

**4 November 2014**

**[23–14]**

Approval Report – Proposal P1029

Maximum Level for Tutin in Honey

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to review the maximum levels for tutin in honey and comb honey.

On 10 July 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variation on 29 October 2014. The Australia and New Zealand Ministerial Forum on Food Regulation[[1]](#footnote-1) (Forum) was notified of FSANZ’s decision on 3 November 2014.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of Contents

[Executive summary 2](#_Toc402434235)

[1 Introduction 3](#_Toc402434236)

[1.1 Background 3](#_Toc402434237)

[1.2 The Proposal 3](#_Toc402434238)

[1.3 The current Standards 3](#_Toc402434239)

[1.3.1 Australia New Zealand Food Standards Code 3](#_Toc402434240)

[1.3.2 New Zealand Standard 4](#_Toc402434241)

[1.4 Reasons for preparing Proposal 4](#_Toc402434242)

[1.5 Procedure for assessment 4](#_Toc402434243)

[2 Summary of the findings 4](#_Toc402434244)

[2.1 Risk assessment 4](#_Toc402434245)

[2.2 Risk management 6](#_Toc402434246)

[2.2.1 Maximum level for tutin in honey 6](#_Toc402434247)

[2.2.2 Maximum level for tutin in comb honey 7](#_Toc402434248)

[2.2.3 Amendment to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi 8](#_Toc402434249)

[2.2.4 Industry education 8](#_Toc402434250)

[2.3 Cost benefit analysis 8](#_Toc402434251)

[2.3.1 Recommended option 10](#_Toc402434252)

[2.4 Summary of issues raised in submissions 10](#_Toc402434253)

[2.5 Decision 14](#_Toc402434254)

[2.6 Risk communication 14](#_Toc402434255)

[2.6.1 Targeted consultation 14](#_Toc402434256)

[2.7 FSANZ Act assessment requirements 15](#_Toc402434257)

[2.7.1 Section 59 15](#_Toc402434258)

[2.7.2 Subsection 18(1) 15](#_Toc402434259)

[3 Transitional arrangements 16](#_Toc402434260)

[3.1 Transitional arrangements for Code Revision 17](#_Toc402434261)

[4 References 17](#_Toc402434262)

[Attachment A – Approved draft variations to the *Australia New Zealand Food Standards Code* 19](#_Toc402434263)

[Attachment B – Explanatory Statement 22](#_Toc402434264)

[Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions) 24](#_Toc402434265)

[Attachment D – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025 26](#_Toc402434266)

Attachment E – Decision Regulation Impact Statement (separate document)

**Supporting document**

The following documents which informed the assessment of this Proposal are available on the FSANZ website at <http://www.foodstandards.gov.au/code/proposals/Pages/P1029-Maximun-Level-for-Tutin-in-Honey.aspx>

SD1 Risk Assessment (at approval)

# Executive summary

Tutin is a plant-derived neurotoxin, which can sometimes be present in honey produced in New Zealand. Following a severe poisoning incident in New Zealand in 2008, temporary maximum levels (MLs) for tutin in honey and comb honey were adopted into the *Australia New Zealand Food Standards Code* (the Code) while further research and evaluation was conducted. The temporary ML of 2 mg/kg for tutin in honey (extracted/blended honey) was derived from animal studies using purified tutin. The temporary MLs are due to expire on

31 March 2015.

The main findings from the recent research show that:

(i) The effective concentration of tutin in honey can be higher than previously measured due to the presence of previously unidentified forms of tutin. These other forms of tutin have glucose attached and are chemically known as tutin glycosides.

(ii) Tutin glycosides in honey are most likely converted in the human gut to tutin which then appears in plasma several hours after consumption.

(iii) Some individuals are able to very efficiently convert tutin glycosides into tutin and therefore the current temporary ML for tutin in honey is unlikely to be protective of human health.

In assessing this Proposal, FSANZ considered regulatory and non-regulatory options to appropriately manage the food safety risks posed by tutin contamination of honey. A Regulation Impact Statement (RIS) has been completed for this Proposal which evaluates the costs and benefits of these options. The RIS takes into account information provided in stakeholder submissions on the analysis of the options and potential impacts of the draft variation.

FSANZ released a call for submissions on a proposed draft variation to the Code in July 2014. Most submissions supported the draft variation. However, the New Zealand Ministry for Primary Industries (MPI) expressed concern that the draft variation set an ML for comb honey of 0.01 mg/kg. MPI noted that this ML would conflict with the New Zealand Food (Tutin in Honey) Standard 2010. FSANZ has now amended the draft variation to set an ML 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 Standard in relation to comb honey. The compliance options mandated by the New Zealand Standard will assure the safety of comb honey at retail sale.

After having regard to the assessment findings, the cost-benefit analysis and issues raised in submissions, FSANZ has approved a draft variation to Standard 1.4.1 – Contaminants and Natural Toxicants to amend the MLs for tutin in honey (from 2 mg/kg) and comb honey (from 0.1 mg/kg) to 0.7 mg/kg. The continued use of an ML based on the level of tutin instead of total tutin equivalents (tutin + tutin glycosides) is necessary because there is no method currently available to quantify the tutin glycosides in honey.

FSANZ has also approved a minor amendment to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi to clarify the application of that Standard to the presence of natural toxicants such as tutin.

# 1 Introduction

## 1.1 Background

Tutin is a neurotoxic compound produced by the shrub *Coriaria arborea* (‘tutu’) which is native to New Zealand. Tutin contamination of New Zealand honey can occur when bees gather honeydew excreted from a vine hopper insect (*Scolypopa australis*) that feeds on the sap of tutu. The tutin present in the tutu sap is transferred to the vine hopper honeydew which is then transferred to honey.

Human poisonings associated with the consumption of tutin-containing honey have occurred sporadically in New Zealand since the late 19th century. This issue appears to be unique to New Zealand. FSANZ is not aware of reports of poisoning from honey containing tutin in Australia or any other country. In New Zealand in 2008, at least 20 people were poisoned due to the consumption of honey containing tutin.

In December 2008, a New Zealand food standard for tutin in honey, issued under the New Zealand *Food Act 1981,* was introduced and it came into force in January 2009 (NZFSA, 2008). The standard set a maximum level (ML) of 2 mg/kg for tutin in honey (extracted/blended honey)[[2]](#footnote-2) and a ML of 0.1 mg/kg for comb honey based on a preliminary risk assessment carried out by the then New Zealand Food Safety Authority (now Ministry for Primary Industries, MPI). These MLs were introduced as an interim risk management measure in response to the poisoning episode.

FSANZ adopted these MLs in August 2009 as a temporary measure into Standard 1.4.1 – Contaminants and Natural Toxicants in the Code. This was undertaken as part of Proposal P1008 – Code Maintenance Proposal VIII. These temporary MLs were considered to be an appropriate risk management measure while further research and evaluation was completed. The New Zealand food standard for tutin (NZFSA, 2008) provided options for demonstrating compliance with these MLs in the Code. This has since been replaced with the 2010 New Zealand standard (MAF, 2010).

The temporary MLs in the Code were initially due to expire on 31 March 2011. FSANZ extended the expiry date to 31 March 2015 to allow time for further research and evaluation. The extensions were made under Proposals P1009 – Maximum Limits for Tutin in Honey and P1023 – Tutin, Tocopherol & Food for Special Medical Purposes Amendments.

## 1.2 The Proposal

The purpose of this Proposal is to review the adequacy and appropriateness of the current risk management measure for tutin in honey and comb honey (i.e. the MLs for tutin in Standard 1.4.1).

## 1.3 The current Standards

### 1.3.1 *Australia New Zealand Food Standards Code*

Standard 1.4.1 currently prescribes temporary MLs for tutin of 2 mg/kg in honey and 0.1 mg/kg in comb honey. These are listed in the table to clause 5 of the Standard. These levels will expire on 31 March 2015 (subclause 5(5) of the Standard).

The Standard also provides a formula to determine the ML which applies to a contaminant or natural toxicant in a mixed food (subclause 1(6) of the Standard).

Standard 1.4.4 – Prohibited and Restricted Plants and Fungi currently prohibits the tutu plant (species *Coriaria* spp. as listed in Schedule 1), or a part or a derivative of the plant, or a substance derived from the plant, from being intentionally added to food or offered for sale as food.

### 1.3.2 New Zealand Standard

In New Zealand, the Food (Tutin in Honey) Standard 2010 (MAF, 2010) issued under the *Food Act 1981*, provides a number of options for demonstrating compliance with the tutin MLs set in the Code.

The Standard requires the last person to pack honey that is intended for sale for human consumption and any person who is exporting honey, to demonstrate compliance with at least one of the options provided in the Standard. The options are:

* two options relating to testing honey and comb honey for the presence of tutin (the sampling and testing requirements are prescribed in the Standard and include testing of representative samples of honey and comb honey to demonstrate compliance)
* demonstrating that honey has been harvested within the low risk harvest date[[3]](#footnote-3)
* demonstrating that tutu is not present in the predictable range of bee foraging from the hives location
* demonstrating that hives are in a low risk area[[4]](#footnote-4).

MPI is responsible for developing and administering this New Zealand Tutin Standard, which is currently under review. The existing Standard and the compliance options it provides will continue to remain in place pending the outcome of this review. The review will consider the specific compliance options that are warranted to ensure the safety of honey in light of the four years experience with the current Standard. This review is a separate and independent process to FSANZ’s Proposal P1029 outlined in this report on the tutin MLs in the Code. However, MPI will take into account any regulatory changes made under this Proposal in its review.

## 1.4 Reasons for preparing Proposal

This Proposal was prepared to review the MLs for tutin in honey and comb honey in Standard 1.4.1, taking account of recent research, before the existing temporary MLs expire.

## 1.5 Procedure for assessment

The Proposal was assessed under the General Procedure.

# 2 Summary of the findings

## 2.1 Risk assessment

FSANZ’s risk assessment for tutin in honey is provided in **Supporting Document 1 (SD1)**.

Consumption of honey containing tutin has resulted in serious acute adverse health effects. In response, a temporary ML of 2 mg/kg for tutin was established using data derived from the oral administration of purified tutin in mice. However, 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 the cause of this delayed onset, six healthy adult male volunteers were invited to ingest honey naturally contaminated with a small amount of tutin.

At various time intervals, the concentration of tutin in their blood was measured. This type of investigation, known as a pharmacokinetic study, does not specifically consider the amount of tutin which may be safely consumed. However, clinical signs and symptoms are monitored. No adverse effects were anticipated based on the preclinical data in mice and the low tutin dose chosen for the study in humans. The study was conducted in accordance with Good Clinical Practice and was reviewed and approved by an appropriate human research ethics committee. The number of subjects in the study was consistent with internationally accepted guidelines for the conduct of human pharmacokinetic studies. The study has been recently published in a peer-reviewed scientific journal (Fields et al. 2014).

The pharmacokinetic study revealed that the effective concentration of tutin in the administered honey sample was higher than had been previously measured. However, this additional tutin in honey was not in the same form as that previously known. It was present as tutin with glucose attached (i.e. as glycosides). Following ingestion by humans, the tutin is slowly released from these glycoside forms and absorbed into the blood stream over many hours. As different individuals are able to release tutin from these previously unidentified glycoside forms of tutin at different rates, and the ratio of tutin to tutin glycosides varies among honey samples, it is necessary to reduce the temporary ML of 2 mg/kg in order to ensure the public health and safety of consumers.

Based on the results of the pharmacokinetic study, it is considered possible that adverse effects such as mild light-headedness and headache may be experienced following the consumption of honey containing tutin at the current ML of 2 mg/kg. Such adverse effects are more likely if a large amount of honey (≥0.9 g of honey per kg bodyweight) is consumed in one sitting, as was the case in the pharmacokinetic study. The risk of adverse effects is increased if the ingested honey has a ratio of tutin glycosides to tutin at the high end of the observed range.

No method is currently available to reliably quantify tutin glycosides in honey. Therefore, the continued use of a surrogate ML based on the level of free tutin (i.e. without any glucose attached) is necessary. FSANZ has calculated that a reduction of the current ML from 2 mg/kg to 0.7 mg/kg for extracted/blended honey should provide an adequate margin of safety for consumers. This takes into account the individual variability observed in the pharmacokinetic study and the variability in the ratios of tutin glycosides to free tutin found in different honey samples.

Assessing the risk for comb honey is not possible because there are insufficient data on the degree of variability of tutin levels across combs. 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. Similarly, the tutin level determined for a representative sample (i.e. the drip and leftover comb) may differ markedly from that in a portion of comb taken from that hive. Provided consumers are not exposed to tutin concentrations above 0.7 mg/kg in comb honey, the risk of adverse effects is low.

## 2.2 Risk management

FSANZ considered both regulatory and non-regulatory options in assessing this Proposal. The regulatory options considered included maintaining the existing MLs in the Code (*status quo*), or setting a new ML based on recent scientific research. The non-regulatory options considered included allowing the existing MLs in the Code to expire with no new levels or measures in place, and the development of an industry code of practice. Each of these options has been analysed in the Regulation Impact Statement (RIS) for this Proposal (see section 2.3 below and Attachment E).

Currently, the risk of tutin poisoning is managed in the Code by prescribing MLs for tutin. Other more restrictive regulatory measures, such as prohibiting the production of honey in certain areas, were considered to be unnecessary options and were not analysed as part of the RIS. FSANZ considers that such regulatory measures would be excessive given that there have been no reported tutin poisonings associated with honey that meets the existing MLs since their introduction in the Code and since the introduction of the compliance options in the New Zealand Tutin Standard (see section 1.3.2).

Recent research indicates, however, that the current ML for honey may not adequately protect consumers as honey contains higher levels of tutin than previously recognised due to the presence of tutin glycosides (see section 2.1 above). It is therefore necessary to reduce the tutin ML for extracted honey in the Code to protect public health and safety.

### 2.2.1 Maximum level for tutin in honey

In determining the appropriate ML for tutin in honey (extracted/blended honey), a critical factor has been the finding that honey may effectively contain higher levels of tutin than previously recognised. This is due to previously unidentified glycoside forms of tutin (tutin glycosides) which are converted to free tutin when consumed. Furthermore, there is variation in the ratio of tutin glycosides to free tutin in different honey samples and higher ratios are found in some samples than the sample used in the human study (see SD1); thus the effective concentration of tutin in honey may be higher in some honeys than those observed in the honey samples analysed.

Other factors were also considered in determining an appropriate ML. As discussed in FSANZ’s risk assessment (SD1), it is likely that there would be individuals in the population who could efficiently convert the tutin glycosides to free tutin resulting in delayed adverse neurological effects.

As no method is currently available to quantify the tutin glycosides in honey, the continued use of a ML based on the level of free tutin instead of total tutin equivalents (free tutin + tutin glycosides) is necessary.

Consequently, it was concluded that in order to protect the health and safety of consumers, it is necessary to reduce the ML for tutin in extracted/blended honey to take account of these factors. A reduction factor of three has been applied to give a new ML of 0.7 mg/kg for tutin in honey.

In order to determine the achievability of this lower level in honey, the results of analyses conducted for compliance testing as specified in the New Zealand Tutin Standard have been taken into account. Most honey produced in New Zealand over recent years would meet this lower ML (see section 1.1.1 of Attachment E).

### 2.2.2 Maximum level for tutin in comb honey

As tutin distribution can vary widely across honeycombs, comb honey has been considered separately to honey (extracted/blended honey). For extracted honey, the presence of high levels of tutin in certain honey may be diluted with other honey through the mixing process during production. This would provide a lower overall tutin level. For comb honey, there is no blending or dilution effect. It is conceivable that the tutin level in a specific portion of comb could differ markedly from the tutin level in another part of the comb.

As concluded in FSANZ’s risk assessment, there are insufficient data on the potential variability of tutin distribution in comb honey to characterise the risk for consumers. The limited data that are available (unpublished data) indicate that there are no obvious trends in tutin concentrations across the honeycomb in any direction.

The New Zealand Tutin Standard prescribes the testing requirements for honey and comb honey in New Zealand (see section 1.3.2). The Standard requires testing of a representative sample of comb honey (when the testing compliance options for comb honey are used). This is because it is not currently feasible to test each individual portion of comb honey for tutin. The Standard (clause 15) therefore specifies that all the drip and leftover comb from a comb honey harvest from a single apiary site must be homogenised and sub-sampled.

This means that there could be an overall dilution effect, whereby portions of comb that contain higher levels of tutin are diluted by portions which contain lower levels of tutin. The tutin level determined for the representative sample (i.e. the drip and leftover comb) could therefore also differ markedly from the tutin level in a specific portion of comb. To account for this potential variability, the New Zealand Standard requires the drip and leftover comb to contain less than 0.01 mg/kg tutin (i.e. no detectable tutin)[[5]](#footnote-5) to minimise the risk of high levels of tutin being present in a specific portion of comb.

FSANZ had earlier proposed a separate ML of 0.01 mg/kg for comb honey. However, after considering submissions from MPI, FSANZ agreed that the imposition of such a low ML for comb honey sold at retail was not appropriate. The New Zealand Tutin Standard already specifies that the level of tutin in honey should be less than 0.01 mg/kg for comb honey at the production stage, as prescribed under the testing options in that Standard. MPI advised that the compliance options prescribed by that Standard will ensure the safety of comb honey at retail sale. That is, if the drip and leftover comb of comb honey contains less than 0.01 mg/kg tutin (i.e. no detectable tutin), one can reasonably accept that the likelihood of an individual portion of comb containing more than 0.7 mg/kg will be sufficiently low. For these reasons, FSANZ decided that the imposition of an ML of 0.7 mg/kg would be appropriate for all honey (including comb honey).

Therefore, FSANZ has approved a draft variation that will set an ML of 0.7 mg/kg for honey (including comb honey). This takes account of recent research (see above) and the compliance options in the New Zealand Tutin Standard.

An editorial note has also been added to the drafting which references the compliance options in the New Zealand Tutin Standard.

MPI has indicated it supports the draft variation as amended.

### 2.2.3 Amendment to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi

As explained above, tutin is derived from a plant which is listed as a prohibited plant in Standard 1.4.4. This Standard prohibits a part or derivative of a prohibited plant, or any substance derived from such a plant, from being intentionally added to food or offered for sale as food. This prohibition does not extend to the presence in food of a substance derived from a prohibited plant (e.g. tutu) that occurs as a natural toxicant. The latter is instead regulated or permitted by Standard 1.4.1. FSANZ has approved a minor amendment to the Editorial Note to clause 1 of Standard 1.4.4 to make this distinction clear.

### 2.2.4 Industry education

FSANZ acknowledges that there may continue to be a varying degree of residual risk of tutin poisonings with any of the options considered in the assessment. This is due to a potential lack of awareness of tutin contamination and the requirements in the Code and the New Zealand Tutin Standard by some smaller beekeepers and hobbyists. Additional risk management strategies are in place to mitigate this risk, including ongoing compliance testing and enforcement by MPI and educational information for industry. MPI provides information for honey producers on tutin contamination and the relevant legislation on its website (MPI, 2014).

Other sources of information about tutin for industry that FSANZ is aware of include:

* Information sent to beekeepers by AsureQuality on registration of their hives (registration is a legal requirement in New Zealand).
* A leaflet and video on tutin contamination produced by the New Zealand Bee Products Standards Council[[6]](#footnote-6). The video is available on YouTube and through the Council’s website (BPSC, 2014). It will be distributed to all registered beekeepers and will be available at beekeeping supply companies.
* Information on tutin sponsored by MPI in the National Beekeepers Association of New Zealand publication ‘Starting with Bees’ (NBA, 2014).
* Regular messages about tutin distributed by MPI through The New Zealand Beekeeper journal.
* 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.

## 2.3 Cost benefit analysis

FSANZ is required to have regard to whether the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of this Proposal outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

A RIS was completed for this Proposal and is provided at Attachment E. As the issue of tutin contamination of honey appears to be unique to New Zealand, the RIS was prepared by MPI with assistance from FSANZ. The New Zealand Treasury held primary responsibility for reviewing and approving the RIS in liaison with the Office of Best Practice Regulation (OBPR) in Australia (OBPR RIS ID: 13847).

The RIS examined the impacts of four options as identified below:

* Option 1: *Status Quo* – Retain the current MLs for tutin and make them permanent. Under this option, a draft variation to Standard 1.4.1 would be approved to remove the current expiration date.
* Option 2: Reject the draft variation and let the temporary MLs for tutin expire.
* Option 3: Reject the draft variation and let the temporary MLs for tutin expire and replace with a voluntary industry code of practice.
* Option 4: Approve a draft variation to Standard 1.4.1 following public consultation to amend the current MLs for tutin in honey (from 2 mg/kg) and comb honey (from 0.1 mg/kg) to 0.7 mg/kg, based on new research, and make the ML permanent.

In addition to the changes to Standard 1.4.1, a draft variation to Standard 1.4.4 would also be prepared under options 1 and 4 as discussed in section 2.2.3 above. However, as this variation is for clarity purposes, it was not considered relevant for the cost benefit analysis.

Public consultation on the four options was undertaken by FSANZ. Formal submissions were received addressing specific questions raised in the Consultation RIS. Some targeted consultation has also been undertaken with the honey industry (see section 2.6.1). The Decision RIS (Attachment E) takes account of information provided from the consultation relevant to the cost benefit analysis.

The options listed in the Decision RIS differ slightly from those listed in the Consultation RIS. Option 1 (status quo) in the Consultation RIS was to allow the MLs to expire instead of retaining the current MLs in the Code. Option 1 was amended in the Decision RIS to refer to the retention of the current MLs in the Code. This was because this accurately reflects the present situation for industry which must currently comply with the existing MLs in the Code. This change made the analysis easier and more intuitive. Option 4 is also different in the Decision RIS. Option 4 was amended for the purposes of the Decision RIS to apply an ML of 0.7 mg/kg to all honey (including comb honey), instead of setting a separate ML of 0.01 mg/kg for comb honey. This change is explained in section 2.2.2 above.

While submissions provided some qualitative information, they provided little in the way of quantitative evidence. The RIS has quantified potential costs and benefits where possible. However, due to the limited information and difficulties in quantifying the specific costs and benefits, the specific overall impacts have not been quantified.

The RIS concludes that option 1 (*retain the current MLs -* *status quo*) has an overall possible high net cost as export markets could impose their own stricter ML based on the recently published research. This option does not take account of the latest research which shows that honey contains more tutin than previously recognised due to the presence of tutin glycosides, and that adverse effects may occur in some individuals at the current levels. Therefore, this option does not adequately protect the health and safety of consumers.

Option 2 (*MLs expire*) and option 3 (*industry code of practice*) have an overall probable high net cost. These options would not provide adequate protection for consumers due to the potential for poisonings to occur and could have an impact on export markets.

Option 4 (*amend MLs*) is the recommended option as it protects public health and safety by taking full account of the risk analysis using the best available scientific evidence. It is also likely to protect access to overseas markets by building confidence and trust with trading partners.

### 2.3.1 Recommended option

Overall, the RIS concludes that the recommended option is Option 4 to prepare a draft variation to amend the current MLs for tutin in honey and comb honey to 0.7 mg/kg.

## 2.4 Summary of issues raised in submissions

FSANZ received eight submissions in total from industry, peak bodies and jurisdictions. Five supported the draft variation proposed following assessment to amend the MLs for tutin in honey and comb honey. MPI supported the proposed reduction for extracted honey but requested a sampling plan for comb honey to ensure the Code does not conflict with the New Zealand Tutin Standard.

The main issues raised in submissions were:

* concerns about the quality and methodology of the research on which the proposed draft variation is based (three industry submitters)
* some opposition to the proposed approach of having no transitional arrangements and a desire for some transitional period (three industry submitters)
* concerns that the stock-in-trade provision only applies to honey packaged for retail sale and not to bulk honey (two industry submitters)
* some additional costs could be incurred from the proposed lower levels due to increased blending and testing (MPI and the National Beekeepers Association). The National Beekeepers Association also 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.

These and further issues raised in submissions are provided in Table 1 below.

One industry submitter provided specific comments about the New Zealand Tutin Standard in relation to the compliance option of demonstrating that tutu is not present in the hives location (see section 1.3.2). As indicated above, MPI is responsible for developing and administering the New Zealand Tutin Standard which is currently under review. The review will consider the specific compliance options that are warranted to ensure the safety of honey. This review is separate to FSANZ’s Proposal P1029.

A late comment was received from the Bee Products Standards Council after the closing date for receipt of submissions. Whilst FSANZ is not required to have regard to late comments, we note that the Council supported the proposed draft variation.

Table 1: Summary of issues

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
| --- | --- | --- |
| The proposed MLs are not based on sound, peer reviewed research. | National Beekeepers Association of New Zealand (NBA)  Bay of Plenty Branch of NBA  Hikutaia Honey Ltd | The human pharmacokinetic study was of a design appropriate to address the question regarding the delayed onset of signs and symptoms of toxicity following honey ingestion. The study was not intended to be a safety study and no adverse effects were anticipated based on the low tutin dose chosen. The study was conducted in accordance with Good Clinical Practice and was reviewed and approved by an appropriate human research ethics committee. The number of subjects in the study was consistent with internationally accepted guidelines for the conduct of human pharmacokinetic studies (e.g. guidelines issued by the European Medicines Agency) and endorsed by the Therapeutic Goods Administration, Australia. The study has recently been published in a peer-reviewed scientific journal (Fields et al. 2014). |
| Does not support the approach of no transitional arrangements. There should be a transitional period to allow for stock of bulk honey. | NBA  Bay of Plenty Branch of NBA  Hikutaia Honey Ltd | As the basis for amending the ML is to protect public health and safety, FSANZ has maintained the approach of no transitional arrangements for bulk honey so that the draft variation will take effect immediately on gazettal in the Code. As noted in section 2.6 of this Report, industry have been given prior notice of the proposed reduced level for extracted honey to help minimise the likely impact. There is likely to be minimal impact for comb honey products as the drafting has been amended to ensure the Code does not conflict with the New Zealand Tutin Standard (see section 2.2.2 for further discussion). In practice, this means there is no change for industry implementation for comb honey under the New Zealand Tutin Standard. |
| The stock-in-trade provision for packaged honey and not bulk honey constitutes a double standard. | Bay of Plenty Branch of NBA  Hikutaia Honey Ltd | As discussed in section 3 of this Report, 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 level of 0.7 mg/kg, 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 little additional cost. Determining which retail products are made from bulk honey stocks which existed prior to gazettal from those made with bulk honey existing after gazettal would make enforcement difficult. The Decision RIS (Attachment E) has identified and weighed the potential costs, including blending and testing costs, and benefits of the draft variation. |
| The ML for comb honey should be linked to a sampling plan to ensure it doesn’t conflict with compliance options in the NZ tutin Standard. | NZ MPI | FSANZ considers that a sampling plan would be more appropriate in the New Zealand Tutin Standard instead of the Code. However, we have amended the drafting to set an ML of 0.7 mg/kg for all honey (including comb honey) in the Code. This amendment ensures that the Code does not conflict with the New Zealand Standard in relation to comb honey, and that comb honey at retail sale is safe due to the compliance options mandated in the New Zealand Tutin Standard. In effect, this does not impose any change on industry practices from the present-day situation for comb honey as the compliance options for comb honey in the New Zealand Standard continue to apply. The risk management section of this Report (section 2.2.2) has been amended to further address this matter.  FSANZ has further consulted with MPI on this issue. MPI support the drafting amendment and the decision not to include a sampling plan in the Code. They will take the amended drafting into account in their independent review of the New Zealand Tutin Standard. |
| The significant reduction in the ML for comb honey is unreasonable given the most likely proportion to have tutin is the outer comb which is the area that is cut out and tested (in accordance with testing option in the NZ tutin standard). | NBA | As indicated above, FSANZ has amended the drafting to set an ML of 0.7 mg/kg to all honey (including comb honey) in the Code. In effect, this does not change current industry practices for comb honey as the compliance options for comb honey in the New Zealand Tutin Standard will continue to apply. This includes the requirement (under the testing options) for the drip and leftover comb to contain no-detectable tutin (i.e. below 0.01 mg/kg).  As indicated in section 2.1 of this Report, there are insufficient data available on the degree of variability of tutin across honey combs. The limited data that are available (unpublished data) indicate that there are no obvious trends in tutin concentrations across the honeycomb in any direction. We therefore have no data to support the suggestion that the outer comb is more sensitive to tutin contamination. As we are uncertain of the degree of variability across a comb, the presence of any tutin in a representative sample (i.e. drip and leftover comb) of comb honey is of concern as there may be other areas of the comb in different parts of the apiary with higher levels. To minimise the risk of a specific portion of comb containing an unsafe level of tutin, the New Zealand Tutin Standard requires non-detection of tutin in the drip and leftover comb under the testing compliance options (see section 2.2.2). |
| Additional costs could be incurred due to increased blending and testing. | NZ MPI  NBA - specifically noted that there could be significant cost and lost value for Active Manuka Honey. | Submissions provided qualitative information, but little in the way of estimates of additional costs from the impact of the variation to Standard 1.4.1. The Decision RIS (Attachment E) has identified and weighed the potential costs and benefits of the variation, including the potential blending and testing costs and potential loss of value for Active Manuka Honey. Where possible, the potential costs and benefits of the variation have been estimated. The Decision RIS concludes that the recommended option is to amend the MLs to take full account of the risk analysis using the best available scientific evidence and to protect public health and safety. |
| The potential effect of the lower limit could be cessation of comb honey in risk areas in favour of extracted honey. This will mainly impact small beekeepers with no extraction plants. | NZ MPI | As indicated above, FSANZ has amended the drafting to set an ML of 0.7 mg/kg to all honey (including comb honey) in the Code. In effect, this does not change current industry practices for comb honey as the compliance options for comb honey in the New Zealand Tutin Standard continue to apply. The risk management section of this report (section 2.2.2) provides further discussion on this matter. |
| As highest risk of poisoning is from small beekeepers, suggest subsidising tutin testing costs and conduct education and publicity campaigns targeting small beekeepers and hobbyists. | NBA | Subsidising testing costs is outside of FSANZ’s remit. FSANZ notes, however, that testing costs have reduced over recent years. We are also aware that there are means used by small beekeepers to reduce testing costs, such as, drawing samples together from a number of beekeepers to enable cheaper, composite testing.  FSANZ recognises that there is an inherent residual risk of tutin poisoning due to a potential lack of knowledge by some small beekeepers and hobbyists. To mitigate this risk, MPI and industry organisations have made a considerable effort over the past few years to educate the industry about tutin in honey. The industry education section of this Report (section 2.2.4) has been amended to identify further measures that have been undertaken to communicate with industry. |
| A code of practice could greatly assist with compliance with the regulation. | New Zealand Food and Grocery Council | FSANZ notes that information for the honey industry about tutin in honey, including regulatory requirements, is provided on MPI’s website (MPI, 2014). A compliance guide to the New Zealand Tutin Standard is also available via MPI’s website (NZFSA, 2010).  FSANZ considers that this guidance along with education material for industry, as discussed in section 2.2.4 of this Report, is adequate to support the regulation. As identified in the RIS (section 4.4 of Attachment E), a code of practice could be costly and time consuming to develop and implement, and we consider that it would add little further value to the existing measures. However, this does not preclude industry from developing its own code of practice. |

## 2.5 Decision

After having regard to the assessment findings, the cost-benefit analysis and issues raised in consultation, the draft variation as proposed following assessment was approved with amendments. The approved draft variation amends the MLs in Standard 1.4.1 for tutin in honey (including comb honey) to 0.7 mg/kg.

The variation takes effect on the date of gazettal. However, a stock-in-trade provision has been provided so that any honey packaged for retail sale before the commencement of this variation will not have to comply with the new ML as long as the honey complies with the MLs for tutin set out in the Code before the variation commenced.

The approved draft variation, as varied after consideration of submissions, is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

The draft variation on which submissions were sought is at Attachment C.

## 2.6 Risk communication

Consultation is a key part of FSANZ’s standards development process. The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent.

Public submissions were sought to obtain the views on a proposed draft variation to the Code and on questions raised in the Consultation RIS. The call for submissions period was from 10 July 2014 to 21 August 2014. Submissions were invited via the FSANZ Notification Circular, media release and through FSANZ’s social media tools and Food Standards News. Subscribers and interested parties were also notified via email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal.

A total of eight submissions were received. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. A summary of the submissions and the response to these are provided in Table 1 above.

### 2.6.1 Targeted consultation

As the issue of tutin in honey appears to be unique to New Zealand, FSANZ worked closely with MPI throughout the assessment of this Proposal.

Regular updates were provided to the New Zealand Bee Products Standards Council on the progress of this Proposal and the likely amendments to the MLs. The Council indicated their support for amending the tutin levels based on recent research.

FSANZ further sought to provide information to industry on the Proposal and the opportunity to provide submissions via articles in the April and October 2014 edition of the New Zealand Beekeepers industry journal and a presentation at the New Zealand Apiculture Industry Conference in June 2014.

## 2.7 FSANZ Act assessment requirements

### 2.7.1 Section 59

#### 2.7.1.1 Cost benefit analysis

A RIS (OBPR RIS ID: 13847) has been prepared for this Proposal (Attachment E) and discussed above in Section 2.3.

The direct and indirect benefits that would arise from the food regulatory measure developed or varied as a result of the Proposal outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

#### 2.7.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

#### 2.7.1.3 Any relevant New Zealand standards

This is addressed in sections 1.3.2 and 2.2.2 on the New Zealand Food (Tutin in Honey) Standard 2010.

#### 2.7.1.4 Any other relevant matters

None identified.

### 2.7.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### 2.7.2.1 Protection of public health and safety

The draft variation to Standard 1.4.1 in the Code protects consumers from the risks arising from contamination of honey by tutin.

#### 2.7.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

No relevant issues concerning the provision of adequate information relating to food to enable consumers to make informed choices were identified for this Proposal.

#### 2.7.2.3 The prevention of misleading or deceptive conduct

No relevant issues relating to the prevention of misleading or deceptive conduct were identified for this Proposal.

**2.7.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

* **the need for standards to be based on risk analysis using the best available scientific evidence**

The temporary MLs for tutin in honey and comb honey were established using the best available scientific evidence at the time. Since their introduction, additional scientific research has been completed to more accurately characterise the public health and safety risk arising from tutin contamination of honey (see SD1).

* **the promotion of consistency between domestic and international food standards**

The draft variation to Standard 1.4.1 was amended following assessment to avoid any conflict between the Code and the compliance options in the New Zealand Tutin Standard (see section 2.2.2).

There are no international food standards for tutin. The issue of tutin contamination of honey appears to be unique to New Zealand.

As such, FSANZ does not foresee any issues relating to the promotion of consistency between domestic and international food standards.

* **the desirability of an efficient and internationally competitive food industry**

It is expected that the draft variation to Standard 1.4.1 based on recent scientific evidence would reassure international markets that all honey products produced in New Zealand are safe to consume. This regulatory measure supports an efficient and internationally competitive food industry.

* **the promotion of fair trading in food**

The draft variation to Standard 1.4.1 will apply to all honey sold or prepared for sale in New Zealand and Australia. As such, FSANZ does not foresee any issues relating to the promotion of fair trading in food.

* **any written policy guidelines formulated by the Ministerial Council[[7]](#footnote-7)**

There are no relevant policy guidelines for this Proposal.

# 3 Transitional arrangements

There are to be no transitional arrangements.

However, to minimise the impact of the variations on the honey industry, a stock-in-trade provision is provided so that any honey packed for retail sale before the date of gazettal will not need to comply at any time with the new requirement as long as such honey complies with the MLs in the Code before this draft variation commences.

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 ML is gazetted, the amount of honey remaining for an extended period 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 amended ML is considered to outweigh the potential public health costs of leaving this honey on shelves. Although the stock-in-trade provision also applies to comb honey packaged for retail sale, this is expected to have minimal impact on comb honey products as in practice there is no change to implementation for comb honey under the New Zealand Tutin Standard.

FSANZ considered the concerns raised in some industry submissions on these transitional and stock-in-trade arrangements. A response to these submission issues is provided in Table 1 above.

FSANZ has decided to maintain the approach, as outlined above, for the transitional and stock-in-trade arrangements.

## 3.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website[[8]](#footnote-8). FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code’s structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code. The amendment to the new Code resulting from Proposal P1029 is provided at Attachment D.

# 4 References

Bee Products Standards Council, BPSC (2014). Video - Preventing Toxic Honey <http://www.bpsc.org.nz/>. Accessed 19 September 2014.

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

Ministry for Primary Industries, MPI (2014). Managing tutin contamination in honey <http://www.foodsafety.govt.nz/industry/sectors/honey-bee/tutin/index.htm>. Accessed 29 May 2014.

Ministry of Agriculture and Forestry (New Zealand Food Safety), MAF (2010). Food (Tutin in Honey) Standard 2010. <http://www.foodsafety.govt.nz/elibrary/industry/tutin-honey-standard-2010.pdf>. Accessed 29 May 2014.

National Beekeepers Association of New Zealand, NBA (2014). Publications – Starting with Bees <http://nba.org.nz/publications>. Accessed 23 September 2014.

New Zealand Food Safety Authority, NZFSA (2008). Food (Tutin in Honey) Standard 2008. <http://www.foodsafety.govt.nz/elibrary/industry/Food_Tutin-Sets_Maximum.pdf>. Accessed 29 May 2014.

New Zealand Food Safety Authority, NZFSA (2010). Compliance Guide to the Food (Tutin in Honey) Standard 2010 <http://www.foodsafety.govt.nz/elibrary/industry/tutin-compliance-guide-2010.pdf>. Accessed 23 September 2014.

**Attachments**

A. Approved draft variations to the *Australia New Zealand Food Standards Code*

B. Explanatory Statement

C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)

D. Draft variations to the Australia New Zealand Food Standards Code in March 2015 following P1025

E. Decision Regulation Impact Statement

## Attachment A – Approved draft variations to the *Australia New Zealand Food Standards Code*



**Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

**[1] Standard 1.4.1** is varied by

[1.1] inserting in subclause 5(1) in alphabetical order

“**honey** includes comb honey.”

[1.2] omitting subclause 5(5), and substituting

“(5) Subclause 1(2) of Standard 1.1.1 does not apply to honey for the purposes of the Table to clause 5.

(6) Notwithstanding subclauses 5(2) and (3), honey that was packaged for retail sale before the commencement of the Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation is taken to comply with this clause if the product otherwise complied with the Code before that variation commenced.”

[1.3] omitting from the Table to clause 5

“

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

”

and substituting

“

|  |  |  |
| --- | --- | --- |
| Tutin | Honey | 0.7 |
|  |  |  |

”

[1.4] inserting after the Table to clause 5

“

Editorial note:

The New Zealand *Food (Tutin in Honey) Standard 2010* also regulates beekeepers, packers and exporters of honey in New Zealand. It provides options for demonstrating compliance with the maximum level for tutin in honey set by clause 5 of Standard 1.4.1.

”

[**2] Standard 1.4.4** is varied by omitting the Editorial Note after clause 1, and substituting

“

Editorial note:

Subclause (1) is not intended to prohibit the natural presence of plants and fungi in food; or the unintentional addition of plants and fungi to food that occur within the bounds of recognised acceptable Good Agricultural Practice or Good Manufacturing Practice. If a public health and safety concern is identified because of the presence of such substances, they will be addressed through the setting of a limit on these substances in final food products. Standard 1.4.1 establishes maximum limits for some natural toxicants in food.

”

## Attachment B – Explanatory Statement

**1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1029 to review the maximum levels for tutin in honey and comb honey. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[[9]](#footnote-9), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92, is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

**2. Purpose**

The Authority has approved a draft variation to Standard 1.4.1 – Contaminants and Natural Toxicants to amend the maximum levels for tutin in honey and comb honey based on recent scientific evidence and set these as permanent levels. The amended maximum levels will protect consumers from the risks arising from tutin contamination of honey and comb honey.

The stock-in-trade provision provided for honey and comb honey packaged for retail sale prior to commencement of the draft variation is to assist in minimising the impacts of the draft variation on the honey industry.

A minor amendment to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi aims to clarify the application of that Standard to substances, such as tutin, that are present in food and derive from a prohibited plant.

**3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

**4. Consultation**

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority’s consideration of Proposal P1029 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 10 July 2014 for a six-week consultation period.

A Regulation Impact Statement was required because the proposed variations to Standard 1.4.1 are likely to have an impact on business and individuals.

**5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

**6. Variation**

***6.1 Standard 1.4.1***

Subitem [1.1] inserts a definition of ‘honey’ in subclause 5(1). The definition defines honey to include comb honey. This definition applies for the purposes of clause 5.

Subitem [1.2] omits the current subclause 5(5) to remove the expiry date which applies to the current maximum levels prescribed for tutin in honey and comb honey in the Table to clause 5. This means that the new maximum level for tutin in honey will be a permanent measure in the Code.

The current subclause 5(5) is replaced with new subclauses 5(5) and 5(6).

New subclause 5(5) expressly provides that the stock-in-trade provision in subclause 1(2) of Standard 1.1.1 does not apply to honey for the purposes of the Table to clause 5.

New subclause 5(6) provides that honey packaged for retail sale before the commencement of this draft variation is taken to comply with the new maximum level for tutin in honey in clause 5 if the honey had complied with the maximum levels for tutin set out in the Code before the draft variation commenced.

Subitem [1.3] replaces the previous maximum levels for tutin in honey (2 mg/kg) and comb honey (0.1 mg/kg) in the Table to clause 5 with a new maximum level of 0.7 mg/kg for both honey and comb honey.

Subitem [1.4] inserts a new editorial note after the Table to clause 5 to explain that the New Zealand *Food (Tutin in Honey) Standard 2010* also regulates beekeepers, packers and exporters of honey in New Zealand and that it provides options for demonstrating compliance with the maximum level for tutin in honey set by clause 5 of Standard 1.4.1.

***6.2 Standard 1.4.4***

Item [2] omits the current Editorial Note to clause 1 of Standard 1.4.4 and substitutes a new Editorial Note. Standard 1.4.4 prohibits a prohibited plant, or any substance derived from such a plant, from being intentionally added to food or offered for sale as food. The new Editorial Note clarifies that this prohibition does not extend to the presence in food of a substance derived from a prohibited plant that occurs as a natural toxicant (e.g. tutu). The latter is instead regulated or permitted by Standard 1.4.1.

## Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)



**Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

**[1] Standard 1.4.1** is varied by

[1.1] omitting subclause 5(5), and substituting

“(5) Subclause 1(2) of Standard 1.1.1 does not apply to honey and comb honey for the purposes of the Table to clause 5.

(6) Notwithstanding subclauses 5(2) and (3), honey or comb honey that was packaged for retail sale before the commencement of the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation* is taken to comply with this clause if the product otherwise complied with the Code before that variation commenced.”

[1.2] omitting from the Table to clause 5

“

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

”

and substituting

“

|  |  |  |
| --- | --- | --- |
| Tutin | Honey | 0.7 |
|  | Comb honey | 0.01 |
|  |  |  |

”

**[2] Standard 1.4.4** is varied by inserting after clause 1

“1A Exemption for Tutin in honey and comb honey

Clause 1 does not apply to Tutin that is present in honey or in comb honey by natural occurrence.”

## Attachment D – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

**Background**

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variations proposed by P1029. This is the rationale for the draft variation below. It is provided for background only. Its content and structure may change as P1025 progresses.

**Draft instrument**

Food Standards Code—Variation

Made under the Food Standards Australia New Zealand Act 1991

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 2)*.

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Standard 1.4.1

Schedule 1 varies the Australia New Zealand Food Standards Code – Standard 1.4.1 – Contaminants and natural toxicants

4 Variation of Standard 5.1.1

Schedule 2 varies the Australia New Zealand Food Standards Code – Standard 5.1.1 – Revocation and transitional provisions—2014 Revision

5 Variation of Schedule 19

Schedule 3 varies the Australia New Zealand Food Standards Code – Schedule 19 – Maximum levels of contaminants and natural toxicants.

Schedule 1 Variation of Standard 1.4.1

(section 3)

[1] Insert after section 1.4.1—3 Maximum levels of contaminants and natural toxicants in food

1.4.1—4 Exception relating to honey and comb honey

(1) Section 1.1.1—9 does not apply to honey and comb honey for the purposes of section 1.4.1—3.

(2) Notwithstanding section 1.4.1—3, honey and comb honey that was packaged for retail sale before the commencement of the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation* is taken to comply with the level of Tutin listed in section S19—6 if the product otherwise complied with the Code before that variation commenced.

Schedule 2 Variation of Standard 5.1.1

(section 4)

[1] Omit section 5.1.1—6.

Schedule 3 Variation of Schedule 19

(section 5)

[1] Insert into section S19—2 Definitions, in alphabetical order

***honey*** includes comb honey.

[2] Omit from the table to section S19—6 Maximum levels of natural toxicants

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

[3] Insert into the table to section S19—6 Maximum levels of natural toxicants, in alphabetical order

|  |  |  |
| --- | --- | --- |
| Tutin | Honey | 0.7 |

[4] Insert after the table to section S19—6 Maximum levels of natural toxicants

Editorial note:

The New Zealand *Food (Tutin in Honey) Standard 2010* also regulates beekeepers, packers and exporters of honey in New Zealand. It provides options for demonstrating compliance with the maximum level for tutin in honey set by clause 5 of Standard 1.4.1.

1. convening as the Australia and New Zealand Food Regulation Ministerial Council [↑](#footnote-ref-1)
2. When referring to ‘honey’ and not ‘comb honey’, the terms ‘extracted’ or ‘blended’ are commonly used to assist in further distinguishing ‘honey’ from ‘comb honey’. [↑](#footnote-ref-2)
3. **Low risk harvest date** applies to honey that has been taken from honey supers placed onto hives after 1 July and before 31 December of any year. [↑](#footnote-ref-3)
4. **Low risk area** is the South Island below latitude 42 degrees south including all offshore islands below latitude 42 degrees south. [↑](#footnote-ref-4)
5. Current testing sensitivity provides a limit of detection of 0.01 mg/kg. [↑](#footnote-ref-5)
6. Members of the Bee Products Standards Council comprises representatives from the National Beekeepers Association of New Zealand, Federated Farmers Bee Industry Group, New Zealand Honey Packers and Exporters Association and MPI. [↑](#footnote-ref-6)
7. Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council) [↑](#footnote-ref-7)
8. <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx> [↑](#footnote-ref-8)
9. convening as the Australia and New Zealand Food Regulation Ministerial Council [↑](#footnote-ref-9)