

SUBMISSION TO FOOD STANDARDS AUSTRALIA NEW ZEALAND

In response to the Call for Submission on Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods

EXECUTIVE SUMMARY

Submitted by: FoodLegal on behalf of GNT International B.V.

Date submitted: 23 March 2016

Objective of Submission:

The Submitters seek clarification of the definition of nutritive substance, in particular the requirement in Standard 1.1.1 that a substance can meet the definition of “*used as a nutritive substance*” if it has been “*concentrated, refined or synthesised, to achieve a nutritional purpose*”.

The Submitters seek clarification of when a substance is to be regulated as a traditional food ingredient or as being used as a nutritive substance under the new *Australia New Zealand Food Standards Code* (**the Food Standards Code**).

This Submission proposes that a threshold of “*selective extraction*” be expressly included in the definition of when a substance can be found to be “*used as a nutritive substance*”.

This Submission proposes that the threshold of selective extraction ought to extend to other aspects of the Food Standards Code where the term “*concentrated, refined or synthesised*” is used, so as to provide a clearer understanding of when a substance may stop being a traditional food ingredient and instead be regulated (or even prohibited) as a novel food, nutritive substance, or food additive.

The difference in the regulation between a concentrated food ingredient and a novel food, nutritive substance or food additive is significant and can have severe regulatory consequences. If a substance is refined to the point that it stops being a food ingredient under the new Food Standards Code, that substance could be:

- prohibited from use;
- restricted on what categories of products it can be added to;
- restricted on the quantity in which it can be used; and
- declared differently in a statement of ingredients.

The Submitters believe that there would be benefits to all stakeholders – including consumers, regulators and industry – if the line of concentration or refinement between a traditional food ingredient and restricted substances were clarified within the new Food Standards Code to mean “*selective extraction*”.

Summary of Specific Submissions:

FoodLegal submits that:

- The definitions of “*used as a nutritive substance*” and “*used as a food additive*” in the Food Standards Code ought to be amended so as to include a threshold of “*selective extraction*”.
- It is within the scope of Proposal P1024 to make such amendments.
- There is currently no guidance for industry and regulators as to the level of concentration or refinement where a traditional food ingredient ought to be regulated for being used as either a nutritive substance or food additive.
- Early drafts of the Code Revision included a threshold of “*selective extraction*”, only for the word “*selectively*” to have been removed from the final approved Draft.
- The absence of “*selective extraction*” as a clear, express threshold between traditional food ingredients and substances being used as either a nutritive substance or a food additive has led to unnecessary regulatory actions and placed an unreasonable burden on the food industry.
- FSANZ has publicly stated in stakeholder consultation that “*selective extraction*” is the level of concentration or refinement for a traditional food ingredient to be regulated as being used as a nutritive substance or food additive, but has yet to expressly include this threshold in regulation.
- Amending the definitions of “*used as a nutritive substance*” and “*used as a food additive*” so as to include a threshold of “*selective extraction*” would align with FSANZ principles of: achieving consistency with international regulation; providing clear, objective and enforceable regulations; and avoiding placing undue burden on industry.

Submitters:

Founded in 1986 by Managing Principal Joe Lederman, **FoodLegal** has developed into a leading regulatory specialist firm offering services in food law, regulatory compliance, education and training. FoodLegal advises organisations of all types and sizes from all around the world and throughout Australia. Its clientele includes many of Australia’s most well-known food companies, health and nutrition groups, government agencies, industry bodies, manufacturers, start-ups and many food importers and exporters.

GNT International B.V. is located in Mierlo, The Netherlands and is the Headquarters of the independent, family-owned GNT Group which was founded in 1978. GNT International B.V. manufactures concentrates from edible fruits, vegetables and plants using gentle physical methods such as pressing, crushing and filtering. Artificial additives, chemicals or organic solvents are not used. The concentrates are sold under the EXBERRY® brand name worldwide and are used by the food industry to impart colour to a variety of food and beverage products.

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SUBMISSION

We now make the following submissions in support of our request for industry guidance:

1. Addressing the scope of Proposal P1024

- 1.1 Option 2 of FSANZ Proposal P1024 is to amend the definitions of nutritive substances and novel foods. While it is not FSANZ's preferred option, it is a clear call for submitters to address concerns over the term "*concentrated, refined or synthesised*" and an appropriate forum to consider a regulatory threshold of "*selective extraction*".
- 1.2 This term "*concentrated, refined or synthesised*" is used in one other definition in the Food Standards Code; namely the definition of being "*used as a food additive*". FoodLegal believes that the lack of certainty between a traditional food ingredient and a substance "*used as nutritive substance*" applies equally to the lack of certainty between traditional food ingredient and a substance "*used as a food additive*".
- 1.3 While amending the definition of food additives may prima facie appear outside the scope of Proposal P1024, the amendment of the term "*concentrated, refined or synthesised*" to include a threshold of "*selective extraction*" would be well within the scope. It would perhaps be seen as a waste of resources not to extend the same amendment to the only other place in the Food Standards Code where that term is used; especially such an amendment would achieve the same outcomes of clarity for industry and regulators whilst protecting public health and safety.

We submit that it is within the scope of Proposal P1024 to amend the term "*concentrated, refined or synthesised*" in the Food Standards Code to establish "*selective extraction*" as a threshold between traditional food ingredient and a substance "*used as nutritive substance*" or "*used as a food additives*".

2. The impact of "concentrated, refined or synthesised"

- 2.1 With the introduction of the Code Revision on 1 March 2016, the Food Standards Code was altered to include substances that had been previously defined as being "*other than food*" within the legal definition of "*food*" as found in the application Acts. This means that substances such as nutritive substances and food additives now meet the legal definition of "*food*".
- 2.2 In order to maintain the legal framework where traditional food ingredients are permitted but nutritive substances and food additives are restricted, ingredients are now classified under the new Food Standards Code by what they *do*, not for what they *are*. For example, the permission to use calcium carbonate in a specific product, the quantity in which it can be added and how it must be declared in the ingredient list will depend entirely on whether it is being added to achieve a nutritional purpose or a technological purpose.
- 2.3 In order to restrict the use of substances that are not expressly listed in the Food Standards Code, substances added to perform a nutritional or technological purpose will only be regulated as being "*used as a nutritive substance*" or "*used as a food additive*" if they have been "*concentrated, refined or synthesised*" in order to achieve that purpose. The regulatory threshold between a traditional food ingredient that provides an incidental nutritional or technological purpose and a regulated (or

prohibited substance) is now one of concentration or refinement.

- 2.4 However, the new Code does little to protect the legitimate desire of food businesses to refine or concentrate a food ingredient in order to achieve a technological or nutritional purpose, but **not** have that ingredient regulated (and potentially prohibited) for being “used as a nutritive substance” or “used as a food additive”.

In other words, there is a lack of clarity in the new Food Standards Code as to the level of concentration of or refinement where a traditional food ingredient will stop being a traditional food ingredient and become a regulated one.

- 2.5 Interestingly, during the development of the new Food Standards Code, a proposed draft was released with the 2nd Call for Submissions on Proposal P1025.¹ In this proposed draft, both the definitions for “*used as a nutritive substance*” and “*used as a food additive*” included the following term:

...***selectively*** concentrated, refined or synthesised. [Emphasis added]

From this draft, it appears that the original intention of FSANZ in drafting the new Food Standards Code was to limit the operation of the definitions of “*used as a nutritive substance*” and “*used as a food additive*” to substances that had been selectively extracted. Unfortunately, the word “selectively” is not present in the final approved version of the Food Standards Code.

- 2.6 FoodLegal is concerned by the potential for food ingredients to be incorrectly regulated as either nutritive substances or food additives because they are concentrated or refined food ingredients (but retain the nutritive and aromatic characteristics and are not selectively extracted). In the words of FSANZ in the Call for Submissions:

[I]t has become apparent that these definitions are not effectively achieving their intended purpose. The definitions include ambiguous terms that create uncertainty in the market place. This uncertainty creates difficulties for industry and food enforcement agencies in determining whether particular foods require specific permission in the Code before they can be added to, or sold as, foods.

We submit that there is currently no guidance for industry and regulators as to the level of concentration or refinement where a traditional food ingredient ought to be regulated for being used as either a nutritive substance or food additive.

3. Regulatory actions and industry concern drives need for further clarity

- 3.1 FoodLegal is aware of a number of regulatory actions and outcomes that demonstrate that the lack of clarity over the threshold of “concentrated, refined or synthesised” can lead to inappropriate and unnecessary regulatory action, which is a clear burden on both industry and regulators. Additionally, stakeholder submission

¹ See <http://www.foodstandards.gov.au/code/proposals/Documents/P1025-Code-Revision-AppR-Attach-C.pdf>

on the Code Revision demonstrate clear industry concern over the term “concentrated, refined or synthesised” where it appears in the Code.

3.2 The Advisory Committee on Novel Foods (**ACNF**) has previously made some interesting – and potentially confusing – distinctions as to when substances are either novel foods, traditional or non-traditional foods, nutritive substances or even food additives. FoodLegal acknowledges that the ACNF is an ad hoc body whose decisions are not legally binding. However, this is somewhat of a fallacy as the ACNF members are also regulatory enforcement agents and regulatory enforcement agencies often take regulatory action on the basis of ACNF findings.

3.3 The ACNF has made the following findings:

- The dried powder of African Mango Seed to be a non-traditional food but not a novel food, but the aqueous extract of the same substance to be a novel food.
- An apple polyphenol extract to be a non-traditional food but not a novel food, but then a more concentrated and refined apple polyphenol extract to be a novel food due to greater dietary exposure.
- Milk basic protein to not be a novel food but to be a nutritive substance, despite the fact that other isolated nutritional constituents of milk (such as whey protein isolate) are considered traditional food ingredients.
- Luo han guo (or monk fruit extract) to be a traditional food ingredient when only concentrated to contain 5% mogroside content; but separately on two occasions to be regulated as a food additive when concentrated or refined to contain a high level of mogrosides.
- On two separate occasions, a white kidney bean extract was found alternatively to be a novel food and then a non-traditional food but not a novel one.

In all cases, a threshold of “selective extraction” would have provided the ACNF, industry and regulators with a firmer idea of the regulatory principles being applied in distinguishing between the different substances mentioned above.

3.4 In terms of the dividing line between traditional food ingredients and food additives, in 2008 the Australian Quarantine and Inspection Service (**AQIS**) found the extract of safflower to be a non-permitted food additive as opposed to a permitted vegetable extract or concentrate. In this specific case the safflower extract was used for the purpose of colouring. Due to fact that this safflower extract was processed with physical processes, and that the pigments were not selectively extracted in relation to the nutritive and aromatic constituents, and the safflower extract retained the characteristic properties of the source material, the safflower extract should have considered to be a permitted food ingredient.

The AQIS finding that the product was a failing food and subsequent refusal of entry into Australia led to several policy decisions and risk assessments, until it was confirmed by authorities that this safflower extract was clearly classified as a food ingredient and not as a non-permitted food additive. In the meantime, the usage of safflower extract for its colouring properties (but where colouring pigments are not

selectively extracted) as a traditional food ingredient remains common practice in Australia and New Zealand.

- 3.5 Even though this decision was made prior to the new Food Standards Code, the new definition of “used as a food additive” could equally apply in these circumstances because the ingredient has been “concentrated, refined or synthesised” and could also be viewed by a regulator to be a non-traditional food. If there had been a threshold of “selective extraction” between traditional food ingredients and nutritive substances or food additives, this regulatory action and significant industry fallout would have been avoided.

We submit that the lack of “*selective extraction*” as a clear, express threshold between traditional food ingredients and substances being used as either a nutritive substance or food additive has led to unnecessary regulatory actions and placed an unreasonable burden on the food industry.

4. FSANZ views expressed on selective extraction

- 4.1 In addition to the earlier draft of the Food Standards Code where selective extraction was expressly included as a threshold, FSANZ has elsewhere publicly stated its view. In 2009 FSANZ proposed to amend the definition of food additive in Standard 1.3.1. In Proposal P1008, FSANZ stated that:

This revision to the definition of a ‘food additive’ aims to clarify that certain substances would not typically be considered food additives. These substances are specified to include:

[...]

*Substances derived from foods through physical, enzymatic or mechanical processes (e.g. juicing, cooking) provided that these processes do not result in the **selective extraction** or **selective production of a specific chemical substance** that has a technological function in food. [Emphasis added]*

While this specific revision to the Food Standards Code did not progress as part of Proposal P1008, it is clear that FSANZ held the view that selective extraction was a key threshold in distinguishing between a food ingredient and a food additive.

- 4.2 In 2014, as part of the stakeholder consultation on the Code Revision, industry raised several concerns over the term “*concentrated, refined or synthesised*”. For example, the Brewers Association of Australia and New Zealand submitted:

The new definition fails to recognise the nuances between concentrated or refined substances that are generally recognised to be safe as unstandardized food ingredients, despite being used to perform food additive type technological purposes, and those that are considered to be food additives.

In response, FSANZ stated:

*It is acknowledged there is a small group of foods that have a traditional use in brewing, whether the concentrated or refined foods perform a technological function, eg extracts of coloured malt used in colouring, or clouding agents derived from yeast or pectin. FSANZ considers that **such products are***

*ingredients as they are not **selectively concentrated or refined** to perform a technological function, although they can perform a range of functions related to colouring and flavouring. [Emphasis added]*

- 4.3 A submission by the Beverages Council raised the issue that:

... fruit or vegetable juice sometimes used as a colouring agent would no longer be permitted as a colouring agent under the new definition. The new term 'any substance that has been selectively concentrated or refined or synthesised' has made the situation even less clear and the impact much wider to potentially include ingredients/substances that have never been considered food additives.

FSANZ responded to say that:

[T]he fruit or vegetable juice would not be prohibited in the manner suggested as fruit juice is a food itself and is not a substance that has been concentrated, refined or synthesised to perform a technological purpose. It is simply a food ingredient that incidentally performs a technological purpose.

***The term selective indicates** that the process of concentration, refining or synthesis is a selective process that has the purpose of providing a substance that can perform a technological purpose. [Emphasis added]*

- 4.4 As FSANZ is not an enforcement agency and did not pass the “selective extraction” threshold into law, any enforcement agency still has the discretion to interpret the term “concentrated, refined or synthesised” in a much broader fashion, thus placing an unreasonable burden on industry.

We submit that FSANZ has publicly stated in stakeholder consultation that “selective extraction” is the level of concentration or refinement for a traditional food ingredient to be regulated as being used as a nutritive substance or food additive, but has yet to expressly include this threshold in regulation.

We submit that the definitions of “used as a nutritive substance” and “used as a food additive” ought to be amended so as to include a threshold of “selective extraction”.

5. The classification of food extracts with colouring properties in the EU and defining the term “selective extraction”

- 5.1 Within the EU there are guidance notes which define the term “selective extraction”. The benefit of this EU classification system is that it does not prevent innovation and improvement of food ingredients, but instead delivers a definition of the term “selective extraction” and a clear line between traditional food ingredients and substances being used as food additives.
- 5.2 In November 2013, the European Union (**EU**) introduced *Guidance notes on the classification of food extracts with colouring properties*.² This document provides guidance for classifying food extracts or concentrates as either colours (food additives) or foods with colouring properties (so called Colouring Foods). This classification for both types acknowledges the purpose of these ingredients is

² http://ec.europa.eu/food/safety/docs/fs_food-improvement-agents_guidance_additive-eu-rules.pdf

primarily to provide colour into a food product. However, any particular ingredient will only be classified as a Colouring Food or a food additive depending on the source material and processing (i.e. was the product is selectively extracted or not).

- 5.3 Based on the criteria of the EU Guidance notes, those colouring products which have been manufactured from a source material which is a food or a characteristic ingredient of food and which are extracted in order to deliberately retain characteristics similar to the original source material can be classified as Colouring Foods. In order to determine whether sufficient properties of the original source material have been retained, the Guidance note includes an Enrichment Factor Formula which sets a threshold of the term “*selective extraction*” whereby Colouring Foods – while refined or concentrated – proportionally maintain the nutritive and aromatic properties of the source material. This principally requires that the finished colouring product is a scientifically recognisable extract from its source material.

We submit that amending the definitions of “*used as a nutritive substance*” and “*used as a food additive*” so as to include a threshold of “*selective extraction*” would align with FSANZ principles of: achieving consistency with international regulation; providing clear, objective and enforceable regulations; and avoiding placing undue burden on industry.