Survey of patulin in apple juice and other apple products

August 2023

Key findings

- The Survey of patulin in apple juice and other apple products investigated a broad range of Australian apple juice and other apple products for levels of patulin. The findings of the survey confirm the current safety of the general Australian food supply with regards to patulin levels.
- Patulin is a natural toxin sometimes found in mouldy foods. Apple products such as juice are the main potential sources of dietary exposure to patulin.
- Patulin levels were generally low, with the majority of results below Codex Alimentarius and other overseas regulatory limits. This indicates that patulin levels in most products are as low as reasonably achievable.
- Some apple juice product categories showed considerable variability and a high range in patulin concentrations across the duration of sampling.
- The estimated dietary exposure for Australian consumers based on the foods in this survey was below the provisional maximum tolerable daily intake (PMTDI) for patulin, indicating no food safety concerns for the general food supply. Hence, there is no requirement for food regulatory measures such as maximum levels (MLs) for patulin in the Australia New Zealand Food Standards Code (the Code).
- FSANZ has recommended several risk management measures to ensure that patulin levels in Australian apple juice are kept safe and as low as reasonably achievable in the future.

Executive summary

The Survey of patulin in apple juice and other apple products was undertaken in response to several recent food recalls of Australian apple juice products due to elevated patulin levels.

Patulin is a natural toxin sometimes found in mouldy foods including fruits, vegetables and cereals. Apple products such as juice are the main potential sources of dietary exposure to patulin. Evidence of toxicity associated with patulin exposure has come largely from animal studies. There have been no known cases of toxicity in humans associated with patulin ingestion in apple juice.

There are currently no maximum levels (MLs) for patulin in the Australia New Zealand Food Standards Code (the Code). Codex Alimentarius (Codex) has set an ML of 50 µg/kg for patulin in apple juice which has been adopted by several overseas food regulatory authorities. It is generally considered that the control of patulin in apple juice at or below the Codex ML is achievable through the application of good agricultural and manufacturing practices.

A total of 299 apple products were sampled from across all Australian states and territories. Samples were collected over two sampling periods from March to May 2021 and September 2021 to February 2022. The sampled products were apple juice (259 samples), solid apple products for infants (24), apple puree (5), apple sauce (4), canned apple (3) and dried apple (4). All samples were analysed for levels of patulin, with results used to estimate dietary exposure and assess public health and safety risks for the general Australian population. The outcomes of the risk assessment were used to determine whether risk management measures are required to ensure the continued safety of the general Australian food supply.

Of the 299 samples analysed, 193 (65%) contained concentrations of patulin above the limit of reporting (LOR; 5.0 µg/kg). Patulin levels were higher in apple juice (mean lower bound (LB[1]): 28 µg/kg, compared with solid apple products (mean LB: 4.6 µg/kg). Within the apple juice category, patulin levels in not from concentrate (NFC) varieties (mean LB: 32 µg/kg) were higher than reconstituted (mean LB: 4.3 µg/kg) and freshly made juice (mean LB: 1.5 µg/kg).

Almost 90% (231 of 259) of apple juice products had patulin levels below the Codex ML of 50 µg/kg. There was considerable variability and a large range of patulin concentrations in NFC apple juices. Detections above 50 µg/kg, and up to 532 µg/kg, were observed sporadically across the two sampling periods.

A dietary exposure assessment was undertaken for two subgroups of the general Australian population: consumers aged 2 years and above, and 9 month old infants. Exposure estimates were below the provisional maximum tolerable daily intake (PMTDI) of 0.4 µg/kg bw/day. Mean dietary exposure estimates for the various models were 6–25% of the PMTDI, and P90 dietary exposure estimates were 15–45% of the PMTDI. As the exposures are well below the PMTDI, FSANZ concludes that there are no food safety concerns associated with dietary exposures to patulin.

The findings of the survey indicate that dietary exposure to patulin for the general Australian population is acceptable from a food safety perspective. Hence there is no current need for specific food regulatory measures, such as MLs in the Code for apple products. In the absence of an ML or other specific regulatory measures for patulin, general Code provisions apply including that food must be safe and suitable for human consumption and contamination should be kept as low as reasonably achievable.

[1] Assuming patulin concentration for non-detects (<LOR) = 0 µg/kg.

Due to the variability and range of patulin detections in apple juice, particularly NFC juice, FSANZ considers there is the potential for patulin contamination of apple juice to occur in the future. To ensure that patulin levels in Australian apple juice are kept safe and as low as reasonably achievable, FSANZ recommends:

- notification of survey outcomes and risk management recommendations to relevant government, food industry and other non-government stakeholders
- consolidation and promotion of existing education and risk management resources such as the Codex Code of Practice
- continued industry quality control practices (including good agricultural and manufacturing practices)
- continued monitoring and assessment of apple juice products with potential for higher levels of patulin including:
    - maintenance of current routine industry testing
    - targeted government surveillance programs as required to supplement existing data sources
- FSANZ and key government and non-government stakeholders maintain oversight of patulin levels in apple juice and respond to new developments as required.

Contents

Acronyms and abbreviations

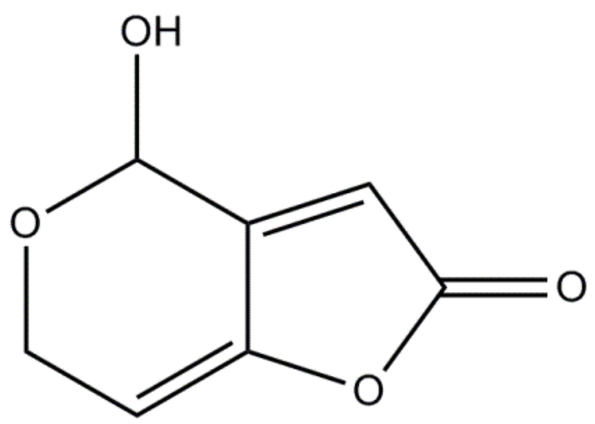
µg	Microgram
ABS	Australian Bureau of Statistics
Codex	Codex Alimentarius Commission
COM	Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (UK)
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (UK)
EC	European Commission
FAO	Food and Agriculture Organisation
FSANZ	Food Standards Australia New Zealand
ISFR	Implementation Sub Committee for Food Regulation
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
JECFA	Joint Expert Committee on Food Additives
kg	Kilogram
LB	Lower bound
LC-HRMS	Liquid chromatography-high resolution mass spectrometry
LOD	Limit of detection
LOR	Limit of reporting
ML	Maximum level
NATA	National Association of Testing Authorities
nd	Not detected
NFC	Not from concentrate
NRS	National Residue Survey
NZ MPI	New Zealand Ministry for Primary Industries
PMTDI	Provisional maximum tolerable daily intake
SEAWG	Surveillance, Evidence and Analysis Working Group
UB	Upper bound
US FDA	United States Food and Drug Administration
WHO	World Health Organization

1. Introduction

1.1. Patulin

Patulin is a natural toxin sometimes found in mouldy foods. It is produced by certain species of mould including *Penicillium expansum*, a common spoilage microorganism in apples. Apples and apple products such as juice are the main sources of dietary exposure to patulin but patulin has also been found in other fruits including pears, figs and tomatoes, vegetables including capsicums, and grains such as wheat and corn (Ioi et al 2017).

Table 1: Patulin identity

Common name	Patulin
Other names	4*H*-Furo[3,2-*c*]pyran-2(6*H*)-one, 4-hydroxy-; Patulin; 4-Hydroxy-4*H*-furo[3,2-*c*]pyran-2(6*H*)-one; Clairformin; Clavacin; Clavatin; Claviformin; Expansin; Expansine; Mycoin; Penicidin; Acetic acid, (2,4-dihydroxy-2*H*-pyran-3(6*H*)-ylidene)-, 3,4-lactone; Mycoin C; Patuline; Mycoin C_3; Terinin; DL-Patulin; NSC 32951; NSC 8120; Expansin (antibiotic); Leucopin; Gigantin
CAS number	149-29-1
Molecular formula	$C_7H_6O_4$
Chemical structure	

CAS: Chemical Abstracts Service[2]

Patulin was originally studied as an antimicrobial agent, with early studies suggesting it could be used for treatment of the common cold (Pitt 2014). It has been associated with a variety of adverse health effects after acute and chronic exposure in animal studies.

The Codex Alimentarius Commission (Codex) has published a Code of Practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages (Codex 2003). It includes guidance covering the lifecycle of the product including good agricultural and manufacturing practices (GAP and GMP), see Table 2.

[2] https://commonchemistry.cas.org/detail?cas_rn=149-29-1

Table 2: Key components of the Codex Code of Practice for Patulin in Apple Juice

Good agricultural practice	Good manufacturing practice
• Cultivation and pre-harvest quality control measures • Harvest and transport of fresh apples • Post-harvest handling including storage • Grading of fruit for juice manufacture	• Transport of apples for juicing, inspection, cleaning and sanitising pressing equipment • Packaging and final processing of juice • Quality assessment of juice (including monitoring patulin levels and other quality indicators)

The likelihood of patulin contamination in apples is influenced by the condition of fruit at harvest, subsequent handling, and storage conditions. The use of sub-optimal apples for juicing can result in patulin-producing moulds being present in juice. For example, juice made from fallen fruit is at higher risk of patulin contamination than that made from apples harvested from the tree. Controlling the temperature and atmosphere during storage reduces the risk of mould growth, as does limiting the time between harvest and juicing.

Appropriate heat treatment (pasteurisation) mitigates the risk of patulin formation during juice manufacture and subsequent storage as it kills the responsible microorganisms. However, any patulin already present in the apples will not be destroyed by pasteurisation. Fruit should be inspected upon receipt at the manufacturing facility and again prior to juicing and any mouldy apples identified at either point should be excluded.

1.2. Patulin regulation

There are no maximum levels (MLs) for patulin in the Australia New Zealand Food Standards Code (the Code). In the absence of MLs, patulin levels should be kept as low as reasonably achievable[3], and foods must be safe and suitable for human consumption.

The Codex Alimentarius Commission established a ML for patulin in apple juice of 50 µg/kg (Codex 1995). The Codex ML has been adopted by several overseas food regulatory authorities and is used by several Australian trading partners.

The European Commission (EC) has set MLs for patulin in several foods including fruit juices (50 µg/kg), fermented drinks (apple-based) (50 µg/kg), apple juice and solid apple products for infants and young children (10 µg/kg), baby foods other than processed cereal-based foods (10 µg/kg), and other solid apple products (25 µg/kg) (EC 2006).

The US Food and Drug Administration (US FDA) has established a non-regulatory action level for patulin in apple juice of 50 µg/kg (US FDA 2005).

1.3. Survey background

In 2020, there were several domestic and overseas food recalls of Australian apple juice products due to elevated patulin levels significantly exceeding the Codex ML (FSANZ 2023a). FSANZ, in consultation with Australian government and relevant state and territory health authorities, commenced a pilot survey of patulin in apple juice to assess risks for consumers and consider the need for risk management measures.

The pilot survey was conducted under the Implementation Sub Committee for Food Regulation (ISFR) Coordinated Food Survey Plan (CFSP) with the participation of all

[3] Keeping levels 'as low as reasonably achievable' (the ALARA principle) involves ensuring the lowest level of contamination that can be reasonably achieved without removing the food from the food supply (FAO 2009).

Australian states and territories (FSANZ 2023b). It found patulin levels were higher in NFC apple juices compared to reconstituted and freshly made juices. FSANZ considered these results warranted further investigation and commenced a second sampling period (Stage 2), focused on NFC apple juices. This enabled the acquisition of more statistically dependable and seasonally representative data on patulin levels in NFC apple juices. Stage 2 of the survey also sampled other apple products associated with potential patulin contamination including infant apple products, dried apples, apple purees and sauces.

A report from the New Zealand Mycotoxin Surveillance Program (NZ MPI 2014) indicated there were no concerns about patulin exposure in New Zealand, therefore this survey only sampled products available in Australia.

2. Methods

2.1. Food sampling

Food samples were purchased from retail outlets in capital cities and major regional centres from all Australian states and territories.

Samples for the pilot survey (Stage 1) were collected from March to May 2021. Apple juice products representing the range available at retail outlets were sampled, including NFC, reconstituted and freshly squeezed products (from juice bars etc).

Stage 2 sampling took place from September 2021 to February 2022. Jurisdictions provided samples of apple juice, primarily NFC juices although two samples were later identified as reconstituted juice. These were purchased from a range of retail outlets including major supermarkets, local greengrocers, and refrigerators in local cafes, restaurants and bakeries. A variety of other apple products were also purchased from supermarkets.

The selection of product brands for purchase was largely at the discretion of the jurisdictional sampling officers, however guidance was provided to ensure an adequate representation of market leading brands. Further details for the different product categories is provided below.

Apple juice

Only apple juice products were sampled, with no juice from other sources or mixed products. Products could contain other ingredients such as vitamin C, natural flavours, antioxidants, or dietary fibre. Both cloudy and non-cloudy varieties were sampled, regardless of whether they were described as cloudy on the label. Sparkling juice, apple juice drinks containing water or intense sweetener, and apple juice concentrate were not included in the survey.

Other apple products

A variety of solid apple products including infant foods, apple puree, apple sauce, canned apple, and dried apple were sampled. 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.

The alcoholic fermentation process can destroy patulin, and therefore, fermented products such as cider typically do not contain high levels of patulin (WHO 2003). A market scan of apple cider drinks indicated that apple cider with apple juice added after fermentation is extremely uncommon at retail in Australia. This means apple cider is unlikely to contain patulin. As a result, apple cider was excluded from the scope of this survey.

All samples

Samples were labelled and photographed after purchase. Those requiring refrigeration were stored in a refrigerator (0–5°C) before transport to the laboratory. Other products were stored in a cool, dark place. The laboratory provided sampling kits including boxes and ice packs to keep samples cold (5–7°C) during transport.

2.2. Sample preparation and analysis

Symbio Laboratories prepared and analysed the food samples. Samples were logged on arrival at the laboratory before subsampling for analysis. Shaking or vortexing ensured that a homogeneous subsample was taken.

The analyses were conducted in a National Association of Testing Authorities (NATA)-accredited facility using a fully validated NATA-accredited method (In-house method CR60.6 – Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS)). The results were subject to quality assurance and quality control procedures in accordance with ISO/IEC/17025[4] requirements.

The Limit of Reporting (LOR[5]) was 5.0 µg/kg for all sample types.

3. Analytical results

3.1. Treatment of analytical results

Good agricultural and manufacturing practices keep patulin levels in apple juice and other apple products to a minimum. However, it is not unreasonable to expect that it may be present at levels below that which can be detected by laboratory testing. Mean concentrations in this survey are therefore reported as both upper bound (UB) and lower bound (LB) scenarios. When calculating the upper bound mean, results recorded as below the LOR (in this case 5.0 µg/kg) were assigned a concentration of 5.0 µg/kg. This represents the worst case scenario. When calculating the lower bound mean, results recorded as below the LOR were assigned a concentration of 0 µg/kg.

3.2. Prevalence and concentrations

Of the 299 samples analysed, 193 (65%) contained concentrations of patulin above the LOR (5.0 µg/kg). The highest patulin concentration (532 µg/kg) was found in a sample of NFC juice. There were 259 juices sampled—175 (68%) of these had patulin detected above the LOR and 29 (11%) had concentrations over the Codex ML for this category (50 µg/kg). The mean patulin concentration in juices (LB: 29 µg/kg; UB: 30 µg/kg) was higher than in other solid apple products (LB: 4.6 µg/kg; UB: 7.3 µg/kg). Table 3 contains a summary of the analytical results.

Within the juice category, NFC juices had the highest mean patulin concentration (n = 231; LB: 32 µg/kg; UB: 33 µg/kg). This was followed by reconstituted juices (n = 18; LB: 4.3 µg/kg; UB: 7.6 µg/kg) and freshly squeezed juices (n = 10; LB: 1.5 µg/kg; UB: 6.0 µg/kg). Apples with visible mould growth are not likely to be selected to produce freshly squeezed juice so these products are less likely to contain patulin. Steps in the manufacture of apple juice concentrate used in reconstituted juices have been shown to reduce the concentration of patulin in these products compared to NFC juices (Zhong et al 2018). The subcategory with the highest mean patulin concentration was NFC cloudy juices (n = 181; UB: 35 µg/kg; LB: 37 µg/kg). Clarification techniques, including both physical filtration and enzymatic approaches, have been shown to reduce patulin concentration in juices (Ioi et al 2017).

[4] International Organisation for Standardisation/International Electrotechnical Commission (ISO/IEC) 17025 – Standard for general requirements for the competence of testing and calibration laboratories.

[5] LOR: The lowest concentration of an analyte reported by the laboratory using a certain analytical procedure.

Of the solid apple products, all samples of apple puree (n = 5) and canned apple (n = 3) had patulin concentrations above the LOR. However, no samples of dried apple (n = 4) contained patulin above the LOR. Almost two-thirds (15 of 24 samples) of foods for infants and young children contained patulin concentrations below the LOR. There is no Codex limit for patulin in apple products for infants and young children but the EC has set an ML of 10 µg/kg for foods in this category. In this survey, four of the samples (17%) contained patulin concentrations higher than this level. The mean concentration was below the EC ML (LB: 3.7 µg/kg; UB: 6.8 µg/kg).

An overview of mean LB concentrations for solid apple products and different types of apple juice are shown in Figure 1.

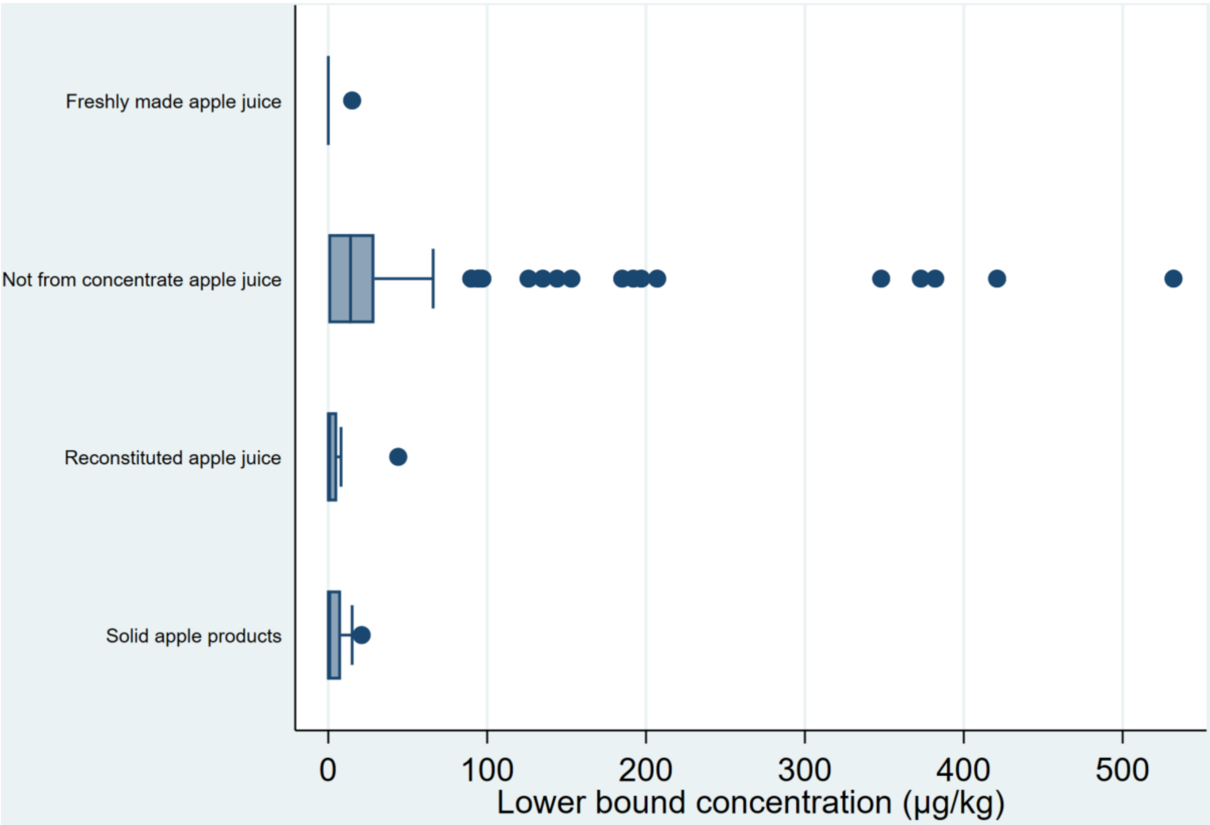


Figure 1: Box plot of lower bound patulin concentrations by sample type

Table 3: Patulin concentrations by food category

	Samples (no.)	Detections (no.)	Minimum (µg/kg)	Maximum (µg/kg)	Mean LB (µg/kg)	Mean UB (µg/kg)
NFC juice	231	168	<LOR	532	32	33
NFC cloudy juice	*181*	*128*	*<LOR*	*532*	*35*	*37*
Reconstituted juice	18	6	<LOR	44	4.3	7.6
Fresh juice	10	1	<LOR	15	1.5	6.0
All juice	**259**	**175**	**<LOR**	**532**	**29**	**30**
Apple puree	5	5	6.2	14	9.2	9.2
Apple sauce	4	1	<LOR	21	5.3	9.0
Canned apple	3	3	6	13	8.8	8.8
Dried apple	4	0	<LOR	<LOR	0.0	5.0
Products for infants and small children with apple as the main ingredient	14	4	<LOR	15	3.1	6.6
Products for infants and small children with apple as the sole ingredient	10	5	<LOR	12	4.6	7.1
Total	**299**	**193**				

LB: Lower bound; UB: Upper bound; NFC: Not from concentrate; LOR: Limit of reporting (5.0 µg/kg)

4. Risk assessment

4.1. Hazard characterisation

Evidence of toxicity associated with patulin exposure has come largely from animal studies. There have been no known cases of toxicity in humans associated with patulin ingestion in apple juice. Patulin was tested as an antibiotic for treatment of the common cold in humans in the 1940s. A controlled trial reported no adverse effects, but the report did not identify the number of patients tested or the clinical tests performed.

The Joint Expert Committee on Food Additives (JECFA) reviewed patulin in 1995. In acute and short-term studies in experimental animals, patulin caused a range of effects in the gastrointestinal tract including villous hyperaemia (engorgement of the blood supply), distension, haemorrhage and ulceration. The no observed adverse effect level (NOAEL) in a 13-week oral toxicity study in rats was 0.8 mg/kg bw/day, based on slight impairment of kidney function and villous hyperaemia at higher doses. Pigtail monkeys (*Macaca nemestrina*) tolerated consumption of up to 0.5 mg/kg bw/day for 4 weeks without adverse effects.

No reproductive or teratogenic effects were noted in mice and rats at dose levels up to 1.5 mg/kg bw/day (administered 3 times weekly, equivalent to 640 µg/kg bw/day). Maternal toxicity and an increased frequency of fetal resorptions were observed at higher levels.

Results of genotoxicity studies with patulin were variable, but based on the available data JECFA concluded that patulin is genotoxic. No evidence of carcinogenicity has been reported, however.

In a combined reproductive toxicity, chronic toxicity and carcinogenicity study, FDRL Wistar rats (70/sex/group) were gavaged with 0, 0.1, 0.5, or 1.5 mg/kg bw patulin in citrate buffer 3 times/week for 24 months (equivalent to 0, 43, 214 or 640 µg/kg bw/day) for up to 2 years. Mortality was increased in both sexes at the highest dose. Body weights of males, but not females, were reduced at the mid and high doses. No difference in tumour incidence was observed. The NOAEL was 0.1 mg/kg bw, administered 3 times/week, equivalent to 43 µg/kg bw/day (Becci et al 1981).

JECFA established a provisional maximum tolerable daily intake (PMTDI) for patulin of 0.4 µg/kg bw/day, based on the NOAEL of 43 µg/kg bw/day and an uncertainty factor of 100 (JECFA 1995).

In a review of the potential risks from contaminants in the diet of infants and children, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) considered more recent toxicological data on patulin in 2019.

The COT concluded the newly available toxicological information did not indicate a need to revise the PMTDI, but referred the genotoxicity studies to the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM). The COM concluded the available genotoxicity studies were inadequate, highlighting a need for standard regulatory genotoxicity tests conducted to acceptable standards.

Based on this, the COT concluded that until further genotoxicity data are available the current PMTDI should continue to be used for risk assessment of patulin (COT 2020).

FSANZ has not identified any further toxicity or genotoxicity studies with patulin that would indicate a need to amend this conclusion.

4.2. Dietary exposure assessment

The objective of this dietary exposure assessment is to estimate the chronic or long term dietary exposure to patulin from apple juice and other apple products and identify the major food contributors to dietary exposure.

Dietary exposure assessments require data on the concentration of the chemical of interest in the relevant foods, and consumption data for these foods which is usually collected through a national nutrition survey. Details of the two datasets used for this assessment are described further below.

4.2.1 Population groups assessed

As there were no concerns about patulin exposure in New Zealand, dietary exposure assessments were undertaken for Australia only.

The hazard characterisation did not identify any population sub-groups for which there were any specific safety concerns in relation to dietary exposure to patulin. Therefore the dietary exposure assessment was undertaken for the Australian population group aged 2 years and above (i.e. the whole 2011–12 national nutrition survey population). As solid apple products for infants and small children were included in Stage 2 of the analytical survey, infants aged 9 months were also included in the assessment to represent consumers of these foods.

For Australians aged 2 years and above, patulin exposures were estimated for two groups of consumers:

(1) nutrition survey respondents who reported consuming commercial apple juice as a beverage (not when used as an ingredient in other foods or mixed dishes e.g. mixed fruit juices) were classified as consumers of apple juice 'as is'

(2) nutrition survey respondents who reported consuming commercial apple juice and other apple products as single foods and as ingredients in other foods or mixed dishes were classified as consumers of apple juice and other apple products.

Further details on the two consumer models are in Appendix 1.

4.2.2 Food consumption data used

The food consumption data used for the dietary exposure assessment for Australians aged 2 years and above were from the 2011–12 Australian National Nutrition and Physical Activity Survey (2011–12 NNPAS). Consumption data from one 24-hour food recall were available for 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% (n = 7735) of respondents (ABS 2014). The two-day average was used for estimating consumption amounts and dietary exposure as it reflects longer term food consumption patterns, and therefore provides a better estimate of longer term exposure, compared to a single 24-hour recall. This is appropriate for patulin as the health-based guidance value is the PMTDI which relates to chronic or long term exposures. Day one consumption data were used to identify major food group contributors to dietary exposure. Key attributes of this survey, including survey limitations, are in the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

For 9 month old infants, mean and 90th percentile (P90) consumption amounts of the food group *Infant fruit and fruit-based desserts* were obtained from data analysed as part of the Melbourne Infant Feeding, Activity and Nutrition Trial (InFANT) Program (Campbell et al 2008). As part of the InFANT Program, three day multi-pass 24 hour dietary recalls were collected from parents when their infants were 9 months old (mid-intervention) and 20 months old (post-intervention) (Campbell et al 2013). For infants in the control group, food consumption data were coded into food groups using AUSNUT 2007 (FSANZ 2008) and aggregated data were provided to FSANZ.

In the Melbourne InFANT Program, the food group *Infant fruit and fruit-based desserts* was consumed by 38% (n = 80) of 9 month old infants over the three days of data collection. For these consumers, the three day mean and P90 consumption was 49 g/day and 116 g/day respectively.

4.2.3 Analytical data used

The patulin concentration data used in the dietary exposure assessment were the mean LB and UB concentrations for each food category as shown in Table 3. This was the case for all foods except apple puree and canned apple, for which the values were combined and both LB and UB were 9.0 µg/kg. As there were a high number of analytical results for patulin that were below the LOR, mean rather than median analytical concentrations were used in the dietary exposure calculations.

The mapping used to match the foods consumed in the 2011–12 NNPAS to the analysed samples for the purpose of assigning concentrations to relevant foods for the dietary exposure assessment can be found in Appendix 1, Table A1.1.

As described in Section 3 of this report, the highest patulin concentrations were detected in cloudy NFC apple juice. Therefore, dietary exposures were calculated for two scenarios:

- *Cloudy NFC apple juice* scenario
- *All apple juice* scenario.

The *Cloudy NFC apple juice* scenario is therefore a worst case assessment assuming consumers might be brand loyal or always select a cloudy NFC apple juice type. This scenario assesses whether high consumers' dietary exposures would be at acceptable levels. The *All apple juice* scenario is more reflective of dietary exposures for a consumer who may over a long period of time or lifetime consume a mix of all types of apple juice.

In summary, only the concentrations applied to apple juices changed for each scenario, whereas for all other foods the concentrations remained the same. The concentrations applied to apple juices for the *Cloudy NFC apple juice* scenario were a LB of 35 µg/kg and an UB of 37 µg/kg, and for the *All apple juice* scenario a LB of 29 µg/kg and an UB of 30 µg/kg. These scenarios were used for both the apple juice 'as is' consumer model and the apple juice and other apple products consumer model, and are outlined in further detail in Appendix 1.

4.2.4 Methodology

The dietary exposure assessment for Australians aged 2 years and above was undertaken using FSANZ's dietary modelling computer program Harvest[6] and compared to the PMTDI of 0.4 µg/kg bw/day. The dietary exposure assessment for infants was conducted deterministically using spreadsheets. A summary of the general FSANZ approach to conducting the dietary exposure assessment for this project is on the FSANZ website[7]. A detailed discussion of the FSANZ methodology and approach to conducting dietary exposure assessments is set out in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

The aim of the dietary exposure assessment was to make the most realistic estimation of dietary exposure to patulin as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the estimated dietary exposure was not an underestimate of exposure. Details of the assumptions and limitations of this dietary exposure assessment are in Appendix 1.

[6] https://www.foodstandards.gov.au/science/exposure/Pages/fsanzdietaryexposure4439.aspx
[7] https://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx

The estimated dietary exposures to patulin were calculated for 'consumers' of patulin only, that is only the respondents in the survey population who reported consuming a food which may contain patulin from the foods analysed. In Table A2.3 the proportion of consumers is reported as the weighted[8] proportion of consumers to respondents in the 2011–12 NNPAS.

4.2.5 Dietary exposure assessment results

The mean and P90 dietary exposures to patulin were estimated in micrograms per kilogram body weight per day (µg/kg bw/day) units as this is consistent with the units for the patulin PMTDI.

In some cases the LB exposure estimates are higher than the corresponding UB scenario. This can occur in dietary modelling when specific foods or food groups are assigned a concentration of zero for the LB scenario, as opposed to the LOR for the UB scenario. In these cases, LB and UB statistics are derived from two different sets of consumers and different exposure distributions. A more detailed explanation is available in Appendix 1. These results demonstrate the range of potential dietary exposures taking into account the uncertainty (the non-detections) in the analytical results.

4.2.5.1 Apple juice 'as is'

Approximately 5% of all respondents in the 2011–12 NNPAS reported consuming apple juice 'as is' over the two 24-hour recall days. For these consumers, estimated mean and P90 consumption of commercial apple juice were 172 g/day and 341 g/day respectively.

For the *All apple juice* scenario, mean and P90 dietary exposures to patulin from apple juice 'as is' were estimated to be 0.070–0.074 µg/kg bw/day (20% of the PMTDI), and 0.14–0.15 µg/kg bw/day (35% of the PMTDI) respectively.

For the *Cloudy NFC apple juice* scenario, mean and P90 dietary exposures to patulin from apple juice 'as is' were estimated to be 0.087–0.090 µg/kg bw/day (20–25% of the PMTDI), and 0.17–0.18 µg/kg bw/day (45% of the PMTDI) respectively.

For further details refer to Appendix 1, Table A1.3 and Figure 2.

4.2.5.2 Apple juice and other apple products

The ratio of consumers to respondents for patulin exposure was 29.8% at the LB and 42.6% at the UB. This difference was due to the LB patulin concentration for dried apples being zero therefore even if a respondent consumed this food, they were not a consumer of patulin and not included in the count of consumers.For the *All apple juice* scenario, mean and P90 dietary exposures to patulin from apple juice and other apple products were estimated to be 0.028–0.038 µg/kg bw/day (7–10% of the PMTDI), and 0.081–0.11 µg/kg bw/day (20–25% of the PMTDI) respectively.

For the *Cloudy NFC apple juice* scenario, mean and P90 dietary exposures to patulin from apple juice and other apple products were estimated to be 0.034–0.047 µg/kg bw/day (9–10% of the PMTDI), and 0.098–0.13 µg/kg bw/day (25–30% of the PMTDI) respectively.

For further details refer to Appendix 1, Table A1.3 and Figure 2.

[8] Survey sample weighting factors are used to adjust the results of surveys to better reflect the results that would have been obtained if a truly representative sample from the population had been able to be obtained, and to make population based estimations of results.

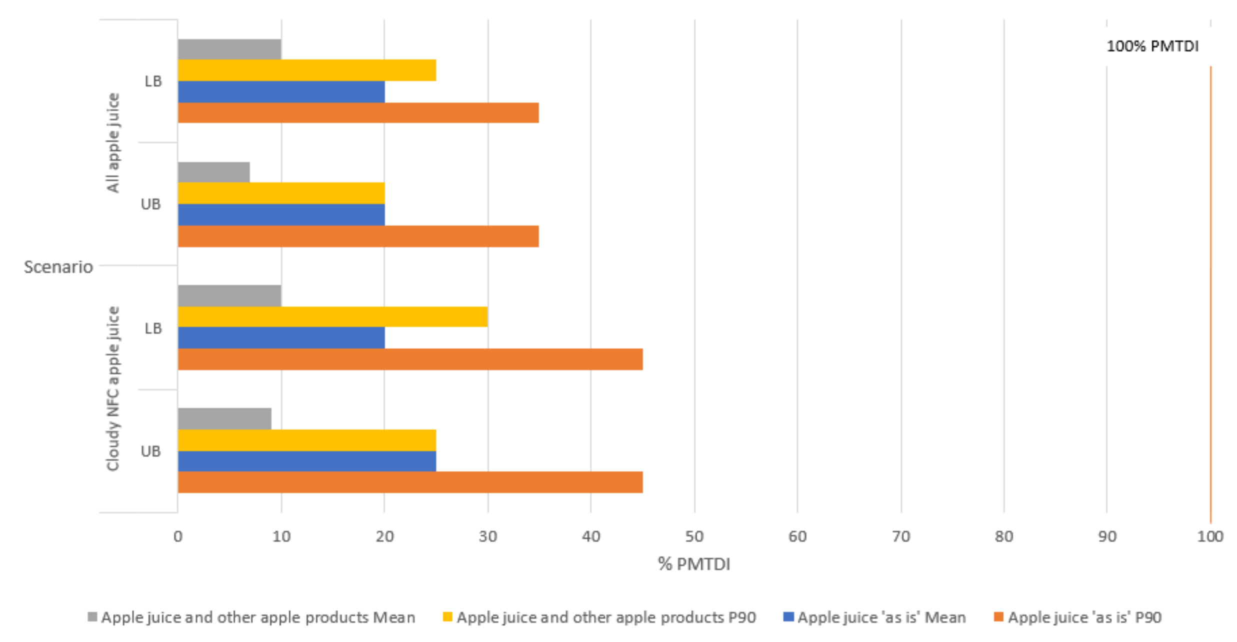


Figure 2: Estimated mean and 90th percentile (P90) dietary exposures to patulin as a % PMTDI, from apple juice consumed 'as is', and from apple juice and other apple products for Australian consumers aged 2 years and above

4.2.5.3 Food contributors

Major contributors are those food groups that contribute ≥5% of dietary exposures. The major contributors were derived from the assessment including apple juice and other apple products using the LB scenario to make sure that foods with no detectable concentrations were not captured.

Ninety eight percent (98%) of patulin dietary exposures were from non-alcoholic beverages. The major (≥5%) contributing food group to dietary exposures was *fruit and vegetable juices, and drinks* (94%). Food contribution results can be found in Appendix 1, Table A1.4.

4.2.5.4 Infant fruit and fruit-based desserts

For 9 month old infants, mean and P90 dietary exposures to patulin from the food group *Infant fruit and fruit-based desserts* were estimated to be 0.025–0.039 µg/kg bw/day (6–10% of the PMTDI) and 0.060–0.092 µg/kg bw/day (15–25% of the PMTDI), respectively.

4.3. Risk characterisation

Mean and P90 dietary exposure estimates for patulin for consumers aged 2 years and above, and for 9 month old infants, were below the PMTDI of 0.4 µg/kg bw/day. Mean dietary exposure estimates for the various models were 6–25% of the PMTDI, and P90 dietary exposure estimates were 15–45% of the PMTDI. FSANZ concludes that there are no food safety concerns associated with current dietary exposures to patulin.

Because the health-based guidance value is based on a long-term study, slight and transient exceedances of the PMTDI for patulin would not be considered to be a public health concern.

5. Risk management

The findings of the survey indicate that dietary exposure to patulin for the general Australian population is acceptable from a public health and safety perspective. Hence there is no current need for specific food regulatory measures, such as MLs in the Code.

FSANZ only sets MLs to achieve specific public health and safety objectives according to the following principles:

- only for those contaminants that represent a significant risk to public health and safety; and
- only for those foods that significantly contribute to the dietary exposure of the contaminant; and
- to ensure that levels are as low as reasonably achievable.

In the absence of an ML or other specific regulatory measures for patulin, general Code provisions apply including that food must be safe and suitable for human consumption and contamination should be kept as low as reasonably achievable. As noted by JECFA apple juice can occasionally be heavily contaminated and continuing efforts are needed to minimise exposure to patulin by avoiding the use of rotten or mouldy fruit.

Most overseas and international risk assessment and risk management activities for patulin have focused on apple juice. There is an internationally accepted Codex ML of 50 µg/kg for patulin in apple juice. There are resources[9] available to assist industry to keep patulin levels in apple juice as low as reasonably achievable and below the Codex ML including a Codex Code of Practice.

With respect to patulin levels in apple juice observed in the survey, FSANZ notes:

- patulin levels in most apple juice samples were as low as reasonably achievable
- almost 90% (231 of 259) of apple juice products had patulin levels below the Codex ML of 50 µg/kg
- patulin levels were highest in NFC apple juice products compared with reconstituted and freshly made varieties
- there was considerable variability and a large range of patulin concentrations in NFC apple juice. Detections above 50 µg/kg were observed across both sampling periods (9% of apple juice samples in Stage 1 and 12% of apple juice samples in Stage 2).

There are no Codex food standards for the other apple products sampled in the survey including solid infant products, sauces, purees, canned and dried apple. Patulin concentrations in these foods were lower than in apple juices. A small number (four) of these samples slightly exceeded the relevant EC MLs, however there are no food safety concerns for consumers based on the dietary exposure assessment.

[9] Codex Alimentarius Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CXC 50-2003).

The USFDA Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (docket number FDA-2002-D-0298).

The EC (2003) Recommendation on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages.

Apple and Pear Australia Limited (2020) and the Australian Beverages Council (2022) have published guidance for Australian industry.

6. Conclusions and recommendations

The findings of the survey confirm the current safety of the general Australian food supply with regards to patulin levels. Hence there is no requirement for food regulatory measures for patulin in foods.

However, there was considerable variability and a large range of observed patulin concentrations in apple juice. A proportion of apple juice samples (11%) had patulin concentrations exceeding the Codex ML of 50 µg/kg. These were observed across both sampling periods. FSANZ considers there is potential for high levels of patulin contamination of apple juice to occur occasionally in the future. It is important that industry continue to apply quality control measures. The control of patulin levels in apple juice is achievable through the application of good agricultural and manufacturing practices.

To ensure that patulin levels in Australian apple juice are kept safe and as low as reasonably achievable, FSANZ recommends:

- notification of survey outcomes to relevant government, food industry and other non-government stakeholders
- consolidation and promotion of existing education and risk management resources such as the Codex Code of Practice
- continued industry quality control practices (including good agricultural and manufacturing practices)
- continued monitoring and assessment of apple juice products with potential for higher levels of patulin including:
    - maintenance of current routine industry testing
    - targeted government surveillance programs as required to supplement existing data sources
- FSANZ and key government and non-government stakeholders maintain oversight of the issue and respond to new developments as required.

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Appendix 1. Detailed dietary exposure assessment methods and results

Approach to estimating patulin dietary exposure

Australians 2 years and above

Estimated patulin exposure from apple juice ‘as is’ was estimated using a nutrient model in Harvest. Mean and P90 consumption of commercial apple juice consumed ‘as is’ (e.g. as glasses of apple juice) were multiplied by mean LB and UB patulin concentrations. This did not include apple juice consumed in any mixed foods or recipes including juice blends or drinks. To estimate dietary exposure to patulin on a body weight basis, this was done deterministically outside of Harvest using the mean body weight of all respondents in the 2011–12 NNPAS (70 kg).

A raw commodity Harvest model was used to estimate patulin exposure from all commercial apple juice and other apple products consumed in the 2011–12 NNPAS. This approach estimated exposure to patulin from ‘all sources’, that is commercial apple juice and other apple products consumed ‘as is’ and in mixed dishes (e.g. mixed fruit juices, commercial apple pie). The Harvest program multiplied the mean LB and UB concentrations of patulin for an individual food by the amount of the food that an individual consumed in the survey to estimate the exposure to patulin from each food. Once this had been completed for all of the foods specified to contain patulin, the total amount of patulin consumed from all foods was summed for each individual. Daily dietary exposures were derived by averaging the two days of exposures for each consumer, and where results were expressed on a body weight basis, each individual’s body weight was used. Estimated mean and P90 dietary exposures were then derived from the individuals’ ranked exposures and compared to the PMTDI for risk characterisation purposes.

Infants

For 9 month old infants, the mean and P90 consumption amounts of the food group *Infant fruit and fruit-based desserts* was multiplied by the mean LB and UB patulin concentrations for the analysed food type *Products for infants and small children, with apple as the sole ingredient*. To estimate dietary exposure to patulin from this food group on a body weight basis, the 50th percentile weight for a 9 month old boy (8.9 kg) (WHO 2006) was used.

Mapping of foods consumed in the dietary survey to foods analysed

The mapping used to match the foods consumed in the 2011–12 NNPAS to the analysed samples for the purpose of assigning patulin concentrations to relevant foods in the apple juice and other apple products consumer model can be found in Table A2.1. As consumption of canned and pureed apple were reported in the 2011–12 NNPAS as Apple, canned or puree, analytical data from all canned and pureed apple samples were combined to derive the mean LB and UB patulin concentrations for Canned/pureed apple.

For the apple juice ‘as is’ consumer model, 2011–12 NNPAS foods *Juice, apple, commercial* and *Juice, apple, commercial, added vitamins C, E and folate and fibre* were mapped to apple juice analysed in the survey.

Table A1.1: Sampled food types and survey foods included in mapping for dietary exposure assessment

Sampled food type	Survey foods included*
Apple juice	Juice, apple, commercial (fortified and not fortified) Juice concentrate, apple
Reconstituted apple juice	Juice, apple, sparkling, commercial (fortified and not fortified)
Apple sauce	Sauce, apple, commercial
Canned/Pureed apple	Apple, canned or puree Fruit, puree or stewed, not further defined
Dried apple	Apple, dried
Products for infants and small children, with apple as the sole ingredient	Fruit, puree or stewed, infant

** These foods are also used as ingredients in mixed foods consumed in the survey.*

Scenarios and patulin concentrations used in the dietary exposure assessment

In the most conservative approach, referred to as the *Cloudy NFC apple juice* scenario, the mean LB and UB patulin concentrations for NFC apple juice either labelled as cloudy or with a cloudy appearance was applied to all commercial apple juice consumed in the 2011–12 NNPAS. This approach overestimated dietary exposure as it assumed that all commercial apple juice consumed in the survey was cloudy NFC apple juice.

In a more realistic approach, referred to as the *All apple juice* scenario, the mean LB and UB patulin concentrations from all apple juice samples (cloudy and clarified) analysed in the survey were applied to all commercial apple juice consumed in the 2011–12 NNPAS.

In both scenarios, the mean LB and UB patulin concentrations for reconstituted apple juice, apple sauce, canned/pureed apple, dried apple, and solid apple products for infants and small children remained the same. The patulin concentrations used in the dietary exposure assessment are shown in Table A2.2. The mean LB and UB concentrations for reconstituted apple juice were applied to consumption of sparkling apple juice only as it was assumed that all juice of this type is made from reconstituted apple juice.

Table A1.2: Patulin concentrations used in the dietary exposure assessment

	All apple juice scenario		Cloudy NFC apple juice scenario	
Food type	**Mean LB (µg/kg)**	**Mean UB (µg/kg)**	**Mean LB (µg/kg)**	**Mean UB (µg/kg)**
Apple juice	29	30	35	37
Reconstituted apple juice	4.3	7.6	4.3	7.6
Apple sauce	5.3	9.0	5.3	9.0
Canned/Pureed apple	9.0	9.0	9.0	9.0
Dried apple	0.0	5.0	0.0	5.0
Products for infants and small children, with apple as the sole ingredient	4.6	7.1	4.6	7.1

NFC: Not from concentrate; LB: Lower bound; UB: Upper bound

Assumptions and limitations

Assumptions made in the dietary exposure assessment included:

- In the *Cloudy NFC apple juice* scenario all commercial apple juice consumed in the 2011–12 NNPAS was cloudy NFC apple juice.
- All sparkling apple juice consumed in the 2011–12 NNPAS contained reconstituted apple juice.
- All commercial infant *'apple or pear'* juice consumed in the 2011–12 NNPAS was apple juice.
- All pureed or stewed infant fruit consumed in the 2011–12 NNPAS was an infant product with apple as the sole ingredient.
- All pureed or stewed fruit (not further defined) consumed in the 2011–12 NNPAS was commercial apple puree.
- All apple cider consumed in the 2011–12 NNPAS had a zero concentration of patulin.
- All homemade apple juice and apple sauce consumed in the 2011–12 NNPAS had a zero concentration of patulin.
- For the Harvest raw commodity model, where a food has a specified patulin concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. commercial apple juice in mixed fruit juices, canned apple in apple pie.
- All foods consumed from the food group *Infant fruit and fruit-based desserts* in the InFANT Program were products for infants or small children with apple as the sole ingredient.
- There were no other contributions to dietary exposure to patulin, for example from other pome fruit.

In addition to the specific assumptions made in relation to this dietary exposure assessment, there are a number of limitations associated with the nutrition surveys from which the food consumption data used for the assessment are based. A discussion of these limitations is included in Section 6 of the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

Dietary exposure assessment results – further details

The results for LB and UB were derived from two different sets of consumers and different exposure distributions which influenced the statistics derived. These results demonstrate the range of potential dietary exposures taking into account the uncertainty (the non-detections) in the analytical results.

For consumers of apple juice ‘as is’ and the food group *Infant fruit and fruit-based desserts*, the lower end of the estimated range of exposures represents LB exposures and the upper end of the range represents UB exposures.

Conversely, for the apple juice and other apple products consumer model, the lower end of the estimated range of exposures represents UB exposures and the upper end of the range represents LB exposures. Some survey participants reported consuming dried apple (or products containing dried apple) but not any other patulin-containing products such as apple juice. In the LB scenario, dried apple was assigned a patulin concentration of zero, therefore these people were not considered patulin consumers for the calculation of LB scenario exposures. In the UB scenario, dried apple was assigned a low (but non-zero) patulin concentration, therefore these people were considered patulin consumers for the calculation of UB scenario exposures. Because consumers of dried apple and no other patulin-containing products had relatively low patulin exposure levels compared to people who reported consuming other patulin-containing products such as apple juice, the exposure values were higher in the LB scenario (where people consuming dried apple and no other patulin-containing products were not included in the patulin exposure calculations) than in the UB scenario.

Table A1.3: Estimated mean and 90th percentile (P90) dietary exposures* to patulin from apple juice 'as is', and from apple juice and other apple products for Australian consumers aged 2 years and above

	All apple juice scenario				Cloudy NFC apple juice scenario			
	LB exposure (µg/kg bw/day)	% PMTDI[ж]	UB exposure (µg/kg bw/day)	% PMTDI[ж]	LB exposure (µg/kg bw/day)	% PMTDI	UB exposure (µg/kg bw/day)	% PMTDI
Apple juice 'as is'[¥]								
Mean	0.070	20	0.074	20	0.087	20	0.090	25
P90	0.14	35	0.15	35	0.17	45	0.18	45
Apple juice and other apple products[β]								
Mean	0.038	10	0.028	7	0.047	10	0.034	9
P90	0.11	25	0.081	20	0.13	30	0.098	25

NFC: Not from concentrate; LB: Lower bound; UB: Upper bound; PMTDI: Provisional maximum tolerable daily intake; P90: 90th percentile

** Based on the average of two days of consumption data from the 2011–12 NNPAS.*

ж The PMTDI for patulin is 0.4 µg/kg bw/day.

¥ The ratio of consumers to respondents for patulin exposure from apple juice 'as is' is 4.9%.

β The ratio of consumers to respondents for patulin exposure from apple juice and other apple products is 29.8% at LB and 42.6% at UB.

Table A1.4: Food group contributors to total dietary exposure* to patulin from apple juice and other apple products, based on Day 1 of the 2011–12 NNPAS for Australian consumers aged 2 years and above

Major and minor food groups	Percent contribution to total dietary exposure
Alcoholic beverages	<1
Cereal based products and dishes	<1
Cereals and cereal products	<1
Confectionery and cereal/nut/fruit/seed bars	<1
Dairy and meat substitutes	<1
Fruit products and dishes	<1
Infant formulae and foods	<1
Meat, poultry and game products and dishes	<1
Milk products and dishes	<1
Non-alcoholic beverages	**98**
Cordials	*4*
Fruit and vegetable juices, and drinks	***94***
Soft drinks, and flavoured mineral waters	*<1*
Tea	*<1*
Savoury sauces and condiments	<1
Special dietary foods	<1
Sugar products and dishes	<1

Note: Bold text indicates that the food group is a major contributor to dietary patulin exposures.

* Based on LB results to include only food with detectable concentrations. Food groups for which there is no contribution to patulin exposure are not included in the table.