FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 3

Eligible Food Criteria – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

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1 Introduction

FSANZ has developed objective criteria to identify the types of **new** foods that should or should not be subject to pre-market assessment before they are sold to consumers. The criteria were developed in recognition of the current difficulties in adequately defining nutritive substances and novel foods in the Code. FSANZ has attempted to clearly identify those foods that are known or evidenced to be low risk. That is, as part of a potential alternative approach to addressing the regulation of nutritive substances and novel foods, FSANZ is suggesting that more objectivity can be achieved by identifying foods for which the risk is known to be low and can be managed without requiring pre-market approval by FSANZ. The role of the eligible food criteria in a graduated risk approach is described in more detail in section 4.2.3 of the assessment summary.

The criteria have been termed 'eligible food criteria' for the purposes of this report. FSANZ's intention, under the framework of a potential alternative approach, is that foods (subject to certain exclusions) that meet at least one of the eligible food criteria should be able to be sold to consumers as long as other general requirements for the sale of food are met (for example, other requirements in the Code and general requirements to supply safe and suitable foods as set out in jurisdictions Food Acts). Conversely, foods that do not meet any of the eligible food criteria should undergo some form of pre-market assessment before they could be sold to consumers. Under the framework of a potential alternative approach, the eligible food criteria would be included in the Code.

This document provides detail on how the eligible food criteria were developed and provides examples of foods that FSANZ considers would or would not meet each criterion (section 2). A full list of eligible food criteria is included in section 3. The Appendix lists a number of examples of how a particular food and its derivatives could be considered eligible against each of the criteria (except criterion 1 which is specific to microorganisms).

2 Development of eligible food criteria

The eligible food criteria were developed as an initial risk management measure to limit or prevent foods of unknown risk entering the food supply without appropriate pre-market assessment, while also ensuring that known low-risk foods new to the market can be sold to consumers without undue regulatory requirements. The views of the FSANZ Advisory Committee on Novel Foods (ACNF) and its predecessor, the Novel Foods Reference Group (NFRG), provided an important platform on which to base FSANZ's development of eligible food criteria. FSANZ also noted data on food incidents, food recalls and international rejections of novel food applications in its consideration of potential risks associated with foods.

The ACNF/NFRG essentially performs a risk profiling role in relation to new foods that are intended to be supplied on the market in Australia and New Zealand. The eligible food criteria capture the type of foods considered by the ACNF/NFRG not to require additional assessment under the pre-market assessment requirements of Standard 1.5.1 – either because these foods were traditional in Australia and New Zealand, or no safety concerns were identified to warrant additional assessment. The criteria also reflect a more general understanding of foods including that certain processes applied to foods have a long history of use and as such are not likely to increase risk associated with new foods.

Conversely, the ACNF/NFRG also identified foods that required pre-market assessment to ensure their safety for consumption before being sold to consumers. The eligible food criteria are therefore also intended to ensure that non-eligible foods of concern are readily identified and are subject to pre-market assessment before they are sold to consumers.

FSANZ also considered that foods bearing certain characteristics should be excluded from consideration under the eligible food criteria. These exclusions recognise that some foods that would otherwise meet certain eligible food criteria should not be considered eligible because they warrant additional assessment to ensure they are safe for consumption before they are sold.

A summary of the views of the ACNF/NFRG is provided in Table 1.

Table 1: Summary of ACNF/NFRG views

Category	Total	Not novel		Novel
		Traditional	Non-traditional	
Whole	74	32	31	11
Minimally processed	65	14	36	15
Extract	14	4	7	3
Substance	41	6	6	29
Microbiological	8	5	2	1
Process	1	1	0	0
Other	5	0	3	2
		(62)	**(85)**	
	208	**147**		**61**

The reasons for the ACNF/NFRG considering a food as not novel or novel were analysed in order to assist in the development of eligible food criteria. Sections 2.1 to 2.5 include discussion of these reasons. However, as noted in Table 1, a 'process' and five 'other' categorised foods were considered by the ACNF/NFRG; these did not fit neatly within the other categories of relevance to the eligible food criteria; these are discussed briefly below.

The ACNF/NFRG provided a view in relation to only one processing technique (high pressure processing). However, other than basic processing techniques discussed in section 2.2.3, FSANZ does not propose to regulate new processes under the framework of a potential alternative approach to regulating nutritive substances and novel foods. The ACNF/NFRG considered five foods categorised as 'Other' in Table 1. Three of these foods, (bentonite clay, birds nest and diatomaceous earth) were not considered to be 'novel' by the ACNF. However the remaining two foods (blackberry roots and leaves and dried bark from slippery elm) were considered novel. FSANZ has not developed criteria relating specifically to these types of foods. The criteria developed by FSANZ mean it is likely these types of foods would not be eligible and would require additional pre-market assessment of safety, at least to the level provided by the ACNF process, before safety can be assured.

More detail on the development of the criteria and the exclusions is provided below.

2.1 Eligible Food Criterion 1: Microorganisms

Eligible food criterion 1

Microorganisms are eligible if they are listed in the Standard (in the Code) and are cultured to maintain genetic stability.

The use of microorganisms as food or ingredients in foods is specifically addressed in only a limited sense in the Code.

Infant formula, infant foods and some dairy commodities in Chapter 2 of the Code are permitted to contain lactic acid producing microorganisms, without further clarification on particular species. The novel food standard is also potentially relevant for some microorganisms, but only if they are considered to meet the definition of novel food, which is subject to the uncertainty described in section 2 of the assessment summary. The ACNF has received only eight enquiries that related to the use of microorganisms as food. In general, these enquiries related to the use of microorganisms as probiotics. Under an alternative regulatory approach, FSANZ considers that specifically addressing the use of microorganisms (as food) in the Code would provide greater clarity and certainty than exists currently.

Due to the small number of enquiries to the ACNF/NFRG for opinions on microorganisms FSANZ has approached the development of an eligible food criterion for microorganisms differently than for the other types of foods described in the following sections of this document. FSANZ proposes to develop a list of microorganisms with a known history of safe use to harmonise risk assessment and focus the need for pre-market approval on the biological agents with the greatest risks or uncertainties. This approach is consistent with that taken by the European Food Safety Authority (EFSA) in developing a list of microorganisms with a Qualified Presumption of Safety (QPS). Organisms listed in the QPS are not required to undergo additional safety assessment in the EU when determining their safe use in food, as long as the intended use is in accordance with the basis for the listing in the QPS and any conditions associated with the QPS are met.

The risk assessments undertaken by EFSA for microorganisms listed in the QPS are applied to a defined taxonomic group (e.g. species) and based on four pillars: (i) establishing the identity of the taxonomic unit; (ii) body of knowledge of the taxonomic unit with regard to history of use, clinical aspects, industrial use and other factors; (iii) possible pathogenicity and safety concerns; and (iv) end use. FSANZ is proposing to use the QPS list as the basis for a specific list of microorganisms to be included in the Code as part of an eligible food criterion. The QPS list itself would not be referenced in the Code because the QPS includes other uses of microorganisms that are not regulated by the Code (such as animal feed and plant protection).

FSANZ considers it important to specify that microorganisms must also be cultured to maintain genetic stability in order to be considered eligible foods. This will assist in ensuring that the microorganism listed as an eligible food maintains the characteristics that were assessed by EFSA in arriving at a qualified presumption of safety. Other aspects of the QPS process may also need to be attached to this criterion, such as demonstrating that microorganisms do not produce toxins and do not carry acquired antimicrobial resistance genes.

New microorganisms not included in the list of eligible microorganisms would need to undergo a form of pre-market assessment before they could be sold as food or added as ingredients to foods (see section 4.2.3 of the assessment summary for more information on pre-market assessment under an alternative regulatory approach). More information on the safety considerations of microorganisms is included in Supporting Document 2.

FSANZ has not developed a list of eligible microorganisms at this 1st call for submissions stage of the Proposal, but will follow the principles discussed above if this graduated risk approach is to be further developed as this Proposal progresses.

2.2 Eligible Food Criterion 2: Animal and plant commodities

Eligible food criterion 2

Animal food commodities 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** (including chopping, cutting, peeling, grinding, squeezing, pressing, steeping, infusion, filtering and dehydration).

2.2.1 Whole foods

The majority of whole foods considered by the ACNF/NFRG were not considered to require additional pre-market assessment before they could be sold as food in Australia and New Zealand (Table 1). Whole foods, in this context, are animal and plant commodities that have not been processed (for example, fruits and vegetables, grains and dried herbs, algae and fungi).

Other than the novel food standard (and foods derived from genetic modification and irradiated whole foods), the Code does not include requirements for whole foods to undergo pre-market assessment before they can be sold. The second eligible food criterion reflects a general acceptance that the composition of most whole foods is likely to be low risk for human consumption. This criterion is also supported by the existence of other regulatory controls in the Code that mitigate the majority of potential risks associated with whole foods.

Of the 74 whole foods considered by the ACNF/NFRG, only 11 were regarded as novel. More than half of these (6) were herbs and fungi that had potential pharmacological properties (including weight loss – see section 2.5 for discussion of these properties in the context of the eligible food criteria). The remaining five whole foods were regarded as novel on the basis of their composition, potential for pharmacological effects or from observed adverse effects associated with consumption. Two of these foods may have contained potentially toxic components including a neurotoxin (gingko nuts) and cyanobacterial toxins (algal source); and three foods had either the potential for adverse effects in some population groups and/or a lack of knowledge or available data to establish safety. It is not possible to establish that a food is likely to be safe when there is little supporting information available (for example, compositional data) and the food does not have a significant history of safe consumption as a food in Australia, New Zealand or other countries.

Based on ACNF/NFRG considerations, fungi and algae may present a higher risk than other whole foods and have been excluded from this criterion (they are not included in the food classes identified in section 2.2.2). The use of some foods in a medicinal context (as either traditional medicines or contemporary supplements), which may be suggestive of potential pharmacological effects, is also a property of foods that has been excluded from the eligible food criteria (see section 2.5).

Although most other whole foods are of known low risk, the whole foods identified by the ACNF/NGRG to be novel highlights that there may be potential for adverse effects from a small number of these foods that would otherwise be considered eligible to be sold without pre-market approval. For example, ackee fruit is a whole food that was considered novel by the ACNF/NFRG because it is toxic if consumed before it is ripe however; it would meet eligible food criterion 2.

FSANZ considers that food businesses should therefore be required to hold information to support the safety of foods that meet any of the eligible food criteria. If an eligible animal or plant commodity that is a whole food contains a known toxin or other unsafe component, the toxin or unsafe component should be managed to ensure safety of the food when it is sold. This may be achieved by removing or reducing the components before sale, or providing appropriate instructions for use or preparation with the food when it is sold. The information that food businesses should hold would need to adequately address such risks and how they have been mitigated. A history of safe consumption in countries other than Australia and New Zealand should also be held, when relevant, to inform the safety of an eligible food. If a food business cannot satisfactorily show that their eligible food is safe, based on these basic information requirements, the food should not be sold as an eligible food. The requirement for food manufacturers to hold basic information to support the safety of eligible foods would be included in the Code. This concept is discussed in the assessment summary (section 4.2.3.1).

Biofortification is an area that may require additional consideration in the context of the eligible food criteria for whole foods. Biofortification is a relatively new development that FSANZ considers could utilise a range of processes to intentionally enhance the nutrient composition of animal and plant commodities. For example, biofortification processes may include conventional breeding of selective traits, the use of fertilisers and other chemicals in farming to promote growth of crops with certain nutrient profiles and the use of nutrient-enhanced feeds (such as providing omega fatty acid rich feed to chickens to produce eggs with preferred omega fatty acid content). Biofortification is distinct from the direct addition of nutrients to food. FSANZ recognises that biofortification is currently utilised in the production of some animal and plant commodities and considers biofortified whole foods should be considered eligible foods in keeping with the eligible food criterion for animal and plant commodities. FSANZ acknowledges that eligible biofortified foods may require specific data requirements to be held by food businesses, in addition to the basic information requirements described in the previous paragraph, to support their safety. However, these have not been developed at this stage.

Examples of animal and plant commodities considered by the ACNF/NFRG and how they may be considered in relation to the eligible food criterion are included below.

Example: Eligible animal or crop commodities

The ACNF/NFRG considered a number of Australian and New Zealand native foods that would meet this criterion. These native foods have varying levels of consumption dating back several generations, through to more recent niche marketing. These native foods are not prohibited or restricted by Standard 1.4.4. A food business supplying these foods would need to hold basic information to support the safety, which could include information on safe history of consumption and compositional information (noting that the detail of information requirements to support the safety of eligible foods is yet to be developed). Examples of these native foods include anise myrtle, lemon myrtle, akudjera (bush tomato), finger lime and Illawarra plum.

Example: Foods that would not meet requirements for eligible foods

Dieffenbachia amoena is an indoor plant that was intended to be imported to Australia for consumption. However, the ACNF highlighted that the plant did not have a history of safe human consumption and there were reports of potential hallucinogenic effects associated with ingestion of the plant. Therefore, the ACNF considered *D. amoena* to be a novel food that required pre-market assessment.

D. amoena may be unlikely to be considered to belong to one of the classes of plant commodities listed in Table 1 below, so may not meet eligible food criterion 2 (listed below in blue box under Table 1). Regardless, *D. amoena* would not meet the basic safety information requirements that food businesses would need to hold for eligible foods they supply for sale. Although the detail of these information requirements are still to be developed by FSANZ, the lack of a history of safe human consumption and the potential for hallucinogenic effects are the type of issues that would need to be addressed by food manufacturers before supplying a food that may otherwise meet the eligible food criteria.

2.2.2 Food classes

The ACNF/NFRG has considered several enquiries that relate to novel sources of food (such as sheep's wool, deer horn velvet and the bark of trees). The ACNF/NFRG were often concerned at the lack of a history of safe consumption of whole foods, extracts and substances derived from these sources, coupled with uncertainty in relation to their composition and potential impact on health. The concerns created uncertainty in relation to safety for human consumption, with the ACNF/NFRG not able to establish safety without additional data and assessment.

Food classes will be defined to ensure that eligible foods are those foods that are, or are sourced from, classes of foods that are well understood in terms of human consumption. Criteria 3 and 4 are linked to criterion 2, so that only foods meeting criterion 2 can be used as sources of extracts or substances that can meet criteria 3 and 4. Foods that do not fit within the food classes will not be considered eligible; they will require pre-market assessment. FSANZ considers that new algal and fungal sources of foods should be subject to pre-market assessment due to potential for these sources to produce toxins; therefore algae (including seaweed) and fungi are not included in the food classes attached to criterion 2.

The food classes are proposed to be based on those listed in Schedule 22 of the revised Code (Schedule 4 of Standard 1.4.2 – Maximum Residue Limits of the current Code), which reflect the major animal and plant commodities that are produced for food. FSANZ recognises that these food classes may need refinement if the graduated risk approach is developed further during this Proposal, particularly to take account of potential dietary exposure to extracts and substances derived from these foods. The Schedule 22 food classes are listed below in Table 2.

Table 2: Food classes

Mammalian meat products (meat, edible offal, fats)
Mammalian milk products[1]
Poultry (meat, edible offal, fats)
Eggs
Fish (freshwater fish, diadromous fish, marine fish)
Molluscs and other marine invertebrates
Crustaceans
Honey and other bee products (bee pollen, propolis, royal jelly)
Fruit (tropical and sub-tropical, berries and other small fruits, citrus, pome and stone fruits)
Vegetables (brassica, bulb, fruiting, leafy, root, tuber, stalk and stem)
Legume vegetables and pulses
Cereal grains
Grasses for sugar or syrup production
Tree nuts

[1] Mammalian milk products separated from mammalian products as they appear in Schedule 22. FSANZ considers sufficient differences in composition between meat and milk products to create separate food classes.

Oilseed
Seed for beverage and sweets (cacao beans, coffee beans, cola nuts)
Herbs and spices (includes leaves used for tea)

2.2.3 Processed animal and plant commodities

The ACNF/NFRG has considered 65 foods which are obtained by minimal processing of whole foods. Of these, 15 were considered novel. In all cases this opinion was due to their potential for pharmacological effects, including weight management properties. These effects are addressed in the exclusions to the eligible food criteria (see section 2.5). One other food considered under this category was hemp, which is prohibited by Standard 1.4.4. The remaining fifty foods were obtained by minimal processing of whole foods (such as juicing, pulping, grinding, extracting oil or concentrating) and were not considered to be novel.

Eligible food criterion 2 was developed on the basis of these results, recognising that a number of food processing techniques are commonplace and have a history of use in the context of processing whole foods into processed food products. These processes are not considered to increase the risk of foods that would otherwise be considered eligible foods. This assumes that the production of these foods follows appropriate safe food production processes, which are currently required for all foods produced for sale in Australia and New Zealand. Criterion 2 therefore allows for foods that would be considered eligible because they are included in the list of food classes, to retain their eligible status if they are processed in accordance with the listed processing techniques. Schedule 22 (see section 2.2.2 above) also includes more detailed classes of *processed* foods of plant and animal origin. For example, cereal grain milling fractions are listed, including brans and flours. These classes of processed foods could be included in the definition of food classes for the graduated risk approach, specifically as examples of processed commodities identified in criterion 2. However, Schedule 22 does not include detail of all the types of processed foods that FSANZ considers could be included in this criterion. A number of these processing techniques and examples of their use that would likely meet eligible food criterion 2 are described below in Table 3.

Table 3: Processing techniques and examples that would be likely to meet criterion 2

Processing technique	Examples
Physical fractionation	Milling grain to produce flour.
Drying	Drying leaves of *Camellia sinensis* to make tea leaves.
Fermentation	Fermentation of dilute alcoholic liquids to make vinegar (acetic acid).
High Pressure processing	Sterilisation of fruit juice through extreme pressure producing a preservative and additive free drink.
Extraction	Removal of soluble sucrose by water extraction from sugar cane or beet.
Thermal Processing	Effecting sterilisation of canned foods by destroying all microorganisms.
Filtration	Permeate separation from milk by forcing through a screen to retain particles of differing size.
Mixing	Blending of herbs & spices to produce a gourmet rub for meat.
Evaporation	Removal of water from tomatoes to produce tomato paste.
Crystallisation	Changing a liquid into a solid, such as during the production of ice-cream

Some other processing techniques, such as enzymatic processing, are also commonly used in food production. Rennet is an enzyme used to separate milk, producing curds (solids) and whey (liquids) in the production of cheese. Although this is a common process, FSANZ notes enzymatic modification of a new food could alter the characteristics of the food by modifying chemical structure of a component, which may warrant additional consideration of safety. Therefore, other processes have not been included in this eligible criterion at this stage but consideration will be given to broader types of processing following receipt of submissions following the call for submissions

2.3 Eligible Food Criterion 3: Extracts of foods

Eligible Food Criterion 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.

Extracts are often a collection of components. Extracts may be standardised to contain a certain amount of particular components, but this is not always sought after or required. For example, a number of the extracts considered by the ACNF/NFRG were prepared to remove some components of the source food that were not desirable in certain processed food matrices. One such case was an extract sourced from tomato paste, which was prepared to remove the sugar and organic acid components of the tomato, while retaining other water soluble components at proportionately higher levels. The benefit of adding the extract to a processed food was that the extract would contain less sugar/energy than if the tomato paste was used as the ingredient, and proportionately higher amounts of components such as lycopene.

Of the 14 extracts considered by the ACNF/NFRG, three were considered to be novel. One extract was intended to be used for its weight management properties, one had adverse effects in humans and the other contained a chemical that the ACNF/NFRG considered required additional assessment before the product should be sold. The remaining 11 extracts were not considered to be novel. Four of those extracts were considered traditional because there was a history of consumption of the extracts as food in Australia and New Zealand. A soy protein extract (similar in principle to whey produced from milk) and a cranberry fruit extract are examples of these extracts. The ACNF noted that soy protein and cranberries (particularly as juice) have a history of consumption in a variety of foods in Australia and New Zealand. The intended use of the extracts would result in similar levels of the extract's components in the target foods that are within natural variability of commonly available existing soy protein products and cranberry juices. Based on the similarity of composition, the ACNF considered the potential dietary exposure to the components of these extracts was consistent with existing exposure from a variety of commonly consumed existing products.

The remaining seven extracts were considered non-traditional but not novel. The ACNF/NFRG noted that these extracts were derived from food sources. However, unlike the traditional extracts noted above, the ACNF/NFRG did not consider there was a history of consumption of the extracts in the context of being added to foods. The extracts were generally prepared to standardise the content of a particular component or components, and often resulted in the removal of unwanted or undesired components such as sugar (in the case of a lycopene enriched tomato paste) or anti-nutritional factors (such as lectins removed from a white kidney bean extract). The benefit of using the extract in place of the source food as an ingredient was to ensure a certain level of components were present in the target food and/or other components would be reduced or not present.

Some of the extracts contained levels of desired components at comparatively greater levels than were naturally present in the source food. Therefore, the ACNF/NFRG noted there was potential for increased dietary exposure if an extract was used, in place of the source food, as an ingredient of a target food. The ACNF/NFRG considered each of these extracts on a case by case basis, determining whether there was likely to be an increase in dietary exposure to the components of the extract and whether an increase in exposure was likely to present safety concerns. For each of the seven extracts regarded as non-traditional but not novel the ACNF/NFRG did not identify safety concerns associated with the intended use of the extracts, even when there was potential to increase dietary exposure. In contrast, the ACNF/NFRG did identify potential concerns associated with the use of the three extracts that were regarded as novel.

These considerations of the ACNF/NFRG relied on the technical and scientific knowledge and experience of members of the committees to determine whether the potential risk of increased dietary exposure was low or not. FSANZ noted the source of an extract and the potential for increased dietary exposure to components of an extract were important factors to consider in drafting a criterion for extracts. The potential for increased dietary exposure could occur if the source of the extract is not normally consumed as a food or if the components of an extract from a food source are concentrated. In addition to the potential to increase dietary exposure, FSANZ notes that extraction of components from a source that is not normally consumed as a food presents uncertainty in relation to the safety of consumption of these components, irrespective of the levels present in the extract. There is unlikely to be a history of safe human consumption to consider, particularly in a food context, and the composition of the extract may not be well characterised. FSANZ therefore considered it important that the source of extracts is linked to the second criteria to ensure that only extracts obtained from particular classes of foods can be considered eligible.

The dietary exposure considerations undertaken by the ACNF/NFRG were based on the levels of components present in extracts compared to the levels of the components naturally present in the source food (or within a natural range for the source food[2]). The ACNF also considered the intended use of the extract in target foods, in terms of both the levels of addition and the number of different target foods, to provide an indication of the likelihood of potential dietary exposure being greater than exposure in the existing diet from the source food. In the context of developing an eligible food criterion for extracts, FSANZ considers it important to take potential dietary exposure into account. FSANZ considers that if extraction were used as a method of concentrating specific components and adding such an extract to foods would achieve higher levels than would otherwise be contributed by the use of the source food, then that extract would not be considered an eligible food.

The eligible food criterion for extracts links the level of components contributed by the extract to that contributed by the use of the source food in the target food. FSANZ has made this linkage in an attempt to retain an element of practicality and to reduce the likelihood of unrealistic theoretical levels of source food additions to target foods. For example, a food business may theorise that a source food could have constituted 90% of the target processed food and base its compliance with the eligible food criterion on this. However, there may be physical limitations to the practical level of addition of the source food, for example due to palatability, texture or other properties.

Substantiation of eligible food criterion 4 may require evidence of a recipe in which the source food is used as an ingredient, or other physical and technical considerations, to aid determining the eligible level of addition of the extract.

[2] Noting there may be some variation in levels of components naturally present in different varieties of a source food (such as different apple varieties) or due to seasonal factors.

Guidance on this could be developed in future. However, this may also introduce a level of complexity to consideration of whether an extract meets the criterion.

In order for an extract to be considered an eligible food, it must be:

1. sourced from an animal or plant commodity (under criteria 2); and
2. added to processed foods; and
3. added at a level that ensures the concentration of the naturally occurring and added components in the target food is no higher than that present as if the source commodity or a product described in criterion 2 were used as an ingredient; and
4. added at a level that is consistent with practical levels of addition of the source food to the target food.

Components of extracts added to foods at higher levels may not necessarily be unsafe. However, FSANZ has not identified a common value, or factor, of addition of an extract to food above a natural level that would ensure safety in all situations. Under the graduated risk approach, extracts intended to be added to food, but which do not meet eligible food criterion 3 would be subject to pre-market assessment. If this graduated approach is progressed, FSANZ will investigate whether a graduated approach to pre-market assessment can take into account different levels of addition of extracts so that assessment requirements are commensurate with risk.

Examples of extracts considered by the ACNF/NFRG and how they may be applied to the eligible food criterion for extracts are provided below in Tables 4 and 5.

Table 4: ACNF/NFRG considerations likely to meet eligible food criterion 3 for extracts

Product	ACNF view	Rationale
Olive fruit extract	Non-traditional Not novel	Derived from a food source and the total concentration of naturally occurring and added components in target foods is not higher than if olives were used as an ingredient. Extract is standardised for polyphenol content and intended use in target foods would result in exposure to polyphenol content of 12.5 – 50 grams of olives.
Cranberry extract	Traditional Not novel	Derived from a food source (cranberry juice concentrate). Extraction removes sugars and organic solids while retaining phenolic compounds of interest. Intended to be added to beverages, which will result in similar levels of phenolic compounds to existing cranberry juice products. In this case, the ACNF view related only to the addition of the extract to beverages. Use in a wider range of foods or at higher levels may not meet the criterion.
Lycopene enriched tomato extract	Non-traditional Not novel	Derived from tomato paste. Extraction removes water soluble components, such as salt and sugar, retaining water and other components such as lycopene. Level of remaining components comparatively higher than the composition of existing tomato paste products that are commonly used as ingredients in foods. The extract would be eligible if it was added at a level that ensured the concentration of components (lycopene) in target foods would be no higher than if the source tomato paste was used as an ingredient. This may mean the extract would need to be added at a lower level than the source food would have been added (to take account of the comparatively higher lycopene content of the extract).

Table 5: ACNF/NFRG considerations NOT likely to meet eligible food criterion 3 for extracts

Product	ACNF view	Rationale
Deer horn extract	Non-traditional Novel	Deer horn extract is not sourced from a food that would meet criterion 2 so would also not be eligible in this context. In addition, deer horn extract is associated with numerous therapeutic claims, which makes it likely that the extract would also be subject to the exclusion for foods that have potential for pharmacological effects (section 2.5).
Olive leaf extract	Non-traditional Novel	Olive leaf extract is permitted to be used as an active ingredient in complementary medicines in Australia and is associated with therapeutic effects. Therefore, this extract would be subject to the exclusion for foods that have potential for pharmacological effects, which would exclude it from consideration under the eligible food criteria. In addition, olive leaf is not likely to meet criterion 2 because it is not included in a food class identified in Schedule 22 of the revised Code (section 2.2).
African mango seed extract	Non-traditional Novel	African mango seed extract is purported to have weight loss effects at the intended levels of use. Therefore, this extract would be subject to the exclusion for foods that have weight loss properties (section 2.5). In addition, mango seed is not normally consumed as a food in Australia and New Zealand, although there is some history of use in Africa. The intended use of the extract is not consistent with the way in which mango seed has been traditionally used in an African context, where it was made into a paste. Therefore, the extract is likely to result in greater concentration of components than if the seed paste was used as an ingredient.

2.4 Eligible Food Criterion 4: Substances derived from food

Eligible Food Criterion 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 when added to processed 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 in that food class.

Almost three quarters of the substances considered by the ACNF/NFRG were viewed as novel and therefore required additional pre-market assessment before they could be sold to consumers. Generally, substances were considered novel because of possible pharmacological (including weight loss) effects associated with the substance, their potential for increased dietary exposure or because insufficient safety information was available. Some were sourced from non-food products; including sheep wool derived proteins and isoflavones from red clover.

Without further restriction, dietary exposure to substances added to food would generally increase compared to the level which would arise from consuming the whole food because the substance is extracted and refined from a certain food (or is a synthetic counterpart[3]) and added to different foods at a level that is greater than its natural presence in the source food.

The substances the ACNF/NFRG did not consider to be novel were sourced from more commonly consumed foods and were intended to be added to foods in a way that was not expected to increase dietary exposure beyond what would be expected if the source food was traditionally or theoretically used as an ingredient (rather than the substance being extracted and then added). Examples of these substances derived from foods are beta-glucan from barley, beta-glucan derived from *Saccharomyces cerevisciae* (a yeast commonly used in foods), milk basic protein, lactoferrin (derived from and added to dairy products) and potato protein isolate.

The most important aspects relating to the safe use of substances in foods were considered to be:

i) the source of the substance
ii) the intended use of the substance (the type of foods it would be added to and at what levels
iii) the effect of such addition on dietary exposure to the substance from all dietary sources.

The potential for increased dietary exposure resulted from a number of situations considered by the ACNF:

- The substance is present at low levels in foods, but is intended to be added to processed foods at higher levels.

- The substance is present in a limited range of foods and is intended to be added to a greater range of processed foods, potentially also at higher levels.

- The substance is present in a food source, but not in the portion of the source that is generally consumed. For example, a substance sourced from the rind of the fruit when the rind is not normally consumed. The dietary exposure to such a substance is likely to be minimal. Extraction of the substance from the rind and its addition to processed foods is likely to increase dietary exposure to the substance. It may not be known whether increased dietary exposure to the substance is safe.

- The substance is sourced from a non-food source, so that existing dietary exposure from that source is non-existent or at most minimal. Addition of the substance to processed foods would result in increased dietary exposure to the substance, which requires the establishment of safety.

- The substance is a newly synthesised substance that does not have a history of human consumption.

- The substance is a permitted food additive that may currently be added to foods to fulfil a technological function in accordance with Standard 1.3.1 of the Code. However, the novel intent is to add the substance to processed foods for purposes other than technological, which may result in addition at different levels and in a wider variety of foods than currently permitted. This may also result in increased dietary exposure to the substance.

[3] More discussion of synthetic substances is included at the end of section 2.4.

Therefore, eligible food criterion 4 reflects that substances obtained only from animal or plant commodities (criterion 2) could be considered as eligible foods. Furthermore, criterion 4 also refers to food classes, both from which the substance is obtained and to which the substance is added, as a mechanism to take into account potential increases in dietary exposure. In order for a substance to be considered as an eligible food, it must be:

i) sourced from an animal or plant commodity
ii) added to a processed animal or plant commodity from the same food class
iii) added at a level that ensures the concentration of the total of the naturally occurring and added substance is within the natural range in that food class.

These conditions are intended to place a level of control on the potential increase in dietary exposure that may be possible from the addition of substances to foods.

This criterion is also intended to ensure that some common food processing practices may continue to be utilised without the need for additional pre-market assessment. The processing of some foods may remove certain components that are naturally present in foods. It is a common practice to add removed components back into the processed food product to restore them to natural levels. For example, permeate is added to milk to standardise the nutrient (fat, protein, vitamins) levels due to seasonal variation.

FSANZ acknowledges the possibility that some foods within a food class may contain a particular substance at significantly higher levels than the majority of foods within that food class. This higher natural content may be used as a theoretical benchmark level for the natural range of a substance in a particular food class. It is possible that this source food is not commonly consumed in the diet, or is commonly consumed at low levels. It is therefore possible that the use of these 'outlier' sources of substances may result in higher dietary exposure than if more commonly consumed foods within a food class were used as the basis for determining the natural range. It is therefore possible that additional definition of 'natural range' may be required for this criterion (for example, based on compositional percentages).

FSANZ has not provided additional definition of 'natural range' at this stage, however considerations could include limiting the addition of substances to processed commodities at a level that is consistent with the level of the substance that would be present if the source food was used as an ingredient (similar to criterion 3 above for extracts). This may limit the potential for outliers being used to derive a natural range for a food group, but may also be overly restrictive and limit innovation by requiring a higher level of pre-market assessment of simple uses of substances. 'Natural range' could be defined in a way that limits the use of outliers but should not be overly restrictive or limiting of innovation. This issue may need to be investigated further as this proposal progresses, based on consultation with stakeholders.

FSANZ also acknowledges that the addition of a substance to a food at a level that is greater than the natural range is not necessarily going to increase the risk in all situations. The addition of a particular substance at twice the natural level may be safe or unsafe, depending on the substance. FSANZ has not identified a common value, or factor, of addition of a substance to food above a natural range that would be safe in all situations; and applies equally to all substances.

Therefore, criterion 4 refers only to levels of addition that are consistent with the concentration of the substance in a food class as a means of clearly identifying those substances that would be eligible and not require pre-market approval.

A substance that is intended to be added to food, but does not meet eligible food criterion 4 would require additional pre-market assessment. FSANZ will investigate whether a graduated approach to pre-market assessment of non-eligible foods could be incorporated into this potential alternative approach. The level of addition of substances to foods could be a component of a graduated approach to pre-market assessment of the addition of substances to foods that do not meet this eligible food criterion.

FSANZ considers that although the intent of the eligible food criteria for extracts and substances is similar, sufficient differences may exist to require separate criteria (criterion 3 and 4). Substances are generally subject to selective extraction in order to obtain a specific chemical entity and it may not always be apparent from which food a particular substance is derived. Extracts are more likely to be comprised of a collection of components and are more akin to using the source food as an ingredient. Therefore, the eligible food criterion for extracts is tied to the food from which it is derived. The criterion for substances reflects the potential for alternative sources of a substance, but places a level of control over potential dietary exposure by only allowing the addition of a substance to foods within the same class of foods from which the substance is derived.

However, FSANZ recognises there may be a continuum between extracts and substances and that it may be difficult to always distinguish between them, particularly where an extract is quite refined. FSANZ would appreciate stakeholder views on whether the distinction between extracts and substances should be maintained. If these criteria were combined, consideration would need to be given to whether the potential for increasing dietary exposure would be more appropriately addressed by linking the level of addition to the levels naturally present in the source food (as for the extract criterion) or within the natural range of the food class (as for the substance criterion).

The exclusions to the eligible food criteria described in section 2.5 would mean that substances with potential or actual weight loss properties and substances derived from herbs and fungi and foods with potential or actual pharmacological properties would not be considered as eligible foods and would therefore require pre-market assessment.

The eligible food criterion for substances refers to substances obtained from animal or plant commodities. It does not include synthetically produced analogues of naturally occurring substances. FSANZ recognises that some substances naturally present in foods can also be produced synthetically. However, FSANZ believes this issue requires further consideration before synthetic analogues could be included in the eligible food criterion. Additional parameters may need to be developed to ensure that synthetic analogues are identical to their natural counterparts, both in structure, chemical activity and metabolism.

Examples of substances considered by the ACNF/NFRG and how they may be applied to the eligible food criterion for substances are provided below in Table 6. The intended use of many of the substances considered by the ACNF/NFRG is unlikely to meet the eligible food criterion for substances because the intended uses of the substances were often in a broad range of foods. Therefore, the examples provided below have been amended to reflect intended uses of substances in target foods that may or may not meet the eligible food criterion.

Table 6: ACNF/NFRG considerations in context of eligible food criterion 4 for substances

Product	Rationale
Beta-glucan derived from barley	Derived from barley, which is a food source that would meet criterion 2. Would be an eligible food if added to processed cereal grain products (e.g. pasta) if the total beta-glucan content of the pasta product does not exceed the level of beta-glucan present in cereal grains (or processed cereal grains). Would not be an eligible food if added to a class of foods other than cereal grains (e.g. dairy products). Would not be an eligible food if added to processed cereal grain products at a level that would result in total beta-glucan content in the target food that is greater than the level of beta-glucan naturally present in cereal grains (criterion 2) or processed cereal grains (criterion 2, processed).
Keratin from sheep wool	Derived from a source that would not meet criterion 2. Therefore, cannot meet criterion for substances (must be derived from commodity listed in criterion 2).
1, 3 dimethylamylamine (DMAA)[4]	DMAA is a synthetically derived substance and would therefore not meet the eligible food criterion for substances. Only substances derived from animal or plant commodities that meet criterion 2 can be considered eligible.

2.5 Exclusions from eligible food criteria

Although the majority of whole foods were considered low risk, the ACNF/NFRG consistently expressed concerns about foods having potential pharmacological activity, including weight loss properties and phytoestrogenic effects, when consumed. FSANZ has separated consideration of weight loss from other potential pharmacological effects in this document (section 2.5.2). Therefore FSANZ proposes two categories of food which should be considered to be higher risk (and therefore not eligible), regardless of them meeting the eligible food criteria. These are described below.

2.5.1 Exclusion 1: Potential for pharmacological effects

Exclusion 1

Processed or unprocessed animal or plant commodities, including their extracts or substances, which have, or have reasonable potential to have, pharmacological effects at the intended levels of consumption are excluded from being considered against the eligible food criteria and must undergo pre-market assessment.

FSANZ recognises the current challenges in relation to the existing regulatory grey area that exists at the food-medicine interface. 'Therapeutic goods' and 'therapeutic use' are defined in the Australian *Therapeutic Goods Act 1989*. This proposal recognises that the **prospective** regulation of novel foods and nutritive substances could never be so definitive as not to potentially traverse the food-medicine interface from time to time. However, it is also the case that food can contain compounds that may produce effects in the human body beyond the fundamental purpose of food to nourish and maintain life, including pharmacological effects.

[4] More detail on DMAA is provided in a case study in the assessment summary (Attachment B)

Some of these compounds such as phytosterols added to food may reduce the risk to health whereas others that are the subject of this exclusion criterion may potentially increase health risk for some or all of the population through drug-like effects. The potential for foods to have pharmacological effects beyond nourishment and maintenance of life is a characteristic of **new** foods that FSANZ considers may warrant pre-market assessment of safety before such foods should be permitted to be sold to consumers.

FSANZ has considered potential terms to describe or define the type of effects that may warrant pre-market assessment. The ACNF/NFRG has considered a number of enquiries for products that are associated with numerous medicinal or therapeutic effects, either in a traditional medicine or supplement type context. FSANZ considers the type of effects that would warrant pre-market assessment would extend beyond just potential therapeutic effects and would also need to encompass potential adverse effects, such as drug-like effects[5]. The use of a term like 'pharmacological' would address more than just therapeutic effects and extends to other potential adverse effects which FSANZ considers are important to capture. However, there does not appear to be an internationally recognised consistent definition of 'pharmacological' in the literature and using that term may create difficulties or cross-over with other legislation that addresses the regulation of goods with pharmacological properties.

A term like 'biologically active substance' that is used as a labelling term in Standard 1.2.7 – Nutrition, Health and Related Claims may be too broad to adequately capture the type of effects that warrant pre-market assessment. This term is used in a different context in that standard and may capture foods that have properties that FSANZ does not consider warrant pre-market assessment. Therefore, the wording of this exclusion will require further development after consultation with stakeholders.

Over half of the whole foods[6] considered by the ACNF/NFRG to require pre-market assessment were associated with potential or demonstrated therapeutic or other effects. Their potential or demonstrated therapeutic or other effects were associated with either previous medicinal use (traditional and/or current use) and/or with the use of therapeutic type claims about the food. Extracts and substances derived from these foods would also be subject to similar concerns about potential pharmacological effects. Some of the foods considered novel by the ACNF/NFRG had been subject to assessment for safety by the Australian Therapeutic Goods Administration (TGA) for use as active ingredients in complementary medicines. However, approval by the TGA does not mean that a food does not require a safety assessment by FSANZ to determine the safety of consumption of the product in a food context. The use of products in a medicinal context is generally more closely controlled than in a food context. Medicines are subject to dosage instructions and warnings to prevent adverse effects as a result of overdose, interaction with medications, or as a result of use by vulnerable subpopulations such as children or pregnant women. The marketing and consumption of foodstuffs are subject to less stringent control and therefore pose greater inherent risk to consumer safety, particularly for vulnerable subpopulations.

Because the word 'potential' can refer to any level of chance, the intent here is that the potential for adverse effects should be based on evidence that raises a reasonable level of concern, rather than being a theoretical potential only.

[5] For example, the ACNF considered *Dieffenbachia amoena,* which may have potential hallucinogenic properties, in addition to purported medicinal effects.

[6] In this context, animal and plant commodities that have not been processed or have only been minimally processed (for example, fruits and vegetables, herbs, fungi, grains)

Exclusion 1 therefore refers to demonstrated or reasonable potential for pharmacological effects of foods, including extracts and substances derived from foods. The detail of the wording of this exclusion will be further investigated as this proposal progresses. The complexities of determining the appropriate regulatory status of products in the grey area between foods and therapeutic goods will need to be taken into account in considering foods proposed to be subject to this exclusion criterion.

Example: *Rhodiola rosea*

Rhodiola rosea is a herb that is permitted to be used as an active ingredient in complementary medicines in Australia and also has a tradition of use as a medicine in other countries. Based on traditional and current medicinal uses, and the wide variety of purported therapeutic/pharmacological effects associated with *Rhodiola rosea*, and the lack of information available on the safety of use in a food context, the ACNF considered an assessment of safety was required and that *Rhodiola rosea* was therefore a novel food.

Other similar examples considered by the ACNF include *Cordyceps sinensis*, *Ganoderma lucidum*, olive leaf extract, Siberian chaga (*Inonotus obliquus*).

2.5.2 Exclusion 2: Weight loss properties

Exclusion 2

Processed or unprocessed animal or plant commodities including their extracts and substances that have, or are reasonably expected to have, weight loss purpose/properties at the intended levels of consumption are excluded from being considered against the eligible food criteria.

The exclusion does not apply to foods without these properties that otherwise qualify to carry diet, low energy or similar claims, or that are regulated as meal replacements by Standard 2.9.3 or as food for special (medical) purposes by Standards 2.9.5 or 1.1A.6.

A common concern expressed by the ACNF/NFRG related to the purported intrinsic properties of foods, extracts and substances associated with weight loss. Weight loss may be considered a pharmacological effect and could be captured under Exclusion 1 above. However, given the ACNF/NFRG was consistently concerned about potential weight loss effects and issues with the weight loss segment of the market, FSANZ considered a separate exclusion was warranted.

Although weight loss may be desirable for some members of the population, it may not be suitable or desirable for all population subgroups (such as pregnant and lactating women, children or the elderly). In addition, there are a number of potential mechanisms of action for foods and their components to affect body weight. Some may increase metabolism, whereas others may have effects on fluid levels in the body, absorption of other dietary components, appetite suppression and changes to hormone levels. The potential mechanisms of action of weight loss type foods presented to the ACNF/NFRG were often not well characterised or understood and safety could not be established without additional pre-market assessment.

However, this exclusion is not intended to apply to ‘weight loss’ foods such as those having modified macronutrient composition that qualify to carry diet, low energy or similar claims, or that are regulated as meal replacements by Standard 2.9.3 or as medical foods by Standard 2.9.5 (and Standard 2.9.6, which is a New Zealand only standard).

Based on the above concerns, FSANZ considers that all other foods, with potential weight loss properties (or purpose) at the intended level of consumption should not be eligible foods and should be subject to pre-market assessment. Exclusion 2 addresses this intention.

FSANZ has observed a number of recent incidents associated with food products with purported weight loss properties. Some of these incidents relate to misidentified ingredients, adulteration with stimulant type ingredients (or prescription medicines in some cases) and reporting of adverse events associated with consumption of the products. The use of prescription medicines in food is prohibited and this proposal does not address this issue. However, this and other incidents highlight that the weight loss segment of the food market is prone to misuse by some food suppliers. Additional rigour in relation to the safety of weight loss food products, by Exclusion 2, may help to address some of these issues.

Example: Hydroxycitric acid

Hydroxycitric acid (HCA) is extracted from the rind of the fruit of the plant *Garcinia cambogia*. It is marketed as an ingredient that can promote weight loss. The NFRG considered that it did not have a history of consumption because the rind of the fruit of *Garcinia cambogia* is not traditionally considered an edible portion. The NFRG considered HCA should be assessed before it could be sold as a food ingredient and recommended HCA should be considered a novel food. The NFRG was concerned that weight loss may not be suitable for all population subgroups. The NFRG also noted that additional assessment was required on the potential for HCA consumption to impact on other parameters in the human body (including sterol production) which may not be appropriate for pregnant and lactating women or other population subgroups.

3. Summary

The full list of eligible food criteria is compiled below. Under the graduated risk approach presented by FSANZ, new foods that meet at least one of these criteria could be sold in Australia and New Zealand (subject to certain information requirements being held by food businesses).

Eligible food criteria

1. Microorganisms are eligible if they are listed in the Standard (in the Code) and are cultured to maintain genetic stability.

2. Animal food commodities 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** (including chopping, cutting, peeling, grinding, squeezing, pressing, steeping, infusion, filtering and dehydration).

3. Extracts are eligible if they are prepared from foods described in criteria 2 when added to processed foods where the total concentration of the naturally occurring and added components in the target food is no higher than that present as if the source food were used as an ingredient.

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 when added to processed 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 in that food class.

However, if a new food is subject to either of the two exclusions below, regardless of whether it would otherwise meet an eligible food criterion, the food cannot be an eligible food and would be required to undergo pre-market assessment before it could be sold in Australia and New Zealand.

Exclusions to the eligible food criteria

1. Processed or unprocessed animal or plant commodities, including their extracts or substances, which have, or have reasonable potential to have, pharmacological effects at the intended levels of consumption are excluded from being considered against the eligible food criteria and must undergo pre-market assessment.

2. Processed or unprocessed animal or plant commodities including their extracts and substances that have, or are reasonably expected to have, weight loss purpose/properties at the intended levels of consumption are excluded from being considered against the eligible food criteria.

   The exclusion does not apply to foods without these properties that otherwise qualify to carry diet, low energy or similar claims, or that are regulated as meal replacements by Standard 2.9.3 or as food for special (medical) purposes by Standards 2.9.5 or 2.9.6.

As noted in the assessment summary, the potential alternative regulatory approach would apply only to new foods. Foods that have been marketed prior to the implementation date would not be subject to the approach.

Appendix

Eligible Food Criteria – worked examples

The following tables highlight examples of foods that would be considered eligible against the eligible food criteria if they were new foods. These simple examples indicate how particular commodities, simply processed commodities and substances and extracts derived from the commodities would be considered eligible in accordance with the eligible food criteria. More complex aspects of calculations such as changes in moisture content on cooking that affect component concentrations are not shown.

Table A1: Mammalian meat containing L-carnitine at 133 mg/100 g

Criterion	Eligible
2 (commodity)	Mammalian meat with naturally high levels of L-carnitine (e.g. veal) (contains 133 mg/100 g of L-carnitine)
2 (simply processed)	Dried meat – e.g. jerky (contains 279 mg/100 g of L-carnitine[7])
3 (extract)	L-carnitine obtained via a single step extract from mammalian meat (veal) could be added to any processed food up to a level as if the meat was used as an ingredient and after taking account of natural content. Example: Prepared meal product where 10% could have been jerky could contain up to 28 mg/100 g of L-carnitine from extract and natural sources.
4 (substance)	L-carnitine from meat – added to processed meat at up to 133 mg/100 g (total natural and added) OR L-carnitine from dried meat and added to dried processed meat products at up to 279 mg/100 g (total natural and added)

[7] Assuming veal meat contains 57% moisture

Table A2: Cereal grain containing gamma-oryzanol at 84 mg/kg[8]

Criterion	Eligible
2 (commodity)	Cereal grain with naturally high levels of gamma-oryzanol (e.g. rice) (contains 84 mg/kg of gamma-oryzanol)
2 (simply processed)	Bran (contains 600 mg/kg of gamma-oryzanol) Bran oil (contains 20 g/kg of gamma-oryzanol)
3 (extract)	Gamma-oryzanol obtained via a single step extract from bran oil could be added to any processed food up to a level as if the bran oil was used as an ingredient and after taking account of natural content. Example: Table spread where half the fat[9] could be bran oil containing up to 6 g/kg of gamma-oryzanol from extract and natural sources.
4 (substance)	Gamma-oryzanol from cereal grain – added to processed cereals at up to 84 mg/kg (total natural and added) OR Gamma-oryzanol from bran – added to processed bran at up to 600 mg/kg (total natural and added) OR Gamma-oryzanol from bran oil – added to cereal-derived oils at up to 20 g/kg (total natural and added)

[8] Gamma-oryzanol is permitted in Standard 2.9.4 to be added to 'formulated supplementary sports foods' at a maximum one day quantity of 25 mg. This example is outside of the context of the existing permission
[9] Assuming table spread contains 60% fat

Table A3: Milk containing lactoferrin at up to 20 mg/100 mL

Criterion	Eligible
2 (commodity)	Bovine milk (contains up to 20 mg/100 mL of lactoferrin)
2 (simply processed)	Sweet whey (liquid portion remaining after curdling of milk for cheese production) (contains up to 30 mg/100 mL of lactoferrin) Dried sweet whey (contains up to 300 mg/100 g[10])
3 (extract)	Lactoferrin obtained via a single step extract from bovine milk could be added to any processed food up to a level as if the milk was used as an ingredient and after taking account of natural content. OR Lactoferrin obtained via a single step extract from dried sweet whey could be added to any processed food up to a level as if the dried sweet whey was used as an ingredient and after taking account of natural content. Example: Protein powder product where 50% could have been dried sweet whey could contain up to 150 mg/100 g of lactoferrin from extract and natural sources.
4 (substance)	Lactoferrin from bovine milk – added to yoghurt at up to 20 mg/100 g (total natural and added) OR Lactoferrin from dried whey – added to dried processed milk products at up to 300 mg/100 g (total natural and added)

[10] Assuming sweet whey contains 90% moisture

Table A4: Tea leaves containing 0.4 mg/100 g of theanine

Criterion	Eligible
2 (commodity)	Tea leaves (from *Camellia sinensis*) (contains up to 0.4 mg/100 g of theanine)
2 (simply processed)	Dried tea leaves (contains up to 2 g/100 g of theanine[11])
3 (extract)	Theanine obtained via a single step extract of dried tea leaves could be added to any processed food up to a level as if dried tea leaves were used as an ingredient and after taking account of natural content. Example: Iced tea beverage product where 100% infused dried tea leaves could have up to 2 g/100 g of theanine from extract and natural sources.
4 (substance)	Theanine from dried tea leaves – added to herbal infusion tea bag/sachet (e.g. powder) at up to 2 g/100 g (total natural and added)

[11] Assuming fresh tea leaves contain 80% moisture