

15 December 2010
[25-10]

PROPOSAL P1009

MAXIMUM LIMITS FOR TUTIN IN HONEY

APPROVAL REPORT

Executive Summary

Purpose

In August 2009, temporary maximum levels (MLs) for tutin in honey and comb honey were included in the *Australia New Zealand Food Standards Code* (Standard 1.4.1 – Contaminants and Natural Toxicants). These MLs are identical to those brought into force in New Zealand in January 2009 (*Food (Tutin in Honey) Standard 2008* of the *Food Act 1981*). They were introduced as a temporary risk management measure in response to an incident in Coromandel, New Zealand when 22 people were poisoned following the consumption of honey containing tutin. The temporary MLs are due to expire on 31 March 2011. Food Standards Australia New Zealand (FSANZ) has therefore prepared Proposal P1009 to consider whether the current interim standard for tutin should be allowed to expire by the nominated date or be extended temporarily or permanently.

Safety of tutin

Tutin is a naturally-occurring toxin produced by several plants (*Coriaria sp.*) native to New Zealand. Honey produced in New Zealand may contain unsafe levels of tutin as a result of bees foraging on honey dew excreted by passion vine hopper insects (*Scolypopa australis*) that have fed on *Coriaria sp.* e.g. Tutu bush. Tutin is a potent neurotoxin in animals and humans. Symptoms in humans may include dizziness, vomiting, seizures and coma. Reported cases of honey poisoning go back to the 1880s. There have been several deaths, the last fatality being in 1917. In the most recent poisoning episode (March 2008), 22 people were reported to have been affected, some requiring hospitalisation.

Risk management of Tutin in honey

This evaluation has primarily considered whether the interim MLs for tutin in honey and comb honey represent effective risk management measures.

The key findings of the evaluation are:

- Comb honey, obtained from certain areas in New Zealand, is a relatively high risk product because high levels of tutin may occur in a single piece of comb honey. In contrast, extracted honey is typically produced from multiple frames of honeycomb resulting in dilution of any tutin present.

Based on the potential risk to honey consumers, a standard specifying MLs for tutin in honey and comb honey is warranted.

- There have been no further reports of tutin intoxication from honey consumption since the 2008 incident.
- It is considered likely that honey containing tutin at levels greater than 2 mg/kg has been widely consumed historically without adverse effects. However, levels of 30 mg/kg and greater are known to result in acute intoxication in some individuals.
- The MLs for tutin of 2 mg/kg for honey and 0.1 mg/kg for comb honey appear to be sufficiently protective to the population.
- Industry and survey data showed that 1 to 2% of honey samples tested since 2008 contained tutin at greater than 2 mg/kg.

Following an evaluation of the effectiveness of these MLs in safeguarding public health, FSANZ is proposing that an interim regulatory measure is still required to ensure that the presence of tutin in honey and comb honey does not exceed safe levels, whilst allowing time for further research into the toxicity and further evaluation of the current and proposed risk management measures.

The food regulatory measure proposed is the extension of the existing interim MLs of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey. Compliance with this measure would limit dietary exposure to tutin and would address the potential public health implications that have been identified from episodes of human poisoning from the consumption of tutin-contaminated honey.

While not currently within the scope of this Proposal, additional regulatory and non-regulatory measures may be required as investigations continue into tutin. The extension of the existing MLs for tutin in honey and comb honey is considered an appropriate risk management measure while these investigations continue.

Assessing the Proposal

The Proposal has been assessed under the General Procedure. In assessing the Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
- There are no other measures that would be more cost-effective than a variation to Standard 1.4.1 that could achieve the same end;
- Any relevant New Zealand standards:
 - Food (Tutin in Honey) Standard 2008.
 - Compliance Guide to the Food (Tutin in Honey) Standard 2008.
- Any other relevant matters.

Decision

To approve the variation to the Standard 1.4.1 – Contaminants and Natural Toxicants to maintain an interim maximum level of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey. The interim standard to be extended by 2 years with an expiry date of 31 March 2013.

Reasons for Decision

- Honey and comb honey are, in general, safe to consume.
- The occasional presence of high levels of tutin in honey and comb honey, however, represents a risk to public health and safety.
- As tutin is a colourless, odourless and tasteless toxin, consumers cannot differentiate between honey products that may or may not contain the toxin.
- Due to the adventitious presence of tutin in honey produced in New Zealand and the severity of intoxication from consumption of honey containing high levels of tutin, a food regulatory measure is recommended.
- Recent human poisonings indicate that comb honey is a relatively high risk product compared to extracted and blended honey, and warrants a lower tutin level because of the potential for high levels of tutin in comb honey.
- The extension of the existing MLs for tutin in Standard 1.4.1 is considered to be an appropriate risk management measure while additional information is gathered about the toxicity of tutin.
- MLs of 2 mg/kg in honey and 0.1 mg/kg in comb honey are considered practical and reasonably achievable as demonstrated from the results of the current testing regimen by the responsible food enforcement authority, NZFSA.
- The regulatory environment for tutin in New Zealand is comprehensive and well supported to ensure industry compliance and enforcement. Furthermore, it plays an important role in safeguarding public health and safety while further investigations into tutin toxicity continue.
- Limited or negligible additional costs to industry or consumers would arise from this food regulatory measure.

Consultation

Public submissions were invited on the Assessment Report between 12 October and 9 November 2010. Comments were specifically requested on the scientific aspects of this Proposal, in particular, information relevant to the risk assessment of tutin. A total of four submissions were received as a result of the public consultation. A summary of these is included at **Attachment 2** to this Report.

As this Proposal was assessed as a General Procedure, there was one round of public comment following the preparation of an Assessment Report. Responses to the Assessment Report were used to develop the Approval Report. The main issues raised in public comments are discussed in the Approval Report.

CONTENTS

INTRODUCTION	2
1. THE ISSUE / PROBLEM.....	2
2. CURRENT STANDARDS	2
2.1 <i>Australia New Zealand Food Standards Code</i>	2
2.2 <i>New Zealand regulations</i>	3
2.3 <i>Other International regulations</i>	3
3. OBJECTIVES	3
4. QUESTION TO BE ANSWERED	4
4.1 <i>Background</i>	4
5. LEVELS OF TUTIN REPORTED IN HONEY SINCE 2008.....	6
5.1 <i>2008 NZFSA targeted survey</i>	6
5.2 <i>2010 NZFSA targeted survey</i>	7
5.3 <i>NZFSA retail industry data</i>	7
5.4 <i>Summary and Conclusions</i>	7
RISK MANAGEMENT	7
6. RISK MANAGEMENT STRATEGY	7
7. OPTIONS	8
8. IMPACT ANALYSIS (RIS ID: 11832).....	8
8.1 <i>Affected Parties</i>	8
8.2 <i>Benefit Cost Analysis</i>	9
8.3 <i>Comparison of Options</i>	10
COMMUNICATION AND CONSULTATION STRATEGY.....	11
9. COMMUNICATION	11
10. CONSULTATION.....	12
10.1 <i>Public consultation</i>	12
10.2 <i>Issues raised in submissions</i>	12
10.3 <i>World Trade Organization (WTO)</i>	13
CONCLUSION.....	13
11. CONCLUSION AND PREFERRED OPTION	13
11.1 <i>Reasons for Decision</i>	14
11.2 <i>Transitional Arrangements</i>	15
12. IMPLEMENTATION AND REVIEW	15
REFERENCES	15
ATTACHMENT 1 - DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS</i> <i>CODE</i>	17
ATTACHMENT 2 - SUMMARY OF PUBLIC SUBMISSIONS ON THE ASSESSMENT REPORT	18

Introduction

Tutin (CAS No. 2571-22-4) is a honey contaminant which has been responsible for human poisonings in New Zealand, with a number of fatalities occurring prior to 1917 and a number of incidents resulting in hospitalisation or sickness of individuals or groups in the intervening years up to 2008.

Following the most recent poisoning episode in 2008 where 22 people were poisoned, some severely, due to the consumption of comb honey containing tutin, interim measures were introduced in New Zealand. A New Zealand only food standard for tutin in honey and comb honey came into force on 25 January 2009¹. The standard set MLs for extracted honey and comb honey. It was developed to ensure that honey sold in or exported from New Zealand did not contain dangerous levels of tutin. A risk management strategy was also implemented by the New Zealand Food Safety Authority (NZFSA)², including a compliance guide for the management of tutin in honey³.

Interim MLs for tutin in honey and comb honey to align with the existing New Zealand standard were incorporated into the *Australia New Zealand Food Standards Code* (the Code) in 2009. This was undertaken as part of Proposal P1008 – Code Maintenance VIII. This interim Standard will expire on 31 March 2011.

1. The Issue / Problem

Contamination of honey and comb honey by tutin represents a continuing risk to the safety of food for human consumption. As part of an earlier risk management strategy, interim MLs for tutin in the Code were put in place but will expire on 31 March 2011. This Proposal addresses whether the current interim standard for tutin should be allowed to expire by the nominated date of 31 March 2011 or extended temporarily or permanently.

2. Current Standards

2.1 *Australia New Zealand Food Standards Code*

Natural plant toxins are regulated under Standard 1.4.1 – Contaminants and Natural Toxicants.

The table to clause 5 contains a list of maximum levels of other natural toxicants in food and currently has two entries for tutin. Note that this is an interim standard, and the entry also contains an expiry date of 31 March 2011.

Column 1	Column 2
The ML for Tutin to cease on 31 March 2011	
Tutin	
Tutin in honey	2
Tutin in comb honey	0.1

¹ <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/tutin-standard-final.pdf>

² http://www.nzfsa.govt.nz/animalproducts/subject/bee-products/#P82_7255

³ <http://www.nzfsa.govt.nz/animalproducts/publications/manualsguides/tutin-standard-compliance-guide/index.htm>

2.2 New Zealand regulations

The *Food (Tutin in Honey) Standard 2008* was issued pursuant to section 11C of the *Food Act 1981*, and came into force on 25 January 2009. Two key clauses are noted below that makes reference to the MLs and expiry of this standard.

Clause 6 *Maximum level of tutin in honey and comb honey* specifies at subclauses (2) and (3) the maximum level of tutin in these matrices

(2) The maximum level of tutin in honey is 2 milligrams per kilogram.

(3) The maximum level of tutin in comb honey is 0.1 milligrams per kilogram.

Clause 7 contains criteria for the expiry of Clause 6:

(1) Clause 6 expires on the earlier of the following dates

a. On the date on which a standard in the Australia New Food Standards Code (setting a maximum level of tutin in honey and comb honey) comes into force in New Zealand; or

b. On 1 February 2010.

(2) Despite subclause (1), if on the 1 February 2010 there is no standard in the Australia New Zealand Food Standards Code (setting a maximum level of tutin in honey and comb honey) in force in New Zealand but a standard in the Australia New Zealand Food Standards Code is under development by Food Standards Australia New Zealand, then clause 6 does not expire until the date that the standard that is under development comes into force in New Zealand.

The effect of Clause 7 was to terminate the limits set in the New Zealand standard once the interim standard was inserted into the Code.

2.3 Other International regulations

FSANZ is unaware of any other regulations that stipulate a ML for tutin in food.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Question to be answered

Is there a need to have MLs for tutin in honey and comb honey in the Code?

4.1 Background

4.1.1 Occurrence of Tutin

Tutin is a potential honey contaminant which has been responsible for a number of human poisoning cases in New Zealand since the late 19th century (Turner et al, 2005; NZFSA, 2008).

Tutin is present in the tutu shrub (*Coriaria arborea*), a plant traditionally used for medicinal and food purposes by New Zealand Māori but with care because of its poisonous nature. The tutu plant has been responsible for the deaths of livestock including sheep introduced in the late 1700s by Captain James Cook (Fitchett and Malcolm, 1909). Tutin was eventually identified as the compound responsible for tutu toxicity and has been studied for over 100 years (Fitchett, 1908). However, the identification of tutin as the toxin responsible for honey poisoning in humans was only established in the 1940s (Palmer-Jones, 1965).

Tutin contamination of honey occurs when bees gather honeydew from the excretion of an insect that feeds on sap from the tutu plant (*C. arborea*). The insect, a vine hopper (*Scolypopa australis*) native to Australia, is thought to have been introduced into New Zealand before 1870 (Palmer-Jones, 1965). The tutin present in tutu sap is transferred to the vine hopper honeydew which is then transferred to honey.

Several species of *Coriaria* are native to New Zealand with *C. arborea* the most widespread. It is not known whether the other *Coriaria* species that grow in New Zealand contain tutin and may therefore contribute to tutin contamination of honey. Tutin is present in *Coriaria* species that grow in other parts of the world, for example the Asian *C. nepalensis* (Wei et al, 1998) and *Coriaria japonica* (Kinoshita et al, 2005), and the South American *C. ruscifolia* (Fuentealba et al, 2007). The root of *C. nepalensis*, also known as *C. sinica* Maxim, is used as a Chinese herbal medicine and contains tutin along with several related compounds (Wei et al, 1998; Shen et al, 2004).

The situation in New Zealand would appear to be unique, in that the presence of tutin in honey is dependent on the relationship between the tutu shrub (*C. arborea*), the passion vine hopper and foraging bees. FSANZ is not aware of any reports from elsewhere in the world which indicate the presence of other tutin-like/picrotoxin contamination in honey. However, FSANZ is aware that a different mechanism of action is associated with grayanotoxin-induced neurotoxicity from the consumption of honey produced from the nectar of *Rhododendrons* (Koca & Koca, 2007).

4.1.2 Human toxicity

There is a lack of reliable data on tutin levels and honey consumption resulting in past poisoning cases and a lack of data on tutin levels which can be tolerated by humans. The most recent incident occurred in March 2008 and the last recorded death was in 1917.

In the 2008 incident there were 22 reported cases of tutin comb honey poisoning with the main symptoms being seizures and vomiting (Beasley, 2008; NZFSA unpublished data). Earlier reports of human poisoning indicate that the more obvious effects typically last no more than a few days, and this was the case in the 2008 incident. Analysis of honey samples from uneaten portions associated with the 2008 incident gave tutin levels of 30 to 50 mg per kg of honey (NZFSA, 2008).

The measurement of the doses associated with earlier poisoning incidents are of lower reliability. Most of the analyses done prior to the 1980s were based on animal bioassays. Subsequent analytical methodology developments have led to improved precision, including further improvements since the 2008 poisoning incident. An historical account of New Zealand toxic honey up to the mid-1960s was presented by Palmer-Jones (1965) who concluded that the minimum tutin dose resulting in human intoxication could not be determined from the information available at the time.

As noted by Turner et al (2005): 'Incidents and outbreaks of honey poisoning have been recorded in New Zealand since the 1920s. A large outbreak occurred in 1945 involving 18 people in the Bay of Plenty area (Pongakawa valley, Putaruru), of which 12 were hospitalised. The privately produced honey was from a mixture of flowers, manuka predominating, and the toxin was present at about 15 mg per 100 g honey (Palmer-Jones, 1947; Sutherland & Palmer-Jones, 1947). There have been no cases of poisoning associated with commercially-produced honey since 1974, when an outbreak occurred that involved 13 people. Between 1974 and 1991 there were nine cases associated with privately produced honey, but none have been reported since (NZFSA, 2003). No incidents of poisoning from consumption of wild honey have been reported.'

From the early 1960s to the mid-1970s, test hives were established in the northern districts of the North Island in order to obtain toxic honey for characterisation of tutin levels (Clinch and Turner, 1968; Clinch and Turner, 1975). The sites chosen were close to large areas of tutu bush that had been heavily infested with the passion vine hopper. Using a mouse toxicity bioassay, the maximum level of tutin in honey obtained from the test hives was approximately 70 mg/kg. No human consumption of honey from test hives was reported.

A gas chromatographic (GC) method for the determination of tutin in honey was published in 1980 (Swallow et al, 1980). This method was used to analyse four samples of honey collected from areas restricted to beekeeping (Clinch & Turner, 1975) and responsible for human poisoning in Te Teko (1959), Whitianga (1974)⁴ and Whangamata (1979). The levels of tutin in honey associated with these documented poisoning cases ranged from 34 to 95 mg/kg using this GC method. Of the four honey samples analysed by the GC method, two of the samples were also tested by mouse bioassay. The data showed comparable results between the methods, albeit for a limited set of samples. The authors noted that agreement between the two methods was further confirmed when 35 samples of toxic honey collected from test hives were tested (data not shown). Only four results were not in close agreement and these differed by no more than a factor of two.

An HPLC method for the determination of tutin in honey was subsequently published (Love et al, 1986). This method was used to analyse 20 honey samples collected from Marlborough during 1985. The source of the honey samples was not stated although a subsequent report indicated that the samples originated from commercial hives (Turner et al, 2005). Thirteen of the 20 samples contained no detectable tutin, six samples contained trace quantities of tutin (<1 mg/kg) and one sample contained 2 mg/kg.

⁴ Two samples from Whitianga came from the same apiary but were responsible for two separate poisonings (Swallow et al, 1980).

Overall, there is a lack of scientific data that adequately characterise the human toxicity of tutin-affected honey. This is due to a number of reasons, including: the relative infrequency of tutin poisoning; the difficulty in obtaining exposure data in cases of poisoning; the limited known geographical distribution of tutin-containing plants in the world; and the paucity of scientific publications on the subject.

To bridge these data gaps, FSANZ and NZFSA have been working together to develop a more robust scientific evidence base to determine the most appropriate regulatory measures and this work will be ongoing over the next 18 months.

5. Levels of tutin reported in honey since 2008

The March 2008 incident resulted in 22 probable cases of intoxication from the consumption of comb honey containing tutin. Eight partially-eaten comb honey samples associated with intoxication were available for analysis giving tutin levels ranging from 30 to 50 mg/kg honey. NZFSA subsequently established an ML of 2 mg/kg based on mouse toxicity data combined with an estimate of high exposure (the 97.5th percentile honey consumer).^{5,6} A 20-fold safety factor, to account for variations in distribution within the comb, was applied to this ML to arrive at a value of 0.1 mg/kg for comb honey. The comb honey ML was calculated by allowing for all the tutin in a piece of comb honey at 2 mg/kg on average being contained in a modest portion such as might reasonably be expected to be consumed at one time.

Following the 2008 incident, NZFSA conducted two surveys on the levels of tutin in honey produced in various locations in New Zealand. These surveys, conducted in 2008 and 2010, are described below. NZFSA has also analysed 132 samples of honey for retail sale over this period and found only 3 samples with detectable tutin, with levels ranging from 0.2 to 0.7 mg/kg. In addition, NZFSA has also obtained information from testing laboratories on tutin levels in honey samples submitted by beekeepers for analysis. This information is also presented below.

5.1 2008 NZFSA targeted survey

This survey was conducted subsequent to the poisoning incident but prior to the introduction of the interim MLs and associated risk management levels. A total of 144 samples were analysed comprising 123 samples from extracted honey, 14 from comb honey, and 7 samples for which the honey type was not recorded. The honey samples were obtained from 10 locations in New Zealand (six in the North Island and four in the South Island). The harvest dates of the tested honeys ranged from May 2006 to May 2008, however, 28 samples (19% of the total) were of unknown harvest date. The analytical method used in this survey had a limit of quantification (LOQ) of 2 mg/kg.

Tutin was not detected in 7 of the 14 comb honey samples. Trace amounts (level not quantifiable but less than 2 mg/kg) were observed in 5 of the comb honey samples. The two remaining comb honey samples had tutin levels of 2.6 mg/kg and 21 mg/kg.

Of the 123 extracted honey samples, 88 (72%) contained no detectable tutin, 33 (28%) contained trace levels, and only one sample contained a quantifiable level of tutin (11 mg/kg).

Of the 7 samples that were not recorded as either extracted honey or comb honey ('unknown' samples), two contained no detectable tutin, two contained trace levels, while the three quantified samples had levels of 2.7, 2.9 and 3.3 mg/kg.

⁵ http://www.nzfsa.govt.nz/animalproducts/subject/bee-products/#P82_7255

⁶ <http://www.nzfsa.govt.nz/publications/food-focus/2009-02/page-15.htm>

5.2 2010 NZFSA targeted survey

This survey was conducted on samples obtained in the first full season of honey production subsequent to the introduction of the interim MLs in the Code and the compliance measures required by the New Zealand standard. A total of 276 honey samples were tested (255 from extracted honey and 21 from comb honey). The honey samples were obtained from 37 locations in New Zealand (29 in the North Island and 8 in the South Island). The harvest dates of the tested honeys ranged from January 2009 to May 2010. The analytical method used in this survey had an LOQ of 0.01 mg/kg (i.e. 200-times lower than the LOQ of the method used for the 2008 survey).

None of the comb honey samples contained quantifiable levels of tutin. Of the 255 extracted honey samples, 160 (63%) were below the LOQ, 65 (25%) contained tutin at levels ranging from 0.01 to 0.1 mg/kg, 25 (10%) contained tutin at levels ranging from 0.1 to 2 mg/kg, while 5 samples (2.0%) contained tutin at levels greater than the current ML of 2 mg/kg. All of the 5 samples that exceeded the ML were obtained from one producer in the Eastern Bay of Plenty region. The highest measured tutin level was 8.5 mg/kg. Of the 69 samples of extracted honey obtained from the 8 South Island locations, 21 samples contained quantifiable levels of tutin and the highest level was 0.19 mg/kg.

5.3 NZFSA retail industry data

NZFSA has provided summary data from testing laboratories on the levels of tutin in honey samples submitted for analysis by beekeepers. Of the 2601 samples submitted, 286 samples (11%) contained tutin at ≥ 0.1 mg/kg and 25 samples (1.0%) contained tutin at > 2 mg/kg.

5.4 Summary and Conclusions

Prior to the 2008 incident there were very little data on the levels of tutin in New Zealand honey. Data from subsequent analyses showed that 1% (industry data) to 2% (2010 NZFSA survey) of extracted honey samples contained tutin at levels greater than 2 mg/kg. The highest level measured in an extracted honey sample was 11 mg/kg. The highest level measured in a comb honey sample was 21 mg/kg, however only minimal comb honey data are available.

Tutin intoxication from the consumption of honey only occurs sporadically and has reportedly affected a relatively small number of individuals over a period of greater than 100 years. Since the 2008 incident there have been no reports of intoxication from the consumption of honey containing tutin. It is considered likely that honey containing tutin at levels greater than 2 mg/kg has been widely consumed historically without adverse effects. However, the threshold dose for human toxicity remains to be fully characterised.

Risk Management

6. Risk Management Strategy

To minimise the risk to honey consumers from tutin toxicity the levels should be below those currently known to be associated with tutin poisoning. Designating MLs for tutin in Standard 1.4.1 of the Code has to date been an effective risk management function for those foods that provide the most significant contribution to the total dietary exposure to the toxin. In addition to the development of MLs for tutin, several additional risk management strategies are being put in place to mitigate the risk of tutin poisoning:

- NZFSA is further developing its educational package for New Zealand beekeepers. This will provide comprehensive reference materials for beekeepers to understand the legislative and practical requirements of beekeeping, and in particular the compliance obligations associated with the control of tutin in honey and comb honey.
- NZFSA, in association with the Ministry of Health and Public Health Units in New Zealand, is developing an awareness strategy for the medical community in the at-risk geographical areas to assist in better understanding the risks and symptoms associated with tutin. Most of the data collected to date has been the result of severe or multiple poisoning incidents. This strategy is intended to encompass the potential risk of less severe health effects arising from levels of tutin lower than those which have been associated with reported poisonings to date.
- NZFSA will continue to enforce the MLs through routine testing of product sampled from retail outlets, through the National Residues Surveillance programme which targets premises exporting animal products including honey and through targeted audits. Persons found selling honey that breaches the tutin limits set in the Code will be subject to enforcement action. This may include detention and recall of products and prosecution as appropriate.
- NZFSA has produced a Compliance Guide to the Food (Tutin in Honey) Standard. This sets out the compliance options for meeting the MLs for tutin in honey. Currently NZFSA is proposing to retain the New Zealand standard and is reviewing the compliance options. One of the intentions of the review is to more effectively minimize the risk of illness from toxic honey.

7. Options

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sections of the community, including consumers, food industries and governments. In this case, non-regulatory options, such as codes of practice, advisory statements and public health education initiatives, on their own were not considered appropriate given that there is significant potential for adverse human health effects. A regulatory option was considered the most prudent outcome to safeguard human health and safety.

The regulatory options available for this Proposal are:

1. Reject the Proposal and allow the Standard for tutin to lapse.
- 2A. To approve a draft variation to the Code to maintain the current MLs for tutin in honey and comb honey as an interim measure in Standard 1.4.1, and establish a new expiry date (31 March 2013).
- 2B. To approve a draft variation to the Code to introduce permanent MLs for tutin in honey and comb honey.

8. Impact Analysis (RIS ID: 11832)

8.1 Affected Parties

- People who suffered illness from the recent poisoning incident and their families
- Consumers of honey, comb honey and food products containing honey.
- Industry sectors, such as:

- Beekeepers
 - Honey packers and processors
 - Manufacturers of honey containing products
 - Food retailers
- Agricultural sectors dependent on pollination services
 - Government agencies

The identified plant source of tutin, namely *C. arborea*, is not known to be present in Australia and therefore no impacts on honey producers or consumers in Australia are expected.

The Office of Best Practice Regulation (OBPR), Australian Commonwealth Department of Finance and Deregulation, was consulted on the need for a regulatory impact analysis for the proposed two year extension of the interim standard related to the maximum limits for tutin in honey (Reference No. 11832). They consulted with the Regulatory Impact Analysis Team of the New Zealand Treasury and consequently concluded that a Regulation Impact Statement (RIS) was not required at this time, but advised that a RIS may be required as part of developing a permanent standard.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Reject the Proposal

8.2.1.1 Benefits

- There are no particular benefits for consumers, industry or government agencies with this option. There would be a reduction in compliance costs associated with this option for industry in relation to laboratory testing and regulatory requirements. Government may also make savings in terms of its regulatory costs.

8.2.2.2 Costs

- For consumers, there would be the real potential for further harm from exposure to tutin-contaminated honey.
- For industry, there could be a loss in business and reputation if honey was seen as unsafe by consumers and markets. The onus would be placed on industry to demonstrate appropriate self education and enforcement.
- For government agencies, there may be costs associated with managing responses to the detection of tutin in honey products and for the public service in the clinical treatment of any future poisoning cases.

8.2.2 Option 2A – To approve a draft variation to the Code to maintain the current MLs for tutin in honey and comb honey as an interim measure

8.2.2.1 Benefits

- For consumers, this would provide a continuing level of reassurance of the safety of New Zealand produced honey products. Savings would also arise from consumers avoiding tutin-related illnesses.

- For beekeepers, honey packers and processors, manufacturers and retailers, this option would provide a specific level which all honey products should comply with.
- For government agencies, this option would enhance community confidence that regulatory authorities are maintaining standards that minimise dietary exposure to tutin. An extension to the expiry date of this standard would permit additional safety data to be obtained and analysed and the effectiveness of the current and proposed risk management measures to be evaluated.

8.2.2.2 Costs

- The maximum levels for tutin in honey and comb honey have been in place in the Code since 2009, with the industry substantially meeting the compliance requirements associated with those levels. Little or no additional costs are envisaged by this option for consumers, industry or government as compliance systems are already in place.

8.2.3 *Option 2B – To approve a draft variation to the Code to introduce permanent MLs*

8.2.3.1 Benefits

- The major benefit of this option would be regulatory certainty from a permanent standard.

8.2.3.2 Costs

- The costs of this option are unable to be evaluated at this stage due to the limited scientific data currently available. Any move to alter the MLs for tutin in honey and comb honey at this stage would not be able to be adequately supported.

8.3 Comparison of Options

In assessing proposals, FSANZ considers the impact of various regulatory and non-regulatory options on all sectors of the community, including consumers, food industries and governments in both Australia and New Zealand.

8.3.1 *Option 1 – Reject the Proposal*

Since 1991, regulations required beekeepers to minimise the risk of contamination of honey with tutin by removing hives from some designated areas endemic to tutu bush before the risk period (late December to end of April) or by ensuring that tutu was not present in areas foraged by bees. However, while this self-regulatory measure appeared to be an effective mechanism to limit tutin intoxication of honey, it failed as a risk management approach to prevent the 2008 Coromandel tutin poisoning episode.

An enforceable limit of tutin in honey coupled with a feasible laboratory testing programme and an extensive awareness programme that targets all New Zealand beekeepers, i.e. from large commercial apiaries to the small hobbyists, is a better strategy to effectively manage this issue.

8.3.2 *Option 2A - To approve a draft variation to the Code to maintain the current MLs for tutin in honey and comb honey as an interim measure*

This is the current risk management approach in effect in New Zealand and enforced by the NZFSA. It provides an acceptable measure of confidence in the safety of honey products complying with the current MLs.

8.3.3 Option 2B – To approve a draft variation to the Code to introduce permanent MLs

The inclusion of permanent MLs for tutin in honey and comb honey is not justified at present given the currently limited data on the toxicity of tutin. It is not known at this stage whether there would be a benefit of lowering the MLs for Tutin because of the limited scientific data currently available on the toxicity of tutin to humans. If the outcome of further research indicated a need to amend the limit downwards it is likely that this would have a major impact on the honey bee industry and negative flow on effects to other agricultural sectors. A full regulatory impact statement (RIS) would need to be undertaken to fully and fairly assess the impact on the New Zealand honey industry and agricultural sector in general. Thus, due to less than adequate data underlying the human toxicity of tutin-affected honey, the costs associated with this option, so as to provide an informed cost-benefit analysis, have not been fully explored at this stage.

8.3.4 Preferred option

For this Proposal, Option 1 is considered unacceptable because of the ongoing risk to public health and safety. Option 2B is not a preferred option at this point because there is insufficient information on the human toxicity of tutin and the impacts on all affected parties would need to be assessed if any different MLs were to be recommended. Option 2A is the preferred option at this point in time because:

- It continues to limit dietary exposure to tutin from honey and comb honey, and therefore protects public health and safety.
- It is based on the best data currently available, notwithstanding the need to further investigate the toxicity of tutin.
- The extension in the expiry date for the interim standard would permit resolution of the science underpinning the MLs.
- It is achievable for industry as the proposed MLs are identical to the current MLs for tutin, and the New Zealand beekeeping industry can demonstrate compliance with these MLs.
- Compliance data from the last 2 years since the 2008 poisoning episode has shown that the MLs are practical and feasible. This is further supported by the absence of any new poisonings.
- It should not impede trade as the MLs are already in force. New Zealand can demonstrate industry and regulatory responsibility in safeguarding human health and safety for both domestic and international consumers.

The expiry date for the Standard should be extended by 2 years to allow additional data to be sought and analysed. The new expiry date for the MLs for tutin in honey and comb honey would be 31 March 2013.

Communication and Consultation Strategy

9. Communication

It is proposed that existing interim MLs of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey be maintained in the Code. These values are equivalent to those in place in the Code since 2009. FSANZ has applied a basic communication strategy for this Proposal.

This included notifying interested parties advising of the availability of the Assessment Report for public comment and making the report available on the FSANZ website. FSANZ approached the National Beekeepers' Association of New Zealand about the availability of the Assessment Report, with the suggestion to include a reference to it on their website. Similarly, an article was also submitted to *The New Zealand Beekeeper* (October 2010), about the FSANZ Proposal.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the Proposal and the impacts of regulatory options. The issues raised in the public submissions have been evaluated and are addressed in the Approval Report.

The decision by the FSANZ Board to approve the variation to the Code will be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of its decision. If a request to review the decision is not made by the Ministerial Council, the variation will be gazetted. Stakeholder and submitters will be notified on the gazettal of changes to the Code via email and on the FSANZ website.

The New Zealand Government (NZFSA) is responsible for the implementation of the tutin standard in the Code. Currently, NZFSA is reviewing the New Zealand only standard - *Food (Tutin in Honey) Standard 2008*⁷ and has sought comment during a recent consultative period on a range of educative and enforcement strategies to be undertaken by the NZFSA in consultation with the beekeeping industry. Moreover, the NZFSA is seeking public comment on a recent proposal to issue the *Food (Tutin in honey) Standard 2010*⁸. These processes are separate and independent processes to the current Proposal outlined here.

10. Consultation

While an interim standard for tutin in honey and comb honey has been in place in the Code since 2009, FSANZ acknowledges that extending the implementation of MLs for tutin may have impacts on various industries associated with honey production and beekeeping, especially in New Zealand. In particular, FSANZ sought information regarding the costs and lost business opportunities this interim standard has had on the beekeeping industry and what the effect of maintaining this interim standard may have in the future.

10.1 Public consultation

The Assessment Report was available for public comment between 12 October 2010 and 9 November 2010. Comments were specifically requested on the scientific aspects of this Proposal, in particular, information relevant to the risk assessment of tutin. As the Proposal was assessed under a General Procedure, only one round of public comment was applicable.

A total of four submissions were received as a result of the public consultation. A summary of these is included at **Attachment 2**.

10.2 Issues raised in submissions

10.2.1 *The worldwide distribution of Coriaria species*

NZFSA drew attention to the fact that *Coriaria* species are distributed worldwide and could cause poisoning by their picrotoxin content. Low levels of contamination of other honeys could therefore be a possibility. Changes to the report's text were suggested to reflect this issue.

⁷ <http://www.nzfsa.govt.nz/consultation/tutin-in-honey-review/index.htm>

⁸ <http://www.nzfsa.govt.nz/consultation/tutin-in-honey-revised-standard/revised-standard/index.htm>

10.2.1.1 Response

FSANZ agrees with NZFSA that *Coriaria* species are distributed worldwide and that there have been reports of toxicity associated with the ingestion of the plant material or the related plant-containing picrotoxin. Given the limited information about *Coriaria* species worldwide and the negligible information about honey contamination by similar picrotoxins, FSANZ has altered the report's text (see Section 4.1) to reflect this gap in the scientific literature.

10.2.2 The expiry date of the draft variation

Federated Farmers Bees (New Zealand) have strongly recommended that in the draft variation to the Code, the wording '*cease to have effect*' be removed and replaced with '*shall be reviewed by*'.

10.2.2.1 Response

As noted in the report, FSANZ is of the opinion that additional research is required to fully characterise the hazard of tutin in honey and comb honey. The extension to the expiry date should permit additional scientific information to be sought or generated. In effect, FSANZ will review the tutin standard prior to the proposed new expiry date of 31 March 2013. This was supported by other submissions that noted the need for a greater scientific evidence base to determine the most appropriate regulatory measure(s).

10.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for tutin. Amending the Code to allow for an extension in the expiry term to the current interim tutin MLs in honey and comb honey is unlikely to have a significant effect on international trade as:

- The presence of tutin in honey seems to be unique to New Zealand. As there are no indications that tutin is present in honey from any other country, it is considered highly probable that there would be no imposts on imported honey from other countries.
- Interim standards for tutin by New Zealand and FSANZ have been in place since 2008 and 2009, respectively, for the protection of human health and safety.
- This measure may improve trade due to jurisdictional measures to ensure the safety of New Zealand honey products for domestic and international markets.

For these reasons it was determined that there was no need to notify this Proposal under the Sanitary and Phytosanitary Agreement.

Conclusion

11. Conclusion and Preferred Option

Following consideration of the risks to public health and safety, and based on the best data available to date, FSANZ is proposing that an interim standard for tutin in honey and comb honey should continue in the Code.

The occasional presence of high levels of tutin in honey and comb honey can represent a risk to public health and safety. The proposed food regulatory measure will maintain an interim maximum level for tutin of 2 mg/kg in honey and 0.1 mg/kg in comb honey in the Code. The purpose of this measure is to set limits for tutin levels in honey and comb honey that are considered to be safe based on current knowledge, and which are enforceable. The ongoing compliance with the proposed food regulatory measure would reduce the dietary exposure to tutin and address the potential for public health implications that have identified with this naturally-occurring toxin.

While not currently within the scope of this Proposal, additional regulatory and non-regulatory measures may be required in the future as investigations continue into tutin. Ongoing research by NZFSA and FSANZ will permit a more robust risk assessment of tutin toxicity. This would also support a more comprehensive evaluation of the current and proposed risk management measures. The continuation of the interim MLs for tutin in honey and comb honey is therefore considered an appropriate risk management measure while these investigations continue.

Decision

To approve the variation to the Standard 1.4.1 – Contaminants and Natural Toxicants to maintain an interim maximum level of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey. The interim standard to be extended by 2 years with an expiry date of 31 March 2013.

11.1 Reasons for Decision

- Honey and comb honey are in general safe to consume.
- The occasional presence of high levels of tutin in honey and comb honey, however, represents a risk to public health and safety.
- As tutin is a colourless, odourless and tasteless toxin, consumers cannot differentiate between honey products that may or may not contain the toxin.
- Due to the adventitious presence of tutin in honey produced in New Zealand and the severity of intoxication from consumption of honey containing high levels of tutin, an ongoing food regulatory measure is recommended.
- It is considered that the appropriate food regulatory measure is to include MLs for tutin in honey and comb honey in Standard 1.4.1.
- Recent human poisonings indicate that comb honey is a relatively high risk product compared to extracted and blended honey, and warrants a lower tutin level because of the potential for high levels of tutin in comb honey.
- The inclusion of MLs for tutin in Standard 1.4.1 is considered to be an appropriate risk management measure while additional information is gathered about the toxicity of tutin.
- MLs of 2 mg/kg in honey and 0.1 mg/kg in comb honey are considered practical and reasonably achievable as demonstrated from the results of the current testing regimen by the responsible food enforcement authority, NZFSA.

- The regulatory environment for tutin in New Zealand is comprehensive and well supported to ensure industry compliance and enforcement. Furthermore, it plays an important role in safeguarding public health and safety while further investigations into tutin toxicity continue.
- Limited or negligible additional costs to industry or consumers would arise from this food regulatory measure.

11.2 Transitional Arrangements

Given the public health concerns with tutin and that an interim standard for tutin in honey and comb honey have been in place in the Code since 2009, FSANZ is not proposing any transitional arrangements for the proposed level i.e. it is currently proposed that the level would come into effect upon gazettal.

12. Implementation and Review

The current risk management practices in New Zealand, including testing honey for compliance with the Standard, suggest that the risk from a further poisoning episode is low. FSANZ and NZFSA will endeavour to seek additional data that would support a comprehensive risk assessment.

References

- Beasley DM. (2008). A recent outbreak of honey poisoning linked to the tutu plant (*Coriaria arborea*). Abstracts of the 2008 North American Congress of Clinical Toxicology Annual Meeting, September 11–16, 2008, Toronto, Canada. *Clin Toxicol*, **46**:617.
- Clinch PG, Turner JC. (1968). Estimation of tutin and hyenanchin in honey. 2. The toxicity of honey samples from test hives during the period 1962-67. *New Zealand Journal of Science*, **11**:346-351.
- Clinch PG, Turner JC. (1975). Estimation of tutin and hyenanchin in honey. 3. Toxicity of honey samples from test hives, 1968-74. *NZ J Sci*, **18**:323-328.
- Fitchett F. (1908). A contribution to our knowledge on the physiological action of tutin. *Trans NZ Inst*, **41**:286-366.
- Fitchett F and Malcolm J. (1909). On the physiological action of tutin. *Exp Physiol*, **2**:335-362.
- Fuentealba J, Guzmán L, Manríquez-Navarro P, Pérez C, Silva M, Becerra J, Aguayo LG. (2007). Inhibitory effects of tutin on glycine receptors in spinal neurons. *Eur J Pharmacol*, **559**:61-64.
- Kinoshita T, Itaki N, Hikita M, Aoyagi Y, Hitotsuyanagi Y, Takeya K. (2005). The isolation and structure elucidation of a new sesquiterpene lactone from the poisonous plant *Coriaria japonica* (Coriariaceae). *Chem Pharm Bull (Tokyo)*, **53**:1040-1042.
- Koca I and Koca AF. (2007). Poisoning by mad honey: A brief review. *Food Chem Toxicol*, **45**:1315-1318.
- Love J, Swallow W, Maister SG. (1986). The determination of tutin and hyenanchin in honey by HPLC. *NZ J Tech*, **2**(3):179-182.
- NZFSA. (2003). Background on toxic honey. New Zealand Food Safety Authority. (Article updated 1 April 2008). <http://www.nzfsa.govt.nz/animalproducts/publications/info-pamphlet/bee-products/toxic-honey.htm>

NZFSA. (2008). Tutin in honey. NZFSA Public Discussion Paper; no. 09/08. 31 October 2008. <http://www.nzfsa.govt.nz/consultation/tutin-in-honey/discussion-paper/tutin-in-honey-discussion-paper-final-for-web.pdf>

Palmer-Jones T. (1947). A recent outbreak of honey poisoning: Part I. Historical descriptive. *NZ J Sci Tech*, **29**:107-114.

Palmer-Jones T. (1965). Poisonous honey overseas and in New Zealand. *NZ Med J*, **64**:631-637.

Shen YH, Li SH, Li RT, Han QB, Zhao QS, Liang L, Sun HD, Lu Y, Cao P, Zheng QT. (2004). Coriatone and corianlactone, two novel sesquiterpenes from *Coriaria nepalensis*. *Org Lett*, **6**:1593-1595.

Sutherland M, Palmer-Jones T. (1947). A recent outbreak of honey poisoning: Part V. The source of the toxic honey - laboratory investigations. *NZ J Sci Tech*, **29**:129-134.

Swallow WH, Curtis JF, Clinch PG, Turner JC. (1980). Estimation of tutin and hyenanchin in honey. 4. Comparison of a new gas chromatographic method with intracerebral injection of mice. *NZ J Sci*, **23**(4):365-369.

Turner N, Cressey P, Lake R and Whyte R. (2005). Review of non-commercial wild food in New Zealand. Report to New Zealand Food Safety Authority from the Institute of Environmental Science & Research Ltd by. February 2005. <http://www.foodsmart.govt.nz/elibrary/commercial-zealand-report-wild-foods-review/>

Wei H, Zeng F, Lu M, Tang R. (1998). Studies on chemical constituents from the root of *Coriaria nepalensis* Wall (*Coriaria sinica* Maxim), *Yao Xue Xue Bao*, **33**:688-692. [Article in Chinese. Abstract available in English].

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

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

[1] **Standard 1.4.1** is varied by –

[1.1] *inserting after subclause 5(4) –*

(5) The maximum levels for tutin in honey and tutin in comb honey cease to have effect on 31 March 2013.

[1.2] *omitting from the Table to clause 5 –*

The ML for Tutin to cease on 31 March 2011 Tutin Tutin in honey Tutin in comb honey	2 0.1
------------------------------------------------------------------------------------------------------------	----------

substituting –

Tutin Tutin in honey Tutin in comb honey	2 0.1
-------------------------------------------------------	----------

Attachment 2

Summary of Public Submissions on the Assessment Report

Four submissions were received during the public consultation period in response to the Assessment Report.

Support for the Proposal was noted from three government agencies and one industry group. No submissions were received from any professional organisations, consumer groups or individuals. All submissions were in support of Option 2A: Maintain the current MLs for tutin in honey and comb honey as an interim measure in Standard 1.4.1, and establish a new expiry date (31 March 2013).

Some minor changes to the report were also suggested by two submitters. These suggested changes were incorporated where applicable.

A summary of all submissions received is provided in the table below.

Table 1: Summary of Submissions

Submitter	Group	Comments
Queensland Health	Government	Supports Option 2A.
Department of Health & Department of Primary Industries, Victoria	Government	Supports Option 2A. Subject to ongoing work of FSANZ & NZFSA to develop scientific evidence base.
New Zealand Food Safety Authority	Government	Supports Option 2A. Additional comments noted in the Assessment Report.
Federated Farmers Bees (New Zealand)	Industry group	Supports Option 2A. Additional comments noted in the Assessment Report.