



**RISK PROFILE:
CAFFEINE IN ENERGY DRINKS
AND ENERGY SHOTS**

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AND ENERGY SHOTS**

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EXECUTIVE SUMMARY

This Risk Profile addresses the risk from exposure to caffeine from energy drinks and energy shots available in New Zealand against a background dietary exposure from naturally occurring caffeine in foods and beverages and kola type soft drinks.

In the New Zealand diet, caffeine occurs naturally in coffee, tea, cocoa and foods containing these ingredients. Caffeine may also be added to a range of beverages including energy drinks, energy shots, kola type soft drinks and alcoholic beverages. A total of 28 energy drinks and 16 energy shots were identified as available on the New Zealand market at February 2010.

Caffeine has a range of adverse effects. Common acute adverse effects associated with stimulation of the central nervous system following caffeine ingestion include dizziness, rapid heartbeat, irritability, anxiety, tremors and insomnia. Irritation of the gastrointestinal tract can result in diarrhoea, nausea and/or vomiting. Single high doses of caffeine can affect the cardiovascular system causing rapid heart beat and high blood pressure. The risk of high blood pressure associated with coffee consumption may be higher in certain genotypes and in individuals with reduced liver function. Caffeine intake is associated with a slight deterioration in calcium balance, particularly if calcium intake is low. There is limited evidence for caffeine as a carcinogen but results are inconsistent and not conclusive. Caffeine consumption during pregnancy has been associated with an increased risk of foetal growth restriction. No studies have been reported for potential chronic effects of caffeine consumption by children. Tolerance to effects on blood pressure and heart rate, but not to sleep disturbance, develop quickly and virtually completely. Deaths attributed to caffeine consumption are rare.

Moderate daily caffeine intake by healthy adults with adequate nutrition, up to 400 mg/day (5.7 mg/kg bw/day for a 70kg adult) is unlikely to result in adverse effects.

Twenty calls relating to energy drinks and energy shots were recorded at the New Zealand National Poisons Centre in the five year period 2005 to 2009. Minimum and maximum self reported intakes that elicited symptoms of caffeine toxicity were 4.0 mg/kg and 35.5 mg/kg for persons 13 and 14 years of age respectively.

There is currently no recognised reference health standard established for caffeine exposure, such as an Acceptable Daily Intake (ADI). An upper exposure of 2.5 mg/kg bw/day has been suggested as a cautious toxicological limit on which to base risk assessments for children, based on limited evidence. An adverse effect level of 3 mg/kg bw/day for adults is a conservative reference level based on limited evidence of acute anxiety effects. A reference level of 200 mg/day for pregnant women is used in this report and is based on recent evidence of foetal growth restriction.

Baseline dietary exposure to caffeine (including coffee, tea, chocolate, kola type soft drinks and any foods containing these ingredients) was estimated for seven New Zealand population groups based on New Zealand caffeine concentration data for 52 foods and consumption information from the 1997 National Nutrition Survey and the 2002 Children's Nutrition Survey. Most survey respondents consumed products containing caffeine on the surveyed day, with the proportion of caffeine consumers varying from 73 to 96 percent across the

seven population groups. Between two and 38 percent of New Zealand caffeine consumers were estimated to have a baseline dietary caffeine exposure above an adverse effect level of 3 mg/kg bw/day, depending on the population group to which they belonged.

Retail units of energy drinks ranged from 250 to 600 ml resulting in caffeine exposures of 75 to 240 mg caffeine per retail unit. Energy shots ranged from 30 to 120 ml resulting in exposures of 10 to 300 mg caffeine per retail unit consumed.

The estimated caffeine exposure following the consumption of energy drinks or energy shots was calculated for New Zealand children (5-12 yrs), teenagers (13-19 yrs) and young males (19-24 yrs). Scenarios were estimated for consumption of one, two, three or four retail units of any of the energy drinks or energy shots available in New Zealand. Our estimates indicate that approximately 70% of children and 40% of teenagers who consume caffeine are estimated to exceed an adverse effect level of 3 mg/kg bw/day after consumption of a single retail unit of an energy drink or energy shot in addition to a baseline dietary exposure.

Areas of uncertainty are: further products on the market not identified, out-dated consumption and concentration information, inappropriate mapping and caffeine concentration data, weak evidence of adverse effects on which to base safety levels, lack of market share weighting in the risk scenario modeling, inappropriate assumptions with respect to energy drink and energy shot choices and the contribution of caffeinated alcoholic beverages to caffeine exposure.

Risk management options include revision of regulations with respect to the composition and/or volume of energy drinks or energy shots and additional risk communication for children, teenagers, pregnant and caffeine sensitive individuals.

The most significant data gap in this assessment is the lack of current information on consumption of energy drinks and energy shots. There is no current information on how many New Zealanders are consuming which energy drinks or energy shots or how much they are consuming. Further data gaps are the lack of independently verified caffeine levels in energy drinks and energy shots and evidence of health effects of frequent high caffeine intakes for children and adults. For these reasons the present risk to New Zealanders from energy drinks and energy shots cannot be accurately quantified.

GLOSSARY OF TERMS, ABBREVIATIONS AND ACRONYMS

1997 NNS	The (New Zealand) National Nutrition Survey conducted in 1997.
2002 CNS	The (New Zealand) National Children's Nutrition Survey conducted in 2002.
ADI	Acceptable Daily Intake. The amount of a chemical that an individual may consume on a daily basis over a lifetime with no adverse effect to health
caffeinated ¹ beverage	A beverage to which caffeine has been added. May include energy drink, energy shot, kola type soft drink or caffeinated alcoholic beverage.
CNS	Central Nervous System.
energy drink ¹	A beverage containing added caffeine, vitamins and other bioactive substances marketed in retail units typically between 250ml and 600ml.
energy shot ¹	A small volume liquid product containing added caffeine, vitamins and other bioactive substances.
FCT	New Zealand Food Composition Tables.
FSANZ	Food Standards Australia New Zealand.
IARC	International Agency for Research on Cancer
kola type soft drink ¹	A flavoured carbonated beverage containing added caffeine. Caffeine can be added to a maximum level of 145mg/l (Standard 1.3.1 of the Australia New Zealand Food Standards Code)
mg/kg bw/day	A dosage unit of milligrams per kilogram body weight per day.
NIP	Nutrition Information Panel.
NZFSA	New Zealand Food Safety Authority.
QFFQ	Qualitative Food Frequency Questionnaire, a component of the 1997 NNS
RMF	Risk Management Framework.

¹ definitions for the purposes of this report

1 STATEMENT OF PURPOSE

The purpose of a Risk Profile is to provide contextual and background information relevant to a food/hazard combination so that risk managers can make decisions and, if necessary, take further action. Risk Profiles are part of the Risk Management Framework (RMF, <http://www.nzfsa.govt.nz/about-us/risk-management-framework/index.htm>) approach taken by the New Zealand Food Safety Authority (NZFSA). The Framework consists of a four step process, as shown in Figure 1.

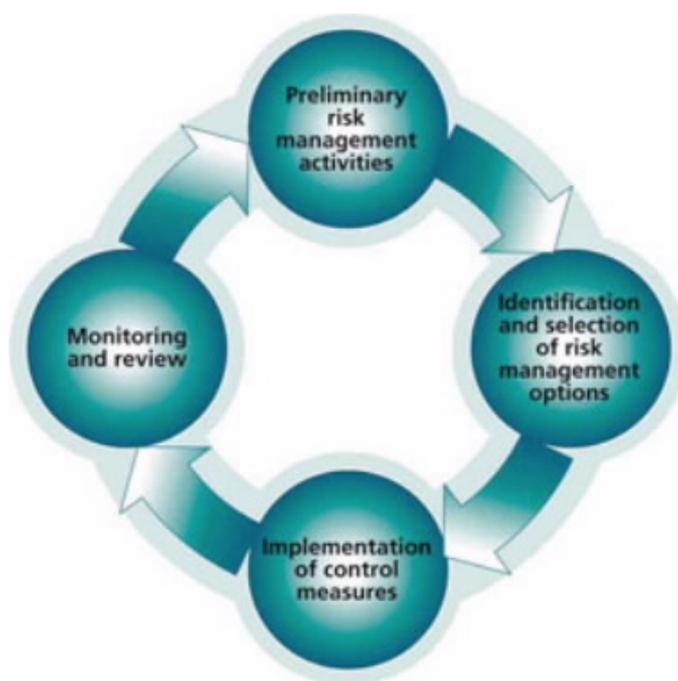


Figure 1: The four steps of the Risk Management Framework

This initial step in the RMF, Preliminary Risk Management Activities, includes a number of tasks:

- identification of food safety issues
- risk profiling
- establishing broad risk management goals
- deciding on the need for a risk assessment
- if needed, setting risk assessment policy and commissioning of the risk assessment
- considering the results of the risk assessment
- ranking and prioritisation of the food safety issue for risk management action.

Risk profiling may be used directly by risk managers to guide identification and selection of risk management options, for example where:

- rapid action is needed
- there is sufficient scientific information for action
- embarking on a risk assessment is impractical.

The sections in this Risk Profile are organised as much as possible as they would be for a conventional qualitative risk assessment, including hazard and food, evaluation of adverse health effects, evaluation of risk, and availability of control measures.

1.1 Hazard/Food Combination and Risk Management Questions

There is current public and regulatory concern regarding the exposure of children to caffeine from beverages to which caffeine has been added. There is now a wide range of energy drinks and energy shots available on the New Zealand market.

NZFSA has commissioned this Risk Profile in order to address the following specific risk management question:

Is any sub group of the New Zealand population at risk of adverse effects from the consumption of energy drinks or energy shots currently available in New Zealand?

This Risk Profile considers the potential risk from the consumption of energy drinks and energy shots in addition to a background exposure from the more traditional food sources of caffeine, namely, coffee, tea, chocolate and kola type soft drinks.

2 HAZARD AND FOOD

2.1 Caffeine

2.1.1 Caffeine structure and nomenclature

Caffeine (CAS 58-08-2) belongs to a class of compounds called methylxanthines. Its chemical structure is shown in Figure 2. Caffeine is found in many plant species and is believed to help protect the plant from insect pests (Nathanson, 1984).

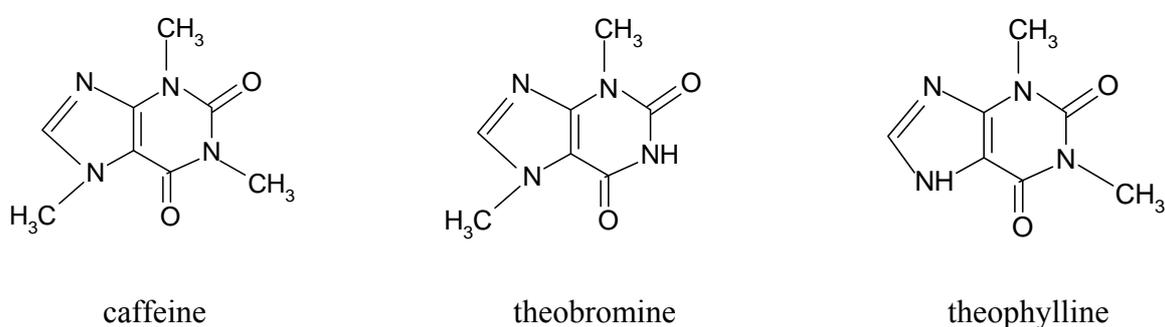


Figure 2: Chemical structures of caffeine, theobromine and theophylline

2.2 Sources of Caffeine

Caffeine is produced commercially by both extraction from plant material and by synthesis (IARC, 1991).

Caffeine is found in more than 60 plant species worldwide, although there are only a few varieties that humans commonly eat (IARC, 1991; Steffen, 2000). Information on plant species and typical levels of caffeine found in them are summarised in Table 1. Caffeine content of plant materials may be affected by genetic and climatic factors, as well as fertiliser use (IARC, 1991). Caffeine content of tea leaves decreases with leaf maturity (Yao *et al.*, 2006).

Guarana is used to refer both to the plant *Paullinia cupana* and the extract from its berries that may be used as an ingredient in energy drinks. The berries of the guarana plant contain large amounts of caffeine (4-8%), as well as significant amounts of the related methylxanthines, theobromine and theophylline (Figure 2) (Babu *et al.*, 2008). Guarana is the richest known natural source of caffeine (Walker *et al.*, 2000).

Table 1: Caffeine content of various plant materials and products

Plant species	Part of plant	Processed form	Typical caffeine content of processed form (%)	Reference
Coffee (<i>Coffea arabica</i>)	Berry/bean	Dried green beans	0.9-1.4	(IARC, 1991)
Coffee (<i>Coffea canephora</i> Var. <i>robusta</i>)	Berry/bean	Dried green beans	1.5-2.6	(IARC, 1991)
Tea (<i>Camellia sinensis</i>)	Leaf	Dried processed leaf	Mean = 3.5 (wide range)	(IARC, 1991)
Cacao (<i>Theobroma cacao</i>)	Bean		0.07-1.7	(IARC, 1991)
Mate (<i>Ilex paraguariensis</i>)	Leaf	Dried	0.5-2.2	(Cardozo Jr <i>et al.</i> , 2007; IARC, 1991)
Guarana (<i>Paullinia cupana</i>)	Berry	Dried	2.0-4.5 3.5-7.0	(Bempong <i>et al.</i> , 1993) (Walker <i>et al.</i> , 2000)
Kola <i>Cola acuminata</i> <i>Cola nitida</i> <i>Cola anomola</i>	Nut	Fresh	0.5-1.6 0.9-1.9 0.4-1.2	(Niemenak <i>et al.</i> , 2008)

2.3 Caffeine in Food and Beverages

In the New Zealand diet, caffeine occurs naturally in coffee, tea, cocoa and foods containing these ingredients. The caffeine content of foods containing naturally occurring caffeine is not regulated.

Caffeine may also be added to a range of beverages including energy drinks, energy shots, kola type soft drinks and alcoholic beverages. Energy drinks and energy shots are beverages containing added caffeine, vitamins and other bioactive substances. For the purposes of this report, larger retail units of 250 ml or more, were considered as energy drinks and smaller retail units of 120ml or less, were considered as energy shots.

Caffeine added to food and beverages in New Zealand is regulated (see 5.1.1). A formulated caffeinated beverage must contain no less than 145 mg/L and no more than 320 mg/L total caffeine, regardless of the source of caffeine (Standard 2.6.4 of the Australia New Zealand Food Standards Code) (FSANZ, 2010). Prior to 31 March 2010 energy shots marketed as Dietary Supplements, had to include caffeine in the ingredient list but did not need to specify the amount of caffeine nor were advisory statements required (New Zealand Legislation, 2007). From 31 March 2010 food type dietary supplements such as energy shots are regulated by the New Zealand Food (Supplemented Food) Standard 2010. This new standard requires caffeine to be listed in the ingredient list and if the supplemented food contains

added caffeine greater than 145mg/L the level of caffeine and the advisory statements that apply to formulated caffeinated beverages regulated under Standard 2.6.4 of the Australia New Zealand Food Standards Code must be included on the label (NZFSA,2010).

Kola type soft drinks, which include Cola, Coke, and Pepsi products, contain added caffeine. The maximum permissible level of caffeine in these soft drinks is 145 mg/L (mg/kg) (Standard 1.3.1, Schedule 1) (FSANZ, 2010). Kola type soft drinks have been included in background exposure to caffeine within this Risk Profile.

The global energy drink market was 3.9 billion litres in 2008 and the market has shown 14% growth over the period 2003 to 2008. Consumption per person, globally, has risen from 0.4 litres in 2003 to 0.8 litres in 2008. North America is the leading region with a 37% share of global volume, followed by Asia Pacific with 30% share, and West Europe with 15% (Zenith, 2010).

2.4 Exposure Assessment

Exposure to caffeine from added caffeine in energy drinks and energy shots occurs against a background exposure from naturally occurring caffeine and kola type soft drinks.

2.4.1 Caffeine concentrations in New Zealand foods and beverages from natural sources and kola type soft drinks

Data on the caffeine content of non-alcoholic beverages, chocolate or cocoa flavoured foods and confectionery are reported in the New Zealand Food Composition Tables (Lesperance, 2009). Most of these data were sourced, or derived, from Australian analytical data (42/48) except for two foods (Milo made with water and self-saucing chocolate pudding) that were calculated from New Zealand data, and three foods (espresso brewed coffee, chocolate éclairs and McDonalds sundae) that were derived from a United States Department of Agriculture database (FOODfiles, 2006). Caffeine concentrations per 100 g (or 100 ml) and caffeine content per serving of food are shown in Appendix 1.

2.4.2 New Zealand data for dietary caffeine concentrations compared with overseas data

A compilation of caffeine levels reported in the open literature, for overseas countries, is shown in Appendix 2. Whilst the majority of these data are from publications in the peer reviewed scientific literature, some government website (NSW Food Authority, 2009) and industry supplied data on caffeine content of energy drinks is also included (Meltzer *et al.*, 2008).

A comparison of the New Zealand and international concentration data for the caffeine content of foods and beverages shows reasonable consistency except for the concentrations of caffeine per serving of latte and espresso (Appendices 1 and 2). For these beverages, the New Zealand levels per serve appear unrealistically high. The New Zealand values for caffeine per serve are extrapolated from a concentration per 100g to a serve of 272 ml (i.e. the caffeine concentration per 100g is multiplied by 272/100). It is likely a serve of latte or espresso is equivalent to a coffee shot, typically of 50-100 mg per shot, rather than a

multiplication factor based on volume. This may account for the apparent difference between New Zealand and overseas data for these two beverages.

The caffeine content of coffee and tea beverages varies greatly depending on the preparation of the beverage. McCusker *et al.* (2003, 2006) reported variabilities expressed as coefficient of variation of 81% and 34% for the caffeine content of the same coffee purchased from the same outlet on different occasions. A comprehensive study of caffeine levels in 400 samples of teas, instant and ground coffee beverages as consumed, was undertaken by the UK Food Standards Agency in 2004. These samples were collected from family homes, workplaces, cafes and restaurants from 10 areas over the UK and measured by validated methodology. This data set provides robust data on the variability of caffeine concentrations, as likely to be encountered by the consumer (FSA, 2004).

2.4.3 New Zealand caffeinated beverages

Information on caffeinated beverages available in New Zealand, and their claimed caffeine content was retrieved by browsing retail outlets, representing both the major supermarket companies, namely Progressive and Foodstuffs, two independent outlets (dairies), two petrol service station outlets and four liquor outlets in Christchurch, augmented with information from NZFSA (Ursula Egan, NZFSA, personal communication, October 2009). Further information was sourced from the Manufactured Food Database (Alannah Steeper, Manufactured Food Database, personal communication, October 2009) from the Energy Fiend website (Energy Fiend, 2009) and other New Zealand websites relating to specific products. The availability of drinks was also confirmed against those analysed by the NSW Food Authority (Ursula Egan, NZFSA, personal communication, October 2009).

As independent analytical data were not available, information on the claimed caffeine content of energy drinks and energy shots are summarised in Table 2. Information on the claimed caffeine content of caffeinated alcoholic beverages and kola type soft drinks are shown in Table 3.

A total of 64 products containing added caffeine were identified as available on the New Zealand market at the present time. These comprised energy drinks (28), energy shots (16), caffeinated alcoholic beverages (5) and kola type soft drinks (15) including multiple flavours and sugar free options when available. In addition, and excluded from product summaries, some products are available in more than one retail unit volume. The caffeinated beverage market is dynamic with online purchasing available. It is possible that additional products are currently being sold in New Zealand that were not captured in this report.

Retail units of energy drinks ranged from 250 to 600 ml resulting in caffeine exposures of 75 to 240 mg caffeine per retail unit consumed. Energy shots ranged from 30 to 120 ml resulting in exposures of 10 to 300 mg caffeine per retail unit consumed. The caffeine dose per retail unit consumed was similar for energy drinks and energy shots.

Caffeinated alcoholic beverages ranged in volume from 250 to 300 ml. These products claimed to contain between 7 and 32 mg/100ml of caffeine. Consumption of any one of these five products would provide between 21 and 96 mg caffeine per retail unit consumed.

Table 2: Claimed caffeine content of energy drinks and energy shots available in New Zealand

Product	Retail Unit Size (ml)	Caffeine concentration (mg/100 ml)	Caffeine per retail unit consumed (mg)	Guarana concentration (mg/100ml)	Reference
<i>Energy Drinks</i>					
Angel Energy Drink	300	32	96	NA	1,2,3,6
Big Cock	440	30	132	NA	1,2,6
Charlie's Vitamin Water, Energy	500	15	75	Ingredient	2
Cocaine	250	32	80	Nil	2
Demon Energy Drink	250 and 500	32	80/160	NA	1,2,3,6
Demon Killa Troppo Energy Drink	500	32	160	NA	1,3,6
Hemp Huge	440	32	141	45	2,6
Ink	500	32	160	120	1,2,4
Monster Original	500	32	160	Ingredient	1,2,3
Monster Ripper	500	32	160	NA	1,2,3
Mother	500	32	160	Nil	1,2,3
Mother Inferno	500	32	160	Nil	1,2,3
NOS Liquid Energy	500	48	240	20	2
Nutrient Water - Passionfruit Citrus	575	14	81	25	2,3
Rasta Blasta	500	32	160	20	2
Red Bull	473	17	80	Nil	1,2,3
Red Bull Sugar Free	473	17	80	Nil	1,2,3
Rockstar Juice	473	32	151	Nil	1,2,3
Rockstar Original	473	32	151	Nil	1,2,3
Rockstar Punched	500	32	151	NA	1,3,6
Supplement Water - Energise	600	17	102	Nil	2,4
Supplement Water - Revive	600	15	90	Nil	2
V Berry	250	31	77	120	2,3
V Black	250 and 500	31	77/155	120	1,2,3,4
V Green	250 and 500	31	77/155	120	2,3,4
V Lemon	250	31	77	500	2,3,4
V Sugarfree	250	31	77	120	2,3,4
Vitaminwater Energy	600	16	96	Ingredient	2,4
<i>Energy shots</i>					
Bacchus D	100	30	30	Nil	2,3
6 Hour Power	60	208	125	Nil	1,6
Clear Shot	60	208	125	Nil	5

Product	Retail Unit Size (ml)	Caffeine concentration (mg/100 ml)	Caffeine per retail unit consumed (mg)	Guarana concentration (mg/100ml)	Reference
Demon Citrus Blast	60	333	200	12	2,3
Demon Tropical Punch'd	60	333	200	12	2,3
Monster Hitman	89	Ingredient	NA	Ingredient	2
NOS Energy Shot	60	416	250	NA	1,6
NOS High Octane	60	333	200	12	2
NOS Supercharged	60	333	200	12	2
Octane	30	33	10	Nil	1,2
Octane Citrus	30	50	15	Nil	2
Reckless Energy Shot	70	178	125	NA	1,6
Red Bull Energy Shot	60	133	80	Nil	1,2,3
Top Flight	60	Ingredient	NA	Nil	5
V Pocket Rocket Energy Shot	60	267	160	Nil	1,2
X Shot	120	250	300	20	5

NA = not available, Nil = none present, Ingredient = present, but amount not specified

1=Energy Fiend, 2009, A website run by caffeine enthusiasts James Foster and Ted Kallmyer, owned by Exis Holdings Limited, a New Zealand corporation that is neither a beverage manufacturer nor lobby group. Caffeine amounts reported on this website were obtained from brand websites, nutrition panels or directly from beverage manufacturers. The site includes links to a number of scientific papers, consumer reports, and governmental sources or reports.

2=Christchurch retail outlets

3=Included in NSW study, October 2009

4=Alannah Steeper, Manufactured Foods Database, personal communication, identifies caffeine and guarana as ingredients but not amounts

5=Ursula Egan, NZFSA, personal communication, 9 November, 2009.

6=New Zealand company websites

Table 3: Claimed caffeine content of caffeinated alcoholic beverages and kola type soft drinks available in New Zealand

Product	Retail Unit Size(s) (ml or g)	Caffeine concentration (mg/100 ml or mg/100 g)	Caffeine per retail unit consumed (mg)	Guarana concentration (mg/100ml)	Reference
<i>Caffeinated Alcoholic Beverages</i>					
Pulse Red	300	32	96	100	1,2
Pulse Blue	300	7	21	150	2
Pulse Green	300	32	96	100	2
Pulse Black	300	9	27	150	2
Vudu	250	31	77	150	2
<i>Kola type soft drinks</i>					
Coca-Cola	250,420,440,600,1500,2250	10	25/250ml	Nil	1,2,3
Coke Zero	250,420,440,600,1500,2250	10	25/250ml	Nil	1,2,3
Vanilla Coke	NA	Ingredient	NA	Nil	3
Diet Coke	200,250,355,420,440,600,1500,2250	10	25/250ml	Nil	1,2,3
Diet Coke Vanilla, Lime, Raspberry	NA	Ingredient	NA	Nil	3
Diet Pepsi	355,1500	Ingredient	NA	Nil	2,3
Frozen Coke	355,1500	Ingredient	NA		2,3
Dr Pepper Cherry	355	39	138	Nil	2
Illigit	1500	Ingredient	NA	Nil	2
Lift Plus	249	15	37	Nil	1,2
Lift Plus Sugar Free	355	14	50	Nil	2
Mountain Dew	1500	14	35/250ml	Nil	2,3
Pepsi- Max	1500	12	30/250ml	Nil	1,2,3
Pepsi Cola	1500	11	27/250ml	Nil	2,3
Royal Crown Draft Premium Cola	340	Ingredient	NA	Nil	2

1=Energy Fiend, 2009,

2=Christchurch retail outlets,

3=Alannah Steeper, Manufactured Foods Database, personal communication, identifies caffeine and guarana as ingredients but not amounts.

NA = not available

2.4.4 New Zealand data for concentrations of caffeine in caffeinated beverages compared with overseas data

Caffeine levels for ten energy drinks available in Ireland ranged from 50 to 80 mg per retail unit (250ml) consumed (Stimulant Drinks Committee 2002).

The caffeine content of energy drinks in Nordic countries, as supplied by the brewery industry, was 15 or 32 mg/100g (equivalent to mg/100ml), equating to 37.5 or 80 mg/250ml serving (Meltzer *et al.*, 2008).

The caffeine content of energy drinks and energy shots in New Zealand, per retail unit consumed, cover a wider range than those from Ireland and the Nordic countries. This could be because many of the energy drinks and energy shots now available in New Zealand did not exist at the time of the work undertaken in Ireland in 2002.

2.4.5 Caffeinated beverage consumption information

It should be noted that the market for caffeinated beverages is relatively recent but rapidly developing. For this reason existing sources of information on the consumption of these products may not be representative of the current situation.

Frequency of consumption of caffeinated beverages in New Zealand

The Qualitative Food Frequency Questionnaire (QFFQ) administered as part of the 1997 National Nutrition Survey (1997 NNS; covering adults 15 years and older) (Russell *et al.*, 1999) did not ask respondents for information concerning their consumption of caffeinated beverages or foods. Examination of the 24-hour dietary recall records from the 1997 NNS, revealed six instances of consumption of Red Bull, with five of these by the same person, and one instance of consumption of V. This would equate to 3/4636 of respondents (0.06%) consuming caffeinated beverages on any day.

The 2002 National Children's Nutrition Survey (2002 CNS; children 5-15 years) (Ministry of Health, 2003) asked questions related to consumption of 'New Age Drinks'. While this food description contains both caffeinated (V, Red Bull) and non-caffeinated (E2, Lift) beverages it can be treated as useful indicative information on potential frequency of consumption of caffeinated beverages. Overall, 7.6% of respondents reported consuming 'New Age Drinks' at least once per week. However, only 0.6% reported consuming these foods daily. Approximately 81% of respondents reported never consuming these beverages or consuming them less frequently than once per month. Of the 'New Age Drinks' listed the most frequently consumed were E2 (39%), V (23%) and Lift (16%). It should be noted that of these three brands only V is definitely caffeinated. Examination of records from the 24-hour dietary recall study gave consistent results with only 0.3% of respondents reporting consumption of caffeinated beverages in the previous 24-hour period. Non-caffeinated 'New Age Drinks' were far more frequently consumed. One respondent reported consuming three servings of a beverage (Burn, no longer on the market) in a 24-hour period. Given that most of the products listed in Table 2 were not reported as consumed, this consumption information is clearly dated and represents a data gap.

Consumption of caffeinated beverages overseas

A 1994 German study of 1265 children aged between 10 and 19 years, indicated that 40% of children aged 10-13 years had tasted stimulant drinks (equivalent to an energy drink or energy shot in this report), with 23% drinking on average one 250 ml can of a stimulant drink per week (Stimulant Drinks Committee, 2002). An Austrian survey in 1999 reported that 45% of respondents 15-50 years had consumed one or more cans of Red Bull during the previous week (Stimulant Drinks Committee, 2002). In an Australian study of 381 children, 27% of males and 12% of females aged between 8 and 13 years old reported having tasted stimulant drinks (O'Dea and Rawstorne, 2000). A study of 1260 individuals, 11-35 year olds, undertaken in Ireland showed that 10% of respondents were regular consumers, with the highest prevalence among those aged 19-24 years (Stimulant Drinks Committee, 2002). The weekly consumption for this group was approximately three cans among consumers, rising to about eight cans among the highest consumers. Similar quantities were consumed in single sessions, suggesting that weekly consumption took place in a single session. This latter finding is important when modelling various consumption scenarios. For the Irish study group, stimulant drinks were frequently consumed with alcohol.

2.4.6 New Zealand baseline dietary exposure estimate for caffeine

New Zealand dietary exposures were estimated for seven population groups using published techniques (Thomson, 2009). Concentration data of foods and beverages containing caffeine (including tea, coffee, chocolate and kola type soft drinks) (Appendix 1) were combined with 24 hour diet recall information from the 1997 NNS and the 2002 CNS using Microsoft Foxpro software. Details of the exposure assessment are provided in Appendix 3.

Most respondents consumed caffeine containing products (Table 4).

Table 4: Respondent numbers and proportion (%) of caffeine consumers for exposure estimates

	Children 5-12 yrs	Teenagers 13-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs *	Older people 65+ yrs	Females 16-44 yrs *	Females 16-44 yrs pregnant
# respondents	2579	803	141	3282	774	1388	64
% respondents consuming caffeine	73	79	78	95	96	92	86

* excluding pregnant women

Exposure estimates for those respondents who consumed caffeine within seven population groups are shown in Table 5.

Table 5: Dietary baseline caffeine exposure estimates for various New Zealand population groups (mg/day).

	Children 5-12 yrs	Teenagers 13-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs*	Older people 65+ yrs	Females 16-44 yrs*	Females 16-44 yrs pregnant
Mean	20	82	277	236	156	226	125
Median	7	41	148	180	140	149	57
Min	<1	<1	<1	<1	<1	<1	<1
Max	644	2664	2220	3785	1998	3256	795
P5	1	1	1	22	33	8	0
P95	74	294	1080	666	354	623	479

P5=5th percentile and P95 = 95th percentiles, representing low and high consumers respectively.

* excluding pregnant women

Since the adverse effect level is expressed in mg/kg bw/day, except for pregnant women, exposure was also calculated in mg/kg bw/day by dividing the exposure (mg/day) by the body weight for each individual (Table 6).

Table 6: Dietary baseline caffeine exposure estimates for caffeine consumers for various New Zealand population groups (mg/kg bw/day)

	Children 5-12 yrs	Teenagers 13-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs *	Older people 65+ yrs	Females 16-44 yrs*	Females 16-44 yrs pregnant
Mean	0.6	1.2	3.5	3.5	2.3	3.4	NA
P95	2.0	4.5	14.4	9.1	5.3	9.6	NA

NA = not available because of changing weight during pregnancy.

P95 = 95th percentile and represents a high consumer.

* excluding pregnant women

The distribution of exposure estimates for each population groups was skewed, with more people having exposures lower than the mean value. This is shown graphically for three population groups (Figures 3-5) with the 95th percentile exposure shown as a reference point.

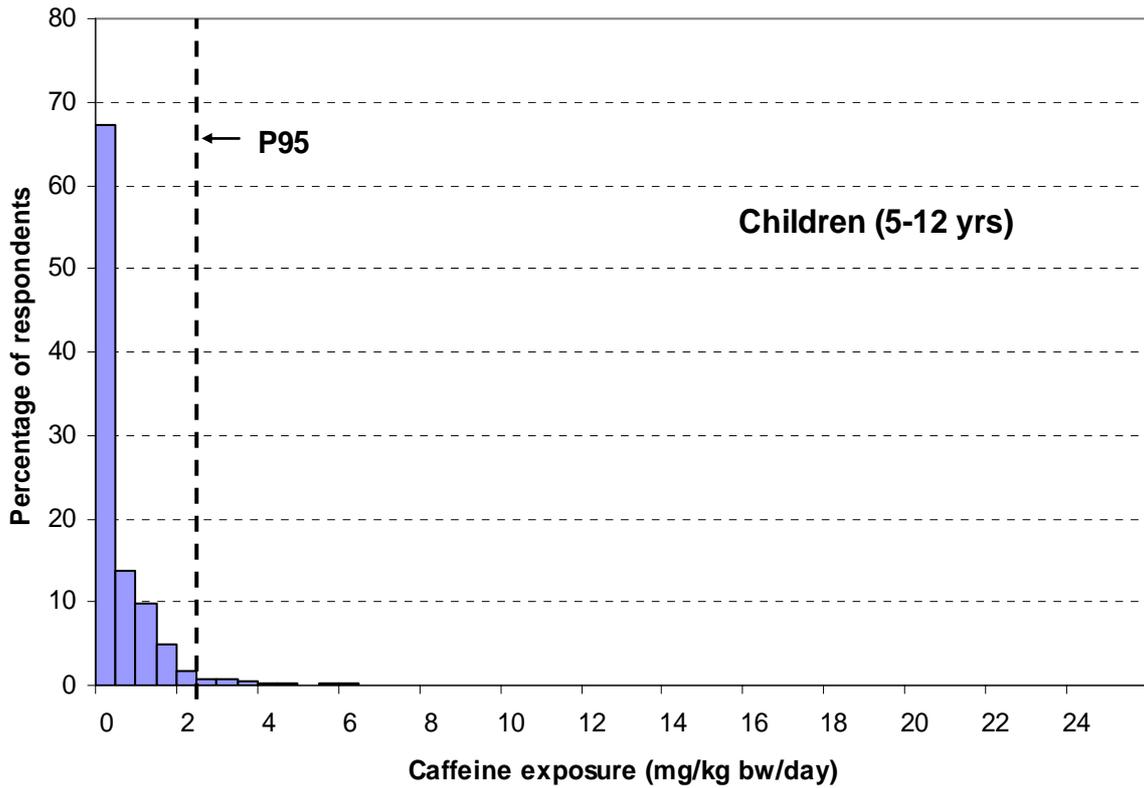


Figure 3 : Distribution of dietary baseline caffeine exposure estimates for children (5-12 yrs)

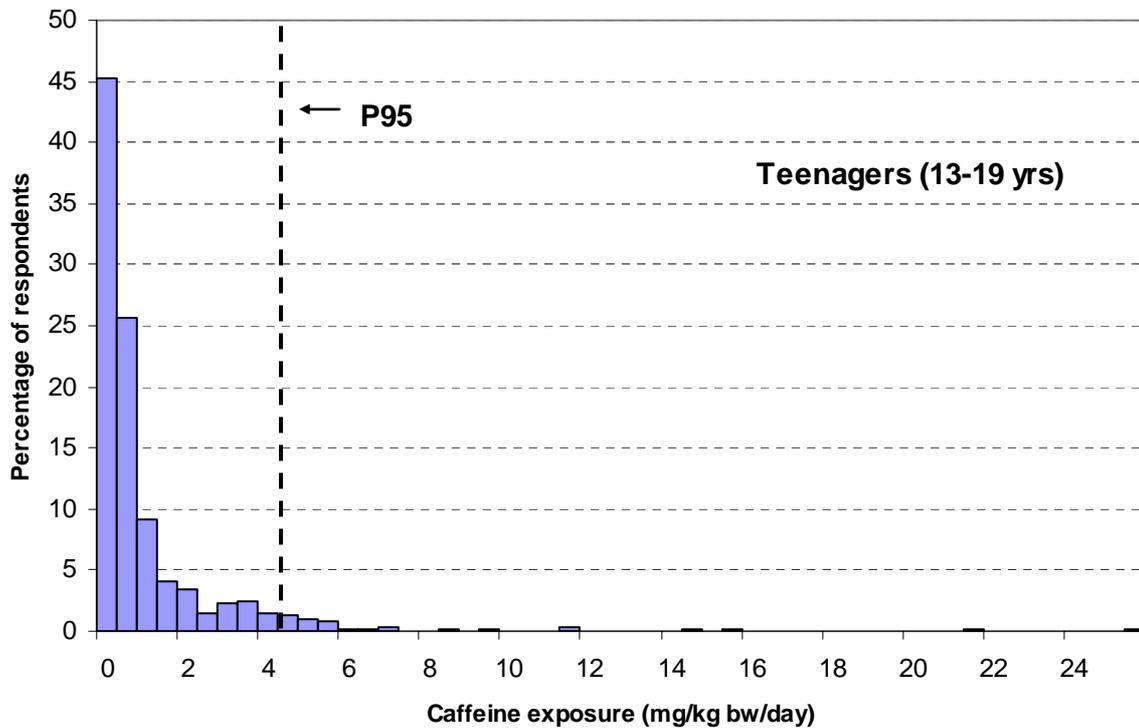


Figure 4: Distribution of dietary baseline caffeine exposure estimates for teenagers (13-19 yrs)

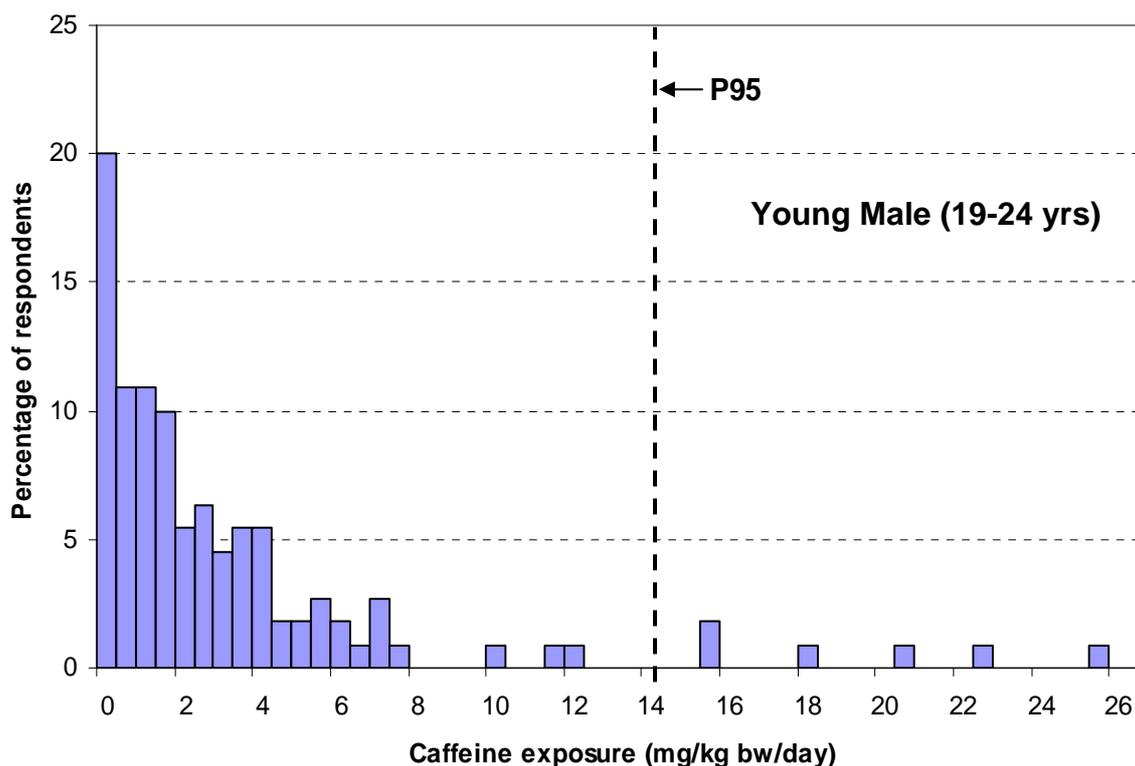


Figure 5: Distribution of dietary baseline caffeine exposure estimates for young males (19-24 yrs)

2.4.7 Overseas estimates of caffeine exposure

Details of estimated caffeine exposures reported in the scientific literature are given in Appendix 4. Average caffeine consumption in the United States and Canada varied from 0.4 to 1 mg/kg bw/day for children, and 1.8 to 3 mg/kg bw/day for adults (Babu *et al.*, 2008; Frary *et al.*, 2005). Average intakes in Argentina were around 1 mg/kg bw/day for children, 3 mg/kg bw/day for teenagers and up to 5 mg/kg bw/day for adults with high consumers estimated to consume up to 13 mg/kg bw/day (Olmos *et al.*, 2009). The average consumption of caffeine in Brazil, across all population groups from 10 to over 60 years was 2.7 mg/kg bw/day (Rojo Carmargo, 1999). In Denmark, average consumption for children and older teenagers (15-19 yrs) was 0.6 and 2.1 mg/kg bw/day respectively. Danish adults consumed, on average about 8 mg/kg bw/day of caffeine with high consumers up to 18 mg/kg bw/day (Barone and Roberts, 1996). Estimates from the UK (1988) were 2 mg/kg bw/day for children and teenagers and about 4.5 mg/kg bw/day for adults, with high consumers exposed to around 8 mg/kg bw/day.

2.4.8 Comparison of New Zealand dietary caffeine exposures with overseas estimates

The New Zealand estimates for average caffeine intake by children are similar to those from the USA (Frary *et al.*, 2005) and Denmark (Barone and Roberts, 1996) but lower than those for Argentina (Olmos *et al.*, 2009) and the UK where mate (a traditional South American drink made from infused dried mate leaves), coffee and tea account for major contributions to

caffeine exposure. For adults, the New Zealand estimates are higher than the more recent assessments from the USA (Frary *et al.*, 2005), similar to those from the UK (Barone and Roberts, 1996), and lower than those for European and South American countries where a coffee culture is more traditional (Barone and Roberts, 1996, Olmos *et al.*, 2009, Rojo Camargo, 1999). The estimate of average caffeine exposure for New Zealand pregnant women (125 mg/day) is in near agreement with the more recent estimate from the UK (159 mg/day) (CARE Study Group, 2008).

2.4.9 Major contributing foods

The major contributing foods for each population group were calculated by summing the caffeine exposure from each food across all consumers in each population group (mg/day) and expressing that sum as a percentage of total caffeine exposure for that population group. The individual foods were grouped into nine broader groups. The relative contributions of these food groups are shown in Table 7.

The 13-15 year and 15-19 year teenagers are presented as two different groups as their consumption information came from two different surveys.

For children (5-12 yrs) and younger teenagers (13-15 yrs), caffeine exposure was mostly from tea and kola type soft drinks with a lesser contribution from coffee. For older teenagers (15-19 yrs) interviewed in the 1997 NNS, and all adults, coffee was the major contributor to caffeine exposure followed by tea. Older people had a greater contribution to caffeine exposure from tea than for other adult population groups but coffee was still the highest contributing food for older people.

Table 7: Percentage contributions of caffeine containing foods to caffeine dietary exposure for different population groups

Food	Children 5-12 yrs	Teenagers 13-15 yrs	Teenagers 15-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs *	Older people 65+ yrs	Females 16-44 yrs *	Females 16-44 yrs pregnant
Biscuits, cakes, pastries	11	6	1	<1	<1	<1	<1	1
Cereal	<1	<1	<1	<1	<1	<1	<1	<1
Choc desserts	1	<1	<1	<1	<1	<1	<1	<1
Chocolate confectionery	6	4	1	<1	<1	<1	<1	1
Cocoa & choc drinks	7	4	1	1	<1	<1	1	<1
Coffee	10	23	73	83	75	61	76	57
Energy drink	2	3	<1	1	<1	<1	<1	<1
Soft drinks	30	32	13	10	3	0	3	2
Tea	32	29	10	5	20	38	19	39

Those food groups contributing 10 or more percent to total caffeine exposure are bolded.

* excluding pregnant women

2.4.10 Potential caffeine exposures from ingestion of energy drinks and energy shots, additional to a baseline dietary exposure for children, teenagers and young males

The exposure to additional caffeine from the consumption of energy drinks and energy shots was calculated for children (5-12 yrs), teenagers (13-19yrs) and young males (19-24 yrs). Scenarios were estimated for one, two, three or four retail units of any of the energy drinks and energy shots identified in Table 2 for which caffeine concentration data were available. Details of the exposure methodology are provided in Appendix 3. Caffeinated alcoholic beverages were not included since these are not legally available for purchase by young people aged less than 18 years.

The distributions of exposures are illustrated in Figures 6-8, for scenarios of one, two, three or four energy drinks or energy shots in addition to baseline dietary caffeine exposure. An adverse effect level of 3 mg/kg bw/day was used as a basis for risk evaluation (see 4.1.1 for details). The area under each curve to the right of the adverse effect line represents the proportion of consumers potentially at risk from adverse effects of caffeine or the probability of a random consumer exceeding the adverse effect level. As expected, there is a much wider range of exposures when four retail units are consumed than for consumption of a single retail unit.

An alternative representation of consumers that are potentially at risk is illustrated by cumulative probability curves (Appendix 5).

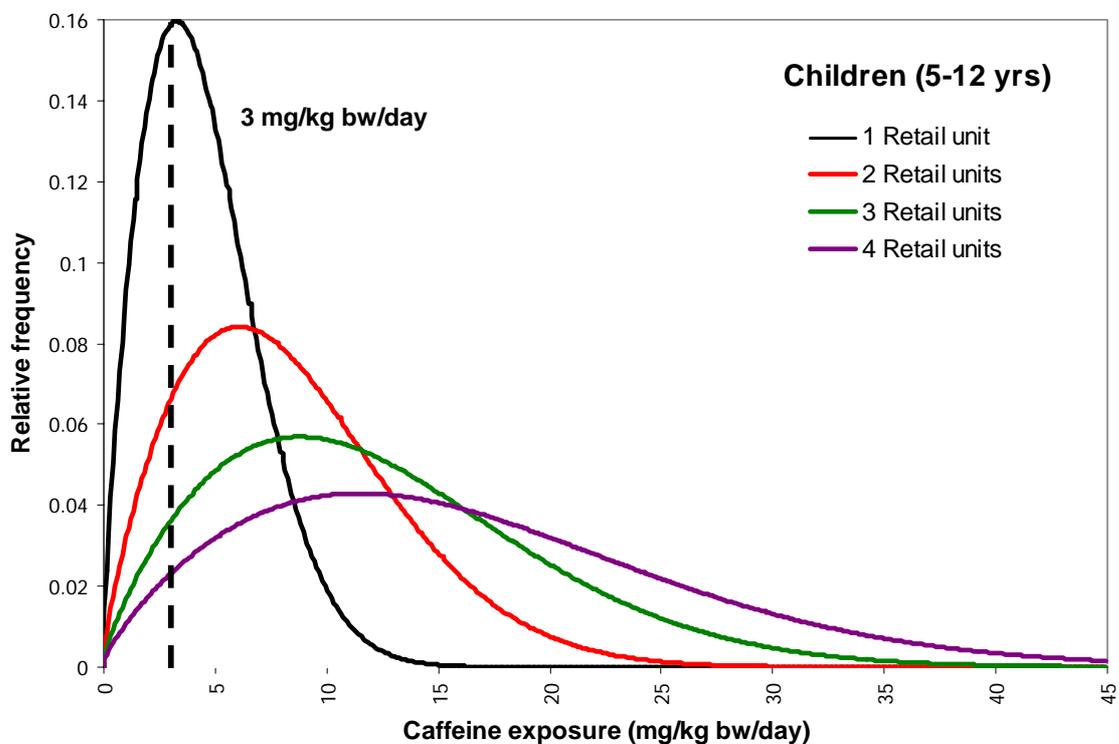


Figure 6: Estimated distribution of exposure for children (5-12 yrs) following the consumption of 1-4 retail units of energy drinks or energy shots.

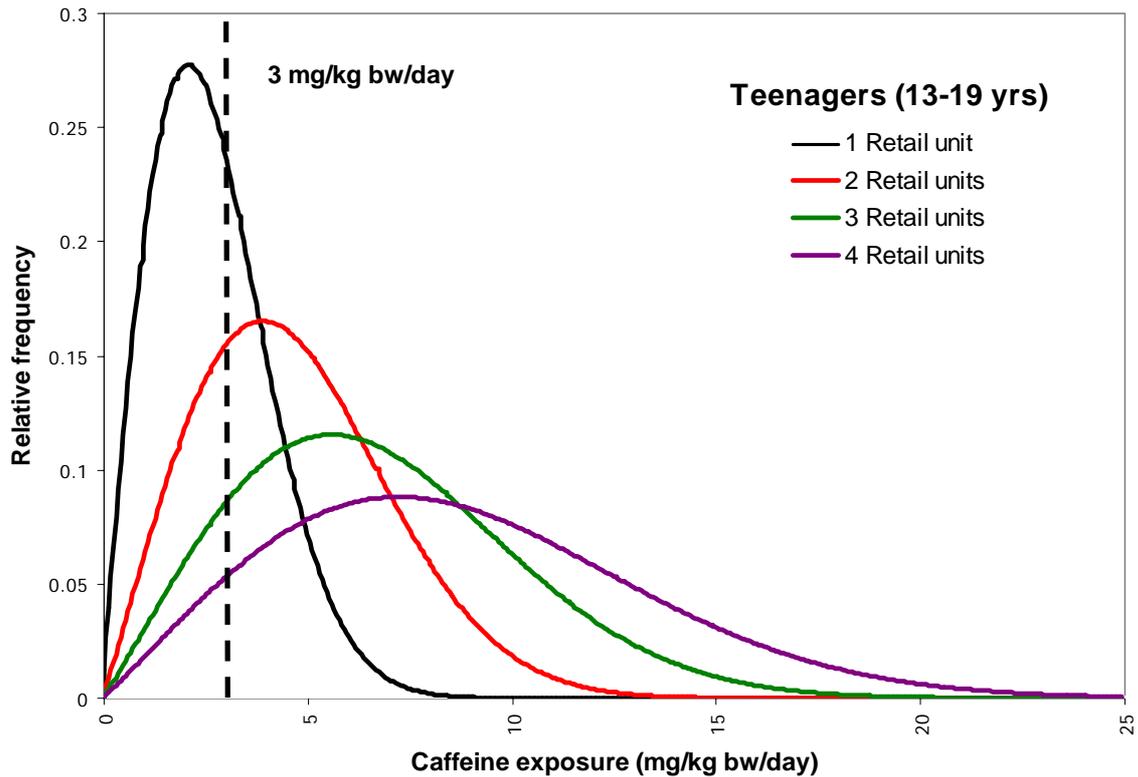


Figure 7: Estimated distribution of exposure for teenagers (13-19 yrs) following the consumption of 1-4 retail units of energy drinks or energy shots.

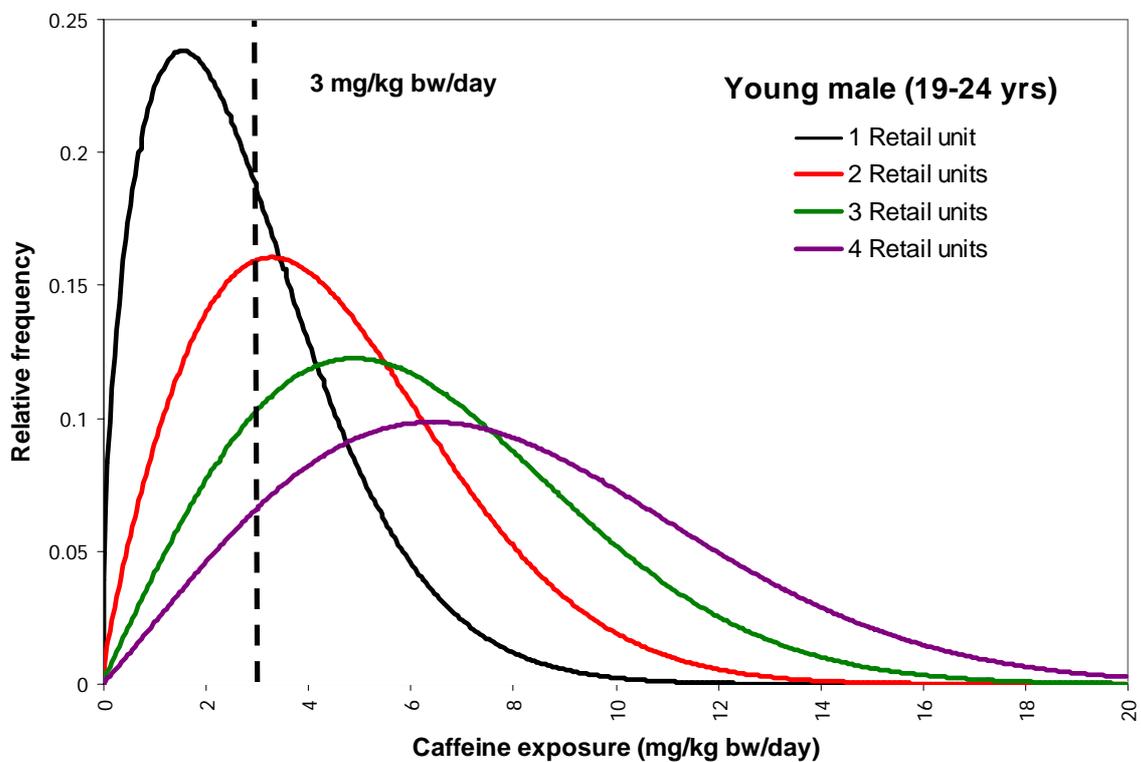


Figure 8: Estimated distribution of exposure for young males (19-24 yrs) following the consumption of 1-4 retail units of energy drinks or energy shots.

The impact of consumption of energy drinks and/or energy shots on mean and 95th percentile caffeine exposures is tabulated in Table 8.

Table 8: Mean and 95th percentile (P95) daily baseline caffeine exposures (mg/kg bw/day) of New Zealand children, teenagers and young males and potential additional exposures if 1-4 retail units of energy drinks or energy shots are consumed

	Children 5-12 yrs		Teenagers 13-19 yrs		Young males 19-24 yrs	
	Mean	P95	Mean	P95	Mean	P95
Baseline	0.6	2.0	1.2	4.5	3.5	14.4
Baseline + 1 retail unit	4.4	9.1	3.2	6.9	5.1	16.9
Baseline + 2 retail units	8.3	17.2	5.2	10.3	6.8	18.1
Baseline + 3 retail units	12.2	25.3	7.2	14.0	8.4	19.7
Baseline + 4 retail units	16.0	33.6	9.2	17.8	10.0	22.1

The mean baseline dietary exposure of children and teenagers to caffeine is low compared with the contribution from the consumption of energy drinks or energy shots.

An individual child (5-12 years), teenager (13-19 years) and young male (19-24 years) would all, on average, exceed the adverse effect level (3 mg/kg bw/day) from a single retail unit of energy drink or energy shot consumed over and above a baseline dietary caffeine exposure.

3 EVALUATION OF ADVERSE HEALTH EFFECTS

3.1 Absorption, Distribution and Pharmacokinetics

Following ingestion, caffeine is rapidly absorbed from the gastrointestinal tract with 99% of ingested caffeine absorbed in humans within 45 minutes after ingestion. Absorption is less complete when caffeine is consumed as coffee (Fredholm *et al.*, 1999). Ingestion of a single cup of coffee provides a dose of 0.4 to 2.5 mg/kg and peak plasma caffeine concentration is reached within 1-1.5 hours of ingestion. Absorbed caffeine is readily distributed throughout the entire body. It passes across the blood-brain barrier, through the placenta into amniotic fluid and the foetus, and into breast milk. Caffeine has also been detected in semen (Nawrot *et al.*, 2003). Saliva concentrations of caffeine reach 65 to 85% of plasma concentrations (Fredholm *et al.*, 1999).

Caffeine is metabolised in the liver. In adults, virtually all caffeine is metabolized to 1-methylxanthine and 1-methyluric acid from a paraxanthine intermediate. Some metabolites, including paraxanthine are pharmacologically active (Nawrot *et al.*, 2003). Caffeine half-lives range from 2.5 to 4.5 hours in humans with no differences in caffeine half-life with age except for newborns, due to their lower cytochrome P-450 activity and the immaturity of some metabolic pathways. In adult males, caffeine half-life is reduced by 30 to 50% (disappears more quickly) in smokers compared with non smokers, whereas it is approximately doubled in women taking oral contraceptives (Fredholm *et al.*, 1999).

3.2 Adverse Effects

Caffeine has a range of pharmacological and psychological effects both beneficial (increased energy, alertness, motivation and concentration) and potentially harmful. The prevalence of caffeine consumption has stimulated both public and scientific interest in potential adverse effects of caffeine and a number of extensive reviews have been published (Nawrot *et al.*, 2003; Smith *et al.*, 2000; Stimulant Drinks Committee, 2002). This section draws on the findings of these reviews with reference to more recent publications where appropriate.

The most important mechanism of action of caffeine is the competitive binding to adenosine receptors, resulting in the release of norepinephrine, dopamine and serotonin in the brain and the increase of circulating catecholamines (Nawrot *et al.*, 2003).

3.2.1 General adverse effects

Ingested caffeine may also irritate the gastrointestinal tract resulting in diarrhoea, nausea and vomiting (Durrant, 2002; Nawrot *et al.*, 2003). Caffeine may reduce bladder control for women (Nawrot *et al.*, 2003).

3.2.2 Central nervous system effects

The most significant effect of caffeine is its role as a potent stimulant of the central nervous system (CNS) although its effects are generally milder and of shorter duration than those of amphetamines (Durrant, 2002). Common adverse effects associated with excessive CNS stimulation from caffeine ingestion include dizziness, rapid heartbeat, irritability, anxiety, tremors and insomnia (Durrant, 2002; Nawrot *et al.*, 2003).

3.2.3 Cardiovascular effects

A single high dose of caffeine (4-6 mg/kg/day, equating to 300-400 mg for an average male) can cause tachycardia (abnormally rapid heartbeat) and increased blood pressure (Stimulant Drinks Committee, 2002). The evidence for an association between habitual caffeine intake and cardiovascular disease is less clear (Stimulant Drinks Committee, 2002). Nawrot *et al.* (2003) concluded that moderate caffeine intake (≤ 400 mg/day) does not adversely affect cardiovascular health but that there was insufficient evidence to draw conclusions about the risk of cardiovascular effects associated with high caffeine consumption (≥ 1000 mg/day). In a recent review of experimental and epidemiological studies, Riksen *et al.*, (2009) postulated that coffee drinking (as a major source of caffeine) may have an acute effect in triggering coronary events, rather than a chronic effect of promoting the development of atherosclerosis in the general population. The risk of high blood pressure associated with coffee consumption varies according to genotype. Individuals with a slow CYP1A2 allele (the key enzyme in caffeine metabolism) are at increased risk of hypertension from coffee whereas individuals with a fast CYP1A2 allele are not (Palatini *et al.*, 2009). Whilst the causal link between genotype and hypertension in this study was clinically based, the association with coffee or caffeine was based on a dietary questionnaire and warrants confirmation. Limited evidence of the prevalence of slow and fast CYP1A2 alleles in the general population was found. In a single study of 229 healthy Chinese, 5% of subjects were poor CYP1A2 metabolizers (Ou-Yang *et al.*, 2000). Assuming “poor” equates to “slow” and a similar prevalence applies to the New Zealand population, 5% of individuals may be at increased risk of acute coronary effects from coffee consumption.

3.2.4 Mutagenicity, carcinogenicity

Although caffeine was reported to induce mutations and inhibit DNA repair in a number of microorganisms and cell lines, it is considered unlikely that at normal levels of exposure, caffeine would result in mutagenic effects in humans (Nawrot *et al.*, 2003).

In 1991, the International Agency for Research on Cancer concluded that caffeine was not classifiable as to carcinogenicity of caffeine to humans (Group3) (IARC, 1991).

Caffeine exposure, as measured by coffee consumption, has been associated with cancer development at some, but not all sites. Overall, the evidence indicates that caffeine, as present in coffee, does not cause bowel cancer. The evidence for caffeine as a carcinogen for bladder and pancreatic cancer is inconsistent and not conclusive. At other sites (ovary, stomach, liver) data are insufficient to conclude that caffeine consumption is related to carcinogenesis (Nawrot *et al.*, 2003). More recently Tang *et al.* (2009) concluded a possible influence of high coffee consumption or increased coffee consumption, on the risk of breast cancer, although the meta analysis is not compelling. Overall, Nawrot *et al.* (2003) concluded that caffeine is not likely to be a human carcinogen when consumed at <500 mg/day.

3.2.5 Pregnancy outcomes and reproductive effects

Caffeine consumption above 200 mg/day was associated with an increased risk of fetal growth restriction (generally measured as low birth weight) with a significant trend for greater reduction in birth weight with higher caffeine intake. This finding held after accounting for maternal age, weight, height, ethnicity, parity, duration of gestation, sex, maternal smoking status and alcohol consumption (CARE Study Group, 2008). Based on the

CARE and other studies, the Committee on Toxicity (COT) concluded that caffeine intake during pregnancy is associated with an increased risk of fetal growth restriction. COT concluded that although there is some uncertainty, it was prudent to assume this relationship was causal. Furthermore, COT concluded that based on current evidence, it is not possible to identify a threshold level of caffeine intake below which there is no elevation of risk, although it seems likely that risk is increased in association with intakes in the order of 200 mg/day and perhaps lower (COT, 2008).

Nawrot *et al.* (2003) concluded, from epidemiological studies, that consumption of caffeine at doses >300 mg/day may reduce women's fertility and increase the risk of miscarriage. The COT review also concluded a positive association of caffeine intake with miscarriage, but there are uncertainties relating to possible recall bias and confounding factors (COT, 2008). In addition, COT concluded that data on caffeine consumption during pregnancy and associations with other adverse effects such as pre-term birth and congenital malformations are inconclusive (COT, 2008).

Based on limited data, caffeine consumption >400 mg/day may decrease sperm motility and/or increase the percentage of dead spermatozoa (in heavy smokers) but is unlikely to adversely affect male fertility in general (Nawrot *et al.*, 2003).

3.2.6 Effects on bone and calcium balance

Caffeine intake is associated with a slight deterioration in calcium balance (Nawrot *et al.*, 2003). Caffeine may be a risk factor for bone fracture but results are inconsistent. The association between caffeine exposure and bone metabolism is complicated by other risk factors for osteoporosis (calcium intake, age, smoking and alcohol consumption). Overall, current evidence suggests that caffeine exposures of <400 mg/day do not have significant effects on bone status or calcium balance in individuals ingesting at least 800 mg calcium per day. Since more than 50% of New Zealand women do not achieve an adequate calcium intake (Russell *et al.*, 1999), those women with a caffeine exposure >400 mg/day may be at risk of adverse calcium balance and impaired bone health.

3.2.7 Effects on children

Only a few studies have considered the adverse effects of caffeine on children and these have mostly included only a small number of subjects. Results are variable. Caffeine has been reported to cause nervousness, jitters, stomach aches and nausea in children (Nawrot *et al.*, 2003; Smith *et al.*, 2000; Stimulant Drinks Committee, 2002). More recently, Luebbe and Bell (2009) reported depression, but not increased anxiety in both children (10-12 years) and teenagers (15-17 years) who consumed caffeine (Luebbe and Bell, 2009). No studies have been reported for potential chronic effects of caffeine consumption by children. Given that the human nervous system (including the brain) continues to develop and mature throughout childhood, it is possible that children may be more sensitive to any adverse effects of caffeine than other population groups (Nawrot *et al.*, 2003).

3.2.8 Death

Death due to excessive caffeine ingestion is not common but cases of death due to caffeine intoxication have been reported (Garriott *et al.*, 1985; Kerrigan and Lindsey, 2005), including cases linked to consumption of caffeinated beverages (Cannon *et al.*, 2001). Pre-existing medical conditions (Cannon *et al.*, 2001), consumption after exercise (Kapner, 2008) or

consumption in combination with alcohol (Kapner, 2008) have been reported as contributory factors in caffeine-related fatalities.

3.2.9 Tolerance, dependence and sensitivity

Tolerance, dependence and sensitivity to caffeine is widely assumed to occur but is poorly documented.

Tolerance develops to some caffeine effects but not to others (Fredholm *et al.*, 1999; Meltzer *et al.*, 2008). Tolerance to effects on blood pressure and heart rate develop quickly and virtually completely. The CNS stimulant effects show partial tolerance while there is little tolerance to the effects on sleep. Although Meltzer *et al.* (2008) cite much variation in tolerances between individuals, it is not clear if this variability relates to the degree, or the time taken, to develop tolerance.

Caffeine meets the criteria for substance dependence defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) with some people compelled to continue caffeine use despite efforts to the contrary (Meltzer *et al.*, 2008). However, dependence is not universally accepted (Satel, 2006). The mechanisms of caffeine dependence are not fully understood.

A variety of withdrawal symptoms are described by most regular caffeine consumers who abruptly halt caffeine consumption, with the most frequent symptom being headaches. Other symptoms include drowsiness, depression, anxiety, fatigue, irritability and lack of concentration (Meltzer *et al.*, 2008). The frequency of withdrawal symptoms is highly variable. Between 11 and 100% of caffeine consumers have claimed to experience withdrawal symptoms on stopping caffeine (Dews *et al.*, 2002). Based on limited evidence, Meltzer *et al.* (2008) reported muscle ache as the predominant withdrawal symptom for 10-12 years olds and headaches to be more common in adolescents. Children consuming high amounts of caffeine were reported to be more angry and unfocused when deprived of caffeine compared with low consumers, implying a dose-response effect for withdrawal symptoms. Withdrawal effects in children can be induced at exposures of 50 mg caffeine (half a cup of coffee) (Dews *et al.*, 2002).

Individuals with compromised liver function, and some individuals who consume caffeine in combination with medications that inhibit caffeine metabolism, are sensitive to caffeine exposure (Smith *et al.*, 2000). No other substantiated sensitivities were identified.

3.3 **Dose Response**

Further to the description of adverse effects covered in the previous section, the doses at which effects from caffeine are observed are summarized as follows:

Fatalities are usually associated with ingestion of caffeine in excess of 5 g, although recovery after ingestion of 30 g has been reported (Nawrot *et al.*, 2003; Kerrigan and Lindsey, 2005). Caffeinism, or caffeine intoxication, may occur with doses greater than 250 mg and can result in symptoms of anxiety (restlessness, nervousness, facial flushing) and diuresis (increased urine production). In a comprehensive review Nawrot *et al.* (2003) concluded that for the healthy adult population, moderate daily caffeine intake at a dose up to 400 mg/day was not associated with adverse effects such as general toxicity, cardiovascular effects, effects on bone status and calcium balance (so long as enough calcium is consumed) behavioural changes, cancer and male fertility. The implication is that habitual daily use of more than

500-600 mg (four to seven cups of coffee or seven to nine cups of tea) is a health risk for healthy adults. However, clinical data concerning health effects of persistent, high caffeine intakes is lacking.

Increased anxiety levels in children (8-12 years) at doses of 2.5 mg/kg bw/day and at 3 mg/kg bw/day in 70kg adults have been reported in a limited number of studies (Bernstein *et al.* 1994; Nickell and Uhde, 1994).

Positive mood effects, such as feelings of increased energy, imagination, efficiency, self-confidence, alertness, motivation and concentration were associated with low doses of caffeine (20-200 mg/day) (Smith *et al.*, 2000; Stimulant Drinks Committee, 2002).

A reduced ability to sleep, for some people, at doses of 100mg (1.4 mg kg bw/day in 70kg adults) at bedtime has been reported (Smith *et al.*, 2000).

A recent longitudinal study of 2635 pregnant women, reported a statistically significant increased risk of foetal growth retardation with caffeine exposures of 200-299 mg/day and above (Care Study Group, 2008). This finding confirmed an earlier conclusion of Nawrot *et al.* (2003).

3.4 Establishment of Safe Limits

There is currently no recognised reference health standard for caffeine exposure, such as an Acceptable Daily Intake (ADI). A number of assessments have been made overseas and exposure limits adopted for different population groups.

3.4.1 General population

In their review, Nawrot *et al.* (2003) concluded that for the general population of healthy adults, moderate caffeine exposure of 400 mg/day (5.7 mg/kg bw/day for a 70 kg adult) is not associated with adverse effects such as general toxicity, cardiovascular effects, changes in adult behaviour, increased incidence of cancer and effects on male fertility.

This level of exposure is higher than an adverse effect level of 3 mg/kg bw/day, (210 mg/day for a 70kg adult) based on observations of increased anxiety, suggested by Smith *et al.* (2000).

3.4.2 Children

Based on limited evidence for altered behaviour, including anxiety (Bernstein *et al.*, 1994), the fact that the nervous system in children is continually developing, and the lack of information on long term effects of caffeine, an upper exposure of 2.5 mg/kg bw/day has been suggested as a cautious toxicological limit on which to base risk assessments for children (Nawrot *et al.*, 2003). Based on these findings, Health Canada recommends a maximum daily caffeine intake of no more than 2.5 mg/kg bw/day for children aged 12 and under (Health Canada, 2007).

Smith *et al.* (2000) proposed a comparable effect level for children based on the same study as Nawrot *et al.* (2003), namely that by Bernstein *et al.* (1994), but rounded this number to 3 mg/kg bw/day.

In a risk assessment of caffeine among children and adolescents in Nordic countries (Meltzer *et al.*, 2008), a no observed adverse effect level (NOAEL) of 0.3 mg/kg bw/day for caffeine tolerance development, and lowest adverse effect levels (LOAEL)s of 1.0-1.25 mg/kg bw/day, 2.5 mg/kg bw/day and 1.4 mg/kg bw/day were identified for tolerance development, anxiety and sleep disturbance respectively.

3.4.3 Reproductive aged women

Reproductive-aged women are a group “at risk” of possible adverse reproductive effects (Nawrot *et al.*, 2003). Health Canada recommends a maximum caffeine exposure of 300 mg, or a little more than two cups of coffee per day (Health Canada, 2010). In November 2008 the UK Food Standards Agency issued new advice on caffeine consumption during pregnancy, advising pregnant women to limit their daily caffeine intake to 200 mg/day (FSA, 2008).

The New Zealand Ministry of Health in its “Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women” advises pregnant and breastfeeding women to limit caffeine consumption to 300mg per day which is roughly equivalent to one large long black, or three cappuccinos, or four cups of plunger coffee, or six cups of instant coffee, or six cups of tea, or 400g of plain chocolate. Breastfeeding women should consider their caffeine intake if the infant is irritable or wakeful. (Ministry of Health, 2006).

3.5 **New Zealand reports of Caffeine Poisoning**

3.5.1 National Poisons Centre

In the five year period from February 2005 to December 2009, the New Zealand National Poisons Centre received 82 calls relating to caffeine containing substances (Lucy Shieffelbien, National Poisons Centre, University of Otago, personal communication, January 2010). Approximately a quarter (20/82) involved the consumption of energy drinks or energy shots. The remainder related to capsules or tablets, most notably No-Doz which accounted for 44/82 calls. The following summary of caffeine calls is based on self reported information

Twenty calls related to the consumption of energy drinks (18 calls) or energy shots (2 calls). Of these, the most prevalent product was the energy drink V. Twelve of the individuals were referred for medical treatment on the basis of these calls. Symptoms presented included vomiting, nausea, abdominal pain, jitteriness, racing heart, and agitation.

Four calls related to instant coffee, three of these by children less than two years old.

Caffeine levels are not available for all 20 energy drink or energy shot calls. The minimum caffeine level available that elicited symptoms was 200 mg, or 4.0 mg/kg of caffeine consumed by a 13 year old patient who presented with jitteriness 15 minutes after consuming one Demon Energy Shot. The maximum volume consumed by any patient was 15 x 250 ml cans, equivalent to 11.5 mg/kg of caffeine for this patient, over a one-hour period. This patient reportedly did not sleep, had a steady slow (rather than the more common quickened) heart rate, minor abdominal discomfort and no chest palpitations. A maximum total intake of caffeine of 1622 mg or 35.5 mg/kg was estimated for a 14 year old (40 kg) who reportedly consumed 14 No-Doz, capsules (1400 mg) plus 600 ml of V energy drink (222 mg).

3.5.2 Additional report

A 23-year-old Auckland mother claims to have lost 45 kg in eight months by drinking only Red Bull, 10-14 cans per day, with a handful of dry cereal. The woman who gained weight during pregnancy found Red Bull was an appetite suppressant and as she was losing weight, continued to drink it. The energy drink habit became an addiction and led to a minor heart attack and two weeks in hospital. The woman suffered severe withdrawal symptoms such as sweating, nausea and shaking and has been left with a residual heart murmur, severe pain and cramping in her stomach and bowel, and anxiety attacks (Medical-News, 2009). This was an extreme diet and the symptoms may not have been related to the energy drink *per se*.

4 EVALUATION OF RISK

4.1 Estimate of Risk for New Zealand

4.1.1 Adverse effect levels applied to New Zealand exposures

In the absence of a recognised reference health standard for caffeine, the estimated exposures from caffeine-containing foods were compared with an adverse effect level of 3 mg/kg bw/day for all population groups except pregnant women for whom an adverse effect level of 200 mg/day was applied. An adverse effect level of 3 mg/kg bw/day for children is consistent with international reviews (Nawrot *et al.*, 2003; Smith *et al.*, 2000). An adverse effect level of 3 mg/kg bw/day for adults is a conservative reference dose based on acute anxiety effects (Nickell and Uhde, 1994) and adopted by Smith *et al.*, (2000) but is less than recommendations by Health Canada (see 5.2.1). A reference dose of 200 mg/day for pregnant women is based on recent evidence of an association between caffeine exposure and foetal growth restriction (Care Study Group, 2008) and is a little more conservative than the earlier conclusions drawn by Nawrot *et al.*, (2003).

4.1.2 Comparison of baseline dietary exposure to caffeine with adverse effect level

The exposure of each individual assessed in the exposure assessment, as described in Section 2.4.6 and summarised in Tables 5 and 6, was ranked. The proportion of consumers exceeding an adverse effect level of 3 mg/kg bw/day, or 200 mg/day for pregnant women, from dietary sources excluding energy drinks or energy shots, was calculated as a percentage of all caffeine consumers and as a percentage of all respondents (including those who did not consume caffeine) (Table 9).

Table 9: Proportion (%) of caffeine consumers and respondents with estimated baseline dietary exposure to caffeine greater than caffeine adverse effect levels for different population groups

	Children 5-12 yrs	Teenagers 13-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs *	Older people 65+ yrs	Females 16-44 yrs *	Females 16-44 yrs pregnant
% consumers >adverse effect level**	2	11	35	37	27	38	25
% respondents >adverse effect level**	2	8	28	35	26	35	22

* excluding pregnant women

**An adverse effect level of 3.0 mg/kg/day was applied (Smith *et al.*, 2000) for all population groups except for pregnant females where an adverse effect level of 200 mg/day was applied.

4.1.3 Impact of caffeinated beverages on caffeine exposure relative to adverse effect level

Further to Section 2.4.10, the proportion of children (5-12 yrs), teenagers (13-19 yrs) and young males (19-24 yrs) estimated to exceed an adverse effect level of 3 mg/kg bw/day, hence potentially be at risk from adverse caffeine effects, following the consumption of one, two, three or four retail units of either an energy drink or an energy shot is given in Table 10.

Table 10: Proportion (%) of New Zealand children, teenagers and young males with potential caffeine intakes above an adverse effect level of 3mg/kg bw/day if one - four retail units of energy drinks or energy shots are consumed

	Children 5-12 yrs	Teenagers 13-19 yrs	Young males 19-24 yrs
Baseline	2	11	35
Baseline + 1 retail unit	68	42	62
Baseline + 2 retail units	89	77	84
Baseline + 3 retail units	94	89	92
Baseline + 4 retail units	95	93	95

At a population level, approximately 70% of children and 40% of teenagers who consume caffeine are estimated to exceed an adverse effect level of 3 mg/kg bw/day after consumption of a single retail unit of an energy drink or energy shot in addition to a baseline dietary exposure.

4.2 Uncertainties and Data Gaps

4.2.1 Uncertainties

There are uncertainties and limitations in the baseline exposure estimates relating to mapping and variability in concentration data that are common to any exposure assessment utilizing mean concentration data and 24 hr diet records (see Appendix 3.1.2). Of particular note, it is now 13 years since the 1997 NNS was undertaken. Consumption choices, amounts and available products are likely to have changed over this period, introducing a level of uncertainty in the baseline dietary exposure assessments.

With respect to food concentration data used in this exposure assessment it was assumed that food concentrations of Australian foods purchased in 2002 are the same as for New Zealand foods. This is probably reasonable but the range of products now available will be different. Given that tea, coffee, kola type soft drinks and chocolate flavoured bakery goods are major contributing foods to baseline caffeine exposure, the concentration values used for these foods is particularly important.

The energy drink and energy shot market is dynamic with online purchasing available. It is possible that additional products are currently available in New Zealand that were not captured in this report.

Information on the relative market share for different energy drinks and energy shots was not factored into the exposure scenarios presented. However the assumption used in the scenarios that they are equally likely to be chosen for consumption may not be correct.

The absence of information on current consumption practices necessitated assumptions of no product bias if multiple retail units were consumed, that a full retail unit was always

consumed and that baseline caffeine preferences did not influence consumption of energy drinks or energy shots. There is an element of uncertainty in these assumptions.

Caffeine from alcoholic beverages and Ready to Drink (TD) products containing kola type soft drinks were not included in the exposure scenarios, since alcohol sales are illegal for persons under 18 and alcohol consumption is not encouraged in persons under 18. Neither is the frequency and prevalence of consumption of these products known. Thus the caffeine estimates for individuals consuming either caffeinated alcoholic drinks or RTDs containing kola type soft drinks are underestimated. Since three of the caffeinated alcoholic beverages claimed to have caffeine levels similar to energy drinks, these products are likely to be a significant source of caffeine to those who drink them.

4.2.2 Data Gaps

The priority area of uncertainty in assessing the proportion of the New Zealand population at risk of adverse effects from the consumption of caffeinated beverages currently available in New Zealand is due to the lack of information on current consumption patterns of energy drinks and energy shots in New Zealand. Information on the frequency of consumption, the number of products that may be consumed at any one drinking event and whether energy drinks or energy shots are consumed with alcohol or not, is all lacking. Therefore it is not possible to determine with precision whether any sub-groups of the New Zealand population are at risk currently of adverse effects from caffeine. The scenario simulations indicate that the consumption of one energy drink or energy shot may exceed the adverse effect level of 3 mg/kg bw/day. Limited overseas evidence suggests that perhaps 20% of people under the age of 19 may consume one energy drink or energy shot per week and high consumers may drink up to 8 retail units in a session (Stimulant Drinks Committee, 2002). Limited, and uncorroborated, New Zealand reports indicate some individuals consume up to 15 retail units per session (see sections 3.5.1 and 3.5.2 above).

The contribution of energy drinks and energy shots to caffeine exposure is based on claimed concentrations. There is no independent laboratory data on actual caffeine levels in these products and this represents a data gap.

Current adverse effect levels for children are based on single studies of acute anxiety effects. There is a lack of data concerning health effects of frequent, high caffeine intakes. Further evidence of adverse effects, both acute and chronic, for children and adults would strengthen the evidence and confirm the appropriateness of the adverse effect levels.

5 AVAILABILITY OF CONTROL MEASURES

5.1 Existing Control Measures in New Zealand

5.1.1 Regulatory

Levels of naturally occurring caffeine in coffee, tea and chocolate products are not regulated, and the level of caffeine from these sources is not required on nutrition information panels (NIPs).

Caffeine added to food and beverages is regulated in Standard 1.3.1 ‘Food Additives’ and Standard 2.6.4 ‘Formulated Caffeinated Beverages’ of the Australia New Zealand Food Standards Code. The maximum amount of caffeine permitted in kola type soft drinks is 145 mg/L (mg/kg) (Standard 1.3.1, Schedule 1 of the Australia New Zealand Food Standards Code). A formulated caffeinated beverage must contain no less than 145 mg/L and no more than 320 mg/L total caffeine, regardless of the source of caffeine (Standard 2.6.4 of the Australia New Zealand Food Standards Code). Standard 2.6.4 also prescribes that the quantity of caffeine and advisory statements to the effect that the food contains caffeine and is not recommended for children, pregnant or lactating women, and individuals sensitive to caffeine be included on the label.

Prior to 31 March 2010, energy shots marketed as Dietary Supplements had to include caffeine in the ingredient list, but did not need to specify the amount of caffeine, nor were advisory statements required (New Zealand Legislation, 2007). From 31 March 2010, food type dietary supplements such as energy shots are regulated by the New Zealand Food (Supplemented Food) Standard 2010 (NZFSA, 2010). This new standard requires caffeine to be listed in the ingredient list. If the supplemented food contains added caffeine greater than 145mg/L, the level of caffeine, and the advisory statements that apply to formulated caffeinated beverages regulated under Standard 2.6.4 of the Australia New Zealand Food Standards Code, must be included on the label.

If *Paullinia cupana* or guarana is added as a food ingredient in New Zealand foods the label must include an advisory statement to the effect that the product contains caffeine (Standard 1.2.3 of the Australia New Zealand Food Standards Code). The label on the package of a supplemented food containing guarana must include an advisory statement to the effect that the supplemented food contains caffeine (NZFSA, 2010).

Whilst the concentration of caffeine in kola type soft drinks and formulated caffeinated beverages is regulated, there are no regulations on the volume (pack size) of retail units (hence dose of caffeine consumed per retail unit).

5.1.2 Advisory

The following advisory statement to pregnant women is published on the NZFSA website: “Drinks containing caffeine, including coffee, teas and colas, should be limited during pregnancy. You may want to consider giving up caffeine altogether. Have no more than six cups of tea or instant coffee, or three espresso-style coffees daily. Energy drinks and ‘smart drinks’ are not recommended as they may contain high levels of caffeine and other ingredients not recommended for pregnant and breastfeeding women” (NZFSA, 2009).

The following advisory to pregnant women is issued by the New Zealand Ministry of Health to pregnant women:

“Limit drinks containing caffeine, such as coffee, tea and cola drinks. Have no more than six cups of tea or instant coffee (or three ‘single’ espresso-type coffees or one ‘double’ espresso-type coffee) each day” (Ministry of Health, 2008).

5.2 Existing Control Measures Overseas

5.2.1 Canada

Health Canada recommends:

“For children age 12 and under, Health Canada recommends a maximum daily caffeine intake of no more than 2.5 milligrams per kilogram of body weight. Based on average body weights of children, this means a daily caffeine intake of no more than:

- 45 mg for children aged 4 - 6;
- 62.5 mg for children aged 7 - 9; and
- 85 mg for children aged 10 - 12.

Those recommended maximums are equivalent to about one to two 12-oz (355 ml) cans of cola a day.

Health Canada has not developed definitive advice for adolescents 13 and older because of insufficient data. Nonetheless, Health Canada suggests that daily caffeine intake for this age group is no more than 2.5 mg/kg body weight.”

“For women of childbearing age, the recommendation is a maximum daily caffeine intake of no more than 300 mg, or a little over two 8-oz (237 ml) cups of coffee.

For the rest of the general population of healthy adults, Health Canada advises a daily intake of no more than 400 mg” (Health Canada, 2010).

5.2.2 United Kingdom

In November 2008, the UK FSA issued new advice to pregnant women to limit caffeine consumption to 200 mg/day. The Agency had previously recommended a maximum daily intake of 300 mg but reduced this limit on the basis of new evidence, including, but not only, the CARE Study (Care Study Group, 2008; FSA, 2008).

5.2.3 USA

In a review of caffeine undertaken in 1978, the US Select Committee on GRAS Substances (SCOGS) concluded that “While no evidence in the available information on caffeine demonstrates a hazard to the public when it is used in cola type beverages at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. It is inappropriate to include caffeine among the substances generally recognized as safe (GRAS)” (FDA, 1978). Thus they conclude caffeine is GRAS for cola type beverages but not generally.

The US Food and Drug Administration (FDA) has listed caffeine as GRAS as an ingredient in cola-type beverages in concentrations of no greater than 200 parts per million (mg/kg or 20 mg/100ml). In November, 2009, the FDA announced plans to look into the safety of caffeinated alcoholic beverages (FDA, 2009).

5.2.4 European Food Safety Authority (EFSA)

The EU Directive 2002/67/EC on the labelling of foodstuffs containing quinine, and of food stuffs containing caffeine, requires that beverages, other than those based on coffee or tea, containing more than 150 mg/l (15 mg/100ml) caffeine should be labelled “high caffeine content” and the exact amount present indicated on the label. It also required that where caffeine is used as flavouring in a foodstuff it must be listed in the ingredient list. (EC, 2002).

Caffeine was evaluated by the European Commission Scientific Committee for Food in relation to its presence in “energy” drinks in 1999 and 2003. The 1999 opinion was upheld in 2003, “For caffeine, it was concluded that the contribution of “energy” drinks to overall caffeine intake was not a matter of concern for non-pregnant adults. For children who do not normally consume much tea or coffee, and who might substitute “energy” drinks for cola or other soft drinks, consumption of “energy” drinks might represent an increase in daily caffeine exposure compared with their previous intake. The Committee considered that this could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. For pregnant adults, the Committee concluded that while intakes of caffeine up to 300 mg/day appeared to be safe, the question of possible effects on pregnancy and the offspring at regular intakes above 300 mg/day remained open. This suggested that moderation of caffeine intake, from whatever source, was advisable during pregnancy” (SCF, 2003).

5.2.5 Finnish Food Safety Authority (Evira)

The Finnish Food Safety Authority, Evira, considers the moderate consumption of caffeine is unlikely to present any health risks for most people but that the stimulatory effect of caffeine is very individual lasting from a few to many hours depending on the dose and the person’s metabolism.

Evira considers that labelling according to Directive 2002/67/EC, that a drink that contains more than 150 mg/l (15 mg/100ml) of caffeine from any source must be labelled “high caffeine content”, is not sufficient to protect the most sensitive consumers. Evira requires that drinks, confectionery, chewing gums, chocolate bars and other similar products and food supplements containing added caffeine must also be labeled “Not recommended for children, pregnant women or people sensitive to caffeine”. The drinks and confectionery must also precisely declare the maximum amount to be used daily, for example, “a maximum of two cans per day” (Evira, 2010).

5.3 Control Options

Caffeine exposure could be controlled further by regulation and/or risk communication.

Options could include regulating the permissible volume of a caffeinated beverage, thus limiting the dose per retail unit consumed. No international precedent for this option was noted.

The maximum permissible concentration of caffeine in caffeinated beverages could be lowered.

Advisory information with respect to an amount of caffeine or amounts of caffeine containing foods, for different population groups, represents an option for risk communication. Aside from product labelling requirements current advisory statements in New Zealand are limited to pregnant women.

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APPENDIX 1: Concentration of Caffeine In New Zealand Foods (NZ Food Composition, 8th Edition, 2009)

Food	Caffeine concentration (mg/100g)	Serve/ unit (g)	Caffeine concentration mg/serve
<i>Bakery products</i>			
Biscuit, 'Afghan'	4	1 biscuit/ 17	1
Biscuit, chocolate base, 'Digestive/Wheat'	8	1 biscuit/ 10.5	1
Biscuit, chocolate coated	8	1 biscuit/ 10.5	1
Biscuit, chocolate coated, 'Mallowpuff'	8	1 biscuit/ 21.5	2
Biscuit, chocolate coated, 'Toffee Pop'	8	1 biscuit/ 17	1
Biscuit, cookie, chocolate chip	8	1 biscuit/ 13	1
Biscuit, peanut brownie, commercial	4	1 biscuit/ 12	1
Cake, chocolate, standard	3	1/8 cake/ 79	3
Cake, chocolate, butter icing	3	1/8 cake/ 79	3
Cookies, 'Cookie Time', original	12	1 biscuit/ 92	11
Lamington, chocolate	3	140	5
Muffin, chocolate	3	60	2
Eclairs w/ choc. icing & cream filling	2	1 éclair/ 42	1
<i>Beverages, non alcoholic</i>			
Lucozade	0	1 cup/ 264	0
Milo, made with trim milk	T	1 cup/ 280	1
Milo, made with water	T	1 cup/ 255	1
Milo, powder	10	1 tsp/ 2.5	T
Nesquik, powder	10	1 tsp/ 2.5	T
Chocolate, drinking, powder	51	1 tsp/ 2.5	1
Cocoa, powder	227	1 tsp	4
Coffee, cafe latte, caffeinated	99	1 cup/ 272	269
Coffee, espresso brewed	212	1 cup/ 272	577
Coffee, decaffeinated	160	1 tsp/ 1.8	3
Coffee, instant	3700	1 tsp/ 1.5	56
Fruit Drink, 'V Drink'	28	1 can/ 250 l	72
Soft drink, 'Cola-Diet'	14	1 can/ 350	49
Soft drink, 'Coca-Cola'	9	1 can/ 355	33
		1 bottle/ 500	46
Tea, Indian, infused	22	1 cup/ 251	55
<i>Chocolate confectionery</i>			
Bounty bar, Cadbury	16	1 bar	8
Crunchie bar, Cadbury	16	1 bar	8
Kit Kat, Nestle	16	1 finger/ 12	2
Mars bar	16	1 bar/ 60	10
Pinky bar, Cadbury	16	1 bar/ 45	7
Chocolate, Cadbury, 'Moro',bar	16	1 bar/ 70	11
Chocolate, candy coated, 'Pebbles' etc	16	10 pieces/ 9	1
Chocolate, dark	59	1 cup, grated/ 88	52
Chocolate, white	5	1 cup, grated/ 88	4
Chocolate bar, milk	20	1 large bar/ 120	24
		1 small bar/ 50	10
Chocolate bar, with peanuts	16	1 slab/ 52	8

Food	Caffeine concentration (mg/100g)	Serve/ unit (g)	Caffeine concentration mg/serve
Chocolates, fancy and filled	16	1 chocolate/ 5	1
<i>Chocolate flavoured products</i>			
Chocolate coated Ice cream, 'Jelly Tip'	2	1 cup/ 200	4
Dessert, dairy food, chocolate flavour	2	1 cup/ 246	5
Muesli bar, chocolate chip	2	1 bar/ 32	1
Muesli bar, chocolate coated	2	1 bar/ 33	1
Nutella	11	1 tbsp/ 14	2
Pudding, self-saucing, chocolate, baked	6	100	6
Sauce, chocolate	10	1 tbsp/ 15	1
Sundae, chocolate, McDonald's	1	1 sundae/ 198	2
Coco Pops, Kellogg's	5	1 cup/ 40	2

T = trace

APPENDIX 2: Overseas concentration of caffeine in coffee, tea and chocolate and food products containing coffee or chocolate

Product	Average (range) caffeine concentration (mg/100ml or mg/100g)	Country	Reference
<i>Coffee</i>			
Espresso	74.3 (58.1-92.5) mg/shot 78 (46-159) mg/100ml 106 (25-214) 62 per serving	USA Argentina Australia Various	(McCusker <i>et al.</i> , 2003) (Olmos <i>et al.</i> , 2009) (Desbrow <i>et al.</i> , 2007) (Mandel, 2002)
Brewed/Perhted	57 ¹ 62 (43-83) 39.7 (31.2-54.8) 74-112 per serving 36 49 (7-118)	Various Brazil USA Various USA/Canada UK	(Barone and Roberts, 1996) (Rojo Camargo, 1999) (McCusker <i>et al.</i> , 2003) (Mandel, 2002) (Knight <i>et al.</i> , 2006) (FSA, 2004)
Instant	40 ¹ 73 (62-82) 41 (21-44) 60-71 per serving 32 23 (9-51)	Various Brazil Argentina Various USA/Canada UK	(Barone and Roberts, 1996) (Rojo Camargo, 1999) (Olmos <i>et al.</i> , 2009) (Mandel, 2002) (Knight <i>et al.</i> , 2006) (FSA, 2004)
Decaffeinated	2 ¹ 2.0 (0-2.9) 1-4 per serving 2 0.5-5	Various USA Various USA/Canada UK	(Barone and Roberts, 1996) (McCusker <i>et al.</i> , 2006) (Mandel, 2002) (Knight <i>et al.</i> , 2006) (FSA, 2004)
<i>Tea</i>			
Black (teabag, or not specified)	23 (21-24) 47.3± 0.1 27-40 per serving 5-28 12 (8-17) 20 13 17 (0.4-39)	Brazil Taiwan Various Portugal Argentina USA/Canada USA/Canada UK	(Rojo Camargo, 1999) (Zen <i>et al.</i> , 1998) (Mandel, 2002) (Pena <i>et al.</i> , 2005) (Olmos <i>et al.</i> , 2009) (Knight <i>et al.</i> , 2006) (Knight <i>et al.</i> , 2006) (FSA, 2004)
Green Tea (leaves)	8-30 per serving 27(22-33)	Various Argentina	(Mandel, 2002) (Olmos <i>et al.</i> , 2009)
Decaffeinated	1	UK	(FSA, 2004)
<i>Chocolate</i>			
Dark chocolate	125 43 (33-73)	Various Brazil	(Mandel, 2002) (Rojo Camargo, 1999)
Milk chocolate	21	Various	(Mandel, 2002)
White chocolate	23 (13-40)	Brazil	(Rojo Camargo, 1999)

Product	Average (range) caffeine concentration (mg/100ml or mg/100g)	Country	Reference
Cocoa, hot chocolate	3 ^{1,2} 9 (4-15) ³ 2.1	Various Brazil USA/Canada	(Barone and Roberts, 1996) (Rojo Camargo, 1999) (Knight <i>et al.</i> , 2006)
Chocolate milk	3 3.4 (3.0-4.2)	Various Argentina	(Barone and Roberts, 1996) (Olmos <i>et al.</i> , 2009)
Chocolate candy	3-13	Various	(Barone and Roberts, 1996)
<i>Caffeinated beverages</i>			
Energy drinks	14.5->42 32 26 (13-31) 42 (2-217) 21.5 (11-32) 28 (17-36) 15 32 15 15 32	Australia Various USA Portugal Saudi Arabia Argentina Denmark Finland Iceland Norway Sweden	(NSW Food Authority, 2009) (Mandel, 2002) (McCusker <i>et al.</i> , 2006) (Pena <i>et al.</i> , 2005) (Abourashed and Mossa, 2004) (Olmos <i>et al.</i> , 2009) (Meltzer <i>et al.</i> , 2008) (Meltzer <i>et al.</i> , 2008) (Meltzer <i>et al.</i> , 2008) (Meltzer <i>et al.</i> , 2008) (Meltzer <i>et al.</i> , 2008)
Carbonated sodas	11.6 (10.7-12.9) 9 (5-13) 8-17 10.4 (1.4-20.8) 11 (9-12) 11.5-15.3	Various USA Portugal USA Argentina USA/Canada	(Mandel, 2002) (McCusker <i>et al.</i> , 2006) (Pena <i>et al.</i> , 2005) (Chou and Bell, 2007) (Olmos <i>et al.</i> , 2009) (Knight <i>et al.</i> , 2006)
Water (caffeinated)	120	USA/Canada	(Knight <i>et al.</i> , 2006)
<i>Other</i>			
Cocoa Puffs	7.7	USA	(Caudle <i>et al.</i> , 2001)
Chocolate fudge poptarts	5.4	USA	(Caudle <i>et al.</i> , 2001)
Chocolate instant pudding	12.1	USA	(Caudle <i>et al.</i> , 2001)
Chocolate biscuits	12	USA	(Caudle <i>et al.</i> , 2001)

- 1 Standard values based on data 1975-1993
- 2 concentration in chocolate drink,
- 3 per 13g serving of powder

APPENDIX 3: New Zealand Exposure Estimate to Caffeine

A3.1 Baseline Exposure from Caffeine Containing Foods and Beverages

A3.1.1 Methodology

Concentration data of foods containing naturally occurring caffeine (Appendix 1) were combined with 24 hour diet recall information from the 1997 NNS and the 2002 CNS using Microsoft FoxPro software.

Concentration values for caffeine in 49 New Zealand foods were used (Appendix 1) with three changes to concentration values for coffee to better map to products as itemised in the 1997 NNS and 2002 CNS with reference to more recent overseas data (Appendix 2). Thus, coffee was mapped to:

- coffee, cafe latte, caffeinated (99 mg/100ml), (Appendix 1)
- coffee, instant (3700 mg/100g of dry powder) (Appendix 1) and
- coffee, decaffeinated (2mg/100ml) (Appendix 2).
- coffee, brewed (53 mg/100ml) (Appendix 2),
- coffee, espresso (80 mg/100ml),(Appendix 2)

Chocolate milk was included at a concentration of 3 mg/100ml based on overseas data and a concentration value of 17 mg/100ml was included for Red Bull (Table 2). Where a trace was noted in Appendix 1 (milo products) this was assigned a concentration value of 0.5 mg/100ml to represent a low, but non zero level of caffeine.

Exposures were estimated for seven population groups, namely, children (5-12 yrs), teenagers (13-19 yrs), young males (19-24 yrs), adults (20 to 64 yrs), older people (over 65 years old), non pregnant females of childbearing age (16 to 44 yrs) and pregnant females (16-44 yrs). The number of respondents for these population groups ranged from 64 to 3282 individuals (Table 4). Children (5-12 yrs) were assessed because of concern over the effects of caffeine on children and availability of consumption information. Teenagers (13-19 yrs) were assessed as the target group for energy drinks and energy shots. Young males (19-24 yrs) were included as a group representing high consumers and for consistency with the New Zealand Total Diet Survey population groups. An exposure assessment of women of childbearing age, both those who identified themselves as pregnant and not pregnant, was included because of concerns of caffeine exposure on pregnancy outcomes. Adults and older people were also included as separate groups due to a higher perceived level of consumption of coffee and tea by these population groups.

Each food descriptor identified by each consumer in the previous 24 hour period (approximately 6000 in total) was mapped to one of 52 foods for which a caffeine concentration was available. All other foods were mapped to "other" and assigned a caffeine concentration of 0 mg/100g. The modelling software multiplies the specified concentration of caffeine by the amount of food that an individual consumed in any one serving in order to estimate the exposure from each food item. Once completed for all foods, the total amount of caffeine consumed from all foods is summed for each individual. All individual's exposures were then ranked and population statistics (mean, median, high and low percentiles) were derived.

The exposure estimates were for individual respondents and were not statistically weighted to the New Zealand population. Exposure estimates were based on food consumption on a single day, given that effects are based on acute and not habitual exposures.

A3.1.2 Limitations of the exposure assessment

Whilst the methodology described provides a realistic estimate of the actual caffeine exposure for the selected sub populations, there are recognized limitations. Not all caffeine containing foods will have been included in the assessment. Whilst every effort was made to include the likely major contributors, for which caffeine concentration data are available, it was not practical to include the complete array of foods that exists and therefore exposures will be underestimated for some consumers. The 52 foods included in the study were mapped to a very much wider range of foods described in the 1997 NNS/2002 CNS (approximately 6000) requiring assumptions that mapped foods have similar caffeine concentrations to the analysed foods. There is a measure of uncertainty around these assumptions. The variability of caffeine in coffee and tea is problematic for an exposure and risk assessment as clearly, the method of preparation will influence the level of exposure. The 24-hour dietary recall records from the 1997 NNS and 2002 CNS are a snapshot of consumption on any one day and will not necessarily represent the typical diet for the individual respondent. The 1997 NNS data is now dated and will likely differ from current consumption practices. These arguments also apply to comparative studies from overseas.

A3.2 **Estimated exposure from Additional Caffeine from the Consumption of Energy Drinks or Energy Shots**

Given that energy drinks and energy shots are targeted to young people, and based on overseas consumption intelligence, exposure to additional caffeine from the consumption of these products was calculated for children (5-12 yrs), teenagers (13-19 yrs) and young males (19-24 yrs). Scenarios were defined for one, two, three or four servings of any of the 42 energy drinks or energy shots identified in Table 2 for which caffeine concentration values were available. Two products that listed caffeine as an ingredient but did not state a quantity were not included. Caffeinated alcoholic beverages were not included since these are not legally available for purchase by young people aged less than 18 years.

A3.2.1 Methodology

Exposure estimates were simulated using @Risk software and a Monte Carlo approach for the selected population groups. Each iteration of the simulation randomly selected a base caffeine exposure (mg/day), the body weight of the respondent with that exposure (kg), and a retail unit of any one caffeinated beverage (mg) and used this combination to calculate an overall caffeine exposure adjusted for body weight (mg/kg bw/day). Simulations were run for 20,000 iterations for each scenario (one, two, three or four caffeinated drinks). An advantage of a Monte Carlo approach over point estimates is that it allows inclusion of all respondents and all food products, reducing bias towards any particular product.

In the absence of detail regarding market share and current consumption practices of caffeinated energy drinks or energy shots in New Zealand, the following assumptions were made:

- Only consumers with a background caffeine exposure were included since consumers who do not currently consume caffeine are assumed to be unlikely to seek caffeine from caffeinated beverages.

- There is no selection bias to particular products and all 42 products (energy drinks and energy shots) were equally weighted.
- Energy drinks and energy shots were assumed to be alternatives. That is, a consumer would choose either an energy drink, or an energy shot.
- If a person consumed more than one serving of caffeinated beverage, all servings were assumed to be of the same product. There is no data to inform this assumption, but is plausible if it is assumed that consumers are likely to display some brand loyalty.
- All individuals are equally likely to consume these products irrespective of base caffeine intake (i.e. those with high or low base caffeine exposures are equally likely to consume caffeinated beverages).
- A serving equalled a full retail unit.

APPENDIX 4: Overseas Estimates Of Caffeine Exposure

Country	Year	Population group	Caffeine exposure (mg/kg/day)	Major Contributors (In descending order of importance)	Reference
Argentina	2005		Mean (95th percentile)		(Olmos <i>et al.</i> , 2009)
		2-10 years	1.3 (3.2)	Soft drinks, chocolate milk	
		11-15 years	2.3 (6.6)	Mate, coffee, soft drinks	
		16-20 years	4.1 (12.7)	Mate, coffee, soft drinks	
		21-30 years	3.8 (7.7)	Mate, coffee, soft drinks	
		31-40 years	4.8 (10.5)	Mate, coffee	
		41-50 years	5.1 (9.6)	Mate, coffee	
		51-60 years	4.2 (9.6)	Mate, coffee	
	60+ years	3.7 (8.4)	Coffee, mate		
Brazil	1993		Mean mg/day		(Rojo Camargo, 1999)
		10-19 years	127	Coffee, tea, soft drinks	
		20-29 years	150		
		30-39 years	189	Coffee, tea	
		40-49 years	192	Coffee, tea	
		50-59 years	178	Coffee, tea	
		60+ years	195	Coffee, tea, soft drinks chocolate,	
	Overall	2.74 mg/kg/day			
Denmark	1991 (7 day average)		Mean (90th percentile)		(Barone and Roberts, 1996)
		1-5 years	0.3 (0.7)	Tea	
		6-9 years	0.6 (2.5)	Tea	
		10-14 years	0.7 (1.5)	Coffee, tea	
		15-19 years	2.1 (5.5)	Coffee, tea	
		20-24 years	4.8 (12.3)	Coffee, tea	
		25-34 years	7.9 (15.7)	Coffee, tea	
		35-49 years	9.9 (17.6)	Coffee, tea	
		50-64 years	8.9 (17.1)	Coffee, tea	
		65+ years	7.8 (15.0)	Coffee, tea	
	Pregnant	5.8 (12.1)	Coffee, tea		
UK	1988 (7 day average)		Mean (90th percentile)		(Barone and Roberts, 1996)
		1-5 years	2.29 (6.86)	Instant coffee, tea	
	6-9 years	1.77 (4.23)	Brewed coffee, tea		

Country	Year	Population group	Caffeine exposure (mg/kg/day)	Major Contributors (In descending order of importance)	Reference
		10-14 years	2.04 (5.19)	Instant coffee, brewed coffee, tea	
		15-19 years	2.58 (6.81)	Brewed coffee, instant coffee, tea	
		20-24 years	4.25 (8.16)	Brewed coffee, tea, instant coffee	
		25-34 years	4.23 (8.34)	Instant coffee, tea, brewed coffee	
		35-49 years	5.16 (8.80)	Brewed coffee, instant coffee, tea	
		50-64 years	4.87 (7.70)	Tea, brewed coffee, instant coffee	
		65+ years	3.95 (6.33)	Tea, brewed coffee, instant coffee	
		Pregnant	3.43 (6.51)	Tea, brewed coffee, instant coffee	
UK	2003	Pregnant women	Mean		(Care Study Group, 2008)
			mg/day mg/kg/day*	Tea (62%), coffee (14%), cola drinks (12%), chocolate (8%), soft drinks (2%), energy drinks (1%)	
		Before pregnancy	238 3.5		
		5-12 weeks	139 2.1		
		Third trimester	153 2.3		
		Throughout pregnancy	159 2.4		
USA	1975 (14 day average)		Mean (90th percentile)		(Barone and Roberts, 1996)
		0-11 months	0.47 (0.51)	Tea	
		1-5 years	1.21 (3.14)	Tea, coffee, soft drinks	
		6-11 years	0.86 (2.04)	Tea, coffee, soft drinks	
		12-17 years	0.75 (1.79)	Tea, coffee, soft drinks	
		18+ years	2.64 (5.19)	Coffee, tea	
USA	1989 (14 day average)		Mean (90th percentile)		(Barone and Roberts, 1996)
		0-11 months	0.32 (0.68)	Coffee, tea	
		1-5 years	0.95 (2.10)	Coffee, tea, soft drinks	
		6-11 years	0.67 (1.40)	Tea, coffee, soft drinks	
		12-17 years	0.65 (1.40)	Coffee, tea, soft drinks	
		18-24 years	1.10 (2.80)	Coffee, tea, soft drinks	
		25+ years	2.40 (5.20)	Coffee, tea, soft drinks	
		Pregnant/nursing	0.91 (2.50)	Coffee, tea, soft drinks	
USA	1987-1988 (3 day average)		Mean (90th percentile)		(Barone and Roberts, 1996)
		1-5 year	1.33 (2.79)	Coffee, tea, soft drinks	
		6-9 years	1.10 (2.38)	Coffee, tea, soft drinks	
		10-14 years	1.08 (2.03)	Coffee, tea, soft drinks	
		15-19 years	0.98 (1.82)	Coffee, tea, soft drinks	
		20-24 years	1.79 (3.99)	Coffee, tea, soft drinks	

Country	Year	Population group	Caffeine exposure (mg/kg/day)	Major Contributors (In descending order of importance)	Reference
USA	1994-1996, 1998 (2 day average)	25-34 years	3.13 (7.51)	Coffee, tea, soft drinks	(Frary <i>et al.</i> , 2005)
		35-49 years	3.69 (8.16)	Coffee, tea, soft drinks	
		50-64 years	3.81 (8.11)	Coffee, tea, soft drinks	
		65+ years	3.05 (6.69)	Coffee, tea, soft drinks	
		Pregnant women	1.47 (3.33)	Coffee, tea, soft drinks	
		Nursing women	2.63 (5.74)	Coffee, tea, soft drinks	
		Mean			
		2-5 years	0.4	Soft drinks, tea	
		6-11 years	0.4	Soft drinks, tea	
		12-17 years Female	0.5	Soft drinks, tea	
		12-17 years Male	0.6	Soft drinks, tea	
		18-34 years Female	1.2	Coffee, soft drinks, tea	
		18-34 years Male	1.1	Coffee, soft drinks, tea	
		35-54 years Female	1.7	Coffee>>soft drinks, tea	
		35-54 years Male	1.8	Coffee>>soft drinks, tea	
		55-64 years Female	1.5	Coffee	
		55-64 years Male	1.8	Coffee	
65+ years Female	1.3	Coffee>>tea			
65+ years Male	1.3	Coffee			
Pregnant women	0.8	Coffee, soft drinks, tea			

Assuming average 67 kg body weight

APPENDIX 5: Cumulative probability curves of total caffeine exposure for children, teenagers and young males consuming 1-4 energy drinks or energy shots in addition to baseline dietary exposure.

An adverse effect level of 3 mg/kg bw/day is shown on each graph as a reference point. The portion of each curve to the right of the adverse effect level represents the proportion of the population group potentially at risk from adverse effects of caffeine. The exposure of any percentile may be read off the x- axis by extrapolating from the intersection of the selected percentile on the y-axis with the curve of one, two, three or four retail units consumed, where cumulative probability = 0.2 represents the 20th percentile, 0.4 = 40th percentile etc.

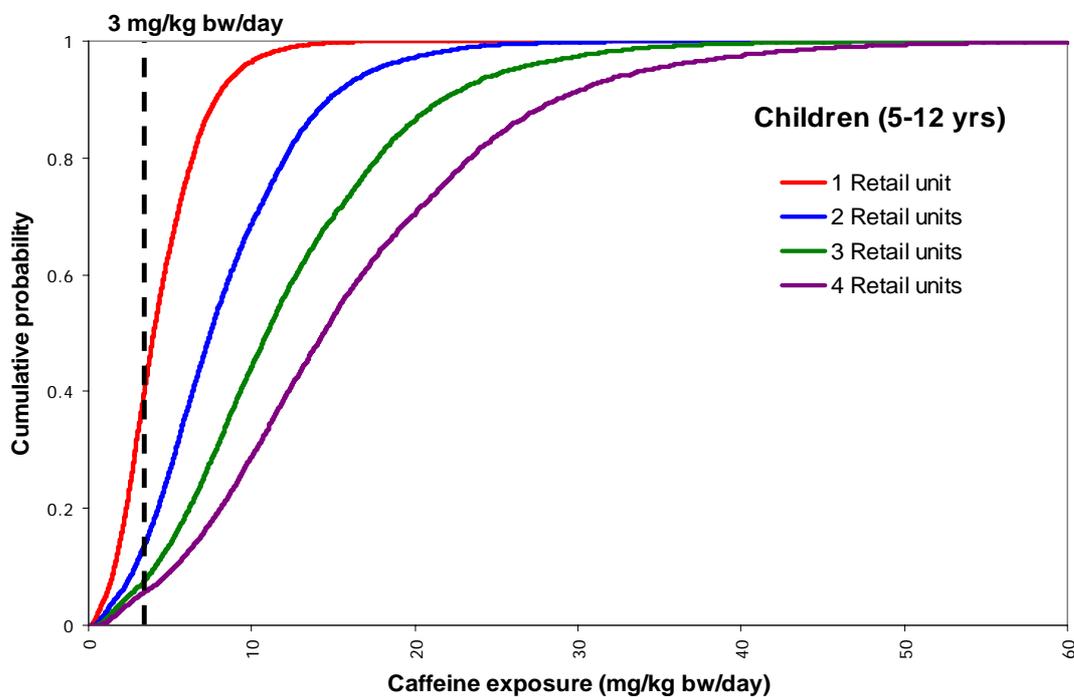


Figure 9: Cumulative probability curve of children (5-12 yrs) consuming 1-4 retail units of energy drinks or energy shots

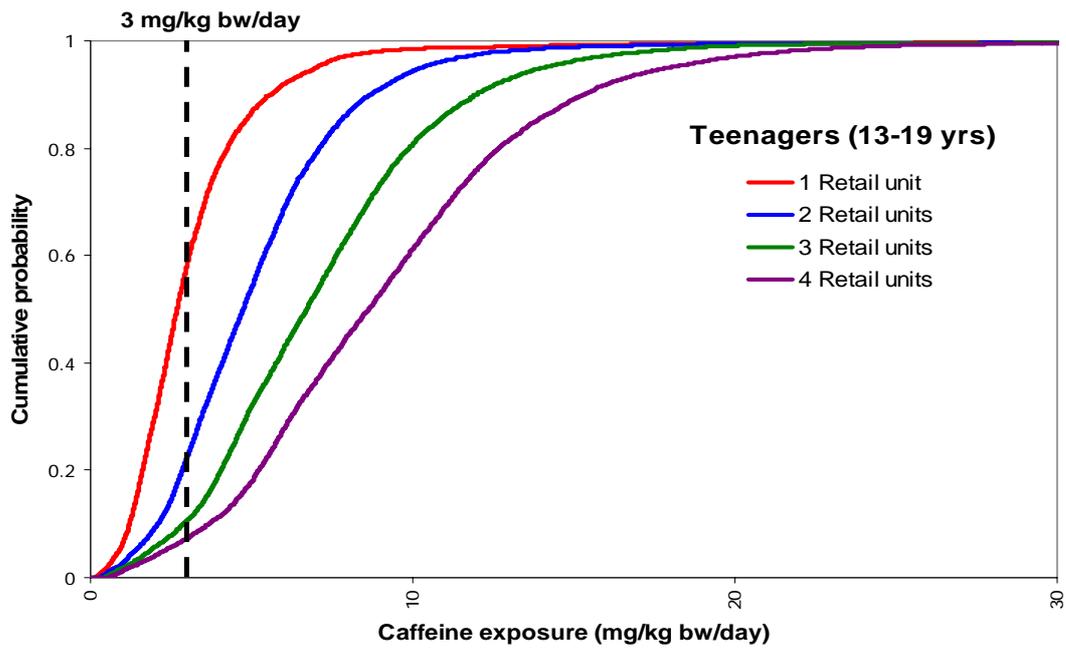


Figure 10: Cumulative probability curve of teenagers (13-19 yrs) consuming 1-4 retail units of energy drinks or energy shots

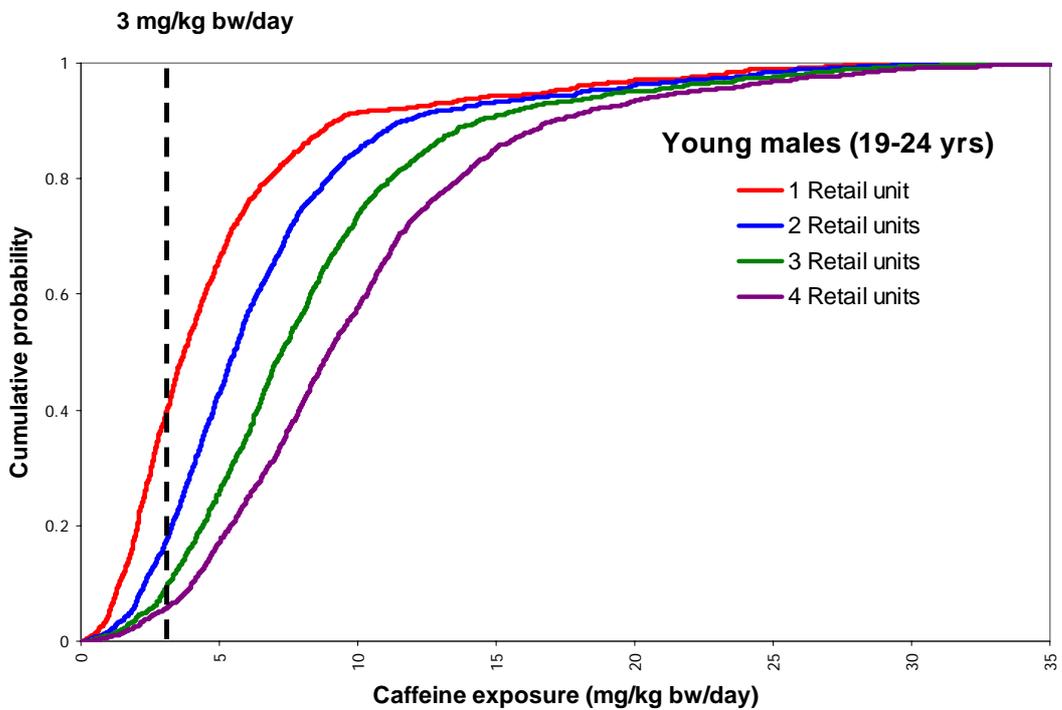


Figure 11: Cumulative probability curve of young males (19-24 yrs) consuming 1-4 retail units of energy drinks or energy shots