Metals in Apple Juice and other Apple Products

Survey Report

March 2025

Executive summary

Food Standards Australia New Zealand (FSANZ) managed an analytical survey measuring levels of various metal contaminants in apple juice and other apple products. The metals surveyed included arsenic[1] (total and inorganic), cadmium, lead, mercury, and tin. The products sampled included apple juice, apple based infant foods, apple puree, apple sauce, canned apple, and dried apple. The samples were collected in all Australian states and territories in 2021 and 2022 as part of a previous national patulin survey (FSANZ, 2023).

Metal contaminants are present in the environment through natural and anthropogenic processes, which may lead to small amounts being unavoidably present in food. FSANZ manages the presence of contaminants in food through the provisions in the Australia New Zealand Food Standards Code, including setting maximum levels (MLs) in Standard 1.4.1 and Schedule 19. Food at the point of sale, must comply with these MLs.

The survey found that metal concentrations in apple juice and other apple products were very low. Most samples (82%) had no detectable levels of any of the analysed metals. Lead was detected in 12 of 71 (17%) samples. Arsenic (total) was detected in 2 of 71 (3%) samples. Tin was detected in 2 of 2 (100%) canned apple samples. Inorganic arsenic, cadmium and mercury were not detected in any samples. All metal concentrations were below identified Australian MLs, or other relevant country specific and international regulatory limits. This indicates metal levels in the sampled apple juices and other apple products are as low as reasonably achievable. On that basis, FSANZ concluded that there are no public health and safety concerns for Australian consumers.

The survey provides valuable data on metal concentrations in apple juices and other apple products. Information from the survey will support a comprehensive FSANZ assessment of overall dietary exposure to metals from a broad range of foods as part of the 28th Australian Total Diet Study (ATDS) (2024). The data will also be loaded into the Global Environment Monitoring System (GEMS) database to support future international risk assessments and consideration of international maximum levels by the Codex Alimentarius Commission.

[1] Arsenic is a metalloid, however, is referred to as a metal in this report for simplicity.

Contents

Executive summary 2

Acronyms and abbreviations 4

1 Introduction 5

1.1 Regulation of metal contaminants in food 5

1.1.1 Australia 5

1.1.2 Overseas and international 6

2 Methods 6

2.1 Food sampling 6

2.2 Sample preparation and analysis 7

3 Survey results 7

3.1 Overall summary 7

3.2 Arsenic 9

3.3 Cadmium 10

3.4 Lead 11

3.5 Mercury 13

3.6 Tin 14

4 Conclusions 15

5 References 16

Acronyms and abbreviations

ATDS	Australian Total Diet Study
Codex	Codex Alimentarius Commission
EC	European Commission
FSANZ	Food Standards Australia New Zealand
HBGV	Health-based Guidance Values
HPLC-ICP-MS	High Performance Liquid Chromatography Inductively Coupled Plasma Mass Spectrometer
ICP-MS	Inductively Coupled Plasma Mass Spectrometer
ISFR	Implementation Sub Committee for Food Regulation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	Kilogram
LB	Lower bound
LOR	Limit of reporting
ML	Maximum level
NATA	National Association of Testing Authorities
UB	Upper bound
USFDA	United States Food and Drug Administration

1 Introduction

Arsenic, cadmium, lead, mercury, and tin are naturally occurring elements. Their presence and distribution in the environment are influenced by natural and anthropogenic processes such as erosion, transport by air and water, chemical and biological transformation, bioaccumulation, mining, agricultural practices, and industrial uses. Due to their ubiquitous nature in the environment and industrial applications, small amounts of metal contaminants are sometimes unavoidably found in food (EFSA, 2024).

FSANZ undertakes ongoing monitoring of the safety of metals in the food supply, primarily through the ATDS. FSANZ also undertook a small, targeted survey of arsenic levels in apple and pear juice. (FSANZ, 2014) The ATDS and other surveys have consistently demonstrated the safety of the general food supply and help FSANZ prioritise risk management measures to reduce dietary exposure to contaminants of concern.

Metals have been subject to recent overseas and international assessments and regulatory developments. In 2011, the Joint FAO/WHO[2] Expert Committee on Food Additives (JECFA) withdrew the health-based guidance values (HGBVs) for inorganic arsenic and lead on the basis that they were considered no longer protective of human health. The Committee established revised HBGVs for cadmium and inorganic mercury (JECFA 2011a, 2011b). More recently, the United States Food and Drug Administration (USFDA) has published guidance for industry including an action level for inorganic arsenic and proposed action level for lead in apple juice (USFDA 2023, 2022).

Considering recent developments, the generation of contemporary data for metals in apple juices and other apple products is a priority for FSANZ. These foods are important components of the diet, including for infants and young children. The data will be available to support the 28th ATDS, which will investigate Australian consumers exposure to metal contaminants from the total diet.

1.1 Regulation of metal contaminants in food

1.1.1 Australia

FSANZ manages risks associated with metal contaminants in food through developing and maintaining the Food Standards Code. The Food Standards Code sets out legal requirements for food at the point of sale in Australia. Where required, FSANZ regulates specific metals which can contaminate food and may pose a risk to public health and safety, through the establishment of MLs in Standard 1.4.1 and Schedule 19. FSANZ uses internationally accepted best practice criteria in considering whether an ML is justified as the most appropriate measure to manage dietary exposure to metals. MLs are only set by FSANZ to achieve specific public health and safety objectives according to the following principles:

- Only for contaminants that represent a significant risk to public health and safety; and

[2] FAO – Food and Agriculture Organization of the United Nations. WHO – World Health Organization.

- Only for those foods that significantly contribute to dietary exposure for the contaminant; and
- To ensure that levels are ALARA.

A summary of relevant Australian MLs for metals in apple juice and other apple products sampled in the survey is provided in Section 3, Table 1 to Table 5 below.

In the absence of MLs, food safety risks are managed by food regulators through provisions in the Australian State and Territory and Imported Food Acts, including that food for sale must be safe and suitable for consumption and contamination levels should be ALARA.

1.1.2 Overseas and international

FSANZ has also identified domestic and international MLs for metals in apple juice and other apple products established in other jurisdictions (summarised in Section 3, Table 1 to Table 5 below). These include international MLs established by Codex (Codex, 2022) which do not apply in Australia but are referenced and/or adopted by many countries. Other MLs identified by FSANZ include those established by the European Commission (EC) (EU, 2006) and Health Canada (Government of Canada, 2023).

The USFDA have published guidance for industry including an action level for inorganic arsenic and a draft action level for lead in apple juice. (USFDA 2023, 2022) These guidance values are recommendations to protect public health by reducing exposure to levels that are achievable by industry with the use of current good manufacturing practices.

2 Methods

2.1 Food sampling

This survey utilised existing samples which were recently collected as part of the Survey of Patulin in Apple Juice and other Apple Products. A total of 299 food samples were purchased from a range of retail outlets in capital cities and major regional centres from all Australian states and territories. Product brands were selected to represent the general buying habits of the Australian population. Of the sample types collected, 259 were apple juices and 40 were other apple products including solid apple products for infants (24), apple puree (5), apple sauce (4), canned apple (3) and dried apple (4) (FSANZ, 2023) Two hundred and eighty-three (283) of the stored samples were available for the metals survey, while 16 had insufficient remaining sample for further analysis.

The primary focus of the survey was on apple juice products. A large majority of sample purchases were not from concentrate apple juice, including both cloudy and non-cloudy (clarified) varieties. A limited number of reconstituted and freshly squeezed apple juices were also sampled. Only pure (100%) apple juice products were sampled, with no juices from other sources or mixed products. Sparkling juice, apple juice drinks containing water or intense sweetener, and apple juice concentrate were not included in the survey.

A variety of solid apple products including infant foods, apple puree, apple sauce, canned apple, and dried apple were included in the survey. Solid apple products for infants and young children included both those that had apple as the sole ingredient and those in which apple was the main ingredient in a mixture.

Sampling was undertaken over two sampling periods from March to May 2021, and September 2021 to February 2022. Further details are provided in the Patulin report published on the FSANZ website (FSANZ, 2023).

2.2 Sample preparation and analysis

After sample analysis for the Patulin Survey was completed in 2022, all samples were stored in a manner that preserved them for future testing, allowing them to be utilised for this survey.

Samples were prepared and analysed at Symbio Laboratories, a National Association of Testing Authorities (NATA) accredited facility in Brisbane. Two hundred and seventy-three (273) of the stored individual samples were pooled into 61 composite samples for analysis. These samples were pooled according to food type, jurisdiction of purchase, and sampling date. For example, three samples of freshly made apple juice purchased in a single Australian city on the 15/04/2021 were combined into a composite sample for analysis. Ten samples were analysed individually as they were not suitable for pooling. Appendix 1 provides details of the sample preparation and pooling protocols.

All 71 samples were analysed for metal contaminants including total arsenic, cadmium, lead, and mercury. Samples with detectable concentrations of arsenic (two) were re-analysed for inorganic arsenic. The levels of tin were investigated in two canned apple samples. Samples were analysed via Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and High-Performance Liquid Chromatography (HPLC)-ICP-MS techniques. The methods were all fully validated. Analytical methods were all NATA accredited except for inorganic arsenic in solid apple products other than juice. All sample analysis was accompanied by comprehensive quality assurance and quality control measures applied on a batch-by-batch basis. The method Limit of Reporting (LOR)[3] was 0.010 mg/kg for all tests, except for arsenic (total and inorganic) in dried apple, for which the LOR was 0.025 mg/kg. The reported LORs were equal to the Limit of Quantitation (LOQ)[4] and 2 – 2.5 times the Limit of Detection (LOD)[5].

3 Survey results

3.1 Overall summary

The metal concentrations in apple juice and other apple products were very low. None of the analysed metals were found in 58 of 71 (82%)) of the samples.

- Lead was detected in 12 of 71 (17%) of samples, at concentrations ranging from 0.010 mg/kg to 0.020 mg/kg.
- Arsenic was detected in 2 of 71 (3%) of samples.
- Tin was detected in 2 of 2 (100%) canned apple samples.
- Inorganic arsenic, cadmium and mercury were not detected in any samples.

All metal concentrations were below Australian, overseas, and international regulatory limits.

[3] LOR: the lowest concentration of an analyte reported by the laboratory using a certain analytical procedure.
[4] LOQ: the lowest concentration of an analyte that can be quantitatively determined with acceptable accuracy and precision.
[5] LOD: the lowest concentration of an analyte that can be detected with acceptable reliability.

This indicates that metal levels in the sampled products are as low as reasonably achievable.

A summary of results is provided in Table 1 to Table 5 below. Detailed occurrence data is reported in Appendix 1.

3.2 Arsenic

Arsenic (total) was detected in two samples (dried apple (0.035 mg/kg) and solid apple products for infants (0.016 mg/kg)). These two samples were re-analysed for the more toxicologically significant inorganic arsenic which returned results <LOR. There were no exceedances of Australian, overseas, or international limits, identified in Table 1 below.

Table 1 - Summary of Results for Arsenic

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)
Arsenic	Apple juice	0/47 (0%)	Not detected		<0.010	<u>Inorganic arsenic</u> Canada – 0.01 (apple juice) EU – 0.020 (fruit juice) US – 0.010 (apple juice – action level)
	Apple puree	0/3 (0%)	Not detected		<0.010	Not applicable
	Apple sauce	0/2 (0%)	Not detected		<0.010	
	Apple (canned)	0/2 (0%)	Not detected		<0.010	
	Apple (dried)	1/2 (50%)	0.018	0.030	<0.025 – 0.035	
	Solid apple products for infants	1/15 (7%)	0.0011	0.010	<0.010 – 0.016	<u>Inorganic arsenic</u> EU – 0.020 (baby foods)
Arsenic, inorganic	Apple (dried)	0/1 (0%)	Not detected		<0.010	Not applicable
	Solid apple products for infants	0/1 (0%)	Not detected		<0.010	<u>Inorganic arsenic</u> EU – 0.020 (baby foods)

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)

*LB – lower bound, concentrations <LOR are assigned a concentration of zero.

^UB – upper bound, concentrations <LOR are assigned a concentration equal to LOR.

3.3 Cadmium

Cadmium was not detected in any samples as indicated in Table 2 below.

Table 2 – Summary of Results for Cadmium

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)
Cadmium	Apple juice	0/47 (0%)	Not detected		<0.010	Australia – not applicable EU – 0.020 (pome fruits, apple juice for infants and young children)
	Apple puree	0/3 (0%)	Not detected		<0.010	Australia – not applicable EU – 0.020 (pome fruits)
	Apple sauce	0/2 (0%)	Not detected		<0.010	
	Apple (canned)	0/2 (0%)	Not detected		<0.010	
	Apple (dried)	0/2 (0%)	Not detected		<0.010	
	Solid apple products for infants	0/15 (0%)	Not detected		<0.010	

*LB – lower bound, concentrations <LOR are assigned a concentration of zero.

^UB – upper bound, concentrations <LOR are assigned a concentration equal to LOR.

3.4 Lead

A summary of lead results is provided in Table 3 below. Lead was detected at low levels in the following foods:

- *Apple juice* – Lead was detected in 6 of 47 (13%) samples of apple juice at concentrations of 0.010 mg/kg (equal to LOR). Lead was not detected in the remaining 41 samples. The detections of lead were found in all types of sampled apple juice including not from concentrate (detected in 3 of 34 samples), reconstituted (2 of 9), and fresh (1 of 4).
- *Apple puree and sauce* – Lead was not detected in any of the 3 apple puree samples.
- *Apple sauce* – Lead was detected in 1 of 2 (50%) samples of apple sauce at a concentration of 0.010 mg/kg (equal to LOR).
- *Canned apple* – Lead was detected in 2 of 2 (100%) samples of canned apple, with a maximum concentration of 0.020 mg/kg.
- *Dried apple* – Lead was detected in 1 of 2 (50%) samples at a concentration of 0.010 mg/kg (equal to LOR).
- *Solid apple products for infants* – Lead was detected in 2 of 15 (13%) samples at concentrations of 0.010 and 0.020 mg/kg.

Lead concentrations found in apple juice and other apple products were lower than Australian MLs. As indicated in Table 3 below, the Australia New Zealand Food Standards Code (Standard 1.4.1 and Schedule 19) specifies an ML for lead in fruit of 0.1 mg/kg. For foods with fruit (including apple) as an ingredient, the provisions under Standard 1.4.1 - 3 (3) apply for calculating an ML for mixed foods with two or more ingredients.

Lead concentrations found in apple juice and other apple products were also lower than identified overseas and international MLs, including those set by Canada, Codex, and the EC. The USFDA has proposed a draft action level of 10 µg/kg (0.010 mg/kg) for lead in apple juice (USFDA, 2022). This is a non-regulatory guidance level for industry and regulators to keep lead levels as low as reasonably achievable and help reduce dietary exposure. The observed concentrations of lead detected in apple juice were lower than or equal to the USFDA draft action level.

Table 3 – Summary of Results for Lead

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)
Lead	Apple juice	6/47 (13%)	0.0013	0.010	<0.010 – 0.010	Australia – 0.1 (fruit) Canada – 0.05 (apple juice) Codex – 0.03 (apple juice), 0.1 (fruit) EU – 0.020 (apple juice for infants and young children) US – 0.010 (apple juice – proposed action level)
	Apple puree	0/3 (0%)	Not detected		<0.010	Australia – 0.1 (fruit) Codex – 0.1 (fruit)
	Apple sauce	1/2 (50%)	0.0050	0.010	<0.010 – 0.010	
	Apple (canned)	2/2 (100%)	0.015	0.015	0.010 – 0.020	
	Apple (dried)	1/2 (50%)	0.0050	0.010	<0.010 – 0.010	
	Solid apple products for infants	2/15 (13%)	0.0020	0.011	<0.010 – 0.020	

*LB – lower bound, concentrations <LOR are assigned a concentration of zero.

^UB – upper bound, concentrations <LOR are assigned a concentration equal to LOR.

3.5 Mercury

Mercury was not detected in any samples as indicated in Table 4 below.

Table 4 - Summary of Results for Mercury

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)
Mercury	Apple juice	0/47 (0%)	Not detected		<0.010	Not applicable
	Apple puree	0/3 (0%)	Not detected		<0.010	
	Apple sauce	0/2 (0%)	Not detected		<0.010	
	Apple (canned)	0/2 (0%)	Not detected		<0.010	
	Apple (dried)	0/2 (0%)	Not detected		<0.010	
	Solid apple products for infants	0/15 (0%)	Not detected		<0.010	

*LB – lower bound, concentrations <LOR are assigned a concentration of zero.

^UB – upper bound, concentrations <LOR are assigned a concentration equal to LOR.

3.6 Tin

A detailed summary of tin results is provided in Table 5 below. Tin was detected in 2 of 2 (100%) samples of canned apple at concentrations of 32 mg/kg and 124 mg/kg. Both detections were well below Australian and identified overseas and international MLs.

Table 5 - Summary of Results for Tin

Metal	Food	Number of detects/samples	Mean LB* (mg/kg)	Mean UB^ (mg/kg)	Range (mg/kg)	MLs and other limits (mg/kg)
Tin	Apple (canned)	2/2 (100%)	78	78	32 – 124	Australia – 250 (canned food) Canada – 250 (canned food) Codex – 250 (canned food other than beverages) EU – 200 (canned foods other than beverages)

*LB – lower bound, concentrations <LOR are assigned a concentration of zero.

^UB – upper bound, concentrations <LOR are assigned a concentration equal to LOR.

4 Conclusions

The survey provides valuable data on metal concentrations in apple juices and other apple products. Metal concentrations were low with most samples (82%) containing no detectable levels of any of the analysed metals. All metal concentrations were below Australian, and identified overseas, and international regulatory limits.

The results of the survey indicate that metal levels in the sampled apple juices and other apple products were as low as reasonably achievable. On that basis FSANZ has concluded that there are no public health and safety concerns to Australian consumers. FSANZ will utilise results to:

- Supplement a comprehensive assessment of Australian consumers' dietary exposure to metal contaminants as part of the 28th ATDS (2024).
- Load data into the international GEMS database to support international risk assessments and consideration of international MLs by Codex.
- Communicate findings with Australian food regulators and food industry.

5 References

Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry, 2023, FDA-2012-D-0322, Guidance Document. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-apple-juice (Accessed: 19 June 2024).

Action Levels for Lead in Juice: Guidance for Industry, 2022, FDA-2012-D-0322, Draft Guidance Document. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice (Accessed: 19 June 2024).

Codex (2022) General Standard for Contaminants and Toxins in Food and Feed. Codex Alimentarius CXS 193-1995. Standard 193-1995. Codex Alimentarius Commission, Rome.

EFSA (2024) Metals as contaminants in food, European Food Safety Authority. Available at: https://www.efsa.europa.eu/en/topics/topic/metals-contaminants-food. (Accessed: 21 June 2024).

European Union (2006) 'COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance)', *Official Journal of the European Union* [Preprint].

FSANZ (2014) *Analytical Survey of Total and Inorganic Arsenic in Apple and Pear Juice*. Canberra, ACT: Food Standards Australia New Zealand (FSANZ).

FSANZ (2023) *The Survey of Patulin in Apple Juice and Other Apple Products*. Canberra, ACT: Food Standards Australia New Zealand (FSANZ).

Government of Canada (2023) Food and Drug Regulations C.R.C., c. 870, Division 15, Adulteration of Food. Available at: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/page-42.html#docCont (Accessed: 20 June 2024)

JECFA (2011a) *Safety evaluation of certain contaminants in food: Seventy-second report of the joint FAO/WHO expert committee on food additives.* Rome: Food and Agriculture Organization of the United Nations (63).

JECFA (2011b) *Safety evaluation of certain food additives and contaminants: prepared by the seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*. Geneva: World Health Organization (64).