Attachment E – Decision Regulation Impact Statement

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

Proposal P1029 – Maximum Level for Tutin in Honey

Purpose of this document

This document is a Decision Regulation Impact Statement (RIS). It has been prepared by the Ministry for Primary Industries, with assistance from Food Standards Australia New Zealand (FSANZ). It incorporates information provided in submissions to the Consultation RIS and sets out risk management options, evaluates their costs and benefits and recommends which option should be adopted.

Executive summary

Apiculture is an important part of New Zealand's primary sector. The value of honey exports is growing significantly. Between 2009 and 2014 export value grew from $NZ81 million to $NZ187 million: a compound annual growth rate of 18.21% per year. Demand for New Zealand honey is highest in the United Kingdom, Australia, China, Hong Kong and Singapore.

To ensure this growth continues, New Zealand's honey needs to be safe. New Zealand has had problems with contamination of honey by tutin since bees were first brought into New Zealand. Tutin is a neurotoxic compound produced by the shrub *Coriaria arborea* (tutu) which is native to New Zealand. The vine hopper insect *Scolypopa australis* feeds on tutu and excretes honeydew that contains the toxin tutin. This honeydew can be collected by bees for honey production. Tutin is highly toxic to humans; high levels can cause severe effects, including death.

A poisoning incident in the Coromandel in 2008 prompted the former New Zealand Food Safety Authority (NZFSA) to establish a temporary maximum level of tutin in honey of 2 mg/kg and of tutin in comb honey of 0.1 mg/kg while more research was undertaken. These levels were incorporated in Standard 1.4.1 of the *Australia New Zealand Food Standards Code* (the Code) in August 2009 and will expire on 31 March 2015. A review of the maximum levels needs to be undertaken before the current levels expire. Since the original maximum levels were set, more research on tutin in honey has been undertaken. The results of this research indicate that the current maximum levels do not reflect the best available science and may not sufficiently protect human health.

Tutin research

The results of this further research revealed that the effective concentration of tutin in honey was several times higher than had been previously measured. However, this additional tutin was not in the same form. It was present as tutin with glucose attached (as glycosides), which break down in the body to release tutin over a number of hours.

Different individuals were able to release tutin from this previously unidentified form of tutin in honey at different rates. The ratio of tutin to tutin glycosides also varies among honey samples. It is therefore necessary to reduce the maximum level of 2 mg/kg in order to ensure the public health and safety of consumers. Using an adjustment factor that accounts for this variability in the rate of tutin release, and variability in the ratio of tutin to tutin glycosides in honey a new maximum level for tutin in honey of 0.7 mg/kg is proposed. This maximum level is considered to protect consumers of New Zealand honey containing tutin.

Comb honey however, will contain variable amounts of tutin in different parts of the comb. This reflects bee foraging habits and different times of collection. This requires additional controls to ensure that no single piece of comb honey will exceed this limit. These controls are currently contained in the Food (Tutin in Honey) Standard 2010 (the Tutin Standard) made under the New Zealand Food Acts 1981 and 2014.

Changes to legislative options following consultation

A Consultation RIS (Office of Best Practice Regulation (OBPR) reference 13847) was released for consultation on 10 July 2014 as Supporting Document 2 to FSANZ's Proposal P1029 – Maximum Level for Tutin Honey. FSANZ sought public feedback on a proposal to reduce the maximum levels for tutin in honey and comb honey in the Code and on questions raised in the Consultation RIS. The closing date for submissions was 21 August 2014. This Decision RIS takes into account relevant information provided in the 8 submissions received by FSANZ on this issue.

Further consideration since the Consultation RIS has led to changing the status quo from letting the temporary maximum levels expire with no new levels or measures in place to retaining the current maximum levels. This more accurately reflects the present situation for industry.

The drafting approach for Option 4 has also been amended since the Consultation RIS to apply a maximum level of 0.7 mg/kg to all honey (including comb honey), instead of setting a separate maximum level of 0.01 mg/kg for comb honey as previously proposed. This change is a result of concern raised by the Ministry for Primary Industries (MPI) that the previous approach of setting a maximum level of 0.01 mg/kg for comb honey in the Code conflicted with the compliance options in the New Zealand Tutin Standard. This standard requires a level below 0.01 mg/kg (i.e. non-detection of tutin) at the point of comb honey harvest rather than at retail sale.

After considering submissions, FSANZ agrees that the imposition of a maximum level of 0.01 mg/kg at retail sale is not appropriate. Therefore, Option 4 has been amended to apply a maximum level of 0.7 mg/kg to all honey (including comb honey). This avoids any conflict between the Code and the New Zealand Tutin Standard. The compliance options mandated by the New Zealand Tutin Standard will assure the safety of comb honey at retail sale. The New Zealand Tutin Standard is currently under review. The review will take account of the proposed maximum levels in the Code.

Consequentially, the four options considered for this analysis were:

- Option 1: Status Quo: Retain the current maximum levels
- Option 2: Temporary maximum levels expire and are not replaced
- Option 3: Temporary maximum levels expire and are replaced with a voluntary industry code of practice.
- Option 4: Amend the maximum levels in line with the results of recent research

Evaluation of options

Option 1 has a possible high[1] net cost. Although it has no additional direct costs for industry, the possible high net cost could come from:

- the possible risk of export markets imposing their own testing regimes based on the recent published research; and
- consequential compliance costs for the New Zealand industry if the maximum levels are not changed to take account of recently published research.

Maximum levels imposed by export markets would likely be stricter than current maximum levels. This option would likely also lead to MPI having to implement maximum limits itself or to continue to apply controls under the Animal Products Act. It also does not meet the FSANZ Act objective to protect public health and safety or the requirement to base standards on risk analysis using the best available science.

Option 2 has a probable high net cost as the increased likelihood of a poisoning incident outweighs the small benefit (for producers who operate under the Food Acts) of reduced testing costs. Export markets may impose stricter maximum tutin levels under this option than under the status quo, which could lead to the increased compliance costs noted above for Option 1. Option 2 also fails to meet the FSANZ Act objective to protect public health and safety and the requirement to base standards on risk analysis using the best available science.

Option 3 is not likely to be viable given the high risk to health and safety, the lack of a single cohesive industry association and the lack of industry support for this option. If implemented, it would constitute a probable high cost for industry of developing and monitoring an industry code of practice. Depending on how the code of practice is set up, there may be an increased risk of people getting poisoned and difficulty enforcing the code. This option may also not meet the FSANZ Act requirement to base standards on risk analysis using the best available science and may have a negative impact on exports.

The recommended option is Option 4: to amend the maximum levels for tutin in honey (from 2 mg/kg) and comb honey (from 0.01 mg/kg) to 0.7 mg/kg. The compliance options in the New Zealand Food (Tutin in Honey) Standard will still apply. For comb honey, all the drip and leftover comb from a comb honey harvest from a single apiary site must be homogenised and sub-sampled and tested for tutin. Cut comb honey will only comply if the if individual samples contain less than 0.01 mg/kg of tutin.

Option 4 has a high net benefit. There will be some cost to industry—in particular a potential loss of value for high-value early[2] manuka honey which may exceed the new tutin limits. These costs are however, outweighed by the support this option provides for maintaining the reputation of the New Zealand honey industry and its long term growth and value. This option provides a good environment for the compound annual growth rate (CAGR) of 18.21 per cent per year experienced by honey exports in the period 2009-2014, to continue. In summary, it is the only option that:

- takes full account of the risk analysis using the best available scientific evidence,
- 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.

[1] Low is defined as being under $NZ100, 000. Medium is between $NZ100,000 and $NZ1 million. High is defined as over $NZ1 million.

[2] The National Beekeepers' Association did not define what they meant by 'early' manuka honey in their submission

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1 Statement of the problem

High levels of tutin in honey can cause severe illness or death in humans. FSANZ has prepared Proposal P1029 to review the maximum levels for tutin in honey and comb honey in Standard 1.4.1 of the *Australia New Zealand Food Standards Code* (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 on tutin in honey has been undertaken. The results indicate that the current maximum levels do not reflect the best available science and may not protect human health enough.

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 appear to only occur in New Zealand.

1.1 Background and context

New Zealand had over 4,800 beekeepers in June 2014. They produced 17,608 tonnes of honey in the year to June 2014 and exported 8,758 tonnes. More information on the New Zealand honey industry can be found in Appendix 1.

New Zealand has had problems with contamination of honey by tutin since bees were first brought into New Zealand. A poisoning incident in the Coromandel in 2008 prompted the former New Zealand Food Safety Authority (NZFSA) to establish a temporary maximum level of tutin in honey of 2 mg/kg and of tutin in comb honey of 0.1 mg/kg while more research was undertaken. These levels were incorporated in Standard 1.4.1 of the *Australia New Zealand Food Standards Code* (the Code) in August 2009 and will expire on 31 March 2015. A review of the maximum levels needs to be undertaken before the current levels expire. Since the original maximum levels were set, more research on tutin in honey has been undertaken. The results of this research indicate that the current maximum levels do not reflect the best available science and may not sufficiently protect human health.

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). The latitude 42 degrees south line runs across the top of the South Island, from above Greymouth in the west to between Kaikoura and Blenheim in the east. This proposal may also affect those selling honey produced during periods of the year considered to be low risk as it is known that small amounts of tutin can be found in honey throughout the year. MPI plans to conduct further research to determine whether its production controls in the Food (Tutin in Honey) Standard 2010 remain appropriate. No specific groups will be affected in Australia as the issue of tutin in honey appears to only occur in New Zealand. The particular groups in New Zealand that may be affected by the standard for tutin are:

- consumers of honey;
- beekeepers, honey packers and processors;
- health sector (including hospitals, emergency care, and general practitioners);
- laboratories that test honey for tutin contamination; and
- Government departments: particularly the Ministry for Primary Industries and the Ministry of Health.

1.1.1 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 mainly found on tutu bushes north of latitude 42 degrees south. Areas south of this line are not believed to be at risk of honey being contaminated with tutin. The highest risk areas for honey contaminated with tutin are in Northern Hawkes Bay, Bay of Plenty and Coromandel. Poisonings have also been reported in the Marlborough Sounds and Northland. Approximately 72 per cent of the volume of honey harvested in New Zealand comes from high risk areas. Approximately 73 per cent of beekeepers harvest honey from high risk areas. Seasonal risk is highest for harvest dates between 1 January and 30 June each year.

Data from Hill Laboratories on the results of laboratory tests for tutin[3] for the year to June 2014, shows that 2 per cent of composite tests (where up to 10 samples are tested) have tutin levels over the maximum level of 0.7 mg/kg proposed in this paper. No composite samples were found to exceed the current maximum level of 2 mg/kg of tutin. For single sample tests, 3.8 per cent of samples had tutin levels over 0.7 mg/kg and 0.9 per cent had tutin levels over the current maximum level of 2.0 mg/kg.

1.1.2 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.

Signs and 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, a heavy stiff numb feeling and death[4].

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

Area honey originated from	***Honey type***	***Year***	***Affected persons***	***Severity[5]***
Warkworth	Extracted	1980	3	Medium
Whangamata	Extracted	1981	3	Medium
Pelorous Sound	Comb	1982	1	Medium
Pelorous Sound	Comb	1983	1	Medium

[3] Tests for tutin in honey are undertaken at a variety of places in the supply chain – for example from honey immediately after it is extracted from the honeycomb, when it is packed in bulk drums, or when it is packed for retail sale.

[4] Goodwin, Mark (2013) A New Zealand History of Toxic Honey Page 155

[5] 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

Area honey originated from	*Honey type*	*Year*	*Affected persons*	*Severity*[5]
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

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 leftovers of the honey consumed by the poisoned 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 reported by the person were not typical of 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.

1.1.3 MPI communication of the risks of tutin

People selling honey are primarily responsible under the Food Acts 1981 and 2014 for ensuring that their products are safe and suitable to consume. In addition, MPI and FSANZ have made a considerable effort over the past few years to work in partnership with the National Beekeepers' Association (NBA), Federated Farmers Bee Industry Group, and the Honey Packers and Exporters Association through the Bee Products Standards Council[6] to ensure that the beekeeping community is well informed on tutin, the need to take precautions, and raising awareness that when the honey is sold, it must comply with regulatory requirements. Measures to communicate this risk include:

- information on tutin is sent by AsureQuality to all people registering beehives for the first time;
- MPI sponsorship of the tutin pages in the NBA publication "Starting with Bees";
- provision of regular messages about tutin to beekeepers in "The New Zealand Beekeeper" magazine, sent to all registered beekeepers twice a year;
- a video on tutin developed by the Bee Products Standards Council (BPSC) is currently available on the BPSC website and will be sent to all registered beekeepers by the BPSC;
- provision of comprehensive information on MPI's website; and
- joint development of an advisory document by MPI and Farmers Markets NZ for market organisers, stall holders, and local authorities that includes information on the regulatory requirements for honey.

[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.

1.1.4 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. This was because there was a need to put in place urgent risk management measures while further research and evaluation was undertaken.

Research studies

A temporary maximum level of 2 mg/kg for tutin in extracted honey was established using data derived from the oral administration of purified tutin in mice. A lower maximum level of 0.1 mg/kg was established for comb honey to account for potential heterogeneity in tutin distribution across a honey comb in a hive.

In contrast to mice, which consistently exhibited rapid onset of toxicity following tutin administration, the onset time of toxicity following honey ingestion in humans is highly variable and the more severe adverse effects are often markedly delayed. To investigate this difference, a human pharmacokinetic study was conducted where 6 volunteers consumed an amount of honey containing tutin in a dose equivalent to that received by high consumers of honey (0.9 g honey per kg of bodyweight[7]) containing tutin at the current maximum level of 2 mg/kg (Fields et al)[8]. The study was conducted in accordance with Good Clinical Practice (GCAP) and was based on European Medicines Agency Guidelines[9] for pharmacokinetic studies in humans. The study protocol was reviewed and approved by the Lower South Regional Ethics Committee, Dunedin, New Zealand.

The study was not designed to specifically investigate safety and no adverse effects were expected based on the low tutin dose chosen, however monitoring of certain safety parameters is typical for a human pharmacokinetic study. The volunteers were monitored by assessing vital signs (body temperature, heart rate, blood pressure), laboratory values for haematology, biochemistry and complete urinalysis, and electrocardiograms.

During the study, the serum tutin concentration profile for all volunteers exhibited two discrete peaks, rather than the expected one. The first peak was at 0.5–1.5 hours post dose, with 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 effects of consuming tutin in honey. The second peak was not. Subsequent experiments led to the discovery of tutin glycosides (tutin that is chemically bound to carbohydrates), a ‘masked’ form of tutin in addition to free tutin. The time taken to convert this ’masked’ form of tutin to free tutin explained the second peak observed in blood.

Conclusions

Based on these results, it is possible that adverse effects may be experienced following the consumption of honey containing tutin at the current maximum level of 2 mg/kg.

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[7] Consumption data were obtained from the 1997 New Zealand National Nutrition Survey which 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. Honey consumption data from a subsequent New Zealand adult nutrition survey (2008-09) indicated slightly lower consumption for 97.5th percentile consumers aged 15 years and above: 0.8 g honey/kg bodyweight per day.

[8] Fields BA, Reeve J, Bartholomaeus A, Mueller U. (2014) Human pharmacokinetic study of tutin in honey; a plant-derived Neurotoxin. Food Chem. Toxicol. **72:** 234–241

[9] See European Medical Agency website

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 honey[10] 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 of bodyweight than adults.

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 adverse effects seen in 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 who are able to more efficiently convert the tutin to free tutin and therefore would experience more severe effects such as nausea, vomiting and dizziness.

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 is necessary. In order to protect consumers from adverse effects, a reduction in the maximum level by a factor of 3 is proposed. This reduction factor is comprised of a factor of 1.5 to account for variation between individuals in the release of tutin from tutin glycosides, multiplied by a factor of 2 to account for the variability in the ratio of tutin to tutin glycosides in honey. This gives a revised maximum level of 0.67 mg/kg or 0.7 mg/kg (rounded) for honey.

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. Provided consumers are not exposed to tutin concentrations above 0.7 mg/kg in comb honey, the risk of adverse effects is low.

More information on this research can be found in other FSANZ documents about this proposal on the FSANZ website[11].

1.2 Legislation

Those who process, store, sell, or export honey in New Zealand must comply with the requirements of the *Food Act 1981*, the *Food Act 2014*, and the *Animal Products Act 1999*. 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 Acts. 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.

[10] Assumes a standard New Zealand tablespoon is 15 mL.

[11] See FSANZ website for p1029 information

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; and
- 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 levels in the Code.

Additional requirements to be met by RMP operators under the *Animal Products Act 1999* are also found in the Animal Products (Harvest Statement and Tutin requirements for Export Bee Products) Notice 2010.

This RIS focuses on the maximum levels in Standard 1.4.1 of the Code as these limits form the basis for controls in the *Food Act 1981* and 2014 and in Standards under the *Animal Products Act 1999*.

1.2.1 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 is that the levels of contaminants and natural toxicants in food should be kept as low as reasonably achievable, regardless of whether or not a maximum level is set.

Standard 1.4.1 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. The temporary maximum levels were introduced as a temporary risk management measure in response to a poisoning incident in Coromandel while further research on tutin in honey was undertaken. 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.

1.2.2 Food (Tutin in Honey) Standard 2010

While the New Zealand Food (Tutin in Honey) Standard 2010 (the Tutin Standard) is not the subject of this RIS, 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.

If comb honey is harvested from apiaries located above latitude 42 degrees south, all the drip and leftover honey from a comb honey harvest from a single apiary site must be homogenised and sub-sampled and tested for tutin. The test result must be lower than 0.01 mg/kg. If the level of tutin is 0.01 mg/kg or higher, the honey cannot be sold in combs and must be extracted.

1.2.3 Regulation prior to 2008

Prior to the introduction of the Tutin Standard 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 tutin. Prior to the introduction of the Animal Products Act in 1999, risk areas for toxic honey were determined by the then Ministry of Agriculture and Fisheries and periodically reviewed. The last review of these areas was in 1985. Over time the risk areas could 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 and the distribution of vine hoppers. This is costly and difficult to accurately assess as tutu bushes often grow in areas that are difficult to access. It can be 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 temporary maximum levels were set to manage tutin in honey.

2 Objectives

2.1 Legislation

Where statutory interventions are required under statutory requirements in the FSANZ Act (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; and
- 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; and
- 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 RIS. These are:

- protection of public health and safety;
- standards should be based on risk analysis using the best available scientific evidence;
- supporting an efficient and internationally competitive food industry; and
- minimising implementation costs for industry and government.

3 Options

3.1 Changes to options following consultation

A status quo, or do nothing option, is normally used to compare options against in a cost benefit analysis. For this analysis, deciding on a status quo option was not straight forward. While the status quo could be considered to be the situation beyond the expiry of the maximum levels on 31 March 2015, the present-day situation for industry is the requirement to comply with the existing maximum levels in the Code. Therefore, the status quo for this analysis has been amended since the Consultation RIS to the option which retains the current maximum levels. This has made analysis easier and more intuitive.

The drafting associated with Option 4 has been amended since the Consultation RIS to apply a maximum level of 0.7 mg/kg to all honey (including comb honey), instead of setting separate maximum levels of 0.7 mg/kg for honey and 0.01 mg/kg for comb honey as proposed in the Consultation RIS. This change is a result of concern raised in MPI's submission about the previously proposed drafting for comb honey (see section 5 on consultation). MPI noted that the maximum level of 0.01 mg/kg would conflict with the New Zealand Tutin Standard which requires the drip and leftover comb to contain less than 0.01 mg/kg at production stage (under the testing compliance options), rather than at retail sale.

After considering the submissions, FSANZ agreed that the imposition of such a low maximum level (of 0.01 mg/kg) sold at retail sale is not appropriate. As noted above, the New Zealand Tutin Standard already specifies that the level of tutin should be less than 0.01 mg/kg for comb honey at the point of production. MPI advised that the compliance options prescribed by the New Zealand Tutin Standard will ensure the safety of comb honey at retail sale. That is, if the drip and leftover comb at production stage contain less than 0.01 mg/kg tutin (i.e. no detectable tutin) as required under the testing options in the New Zealand Standard, the likelihood of an individual portion of comb containing more than 0.7 mg/kg at retail sale, is expected to be low. In effect there is no change in the level of safety protection, regardless of whether the maximum level is set at 0.1 mg/kg (as currently prescribed) or 0.7 mg/kg (as proposed) because the compliance options in the New Zealand Standard for comb honey remain unchanged i.e. 0.01mg/kg needs to be met for the drip and leftover comb honey. As noted in section 1.1.4, FSANZ's risk assessment indicates that provided consumers are not exposed to tutin concentrations above 0.7 mg/kg in comb honey, the risk of adverse effects is low.

Consequently, Option 4 has been amended to apply a maximum level of 0.7 mg/kg for all honey (including comb honey) in the Code. This avoids any conflict between the Code and the New Zealand Tutin Standard in relation to comb honey. In practice, this does not impose any change on current industry practices for comb honey since the compliance options in the New Zealand Tutin Standard for comb honey remain unchanged.

3.2 Option 1: *Status Quo*: Retain the current maximum levels

Description: Retain the current maximum levels and make them permanent

Under this option the existing 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 expiry date for the current maximum levels of 31 March 2015 would be removed. The options for compliance in the Tutin Standard would still apply.

There would also continue to be protection for consumers, initially under section 9 of the *Food Act 1981* and then under section 14 of the *Food Act 2014*, which prohibit the sale of unsafe or contaminated food. The export requirements under the New Zealand Animal Products Act would still apply.

3.3 Option 2: Temporary maximum levels expire and are not replaced

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. This option does not provide clarity on what constitutes unsafe food and 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 and would probably need to be strengthened to include maximum limits for tutin.

3.4 Option 3: Temporary maximum levels expire and are replaced with a voluntary 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. Industry would then 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 education of the honey industry and would independently monitor the effectiveness of the code. As under Option 1, the sale of unsafe food would be prohibited under the New Zealand Food Acts and the export requirements under the New Zealand Animal Products Act would still apply and would probably need to be strengthened to include maximum limits for tutin.

3.5 Option 4: Amend maximum levels

Description: Amend the maximum levels due to the results of recent research.

Under this option, the current maximum levels for tutin in honey of 2 mg/kg and tutin in comb honey of 0.1 mg/kg would both be amended to a permanent maximum level of 0.7 mg/kg. The amendments to the 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. As under Option 1, the sale of unsafe food would be prohibited under the New Zealand Food Acts and the export requirements under the New Zealand Animal Products Act would still apply.

4 Impact analysis

The criteria derived in section 2.2 have been used below to undertake a qualitative analysis of the costs and benefits of each of the options in section 3. Analysis of whether the objective of the need for standards to be based on risk analysis using the best available scientific evidence is discussed in the text on each option.

4.1 Cost of the 2008 tutin poisoning outbreak

The cost of lost productivity and medical costs for the 22 cases in the 2008 poisoning incident in Coromandel has been estimated at around $NZ28,000. While 9 cases did not seek any medical care, 4 cases visited a general practitioner and 9 sought hospital care. The main cost for people that do not seek medical attention would be any time needed to recover from the symptoms. The costs for people that seek general practitioner treatment have been estimated at $NZ220[12] (a visit to a general practitioner and a day off work). Costs for severe cases include hospitalisation for several days and recovery at home afterwards and often include paramedic assistance. Based on experiences in 2008, the estimated public health costs for severe cases per person can vary from $NZ1,566[13] to $NZ4,674[14] excluding drugs and tests. Additional costs such as the cost of suffering were unable to be quantified. The costs of specific poisoning incidents vary according to the number of people affected and their symptoms.

Industry costs include:

- The company that produced the contaminated honey experienced a loss of honey sales and had to pay recall costs;
- Other honey companies experienced a temporary loss of sales until consumer confidence in the safety of honey returned; and
- Export sales – companies experienced a temporary reduction in orders until overseas markets regained confidence in the safety of New Zealand honey.

Government costs include:

- Costs of investigating the incident; and
- Prosecution costs for the charges laid against the beekeeper that sold the contaminated honey.

[12] This analysis assumes that a general practitioner visit costs $NZ48. The cost of a day of lost wages is estimated using the median wage per hour of $NZ21.48 and assumes an 8 hour day for a total cost of lost wages per day of $NZ172.64. Median wage available at Statistics New Zealand

[13] 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 New Zealand Herald. 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 from Statistics NZ as per above. The cost of a bed night in hospital has been estimated at $NZ349.5 in 2005 dollars based on the cost of a night in a tertiary hospital from World Health Organisation

[14] 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 ACC Focus. The cost of a day of lost wages is estimated using the median wage per hour as per above and the cost of a night in hospital has also been estimated as per above.

4.2 Option 1: *Status Quo*: Retain the current maximum levels

The costs of this option are described below.

4.2.1 Honey industry

The industry will face no additional costs as the industry is currently required to comply with this option. Current testing costs for the honey industry, based on averaging the known costs and volumes, have been estimated at between $NZ138,000 and $NZ213,000 per year. This option has provided further information on the presence of tutin in honey than was available prior to 2008. Before 2008, beekeepers were required to ensure that honey was not harvested from areas where it was likely that the honey would be contaminated with high levels of tutin (see section 1.2.3). The introduction of maximum levels has enabled beekeepers to collect honey from these high risk areas. It has also enabled beekeepers to maintain quality and safety assurance over their product.

4.2.2 Health sector

The impact on the health system will be similar to what has been experienced since 2008. The estimated costs for tutin poisonings are given in section 4.1 above. There has only been one confirmed poisoning (in 2014) since 2008 where the person was hospitalised (a severe case).

While there have been no reported poisoning incidents since 2008 from honey that complied with the temporary maximum levels, the latest research suggests that adverse effects may be occurring in some individuals that are not being attributed to tutin. Therefore, this option provides inadequate protection for consumers from the risk of consuming honey contaminated with tutin.

4.2.3 Best available science

Now that additional research has been completed on tutin, as discussed in section 1.1 above, this option does not satisfy FSANZ's requirements to base standards on the best available scientific evidence. This research shows that honey contains higher levels of tutin than previously recognised due to the presence of formerly unidentified tutin glycosides.

4.2.4 Internationally competitive food industry

As the results of recent research have now been published, if the maximum levels are not changed to take account of this research there is a risk that there may be negative impacts on honey exports. While it is unlikely that there would be any disruption to exports, overseas markets could impose their own testing regimes based on the latest research. This would likely add cost for the New Zealand honey industry because of the need to comply with multiple testing regimes, rather than a single one imposed by the New Zealand government. Testing in New Zealand would provide for more targeted testing to ensure compliance at a local level and lower cost to New Zealand industry.

Option 2: Temporary maximum levels expire and are not replaced

Table 2: Analysis of costs and benefits for Option 2

Criteria	*Costs*	*Benefits*	*Overall*
Minimising implementation costs	*Honey industry* Beekeepers, packers and processors that do not operate under a Risk Management Programme (RMP) would no longer be required to meet the maximum level. However, many companies would likely continue to test to ensure their products were safe. *Honey exporters* These businesses will 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. *Testing laboratories* If the number of tests overall dropped, testing laboratories may increase how much they charge for each tutin test. *Government* MPI would likely impose maximum limits themselves or apply controls involving testing under other legislation. 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.	*Honey industry* Lowered compliance costs for those that do not operate under an RMP. The current cost of testing, based on averaging the known costs and volumes, is between $NZ138,000 and $NZ213,000 per year. It is not possible to estimate how many companies producing solely for the domestic market would actually stop testing and thence the costs that would be saved. 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 benefit[15] for producers under the Food Acts who stop testing for tutin.

[15] Cost savings likely to be under $NZ100,000. It is difficult to know how many producers operate under the Food Acts and would stop testing. As 80 percent of hives are managed by 221 commercial beekeepers that would operate under RMPs, most testing would probably continue.

Criteria	*Costs*	*Benefits*	*Overall*
Protection of Public health and safety	*Consumers* Inadequate protection from the risk of consuming honey contaminated with tutin. *Health Sector* A possible increase in the frequency of tutin poisonings from honey packed for the domestic market, and possible incidents affecting more than just one or two individuals. The estimated costs for mild and severe poisonings are given in section 4.1 above. Costs would be higher if more people were affected. Poisoning incident frequency and severity are difficult to predict.	No benefits	Small net costs of up to $NZ5,000 per case. Costs increase with the number of cases and their severity.
Internationally competitive food industry	*Honey exporters* New Zealand's honey exports have grown from $NZ81 million in 2008–09 to $NZ187 million in 2013–14. The proportion of New Zealand's honey exported to China grew from 3% in 2011–12 to 12% in 2013–14. China is very sensitive to food safety issues. A loss of confidence in overseas markets could also mean overseas countries may impose their own testing regimes or suspend or restrict exports.	No benefits	Probable high net cost if export markets impose their own testing regimes or restrict or suspend exports. $NZ187 million of exports at risk

4.2.5 Conclusion

This option is not based on the best available science as research undertaken since the 2008 poisoning would not be taken into account. 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.

4.3 Option 3: Temporary maximum levels expire and are replaced with a voluntary industry code of practice

As there is a strong public health and safety risk, and two industry organisations that operate independently of each other, a voluntary code of practice (CoP) is unlikely to be a viable option. In addition, many members of the industry do not belong to either industry group. Industry also supports the current tutin regulation rather than a CoP. No submissions on the consultation RIS supported a CoP, and the Food and Grocery Council's submission acknowledged that overall a CoP alone would not necessarily address the issues. More information can be found in section 5.

Table 3: Analysis of costs and benefits of Option 3

Criteria	***Costs***	***Benefits***	***Overall***
Minimising implementation costs	*Honey industry bodies* Based on similar processes in other sectors, the cost of developing the CoP would likely range between $NZ100,000 and $NZ200,000[16]. Alternatively, industry may decide to use what has already been developed by FSANZ and MPI so may face few additional costs. There would also be costs for ongoing management and auditing of the CoP. *Honey industry* Assuming a CoP was developed by the two major industry associations, it would only apply to those beekeepers and producers that are members of one of the organisations. Beekeepers and producers that were not members of either body would not have to comply with the CoP.	*Honey Industry* The key benefits will derive from a high level of buy-in to the CoP from the industry, as they own it. However, this buy-in is unlikely given the low membership of the two industry organisations. *Government* There could be a small cost saving for government as they may no longer need to do as much ongoing monitoring.	Medium net cost: one off set up cost of around $NZ200,000 plus ongoing monitoring costs

[16] No estimate of cost available. The cost is likely to be similar to the costs of FSANZ developing a new standard under the code so this has been used a proxy. Section 2.1.4 of the FSANZ *Application Handbook* list fees for a general procedure ranging between $NZ62,815 and $NZ156,250 depending on complexity. Major procedures cost at least $NZ185,000. The cost is expected to be higher as this would be a one-off process.

Criteria	*Costs*	*Benefits*	*Overall*
	Government The time needed to develop a CoP may mean that the expiry dates of the maximum levels in the Code need to be extended. Government would also face costs for monitoring the effectiveness of the CoP. The Government may also face greater costs for investigation and prosecution if the code proves ineffective and poisonings result.		
Protection of public health and safety	*Consumers* During the development of a CoP and in the transition period, there is increased risk of a tutin poisoning incident. *Health Sector* 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 those for Option 2. See information given on the costs of mild and severe cases in section 4.1 above. There is potential for poisonings to increase unless the CoP reflected up to date science and the whole industry complied with it.	*Health Sector* Once successfully implemented, and if recent scientific evidence is reflected, the CoP would assist in minimising the costs on the public health system of tutin in honey.	Small net cost Up to $NZ5,000 per case
Internationally competitive food industry	*Honey exporters* The greatest risk for honey exporters is the perception of trading partners. Any CoP would need to be sufficiently rigorous so that export markets would accept the CoP without imposing their own testing regimes or restricting or suspending exports.	No significant benefits, relative to status quo.	Probable high net cost $NZ187 million of export revenue at risk

4.3.1 Conclusion

There is likely to be a diversity of views in the industry, as evidenced in the submissions, during the development of the CoP. This could lead to difficulty in getting agreement on a CoP. Depending on the content of the CoP, this option may not adequately protect public health and safety and may not meet the FSANZ Act objective for standards to be based on risk analysis using the best available science.

The effect of the CoP may be limited because many industry members are not members of either industry group. 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.

4.4 Option 4: Amend maximum levels

Table 4: Analysis of costs and benefits of Option 4

Criteria	***Costs***	***Benefits***	***Overall***
Minimising implementation costs	*Honey industry* In addition to the testing costs estimated for Option 1, there would also be costs arising from extracted honey that meets the temporary maximum level but would not meet the reduced maximum level. Data from Hill laboratories for 2014 shows that 3.8 per cent of single samples had more than 0.7 mg/kg while 0.9 per cent had tutin levels over 2.0 mg/kg. The additional costs for this honey would include blending and retesting extracted honey to ensure it met the proposed new maximum level. Management practices may also need to be changed so honey meets the lower maximum level. The estimated additional re-testing cost is $NZ12,000 across the honey industry depending on whether re-testing is done using composite or single sample tests. This cost may fall more on some operators than on others. It also may vary between years as tutin levels in honey vary from year to year.	*Honey industry* It may enable beekeepers to collect manuka honey from areas that have high levels of tutin by providing an assurance that this product is safe. If the manuka honey has high levels of activity, this could bring considerable benefits.	Possible medium net cost due to potential loss of value for high value early manuka honey. The National Beekeepers Association commented in their submission that it would not surprise them if this impact would cost the New Zealand beekeeping industry perhaps $NZ1 million per year. However they did not provide justification for this assertion.

Criteria	*Costs*	*Benefits*	*Overall*
	The National Beekeepers Association commented in their submission that lower maximum levels could cause significant problems for some early[17] manuka areas that produce active manuka honey of high value. Blending could result in considerable loss of value for this honey. This is a small sector of the industry that has high profit and high retail prices. Industry would also face a cost to learn about the changes and determine if any changes need to be made to their systems.		
Protection of public health and safety	*Health system* The direct impacts on the health system will be similar to what has been experienced since 2008. See information given on the costs of mild and severe cases in section 4.1 above.	*Consumers* A reduction in ongoing costs such as loss of income and/or lower productivity from minor tutin poisoning incidents.	Small net benefit Likely saving of one day of lost productivity per case at $NZ172.64.
Internationally competitive food industry	There are unlikely to be any costs for this option.	*Overseas markets* This change will send clear signals to NZ's markets that food safety is a paramount concern. Given the sensitivity of some markets around food safety, this messaging is critical. Honey exports have been growing at a compound annual growth rate (CAGR) of 18.21% per year since 2009.	High net benefit as compound annual growth rate of 18.21% per year likely to continue. Honey exports were $NZ187 million for 2014.

[17] Not defined in the submission. This is likely to be areas that yield honey prior to 31 December such as Northland and the Coromandel.

4.4.1 Conclusion

While this option will impose higher costs on industry, in particular a potential loss of value for high value early manuka honey which may exceed the new tutin limits, it will reduce public health costs as fewer people will experience the minor effects of a poisoning. It is the only 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. The costs will likely be outweighed by the support this option provides for maintaining the reputation of New Zealand honey, and the confidence and trust of consumers. It works to grow and protect access to markets by maintaining the confidence of overseas markets and trading partners, by using the best available science to support food safety.

5 Consultation

The honey industry has been kept updated on the review of the maximum levels for tutin in honey and comb honey through ongoing regular presentations at industry forums and conferences. FSANZ and MPI provided regular updates to the Bee Products Standards Council on the progress of the review and the proposed changes to the maximum levels at Council meetings. The Council has been supportive of amending the maximum levels based on recent research. FSANZ also provided information on the Proposal P1029 and the opportunity to provide submissions at the New Zealand Apiculture Industry Conference in June 2014.

5.1 Industry views

Overall feedback from industry since 2008 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. Testing also provides a management tool that allows hives to be placed in areas previously considered to be too high risk.

5.2 2014 consultation

A Consultation RIS (OBPR reference 13847) was released for comment as part of FSANZ's formal consultation on the Call for Submissions for Proposal P1029 – Maximum Level for Tutin in Honey on 10 July 2014. Consultation closed on 21 August 2014. Public feedback was sought on the proposed option of reducing the maximum levels for tutin in honey and comb honey in the Code. A total of eight submissions were received from industry, peak bodies and jurisdictions as follows:

- National Beekeepers Association of New Zealand (NBA)
- Bay of Plenty Branch of the National Beekeepers Association (BOP Branch NBA)
- Hikutaia Honey Ltd
- New Zealand Food and Grocery Council (NZFGC)
- New Zealand Ministry for Primary Industries (MPI)
- Department of Health, Victoria
- Federated Farmers of New Zealand, Bee Industry Group (FF BIG)
- Food Technology Association of Australia

Five submissions from industry and government agencies supported the draft variation proposed in FSANZ's Call for Submissions to reduce the maximum levels for tutin in honey and comb honey. Supporters were NZFGC, MPI, FF BIG, Department of Health (Victoria) and the Food Technology of Australia. While MPI supported the proposed reductions to the maximum levels, they requested a sampling plan for comb honey to ensure the Code does not conflict with the New Zealand Tutin Standard. A late submission was also received from the Bee Products Standards Council that supported the proposed draft variation to reduce the maximum levels for tutin in honey and comb honey.

The NBA said that they could support the proposal if they were satisfied that the methodology behind the pharmacological study was sound.

The Bay of Plenty Branch of the NBA and Hikutaia Honey Ltd did not support the proposal as they have concerns about the quality and methodology of the research the proposed was based on.

The main issues raised in submissions relevant to this RIS and the responses are given in Table 5 below. Other issues that were raised that are not relevant to the Decision RIS are addressed in FSANZ documents about this proposal on their website.[18]

Table 5: Issues raised in submissions relevant to the RIS

Issue	*Response*
Three industry submissions raised concerns about the quality and methodology of the research on which the proposed draft variation is based.	The research on which the draft variation is based included a human pharmacokinetic study which was conducted in accordance with Good Clinical Practice and based on European Medical Agency Guidelines for human pharmacokinetic studies. The study has recently been published in a peer-reviewed scientific journal. More information can be found in section 1.1.4.
Three industry submissions did not support the proposed approach of having no transitional arrangements and sought some transitional period. Two also questioned why honey packaged for retail sale should have a stock-in-trade provision but not bulk honey as this constitutes a double standard.	As the main reason for amending the maximum levels is to protect public health and safety, FSANZ is maintaining its approach of no transitional arrangements for bulk honey. As noted in section 5, industry has been given prior notice of the proposed reduction for extracted honey help minimise the impact. There is likely to be minimal impacts for comb honey as the drafting has been amended to ensure that the Code does not conflict with the New Zealand Tutin standard (see section 3). In effect, this means that there will be no change to industry practices for comb honey. The stock-in-trade provision has been applied to honey packaged for retail sale as the cost to recall, re-blend and re-package retail products could be substantial. As laboratory test results in recent years indicate that most honey samples tested already meet the lower maximum levels, the risk from existing retail product stocks is expected to be low. FSANZ has not applied a stock-in-trade to bulk honey as industry can test and re-blend stock according to the new level prior to packaging at minimal additional cost. Determining which retail products are made from bulk honey stocks which existed prior to gazettal from those made with bulk honey procured after gazettal would make enforcement difficult.
Two submissions identified that some additional costs could be incurred from the proposed lower levels due to increased blending and testing. One industry submission noted that the lower levels could cause significant problems and expense for early manuka areas that provide active manuka honey of very high value. Blending could result in a loss of value of this honey.	The additional costs have been incorporated into the analysis of options in sections 4 and 6 of this Decision RIS. This is a small sector of the industry that has the highest profit and retail prices. These costs are likely to be outweighed by the benefit of maintaining NZ's reputation for safe food exports.

[18] link FSANZ p1029 webpage

Issue	*Response*
The maximum level for comb honey should be linked to a sampling plan to ensure it doesn't conflict with compliance options in the NZ Tutin Standard.	FSANZ considers that a sampling plan would be more appropriate in the New Zealand Tutin Standard instead of the Code. As a result of this submission, the drafting has been amended to apply one maximum level to all honey of 0.7 mg/kg. Options for compliance for comb honey will remain the same as those currently in the New Zealand Tutin Standard. This will not impose any change on industry practices for comb honey as the current compliance options in the New Zealand Tutin Standard will continue to apply (see section 3). FSANZ has further consulted with MPI on this issue. MPI supports the drafting amendment and the decision not to include a sampling plan in the Code. MPI will take the amended drafting into account in its review of the New Zealand Tutin Standard.

6 Evaluation and conclusions

As discussed in section 3 above, status quo for this analysis has been changed to retain the current maximum levels as this reflects the current practice. Table 6 below provides a summary of the costs and benefits for each option against the criteria derived in section 2.

Table 6: Summary of the net benefits for each option

	Option 1: Status Quo: Retain the current maximum levels	***Option 2: Temporary maximum levels expire and are not replaced***	***Option 3: Temporary maximum levels expire and are replaced with a voluntary industry code of practice***	***Option 4: Amend maximum levels***
Implementation costs	No change	Small[19] net benefit	Medium net cost	Possible medium net cost
Protection of public health and safety	Possible small net cost	Small net cost	Small net cost	Small net benefit
Standards to be based on risk analysis using best available science	Does not meet this criteria	Does not meet this criteria	May or may not meet this criteria	Meets this criteria
Internationally competitive food industry	Possible high net cost	Probable high net cost	Probable high net cost	High net benefit
Overall	**Possible high**	**Probable high**	**Probable high**	**High net**

[19] Small costs are defined as those estimated to be under $NZ100,000. Medium costs are estimated to be between $NZ100,000 and $NZ1 million. High net costs are estimated as being over $NZ1 million.

	Option 1: Status Quo: Retain the current maximum levels	***Option 2: Temporary maximum levels expire and are not replaced***	***Option 3: Temporary maximum levels expire and are replaced with a voluntary industry code of practice***	***Option 4: Amend maximum levels***
	net cost	**net cost**	**net cost**	**benefit**

Option 1 has a possible high net cost. Although it has no additional direct costs for industry, the possible high net cost could come from:

- the possible risk of export markets imposing their own testing regimes based on the recent published research and
- consequential compliance costs for New Zealand industry if the maximum levels are not changed to take account of recently published research.

Maximum levels imposed by export markets would likely be stricter than current maximum levels. This option would likely also lead to MPI having to implement maximum limits itself or to continue to apply controls under the Animal Products Act. It also does not meet the FSANZ Act objective to protect public health and safety or the requirement to base standards on risk analysis using the best available science.

Option 2 has a probable high net cost as the increased likelihood of a poisoning incident outweighs the small benefit (for producers who operate under the Food Acts) of reduced testing costs. Export markets may impose stricter maximum tutin levels under this option than under the status quo, which could lead to the increased compliance costs noted above for Option 1. Option 2 also fails to meet the FSANZ Act objective to protect public health and safety or the requirement to base standards on risk analysis using the best available science.

Option 3 is not likely to be viable given the high risk to health and safety, the lack of a single cohesive industry association and the lack of industry support for this option. If implemented, it would constitute a probable high cost for industry of developing and monitoring an industry code of practice. Depending on the how the code of practice is set up, there may be an increased risk of people getting poisoned and difficulty enforcing the code. This option may also not meet the FSANZ Act requirement to base standards on risk analysis using the best available science and may have a negative impact on exports.

The recommended option is Option 4: to amend the maximum levels for tutin in honey (from 2 mg/kg) and comb honey (from 0.01 mg/kg) to 0.7 mg/kg. The compliance options in the New Zealand Food (Tutin in Honey) Standard will still apply. For comb honey, all the drip and leftover comb from a comb honey harvest from a single apiary site must be homogenised and sub-sampled and tested for tutin. Cut comb honey will only comply if the if individual samples contain less than 0.01 mg/kg of tutin.

Option 4 has a high net benefit. There will be some cost to industry—in particular a potential loss of value for high-value early manuka honey which may exceed the new tutin limits. These costs are, however, outweighed by the support this option provides for maintaining the reputation of the New Zealand honey industry and its long term growth and value.

This option provides a good environment for the compound annual growth rate (CAGR) of 18.21 per cent per year experienced by honey exports in the period 2009-2014 to continue. It is the only option that:

- takes full account of the risk analysis using the best available scientific evidence,
- 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

If regulatory changes are made, they will come into effect immediately on gazettal in the Code and there will be no transitional arrangements. The draft variation is expected to be gazetted in the Code in January 2015. A Standard giving legal effect to the changes in New Zealand will then be issued under the New Zealand *Food Act 1981* and will come into force in New Zealand 28 days after that date.

Whilst there will be no transitional arrangements, there will be a stock-in-trade provision so that any honey packed for retail sale before the date of gazettal will not need to comply at any time with the new requirements. These products will 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 five years after the permanent maximum levels are gazetted, this amount of honey is expected to be small. The cost of requiring extracted honey already packaged for retail sale to be recalled, re-blended and re-packaged to meet the new maximum level is estimated to outweigh the potential public health costs of leaving this honey on shelves. Although the stock-in-trade provision includes comb honey packaged for retail sale, it is expected to have a minimal impact on comb honey products as in practice there is no change to implementation for comb honey under the current New Zealand Tutin Standard.

Three submissions on the consultation RIS supported having transitional arrangements and two commented that there should be a transitional period as well as a stock in trade provision for bulk honey. FSANZ has decided against a transition period for bulk honey as the main reason to amend the maximum level for extracted honey is to protect public health and safety. FSANZ has not applied a stock-in-trade to bulk honey as industry can re-blend this stock according to the new level at minimal additional cost. More information can be found in section 5 or in other FSANZ documents about this proposal on their website.[20]

7.2 Review

If the new maximum level is implemented, FSANZ and MPI will continue to monitor reported poisonings and relevant science as part of ongoing oversight of the effectiveness of regulations in fulfilling the objectives of the FSANZ Act.

[20] http://www.foodstandards.gov.au/code/proposals/Pages/P1029-Maximun-Level-for-Tutin-in-Honey.aspx

Appendix 1: Honey industry profile

Apiculture is a significant contributor to New Zealand's primary production sector. There were over 4,800 beekeepers in New Zealand as at June 2014 with 30,688 apiaries and 507,247 hives as at June 2014.

Most registered beekeepers (85 per cent) have fewer than 50 hives and over half of these have fewer than 5 hives (66.1per cent). Small beekeepers (those with fewer than 50 hives) average 4 hives per apiary while commercial beekeepers (those with over 500 hives) average 21 hives per apiary. About 80 per cent 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 Island[21].

The New Zealand honey crop has averaged 13,356 tonnes per year[22] since 2009. The crop for the year to June 2014 is estimated at 17,608 tonnes. The value of honey exports has grown significantly in recent years: between 2009 and 2014 exports grew from $NZ81 million to $NZ187 million (a compound annual growth rate of 18.21 per cent per year). The volume of honey exported in the year to 2014 was 8,704 tonnes, valued at $NZ187 million[23]. This included exports of 53.3 tonnes of comb honey valued at $NZ1.5 million[24].

While the United Kingdom took around a third of New Zealand's honey exports between 1 July 2011 and 30 June 2012, this began to decline in 2013. China's share of New Zealand exports is beginning to increase. While it took only 3 per cent in the year to June 2012, this increased to 11 per cent in 2013 and to 12 per cent in 2014. Other important markets are Hong Kong, the European Union and Singapore.

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. Honey not packed under an RMP is usually packed by small producers solely for the domestic market.

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 Blenheim on the other side. Around 73 per cent of all beekeepers harvest honey in areas above latitude 42 degrees south.

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

[22] This year runs from 1 July to 31 June the following year

[23] Statistics New Zealand harmonised export data for honey products code 0409

[24] Statistics New Zealand harmonised export data for comb honey exports code 0409000011