24th March 2016

Food Standards Australia New Zealand

PO Box 10559

The Terrace WELLINGTON 6143

NEW ZEALAND

Via email: submissions@foodstandards.gov.au

Thank you for the opportunity to provide our submission on the

Proposal P1024 - On the Revision of the Regulation of Nutritive Substances and Novel Foods

Comvita Ltd. is a global, natural health company committed to the development of innovative products, backed by ongoing investment in scientific research. Comvita are the world leaders in Manuka honey and fresh-picked Olive Leaf Extract, which are at the core of the Comvita product range.

Please find our submission below.

If you require any further clarification or information on the below points, please feel free to contact [redacted] at regulatory@comvita.com

Kind regards,

[redacted]

Regulatory Affairs Advisor
Comvita New Zealand Ltd.

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SUBMISSION

Proposal P1024 – Revision of the Revision of the Regulation of Nutritive Substances and Novel Foods

Comvita understand that the purpose of this proposal is to call for views on the development of an improved framework for the regulation of nutritive substances and novel foods. This proposal has been developed as the current definitions for novel foods and nutritive substances are unclear and generating uncertainty for food businesses. The definitions are not effectively achieving their intended purpose.

Comvita **supports Option 3, the development of an alternative framework** which will be used to identify foods that do not require pre-market approval (eligible foods) and which will use a risk-based assessment regimen for non-eligible foods.

Comvita are supportive of a system which protects consumers, provides clarity for industry and supports innovation without undue regulatory burden.

We look forward to a more detailed FSANZ proposal for an alternative framework, including guidance on the gateway tests and as well as tools and guidance for the requirements for self-assessment and notification.

Section 3 Risk Assessment
1) How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?
As a food and natural health business investing in innovation, the current definitions for novel food and nutritive substance create ambiguity regarding the permissions of certain types of foods and nutritive substances that can be marketed, thus hindering innovation projects due to lack of clarity.
2) Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems
We agree with the problems with the current definitions as outlined in the assessment summary. We believe there are further problems with the current definitions, in particular the term '*history of human consumption*' under the definition for non-traditional food is ambiguous due to lack of a quantitative description for the term '*history of*'. In addition to the ambiguity of the above term, a problem with current definition for *non-traditional food* is the specificity that the '*history of human consumption*' would have to have been demonstrated in New Zealand and Australia in order for a food to be regarded as traditional or not (as in not non-traditional). We agree that for a food to be not non-traditional, a history of safe

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human consumption should be demonstrated, however the definition should include population groups from outside of New Zealand and Australia and cover the variety of foods that they eat.

We agree with the proposal for the safety of eligible foods, under Eligible Food Criterion 2 that evidence for 'a history of safe consumption in countries other than Australia and New Zealand should be held, when relevant, to inform the safety of an eligible food' and that a 'history of safe consumption' is defined as described in Supporting Document 2 of P1024, Page 4, Section 2.2, paragraph 5:
"A substance would be considered to have a history of safe use as a food if it has been an ongoing part of the diet for at least three generations in a large, genetically diverse human population where it has been used in ways and at levels that are similar to those expected or intended in Australia and New Zealand".

3) Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in the assessment summary? If so, describe the problems
No comment on this point.

Section 4.2: Options outlined by FSANZ
Option 1: Status Quo
1) Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.
No comment on this point.
2) Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.
Addressed in question 2, section 3 – Risk Assessment (above)
Option 2: Amend the current definitions
3) Do you support amending the definitions of 'novel food' and 'used as nutritive substance' in the Code? Is so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2
No, we do not support amending the definitions of 'novel food' and 'used as nutritive substance', rather we **support option 3 the development of an alternative framework**, provided the alternative framework: • Where consumer safety is a priority • Fosters, rather than hinders, innovation • Allows for the protection of commercially sensitive information • Has no undue regulatory burden

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Option 3: Develop an alternative framework
Eligible Food Criteria Questions
4) Are the EFC appropriate for identifying foods that do not need regulatory approval?
Yes, we agree that the following 'Eligible food criteria' are appropriate for identifying foods that do not need regulatory approval. 1) Microorganisms are eligible if they are listed in the Standard and are cultured to maintain genetic stability 2) Animal food and plant commodities are eligible if they are included in the list of food classes. Animal food commodities and plant commodities included in the list of food classes are also eligible if they are physically fractionated, fermented (using microorganisms that meet criterion 1) and/or physically processed. 3) Extracts are eligible if they are prepared from foods described in criteria 2 when added to processed foods where the total level of the *naturally occurring* and added components in the target food is no higher than that present as if the source food or a product described in criteria 2 were added to the target food. 4) Subject to criterion 2, substances are eligible if they are obtained from animal commodities when added to processed animal commodities from the same food class, or if they are obtained from plant commodities from the same food class provided that the concentration of the total of the naturally occurring and added substance is within the *natural range.* We agree that there may be a continuum between *extracts* and *substances* and so take the view that a clear definition be described, we also agree that the distinction between extracts and substances be maintained. Although we agree that the above eligible food criteria are appropriate, we are however are looking forward to clarification on the following: - Guidance on the requirements for microorganisms that are 'cultured to maintain genetic stability' - the definition of *natural range* as used in eligible food criteria 4
5) Are there foods that may meet the EFC that you consider should be the subject to pre-market assessment? If so, please describe the properties of these foods.
No comment on this point.
6) Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.
No comment on this point.
7) What type of information should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this would support safety.

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For 'new' eligible foods
8) Are the exclusions to the EFC appropriate in identifying foods that should be subject to premarket assessment, despite otherwise meeting EFC?
Yes, we agree with the two exclusions from the EFC, as set out in supporting document 3. However, we are looking forward to clearer guidance on how 'the potential for pharmacological effects at the intended levels of consumption" will be defined and described.
9) What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? *See SD3 for discussion on this issue.*
Consumer safety must be kept a priority at all times. With this in mind, we think that rather than defining what would constitute a '*reasonable potential*' for food to have pharmacological effects, we propose that the definition 'nourishment' and 'maintenance of life' be clearly described. For example, nourishment could be potentially defined as "a food or food component(s) which may be necessary for, or have the capacity to, support or maintain normal and healthy bodily functions." Thus any **new** food that has the capability of exerting any actions beyond supporting normal and healthy bodily functions, would be considered higher risk and therefore required to undergo pre-market assessment. Comvita understand that there are complexities in determining the appropriate regulatory status of certain products, and look forward to seeing FSANZ take a reasonable approach when defining this exclusion.
Draft framework Questions
10) Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?
Yes, we agree that investigating an alternative approach to regulating nutritive substances and novel foods in the code is a viable option.
11) In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework are viable or not viable. Please provide supporting statements for your view.
Yes, in general, Comvita agree that option 3 is a viable option. With the exception of the publication of full dossiers which may contain proprietary information under the self-assessment and notification option for non-eligible foods. We appreciate that the purpose of dossier publication is to provide an element of transparency and give consumers confidence in the safety of these foods. However, the requirement to publish potentially commercially sensitive information is disproportionate to the intention which is to offer consumer protection. We strongly

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agree that there should be an option such that commercially sensitive information is only provided to the authorities, rather than included in a publically available dossier.

12) Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?

Foods or food components which have already received approval in other jurisdictions (e.g. EU Novel foods and FDA GRAS)
Foods which can be demonstrated as having substantial equivalence to an existing food.
https://www.food.gov.uk/sites/default/files/multimedia/pdfs/seguidelines.pdf
https://www.food.gov.uk/science/novel/assess

13) Please provide details of how a self-assessment pathway may or may not provide benefits to industry

We agree that a proportionate approach should be taken to reflect the varying levels of risk on the safety of consumers from food consumption. The self-assessment pathway itself would be beneficial as a level of accountability for the safety of a low-risk non-eligible foods will be held across industry, without the undue burden of pre-market approval. The self-assessment pathway could have the potential to lift the credibility of the industry as a whole, as well as encouraging innovation in the food arena. However, in order to maintain credibility and to ensure consumer protection, clear tools and guidance are required to ensure consistent understanding and application of the assessment pathway.

14) Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.

Comvita believes that a notification system and immediate availability of dossiers on request meets the regulatory requirements that offers the desired level of consumer protection. Whilst we are in support of having a dossier available for inspection, we are opposed to the publication of this information as we do not believe this is helpful to consumers, nor offers businesses protection of potentially commercially sensitive information. Consumers need to have trust in the regulatory system behind food production and advertising, however providing highly detailed scientific information is overly complex and therefore could be misleading for consumers not sufficiently trained to interpret the information. We strongly agree that there should be an option such that commercially sensitive information is only provided to the authorities, rather than included in a publically available dossier.

Section 4.3: Draft framework – other considerations

1) Can you identify any negative impacts that may result from combining the regulation of novel foods and nutritive substances (other than vitamins and minerals) that may occur under a graduated risk approach? Please explain these impacts.

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No comment on this point.

Section 6.2: Exclusive permission for brand and class of food
1) Do you support retain the provision to grant exclusive permission In the Code for foods approved by FSANZ? Please provide reasons for your view
Yes, Comvita supports retaining this provision wherever possible to recognise the level of time and investment made by a food business to bring a novel food to market. Furthermore we would like to see the exclusivity period increased to align with other jurisdictions, for example the EU Novel Foods system offers data protection provisions are also included in the new Regulation - newly developed scientific evidence and proprietary data will not be able to be used for the benefit of another application for 5 years after the novel food has been authorised.
2) Can you identify any issues that may arise if exclusive permission are available for FSANZ approved foods (with permission provided in the Code), but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?
No comment on this point.

Section 7.1: Proposed Transition Period
1) Do you support a cut-off date? Please provide reasons for your view.
Yes, we support a cut-off date. Cut-off dates eliminate ambiguity.
2) Do you see a need for grandfathering provisions? Please provide reasons for your view.
Yes, grandfathering provisions eliminate regulatory burden on foods that were eligible to be put on the market at that time.
3) Do you see a need for a stock in trade provision? Please provide reasons for your view.
We agree that a stock-in-trade provision may not be required depending on the nature of the grandfathering provision.

Section 7.2: Implementation

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1) Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development any future standard is likely to take and will therefore be clearly signposted before changes are made to the code.
No, Comvita welcome the proposed 6 month transition period.
2) Do you have any comments regarding the proposal not to allow a stock-in-trade provisions during the transition period?
No comment on this point.
3) Do you have any suggestions as to which peak body should be involved in familiarising industry of the new provisions?
No comment on this point.
4) Do you have any suggestions on how the implementation process could be approached especially with respect to enhancing awareness and understanding of the potential new provisions?
No comment on this point.
5) Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under option 3?
No comment on this point.
6) Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?
No comment on this point.

Attachment C
1) The exclusions make reference to 'reasonable potential' and 'reasonably expected'. FSANZ's intent is to capture foods that are pharmacologically active or have biological activity beyond basic nutrition at the levels they are intended to be used. Can you make suggestions in relation to how such foods might be captured to ensure they are subject to pre-market assessment?
Please see the comments from Question 9 of Section 4.2 'Options outlined by FSANZ' above.

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