17 December 2012
[29-12]

Approval Report – Proposal P1023

Tutin, Tocopherol & Food for Special Medical Purposes Standards Amendments

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Food Standards Australia New Zealand (FSANZ) has assessed a proposal to: (1) extend the expiry date to 31 March 2015 for the interim maximum levels for tutin in honey and comb honey; (2) correct an error regarding commencement dates for the new tocopherol nomenclature introduced via Proposal P1021; and (3) amend Standard 2.9.5 to bring forward the commencement date and provide transitional arrangements for food for special medical purposes and also to clarify the intent of the exemption of Standard 1.5.1 from Standard 2.9.5.

On 2 October 2012, FSANZ sought submissions on a set of draft variations and published an associated report. FSANZ received ten submissions.

FSANZ approved the draft variations on 6 December 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 13 December 2012.

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

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

Supporting documents

The following documents used to prepare this Report are available on the FSANZ website:

SD1: Approval Report. P1009 – Maximum Limits for Tutin in Honey.
http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1009maximum4809.cfm
SD2: Approval Report. P1021 – Code Maintenance X.
http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1021codemai5492.cfm
SD3: Final Assessment Report. P242 – Food for Special Medical Purposes.
http://www.foodstandards.gov.au/foodstandards/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm

1. Executive summary

1.1 Tutin

Standard 1.4.1 – Contaminants and Natural Toxicants in the *Australia New Zealand Food Standards Code* (the Code) currently contains interim maximum levels for tutin in honey and comb honey. This interim measure will expire on 31 March 2013.

The consumption of honey or comb honey containing tutin at high levels is considered unsafe for humans. FSANZ has extended the interim measures for tutin until 31 March 2015. This is to ensure that a regulatory measure remains in place while FSANZ completes its risk assessment, risk management and regulatory impact analysis for tutin. FSANZ will use the additional time to strengthen the scientific evidence base that would support the introduction into the Code of a permanent regulatory measure for tutin.

1.2 Tocopherol

Transpositional errors occurred during drafting in Proposal P1021 that affected: the prescribed number which must be put on the label to show the presence of the food additive "tocopherols concentrate, mixed" in Standard 1.2.4 – Labelling of Ingredients; the commencement date for some changes; and related editorial notes. This Proposal has corrected those errors.

1.3 Food for Special Medical Purposes (FSMP)

Standard 2.9.5 – Food for Special Medical Purposes regulates foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions, in cases when appropriate nutrition cannot be easily or completely achieved without these products. Almost all FSMP are imported into Australia and New Zealand from Europe and the United States. Standard 2.9.5 was gazetted in June 2012 and commences on 28 June 2014. This two-year period was intended to allow time for manufacturers, distributors and others to make any adjustments to comply with the Standard on the commencement date.

Since the Standard's gazettal, FSANZ has received queries regarding the commencement date, transitional arrangements and compliance. Some FSMPs, including new products, could immediately comply with Standard 2.9.5 but manufacturers of these products are disadvantaged by not having regulatory certainty until 28 June 2014.

At the call for submissions, FSANZ proposed to bring forward the commencement date for Standard 2.9.5 to the date of gazettal of this Proposal. This would allow FSMP that already meet the requirements of the Standard to be lawfully sold in Australia and New Zealand from the earlier date. Also, specific transitional arrangements were proposed to allow time for other FSMP to lawfully transition by 28 June 2014. These amendments have been revised to provide a simpler approach and improve the regulatory certainty for manufacturers and enforcement agencies during the transition period. Consumers might also benefit from certainty of supply.

Standard 2.9.5 includes an exemption from certain standards in the Code, including for Standard 1.5.1 – Novel Foods. After commencement, novel ingredients added to FSMP will not be required to meet the requirements of Standard 1.5.1. However, it was not intended that a novel food or ingredient added to a FSMP could be added to general purpose foods without meeting the requirements of Standard 1.5.1. This Proposal clarifies that a novel food used in an FSMP must meet the requirements of Standard 1.5.1 prior to use in general purpose foods.

2. Introduction

2.1 The Proposal

The Proposal relates to several amendments to the *Australia New Zealand Food Standards Code* (the Code) with respect to tutin, tocopherol and food for special medical purposes.

2.1.1 Tutin

FSANZ has sought to extend the expiry date of the interim maximum levels for tutin in Standard 1.4.1 for a further two years. This extension would permit FSANZ additional time to complete its risk assessment, risk management and impact analysis before setting maximum levels for tutin, without the loss of an important risk management measure.

2.1.2 Tocopherol

FSANZ has sought to correct an error regarding the commencement date for some provisions for tocopherols nomenclature in Standard 1.2.4 introduced via Proposal P1021. Because of the error, the permission to use the INS number for "tocopherols concentrate, mixed" of 306 was removed from the schedule listing food additives in numerical order on gazettal, although not from the schedule listing in alphabetical order. This created regulatory uncertainty. FSANZ also sought to correct other minor typographical errors in the drafting for P1021.

2.1.3 Food for Special Medical Purposes

FSANZ has sought to:

1. Bring forward the commencement date for Standard 2.9.5 – Food for Special Medical Purposes to the date of gazettal of this Proposal with appropriate transitional arrangements that conclude on 28 June 2014.

2. Amend Standard 1.5.1 – Novel Foods to clarify the intent of the exemption for novel foods in Standard 2.9.5.

3. Amend certain original consequential amendments related to Standard 2.9.5 to be consistent with the above variations to the Code.

2.2 The Current Standards

2.2.1 Tutin

The current Standard provides for a maximum level of tutin in honey of 2 mg/kg and comb honey (honey comb) of 0.1 mg/kg. These temporary MLs will expire on 31 March 2013. The maximum levels for tutin in honey and comb honey were first introduced into Standard 1.4.1 in 2009, as an emergency provision following a poisoning episode that affected a number of people after consuming tutin-contaminated honey from the Coromandel region of New Zealand. The MLs were based on a preliminary risk assessment carried out by the then New Zealand Food Safety Authority (now Ministry for Primary Industries).

2.2.2 Tocopherol

Standard 1.2.4 listed the INS number for "tocopherols concentrate, mixed" as 306.

However, JECFA had changed this number to 307b. Proposal P1021 sought to update Standard 1.2.4 with the new INS number for tocopherols concentrate mixed. It was approved by the FSANZ Board in July 2012.

Amendments arising from the Proposal were gazetted in October 2012.

However, the Instrument for P1021 contained a transpositional error. An editorial note was inserted after Item 3.2 resulting in the numbering of all items under Item [3] in the instrument shifting by one. The provision regarding commencement dates was not updated to match the new numbering. As a result, Item 3.4 of the drafting which sought to omit the entry "tocopherols concentrate, mixed 306" from Schedule 2 Part 2 "Food Additive Code Numbers (numerical order)" was set to commence on the date of gazettal, instead of two years later as agreed following consultation. Also, the editorial note in Item 3.3 was set to take effect two years after gazettal, instead of on gazettal.

The correct commencement date has now been applied to Item 3.1 of the drafting which omits "tocopherols concentrate, mixed 306" from Schedule 2 Part 1 "Food Additive Code Numbers (alphabetical order)". If Standard 1.2.4 was not amended, for a period of two years following gazettal of P1021 Schedule 2 of Standard 1.2.4 would have had an inconsistency. Part 1 would have permitted use of the INS number 306 for "tocopherols concentrate, mixed" while Part 2 would not.

Proposal P1023 also corrected typographical errors in the P1021 drafting which inserted an editorial note at the end of "Part 1 of the Schedule 1" instead of "Part 2 of Schedule 2", and referred to "tocopherols, concentrate mixed" instead of "tocopherols concentrate, mixed".

2.2.3 Food for Special Medical Purposes

Standard 2.9.5 regulates foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions, in cases when appropriate nutrition cannot be easily or completely achieved without these products. FSMP may be used as the sole source of nutrition, and also as a specialised supplement. Almost all FSMPs in Australia and New Zealand are imported from Europe or the United States.

FSMP products for sale in Australia do not have provisions specific to FSMP in the Code until Standard 2.9.5 commences. In New Zealand only, special purpose foods, as defined in Standard 1.1A.6 – Transitional Standard for Special Purposes Foods (including Amino Acid Modified Foods) must comply with Standard 1.1A.6 if they are produced in or imported into New Zealand.

Standard 2.9.5 was gazetted in June 2012 and commences on 28 June 2014. However, no specific arrangements were considered for inclusion in the Standard to permit lawful transition to compliance by the commencement date of 28 June 2014.

Standard 1.1A.6 – Transitional Standard for Special Purposes Foods (including amino acid modified foods) will cease to have effect for FSMP on the date of commencement of Standard 2.9.5.

Standard 2.9.5 also exempts some standards in the Code including Standard 1.5.1. This exemption will come into effect on the commencement date.

The development of Standard 2.9.5 also required consequential amendments to be made to Standards 1.1.1, 1.2.1, 1.3.1 and 1.3.4. These are also to come into effect on the commencement date for Standard 2.9.5.

2.3 Reasons for preparing the Proposal

The Proposal was accepted for assessment on the basis of the following.

2.3.1 Tutin

This Proposal was prepared in part to ensure that a regulatory measure remains in force for tutin. The consumption of honey or comb honey contaminated with high levels of tutin can be unsafe for humans. FSANZ together with the New Zealand Ministry for Primary Industries (MPI) have undertaken a number of research studies to better qualify the risk to humans from consuming tutin-contaminated honey and comb honey. Further information supporting that risk assessment is required and is being generated, but will not be available prior to the expiration of the interim standard (31 March 2013). FSANZ has sought an extension to the expiry date so as to complete a comprehensive risk assessment to support an appropriate, permanent regulatory measure for tutin in food.

2.3.2 Tocopherol

The Proposal was also prepared to correct the commencement date for the revised tocopherols nomenclature and other minor typographical errors in P1021.

2.3.3 Food for Special Medical Purposes

Following gazettal of Standard 2.9.5, FSANZ received queries regarding the commencement date, transitional arrangements and implementation of the Standard. FSANZ was also made aware that some FSMP could immediately meet the requirements of Standard 2.9.5 and be imported for sale in Australia and New Zealand.

The current commencement date was determined to allow time for manufacturers, distributors and others to make changes to ensure compliance with the Standard by 28 June 2014. However, no specific transitional arrangements were included. Because of this, FSMP could not legally be fully compliant with the Standard until it had commenced. Manufacturers of compliant products could be disadvantaged by this delay because of the regulatory uncertainty. Bringing forward commencement of the Standard to the date of gazettal of this Proposal would allow FSMP that already meet the requirements of the Standard to be lawfully sold in Australia and New Zealand from the earlier date. Specific transitional arrangements would also allow FSMP that do not yet fully comply with the Standard to be lawfully sold until 28 June 2014, while adjustments were made to meet the new requirements. Under those arrangements, such FSMP are deemed to comply with the Standard during the transition period.

The Proposal was also prepared to clarify the intent of the exemption of Standard 1.5.1 from the FSMP Standard. Novel ingredients added to FSMP were not required to meet Standard 1.5.1. However, it was not intended that a novel food or ingredient added to a FSMP could be added to the general food supply without meeting the requirements of Standard 1.5.1. FSMP are highly specialised formulated products for a very specific and usually small population group and intended to be used under medical supervision. They also have a restriction on sale. This Proposal clarifies that a novel food used in a FSMP would need to meet the requirements of Standard 1.5.1, before use in general purpose foods.

In addition, this Proposal will correct a formatting error in Schedule 1 of Standard 2.9.5. Schedule 1 of Standard 2.9.5 lists the permitted forms for certain substances, should they be added to FSMP. Currently in the table, some permitted forms do not correctly align with the appropriate substance.

2.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

2.5 Decision

The draft variations as proposed following assessment were approved with amendments. The draft variations, as varied after submissions were received, are at Attachment A. The draft variations on which submissions were sought are at Attachment C.

3. Summary of the findings

3.1 Risk assessment

3.1.1 Tutin

The risk assessment conclusions from the previous Proposal (P1009) remain valid and no further assessment was required (refer to the Approval Report for P1009 on the FSANZ website).

Since FSANZ's last formal assessment of the risk to consumers from honey and comb honey containing tutin in 2010 (Supporting Document (SD) 1), there have been no new reports of toxicity from consumption of New Zealand-produced honey. Whilst this kind of information is limited, the lack of new reports suggests current interim MLs for tutin in the Code and the risk management program in place in New Zealand are benefiting consumers and industry. FSANZ develops standards based on risk analysis using the best available scientific evidence. Because of the need to acquire evidence, a permanent ML for tutin cannot be established at this stage. It was therefore appropriate to permit an extension to the expiry date of the interim tutin MLs, so various research studies to support the risk assessment can be completed.

3.1.2 Tocopherol

Errors were introduced in P1021 which resulted in inconsistencies, potentially creating a risk of regulatory uncertainty. FSANZ did not identify any risk arising from correcting the errors, as that reflected the intended approach under P1021 (SD 2).

3.1.3 Food for Special Medical Purposes

Previous assessments (see SD3 – Final Assessment Report for Proposal P242) had identified a potential risk of interrupted FSMP supply to consumers who rely on these products for their nutrition. As there was no specific Standard for these products, regulatory uncertainty had occasionally caused delays in the importation of FSMP. Standard 2.9.5 provides certainty to prevent these delays from occurring once the new Standard comes into effect. This Proposal extends that certainty and reduces the risk of a delay in the supply of FSMP before June 2014.

Also, as noted in Section 2.3.3, novel food or ingredients can be added to FSMP without having to meet the requirements of Standard 1.5.1. There was a risk that this could be interpreted to mean that, if a novel food is added to FSMP, then it has a history of human consumption and so could be used in general foods without meeting the requirements of Standard 1.5.1. This was not the intent and clarification in the Code was needed to mitigate this risk.

Further risk assessment has not been undertaken for Proposal P1023 as the proposed strategy reflects the intent of Standard 2.9.5 as gazetted in June 2012, i.e. that FSMP

products have a set period of time before they are required to comply with the Standard.

3.2 Risk management

3.2.1 Tutin

As previously noted in P1009, a food regulatory measure was warranted due to the adventitious presence of tutin in some honey products produced in New Zealand and the severity of intoxication from the consumption of honey or comb honey containing high levels of tutin. The extension of the existing MLs for tutin in Standard 1.4.1 was considered to be an appropriate risk management measure while additional information is gathered about the toxicity of tutin. Coupled with the comprehensive compliance program administered by MPI[2], these limits were considered practical and achievable by industry and the responsible food enforcement authority, the MPI. No additional costs to consumers or industry were envisaged from maintaining the MLs at their current values for the two year extension of the expiry date.

3.2.2 Tocopherol

FSANZ did not identify any risks associated with either correcting the commencement date for the changes in tocopherol nomenclature in Standard 1.2.4, or with correcting typographical errors introduced in P1021. Therefore, no risk management measures were required in this respect other than correcting the errors arising from P1021.

3.2.3 Food for Special Medical Purposes

Most FSMPs imported for sale in Australia and New Zealand are expected to already comply with many aspects of Standard 2.9.5, as the Standard had been developed to reflect overseas regulations and current practice as much as possible. The current amendments to Standard 2.9.5 and other standards, which bring forward the commencement date and include specific transitional arrangements, aim to provide certainty for stakeholders, particularly manufacturers and enforcement agencies, and also to manage the risk of inappropriate products taking advantage of those transitional arrangements. This earlier commencement date also manages the risk of potential importation delays before mid-2014.

3.2.3.1 Commencement date

Following the assessment, it was proposed that the commencement date for Standard 2.9.5 be brought forward to the date of gazettal of the variations made through this Proposal. Submitters generally supported this earlier commencement as it provides regulatory certainty and allows FSMP that meet the requirements of Standard 2.9.5 at that date to be lawfully sold in Australia and New Zealand.

Therefore, Standard 2.9.5 will commence on gazettal of the variations made under this Proposal.

3.2.3.2 Transitional arrangements

Following the assessment, specific transitional arrangements were proposed to enable current FSMP products to be available for sale from the proposed earlier commencement date until 28 June 2014 (i.e. the current commencement date of Standard 2.9.5).

Prior to the call for submissions, several FSMP manufacturers were informally asked to identify provisions in Standard 2.9.5 that would require more time beyond an earlier commencement date for them to fully comply. From the information provided, the call for

[2] New Zealand Ministry for Primary Industries. Compliance Guide to the Food (Tutin in Honey) Standard 2010. http://www.foodsafety.govt.nz/industry/sectors/honey-bee/tutin/

submissions report proposed the following provisions in Standard 2.9.5 be temporarily excluded from operation of the Standard from gazettal of this Proposal until 28 June 2014 (assumed to be about 15 months):

- clause 5 – restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold
- clause 7(1)(b) – if a food for special medical purposes is represented as being suitable for use as a sole source of nutrition, the food must contain – if applicable, not more than the maximum amount, as prescribed in Column 3 of Schedule 2, of each vitamin and mineral contained in Column 1 of that Schedule
- clause 10(1)(d) – a statement describing the properties or characteristics which make the food appropriate for the medical purpose
- clause 10(1)(e) – if the food has been formulated for a specific age group – a statement to the effect that the food is intended for persons within the specified age group
- clause 10(1)(f) – a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- clause 10(2)(b) – the requirement to label if the food has been modified to vary from the compositional requirements in Schedule 2
- clause 14 – lactose claims in relation to FSMP
- clause 15 – claims in relation to gluten content of FSMP.

With the exception of clause 14 lactose claims, and clause 15 gluten claims, the clauses subject to temporary exemption are new requirements specific to the FSMP standard. It was expected that manufacturers would continue their current practice in relation to lactose and gluten labelling during the transition period. These specific transitional arrangements, based on - industry feedback, were proposed to allow for manufacturers of FSMP products to meet Standard 2.9.5 by June 2014 in a cost effective manner, as was intended when the Standard was originally gazetted.

Submitters to the call for submissions generally supported the proposed exemptions, in conjunction with the earlier commencement date, as summarised in section 3.2.4 below. However, major industry players indicated there were additional elements of Standard 2.9.5 that could not be met at the earlier commencement date, and for which they would require time to transition to full compliance. Further exemptions were requested.

FSANZ further considered how best to allow FSMP to be lawfully sold until 2014 to maintain the supply of these products. Expanding the list of exempted clauses would exempt a significant portion, but not all, of the new Standard. Adding these further exemptions was considered to make implementation of the Standard unnecessarily cumbersome and complex for both enforcement agencies and FSMP manufacturers. Also, the specific exemptions might not precisely conform to the varying needs of all FSMP manufacturers

Therefore, the previous draft variation was amended to remove the proposed exemptions.

Instead, specific transitional arrangements have been provided, that deem FSMP products that meet the definition in Standard 2.9.5, but do not comply with the Standard, to be compliant during the transition period. As a result, existing FSMP, that meets the definition, will be permitted to be lawfully sold in Australia and New Zealand from the earlier commencement date (i.e. on gazettal of this variation), to the end of the transition period (i.e. 28 June 2014).

In addition, FSMP that is produced or imported after the earlier commencement date, will also be permitted to be lawfully sold until 28 June 2014 under those transitional arrangements. If such FSMPs do not comply with the Standard, and meet the definition of a FSMP, they are also deemed to comply with Standard 2.9.5 during this period.

The definition of a FSMP, as defined in Standard 2.9.5, refers to products that are specially formulated; are intended for use under medical supervision; and are represented as being for a medical purpose or for the dietary management of a disease, disorder or medical condition. Any food that does not satisfy the FSMP definition is excluded from the transitional arrangements.

This approach will provide for a more straightforward arrangement by providing a clearly legislated transition scheme for a set period, for both existing and new FSMP unable to meet Standard 2.9.5. At the same time, fully compliant products that could not lawfully be sold if the commencement date remained at June 2014, can now be lawfully sold in accordance with the earlier commencement date.

FSANZ is unaware of any issues with the current FSMP supply, the majority of which will meet the relevant European Union or United States of America (USA) standards. Also, the comprehensive definitional requirements of an FSMP in Standard 2.9.5, provides protection against inappropriate products that might be positioned as FSMP during the transition period.

Therefore, this revised approach:

- reflects the original intent at gazettal of Standard 2.9.5, that a transition period be provided for products to comply with the new Standard
- allows for the maintenance of supply of FSMP products to those who rely on them
- provides a regulation which recognises that current practice is operating without evidence of adverse impacts on health and safety
- provides certainty by allowing FSMP that fully comply on the earlier commencement to be regulated by Standard 2.9.5
- provides the equivalent of a stock in trade arrangement for existing FSMP until 28 June 2014
- provides similar protection to FSMP produced or imported after the earlier commencement date
- protects against the potential risk of other products taking advantage of the FSMP Standard during the transition period.
- could potentially expand the range of products available to consumers.

The specific transitional arrangements are required for FSMP. The general stock in trade provision (subclause 1(2) of Standard 1.1.1) applies only to existing products that comply with the previous requirements of the Code. This is generally not the case for FSMP due to their specialised formulation and the lack of a standard tailored to these products. Reliance on it would be inadequate.

These revised transitional arrangements improve the level and timing of regulatory certainty and allow for FSMP stock that do not fully comply with Standard 2.9.5 at the earlier commencement date to be lawfully sold, while any necessary changes are made. This will result in a smooth transition and avoid disruption to the supply of FSMP.

At the same time, FSMP produced or imported after the earlier commencement are afforded such protection until the end of the transition period. This will enable the supply of these products to continue, particularly to those who rely on them as their sole source of nutrition.

These revised arrangements are considered the most straightforward mechanism to manage any risks for consumers and manufacturers.

3.2.3.3 Novel food exemption

In the call for submissions paper, FSANZ proposed that an amendment be made to Standard

1.5.1 to clarify the intent of the exemption of FSMP from the novel food standard i.e. that a novel food used in a FSMP would need to meet the requirements of Standard 1.5.1 before being used in general purpose foods.

Almost all submitters supported this clarification. However one submitter considered that provision should be made for the use of a novel food in a FSMP to be considered as a factor when considering whether a food has a history of use.

Clause 1 of Standard 1.5.1 defines a novel food as a non-traditional food that requires an assessment of health and safety having regard to a number of factors, including patterns and levels of consumption of the food and the potential for adverse effects in humans. A non-traditional food does not have a history of human consumption in Australia or New Zealand.

The intent of the variation to Standard 1.5.1 is to make clear that the use of a novel food in a FSMP will not constitute a history of human consumption in the context of the Standard. However, the use of a novel food in FSMP could be taken into consideration when undertaking an assessment of the health and safety of the food, in order to determine whether it should be considered as a novel food under Standard 1.5.1

Therefore, no amendments have been made to the variation as proposed at the call for submissions i.e.an amendment has been made to Standard 1.5.1 to clarify the intent of the exemption of FSMP from the novel food standard. This clarification manages the potential risk of a novel food that is added to a FSMP then being added to general purpose foods without the appropriate assessment.

3.2.3.4 Consequential amendments

The New Zealand only Standard 1.1A.6 will be amended to reflect the new commencement date of Standard 2.9.5, and will cease in relation to FSMPs that are sold in New Zealand on the earlier commencement date for Standard 2.9.5. Standard 1.1A.6 provisions will remain for other special purpose foods in New Zealand. The revised transitional arrangements above will apply to New Zealand products from gazettal of this Proposal until 28 June 2014. This period will cover any stock in trade in New Zealand.

This approach maintains consistency across Australia and New Zealand and provides simplicity and regulatory certainty for stakeholders in both countries.

The consequential amendments to Standards 1.1.1, 1.2.1, 1.3.1 and 1.3.4 set out in the Call for Submissions paper have not changed. However, their commencement date will be brought forward. The consequential amendments to these Standards, that were to come into effect when Standard 2.9.5 commenced on 28 June 2014, will now come into effect on the earlier commencement date.

3.2.3.5 Correction in formatting of Schedule 1 of Standard 2.9.5

Schedule 1 of Standard 2.9.5 lists the permitted forms for certain substances if they are added to FSMP.

The formatting error in this table has been corrected so that the permitted forms listed in column 2 correctly align with the appropriate substance in column 1 of the table. This ensures accuracy and clarifies the current situation for manufacturers of FSMP.

3.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Tutin		
Cease testing for tutin in honey. Consider reducing the areas of risk from tutin contamination to minimise the cost to beekeepers.	Mountain Beech Apiaries Ltd	These aspects are covered by the New Zealand standard, not the Code. However, FSANZ has taken account of the existence of complementary risk management measures when considering the risk of extending a temporary standard. The testing for the levels of tutin in honey is a valid and valuable risk management action to prevent the poisoning of consumers, given that tutin is a colourless, tasteless and odourless toxin. As an interim measure, the maximum levels of tutin in honey and comb honey are supported by other submitters, e.g. New Zealand Ministry for Primary Industries and Federated Farmers of New Zealand. An analysis of risk-prone areas is outside the scope of the current Proposal. This matter is best considered by the appropriate agency responsible for compliance with the Code, the New Zealand Ministry for Primary Industries.
Consider extending the interim maximum levels for tutin by 3-4 years.	VIC Department of Health	FSANZ is collaborating with the New Zealand Ministry for Primary Industries to complete the substantive risk assessment, risk management and impact analysis required to support a permanent regulatory measure for tutin. FSANZ is confident that it will be able to complete this work within the proposed two year extension, i.e. before March 2015.
Tocopherol		
1. In Attachment A, points [1.1] and [1.2] are identical and appear to be repeated from the original proposal. 2. Point [1.5] in Attachment A: Standard 1.2.4, Schedule 1 does not relate to tocopherols and there is no Editorial Note at the end of Schedule 1.	Food Technology Association of Australia	1. Item [1.1] reinserts into Standard 1.2.4 the old nomenclature for "tocopherols concentrate, mixed" from the date of gazettal of P1023, while item [1.2] removes the old nomenclature two years after gazettal of P1023. This is to allow transition to the new nomenclature introduced via P1021. 2. Item [1.5] in Schedule A removes the editorial note that is inserted erroneously at the end of Schedule 1 by P1021. The submitter comment is based on the current Code and not on the variations which will arise from the Approval of P1021.
The draft instrument both inserts the correct terminology and omits the correct terminology, see items [1.1] and [1.2].	Department of Health, Victoria	Item [1.1] reinserts into Standard 1.2.4 the old nomenclature for "tocopherols concentrate, mixed" from the date of gazettal of P1023, while item [1.2] removes the old nomenclature two years after gazettal of P1023. This is to allow transition to the new nomenclature introduced via P1021.
FSMP		
Notes original intention was to allow time for transition when 2.9.5 was gazetted.	Nestlé	The revised variation to Standard 2.9.5 reflects this intent.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Further exemptions requested – need time to comply	Nestle, Nutricia, Abbotts, AFGC, NZFGC	Exemptions now removed in the revised variation and transition period allows time to comply with Standard 2.9.5.
Need time to make any compositional changes.	Abbotts, Nestlé	The transition period allows time to comply with Standard 2.9.5.
Seeks confirmation that stock in trade provisions will apply to the exemptions i.e. from June 2014 until June 2015. Further clarification of stock-in-trade would be helpful.	AFGC, MPI, NZ	Exemptions have been removed in the revised variation and transition arrangements allow for stock in trade from the earlier commencement date until June 2014.
Provision for use of novel food in FSMP should be "a factor' in assessing history of safe use.	NZFGC	The amendment to Standard 1.5.1 prevents a novel substance used in FSMP from being automatically taken to be safe for general foods, without the required health and safety assessment. Drafting of the variation to Standard 1.5.1 does not preclude consideration of the use of a novel food in FSMP as part of this safety assessment. See section 3.2.3.3 of this report.
Supports a phased transition and novel food Standard amendment. Notes novel food standard is being reviewed – so FSANZ will need to consider this exemption for FSMP.	Department of Health, Victoria	FSANZ will consider as part of a new Proposal to regulate nutritive substances and novel foods.
Supports earlier commencement date but does not support immediate compliance with a selected number of provisions.	NZFGC	Amended variation reflects this.
Need to provide explanation around the need for three draft variations.	MPI	See Explanatory notes.
More clarity required on the mechanism that allows compliance sooner than 28 June 2014 for the exemptions.	MPI	Exemptions have been removed in the revised variation.
Two other issues raised were noted, but have not been included in this table as they are out of scope of this Proposal.		

3.4 Risk communication

A basic communication strategy was applied to this Proposal.

The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent. Public submissions were sought to obtain the views of interested parties on the issues raised by the Proposal and the impacts of regulatory options.

Submissions were invited via the FSANZ Notification Circular and email alert, a media release and through FSANZ's social media tools and Food Standards News.

Some targeted consultation was undertaken in developing this Proposal, specifically with some manufacturers and enforcement agencies in relation to FSMP. Further targeted consultation was undertaken to resolve issues that were identified through public consultation.

Individuals and organisations who made submissions on this Proposal were notified at each stage of assessment.

4. Reasons for decision

FSANZ had regard to the following matters under section 59 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal
- any relevant New Zealand standards
- any other relevant matters.

4.1 Analysis of options

Two options were available to FSANZ.

Option 1: Approve the variations to Standards 1.1A6, 1.2.4, 1.4.1 and 1.5.1 as prepared prior to the call for public submissions; and the variations to Standards 1.3.1 and 2.9.5 subject to the amendments considered necessary following the call for public submissions; and the consequential amendments to other Standards. That is:

- Correct the commencement date for the change in INS number for 'tocopherol concentrate, mixed' in Standard 1.2.4 Schedule 2 Part 2 and Standard 1.3.1, and other typographical errors.
- Extend the expiry date for the interim maximum levels for tutin in honey and comb honey until 31 March 2015 in Standard 1.4.1.
- Clarify the intent of the novel food exemptions for FSMP in Standard 1.5.1.
- Bring forward the commencement date and provide specific transitional arrangements in Standard 2.9.5.
- Make consequential amendments as a result of the above variations.
- Amend Schedule 1 of Standard 2.9.5 so that the permitted forms listed in column 2 correctly align with the relevant substance in column 1 of the table.

Option 2: reject the draft variations which would:

- Allow the interim tutin maximum levels in Standard 1.4.1 to lapse.
- Allow an inconsistency to exist in Standard 1.2.4 Schedule 2 for a period of two years, with Part 1 permitting use of the INS number 306 for 'tocopherols concentrate, mixed', and Part 2 not permitting it. It would also allow editorial notes to be inserted in the wrong place or at the wrong time.
- Retain the current exemption for FSMP from Standard 1.5.1, which would not clarify that the exemption does not extend to general purpose foods.
- Retain the current commencement date for Standard 2.9.5 at 28 June 2014, and provide no specific transitional arrangements.

Option 1 was considered preferable over Option 2 for the reasons given below.

4.1.1 Option 1 – Prepare draft variations as above

Consumers

- Consumers would benefit from purchasing honey that is required to meet the regulatory measure (ML) for the presence of tutin in honey. There are no perceived costs or impacts on consumers from adopting this option.

  With respect to tocopherol, Option 1 would benefit consumers by ensuring they have access to accurate information on the ingredients in their food.

- For consumers of FSMP and health professionals, bringing the commencement date forward in conjunction with specific transition arrangements for manufacturers would benefit those who rely on a supply of FSMP by enabling certainty of supply of FSMP. This option also supports the lawful introduction of new products which may benefit consumers. Option 1 would also avoid potential importation delays from an earlier date, so consumers who rely on these products would continue to receive the FSMP they require.

- The health and safety of consumers of general purpose foods would also be protected by ensuring a novel food added to FSMP is not added to the general food supply without first having been assessed under the requirements of Standard 1.5.1.

Industry

- The beekeeping and honey industries in New Zealand would benefit from having an ongoing, industry-wide standard that ensures the presence of tutin is controlled in honey and comb honey.

  Industry reputation is maintained as the likelihood of a further tutin poisoning episode is reduced as a result of compliance with a comprehensive risk management programme linked to the Code[3]. There were no perceived costs or impacts on industry from adopting this option as they are already required to comply with the temporary ML.

- Option 1 will benefit industry by clarifying the requirements of Standard 1.2.4 with regard to tocopherols nomenclature.

- Manufacturers of existing and new FSMP that can comply with Standard 2.9.5 could lawfully sell FSMP from the earlier commencement date, and would not need to wait until mid-2014 to do so. Other manufacturers that require time to comply with Standard

[3] New Zealand Ministry for Primary Industries. Compliance Guide to the Food (Tutin in Honey) Standard 2010. http://www.foodsafety.govt.nz/industry/sectors/honey-bee/tutin/

2.9.5 would have regulatory certainty and be able to lawfully sell their FSMP products throughout the transition period while they make any necessary adjustments. This provides a more even 'playing field' for all manufacturers of FSMP, and allows for the supply of FSMP to be maintained. This regulatory certainty may create new opportunities for product development and innovation, facilitate trade and potentially make a wider range of products available.

- The intent of the exemption for novel foods would be clear and provide regulatory certainty for manufacturers of general purpose foods.

- Correcting the formatting error in Schedule 1 of Standard 2.9.5 ensures accuracy and clarity for manufacturers regarding the permitted forms of some substances.

Government

- This option ensures current controls for the risk management of tutin in honey and comb honey are maintained for the ongoing safety of consumers and the economic viability of the beekeeping and honey industries. It supports the actions of government to minimise the risk posed from high levels of tutin in honey and comb honey to the health and safety of consumers, the viability of industry and the imposts that an additional poisoning episode may have on government medical and regulatory services. There were no perceived costs or impacts on government from adopting this option.

- This option removes regulatory uncertainty by clarifying the requirements of Standards 1.2.4 and 1.3.1 with regard to tocopherol nomenclature.

- For FSMP, the amendments provide regulatory certainty and enable enforcement agencies to assess compliance of FSMP with the definition of FMSP in Standard 2.9.5 and other parts of the Code during the transition period. The transitional arrangements also enable enforcement of potentially inappropriate products.

- Clarification of the intent of the exemptions for novel food requirements would also provide certainty for enforcement purposes.

4.1.2 Option 2 – reject the draft variations

- For tutin, Option 2 was considered unacceptable, primarily because the consumption of honey and comb honey containing tutin can be unsafe for humans. There is the potential that tutin-contaminated honey will cause harm to consumers.

  In addition, this option would potentially have negative effects on industry. This could include a loss in business and reputation for industry if honey was considered to be unsafe by domestic and international consumers.

  Government agencies may have to shoulder additional financial and resource demands in response to any future poisoning episode.

- For tocopherol, rejecting the draft variations will introduce regulatory uncertainty because Parts 1 and 2 of Schedule 2 in Standard 1.2.4 will become inconsistent with each other.
  As a result, it may not be clear to industry and enforcement agencies which requirements to comply with.

  Consumers relying on Schedule 2 Part 2 Food Additive Code Numbers (numerical order) will not be able to identify additive 306 in products labelled using the old INS

number. This may cause unnecessary consumer concern and confusion.

- For FSMP, Option 2 is considered less attractive because of the continuation of regulatory uncertainty relating to enforcement before the commencement of the Standard.

  Some new products that are able to comply with Standard 2.9.5 now could not be lawfully sold in Australia and New Zealand until June 2014. This could result in some costs for industry if these products are manufactured but not sold in Australia and New Zealand. This situation could disadvantage some manufacturers and possibly consumers.

  The potential for identified novel ingredients used in FSMP to be added to general purpose foods without assessment would remain a risk to consumers.

  Also, the formatting error in Schedule 1 of Standard 2.9.5 would not be corrected so the inaccuracy would remain.

4.2 Conclusion of impact analysis

Given the consideration of the costs and benefits associated with the two options and the issues raised by submitters outlined above, FSANZ has prepared the variations to the Code in line with the preferred option, as at Attachment 1.

The Office of Best Practice Regulation (OBPR) advised (13 September 2012) that on the information provided to it by FSANZ with regards to this Proposal, that a Regulation Impact Statement (RIS) was not required for the proposed amendments (Reference No. 14236).

4.3 Addressing FSANZ's objectives for standards-setting

FSANZ also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Proposal as follows.

4.3.1 Protection of public health and safety

The protection of public health and safety was the paramount consideration for this Proposal.

The extension of the tutin MLs will protect consumers from the risks arising from contamination of honey and comb honey by tutin.

No public health and safety aspects were identified in relation to the consideration of the labelling for mixed tocopherols.

The amendments related to FSMP protect the health and safety of consumers by:

- Providing an earlier commencement date and transitional arrangements that enable FSMP to be appropriately regulated and lawfully sold, including throughout the transition period. This will maintain the supply of products to those who rely on them for their nutrition.

- Requiring a novel food that is added to FSMP to undergo assessment before use in general purpose foods protects the safety of consumers of the general food supply.

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

For tutin, no relevant issues were identified in the consideration of this Proposal with respect to this objective.

Some consumers may wish to avoid foods containing added tocopherols. Correcting the commencement date for the revised tocopherols nomenclature enables such consumers to identify tocopherol-containing products.

For FSMP, many of the labelling and information elements in Standard 2.9.5 already exist on current products or associated documentation. This provides information for consumers and health professionals during the transition period. However, some products will need time to conform to the complete set of requirements of Standard 2.9.5. As FSMP are intended to be used under medical advice, consumers that require additional information during the transition period can source this information from their health care professional.

4.3.3 The prevention of misleading or deceptive conduct

No relevant issues were identified in the consideration of this Proposal with respect to this objective for tutin and tocopherols.

The requirement for FSMP to meet the definition of FSMP as described in Standard 2.9.5, from gazettal, would discourage inappropriate products from positioning themselves as FSMP.

4.3.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2):

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Ministerial Council[4].

The interim MLs for tutin in honey and comb honey were established using the best available scientific evidence at the time. Since their incorporation into the Code in 2009, FSANZ and the MPI have sought additional scientific evidence to support the creation of a permanent standard for tutin. Whilst information from several studies is still pending, the existing interim maximum levels were considered adequate and supported the comprehensive New Zealand risk management program for the control of tutin in honey.

The continued control of tutin in honey and comb honey should reassure international markets that all honey products produced in New Zealand are safe to consume. Together, these measures support an efficient and internationally competitive food industry. There are no international food standards for tutin, and there have been no policy guidelines on this matter formulated by the Ministerial Council.

Providing an earlier commencement date and revised transitional arrangements for Standard

[4] Now known as the COAG Legislative and Governance Forum on Food Regulation

2.9.5 is based on risk analysis of currently available evidence. Since FSMP are almost all imported from overseas, the compositional and labelling requirements in Standard 2.9.5 are consistent primarily with EU regulations and with the USA or current practice where possible.

Companies in Australia and New Zealand that import FSMP would be able to lawfully sell products that already comply with Standard 2.9.5 sooner, so encouraging an efficient and internationally competitive food industry. The earlier commencement date and transitional arrangements create a fair and even playing field for FSMP manufacturers by allowing products that can immediately comply, and those requiring time to comply, to be sold during the transition period. Amending the transitional arrangements regarding Standard 1.1A.6 also ensures consistency between Australia and New Zealand.

For FSMP, the amendments in this Proposal remain consistent with the Ministerial Council Policy Guideline on the Intent of Part 2.9 of the Code which provided guidance in the development of Standard 2.9.5.

The matters listed in subsection 18(2) were not applicable to the consideration of the tocopherol variations given their nature and scope.

4.4 Transitional arrangements

With respect to mixed tocopherol concentrate, the drafting allows the Codex name and number to be used immediately, and provides a two year delay in the commencement of the clauses removing the current name and number in the Code.

For FSMP, the amendments to Standard 2.9.5 will commence on gazettal of the variations made under this Proposal. Transitional arrangements are to be in place from gazettal of the variations until 28 June 2014 i.e. the Standard's current commencement date. Details of the transitional arrangements are described in Section 3.2.3.2 above.

5 Implementation

The variations will come into effect on gazettal unless stipulated in the variations.

Attachments

A. Approved variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft Food Regulatory Measure at call for submissions

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

Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) 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 variation commences on the date specified in clause 3 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation.*

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

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

3. Commencement

The variations commence on **the date of gazettal** except for Item 1.2 of the Schedule which commences two years from **the date of gazettal**.

SCHEDULE

[1] ***Standard 1.2.4*** is varied by

[1.1] inserting into Part 2 of Schedule 2

"Tocopherols concentrate, mixed 306"

[1.2] omitting from Part 2 of Schedule 2

"Tocopherols concentrate, mixed 306"

[1.3] omitting "Tocopherols, concentrate mixed" (wherever occurring) and substituting "Tocopherols concentrate, mixed"

[1.4] inserting at the end of Part 1 of Schedule 2

"

Editorial note:
The permissions for food additive Tocopherols concentrate, mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[1.5] omitting from the end of Schedule 1

"

Editorial note:
The permissions for food additive Tocopherols, concentrate mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[1.6] inserting at the end of Part 2 of Schedule 2

"

Editorial note:
The permissions for food additive Tocopherols concentrate, mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[2] **Standard 1.3.1** is varied by omitting "Tocopherols, concentrate mixed" (wherever occurring) and substituting "Tocopherols concentrate, mixed"

[3] **Standard 1.4.1** is varied by omitting from subclause 5(5) "31 March 2013" and substituting

*"*31 March 2015*".*

[4] Standard 1.5.1 is varied by

[4.1] inserting after clause 1

"2A. Foods for Special Medical Purposes

To avoid doubt, the presence of a food in a food for special medical purposes or the use of a food as a food for special medical purposes does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this Standard.

Editorial note: Standard 1.5.1 does not apply to foods for special medical purposes. See paragraph 3(1)(b) of Standard 2.9.5.

"

[4.2] updating the Table of Provisions to reflect these variations.

[5] Standard 2.9.5 is varied by

[5.1] inserting after clause 2

"2A. Deemed compliance with Standard for certain periods

(1) This clause applies to a food for special medical purposes that does not comply with this Standard.

(2) If the food for special medical purposes is present in Australia or New Zealand on the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts on that date of commencement and ends on 28 June 2014.

(3) If the food for special medical purposes is imported into Australia or New Zealand on a date after the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts immediately prior to importation and ends on 28 June 2014.

(4) If the food for special medical purposes is produced in Australia or New Zealand on a date after the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts on the date the food for special medical purposes was produced and ends on 28 June 2014."

[5.2] inserting after subclause 3(2)

"(3) Subclause 1(2) of Standard 1.1.1 does not apply in relation to a food for special medical purposes that did not comply with Standard 2.9.5 on the date that Standard 2.9.5 commenced."

[5.3] omitting from Column 2 of Schedule 1 for Amino acids "L-carnitine"

[5.4] omitting from Schedule 1

"

Carnitine	L-carnitine hydrochloride
	L-carnitine L-tartrate
	Choline
Choline	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
	Inositol
Inositol	Adenosine 5′-monophosphate
Nucleotides	Adenosine 5′-monophosphate sodium salt
	Cytidine 5′-monophosphate
	Cytidine 5′-monophosphate sodium salt

	Guanosine 5′-monophosphate
	Guanosine 5′-monophosphate sodium salt
	Inosine 5′-monophosphate
	Inosine 5′-monophosphate sodium salt
	Uridine 5′-monophosphate
	Uridine 5′-monophosphate sodium salt

”

and substituting

“

Carnitine	L-carnitine
	L-carnitine hydrochloride
	L-carnitine L-tartrate
Choline	Choline
	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
Inositol	Inositol
Nucleotides	Adenosine 5′-monophosphate
	Adenosine 5′-monophosphate sodium salt
	Cytidine 5′-monophosphate
	Cytidine 5′-monophosphate sodium salt
	Guanosine 5′-monophosphate
	Guanosine 5′-monophosphate sodium salt
	Inosine 5′-monophosphate
	Inosine 5′-monophosphate sodium salt
	Uridine 5′-monophosphate
	Uridine 5′-monophosphate sodium salt

”

[5.5] updating the Table of Provisions to reflect these variations.

Standard 2.9.5 – Food for Special Medical Purposes Notice Amendment 2012 (No. 1)

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*. This variation commences on the date specified in clause 2 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Standard 2.9.5 – Food for Special Medical Purposes Notice Amendment 2012 (No.1).*

2. Commencement

This instrument commences on **the date of gazettal**.

3. Variation to instrument

The Schedule varies the notice given under section 92 of the *Food Standards Australia New Zealand Act 1991* for *Standard 2.9.5 – Food for Special Medical Purposes* (Federal Register of Legislative Instruments (*FRLI*) No. F2012L01347).

SCHEDULE

[1] The notice given under section 92 of the *Food Standards Australia New Zealand Act 1991* for ***Standard 2.9.5 – Food for Special Medical Purposes*** (Federal Register of Legislative Instruments (*FRLI*) No. F2012L01347) is varied by omitting the sentence "The Standard commences on 28 June 2014." and substituting "The Standard commences on the date of gazettal of *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation*."

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation Amendment 2012 (No. 1)

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*. This variation commences on the date specified in clause 2 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation Amendment 2012 (No. 1).*

2. Commencement

This instrument commences on **the date of gazettal**.

3. Variation to Legislative Instrument

The Schedule varies *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation*.

SCHEDULE

[1] ***Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation*** is varied by

[1.1] omitting from clause 3 "28 June 2014" and substituting "the date of gazettal of Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation."

[1.2] omitting Item [2] of the Schedule and substituting

"**[2] Standard 1.1A.6** is varied by omitting subclause 2(3), substituting

(3) This Standard ceases to have effect in relation to:

(a) food for special medical purposes on the date of gazettal of Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation; and

(b) other special purposes food, including food formulated and represented as being for the dietary management of obesity or overweight, two years from the commencement of any alternative applicable provisions elsewhere in this Code."

Attachment B – Explanatory Statements

Explanatory Statement

Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation

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.

FSANZ prepared Proposal P1023 to (1) extend the expiry date to 31 March 2015 for the interim maximum levels for tutin in honey and comb honey; (2) correct an error regarding commencement dates for the new tocopherol nomenclature introduced via Proposal P1021; and (3) amend Standard 2.9.5 to bring forward the commencement date and provide specific transitional arrangements for food for special medical purposes and also to clarify the intent of the exemption of Standard 1.5.1 from Standard 2.9.5. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

Following consideration by COAG Legislative and Governance Forum on Food Regulation[5], 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 and operation

The Authority has approved a draft variation to Standard 1.4.1 – Contaminants and Natural Toxicants to set a new expiry date of 31 March 2015 for the interim maximum levels for tutin in honey and comb honey. This new expiry date provides regulatory certainty while additional scientific evidence is sought in support of a comprehensive risk assessment for tutin in honey, and subsequently the development of a permanent regulatory measure for tutin in the Code.

The Authority has approved draft variations to Standards 1.2.4 – Labelling of Ingredients and 1.3.1 – Food Additives, to correct minor typographical errors and inconsistencies in relation to tocopherol nomenclature in those Standards.

The Authority has approved a draft variation to Standard 2.9.5 – Food for Special Medical Purposes to bring forward the commencement date of the Standard and to provide specific transitional arrangements for FSMP. These amendments provide greater regulatory certainty particularly for manufacturers and enforcement agencies.

[5] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

The Authority has also approved a draft variation to Standard 1.5.1 to remove any doubt that a potential novel food used in FSMP must meet the requirements of Standard 1.5.1 before it can be added to a general purpose food.

A separate legislative instrument was prepared for the variations to the above mentioned standards in accordance with accepted drafting practice.

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 P1023 has included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 2 October 2012 for a four-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations were administrative in nature and unlikely to have a negative 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. Variations

6.1 Standard 1.2.4

Items [1.1] to [1.4] of the Schedule to the instrument correct minor typographical errors and inconsistencies in Standard 1.2.4 that relate to the entry in that Standard for tocopherols.

Item [1.1] inserts a new entry for tocopherols concentrate, mixed into Part 2 of Schedule 2 of the Standard 1.2.4. This Item takes effect on gazettal of the variation.

Item [1.2] removes the above entry from Part 2 of Schedule 2 two years after the date of the gazettal of the variation.

Item [1.3] corrects a typographical error in Standard 1.2.4.

Items [1.4] and [1.6] insert Editorial notes into the Standard. Editorial notes are not, by virtue of the definition of 'standard', part of a draft standard and are therefore not subject to the standards development process under the FSANZ Act. The Editorial notes have only been provided for completeness.

Item [1.5] removes an Editorial note from the Standard.

6.2 Standard 1.3.1

Item [2] of the Schedule corrects a typographical error in Standard 1.3.1 relating to the entry in that Standard for tocopherols.

6.3. Standard 1.4.1

Item [3] of the Schedule amends subclause 5(5) of Standard 1.4.1 to extend the expiry date for the maximum limit set by that Standard for tutin in honey and comb honey to 31 March 2015.

6.4 Standard 1.5.1

Item [4.1] of the Schedule inserts clause 2A into Standard 1.5.1. Clause 2A clarifies the application of the exemption provided by paragraph 3(1)(b) of Standard 2.9.5 for food for special medical purposes from Standard 1.5.1. It makes clear that a potential novel food that is used in food for special medical purposes, must meet the requirements of Standard 1.5.1 before being used in a general purpose food.

Item [4.2] updates the Standard's Table of Provisions to reflect the above change.

6.5 Standard 2.9.5

Item [5.1] varies Standard 2.9.5 by inserting a new clause 2A.

Subclause 2A(1) provides that the clause applies to FSMP that do not comply with the Standard.

Subclause 2A (2) allows FSMP present in Australia or New Zealand on the date that Standard 2.9.5 commences to be lawfully sold by deeming them to comply with the Standard. They can be sold until the end of the transition period i.e. until 28 June 2014. This is equivalent to an extended stock in trade provision for these existing products.

Subclauses 2A (3) and (4) also allows FSMP that are imported into, or produced in, Australia or New Zealand on a date after Standard 2.9.5 has commenced, to be lawfully sold in Australia or New Zealand. Again, this is done by deeming the FSMP to comply with the Standard. They can be sold from the date the FSMP was imported or produced until the end of the transition period i.e. until 28 June 2014. This is a special transitional arrangement for newly produced or imported FSMP.

Standard 2.9.5 provides a definition of FSMP. If a food does not satisfy the definition of FSMP, it will not be afforded the protection provided by clause 2A.

Item [5.2] clarifies that the existing stock in trade provision in subclause 1 (2) of Standard 1.1.1 of the Code does not apply to FSMP that did not comply with Standard 2.9.5 on the date that Standard 2.9.5 commenced. In the absence of this item, subclause 1 (2) of Standard 1.1.1 would automatically apply. This would be problematic as FSMP are currently unregulated under the Code.

Item [5.3] removes the entry "L- carnitine" from column 2 of Schedule as it is incorrectly aligned to the substance Amino acids, listed in Column 1.

Item [5.4] inserts "L- carnitine" (previously removed under [5.3]) in the correct row of Column 2 so that it is accurately aligned to the substance Carnitine, listed in Column 1.

Item [5.4] also removes a section of Schedule 1 which contains some errors, and substitutes a corrected version of this section back into the Schedule. As a result, some permitted forms (i.e. choline, inositol, and adenosine 5'-monophosphate) that were listed in incorrect rows, have been moved into the correct row so that they now align with the appropriate corresponding substance, listed in Column 1.

Item [5.5] updates the Standard's Table of Provisions to reflect the above changes.

6.6. Commencement dates

Clause 3 of the instrument provides that the variations commence on the date of gazettal of the instrument except for Item 1.2 of the Schedule which commences two years from that date.

Explanatory Statement

Standard 2.9.5 – Food for Special Medical Purposes Notice Amendment 2012 (No. 1)

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. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1023 to, among other things, set a new commencement date for Standard 2.9.5 – Food for Special Medical Purposes.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation to amend the commencement dates for Standard 2.9.5.

2. Purpose and operation

The Authority has approved a draft variation to commence Standard 2.9.5 on the date of gazettal of *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation* with specific transitional arrangements until 28 June 2014. Standard 2.9.5's earlier commencement date and the transition arrangements enable and provide greater regulatory certainty for stakeholders, particularly manufacturers of food for special medical purposes and enforcement agencies.

The variation was prepared as a separate legislative instrument having regard to its technical nature, that is, it actually varies the notice given under section 92 of the *Food Standards Australia New Zealand Act 1991* for *Standard 2.9.5 – Food for Special Medical Purposes* (Federal Register of Legislative Instruments (*FRLI*) No. F2012L01347).

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 P1023 has included one round of public consultation following an assessment and preparation of a draft Standard and associated report. Submissions were called for on 2 October 2012 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variations were administrative in nature and unlikely to have a negative 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. Variations

6.1 Variations

Item [1] of the Schedule varies the notice given under section 92 of the *Food Standards Australia New Zealand Act 1991* for *Standard 2.9.5 – Food for Special Medical Purposes* (Federal Register of Legislative Instruments (*FRLI*) No. F2012L01347). The effect of this variation is to change the commencement date of Standard 2.9.5 to the date of gazettal of the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation*.

6.2 Commencement

Clause 2 of the amending instrument provides that it commences on the date of its gazettal.

Explanatory Statement

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation Amendment 2012 (No. 1)

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. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1023 to: set a new commencement date for consequential variations related to the commencement of Standard 2.9.5 – Food for Special Medical Purposes; and amend Transitional Standard 1.1A.6 – Transitional Standard for Special Purposes Foods (Including Amino Acid Modified Foods) so that is ceases to apply to food for special medical purposes sold in New Zealand when Standard 2.9.5 commences.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation to implement the above.

2. Purpose and operation

The Authority has approved a draft variation to set a new commencement date for the consequential variations related to Standard 2.9.5. A separate legislative instrument was required for this purpose, that is, varying a variation.

This new date reflects the Authority's separate approval of a draft variation to commence Standard 2.9.5 on the date of gazettal of *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation*,

The Authority also approved a draft variation to amend Transitional Standard 1.1A.6, (which applies to New Zealand only, not Australia) so that it ceases to have effect for FSMP sold in New Zealand once Standard 2.9.5 commences. FSMP sold in New Zealand will then be regulated by Standard 2.9.5 including the transitional arrangements in that Standard. The draft variation clarifies that other special purpose foods in New Zealand (including products formulated and represented for the management of overweight and obesity) will continue to be regulated under Standard 1.1A.6 until 2 years after any alternative provisions are made for such foods in the Code.

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 P1023 has included one round of public consultation following an assessment and preparation of a draft Standard and associated report. Submissions were called for on 2 October 2012 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variations were administrative in nature and unlikely to have a negative 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. Variations

6.1 Variations

Item [1] of the Schedule amends the commencement date of the original consequential amendments required when Standard 2.9.5 was prepared. These consequential amendments to Standards 1.1.1, 1.2.1, 1.3.1 and 1.3.4 were to come into effect when Standard 2.9.5 commenced on 28 June 2014. They will now come into effect on the earlier commencement date i.e. on the date of gazettal for the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation.*

Item [2] of the Schedule replaces Item 2 of the Schedule of the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation* to provide that Transitional Standard 1.1A.6 ceases to apply to FSMP on the date of gazettal for the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation.* That date is the date on which Standard 2.9.5 commences. Other special purpose foods in New Zealand (including products formulated and represented for the management of overweight and obesity) will continue to be regulated under Standard 1.1A.6 until 2 years after any alternative provisions are made for such foods in the Code.

6.2 Commencement

Clause 2 of the amending instrument provides that it commences on the date of its gazettal.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* at Call for Submissions

Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) 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 variation commences on the date specified in clause 3 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation.*

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

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

3. Commencement

The variations commence on **the date of gazettal** except for Item 1.2 of the Schedule which commences two years from **the date of gazettal**.

SCHEDULE

[1] Standard 1.2.4 is varied by

[1.1] inserting into Part 2 of Schedule 2

"Tocopherols concentrate, mixed 306"

[1.2] omitting from Part 2 of Schedule 2

"Tocopherols concentrate, mixed 306"

[1.3] omitting "Tocopherols, concentrate mixed" (wherever occurring) and substituting "Tocopherols concentrate, mixed"

[1.4] inserting at the end of Part 1 of Schedule 2

"

Editorial note: The permissions for food additive Tocopherols concentrate, mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[1.5] omitting from the end of Schedule 1

"

Editorial note: The permissions for food additive Tocopherols, concentrate mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[1.6] inserting at the end of Part 2 of Schedule 2

"

Editorial note: The permissions for food additive Tocopherols concentrate, mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[2] Standard 1.3.1 is varied by omitting "Tocopherols, concentrate mixed" (wherever occurring)

and substituting “Tocopherols concentrate, mixed”

[3] **Standard 1.4.1** is varied by omitting from subclause 5(5) “31 March 2013” and substituting *“*31 March 2015*”.*

[4] **Standard 1.5.1** is varied by inserting after clause 1

“2A Foods for Special Medical Purposes

To avoid doubt, the presence of a food in a food for special medical purposes or the use of a food as a food for special medical purposes shall not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this Standard.

Editorial note:

Standard 1.5.1 does not apply to foods for special medical purposes. See paragraph 3(1)(b) of Standard 2.9.5.

”

[5] **Standard 2.9.5** is varied by inserting after subclause 3(2)

“(3) Subclause 1(2) of Standard 1.1.1 does not apply in relation to a food for special medical purposes that did not comply with Standard 2.9.5 on the date that Standard 2.9.5 commenced.”

Standard 2.9.5 – Food for Special Medical Purposes Amendment 2012 (No.1)

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*. This variation commences on the date specified in clause 2 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Standard 2.9.5 – Food for Special Medical Purposes Amendment 2012 (No.1).*

2. Commencement

This instrument commences on **the date of gazettal**.

3. Variation to Legislative Instrument

The Schedule varies Standard 2.9.5 – Food for Special Medical Purposes.

SCHEDULE

[1] Standard 2.9.5 – Food for Special Medical Purposes is varied by omitting the sentence "The Standard commences on 28 June 2014." and substituting

"The Standard commences on the date of gazettal of *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation* except for the following provisions which commence on 28 June 2014 –

(a) clause 5;
(b) paragraph 7(1)(b);
(c) paragraphs 10(1)(d),(e) and (f);
(d) paragraph 10(2)(b);
(e) clause 14;
(f) clause 15."

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation Amendment 2012 (No. 1)

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*. This variation commences on the date specified in clause 2 of this instrument.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation Amendment 2012 (No. 1).*

2. Commencement

This instrument commences on **the date of gazettal**.

3. Variation to Legislative Instrument

The Schedule varies *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation*.

SCHEDULE

[1] ***Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation*** is varied by

[1.1] omitting from clause 3 "28 June 2014" and substituting "the date of gazettal of Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation."

[1.2] omitting Item [2] of the Schedule and substituting

"**[2] Standard 1.1A.6** is varied by omitting subclause 2(3), substituting

(3) This Standard ceases to have effect in relation to:

(a) foods for special medical purposes on the date of gazettal of Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation; and

(b) other special purposes food, including food formulated and represented as being for the dietary management of obesity or overweight, two years from the commencement of any alternative applicable provisions elsewhere in this Code."