Food Safety
AUTHORITY OF IRELAND

Report of the Scientific Committee
of the Food Safety Authority of Ireland

Metals of Toxicological Importance in the Irish Diet

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Metals of Toxicological Importance in the Irish Diet

CONTENTS

EXECUTIVE SUMMARY 3

GLOSSARY 4

CHAPTER 1. INTRODUCTION 6

1.1 Background 6
1.2 Sources of Exposure 6
1.3 Regulatory Maximum Limits for metals 8

CHAPTER 2. HEAVY METAL GEOCHEMISTRY AND OCCURRENCE IN IRELAND 10

2.1 Anthropogenic Sources of Metals in Ireland 10
2.2 Geochemical Sources and Occurrence of Heavy Metals in Ireland 13

CHAPTER 3. OCCURRENCE OF METALS IN FOOD AND WATER 17

3.1 Aluminium 17
3.2 Arsenic 19
3.3 Cadmium 22
3.4 Lead 25
3.5 Mercury 28

CHAPTER 4. RISK ASSESSMENT OF ALUMINIUM, ARSENIC, CADMIUM, LEAD AND MERCURY PRESENT IN FOOD IN IRELAND 30

4.1 Aluminium 30
4.2 Arsenic. 33
4.3 Cadmium 38
4.4 Lead 41
4.5 Mercury. 46

CHAPTER 5. CONCLUSIONS 51

Dietary exposure 51
Biomonitoring. 51
Food monitoring and risk management. 51
At-risk populations. 53

APPENDIX I 54

REFERENCES 56

ACKNOWLEDGEMENTS 64

EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) has a statutory responsibility to ensure the safety of food consumed, distributed, produced and sold on the Irish market. In this respect, the FSAI co-ordinates the collation of food safety surveillance information in conjunction with its official agencies, the Health Service Executive (HSE), the Department of Agriculture, Food and the Marine (DAFM), the Marine Institute (MI), the National Standards Authority of Ireland (NSAI), the Sea-Fisheries Protection Authority (SFPA), and County and City Councils.

In recent years, the European Food Safety Authority (EFSA) has adopted several opinions on the risks to health associated with dietary exposure to certain metals of toxicological importance, including aluminium, arsenic, cadmium, lead and mercury. Exposure to one or more of these metals could present risks to the health of consumers because of localised elevated levels in the environment, including groundwater (lead, arsenic and cadmium) and/or presence in particular foods.

This report provides an overview of the geochemical and food occurrence of aluminium, arsenic, cadmium, lead and mercury in Ireland. It describes the health hazards, effect levels and health-based guidance values (HBGV) as established by EFSA and other international bodies and evaluates exposure of the population resident in Ireland (adults >18 years and children 5-12 years of age) via diet and drinking water. Finally, it concludes on possible risks to the health of the adult and child populations resident in Ireland arising as a result of exposure to these metals.

The main route of exposure to metals in the population resident in Ireland is by food and, to a much lesser extent, drinking water. Exceptions are cadmium and mercury, where exposure from tobacco smoking or dental amalgam fillings respectively, can potentially contribute significantly to total exposure. Also, users of medicinal products, such as buffered analgesics and antacids may have an increased exposure to aluminium. Geochemical sources are likely to be the primary influencing factor on levels of these metals in food and drinking water produced in Ireland. However, the globalisation of food supply makes assessment of local influences on dietary exposure difficult and such exposure is best assessed by means of biomarker studies.

With regard to the latter, several such studies have informed risk assessments carried out in Ireland and supported the general conclusion that the risk to the general adult and child populations from dietary exposure to these metals in Ireland is of low concern.

Occurrence data reported from existing systems of food monitoring by the FSAI, the HSE (Environmental Health Service (EHS), Public Analyst Laboratories), DAFM, Environmental Protection Agency (EPA), SFPA, MI, County and City Councils indicate that compliance with legislative maximum limits is very high and, where infringements have been found, produce has been removed from the market. Similarly, results reported for drinking water by the EPA indicate a very high rate of compliance.

In general, the results of food and drinking water surveillance programmes to date are reassuring in that there is no current concern regarding the levels of these metals in the Irish diet or their possible impact on the health of the population resident in Ireland.

The European Commission has implemented several risk management actions, such as the introduction of maximum legislative limits for inorganic arsenic in rice and rice-based products, the reduction of maximum limits for aluminium-containing food additives and the reduction of existing maximum levels and setting additional maximum levels for lead in relevant commodities to reduce long term exposure of the European population. Regarding mercury, reduction of dietary exposure by lowering of existing maximum levels is currently being discussed.

While this report has found that the risk from dietary exposure to the metals under consideration is of low concern for the general population, specific advice to certain sub-population groups is warranted. For example, the FSAI has provided advice on (a) fish consumption for children, pregnant women and women of reproductive age with regard to mercury exposure and (b) consumption advice relating to arsenic in Hijiki seaweed and rice milk.

GLOSSARY

Adenoma: A generic term for a benign epithelial tumour composed of glands and/or glandular elements

ADI: Acceptable Daily Intake

ALARA: As Low as Reasonably Achievable

Anthropogenic: Related to the influence of humans on the environment

Biocides: Active substance or a preparation containing one or more active substances, in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means

BMD: The Benchmark Dose is based on a mathematical model being fitted to the experimental data within the observable range and estimates the dose that causes a low but measurable response (the benchmark response BMR) typically chosen at a 5 or 10% incidence above the control. The BMD lower limit (BMDL) refers to the corresponding lower limits of a one-sided 95% confidence interval on the BMD. Using the lower bound level takes into account the uncertainty inherent in a given study, and assures (with 95% confidence) that the chosen BMR is not exceeded

BMDL: Benchmark Dose Lower Limit (see BMD)

BMR: Benchmark Response (see BMD)

bw: Bodyweight

Carcinogenic: Causing cancer

Carcinoma: A malignant new growth made up of epithelial cells tending to infiltrate surrounding tissues and to give rise to metastases

Cerebrovascular stroke: Death of brain cells due to lack of oxygen due to impaired blood flow to the brain

Clastogenicity: Clastogenicity is the effect of a clastogen. A clastogen is a material that can cause breaks in chromosomes leading to sections of the chromosomes being deleted, added or rearranged

CONTAM: EFSA Panel on Contaminants

DAFM: Department of Agriculture, Food and the Marine

DECLG: Department of the Environment, Community and Local Government

DEFRA: Department for Environment, Food & Rural Affairs – UK GOV

dL: Deci-liter = 0.010 L

DNA-reactive: Direct interaction with DNA

DoH: Department of Health

DRV: Dietary reference value

EC: European Community

EFSA: European Food Safety Authority

EHS: Environmental Health Service

Epigenetic: Relating to, being, or involving a modification in gene expression that is independent of the DNA sequence of a gene

EU: European Union

FAO: Food and Agriculture Organization

FCM: Food Contact Material

Genotoxic: Damaging to DNA and capable of causing mutations or cancer

Geochemistry: The study of the chemical elements, their isotopes, and related processes with respect to the abundance and distribution of materials within the Earth's waters, crust, and atmosphere

Geometric mean: The nth root of the product of n quantities

GSI: Geological Survey of Ireland

HBGV: Health-Based Guidance Value, e.g. Tolerable Daily Intake (TDI), etc.

Herbicide: Biocide used to kill plants

HSE: Health Service Executive

IARC: International Agency for Research into Cancer

In utero: In the womb

Insecticide: Biocide used to kill insects

Interstitial nephropathy: Injury to renal tubules and interstitium resulting in decreased renal function

IQ: Intelligence quotient

Ischaemic heart disease: Disease characterised by reduced blood supply to the heart

JECFA: WHO/FAO Joint Expert Committee on Food Additives and Contaminants

Kg: Kilogram

kPa: Kilopascal is a measure of pressure

LB: Lowerbound (<LOD=0)

LCPUFA: Long-Chain Polyunsaturated Fatty Acid

LOD: Limit of Detection

LOQ: Limit of Quantitation

mg: Milligram = 10^{-3}g = 0.001 gram

MI: Marine Institute

MoE: Margin of Exposure (MoEs are calculated by dividing the BMDL values derived from dose-response data for the different endpoints by the estimates of dietary exposure)

Mutagenesis: changing the genetic information of an organism

µg: Microgram = 0.000001 gram

NANS: National Adult Nutrition Survey

NDNA: EFSA Panel on Dietetic Products, Nutrition and Allergies

Neoplastic: An abnormal new growth of tissue; a tumour

ng: Nanogram = 10^{-9} = 0.000000001 gram

NSAI: National Standards Authority of Ireland

NTP: National Toxicity Programme

Official agencies: Health Service Executive, Department of Agriculture, Food and the Marine, local authorities and the Sea-Fisheries Protection Authority

P97.5: 97.5th Percentile of a Distribution

PAH: Polycyclic Aromatic Hydrocarbons

Parametric Value: The parametric value for a chemical element or substance in drinking water is the maximum level established in legislation in order to ensure that water intended for human consumption can be consumed safely on a life-long basis, and thus represents a high level of health protection

PRI: Population Reference Intake

Proximal tubular necrosis: Death of tubular epithelial cells that form the renal tubules of the kidneys

PTWI: Provisional Tolerable Weekly Intake

Quantum satis: The term 'quantum satis' is applied to usage for a large number of additives. 'Quantum satis' indicates that no maximum level is specified. However, additives must be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer

RDA: Recommended Daily Allowance

Rodenticides: Biocide used to kill rodents

SCF: Scientific Committee on Food

SCOOP: Scientific Cooperation Task (EC)

SFPA: Sea-Fisheries Protection Authority

SML: Specific migration limits (defined as the maximum permitted amount of a given substance that can be released from a material or article into food or food simulant)

Tailings: Materials left over after the process of separating the valuable fraction from the uneconomic fraction of an ore

TDI: Tolerable Daily Intake

TDS: Total Diet Study

TWI: Tolerable Weekly Intake

UB: Upperbound (<LOD=LOD)

Valency: Describes how an atom or radical can combine with other chemical species, based on the number of electrons added, lost or shared with another atom(s)

WHO: World Health Organization

CHAPTER 1. INTRODUCTION

1.1 Background

The Food Safety Authority of Ireland (FSAI) has a statutory responsibility to ensure the safety of food consumed, distributed, produced and sold on the Irish market. In this respect, the FSAI co-ordinates the collation of food safety surveillance information in conjunction with its official agencies, the Health Service Executive (HSE), the Department of Agriculture, Food and the Marine (DAFM), the Marine Institute (MI), the National Standards Authority of Ireland (NSAI), the Sea-Fisheries Protection Authority (SFPA), and County and City Councils.

In recent years, the European Food Safety Authority (EFSA) has adopted several opinions on the risks to health associated with dietary exposure to certain metals of toxicological importance, including aluminium, arsenic, cadmium, lead and mercury (EFSA, 2008; EFSA 2009b; EFSA 2010a; EFSA 2012; EFSA 2009a). Exposure to one or more of these metals could present risks to the health of consumers because of localised elevated levels in the environment, including groundwater (lead, arsenic and cadmium) and/or presence in particular foods.

This report aims to:

- Provide an overview of the geochemical and food occurrence of aluminium, arsenic, cadmium, lead and mercury in Ireland
- Describe the health hazards, effect levels and health-based guidance values (HBGV) as established by EFSA and other international bodies
- Evaluate exposure of the population resident in Ireland (adults >18 years of age and children 5-12 years of age) via diet and drinking water, and
- Conclude on possible risks to the health of the population resident in Ireland arising from exposure to these metals

1.2 Sources of Exposure

Aluminium, arsenic, cadmium, lead and mercury are ubiquitously present in the environment, due to natural and/or anthropogenic sources.

The major sources of exposure of the population resident in Ireland to these metals are food and drinking water, with the exception of cadmium, for which smoking of tobacco is known to be contributing in equal proportion. For individuals with a large number of dental amalgam fillings, these may account for 87% of total absorbed mercury and approximately 50% in individuals with only a few amalgam fillings (ATSDR, 1999; EFSA, 2012). The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) noted that removal of amalgam fillings results in an acute relatively high exposure of the individual patient to mercury, compared with leaving the amalgam filling in place. The committee found no clinical evidence to justify removal of satisfactory amalgam fillings, with the exception of patients suspected of having allergic reactions (SCENIHR, 2008).

Environmental levels may be elevated because of local geochemistry and/or pollution. Activities such as mining and refining of metals and heavy engineering have historically been limited in Ireland and have not impacted greatly on the Irish environment. However, spoil resulting from historical mining has resulted in localised soil contamination particularly by lead and zinc and to a lesser extent, copper and mercury. Thus, geochemical factors are likely to be the primary influencing factor on levels of these metals in food produced in Ireland and in drinking water.

Table 1. An overview of potential sources of exposure

Metal	Dietary exposure routes
Aluminium	Geological sources
	Food and drinking water
	Release from mining and industrial uses in the production of aluminium metal, aluminium oxide and other aluminium compounds
	Aluminium-containing food additives
	Release to food from aluminium-containing food contact materials
	Pharmaceuticals and consumer products
Arsenic	Geological sources
	Food and drinking water
	Release from industrial applications, e.g. past production of wood preservatives, herbicides and insecticides
Cadmium	Geological sources
	Food and drinking water
	Release from cadmium-containing food contact materials
	Release from industrial applications such as steel electroplating, use in batteries, cadmium-containing pigments, ornament glazing etc.
Lead	Geological sources
	Food and drinking water
	Use of complementary and alternative medicine
	Release to food from lead-containing food contact materials (such as lead-glazed ceramics)
	Release from industrial applications such as mining, smelting, battery manufacturing and the previous use of leaded petrol and lead-containing paint
	Release to water from lead pipes
Mercury	Geological sources
	Food and drinking water
	Dental amalgams
	Mercury-containing appliances, e.g. thermometers, barometers and other measuring equipment
	Anthropogenic sources (mining operations, industrial processes, combustion of fossil fuels (especially charcoal), production of cement, and incineration of municipal, chemical, and medical wastes)

To identify the main contributors to dietary exposure to metals (and other contaminants), the FSAI periodically carries out Total Diet Studies (TDS). In carrying out a TDS at national level, the most commonly consumed foods in the country are selected based on food consumption data, and the respective predominant preparation methods are determined. The selected foods representative of the normal diet consumed by the population over a given period of time are collected from defined surveillance areas and consist of a number of sub-samples per sample (for example, a bread sample could contain five different sub-samples of the particular type of bread being analysed). The samples are prepared following the most commonly used preparation practice and are subsequently analysed for the chemicals of interest. The chemical occurrence data are then combined with consumption data and exposure estimates of the population to the chemicals via the selected foods can be calculated. A TDS explicitly takes into account the kitchen preparation of foods to assess the levels of contaminants in foods as consumed, as these may change during preparation and cooking.

The results from the most recent TDS (FSAI, 2016) have been used to describe occurrence of metals in food (see Chapter 3) and to provide exposure estimates to the metals covered in this report (see Chapter 4).

1.3 Regulatory Maximum Limits (MLs) for metals

Food

The presence of chemical contaminants in the raw materials from which food is derived, and often in the food itself, is in most cases unavoidable as they arise as a result of, for example, environmental pollution, growing and harvesting conditions and processing factors that may be difficult to control. The EU legislation on food safety introduced over many years has the primary objective of a high level of consumer protection, and the legislation on contaminants in particular is based on the principle of 'ALARA' (As Low as Reasonably Achievable). In practice however, it may be impossible to achieve a level that is totally protective of health; a number of the contaminants of concern may have carcinogenic properties and a genotoxic mode of action. For such substances, the conventional scientific principle is that there is no safe level of exposure. Establishment of maximum levels for chemical contaminants in food is therefore based on achieving the right balance between the risks from the contaminant and the potential benefit of the food, also taking into consideration issues such as the economic cost of achieving low/zero levels of the contaminant and the feasibility of detecting such low levels by chemical analysis.

European Commission Regulation 1881/2006/EC as amended, sets maximum levels for the contaminants of greatest concern for the health of consumers, due to their toxicity or their potential prevalence in the food chain or both.

The contaminants covered by the current European Union legislation on contaminants include the metals arsenic, cadmium, lead and mercury, as well as mycotoxins, tin, process contaminants, PAHs, dioxins and PCBs, melamine, erucic acid, tropane alkaloids and nitrates. The levels are set on the basis of scientific advice provided by EFSA and previously, by the Scientific Committee on Food (SCF).

Aluminium can also be found in food as a consequence of food processing, i.e. as component of food additives. Annex II to Regulation (EC) No 1333/2008 authorises the use of aluminium-containing food additives in a wide number of foodstuffs. However, as a result of the EFSA opinion in 2008 in which the tolerable weekly intake (TWI) for aluminium was lowered to 1 mg/kg bw/week (EFSA, 2008), restrictions on the use of aluminium containing food additives, including aluminium lakes were introduced via Commission Regulation (EU) No 380/2012.

Whilst the food control authorities in Member States, e.g. the FSAI in Ireland, are responsible for monitoring food products to ensure that they comply with the legislation, food business operators have the key responsibility to ensure that the food they produce and supply is safe and compliant with all legislative requirements. Imported foodstuffs cannot be placed on the EU market unless they comply with relevant food law including the legislation on contaminants. It is the responsibility of the importer of food into the EU to ensure that the imported product is in compliance with the legislation, and this is controlled at EU borders and on the market.

Water

The basic standards governing the quality of drinking water intended for human consumption, whether in its original state or after treatment are set out in EU Directive 98/83/EC, which is transposed into Irish law via European Union (Drinking Water) Regulations, 2014.

The parametric values in drinking water for the metals under consideration are 200 μg/L for aluminium, 10 μg/L for arsenic, 5 μg/L for cadmium, 10 μg/L for lead and 1 μg/L for mercury.

Food Contact Materials

Food Contact Materials (FCMs) are regulated by the Framework Regulation (EC) No 1935/2004 which sets out general requirements for all FCMs. In addition, there are specific directives and regulations which cover both the particular materials and articles listed in the Framework Regulation and individual substances or groups of substances used in the manufacture of materials and articles intended to come into contact with food.

Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs sets a limit of 0.3 mg/L for the amount of cadmium and 4 mg/L for the amount of lead permitted to transfer out of ceramic food contact materials and articles (0.1 mg/L for cadmium and 1.5 mg/L for lead from cooking ware, packaging and storage vessels with a capacity of greater than three litres).

CHAPTER 2. HEAVY METAL GEOCHEMISTRY AND OCCURRENCE IN IRELAND

Approximately 90 chemical elements are found in soils. Detailed soil data for Ireland are available from the National Soils Database (Fay *et al.*, 2007a) and from the *Soil Geochemical Atlas of Ireland* (Fay *et al.*, 2007b) and information relating specifically to Irish soils has been assembled in the book *Trace Elements and Metals in Irish Soils* (McGrath *et al.*, 2008). Table 21 in the Appendix provides data on levels of various elements and pH values for a range of Irish soils.

Data on the elemental content of soil can contribute towards an understanding of the excessive or low occurrence of certain elements in food. Localised geochemical anomalies exist, such as high soil cadmium in counties Meath and Dublin, aluminium and arsenic in Wexford, lead in Dublin, and mercury in Wicklow.

In addition to influencing elemental content of plants and animals, soil factors also influence the levels of elements in water.

2.1 Anthropogenic Sources of Metals in Ireland

2.1.1 Industrial sources

Soils in Ireland as elsewhere in Europe have been subjected to pollution by man over the past millennia with the largest effects occurring in the past century. In that latter period, industrialisation has seen the growth of enterprises which in earlier years, characteristically caused modest, by western European standards, discharges of heavy metals to soil, water and air. Polluting enterprises included tanning, metal fabrication and industries for the production of coal gas and cement. However, Ireland has not had a history of extensive industrialisation thus limiting anthropogenic pollution of the environment with metals. Those facilities that existed in the past, e.g. Irish Steel in County Cork, have now closed. Since sites were generally near major centres of population, they have generally been built over and are no longer a threat to food production.

Other anthropogenic sources of elevated levels of metals in the Irish environment include the use, storage and production of fertiliser and pest control chemicals, containing tin, arsenic or copper in orchards, while some soils have been significantly (but arguably, beneficially) enriched in copper as a consequence of the addition of the metal salt to pig rations in the past.

Arsenical compounds have been used in the past in the production of wood preservatives, herbicides, and biocides such as rodenticides and insecticides. While these uses have been largely phased out in the European Union under specific legislation and with certain derogations, residual high soil concentrations may continue to exist in locations such as old orchard sites.

Industrial release of cadmium occurs as a by-product from mining, smelting and the production of fertilisers from phosphate ores (WHO, 2011, Fay *et al.*, 2007b). Atmospheric pollution and application of phosphate fertilisers appear to be major contributors to arsenic levels, rock phosphate being reported to contain up to 200 mg/kg arsenic (EFSA, 2009b).

Probably the major example of anthropogenic pollution by trace elements in Ireland, as in other countries, is the increase of lead in soil arising from the use in the past of tetraethyl lead in petrol. However, blood lead levels in the general population have fallen dramatically since the phasing out of lead from petrol and the reduction of environmental exposure to the metal (Tong, 2000; ATSDR, 2007).

2.1.2 Urban sources

Soils in long-established household gardens or allotments may contain residues from a multitude of wastes and depositions (Culbard *et al.*,1998: Mc Grath,1995). Significant increases have been noted in Ireland (Mc Grath,1995) especially for lead and mercury, but not for cadmium.

For example, lead contamination of gardens is common, particularly in older areas of cities where soil lead concentrations has been influenced by historic use of lead paints, leachate from lead piping and in exhaust emissions (Alloway, 2004).

2.1.3 Sewage sludge

In the past, Ireland, unlike most other European countries, applied little sewage sludge to agricultural land. Treated sludge is now being spread on agricultural land in accordance with the Waste Management Regulations, S.I. No. 267 of 2001 and S.I. No. 148 of 1998.The latter regulation fixes maximum acceptable concentration of metal in soil in receipt of sludge at 1 mg/kg for cadmium, 50 mg/kg for lead and 1 mg/kg for mercury.

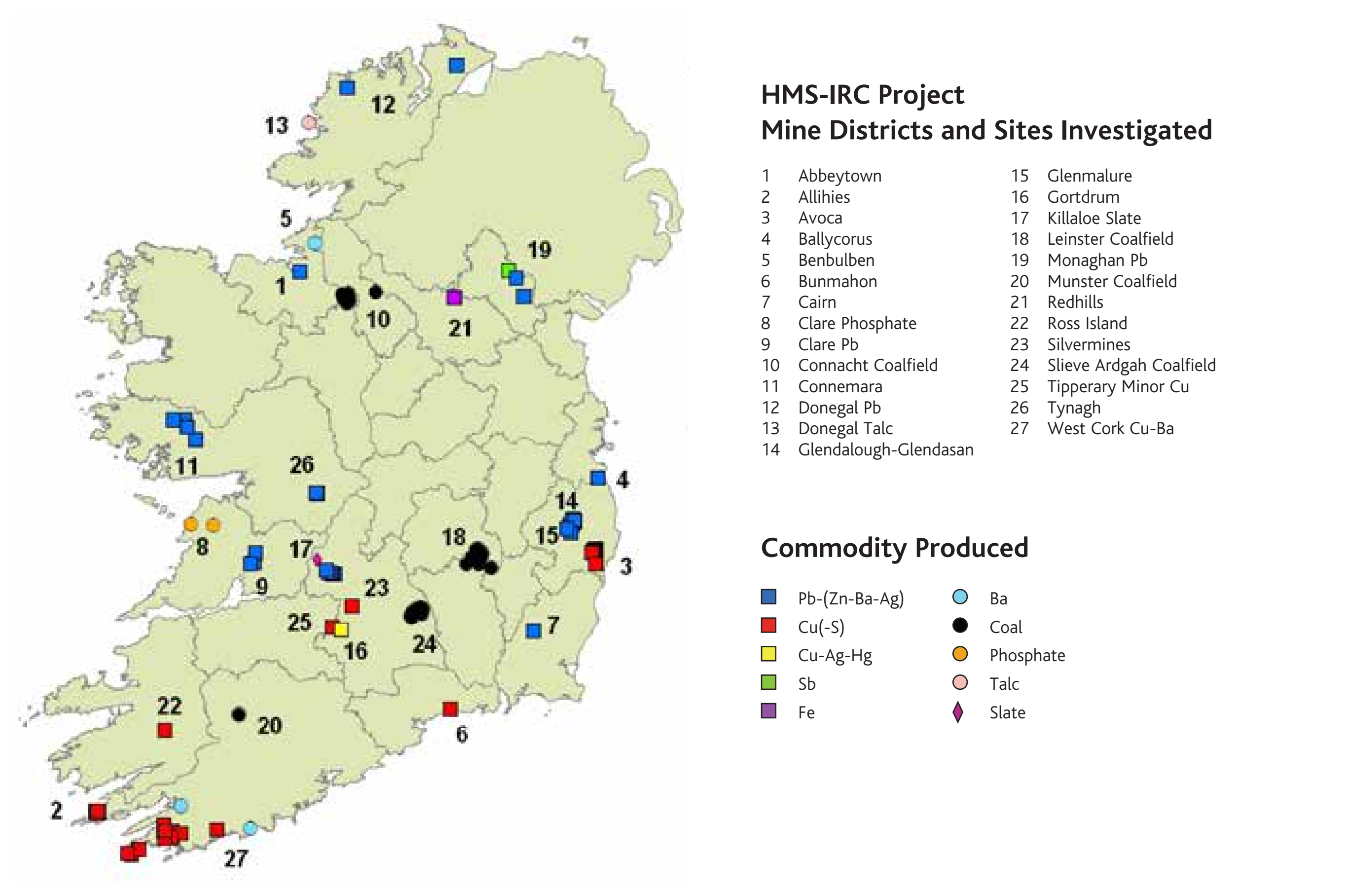
2.1.4 Historic mine sites

Ireland has a long history of mining, e.g. for copper in the Bronze Age and for silver in the Viking period. Up to the start of the twentieth century, most mining operations worked veins of minerals. Most of these were for copper or lead. A considerable amount of historic information exists for mining in Ireland. The Geological Survey of Ireland (GSI) in conjunction with the EPA has produced a comprehensive inventory of significant mine sites, classifying onsite risks including those impacting on the environment, to produce an important benchmark from which future investigations can be directed (Stanley *et al.*, 2009). Historic lead mining facilities (such as Ballycorus, Co. Wicklow and Silvermines, County Tipperary) are located throughout the country (see Figure 1) and the potential risk posed by these sites to human and animal health and to the wider environment has been assessed (Stanley *et al.*, 2009). Many of the mines described in the GSI/EPA investigation, approximately 350, were described as metal producing. Mining activities were widely spread over the country notably in the following areas, a broad belt extending from Clare/ Limerick to Wicklow, an area approximating to the Drumlin area in north Leinster, and in Galway, north Donegal and west Cork (see Figure 1). Metals extracted and recovered were mainly lead, zinc, copper and, in recent years, barium with small quantities of mercury and silver. Significant quantities of other metals present in ores were also extracted and escaped or were released to the environment. These other metals included cadmium and arsenic in addition to aluminium in acidic leachates.

Larger scale operations using modern mining techniques began in the 1960s with the opening of mines in Tynagh (Galway) for lead and zinc, Silvermines for lead, zinc and other metals, and Avoca was re-opened for copper. These three mining areas collected the top three negative scores in the GSI/EPA assessment ratings for closed (historic) mines. All three have had the poorest public images featuring animal deaths and leachate emissions. Three more recently-established mines, Navan, Lisheen and Galmoy (now closed, but still operating at the time of the survey) appear not to have impacted negatively. Modern practices that increased the efficiency of metal extraction from ore and ongoing operations to make safe, wastes including tailings and leachates, appear to have ensured this positive situation.

Lead is the single most important contaminant on Irish mine sites in terms of its potential toxicity, the concentration in which it is found, the quantity of lead-enriched material, and its geographical dispersion on and around these sites. While the normal background level for lead in Irish soils is less than 30 mg/kg, soils in the regions of these mines may contain higher levels due to past mining activities (EPA, 2003, 2004). These locally high levels have resulted in high levels in ground water, well water and in agricultural produce from the affected areas, and occurrences of animal poisonings were also recorded. Mine districts and sites most severely contaminated by lead include Caim, Clare Lead Mines, Glendalough, Silvermines and Tynagh (Stanley, 2009).

Figure 1. Map of Ireland showing various mineral deposits



Source: Historic Mine Sites Inventory and Risk Classification (EPA, 2009)

Following the sudden death by acute lead poisoning of three grazing cattle, a comprehensive study on the influence of lead in the Silvermines area, covering a land area of 23 km^2, was initiated by the Department of Agriculture and other agencies. Reports were published in 1990 (Department of Agriculture) and in 2000 (EPA). Soil in the playing field of the village school was found to contain lead up to a level of 40,000 mg/kg. Average blood lead level (n=439) of the resident population was measured repeatedly during this time. The geometric mean blood lead level for the child population was 2.7 µg/dL in 1999, 2.4 µg/dL in 2000 and 2.1 µg/dL in 2001 representing a 0.3 µg/dL decline yearly. This is likely due to risk reduction strategies adopted at that time. Soil samples (n=119), household dust samples (n=118) and hand wipe samples (n=168) were also analysed for lead. There was no evidence to suggest that consumption of home grown fruit or vegetables contributed to increased blood lead levels. The contribution of garden soil, house dust and hand lead accounted for only 16% of the variance in blood lead levels.

2.1.5 Mine sites and farming

Mine sites and mining areas differ widely in the hazards they present to food, i.e. plant and animal. Firstly, sites differ widely. Some are small and clearly separate from their rural surroundings, others larger and spatially intermingled with farming enterprises. Contamination can occur through the agencies of water (including flooding) and air as well as by absorption of contaminated areas or soil (including material from drainage channels) on to pristine areas. In time, grass may become established even though lead content in soil may be significantly elevated (in excess of 1,000 mg/kg).

Localised risk to animals and the food chain may occur in animals that graze land where soil lead exceeds 1,000 mg/kg (EPA, 2000).

Nevertheless, animals feeding on grass, as in Silvermines, have died from toxic levels of lead in ingested soil or waste ore in fields where cattle have previously been farmed without apparent incident. Follow-up investigations after different fatal occurrences (Department of Agriculture, 2000) were able to identify the nature and source of the ingested material. These included sediment in a drainage channel, slurry created by spillage of water, caused by animals milling around a drinking trough, sub-soil ore-rich material that had been used in repairs to an on-farm bridge and earlier, during the construction of the tailings pond, and grass heavily contaminated by wind-blown dust tailings.

Fields devoted to conventional agriculture may be less contaminated than fields closer to populated areas, where alternative methods of crop production are often in use. However, since uptake of lead from soil by plants is low, elevated levels of lead in soil are unlikely to result in significant crop contamination (Fleming, GA and Parle, PJ, 1977).

The norm for lead in soil from fields adjacent to small conurbations now appears to be closer to 50 mg/kg or greater and, in grassed areas in towns, still higher levels can be anticipated. In Galway, urban soil lead averaged 78 mg/kg (range 25-543) (Zhang, 2006). The UK guideline value for lead in soil from residential gardens is 450 mg/kg (Hooker, 2005 citing DEFRA and the UK Environment Agency, 2002e). US EPA guidelines identify 400 mg/kg as the threshold above which some control or abatement may be appropriate depending upon whether the area is expected to be used by children. As a general rule, concentrations below 400 mg/kg do not necessitate site-specific action. The expert group for Silvermines recommended a guideline value of 1,000 mg/kg dry matter for lead in both garden and agricultural soils in Ireland (EPA, 2004).

Concentrations in Irish soil are generally below that which would represent a significant threat to animals or the food chain. Generally, offal or meat from grazing animals will not exceed the maximum limit for lead established in legislation.

The potential for significant exposure to arsenic, cadmium, lead and zinc could arise in limited areas under unfavourable circumstances. Yet, probably because only small areas are affected and the fact that tillage crops occupy less than 10% of the surface area of the country, few, if any increases in metal content in vegetable or animal produce are encountered that are attributable to mining.

2.2 Geochemical Sources and Occurrence of Heavy Metals in Ireland

In mining areas, it is difficult to separate natural (geochemical) occurrence from pollution caused by historic mining activities, especially in areas of Ireland where mining waste has been naturalised over the years.

2.2.1 Aluminium

Aluminium (Al) occurs naturally in the environment, and is the most abundant metal in the earth's crust (WHO, 1997; EFSA, 2008). It occurs naturally in ingenious rocks and shale and is found naturally in Irish soils at levels ranging from 0.6 to 97.4 g/kg, with a median concentration of 34.8 g/kg (Fay *et al.*, 2007a) (see Figure 2). Soil acidification favours the release of aluminium from geological material (soils, rock, etc.) with consequent increase in levels of the metal in both water and crops. A large scale extraction plant for the refining of crude bauxite to alumina is located at County Limerick.

2.2.2 Arsenic

Arsenic (As) is a naturally occurring metal in water and soil. Arsenic is widely distributed in the earth's crust and is present at an average concentration of 2 mg/kg. It occurs naturally in minerals and in soil in small amounts and is often found in ores with copper and lead. It may be also deposited in soil due to anthropogenic activity. In the environment, inorganic arsenic is derived from the geochemistry of the bedrock whereas human activity may result in organic arsenic entering the environment. Shelf seawaters contain approximately 1.5 μg/L dissolved arsenic, which is generally higher than Irish freshwaters (typically < 1 μg/L). However, local sources may lead to elevated levels, such as in the river Drish. This river is known for having elevated metal levels and has shown the highest concentration (18 μg arsenic/L) of all Irish rivers measured. Average Irish soil content for total arsenic, at approximately 10 mg/kg in soil, appears to be slightly lower than in England/Wales but is higher than in most of mainland Europe. Soil guideline values of 32 and 43 mg/kg have been proposed in the UK for arsenic in residential and allotment soils, respectively (Environmental Agency, 2009). About 1% of Irish agricultural soils contain more than 40 mg/kg total arsenic. Elevated levels of total arsenic occur particularly in the southeast of the country, probably related to the high iron content of soils in that region (see Figure 2). However, this is unlikely to cause a significant rise in ground water arsenic, due to adsorption of arsenic to soil particles (Duxbury and Zavala, 2012).

2.2.3 Cadmium

Cadmium (Cd) is geologically associated with zinc and occurs as a minor component in most zinc ores and therefore, is a by-product of zinc mining, but is not mined as such in Ireland. Natural sources of cadmium are rock weathering, volcanoes and forest fires.

Levels of cadmium in Irish, English and Welsh soils are higher than in most mainland European countries (JRC, 2005), where few soils contain more than 0.69 mg/kg. It has been reported that cadmium content exceeds 1 mg/kg in 16% of Irish agricultural soils (Fay *et al.*, 2007a). In particular, high naturally occurring levels of cadmium in the soil (associated with the limestone glacial till (Gardiner *et al.*, 1980)) are found in parts of north Dublin and Meath, which is the main horticultural production region in the country (see Figure 2). The *Final Report of the Expert Group on Silvermines* (EPA, 2004) advised a maximum guideline value of 1.0 mg/kg cadmium in soil with a pH of less than 6.0 in gardens producing vegetables in the area (EPA, 2004). Cadmium from anthropogenic and geochemical sources is released to both groundwater and soil, although cadmium in soil is less mobile than that in water.

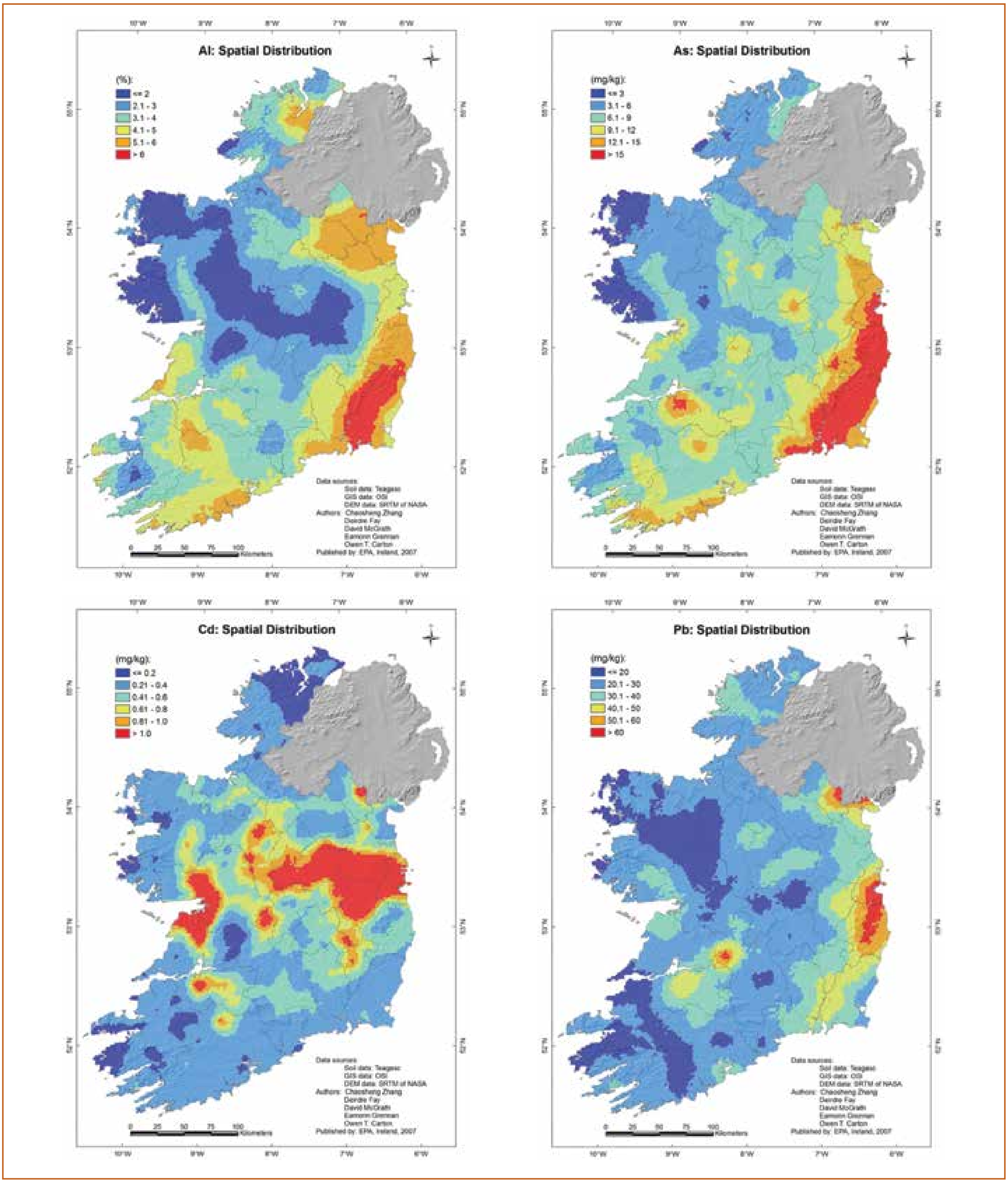
Both plants and animals bio-accumulate cadmium, plants taking up the element directly from soil and water, while both land and marine animals take up cadmium from their diet.

2.2.4 Lead

Lead (Pb) exists in three forms, namely elemental lead, inorganic lead salts and organic lead salts. Lead is often found in ores with zinc and copper.

It is widely dispersed throughout the environment as a result of human activities. While lead in the environment and in food is mainly inorganic, environmental pollution from past usage of organic forms, such as tetra-ethyl lead in petrol and dust from lead-based paints, contributes significantly to human exposure (ATSDR, 2006). Local sources of lead, higher than the background of less than 30 mg/kg, can occur due to disposal of lead-containing waste, geochemistry and mining.

Figure 2. Spatial distribution of Al, As, Cd and Pb in Irish soil



Source: *Soil Geochemical Atlas of Ireland* (Fay *et al.*, 2007)

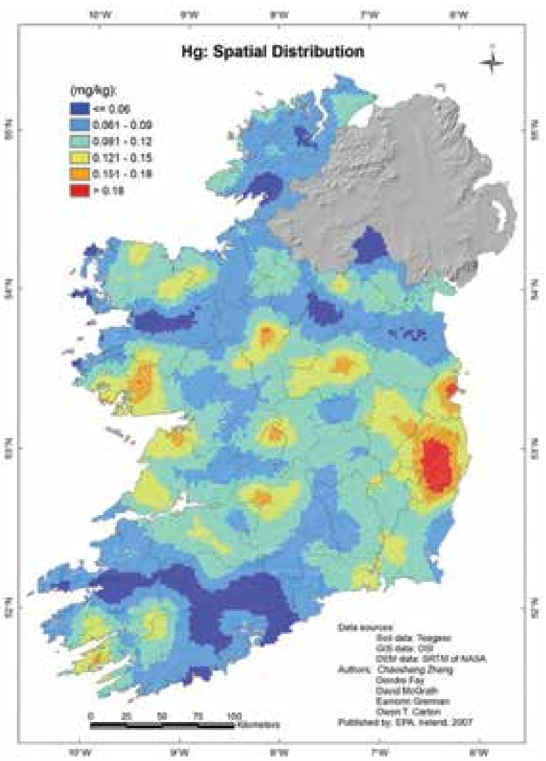
2.2.5 Mercury

Mercury (Hg) is a metal that occurs naturally in the earth's crust and in the environment. Mercury exists in three forms, namely elemental mercury (quicksilver), inorganic mercury salts and organic mercury salts (Kuban *et al.*, 2007; EFSA, 2012).

The geochemical occurrence of mercury is predominantly as deposits of mercuric sulphide or cinnabar ore, which can be utilised to produce mercury metal and inorganic or organic salts of mercury. Elemental mercury is released naturally from land and ocean surfaces due to its high volatility, with larger releases occurring as a result of volcanic eruptions or forest fires.

Elemental mercury is the predominant form of mercury in air, with background concentrations in the range of 1.5-1.7 ng/m^3 in the Northern Hemisphere (EFSA, 2012).

Figure 3. Spatial distribution of mercury content of Irish soils



Source: Soil Geochemical Atlas of Ireland (Fay *et al*, 2007)

Mercury concentration in air at a dedicated measuring site, near Carna in the West of Ireland, averaged 1.68 ng/m^3 over the period 1995-2006 (Leinert *et al.*, 2008). Anthropogenic sources result in releases of elemental mercury, mercuric mercury and particle-bound mercury. Mercury in the environment undergoes biogeochemical cycling, involving mobilisation of elemental mercury, deposition and re-mobilisation (Selin, 2009; EFSA, 2012). Mercury in the Irish environment (soil and water) arises mainly from anthropogenic activity/environmental pollution rather than from natural sources.

Levels in Irish soils are comparable to those in European soils (FOREGS, 2005) outside of Scandinavia, where they are lower. In the Soil Database study (Fay *et al.* 2007b) only three soil mercury values exceeded 1.0 mg/kg, which is the soil/sewage sludge regulatory value, and the maximum level detected was 3.5 mg/kg soil (see Figure 3).

CHAPTER 3. OCCURRENCE OF METALS IN FOOD AND WATER

As part of their responsibility for verifying that the relevant requirements of food law are fulfilled by food business operators at all stages of production, processing and distribution, the FSAI and its agencies carry out monitoring of food on the Irish market. These activities are undertaken in conjunction with the official agencies and their associated laboratories. Similarly, Irish Water is responsible for the production, distribution and monitoring of drinking water from 973 public water supplies, serving 81.9% of the population. The remainder of the population is supplied by group water schemes (6.1%), small private supplies (0.9%) and private wells (11.1%). Private wells are exempt from monitoring under the European Union (Drinking Water) Regulations, 2014 (S.I. No. 122 of 2014) provided the well does not supply a commercial/public activity. Responsibility for the water quality rests with the manager/operator of the supply. Irish Water is responsible for the monitoring of public water supplies and the local authorities are responsible for monitoring of group water schemes and regulated small private supplies. The EPA produces an *Annual Report on Drinking Water Quality*[1] based on these monitoring results.

The FSAI's surveillance programme over many years has shown that levels of aluminium, cadmium, lead and mercury in Irish food are generally well below the maximum limits laid down for the metals in food in Council Regulation 1881/2006, as amended (EC, 2006)[2]. Levels for inorganic arsenic in rice and rice products were adopted in 2015 and came into force in January, 2016.

Since these maximum levels are set in legislation in order to ensure that the population is not exposed to these metals at levels in food that could prove harmful to health, the results of the FSAI surveillance programme are reassuring in this respect.

Results from the above mentioned programmes, including results from the most recent TDS (FSAI, 2016) are provided for each metal under consideration. Results for food samples refer to the sample whole weight, unless otherwise specified.

3.1 Aluminium

The general population is primarily exposed to aluminium through the consumption of food items (ATSDR, 2008; EFSA, 2008) with minor exposure potentially arising from aluminium in drinking water. Aluminium is ubiquitous in many foods such as fruit, vegetables, cereals, seeds and meat. It is taken up in small quantities from soil by most crops with levels in uncontaminated grass lower than 50 mg/kg, although some plant species including tea plants are known to accumulate aluminium (Matsumoto *et al.*, 1976). Levels much higher than normal may occur in harvested crop materials such as cereals, root and leafy vegetables as a consequence of soil or dust contamination during harvesting and can present a route of exposure, through ingestion of inadequately washed vegetables.

As reported by EFSA (2008), most unprocessed foods typically contain less than 5 mg/kg aluminium, but higher concentrations can be found in breads, cakes and pastries, glacé fruits and other foodstuffs due to the use of aluminium-containing food additives such as sodium aluminium phosphate (SALP) and aluminium-containing food colours. Although the use of such additives is authorised, the European Commission has in recent times, reduced the maximum levels that can be used in certain products because of concern regarding high intakes of aluminium by the European population.

[1] See http://www.epa.ie/pubs/reports/water/drinking/

[2] Levels of arsenic and lead in food are also covered nationally through S.I. No. 44 of 1972 and its amendment, S.I. No. 72 of 1992

Other foods reported by EFSA to contain high mean concentrations of aluminium include tea leaves, herbs, cocoa and cocoa products, and spices (EFSA, 2008).

Aluminium levels were analysed in food samples as part of the most recent TDS for Ireland (FSAI, 2016). Table 2 provides an overview of the range of levels (lowerbound (LB) min – upperbound (UB)[3] max) reported for each food group. In total, 141 food samples, prepared as ready for consumption, were analysed. These data were used to estimate exposure of the Irish adult and child populations to aluminium from food and water.

Table 2. Range of aluminium concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	18	<0.1	47.1
Dairy	14	<0.1	3.3
Eggs	1	3	3
Meat	13	<0.1	18
Fish & Shellfish	11	0.1	71.7
Vegetables	28	<0.05	9.5
Fruit	13	0.09	23.6
Nuts & Seeds	2	2	24.9
Herbs & Spices (dried)	2	138.7	639
Soups & Sauces	11	0.1	5.38
Sugars, Preserves, Confectionery	6	<0.2	5.2
Beverages, Alcoholic	5	0.08	0.6
Beverages, Non-alcoholic	11	<0.03	3.37
Beverages, Water (tap)	1	<0.03	0.03
Fats & Oils	2	<0.2	0.2
Snacks	2	3	3.9
Pizza	1	3.1	3.1

Table 3 shows results from monitoring and surveillance programmes reported by the Public Analyst Laboratories for 2014. The results reported in Table 3, although not directly comparable due to the nature of sampling and sample preparation, are generally in good agreement with results reported in Table 2.

[3] Lowerbound values are derived by substituting values below the Limit of Detection (<LOD) with zero, upperbound values are derived by substituting values below the LOD with the LOD. The range refers to the lowest lowerbound and highest upperbound value observed within a food category, consisting of a number of food groups

Table 3. Range of aluminium concentrations (LB min-UB max) in mg/kg reported by the Public Analyst Laboratories for 2014

Food Category	No. of samples per food category	No. of samples < LOD	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals & Bakery Products	62	49	<5	129
Dairy and Dairy Alternatives	5	5	<5	5
Fruit & Vegetables	9	2	<5	24
Water (bottled)	230	222	<0.02	0.07
Ices & Desserts	1	1	<5	5
Soups, Sauces and Condiments	3	3	<5	5
Composite Food	5	1	<5	52
Food for Infants and Small Children	14	14	<5	5

At neutral pH, aluminium concentrations in drinking water range from 1 to 50 μg/L, in more acidic water this can rise to 500-1,000 μg/L (WHO, 1997). In addition to naturally occurring aluminium in untreated water, aluminium may also be present in drinking water due to the use of aluminium compounds, e.g. aluminium sulphate, aluminium polychloride, as flocculants in the treatment of surface waters. In Ireland, the EPA monitors aluminium in drinking water supplies, and data for 2014 (EPA, 2015) indicate that there was 99% compliance for aluminium in drinking water with the EU Drinking Water Limit of 200 μg/L. This covered 1,670 water supply zones and 9,634 samples in total (EPA, 2015).

Aluminium levels in Irish groundwater have been analysed by the EPA and are generally low (typically less than 50 μg/L) but levels up to 7,266 μg/L have been recorded, with 1.2% of 6,846 samples exceeding the EU Drinking Water Limit (EPA Groundwater Analysis, 2008-2014). However, not all groundwater is exploited for drinking water purposes.

3.2 Arsenic

Food products of terrestrial origin generally contain low concentrations of total arsenic and their inorganic arsenic content is also proportionally low. An exception is rice, which can contain up to 0.4 mg/kg arsenic with a considerable proportion being of the inorganic form. Fish and seafood on the other hand, generally have a high total arsenic content. EFSA reported a mean value of 5.0 mg/kg for 1,347 samples of seafood and seafood products analysed in 14 Member States and Norway (not including Ireland), with a 95th percentile of 21.3 mg/kg and a maximum of 150 mg/kg (EFSA, 2009b). However, the levels of inorganic arsenic are typically low with the exception of the edible marine alga Hijiki (Hizikia fusiforme), which can contain inorganic arsenic at concentrations of >60 mg/kg, and blue mussels (Mytilus edulis), which have been reported to contain inorganic arsenic concentrations up to 30 mg/kg dry matter (EFSA, 2009b). Data from the EC Scientific Cooperation Task Force (SCOOP) *Report on exposure to metals in the diet* and from EFSA show that, with the exception of seafood and animal offal, the concentration of arsenic in food is generally less than 0.25 mg/kg (EC, 2004; EFSA, 2009b).

The Marine Institute in cooperation with the FSAI has included total arsenic in its monitoring programme for shellfish since 2004 (McGovern *et al.*, 2011). Findings are comparable to levels in shellfish farmed elsewhere in Europe. The mean level of arsenic in 43 samples of blue mussels sampled in the period 2007 – 2014 was 2.0 mg/kg, with a maximum level of 3.9 mg/kg, while in Pacific oysters farmed in Ireland, the levels were 2.2 and 5.4 mg/kg. The Marine Institute has also analysed a range of fish species for total arsenic since 2008, and concentrations are very species dependent. The average concentration of total arsenic in most species is typically <10 mg/kg but there are clear exceptions such as cartilaginous fish including rays, plaice (*Pleuronectes platessa*) and most obviously lemon sole (*Microstomus kitt*) for which values have been reported from 5.8 to 176.5 mg/kg (mean 61.9 mg/kg for 32 samples) (McGovern *et al.* in prep). Limited studies of inorganic arsenic in fish by the Marine Institute have indicated low concentrations of inorganic arsenic, typically less than the detection limit, including species with high concentrations of total arsenic, such as lemon sole.

Since arsenic in fish and seafood primarily occurs in the organic form and intake from fish and seafood represented only a small proportion of inorganic arsenic intake, the WHO/FAO Joint Expert Committee on Food Additives and Contaminants (JECFA), taking into account the nutritious value of fish and the low toxicity and rapid metabolism of organoarsenicals, considered that there was no need to restrict the consumption of fish (JECFA, 1989a).

Regarding groundwater, concentrations of arsenic in groundwater in the EU are usually less than 10 µg/L with essentially all the arsenic being present in the form of inorganic arsenic (EFSA, 2009b). Arsenic levels in Irish groundwater are generally low (typically less than 5 µg/L) but levels up to 158 µg/L have been recorded, with 2.5% of 6,848 samples exceeding the EU Drinking Water Limit (EPA Groundwater Analysis, 2008-2014). These exceedances were almost invariably recorded in poorly productive wells which are not exploited for drinking water purposes. Drinking water (approximately 4,000 samples) in Germany contained an average of 4 µg/L (EC, 2004), while in a study of drinking water in Romania, the Slovak Republic and Hungary, the Romanian and Slovakian study areas had relatively low arsenic levels with, at the most, 8% of the drinking water concentrations exceeding 10 µg/L, while in Hungary, nearly 70% of samples had arsenic levels above 10 µg/L.

In Ireland, the EPA monitors arsenic in drinking water supplies. Data for 2014 (EPA, 2015) indicate that there was 100% compliance limiting arsenic below the parametric value of 10 µg/L in drinking water. This covered 763 water supply zones and 1,469 samples in total. There is one small supply in County Waterford where a filter is required to keep the arsenic concentration at a level below the parametric value of 10 µg/L (EPA, 2015). There have also been a small number of sporadic instances in recent years where elevated levels of arsenic have occasionally been detected above the parametric value in private wells.

Arsenic levels were analysed in food samples as part of the most recent TDS for Ireland (FSAI, 2016). Table 4 provides an overview of the range of levels (LB min – UB max) reported for each food group. In total, 141 food samples, prepared as ready for consumption, were analysed. These data were used to estimate exposure of the Irish adult and child populations to arsenic from food and water.

Table 4. Range of total arsenic concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	16	<0.01	0.15
Dairy	14	<0.003	0.02
Eggs	1	<0.01	0.01
Meat	13	<0.01	0.01
Fish & Shellfish		0.35	4.07
Vegetables	26	<0.003	0.02
Fruit	13	<0.005	0.02
Nuts & Seeds	2	<0.02	0.02
Herbs & Spices		0.04	0.19
Soups & Sauces	9	<0.005	0.011
Sugars, Preserves, Confectionery	6	<0.02	0.02
Beverages, alcoholic	4	<0.003	0.008
Beverages, non-alcoholic	11	<0.003	0.02
Beverages, Water	1	<0.003	0.003
Fats & Oils	2	<0.02	0.02
Snacks	1	<0.02	0.02
Pizza	1	<0.02	0.01

Table 5 provides results for inorganic arsenic collected as part of the TDS.

Table 5. Range of inorganic arsenic concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	6	<0.02	0.06
Fish & Shellfish	11	<0.01	0.05
Vegetables	1	<0.01	0.01
Fruit	1	<0.02	0.02
Nuts & Seeds	1	0.02	0.02
Herbs & Spices	2	0.03	0.16
Soups & Sauces	1	0.01	0.01
Snacks	2	<0.02	0.02

Table 6 shows results from monitoring and surveillance programmes reported by the Public Analyst Laboratories for 2014. The results reported in Table 6, although not directly comparable due to the nature of sampling and sample preparation, are generally in good agreement with results reported in Table 4.

Table 6. Range of total arsenic concentrations (LB min-UB max) in mg/kg reported by the Public Analyst Laboratories for 2014

TDS Food group	No. of samples per food category	No. of samples < LOD	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals & Bakery Products	28	27	<0.2	0.20
Dairy and Dairy Alternatives	5	5	<0.05	0.05
Meat & Offal (incl. products)	9	9	<0.2	0.20
Fish, Shellfish & Molluscs	51	7	<0.2	3.31
Fruit & Vegetables	9	9	<0.2	0.20
Herbs & Spices	3	3	<0.2	0.20
Confectionery incl. Sugar and Honey	1	1	<0.2	0.20
Chocolate, Cocoa, Cocoa Preparations	7	7	<0.2	0.20
Alcoholic Beverages	2	2	<0.2	0.20
Non-alcoholic Beverages	1	1	<0.05	0.05
Water (bottled)	189	168	<0.001	0.01
Tea and Tea Preparations	10	10	<0.2	0.20
Soups, Sauces and Condiments	7	7	<0.2	0.20
Nuts, Seeds and Snack foods	2	2	<0.2	0.20
Food for Infants and Small Children	2	2	<0.2	0.20
Food Supplements/Foods for Particular Nutritional Purposes	57	44	<0.2	4.52
Seaweed/Algae (retail samples)	37	0	2.68	68.5

3.3 Cadmium

Cadmium is present at low levels in most foods, being found in commodities such as cereals, fruit and vegetables, meat, shellfish and at higher levels, in offal. Due to the ubiquitous presence of cadmium in food, the food categories that contribute significantly to the dietary exposure are determined either by a high level of contamination of the food or by high amounts consumed of a food with lower contamination levels (EFSA, 2009a).

High naturally occurring levels of cadmium in soil are found in parts of north Dublin and Meath, the main horticultural production region in the country, which is associated with the underlying limestone bedrock geology. A national research project commenced in 2013 to examine a number of parameters that may influence uptake of cadmium by potatoes and other vegetables, including potato variety, soil cadmium content and pH, effect of fertiliser use and of zinc application, with a view to developing strategies to mitigate cadmium uptake.

As mentioned in Section 2.2.3, high naturally occurring levels of cadmium in the soil are found in some parts of the country. A study carried out by Canty *et al.* (2014) found that the soil concentration amongst other factors was a predictor for concentration in the kidneys of cattle. Concentrations in cattle kidney at slaughter (n=393) varied between 0.040 and 8.630 mg/kg. The estimated weighted proportion of animals with kidney cadmium ≥1 mg/kg was 11.25%. Key predictors for high kidney cadmium concentration were soil cadmium, animal age and province.

At a soil cadmium concentration of 1.5 mg/kg, it was predicted that an age threshold to avoid exceeding a kidney cadmium concentration of 1 mg/kg in most animals would be ~3 years in Connacht, >4 years in Ulster, and >5 years in Leinster and Munster. Kidneys of most cattle under three years of age will conform with EU requirements (Canty, 2014). Offal from older animals is a source of cadmium for consumers and is addressed in official controls. Cadmium concentrations are very low in wild and farmed finfish at <0.005 mg/kg, and cadmium is found in mussels and oysters in Irish waters at concentrations below the EC maximum limit of 1 mg/kg for bivalve molluscs (McGovern *et al*. 2011, Glynn *et al*. 2013, 2015).

Contamination of drinking water may occur as a result of the presence of cadmium as an impurity in the zinc of galvanised pipes or cadmium-containing solders in fittings (WHO, 2011).

Data for 2014 (EPA, 2015) indicate that there was 100% compliance with the limit for cadmium in drinking water. This covered 826 water supply zones and 1,539 samples in total (EPA, 2015).

In Ireland, cadmium levels in non-contaminated groundwater are usually below 1 μg/L. 6,846 Irish groundwater samples were analysed by the EPA (2008-2014) for cadmium and only one sample was above the EU Drinking water limit of 5 μg/L with the maximum level found being 8.6 μg/L.

Cadmium levels were analysed in food samples as part of the most recent TDS for Ireland (FSAI, 2016).

Table 7 provides an overview of the range of levels (LB min – UB max) reported for each food group. In total, 141 food samples, prepared as ready for consumption, were analysed. These data were used to estimate exposure of the Irish adult and child populations to cadmium from food and water.

Table 7. Range of cadmium concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	18	<0.005	0.14
Dairy	14	<0.001	0.013
Eggs	1	<0.005	0.005
Meat	13	<0.005	0.059
Fish & Shellfish	11	<0.005	0.099
Vegetables	28	<0.003	0.069
Fruit	13	<0.003	0.01
Nuts & Seeds	2	0.010	0.12
Herbs & Spices	2	0.090	0.12
Soups & Sauces	11	<0.001	0.015
Sugars, Preserves, Confectionery	6	<0.01	0.01
Beverages, Alcoholic	5	<0.001	0.016
Beverages, Non-alcoholic	11	<0.001	0.01
Beverages, Water	1	<0.001	0.001
Fats & Oils	2	<0.01	0.01
Snacks	2	0.020	0.08
Pizza	1	0.017	0.017

Table 8 shows results from monitoring and surveillance programmes reported by the Public Analyst Laboratories for 2014.The results reported in Table 8, although not directly comparable due to the nature of sampling and sample preparation, are generally in good agreement with results reported in Table 7.

Table 8. Range of cadmium concentrations (LB min-UB max) in mg/kg reported by the Public Analyst Laboratories for 2014

Food Category	No. of samples per food category	No. of samples < LOD	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals & Bakery Products	38	11	<0.01	0.11
Dairy and Dairy Alternatives	19	18	<0.01	0.02
Meat & Offal (incl. products)	21	21	<0.01	0.01
Fish, Shellfish & Molluscs	78	29	<0.01	1.15
Fruit & Vegetables	170	30	<0.01	0.77
Herbs & Spices	3	3	<0.2	0.20
Confectionery incl. Sugar and Honey	1	1	<0.01	0.01
Chocolate, Cocoa, Cocoa Preparations	8	0	0.02	0.97
Alcoholic Beverages	5	5	<0.01	0.20
Non-alcoholic Beverages	4	3	<0.01	0.01
Water (bottled)	189	189	<0.001	0.001
Tea and Tea Preparations	16	10	<0.2	0.20
Coffee, Coffee Preparations	8	7	<0.01	0.01
Ices & Desserts	1	1	<0.01	0.01
Materials and Articles Intended to come into contact with Foodstuffs	46	46	<0.003	0.02
Soups, Sauces and Condiments	7	2	<0.01	0.04
Nuts, Seeds and Snack Foods	6	4	<0.01	0.04
Composite Food	1	1	<0.01	0.01
Food for Infants and Small Children	3	2	<0.01	0.20
Food Supplements/Foods for Particular Nutritional Purposes	59	39	<0.01	0.26
Seaweed/Algae	37	12	<0.2	1.85

3.4 Lead

Food and water represent the major sources of exposure to lead for the general population (JECFA, 2000a; EFSA, 2010a; JECFA, 2011a). Data from EFSA and from the SCOOP report on metals show that levels of lead in most commonly consumed foodstuffs are generally low (EC, 2004; EFSA, 2010a). Lead can accumulate in fish and shellfish and, in addition, can be found at higher levels in the offal (liver and kidney) of food animals. However, in general, cereal products contribute most to dietary lead exposure. Levels of lead in these particular foods and in fruit and vegetables are regulated in the EU.

The Marine Institute, in conjunction with the FSAI, has surveyed levels of lead in bivalve molluscs, finfish (including farmed finfish) and crustaceans landed at Irish ports over the period 2004 – 2008 (McGovern *et al.*, 2011). European Community legislation (Regulation 1881/2006, as amended) establishes maximum levels for lead in fish muscle meat (0.3 mg/kg), crustaceans (0.5 mg/kg), cephalopods (1.0 mg/kg (to be lowered to 0.3 mg/kg)) and bivalve molluscs (1.5 mg/kg). The mean lead level in Irish Blue mussels (n = 125) was 0.22 mg/kg, with a highest level of 1.15 mg/kg, while the mean for Pacific oysters was 0.14 mg/kg and for native oysters 0.08 mg/kg. Levels of lead in wild fish over this period (109 samples from 25 fish species) were all below 0.05, mg/kg, lower than the current EC maximum level (0.30 mg/kg). Low levels of lead in Irish farmed salmon were determined in 2011 – 2014, when the highest lead concentration measured in 41 samples analysed was 0.09 mg/kg (Glynn *et al.*, 2013, 2015).

Livestock produce (meat, milk, dairy products) is a major part of the human diet. Liver and kidney selectively accumulate lead and may contain concentrations higher than other foods (EFSA, 2010a). The maximum level for lead in meat and offal established under Regulation 1881/2006 is 0.1 mg/kg and 0.5 mg/kg, respectively, for cattle, sheep, pigs and poultry. Using current maximum level criteria, a review of liver and kidney data from 1991 to 1994 of healthy cattle at slaughter (n= 151) did not identify any exceedances in liver, kidney or muscle for lead. Exceedances in muscle from cattle were also not observed from 2009 – 2011 (n=105) under the national residue monitoring programme. A more recent study (Canty *et al.* 2014) found that the median kidney value for lead was 0.03 mg/kg (n=393). In official monitoring from 2009-2011, levels above the legal maximum level for muscle were not seen in sheep, pig, farmed deer, poultry and milk (n=45, 30, 24, 43 and 209, respectively). The only exceedance in 2011 was one, in a wild deer sample (n= 74). Those consuming diets high in wild-game risk exposure to bioavailable lead from lead shot in edible tissue (Andree, 2010; EFSA, 2010a).

Lead toxicity is the most common cause of poisoning in cattle (Anon, 2013). It is generally due to careless disposal of lead-containing materials that inadvertently enter animal feed, e.g. silage, on the affected farm. Where lead toxicity is diagnosed in a herd, similarly exposed asymptomatic animals may exist (Bischoff, 2012) and thus present a risk if entering the food chain before sufficient time has elapsed to allow tissue depletion of the lead. Kidney lead concentrations in cattle, diagnosed at post-mortem by the DAFM Veterinary Laboratory Service from 2010 to 2015, ranged up to 364 mg/kg (DAFM, unpublished data).

It is recommended that where lead toxicity is identified in animals on a farm, risk assessment of cohorts is carried out before entry to the food chain.

With regard to drinking water, the past use of lead as a material for water pipes in many older houses may result in high levels in water supplies. The European Union (Drinking Water) Regulations, 2014 (S.I. No. 122 of 2014), in line with WHO recommendations, set a revised limit of 10 μg/L for lead in drinking water from 25/12/2013 (EPA, 2012). Until 25/12/2013, the limit was 25 μg/L. The amount of lead contained in pipes and plumbing fittings has been regulated since 1988; however, human exposure to lead from drinking water still occurs as a consequence of leaching of lead from service pipes in older houses and fixtures or lead containing solder.

In 2013, the HSE and the EPA issued a joint position paper summarising the issues in relation to lead in drinking water including health, legislation and interventions (EPA/HSE, 2013). There is now a *National Strategy to Reduce Exposure to Lead in Drinking Water* published by the Department of Health and the Department of the Environment, Community and Local Government which is used by the EPA to track progress. Irish Water has also published a *National Implementation Plan* to reduce levels of lead in drinking water. EPA enforcement activities have also resulted in all lead distribution mains being removed; however, lead remains in 5-10% of lead communication or service pipes.

In Ireland, the EPA monitors lead in drinking water supplies. Data for 2014 (EPA, 2015) indicated that there was 98.7% compliance with the new limit of 10 µg/L for lead in drinking water. This covered 1,337 water supply zones and 3,010 samples in total. Lead levels in Irish groundwater samples have been analysed by the EPA and are generally low with only 0.2% of 6,846 samples exceeding the above EU Drinking Water Limit with a maximum value recorded of 109 µg/L (EPA Groundwater Analysis, 2008-2014). Again, not all groundwater is exploited for drinking water purposes.

Lead levels were analysed in food samples as part of the most recent TDS for Ireland (FSAI, 2016). Table 9 provides an overview of the range of levels (LB min – UB max) reported for each food group. In total, 141 food samples, prepared as ready for consumption, were analysed. These data were used to estimate exposure of the Irish adult and child populations to lead from food and water.

Table 9. Range of lead concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	18	<0.005	0.01
Dairy	14	<0.001	0.01
Eggs	1	<0.005	0.01
Meat	13	<0.005	0.03
Fish & Shellfish	11	<0.005	0.22
Vegetables	28	<0.001	0.03
Fruit	13	<0.003	0.11
Nuts & Seeds	2	<0.01	0.01
Herbs & Spices	2	0.100	0.51
Soups & Sauces	11	<0.001	0.01
Sugars, Preserves, Confectionery	6	<0.01	0.01
Beverages, Alcoholic	5	<0.001	0.01
Beverages, Non-alcoholic	11	<0.001	0.01
Beverages, Water	1	<0.001	0.00
Fats & Oils	2	<0.01	0.01
Snacks	2	<0.01	0.01
Pizza	1	0.007	0.01

Table 10 shows results from monitoring and surveillance programmes reported by the Public Analyst Laboratories for 2014. The results reported in Table 10, although not directly comparable due to the nature of sampling and sample preparation, are generally in good agreement with results reported in Table 9.

Table 10. Range of lead concentrations (LB min-UB max) in mg/kg reported by the Public Analyst Laboratories for 2014

Food Category	No. of samples per food category	No. of samples < LOD	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals & Bakery Products	38	36	<0.12	0.46
Dairy and Dairy Alternatives	18	17	<0.03	0.12
Meat & Offal (incl. products)	20	20	<0.12	0.12
Fish, Shellfish & Molluscs	72	67	<0.05	1.20
Fruit & Vegetables	169	169	<0.12	0.20
Herbs & Spices	3	3	<0.2	0.20
Confectionery incl. Sugar and Honey	1	0	0.20	0.20
Chocolate, Cocoa, Cocoa Preparations	8	7	<0.12	0.20
Alcoholic Beverages	3	3	<0.03	0.12
Non-alcoholic Beverages	4	4	<0.12	0.12
Water (bottled)	237	237	<0.001	0.004
Tea and Tea Preparations	16	4	<0.2	1.97
Coffee, Coffee Preparations	8	7	<0.12	0.16
Ices & Desserts	1	1	<0.12	0.12
Materials and Articles Intended to come into contact with Foodstuffs	46	46	<0.003	0.20
Soups, Sauces and Condiments	7	7	<0.12	0.12
Nuts, Seeds and Snack Foods	6	6	<0.12	0.12
Composite Food	1	1	<0.12	0.12
Food for Infants and Small Children	24	24	<0.03	0.20
Food Supplements/Foods for Particular Nutritional Purposes	59	37	<0.12	0.88
Seaweed/Algae (retail samples)	25	14	<0.2	1.64

3.5 Mercury

Recent data from EFSA reflecting monitoring data from 20 European countries (not including Ireland) and almost 60,000 analytical results shows that mercury is relatively widely distributed in food but at very low levels (EFSA, 2012). The majority of the analytical results (98.2%) were for total mercury without further differentiation, while 1.8% were for methyl mercury and only three samples were analysed for inorganic mercury. More than 60% of the results were below the LOD or the Limit of Quantification (LOQ), and mercury was primarily detected in fish and other seafood and in meat and meat products (36.8% and 17.6%, respectively). Mercury was detected in 7.8% of grain and grain-based products and in 7.3% of vegetables and vegetable products (EFSA, 2012).

The most toxic form of mercury, methylmercury, is considered to occur at significant levels only in fish and seafood, in particular, top predatory fish such as swordfish and marlin (EFSA, 2004a; EC, 2004; JECFA, 2004). As outlined by both EFSA (EFSA, 2004a; EFSA 2012) and JECFA (JECFA, 2004; JECFA 2007b; JECFA, 2011b), it has been estimated that methylmercury comprises 75–100% of the total mercury in seafood, occurring primarily as a consequence of industrial releases of inorganic mercury into marine environments, followed by uptake into marine microorganisms which convert it into the more toxic methylmercury. The methylmercury then accumulates, reaching potentially toxic levels in species at the top of the food chain which may then form part of the human diet.

It is however, difficult to assess the contribution from anthropogenic versus natural mercury sources (which, for example, is high in the mid-Atlantic ridge). However, Lamborg *et al*. (2014) have estimated a tripling of mercury content in surface oceans compared to pre-anthropogenic times.

The amount of methylmercury in fish and shellfish correlates with a number of factors including the size and age of the fish, the species, their diet and position in the food web and the level of mercury and conditions in the waters that form their primary habitat. Larger, older, predatory species such as shark, marlin, swordfish and tuna usually contain higher levels than other marine fish. On average, canned tuna has been found to contain half the amount of mercury as fresh tuna. This is because different species and smaller more immature fish are used for canning. Shellfish, particularly filter feeders such as mussels and scallops can also take up and accumulate mercury from their environment, and hence, may contribute significantly to dietary exposure though concentrations are usually lower than for fish.

European Community legislation (Regulation 1881/2006, as amended) establishes a maximum level of 0.5 mg/kg for mercury in fishery products and muscle meat of fish with the exception of certain species including marlin, sea bream, swordfish, shark and tuna for which the maximum level is 1.0 mg/kg. The Marine Institute in conjunction with the FSAI, has analysed mercury in fish and fishery products over the period 2004 to 2008 (McGovern *et al.*, 2011). Levels of mercury in finfish (including farmed finfish), bivalve molluscs, and crustaceans consistently complied with the EC maximum levels, with mean levels in finfish (322 samples from 27 fish species) ranging from 0.04 mg/kg in farmed salmon and trout to 0.25 mg/kg in spurdog (n = 60). However, a sample of marlin imported from Indonesia contained 3.46 mg/kg, a level which is in excess of the EC maximum level, with high mercury levels also evident in imported swordfish. Low levels of mercury in Irish farmed salmon were confirmed in 2011-2014, when the highest mercury concentration measured in 41 samples analysed was 0.07 mg/kg (Glynn *et al.*, 2013, 2015). The mean mercury level in Irish blue mussels (n = 125) was 0.03 mg/kg, with a highest level of 0.05 mg/kg, while the mean for Pacific oysters was 0.02 mg/kg and for native oysters 0.03 mg/kg.

Regarding Irish drinking water, data for 2014 covering 757 water supply zones and 1,333 samples in total, indicated that there was 100% compliance with the limit of 1 µg/L for mercury in drinking water (EPA, 2015). A maximum limit for mercury in natural mineral water of 1 µg/L also applies (Commission Directive 2003/40/EC). Mercury levels in Irish groundwater were analysed by the EPA (2008-2014) and were almost always below detection with only one sample (1.3 µg/L) exceeding the above limit for drinking water.

Mercury levels were analysed in food samples as part of the most recent TDS for Ireland (FSAI, 2016). Table 11 provides an overview of the range of levels (LB min – UB max) reported for each food group. In total, 141 food samples, prepared as ready for consumption, were analysed. These data were used to estimate exposure of the Irish adult and child populations to mercury from food and water.

Table 11. Range of mercury concentrations (LB min-UB max) in mg/kg reported in the TDS

TDS Food group	No. of samples per food group	Minimum (LB) mg/kg	Maximum (UB) mg/kg
Cereals	18	<0.005	0.01
Dairy	14	<0.001	0.01
Eggs	1	<0.005	0.005
Meat	13	<0.005	0.006
Fish & Shellfish	11	0.014	0.148
Vegetables	28	<0.001	0.01
Fruit	13	<0.003	0.01
Nuts & Seeds	2	<0.01	0.01
Herbs & Spices	2	0.01	0.02
Soups & Sauces	11	<0.001	0.005
Sugars, Preserves, Confectionery	6	<0.01	0.01
Beverages, Alcoholic	5	<0.001	0.002
Beverages, Non-alcoholic	11	<0.001	0.01
Beverages, Water	1	<0.001	0.001
Fats & Oils	2	<0.01	0.01
Snacks	2	<0.01	0.01
Pizza	1	<0.005	0.005

The Public Analyst Laboratories also analyse on average, 70 fish samples per year taken at retail for mercury, covering a wide range of products. Findings are in line with results reported by the Marine Institute.

CHAPTER 4. RISK ASSESSMENT OF ALUMINIUM, ARSENIC, CADMIUM, LEAD AND MERCURY PRESENT IN FOOD IN IRELAND

4.1 Aluminium

4.1.1 Hazard identification/characterisation of aluminium

Aluminium is overall of lower toxicity than many other metals. Uptake from the gastrointestinal tract following ingestion is very poor. Like other metals however, once absorbed into the body, it is persistent, with the whole-body half-life of aluminium in humans being estimated to be 50 years (JECFA, 2007a; EFSA, 2008).

The main health effect of aluminium is neurotoxicity, which has been demonstrated in experimental animal studies and also in patients undergoing dialysis, who are chronically exposed to aluminium via dialysis water. It has also been suggested that aluminium may be a causative factor in Alzheimer's disease and may be associated with other neurodegenerative diseases in humans, although these hypotheses are controversial and remain unproven (EFSA, 2008). The developing nervous system appears to be particularly at risk, as demonstrated in a number of developmental neurotoxicity studies in animals, and there is also evidence of effects on the reproductive system (developmental toxicity and effects on fertility) (JECFA, 2007a; EFSA, 2008).

In view of the cumulative nature of aluminium in the organism after dietary exposure, EFSA established a TWI for aluminium based on the combined evidence from several studies.

The TWI established by EFSA for ingested aluminium from all sources is 1 mg/kg bw/week (EFSA, 2008). This EFSA TWI is in agreement with the 2007 provisional tolerable weekly intake (PTWI) of JECFA (JECFA, 2007a). However in 2011, JECFA increased its PTWI for aluminium to 2 mg/kg bw/week (JECFA 2011a), while EFSA has not yet re-evaluated aluminium.

4.1.2 Exposure assessment for aluminium in the population resident in Ireland

Dietary exposure to aluminium in the Irish adult and child populations was estimated based on the most recent TDS carried out in Ireland (FSAI, 2016), which also takes into account, aluminium migration from aluminium cook-ware, cans, take-away food trays, etc.

Table 12 presents the estimated LB and UB daily mean and 97.5th percentile aluminium exposure of the Irish adult and child populations from all food groups.

Table 12. Estimated aluminium exposure of the Irish adult and child populations from all food groups, expressed as mg/d, mg/kg bw and % of the EFSA TWI

ADULTS											
Daily Intake mg				Daily Intake mg/kg bw (weekly intake in parenthesis)				% of EFSA TWI (1 mg/kg bw/week)			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
3.73	3.78	8.54	8.60	0.05 (0.35)	0.05 (0.35)	0.12 (0.83)	0.12 (0.84)	35%	35%	83%	84%

CHILDREN											
Daily Intake mg				Daily Intake mg/kg bw (weekly intake in parenthesis)				% of EFSA TWI (1 mg/kg bw/week)			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
1.60	1.63	3.20	3.23	0.05 (0.36)	0.05 (0.37)	0.11 (0.74)	0.11 (0.75)	36%	37%	74%	75%

As can be seen from Table 12, for adults, the average mean intake of aluminium from food was estimated at 0.05 mg/kg bw/ day, which is equivalent to 0.35 mg/kg bw/week. This corresponds to 35% of the EFSA TWI. The above average (97.5th percentile) intake was estimated at 0.12 mg/kg bw/day, equivalent to 0.84 mg/kg bw/week and corresponds to 84% of the EFSA TWI. The estimated intakes for aluminium determined in this TDS compare well with estimates of the previous TDS (35% and 77% for mean and P97.5 contribution to the TWI, respectively) (FSAI, 2011).

The results for daily intake are also within the range of 1.6 to 13 mg/day estimated by EFSA, based on total diet studies (EFSA, 2008).

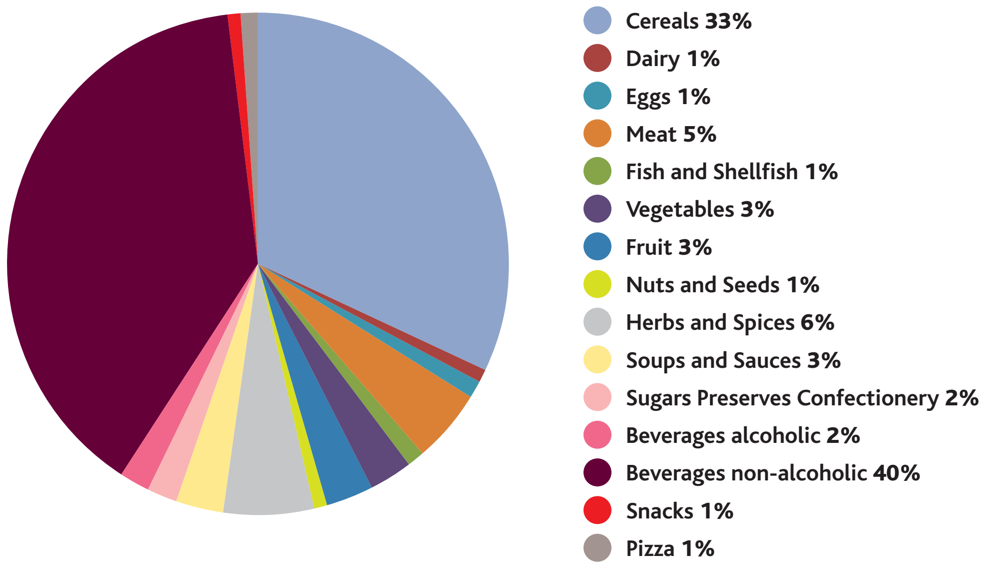
For children, average intake of aluminium from food was estimated at 0.05 mg/kg bw/day, which is equivalent to 0.37 mg/kg bw/week. This corresponds to 37% of the EFSA TWI. The above average (97.5th percentile) intake was estimated at 0.11 mg/kg bw/day, equivalent to 0.75 mg/kg bw/week and corresponding to 75% of the EFSA TWI.

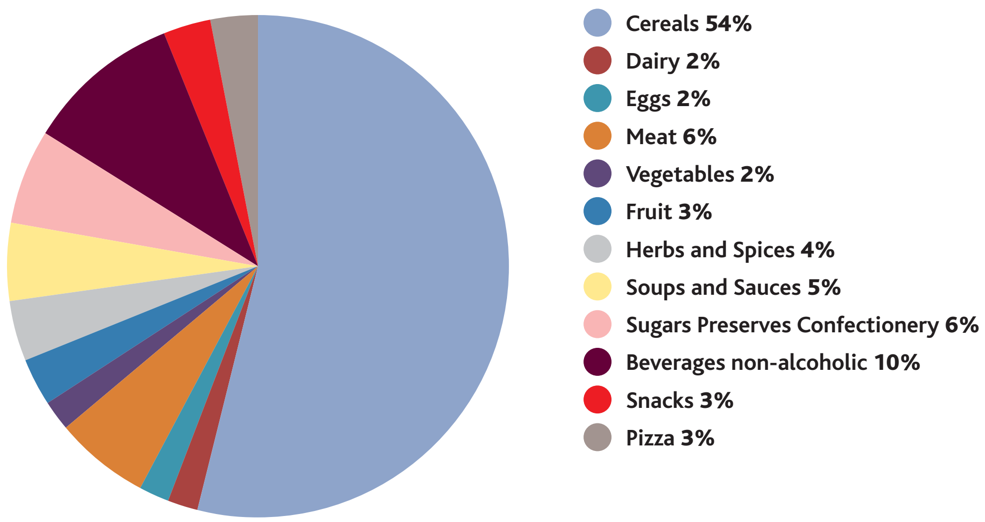
Contribution from other sources (with the exception of cooking utensils and food containers which are accounted for in the TDS), e.g. topical creams and cosmetics, has not been taken into account here but compared to dietary sources, these may be minor contributors to exposure to aluminium (EFSA, 2008).

Aluminium compounds are however, also found in over-the-counter medicinal products such as in aluminium hydroxide in antacids to control gastric hyperacidity and in buffered analgesics (aspirin). Daily doses of aluminium in antacids range from 840 to 5,000 mg and from 130-730 mg/day for buffered analgesics (Lione, 1985). Therefore, users of such medications are likely to have an increased exposure to aluminium in addition to exposure from food sources.

Aluminium was detected in 83% of all samples analysed. Figure 4 shows the main contributing food groups to dietary aluminium exposure, based on LB measurements, revealing that non-alcoholic beverages (40%) and cereals (33%) were the major contributors to dietary intake for adults, and for children also cereals (54%) and non-alcoholic beverages (10%) were found to be the major contributors.

Figure 4. Contribution of the various food groups in which aluminium was detected (LB) as a percentage of total aluminium intake





4.1.3 Risk characterisation

In establishing a TWI for aluminium, EFSA estimated that the daily dietary exposure to aluminium in the general population, assessed in several European countries, varied from 0.2 to 1.5 mg/kg bw/week at the mean and was up to 2.3 mg/kg bw/week in highly exposed consumers (EFSA, 2008a). The intakes for the population resident in Ireland (both adults and children) lie towards the lower end of this range for both the mean and the 97.5th percentile, and do not exceed the EFSA TWI.

To reduce exposure to aluminium, the European Commission (2012) lowered the maximum permitted levels and amended the conditions of use for aluminium containing food additives, including aluminium lakes.

With regard to infants, the concentration of aluminium in general, is higher in infant formula than in human milk. The mean concentration of aluminium in human breast milk is reported to range from 0.009 to 0.380 mg/L (EFSA, 2008). In infant formula, aluminium has been measured at 0.176-0.700 mg/L in prepared milk (Burrell and Exley, 2010), the highest levels measured in a soy-based product (EFSA, 2008). These authors have suggested that the levels of aluminium in soy-based infant formula are of concern, given the potential susceptibility of the immature nervous system.

Aggregate samples (ten samples of each) of infant formula, follow-on formula and soy-based formula, taken by the FSAI in 2014 (unpublished data) showed lower levels than reported by Burrell and Exley (2010). Assigning a dilution factor of eight to convert powder to formula as consumed, which is generally used by EFSA (EFSA, personal communication), the results for the three types of formula mentioned above were 0.05, 0.06 and 0.22 mg/L, respectively. Exposure to aluminium from these types of formula, even when taking into account additional aluminium from the water used (see Section 3.1), would be below the EFSA TWI.

4.2 Arsenic

4.2.1 Hazard identification/characterisation of arsenic

The toxicity of arsenic is dependent on its chemical form and valency. Inorganic arsenic is significantly more toxic than organic arsenic compounds such as dimethylarsinate. In terms of valency, the trivalent forms of arsenic, e.g. arsenic trichloride, are more toxic than the pentavalent arsenates. The latter are considered to be toxic only after metabolic conversion to the trivalent form of arsenic. Arsenic is also more acutely toxic than other metallic compounds, hence its use in earlier times as a rodenticide.

In humans, exposure to inorganic arsenic is primarily of concern because of its cancer-causing properties. Arsenic and inorganic arsenic compounds have been classified by the International Agency for Research into Cancer (IARC) as carcinogenic to humans (Group 1) (IARC, 2012). Continual low level exposure to arsenic is associated with skin lesions, developmental toxicity, neurotoxicity, cardiovascular diseases, abnormal glucose metabolism, and diabetes (EFSA, 2009b). There is evidence of negative impacts on foetal and infant development, particularly reduced birth weights (EFSA, 2009b).

No tolerable daily or weekly intakes have been established for organic arsenic compounds. In 2009, the EFSA Expert Panel on Contaminants (CONTAM Panel) noted that since the PTWI of 15 μg/kg bw/week had been established by JECFA, new data had established that inorganic arsenic causes cancers of the lung and urinary tract in addition to skin lesions, and that a range of adverse effects had been reported at exposures lower than those reviewed by JECFA. The Panel further noted that inorganic arsenic is not directly DNA-reactive, rather it is co-carcinogenic in that it increases the genotoxicity, mutagenesis and clastogenicity of other DNA damaging agents, possibly by epigenetic means and interference with DNA damage response mechanisms. Consequently, the Panel noted that there are a number of proposed mechanisms of carcinogenicity, for each of which a thresholded mechanism could be postulated (EFSA, 2009b). However, taking into account the uncertainty with respect to the shape of the dose-response relationships, it was not considered appropriate to identify from the human data a dose of inorganic arsenic with no appreciable health risk, i.e. a tolerable daily or weekly intake could not be established. Therefore, the Panel concluded that the margins of exposure (MoEs) should be assessed between the identified reference points from the human data and the estimated dietary exposure to inorganic arsenic in the EU population (EFSA, 2009b). The Panel modelled the dose-response data from key epidemiological studies and selected a benchmark response of 1% extra risk for cancers of the lung, skin and bladder, as well as skin lesions. The Panel concluded that the overall range of Benchmark Dose (Lower Limit) $(BMDL)_{01}$ values of 0.3 to 8 µg/kg bw/day should be used instead of a single reference point in any risk characterisation for inorganic arsenic. In 2011, JECFA withdrew the TWI of 15 µg/kg bw/week and established $BMDL_{0.5}$ (0.5% extra risk) values of 3 µg/kg bw/day (lung cancer), 5.2 µg/kg bw/day (bladder cancer) and 5.4 µg/kg bw/day (skin lesions) (WHO, 2011).

4.2.2 Exposure assessment for arsenic in the population resident in Ireland

Dietary exposure to arsenic and inorganic arsenic in the Irish adult and child populations was estimated based on the most recent TDS carried out in Ireland (FSAI, 2016). Tables 13 and 14 present the estimated LB and UB daily mean and 97.5th percentile arsenic and inorganic arsenic exposure of the Irish adult and child populations from all food groups. The LB intakes of arsenic are considered to be more representative of exposure of the population resident in Ireland, as the UB estimates, which are considerably higher, reflect the assumption that in food where the arsenic levels were <LOD, arsenic was present at the LOD (see Section 3.2 on arsenic occurrence in food).

Table 13. Estimated daily total arsenic intake of the Irish adult and child populations

ADULTS							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		P97.5		Mean		P97.5	
LB	UB	LB	UB	LB	UB	LB	UB
56	71	294	310	0.7	0.9	3.9	4.2
CHILDREN							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		P97.5		Mean		P97.5	
LB	UB	LB	UB	LB	UB	LB	UB
17.9	27.3	88.5	97.5	0.6	0.9	2.9	3.3

Table 14. Estimated daily inorganic arsenic intake of the Irish adult and child populations

ADULTS							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB
1.03	1.7	4.3	5.7	0.01	0.02	0.06	0.08

CHILDREN							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB
0.98	1.48	3.81	4.14	0.03	0.05	0.13	0.14

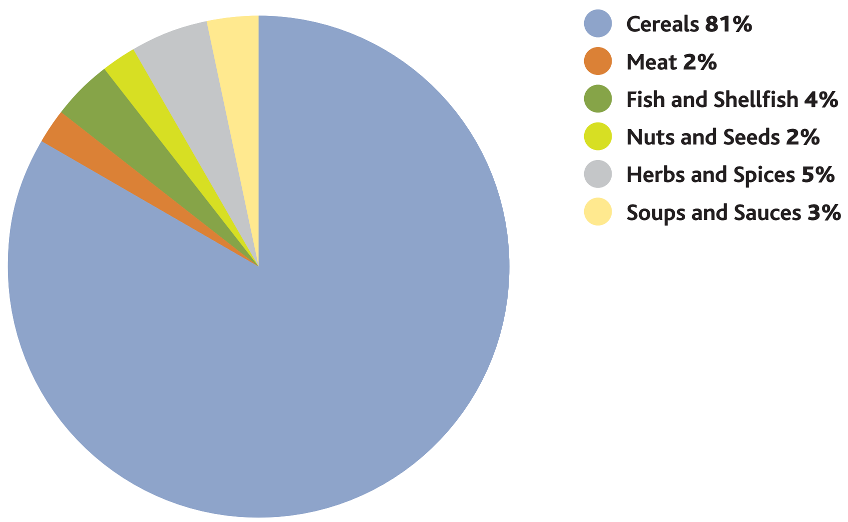
As can be seen from Table 13, for adults the average intake of total arsenic was estimated to fall between 0.7-0.9 µg/kg bw/day and for above average consumers between 3.9-4.2 µg/kg bw/day. The average intake of inorganic arsenic was much lower (see Table 14), falling between 0.01-0.02 µg/kg bw/day and for above average consumers between 0.06-0.08 µg/kg bw/day.

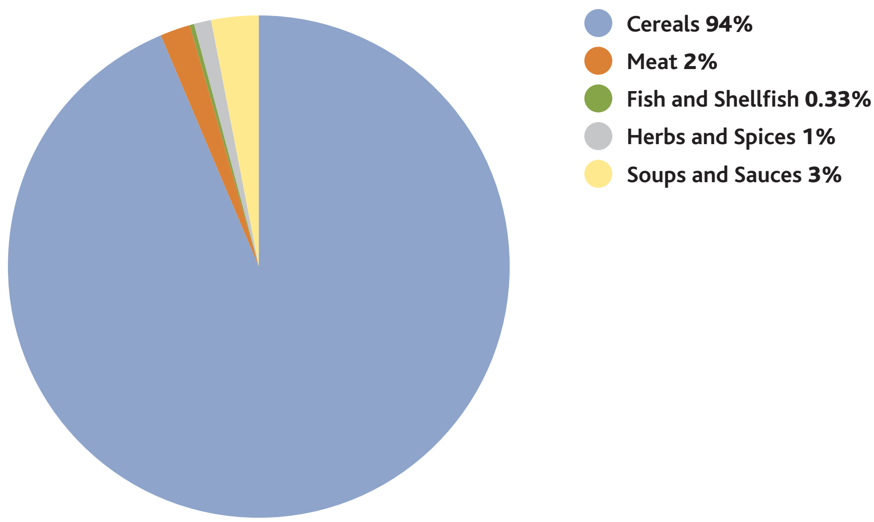
For children (see Table 13), the average intake of total arsenic was estimated to fall between 0.6-0.9 µg/kg bw/day and for above average consumers between 2.9-3.3 µg/kg bw/day. The average intake of inorganic arsenic (see Table 14) was much lower, falling between 0.03-0.05 µg/kg bw/day and for above average consumers between 0.13-0.14 µg/kg bw/day.

Arsenic was detected above the LOD in 18% of all analysed foods. Those foodstuffs which contained detectable levels of arsenic were further analysed for inorganic arsenic and, of these, 35% contained levels of inorganic arsenic above the LOD.

Fish and seafood were the main contributors to total arsenic intake in both adults and children, contributing 95% and 89% respectively, to overall intake. However, it should be noted that the arsenic in fish and seafood is primarily in the organic form. Figure 5 shows that the contribution from fish and seafood to total inorganic arsenic exposure represented only a small proportion (4% in adults and 0.3% in children). The main contributor to inorganic arsenic (81% in adults and 94% in children) was found to be cereals (see Figure 5), and arsenic is known to particularly occur as inorganic arsenic in rice (Laparra *et al.*, 2005).

Figure 5. Contribution (%) of different food groups to total inorganic arsenic intake





An updated exposure assessment was undertaken by EFSA in 2014 (see Table 15), which resulted in considerably lower dietary arsenic exposure estimates than in the original opinion (EFSA, 2009b). The observed reduction in exposure was due to the use of more refined consumption data, and better matching of and increased use of actual concentration data for inorganic arsenic (EFSA, 2014).

Table 15. Summary statistics of the dietary chronic exposure assessment (µg/kg bw/day) to inorganic arsenic across European dietary surveys reported by EFSA (2014)

EU population group	Mean µg/kg bw/day		95th percentile µg/kg bw/day	
Infants, toddlers and children	0.20-0.45 (min-max LB)	0.47-1.37 (min-max UB)	0.36-1.04 (min-max LB)	0.81-2.09 (min-max UB)
Adults, elderly/ very elderly	0.09 to 0.38 (min LB-max UB)		0.14 to 0.64 (min LB-max UB)	

As can be seen from Table 14, estimates for inorganic arsenic intake by adults derived in the most recent TDS indicate considerably lower values, falling between 0.01-0.02 µg/kg bw/day for the mean and between 0.06-0.08 µg/kg bw/day for above average consumers. The observed difference is most likely due to results for the TDS being derived from actual measured values for inorganic arsenic in the food samples, whereas EFSA, due to lack of occurrence data for inorganic arsenic for all food groups, extrapolated most of the values from total arsenic, assuming a conservative proportion of (generally) 70% inorganic arsenic to the total arsenic measured in food.

4.2.3 Risk characterisation

EFSA (EFSA, 2009b), in its most up-to-date risk assessment, has recommended that a range of BMDLs_{01} of 0.3 to 8 µg/kg bw/day should be used in any risk characterisation for inorganic arsenic.

Table 16 provides MoEs for the lower and upper end of the range of BMDLs_{01} calculated by EFSA, derived for both average and above average intake estimates of inorganic arsenic in the Irish adult and child populations.

Table 16. MoEs for inorganic arsenic derived for Irish adults and children based on Benchmark Doses of 0.3 to 8 µg/kg bw/day as set by EFSA (EFSA, 2009)

Estimated intake of inorganic arsenic (µg/kg bw/day LB-UB) (FSAI, 2016)		MoE based on BMDL_{01} of 0.3 µg/kg bw/day	MoE based on BMDL_{01} of 8 µg/kg bw/day
Adults Mean	0.01-0.02	30-15	800-400
Adults 97.5th percentile	0.06-0.08	5-4	133-100
Children Mean	0.03-0.05	10-6	267-160
Children 97.5th percentile	0.13-0.14	2-2	62-57

Estimated dietary intake for both adults and children are below EFSA's benchmark doses with MoEs ranging from 30-6 for average consumers (adults and children) and 5-2 for above average consumers when measured against the lower end of the BMDL_{01} range of 0.3 µg/kg bw/day.

These MoEs indicate that the exposure to inorganic arsenic in adults and children resident in Ireland is at least two-fold lower than the lower limit of the 95th percent confidence interval benchmark dose of 0.3 µg/kg bw/day, associated with a 1% increased risk of developing lung cancer. However, the calculated MoEs between the estimated exposure and BMDLs are low and a further effort to decrease exposure to the population is warranted.

In 2009, EFSA concluded that the estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the $BMDL_{01}$ values identified by the CONTAM Panel, and therefore there is little or no MoE and the possibility of a risk to some consumers cannot be excluded. The CONTAM Panel therefore, recommended that dietary exposure to inorganic arsenic should be reduced and further data to produce speciation data for different food commodities to support dietary exposure assessment and dose-response data for the possible health effects should be collected.

To mitigate the risks of exposure to arsenic, the Commission introduced maximum legislative limits for inorganic arsenic in rice and rice-based products in tandem with a monitoring recommendation covering a wider range of foods to examine the need for further management actions.

According to EFSA (EFSA, 2009b), infants below six months of age fed only on breast milk have very low intakes of inorganic arsenic. Infants fed only on cows' milk formula, reconstituted with water containing arsenic at the average European concentration level, have intakes of inorganic arsenic that are about three fold higher than those of breastfed infants, but below the range of $BMDL_{01}$ values. Substitution of milk with rice milk might lead to a daily inorganic arsenic intake that is higher than for other consumers. With regard to the latter practice, the FSAI advises that, as a precautionary measure, infants and young children up to 4.5 years of age should not consume rice milk as a substitute for cows' milk, breast milk or infant formula. This advice is based on findings that indicate that there are low levels of inorganic arsenic found in rice milk (FSAI, 2009).

4.3 Cadmium

4.3.1 Hazard identification/characterisation of cadmium

Cadmium is relatively poorly absorbed into the body, but once absorbed is slowly excreted, like other metals, having a half-life of 10-20 years. Most of the body burden of cadmium is retained in the liver and the kidneys. The kidney is the target organ for cadmium, producing proximal tubular necrosis. Bone demineralisation, either through direct bone damage or indirectly due to kidney damage may also occur. Cadmium has also been associated with lung damage and development of lung tumours and skeletal changes through occupational exposures. Cadmium and cadmium compounds are carcinogenic to humans (Group 1) (IARC, 2012). Newer data on exposure to cadmium in the general population have been statistically associated with increased risk of cancer such as in the lung, endometrium, bladder, and breast (EFSA, 2009a).

In March 2009, EFSA published a scientific opinion on health risks related to the presence of cadmium in food (EFSA, 2009a). The EFSA CONTAM Panel identified kidney damage as the key health effect on which to base its assessment. The CONTAM Panel concluded that the mean intake for adults across Europe is close to or slightly exceeding, the TWI of 2.5 µg/kg bw/week, based on the available data on cadmium levels in food. They noted that subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about two fold. In contrast, JECFA has established a PTMI for cadmium of 25 µg/kg bw/month (JECFA, 2010), an intake which is 2.5 times greater than that considered acceptable by EFSA.

4.3.2 Exposure assessment for cadmium in the population resident in Ireland

Dietary exposure to cadmium in the Irish adult and child populations was estimated based on the most recent TDS carried out in Ireland (FSAI, 2016). Table 17 presents the estimated LB and UB daily mean and 97.5th percentile cadmium exposure of the Irish adult and child populations from all food groups.

Table 17. Estimated cadmium exposure of the Irish adult and child populations from all food groups

ADULTS											
Daily Intake µg				Daily Intake µg/kg bw (weekly intake in parenthesis)				% of EFSA TWI (2.5 µg/kg bw/week)			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
11.75	16.55	22.44	29.12	0.16 (1.1)	0.22 (1.5)	0.33 (2.3)	0.42 (3)	44%	62%	92%	118%

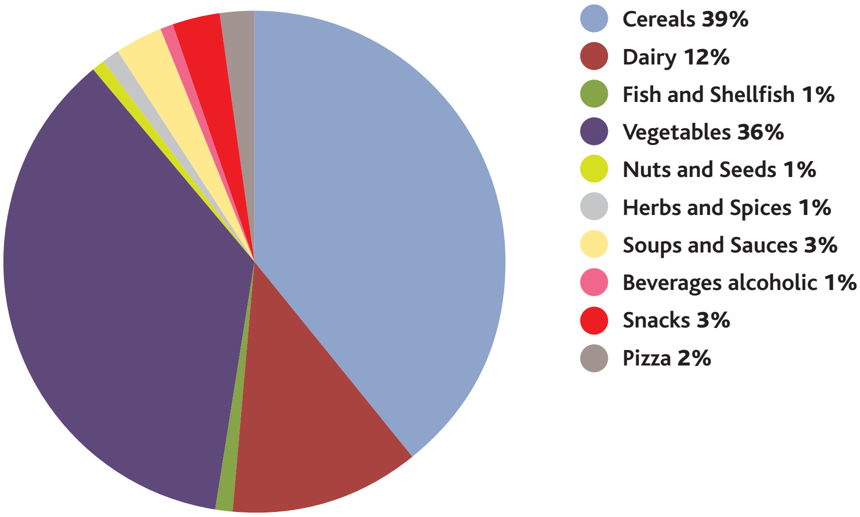
CHILDREN											
Daily Intake µg				Daily Intake µg/kg bw (weekly intake in parenthesis)				% of EFSA TWI (2.5 µg/kg bw/week)			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
7.31	10.02	14.65	17.85	0.24 (1.7)	0.32 (2.3)	0.47 (3.3)	0.59 (4.1)	66%	91%	132%	164%

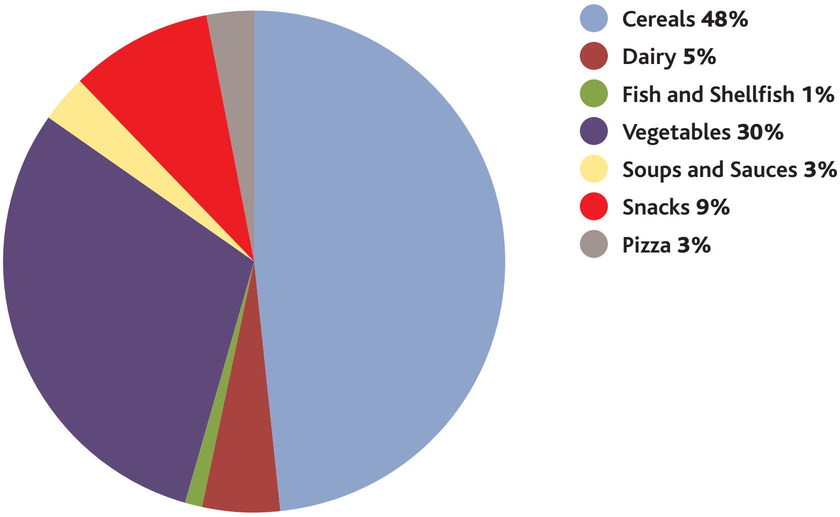
As can be seen from Table 17, for adults, the average intake of cadmium was estimated to fall between 1.1-1.5 µg/kg bw/week. This corresponds to between 44 and 62% of the EFSA TWI. The above average (97.5th percentile) intake was estimated to fall between 2.3-3.0 µg/kg bw/week. This corresponds to between 92 and 118% of the TWI. This presents a considerable reduction compared to results obtained in the previous TDS (FSAI, 2011), which estimated an average % TWI of 95-123% and a 97.5th percentile % TWI of 216-244%. The change observed is mainly due to a change in dietary patterns observed between the two studies (FSAI, 2011; FSAI, 2016), indicating a shift from a predominantly vegetable contribution to cadmium exposure to a more levelled contribution from both cereals and vegetables.

For children, average intake of cadmium at the time of this study was estimated to fall between 1.7-2.3 µg/kg bw/week. This corresponds to between 66 and 91% of the EFSA TWI. The above average (97.5th percentile) intake was estimated to fall between 3.3-4.1 µg/kg bw/week. This corresponds to between 132 and 164% of the TWI.

Cadmium was detected in 42% of all samples analysed. Figure 6 shows that cereals (39% and 48%) and vegetables (36% and 30%) were the major contributing sources in adults and children, respectively.

Figure 6. Contribution of the various food groups in which cadmium was detected (LB) as a percentage of total cadmium intake in adults and children





4.3.3 Risk characterisation

As indicated in Section 4.3.2, the estimated average dietary intakes of cadmium for the Irish adult and child populations were below the EFSA TWI, whereas exposure in 2.5% of the adult and child populations was observed to slightly exceed the EFSA TWI. Figure 6 reveals that vegetables and cereals are the main food groups contributing to cadmium exposure from the Irish diet.

Results from the previous TDS (FSAI, 2011) indicated that average consumers also exceeded the TWI and that vegetables, particularly potatoes, were found to be the major contributors to dietary cadmium exposure in adults (children were not included in the previous TDS). The considerable drop in exposure can be attributed to a change in eating pattern observed in adults with the shift in dietary food groups from predominantly vegetables to cereals and vegetables. A comparison between the first adult food consumption survey (IUNA, 2001) used in the previous TDS and the most recent National Adult Nutrition Survey (NANS, 2008-2010) used in the most recent TDS, indicates that potato consumption has decreased in the region of 50% over the last ten years.

The FSAI undertook a study of urinary cadmium levels in samples from individuals who participated in the National Adult Nutrition Survey published in 2011. This study examined urinary cadmium excretion in women aged >50 years, and also urinary cadmium excretion in the general population. The results of the study show that 95% of the population (including women aged over 50, who are considered to be the most 'at-risk' sub-group) have urinary cadmium levels below the critical value of 1 µg cadmium/g creatinine identified by EFSA in its opinion.

The results from the most recent TDS (FSAI, 2016) indicate that current intake of cadmium by consumers in Ireland is appreciably lower than that previously estimated, most likely due to a change in dietary behaviour. Based on the findings of a biomarker study undertaken on urine samples collected from subjects partaking in the most recent adult food consumption survey, and which reflect long-term chronic exposure to cadmium, the levels of cadmium in the Irish diet do not present an unacceptable risk to the consumer.

4.4 Lead

4.4.1 Hazard identification/characterisation of lead

Lead is a chronic or cumulative toxicant and competes with calcium for gastrointestinal absorption. Approximately 40–50% of ingested lead is absorbed by children, as opposed to 3-10% in adults. After absorption it enters blood where the majority is taken up by red blood cells. Here lead has a half-life of two to three weeks, during which there is some redistribution to liver and kidney and excretion into bile or deposition in bone, forming a long term repository of the metal. In adults and children, approximately 94% and 73% respectively, of the total body burden of lead is found in the bones. Pregnant and menopausal women may have increased redistribution from bone.

There are two main populations at risk, those aged between nine months and three years of age, and those living near point sources of lead pollution (Sanborn *et al.*, 2002). Exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes (JECFA, 2011a). It has been estimated that lead exposure was responsible in 2004 for 143,000 deaths and 0.6% of the global burden of disease, taking into account, mild mental retardation and cardiovascular outcomes resulting from exposure to lead (WHO, 2009).

Effects following acute high exposures, generally observed in occupational settings, are not discussed here. Associations with clinically relevant renal outcomes have been observed in populations with mean blood lead levels as low as 2.2 µg/dL (U.S. EPA, 2006); the functional impairment of renal tubular cells adversely affects resorption and secretion of solutes and metabolites and the resulting interstitial nephropathy, should it develop, is irreversible. The contribution of lead to cardiovascular disease is still incompletely understood and may be a result of renal impairment causing hypertension.

For adults, the adverse effect associated with lowest blood lead concentrations is a lead-associated increase in systolic blood pressure. The weight of evidence for this effect is consistent. A population increase in blood pressure of approximately 2 mm Hg (0.3 kPa) would be expected to occur with mean dietary lead exposure estimates ranging from 0.02 to 3.0 µg/kg body weight/day, which are associated with a modest increase in the risk of ischaemic heart disease and cerebrovascular stroke (JECFA, 2011a).

Children are particularly sensitive to lead. Their risk of exposure is greater because of potential *in-utero* exposure, hand to mouth behaviour, greater consumption of food per unit body weight and nutritional deficiencies that increase absorption of lead (WHO, 2010; JECFA, 2011a). Susceptibility is enhanced because of pronounced gastrointestinal absorption of lead, via the calcium transport system (up to 50% of ingested lead is absorbed by children, as compared with 10% in adults (ATSDR, 2007), higher intake per unit body weight and immaturity of the blood brain barrier. Likewise, there is strong epidemiological evidence that the most critical effect of lead at low concentrations in children, is impaired cognitive development and intellectual performance which can be observed at blood lead concentrations below 10 µg/dL (U.S. EPA, 2006). There appears to be no threshold level below which lead causes no injury to the developing human brain (JECFA, 2011a). It is likely that the initial neurodevelopmental lesions at low concentrations occur by disruption of formative biological mechanisms.

In June 2010, JECFA re-evaluated lead and withdrew the PTWI guideline value of 25 µg/kg bw/week (JECFA 2000a, 2011a), on the grounds that it was inadequate to protect against IQ loss (JECFA, 2011a). EFSA (2010a) also concluded that a PTWI of 25 µg/kg bw/week was no longer appropriate as there was no evidence for a threshold for critical lead-induced effects. The EFSA CONTAM Panel identified developmental neurotoxicity (DNT) in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for the risk assessment. The respective BMDLs derived from blood lead levels in µg/L (corresponding dietary intake values in µg/kg bw/day) were: developmental neurotoxicity $BMDL_{01}$, 12 µg/L (0.50 µg/kg bw/day); effects on systolic blood pressure (SBP) $BMDL_{01}$, 36 µg/L (1.50 µg/kg bw/day); effects on prevalence of chronic kidney disease (CKD) $BMDL_{10}$, 15 µg/L (0.63 µg/kg bw/day). In adults, children and infants, the MoEs were such that the possibility of an effect from lead in some consumers, particularly in children from 1-7 years of age, cannot be excluded. Protection of children against the potential risk of neurodevelopmental effects would be protective for all other adverse effects of lead, in all populations (EFSA, 2010a).

4.4.2 Exposure assessment for lead in the population resident in Ireland

Dietary exposure to lead in the Irish adult and child populations was estimated based on the most recent TDS carried out in Ireland (FSAI, 2016). Table 18 presents the estimated LB and UB daily mean and 97.5th percentile lead exposure of the Irish adult and child populations from all food groups.

Table 18. Estimated lead exposure of the Irish adult and child populations from all food groups

ADULTS							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB
2.61	8.72	7.90	15.04	0.04	0.12	0.11	0.22

CHILDREN							
Daily Intake µg				Daily Intake µg/kg bw			
Mean		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB
1.27	5.10	2.7	7.7	0.04	0.17	0.09	0.27

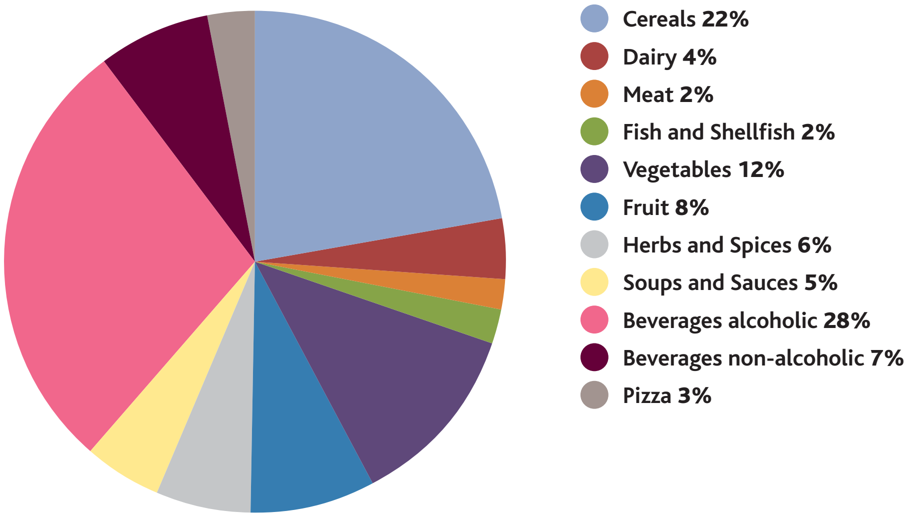
As can be seen from Table 18, for adults the average daily intake of lead at the time of this study was estimated to fall between 0.04-0.12 µg/kg bw/day. The above average (97.5th percentile) daily intake was estimated to fall between 0.11-0.22 µg/kg bw/day. These estimates are in line with results reported in the previous TDS (FSAI, 2011).

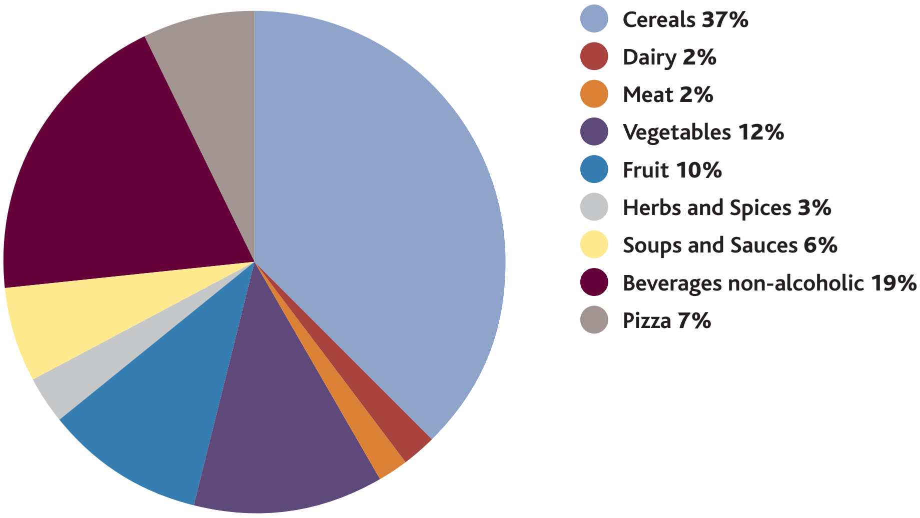
For children, the average intake of lead at the time of this study was estimated to fall between 0.04-0.17 µg/kg bw/day. The above average (97.5th percentile) intake was estimated to fall between 0.09-0.27 µg/kg bw/day.

EFSA reported that in average adult consumers over the whole EU, lead dietary intake ranges from 0.36 to 1.24 µg/kg bw/day, and up to 2.43 µg/kg bw/day in high consumers in Europe (EFSA, 2010a), which are much higher than the intake levels found for Irish adults.

Lead was detected above the LOD in 29% of all samples analysed. Figure 7 shows the main contributing food groups to dietary lead exposure, based on LB measurements, revealing that alcoholic beverages, cereals and vegetables were the major contributors (28, 22 and 12% of total intake, respectively) in adults. In children, cereals, beverages and vegetables were found to be the major contributors (37, 19 and 22% of total intake, respectively).

Figure 7. Contribution of the various food groups in which lead was detected (LB) as a percentage of total lead intake in adults and children





4.4.3 Risk characterisation

As a consequence of the withdrawal of the PTWI of 25 µg/kg bw/week, EFSA (2012) considered it appropriate to calculate MoEs to characterise the risk from lead exposure.

Table 19 provides MoEs derived for both average and above average intake estimates of lead in the Irish adult and child populations, based on the EFSA $BMDL_{01}$ of 0.50 µg/kg bw/day for developmental neurotoxicity (DNT), $BMDL_{01}$ of 1.50 µg/kg bw/day for effects on systolic blood pressure (SBP) and the $BMDL_{10}$ of 0.63 µg/kg bw/day for effects on prevalence of chronic kidney disease (CKD). Estimates of dietary exposure to lead in both adults and children were found to be lower than the BMDL intake values for effects on SBP, CKD and DNT (see Table 19).

Table 19. MoEs for lead derived for Irish adults and children based on BMDLs as set by EFSA (EFSA, 2010a)

Estimated intake of lead (µg/kg bw/day LB-UB) (FSAI, 2016)		MoE based on $BMDL_{10}$ (0.63 µg/kg bw/day) for CKD[1]	MoE based on $BMDL_{01}$ (1.50 µg/kg bw/day) for SBP[1]	MoE based on $BMDL_{01}$ (0.5 µg/kg bw/day) for DNT[2]
Adults Mean	0.04 – 0.12	16-5	38-13	
Adults 97.5th percentile	0.11 – 0.22	6-3	14-7	
Children Mean	0.04 – 0.17			13-3
Children 97.5th percentile	0.09 – 0.27			6-2
[1] Critical for adults [2] Critical for children				

The CONTAM Panel concluded that a margin of exposure of 10 or greater would be sufficient to ensure that there was no appreciable risk of a clinically significant effect on SBP or of a clinically significant change in the prevalence of CKD, and that overall, the risk at MoEs of greater than 1.0 would be very low. With regard to effects on IQ, EFSA concluded that MoE of ten or greater should be sufficient to ensure that there was no appreciable risk of a clinically significant effect on IQ. At lower MoEs, but greater than 1.0, the risk is likely to be low, but not such that it could be dismissed as of no potential concern (EFSA, 2010b).

Based on the MoEs derived for both children and adults in the population resident in Ireland and the CONTAM Panel's conclusions, the risks from exposure to lead are likely to be low, however, given EFSA's conclusion that exposure margins between 1-10 should not be dismissed as of no potential concern with regard to effects on IQ, further efforts to reduce exposure should be made.

Consequently, the European Commission in 2015[4] undertook measures to reduce the dietary exposure to lead in food by lowering existing maximum levels and setting additional maximum levels for lead in relevant commodities.

[4] Commission Regulation (EU) 2015/1005 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs

4.5 Mercury

4.5.1 Hazard identification/characterisation of mercury

Excessive exposure to mercury is associated with a wide spectrum of adverse health effects, including damage to the central nervous system (neurotoxicity), the kidney, the reproductive system including development, the immune system and the cardiovascular system (EFSA, 2004a; EFSA 2012; JECFA, 2004; JECFA 2007b; JECFA, 2011b). Different forms of mercury, i.e. mercury metal, inorganic mercury salts such as mercuric chloride and organic forms of mercury such as methylmercury, produce different patterns of toxicity. For example, elemental mercury and organic forms of mercury such as methylmercury can cross the blood-brain barrier and cause neurotoxicity. Inorganic mercury salts such as mercuric chloride cannot cross the blood-brain barrier but the mercury is sequestered by and accumulates in the kidney, causing nephrotoxicity. Both JECFA and EFSA have also noted that there is an increasing body of data indicating that increased exposure to methylmercury may augment the risk of cardiovascular morbidity and mortality (EFSA, 2004a; EFSA, 2012; JECFA, 2004; JECFA, 2007b). IARC has concluded that methylmercury compounds are possibly carcinogenic to humans (Group 2B) (IARC, 1993).

The main concern in relation to the toxicity of mercury in the general population exposed to low levels of mercury in their diet relates to the potential neurotoxicity of organic forms of mercury, e.g. methylmercury, in young children. Organic forms of mercury can cross the placental barrier between the mother and the unborn baby, and epidemiological studies in exposed populations of humans and toxicological studies in animals have shown that this can result in a range of neurological disturbances from impaired learning to obvious brain damage (EFSA, 2004a; EFSA, 2012; JECFA, 2004; JECFA, 2007b; JECFA, 2011b). Exposure during pregnancy is therefore, considered to present particular risks.

In 2004, EFSA concluded that methylmercury toxicity has been demonstrated at low exposure levels, and exposure to this compound should therefore be minimised, while recognising that fish constitutes an important part of a balanced diet (EFSA, 2004a). In 2012, EFSA concluded again that exposure to methylmercury above the TWI is of concern, but if measures to reduce methylmercury exposure are being considered, also the potential beneficial effects of fish consumption should be taken into account.

Subsequently, the European Commission requested EFSA to carry out a risk benefit analysis regarding the risks and benefits to human health of fish/seafood consumption related to methylmercury. The EFSA Scientific Committee used previous work performed by the EFSA CONTAM Panel and the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDNA) to create scenarios based on typical fish consumption patterns of population groups at risk of exceeding the tolerable weekly intake (TWI) for methylmercury and estimated how many servings of fish/seafood per week these population groups would need to reach the TWI for methylmercury and the dietary reference value (DRV) for n-3 (Long-Chain) Polyunsaturated Fatty Acid (LCPUFA). When consuming species with a high methylmercury content, only a few numbers of servings (<1–2) can be eaten before reaching the TWI, which may be attained before the DRV. To protect against neurodevelopmental toxicity of methylmercury and achieve the benefits of fish consumption (effect of fish/seafood consumption during pregnancy on functional outcomes of children's neurodevelopment and on cardiovascular diseases in adults), which are associated with 1–4 fish servings per week, fish/seafood species with a high content of mercury should be limited in the daily diet. Because a variety of fish species are consumed across Europe, it was not possible to make general recommendations on fish consumption. The Scientific Committee therefore, recommended that each country needs to consider its own pattern of fish consumption, especially the species of fish consumed, and carefully assess the risk of exceeding the TWI for methylmercury while obtaining the health benefits from consumption of fish/seafood (EFSA, 2015). The FSAI provides advice on fish consumption for children, pregnant women and women of reproductive age with regard to mercury exposure[5].

[5] https://www.fsai.ie/faqs/mercury_and_fish_consumption.html

In 1972, JECFA established a PTWI of 5 μg/kg bw/week for total mercury, of which no more than 3.3 μg/kg bw/week should be in the form of methylmercury (JECFA, 1972). JECFA maintained this PTWI until 2003, when it revised the guidance value to 1.6 μg/kg bw/week based on the results of epidemiological studies in the Faroe Islands and the Seychelles showing neurobehavioral changes in young children exposed *in-utero* to methylmercury in the diet of their mothers (JECFA, 2004). JECFA re-confirmed the PTWI of 1.6 μg/kg bw/week for methylmercury at its 2006 meeting (JECFA, 2007b), stating that this PTWI was based on developmental neurotoxicity, the most sensitive toxicological endpoint in humans, the most susceptible species. In 2010, JECFA reviewed the PTWI for total mercury (JECFA, 2011b). The Committee concluded that the predominant form of mercury in foods other than fish and shellfish is inorganic mercury, and that the PTWI for inorganic mercury should be based on the nephrotoxicity induced by mercuric chloride. On this basis, JECFA established a PTWI of 4 μg/kg bw/week for inorganic mercury which the Committee considered was also applicable to dietary exposure to total mercury from foods other than fish and shellfish (JECFA, 2011b).

In its 2004 evaluation, the EFSA CONTAM panel concluded, in line with JECFA and other evaluations, that the developing brain should be considered the most sensitive target organ for methylmercury and endorsed the PTWI of 1.6 μg/kg bw/week for methylmercury (EFSA, 2004a). In its 2012 re-evaluation of mercury and methylmercury in food, using the same critical endpoint of developmental neurotoxicity and the same critically exposed populations in the Faroe Islands and the Seychelles, but using slightly different uncertainty factors, EFSA established a TWI for methylmercury of 1.3 μg/kg bw/week expressed as mercury (EFSA, 2012). EFSA also established a TWI for inorganic mercury of 4 μg/kg bw/week, expressed as mercury, based on nephrotoxicity, as also used by JECFA (EFSA, 2012).

Individuals consuming a diet containing a high content of predatory fish and/or shellfish may exceed the TWI for methylmercury, established by EFSA in 2012, of 1.3 μg/kg bw/week and therefore, may be at risk. EFSA in its 2004 and 2012 evaluations of mercury and methylmercury looked at exposure of the European population to mercury in their diet. The estimated intakes of mercury in Europe varied by country, depending on the amount and the type of fish consumed. The mean intakes were in most cases below the TWI, but high intakes exceeded the TWI. In its 2012 evaluation, EFSA noted that the medians of 95th percentile dietary exposures across surveys were close to or above the TWI for all age groups, and that high consumers of fish meat may exceed the TWI by up to approximately six-fold. However, estimates derived by EFSA for the Irish adult population, i.e. 0.86 μg/kg bw, were below the TWI.

4.5.2 Exposure assessment for mercury in the population resident in Ireland

Dietary exposure to mercury in the Irish adult and child populations was estimated based on the most recent TDS carried out in Ireland (FSAI, 2016). Table 20 presents the estimated LB and UB mean and 97.5th percentile mercury exposure of the Irish adult and child populations from all food groups. Of all the foods analysed only 11% were found to contain mercury. Of these, 97% were fish and seafood samples, and the LB intakes of mercury, as presented in Table 20, reflect this source. The UB estimates, which are considerably higher, reflect the assumption that in food where the mercury levels were <LOD, mercury was present at the LOD (see Section 3.5 on mercury occurrence in food).

Table 20. Estimated mercury exposure of the Irish adult and child populations from all food groups

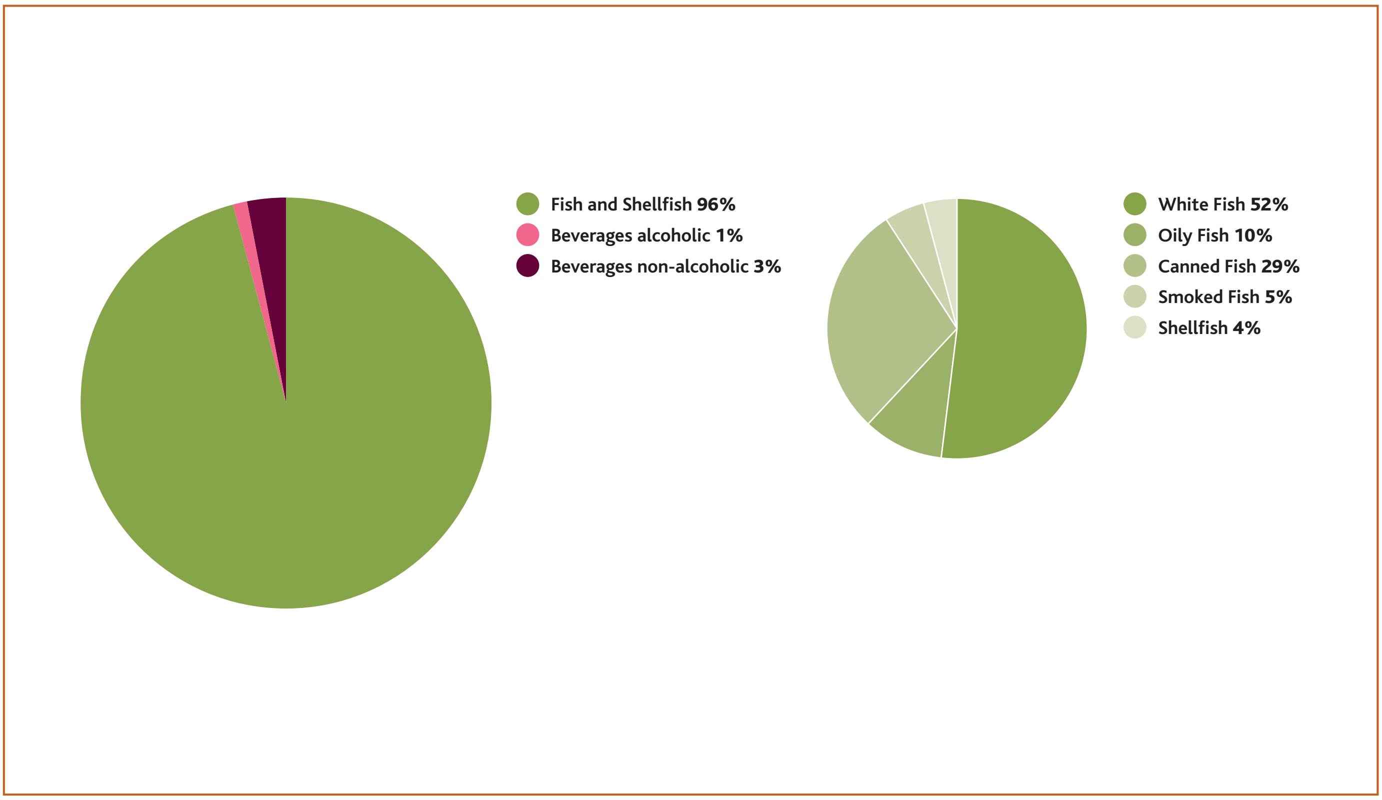
ADULTS											
Daily Intake µg				Daily Intake µg/kg bw (weekly intake in parenthesis)				% of EFSA PTWI (1.6 µg/kg bw/week) for methylmercury			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
1.78	9.00	9.47	18.00	0.02 (0.17)	0.12 (0.84)	0.12 (0.84)	0.25 (1.74)	10%	52%	53%	109%
CHILDREN											
Daily Intake µg				Daily Intake µg/kg bw (weekly intake in parenthesis)				% of EFSA PTWI (1.6 µg/kg bw/week) for methylmercury			
Mean		**P97.5**		**Mean**		**P97.5**		**Mean**		**P97.5**	
LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
0.61	5.20	3.17	8.31	0.02 (0.14)	0.17 (1.19)	0.11 (0.77)	0.31 (2.18)	9%	74%	48%	136%

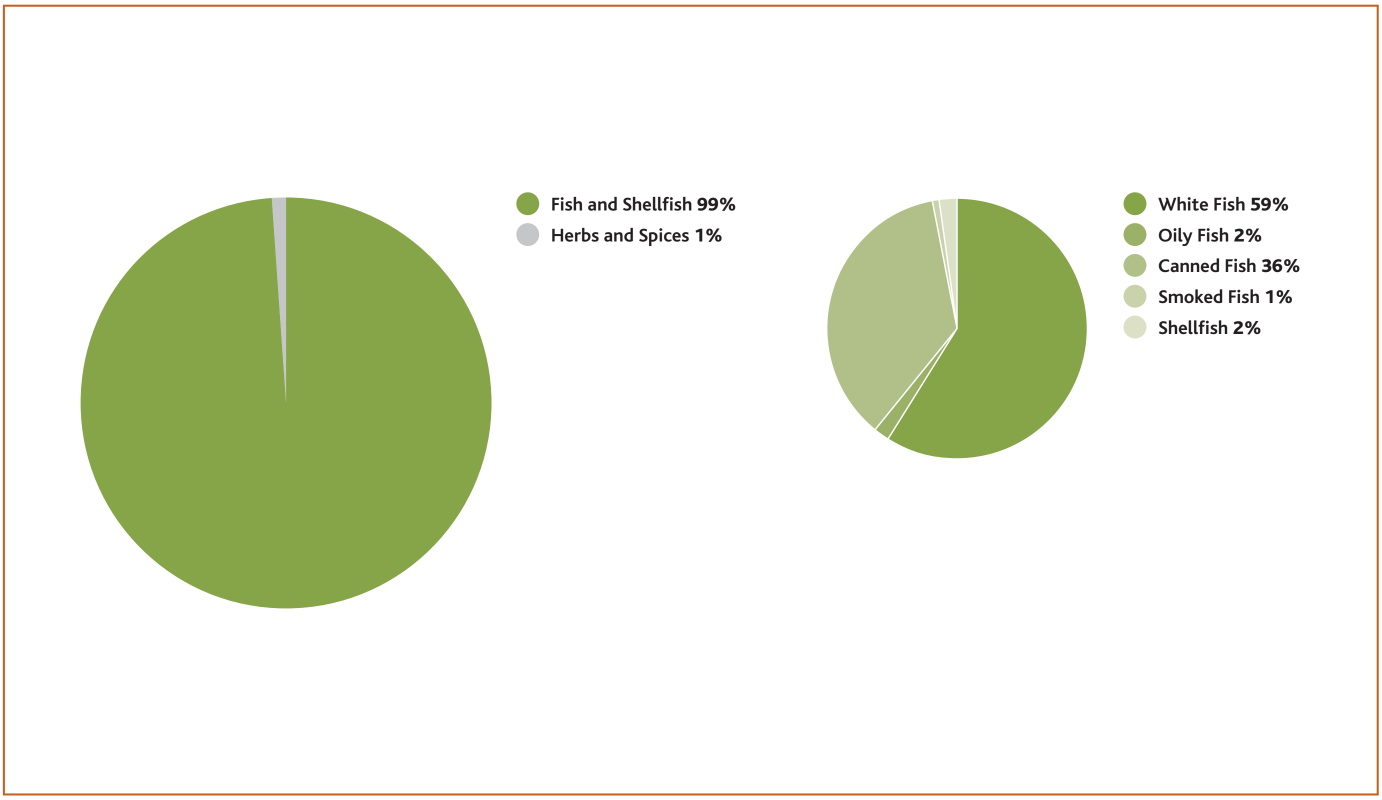
Assuming that all mercury in fish is present in the form of methylmercury, the average intake of methylmercury, based on LB estimates (the most valid comparison, since this represents intake from fish, likely to be the only source of mercury in the diet) in adults corresponds to 10% of the PTWI and above average intake corresponds to 53% of the PTWI (see Table 20). These levels compare well with estimates derived in the previous TDS (FSAI, 2011).

For children, based on the same assumptions, exposure corresponds to 9% of the PTWI and above average intake corresponds to 48% of the PTWI.

For both adults and children, white fish was found to be the main contributor to mercury intake, as shown in Figure 8.

Figure 8. Contribution of the various food groups in which mercury was detected (LB) as a percentage of total mercury intake in adults and children





These findings are in line with EFSA's risk assessment of 2012, that fish muscle meat was the main contributor to methylmercury dietary exposure for all age classes, followed by fish products (EFSA, 2012).

Assuming all mercury in fish is present in the form of methylmercury, the average intake by Irish adults of methylmercury, based on LB estimates, corresponds to 10% of the TWI and above average intake corresponds to 53% of the TWI. This is similar to the estimate of an average intake of 15% of the TWI for adult 'seafood only consumers' calculated using upper bound species specific data (McGovern *et al.* 2011).

4.5.3 Risk characterisation

Estimated (LB) dietary exposure for both adults and children did not exceed the TWI for methylmercury or for inorganic mercury (for which the TWI is three fold higher).

These findings are supported by the results of a recent pilot biomonitoring study (Cullen *et al.*, 2014), entitled "*Demonstration of a study to Coordinate and Perform Human Biomonitoring on a European Scale (DEMOCOPHES)*". For this study, hair mercury concentrations were determined from 120 Irish mother/child pairs, in order to determine the extent of mercury exposure among mothers and their children in Ireland, and to identify factors associated with elevated levels. Average levels in mothers (0.262 µg/g hair) and children (0.149 µg/g hair) did not exceed the US EPA guidance value (1.0 µg/g). Although hair mercury levels were significantly higher in those who frequently consumed fish, these were also below guidance values.

CHAPTER 5. CONCLUSIONS

Dietary exposure

The findings of this study indicate that, in general, risks from dietary exposure to the metals under consideration are of low concern for the adult and child populations in Ireland.

National exposure estimates derived for adults and children resident in Ireland in the TDS are generally lower than those derived by EFSA for the European population as a whole, which is most probably due to the higher level of detail in the Irish exposure assessment coupled with the collection of purpose specific concentration data for Ireland. In this regard, levels of metals determined in the TDS are in good agreement with data collected under compliance monitoring schemes.

Biomonitoring

Calculated estimates of dietary exposure to assess the risks posed to consumers from consumption of food available in Ireland are also supported by biomonitoring data, such as the 'cadmium in urine' study and the 'mercury in hair' study. Specific studies on blood lead in former mining areas have also informed mitigation strategies in the past. The availability of such data for the purposes of risk characterisation and risk management highlights the benefit of human biomonitoring.

Human biomarker studies also take into account non-dietary exposure sources, such as hand-to-mouth and object-to-mouth activity of young children, which can contribute significantly to exposure to metals from sources such as soil and dust (Moya, 2004).

Food monitoring and risk management

Occurrence data reported from existing systems of food monitoring by the FSAI, the HSE (EHS, Public Analyst Laboratories), DAFM, EPA, MI, SFPA, County and City Councils indicate that compliance with legislative maximum limits is very high, and where infringements have been found, produce has been removed from the market.

Global trade in food necessitates harmonised control and risk management actions at European wide level to reduce exposure of the European population to contaminants and pesticide residues. This is realised via harmonised European Commission food contaminants and residues legislation within Europe. Ireland participates in all relevant EU Expert Working Groups and provides food consumption and occurrence data to EFSA to ensure that the safety of Irish consumers is accounted for.

Where EFSA has identified potential risks to consumers in Europe, the European Commission has implemented risk management actions.

- In the case of **aluminium**, the Commission introduced a reduction of maximum limits for aluminium containing food additives to reduce long term exposure of the population in Europe.
- To mitigate the risks of exposure to **arsenic**, the Commission introduced maximum legislative limits for inorganic arsenic in rice and rice-based products in tandem with a monitoring recommendation covering a wider range of foods to examine the need for further management actions.
- Regarding **lead**, the European Commission in 2015, undertook measures to reduce the dietary exposure to lead in food by lowering existing maximum levels and setting additional maximum levels for lead in relevant commodities.

Whereas the risk from dietary exposure to lead is considered low in Ireland, attention has to be paid to sporadic cases of excess exposures that may occur in groups of animals due to inadvertent access to concentrated lead sources or in areas of pronounced high lead levels such as adjacent to historic mines. It is recommended that confirmed lead toxicity in food producing animals should be reportable to veterinary public health specialists, and should trigger a defined response to ameliorate potential risk. Site-specific risk assessment may be considered for farms with geochemically high lead. Geochemical anomalies or anthropogenic deposits may result in raised lead concentration in soils and thus may present localised risk. Potential anomalous sources such as hunted venison, wild pheasant and wild duck (lead shot) and offal consumption from a very limited number of cattle potentially exposed to anthropogenic sources may benefit from precautionary guidance.

The past use of lead as a material for water pipes in many older houses may result in unacceptably high levels in water supplies. Irish Water, in 2015, estimated that lead pipework is in up to 200,000 residential properties in Ireland as well as many of the commercial and public buildings (Irish Water, 2015). There is now a *National Strategy to Reduce Exposure to Lead in Drinking Water* published by the Department of Health (DoH) and Department of the Environment, Community and Local Government (DECLG) which is used by the EPA to track progress. Irish Water has also published a *Mitigation Plan* to reduce levels of lead in drinking water, part of which is mapping areas likely to have lead pipework and using water sampling programme data to identify those at risk. Irish Water has also begun the process of advising customers where lead pipes have been identified through the national metering programme (Irish Water, 2015).

- For **cadmium**, an EU monitoring recommendation on the investigation and/or introduction of mitigation strategies to reduce dietary exposure to cadmium was implemented by DAFM, in collaboration with Teagasc, University College, Dublin and Bord Bia (the Irish Food Board). High naturally occurring levels of cadmium in soil are found in parts of north Dublin and Meath, the main horticultural production region in the country, which is associated with the underlying limestone bedrock geology. A national research project commenced in 2013 to examine a number of parameters that may influence uptake of cadmium by potatoes and other vegetables, including potato variety, soil cadmium content and pH, effect of fertiliser use and of zinc application, with a view to developing strategies to mitigate cadmium uptake. Offal from older animals is also a potential source of cadmium for consumers and consequently, has been addressed through introduction of official controls.
- In order to reduce **mercury** levels in the environment and consequent human exposure, the European Commission launched the European Union (EU) mercury strategy in 2005. It is a comprehensive plan that includes 20 measures to reduce mercury emissions to reduce the supply and demand for mercury and to protect against exposure. In 2010, the European Commission reviewed the mercury strategy and concluded that the implementation of the strategy is in an advanced stage and almost all actions are delivered. The implementation of these policies is expected to reduce the emissions, although data are not yet available.

  The major highlights of the Minamata Convention on Mercury in 2013, an international treaty ratified by delegates from 140 countries, include a ban on new mercury mines, the phase-out of existing ones, control measures on air emissions, and the international regulation of the informal sector for artisanal and small-scale gold mining. This international agreement is anticipated to cause further reduction in mercury levels in the environment over time, thus meeting the objective of protecting human health and the environment. This convention is due for ratification by the EU in 2015.

  Maximum legislative limits for mercury in fish are also currently under review in Europe.

At-risk populations

While this Irish study has found that the risk from dietary exposure to the metals under consideration is low for the general population, specific advice to certain sub-population groups is warranted.

The FSAI has thus far provided advice on fish consumption for children, pregnant women and women of reproductive age with regard to mercury exposure and consumption advice relating to arsenic in Hijiki seaweed and rice milk.

However, current monitoring and exposure studies are in the main, designed to evaluate the general population status and are not targeted at specific areas with elevated background levels of the metals under consideration, and exceedance of the HBGVs in such situations cannot be precluded. Due to the global nature of the food supply, exposure of certain at-risk populations would be best addressed by means of biomarker studies, in addition to calculated specific exposure estimates.

APPENDIX I

Data on levels of various elements and pH of a range of Irish soils (n = 1,310) (Fay *et al.*, 2007).

Table 21. Summary statistics for concentrations of various elements in Irish soils*

	5th Percentile	Median	95th Percentile
pH	3.7	5.3	7.0
Organic carbon %	2.86	7.00	48.01
Aluminium %	0.20	3.48	6.65
Antimony	0.10	0.53	1.54
Arsenic	1.43	7.25	21.90
Barium	21.3	230.2	454.5
Cadmium	0.111	0.326	1.652
Calcium %	0.102	0.358	2.591
Cerium	1.9	34.8	62.3
Chromium	2.6	42.6	86.8
Cobalt	0.5	6.2	15.1
Copper	3.5	16.2	45.9
Gallium	0.60	8.46	17.76
Germanium	<0.1	1.26	2.00
Iron %	0.20	1.87	3.80
Lanthanum	1.1	20.0	33.1
Lead	11.7	24.8	61.9
Lithium	<2	19.7	54.2
Magnesium	0.107	0.298	0.824
Manganese %	25	462	1903
Mercury	0.022	0.086	0.237
Molybdenum	0.32	0.91	3.29
Nickel	1.9	17.5	50.0
Niobium	0.34	6.83	12.01
Phosphorus &	0.036	0.105	0.202
Potassium %	0.08	0.98	1.85
Rubidium	2.2	53.5	117.5
Scandium	0.36	5.85	12.33
Selenium	0.34	0.74	2.67
Sodium %	0.053	0.338	1.091
Strontium	20.7	49.7	115.0
Sulphur %	0.035	0.073	0.319
Tantalum	<0.05	0.45	0.85
Thallium	<0.02	0.430	0.818

	5th Percentile	Median	95th Percentile
Thorium	0.25	4.65	8.50
Tin	0.54	1.68	4.72
Titanium	125	2133	3773
Tungsten	<0.1	0.59	1.31
Uranium	0.20	1.96	4.74
Ytterbium	0.73	10.33	24.04
Zinc	15.9	62.6	144.7
* Units are reported in mg/kg except organic carbon, aluminium, calcium, iron, potassium, magnesium, sodium, sulphur and phosphorus, reported as %; pH reported in pH units.			

Concentrations in soil reflect concentrations in the geological material from which soil is formed by subsequent glacial activity, by the action of weather and biological activity and by anthropogenic activity. The last includes fertiliser application, animal waste additions and aerial deposition. Losses from soil occur mainly from leaching and as a consequence of crop and animal off-take.

Detailed soil data are available from the National Soils Database (Fay *et al.*, 2007a) and from the Soil Geochemical Atlas of Ireland (Fay *et al.*, 2007b). Data on mineral content of plants other than grass in Ireland appear to be very limited. A similar situation holds for animals used for food. Other published information relating specifically to Irish soils has been assembled in *Trace Elements and Metals in Irish Soils* (McGrath *et al.*, 2008).

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