



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

11 November 2008
[19-08]

FIRST REVIEW REPORT

APPLICATION A552

CADMIUM IN PEANUTS

For information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

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Decision

FSANZ re-affirms the variation to Standard 1.4.1 of the Code to increase the ML for cadmium in peanuts from 0.1 to 0.5 mg/kg, as notified to the Ministerial Council at Final Assessment.

The decision to increase the ML for cadmium in peanuts:

- ensures adequate protection of public health and safety based on the best available scientific information. Dietary exposure to cadmium for Australian and New Zealand consumers is well within internationally recognised safe limits;
- is more consistent with the approach used in other developed countries compared with retaining an unnecessarily restrictive current ML;
- will not be an unreasonable cost burden on industry or consumers, but rather it will assist the food industry in achieving continuity of supply of peanuts and peanut-based food products for consumers; and
- continues to support current measures to minimise cadmium in agricultural production systems.

Summary Table

Matters addressed in the First Review of Application A552 seeking to increase the maximum level for cadmium in peanuts from 0.1 to 0.5 mg/kg

MINISTERIAL COUNCIL ISSUES RAISED	FSANZ RESPONSE
<p>Objectives of the legislation which established FSANZ</p> <ul style="list-style-type: none">• Cadmium is capable of causing adverse health effects• There is only a small margin of safety between dietary intakes of cadmium and the Provisional Tolerable Weekly Intake (PTWI)• FSANZ has used out of date data in dietary exposure calculations	<ul style="list-style-type: none">• FSANZ acknowledges that cadmium can cause adverse health effects at high doses.• The current PTWI set by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) remains an internationally accepted value for the safe level of intake for cadmium over a lifetime of exposure.• Although JECFA has acknowledged that there is only a relatively small safety margin between exposure in the diet and exposure that produces a deleterious effect, Australian and New Zealand consumers' dietary exposure to cadmium is below the PTWI.• FSANZ is aware of the lapse of time since the 1995 NNS. However, there is no evidence to suggest that there has been a major change in peanut consumption which would underestimate the dietary exposure estimates (incorporating a limit of 0.5 mg/kg for cadmium in peanuts) in relation to the PTWI. The in-built assumptions in the dietary exposure assessment overestimate consumption adding an additional safety factor in the calculations.• Peanuts are a minor contributor to overall exposure to cadmium in both Australia and New Zealand.

MINISTERIAL COUNCIL ISSUES RAISED	FSANZ RESPONSE
<p>Protection of public health and safety</p> <ul style="list-style-type: none"> • High-risk groups such as Aboriginal and Torres Strait Islander populations may not be adequately protected by the PTWI • It is not apparent that variation in individual uptakes of cadmium is accounted for by the PTWI • The cost-benefit analysis is not persuasive in light of the public health issues with cadmium in the diet 	<ul style="list-style-type: none"> • The PTWI is adequately protective of all populations including groups that may be considered high-risk (e.g. Aboriginal and Torres Strait Islander populations). • Various factors influence cadmium absorption in humans; however, the PTWI takes into account these differences and also any differences in respect of groups that may be deemed as high risk to cadmium exposure from the diet. • The proposed increase to the ML for cadmium in peanuts still ensures adequate protection of public health and safety. The cost-benefit analysis adequately addresses all the significant factors and impacts, demonstrating a net benefit.
<p>Unreasonable cost burden on industry or consumers</p> <ul style="list-style-type: none"> • Australian peanut producers do not appear to have difficulty in meeting the current ML for cadmium in peanuts. • Increasing the ML may negate the practices that Australian industry has introduced which have lowered cadmium levels in soils. 	<ul style="list-style-type: none"> • The proposed ML of 0.5 mg/kg enables the current shortfall between domestic production and imported peanuts claimed by the Applicant (Confectionery Manufacturers of Australasia) as significant to be met by imports from a variety of countries. This will assist specific industry sectors when supplies are short (e.g. during times of drought). It is also more consistent with the approach used in other developed countries. • FSANZ contends that increasing the ML is not a burden on industry as it extends the spectrum of acceptable cadmium levels in peanuts. • Retaining an unnecessary restrictive ML is inconsistent with the principles of setting an ML and the section 18 objectives of the FSANZ Act including promotion of consistency between domestic and international standards; and, is not consistent with Australia's and New Zealand's obligations and commitment to the World Trade Organisation.

1. Introduction

On 8 September 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Application A552, which seeks an increase to the current maximum limit (ML) for cadmium in peanuts from 0.1 to 0.5 mg/kg. The Applicant, the Confectionery Manufacturers of Australasia (CMA) claim that this will enable increased flexibility to source peanuts from a variety of countries to meet changes in supply that may result from crop seasonality and variations in product quality.

Approval of this Application involves a variation to Standard 1.4.1 – Contaminants and Natural Toxicants of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a first review, FSANZ has three months to complete a response. In this instance, FSANZ was required to review the decision by 8 December 2008.

2. Objectives of Review

The objective of this Review is to reconsider the draft variation to Standard 1.4.1 in light of the Ministerial Council's grounds for review as outlined in Section 3 below.

3. Grounds for the Review requested by the Ministerial Council

A First Review of FSANZ's decision to approve Application A552 was sought on the grounds that the proposed amendment to Standard 1.4.1, to increase the ML for cadmium in peanuts from 0.1 to 0.5 mg/kg:

- is not consistent with the objectives (Section 3) of the legislation which established FSANZ;
- does not protect public health and safety; and
- places an unreasonable cost burden on industry or consumers.

3.1 Summary of Ministerial Council's Grounds for review

3.1.1 It is not consistent with the objectives of the legislation (Section 3 Object of the Act) which establishes FSANZ

The object of the FSANZ Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

- (a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- (b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- (c) the provision of adequate information relating to food to enable consumers to make informed choices;
- (d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

The Council identified the following issues as being representative of where FSANZ has been inconsistent with its legislative objectives, particularly in regard to part (d) of Section 3 above, where food regulatory measures should not reduce any safeguards applying to public health and consumer protection:

- cadmium is capable of causing a range of adverse health effects on the kidney, bone, pulmonary and cardiovascular systems and may accumulate in organs (especially kidneys) at low exposures;
- FSANZ has relied on out-of-date 1995 National Nutrition Survey data which may not represent current intakes of peanuts; and
- there is an erosion of an already narrow margin of safety between the Provisional Tolerable Weekly Intake (PTWI) and estimated dietary exposure to cadmium in peanuts if the ML is increased.

Therefore, the Review request asserts that, without knowing current dietary exposure for peanuts (particularly in the snack food sectors), the precautionary principle should be applied to foods that pose a risk to human health, especially as there are local and overseas peanut growers that can meet the current ML of 0.1 mg/kg.

3.1.2 Protection of public health and safety

A number of reasons were put forward in asserting that the decision to increase the ML for cadmium in peanuts does not protect public health and safety:

- the assessment of the risk for Aboriginal and Torres Strait islander populations and vegetarians is not convincing and persuasive;
- there is also a lack of evidence in the assessment in regard to the impact of increased cadmium levels in peanuts for vegetarians, who may rely on peanut consumption for protein needs;
- given the narrowness of the margin of safety in the PTWI for cadmium, the proposal to increase the ML needs reviewing;
- whether the PTWI takes into account variations in individual uptake of cadmium from foods is not apparent in the Final Assessment Report (FAR);
- considering the current obesity epidemic, there appears to be no public benefit in making it potentially easier and cheaper for manufacturers to produce and sell peanut based confectionery; and
- the benefit cost analysis is far from persuasive in light of the adverse health aspects with cadmium.

3.1.3 Cost burden on industry and consumers

The Review request states that Australian peanut producers do not appear to have difficulty in meeting the existing ML. Increasing the ML may negate the work done to date to improve practices that have led to lower levels of cadmium in Australian soils and hence lower levels of cadmium in foods.

4. Background

FSANZ received an unpaid Application from the CMA to amend Standard 1.4.1 – Contaminants and Natural Toxicants. The CMA originally requested deletion of the Maximum Level (ML) for cadmium in peanuts to align with Codex. The current ML for cadmium in peanuts specified in the Table to clause 2 of Standard 1.4.1 is 0.1 mg/kg. This ML was established after a review in the mid-1990s on the basis that it would not increase public health and safety risk and was less likely to be perceived as a non-tariff barrier to trade (than the previous ML of 0.05 mg/kg).

The CMA advised FSANZ on 8 February 2008 that it had amended the Application, and rather than deleting the ML, was now seeking to increase the current ML from 0.1 to 0.5 mg/kg. This would enable the CMA to source peanuts from a variety of countries for use in confectionery. It argued that demand was unable to be met from Australian sources due to crop seasonality and variations in product quality. The CMA suggested that retaining the current ML for cadmium in peanuts could be perceived as a Technical Barrier to Trade. Codex has not established a ML for cadmium in peanuts because they are a low contributor to overall global cadmium exposure.

FSANZ has undertaken an extensive risk assessment and reviewed the first and second round of public submissions from stakeholders. Many of the submissions were of benefit in understanding industry, consumer and jurisdictional views on the proposed risk management options.

The risk assessment has concluded that increasing the ML to 0.5 mg/kg retains adequate protection of public and safety. If the ML were increased the dietary exposure to cadmium in Australia and New Zealand would remain below the provisional tolerable weekly intake (PTWI) of 7 µg/kg bw/week and therefore within acceptable safety standards. Peanuts are a minor contributor to overall exposure to cadmium in both Australia and New Zealand.

5. Conclusions from the Final Assessment Report

The Executive Summary and the reasons for the decision, which were approved by the FSANZ Board at the 25 June teleconference 2008, are provided in this Report at **Attachment 2**.

The Board agreed to the recommendation at Final Assessment to increase the ML for cadmium in peanuts from 0.1 to 0.5 mg/kg.

6. Issues addressed in First Review

6.1 Application A552 is not consistent with the objectives of the legislation which establishes FSANZ

The Ministerial Council's first ground for review was that an increase to the current ML for cadmium in peanuts is inconsistent with the objectives of the legislation which established FSANZ. In particular, the Council highlighted the adverse health effects of cadmium, that FSANZ had relied on out-of-date National Nutrition Survey data for dietary exposure estimates and that there is already an erosion of the margin of safety between the PTWI and estimated intakes of cadmium from peanuts and other dietary sources.

6.1.1 Adverse health effects of cadmium and the margin of safety between the PTWI and estimated dietary exposure

Cadmium is a cumulative toxin, has a long biological half-life and the kidney is the critical target organ for toxic effects of long-term dietary exposure to cadmium.

The FAO/WHO Joint Expert Committee on Food Additives (JECFA) established a Provisional Tolerable Weekly Intake (PTWI) of 7 µg/kg bw for cadmium in food. The PTWI was re-confirmed by subsequent considerations by JECFA, in 1988, 1993, 2000 and 2003. The JECFA assessments have acknowledged that there is only a relatively small safety margin between exposure in the diet and exposure that produces an adverse effect. FSANZ's risk assessment concurs with that of JECFA and the current PTWI of 7µg/kg bw has been used as the reference health level for dietary exposure assessments for this Application.

In 2003, JECFA reaffirmed that ‘no excess prevalence of renal tubular dysfunction would be predicted to occur at the current PTWI under the most appropriate assumptions about the fractional bioavailability of cadmium and the percentage of the absorbed cadmium that is excreted in urine.’ The JECFA PTWI remains the internationally accepted value for the safe level of intake for cadmium over a lifetime of exposure¹.

The PTWI is based on the most sensitive parameter for kidney damage in humans, namely, an increase in the urinary excretion of low molecular weight protein as a result of reduced re-absorption in the renal tubules. The toxicological significance of this observed change with respect to kidney damage is still not established as it is clear that the excretion of low molecular weight proteins normally increases with age.

An important factor to consider when interpreting the potential risk of intake levels near or above the PTWI for cadmium is that it has been established on the basis of cumulative intake. Thus, intake above this figure may be tolerated provided it is not sustained for long periods of time and does not produce a significant increase in the integrated life-time dose.

The exposure assessment indicated that the highest consumption estimated for Australian children aged 2-6 years was at 65-75% of the PTWI. Dietary modelling often identifies children as the sub-population most likely to have the highest exposure to various food components, partly because young children have relatively high food consumption levels when expressed on a body weight basis. At its 33rd meeting, JECFA recognised that exposure to cadmium will not be uniform with age, and that the estimate of the PTWI takes into account the higher cadmium intake on a body weight basis by infants and children². Higher intakes during childhood are unlikely to be maintained over the long-term. The exposure estimates for the whole population include data from all age groups including 2-6 year olds and are a more accurate estimate of lifetime exposure to cadmium.

In conclusion and based on the best available scientific information, there is no evidence to suggest that Australian and New Zealand consumers’ dietary exposure to cadmium is approaching the PTWI. This has been confirmed by numerous follow up dietary surveys in Australia and New Zealand and the dietary exposure assessment conducted by FSANZ for Application A552 (refer to Section 6.1.2 below). The risk assessment has concluded that dietary exposure to cadmium in Australia and New Zealand is below the PTWI. In addition, peanuts are a minor contributor to overall exposure to cadmium in both Australia and New Zealand.

The dietary exposure calculations for the whole population groups are reflective of life-time exposure to cadmium in the diet and are consistent with the current PTWI which is based on life-time accumulation of cadmium in the kidneys.

International concentration data for cadmium in peanut and peanut products for the dietary exposure assessment were sourced from both within Australia and from overseas agencies.

¹ WHO. (2004) Cadmium. In: *Safety evaluation of certain food additives and contaminants. Sixty-first meeting of JECFA*. World Health Organization, Geneva. WHO Food Additive Series 52.

² WHO. (1989) Cadmium. In: *Toxicological evaluation of certain food additives and contaminants. Thirty-third meeting of JECFA*. World Health Organization, Geneva. WHO Food Additive Series 24

These sources are summarised in Table 1 below from Appendix 1 of Attachment 3 to the Final Assessment Report at <http://www.foodstandards.gov.au/srcfiles/A552%20Cadmium%20in%20peanuts%20FAR%20FINAL.pdf#search=%22A552%22>

Table 1: Summary of cadmium concentrations for peanuts available from Australia and internationally

Country	Source	Year	Cadmium Concentration (mg/kg)		
			Mean	Lowest Concentration	Highest Concentration
China	Chinese Total Diet Study	2000	0.087	0.020	0.239
United States	United States Total Diet Survey	1991-2004	0.057	0.020	0.117
Australia (imports)	Australian Quarantine and Inspection Service	2001-2006	0.090	0.010	0.410
New Zealand	Total Diet Survey	2003-2004	0.075	0.028	0.157

The ML of 0.5 mg/kg was not only the proposed ML requested by the Applicant, but also the upper end of the range of concentration data for cadmium in peanuts reported both internationally as well as from Australian data received by FSANZ.

The exposure estimates for all population groups are likely to be overestimates because the estimate assumes that all peanuts contain cadmium at 0.5 mg/kg. However, this is extremely unlikely as the available data on cadmium levels in peanuts indicates that most peanuts will have cadmium concentrations well below this level. Also, the data used for modelling is a 24-hour record, which overestimates food consumption for consumers as they are unlikely to consume the same foods in the same quantities every day (The use of multiple day records tends to significantly reduce predicted high consumer exposure).

Therefore, the proposal to raise the maximum limit for cadmium in peanuts to 0.5 mg/kg is sufficient to maintain exposure within acceptable limits for all consumers including high-risk groups, even assuming that all peanuts contain cadmium at the proposed maximum limit of 0.5 mg/kg.

6.1.2 *Dietary survey data is out-of-date and may not reflect current exposure to cadmium*

6.1.2.1 Exposure to cadmium in Australia and New Zealand

Recent Total Diet Surveys in both Australia (ATDS) and New Zealand (NZTDS) have confirmed that cadmium exposures are below the PTWI of 7 µg/kg bw. In the 20th ATDS in 2002 it was reported that all estimated dietary exposures to cadmium were below the tolerable limit of 7 µg/kg bw, and consequently within acceptable safety standards. The highest mean exposure to cadmium was for infants because of their high food consumption relative to body weight. This exposure ranged from 13% to 68% of the tolerable limit.

Cadmium dietary exposures are similar for the New Zealand population as reported the 2003-2004 NZTDS. Levels of cadmium were consistent with internationally documented levels and the estimated weekly dietary exposures for eight age-sex groups were all well below the PTWI.

6.1.2.2 Dietary exposure assessment for Application A552

FSANZ’s dietary exposure assessment estimated that peanuts contribute less than 5% of the total dietary exposure to cadmium. This estimate is derived from the best scientific data currently available.

In order to determine if the level of exposure to cadmium will be of concern to public health and safety, the estimated dietary exposures were compared to the PTWI of 7 µg/kg bw/week. The estimated current and proposed dietary exposures to cadmium for Australia and New Zealand, as assessed against the PTWI are shown below in Figures 1 and Figure 2.

The proposed value of 0.5 mg/kg was not only the proposed ML requested by the applicant, but was also the upper end of the range of concentration data for cadmium in peanuts reported both internationally as well as from Australian data received by FSANZ from the Applicant.

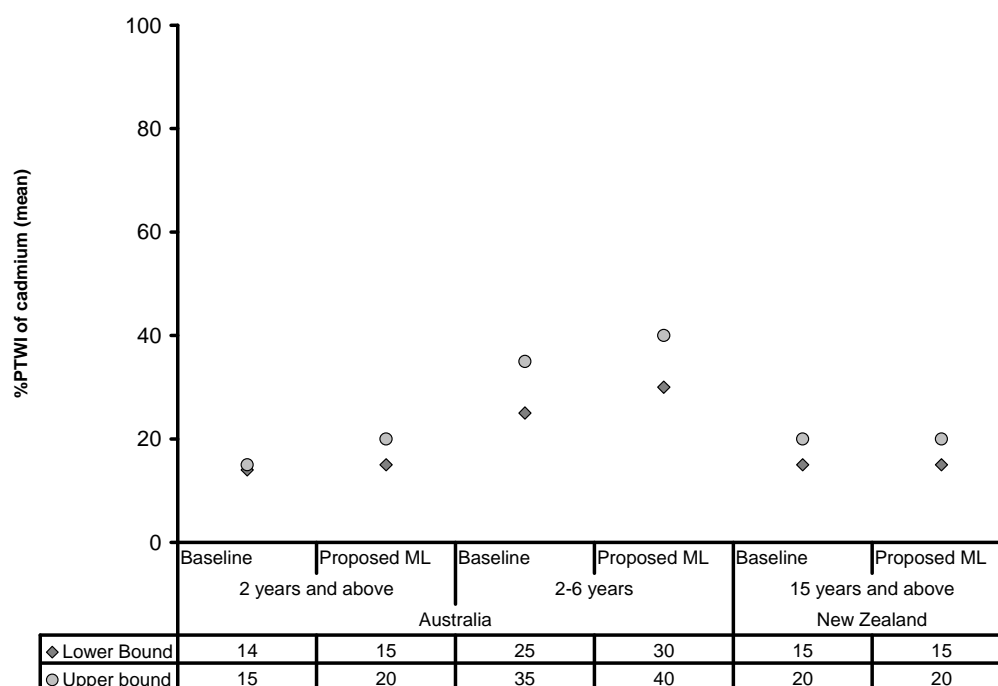


Figure 1: Estimated mean dietary exposures to cadmium for Baseline (current exposure) and Proposed ML (0.5 mg/kg) scenarios for all population groups assessed as a percent of the PTWI³

³ Where foods included in the dietary exposure assessment were found to have cadmium concentrations at or below the limit of reporting (i.e. the lowest concentration of cadmium that could be detected and quantified with an acceptable degree of certainty), upper bound and lower bound cadmium concentrations were assigned to the food. The lower bound is where foods with a ‘not detected’ concentration for cadmium were assigned a zero concentration and the upper bound where they were assigned a concentration equal to the limit of reporting.

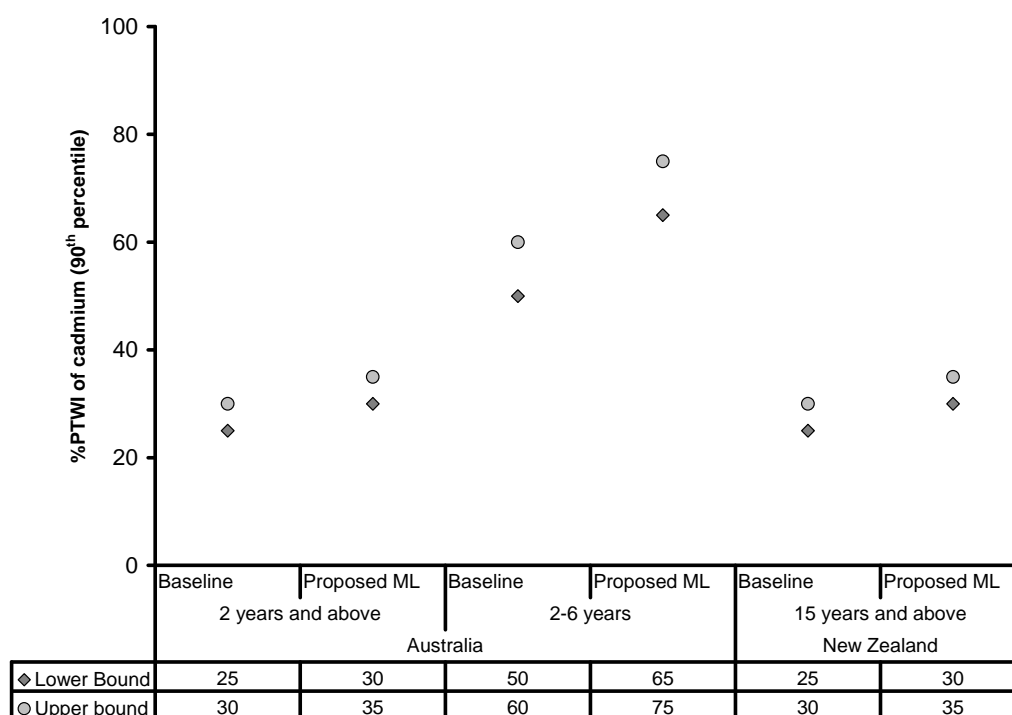


Figure 2: Estimated 90th percentile dietary exposures to cadmium for Baseline (current exposure) and Proposed ML (0.5 mg/kg) scenarios for all population groups assessed as a percent of the PTWI

Estimates of total dietary exposure to cadmium from all dietary sources, assuming that all peanuts consumed contain cadmium at 0.5 mg/kg, indicate that Australian and New Zealand consumers, including children, would not be exposed to cadmium above safe limits. At the 90th percentile, Australian and New Zealand consumers were exposed to 30-35% of the PTWI (Figure 2; Table 2). The highest exposure estimated was 65-75% of the PTWI at the 90th percentile for Australian children aged 2-6 years.

Table 2: Estimated dietary exposures to cadmium from all sources with peanuts assumed to contain 0.5 mg/kg, as a percentage of the PTWI

Country	Population group	90 th percentile consumers % PTWI
Australia	2 years +	30 - 35
	2-6 years	65 - 75
New Zealand	15 years +	30 - 35

However, the available data on cadmium levels in peanuts indicates that most peanuts will have cadmium concentrations well below the proposed ML (median 0.04 mg/kg). The exposure estimates for all population groups are therefore conservative because the estimate assumes that all peanuts have levels of cadmium at 0.5 mg/kg. In addition, the data used for modelling is a 24-hour record: this overestimates food consumption for high consumers, as they are unlikely to consume the same foods in the same quantities every day. The use of multiple day records tends to reduce predicted high consumer exposure substantially.

In conclusion, the dietary exposure assessment indicates that due to the small contribution of peanuts to total dietary exposure to cadmium there is a relatively small increase to overall cadmium exposure at the proposed ML for cadmium in peanuts of 0.5 mg/kg, compared to current exposure. Dietary exposure to cadmium for Australian and New Zealand consumers is well within the internationally recognised safe level.

6.1.2.3 Has consumption of peanuts changed since 1995?

FSANZ examined additional sources of consumption data to clarify if peanut consumption may have changed substantially since 1995. On balance, FSANZ has concluded that peanut consumption most likely has remained relatively constant in Australia, or has only increased by a small amount. A number of data sources were used to form this view:

- Retail Worlds Australasian Grocery Guide⁴
- the Australian Bureau of Statistics (ABS) Apparent Consumption of Food Stuffs
- Roy Morgan Single Source data for the period from 2001-2007.

The Retail Worlds Australasian Grocery Guide estimates the volumes of products sold to the public by the major retailers. After following these Guides back to 1996 it can be estimated that the amount of peanuts and peanut butter sold at retail sale has remained fairly constant from 1996-2006, while the amount of nuts sold may have decreased⁵.

The ABS Apparent Consumption of Food Stuffs provides data on peanut consumption from 1948-1999⁶. There is some variation in the apparent peanut consumption, with the overall trend suggesting a decrease in peanut consumption since the 1940s, with slight reversal in this trend in the 1990s. Tree nut consumption has been apparently increasing, but in 1998-99 it was still below the peak in 1968-69.

FSANZ also considered Single Source data for the period from 2001-2007. Single Source does not differentiate between peanuts and tree nuts. It only reports frequency of consumption, not amounts consumed. Generally, there is a universal trend for increasing consumption of nuts across the whole population. There are no particular consumer segments where this trend is most pronounced, but increases are slightly smaller in families with school age children. While there is an increase in the consumption of snack foods, and it could be construed that nuts are considered a healthy snack, the consumer segments that are interested in health have not increased their frequency of consumption more than the general population. Frequency of peanut butter consumption has decreased for the whole population.

FSANZ has used 3 additional yet different data sets to examine if there have been any substantial increases in peanut consumption since the National Nutrition Survey (NNS) was conducted in 1995. Although these data sets cannot be compared directly, the trend within individual data sets is that there has not been a substantial increase in peanut consumption.

⁴ formerly the Australian Grocery Industries Marketing Guide

⁵ The data for nuts and peanuts is based on peanuts eaten as snacks and does not include nuts used in other foods such as biscuits, confectionery etc.

⁶ These data are based on nuts in shell, and might include uses such as oils and stock feed production and cannot easily be compared to the individual consumption data of the NNS.

Therefore, it is concluded that it is unlikely that changes in peanut consumption that may have occurred since 1995 were substantial enough to result in any sizeable underestimate of dietary exposure to cadmium in relation to the PTWI. The 1995 Australian and 1997 New Zealand NNS are the most recent comprehensive set of quantitative data on food consumption patterns available to FSANZ. FSANZ determined that this data would provide an accurate assessment of the risk to public health and safety and that it was not necessary to seek any additional data to conduct a comprehensive dietary exposure assessment.

Although the 2002 New Zealand Children's Nutrition Survey and the 2007 Australian National Children's Nutrition & Physical Activities Survey will be available for dietary exposure assessment for contaminants (e.g. cadmium) by July 2009, FSANZ does not consider there is a need to delay the progression of this application until the data are available because there is no evidence of a substantial change in consumption levels on the basis of the information described above. In addition, the dietary exposure assessment made conservative assumptions about the concentration of cadmium in peanuts and the amount of peanuts consumed.

6.2 Application A552 does not protect public health and safety

The Ministerial Council's second ground for review is that an increase to the current ML for cadmium in peanuts does not protect public health and safety. In particular, Aboriginal and Torres Strait Islander people and vegetarians may not be adequately protected if the ML for cadmium is increased in peanuts. The issue of variation in individual uptake of cadmium from foods as being accounted for by the PTWI was also questioned. Furthermore, the Ministerial Council suggested that the cost-benefit analysis was not persuasive in light of the public health issues raised.

6.2.1 Are Torres Strait Islanders and Australian Aborigines likely to consume significantly more peanuts than the general population?

Based on the currently available scientific data that FSANZ used in its risk assessment, the internationally recognised and accepted PTWI for cadmium provides adequate protection to high-risk groups. This includes Aborigines and Torres Strait Islander (TSI) populations.

Due to the small number of Aboriginals and TSI sampled in the 1995 NNS, there is insufficient information on dietary exposures for this population subgroup. However, FSANZ used a number of data sources in addition to the 1995 NNS in the Final Assessment Report, in order to determine whether the peanut consumption patterns of Aboriginals and TSI populations could result in a substantial underestimate of dietary exposure to cadmium in relation to the PTWI.

Cadmium is known to accumulate in the kidney and liver of long living animals. Dugong, turtle, or other foods traditionally consumed by TSI are likely to have high cadmium concentrations and may contribute substantially to cadmium exposure in these populations⁷ http://www.gbrmpa.gov.au/corp_site/info_services/publications/misc_pub/misc_003/index.html.

⁷ Gladstone W. (1996) Trace metals in sediments, indicator organisms and traditional seafoods of the Torres Strait. Great Barrier Reef Marine Park Authority, Townsville, Qld, Australia.

The importance of these foods to cadmium exposure of TSI peoples is well understood by State and Territory Health Departments, who have carried out health education campaigns in northern Queensland and the Northern Territory that specifically advise against the consumption of organ meat from dugong and turtles. Given these likely major sources of cadmium dietary exposure, and the minor contribution to exposure from peanuts, it is reasonable to conclude that cadmium exposure for Aboriginals and TSI will not substantially increase if the ML for cadmium in peanuts is increased.

Neither the 1995 NNS, nor Roy Morgan Single Source⁸ provides data on consumption of peanuts by Aboriginals or TSI. Therefore, FSANZ approached health professionals at the Tropical Public Health Unit based in Cairns and the Menzies School of Health Research in Darwin to seek their views. In particular, FSANZ sought information on whether Aboriginals and TSI are at higher risk from consumption of cadmium-containing foods and data on consumption of cadmium-containing foods by indigenous populations. Although the health professionals recognised the high prevalence of renal disease among Aboriginal and TSI people and raised concerns about cadmium exacerbating this problem, they were unable to confirm that consumption of peanuts with higher levels of cadmium would place these populations at higher risk of renal disease. They agreed that sources of cadmium in Aboriginal and TSI diets included marine animals such as turtle and dugong, which are favoured foods and widely consumed by Aboriginals and TSI.

Given there are other major sources of cadmium dietary exposure in the Aboriginal and TSI diet, and that peanuts are only a minor contributor to exposure, it is highly unlikely that there is a substantial underestimate of dietary exposure to cadmium in relation to the PTWI. In conclusion, the internationally recognised and accepted PTWI for cadmium provides adequate protection to high-risk groups such as Aboriginal and TSI populations because it includes a safety factor based on individual variation.

6.2.2 *Risks for Vegetarians*

In the 1995 NNS, 2.5% of respondents identified themselves as vegetarians⁹. The dietary exposure assessment conducted by FSANZ includes these self-reported vegetarians. The dietary exposure assessment concluded that any high consumers of peanuts at the proposed ML of 0.5 mg/kg and other cadmium-containing foods, including vegetarians, were exposed well below the PTWI and therefore are adequately protected.

The Roy Morgan Single Source data provides additional information on self-reported vegetarians. The data suggest that vegetarians consume nuts (including peanuts) only 4% more frequently than other consumers do. As peanuts are only a minor contributor to cadmium exposure, peanut consumption patterns of vegetarians are highly unlikely to result in a substantial underestimate of dietary exposure to cadmium in relation to the PTWI in this population group.

In conclusion, the internationally recognised and accepted PTWI for cadmium provides adequate protection to vegetarians. Given that peanuts are only a minor contributor to dietary cadmium exposure, peanut consumption by vegetarians is highly unlikely to result in a substantial increased risk of dietary exposure to cadmium in relation to the PTWI.

⁸ Single Source only identifies ethnicity by country of birth

⁹ Self-reported type of diet. ABS (1997) National Nutrition Survey Selected Highlights Australia 1995, p.26

6.2.3 *Variations in uptake of cadmium from foods*

Experimental studies have identified various factors that can significantly influence the extent of absorption and retention of cadmium from the diet, including gender, developmental stage and nutritional status.

The gastrointestinal absorption in humans is influenced by the type of diet and the nutritional status. On average, 5% of the total oral intake of cadmium is absorbed, but individual values range from less than 1% to more than 20%. Low dietary consumption of protein and of essential minerals such as zinc, calcium, copper, and iron have been shown to promote the absorption of cadmium in rats, while, in contrast, high or adequate dietary consumption reduce absorption and retention.

Although it has been suggested that low iron status increases the uptake of cadmium from the gastrointestinal tract, not all the studies have confirmed this and a recent study of female farmers exposed to cadmium at levels close to the current PTWI of 7 µg/kg bw did not find any statistically significant difference in cadmium absorption between women with diabetes mellitus and controls, or women with anaemia and a control group.

The bioavailability of cadmium may be reduced in some foods, for example where cadmium is bound to phytates, metallothionein or other proteins. Phytic acid, a strong chelator of minerals, is found in many plants and is known to impair absorption of nutrients including iron and zinc, and also of contaminants such as cadmium.

Composition of the diet, including fibre, protein and carbohydrates, may also affect cadmium absorption. In a recent study comparing a vegetarian/high-fibre diet and a mixed-diet group, no differences in blood or urinary cadmium concentrations were found, despite the high-fibre diet having a higher concentration of cadmium, suggesting that fibre had an inhibitory effect on cadmium absorption.

In conclusion, the PTWI is based on a lifetime of accumulation of cadmium from dietary sources and includes a safety factor based on effects on the kidney in humans incorporating a large number of subjects which also takes account of individual variability. JECFA has reviewed and confirmed the PTWI on several occasions after considering numerous epidemiological studies encompassing populations with varying cadmium intake levels, varying nutritional status and varying dietary absorption (e.g. both Swedish and Belgian Western diets and Japanese and Chinese farmer diets). This includes data from susceptible populations, such as post-menopausal women with a diet low in iron, calcium and total protein and diabetics.

Although FSANZ acknowledges that various factors influence cadmium absorption in humans, the PTWI takes into account these differences and also any differences in respect of groups that may be deemed at high risk to cadmium exposure from the diet.

6.2.4 *Cost-benefit analysis*

FSANZ addressed a range of issues in the regulatory impact analysis in the Final Assessment Report. This analysis was based on the public health and safety issues and further justification on costs submitted by the Applicant.

The analysis was consistent with the Council of Australian Governments (COAG) requirements for best practice regulation and complies with similar requirements in relation to regulation in New Zealand.

The CMA claims that an increase to the ML will permit the Australian and New Zealand food industry to compete more effectively in the global marketplace as they would have increased flexibility to source peanuts from a variety of countries. The Peanut Company of Australia (PCA) claims that there appears to be no financial benefit or reduced price for products marketed to consumers by obtaining peanuts from countries which contain higher levels of cadmium. No specific benchmark price exists for peanuts, but rather, prices depend on negotiations between the buyer and seller with imported peanuts traded at similar prices to those paid to Australian and New Zealand producers.

FSANZ requested additional data from the Applicant in regard to past instances where the CMA has experienced problems in sourcing peanuts and further clarification and evidence to support its arguments that the current ML of 0.1 mg/kg is in effect resulting in trade difficulties. This has all been detailed in the Final Assessment Report and FSANZ acknowledges that there are differences of view on this point between the CMA and PCA.

In regard to the issue raised on obesity by the Ministerial Council, peanut-based confectionery in a balanced diet should serve as an occasional food that may be consumed. FSANZ did not consider that it was essential to include a cost-benefit analysis on this aspect as it has no relation to increasing the ML for cadmium in peanuts. Rather, this is purely a consumer choice issue on purchase of confectionery foods containing peanuts.

FSANZ consulted with the Office of Best Practice Regulation (OBPR) over the Regulation Impact Statement (RIS), including the cost-benefit analysis under the COAG requirements. The OBPR considered that the RIS was adequate to address the requirements of the food regulatory measure requested by the Applicant. It has endorsed FSANZ's analysis in this regard and also believe that this Application will reduce regulatory impacts.

In conclusion, the proposed increase to the ML for cadmium in peanuts still ensures adequate protection of public health and safety. There are a number of sufficient safety factors built in to the PTWI and there is no evidence that Australian or New Zealand consumers have dietary intakes to cadmium over this internationally recognised reference health level. The cost benefit analysis adequately addresses all the significant factors and impacts, demonstrating a net benefit.

6.3 Unreasonable cost burden on industry or consumers

The Ministerial Council's third ground for review was that an increased ML for cadmium in peanuts places an unreasonable cost burden on industry or consumers. The Ministerial Council suggested that Australian peanut farmers can meet the requirements of the current ML of 0.1 mg/kg. Also, increasing the ML may negate the work done to date under initiatives such as the National Cadmium Minimisation Strategy (NCMS).

6.3.1 FSANZ Evaluation

The focus of this application is about the following:

- removing regulatory barriers to trade while retaining adequate protection of public health and safety; and
- achieving continuity of supply that meets the unique quality specifications of the food industry including the confectionery industry (and potentially other parts of the food industry) and improving the global competitiveness (the risk for the economy is a move to offshore manufacturing).

Therefore, although the Ministerial Council's grounds for a first review suggest that Australian peanut producers do not appear to have difficulty in meeting the existing ML of 0.1 mg/kg in peanuts, maintenance of an ML that is too low to allow continuity of imports, without reasonable grounds, will be an unnecessary burden on the food industry and importers of peanuts.

The former Australia New Zealand Food Standards Council agreed to the following policy principles in July 1997 in that MLs shall be set: (1) only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade; (2) for those foods that are significant for the total exposure of the consumer to the contaminant; and (3) as low as reasonably achievable. The proposed increased ML of 0.5 mg/kg for cadmium satisfies those criteria, particularly criteria 1 and 3 above, taking into account that peanuts are not a major contributor to dietary exposure to cadmium.

In setting an ML, consideration should also be given to Australia's and New Zealand's international trade obligations under the World Trade Organization's Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. Retaining an unnecessarily restrictive ML is not consistent with these obligations.

The PCA has worked closely with the Queensland Department of Primary Industries and Fisheries, CSIRO and the Grains Research and Development Corporation to develop management guidelines for farmers to ensure Australia's peanut production always meets the current ML for cadmium in peanuts. These activities have incurred costs for peanut producers in Australia. However, these costs cannot be used as grounds for retaining an unnecessarily restrictive ML that results in trade difficulties.

Although peanut farmers in Australia may be able to meet the current ML of 0.1 mg/kg, FSANZ disagrees that increasing the ML would negate initiatives such as the National Cadmium Minimisation Strategy (NCMS). An ML is not the principal means of ensuring Good Agricultural Practice (GAP) for any contaminants in the food supply, but rather that the NCMS is a long-term commitment to cadmium reduction. Therefore, maintenance of an ML in peanuts would continue to support adherence to the following NCMS key strategies:

- development of Best Management Practices for the production and processing of agricultural produce for those industries and/or areas which have an existing or potential problem with cadmium levels in their produce;
- development of a Code of Practice by the fertiliser industry to target low cadmium fertiliser to those areas/industries which have an existing or potential cadmium problem;

- encouragement of all State departments to re-affirm their previous commitment to reduce the regulated level of cadmium in phosphatic fertilisers to 300 mg cadmium/kg phosphorous by 2000;
- labelling of fertilisers and soil ameliorants, to alert growers to their cadmium content; and
- raising the awareness by the Standing Committee on Agriculture and Resource Management (SCARM) and all State departments of the risks of the use of biosolids and other soil ameliorants in adding cadmium to the soil, and to take this risk into account when setting standards for their use.

In conclusion, the proposed ML of 0.5 mg/kg is safe and is consistent with the upper range of distribution of cadmium levels in peanuts from the best available scientific survey data. It enables the current shortfall between domestic production and imported peanuts claimed by the CMA as significant to be met by imports from a variety of countries, in order to assist specific industry sectors when supplies are short (e.g. during times of drought). It is also more consistent with the approach used in other developed countries.

FSANZ also considers that an ML, albeit increased, would still facilitate the ongoing management of cadmium levels in soils to ensure that these levels are as low as reasonably achievable (ALARA).

FSANZ's overall review is that increasing the ML for cadmium in peanuts does not impose an unreasonable cost burden on industry and/or consumers. The OBPR's overall assessment confirms FSANZ's view that there are no additional compliance costs and this Application reduces the regulatory burden.

7. Review Options

There are three options proposed for consideration under this Review:

1. re-affirm approval of the draft variation to Standard 1.4.1 of the Code as notified to the Ministerial Council; or
2. re-affirm approval of the draft variation to Standard 1.4.1 subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variation to Standard 1.4.1 as notified to the Council.

8. Decision

FSANZ has considered the issues raised by the Ministerial Council in relation to Application A552 Cadmium in Peanuts.

The First Review concludes that the preferred review option is Option 1. FSANZ has decided to re-affirm the variation to Standard 1.4.1 of the Code to increase the ML for cadmium in peanuts from 0.1 to 0.5 mg/kg, as detailed in **Attachment 1**.

The recommended option is Option 1.

Decision

FSANZ re-affirms the variation to Standard 1.4.1 of the Code to increase the ML for cadmium in peanuts from 0.1 to 0.5 mg/kg, as notified to the Ministerial Council at Final Assessment

The decision to increase the ML for cadmium in peanuts:

- ensures adequate protection of public health and safety based on the best available scientific information. Dietary exposure to cadmium for Australian and New Zealand consumers is well within internationally recognised safe limits;
- is more consistent with the approach used in other developed countries compared with retaining an unnecessarily restrictive current ML;
- will not be an unreasonable cost burden on industry or consumers, but rather it will assist the food industry in achieving continuity of supply of peanuts and peanut-based food products for consumers; and
- While continuing to support current measures to minimise cadmium in agricultural production systems.

9. Implementation and review

The draft variation to Standard 1.4.1 of the Code will come into effect on the date of gazettal.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Executive Summary and Reasons for the Decision from the Final Assessment Report

Draft variation to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting.

To commence: on gazettal

[1] *Standard 1.4.1 of the Australia New Zealand Food Standards Code is varied by omitting from the Table to clause 2, under the heading Cadmium, the entry for Peanuts, substituting –*

Peanuts	0.5
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Executive Summary and Reasons for Decision from the Final Assessment Report

Food Standards Australia New Zealand (FSANZ) received an unpaid Application from the Confectionery Manufacturers of Australasia Limited (CMA) on 15 November 2004 to amend Standard 1.4.1 – Contaminants and Natural Toxicants of the *Australia New Zealand Food Standards Code* (the Code) with respect to the maximum permitted level of cadmium in peanuts. The CMA originally sought an amendment to the Table to clause 2 of Standard 1.4.1 to remove the existing Maximum Level (ML) of 0.1 mg/kg for cadmium in peanuts. However, the CMA amended the original request and advised FSANZ that it would now prefer to increase the ML from 0.1 to 0.5 mg/kg. The CMA claims that this will enable increased flexibility to source peanuts from a variety of countries to meet changes in supply that may result from crop seasonality and product quality.

Following a review of cadmium levels in food in 1997, the then Australia New Zealand Food Authority (ANZFA) recommended a revised ML for cadmium in peanuts of 0.1 mg/kg on the basis that it would not increase the risk to public health and safety and was less likely to be perceived as a non-tariff barrier to trade (than the previous ML of 0.05 mg/kg). Previous policy principles agreed to by the then Australia New Zealand Food Standards Council in July 1997 indicate that contaminant levels in food should be safe and according to the ALARA principle (**as low as reasonably achievable**) which is consistent with the Codex Alimentarius approach to contaminants.

In addition, MLs shall be set: (1) only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade; (2) for those foods that are significant for the total exposure of the consumer to the contaminant; and (3) as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level, which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Therefore, the proposed increased ML of 0.5 mg/kg for cadmium satisfies the above criteria.

In setting an ML, consideration should also be given to Australia and New Zealand's international trade obligations under the World Trade Organization's Sanitary and Phytosanitary (SPS) Agreement and Technical Barriers to Trade (TBT) Agreement.

The risk assessment has concluded that increasing the ML to 0.5 mg/kg will not be a public health and safety issue. The proposed ML is based on the upper range of distribution of cadmium levels in peanuts from the available survey data. Dietary exposure to cadmium in Australia and New Zealand is well below the provisional tolerable weekly intake (PTWI) of 7 µg/kg bw/week even for the highest consumer group (children aged 2-6 years) and is therefore within acceptable safety standards. Peanuts are a minor contributor to overall exposure to cadmium in both Australia and New Zealand. It is recognised that there is a high prevalence of renal disease among Aboriginal and Torres Strait Islander people and concerns have been raised about cadmium exacerbating renal disease. However, the PTWI is also adequately protective of high-risk groups such as Aboriginals and Torres Strait Islanders.

The increase will enable the current shortfall between domestic production and imported peanuts, claimed by the CMA as significant, to be met by imports from a variety of countries, in order to assist specific industry sectors when supplies are short (e.g. during times of drought).

FSANZ received a number of submissions at Draft Assessment that questioned whether or not the current ML is actually a trade barrier to importation of peanuts from other countries. In addition, many of these submissions argued that further justification was needed to quantify the costs to industry if the ML is not increased to 0.5 mg/kg. The CMA has provided further justification to support the increased ML, detailed in Section 7 of the Final Assessment Report.

FSANZ acknowledges that there may be potential costs to Australian industry if the ML is increased. FSANZ also notes that the peanut industry has worked very closely with the Queensland Department of Primary Industries and Fisheries (DPI&F), Commonwealth Scientific Industrial and Research Organisation (CSIRO) and the Grains Research and Development Corporation (GRDC) to develop management guidelines for farmers to ensure Australia's peanut production always meets the current ML for cadmium in peanuts. This considerable investment has delivered safe, high-quality and low cadmium-containing peanuts.

A potential cost that specific Australian industry sectors cited at Draft Assessment was that Australian peanut farmers may choose to use cheaper sources of fertiliser. This would reduce their costs while maintaining high production yields as there would no longer be the requirement to meet the stringent ML of 0.1 mg/kg. It was suggested that these practices may lead to a gradual accumulation of cadmium in the soil and also affect other industries (e.g. fisheries) as a result of agricultural run-off downstream, leading to bioaccumulation in marine life such as prawns, crabs, mussels and other shellfish. However, advice from the Fertilizer Industry Federation of Australia, Inc. (FIFA) to FSANZ is that this is unlikely to occur in practice as the industry has phased out the use of high-cadmium fertilisers under the National Cadmium Minimisation Strategy.

FSANZ considers that issues on fertiliser use are outside of FSANZ's mandate under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Purpose

The Applicant seeks to increase the current Maximum Level (ML) for cadmium in peanuts from 0.1 to 0.5 mg/kg.

Decision

FSANZ has made an assessment and recommends approving the proposed draft variation to Standard 1.4.1 to increase the existing ML for cadmium in peanuts from 0.1 to 0.5 mg/kg.

Reasons for Decision

- the proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act, in particular, it does not raise any public health and safety concerns, it is based on risk analysis using the best available scientific evidence, and helps promote an efficient and internationally competitive food industry;

- FSANZ has conducted an assessment of the safety of cadmium which concludes that the PTWI of 7 µg/kg body weight is adequately protective of consumers. The dietary exposure assessment shows that increasing the current ML from 0.1 to 0.5 mg/kg does not affect public health and safety; and
- the regulatory impact statement concludes that the benefits of the proposed regulatory option outweigh the costs. Adoption of this option will enable the shortfall between domestic peanut production and industry demand to be met by imports, while promoting good agriculture practice, the protection of public health and safety and facilitating trade in peanuts by enabling peanut importers to source peanuts from a wider number of countries.