2 October 2012
[23-12]

Call for submissions – Proposal P1023

Tutin, Tocopherol & Food for Special Medical Purposes Standards Amendments

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FSANZ has assessed a proposal prepared 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. FSANZ has prepared draft food regulatory measures. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measures.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 30 October 2012

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Canberra BC ACT 2610
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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at:

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 is proposing an extension of 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 of the measure and related editorial notes. This Proposal amends 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.

The current Standard 2.9.5 was gazetted in June 2012 and commences on 28 June 2014. The two-year period following gazettal was intended to allow time for manufacturers, distributors and others to make any adjustments to be compliant with the Standard on the commencement date.

Since gazettal, FSANZ has received queries regarding the commencement date, transitional arrangements and compliance. FSANZ has also been made aware that some FSMPs could immediately comply with Standard 2.9.5. Manufacturers of these products are disadvantaged by having to wait until the commencement date of June 2014.

FSANZ is proposing to bring forward the commencement date for Standard 2.9.5 to the date of gazettal of this Proposal. This will 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 will be included for FSMP that do not fully comply with the Standard to allow time to transition by 28 June 2014. This provides regulatory clarity for manufacturers and enforcement agencies during the transition period. Consumers may benefit from certainty of supply and the potential introduction of new products.

Standard 2.9.5 also includes an exemption from certain standards in the Code, including for Standard 1.5.1 – Novel Foods, which would come into effect on the commencement date. After commencement, novel ingredients added to FSMP would 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 then be added to general purpose foods without meeting the requirements of Standard 1.5.1. Proposal P1023 clarifies this intent that a novel food used in an FSMP must meet the requirements of Standard 1.5.1 prior use in general purpose foods.

2. Introduction

2.1 The Proposal

The Proposal relates to several amendments to the Code.

2.1.1 Tutin

FSANZ seeks to extend the expiry date for a further two years, the interim maximum levels for tutin in Standard 1.4.1. This extension will 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 seeks to correct an error regarding the commencement date for the revised 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 is removed from the schedule listing food additives in numerical order on gazettal, although not in the schedule listing alphabetical order. This creates regulatory uncertainty. FSANZ also seeks to correct other minor typographical errors in the drafting for P1021.

2.1.3 Food for Special Medical Purposes

FSANZ seeks 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 transition 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 at 2 mg/kg and comb honey (honey comb) at 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 currently lists the INS number for “tocopherols concentrate, mixed” as 306.

However, JECFA has changed this number to 307b. Proposal P1021 sought to update Standard 1.2.4 to update the INS number for tocopherols concentrate mixed, and was approved by the FSANZ Board in July 2012. The decision was notified to the COAG Legislative and Governance Forum on Food Regulation[1] (the Forum) on 2 August 2012. FSANZ is currently awaiting advice from the Forum.

However, the drafting in P1021 contained a transpositional error. An editorial note was inserted after Item 3.2 resulting in the numbering of all items under Item [3] of the drafting variations 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 was 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 is not amended, for a period of two years following gazettal of P1021 Schedule 2 of Standard 1.2.4 will have an inconsistency. Part 1 will permit use of the INS number 306 for "tocopherols concentrate, mixed" while Part 2 will not.

Proposal P1023 also corrects typographical errors in the P1021 drafting which inserts an editorial note at the end of "Part 1 of the Schedule 1" instead of "Part 2 of Schedule 2", and refers 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.

FSMP products for sale in Australia do not have provisions specific to these products 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. Currently, Standard 1.1A.6 will cease to have effect for FSMP (other than in relation to food formulated and represented as being for the dietary management of obesity) on the date of commencement of Standard 2.9.5.

Standard 2.9.5 was gazetted in June 2012 and commences on 28 June 2014. The two-year period following gazettal was intended to allow time for manufacturers, distributors and others to make any adjustments to be compliant with the Standard on the commencement date.

Standard 2.9.5 also includes an exemption from 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 required consequential amendments to be made to Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4. These are proposed also to come into effect on the commencement date for Standard 2.9.5.

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

2.4 Reasons for preparing the Proposal

2.4.1 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 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 is seeking an extension to the expiry date to complete a comprehensive risk assessment to support an appropriate, permanent regulatory measure for tutin in food.

2.4.2 Tocopherol

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

2.4.3 Food for Special Medical Purposes

Since gazettal of Standard 2.9.5, FSANZ has received queries regarding the commencement date, transitional arrangements and implementation of the FSMP standard.

Although 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, no specific transitional arrangements were provided.

FSANZ is aware that some FSMP could immediately meet the requirements of Standard 2.9.5. However, because the Standard is yet to commence, these FSMP would not be fully compliant with the Code. Manufacturers are disadvantaged by the delay in commencement. Bringing forward commencement of the Standard to the date of gazettal of this Proposal will allow FSMP that already meet the requirements of the Standard to be lawfully sold in Australia and New Zealand from the earlier date. Transitional arrangements are also needed for those products that do not fully comply with the Standard to allow time to transition by 28 June 2014.

A feature of Standard 2.9.5 is the introduction of certain exemptions for FSMP from other Standards such as the exemption from Standard 1.5.1 and the exempted restrictions on addition of vitamins and minerals for some types of FSMP. An earlier commencement date plus specific transitional arrangements would enable FSMP to take advantage of these exemptions.

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 are not required to meet Standard 1.5.1. However it was not intended that a novel food or ingredient added to a FSMP could then 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 will clarity 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.

2.5 Procedure for assessment

The Proposal is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

3.1.1 Tutin

The risk assessment conclusions from the previous Proposal (P1009) remain valid and no further assessment is required at this time (refer to the Approval Report for P1009 on the FSANZ's 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 is therefore appropriate to seek 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 has not identified any risk arising from correcting the errors, as that reflects the intended approach under P1021 (SD 2).

3.1.3 Food for Special Medical Purposes

Previous assessments (see SD 3) identified a potential risk of interrupted FSMP supply to consumers who rely on these products for their nutrition. Regulatory uncertainty had occasionally caused delays in the importation of FSMP. Standard 2.9.5 provides clarity to prevent these delays from occurring once the new Standard comes into effect in June 2014. However, this potential risk will remain until June 2014, unless changes are made.

Also, as noted in Section 2.4.3, novel food or ingredients can be added to FSMP without having to meet the requirements of Standard 1.5.1. There is 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 is needed to mitigate this risk.

Further risk assessment has not been undertaken for Proposal P1023 as the proposed strategy reflects the intent when Standard 2.9.5 was gazetted in June 2012, i.e. that FSMP products have a set period of time to transition to comply with the Standard.

3.2 Risk management

3.2.1 Tutin

As previously noted in Proposal (P1009), a food regulatory measure is warranted due to the adventitious presence of tutin in honey 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 is 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 are considered practical and achievable by industry and the responsible food enforcement authority (MPI). No additional costs to consumers or industry are envisaged from maintaining the MLs at their current values for the period that the extension is proposed.

3.2.2 Tocopherol

FSANZ has not identified 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 are required in this respect other than correcting the errors identified 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 on commencement of the Standard, as it was developed to reflect overseas regulations and current practice where possible. The proposed amendments to Standard 2.9.5 and other standards to bring forward the commencement date and include specific transitional arrangements provide certainty for stakeholders, particularly manufacturers and enforcement agencies.

FSMPs are intended to be used under medical supervision and mandatory labelling to this effect will be required during the transition period to alert consumers to this. Other mandatory labelling will also be required to provide information for both consumers and health professionals e.g. stating the true nature of the food, the medical purpose of the food, and the warning and advisory statements.

3.2.3.1 Commencement date

It is proposed that Standard 2.9.5 would commence on gazettal of this Proposal. Bringing forward the commencement date allows FSMPs that already meet the requirements of Standard 2.9.5 to be lawfully sold in Australia and New Zealand from the earlier date. Manufacturers and consumers would then not be disadvantaged by having to wait until June 2014. This also manages the risk of potential importation delays at the border earlier than mid-2014.

3.2.3.2 Transitional arrangements

The transitional arrangements are proposed to apply to products on sale in Australia and New Zealand during the transition period. These arrangements enable FSMP products that might not fully comply with Standard 2.9.5 on the earlier commencement date to be lawfully sold while any necessary changes are made, thus resulting in a smooth transition and avoiding disruption to the supply of FSMP. Transitional arrangements are proposed to be in place from gazettal until 28 June 2014 i.e. the Standard's current commencement date.

Manufacturers have identified certain provisions in Standard 2.9.5 that require more time beyond the earlier commencement date for them to fully comply. The following provisions in Standard 2.9.5 would be temporarily excluded from operation of the Standard from gazettal of this Proposal until 28 June 2014 (assumed to be about 15 months):

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

- 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 new FSMP standard. The exemptions allow manufacturers time to meet the new requirements in a cost effective manner. It is expected that manufacturers will continue their current practice in relation to lactose and gluten during the transition period.

The transitional arrangements allow for FSMP products to become compliant with Standard 2.9.5 by June 2014, as was intended when the Standard was originally gazetted.

Question for submitters:

Apart from the listed transitional arrangements, are there other elements of Standard 2.9.5 that would require time to transition if the Standard's commencement date were brought forward?

3.2.3.3 Novel food exemption

It is 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. This clarification manages the potential food safety and regulatory risk of a novel food that is added to a FSMP being added to general purpose foods without appropriate assessment.

The changes to the FSMP and novel food standards proposed are considered appropriate strategies to manage any risk for consumers and manufacturers of FSMP.

3.2.3.4 Consequential amendments

The New Zealand only Standard 1.1A.6 also needs amendment to reflect the commencement of Standard 2.9.5. It is proposed that Standard 1.1A.6 will cease in relation to FSMPs that are sold in New Zealand on the earlier commencement date for Standard 2.9.5. The transitional arrangements proposed above would then apply to New Zealand products also from gazettal until 28 June 2014. This period will cover any stock in trade.

This approach would maintain consistency across Australia and New Zealand and provide simplicity and regulatory clarity for stakeholders in both countries.

As the proposed exemptions would not commence until June 2014, a 12 month stock-in-trade period would apply *for those exemptions* when they come into effect in June 2014, as is usual practice.

Consequential amendments are also required to bring forward the commencement date of the original consequential amendments resulting from the establishment of Standard 2.9.5 i.e. Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4.

3.3 Regulatory options and impacts

When assessing this Proposal and the subsequent development of food regulatory measures, FSANZ has had regard to the following matters in 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.

3.3.1 Cost benefit analysis

There were two options available to FSANZ.

Option 1: Prepare draft variations to:

- 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.
- Standard 1.4.1 to extend the expiry date for the interim maximum levels for tutin in honey and comb honey until 31 March 2015.
- Standard 1.5.1 to clarify the intent of the novel food exemptions for FSMP.
- Standard 2.9.5 to bring forward the commencement date and provide specific transitional arrangements.
- make consequential amendments as a result of the above variations.

Option 2: Abandon the proposal which would:

- 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.
- allow the interim tutin maximum levels in Standard 1.4.1 to lapse.
- retain the current exemption for FSMP from Standard 1.5.1, but 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.

3.3.1.1 Option 1 – Prepare draft variations to Standard 1.4.1, 2.9.5, 1.5.1 and 1.2.4, and other consequential amendments, 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, bringing the commencement date forward in conjunction with specific transition arrangements for manufacturers, would provide certainty of product availability and also has potential to support new product introduction for consumers. Health professionals could potentially have a wider range of products available to manage consumers' nutrition. 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 FSMP that can comply with Standard 2.9.5 could lawfully sell FSMP from the earlier commencement date, so would not have to wait until mid-2014 to do so. Others that require time to comply with Standard 2.9.5 would be able to lawfully sell their FSMP products throughout the transition period while they make any adjustments needed. This provides a more even 'playing field' for all manufacturers of FSMP, and would maintain the supply of FSMP as much as possible. Also, Option 1 could enable new and imported products to take advantage of new permissions and exemptions in Standard 2.9.5 e.g. new permissions for specific food additives, the vitamin and mineral permissions and exemptions for novel foods. This 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.

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

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 regulatory clarity provided by the proposed amendments would enable enforcement agencies to identify and assess compliance of FSMP products being imported into and sold in Australia and New Zealand at the commencement date of Standard 2.9.5, and also during the transition period. The transitional arrangements will provide some regulatory oversight of goods that are not fully compliant with Standard 2.9.5 on commencement, as well as potentially inappropriate products.

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

3.3.1.2 Option 2 – Abandon the Proposal

- For tutin, this option 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, adoption of this option would potentially have negative effects on industry and government. This could include a loss in business and reputation for industry if honey was seen 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, abandoning the proposal 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, the status quo is considered less attractive because of the continuation of regulatory uncertainty relating to enforcement during the transition period. Further, 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 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.

3.3.2 Preferred option

Given the consideration of the costs and benefits associated with the two options outlined above, FSANZ decided to proceed to prepare draft variations to the Code.

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).

3.3.3 Addressing FSANZ's objectives for standards-setting

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

3.3.3.1 Protection of public health and safety

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

The extension of the ML protects 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. Also, the mandatory labelling requirements that apply during the transition period and beyond, such as the indication that the product should be used under medical supervision, helps discourage inappropriate products from being developed for sale to consumers. This approach will help maintain the confidence of health professionals who advise consumers needing FSMP.

- 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.

3.3.3.2 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, this Proposal brings forward many of the labelling and/or information requirements of Standard 2.9.5 but also provides for certain labelling exemptions during the transition period. FSMP will be required to meet many of the labelling elements in some form during the transition period to provide sufficient information for consumers and health professionals. However, some products will need time to conform to some of the specific requirements of Standard 2.9.5. These requirements are either new or currently difficult to comply with for FSMP, so some labelling adjustments are needed.

As FSMP are intended to be used under medical advice, if consumers require additional information during the transition period, this can be provided by their health care professional.

3.3.3.3 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 certain elements of Standard 2.9.5 from gazettal, including the definition and several mandatory labelling provisions such as indicating use under medical supervision, would discourage inappropriate products from positioning themselves as FSMP.

3.3.3.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed 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.

The interim maximum levels 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 are adequate and support the comprehensive New Zealand risk management programme 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.

FSMP are almost all imported from overseas. Therefore, 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. Providing an earlier commencement date and appropriate transitional arrangements for Standard 2.9.5 brings forward a standard based on risk analysis.

Importers of FSMP into Australia and New Zealand would be able to import 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 also create a fair and even playing field for manufacturers. 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.

3.4 Risk communication

A basic communication strategy has been applied to this Proposal.

All calls for submissions are notified through the FSANZ Notification Circular, a media release and through FSANZ's social media tools and Food Standards News.

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

Some targeted consultation has been undertaken in developing this Proposal, specifically with some manufacturers and some enforcement agencies in relation to FSMP. If issues are identified through public consultation, further targeted consultation may be required.

Individuals and organisations making submissions on this Proposal will be notified at each stage of assessment.

3.4.1 World Trade Organization (WTO)

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

3.4.1.1 Tutin

There are no relevant international standards for tutin. Amending the Code to extend the expiry date of the interim tutin MLs in honey and comb honey is unlikely to have a significant effect on international trade as:

- The presence of tutin in honey seems to be unique to New Zealand. As there are no reports indicating the presence of tutin in honey from any other country, it is considered high unlikely that there would be any imposts on honey imported from other countries.
- The interim standards for tutin by New Zealand and FSANZ have been in place since 2008 and 2009, respectively, for the primary purpose of protecting human health and safety.
- The continuation of the interim standard for tutin in the Code, should reassure international markets that this measure supports a comprehensive risk management program to ensure the safety of honey produced in New Zealand.

3.4.1.2 Tocopherol

Correcting the error regarding the commencement date for the revised tocopherol nomenclature does not require a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures Agreement.

3.4.1.3 Food for Special Medical Purposes

The WTO was notified in 2003 of Proposal P242 – Food for special medical purposes, through notifications G/TBT/N/AUS/13 and G/TBT/N/NZL/12. The European Commission lodged a submission and this was addressed in the Preliminary Final Assessment Report (August 2004) and in the December 2010 Consultation Paper, with subsequent changes made to Standard 2.9.5.

The amendments proposed in this Proposal are to provide regulatory clarity and are not expected to have any additional imposts on FSMP imported from other countries.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variations

The draft variations to Standards 1.4.1, 2.9.5, 1.5.1, 1.2.4 and any consequential amendments to the Code are at Attachment A.

4.1 Implementation

The variations take effect on gazettal.

Attachments

A. Draft variations to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statements

Attachment A – Draft 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 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."

Attachment B – Draft Explanatory Statements

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 beyond 31 March 2013 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 – Food for Special Medical Purposes (FSMP), to bring forward the commencement date and provide transitional arrangements in that Standard; and also to clarify the intent of the exemption of Standard 1.5.1 – Novel Foods, from Standard 2.9.5.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved draft variations to various Standards.

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 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.

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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (which includes the draft variations) will be released 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 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. Variations

6.1 Standard 1.24

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.

Items [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] 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.

6.5 Standard 2.9.5

Item [5] of the Schedule inserts subclause 3(3) into Standard 2.9.5 to provide that the exemption for stock in trade provided by subclause 1(2) of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions does not apply to food for special medical purposes that did not comply with Standard 2.9.5 on the date the Standard commenced.

Subclause 1(2) of Standard 1.1.1 will continue to apply to the variations made by the following provisions of Standard 2.9.5 which commence on 28 June 2014:

- clause 5
- paragraph 7(1)(b)
- paragraphs 10(1)(d),(e) and (f)
- paragraph 10(2)(b)
- clause 14
- clause 15.

6.6. Commencement dates

Clause 2 of the instrument provides that the variations commence on the date of that instrument's gazettal except for Item 1.2 of the Schedule which commences two years from that date.

Standard 2.9.5 – Food for Special Medical Purposes 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 new commencement dates 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 a later commencement date of 28 June 2014 for some specified provisions of that Standard. Standard 2.9.5's earlier commencement date and the transition arrangements for the specified provisions provided by their commencement date of 28 June 2014 enable and provide regulatory certainty for stakeholders, particularly manufacturers of food for special medical purposes and enforcement agencies.

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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (which includes the draft variations) will be released 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 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. Variations

6.1 Variations

Item 1 of the Schedule to the instrument provides that Standard 2.9.5 will commence on the date of gazettal for the *Food Standards (Proposal 1023 – Tutin, Tocopherols & Food for Special Medical Purposes Standards Amendments) Variation*, except for the following provisions which will commence on 28 June 2014:

- clause 5
- paragraph 7(1)(b)
- paragraphs 10(1)(d),(e) and (f)
- paragraph 10(2)(b)
- clause 14
- clause 15.

6.2 Commencement

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

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 draft variation to set a new commencement date for the consequential variations related to Standard 2.9.5.

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*, with a later commencement date of 28 June 2014 for specified provisions of Standard 2.9.5. Standard 2.9.5's earlier commencement date and the transition arrangements for the specified provisions provided by the 28 June 2014 commencement date enable and provide regulatory certainty for stakeholders, particularly manufacturers of food for special medical purposes and enforcement agencies.

The Authority also approved a draft variation to amend Transitional Standard 1.1A.6, (which applies to New Zealand only, not Australia) so that is ceases to have effect for food for special medical purposes sold in New Zealand once Standard 2.9.5 commences. Food for special medical purposes sold in New Zealand will then be regulated by Standard 2.9.5 including the transitional arrangements in that Standard. The draft variation also 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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (which includes the draft variations) will be released 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 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. Variations

6.1 Variations

Item [1] of the Schedule amends clause 3 of the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation* to provide that that instrument commences 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.

Item [2] of the Schedule amends 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 food for special medical purposes 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.

6.2 Commencement

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