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**[08–17]**

## **Supporting document 1**

Updated estimates of dietary exposure to 9-tetrahydrocannabinol (THC) and cannabidiol (CBD) from foods containing low THC hemp seed (at Approval) – Proposal P1042

Low THC Hemp Seeds as Food

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### **Executive summary**

Chronic dietary exposure to  $\Delta^9$ -tetrahydrocannabinol (THC) was previously estimated as part of the risk assessment in Applications A360 and A1039. The purpose of the estimates was to calculate potential exposure to THC assuming proposed Maximum Levels (ML) for THC for low THC hemp seed foods. Dietary exposure estimates were compared to the Tolerable Daily Intake (TDI) of THC of 6  $\mu\text{g}/\text{kg}$  body weight (bw). The aim of this exposure assessment was to confirm that the MLs proposed for THC previously are sufficiently protective of consumers. For this purpose, the previous dietary exposure estimates for Australia and New Zealand were updated to incorporate more current national nutrition survey data.

The updated dietary exposure assessment presented in this Proposal confirms that, using the most up-to-date available food consumption data, no Australian and New Zealand population groups examined would exceed the TDI for THC at the mean and 90<sup>th</sup> percentile of estimated dietary exposure. Dietary exposure estimates ranged between 5-26% of the TDI of 6  $\mu\text{g}/\text{kg}$  bw for the Australian and New Zealand populations.

Dietary exposure to THC reported here is lower than that reported previously, most likely due to changes in food consumption patterns in more recent nutrition surveys and the replacement of dairy milks with non-dairy beverages consumption as a more realistic proxy for hemp seed based non-dairy beverage consumption. Dietary exposure estimates are based on conservative assumptions and therefore likely to be overestimates.

Estimates of dietary exposure to cannabidiol (CBD) indicated that consumption of low THC hemp seed foods would not result in any Australian and New Zealand population groups assessed reaching the Lowest Oral Human Therapeutic Dose (LOHTD) for CBD of 2 mg/kg bw/day at the mean and 90<sup>th</sup> percentile of exposure. The maximum estimate of dietary exposure to CBD was <1% of the LOHTD, making even more conservative assumptions than those made for THC exposure. The amount of low THC hemp seed foods that would need to be consumed to reach the LOHTD for CBD is many orders of magnitude higher than is realistically possible.

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# 1 Introduction

The Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) has requested FSANZ to develop a proposal on how, if it was considered appropriate, low- $\Delta^9$ -tetrahydrocannabinol (THC) hemp could be legally designated as a food. FSANZ has interpreted this to be a request for developing a food regulatory measure to permit the sale of foods containing the seeds, or substances extracted or derived from the seeds of low THC hemp.

## 1.1 Previous estimates of dietary exposure to THC by FSANZ

Chronic dietary exposure to THC from low THC hemp seed foods was previously estimated as part of the risk assessment in Applications A360<sup>1</sup> and A1039<sup>2</sup>. The purpose of the estimates was to calculate potential dietary exposure to THC assuming proposed Maximum Levels (ML) for THC within low THC hemp seed foods. Dietary exposure estimates were compared to the tolerable daily intake (TDI) of THC of 6  $\mu\text{g}/\text{kg}$  body weight (bw). Details on how dietary exposure assessments were conducted are provided in the supporting documents to the Applications.

## 1.2 Purpose of this assessment

The aim of the exposure assessment was to confirm that the MLs proposed for THC previously are sufficiently protective of consumers. For this purpose, the previous dietary exposure estimates for Australia were updated to incorporate data from the Australian 2011-12 National Nutrition and Physical Activity Survey (2011 NNPAS). Estimates for the New Zealand population aged 15 years and older were updated with consumption data from the 2008-09 New Zealand Adult Nutrition Survey (2008 NZANS).

## 1.3 Estimates of dietary exposure to CBD

The Forum also requested FSANZ to consider the need to set a cannabidiol (CBD) limit in foods. FSANZ has not previously prepared a dietary exposure assessment for CBD. For the purposes of this assessment, dietary exposure to CBD was estimated using a similar methodology as for THC, as described below.

However, because there is no health based guidance value that is applicable to CBD, estimates of dietary exposure were compared to a 'lowest oral human therapeutic dose' (LOHTD) estimated by FSANZ to be 120 mg/day. This is equivalent to 2 mg/kg body weight/day based on a body weight of 60 kg, used to derive the LOHTD. It should be noted that the LOHTD is not a health based guidance value nor does it represent a dose of CBD that causes unacceptable side effects.

# 2 Food consumption data

Estimates of dietary exposure to THC and CBD were derived using food consumption data from 24-hour dietary recalls, for day 1 only, from the following surveys:

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<sup>1</sup> Application A360 - Hemp as a Novel Food

<http://www.foodstandards.gov.au/code/applications/pages/applicationa360hempasanovelfood/index.aspx>

<sup>2</sup> Application A1039 - Low THC Hemp as a Food

<http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

- *2011-12 National Nutrition and Physical Activity Survey (2011 NNPAS)*<sup>3</sup> a survey of 12,153 respondents aged 2 years and older
- *2008-09 New Zealand Adult Nutrition Survey (2008 NZANS)*<sup>4</sup> a survey of 4,721 respondents aged 15 years and older
- *2002 New Zealand Children's Nutrition Survey (2002 NZCS)*<sup>5</sup> a survey of 3,275 people aged 5-14 years.

As there are no data available on consumption of low THC hemp seeds or seed products, proxy foods were identified and assumed to represent hemp seed and hemp seed product consumption (see Section 0 below). Consumption data represented commodities consumed on their own (e.g. glass of hemp seed based beverage) and when used in a mixed food (e.g. bread made with hemp seed flour), where recipes were applied to determine the contribution from the hemp seed derived ingredients.

For all surveys, dietary exposures were calculated for consumers (i.e. eaters) of foods assumed to contain THC or CBD only on the first day of the survey, giving a more conservative (higher) mean and 90<sup>th</sup> percentile exposure estimate than averaging consumption over a number of days.

*Harvest*, FSANZ's custom built data base risk analysis platform, allows aggregation of each individual's dietary records, and their associated bodyweight data, from each nutrition survey into distributions of dietary exposure from which descriptive statistics can be derived. Distributions provide more certain dietary exposure estimates than those based on point estimates of population food consumption.

## 2.1 Population groups assessed

The Australian and New Zealand populations were broken down, within the limits of the nutrition surveys, into age groups to better characterise the risk associated with potential THC and CBD exposure in children, adolescents and adults. Children may be more likely to exceed a health based guidance value due to their large food consumption compared to their small body weight. Adolescents may also eat large quantities of foods per kilogram of body weight.

Calculations were carried out for the following ages:

- 2-4 years old (2011 NNPAS only)
- 5-14 years old (all nutrition surveys)
- 15 years and older (all nutrition surveys)

**A breakdown of population sample details can be found in**

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<sup>3</sup> ABS: [4363.0.55.001 - Australian Health Survey: Users' Guide, 2011-13](#)

<sup>4</sup> Ministry of Health NZ [Methodology Report for the 2008/09 NZ Adult Nutrition Survey](#)

<sup>5</sup> Ministry of Health NZ [Food NZ Children. Key results of the 2002 National Children's Nutrition Survey](#)

Table 1.

**Table 1: Population sample details for THC and CBD dietary modelling for Australia and New Zealand**

Survey Population	Age group (years)	Respondents (count)	Consumers (count)	Consumers (%)	Consumers Mean Body Weight (kg)
Australia 2011 NNPAS	2-4	495	493	99%	17
	5-14	1594	1589	99%	39
	15 years and above	10064	9999	99%	77
New Zealand 2002 NZCNS	5-14	3275	3267	99%	40
New Zealand 2008 NZANS	15 years and above	4721	4672	99%	79

### 3 Assumptions and scenarios

Proxy foods, market share and technical factors used in this assessment are based on those used for the assessment of A1039, except that dairy milks consumption was replaced with non-dairy beverages consumption as a more realistic proxy for hemp seed based non-dairy beverage consumption.

#### 3.1 Assumptions for consumption data applied to all exposure scenarios

There is currently no information available in national nutrition surveys on consumption of low THC hemp seeds or hemp seed products. Therefore, assumptions were made about how low THC hemp seed foods might be consumed when estimating potential dietary exposure to THC and CBD from low THC hemp seed products. The following foods were identified as proxy foods and assumed to represent potential low THC hemp seed or hemp seed product consumption:

1. Hemp seed flour would be used in a similar manner to flour from all grains (e.g. wheat, barley, rice, corn, rye, oat) and to corn and wheat starches. However, due to the technical limitations of substituting wheat flour with hemp seed flour, only 25% of grains, corn and wheat starches could be replaced by hemp flour
2. Hemp seed protein powder would be used in a similar way to dairy and soy based protein powders
3. Hemp seed oil would be used in a similar way to canola, cottonseed, olive, rice bran, safflower, soybean and sunflower oils
4. Hemp seeds would be used in a similar way to linseed, poppy seed, sesame seed, sunflower seed, chia seed and mustard seed
5. Hemp seed based non-dairy milk would be used in a similar way to legume-based, cereal-based or nut- or seed-based non-dairy milks.

#### 3.2 Assumptions for concentration data

Only limited data on concentration of THC and CBD in Australian or New Zealand low THC hemp seed foods were available as inputs into exposure estimates. The following assumptions were made regarding concentration of THC and CBD in foods:

1. Where proposed MLs were used as inputs, potential dietary exposures to THC were estimated assuming all foods contained THC at the proposed ML.
2. Where proposed MLs were used as inputs it was assumed that were MLs to be established there would be no products on the market with THC levels above the ML.
3. Where analytical data were used as inputs, potential dietary exposures were estimated assuming all foods contained THC or CBD at the highest concentration reported in the analytical survey.
4. Where there were no detections it was assumed that the compound was not present in the food.
5. Hemp seed based non-dairy milk was not analysed. To calculate maximum detected levels it was assumed that 4% of the low THC hemp seed highest reported value was present in the seed based non-dairy milk.

### **3.3 Scenarios**

#### **3.3.1 Maximum Level/Market Share Scenario (THC)**

For this Scenario, the proposed MLs derived for THC adjusted with the factors based on the assumptions for consumption data described above were used as dietary modelling inputs.

As it is unlikely that low THC hemp seeds or hemp seed products would replace all of the foods identified above all of the time a 'market share' factor of 10% was applied to all consumption. This represents a maximum amount of the mainstream commodity (oils, seed, non-dairy milks and flour) that may potentially be replaced by low THC hemp seed foods for the Australian and New Zealand populations.

#### **3.3.2 Highest Detected/ Market Share Scenario (THC)**

For this Scenario, the highest levels of THC from an analytical survey adjusted with the factors based on the assumptions for consumption data were used as dietary modelling inputs. The market share factor was applied the same way as in Maximum Level/Market Share Scenario.

#### **3.3.3 Highest Detected Scenario (CBD)**

For this Scenario, the maximum levels of CBD from an analytical survey adjusted with the factors based on the assumptions for consumption data were used as dietary modelling inputs. However, no market share scenario was applied. In this scenario 100% of foods consumed were assumed to contain CBD at the highest level detected.

## **4 Food chemical concentration data**

### **4.1 THC concentration data**

For the previous applications, no information was available on actual concentrations of THC in foods that could be used as an input into dietary exposure computations, so proposed MLs were used. Briefly, MLs were derived by estimating a maximum concentration of THC in each commodity used to represent low THC hemp seed foods (see Section 0) that would result in consumers being below the TDI for THC, assuming consumption of the commodity at the 95<sup>th</sup> percentile level.

For details refer to the supporting documents from Applications A360<sup>6</sup> and A1039<sup>7</sup>. The proposed MLs from previous applications were used in this Proposal.

In 2015, NSW Health commissioned an analytical survey of low THC hemp seed foods to ascertain the concentrations of a range of phytocannabinoids, including THC, CBD and their precursors, in low THC hemp seed products. A total of 200 samples of low THC hemp seed foods, incorporating hemp protein powder, hemp flour, hemp seed and hemp oil were analysed.

The unpublished results have been provided to FSANZ by NSW Health for the purposes of undertaking this assessment. A summary of THC analytical results and proposed MLs for low THC hemp seed foods is at **Table 2**. Mean THC analytical results were lower than proposed THC MLs; however, maximum analytical values exceeded the proposed MLs for low THC hemp seed oil and protein powder.

Proposed MLs for various commodities likely to contain low THC hemp seed used in the previous Applications were used in this assessment, assuming that were MLs to be established, there would be no products on the market with THC levels above the ML (Maximum Level/Market Share Scenario). Potential dietary exposures to THC were also estimated assuming all foods contained THC at the maximum concentration reported (Highest Detected/Market Share Scenario).

**Table 2: Mean and maximum concentrations and proposed ML (mg/kg) of THC in a range of low THC hemp seed foods**

Food	THC Analytical Concentration (mg/kg) <sup>#</sup>		Proposed THC ML (mg/kg)
	Mean	Maximum	ML
Hemp seed	0.1	2.2	5
Hemp seed oil	6.5	126	10
Hemp seed flour	n/a <sup>*</sup>	nd <sup>&amp;</sup>	5
Hemp seed protein powder	1.0	26	5

<sup>#</sup>all analytical concentrations have been rounded to the nearest whole number or 2 significant figures

<sup>\*</sup>n/a = not applicable

<sup>&</sup>nd = not detected

## 4.2 CBD concentration data

The unpublished CBD results provided to FSANZ by NSW Health were used to undertake a dietary exposure assessment for the purposes of this Proposal. A summary of CBD concentrations in low THC hemp seed foods is provided at

<sup>6</sup> Application A360 - Hemp as a Novel Food

<http://www.foodstandards.gov.au/code/applications/pages/applicationa360hempasanovelfood/index.aspx>

<sup>7</sup> Application A1039 - Low THC Hemp as a Food

<http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

**Table 3.** Maximum CBD concentrations were used as inputs into the dietary exposure calculations (Highest Detected Scenario).

**Table 3: Mean, median and maximum concentrations (mg/kg) of CBD in a range of low THC hemp seed foods**

Food	CBD Analytical Concentration (mg/kg) <sup>#</sup>	
	Mean	Maximum
Hemp seed	0.44	4.9
Hemp seed oil	7.9	23
Hemp seed flour	0.36	2.0
Hemp seed protein powder	0.87	6.3

<sup>#</sup>all analytical concentrations have been rounded to the nearest whole number or 2 significant figures

### 4.3 Concentrations used as inputs to dietary exposure estimates

#### 4.3.1 THC

Final concentrations for THC used as inputs into dietary exposure estimates were based on the assumptions listed in Section 0.0. For the various foods associated market share and technical factors (food factor) to derive exposure scenarios are given in **Table 4**.

**Table 4: THC concentrations used in dietary exposure scenarios for various low THC hemp seed foods**

Food	Concentrations mg/kg		Factors		Scenarios mg/kg	
	Proposed Maximum Level (ML)	Highest Analytical value	Market Share <sup>#</sup>	Food	Maximum Level Market Share Scenario	Highest Detected Market Share Scenario
Hemp seed based non-dairy milk	0.2		0.1	1	0.02	
		2.2 <sup>&amp;</sup>	0.1	0.04 <sup>&amp;</sup>		0.009
Hemp seeds	5	2.2	0.1	1	0.5	0.223
Hemp seed oils	10	126	0.1	1	1.0	12.578
Hemp seed flour	5	0	0.1	0.25 <sup>+</sup>	0.125	0
Hemp seed protein powder	5	26	0.1	1	0.5	2.599

<sup>#</sup>10% of conventional products are replaced with hemp seed products, i.e. the market share is 10%

<sup>+</sup> substituting wheat and other flour with 25% hemp seed flour

<sup>&</sup> hemp seed based non-dairy milk was not analysed. To calculate maximum detected scenario, assumes 4% of the seed value in the hemp seed based non-dairy milk

#### 4.3.2 CBD

Final concentrations for CBD used as inputs into dietary exposure estimates were based on the assumptions listed in Section 0.0. For the various foods associated food factors to derive the exposure scenario are set out in **Table 5**.

**Table 5: CBD concentrations used in dietary exposure estimates for various low THC hemp seed foods**

Food	Concentrations mg/kg		Factors	Scenario mg/kg
	Maximum	Analytical value	Food	Highest Detected Scenario
Hemp seed based non-dairy milk	4.9		0.04 <sup>&amp;</sup>	0.2
Hemp seeds	4.9		1	4.9
Hemp seed oils	23		1	23
Hemp seed flour	2.0		0.25 <sup>*</sup>	0.5
Hemp seed protein powder	6.3		1	6.3

\* substituting wheat and other flour with 25% hemp seed flour & hemp seed based non-dairy milk was not analysed. To calculate maximum detected scenario, assumes 4% of the seed value in the hemp seed based non-dairy milk

## 5 Estimates of dietary exposure

### 5.1 Updated estimates of dietary exposure to THC

#### 5.1.1 Exposure estimates based on proposed ML for THC (3.3.1 Maximum Level/Market Share Scenario)

Dietary exposure estimates for mean and 90<sup>th</sup> percentile consumers of low THC hemp seed foods, assuming concentrations at the proposed ML for these foods, are set out in **Table 6**. Results are given on a µg THC/kg bw/day basis and expressed as a percentage of the TDI for THC of 6 µg/kg bw.

**Table 6: Dietary exposure estimates to THC for mean and 90<sup>th</sup> percentile consumers of low THC hemp seed foods (3.3.1 Maximum Level/Market Share Scenario)**

Survey Population	Age group (years)	Dietary exposure estimates*			
		% TDI	Mean µg/kg bw/day	90th percentile % TDI	90th percentile µg/kg bw/day
Australia 2011 NNPAS	2-4	15	0.9	26	1.5
	5-14	10	0.6	19	1.1
	15 years and above	5	0.3	10	0.6
New Zealand 2002 NZCS	5-14	10	0.6	17	1.0
New Zealand 2008 NZANS	15 years and above	5	0.3	9	0.5

\* Estimates of exposure based on proposed MLs for low THC hemp seed foods

The assessment indicates that it is unlikely that consumers in Australia or New Zealand of low THC hemp seed foods are at risk of exceeding the TDI for THC, assuming all such foods contain THC at the proposed MLs. This holds true for the adult population, children and young children at the mean and 90<sup>th</sup> percentile of dietary exposure. Dietary exposure estimates ranged between 5-26% of the TDI of 6 µg/kg bw for the Australian and New Zealand populations. The highest potential dietary exposure was 1.5 µg/kg bw/day for 2-4 year old Australian children, equivalent to 26% of the TDI, at the 90<sup>th</sup> percentile of exposure.

These dietary exposure estimates for THC based on proposed MLs are lower than previous estimates provided in A1039, which ranged from 14-59% of the TDI with the highest potential dietary exposure 3.5 µg/kg bw/day for 5-14 year old New Zealand children. The decrease in estimated exposure is likely to be due to changes in food consumption patterns in more recent nutrition surveys and the use of legume, cereal, nut and seed based non-dairy beverages as a proxy for hemp seed based non-dairy beverage. Previous assessments had used a proportion of dairy milks consumption to represent hemp seed based non-dairy beverage consumption.

### 5.1.2 Exposure estimates based on reported highest concentrations of THC (3.3.2 Highest Detected/ Market Share Scenario)

Additional dietary modelling based on maximum analytical concentrations of THC in low THC hemp seed foods (refer to **Table 7**) indicated that the TDI could potentially be exceeded at the 90<sup>th</sup> percentile estimate of dietary exposure for Australian children aged 2-4 years (128% of the TDI). Estimated dietary exposure to THC for 5-14 year old Australian children was 98% of the TDI. This indicates that application of the proposed MLs to low THC hemp seed foods is likely to assist in ensuring estimates of dietary exposure do not exceed the TDI for THC.

**Table 7 Dietary exposure estimates to THC for mean and 90<sup>th</sup> percentile consumers of low THC hemp seed foods (3.3.2 Highest Detected/ Market Share Scenario)**

Survey Population	Age group (years)	Dietary exposure estimates*			
		% TDI	Mean µg/kg bw/day	90th percentile % TDI	90th percentile µg/kg bw/day
Australia 2011 NNPAS	2-4	62	3.7	128	7.7
	5-14	43	2.6	98	5.9
	15 years and above	27	1.6	61	3.6
New Zealand 2002 NZCS	5-14	35	2.1	76	4.6
New Zealand 2008 NZANS	15 years and above	23	1.4	52	3.1

\* Estimates of exposure based on highest detections of THC reported for low THC hemp seed foods

### 5.2 Estimates of dietary exposure to CBD (3.3.3 Highest Detected Scenario)

Dietary exposure estimates for mean and 90<sup>th</sup> percentile consumers of low THC hemp seed foods, based on highest analytical concentrations of CBD, are displayed below in **Table 8** on a µg CBD/kg bw/day basis and expressed as a percentage of the LOHTD for CBD of 2 mg/kg bw/day.

**Table 8 Estimated chronic dietary exposures to CBD (3.3.3 Highest Detected Scenario) by consumers of low THC hemp seed foods for various Australia and New Zealand age groups**

Survey Population	Age group (years)	Dietary exposure estimates*			
		% LOHTD	Mean $\mu\text{g/kg bw/day}$	% LOHTD	90th percentile $\mu\text{g/kg bw/day}$
Australia 2011 NNPAS	2-4	<1	9.3	<1	17.5
	5-14	<1	6.4	<1	12.8
	15 years and above	<1	3.7	<1	7.7
New Zealand 2002 NZCS	5-14	<1	4.8	<1	9.4
New Zealand 2008 NZANS	15 years and above	<1	2.8	<1	5.9

\* Estimates of exposure based on highest analytical concentrations for low THC hemp seed foods

The dietary exposure assessment for CBD based on highest analytical concentrations reported indicates that there it is extremely unlikely that consumption of low THC hemp seed foods could result in exposures reaching the LOHTD for any population groups assessed. Estimated dietary exposure to CBD at the 90<sup>th</sup> percentile was highest for Australian children aged 2-4 years, at 17.5  $\mu\text{g CBD/kg bw/day}$ . This is equivalent to less than 1% of the LOHTD for CBD of 2 mg/kg bw/day (2000  $\mu\text{g/kg bw/day}$ ).

### 5.3 Confidence in estimate

It should be noted that dietary exposures to THC and CBD are likely to be overestimated (conservative), for the following reasons:

- Assuming that 10% of all foods consumed from the food groups will contain low THC hemp seed is most likely an overestimate of market share
- The exposure estimates assume that all foods contain THC or CBD at the scenario concentration, the actual THC or CBD levels in the food most likely will be lower
- A single day of food consumption data tends to overestimate habitual consumption of a given commodity, leading to higher estimates of potential dietary exposure than would actually be the case over a long period of time or a lifetime.

### 5.4 Maximum consumption amounts of low THC hemp seed foods to reach the TDI for THC

Calculations were undertaken, based on highest analytical concentrations reported and proposed MLs, to provide an indication of how much of each low THC hemp seed food could be consumed (individually) before the TDI for THC is reached.

**Table 9** shows that based on highest concentration of THC reported the amount of each food that could be consumed before the TDI of 6  $\mu\text{g/kg bw/day}$  (42  $\mu\text{g/day}$  for a 70 kg person) for THC is reached is 20 g/day for low THC hemp seed protein powder and 3 g/day for low THC hemp seed oil. While it is feasible that such amounts of these foods may be consumed, it should be noted that their highest analytical values reported are much higher than the proposed MLs (**Table 2**).

Based on the proposed MLs, the amount of each food that could be consumed before the TDI for THC is reached is larger. Approximately 40 g/day (approximately two tablespoons) of hemp seed oil would need to be consumed every day to reach the TDI and approximately 80 g/day of other foods. These consumption amounts can be compared to the amount of food that has been reported for the adult populations in the Australia 2011 NNPAS and the New Zealand 2008 NZANS. Where more than a quarter of the adult population reported eating the food (i.e. consumer to respondent ratio >25%) the 90<sup>th</sup> percentile consumption amount is suitable as an indication of the amount eaten by a high consumer. Where less than a quarter of the population have eaten the food the median (50<sup>th</sup> percentile) is used instead.

This consumption amount of low THC hemp seed foods that can be consumed before the TDI for THC is reached in all cases exceeds the consumption amount reported for a high consumer of the food. It is also noted that over time consumers would expect to consume low THC hemp seed foods containing THC at a range of values (limit of detection of THC to proposed MLs) as it is highly unlikely that all foods would contain THC at the proposed MLs.

**Table 9 Estimated maximum amounts of low THC hemp seed foods that can be consumed before the TDI<sup>^</sup> for THC is reached**

Food	Maximum amount of hemp seed based food that can be consumed*(g/day)		Consumer to respondent ratio		Consumption for adult population (g/day) <sup>&amp;</sup>		
	Based on highest analytical concentrations	Based on proposed MLs	Australia 2011 NNPAS	New Zealand 2008 NZANS	Percentile used	Australia 2011 NNPAS	New Zealand 2008 NZANS
Hemp seeds	190	80	51%	65%	90	13	9
Hemp seed oils	3	40	91%	83%	90	21	16
Hemp seed flour <sup>+</sup>	N/A <sup>#</sup>	80	98%	98%	90	46	48
Hemp seed protein powder <sup>&lt;</sup>	20	80	10%	6%	50	62	25

<sup>^</sup>TDI of THC is 6 µg/kg bw/day (420 µg/day for a 70 kg person) <sup>#</sup>N/A = no THC detected in low THC hemp seed flour. <sup>\*</sup> Estimated food consumption based on a body weight of 70 kg <sup>&</sup>15 years and older, based on 2011 NNPAS (Australia) and 2008 NZANS <sup>+</sup>assuming only 25% of grains, corn and wheat starches could be replaced by hemp flour. <sup><</sup>Only Protein powders of the sport supplement type are included in consumption estimates

### Maximum consumption amounts of low THC hemp seed foods to reach the LOHTD of CBD

Calculations were undertaken, based on maximum concentrations to provide an indication of how much of each low THC hemp seed food could be consumed (individually) before the LOHTD for CBD of 2 mg/kg bw/day(140 mg/day for a 70 kg person) is reached.

**Table 10** shows that the amount of low THC hemp seed food that could be consumed before the LOHTD for CBD was reached, based on maximum concentrations of CBD found in the analytical survey, is many orders of magnitude higher than that for THC, ranging from 6 kg/day for hemp seed oil to 70 kg/day for hemp seed flour.

It is unrealistic to expect that consumption of any low THC hemp seed food or combination of foods containing CBD would result in any consumers reaching the LOHTD.

**Table 10: Estimated maximum amount of low THC hemp seed foods that can be consumed before a LOHTD<sup>#</sup> for CBD is reached**

Food	Maximum amount of hemp seed based food that can be consumed* (grams/day) CBD Maximum analytical concentration
Hemp seeds	29,000
Hemp seed oil	6,000
Hemp seed flour	70,000
Hemp seed protein powder	22,000

# LOHTD is 2 mg/kg bw/day (140 mg/day for a 70 kg person)

\*Estimated food consumption based on a body weight of 70 kg

## Conclusion

In conclusion, the updated dietary exposure assessment for Proposal P1042 confirmed that, using the most up-to-date available food consumption data, no Australian and New Zealand population groups assessed were likely to exceed the TDI for THC at both the mean and 90<sup>th</sup> percentile of exposure, assuming the proposed MLs were in place. These estimates are based on conservative assumptions about the proportion of the food supply likely to contain low THC hemp seed food products and the concentration levels of THC in those foods, and therefore likely to be overestimates.

Estimates of dietary exposure to CBD indicated that consumption of low THC hemp seed foods would not result in any Australian and New Zealand population groups assessed reaching the LOHTD for CBD of 2 mg/kg bw/day at the mean and 90<sup>th</sup> percentile of exposure. The maximum estimate of dietary exposure to CBD was <1% of the LOHTD, making even more conservative assumptions than those made for THC exposure calculations. The amount of low THC hemp seed food that would need to be consumed to reach the LOHTD for CBD is many orders of magnitude higher than is realistically possible.