese. That shows that the maximum levels are set too high. One gruel and two products for children with special medical needs exceeded the maximum mineral content levels for at least one of the minerals studied. Livsmedelsverket is referring the case to the responsible control authority for further processing.

It is common that minerals are added to products for children. In the study, the mineral contents declared by the companies themselves on the packaging have been compared with the iron, copper and manganese levels resulting from the analysis. The results showed unacceptable differences between the analysed content and the declared content in eleven of the products. This indicates deficiencies in companies' controls on the products, particularly when it comes to products for special medical purposes, where 26 per cent of the products deviated. The responsible control authority is being informed of the results.

Deficiencies in the legislation regarding heavy metals and minerals

Livsmedelsverket's study reveals remarkable deficiencies in the rules for heavy metals in products intended for young children. For example, there is no legislation governing levels of arsenic in food and there are no maximum levels for cadmium in foods for infants and young children. As far as lead is concerned, there are maximum levels for different types of foods for children, but the study shows that these are not set low enough to protect children from potentially harmful health effects. The EU maximum levels for heavy metals are currently being revised and both new and revised maximum levels are being discussed.

Livsmedelsverket is actively working in the EU Commission to ensure that these deficiencies are remedied and the results of this study form an important basis for that work.

There are also deficiencies in the rules concerning mineral content. The existing maximum levels are set too high, which means that children are able to ingest significantly greater quantities of the minerals analysed than they need. An excessive intake of minerals can lead to adverse health effects and children are particularly sensitive to those effects. It is possible to question whether it is necessary to add certain minerals to porridge, gruel and products for special medical purposes at all. Livsmedelsverket has informed the EU Commission of these conclusions and of the need to revise the legislation.

There are also doubts concerning the current health-based reference values that set out children's need for certain minerals and harmful intake levels. A proposal has therefore been made to the European Food Safety Authority, Efsa, that the health-based reference values for children should be revised.

Actions by Livsmedelsverket

During the 2011-12 period, Livsmedelsverket has carried out a study on 92 different foods that infants (0-12 months) and young children (1-3 years) are likely to consume. The selection was designed to cover as many different kinds of food as possible from all producers on the Swedish market. The results of previous studies show that it is mainly in cereal-based, including rice, and soya-based products that levels of certain minerals and heavy metals could pose a health risk to infants and young children. For that reason, those products were prioritised in the project. The substances analysed consisted of the minerals iron, copper and manganese and the heavy metals arsenic, lead and cadmium.

The following food groups were included in the project:

- Infant formula and follow-on formula (13 products)
- Cereal-based porridge and gruel for infants and young children (PCBF) (40 products)
- Foods for special medical purposes (FSMP) for infants (0-12 months) and children over one year of age (27 products)
- Foods for normal consumption, i.e. certain ordinary foods that infants and young children are likely to consume, such as soya-, rice- and oat-based alternatives to milk(12 products)

Baby food such as full dishes and fruit-based desserts were not included in the project.

Livsmedelsverket's decisions on action to be taken are summarised below. *The full report in English will be available in a week.*

Advice for consumers

- Parents are advised not to give rice-based drinks to children under the age of six due to the presence of arsenic.
- Parents are advised not to give young children only rice-based porridge and gruel, but to vary the types due to the presence of arsenic.
- Parents are advised to vary the types of porridge and gruel for young children due to the presence of lead and cadmium.
- Parents are advised not to always give the same plant-based drink but to vary the type and the brand due to the presence of cadmium.

Advice for healthcare and medical services

- Healthcare and medical services are temporarily advised, if alternatives are available, not to prescribe MiniMax child enteral formula/Nestlé as the sole source of nutrition until the levels of arsenic have been reduced.
- Healthcare and medical services are temporarily advised, if alternatives are available, not to prescribe the products for special medical purposes that contain manganese in such quantities that the tolerable daily intake, TDI, may be exceeded or to restrict the quantity of the product until the levels of manganese have been reduced.

To inform/refer the case to responsible control authorities in Sweden

- To inform the control authorities concerned that levels of lead in PKU gel/Vitaflo are judged to be so high that the product cannot be considered to meet the requirements for food safety in accordance with Regulation (EC) No 178/2002, article 14.
- To inform the responsible control authorities of the products in which the analysed content exceeds the established maximum levels for iron, copper and manganese, for further processing. The products referred to are porridge and gruel and foods for special medical purposes.
- To inform the responsible control authorities of the products where discrepancies exist between the analysed mineral content and the declared mineral content, for further processing. The products referred to are infant formulae and follow-on formulae (manganese), foods for special medical purposes for infants and young children (iron and manganese) and cereal-based porridge and gruel for infants and young children (iron).

Information for companies

- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values and falling below recommended intake. The products referred to are infant formula and follow-on formula (lead), foods for special medical purposes for infants and young children (iron, copper, manganese, arsenic and lead) and cereal-based porridge and gruel for infants and young children (manganese, arsenic, lead and cadmium).

To inform the EU Commission

- To inform the EU Commission that the legislation regarding added amounts of minerals/maximum levels in the products needs to be reviewed. The products referred to are infant formula and follow-on formulae (manganese), foods for special medical purposes for infants and young children (iron, copper, manganese) and cereal-based porridge and gruel for infants and young children (iron, copper, manganese).
- To inform the EU Commission that the need to add certain minerals in cereal-based porridge and gruel for infants and young children should be considered.
- To work actively for the introduction of an EU-wide maximum level for inorganic arsenic in rice.
- To work actively for the introduction of and a lowering of the EU-wide maximum levels for cadmium and lead in foods intended for infants and young children.

Proposal to the European Food Safety Authority, Efsa

- A proposal has been made to the European Food Safety Authority, Efsa, to develop health-based reference values for children for the minerals iron, copper and manganese.
- To inform Efsa of the content data from the project, which could form a basis for the EU Commission in the work to revise the maximum levels for the heavy metals arsenic, lead and cadmium.

Reason for the administrative action

Risk and benefit assessment

A description of the health effects of the metals analysed is given below. For a more detailed description, see Contaminants and minerals in foods for infants and young children – risk and benefit assessment, Livsmedelsverkets rapport 1/2013, part 2 (3).

Arsenic

Arsenic is ubiquitous in the environment and leakage from bedrock to surrounding groundwater is a common problem worldwide. Food products and drinking water are the major sources of arsenic exposure. Rice is one crop that absorbs relatively high levels of arsenic.

Arsenic mainly occurs in two forms: organic and inorganic. The inorganic form is the most toxic for humans.

Arsenic is classified by the WHO as a human carcinogen and it is suspected that it may cause cancer of the bladder, lungs, skin and possibly also of the kidneys and liver. The National Research Council (USA) considers that the risk of lung and bladder cancer is 3-4 cases per 1000 individuals at a concentration in drinking water of 10 µg/l, which is the EU's maximum permitted level for drinking water.

Arsenic is associated with peripheral vascular insufficiency, diabetes and hypertension. Epidemiological studies also indicate an increased mortality from liver and lung cancer as well as an increase in respiratory disease later in life following exposure during pregnancy. Arsenic can also affect the development of the nervous system and the immune system.

In 2009, EFSA produced a health-based guideline (Lower confidence limit on the benchmark dose, BMDL₀₁) of 0.3-8 µg arsenic/kg of body weight per day for cancers of the lung, skin and bladder, as well as for skin lesions. In 2010, the Joint FAO/WHO Expert Committee on Food Additives (Jecfa) proposed a BMDL of 3.0 µg/kg of body weight per day (2-7 µg/kg of body weight per day) for inorganic arsenic. These values correspond to an increased risk of cancer in the range of 0.5 to 1 per cent. Since the products included in this study are aimed at children, that are more sensitive, Livsmedelsverket has adopted EFSA's lower value, 0.3 µg arsenic/kg of body weight per day, in order to assess the risk to health.

Lead

Lead is a heavy metal that occurs naturally but that is largely introduced into the environment as a pollutant. The largest source of exposure to lead is through food. Children can absorb 40-50 per cent of the lead present in food, whereas adults absorb 3-10 per cent. Children with calcium or iron deficiency have higher levels of lead in their blood than children with normal calcium and iron levels.

Prolonged exposure to lead can damage the nervous system. Foetuses and young children are the most sensitive to lead since their brains and nervous systems are still developing. The effects observed consist of delayed development, lower IQ and behavioural deficits. Lead can also cause renal damage and can affect blood pressure. It is also suspected that lead can increase the risk of cancer in humans.

EFSA does not consider that there is any safe limit for how much lead a person can be exposed to without risking adverse health effects. Instead, they use a guideline value (RP = Reference Point), which is the level at which effects are observed. A reference point based on $BMDL_{01}$ for neurotoxicity during the period of development was set at 12 $\mu\text{g/l}$ (blood lead level). This represents an exposure to lead of 0.5 μg of lead/kg of body weight per day and presupposes negligible exposure from air, soil and dust.

Furthermore, EFSA notes that there is no safe level of exposure when the population of Europe already has blood lead levels that risk adverse health effects. Exposure should therefore be reduced at population level. Studies on Swedish children indicate that current blood lead levels are around 12 $\mu\text{g/l}$.

According to EFSA, the safety margin in relation to RP should be at least a factor of 10, i.e., the intake should be below ten per cent of RP to avoid the risk of adverse health effects. Exposure above this level (10-100 per cent of RP) does not necessarily mean that a risk exists, but neither can it be neglected.

Cadmium

Cadmium is a heavy metal that occurs naturally but which is also introduced into the environment as a pollutant. Food is the main source of cadmium for non-smokers. Most of the cadmium ingested by Swedish consumers comes from cereal-based products and potatoes.

Uptake of cadmium varies from person to person. People with low levels of iron can absorb three to four times more cadmium than people with normal levels of iron. However uptake in children appears to be higher than in adults, regardless of iron levels. In cases of prolonged exposure, the cadmium is stored in the kidneys.

Cadmium exposure through food can cause renal dysfunction and cause damage to the bones. Adverse effects on reproduction, the liver and haematological and

immunological parameters have also been observed. The International Agency for Research on Cancer (IARC) has classified cadmium as a human carcinogen. EFSA has established a tolerable weekly intake (TWI) for cadmium of 2.5 µg/kg of body weight. TWI is the quantity of a substance that a person can ingest every week throughout their life without risk to their health. However, there are a number of uncertainties regarding the protection that the application of this TWI affords when it comes to infants and young children, particularly when it relates to effects during the development stage and differences in cadmium uptake between adults and young children.

EFSA considers that cadmium exposure should be reduced at population level.

Manganese

Manganese is an essential nutrient and occurs naturally in many different foods. Manganese is needed as a co-factor for many enzymes. It is also important for normal development during pregnancy.

As far as food is concerned, the main source of manganese in Sweden is cereal-based products.

Swedish nutrition recommendations (SNR) do not state any recommended level for manganese intake because there is no basis on which to establish one. However, the American Institute of Medicine (IOM) gives an estimated adequate intake (AI = Adequate Intake) of manganese for different age groups: 0-6 months: 3 µg per day, 7-12 months: 600 µg per day, 1-3 years: 1200 µg per day, 4-8 years: 1500 µg per day. The AI for children aged 0-6 months is based on the manganese intake from breast-milk. However, the scientific basis for AI for children is weak and is based on the estimated intake from food in the various age groups.

The effects of manganese deficiency can include impaired growth, poor bone formation and skeletal defects. However, manganese deficiency is extremely rare in humans.

At the same time, manganese is also a known neurotoxicant and high intake by children can affect the nervous system, which can give rise to subtle neurobehavioural effects.

The uptake of manganese is strictly regulated in adults and only 1-5 per cent of the manganese present in food is absorbed. In infants, that ability is not yet fully developed so manganese uptake can be significantly higher. The ability to secrete manganese is also not fully developed in infants. Iron levels also affect the uptake of manganese, with low iron levels increasing the uptake of manganese.

The WHO has established a tolerable daily intake (TDI) for manganese of 60 µg/kg of body weight. TDI is the quantity of a substance a person can ingest every

day throughout their life without risking adverse health effects. However, the scientific basis for this TDI is weak.

When the risk associated with an excessively low manganese intake is weighed against the risk associated with an excessively high manganese intake for infants and young children, the risk associated with an excessive intake outweighs the risk of an intake that is too low. The uncertainty in the health-based guideline values has also been taken into consideration in that assessment.

Copper

Copper is an essential trace element that forms part of many enzymes and proteins. Copper is required for normal growth of infants, the immune system, bone strength, the maturation of red and white blood cells, the transport of iron and brain development.

Beef liver, shellfish and nuts are good sources of copper. Meat, fish, green vegetables and cereals contain lower levels. Since most of the Swedish water-pipe network is made of copper, drinking water also contributes to copper intake.

Absorption and secretion of copper is normally controlled by the liver. Copper is accumulated in the foetus mainly during the third trimester, which serves as a copper reserve during the child's first few months of life. Premature infants and babies with low birth weight may therefore be at risk of copper deficiency.

There is a considerable need for copper during infancy due to the rapid growth of the brain. The recommended intake is 0.3 mg per day for infants and children aged 6-23 months and 0.4 mg per day for children aged 2-5 years.

Severe copper deficiency can cause neutropenia (lack of white blood cells) and anaemia (lack of red blood cells) and impaired development in children. Copper deficiency is not common, but occurs in premature infants and children who have been severely malnourished.

An excessive intake of copper irritates the gastrointestinal tract. Long-term high copper intake can damage the liver. There are also studies that indicate a connection between high levels of copper in drinking water and diarrhoea in children. It is likely that newborn babies are particularly sensitive to high intakes.

EFSA has set limits for upper levels of intake (UL = Upper Level) for children: 1-3 years: 1 mg per day, 4-6 years: 2 mg per day, 7-10 years: 3 mg per day. There is no UL for children below the age of 12 months. UL is the amount of a substance that can be ingested every day throughout life without having a negative health effect.

Iron

Iron is an essential trace element contained in haemoglobin in the blood and in many enzymes involved in a number of functions in the liver, brain and endocrine organs.

Meat, cereals, legumes and green vegetables are important sources of iron. Porridge and gruel to which iron has been added are the primary sources for infants who have begun to eat supplementary foods and for young children.

Infants and young children belong to the group with the greatest need for iron because they are growing rapidly. The recommended intake for children from 6 months to 5 years is 8 mg of iron per day (SNR).

Iron deficiency is the most common nutritional deficiency in both rich and poor countries. A Swedish study from 2011 showed that 10 per cent of children aged one year had depleted iron levels. The risk of iron deficiency is greatest for children born prematurely and children with a low birth weight. Severe iron deficiency – iron deficiency anaemia – can affect mental development and cognitive functions and impair the immune system.

An excessive intake of iron can also be harmful. A regular high intake of iron can be a burden on the liver and can interfere with the uptake of other trace elements. It is suspected that high concentrations of iron in the tissues can also increase the risk of cancer, cardiovascular disease, infections and inflammations. Acute poisoning due to an extremely high iron intake can, in a worst-case scenario, lead to death.

Giving supplements with high iron content to children whose iron levels are satisfactory has been shown to have negative effects on growth and to give rise to increased risk of infection.

Uptake of iron is affected by a range of factors. In a mixed diet, bioavailability is approximately 10 per cent. Uptake is reduced at higher intakes, though research indicates that children under 9 months are unable to regulate an excessively high intake in the same way as older children and adults. This group can therefore be particularly sensitive to high intakes.

EFSA has been unable to determine an upper limit for the maximum tolerable level (UL = Upper Level) for iron due to lack of data.

Legislation and control

The complete titles of the legal acts referred to in this report are listed in appendix 1.

General principles and requirements

Most food legislation is harmonised within the EU. Regulation (EC) No 178/2002 establishes, *inter alia*, a number of general requirements for food and food trade and procedures in matters of food safety. In accordance with article 14 of that Regulation, foods must not be placed on the market if they are not safe. When assessing whether a food can be harmful to health, it is necessary to take into account the particular sensitivity of certain groups of consumers when a food is specifically designed for them. Infants and young children are one such group.

For foods that are specifically intended for infants and young children, for example infant formula, gruel, porridge and purées, specific rules aimed at protecting this sensitive group apply in addition to general food law. The rules establish composition criteria for different types of foods intended for infants and young children and they are required not to contain any substance in such amounts as to endanger the health of children. There are also specific provisions on such matters as labelling and marketing applying to foods for infants and young children. Read more about these rules below.

It is the food business operators' responsibility to ensure that the requirements laid down in the legislation are met, whereas the Member States are responsible for monitoring and controlling that the rules are applied. Article 7 of Regulation (EC) No 178/2002 also establishes the so-called precautionary principle. That principle enables the legislator or the authorities to adopt provisional risk management measures in specific cases where the possibility of effects harmful to health is identified after an assessment of the available information but where scientific uncertainty exists. These measures may apply pending the emergence of further scientific data for more comprehensive risk assessments.

Foods for particular nutritional uses

Due to the specific sensitivity and nutritional needs of infants and young children, there are EU-wide rules for the foods intended for them. These foods belong to the category of foods for particular nutritional uses. To foods for particular nutritional uses belong foods that are composed or manufactured in such a way as to be particularly suitable for people who need special food. Foods for particular nutritional uses are divided into sub-categories for which there are specific provisions regarding aspects such as composition, marketing and labelling.

The overall provisions on foods for particular nutritional uses are contained in Livsmedelsverket's regulation (SLVFS 2000:14) on foods for particular nutritional uses, which transposes Directive 2009/39/EC. According to the regulation,

foods for particular nutritional uses must, for example, always bear a nutrition declaration and be sold prepacked.

Foods for particular nutritional uses are divided into a number of sub-categories. Foods for infants and young children fall within three of these categories:

- a) Infant formula and follow-on formula
- b) cereal-based foods and baby foods for infants and young children
- c) foods for special medical purposes (abbreviated to FSMP).

The different categories of foods for infants and young children regulated through Livsmedelsverket's regulations (see Table 1).

Table 1. Legislation on food for infants and young children

Category	SLVFS	EU Directive
Infant formula and follow-on formula	LIVSFS 2008:2	2006/141/EC
Cereal-based foods and baby foods for infants and young children	SLVFS 1997:27	2006/125/EC
FSMP	SLVFS 2000:15	1999/21/EC

The mineral substances that may be added to certain categories of foods for particular nutritional uses are set out in Regulation (EC) No 953/2009. Foods for healthy infants and young children are not covered by Regulation (EC) No 953/2009 but permitted substances are established in their respective regulation. Appendix 2 contains an overview of the established maximum and minimum levels for minerals in the various categories of foods intended for infants and young children.

The nutrients that may be added to a food, and that hence must be in the nutrition declaration, depend on the product category the food belongs to. The nutrition declaration must state the total content of relevant nutrients. The declared value must include both the natural content and any added amounts. The values must be average values based on the manufacturer's analysis, calculations based on average values for the ingredients or calculations based on generally established and accepted data.

The maximum levels for contaminants, for example lead and cadmium, in foods for infants and young children are established in Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs. The maximum levels for lead in baby food are also set out in Livsmedelsverket's Regulations (LIVSFS 2012:3) on contaminants in food. Appendix 3 contains an overview of the established maximum levels for contaminants in foods for infants and young children.

The establishment of maximum levels for contaminants in foods within the EU is based on what is known as the ALARA principle. ALARA stands for "As low as reasonable achievable" and means that the maximum levels are set as low as possible based on what can be achieved through effective agricultural, fishery and

production methods and taking into consideration the risks associated with consumption. The presence of contaminants in foods intended for infants and young children must be limited. The maximum values are set as low as possible based on what can be achieved through strict selection of raw materials for manufacturing.

Infant formula and follow-on formula

The rules for infant formula and follow-on formula are set out in Livsmedelsverket's regulation (LIVSFS 2008:2) on infant formula and follow-on formula, which is based on Directive 2006/141/EC.

Infant formula must satisfy themselves healthy children's nutritional requirements during the first few months, whereas follow-on formula can be given to infants when they begin to receive taster portions of ordinary food. Follow-on formula must be suitable to constituting the main liquid food for infants from six months of age who are given an progressively diversified diet. The requirements imposed by legislation on infant formula and follow-on formula include such aspects as the composition of the food in terms of ingredients, energy content and nutritional composition. The requirements apply to products ready for use when prepared according to the manufacturer's instructions. There is also a requirement that it must be possible to prepare these products just by adding water.

The requirements regarding composition establish which minerals and what amounts of those minerals the products must contain (see Table 2). The maximum and minimum levels of iron differ for products from different protein sources. The maximum and minimum levels of iron differ between infant formula and follow-on formula. The form of the minerals to be added to formula and follow-on formula is also established in the regulation.

Table 2. Legislation on the minimum and maximum levels of minerals (per 100 kcal of products ready for use)

Category	Regulation (Directive)		Cu (µg)	Fe (mg)	Mn (µg)
Infant formula	LIVSFS 2008:2 (2006/141/EC)	Minimum	35	0.3 ¹ /0.45 ²	1
		Maximum	100	1.3 ¹ /2 ²	100
Follow-on formula	LIVSFS 2008:2 (2006/141/EC)	Minimum	35	0.6 ¹ /0.9 ²	1
		Maximum	100	2 ¹ /2.5 ²	100

¹Infant formula produced from cows' milk protein or hydrolysed proteins.

²Infant formula manufactured from soya protein isolate or soya protein isolate mixed with cows' milk proteins.

No maximum levels have been established in the EU for heavy metals in infant formula and follow-on formula, with the exception of lead. The maximum level for lead (0.020 mg/kg wet weight) is given in Regulation (EC) No 1881/2006. However, LIVSFS 2008:2 contains provisions stating that foods must not contain any substance in such quantity as to endanger the health of infants and young children when they are used in accordance with the manufacturer's instructions.

Table 3. Maximum levels for contaminants in infant formula and follow-on formula

Category	Regulation	Arsenic (mg/kg)	Lead (mg/kg)	Cadmium (mg/kg)
Infant formula	Regulation	*	0.020	*
Follow-on formula	(EC) No 1881/2006	*	0.020	*

* There is no maximum level established, but a food must not contain any substance in such quantity as to endanger the health of infants and young children (see LIVSFS 2008: 2).

As a result of recommendations from EFSA and JECFA to reduce exposure to lead, the maximum level for lead in infant formula and follow-on formula is being reviewed. The maximum levels for cadmium are also being reviewed and in that regard a proposal has been put forward that maximum levels should be set for additional categories of foods such as infant formula and follow-on formula and cereal-based foods and baby foods for infants and young children. The main reason why there are no maximum levels established for arsenic in foods for infants and young children is that there is a limited amount of data inorganic arsenic in these foods. Discussions concerning the introduction of maximum values for arsenic are currently taking place within the EU. The European Commission is encouraging Member States to provide data on arsenic content in foods.

Cereal-based foods for infants and young children (PCBF) – porridge and gruel

Cereal-based foods and baby foods for infants and young children are regulated through Livsmedelsverket's regulation (SLVFS 1997: 27) on cereal-based foods and baby food for infants and young children. The regulation is based on Directive 2006/125/EC. PCBF covers such foods as gruel, porridge, rusks and biscuits. Baby food for infants and young children covers for example purées, which are not included in this study.

The requirements on PCBF are, *inter alia*, that the ingredients have been shown, according to generally accepted science, to be suitable for infants and young children. It is permitted to add vitamins and minerals to PCBF. The substances that may be used are listed in the regulation. It also establishes the maximum levels for various minerals. The maximum levels apply only to products to which the mineral in question is added and they cover the total amount (both naturally occurring and added) in products ready for use.

Table 4. Maximum levels of minerals in products ready for use, if added, in accordance with SLVFS 1997:27

Category	Cu µg/100 kcal	Fe mg/100 kcal	Mn µg/100 kcal
PCBF	40	3	600

With the exception of lead, for which there is a national maximum value (0.05 mg/kg in baby food ready for use, LIVSFS 2012:3), there are no established maximum levels for contaminants in porridge and gruel. However, SLVFS 1997:27 contains provisions stating that the foods must not contain any substance in such quantity as to endanger the health of infants and young children when they are used in accordance with the manufacturer's instructions.

Table 5. Maximum levels for contaminants in cereal-based foods and baby foods for infants and young children

Category	Regulation (Directive)	Arsenic (mg/kg)	Lead (mg/kg)	Cadmium (mg/kg)
PCBF: Porridge and gruel	SLVFS 2012:3	*	0.05	*
Baby food (1-3 years)	SLVFS 2012:3	*	0.05	*

* There is no maximum level, but the food must not contain any substance in such quantity as to endanger the health of infants and young children (see SLVFS 1997: 27).

As stated above (see the section above on infant formula and follow-on formula) the maximum levels for cadmium are being reviewed within the EU. In this context, a proposal has been put forward that maximum levels should be set for additional food categories such as cereal-based foods and baby foods for infants and young children.

Foods for special medical purposes for infants and young children (FSMP)

Foods intended for infants and young children, for example infant formula and follow-on formula for children allergic to cows' milk, enteral formula, supplementary foods and foods for infants and young children with congenital metabolic disorders, are considered to be FSMP and are regulated through Livsmedelsverket's regulation (SLVFS 2000:15) on foods for special medical purposes, which is based on Directive 1999/21/EC. FSMP are intended for people with illnesses or conditions that require a special diet. The products are to be used for dietary treatment under medical supervision and will completely or partially replace ordinary food or other foods for particular nutritional uses.

The regulation contains criteria for composition in terms of vitamins and minerals for FSMP intended for infants. For the other nutrients, the criteria set out in the

regulation on infant formula and follow-on formula apply. The compositional criteria may be waived if shown to be necessary for a product's specific purposes. Compositional requirements for vitamins and minerals in FSMP intended for persons over the age of one year apply to FSMP for young children (1-3 years). These criteria may also be waived if necessary for a product's specific purposes. The mineral compounds that may be used in FSMP are set out in Regulation (EC) No 953/2009.

Table 6. Maximum and minimum levels of minerals in FSMP (per 100 kcal for products ready for use)

Category	Regulation (Directive)		Cu (µg)	Fe (mg)	Mn (µg)
FSMP (0-12 months)	SLVFS 2000:15 (1999/21/EC)	Minimum	20	0.5	1
		Maximum	120	2	100
FSMP (>1 year)	SLVFS 2000:15 (1999/21/EC)	Minimum	60	0.5	50
		Maximum	500	2.0	500

There are no maximum levels established for arsenic, lead and cadmium in FSMP. However, SLVFS 2000:15 contains provisions stating that the foods must not pose a health risk if they are used in accordance with the manufacturer's instructions.

Table 7. Maximum levels of contaminants in FSMP

Category	Arsenic (mg/kg)	Lead (mg/kg)	Cadmium (mg/kg)
FSMP (0-12 months)	*	*	*
FSMP (1-3 years)	*	*	*

* There is no maximum level, but the food must not pose a health risk if they are used in accordance with the manufacturer's instructions. (see SLVFS 2000:15).

Foods for normal consumption

Foods for normal consumption are foods that are not specially intended for infants and young children but that children are likely to eat anyway, such as soya-, oat- and rice-based drinks. General food law applies to these.

The addition of minerals to foods for normal consumption is regulated through Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to food. No maximum and minimum levels for added minerals have yet been established. A list of the vitamins and minerals and the forms in which they may be added to foods for normal consumption, including food supplements, is contained in Regulation (EC) No 1170/2009.

The presence of contaminants in foods is regulated through Regulation (EC) No 1881/2006.

Table 8. Maximum levels for contaminants in certain foods

Category	Ordinance	Arsenic (mg/kg)	Lead (mg/kg)	Cadmium (mg/kg)
Cereals	Regulation	*	*	0.10 ¹
Wheat and rice	(EC) No	*	*	0.20 ²
Soya beans	1881/2006	*	0.20 ³	*

* There is no maximum level, but under Regulation 178/2002 foods placed on the market must be safe to consume.

¹ Cereals, with the exception of bran, germ, wheat and rice.

² Bran, germ, wheat and rice

³ Cereals, legumes and pulses

Discussions concerning the introduction of maximum levels for arsenic in food are currently taking place within the EU. The European Commission is encouraging Member States to provide data on content.

Control

The responsibility for operational control in the area of food is divided among Livsmedelsverket, the county administrative boards and the municipalities. Paragraphs 23 and 25 of the Food Decree (2006:813) state which authority is competent to exercise public control over different types of food establishments. The authority responsible for operational control makes decisions on prohibitions and orders.

Most of the food for infants and young children included in the study is manufactured abroad, where manufacturing controls, etc. take place. In Sweden, the municipality in which the selling company has its office/warehouse is responsible for inspections of such aspects as product labelling. Livsmedelsverket is responsible for inspections of Semper's products manufactured in Sweden and Semper's headquarters.

It is the food business operator's responsibility to ensure that the requirements laid down in the legislation are met, whereas the control authorities are responsible for controlling that the rules are observed.

Examination

Comparison between analysed contents and declared values

Product labelling was examined for products which, according to the list of ingredients, contained added minerals (iron, copper or manganese). The values determined by analysis and the corresponding values in the nutrition declaration on the package were compared for these products. The other information on the label was not examined. Contaminants are not added to food but are present in soil and plants, for example, and therefore they are not required to be declared in the list of ingredients.

Because the values to be declared in the nutrition declaration should be average values (see the section on legislation and SLVFS 1993:21) an individual analysis result can deviate from the declared value. There are no EU-wide rules on the extent to which declared values can differ from values determined by analysis in official controls. Neither does Sweden have any national legislation or guidance with regard to this. Within the EU, however, guidelines for control of nutrition declarations are being developed. In the absence of established guidelines, Livsmedelsverket has decided to apply a maximum deviation between contents determined by analysis and declared contents of ± 35 per cent (including measurement uncertainty) in this project. This corresponds to a deviation of approximately the measurement uncertainty times two, which is considered sufficient to cover for the possible variation in a single analyse value. If the deviation exceeds 35 per cent, Livsmedelsverket considers it to be misleading. This can result in infants and young children who are prescribed the products ingesting too little or too much of certain nutrients.

The products in which the mineral content determined by analysis differs by more than 35 per cent from the declared content (product as sold) are listed in appendix 4.

Comparison between analysed contents and established maximum and minimum levels for minerals

In some cases, the legislation establishes maximum levels for minerals and contaminants in the product groups included in the project, see the section on legislation.

In the legislation, the maximum levels for minerals are set per 100 kJ or per 100 kcal in products ready for use. For products sold as a powder that only requires dilution with water, the levels, which were analysed per 100 g "as sold", could be

converted to per 100 kcal of product "as sold" using the energy value declared in the nutrition declaration. Since only water is to be added, the content per 100 kcal in products ready for use is the same as the content per 100 kcal of product "as sold", given that we disregard the presence of minerals and contaminants in drinking water. In this project, any possible contribution of minerals and contaminants from the water used for dilution was not taken into account. For FSMP for infants to which breast milk is to be added, the contribution of energy from the breast milk was taken into consideration when calculating the mineral content per 100 kcal in products ready for use. The calculations disregarded the mineral content of the breast milk. For the porridge and gruel products to which, according to the manufacturer's instructions, infant formula, breast milk or other liquid should be added, the calculations have been carried out on infant formula/follow-on formula with an energy value of 65 kcal/100ml (in accordance with LIVSFS 2008:2, the energy content must be 60-70 kcal/100ml for both these product categories). Any possible contribution of minerals from the liquid used to dilute the product was also not taken into account in these cases.

The levels analysed, taking into account the measurement uncertainty inherent in the methods, must not deviate from the established minimum and maximum levels. In order for an analyse value to be considered to deviate from a maximum or minimum level established in the legislation, the entire interval must exceed or fall below the value set out in the legislation.

The results of the analyses in Livsmedelsverkets rapport 1/2013, part 1 (3) have been adjusted for the measurement uncertainty associated with the methods of analysis specified in Table 1 in that report.

For comparisons between the levels determined by analysis in products ready for use and the applicable maximum and minimum levels, see appendix 5.

Comparison between analysed content and established maximum levels for heavy metals

Of the product groups included in the project, maximum levels only exist in the legislation for lead in infant formula, follow-on formula and cereal-based porridge and gruel for infants and young children, see the section on legislation. In the absence of corresponding maximum levels for infant formula intended for sick infants (FSMP), in this project we have decided to apply the maximum levels for infant formula for healthy babies. Regarding FSMP for children over 1 year of age, there are no corresponding maximum levels to compare with.

When assessing whether the levels determined by analysis exceed the applicable maximum and minimum levels, the measurement uncertainty associated with the method of analysis used was taken into consideration. In order for a result to be

considered to exceed an established maximum or minimum level, the entire range of its measurement uncertainty must exceed it.

In some cases, there are maximum levels for contaminants in raw materials. Those maximum levels apply to all food categories. No process factors are established for assessing the contribution of the individual raw material to levels measured in the composite products included in the project. Therefore, in these cases it was not possible to assess contents determined by analysis against applicable maximum levels.

For comparisons between the levels resulting from analysis in products ready for use and the applicable maximum levels, see appendix 5.

Comparison of contents determined by analysis and health-based guideline values

There are risks associated with both too low and too high intakes of the minerals iron, copper and manganese. For that reason, in many cases health-based guideline values are established for these substances that state what intake is considered as a recommended or adequate intake per day and what is considered as a high intake that may give rise to a risk.

Guideline values exist for what is considered to be a high intake that may give rise to a risk for the heavy metals arsenic, lead and cadmium.

In the evaluation of the content of minerals and heavy metals in the products analysed, the project has used the estimated intake presented in the report Contaminants and minerals in foods for infants and young children – risk and benefit assessment, Livsmedelsverkets rapport 1/2013, part 2 (3).

For infant formula and foods for special medical purposes that are intended to meet a child's complete nutritional needs, the intake of minerals has been compared to both recommended/adequate intake and the limits for what is considered as a high intake that may give rise to a risk. For products that do not constitute the sole source of nutrition, i.e. follow-on formula for children over the age of six months, foods for special medical purposes used as a supplement to other foods, cereal-based porridge and gruel and the foods for normal consumption that were analysed, the intake was compared to what is considered as the upper intake that may be associated with a risk if such an intake has been established.

In the case of heavy metals, the intake has been compared to the limit for what is considered as a high intake that may be associated with a risk.

Livsmedelsverket's advice on food for infants and children from one to two years of age recommends a maximum of three portions of porridge or gruel per day.

This is to meet the child's need for a varied diet. When evaluating these products, the calculated intake was therefore based on the fact that the child must be able to eat three portions per day of a product without exceeding any health-based guideline.

For children over one year of age, Livsmedelsverket recommends five dl of milk or vegetable-based drink with added calcium per day to meet their need for calcium. When evaluating these products, the calculated intake was therefore based on the fact that the child must be able to drink five dl per day of the drinks analysed without exceeding any health-based guideline.

The products analysed often come in the form of powder and are mixed with water for food ready for use. In Sweden, tap water contains metals in varying concentrations. However, the contribution of metals from water has not been included in the intake calculations. The actual intake of the minerals and heavy metals analysed may therefore be higher than is stated in this report.

For the results of the intake calculations and comparisons with health-based guideline values, see appendix 6.

Results and conclusions from the examination

The results for each product group and metal and the action taken are presented below. For an overview of the products where deviations have been identified, see appendix 7. For the background to the selection of risk management measures, see also the section entitled " Risk and benefit assessment."

It should be noted that the products studied were purchased between May and October 2011. Corresponding products available on the market at present may have been changed, for example in terms of composition and labelling.

Minerals and contaminants are present in varying degrees in drinking water, breast milk and other liquids used for diluting products that are not sold ready for use. In this project, the possible contribution of metals from the liquid used to dilute the products has not been taken into account in the intake and content calculations. Actual intakes and contents may therefore be higher than is reported in this project.

In the legislation, the maximum levels for minerals are set per 100 kJ or per 100 kcal in products ready for use. The energy value declared on the packaging and the energy values set out in tables for breast milk and other liquids used to dilute the products were used in calculations of content per 100 kcal in products ready for use (see appendix 5). That is a possible source of error for the results of the examination.

Infant formula and follow-on formula

Infant formula and follow-on formula are given to infants who are not breastfed. The products are produced to meet an infant's nutritional and energy requirements alone and are designed to resemble the nutritional content of breast milk as closely as possible. Unlike infant formula, follow-on formula is not intended to form the child's whole diet, but constitute the main liquid part of the diet, to avoid giving the child ordinary cow's milk. Follow-on formula may be given to children from the age of 6 months.

Nine infant formula products and four follow-on formula products were analysed in the study.

Iron

Deviations from health-based guideline values

There is no recommended intake of iron for children under the age of six months. It is therefore not possible to compare the iron content of the products analysed with the recommended intake (RI) for this age group.

For children over six months of age, other foods also contribute to the iron intake. It is therefore not relevant to assess the extent to which the follow-on formula products analysed contribute to the recommended iron intake for children over the age of 6 months.

There is no health-based guideline value for iron when it comes to risks due to excessive intake and for that reason it is not possible to assess the iron content of the products analysed based on tolerable upper intake.

Deviations from maximum and minimum levels

None of the analysed products in these categories deviated from the established maximum or minimum levels.

Difference between analysed levels and declared content

In all infant formula and follow-on formula products, the difference between the analysed iron levels and the value declared on the packaging was acceptable.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – iron

No deviations from current legislation.

For this product category there is no recommended intake of iron for children under the age of six months or health-based guideline value for iron when it comes to risks due to excessive intake. This means that it is not possible to assess whether the levels found are adequate or whether they entail a risk due to excessive intake.

Livsmedelsverket is taking the following action:

- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values for iron for children should be established.

Copper

Deviations from health-based guideline values

There is no recommended intake of copper for children under the age of six months. It is therefore not possible to compare the copper content in the products analysed with recommended intake (RI) for this age-group.

One follow-on formulae for children from the age of 8 months (Baby Semp 3/ Semper) contained less copper than the recommended intake for children over the age of 6 months (55 per cent of RI). At that age other foods and drinking water also contribute copper, which is why the levels not are considered to be too low.

There is no health-based guideline value for copper when it comes to risks due to excessive intake for children under the age of 12 months. It is therefore not possible to assess the copper content of the products analysed based on the tolerable upper intake (Upper Level, UL) for this age group. However, no product exceeds the UL for children *over* the age of 12 months.

Deviations from maximum and minimum levels

None of the analysed products in these categories deviated from the established maximum or minimum levels.

Difference between analysed levels and declared content

In all infant formula and follow-on formula products, the difference between the analysed copper levels and the values declared on the packaging was acceptable.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – copper

No deviations from current legislation.

There is no recommended intake of copper for children under the age of six months or health-based guideline value for copper when it comes to risks due to excessive intake. This means that it is not possible to assess whether the levels found are adequate or whether they entail a risk due to excessive intake.

Livsmedelsverket is taking the following action:

- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values of copper for children should be established.

Manganese

Deviations from health-based guideline values

All products for children under the age of six months contained manganese, which would give rise to an intake of 500-3,700 per cent of what is considered to be an "adequate intake" (Adequate Intake, AI) for this age group. Despite this, the tolerable daily intake (TDI) for manganese was not exceeded.

One follow-on formulae for children from 8 months of age (Baby Semp 3 Till-skottsnäring [Follow-on formula]/Semper) contained less manganese than the AI for children over the age of six months (30 per cent of AI). Other foods and drinking water also contribute manganese, which is why the content is not considered to be too low.

Deviations from maximum and minimum levels

None of the analysed products in these categories deviated from the maximum or minimum levels.

Difference between analysed levels and declared content

One follow-on formula (Eko tillskottsnäring [follow-on formula] 2/Holle) contained 37 per cent *more* manganese than was declared on the packaging.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelverket's conclusions and actions – manganese

No discrepancies as far as health-based guideline values were concerned.

The fact that the tolerable daily intake was not exceeded even though in some cases the products contained several thousand times more than the "adequate" intake (Adequate Intake, AI) is due to the fact that the AI for children under the age of six months is very low and corresponds to the level of manganese present in breast milk (3 µg per day). For children over the age of six months, AI is two hundred times higher (600 µg per day). Such a significant increase in the need is not due to physiological causes. The current health-based guideline values should therefore be overhauled as soon as possible by the European Food Safety Authority, EFSA, both in terms of nutritional needs and excessive intake.

ESPGHAN (the European Society for Paediatric Gastroenterology, Hepatology and Nutrition) has recommended that the maximum level of manganese in infant formula products should be 50 µg/100 kcal, which represents a reduction by half compared with the current level of 100 µg/100 kcal. Even though the analysed levels do not lead to an intake that exceeds the tolerable daily intake, the maximum levels for manganese should be reviewed. The risks associated with ingesting too much manganese are considered to be greater than the risks associated with ingesting too little.

In one follow-on formula product, the manganese level determined by analysis was more than 35 per cent *higher* than the declared level. If the declared mineral content does not match the actual contents of the product, this would be misleading and could pose a health risk to the children to whom the product is given. For that reason it is important for companies to have procedures to ensure that the value in the nutrition declaration does not deviate to an unacceptable degree from the product's actual mineral content.

Livsmiddelsverket is taking the following action:

- To inform the responsible control authorities of the products where discrepancies exist between the analysed manganese content and the declared manganese content for further processing.
- To inform the EU Commission that the legislation regarding added amounts of manganese in the products needs to be reviewed.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values for manganese that are adapted for children should be established.

Arsenic

Exceeding health-based guideline values

No deviation.

Exceeding maximum levels

There is no legislation establishing maximum levels of arsenic in food, with the exception of drinking water. However, discussions are on-going within the EU concerning the establishment of maximum levels for arsenic in rice. A maximum level is likely to also affect composite rice products.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmiddelsverket's conclusions and actions – arsenic

No deviations from current legislation.

There is no legislation establishing maximum levels of arsenic in food, with the exception of drinking water.

Livsmiddelsverket is taking the following action:

- To provide EFSA with content data from the project, which could form a basis for the European Commission's work to introduce maximum levels for arsenic.

Lead

Exceeding health-based guidance values

Three infant formula products (NAN 1 Modersmjölk ersättning [infant formula] /Nestlé, NAN HA1 Modersmjölk ersättning [infant formula]/Nestlé, Eko Modersmjölk ersättning [infant formula] 1/Holle) contained lead at levels that mean that a child obtaining its full nutritional intake from these products will have an intake of lead of 10-19 per cent of the so-called reference point (RP).

One follow-on formula product (NAN Pro 2 Tillskottsnäring [follow-on formula]/Nestlé) contained lead at levels representing 10-19 per cent of RP and one follow-on formula (Eko Tillskottsnäring [follow-on formula] 2/Holle) 20-30 provided per cent of RP.

Exceeding maximum levels

In accordance with Regulation (EC) No 1881/2006, the maximum level for lead in infant formula and follow-on formula is 0.02 mg/kg. None of the products studied exceeded the maximum level.

Other factors affecting the assessment

All the products contained lead. The levels can probably be reduced through improved own checks.

Conclusions and actions – lead

Lead causes damage to the nervous system and infants are particularly sensitive to these effects since their brains and nervous systems are still developing. The so-called reference point (RP) is the level at which health effects can be observed. No safety margin is therefore included. According to EFSA, the safety margin in relation to RP should be at least a factor of ten, i.e., intake should be below ten per cent of RP. For intakes at these levels, EFSA considers that the risk of adverse health effects is small, but must not be neglected.

Four of the products analysed would give rise to an intake of between 10-20 per cent of RP. One product would give rise to an intake of almost 30 per cent of RP. This is above the level deemed safe by EFSA. However, levels of lead did not exceed the current maximum levels. However, it should be possible for companies to lower the levels through improved own checks.

Livsmedelsverket is taking the following action:

- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for lead.
- To work actively to bring about a reduction of the EU-wide maximum levels for lead in foods intended for infants and young children.

- To provide EFSA with data from the project, which could form a basis for the European Commission's work to revise the maximum levels for lead.

Cadmium

Exceeding health-based guidance values

No deviations.

Exceeding maximum levels

In Regulation (EC) No 1881/2006 maximum levels are only established for the raw materials cereals and soya beans. These maximum levels apply to all categories of foods made from these raw materials. No process factors are established to assess whether the contents measured in infant formula and follow-on formula exceed the maximum levels for the raw materials included. However, discussions are on-going within the EU concerning the establishment of maximum values for cadmium in infant formula.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – cadmium

No deviations from current legislation.

Livsmedelsverket is taking the following action:

- To work actively to bring about the introduction of an EU-wide maximum level for cadmium in foods intended for infants and young children.
- To provide EFSA with data from the project, which could form a basis for the European Commission's work to revise the maximum levels for cadmium.

Cereal-based porridge and gruel for infants and young children

The cereal-based porridges and gruels for infants and young children (Processed Cereal Based Foods, PCBF) analysed were intended for children aged from 4 months to 3 years. Porridge and gruel are important sources of minerals for infants and young children. In view of Swedish eating habits, it can be difficult to find equally nutritious alternatives to give as breakfast, supper and snacks.

Livsmedelsverket currently does not recommend giving porridge or gruel more than three times a day due to children's need for a varied diet.

The study analysed 26 porridge products and 14 gruel products.

Iron

Deviations from health-based guideline values

There is no recommended intake of iron for children under the age of six months. It is therefore not possible to compare the iron content of the products analysed with the recommended intake for this age group. For children over six months of age, other foods also contribute to the iron intake. It is therefore not relevant to assess the extent to which the products analysed contribute to the recommended iron intake.

There is no health-based guideline value for iron when it comes to risks due to excessive intake and for that reason it is not possible to assess the iron content of the products analysed based on tolerable upper intake.

Deviation from the maximum level

None of the analysed products to which iron was added exceeded the maximum level. There is no maximum level established for iron for products to which no iron is added. It may be noted, however, that the iron content in the products to which iron was not added was below the existing maximum level for products with added iron. There is no minimum level established for iron in PCBF, either for quantities added or natural quantities.

Difference between analysed levels and declared content

Three porridges (Fullkornsgröt multikorn [wholemeal porridge, multigrain], Mild havregröt [Mild oat porridge], Risgröt med banan och persika [Rice porridge with banana and peach]/all HiPP) contained, respectively, 38, 38 and 61 per cent *less* iron than was declared on the packaging.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – iron

No discrepancies as far as health-based guideline values were concerned.

In a total of three porridges the level of iron determined by analysis was more than 35 per cent *lower* than the declared level. If the mineral content as declared on the nutrition label on the packaging does not match the actual contents of the product, this would be misleading and would pose a health risk to the children to whom the product is given. For that reason it is important for companies to have procedures to ensure that the value declared on the nutrition label does not deviate to an unacceptable degree from the product's actual mineral content.

Livsmedelsverket is taking the following action:

- To inform the responsible control authorities of the products where discrepancies exist between the analysed content and the declared iron content for further processing.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that a tolerable upper level (Upper Level, UL) for iron should be established.
- To inform the EU Commission that the legislation regarding added amounts and natural amounts of iron in the products needs to be reviewed.

Copper

Deviations from health-based guideline values

There is no recommended intake of copper for children under the age of six months. It is therefore not possible to compare the copper content in the products analysed with recommended intake (RI) for this age-group. For children over six months of age, other foods also contribute to the copper intake. It is therefore not relevant to assess the extent to which the products analysed contribute to the recommended copper intake.

There is no health-based guideline value for copper when it comes to risks due to excessive intake for children under the age of 12 months. It is therefore not possible to assess the copper content of the products analysed based on the tolerable upper intake (Upper Level, UL) for this age group. However, no product, regardless of the age for which it is intended, exceeded the UL for children *over* the age of twelve months.

Deviation from the maximum level

One gruel to which copper is added (Majsvälling [maize gruel]/HiPP) exceeded the maximum level for copper. It contained 49 µg copper/100 kcal. There is no maximum level established for copper for products to which no copper is added.

Among the products to which copper was *not* added, 11 products had a copper content over 40 µg/100 kcal, which is the maximum level in products to which copper is added. The distribution for products exceeding 40 µg/100 kcal is from 43 to 185 µg copper /100 kcal, including the measurement uncertainty. Therefore, among porridge and gruel products, it is the products to which copper is not added that contain the highest levels of copper.

There is no minimum level for copper in PCBF, either for quantities added or natural contents.

Difference between analysed levels and declared content

In all porridge and gruel products, the difference between the analysed copper content and the content declared on the packaging was acceptable.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – copper

No discrepancies as far as health-based guideline values were concerned.

According to the EU Scientific Committee on Foods report of 19 September 1997, copper is not suitable for adding to cereal-based foods and baby food for infants and young children. Since that report was published, EFSA has also revised the limits for tolerable upper intake (Upper Level, UL) for adults and children, which has led to a reduction in the level. No corresponding adjustment of the permitted levels of copper has been made for foods intended for infants and young children.

Livsmedelsverket is taking the following action:

- To inform the responsible control authorities of the product where the analysed content exceeds the established maximum levels for further processing.
- To inform the EU Commission that there is a need to review the legislation regarding added amounts and natural amounts of copper in the products.
- To convey to the European Food Safety Authority, EFSA, that an upper tolerable intake (Upper Level) for copper should be established for children under the age of twelve months.

Manganese

Deviations from health-based guideline values

All products analysed contained manganese. However, in the maize-based varieties the levels were low.

In 27 of the 35 porridge and gruel products for infants analysed, the levels of manganese were such that consumption of three portions per day, or less, leads to a manganese intake in excess of the tolerable daily intake (TDI).

All 5 products intended for children over the age of 12 months contained manganese levels implying that 1-2.5 portions lead to an intake that exceeds the TDI.

Deviation from the maximum level

None of the six products to which manganese is added exceeded the maximum level.

There is no maximum level for manganese for products to which no manganese is added.

Among the porridge and gruel products analysed to which manganese is *not* added, two products exceeded 600 µg manganese/100 kcal, which is the highest level permitted in products to which manganese is added (Eko havregröt [oat porridge], Eko dinkelgröt [spelt porridge]/both from Holle). They contained 1025 µg and 817 µg manganese/100 kcal, respectively.

Therefore, among porridge and gruel products, it is the products to which manganese is not added that contained the highest levels of manganese.

There is no minimum level for manganese in PCBF, either for quantities added or natural content.

Difference between analysed levels and declared content

In all porridge and gruel products, the difference between the analysed manganese content and the content declared on the packaging was acceptable.

Other factors affecting the assessment

Manganese occurs naturally in cereals (including rice) and the levels vary depending on the soil when the raw material is cultivated. Manganese is also present as a micro-nutrient in fertilisers. It should be possible to reduce the manganese content through selection of raw materials.

Most porridge and gruel products contained significant levels of manganese. The only products containing low levels of manganese were maize-based. Advice to parents about varying the kinds of porridge and gruel would therefore not affect children's exposure to manganese to any great extent. The porridge oats and

roasted oat flour analysed also contained significant levels of manganese. This means that it is not possible to reduce exposure to manganese by serving home-made porridge.

Livsmedelsverket's conclusions and actions – manganese

High levels of manganese can affect the nervous system. Infants are particularly sensitive to these effects since their brains and nervous systems are still developing. Young children's ability to regulate the uptake and secretion of manganese is, unlike adults', not fully developed. The point at which this ability is fully developed is not known at present. Young children can therefore be particularly sensitive to the adverse effects of manganese for several reasons.

Most of the porridges and gruels contained levels of manganese that could imply that a child risks exceeding the previously established tolerable daily intake, depending on the number of portions per day. At present there is little research on the health effects of such an intake.

Livsmedelsverket does not consider that there is sufficient justification for advising parents not to give their children cereal- and rice-based porridge and gruel because the scientific basis for both the tolerable daily intake and for what is considered to be an "adequate" intake (Adequate Intake, AI) is too weak. However, it is important for the current health-based guideline values to be revised as soon as possible by the European Food Safety Authority, EFSA, in terms of both nutritional needs and excessive intake.

Most porridge and gruel products contained significant levels of manganese. Manganese occurs naturally in crops, but is also present as a micro-nutrient in fertiliser. Uptake of naturally occurring manganese is pH-dependent and manganese-rich soils with low pH can give rise to significant uptake in crops. Manganese levels should be reduced through selection of raw materials in combination with review of fertiliser use.

Livsmedelsverket is taking the following action:

- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for manganese.
- To convey to the EU Commission that the need for adding manganese to cereal-based porridge and gruel should be investigated along with the need for maximum levels for manganese that also include products to which manganese is not added.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values for manganese that are adapted for children should be established.

Arsenic

Exceeding health-based guidance values

All rice-based gruels analysed¹ (four products) contained arsenic at levels that mean that three portions lead to an intake in excess of the health-based guideline value BMDL₀₁ (Lower confidence limit on the benchmark dose). These are intended for children aged 6-8 months. For three of these, *one* portion leads to an intake in excess of BMDL. The levels in these three products exceeded the level for arsenic in drinking water of 10 micrograms per litre.

Six out of ten rice-based porridges analysed² contained arsenic at levels that mean that *one* portion leads to an intake in excess of BMDL. For the remaining four rice products³, three portions lead to an intake in excess of BMDL. Nine of the rice-based porridges contained arsenic at levels in excess of the maximum levels for drinking water.

Exceeding maximum level

There is no legislation establishing maximum levels of arsenic in food, with the exception of drinking water. However, discussions are going on within the EU concerning the establishment of maximum values for arsenic in rice. A maximum level is likely to also affect composite rice products.

Other factors affecting the assessment

Arsenic is present mainly in rice raw materials. Levels of arsenic vary depending on the place of cultivation and whether water containing arsenic is used for irrigation. Companies can reduce arsenic levels through their selection of rice raw materials.

Livsmedelsverket's conclusions and actions – arsenic

Arsenic is a carcinogen and ingestion should therefore be kept as low as possible. All rice-based porridge and gruel products analysed contained relatively high levels of arsenic.

At present there is no maximum level established for arsenic in food. Arsenic levels are not, however, considered to be so high that there is reason to consider that the products do not conform to the food-safety requirements in accordance with Regulation (EC) No 178/2002, article 14.

¹ Välling Mjölkfri [gruel, milk-free]/EnaGo, Kvällsvälling ris och vete [evening gruel rice and wheat]/Semper, First Flavor/BabyNat, Cereales Cacao/Babybio

² Sinlac specialgröt [special porridge]/Nestlé, Risgröt med apple och mango [rice porridge with apple and mango]/Semper, Cerelac risgröt [rice porridge]/Nestlé, God Natt! Risgröt med grönsaker [rice porridge with vegetables]/HiPP, Organic seven grain cereal/Organix, Eko risgröt [rice porridge]/Holle

³ Banangröt mjölkfri [banana porridge, milk-free]/EnaGo, Banangröt [banana porridge]/Semper, Risgröt med banan och persika [rice porridge with banana and peach]/HiPP, Baby's first food The ultimate four grain porridge/Plum

However, it should be possible to reduce the levels through more careful selection and control of raw materials by the companies concerned.

Porridge and gruel intended for young children is consumed during a short period of the child's life and therefore makes a limited contribution to lifetime exposure to arsenic. On the other hand, other foods also contribute to the arsenic intake and intake should therefore be kept as low as possible. Livsmedelsverket considers that the levels are not so high that there is any reason to advise against giving rice-based porridge and gruel. However, there is justification for issuing the advice that not just rice-based products should be given but that they should be varied with other kinds of products. For gluten intolerant children, they could be varied with maize-based products.

Livsmedelsverket is taking the following action:

- To advise parents to not to give just rice-based porridge and gruel to young children, but to vary it with other kinds.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for arsenic.
- To work actively to bring about the introduction of an EU-wide maximum level for inorganic arsenic in rice.
- To provide EFSA with content data from the project, which could form a basis for the European Commission's work to produce maximum levels for inorganic arsenic in rice.

Lead

Exceeding health-based guidance values

One rice-based gruel (Välling mjölkfri [gruel, milk-free]/EnaGo) for children from 6 months of age contained lead at levels that mean that one portion provides an intake of 42 per cent of the so-called reference point (RP). Three portions lead to an intake exceeding the RP (126 per cent).

One rice-based porridge (Banangröt, mjölkfri [banana porridge, milk-free]/EnaGo) for children from 6 months of age contained lead at levels that mean that one portion leads to an intake of 52 per cent of RP. Two portions lead to an intake exceeding the RP (104 per cent).

Exceeding the maximum level

Sweden has established a national maximum level for lead in baby food (see LIVSFS 2012:3). The maximum level is 0.05 mg/kg for a product ready for use. The analysed levels did not exceed the maximum level.

The EU maximum levels for contaminants in food, including lead, are currently being revised.

Other factors affecting the assessment

All the products contained lead. The levels can probably be reduced through improved own checks.

Livsmedelsverket's conclusions and actions – lead

High levels of lead can affect the nervous system and infants and young children are particularly sensitive to these effects since their brains and nervous systems are still developing. The so-called reference point (RP) is the level at which health effects can be observed. No safety margin is therefore included. According to EFSA, the safety margin in relation to RP should be at least a factor of ten, i.e., intake should be below ten per cent of RP. For intakes at these levels, EFSA considers that the risk of adverse health effects is small, but must not be neglected. However, this applies to total lead exposure from all foods.

Two of the products analysed, both for children from 6 months of age, lead to an intake of between 40-50 per cent of RP per portion. The fact that individual foods contribute so much of RP is not acceptable from a health point of view, particularly since infants are the group most sensitive to lead exposure.

However, the levels do not exceed the national maximum level for lead. In its risk assessment, EFSA has clearly indicated that exposure to lead should be reduced at population level. This has led to discussions at the European Commission to reduce the EU-wide maximum level for lead in foods and there is also reason to revise the national maximum level. However, it will take time before any review is complete and takes effect.

Most of the products analysed contained low levels of lead. It should therefore be possible for the companies whose products contain higher levels of lead to lower the levels through improved own checks.

Livsmedelsverket considers that there is no justification for advising against giving these products because the best-before dates have passed and the products analysed are therefore not on the market. However, the study shows that lead may be present at varying levels in foods intended for infants and young children. There is therefore reason to advise parents not to always choose the same product, but to vary the choice of porridge and gruel.

Livsmedelsverket is taking the following action:

- To advise parents to vary the kinds of porridge and gruel they give young children.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for lead.
- To work actively to bring about the introduction of an EU-wide maximum level for lead in foods intended for infants and young children.

- To provide EFSA with content data from the project, that could form a basis for the European Commission's work to revise the maximum levels for lead.

Cadmium

Exceeding health-based guidance values

Two rice-based gruels (Cereals Cacao/Babybio, Välling mjölkfri [gruel milk-free]/EnaGo), for children aged from 8 and 6 months respectively, contained cadmium at levels that mean that two and three portions, respectively, lead to intakes that exceed tolerable daily intake, TDI.

Three rice-based porridges (Sinlac specialgröt [special porridge]/Nestle, Banangröt mjölkfri [banana porridge, milk-free]/EnaGo, God Natt! Risgröt med grönsaker [rice porridge with vegetables]/HiPP) for children aged 4-6 months contained cadmium at levels that mean that three portions lead to an intake that exceeds TDI. For one of these (God Natt! Risgröt med grönsaker [rice porridge with vegetables]/HiPP), TDI is exceeded with two portions.

Exceeding maximum the level

In accordance with Regulation (EC) No 1881/2006, maximum levels are only established for the raw materials rice, other cereals and soya beans. These maximum levels apply to all food categories. No process factors are established for assessing whether the contents measured in cereal-based foods for infants and young children (PCBF) exceed the maximum levels for the raw materials included.

Discussions are being carried on within the EU to establish a maximum level for cadmium in foods intended for infants and young children.

Other factors affecting the assessment

Cadmium is mainly present in rice and cereals. The levels vary depending on the place of cultivation and whether fertiliser contaminated with cadmium is used for cultivation. Companies can reduce the cadmium content through selection of raw materials.

Livsmedelsverket's conclusions and actions – cadmium

Cadmium can affect the kidneys and bones, but also affects the ability to reproduce and the immune system. It is suspected that cadmium may also be carcinogenic. Five rice-based products contained relatively high levels of cadmium.

Porridge and gruel for young children is consumed during a short period in life and therefore makes a limited contribution to lifetime exposure to cadmium. On the other hand, other foods also contribute cadmium and intake should therefore be kept as low as possible.

However, the levels do not exceed the maximum level for cadmium. A revision of the maximum levels for cadmium is currently being carried out and a discussion is being carried on concerning the specific maximum levels for foods intended for infants and young children. Most of the products analysed contained low levels of cadmium. The companies whose products contained higher levels should therefore be able to reduce the levels through more careful selection of and controls on raw materials.

Livsmedelsverket considers that the levels are not so high that there is any reason to advise against giving these products. However, the study shows that cadmium may be present at varying levels in foods intended for infants and young children. There is therefore reason to advise parents not to always choose the same product, but to vary the choice of porridge and gruel.

Livsmedelsverket is taking the following action:

- To advise parents to vary the kinds of porridge and gruel they give young children.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for cadmium.
- To work actively to bring about the introduction of an EU-wide maximum level for cadmium in foods intended for infants and young children.
- To inform EFSA of the data from the project, which could form a basis for the EU Commission's work to introduce maximum levels for cadmium in food intended for infants and young children.

Foods for special medical purposes for infants and young children

The foods for special medical purposes (FSMP) that were analysed in the project consisted of infant formula and enteral formula intended for infants and young children with various medical conditions such as premature babies, children with allergies to certain foods, metabolic disorders and children who for various reasons are unable to obtain their complete nutritional intake through ordinary food. These products are prescribed by healthcare and medical personnel.

Some FSMP can be used as a sole source of nutrition, whereas others are intended as a complement to other foods. These products are prescribed individually, based on the child's specific needs. Some children receive a product temporarily for a short period of time, whereas for others a product can form their sole source of nutrition for many years.

27 FSMP products were analysed in the study.

Iron

Deviations from health-based guideline values

There is no recommended intake of iron for children under the age of six months. It is therefore not possible to compare the iron content of the products analysed with the recommended intake (RI) for this age group.

Two products designed for total nutrition (MiniMax barnsondnäring [child enteral formula]/Nestle, Neocate advance/SHS) for children aged 6 and 12 months respectively, provided less than the recommended intake for children over the age of six months (68 per cent of RI).

There is no health-based guideline value for risks due to excess intake for all age groups.

Deviations from maximum and minimum levels

No FSMP for infants exceeded the established maximum level for iron. Two FSMP intended for young children (PKU gel/Vitaflo, XP Maxamaid/SHS) exceeded the maximum level. They contained 4.4 mg iron/100 kcal and 4.1 mg iron/100 kcal, respectively.

All FSMP products met the minimum requirements for iron content.

Difference between analysed levels and declared content

One FSMP for infants (PKU Anamix Infant lcp+/SHS) contained 37 per cent *less* iron than was declared on the packaging.

One FSMP for young children (PKU gel/Vitaflo) contained 51 per cent *more* iron than was declared on the packaging.

Other factors affecting the assessment

FSMP adapted to medical conditions can, in accordance with the legislation, exceed the maximum levels for minerals if the purpose of the product makes it necessary to alter the levels of one or more minerals or other nutrients. The Livsmedelsverket group of experts on paediatric nutrition has determined that there is no need to exceed the maximum levels established in the legislation for iron, copper and manganese in FSMP for infants and young children. The assessment of whether levels are exceeded was therefore carried out in comparison with the maximum levels set out in the legislation.

Livsmedelsverket's conclusions and actions – iron

Two products designed to meet the child's entire energy and nutritional needs (MiniMax barnsondnäring [child enteral formula]/Nestlé, Neocate advance/SHS) lead to an intake of 68 per cent of RI for children aged over six months. However, both these products met the minimum requirements for iron content. Infants and young children belong to the groups with the greatest need for iron because they are growing so rapidly. Severe iron deficiency can affect mental development and impair the immune system.

Since iron is actively added to the products, companies can control the content. The companies concerned should therefore consider to adapt the iron content of their products to the recommended intake for children.

The analysed iron content deviated from the maximum level in a total of two FSMP for young children analysed. Companies must have procedures to ensure that their products meet the requirements in the legislation, for example to ensure that the mineral content is kept within the established maximum and minimum levels.

In one FSMP for infants, the analysed level of iron was more than 35 per cent *lower* than the declared content. In one FSMP for young children, the analysed level of iron was more than 35 per cent *higher* than the declared content. If the mineral content declared on the nutrition label on the packaging does not match the actual contents of the product, this would be misleading and could pose a health risk to the children to whom the product is given. For that reason it is important for companies to have procedures to ensure that the values in the nutrition declaration do not deviate to an unacceptable degree from the product's actual mineral content.

Livsmedelsverket is taking the following action:

- To inform the responsible control authorities of the products in which the analysed content exceeds the established maximum levels for iron for further processing.
- To inform the responsible control authorities of the products where discrepancies exist between the analysed content and the declared iron content for further processing.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to falling below recommended intake of iron.
- To convey to the European Commission that there is reason to review the minimum levels of iron in FSMP.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that a tolerable upper level (Upper Level) for iron should be established.

Copper

Exceeding health-based guidance values

There is no recommended intake (RI) of copper for children under the age of six months. It is therefore not possible to compare the copper content in the products analysed with recommended intake for this age-group.

The products for children from six and twelve months of age, which can be used as a sole source of nutrition, lead to an intake of 170-400 per cent of RI for these age groups.

There is no health-based guideline value for copper when it comes to risks due to excessive intake for children under the age of 12 months. It is therefore not possible to assess the copper content of the products analysed based on the tolerable upper intake (Upper Level, UL) for this age group. However, no product intended for children under twelve months of age exceeded the UL for children *over* twelve months of age.

In one product that can be used as a sole source of nutrition (Fresubin Soya Fibre/Fresenius Kabi) for children *over* 12 months of age, the copper content was such that children who have their full nutritional needs met by this product exceed the upper tolerable intake, UL (123 per cent) and receive 400 per cent of the recommended intake of copper. Copper was added to the product.

One product (Fresubin Energy Fibre/Fresenius Kabi) designed for partial nutrition leads to an intake of approximately 150 per cent of UL and nearly 500 per cent of RI if it is given according to the instructions on the packaging (200 ml 2-3 times a day).

Deviations from maximum and minimum levels

No FSMP for infants exceeded the established maximum level for copper.

One FSMP for young children (XP Maxamaid/SHS) exceeded the maximum level for copper. It contained 679 µg copper/100 kcal.

All FSMP products met the minimum requirement for copper content.

Difference between analysed levels and declared content

In all infant FSMP, the difference between the analysed copper content and the content declared on the packaging was acceptable.

Other factors affecting the assessment

FSMP can, in accordance with the legislation, exceed the maximum levels for minerals if the purpose of the product makes it necessary to alter the levels of one or more minerals or other nutrients. The Livsmedelsverket group of experts on paediatric nutrition has determined that there is no need to exceed the maximum levels established in the legislation for iron, copper and manganese in FSMP for infants and young children. The assessment of whether levels are exceeded was therefore carried out in comparison with the maximum levels set out in the legislation.

Livsmedelsverket's conclusions and actions – copper

Copper in high concentrations can cause gastrointestinal problems such as stomach pains, vomiting and diarrhoea. Prolonged/chronic exposure can cause liver damage. Premature babies have a higher risk than full-term infants of suffering from copper deficiency in the neonatal period, which justifies the addition of some copper to FSMP intended for infants. Full-term children do not have the same need for copper.

All products for children of six months of age and over lead to an intake of more than 100 per cent of the recommended intake, some up to 400 per cent. No data showing that children with various medical conditions have a greater need for copper than healthy children is available. There is therefore no reason from a nutritional point of view to add copper over the recommended intake, even if the content is below the current maximum level. In view of this, there is reason to revise the permitted levels of copper in FSMP.

Two products for children from twelve months of age lead to an intake of copper that exceeds the tolerable upper intake level (UL) if dosage instructions are followed, and 400-500 per cent of the recommended intake. These products did not exceed the maximum level for copper. Livsmedelsverket considers that the levels are not so high that there is any reason to advise healthcare and medical personnel and parents against giving children these products. Nevertheless, the companies in question should adjust the copper content of their products so as not to exceed UL.

The analysed copper content deviated from the maximum level in one of the FSMP for young children analysed. Companies must have procedures in place to ensure that their products meet the requirements in the legislation, for example to ensure that the mineral content is kept within the established maximum and minimum levels.

Livsmedelsverket is taking the following action:

- To inform the responsible control authorities of the products in which the copper content determined by analysis exceeds the established maximum levels for copper for further processing.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for copper.
- To convey to the European Commission that there is reason to review the permitted levels of copper in FSMP.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that an upper tolerable intake (Upper Level) for copper should be established for children under the age of twelve months.

Manganese

Exceeding health-based guidance values

Manganese had been added to 25 of the 27 products analysed.

Three products (Neocate Advance/SHS, Resource minimax/Nestle, NutriniKid Multifibre/Nutricia) intended for complete nutrition for children over the age of twelve months lead to an intake lower than what is considered to be an "adequate intake" (Adequate Intake, AI) for this age group (42-90 per cent). Other products for complete nutrition lead to intakes that exceed AI for children in each age group of up to 15,000 per cent.

Seven products for children aged from 0 months⁴ and four products⁵ for children aged from 12 months, intended for complete nutrition, lead to a manganese intake that exceeds tolerable daily intake, TDI.

One product⁶ for children aged from six months and four products⁷ for children aged from 12 months, intended for partial nutrition, leads to a manganese intake over TDI, if the maximum amount stated on the packaging is given.

⁴ Enfamil AR lipil/Mead Johnson, Galactomin 19 formula/SHS, Neocate LCP/Nutricia, Nutramigen 1 lipil/Mead Johnson, Pepti junior/Nutricia, Pregestemil Lipil/Mead Johnson, Profylac/Semper

⁵ Nutrini energy multi fibre drink/Nutricia, Nutrini multi fibre/Nutricia, Fresubin soya fibre/Fresenius Kabi, Isosource junior/Nestlé

Deviations from maximum and minimum levels

No FSMP for infants exceeded the maximum level for manganese.

Two FSMP for young children (PKU gel/Vitaflo, XP Maxamaid/SHS) exceeded the maximum level for manganese. They contained 607 and 673 µg manganese/100 kcal, respectively.

All FSMP products met the minimum requirement for manganese content.

Difference between analysed levels and declared content

Five FSMP for infants (Enfamil Human Milk Fortifier, Nutramigen 2 lipil/both Mead Johnson, FM 85/Nestlé, Neocate advance/SHS, Pepticate/Nutricia) contained 53, 64, 101, 41 and 45 per cent *more* manganese than was declared on the packaging.

Other factors affecting the assessment

Breast milk contains very low levels of manganese. The form of manganese found in breast milk is trivalent, which is absorbed more efficiently than divalent manganese, which is the form that is added to FSMP. Levels of manganese above breast milk levels *can* therefore be justified.

ESPGHAN (the European Society for Paediatric Gastroenterology, Hepatology and Nutrition) has recommended that the maximum level of manganese in infant formula products should be 50 µg/100 kcal, which represents a reduction by half compared with the current level of 100 µg/100 kcal. No data showing that children with various medical conditions have a greater need for manganese than healthy children could be found. It should therefore be possible also to apply the levels recommended by ESPGHAN to infant formula designed for specific medical purposes (FSMP).

FSMP can, in accordance with the legislation, exceed the maximum levels for minerals if the purpose of the product makes it necessary to alter the levels of one or more minerals or other nutrients. The Livsmedelsverket group of experts on paediatric nutrition has determined that there is no need to exceed the maximum levels established in the legislation for iron, copper and manganese in FSMP for infants and young children. The assessment of whether levels are exceeded was therefore carried out in comparison with the maximum levels set out in the legislation.

Livsmedelsverket's conclusions and actions – manganese

High levels of manganese intake can affect the nervous system. Infants are particularly sensitive to these effects since their brains and nervous systems are

⁶ Nutramigen 2 Lipil/Mead Johnson

⁷ Frebini Energy Fibre Drink/Fresenius Kabi, Fresubin Energy Fibre Drink/Fresenius Kabi, PKU-gel/Vitaflo, XP Maxamaid/SHS

still developing. Young children's ability to regulate the uptake and secretion of manganese is, unlike adults', not fully developed. The point at which this ability is fully developed is not known at present. Young children can therefore be particularly sensitive to the adverse effects of manganese for several reasons.

The threshold for “adequate intake” (Adequate Intake, AI) for manganese is poorly substantiated. One of the products analysed leads to an intake corresponding to 100 per cent of AI. This intake means that the tolerable daily intake (TDI) is exceeded by 200 per cent. The fact that the threshold for what is considered to be an adequate intake and what is considered to be the tolerable upper intake overlap is not reasonable. The current health-based guideline values should therefore be revised as soon as possible by the European Food Safety Authority, EFSA, both in terms of nutritional needs and excessive intake. Due to the uncertainty concerning the level for AI, there is therefore no justification for taking action on the three products designed for complete nutrition that lead to intakes below AI.

The amounts of the various nutrients that FSMP may contain is regulated within the EU. However, the current maximum levels are probably set too high when children having their full energy and nutritional needs met by FSMP products exceed TDI. ESPGHAN (the European Society for Paediatric Gastroenterology, Hepatology and Nutrition) has recommended that the maximum level of manganese in infant formula products should be 50 µg/100 kcal, which represents a reduction by half compared with the current level of 100 µg/100 kcal. No data showing that children with various medical conditions have a greater need for manganese than healthy children could be found. It should therefore be possible for ESPGHAN's recommendation to also cover infant formula designed for specific medical purposes (FSMP). EFSA and the European Commission should carry out further research to ascertain what levels are appropriate.

The analysed manganese content deviated from the maximum level in a total of two FSMP for young children analysed. Companies must have procedures to ensure that their products meet the requirements in the legislation, for example to ensure that the mineral content is kept within the established maximum and minimum levels.

In five FSMP for infants, the analysed level of manganese was more than 35 per cent higher than the declared content. If the mineral content declared on the nutrition label does not match the actual content of the product, this would be misleading and could pose a health risk to the children to whom the product is given. For that reason it is important for companies to have procedures in place to ensure that the value declared on the nutrition label does not deviate to an unacceptable degree from the product's actual mineral content.

Livsmedelsverket is taking the following action:

- Healthcare and medical service personnel are temporarily advised, if alternatives are available, not to prescribe the products that contain

manganese in such quantities that TDI may be exceeded or to restrict the quantity of the product until the levels of manganese have been reduced.

- To inform the responsible control authorities of the products in which the analysed manganese content exceeds the established maximum levels for copper for further processing.
- To inform the responsible control authorities of the products where discrepancies exist between the analysed manganese content and the declared manganese content for further processing.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for manganese.
- To convey to the European Commission that there is reason to review the levels of manganese in FSMP.
- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values that are adapted for children should be established.

Arsenic

Exceeding health-based guidance values

One FSMP product (MiniMax barnsondnäring [child enteral formula]/Nestle) from the age of 6 months, that can be given as a complementary food or as the sole source of nourishment, contained arsenic at levels that mean that a child that receives its full nutritional intake from the product has an intake three times higher than the health-based guideline value BMDL (Lower confidence limit on the benchmark dose). This product contains rice flour. The levels in the product were in line with the maximum levels for drinking water.

Exceeding the maximum level

There is no legislation establishing maximum levels of arsenic in food, except for drinking water. However, discussions are going on within the EU concerning the establishment of maximum levels for arsenic in rice. A maximum level is likely to also affect composite rice products.

Other factors affecting the assessment

All the products contained arsenic. Arsenic is present mainly in rice raw materials. The levels vary depending on the place of cultivation and whether water containing arsenic is used for irrigation. Companies can reduce the arsenic content through selection of raw materials.

Livsmedelsverket's conclusions and actions – arsenic

Arsenic is a carcinogen and ingestion should therefore be kept as low as possible. Arsenic can also affect the development of the nervous system and the immune system and young children are particularly sensitive to these effects.

One product contained a relatively high level of arsenic. There is no maximum level for arsenic in food. Arsenic levels are not, however, considered to be so high that there is reason to consider that the products do not conform to the food-safety requirements in accordance with Regulation (EC) No 178/2002, article 14.

Most rice-based FSMP products analysed contained low levels of arsenic. However, it should be possible to reduce the levels through more careful selection and check of raw materials by the companies concerned.

Total arsenic levels have been analysed in Livsmedelsverket's study. The proportion of inorganic arsenic, which is the form that affects health, varies from around 40 to 100 per cent. If the proportion of inorganic arsenic is estimated to represent 50 per cent of the total arsenic content, which is a conservative estimate, the intake exceeds BMDL in any event. Since FSMP products can be used for a long period and levels are high in this product, Livsmedelsverket considers that there is reason to advise healthcare and medical personnel not to prescribe the product as a sole source of nutrition, if possible, until the levels have been reduced.

Livsmedelsverket is taking the following action:

- Healthcare and medical service personnel are temporarily advised, if there are alternatives, not to prescribe MiniMax barnsondnäring [child enteral formula]/Nestlé as a sole source of nutrition until the levels of arsenic have been reduced.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for arsenic.
- To work actively to bring about the introduction of an EU-wide maximum level for inorganic arsenic in rice.
- To provide EFSA with data from the project, which could form a basis for the European Commission's work to introduce maximum levels for arsenic.

Lead

Exceeding health-based guidance values

Ten products⁸ contained lead at levels that mean that children who receive all their nutritional intake from them have an intake of 10-19 per cent of the so-called Reference Point (RP). Six products⁹ lead to an intake of 20-30 percent of RP.

One product (Nutramigen 2 lipil) intended for partial nutrition contained lead levels that lead to an intake of 20 per cent of RP if the child receives the highest quantity stated on the packaging (900 ml).

One product (PKU gel/Vitaflo) designed for partial nutrition for children aged over one year contained lead at levels that mean that one dose (50 grams) provides an intake of 25 per cent of RP.

Exceeding the maximum level

There is no legislation establishing the maximum levels of lead in FSMP. In the absence of maximum levels, the existing maximum levels for infant formula are applied to FSMP intended for infants. The levels measured did not exceed that maximum level. Regarding FSMP for children over 1 year of age, there are no relevant maximum levels for comparison.

Other factors affecting the assessment

All the products contained lead. The levels can probably be reduced through improved own checks.

Livsmedelsverket's conclusions and actions – lead

High levels of lead can affect the nervous system and infants and young children are particularly sensitive to these effects since their brains and nervous systems are still developing. The so-called reference point (RP) is the level at which health effects can be observed. No safety margin is therefore included. According to EFSA, the safety margin in relation to RP should be at least a factor of ten, i.e., intake should be below ten per cent of RP. For intakes at these levels, EFSA considers that the risk of adverse health effects is small, but must not be neglected.

Many of the products analysed lead to an intake of between 10 and 20 per cent of RP and some lead to an intake of almost 30 per cent of RP. This is above the level

⁸ Nutrini energy multi fibre drink/Nutricia, Resource minimax/Nestlé, Pepticate/Nutricia, Neocate LCP/Nutricia, Althéra/Nestlé, Enfamil AR lipil/Mead Johnson, Pepti junior/Nutricia, PreNAN discharge/Nestlé, Enfalac premature/Mead Johnson, Enfamil Human Milk Fortifier/Mead Johnson, NutriniKid multi fibre/Nutricia

⁹ Nutrini multi fibre/Nutricia, Fresubin soya fibre/Fresenius Kabi, Isosource junior/Nestlé, Nutramigen 1 lipil/Mead Johnson, Galactomin 19 formula/SHS, Pregestemil Lipil/Mead Johnson

deemed safe by EFSA. Companies should be able to reduce lead levels through improved own checks.

One product (PKU gel/Vitaflo) had a lead content that means that one dose provides 25 per cent of RP. However, according to information from healthcare and medical services, it is common for children to receive 3-6 doses per day, leading to an intake of up to 150 per cent of RP. The lead levels are judged to be so high that the product cannot be considered to meet the requirements for food safety in accordance with Regulation (EC) no. 178/2002, article 14. The product is considered to pose a possible health risk to children and the lead content should be reduced to the intake level deemed safe by the EFSA.

Livsmedelsverket is taking the following action:

- To contact the responsible control authorities and inform them that the levels of lead in PKU gel/Vitaflo are judged to be so high that the product cannot be considered to meet the requirements for food safety in accordance with Regulation (EC) no. 178/2002, article 14.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for lead.
- To provide EFSA with data from the project, which could form a basis for the European Commission's work to revise the maximum levels for lead.

Cadmium

Exceeding health-based guidance values

No deviation.

Exceeding the maximum level

In accordance with Regulation (EC) No 1881/2006, maximum levels are only established for the raw materials cereals and soya beans. These maximum levels apply to all food categories. No process factors are established to assess whether measured contents in FSMP exceed the maximum levels for the raw material included.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – cadmium

No deviations.

Foods for normal consumption

Four soya drinks, two rice drinks, three oat drinks, one rolled oats product, one roasted oat flour product and one rice porridge were analysed.

Soya, rice- and oat-based drinks to which minerals are added can be used as a milk substitute for children with milk protein allergy or children who do not drink milk for other reasons, children on a vegan diet for example.

For children over one year of age, Livsmedelsverket recommends five dl of milk or plant-based drink with added calcium per day to meet their need for calcium. Infants should not be given large quantities of milk or plant-based alternatives to milk, but should mainly be given breast milk or infant formula.

Iron

Exceeding health-based guidance values

Foods for normal consumption are not specifically adapted for children and neither do they constitute the sole source of iron. It is therefore not relevant to compare the iron content with the recommended intake for children.

There is no health-based guideline value for risks due to excess intake.

Deviations from maximum levels

There are no maximum levels established for iron in foods for normal consumption, either for added or natural content.

Difference between analysed levels and declared content

Iron had not been added to any of the foods for normal consumption analysed. It is therefore not possible to make any comparison between the analysed levels and the levels declared on the packaging.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – iron

No deviations.

Copper

Exceeding health-based guidance values

Foods for normal consumption are not specifically adapted for children and neither do they constitute the sole source of copper. It is therefore not relevant to compare the copper content with the recommended intake for children.

No products contain levels of copper that mean that tolerable upper intake (Upper Level, UL) for children aged over twelve months is exceeded.

Deviations from maximum levels

There are no maximum levels established for copper in foods for normal consumption, either for added or natural content.

Difference between analysed levels and declared content

Copper had not been added to any of the foods for normal consumption analysed. It is therefore not possible to make any comparison between the analysed levels and the levels declared on the packaging.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – copper

No deviations.

Manganese

Exceeding health-based guidance values

Foods for normal consumption are not specifically adapted for children and neither do they constitute the sole source of manganese. It is therefore not relevant to compare the manganese content with "adequate" intake (Adequate Intake, AI) for children.

Of the four soya drinks analysed (Sojadryck/Garant, Sojadryck original + calcium/GoGreen, Soya Drink Natural Fresh/Alpro, Soya Natural/Provamel), they all contained levels of manganese that means that five dl leads to an intake that exceeds tolerable daily intake, TDI. However, the levels were low in both oat- and rice-based drinks.

The roasted oat flour and rolled oats analysed contained levels of manganese that mean that one portion of porridge or gruel made from them provides children with an intake that exceeds the TDI value.

Exceeding maximum levels

There is no maximum level established for manganese in foods for normal consumption, either for added or natural content.

Difference between analysed levels and declared content

Manganese had not been added to any of the foods for normal consumption analysed. It is therefore not possible to make any comparison between the analysed levels and the levels declared on the packaging.

Other factors affecting the assessment

Manganese occurs naturally in soya and cereal raw material, including rice, and the levels vary depending on the soil when the raw material is cultivated. Manganese is also present as a micro-nutrient in fertiliser. It should be possible to reduce the manganese content through selection of raw materials.

The rolled oats and roasted oat flour analysed contained significant levels of manganese, as did the other industrially-manufactured porridge and gruel products analysed. This means that manganese exposure is equally great regardless of whether parents give children industrially-manufactured or home-made porridge/gruel.

Livsmedelsverket's conclusions and actions – manganese

High levels of manganese can affect the nervous system. Infants are particularly sensitive to these effects since their brains and nervous systems are still developing. Young children's ability to regulate the uptake and secretion of manganese is, unlike adults', not fully developed. The point at which this ability is fully developed is not known at present. Young children can therefore be particularly sensitive to the adverse effects of manganese for several reasons.

All the soya drinks analysed contained manganese that mean that children aged 1-3 years who drink five dl of soya drink per day, which is the amount recommended as a milk substitute, exceed the levels for tolerable daily intake, TDI. At present there is little research on the health effects of such an intake.

For infants, an area in which there is a great deal of uncertainty concerning uptake and metabolism of manganese, Livsmedelsverket has already issued advice not to give milk or plant-based alternatives to milk as drinks for nutritional reasons.

The rolled oats and roasted oat flour analysed contained levels of manganese that mean that children who, for example, eat porridge or gruel made from them risk exceeding the TDI value. Manganese occurs naturally in crops, but is also present as a micro-nutrient in fertiliser. Uptake of naturally occurring manganese is pH-dependent and manganese-rich soils with low pH can give rise to significant uptake in crops. Manganese levels should be reduced through selection of raw materials in combination with review of fertiliser use.

Livsmedelsverket considers that the scientific basis for both the TDI and for what is considered to be an "adequate" intake (Adequate Intake, AI) is too weak to justify advice not to give children soya drinks, roasted oat flour or rolled oats. Nevertheless, the current health-based guidance values need to be reviewed by the European Food Safety Authority, EFSA, as soon as possible.

Livsmedelsverket is taking the following action:

- A proposal has been put forward to the European Food Safety Authority, EFSA, that health-based guideline values that are adapted for children should be established.

Arsenic

Exceeding health-based guidance values

Of the two rice-drinks analysed (Risdryck ekologisk [rice drink ecological]/Rice dream, Risdryck naturell [rice drink natural]/Carlshamn) both contained levels of arsenic that mean that 5 dl lead to an intake that is, respectively, three and five times higher than BMDL for children from one year of age (9.8 kg). The levels are two to three times higher than the maximum level for drinking water.

Another rice product (Pama minutris [instant rice]/Quaker) contained levels of arsenic that mean that one portion leads to an intake over BMDL. The levels were above the maximum level for drinking water.

Exceeding maximum levels

There is no legislation establishing maximum levels of arsenic in food, with the exception of drinking water. However, discussions are on-going within the EU concerning the establishment of a maximum level for arsenic in rice. A maximum level is likely to also affect composite rice products.

Other factors affecting the assessment

Arsenic is present in rice raw materials in particular. The levels vary depending on the place of cultivation and whether water containing arsenic is used for irrigation. Other studies of rice drinks show similar levels of arsenic (Contaminants and minerals in foods for infants and young children – risk and benefit assessment, Livsmedelsverkets rapport 1/2013, part 2 (3)). Companies can reduce arsenic levels through their selection of rice raw materials.

Advice concerning giving rice drinks to young children is currently issued in the UK and Denmark because of their arsenic content. In the UK, it is advised that children under the age of five should not be given rice drinks. In Denmark, it is advised that young children should avoid large quantities of rice drinks and children under 10 kg in particular should not be given rice drinks as a milk substitute.

Livsmedelsverket's conclusions and actions – arsenic

It is common for children over one year of age who do not drink ordinary cows' milk due to milk protein allergy or a vegan diet, for example, to be given vegetable drinks as substitutes. These drinks are consumed over a long period, perhaps throughout the child's whole life. Arsenic can cause adverse health effects after

prolonged exposure. Arsenic can also affect the development of the nervous system and the immune system and young children are particularly sensitive to these effects.

Total arsenic levels have been analysed in Livsmedelsverket's study. The proportion of inorganic arsenic, which is the form that affects health, varies from around 40 to 100 per cent. If the proportion of inorganic arsenic is estimated to make up 50 per cent of total arsenic, which is a conservative estimate, children under 20 kg cannot drink five dl of these drinks without exceeding BMDL. Children under 20 kg corresponds to an age of around five or six years. Livsmedelsverket therefore considers that there is reason to advise against giving these products to children under the age of six until the levels have been reduced.

There is no maximum level established for arsenic in food. However, discussions on the maximum levels for arsenic in rice are on-going within the EU, but it will take time for legislation to be adopted and to take effect. Arsenic levels are not, however, considered to be so high that there is reason to consider that the products do not conform to the food-safety requirements in accordance with Regulation (EC) No 178/2002, article 14. The products analysed are not specifically intended for children and for that reason it is not possible to impose such strict requirements on them as on baby food products.

Livsmedelsverket is taking the following action:

- To advise parents not to give rice drinks to children under the age of six.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for arsenic.
- To work actively to bring about the introduction of an EU-wide maximum level for inorganic arsenic in rice.
- To provide EFSA with data from the project, which could form a basis for the European Commission's work to establish maximum levels for inorganic arsenic in rice.

Lead

Exceeding health-based guidance values

No deviations.

Exceeding maximum levels

In accordance with Regulation (EC) No 1881/2006, maximum levels are only established for the raw materials cereals and dried leguminous plants (0.2 mg/kg). These maximum levels apply to all food categories. No process factors are established for assessing whether the measured contents in the products for normal consumption analysed exceed the maximum level for raw material

included. For that reason, it was not possible to assess the levels determined by analysis against any applicable maximum levels.

Other factors affecting the assessment

No other factors affected the assessment.

Livsmedelsverket's conclusions and actions – lead

No deviations.

Cadmium

Exceeding health-based guidance values

Two of the four soya drinks analysed (Sojadryck original + Kalcium [soya drink original + calcium]/GoGreen, Sojadryck [soya drink]/Garant) contained cadmium at levels that mean that five dl of the products leads to an intake that equals or exceeds tolerable daily intake (TDI).

One other product (Skrädmjöl [roasted oat flour]/Saltå Kvarn) contained cadmium at levels that mean that children who eat three portions of porridge or gruel made from it receive an intake that exceeds TDI.

Exceeding maximum levels

In accordance with Regulation (EC) No 1881/2006, maximum levels are only established for the raw materials cereals and soya beans. These maximum levels apply to all categories of foods that are made from these raw materials. No process factors are established for assessing whether the measured contents in the products for normal consumption analysed exceed the maximum level for raw material included. For that reason, it was not possible to assess the levels determined by analysis against any applicable maximum levels.

Discussions on stricter maximum values for cadmium in food are being carried on within the EU.

Other factors affecting the assessment

Cadmium is mainly present in soya and cereal raw materials, including rice. The levels vary depending on the place of cultivation and whether fertiliser contaminated with cadmium is used for cultivation. Companies can reduce the cadmium content through selection of raw materials.

Livsmedelsverket's conclusions and actions – cadmium

Cadmium can affect the kidneys and bones, but also affects the ability to reproduce and the immune system. It is suspected that cadmium may also be carcinogenic. Two soya-based drinks and roasted oat flour contained cadmium in concentrations that mean that five dl or three portions of porridge or gruel made from the

roasted oat flour analysed lead to an intake that exceeds the tolerable daily intake (TDI) for cadmium.

It is common for children over one year of age who do not drink ordinary cows' milk due to milk protein allergy or a vegan diet, for example, to be given vegetable drinks as substitutes. These drinks are consumed over a long period, perhaps throughout the child's whole life. Other foods also contribute cadmium and intake should therefore be kept as low as possible.

A review of the maximum levels for cadmium in food is currently being carried on. However, it will take time before any review is complete and takes effect. Most of the products analysed contained low levels of cadmium. The companies whose products contained higher levels should therefore be able to reduce the levels through more careful selection of and controls on raw materials.

Livsmedelsverket considers that there is no justification for advising against giving these products because the best-before dates have passed and the products analysed are therefore not on the market. However, the study shows that cadmium may be present at varying levels in soya drinks. There is therefore reason to advise parents not to always choose the same product for children, but to vary the choice of vegetable drinks.

Livsmedelsverket is taking the following action:

- To advise parents not to always give the same product to children but to vary among different brands of vegetable drinks.
- To inform the companies concerned of the results of the analysis and Livsmedelsverket's conclusions with regard to exceeding health-based guideline values for cadmium.
- To work actively to bring about a reduction in the EU-wide maximum levels for cadmium.
- To provide EFSA with content data from the project, which could form a basis for the European Commission's work to revise the maximum levels for cadmium.

References

Contaminants and minerals in foods for infants and young children – analytical results, Livsmedelsverkets rapport 1/2012, part 1 (3)

Contaminants and minerals in foods for infants and young children – risk and benefit assessment, Livsmedelsverkets rapport 1/2012, part 2 (3).

Appendix 1

List of legislation

Swedish National Code of Statutes	Title
2006:813	The Food Ordinance
SLVFS 1993:21	Livsmedelsverket regulation on the nutrition label
SLVFS 1997:27	Livsmedelsverket regulation on cereal-based foods and baby foods for infants and young children
SLVFS 2000:14	Livsmedelsverket regulation on foods for particular nutritional uses
SLVFS 2000:15	Livsmedelsverket regulation on food for special medical purposes
LIVSFS 2004:27	Livsmedelsverket regulation on labelling and presentation of food
LIVSFS 2008:2	Livsmedelsverket regulation on infant formula and follow-on formula
LIVSFS 2012:3	Livsmedelsverket regulation on contaminants in food
EU Regulations	
178/2002	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
1881/2006	Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
1925/2006	Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods
953/2009	Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses
1170/2009	Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements
EU Directives	
90/496/EEC	Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs
1999/21/EC	Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes
2000/13/EC	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
2006/125/EC	Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children
2006/141/EC	Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-on formula and amending Directive 1999/21/EC
2009/39/EC	Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses

Appendix 2

Permitted levels for certain minerals in food for infants and young children (ready for use)

Product category		Infant formula	Follow-on formula	Baby food		FSMP	
				Cereal-based + other	"Milks for small children"	Infants (up to 1 year)	Persons from 1 year
Legislation		LIVSFS 2008:2 (2006/141/EC)		SLVFS 1997:27 (2006/125/EC)	LIVSFS 2000:14 (2009/39/EC)	SLVFS 2000:15 (1999/21/EC)	
						LIVSFS 2008:2 (2006/141/EC)	
Cu	Minimum-maximum content (µg/100 kcal)	35-100	35-100			20-120 ³	60-500 ³
	Total maximum content, if added (µg/100 kcal)			40			
Fe	Minimum-maximum content (mg/100 kcal)	0.3-1.3 ¹ 0.45-2 ²	0.6-2 [□] 0.9-2.5 ²			0.5-2 ³	0.5-2.0 ³
	Total maximum content, if added (mg/100 kcal)			3			
Mn	Minimum-maximum content (µg/100 kcal)	1-100	1-100			1-100 ³	50-500 ³
	Total maximum content, if added (µg/100 kcal)			600			

FSMP: Food for special medical purposes

¹ infant formula manufactured from cows' milk proteins or protein hydrolysates.

² infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins.

³ FSMP that are adapted to a particular medical condition may be permitted to deviate in terms of the content of one or more nutrients if the purpose of the product makes it necessary (according to the Livsmedelsverket group of experts on paediatric nutrition, there is no need to add quantities of the minerals in question that exceed the specified maximum permitted levels).

Appendix 3

Maximum permitted levels for certain contaminants in food for infants and young children (ready for use)

Product category		Infant formula mg/kg	Follow-on formula mg/kg	Baby food		FSMP	
				Cereal-based + other mg/kg	"Milks for small children" mg/kg	Infants (up to 1 year)	Persons from 1 year
Legislation		Regulation (EC) No 1881/2006		LIVSFS 2012:3			
Cd	There are maximum levels for raw materials that apply to all food categories	none exists*	none exists*	none exists	none exists	none exists	none exists
Pb		0.020	0.020	0.05	0.05	none exists	none exists
As	There is no maximum level that apply to all food categories	none exists	none exists	none exists	none exists	none exists	none exists

FSMP: Food for special medical purposes

*There is a draft proposal on Regulation (EC) 1881/2006 for a maximum level for cadmium of 0.01 mg/kg for infant formula manufactured from cows' milk proteins or protein hydrolysates and a maximum level of 0.02 mg/kg for infant formula manufactured from soya protein isolate, alone or in a mixture with cows' milk proteins.

Appendix 4

Products in which the mineral content determined by analysis differs by more than 35 per cent from the declared content (product as sold)¹

Product name	Company	ID	Iron			Manganese		
			Analysed (mg/100g)	Declared (mg/100g)	A/D	Analysed (µg/100g)	Declared (µg/100g)	A/D
Follow-on formula								
Eko tillskotts näring 2 [follow-on formula]	Holle	M52				133	97	1.37
PCBF - Porridge								
Fullkornsgröt multikorn [wholemeal porridge multigrain]	HiPP	M39	2.6	4.2	0.62			
Mild havregröt [mild porridge oats]	HiPP	M22	2.5	4	0.62			
Risgröt med banan och persika [rice porridge with banana and peach]	HiPP	M59	1.3	3.3	0.39			
FSMP for infants								
Enfamil Human Milk Fortifier	Mead Johnson	M61				538	352	1.53
FM 85	Nestlé	M60				261	130	2.01
Nutramigen 2 lipil	Mead Johnson	M48				458	279	1.64
Pepticate	Nutricia	M54				80	55	1.45
PKU anamix infant lcp+	SHS	M85	5.1	8.1	0.63			
FSMP for young children								
Neocate advance	SHS	M81				282	200	1.41
PKU gel (pooled sample of different flavours)	VitaFlo	M28	15.1	10	1.51			

¹ In all products analysed, the difference between the copper content determined by analysis and the content declared on the packaging was acceptable.

Appendix 5

Comparisons between the levels determined by analysis in products ready for use and the applicable maximum and minimum levels

Infant formula – ready for use

Product name	Form offered for sale ⁴	Company	ID no.	N	Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal		Lead mg/kg	
					5	±16% ⁶	5	±15% ⁶	5	±15% ⁶	±40% ⁵	
					Permitted levels ^{1,2}		0.3-1.3 ³		35-100		1-100	0.02
BabySemp 1 Modersmjölksersättning [infant formula]	RfU	Semper	M30	3	0.6	0.5-0.7	56	48-64	4	3-5	0.0001-0.0003	
BabySemp 1 Modersmjölksersättning [infant formula]	P	Semper	M2	3	0.6	0.5-0.7	60	51-69	7	6-8	0.0001-0.0003	
BabySemp 2 Lemolac modersmjölksersättning [infant formula]	P	Semper	M14	3	0.9	0.8-1.0	75	64-86	12	10-14	0.0002-0.0005	
ECO 1 Modersmjölksersättning [infant formula]	P	HiPP	M15	3	0.9	0.8-1.0	51	43-59	15	13-17	0.0002-0.0004	
ECO 2 Modersmjölksersättning [infant formula]	P	HiPP	M16	3	1.0	0.8-1.2	59	50-68	13	11-15	0.0002-0.0004	
Organic Infant milk	P	BabyNat	M80	2	1.1	0.9-1.3	57	48-66	8	7-9	0.0002-0.0004	
Eko Modersmjölksersättning [infant formula] 1	P	Holle	M92	3	0.5	0.4-0.6	52	44-60	16	14-18	0.0002-0.0005	
NAN 1 Modersmjölksersättning [infant formula]	P	Nestlé	M10	3	0.6	0.5-0.7	54	46-62	24	20-28	0.0003-0.0007	
NAN HA 1 Modersmjölksersättning [infant formula]	P	Nestlé	M11	3	0.9	0.8-1.0	77	65-89	20	17-23	0.0002-0.0005	

¹ LIVSFS 2008:2 (Directive 2006/141/EC)

² Maximum and minimum total amount

³ The levels apply to infant formula manufactured from cows' milk proteins or protein hydrolysate. Specific levels (0.45-2 mg/100 kcal) apply to products manufactured from soya protein isolate, alone or in combination with milk protein. However, none of the products analysed contained soya protein isolate.

⁴ P = powder, RfU = ready for use

⁵ Calculated on the basis of data determined by analysis and energy value provided in the nutrition labelling on the packaging

⁶ Expanded measurement uncertainty (k=2, 95% confidence level)

Follow-on formula – ready for use

					Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal		Lead mg/kg
					0.6-2 ³		35-100		1-100		0.02
Product name	Form offered for sale ⁴	Company	ID no.	N	Permitted levels ^{1,2}		Permitted levels ^{1,2}		Permitted levels ^{1,2}		Permitted levels ^{1,2}
					⁵	±16% ⁶	⁵	±15% ⁶	⁵	±15% ⁶	±40% ⁶
BabySemp 3 Tillskottsnäring [follow-on formula]	P	Semper	M13	3	1.4	1.2-1.6	50	43-58	54	46-62	0.0003-0.0007
Eko tillskottsnäring [follow-on formula] 2	P	Holle	M52	3	1.2	1.0-1.4	55	47-63	27	23-31	0.0007-0.0016
NAN Pro 2 Tillskottsnäring [follow-on formula]	P	Nestlé	M36	3	1.4	1.2-1.6	72	61-83	19	16-22	0.0004-0.0008
Optima Organic Follow-on-milk	P	BabyNat	M76	2	1.2	1.0-1.4	61	52-70	7	6-8	0.0002-0.0004

¹ LIVSFS 2008:2 (Directive 2006/141/EC)

² Maximum and minimum total amount

³ The permitted level applies to follow-on formula manufactured from cows' milk proteins or protein hydrolysate. Specific levels (0.9 to 2 mg/100 kcal) apply to products manufactured from soya protein isolate, alone or in combination with milk protein. However, none of the products analysed contained soya protein isolate.

⁴ P = powder, RfU = ready for use

⁵ Calculated on the basis of data determined by analysis and energy value provided in the nutrition labelling on the packaging

⁶ Expanded measurement uncertainty (k=2, 95% confidence level)

PCBF – porridge –ready for use – all

Green filling indicates that the mineral is added to the product.

Product name	Form offered for sale ³	Company	ID no.	N	Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal		Lead mg/kg
					⁴	±16% ⁵	⁴	±15% ⁵	⁴	±15% ⁵	±40% ⁵
<i>Maximum level</i> ^{1,2}					3		40		600		0.05
Wholemeal porridge											
Bio-Babybrei Grieß	P	Holle	87	2	0.7	0.6-0.8	95 ⁶	81-109	705	599-811	0.0002-0.0004
Eko dinkelgröt [spelt porridge]	P	Holle	M65	3	0.9	0.8-1.0	146 ⁶	124-168	817 ⁶	694-940	0.0002-0.0004
Eko havregröt [oat porridge]	P	Holle	M63	3	0.8	0.7-0.9	95 ⁶	81-109	1025 ⁶	871-1179	0.0002-0.0005
Fruktgröt fullkorn [fruit porridge wholemeal]	P	Semper	M4	3	1.9	1.6-2.2	35	30-40	202	172-232	0.0004-0.0009
Fullkornsgröt med äpple [wholemeal porridge with apple]	P	HiPP	M17	3	1.1	0.9-1.3	40	34-46	207	176-238	0.0008-0.00184
Fullkornsgröt multikorn [wholemeal porridge multigrain]	P	HiPP	M39	3	0.6	0.5-0.7	42	36-48	285	242-328	0.0002-0.0006
Mild fullkornsgröt [mild wholemeal porridge]	P	Nestlé	M32	3	2.5	2.1-2.9	37	31-43	286	243-329	0.0005-0.0012
Mild fullkornsgröt [mild wholemeal porridge]	P	HiPP	M42	3	1.3	1.1-1.5	43	37-49	305	259-351	0.0003-0.0006
Mild fullkornsgröt [mild wholemeal porridge]	P	Semper	M33	3	1.8	1.5-2.1	43	37-49	312	265-359	0.0003-0.0007
Mild havregröt [mild porridge oats]	P	HiPP	M22	3	0.6	0.5-0.7	31	26-36	206	175-237	0.0003-0.0006
Musligröt Päron-banan [muesli porridge pear-banana]	P	Nestlé	M9	3	2.2	1.8-2.6	51 ⁶	43-59	418	355-481	0.0012-0.00274
Eko hirsgröt [millet porridge]	P	Holle	M64	3	0.8	0.7-0.9	161 ⁶	137-185	205	174-236	0.0005-0.0012
Organic seven grain cereal ⁷	P	Organix	M51	3	0.40	0.34-0.46	50 ⁶	42.5-58	339	288-390	0.0003-0.0007

¹ SLVFS 1997:27 (Directive 2006/125/EC)

² Maximum total amount if added

³ P = powder, KF = product ready for consumption

⁴ Calculated on the basis of data determined by analysis and energy value according to the nutrition label on the packaging

⁵ Expanded measurement uncertainty (k=2, 95% confidence level)

⁶ The mineral is not added to this product. However, the content (including the measurement uncertainty) exceeds the existing permitted level for products to which the mineral in question is added.

⁷ Diluted according to the manufacturer's instructions with infant formula, breast milk or other suitable liquids. The calculations have been carried out on infant formula with an energy value of 65 kcal/100ml (in accordance with LIVSFS 2008:2, the energy content must be 60-70 kcal/100ml). Any contribution of minerals from the water used to dilute the product has not been taken into consideration.

Rice porridge											
Baby's first food The ultimate four grain porridge ¹	P	Plum	M90	2	0.54	0.45-0.63	75 ⁶	64-86	294	250-338	0.0004-0.0009
Banangröt [banana porridge]	P	Semper	M3	3	1.8	1.5-2.1	23	20-26	105	89-121	0.0004-0.0009
Banangröt mjölkfri [banana porridge, milk-free]	P	EnaGo	M23	3	1.4	1.2-1.6	89 ⁶	76-102	348	296-400	0.0105-0.0246
Cerelac risgröt [rice porridge]	P	Nestlé	M31	3	1.8	1.5-2.1	23	20-26	158	134-182	0.0003-0.0006
First organic wholegrain baby rice ²	P	Organix	M56	3	0.23	0.19-0.27	36	31-41	285	242-328	0.0003-0.0008
God natt! Risgröt med grönsaker [rice porridge with vegetables]	RfU	HiPP	M40	3	0.18	0.16-0.21	42	36-48	150	128-173	0.0011-0.0026
Eko risgröt [rice porridge]	P	Holle	M91	3	0.26	0.22-0.31	53 ⁶	45-61	691	587-795	0.0002-0.0004
Risgröt med banan och persika [rice porridge with banana and peach]	P	HiPP	M59	3	0.30	0.25-0.35	30	26-35	69	59-79	0.0009-0.0021
Risgröt med äpple och mango [rice porridge with apple and mango]	P	Semper	M25	3	2.0	1.7-2.3	18	15-21	83	71-95	0.0008-0.0018
Sinlac specialgröt [special porridge]	P	Nestlé	M12	3	2.3	1.9-2.7	120 ⁶	102-138	455	387-523	0.0008-0.0019
Other porridge											
Cerelac fruktgröt banan apelsin [fruit porridge, banana orange]	P	Nestlé	M37	3	1.7	1.4-2.0	40	34-46	169	144-194	0.0004-0.0009
Dinkelgröt naturell [spelt porridge, natural]	P	Nestlé	M86	2	2.4	2.0-2.8	43	37-47	408	347-469	0.0003-0.0006
Mild havregröt [mild porridge oats]	P	Semper	M35	3	1.9	1.6-2.2	24	20-28	166	141-191	0.0013-0.0030

¹ Diluted according to the manufacturer's instructions with infant formula, breast milk or other suitable liquid and water (1:1)

² Diluted according to the manufacturer's instructions with infant formula, breast milk or other suitable liquid. The calculations have been carried out on infant formula with an energy value of 65 kcal/100ml (in accordance with LIVSFS 2008:2, the energy content must be 60-70 kcal/100ml). Any contribution of minerals from the water used to dilute the product has not been taken into consideration.

PCBF – gruel – ready for use

Green filling indicates that the mineral is added to the product.

Product name	Form offered for sale ³	Company	Maximum level ^{1,2}		Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal		Lead mg/kg	
			ID no.	N	3		40		600		0.05	
					⁴	±16% ⁵	⁴	±15% ⁵	⁴	±15% ⁵	±40% ⁵	
Wholemeal gruel												
Drickfärdig mild fullkornsvälling [ready to drink mild wholemeal gruel]	RfU	Semper	M34	3	1.3	1.1-1.5	15	13-17	105	89-121	0.0001-0.0003	
Fullkornsvälling [wholemeal gruel]	P	Nestlé	M18	3	1.8	1.5-2.1	36	31-41	221	188-254	0.0003-0.0007	
Fullkornsvälling havre vete råg [wholemeal gruel oat wheat]	P	Semper	M5	3	2.1	1.8-2.4	34	29-39	225	191-259	0.0002-0.0004	
Mild fullkornsvälling [mild wholemeal gruel]	P	Semper	M8	3	2.0	1.7-2.3	25	21-29	199	169-229	0.0002-0.0004	
Mild fullkornsvälling havre [mild wholemeal gruel, oats]	P	Nestlé	M21	3	1.7	1.4-2.0	26	22-30	217	184-250	0.0018-0.0043	
Maize gruel												
Låglaktos majsvälling [low lactose maize gruel]	P	Nestlé	M19	3	1.6	1.3-1.9	6	5-7	10	12/9	0.0004-0.0010	
Majsvälling [maize gruel]	P	Semper	M20	3	1.8	1.5-2.1	10	12/9	32	27-37	0.0002-0.0004	
Majsvälling [maize gruel]	P	HiPP	M96	2	0.8	0.7-0.9	49 ⁶	42-56	12	10-14	0.0002-0.0004	
Majsvälling [maize gruel]	P	Nestlé	M7	3	1.5	1.3-1.7	3	2.6-3.5	5	4-6	0.0002-0.0004	
Rice gruel												
Céréales Cacao ⁷	P	Babybio	M74	3	0.22	0.18-0.26	51	43-59	169	144-194	0.0002-0.0005	
First flavor ⁸	P	Babynat	M73	3	0.08	0.07-0.09	26	22-30	138	117-159	0.0001-0.0003	
Kvällsvälling ris och vete [evening gruel, rice and wheat]	P	Semper	M55	3	1.8	1.5-2.1	16	14-18	79	67-91	0.0004-0.0008	
Välling mjölkfri [gruel, milk-free]	P	EnaGo	M24	3	2.5	2.1-2.9	58 ⁹	49-67	230	196-265	0.0041-0.0096	
Oat gruel												
God natt mild havrevälling [God natt mild oat gruel]	P	Nestlé	M6	3	1.8	1.5-2.1	18	15-21	176	150-202	0.0004-0.0008	

¹ SLVFS 1997:27 (Directive 2006/125/EC)

² Maximum total amount if added

³ P = powder, RfU = ready for use

⁴ Calculated on the basis of data determined by analysis and energy value provided in the nutrition labelling on the packaging

⁵ Expanded measurement uncertainty (k=2, 95% confidence level)

⁶ Exceeds the maximum level (measurement uncertainty taken into consideration)

⁷ Diluted according to the manufacturer's instructions with breast milk or follow-on formula. The calculations have been carried out on follow-on formula with an energy value of 65 kcal/100ml (according to LIVSFS 2008:2, the energy content must be 60-70 kcal/100ml) 100ml=103 g. Any contribution of minerals from the water used to dilute the product has not been taken into consideration.

⁸ Diluted with "infant formula", breast milk or another suitable liquid.

⁹ The mineral is not added to this product. However, the content (including the measurement uncertainty) exceeds the maximum level for products to which the mineral in question is added.

FSMP for infants –ready for use

Product name	Form offered for sale ⁴	Company	Permitted level ^{1,2,3}				Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal	
			ID no.	N	0.5-2		20-120		1-100			
					⁵	± 16% ⁶	⁵	± 15% ₆	⁵	± 15% ₆		
Althéra	P	Nestlé	M75	2	1.0	0.8-1.2	87	74-100	7	6-8		
Enfalac premature	P	Mead Johnson	M98	1	1.3	1.1-1.5	99	84-114	14	12-16		
Enfamil AR lipil	P	Mead Johnson	M78	2	1.1	0.9-1.3	76	65-87	64	54-74		
Enfamil Human Milk Fortifier ⁷	P	Mead Johnson	M61	1	1.6	1.3-1.9	63	54-72	17	15-20		
FM 85 ⁸	P	Nestlé	M60	1	1.2	1.0-1.4	40	34-46	14	12-16		
Galactomin 19 formula	P	SHS	M69	2	0.6	0.5-0.7	58	49-67	59	50-68		
Minimax barnsondnäring [child tube-feeding]	RfU	Nestlé	M82	2	0.8	0.7-0.9	91	77-105	63	54-72		
Neocate LCP	P	Nutricia	M72	2	1.1	0.9-1.3	69	59-79	68	58-78		
Nutramigen 1 lipil	P	Mead Johnson	M1	3	1.8	1.5-2.1	71	60-82	74	63-85		
Nutramigen 2 lipil	P	Mead Johnson	M48	3	1.8	1.5-2.1	82	70-94	98	83-113		
Pepti junior	P	Nutricia	M79	2	1.1	0.9-1.3	57	48-66	66	56-76		
Pepticate	P	Nutricia	M54	3	0.8	0.7-0.9	70	60-81	17	14-20		
PKU anamix infant lcp+	P	SHS	M85	2	1.1	0.9-1.3	87	74-100	102	87-117		
Pregestimil lipil	P	Mead Johnson	M99	1	1.8	1.5-2.1	79	67-91	71	60-82		
PreNAN discharge	P	Nestlé	M95	2	1.1	0.9-1.3	80	68-92	17	14-20		
Profylac	P	Semper	M103	2	1.0	0.8-1.2	67	57-77	75	64-86		

¹ SLVFS 2000:15 (Directive 1999/21/EC)

² Maximum and minimum total amount

³ The maximum permitted levels may be exceeded if the purpose of the product makes it necessary to alter the composition. According to Livsmedelsverket's expert group on paediatric nutrition, there is no need to add quantities of the minerals in question that exceed the specified maximum permitted levels.

⁴ P = powder, RfU = product ready for consumption

⁵ Calculated on the basis of data determined by analysis and energy value provided in the nutrition labelling on the packaging

⁶ Expanded measurement uncertainty (k=2, 95% confidence level)

⁷ Added to breast milk. 2.84g to 100 ml (103 g) breast milk, energy value of breast milk, 75 kcal/100 g (Livsmedelsverket food database).

⁸ Added to breast milk. Maximum 5 g to 100 ml (103 g) breast milk, energy value of breast milk, 75 kcal/100 g (Livsmedelsverket food database).

FSMP for young children (1-3 years) – ready for use

Product name	Form offered for sale ⁴	Company	Permitted levels ^{1,2,3}		Iron mg/100 kcal		Copper µg/100 kcal		Manganese µg/100 kcal	
			ID no.	N	0.5-2.0		60-500		50-500	
					⁵	±16% ⁶	⁵	±15% ⁶	⁵	±15% ⁶
Frebini energy fiber drink (chocolate flavour)	RfU	Fresenius Kabi	M97	1	0.9	0.8-1.0	103	88-118	117	99-135
Fresubin energy fibre (pooled sample of different flavours)	RfU	Fresenius Kabi	M26	3	1.3	1.1-1.5	193	164-222	255	217-293
Fresubin soya fibre	RfU	Fresenius Kabi	M70	2	1.2	1.0-1.4	137	116-158	251	213-289
Isosource junior	RfU	Nestlé	M71	2	0.7	0.6-0.8	83	71-95	136	116-156
Neocate advance	P	SHS	M81	2	0.7	0.6-0.8	71	60-82	71	60-82
Nutrini energy multi fiber	RfU	Nutricia	M83	2	0.9	0.8-1.0	74	63-85	134	114-154
Nutrini multi fiber	RfU	Nutricia	M84	2	1.0	0.8-1.2	76	65-87	162	138-186
NutriniKid multi fibre (pooled sample of different flavours)	RfU	Nutricia	M27	3	0.9	0.8-1.0	86	73-99	119	101-137
PKU gel (pooled sample of different flavours)	P	Vitaflo	M28	3	4.4 ⁷	3.7-5.1	233	198-268	607 ⁷	516-698
Resource minimax (pooled sample of different flavours)	RfU	Nestlé	M29	3	0.9	0.8-1.0	84	71-97	63	54-72
XP Maxamaid (pooled sample of different flavours)	P	SHS	M53	3	4.1 ⁷	3.4-4.8	679 ⁷	577-781	673 ⁷	572-774

¹SLVFS 2000:15 (Directive 1999/21/EC)

² Maximum and minimum total amount

³ The maximum permitted levels may be exceeded if the purpose of the product makes it necessary to alter the composition. According to Livsmedelsverket's expert group on paediatric nutrition, there is no need to add quantities of the minerals in question that exceed the specified maximum levels.

⁴ P = powder, RfU = ready for use

⁵ Calculated on the basis of data determined by analysis and energy value provided in the nutrition labelling on the packaging

⁶ Expanded measurement uncertainty (k=2, 95% confidence level)

⁷ Exceeds the maximum level (measurement uncertainty taken into consideration)

Appendix 6

Arsenic (As)

Table 1. Estimated daily intake of arsenic from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding.

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml /day)	As concentration (µg /kg)	As intake (µg/kg bw/day)
Infant Formula						
NAN 1 Modersmjölksersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	0.78	0.13
NAN HA 1 Modersmjölksersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	0.71	0.12
BabySemp 2 Lemolac modersmjölksersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	0.69	0.08
ECO 1 Modersmjölksersättning (<i>ECO 1 infant formula</i>)	HiPP	0	4.2	700	0.89	0.15
ECO 2 Modersmjölksersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	0.77	0.09
BabySemp 1 Modersmjölksersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	0.69	0.12
BabySemp 1 Modersmjölksersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	0.90	0.15
Organic infant milk	Babynat	0	4.2	700	0.83	0.14
Eko 1 Modersmjölksersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	0.54	0.09
Follow-on-formula						
BabySemp 3 Tillskottsning (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	4.6	0.27
NAN Pro 2 Tillskottsning (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	0.71	0.08
Eko tillskottsning 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	1.1	0.12
Optima Organic Follow-on-milk	Babynat	6	7.7	900	0.71	0.08
FSMP used as sole source of nutrition						
Neocate advance	SHS	12	9.8	900	0.63	0.06
Nutrini energy multi fibre	Nutricia	12	9.8	600	3.4	0.21
Nutrini multi fibre	Nutricia	12	9.8	900	2.7	0.24
Resource minimax	Nestlé	12	9.8	750	1.9	0.15
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	1.3	0.12

Product (English translation)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	As concentration (µg/kg)	As intake (µg/kg bw/day)
Isosource junior	Nestlé	12	9.8	900	1.3	0.12
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	1.5	0.24
Pepticate	Nutricia	0	4.2	700	0.57	0.10
Galactomin 19 formula	SHS	0	4.2	700	0.55	0.09
Neocate LCP	Nutricia	0	4.2	700	0.69	0.12
Althéra	Nestlé	0	4.2	700	0.58	0.10
Enfamil AR lipil	Mead Johnson	0	4.2	700	0.67	0.11
Pepti junior	Nutricia	0	4.2	700	0.69	0.11
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	11	0.86
Profylac	Semper	0	4.2	700	1.3	0.22
PreNAN discharge	Nestlé	Premature/LBW	2.5	400	0.84	0.14
Enfalac premature	Mead Johnson	Premature/LBW	2.5	400	0.97	0.16
Pregestimil lipil	Mead Johnson	0	4.2	700	0.90	0.15
FM 85 ^a	Nestlé	Premature	2.5	400	0.62	0.10
Enfamil Human Milk Fortifier ^a	Mead Johnson	Premature	2.5	400	0.49	0.08
NutriniKid multi fiber	Nutricia	12	9.8	600	3.7	0.23
FSMP used as partial feeding^b						
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	1.4	0.17
XP Maxamaid	SHS	12	9.8	300	0.7	0.02
PKU anamix infant lcp+	SHS	0	4.2	300	0.7	0.05

^aProducts to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

^bThe intake of these products is calculated as daily intakes in accordance with calculations for intakes of follow-on-formula. LBW=low birth weight

Table 2. Estimated intake of arsenic *per consumed single portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	As concentration ($\mu\text{g}/\text{kg}$)	As intake ($\mu\text{g}/\text{kg bw}/\text{portion}$)
Gruel						
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	0.68	0.02
Låglaktos majsvälling (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	0.65	0.02
Majsvälling (<i>Corn gruel</i>)	Semper	6	7.7	229	1.5	0.05
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	0.74	0.02
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	19.2	0.58
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	0.94	0.02
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	0.67	0.02
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	8.4	0.26
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	0.74	0.02
Majsvälling (<i>Corn gruel</i>)	Nestlé	6	7.7	236	0.63	0.02
First flavor ^a	Babynat	6	7.7	234	17.6	0.53
Céréales cacao ^a	Babybio	8	8.5	234	16.5	0.46
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	0.64	0.02
Majsvälling (<i>Corn gruel</i>)	HIPP	6	7.7	220	0.54	0.02
Porridge						
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	28.1	0.56
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	4.6	0.09
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	4.4	0.09
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	11.4	0.23
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	23.1	0.42
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	12.8	0.25

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	As concentration (µg /kg)	As intake (µg/kg bw/portion)
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	28.6	0.56
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	1.3	0.02
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	1.1	0.02
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	0.9	0.02
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	1.9	0.03
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	2.8	0.05
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	1.4	0.02
God Natt! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	22.0	0.63
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	4.6	0.09
Organic seven grain cereal ^b	Organix	7	8.1	105	3.1	0.04
First organic wholegrain baby rice ^b	Organix	4	6.6	51	41.4	0.32
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	4.0	0.10
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	3.0	0.09
Organic millet porridge	Holle	4	6.6	175	1.5	0.04
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	1.2	0.03
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	0.9	0.02
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^a	Holle	4	6.6	225	1.3	0.05
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	6.5	0.08
Baby's first food The ultimate four grain porridge ^a	Plum	4	6.6	110	12.5	0.21
Rice porridge ^a	Holle	4	6.6	188	31.3	0.89
FSMP used as partial feeding						
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	2.3	0.05
PKU gel	VitaFlo	12	9.8	50	3.7	0.02
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	2.0	0.04

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	As concentration (µg /kg)	As intake (µg/kg bw/portion)
Foodstuffs for normal consumption						
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	1.0	0.01
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	2.0	0.02
Pama minutris (Pama ' <i>minute rice</i> ')	Quaker	12	9.8	130	32.3	0.43
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	18.3	0.19
Risdryck naturell (<i>Rice drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	30.4	0.31
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	0.5	0.007
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå Kvarn	12	9.8	130	0.6	0.008
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	0.8	0.009
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	0.8	0.008
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	130	0.9	0.009
Soya drink natural fresh	Alpro	12	9.8	130	1.7	0.018
Soya natural	Provamel	12	9.8	130	1.1	0.011

^aProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water.

Cadmium (Cd)

Table 1. Estimated daily intake of cadmium from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding.

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Cd concentration (µg/kg)	Cd intake (µg/kg bw/day)	% of TDI ^a
Infant formula							
NAN 1 Modersmjölk ersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	0.3	0.05	15
NAN HA 1 Modersmjölk ersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	0.2	0.04	10
BabySemp 2 Lemolac Modersmjölk ersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	0.3	0.04	11
ECO 1 Modersmjölk ersättning (<i>ECO 1 infant formula</i>)	HIPP	0	4.2	700	0.1	0.02	5
ECO 2 Modersmjölk ersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	0.6	0.08	21
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	0.3	0.06	15
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	0.1	0.01	3
Organic nfant milk	Babynat	0	4.2	700	0.1	0.01	4
Eko 1 Modersmjölk ersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	0.4	0.07	19
Follow-on-formula							
BabySemp 3 Tillskotts näring (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	0.6	0.04	11
NAN Pro 2 Tillskotts näring (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	0.2	0.02	6
Eko tillskotts näring 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	0.3	0.03	9
Optima Organic Follow-on-milk	Babynat	6	7.7	900	0.1	0.01	3
FSMP used as sole source of nutrition							
Neocate advance	SHS	12	9.8	900	0.1	0.01	4
Nutrini energy multi fibre	Nutricia	12	9.8	600	0.4	0.02	6
Nutrini multi fibre	Nutricia	12	9.8	900	0.3	0.03	8
Resource minimax	Nestlé	12	9.8	750	0.7	0.05	14

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Cd concentration (µg/kg)	Cd intake (µg/kg bw/day)	% of TDI ^a
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	2.2	0.20	55
Isosource junior	Nestlé	12	9.8	900	0.4	0.04	10
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	0.2	0.03	10
Pepticate	Nutricia	0	4.2	700	0.2	0.03	9
Galactomin 19 formula	SHS	0	4.2	700	0.2	0.03	9
Neocate LCP	Nutricia	0	4.2	700	0.6	0.10	28
Althéra	Nestlé	0	4.2	700	0.2	0.03	9
Enfamil AR lipil	Mead Johnson	0	4.2	700	0.2	0.03	9
Pepti junior	Nutricia	0	4.2	700	0.4	0.07	19
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	0.3	0.02	6
Profylac	Semper	0	4.2	700	0.1	0.02	6
PreNAN discharge	Nestlé	Premature/LBW	2.5	400	0.5	0.08	22
Enfalac premature	Mead Johnson	Premature/LBW	2.5	400	0.3	0.04	12
Pregestimil lipil	Mead Johnson	0	4.2	700	0.3	0.04	12
FM 85 ^b	Nestlé	Premature	2.5	400	0.2	0.03	9
Enfamil Human Milk Fortifier ^b	Mead Johnson	Premature	2.5	400	0.2	0.03	7
NutriniKid multi fiber	Nutricia	12	9.8	600	0.4	0.02	6
FSMP used as partial feeding^c							
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	0.4	0.04	12
XP Maxamaid	SHS	12	9.8	300	0.5	0.01	4
PKU anamix infant lcp+	SHS	0	4.2	300	0.3	0.02	7

^aThe tolerable daily intake (TDI) is 0.36 µg/kg bw/day established by EFSA in 2009. ^bProducts to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

Table 2. Estimated intake of cadmium *per consumed portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cd concentration ($\mu\text{g}/\text{kg}$)	Cd intake ($\mu\text{g}/\text{kg bw}/\text{portion}$)	No. of portions to reach TDI ^a
Gruel							
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	2.4	0.06	6
Låglaktos majsställing (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	0.2	0.01	66
Majsställing (<i>Corn gruel</i>)	Semper	6	7.7	229	0.2	0.01	53
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	1.2	0.03	11
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	3.9	0.12	3
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	0.7	0.02	23
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	2.0	0.05	7
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	0.6	0.02	20
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	1.0	0.03	13
Majsställing (<i>Corn gruel</i>)	Nestlé	6	7.7	236	0.1	0.003	104
First flavor ^b	Babynat	6	7.7	234	3.0	0.09	4
Céréales cacao ^b	Babybio	8	8.5	234	6.9	0.19	2
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	1.3	0.04	10
Majsställing (<i>Corn gruel</i>)	HIPP	6	7.7	220	0.1	0.003	105
Porridge							
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	5.3	0.11	3
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	1.5	0.03	12
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	2.5	0.05	7
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	6.0	0.12	3
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	2.4	0.04	8
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	3.3	0.07	6

Product (English translation)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cd concentration (µg/kg)	Cd intake (µg/kg bw/portion)	No. of portions to reach TDI^a
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	3.8	0.08	5
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	3.7	0.06	6
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	3.8	0.06	6
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	2.3	0.05	8
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	1.6	0.03	14
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	2.2	0.04	10
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	4.3	0.06	6
God Natt! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	5.4	0.16	2
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	2.2	0.04	9
Organic seven grain cereal ^b	Organix	7	8.1	105	2.2	0.03	13
First organic wholegrain baby rice ^b	Organix	4	6.6	51	0.3	0.002	175
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	0.9	0.02	16
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	2.7	0.08	5
Organic millet porridge	Holle	4	6.6	175	2.1	0.06	6
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	3.5	0.10	4
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	1.9	0.04	9
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^b	Holle	4	6.6	225	2.2	0.07	5
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	2.2	0.03	13
Baby's first food The ultimate four grain porridge ^b	Plum	4	6.6	110	2.1	0.04	10
Rice porridge ^b	Holle	4	6.6	188	1.3	0.04	10
FSMP used as partial feeding							
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	1.1	0.02	16

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cd concentration ($\mu\text{g}/\text{kg}$)	Cd intake ($\mu\text{g}/\text{kg bw}/\text{portion}$)	No. of portions to reach TDI ^a
PKU gel	VitaFlo	12	9.8	50	1.1	0.01	67
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	2.1	0.04	9
Foodstuffs for normal consumption							
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	0.3	0.003	105
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	2.4	0.02	15
Pama minutris (<i>Pama 'minute rice'</i>)	Quaker	12	9.8	130	2.7	0.04	10
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	0.5	0.01	71
Risdryck naturell (<i>Rice drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	4.5	0.05	8
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	4.9	0.07	6
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå kvarn	12	9.8	130	10.8	0.14	3
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	8.3	0.09	4
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	7.3	0.07	5
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	100 ml/portion	0.1	0.001	442
Soya drink natural fresh	Alpro	12	9.8	100 ml/portion	1.9	0.02	19
Soya natural	Provamel	12	9.8	100 ml/portion	1.9	0.02	19

^aThe tolerable daily intake (TDI) is 0.36 $\mu\text{g}/\text{kg bw}/\text{day}$ established by EFSA in 2009.

^bProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water.

Lead (Pb)

Table 1. Estimated daily intake of lead from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding.

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Pb concentration (µg/kg)	Pb intake (µg/kg bw/day)	% of RP ^a
Infant Formula							
NAN 1 Modersmjölk ersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	0.5	0.08	16
NAN HA 1 Modersmjölk ersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	0.4	0.06	12
BabySemp 2 Lemolac modersmjölk ersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	0.4	0.04	8
ECO 1 Modersmjölk ersättning (<i>ECO 1 infant formula</i>)	HIPP	0	4.2	700	0.3	0.04	9
ECO 2 Modersmjölk ersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	0.3	0.04	7
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	0.2	0.04	7
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	0.2	0.04	8
Organic infant milk	Babynat	0	4.2	700	0.3	0.04	8
Eko 1 Modersmjölk ersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	0.3	0.06	11
Follow-on-formula							
BabySemp 3 Tillskottsnäring (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	0.5	0.03	6
NAN Pro 2 Tillskottsnäring (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	0.6	0.07	14
Eko tillskottsnäring 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	1.2	0.14	27
Optima organic Follow-on-milk	Babynat	6	7.7	900	0.3	0.03	7
FSMP used as sole source of nutrition							
Neocate advance	SHS	12	9.8	900	0.3	0.03	6
Nutrini energy multi fibre	Nutricia	12	9.8	600	0.9	0.06	12
Nutrini multi fibre	Nutricia	12	9.8	900	1.1	0.10	21

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Pb concentration (µg/kg)	Pb intake (µg/kg bw/day)	% of RP ^a
Resource minimax	Nestlé	12	9.8	750	0.7	0.05	11
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	1.2	0.11	21
Isosource junior	Nestlé	12	9.8	900	1.5	0.14	27
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	0.7	0.11	22
Pepticate	Nutricia	0	4.2	700	0.5	0.08	15
Galactomin 19 formula	SHS	0	4.2	700	0.8	0.13	27
Neocate LCP	Nutricia	0	4.2	700	0.4	0.07	14
Althéra	Nestlé	0	4.2	700	0.3	0.05	10
Enfamil AR lipil	Mead Johnson	0	4.2	700	0.5	0.08	17
Pepti junior	Nutricia	0	4.2	700	0.5	0.09	18
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	0.5	0.04	7
Profylac	Semper	0	4.2	700	0.3	0.04	8
PreNAN discharge	Nestlé	Premature /LBW	2.5	400	0.4	0.06	12
Enfalac premature	Mead Johnson	Premature /LBW	2.5	400	0.4	0.07	13
Pregestimil lipil	Mead Johnson	0	4.2	700	0.6	0.11	22
FM 85 ^b	Nestlé	Premature	2.5	400	0.3	0.04	9
Enfamil Human Milk Fortifier ^b	Mead Johnson	Premature	2.5	400	0.5	0.08	15
NutriniKid multi fiber	Nutricia	12	9.8	600	0.9	0.06	11
FSMP used as partial feeding^c							
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	0.9	0.10	20
XP Maxamaid	SHS	12	9.8	300	0.8	0.02	5
PKU anamix infant lcp+	SHS	0	4.2	300	0.6	0.04	8

^aThe reference point (RP) is 0.5 µg/kg bw/day established by EFSA in 2010.

^b Products to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

^cThe intake of these products is calculated as daily intakes in accordance with calculations for intakes of follow-on formulas.

LBW=low birth weight

Table 2. Estimated intake of lead *per consumed portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Pb concentration (µg/kg)	Pb intake (µg/kg bw/portion)	No. of portion to reach RP ^a
Gruel							
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	0.5	0.01	39
Låglaktos majsställing (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	0.7	0.02	23
Majsställing (<i>Corn gruel</i>)	Semper	6	7.7	229	0.3	0.01	59
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	3.1	0.09	6
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	6.9	0.21	2
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	0.2	0.01	86
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	0.3	0.01	65
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	0.6	0.02	27
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	0.6	0.02	30
Majsställing (<i>Corn gruel</i>)	Nestlé	6	7.7	236	0.3	0.01	51
First flavor ^b	Babynat	6	7.7	234	0.2	0.01	76
Céréales cacao ^b	Babybio	8	8.5	234	0.4	0.01	49
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	0.3	0.01	73
Majsställing (<i>Corn gruel</i>)	HIPP	6	7.7	220	0.3	0.01	63
Porridge							
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	1.4	0.03	18
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	1.3	0.02	20
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	0.5	0.01	50
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	12.6	0.26	2
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	1.3	0.02	22
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	0.6	0.01	39
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	0.5	0.01	56

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Pb concentration (µg/kg)	Pb intake (µg/kg bw/portion)	No. of portion to reach RP ^a
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	0.9	0.01	38
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	0.5	0.01	62
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	2.2	0.04	12
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	0.6	0.01	47
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	0.4	0.01	76
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	0.7	0.01	55
God Nat! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	1.9	0.05	9
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	0.4	0.01	62
Organic seven grain cereal ^b	Organix	7	8.1	105	0.5	0.01	75
First organic wholegrain baby rice ^b	Organix	4	6.6	51	0.5	0.004	119
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	1.5	0.04	13
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	0.3	0.01	52
Organic millet porridge	Holle	4	6.6	175	0.9	0.02	22
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	0.3	0.01	56
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	0.5	0.01	54
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^b	Holle	4	6.6	225	0.3	0.01	55
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	1.9	0.02	22
Baby's first food The ultimate four grain porridge ^b	Plum	4	6.6	110	0.6	0.01	46
Rice porridge ^b	Holle	4	6.6	188	0.3	0.01	64
FSMP used as partial feeding							
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	1.9	0.04	13
PKU gel	Vitaflo	12	9.8	50	22.6	0.12	4
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	2.2	0.04	11
Foodstuffs for normal consumption							
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	0.2	0.003	198
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	1.3	0.01	39

Product (English translation)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Pb concentration (µg/kg)	Pb intake (µg/kg bw/portion)	No. of portion to reach RP^a
Pama minutris (<i>Pama 'minute rice'</i>)	Quaker	12	9.8	130	0.1	0.002	308
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	0.2	0.002	302
Risdryck naturell (Rice drink natural)	Carlshamn	12	9.8	100 ml/portion	1.4	0.01	36
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	0.3	0.004	127
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå kvarn	12	9.8	130	0.6	0.01	63
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	1.3	0.01	37
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	1.1	0.01	43
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	100 ml/portion	0.1	0.001	454
Soya drink natural fresh	Alpro	12	9.8	100 ml/portion	0.2	0.002	277
Soya natural	Provamel	12	9.8	100 ml/portion	0.1	0.001	340

^aThe reference point (RP) is 0.5 µg/kg bw/day established by EFSA in 2010.

^bProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water.

Manganese (Mn)

Table 1. Estimated daily intake of manganese from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding.

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Mn concentration (mg/kg)	Mn intake (µg/day)	% of AI ^a	Mn intake (µg/kg bw/day)	% of TDI ^b
Infant Formula									
NAN 1 Modersmjölk ersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	0.16	110	3680	26	44
NAN HA 1 Modersmjölk ersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	0.13	90	3000	21	36
BabySemp 2 Lemolac modersmjölk ersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	0.07	57	1910	9	14
ECO 1 Modersmjölk ersättning (<i>ECO 1 infant formula</i>)	HIPP	0	4.2	700	0.10	68	2260	16	27
ECO 2 Modersmjölk ersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	0.08	66	2210	10	17
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	0.02	15	510	4	6
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	0.05	32	1070	8	13
Organic infant milk	Babynat	0	4.2	700	0.05	35	1170	8	14
Eko 1 Modersmjölk ersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	0.11	76	2540	18	30
Follow-on-formula									
BabySemp 3 Tillskottsning (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	0.36	180	30	21	35
NAN Pro 2 Tillskottsning (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	0.12	111	3720	14	24
Eko tillskottsning 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	0.18	161	5380	21	35
Optima Organic Follow-on-milk	Babynat	6	7.7	900	0.04	39	1300	5	8
FSMP used as sole source of nutrition									
Neocate advance	SHS	12	9.8	900	0.56	508	42	52	86
Nutrini energy multi fibre	Nutricia	12	9.8	600	2.01	208	101	123	205
Nutrini multi fibre	Nutricia	12	9.8	900	1.62	461	122	149	248

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Mn concentration (mg/kg)	Mn intake (µg/day)	% of AI ^a	Mn intake (µg/kg bw/day)	% of TDI ^b
Resource minimax	Nestlé	12	9.8	750	0.76	566	47	58	96
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	2.51	2256	188	230	384
Isosource junior	Nestlé	12	9.8	900	1.65	1489	124	152	253
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	0.48	336	11190	80	133
Pepticate	Nutricia	0	4.2	700	0.10	73	2440	17	29
Galactomin 19 formula	SHS	0	4.2	700	0.39	275	9170	66	109
Neocate LCP	Nutricia	0	4.2	700	0.45	316	10530	75	125
Althéra	Nestlé	0	4.2	700	0.05	34	1140	8	14
Enfamil AR lipil	Mead Johnson	0	4.2	700	0.41	290	9680	69	115
Pepti junior	Nutricia	0	4.2	700	0.42	297	9890	71	118
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	0.76	454	15130	59	98
Profylac	Semper	0	4.2	700	0.45	312	10390	74	124
PreNAN discharge	Nestlé	Premature/LBW	2.5	400	0.12	48	1590	19	32
Enfalac premature	Mead Johnson	Premature/LBW	2.5	400	0.11	42	1420	17	28
Pregestimil lipil	Mead Johnson	0	4.2	700	0.46	323	10760	77	128
FM 85 ^c	Nestlé	Premature	2.5	400	0.12	48	1600	19	32
Enfamil Human Milk Fortifier ^c	Mead Johnson	Premature	2.5	400	0.14	57	1920	23	38
NutriniKid multi fiber	Nutricia	12	9.8	600	0.14	1074	90	9	15
FSMP used as partial feeding^d									
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	0.64	580	19333	75	125
XP Maxamaid	SHS	12	9.8	300	2.60	780	130	80	133
PKU anamix infant lcp+	SHS	0	4.2	300	0.67	200	6666	48	79

^aThe Adequate intake (AI) is for 0-6 months 3µg, for 7-12 months 600 µg and for 1-3 years 1200 µg (IOM, 2001).

^bThe tolerable daily intake (TDI) is 60 µg/kg bw/day established by WHO in 2003.

^c Products to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

^dThe intake of these products is calculated as daily intakes in accordance with calculations for intakes of follow-on formula.

LBW=low birth weight.

Table 2. Estimated intake of manganese *per consumed portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Mn concentration (mg/kg)	Mn intake (µg/portion)	No. of portions to reach AI ^a	Mn intake (µg/kg bw/portion)	No. of portions to reach TDI ^b
Gruel									
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	1.42	340	4	34	2
Låglaktos majsvälling (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	0.07	20	0	2	28
Majsvälling (<i>Corn gruel</i>)	Semper	6	7.7	229	0.21	50	0	6	10
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	1.43	340	2	40	2
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	1.51	350	0	46	1
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	0.74	150	4	17	3
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	1.39	330	4	34	2
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	0.50	120	0	15	4
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	1.18	260	0	34	2
Majsvälling (<i>Corn gruel</i>)	Nestlé	6	7.7	236	0.04	10	0	1	53
First flavor ^c	Babynat	6	7.7	234	1.09	260	0	33	2
Céréales cacao ^c	Babybio	8	8.5	234	1.32	310	2	36	2
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	1.27	290	2	34	2
Majsvälling (<i>Corn gruel</i>)	HIPP	6	7.7	220	0.08	20	0	2	26
Porridge									
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	4.63	610	0	93	1
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	2.33	390	2	46	1
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	2.25	370	0	49	1
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	3.27	520	0	67	1
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	0.88	110	0	16	4

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Mn concentration (mg/kg)	Mn intake (µg/portion)	No. of portions to reach AI ^a	Mn intake (µg/kg bw/portion)	No. of portions to reach TDI ^b
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	1.11	140	0	22	3
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	1.53	200	0	30	2
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	2.57	330	2	39	2
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	3.32	430	2	51	1
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	1.76	230	0	35	2
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	1.64	210	0	28	2
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	2.51	400	3	40	1
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	2.26	300	4	31	2
God Natt! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	1.24	240	0	36	2
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	2.70	430	2	50	1
Organic seven grain cereal ^c	Organix	7	8.1	105	3.59	380	2	47	1
First organic wholegrain baby rice ^c	Organix	4	6.6	51	2.59	130	0	20	3
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	0.75	120	0	19	3
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	4.40	990	0	128	0
Organic millet porridge	Holle	4	6.6	175	0.89	160	0	24	3
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	3.21	720	0	94	1
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	3.24	500	0	65	1
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^c	Holle	4	6.6	225	2.81	630	0	96	1
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	3.76	440	3	45	1
Baby's first food The ultimate four grain porridge ^c	Plum	4	6.6	110	1.47	160	0	24	2

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Mn concentration (mg/kg)	Mn intake (µg/portion)	No. of portions to reach AI ^a	Mn intake (µg/kg bw/portion)	No. of portions to reach TDI ^b
Rice porridge ^c	Holle	4	6.6	188	2.93	550	0	84	1
FSMP used as partial feeding									
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	3.82	760	2	78	1
PKU gel	Vitaflo	12	9.8	50	8.30	420	3	42	1
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	1.76	350	3	36	2
Foodstuffs for normal consumption									
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	0.80	80	15	8.2	7
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.67	67	18	6.8	9
Pama minutris (<i>Pama 'minute rice'</i>)	Quaker	12	9.8	130	1.06	138	9	14.1	4
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	0.22	22	53	2.3	26
Risdryck naturell (<i>Rice drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.70	70	17	7.1	8
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	4.65	605	2	61.7	1
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå kvarn	12	9.8	130	8.87	1154	1	117.7	1
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	1.95	195	6	19.9	3
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	1.56	156	8	15.9	4
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	100 ml/portion	0.16	16	76	1.6	37
Soya drink natural fresh	Alpro	12	9.8	100 ml/portion	1.57	157	7	16.0	4
Soya natural	Provamel	12	9.8	100 ml/portion	1.98	198	6	20.2	3

^aThe Adequate intake (AI) is for 0-6 months 3µg, for 7-12 months 600 µg and for 1-3 years 1200 µg (IOM, 2001).

^bThe tolerable daily intake (TDI) is 60 µg/kg bw/day established by WHO in 2003.

^cProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water.

Iron (Fe)

Table 1. Estimated daily intake of iron from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding.

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml /day)	Fe concentration (mg/kg)	Fe intake (mg/day)	% of RI ^a
Infant Formula							
NAN 1 Modersmjölk ersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	3.8	2.7	NA
NAN HA 1 Modersmjölk ersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	6.2	4.3	NA
BabySemp 2 Lemolac modersmjölk ersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	5.6	4.5	NA
ECO 1 Modersmjölk ersättning (<i>ECO 1 infant formula</i>)	HIPP	0	4.2	700	5.7	4.0	NA
ECO 2 Modersmjölk ersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	6.4	5.1	NA
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	3.5	2.5	NA
BabySemp 1 Modersmjölk ersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	4.1	2.9	NA
Organic infant milk	Babynat	0	4.2	700	6.9	4.8	NA
Eko 1 Modersmjölk ersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	3.5	2.4	NA
Follow-on-formula							
BabySemp 3 Tillskottsning (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	9.4	4.7	59
NAN Pro 2 Tillskottsning (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	8.8	7.9	99
Eko tillskottsning 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	7.9	7.1	89
Optima Organic Follow-on-milk	Babynat	6	7.7	900	7.8	7.0	88
FSMP used as sole source of nutrition							
Neocate advance	SHS	12	9.8	900	6.0	5.4	68
Nutrini energy multi fibre	Nutricia	12	9.8	600	13.0	7.8	98
Nutrini multi fibre	Nutricia	12	9.8	900	9.9	8.9	111
Resource minimax	Nestlé	12	9.8	750	10.7	8.0	100

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml /day)	Fe concentration (mg/kg)	Fe intake (mg/day)	% of RI ^a
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	11.6	10	125
Isosource junior	Nestlé	12	9.8	900	8.2	7.4	93
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	11.4	8.0	NA
Pepticate	Nutricia	0	4.2	700	5.0	3.5	NA
Galactomin 19 formula	SHS	0	4.2	700	3.9	2.7	NA
Neocate LCP	Nutricia	0	4.2	700	7.4	5.2	NA
Althéra	Nestlé	0	4.2	700	6.5	4.6	NA
Enfamil AR lipil	Mead Johnson	0	4.2	700	7.3	5.1	NA
Pepti junior	Nutricia	0	4.2	700	7.1	4.9	NA
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	9.0	5.4	68
Profylac	Semper	0	4.2	700	6.2	4.3	NA
PreNAN discharge	Nestlé	Premature/L BW	2.5	400	7.5	3.0	NA
Enfalac premature	Mead Johnson	Premature/L BW	2.5	400	10.2	4.1	NA
Pregestimil lipil	Mead Johnson	0	4.2	700	11.5	8.0	NA
FM 85 ^b	Nestlé	Premature	2.5	400	10.4	4.2	NA
Enfamil Human Milk Fortifier ^b	Mead Johnson	Premature	2.5	400	13.4	5.3	NA
NutriniKid multi fiber	Nutricia	12	9.8	600	13.4	8.0	100
FSMP used as partial feeding^c							
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	12.1	10.9	136
XP Maxamaid	SHS	12	9.8	300	15.9	4.8	53
PKU anamix infant lcp+	SHS	0	4.2	300	7.3	2.2	NA

^aThe recommended daily intake (RI) from 6 months is 8.0 mg/d established by SNR 2005.

^b Products to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

^cThe intake of these products is calculated as daily intakes in accordance with calculations for intakes of follow-on formula.

NA=not applicable because the product is intended for infants less than 6 months for which there is no RI.

LBW=low birth weight

Table 2. Estimated intake of iron *per consumed portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Fe concentration (mg/kg)	Fe intake (mg/portion)	No. of portions to reach RI ^a
Gruel							
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	11.4	2.7	3
Låglaktos majsställing (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	10.8	2.6	3
Majsvälling (<i>Corn gruel</i>)	Semper	6	7.7	229	12.1	2.8	3
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	11.1	2.6	3
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	16.2	3.8	2
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	9.4	1.9	4
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	13.0	3.1	3
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	11.4	2.7	3
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	11.9	2.6	3
Majsvälling (<i>Corn gruel</i>)	Nestlé	6	7.7	236	10.1	2.4	3
First flavor ^b	Babynat	6	7.7	234	0.6	0.1	(55)
Céréales cacao ^b	Babybio	8	8.5	234	1.8	0.4	(20)
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	12.8	2.9	3
Majsvälling (<i>Corn gruel</i>)	HIPP	6	7.7	220	5.4	1.2	7
Porridge							
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	23.8	3.1	NA
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	12.0	2.0	4
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	6.2	1.0	8
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	13.2	2.1	4
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	21.6	2.8	NA

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Fe concentration (mg/kg)	Fe intake (mg/portion)	No. of portions to reach RI ^a
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	18.8	2.4	NA
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	17.2	2.2	NA
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	22.3	2.8	3
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	18.7	2.4	3
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	20.2	2.6	NA
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	16.5	2.2	4
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	5.4	0.9	9
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	21.0	2.8	3
God Natt! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	1.5	0.3	NA
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	11.2	1.8	5
Organic seven grain cereal ^b	Organix	7	8.1	105	4.3	0.5	(18)
First organic wholegrain baby rice ^b	Organix	4	6.6	51	2.1	0.1	NA
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	3.2	0.5	NA
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	3.6	0.8	10
Organic millet porridge	Holle	4	6.6	175	3.3	0.6	NA
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	3.6	0.8	10
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	19.1	3.0	3
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^b	Holle	4	6.6	225	2.7	0.6	NA
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	19.5	2.3	3
Baby's first food The ultimate four grain porridge ^b	Plum	4	6.6	110	2.7	0.3	NA
Rice porridge ^b	Holle	4	6.6	188	1.1	0.2	NA
FSMP used as partial feeding							
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	19.7	3.9	2

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Fe concentration (mg/kg)	Fe intake (mg/portion)	No. of portions to reach RI ^a
PKU gel	Vitaflo	12	9.8	50	60.3	3.0	3
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	14.0	2.8	3
Foodstuffs for normal consumption							
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	0.9	0.09	86
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.8	0.08	94
Pama minutris (<i>Pama 'minute rice'</i>)	Quaker	12	9.8	130	0.2	0.03	315
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	0.1	0.01	700
Risdryck naturell (<i>Rice drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.8	0.08	103
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	5.5	0.71	11
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå kvarn	12	9.8	130	9.4	1.22	7
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	6.5	0.65	12
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	5.0	0.50	7
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	100 ml/portion	0.5	0.05	12
Soya drink natural fresh	Alpro	12	9.8	100 ml/portion	4.2	0.42	16
Soya natural	Provamel	12	9.8	100 ml/portion	3.3	0.33	25

^aThe recommended daily intake (RI) is 8.0 mg/d established by SNR in 2005.

^bProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water. NA=not applicable because the product is intended for infants less than 6 months for which there is no RI.

Copper (Cu)

Table 1. Estimated daily intake of copper from ready-to-eat infant formula, follow-on formula, FSMP as sole source of nutrition and FSMP as partial feeding

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Cu concentration (mg/kg)	Cu intake (µg/day)	% of RI ^a	% of TDI ^b
Infant Formula								
NAN 1 Modersmjölksersättning (<i>NAN 1 Infant formula</i>)	Nestlé	0	4.2	700	0.35	246	NA	25
NAN HA 1 Modersmjölksersättning (<i>NAN HA 1 Infant formula</i>)	Nestlé	0	4.2	700	0.51	354	NA	35
BabySemp 2 Lemolac modersmjölksersättning (<i>BabySemp 2 Lemolac infant formula</i>)	Semper	4	6.6	800	0.46	370	NA	37
ECO 1 Modersmjölksersättning (<i>ECO 1 infant formula</i>)	HIPP	0	4.2	700	0.33	232	NA	23
ECO 2 Modersmjölksersättning (<i>ECO 2 infant formula</i>)	HIPP	4	6.6	800	0.39	308	NA	31
BabySemp 1 Modersmjölksersättning (<i>BabySemp 1 infant formula</i>), powder	Semper	0	4.2	700	0.34	239	NA	24
BabySemp 1 Modersmjölksersättning (<i>BabySemp 1 infant formula</i>), RFU	Semper	0	4.2	700	0.38	263	NA	26
Organic infant milk	Babynat	0	4.2	700	0.36	252	NA	25
Eko 1 Modersmjölksersättning, (<i>Infant formula 1</i>)	Holle	0.5	4.2	700	0.34	239	NA	24
Follow-on-formula								
BabySemp 3 Tillskottsning (<i>BabySemp 3 follow-on-formula</i>)	Semper	8	8.5	500	0.33	166	55	17
NAN Pro 2 Tillskottsning (<i>NAN PRO 2 follow-on-formula</i>)	Nestlé	6	7.7	900	0.47	419	140	42
Eko tillskottsning 2 (<i>Follow-on-formula 2</i>)	Holle	6	7.7	900	0.36	327	109	33
Optima Organic Follow-on-milk	Babynat	6	7.7	900	0.39	353	118	35
FSMP used as sole source of nutrition								
Neocate advance	SHS	12	9.8	900	0.57	511	170	51
Nutrini energy multi fibre	Nutricia	12	9.8	600	1.11	666	222	67
Nutrini multi fibre	Nutricia	12	9.8	900	0.76	684	228	68
Resource minimax	Nestlé	12	9.8	750	1.01	755	252	76

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (ml/day)	Cu concentration (mg/kg)	Cu intake (µg/day)	% of RI ^a	% of TDI ^b
Fresubin soya fibre	Fresenius Kabi	12	9.8	900	1.37	1233	411	123
Isosource junior	Nestlé	12	9.8	900	1.02	914	305	91
Nutramigen 1 lipil	Mead Johnson	0	4.2	700	0.46	325	NA	33
Pepticate	Nutricia	0	4.2	700	0.44	311	NA	31
Galactomin 19 formula	SHS	0	4.2	700	0.39	270	NA	27
Neocate LCP	Nutricia	0	4.2	700	0.46	324	NA	32
Althéra	Nestlé	0	4.2	700	0.57	398	NA	40
Enfamil AR lipil	Mead Johnson	0	4.2	700	0.49	345	NA	35
Pepti junior	Nutricia	0	4.2	700	0.37	258	NA	26
Minimax barnsondnäring (<i>Minimax enteral formula for children</i>)	Nestlé	6	7.7	600	1.09	655	218	66
Profylac	Semper	0	4.2	700	0.40	278	NA	28
PreNAN discharge	Nestlé	Premature/ LBW	2.5	400	0.56	225	NA	23
Enfalac premature	Mead Johnson	Premature/ LBW	2.5	400	0.76	303	NA	30
Pregestimil lipil	Mead Johnson	0	4.2	700	0.51	360	NA	36
FM 85 ^c	Nestlé	Premature	2.5	400	0.35	140	NA	14
Enfamil Human Milk Fortifier ^c	Mead Johnson	Premature	2.5	400	0.54	220	NA	22
NutriniKid multi fiber	Nutricia	12	9.8	600	1.30	778	259	78
FSMP used as partial nutrition^d								
Nutramigen 2 lipil	Mead Johnson	6	7.7	900	0.54	484	161	48
XP Maxamaid	SHS	12	9.8	300	2.62	786	262	79
PKU anamix infant lcp+	SHS	0	4.2	300	0.57	170	NA	17

^aThe recommended intake (RI) from 6 months is 0.3 mg/day established by SNR in 2005.

^bThe tolerable upper intake level (UL) is 1000 µg/day established by EFSA in 2003.

^c Products to be mixed with breast milk according to instruction, calculation in table based on product diluted with water

^dThe intake of these products is calculated as daily intakes in accordance with calculations for intakes of follow-on formulas.

NA=not applicable because the product is intended for infants less than 6 months for which there is no RI

LBW=low birth weight

Table 2. Estimated intake of copper *per consumed portion* from gruel, porridge, FSMP as partial feeding and foodstuffs for normal consumption (products not intended for infants)

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cu concentration (mg/kg)	Cu intake (µg/portion)	No. of portions to reach RI ^a	No. of portions to reach TDI ^b
Gruel								
Fullkornsvälling (<i>Wholegrain gruel</i>)	Nestlé	12	9.8	236	0.23	55	5	18
Låglaktos majsställing (<i>Low lactose corn gruel</i>)	Nestlé	6	7.7	237	0.04	9	33	110
Majsvälling (<i>Corn gruel</i>)	Semper	6	7.7	229	0.06	15	20	67
Mild fullkornsvälling havre (<i>Mild wholegrain gruel oat</i>)	Nestlé	8	8.5	236	0.17	40	7	25
Välling mjölkfri (<i>Gruel dairy free</i>)	EnaGo	6	7.7	233	0.38	89	3	11
Drickfärdig mild fullkornsvälling (<i>Ready for use mild wholegrain gruel</i>)	Semper	8	8.5	200	0.11	22	14	46
Fullkornsvälling havre vete råg (<i>Wholegrain gruel oat wheat rye</i>)	Semper	12	9.8	237	0.21	50	6	20
Kvällsvälling ris och vete (<i>Evening gruel rice and wheat</i>)	Semper	6	7.7	237	0.10	24	12	41
God natt mild havrevälling (<i>Good night mild oat gruel</i>)	Nestlé	6	7.7	220	0.12	27	11	37
Majsvälling (<i>Corn gruel</i>)	Nestlé	6	7.7	236	0.02	5	66	221
First flavor ^c	Babynat	6	7.7	234	0.21	48	6	21
Céréales cacao ^c	Babybio	8	8.5	234	0.40	94	3	11
Mild fullkornsvälling (<i>Mild wholegrain gruel</i>)	Semper	8	8.5	228	0.16	37	8	27
Majsvälling (<i>Corn gruel</i>)	HIPP	6	7.7	220	0.33	73	4	14
Porridge								
Sinlac specialgröt (<i>Sinlac special porridge</i>)	Nestlé	4	6.6	132	1.22	161	NA	6
Fullkornsgröt med äpple (<i>Wholegrain porridge with apple</i>)	HIPP	8	8.5	169	0.45	76	4	13
Mild havregröt (<i>Mild oat porridge</i>)	HIPP	6	7.7	167	0.34	57	5	17
Banangröt mjölkfri (<i>Banana porridge dairy free</i>)	EnaGo	6	7.7	158	0.84	133	2	8
Risgröt med äpple och mango (<i>Rice porridge with apple and mango</i>)	Semper	5	7.2	130	0.19	25	NA	40

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cu concentration (mg/kg)	Cu intake (µg/portion)	No. of portions to reach RI ^a	No. of portions to reach TDI ^b
Banangröt (<i>Banana porridge</i>)	Semper	4	6.6	130	0.25	32	NA	31
Cerelac risgröt (<i>Cerelac rice porridge</i>)	Nestlé	4	6.6	130	0.22	29	NA	35
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Nestlé	8	8.5	128	0.33	43	7	23
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	Semper	8	8.5	130	0.46	59	5	17
Mild havregröt (<i>Mild oat porridge</i>)	Semper	4	6.6	130	0.26	33	NA	30
Cerelac Fruktgröt banan apelsin (<i>Cerelac fruit porridge banana orange</i>)	Nestlé	6	7.7	130	0.39	50	6	20
Fullkornsgröt multikorn (<i>Wholegrain porridge multigrain</i>)	HIPP	12	9.8	158	0.37	58	3	17
Fruktgröt fullkorn (<i>Fruit porridge wholegrain</i>)	Semper	12	9.8	133	0.39	52	4	19
God Natt! Risgröt med grönsaker (<i>Rice porridge with vegetables</i>)	HIPP	4	6.6	190	0.35	66	NA	15
Mild fullkornsgröt (<i>Mild wholegrain porridge</i>)	HIPP	8	8.5	158	0.38	60	5	17
Organic seven grain cereal ^c	Organix	7	8.1	105	0.53	55	5	18
First organic wholegrain baby rice ^c	Organix	4	6.6	51	0.32	17	NA	61
Risgröt med banan och persika (<i>Rice porridge with banana and peach</i>)	HIPP	4	6.6	167	0.32	54	NA	18
Eko havregröt (<i>Organic oat porridge</i>)	Holle	6	7.7	225	0.41	91	3	11
Organic millet porridge	Holle	4	6.6	175	0.70	123	NA	8
Eko dinkelgröt (<i>Organic spelt porridge</i>)	Holle	6	7.7	225	0.58	130	2	8
Dinkelgröt naturell (<i>Spelt porridge natural</i>)	Nestlé	6	7.7	155	0.34	52	6	19
Bio-Babybrei Grieß (<i>Wheat porridge</i>) ^c	Holle	4	6.6	225	0.38	85	NA	12
Musligröt päron-banan (<i>Musli porridge pear-banana</i>)	Nestlé	12	9.8	118	0.46	54	6	18
Baby's first food The ultimate four grain porridge ^c	Plum	4	6.6	110	0.37	41	NA	24

Product (<i>English translation</i>)	Producer	Age (months)	Weight (kg)	Consumption (g/portion)	Cu concentration (mg/kg)	Cu intake (µg/portion)	No. of portions to reach RI ^a	No. of portions to reach TDI ^b
Rice porridge ^c	Holle	4	6.6	188	0.22	42	NA	24
FSMP used as partial feeding								
Fresubin energy fiber, chocolate flavour	Fresenius Kabi	12	9.8	200 ml/portion	2.90	580	1	2
PKU gel	Vitaflo	12	9.8	50	3.19	160	2	6
Frebini energy fiber drink	Fresenius Kabi	12	9.8	200 ml/portion	1.54	308	1	3
Foodstuffs for normal consumption								
Havredryck apelsin & mango (<i>Oat drink orange & mango</i>)	Oatly	12	9.8	100 ml/portion	0.27	27	11	36
Havredryck naturell (<i>Oat drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.22	22	14	46
Pama minutris (<i>Pama 'minute rice'</i>)	Quaker	12	9.8	130	0.24	31	10	33
Ricedrink organic	Rice Dream	12	9.8	100 ml/portion	0.05	5	59	197
Risdryck naturell (<i>Rice drink natural</i>)	Carlshamn	12	9.8	100 ml/portion	0.09	9	32	107
Havregryn (<i>Rolled oats</i>)	Lantmännen	12	9.8	130	0.56	72	4	14
Skrädmjöl (<i>Oat toasted and milled</i>)	Saltå kvarn	12	9.8	130	1.02	132	2	8
Sojadryck (<i>Soya drink</i>)	Garant	12	9.8	100 ml/portion	1.43	143	2	7
Sojadryck original + kalcium (<i>Soya drink original + calcium</i>)	GoGreen	12	9.8	100 ml/portion	1.10	110	3	9
Solhavre naturell (<i>Oat drink natural</i>)	ICA	12	9.8	100 ml/portion	0.15	15	20	65
Soya drink natural fresh	Alpro	12	9.8	100 ml/portion	1.02	102	3	10
Soya natural	Provamel	12	9.8	100 ml/portion	0.90	90	3	11

^aThe recommended intake (RI) is 0.3 mg/day established by SNR in 2005.

^bThe tolerable upper intake level (UL) is 1000 µg/day established by EFSA in 2003.

^cProducts to be mixed with milk product according to instruction, calculation in table based on product diluted with water. NA=not applicable because the product is intended for infants less than 6 months for which there is no RI.

Overview of products with observed deviations

Retailer in Sweden	Manufacturer	Product	ID no.	Product category (1)	Control authority	Deviation from maximum/minimum level (2)	Content determined by analysis compared to declared content (3)	Exceeding health-based guideline values (4)
Arvid Nordquist H.A.B.	HiPP	Fullkornsgröt multikorn [wholemeal porridge multigrain]	M39	PCBF	Solna		38 % lower iron content	High manganese content
Arvid Nordquist H.A.B.	HiPP	God natt! Risgröt med grönsaker [rice porridge with vegetables]	M40	PCBF	Solna			High cadmium content, high arsenic content, high manganese content
Arvid Nordquist H.A.B.	HiPP	Risgröt med banan och persika [rice porridge with banana and peach]	M59	PCBF	Solna		61 % lower iron content	High arsenic content, high manganese content
Arvid Nordquist H.A.B.	HiPP	Mild havregröt [mild porridge oats]	M22	PCBF	Solna		38 % lower iron content	High manganese content
Arvid Nordquist H.A.B.	HiPP	Fullkornsgröt med äpple [wholemeal porridge with apple]	M17	PCBF	Solna			High manganese content
Arvid Nordquist H.A.B.	HiPP	Mild fullkornsgröt [mild wholemeal porridge]	M42	PCBF	Solna			High manganese content
Arvid Nordquist H.A.B.	HiPP	Majsvälling [maize gruel]	M96	PCBF	Solna	exceeds maximum level for copper		
Axfood AB	Garant	Sojadryck [soya drink]	M88	Food for normal consumption	National Food Agency/KA			High manganese content, high cadmium content
Ekologiska Barnmatsbutiken	Organix	First organic wholegrain baby rice	M56	PCBF	Stockholm			High arsenic content, high manganese content
Ekologiska Barnmatsbutiken	Plum	Baby's first food The ultimate four grain porridge	M90	PCBF	Stockholm			High arsenic content, high manganese content
Ekologiska Barnmatsbutiken	Babynat	First flavour	M73	PCBF	Stockholm			High arsenic content, high manganese content
Ekologiska Barnmatsbutiken	Organix	Organic seven grain cereal	M51	PCBF	Stockholm			High manganese content
Ekologiska Barnmatsbutiken	Babybio	Céréales Cacao	M74	PCBF	Stockholm			High cadmium content, high arsenic content, high manganese content
EnaGo AB	EnaGo	Välling mjölkfri [gruel, milk-free]	M24	PCBF	Falun			High lead content, high cadmium content, high arsenic content, high manganese content
EnaGo AB	EnaGo	Banangröt mjölkfri [banana porridge, milk-free]	M23	PCBF	Falun			High lead content, high cadmium content, high arsenic content, high manganese content
Fresenius Kabi AB	Fresenius Kabi	Fresubin soya fibre	M70	FSMP (>1 year)	Upplands Bro			High copper content, high manganese content, high lead content
Fresenius Kabi AB	Fresenius Kabi	Fresubin energy fibre (pooled sample of different flavours)	M26	FSMP (>1 year)	Upplands Bro			High copper content, high manganese content
Fresenius Kabi AB	Fresenius Kabi	Frebini energy fiber drink (chocolate flavour)	M97	FSMP (>1 year)	Upplands Bro			High manganese content
GoGreen AB	GoGreen	Sojadryck original + Kalcium [soya drink original + calcium]	M58	Foods for normal consumption	Stockholm			High manganese content, high cadmium content
Kung Markatta AB	Holle	Eko Modersmjölksersättning [infant formula] 1	M92	IF	Malmö			High lead content

Appendix 7

Retailer in Sweden	Manufacturer	Product	ID no.	Product category (1)	Control authority	Deviation from maximum/minimum level (2)	Content determined by analysis compared to declared content (3)	Exceeding health-based guideline values (4)
Kung Markatta AB	Holle	Eko Hirsgröt [millet porridge]	M64	PCBF	Malmö			High manganese content
Kung Markatta AB	Holle	Eko risgröt [rice porridge]	M91	PCBF	Malmö			High arsenic content, high manganese content
Kung Markatta AB	Holle	Bio-Babybrei Grieß	87	PCBF	Malmö			High manganese content
Kung Markatta AB	Holle	Eko havregröt [oat porridge]	M63	PCBF	Malmö			High manganese content
Kung Markatta AB	Holle	Eko dinkelgröt [spelt porridge]	M65	PCBF	Malmö			High manganese content
Kung Markatta AB	Holle	Eko tillskottsnäring [follow-on formula] 2	M52	Tillskottsnäring [follow-on formula]	Malmö		37% higher manganese content	High lead content
Kung Markatta AB	Alpro	Soja drink natural fresh	M43	Foods for normal consumption	Malmö			High manganese content
Kung Markatta AB	Rice Dream	Rice drink organic	M38	Foods for normal consumption	Malmö			High arsenic content
Mediq Sverige AB	Mead Johnson	Enfamil Human Milk Fortifier	M61	FSMP (0-12 months)	Kungsbacka		53 % higher manganese content	High lead content
Mediq Sverige AB	Mead Johnson	Enfamil AR lipil	M78	FSMP (0-12 months)	Kungsbacka			High manganese content, high lead content
Mediq Sverige AB	Mead Johnson	Nutramigen 1 lipil	M1	FSMP (0-12 months)	Kungsbacka			High manganese content, high lead content
Mediq Sverige AB	Mead Johnson	Pregestimil lipil	M99	FSMP (0-12 months)	Kungsbacka			High manganese content, high lead content
Mediq Sverige AB	Mead Johnson	Nutramigen 2 lipil	M48	FSMP (0-12 months)	Kungsbacka		64 % higher manganese content	High lead content, high manganese content
Mediq Sverige AB	Mead Johnson	Enfalac premature	M98	FSMP (0-12 months)	Kungsbacka			High lead content
Nestlé Sverige AB	Nestlé	FM 85	M60	FSMP (0-12 months)	Helsingborg		101 % higher manganese content	
Nestlé Sverige AB	Nestlé	Althéra	M75	FSMP (0-12 months)	Helsingborg			High lead content
Nestlé Sverige AB	Nestlé	Isosource junior	M71	FSMP (>1 year)	Helsingborg			High manganese content, high lead content
Nestlé Sverige AB	Nestlé	Resource minimax (pooled sample of different flavours)	M29	FSMP (>1 year)	Helsingborg			High lead content
Nestlé Sverige AB	Nestlé	MiniMax barnsondnäring [child tube-feeding]	M82	FSMP (0-12 months)	Helsingborg			Low iron content, high arsenic content
Nestlé Sverige AB	Nestlé	PreNAN discharge	M95	FSMP (0-12 months)	Helsingborg			High lead content
Nestlé Sverige AB	Nestlé	NAN 1 Modersmjölksersättning [infant formula]	M10	IF	Helsingborg			High lead content
Nestlé Sverige AB	Nestlé	NAN HA1 Modersmjölksersättning [infant formula]	M11	IF	Helsingborg			High lead content
Nestlé Sverige AB	Nestlé	Musligröt Päron-banan [muesli porridge pear-banana]	M9	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	Fullkornsvälling [wholemeal gruel]	M18	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	Cerelac risgröt [rice porridge]	M31	PCBF	Helsingborg			High arsenic content, high manganese content
Nestlé Sverige AB	Nestlé	Sinlac specialgröt [special porridge]	M12	PCBF	Helsingborg			High cadmium content, high arsenic content, high manganese content

Appendix 7

Retailer in Sweden	Manufacturer	Product	ID no.	Product category (1)	Control authority	Deviation from maximum/minimum level (2)	Content determined by analysis compared to declared content (3)	Exceeding health-based guideline values (4)
Nestlé Sverige AB	Nestlé	Dinkelgröt naturell [spelt porridge, natural]	M86	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	Cerelac fruktgröt banan apelsin [fruit porridge, banana orange]	M37	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	God natt mild havrevälling [God natt mild oat gruel]	M6	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	Mild fullkornsgröt [mild wholemeal porridge]	M32	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	Mild fullkornsvälling havre [mild wholemeal gruel, oats]	M21	PCBF	Helsingborg			High manganese content
Nestlé Sverige AB	Nestlé	NAN Pro 2 Tillskottsnäring [follow-on formula]	M36	Follow-on formula	Helsingborg			High lead content
Nutricia Nordica AB	Nutricia	Neocate LCP	M72	FSMP (0-12 months)	Solna			High manganese content, high lead content
Nutricia Nordica AB	Nutricia	Pepti junior	M79	FSMP (0-12 months)	Solna			High manganese content, high lead content
Nutricia Nordica AB	SHS	PKU anamix infant lcp+	M85	FSMP (0-12 months)	Solna		37 % lower iron content	
Nutricia Nordica AB	Nutricia	Pepticate	M54	FSMP (0-12 months)	Solna		45 % higher manganese content	High lead content
Nutricia Nordica AB	SHS	Galactomin 19 formula	M69	FSMP (0-12 months)	Solna			High manganese content, high lead content
Nutricia Nordica AB	Nutricia	NutriniKid multi fibre (pooled sample of different flavours)	M27	FSMP (>1 year)	Solna			Low manganese content, high lead content
Nutricia Nordica AB	Nutricia	Nutrini multi fibre	M84	FSMP (>1 year)	Solna			High manganese content, high lead content
Nutricia Nordica AB	Nutricia	Nutrini energy multi fiber	M83	FSMP (>1 year)	Solna			High manganese content, high lead content
Nutricia Nordica AB	SHS	Neocate advance	M81	FSMP (>1 year)	Solna		41 % higher manganese content	Low iron content
Nutricia Nordica AB	SHS	XP Maxamaid (pooled sample of different flavours)	M53	FSMP (>1 year)	Solna	exceeds the maximum levels for copper, iron and manganese		High manganese content
Quaker Oats Scandinavia c/o Valora Trade Sweden AB	Quaker	Pama minutris [instant rice]	M49	Foods for normal consumption	Stockholm			High arsenic content
Raisio Sverige AB	Carlshamn	Risdryck naturell [rice drink, natural]	M45	Foods for normal consumption	Upplands Väsby			High arsenic content
Semper AB	Semper	Profylac	M103	FSMP (0-12 months)	SLV/KA			High manganese content
Semper AB	Semper	Fruktgröt fullkorn [fruit porridge wholemeal]	M4	PCBF	SLV/KA			High manganese content
Semper AB	Semper	Fullkornsvälling havre vete råg [wholemeal gruel oat wheat]	M5	PCBF	SLV/KA			High manganese content
Semper AB	Semper	Banangröt [banana porridge]	M3	PCBF	SLV/KA			High arsenic content, high manganese content
Semper AB	Semper	Mild havregröt [mild porridge oats]	M35	PCBF	SLV/KA			High manganese content

Appendix 7

Retailer in Sweden	Manufacturer	Product	ID no.	Product category (1)	Control authority	Deviation from maximum/minimum level (2)	Content determined by analysis compared to declared content (3)	Exceeding health-based guideline values (4)
Semper AB	Semper	Risgröt med äpple och mango [rice porridge with apple and mango]	M25	PCBF	SLV/KA			High arsenic content
Semper AB	Semper	Kvällsvälling ris och vete [evening gruel, rice and wheat]	M55	PCBF	SLV/KA			High arsenic content
Semper AB	Semper	Mild fullkornsvälling [mild wholemeal gruel]	M8	PCBF	SLV/KA			High manganese content
Semper AB	Semper	Mild fullkornsgröt [mild wholemeal porridge]	M33	PCBF	SLV/KA			High manganese content
Semper AB	Semper	Drickfärdig mild fullkornsvälling [ready to drink mild wholemeal gruel]	M34	PCBF	SLV/KA			High manganese content
Vitafo Scandinavia AB	Vitafo	PKU gel (pooled sample of different flavours)	M28	FSMP (>1 year)	Möndal	exceeds the maximum levels for copper, iron and manganese	51% higher iron content	High lead content, high manganese content

1. PCBF - Processed cereal-based foods for infants and young children;

FSMP - foods for special medical purposes;

2. See appendix 5.

3. The cases in which the difference between the value determined by analysis and the value declared on the packaging is greater than 35 per cent are listed here. Even though there are currently no rules or guidance on the tolerable deviations, companies should be aware of the levels of minerals in the products as well as the average value that is representative and that must be declared on the packaging. The difference must not be excessive. See appendix 4.

4. See appendix 6.

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22. Not published.
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