

Supporting document 2

Consultation Regulation Impact Statement – Proposal P1029

Maximum Level for Tutin in Honey

Purpose of this document

This document is a consultation regulation impact statement. It has been prepared by the Ministry for Primary Industries, with assistance from Food Standards Australia New Zealand (FSANZ). It is supporting document number 2 (SD2) for FSANZ's call for submissions on a draft regulatory measure arising from Proposal P1029 – Maximum Level for Tutin in Honey. SD2 sets out the options, evaluates the costs and benefits of each option, and determines a preferred option. This document contains questions seeking additional information from submitters. Appendix 2 contains a summary of these questions.

Executive summary

Tutin is a neurotoxic compound produced by the shrub *Coriaria arborea* (tutu) which is native to New Zealand. A vine hopper insect (*Scolypopa australis*) that feeds on the tutu excretes honeydew that contains the toxin tutin. This honeydew can be collected by bees for honey production. Tutin is highly toxic to humans.

Human poisoning incidents associated with consuming honey containing tutin have occurred sporadically in New Zealand since the late 1800s. A poisoning incident in the Coromandel in 2008 prompted more research into tutin. Following this incident, the former New Zealand Food Safety Authority (NZFSA) used mouse toxicity data to establish a maximum level of tutin in extracted or blended honey of 2 mg/kg. A lower maximum level of 0.1 mg/kg was established for comb honey to account for potential heterogeneity in tutin distribution across a comb.

These maximum levels were incorporated in Standard 1.4.1 of the *Australia New Zealand Food Standards Code* (the Code) as temporary levels in August 2009 with an initial expiry date of 31 March 2011 as interim protection while further research was undertaken. This expiry date was later extended to 31 March 2015.

This research is now completed. In a pharmacokinetic study, 6 volunteers were given honey containing a dose of tutin equivalent to that which would be ingested (in one day) by a high consumer of honey at the temporary maximum level of 2 mg/kg. The serum tutin concentration profile for all volunteers exhibited two discrete peaks. Transient mild light headedness was reported by two volunteers during the first peak, and transient mild headaches were reported by the same two subjects during the second peak. The first peak was consistent with the known tutin in honey. The second peak is explained by the discovery of tutin glycosides (tutin that is chemically bound to carbohydrates) in honey which results in a delayed release of additional tutin following honey ingestion.

Therefore it is likely that adverse effects may be experienced by some people after consuming honey containing tutin at the current maximum level of 2 mg/kg. Whilst the effects seen in the pharmacokinetic study were mild light headedness and headaches, there is considerable uncertainty in extrapolating the findings from a small scale study to an entire population. Considering that a third of the test population in the small scale study were affected, it is most likely that more sensitive individuals would be present in the population and would experience more severe effects (eg nausea, vomiting, dizziness) if they were high consumers of honey which contained tutin at the current maximum level.

FSANZ is now seeking public feedback on the preferred option of reducing the maximum levels for tutin in honey and comb honey in the Code. In developing this preferred approach, four options were considered:

- Option 1: Let the temporary maximum levels expire with no new levels or measures in place
- Option 2: Let the temporary maximum levels expire and encourage the honey industry to adopt a code of practice
- Option 3: Make the current temporary maximum levels the permanent maximum levels
- Option 4: Reduce the maximum levels in line with the results of recent research and make these levels permanent

Option 1 has an overall net cost. While beekeepers that produce honey for the domestic market will face lower costs, more people are likely to be poisoned than is currently the case. In addition, government will face the costs of revoking the Tutin Standard and may face increased enforcement costs initially under the Food Act 1981 and then under the Food Act 2014, and the Animal Products Act 1999. Option 2 has an overall net cost as any code of practice would not be able to be enforced by government. Option 3 does not adequately protect consumers against the adverse effects found in recent research. It has a possible net cost as overseas markets may react negatively to the recent research not being taken into account in setting the maximum levels.

The preferred option (Option 4) is to reduce the maximum level for tutin in honey from 2 mg/kg to 0.7 mg/kg and the maximum level for tutin in comb honey from 0.1 mg/kg to 0.01 mg/kg. It is the option that takes full account of the risk analysis using the best available scientific evidence which FSANZ is required to have regard to under the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). It also meets the FSANZ Act objective to protect public health and safety and has regard to the desirability of an efficient and internationally competitive food industry.

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1. Statement of the Problem

The presence of tutin in honey can cause human poisonings. FSANZ has prepared Proposal P1029 to review the maximum levels for tutin in honey and comb honey in Standard 1.4.1 of the Code in order to ensure they are protective of human health. The current maximum levels are due to expire on 31 March 2015.

Since the original levels were set, more research has been undertaken into the toxicity of tutin in honey. These results indicate that the current maximum levels do not reflect the best available science.

Although this is a Standard under the Food Standards Treaty, which involves decisions being taken in the Council of Australian Governments (COAG), any replacement standard would only have impacts in New Zealand, as the necessary conditions for tutin poisoning only occur there.

1.1 Background and Context

New Zealand has almost 4,300 beekeepers. They produced 17,825 tonnes of honey in 2012/13, and exported 8,054 tonnes. More information on the New Zealand honey industry can be found in Appendix One.

The main parties affected by this proposal are people selling honey for human consumption or export where that honey is harvested from high risk locations (those located north of latitude 42 degrees south), or between high risk harvest dates in New Zealand. No specific groups will be affected in Australia as the tutu bush does not grow there. The particular groups in New Zealand that may be affected by this policy are:

- Beekeepers, honey packers and processors
- Health sector (including hospitals, emergency care, and general practitioners)
- Laboratories that test honey for tutin contamination
- Government departments: particularly the Ministry for Primary Industries and the Ministry of Health

Tutin

Tutin is a neurotoxic compound produced by the shrub *Coriaria arborea* (tutu) native to New Zealand. A vine hopper insect (*Scolypopa australis*) that feeds on the sap of tutu plants excretes honeydew that contains the toxin tutin. This honeydew can be collected by bees for honey production. Tutin is highly toxic to humans even in extremely small amounts. High levels of tutin in honey can cause severe effects, including death.

Currently vine hopper insects are only found on tutu bushes north of latitude 42 degrees south. This line runs across the top of the South Island, from above Greymouth on one side to between Kaikoura and Nelson on the other side. Areas south of this line are not at risk of honey being contaminated with tutin. The highest risk areas for honey contaminated with tutin are in Northern Hawkes Bay and the Coromandel. Approximately 72 percent of the volume of the honey harvested comes from high risk areas. Approximately 73 percent of beekeepers harvest honey from high risk areas. Seasonal risk is highest for harvest dates between 1 January and 30 June each year.

Tutin poisonings

There have been 34 reported tutin poisonings since 1980. Reported poisonings are likely to be only a percentage of the actual number of poisonings as some people who are poisoned may not connect their illness with honey, particularly if the symptoms are not severe enough to require hospitalisation or if patients and physicians do not connect the symptoms to honey consumption.

Symptoms of tutin poisoning generally last about 48 hours, and include nausea, vomiting, giddiness, headaches, abdominal pain, convulsions, rigidity of limbs, and unconsciousness. Some symptoms last for up to 6 weeks including memory loss, anxiety, pins and needles in fingers and toes, and a heavy stiff numb feeling¹.

			Affected	
Place	Honey type	Year	persons	Severity ²
Warkworth	Extracted	1980	3	Medium
Whangamata	Extracted	1981	3	Medium
Pelorous Sound	Comb	1982	1	Medium
Pelorous Sound	Comb	1983	1	Medium
Great Barrier Island	Not known	1984	1	Low
Opotiki	Comb	1991	1	High
Coromandel	Comb	2008	22	Medium/High
Opotiki	Extracted	2009	1	Unconfirmed
Bay of Plenty	Comb	2014	1	High

Table 1: Known cases of poisonings from toxic honey reported to MPI since 1980

The honey that caused the 2008 Coromandel poisoning was comb honey that was sold commercially. Levels of tutin of between 30 and 50 milligrams per kilogram were found in the leftover honey consumed by the poisoning victims.

The 2009 poisoning involved extracted honey that was sold by a commercial beekeeper. Testing showed that the amount of tutin in the honey was 4.2 mg/kg. This poisoning remains unconfirmed as, while the amount of tutin in the honey exceeded the temporary maximum level, the symptoms exhibited by the person were not typical of a tutin poisoning.

The individual poisoned in 2014 was a commercial beekeeper who consumed untested comb honey from his own hives. Testing showed that the amount of tutin in this honey was 29 mg/kg so it exceeded the temporary maximum level for both honey and comb honey. The beekeeper did not sell any of this comb honey so it unlikely that there were any other poisonings connected to this incident.

¹ Goodwin, Mark (2013) A New Zealand History of Toxic Honey Page 155

² Low – no medical attention sought. Medium - most persons visited a general practitioner but some may have required hospitalisation. High - all persons were hospitalised. Unconfirmed – testing showed high levels of tutin in honey consumed but symptoms were not typical of a tutin poisoning

Tutin research

Following the 2008 poisoning incident, temporary maximum levels for tutin in honey and comb honey were set in the Code in Standard 1.4.1 due to the need to put in place urgent risk management measures while further research was undertaken into the toxicity of tutin in honey. The maximum level for tutin in honey was set at 2 mg/kg. A lower maximum level of 0.1 mg/kg was established for comb honey to account for potential heterogeneity in tutin distribution across a comb.

As it was difficult to determine how much honey contaminated with tutin could be consumed without having an effect, a conventional uncertainty factor of 100 was included in the calculation. For comb honey, a further uncertainly factor of 20 was applied to the maximum level for honey to arrive at a maximum level of 0.1 mg/kg for comb honey. Uncertainty factors are used to provide an adequate margin of safety for the consumer³.

Research was also commissioned to investigate the reasons for the variability in the onset time of clinical signs and symptoms of toxicity following honey ingestion. This research is now completed. It consisted of a pharmacokinetic study where 6 volunteers consumed an amount of honey containing tutin that resulted in a dose equivalent to that received by high consumers of honey (0.9 g honey per kg of bodyweight⁴) containing tutin. The serum tutin concentration profile for all volunteers exhibited two discrete peaks, with the first at 0.5 - 1.5 hours post dose, and the second, higher peak, at 8 - 16 hours post dose. Transient mild light headedness was reported by two volunteers during the first peak, and transient mild headaches were reported by the same two subjects during the second peak. The other volunteers did not report any ill effects.

The first peak observed in the study was consistent with the known tutin in honey, while the second peak was explained by the subsequent discovery of tutin glycosides (tutin that is chemically bound to carbohydrates) in honey which results in a delayed release of additional tutin following tutin ingestion. As no method is currently available for the quantification of tutin glycosides in honey, the continued use of a maximum level based on the level of tutin in honey instead of total tutin equivalents (tutin plus tutin glycosides) is necessary.

Based on these results, it is likely that adverse effects may be experienced following the consumption of honey containing tutin at the current maximum level of 2 mg/kg. Therefore, the current maximum levels are not appropriate due to the evidence that tutin can act as a neurotoxin at these levels (i.e. adversely affect brain function) as manifest in the adverse effects experienced by two of the volunteers. Whilst the effects seen in the pharmacokinetic study were mild light headedness and headaches it should be noted that there is considerable uncertainty in extrapolating the findings from a small scale study to an entire population. Considering that a third of the test population in the small scale study were affected, it is most likely that more sensitive individuals would be present in the population and would experience more severe effects such as nausea, vomiting, and dizziness.

Adverse effects are more likely if 0.9 g of honey per kg of bodyweight (as per high consumers) or greater is eaten in one sitting. For a high consuming adult, this equates to consuming approximately 3 tablespoons of honey⁵ containing tutin at the current level of 2 mg/kg in one sitting. Survey data indicates that New Zealand children (5 to 8 years of age) may be exposed to higher levels of tutin per kg bodyweight than adults.

³ Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) (2009) 'Principles and Methods for the Risk Assessment of Chemicals in Food'

⁴ Consumption data obtained from the 1997 New Zealand National Nutrition Survey indicated that the 97.5th percentile honey consumption for consumers aged 15 years and above was 0.9 g per kg of bodyweight per day.

⁵ Assumes a standard New Zealand tablespoon is 15 ml.

Consequently it is necessary to reduce the maximum levels. A reduction in the maximum level by a factor of 3 is proposed. This gives a revised maximum level of 0.7 mg/kg for honey. This reduction factor takes into account the variability observed between individuals in the pharmacokinetic study and the necessity to base the maximum level on tutin instead of total tutin equivalents. As the ratio of tutin glycosides to tutin can vary over an approximate 5-fold range, the amount of tutin measured in a honey sample could be an underestimate of the total amount present. The safety factor used the highest observed ratio to account for this variance.

Assessing the risk for comb honey is problematic as there are insufficient data on the variability of tutin levels within and between combs. Tutin can be concentrated in small sections of the honey comb and in particular cells and frames in the hive so it is conceivable that the tutin level in honey sampled from a specific portion of comb could differ markedly from the tutin level in another part of the comb. FSANZ's risk assessment concluded that there are insufficient data on the heterogeneity of tutin distribution to characterize the risk for comb honey. A maximum level equivalent to the analytical limit of detection would minimize the health risk posed by comb honey. Consequently, a reduction in the maximum level for comb honey from 0.1 mg/kg to 0.01 mg/kg is recommended.

More information on this research can be found in FSANZ's risk assessment on tutin. The risk assessment is Supporting Document 1 to FSANZ's call for submissions for Proposal P1029 Maximum Level for Tutin in Honey.

Industry views

Overall feedback from the honey industry to date is that they have welcomed the tutin regulation. Comments tend to focus on the increased certainty about the safety of honey due to the additional research since 2008. The current view of the Bee Product Standards Council⁶ is that the costs of testing are outweighed by the peace of mind from knowing customers are unlikely to be poisoned. Testing also provides a management tool that allows hives to be placed in areas previously considered to be too high risk.

Some beekeepers in areas they believe to be low risk for tutin have objected to having to meet the tutin requirements. However, an option was introduced in the 2010 amendment to the Food (Tutin in Honey) Standard that reduced the testing burden for some beekeepers. It allows beekeepers to test only 10 percent of their apiary sites each year if they have three years of test records showing that:

- No individual result has ever exceeded 0.1 mg/kg for honey, and
- No result has ever exceeded 0.01 mg/kg for comb honey.

The beekeeping industry has been kept updated on progress with the review of the maximum levels for tutin in honey and in comb honey through ongoing regular presentations at industry forums and conferences. FSANZ and MPI advised the Bee Products Standards Council at their November 2013 meeting that the maximum level for honey was likely to be lowered to between 1.0 mg/kg and 0.5 mg/kg. FSANZ and MPI also repeated this message at the February 2014 meeting.

⁶ The Bee Products Standards Council is made up of representatives from a number of industry groups with an interest in honey issues: the National Beekeepers Association, Federated Farmers Bees Group and the Honey Packers and Exporters Association.

1.2 Legislation

Those who process, store, sell, or export honey must comply with the requirements of the Food Act 1981, the Food Act 2014, and the Animal Products Act 1999 in New Zealand⁷. Section 9 of the Food Act 1981 and Section 14 of the Food Act 2014 also provides protection for consumers as it prohibits the sale of unsafe or contaminated food. Honey for export is regulated under the Animal Products Act 1999.

Bee product businesses that extract or pack bee products that are only sold in New Zealand, or that are exported to countries that do not require official assurances (export certificates), must comply with the Food Act. Most countries do not require export certificates. Countries that require export certificates for honey include Japan and countries that are part of the European Union. To comply with the Food Act, businesses must have a registered Food Safety Programme, or operate under the Food Hygiene Regulations.

Businesses can also operate under a Risk Management Programme (RMP) under the Animal Products Act. Bee product businesses that export to countries that require official assurances (export certificates) must have a registered RMP, participate in the residues monitoring programme, and meet requirements for export as well as meeting any requirements of the country they are exporting to.

Two standards currently regulate tutin in honey for sale:

- Standard 1.4.1 of the Australia New Zealand Food Standards Code (the Code) that applies in Australia and New Zealand.
- The Food (Tutin in Honey) Standard 2010 made under the New Zealand Food Act 1981 that applies only in New Zealand. It provides options for demonstrating compliance with the maximum level in the Code.

This regulation impact statement focuses on the maximum levels in Standard 1.4.1 of the Code.

Standard 1.4.1 of the Australia New Zealand Food Standards Code

The Code is administered by FSANZ, an independent statutory agency established by the FSANZ Act. FSANZ's role includes developing standards that regulate the use of ingredients, the composition of some foods, and labelling requirements for packaged and unpackaged foods for sale.

Standard 1.4.1 in the Code sets out maximum levels of particular contaminants and natural toxicants in food. Maximum levels are usually only set for risk management purposes for foods that could potentially contain the contaminant or natural toxicant at a level such that it would be a major dietary contributor to the overall intake of that chemical in Australia and New Zealand. For other foods, the general principle, regardless of whether or not a maximum level is set, is that the levels of contaminants and natural toxicants in food should be kept as low as reasonably achievable.

⁷ The Food Act 1981 and the Food Act 2014 refers to New Zealand's two Food Acts

This standard currently contains temporary maximum levels for tutin in honey of 2.0 mg/kg and for comb honey of 0.1 mg/kg. These maximum levels apply to honey and comb honey produced for sale in both New Zealand and Australia. Tutu does not grow in Australia. The temporary maximum levels were introduced as a temporary risk management measure in response to a poisoning incident in Coromandel, New Zealand while further research was undertaken on the toxicity of tutin in honey. These temporary maximum levels had an initial expiry date of 31 March 2011. The expiry date was extended to 31 March 2015 as additional time was required to complete the research.

Food (Tutin in Honey) Standard 2010

While the Food (Tutin in Honey) Standard 2010 (the Tutin Standard) is not the subject of this consultation regulation impact statement, the Tutin Standard sets options for demonstrating compliance that support the maximum levels set in Standard 1.4.1 of the Code. These options relate to matters such as record keeping and testing, with variations according to whether the honey is harvested from high or low risk areas. The requirements in the Tutin Standard apply to the last person to pack honey for sale for human consumption and any person exporting honey. Beekeepers who supply honey to a packer or exporter must hold records that will enable them to demonstrate compliance with the Tutin Standard.

Regulation prior to 2008

Prior to the introduction of the Tutin Standard in 2008 beekeepers were required to ensure that honey was not harvested from beehives in areas where it was likely that the honey would be contaminated with harmful levels of phytotoxins from the tutu plant. Risk areas for toxic honey were determined by the then Ministry of Agriculture and Fisheries and regularly reviewed. The last review of these areas was in 1985. Over time the risk areas change due to reforestation, regenerating scrub and changes in the distribution of vine hoppers. Keeping risk areas up to date requires frequent reviews of the distribution of tutu bushes. This is costly and difficult to accurately assess as tutu bushes often grow in areas that are difficult to accurately locate all bushes in some areas, particularly if tutu has established in new areas. For these reasons, this method was not chosen in 2008 when the temporary maximum level was set as the means to manage tutin in honey.

2. Objectives

2.1 Legislation

Under statutory requirements in the FSANZ Act, where statutory interventions are required (such as 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
- The provision of adequate information relating to food to enable customers to make informed choices
- The prevention of misleading or deceptive conduct.

In developing and varying food regulatory measures, FSANZ must also give consideration 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
- Any written policy guidelines formulated by the Ministerial Council.

2.2 Criteria

Based on the legislative objectives above, a set of criteria in relation to tutin in honey have been derived for the purposes of this consultation regulation impact statement. These are:

- The protection of public health and safety
- The need for standards to be based on risk analysis using the best available scientific evidence
- The desirability of an efficient and internationally competitive food industry (market access).

Another relevant criterion for this consultation regulation impact statement is to avoid any unnecessary cost burdens on industry (implementation).

When assessing the options in the following section, the above criteria will be used as the foundation of the evaluation structure. This analysis will focus on costs and benefits across four categories: implementation, public health, best available science, and market access.

3. Options

3.1 Option 1: Status Quo - Temporary Maximum Levels Expire

Description: Let the temporary maximum levels expire with no new levels or measures in place

Under this option the temporary maximum levels in the Code would expire on 31 March 2015 and the Tutin Standard would be revoked in New Zealand. There would still be some protection for consumers, initially under Section 9 of the Food Act 1981 and then under Section 14 of the Food Act 2014 which prohibits the sale of unsafe or contaminated food. However, this option only allows regulatory action after a poisoning event: it does not provide for intervention to prevent poisonings occurring in the first place. The export requirements under the New Zealand Animal Products Act would still apply.

3.2 Option 2: Industry Code of Practice

Description: Let the temporary maximum levels expire and encourage the honey industry to adopt a code of practice

Under this option the temporary maximum levels in the Code would expire on 31 March 2015 and the Tutin Standard would be revoked in New Zealand. Instead, industry would be encouraged to adopt a code of practice. This code could be developed by industry or government or a combination of both but would be administered by industry. Government could apply additional measures such as consumer education and would independently monitor the effectiveness of the code. As under Option 1, the sale of unsafe or contaminated food would be prohibited under the New Zealand Food Acts and the export requirements under the New Zealand Animal Products Act would still apply.

3.3 Option 3: Retain Temporary Maximum Levels

Description: Make the current temporary maximum levels the permanent maximum levels

Under this option the temporary maximum levels for tutin in honey of 2 mg/kg and in comb honey of 0.1 mg/kg would become the permanent maximum levels. The options for compliance in the Tutin Standard would still apply. As under Option 1, the sale of unsafe or contaminated food would be prohibited under the New Zealand Food Acts and the export requirements under the New Zealand Animal Products Act would still apply.

3.4 Option 4: Reduce Maximum Levels

Description: Reduce the maximum levels due to the results of recent research

Under this option, the maximum levels for tutin in honey would reduce from 2 mg/kg to 0.7 mg/kg. The maximum level for comb honey of 0.1 mg/kg would reduce to 0.01 mg/kg. These would be set as permanent maximum levels. The reductions in maximum levels are based on research commissioned by MPI and FSANZ to gain more information about some of the effects observed in the 2008 poisoning in the Coromandel and further consideration of the potential variability in comb honey deposition. As under Option 1, the sale of unsafe or contaminated food would be prohibited under the New Zealand Food Acts and the export requirements under the New Zealand Animal Products Act would still apply.

QUESTION

Question 1: Are there any other options that are significantly different from the above that should be considered? If so, please provide information to support them.

4. Impact Analysis

A qualitative assessment of the costs and benefits of each option has been performed according to the costs/benefits across four evaluation criteria derived in the objectives section. These are:

- Implementation costs and benefits
- Public health costs and benefits
- Best available science
- Market access costs and benefits

4.1 Option 1: Status Quo – Temporary Maximum Levels Expire

	Costs	Benefits	Overall
Implementation	 Beekeepers that do not operate under a Risk Management Programme (RMP) would no longer be required to meet the maximum level. Some may choose to continue with testing. If the number of tests overall dropped, testing laboratories may need to increase the costs per tutin test. Beekeepers that produce honey for export would still face the costs of a RMP. As most honey is packed by facilities that have an RMP, this may mean few changes to costs for these producers. Government will face the costs of revoking the Tutin Standard. If the number of poisonings increased there would be direct costs to MPI for enforcing Section 9 of the Food Act 1981 initially, then Section 14 of the Food Act 2014, and RMP requirements. 	No financial benefit other than lowered compliance costs for beekeepers that do not operate under an RMP. If all tutin testing stopped, based on averaging the known costs and volumes, industry could save between \$138,000 and \$213,000 per year. It is not possible to estimate what proportion of this testing is undertaken by companies producing honey solely for the domestic market. No information is available on the costs of testing comb honey for tutin. Beekeepers in lower risk areas would no longer be required to keep geographic and harvest records for four years to demonstrate that their product is not affected by tutin.	Small net cost Decrease in costs for beekeepers that produce honey for the domestic market. Government would face the costs of revoking the Tutin Standard. Government enforcement costs initially under Section 9 of the Food Act 1981, then Section 14 of the Food Act 2014, and the Animal Products Act may increase if poisonings increase.
Public health	Inadequate protection for individual consumers from the risk of consuming honey contaminated with tutin. A possible increase in the frequency of tutin poisonings, and	No direct public health benefits for this option.	Net cost No benefits and an increased risk of poisoning incidents for honey packed for the domestic market.

possible incidents affecting more than just one or two individuals.	
For mild cases of poisoning the estimated public health costs per person vary from none (no medical treatment sought and no time off work required) to \$220 (a visit to a general practitioner and a day off work ⁸).	
The effects may be more adverse than those observed in the clinical trials for more sensitive people in the population. Therefore the cost estimate for mild cases may be an under-estimate.	
Serious poisoning cases require hospitalisation for several days and recovery at home afterwards. Based on experiences in 2008, the estimated public health costs for severe cases per person can vary from \$1,566 ⁹ to \$4,674 ¹⁰	

⁸This analysis assumes that a general practitioner visit costs \$48. The cost of a day of lost wages is estimated using the median wage per hour from Statistics New Zealand and assumes an 8 hour day. Median wage available at <u>http://www.stats.govt.nz/browse_for_stats/income-and-</u>work/Income/NZIncomeSurvey_HOTPJun13gtr.aspx

http://www.who.int/choice/country/nzl/cost/en/

⁹ This analysis assumes 3 nights in hospital and 3 days off work as per the cases documented in 'Toxic honey victim released from hospital' New Zealand Herald 23 March 2008 downloaded from

<u>http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10499707</u>. The cost of a day of lost wages is estimated using the median wage per hour from Statistics New Zealand and assumes an 8 hour day. The median wage is available at <u>http://www.stats.govt.nz/browse_for_stats/income-and-</u>

wage is available at <u>http://www.stats.govt.nz/browse_for_stats/income-and-work/Income/NZIncomeSurvey_HOTPJun13qtr.aspx</u>. The cost of a bed night in hospital has been estimated at \$349.5 in 2005 dollars based on the cost of a night in a tertiary hospital from

¹⁰ This analysis assumes 3 nights in hospital and 21 days off work as per the case documented in ACC Focus (15 February 2009) 'Four charges over toxic honey' downloaded from <u>http://accfocus.org/health/item/642-four-charges-over-toxic-honey.html</u>. The cost of a day of lost wages is estimated using the median wage per hour from Statistics New Zealand and assumes an 8 hour day. The median wage is available at http://www.stats.govt.nz/browse for stats/income-and-work/Income/NZIncomeSurvey_HOTPJun13qtr.aspx The

	excluding drugs and tests. Some cases may also require an ambulance trip to hospital. Costs increase if the incident involves more than one person. In extreme cases such as the 2008 poisoning in the Coromandel, a total of 22 people were poisoned. Costs included 9 people being admitted to hospital and 4 people seeking care from a general practitioner.		
Best available science	Research since the 2008 poisoning would not be taken into account.		This option is not based on the best available science.
Market access	New Zealand's honey exports have seen major growth in China over the last 18 months, and China now provides 25% of honey export value (incl. Hong Kong). China is very sensitive to food safety issues, so the possible damage to this relatively new trade relationship could potentially be very serious. A loss of confidence in this market could lead to lower export receipts and higher compliance costs as trade partners may	The benefits may expire even if there is no poisoning event as export markets may still lose confidence. As a result, we assume there are no market access benefits flowing from this option.	Possible small net cost if export markets impose their own testing regimes.
	impose their own testing regimes.		

cost of a bed night in hospital has been estimated at \$349.5 in 2005 dollars based on the cost of a night in a tertiary hospital from http://www.who.int/choice/country/nzl/cost/en/

Overall the costs of this option are potentially higher than currently is the case. There is also little or no benefit for industry, consumers, or government. The intangible cost of increased risk that comes from letting the temporary level expire is of particular importance. This risk extends across the public health system, export markets, and industry and New Zealand's reputation. This option would not provide adequate protection for consumers due to the potentially severe effects of poisonings on some individuals so does not meet the FSANZ Act objective to protect public health and safety. While the honey industry that are only packing for the New Zealand market are likely to save on the cost of testing, many may continue to test due to the benefits testing offers in being able to safely produce honey in high risk areas.

QUESTIONS

NOTE: If you provide answers to these questions, please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter.

Question 2: Do you agree with the analysis of the likely costs and benefits of Option 1?

Question 3: Do you have any additional information that you would like considered in this analysis?

4.2 Option 2: Industry Code of Practice

	Costs	Benefits	Overall
Implementation	Establishing an industry code of practice (CoP) is likely to be a time consuming process and requires a strong unity of purpose across industry stakeholders. For the beekeeping industry, there are two industry bodies. This adds a layer of complexity to the process. Based on similar processes in other sectors, the cost of developing the CoP would likely range between \$100K and \$150K. Alternatively, industry may decide to use what has already been developed by FSANZ and MPI so may face few additional costs. This cost would be carried by the two industry bodies. Ongoing management and auditing of the CoP would also need to be carried out by the industry body, and	The benefits from implementing an industry-led CoP are largely intangible. The key benefits will derive from a high level of buy-in to the CoP from the industry, as they own it. There would be a small cost saving for government as they would no longer need to fund the ongoing monitoring and development of the maximum level and the Tutin Standard.	Net cost There are likely to be few benefits from a CoP and it would be time consuming and costly to develop and implement. The CoP may also end up being quite similar to what is currently in place however with an inability for government to enforce it.

	 this would add a significant operating cost. The time needed to develop a CoP would require extending the temporary maximum levels to bridge the gap. This option may result in an increase in compliance costs for beekeepers as they are required to make changes to their testing and quality assurance processes according to the CoP. The CoP would only apply to those beekeepers that are members of one of the two industry organisations. Beekeepers that were not members of either body would not have to comply with the CoP. 		
	temporary maximum levels		
	increase in compliance costs for beekeepers as they are required to make changes to their testing and quality assurance processes according to the		
	to those beekeepers that are members of one of the two industry organisations. Beekeepers that were not members of either body would not have to comply		
	Government would be unable to enforce compliance with the CoP as it would have no legal standing. Government would also face costs for monitoring the effectiveness of the CoP.		
Public health	During the development of a CoP and in the transition period, there is increased risk of a tutin poisoning incident.	Once successfully implemented, and if recent scientific evidence is reflected, the CoP would assist	Small net cost There is potential for poisonings to increase unless the CoP reflected up to
	There is a risk that the CoP may not fully reflect recent scientific evidence. If this was the case, the public health costs would potentially be similar to	in minimising the costs on the public health system of tutin in honey. However there are no direct benefits to	date science and the whole industry complied with it.
	those for Option 1. See information given in Option 1 above on the direct public health costs.	the health system from the CoP itself.	
	In addition, the impact of such an event could disrupt the development of the CoP, leading to an extended period of increased risk and		

	uncertainty in the sector.		
Best available science	There is a risk that the CoP may not be based on the best available science.		This option may not be based on the best available science.
Market access	The greatest risk for honey exporters is the perception of trading partners. Any CoP would need to be sufficiently rigorous that export markets would accept the CoP without imposing their own testing regimes.	The CoP would not bring significant benefits to export revenue or market access issues.	Possible small net cost Unless the CoP reflected up to date science and the whole industry complied with it there is potential for overseas markets to lose confidence and impose their own testing regimes.

This option provides a small cost saving for government, but would be very costly to the relatively small honey industry. The effect of the code of practice is reduced by the fact that there would be no legislative force behind it, and therefore would be extremely difficult to enforce. It would also be inconsistent with the approach taken for other high-risk foods such as shellfish and would not provide adequate protection for consumers due to the potential for poisonings to occur. It therefore does not meet the FSANZ Act objective to protect public health and safety.

QUESTIONS

NOTE: If you provide answers to these questions, please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter.

Question 4: Do you agree with the analysis of the likely costs and benefits of Option 2?

Question 5: Do you have any additional information that you would like considered in this analysis?

4.3 **Option 3: Retain Temporary Maximum Levels**

	Costs	Benefits	Overall
Implementation	There will be few additional costs to the industry or government for this option as industry are already complying with it. The main costs of the maximum levels arise from the management options in the Tutin Standard. As per Option 1, the total industry cost for testing honey for tutin is estimated	The main benefit of this option is the avoided disruption of introducing a code of practice or having no maximum level. The option provides some benefit through a continuation of the record keeping required under the Tutin Standard.	Neutral The honey industry has systems in place to comply with this option.

	to be between \$138,000 and \$213,000 per year.	These records can provide up-to-date information on the risk of specific apiaries if samples from individual apiaries are composited rather than samples being composited across a number of different apiaries.	
Public health	The direct impacts on the health system will be in line with what has been experienced since 2008. See information given in Option 1 above on the direct public health costs of poisoning incidents. The results of toxicology research carried out in 2012 show that honey with tutin levels at the temporary levels can cause adverse effects in some consumers. Some may not connect their symptoms to honey consumption, nor will they seek medical advice, however these individuals may incur costs related to lost income and/or productivity. The comb honey level may also not adequately address the potential variability of tutin levels across cells. As in Option 1, there are likely to be ongoing costs to individuals including loss of income and/or lower productivity if they suffer from low level effects of tutin poisoning. More sensitive individuals are likely to continue to experience more severe effects.	Honey that complies with the temporary maximum levels is very unlikely to lead to severe adverse events. Since the temporary levels have been in place, there have been no reported tutin poisonings from honey that was compliant with the temporary maximum levels.	Neutral There have been no reported poisonings from honey that complies with the temporary maximum level since 2008.
Best available science	Does not take into account the results of recent research regarding		This option is not based on the best available science.

	individual variability and the onset time of clinical symptoms.		
Market access	It is unlikely that there would be any significant costs arising from export market disruption under this option. Since the temporary level was introduced there have not been any concerns expressed by trading partners that the levels are inappropriate. It has not been known to date that there are mild adverse effects from honey at the current maximum level since the research has not yet been published. There could be a negative impact if this becomes known and the maximum levels are not decreased to avoid all toxic effects.	When the temporary level was introduced, there was no discernible impact on market access or exports. The key benefit here is the lowered risk of adverse events resulting from tutin in honey. The value of the avoided risk is not insignificant for the industry as the potential damage to revenue and reputation from such an event would be a major disruption to the industry.	Possible net cost once latest research is released.

This option has the same costs for industry as they currently face as they already have systems in place to comply with it. A key advantage of this option is that it has given industry more accurate information about the safety of honey being produced. This has enabled beekeepers to collect honey from areas that were previously very high risk, and to maintain quality and safety assurance over their product. The costs of testing for tutin in honey have declined since 2008 as the volume of tests has grown. This provides a good basis for continuing the practice of regular laboratory testing of New Zealand honey. There have also been no reported poisoning incidents since 2008 from honey that complied with the temporary maximum level. The latest research suggests, however, that adverse effects may be occurring in some individuals that are not being attributed to tutin.

QUESTIONS

NOTE: If you provide answers to these questions, please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter.

Question 6: How many kilograms of honey does your business blend to manage high tutin levels each year? What does this cost your business each year?

Question 7: Does your business harvest comb honey from high risk areas at high risk times of the year? If so, how many tests do you undertake per year and what are the costs each year?

Question 8: Do you agree with the analysis of the likely costs and benefits of Option 3?

Question 9: Do you have any additional information that you would like considered in this analysis?

4.4 **Option 4: Reduce Maximum Levels**

	Costs	Benefits	Overall
Implementation	In addition to the testing costs estimated for Option 1, there will be additional costs for honey that met the temporary maximum level but would not meet the reduced maximum level. The additional costs for this honey would include blending and retesting honey to ensure it met the proposed new maximum level. The estimated additional costs of retesting across the honey industry could be as much as \$12,000 depending on whether re- testing is done using composite or single sample tests.	By implementing this option, beekeepers will retain the existing benefits of information collection and record keeping under the options to demonstrate compliance in the Tutin Standard. The option also takes into account improved testing sensitivity for comb honey. The current level for comb honey was set at the level of detection possible in laboratory tests in 2008.	Small net cost There would be additional net costs compared with Option 3.
Public health	The direct impacts on the health system will be similar to what has been experienced since 2008. See information given in Option 1. The ongoing costs to individuals for lower level poisonings mentioned in Option 1 are likely to reduce under this option. This will particularly be the case for more sensitive individuals that are likely to experience more severe effects than those observed in the clinical trial.	In addition to the benefits for Option 3 there is likely to be a reduction in ongoing costs to individuals such as loss of income and/or lower productivity from minor tutin poisoning incidents.	Small net benefit The number of people who suffer mild poisonings is expected to decrease while costs on the public health system will be the same.
Best available science		Recent research on the variability of the onset time of clinical symptoms will be taken into account.	This option is based on the best available science.
Market access	The market access implications of this option are unlikely to cause additional costs to the sector.	Lowering the tutin level has two major benefits from a market access perspective. Firstly,	Likely net benefit This is likely to boost the confidence of the countries we export

by basing the maximum levels on the most recent research, NZ can boost consumer confidence in the products produced by the sector.	to as it shows food safety is important to NZ.
Secondly, it will send clear signals to our markets that food safety is a paramount concern. Given the sensitivity of some markets around food safety, this messaging is more critical to success than ever before.	

While this option will impose higher costs on industry, it will reduce public health costs as fewer people will experience the minor effects of a poisoning. It is the option that takes full account of the risk analysis using the best available scientific evidence, which FSANZ is required to have regard to under the FSANZ Act. It also achieves the objective in the FSANZ Act to protect health and safety. It works to grow and protect access to markets by building confidence and reputation with trading partners. Using the best available science to support food safety is likely to boost the confidence and trust of consumers and overseas markets.

QUESTIONS

NOTE If you provide answers to these questions, please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter.

Question 10: Do you agree with the analysis of the likely costs and benefits of Option 4?

Question 11: What do you think that the additional costs per business or beekeeper would be to move from the temporary maximum level to the lower maximum level?

Question 12: Do you think that the additional costs of this option are justified?

Question 13: Do you have any additional information that you would like considered in this analysis?

Question 14: If the maximum level is lowered to the suggested lower level, what volume of your honey do you estimate would not meet the lower level? What would be the likely impact on your business of this?

5 Consultation

This document forms part of FSANZ's formal consultation on the proposal to amend the maximum level for tutin in honey in the Code. Standard practice for notifying people about the consultation will be followed including public announcements and notification of interested parties. Consultation has also been timed specifically to coincide with the New Zealand annual beekeeper conference in June 2014. MPI and FSANZ intend to update industry on the tutin review at this conference.

The consultation will also seek more information on the impacts of the proposal on industry. The main additional information sought will include information on the blending and testing costs faced by the honey industry since 2008 and on any additional costs or savings for the options considered for consultation.

Information will also be sought about the proposal for the permanent maximum levels to be applied immediately on gazettal and for there to be no transitional arrangements. A summary of the questions asked in this consultation regulation impact statement can be found in Appendix Two.

6. Evaluation and Conclusions

The table below provides a summary of the net benefits of the four options evaluated in Section 4 above. Although Option 1 is the Status Quo (letting the current maximum levels expire), Option 3 (retaining the temporary maximum levels) would actually mean the smallest change to current practice.

	Option 1: Status Quo - Current Maximum Levels Expire	Option 2: Industry Code of Practice	Option 3: Retain Temporary Maximum Levels	Option 4: Reduce Maximum Levels
Implementation	Small net cost	Small net cost	Neutral	Small net cost
Public Health	Net cost	Small net cost	Neutral	Small net benefit
Best Available Science	No	Maybe	No	Yes
Market Access	Possible net cost	Possible net cost	Possible net cost	Likely net benefit
Overall	Net cost	Net cost	Possible net cost	Likely net benefit

Table Two: Summary of the net benefits for each option

Option 1 has an overall net cost. While beekeepers that produce honey for the domestic market will face lower costs, more people are likely to be poisoned than is currently the case. In addition, government will face the costs of revoking the Tutin Standard and may face increased costs to enforce initially section 9 of the Food Act 1981, and then section 14 of the Food Act 2014, and under the Animal Products Act. Option 2 has an overall net cost, as any code of practice would not be able to be enforced by government. Option 3 does not adequately protect consumers against the adverse effects found in recent research. It has a possible net cost as overseas markets may react negatively to the recent research not being taken into account in setting the maximum levels.

The preferred option (Option 4) is to reduce the maximum level for tutin in honey from 2 mg/kg to 0.7 mg/kg and the maximum level for tutin in comb honey from 0.1 mg/kg to 0.01 mg/kg. It is the option that takes full account of the risk analysis using the best available scientific evidence which FSANZ is required to have regard to under the FSANZ Act. It also meets the FSANZ Act objective to protect public health and safety and has regard to the desirability of an efficient and internationally competitive food market.

7. Implementation and Review

7.1 Implementation

An amendment to the Code will be necessary to implement the preferred option. FSANZ is proposing that the new permanent maximum levels will apply immediately on gazettal and that there will be no transitional arrangements. However, a stock-in-trade provision is being proposed so that any honey and comb honey packed for retail sale before the date of gazettal would not need to comply at any time with the new requirements. These products would need to comply with the maximum levels that applied on the day they were packaged for retail sale.

While honey generally has a five year shelf life, and there is likely to be honey that complies with the temporary level available for retail sale for up to 5 years after the permanent maximum levels are gazetted, this amount of honey is expected to be small. The cost of requiring this honey to meet the reduced maximum levels is estimated to outweigh the potential public health costs of leaving this honey on shelves.

The honey industry will be given prior notice of the proposed changes by FSANZ and MPI at industry meetings. This is expected to minimise the impacts of the proposed changes. The FSANZ Board is expected to complete its consideration of this proposed change to the Code in October 2014. Subscribers, interested parties and submitters to FSANZ's call for submissions will be notified of the Board's decision shortly afterwards. If the proposed change to the Council of Australian Government's Legislative and Governance Forum on Food Regulation¹¹ (the Forum).

If the decision is not subject to a request for a review by the Forum, the variation is expected to be gazetted in the Code and come into force in Australia in January 2015. Shortly after the change is gazetted in the Code, a Standard giving legal effect to the variation in New Zealand will be issued under the New Zealand Food Act 1981. It will come into force in New Zealand 28 days after that date.

QUESTIONS

Question 15: How much honey not packaged for retail sale will you have left from the year to June 2014 harvest period by December 2014? What proportion is this of the total amount of honey you harvested in the year to June 2014?

Question 16: Do you agree with having no transitional arrangements for the implementation of the proposed permanent maximum levels for honey and comb honey given the new maximum levels would not apply to products packaged for retail sale prior to the changes being gazetted?

¹¹ The Forum consists of lead Ministers from the Australian State and Territory government and from the Australian and New Zealand governments. More information can be found at http://www.foodstandards.gov.au/code/fofr/Pages/default.aspx

Question 17: If you do not agree with having no transitional arrangements, what alternative do you suggest and why?

7.2 Review

As the development of the permanent maximum levels is the final stage in a process that started in 2008, there are no immediate plans to review the permanent maximum levels after their implementation. FSANZ and MPI will continue to monitor reported poisonings. If reported poisonings showed that the permanent maximum levels are not protective enough, FSANZ would consider reviewing the permanent maximum levels.

Appendix One: Honey Industry Profile

Apiculture is a significant contributor to New Zealand's primary production sector. There were 4,279 beekeepers in New Zealand with 27,106 apiaries and 452,018 hives as at June 2013. The North Island has 63 percent of beekeepers and the South Island has 37 percent of beekeepers.

Most (85%) registered beekeepers have less than 50 hives and over half of these have less than 5 hives (66.1%). Small beekeepers (those with less than 50 hives) average 4 hives per apiary while commercial beekeepers (those with over 500 hives) average 21 hives per apiary. About 80 percent of all hives are managed by 221 commercial beekeepers. There are 133 commercial beekeepers in the North Island and 88 commercial beekeepers in the South Island¹².

The New Zealand honey crop for 2012/13 was estimated at 17,825 tonnes. The volume of honey exported was 8,054 tonnes, valued at \$144.9 million¹³. This included exports of 165 tonnes of comb honey valued at \$3.2 million¹⁴. The United Kingdom is the dominant destination for New Zealand's honey exports. It has typically taken around a third of the total export volume, but this began to decline in 2012/13. The other important markets are Hong Kong and China, the European Union, and Singapore. China's share of New Zealand exports is beginning to increase: while it took only 3 percent in 2011/12, this increased to 11 percent in 2012/13.

A significant proportion of honey that is packed in New Zealand, whether it is sold on the domestic market or exported, is packed under risk management programmes (RMPs) under the Animal Products Act. MPI maintains a public register of RMPs on its website and there are 230 RMPs for honey listed. Honey not packed under an RMP is usually packed by small producers solely for the domestic market. These small producers are likely to be the highest risk for selling honey or comb honey with tutin levels over the maximum level.

The Tutin Standard requires those packing the honey for sale or for export to ensure that the maximum level in the Code is complied with. However, in practice, many packers require their suppliers to provide testing results prior to purchase. So in effect, the costs fall across the whole industry.

Data on the results of laboratory tests for tutin shows that between 0.1 percent and 0.2 percent of composite tests (where up to 10 samples are tested) have tutin levels over the current maximum levels. Data for single sample tests shows that between 1.2 percent and 1.6 percent of samples tested have tutin levels that exceed the maximum levels.

¹² New Zealand Beekeeper Magazine, page 14, 'New Zealand beekeeper, apiary and hive statistics by apiary district as at 30 August 2012'

¹³ Apiculture Monitoring Report, 2013 (December 2013) Ministry for Primary Industries available from <u>http://www.mpi.govt.nz/news-resources/publications?title=farm%20monitoring%20report</u>

¹⁴ Statistics New Zealand Harmonised export data for comb honey exports code 0409000011

Most compliance costs fall on beekeepers harvesting honey in high risk areas above latitude 42 degrees south. This line runs across the top of the South Island, from above Greymouth on one side to between Kaikoura and Nelson on the other side. The number of beekeepers who harvest honey from this area is difficult to determine as regional data for the South Island does not easily provide a breakdown of the number of beekeepers above latitude 42 degrees south. The North Island has 64 percent of beekeepers and the South Island has 36 percent of beekeepers. In the South Island, the Otago Southland region has 11 percent of beekeepers and the Canterbury Kaikoura region has 15.7 percent of beekeepers. Both areas are mostly low risk. Therefore the number of beekeepers who harvest from high risk areas above latitude 42 degrees south is probably around 73 percent of all beekeepers. In the 2012/13 year, the proportion of honey harvested above latitude 42 degrees south was estimated at 72 percent of the total harvest.

Appendix Two: Consultation Questions

NOTE: If you provide answers to these questions please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter.

Alternative options or other information (Section 3)

1. Are there any other options that are significantly different from the above that should be considered? If so, please provide information to support them.

Option 1: Status Quo – Temporary Levels Expire (Section 4.1)

- 2. Do you agree with the analysis of the likely costs and benefits of Option 1?
- 3. Do you have any additional information that you would like considered in this analysis?

Option 2: Industry code of practice (Section 4.2)

- 4. Do you agree with the analysis of the likely costs and benefits of Option 2?
- 5. Do you have any additional information that you would like considered in this analysis?

Option 3: Retain temporary level (Section 4.3)

- 6. How many kilograms of honey does your business blend to manage high tutin levels each year? What does this cost your business each year?
- 7. Does your business harvest comb honey from high risk areas at high risk times of the year? If so, how many tests do you undertake per year and what are the costs each year?
- 8. Do you agree with the analysis of the likely costs and benefits of Option 3?
- 9. Do you have any additional information that you would like considered in this analysis?

Option 4: Reduce maximum level (Section 4.4)

- 10. Do you agree with the analysis of the likely costs and benefits of Option 4?
- 11. What do you think that the additional costs per business or beekeeper would be to move from the temporary maximum level to the lower maximum level?
- 12. Do you think that the additional costs of this option are justified?
- 13. Do you have any additional information that you would like considered in this analysis?
- 14. If the maximum level is lowered to the suggested lower level, what volume of your honey do you estimate would not meet the lower level? What would be the likely impact on your business of this?

Implementation (Section 7.1)

- 15. How much honey not packaged for retail sale will you have left from the year to June 2014 harvest period by December 2014? What proportion is this of the total amount of honey you harvested in the year to June 2014?
- 16. Do you agree with having no transitional arrangements for the implementation of the proposed permanent maximum levels for honey and comb honey given the new maximum levels would not apply to products packaged for retail sale prior to the changes being gazetted?
- 17. If you do not agree with having no transitional arrangements, what alternative do you suggest and why?