

Food Standards Australia New Zealand

PROPOSAL P1023 TUTIN, TOCOPHEROL & FOOD FOR SPECIAL MEDICAL PURPOSES

Standards Amendments

30 October 2012

The New Zealand Food & Grocery Council (the “NZFGC”) welcomes the opportunity to make a submission on *Proposal P1023 Tutin, Tocopherol & Food for Special Medical Purposes: Standards Amendments*.

New Zealand Food & Grocery Council

The NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. Collectively this sector generates \$28.7 billion in the New Zealand domestic retail food, beverage and grocery products market and \$26.3 billion in export revenue from exports to 183 countries. Food and beverage manufacturing is the largest manufacturing sector in New Zealand representing 46% of total manufacturing income and 34% of all manufacturing salaries and wages.

Food and beverage manufacturing and wholesaling in New Zealand directly employs 104,160 people (5% total employment) and, when taking the wider food and beverage value chain (including farming and food retailing/foodservice) into account, employment soars to 344,820 in 85,252 enterprises. This represents around one in five people employed in our country.

No matter how you look at it, the New Zealand food, beverage and grocery sector makes a substantial contribution to the New Zealand domestic economy, to our exports and to the general economic well-being of the country.

Proposal P1023

The NZFGC understands that the key matters addressed in this Proposal are:

- To extend the expiry date of the interim standard for tutin in honey and comb honey from 31 March 2013 to 31 March 2015
- Correct the commencement date for the new tocopherol nomenclature and make technical corrections to the nomenclature
- Amend Standard 2.9.5 to bring forward the commencement date for most of the provisions from 18 June 2014 to the date of gazettal of the amendment and to clarify the status of the exemption for pre-market assessment for novel foods contained in Standard 2.9.5.

Overarching Comment

The NZFGC generally supports the positions recommended by FSANZ for each of the three matters assessed: extending the expiry date of the interim standard for tutin in honey and comb honey from 31 March 2013 to 31 March 2015; correcting the commencement date for the new tocopherol nomenclature and correcting the nomenclature; and amending

Standard 2.9.5 to bring forward the commencement date from 18 June 2014 to the date of gazettal and clarify the status of the exemption for pre-market assessment for novel foods contained in Standard 2.9.5. However, in these last two mentioned areas, NZFGC believes there are complicating factors and suggests additional provisions be made to accommodate these factors.

Specific Comment

Tutin

The interim standard for tutin in honey and comb honey expires on 31 March 2013. FSANZ proposes an extension to this expiry date in Standard 1.4.1 to ensure the ongoing protection of consumers, while it continues its work on risk assessment and risk management of tutin in honey and comb honey. The NZFGC recognises that the research and data collection for determining the future regulatory measures that should apply to tutin are complex and proving difficult to undertake. The NZFGC supports evidence-based standards setting and for this reason supports the continuation of the interim standard for a further two years while the data collection and research into tutin continues.

Tocopherol

FSANZ has identified that the commencement dates for the new tocopherol nomenclature are not correct and that some typographical errors have been made in relation to the term 'tocopherol concentrate, mixed'. As a result, products labelled using the old nomenclature will not have sufficient time to clear the supply chain, and would not be compliant with the requirements of the revised Standard 1.2.4 and confusion as to the correct terminology exists. The NZFGC supports the corrections as reasonable and practicable transition periods are very important for industry and nomenclature of products is important. In this case there are no safety issues and the NZFGC supports the amendments proposed.

Foods for Special Medical Purposes

Three amendments are proposed to Standard 2.9.5 and to other standards in the Food Standards Code as a consequence:

- The first amendment will bring forward the commencement date to allow for products that already meet the requirements of the Standard to enter the market now. Currently they cannot be made available because the future commencement date prevents them from lawfully complying with the Standard.
- At the same time, a second amendment will provide for specific transitional arrangements to allow time for other products to lawfully transition to compliance with Standard 2.9.5 by July 2014.
- The third group of amendments will clarify the scope of the exemption in Standard 2.9.5 from the application of Standard 1.5.1 – Novel foods. The current provision was intended to promote innovation and allow products to enter the market especially where they might contain products novel to the New Zealand and Australian markets without pre-market assessment but where these products have been manufactured to treat specific conditions. This facility is to be clarified by making it clear that the provision is not to constitute “a history of safe use” for the purposes of the general food supply. This is to preserve the pre-market assessment arrangement for novel foods destined for the general food supply.

The NZGC supports the prospect of foods for special medical purposes entering the market as soon as possible to assist those in need.

The NZFGC does not support immediate compliance with a selected number of the provisions in Standard 2.9.5 as is discussed below in response to the “Question for Submitters”.

The NZFGC supports the clarification around ‘history of use’ in relation to novel foods used in medical foods but considers that provision should be made for the use of novel foods in foods for special medical purposes to be considered a factor in considering whether a food has a history of use. The reason for this is that while it may not be the sole factor, widespread safe use by a very vulnerable group in the population should convey a level of satisfaction with that use that should not be discounted out of hand.

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?

A number of the omitted clauses that would support products onto the market with immediate commencement present problems for products on the market that will have to reformulate or re-label due to the earlier commencement.

For example the forms of substances in clause 6 will have a dual impact – allowing new products early entry but potentially creating issues for existing products. Clause 7(2)(b) would appear to be problematic since it refers to subclause 10(2) and transitional arrangements continue to apply to clause 10(2)(b). Mandatory statements relating to medical supervision, medical purpose, not for parenteral use and allergen statements on inner packages may not be included on all products for all purposes at this point in time and while these provisions are supported for the future, the period prior to commencement was looked to for bringing these products into compliance.

One solution could be for commencement to proceed immediately for the entire standard but for compliance not to be mandated until June 2014 when only stock-in-trade provisions will apply.

Conclusion

The NZFGC supports:

- the extension of the interim standard for tutin in honey and comb honey to 31 March 2015 to ensure the ongoing protection of consumers while research and data collection continues on tutin
- the technical correction to the commencement date and nomenclature of ‘tocopherol concentrate, mixed’
- the amendments proposed relating to Standard 2.9.5 concerning the amendment to Standard 1.5.1 and clarification of the exemption from pre-market assessment for novel foods in food for special medical purposes but with allowance for use of a novel food in foods for special medical use to be considered a factor in assessing a ‘history of safe use’ for the general food supply.

The NZFGC supports the earlier than planned commencement of Standard 2.9.5 but suggests that compliance with the provisions not be mandatory until June 2014 to allow existing products the time to transition to the new requirements while at the same time facilitating the entry to the market of a range of new products.