# P1024 Review of Regulation of Nutritive Substances & Novel Foods

**Closing Thursday 24th March 2014**

## The Australian Dairy Industry

Dairy Australia welcomes the opportunity to respond to P1024 Review of Regulation of Nutritive Substances and Novel Foods.

Dairy Australia is the dairy industry-owned service company, limited by guarantee, whose members are farmers and industry bodies, including the Australian Dairy Farmers, and the Australian Dairy Products Federation.

Australian dairy is a $13 billion farm, manufacturing and export industry.

Australia's 6400 dairy farmers produce around 9.2 billion litres of milk a year.

The Australian dairy industry directly employs 43,000 Australians on farms and in factories, while more than 100,000 Australians are indirectly employed in related service industries. Our industry has the potential to grow substantially over the next decade to meet growing domestic and international demand.

Realising this growth potential and expanding the industry's economic, social and environment benefits depends on a positive domestic and international operating environment.

**Underpinning Policy and Regulatory Principles**

When considering the revision of the Novel Foods and Nutritive Substances standard, the dairy industry advocates core principles within which all regulatory requirements must operate.

Regulation should be:

- Minimum but effective;
- Risk (science/evidence) based;
- Cost proportionate to benefit;
- Outcomes focussed;
- Proportionate to risk;
- Nationally consistent and enforceable;

And should:

- Support innovation;
- Support and promote international and domestic trade; and
- Support competition.

The dairy industry has and continues to participate actively in the development and review of regulatory initiatives including FSANZ standards. The industry considers this is critical to responding to changing consumer needs, to supporting innovation and to leveraging the unique nutritional benefits of dairy foods for the benefit of consumers' health and wellbeing.

**Relevance to the Dairy Industry**

We recognise that P1024, consistent with the 2012 consultation, aims primarily to resolve ambiguity and enforceability issues. The dairy industry is appreciative that issues raised in response to the previous consultation have been considered. We take this opportunity to reiterate the significant impact of this standard to the dairy industry.

The policy framework underpinning food regulation should support innovation, trade and competition, and not inadvertently disadvantage Australian dairy manufacturers and processors.

Innovation is critical to the success of the Australian dairy industry, which is among the most innovative in the Western world. Innovation is imperative to minimising the reliance on trade of commodities, to expand exports via differentiation and improvement of existing products, extracting value from waste, and developing new high value products.

The dairy industry has a long history of fractionating, concentrating, separating, use of microbes and enzymes, to produce foods and ingredients from milk that are safe to consume, including cheese, fermented milk products, milk powders, protein concentrates and isolates. It is critical that any regulatory framework recognises this, providing pathways that acknowledge the history of safe and appropriate use.

The breadth of novel food scenarios that currently occur in the dairy industry encompass:

- Non-dairy novel ingredients (including microbes) added to dairy foods,
- Novel ingredients and bioactive substances extracted from dairy foods that can be added,
    - back in to dairy foods,
    - to non- dairy foods and
    - to formulated special purpose foods.

- Novelties may arise as a result of a substantive change to the food composition via process changes, the addition of novel ingredients or microbes with the purpose of a range of outcomes such as:
    - Reduced production costs
    - Improved quality attributes
    - Improved sensory attributes
    - Improved functional attributes
    - Extended shelf life
    - Providing a health effect

The following are a sample of current internationally relevant dairy examples reflecting various scenarios that need to be considered when developing a regulatory framework to manage novel foods. Some of these examples would be expected to be considered normal practices and/or 'eligible foods' within a tiered risk based approach, whereas others could be considered 'Novel':

- UV pasteurisation of milk to significantly extend shelf life results in significantly increased vitamin D content of the milk.
- Lactoferrin has antimicrobial activity and added to special purpose foods, is purified from milk or produced recombinantly.
- Recaldent, a milk-derived tooth re-mineraliser and dental decay preventer, can be applied to the teeth via sugar-free gum, medicated tooth crème and fortified dairy milk.
- Phytosterols and phytostanols to reduce cholesterol added to cheeses and milks.
- Galacto-oligosaccharides (GOS) are a prebiotic produced through the enzymatic conversion of milk lactose, and added to foods for adults and infants including formulated special purpose foods.
- Minerals, nutrients and other milk fraction components extracted from dairy and added to standardise the nutrient composition of general dairy foods.
- Concentrated milk solids added to milk products at levels higher than naturally occurring in milk to improve sensory and nutritional aspects of milks and yoghurts – particularly skim and reduced fat varieties.
- In-house uncharacterised starter cultures used for cheeses and other fermented dairy products that deliver the sensory and quality attributes in the final product.
- Use of enzymes to produce cheese, and whey protein ingredients.

Any framework must have sufficient detail to enable clarity in determining whether products such as the examples outlined above are considered eligible foods, novel foods, or another standard applies. Whilst at the same time, not unintentionally capturing current or future variations of normal practice.

Given the broad reaching implications for the dairy industry, we strongly support a novel foods policy and regulatory framework review that is consistent with outlined sound policy and regulatory development principles. The framework must achieve the purpose of efficiently managing the breadth of both current and future novelty. At the same time, long standing normal practices, as such, should not be considered novel, and must not be inadvertently captured.

In assessing the dairy industry implications of the proposal as outlined in the consultation documents, clear challenges emerge. This is particularly apparent when applying the proposed regime to dairy derived ingredients, microbes and enzymatic processing.

The dairy industry welcomes further engagement with FSANZ to work through viable options that address the challenges in the development of the novel foods framework as it applies to current and future dairy products and dairy derived ingredients.

**Overview**

**1.** P1024 considers **new approaches** to the process of reviewing foods which may potentially be considered as Novel Foods and Nutritive Substances. We are generally supportive of the principles and concept of the proposed **tiered risk based, outcomes focussed approach, including self-assessment for lower risk and application pathways for higher risk.**

- The approach of **self-assessment for lower risk** is consistent with greater facilitation of innovation. This reflects an outcomes focussed approach with the **management of safety proportionate to risk.** It would be expected the same criteria that are assessed for an application would be assed in a 'self-assessment'. However supporting information to address the safety assessment criteria would be less complex and more readily available.
- This **Standard should primarily focus on novelty and safety**. Efficacy, processing methods, or processing aids such as enzymes etc. that do not result in novelty, in that the food itself, or aspects of the food are not substantively changed should not be automatically captured by this standard.
- It is important that the continuum between maintenance of normal function, or normal development through to pharmacological effect is recognised proportionate to risk within the framework. 'Novelty' associated with **pharmacological effects** would be expected to be considered **higher risk** requiring an **application to FSANZ**.
    - The definition of pharmacological/metabolic effect will need to recognise the continuum of effect, ranging from maintenance of normal health functions such as normal appetite/satiety and weight through to drug like effects that abnormally suppress appetite or significantly change biomarkers.
    - It would be expected that there would be consistency with similar definitions that apply to 'General Level Health Claims' and normal function, growth and development versus 'High Level Health Claims' and the association with 'serious disease'.
    - For example dairy proteins naturally occurring and extracted from milk would be considered to be associated with maintaining normal weight and appetite.
- It is crucial that any approach is supported by a clear and transparent enforcement process consistent with proportionate to risk principles for each assessment pathway.
- We **suggest the ANCF is retained in a redefined structure/role integral to the framework**. The ACNF has the potential to play a critical role in review and guidance for both industry and jurisdictions. There may be aspects of international jurisdiction (e.g. UK) similar bodies that if incorporated within the Australian and New Zealand framework, would improve the value and efficiency of the ACNF.
    - Though the ANCF does not have legal status, it may be of broader benefit to make the necessary amendments to address this.
    - It would be of value to redefine the expertise and function of the ANCF to enable a more practicable role in providing assurance to export markets (particularly major Asian markets), industry considering investing in product development and enforcement agencies for self-assessed products.
    - Viability of providing such a service may need to be based on a cost recovery model.

2. The proposed **restructured framework includes new definitions with the potential to perpetuate enforceability issues**. The following examples of proposed definitions will require a level of clarity that limits variability in interpretation:

    - Eligible food
    - Nutritional purpose
    - Normally consumed
    - Tradition of consumption
    - Safe food

    Care must be taken to fully address ambiguity and not exchange one set of ambiguous definitions for another. It is also **critical that definitions do not inadvertently capture normal production processes as novelty** requiring assessment.

    The greater the clarity the more sound the decisions as to the viability of progressing with development of a novel or eligible food/ingredient can be made. The ability to make sound informed decisions is more supportive of innovation. With the introduction of a self-assessment pathway, the first step would be to evaluate pathway eligibility. If eligibility criteria are well understood, progression to the second step of safety 'self-assessment' or 'application' can be confidently expedited.

    To **minimise ambiguity concerns and ensure transparency** of the enforcement approach we suggest that **clear guidance material outlining requirement**s for both industry and jurisdictions be collaboratively developed.

3. We support the **merging of Novel Foods and Nutritive Substances** on the basis nutritive and **efficacy aspects are more than adequately managed via the Health Claims Standard**. The novel foods safety assessment should identify any requirements for managing the safety aspects of a novel food via other standards such as, warning statements, allergen labelling requirements, and special usage requirements. These would all need to be addressed under the complementary relevant Standards on approval.

    - This points to a framework whereby safety concerns associated with novelty are addressed as the focus of a **Novel Foods Standard, functioning complementary to other relevant standards** that cover for example:
        - Health Claims
        - Additives
        - Processing aids
        - Vitamins and minerals
        - Food produced using gene technology
        - Nanotechnology
        - Irradiated foods
        - Labelling

    - It is important that all potential scenarios are clearly captured within a complementary standards framework.
    - We suggest that only when **scenarios are considered to result in 'novelty' of the food/ingredient** would it make sense for these foods to **be assessed as 'novel' foods** by either 'self – assessment' or application depending on associated risk and international assessment opinions.
    - Other **aspects that are not specifically novelty of the food/ingredient** should be **managed through other appropriate complementary standards** and regulatory requirements.

4. In the development of a risk based tiered approach, the current proposal requires further work to provide an appropriate risk based framework suitable for assessing the broad range of scenarios that apply to dairy foods and dairy derived ingredients. For example:

    - The proposals for EFC2, EFC3, and EFC4 are not consistent with appropriately managing currently produced dairy ingredients
        - If rennet is considered an eligible enzyme, then all products using rennet would be produced using the criteria listed in processing techniques listed in SD3 table 3, page 8, which would then exclude them through EFC2
        - In the lactoferrin example, SD3 page 23, dried sweet whey is 'simply processed', however it will have undergone physical fractionation, thermal processing, mixing, enzymatic processing, filtration, evaporation and drying
        - Subsequently there is confusion over what from a regulatory perspective is 'simply processed' commodity, extract or substance
        - Issues are further compounded by the lack of clarity in relation to appropriate 'source food' or 'food class' for an extract or substance
        - To use milk as the only point of comparison for concentration is not viable. By better defining 'simply processed food' in a more workable way, this may provide a more appropriate point of comparison
        - It is critical that these issues are resolved to ensure the long history of safe consumption of dairy foods and dairy derived ingredients is recognised and able to be referenced as a point of comparison for concentration
    - EFC1 (micro-organisms): as currently proposed excludes a number of currently used starter cultures from the list. A more inclusive approach that recognises published lists of micro-organisms with a long history of safe use from all reputable food regulatory authorities, and not be limited to EFSA
    - EFC2 (Enzymes): The current proposal to exclude enzymatic processing from processing techniques that would meet criterion 2 inadvertently excludes many commonly produced and consumed dairy foods and dairy derived ingredients. This exclusion clearly discriminates against products where enzymes are added as opposed to foods where enzymes are produced by micro-organisms in the food. For example:
        - Applying the current proposal, all whey protein ingredients (including the sweet whey powder example used in the lactoferrin example in SD3) would have required an application to FSANZ for pre-market assessment.
        - A more appropriate approach would be, not to make a blanket exclusion based on processing method. Suggested workable options include a CODEX style approach (e.g. general cheese standard) allowing for the use of safe and suitable enzymes. Safe and suitable enzymes however may be better managed via permissions within the processing aids standard, rather than within the novel foods standard.

The Eligible foods criteria as drafted in the current proposal raises considerable issues for dairy foods and dairy derived ingredients. Dairy Australia invites targeted consultation with FSANZ regarding the dairy industry concerns, with a view to find a mutually acceptable resolution prior to drafting the revised proposal.

5. The dairy industry strongly **supports the translation of international novel foods approvals** to the Australian and New Zealand context. The aim should be to ensure international recognition where possible whilst remaining appropriate for the domestic regulatory framework.

    - The outcome of assessments in different jurisdictions that include a recognised process for safety assessment components that demonstrate an evidence based substantiation of safety should not be limited to consideration of the US, Canada and the EU.
    - Recognised international jurisdiction opinions should then be able to be used as the basis for translation to a particular food use within the Australia New Zealand food supply. Similar to the use of an 'existing systematic review' as starting point for building a dossier for a 'self-substantiated health claim'.

6. **Authoritative sources permitted must cover a wide range of jurisdictions, not just primarily the European Commission**. Recognition of 'Authoritative sources' should include major dairy export markets in Asia with robust regulatory frameworks such as Japan. For exporters, a question often asked, is whether the food or ingredient is permitted by the exporting country. Being very restrictive and not taking into consideration foods permitted in countries other than Europe and North America, may put the Australian dairy export industry at risk of an unfair trade disadvantage.

    - The Australian dairy industry exports more product to Asia than North America and the EU. Our top 2 export markets are Japan and Greater China. The Asian region has the highest uptake of dairy bio-actives in the world.
    - For the financial year 2014/2015 Australian dairy exports to Asia accounted for 70% by volume and 67% by value for total Australian dairy exports, and of this Japan accounts for 14% by volume and 17% by value while Greater China account for 18% by volume and 15% by value.
    - Dairy Australia recommends that FSANZ include in the international jurisdiction review the Japanese regulatory model to consider the transferable aspects, such as safety assessment requirements. We recognise that the Japanese framework combines safety with efficacy and has no separate 'Novel Foods' regulation. However the safety assessment component of FOSHU is recognised by other international jurisdictions such as the EU, for example a UK Novel Foods Assessment checklist, lists 'is the food used in the Japanese food supply?' as a consideration.
    - Japan has a highly developed regulatory framework for Novel/functional foods with aspects that could be transferable to the Australia New Zealand context. The country has a large population to protect, and a high uptake of novel foods. As such, Japan is an appropriate jurisdiction to consider for acceptable overseas evaluations. Particularly as a starting point for assessing novelty in the context of the Australia New Zealand food supply, and 'self-assessment' pathways.

Dairy Australia has collated some information about the Japanese FOSHU framework that may be of interest to FSANZ in further considerations of the applicability of the recognition of Japanese approvals.

7. How **novel microbes** are managed in the standard requires careful consideration. A requirement that includes what is considered to be a 'genetically pure strain' may be too restrictive. Dairy product starter cultures are selected on the basis of producing a product of acceptable quality and sensory attributes. In-house starters that may not have been characterised (and may be mixtures) are used with reasonable frequency for making cheese, yoghurt and other fermented dairy products. In these cases, genetic composition may be unknown.

    - A high level of technical expertise can be required to navigate the complexities of microbes, food product technology, health and novelty. Such expertise is not always available in-house, particularly for Small to Medium Enterprises (SME's). The challenge is not to limit new product development and innovation by over specifying what might be permitted, otherwise prohibited without assessment. At the same time it must be ensured that potential safety issues are appropriately managed.

    - The dairy industry support the reference to **EFSA QPS list**, however **only as a starting point**. There are **a number of micro- organisms currently in use not on that list**. Some means must be found to cover the currently in use, but currently excluded micro-organisms. Omission would place a number of traditional European, Australian, and New Zealand cheeses into the category of needing pre-market assessment. Presumably this is not the intention. Examples include:
        - Staphylococcus (most white mould and other specialty cheese, salami, etc.)
        - S. carnosus
        - S. xylosis
        - Penicillium (white mould cheese)
        - Geotricum (white mould cheese)
        - Enterococcus (lots of salamis and other foods)

    - One suggestion is to look to other authorities' permissions for the use of microbes in the food supply to identify alternative or supplementary pathways for assessment, as opposed to a stand-alone uncomprehensive prescriptive permitted list. Microbes that have been assessed by jurisdictions other than the EU should be included in any 'Permitted List'. For example Japanese FOSHU requirements assess microbes for both safety and efficacy.
    - Alternatively development of a set of criteria that recognises lists published by:
        - reputable food regulatory authorities
        - reputable scientific journals as having a long history of safe use
        - Codex approach of permitting 'harmless' micro-organisms

8. **Exclusivity provisions should be retained** to cover instances where patent law does not apply. There is significant costs expended in research, development, meeting regulatory requirements and launch of Novel Foods.

    - The cost of an un-expedited application has been estimated to be at least $25,000 in the instance of supporting evidence being readily available. Further FSANZ administrative costs must be paid up front for expedited applications. FSANZ administrative costs can vary significantly, as they are based on the complexity and estimated hours required to complete the assessment.
    - Costs must be recouped via increased profit compared to alternatives. A typical case might require the sale of 1,500-2,000 tonnes of a typical retail product, just to cover this expense.

- If trials have to be conducted to support the safety dossier, costs are typically a minimum of $100,000 for simple trials, rising to over a million for more complex trials.
- In the case of a dairy component being extracted and concentrated, the development costs, including CAPEX and plant trials need to be added on as well.
- In many cases the high costs incurred means that development of a novel food/ingredient is only viable if there is an overseas market approval where the volumes are large enough to justify the expense.
- If the development is not covered by a patent and a competitor gets in first, the manufacturer can be locked out from recovering their costs by the exclusivity clause.

**In most cases a 15-month exclusivity period only partially supports cost recovery**. However 15 months is not too excessive for competitors to be locked out.

9. The dairy industry is fully supportive of a 'self-assessment' pathway, and recognises the need to administrate compliance in way that meets the needs of regulators, enforcers, consumers and industry. Design of this administration will be critical in determining the utility of this option for industry. **The current proposal to publicise the full dossier provides no intellectual property protection**, negating the significant investment in research and development.

   There are confidentiality and administration concerns regarding the proposal for 'self- assessed' dossiers to be made publicly available via a website link.

   - Publication on a website presumes the entity making the application has an appropriate on-line system which enables presentation of the dossier with all its attendant issues around security, formatting, maintenance. This is highly unlikely for many businesses.
   - A centralised platform with security, administration support and rules for presentation would be required.
   - A Novel foods' self-assessment' pathway that entails exclusive use of assessment dossiers similar to the requirement for each company to hold its own dossier for 'self-substantiated' health claims is the preferred option.
     - This is particularly important for novel foods/ingredients not captured by IP law
     - Transparency and assurance regarding the safety assessment process undertaken could be demonstrated by requiring publication of a notification and executive summary of the safety assessment dossier as opposed to publishing the complete dossier
     - Similar to 'self-substantiated' health claims, requirements could include, full dossiers to be provided to enforcement agencies on request.
     - Notification supported by summaries only, will address confidentiality concerns while balancing the need to protect intellectual property. This will also support the inclusion of requirements that would ensure each new user of a novel food/ingredient undertakes an assessment for their specific product. Sufficient information is also provided to inform consideration of population exposure to any novel food/ingredient already in the food supply.

10. **Grandfathering** to permit any products on the market prior to a certain date to remain without any changes seems a reasonable approach.

**Appendix – Consultation Questions and comments for industry response**

**Questions**

How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.

Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in assessment summary? If so, describe the problems.

Examples where the current Standard has played a role in the viability of ongoing innovation include both novel foods that were brought to the Australian and New Zealand markets and those where the Australia New Zealand Novel Foods and Nutritive Substances regulatory framework contributed to the costs outweighing the benefits in respect to domestic markets. Phytosterols and phytostanol cheeses are currently available in the domestic market, whereas Recaldent, a dairy derived bioactive ingredient is not available in the domestic food supply.

The current Novel Foods regulations control those foods to which phytosterols and phytostanols can be added to dairy products. They aid, via the ACNF, in deciding whether an ingredient is acceptable under current regulations. The development and trade of dairy derived ingredients and constraints on their usage either by product or by quantity are a major issue. The need for the ACNF to provide guidance and authority around decisions on novel foods is in part due to the ambiguous nature of the current definitions. **Although the ACNF has no legal status**, its decisions recognising products as safe and not novel **can assist with international trade of dairy foods and dairy derived ingredients**.

The dairy industry sees that there is really **no essential difference between Novel Foods and Nutritive Substances** with respect to safety and they can and should be treated as one. With the introduction of the Health Claims Standard, and efficacy now appropriately managed, it is now possible to uncouple nutritive and efficacy from novel and safety.

The current Novel Foods Standard does not clearly define safety. There are current foods though unsafe for some sections of the community, for example containing allergens are permitted with safety issues managed by provision of information and warnings defined in other Standards. Any definition of safety must include reference to management of safety risks.

There are issues with the **lack of recognition of international decisions**, and hence transferability to the Australian market. This is becoming increasingly important with increasing international and domestic trade in new dairy products and dairy derived ingredients.

> For example, Recaldent a dairy derived tooth remineraliser didn't end up in Australian milk and gum due to ambiguity in the Australian regulations, lack of ability to make claims at that stage and the cost of making application in Australia. Recaldent is however in Japanese milk and gum (a notoriously difficult market). Thus Australia did not get access to the benefit of a tooth re-mineralising novel food which would be of value particularly in those areas of Australia that do not have fluoridated water. Recaldent has only recently become available in Australia but not in food so is limited in availability through specialty therapeutic dental products, purchased from dentists.

The current provisions are ambiguous, making it difficult to determine if a food is clearly novel and requires an Application. This has resulted in potentially unsafe products on the market produced by un-reputable organisations. Some of these products contain or are based on safe dairy ingredients, with unsafe substances added. These type of products pose reputational risk to the dairy industry more broadly.

The current provisions provide a level of restraint to innovation delivered in the domestic market. This has a flow on effect. Due to reputation for a robust regulatory framework delivering a safe and suitable food supply we are in a position to be trial market for acceptance of novel foods. This can be used to leverage our ability to sell these foods in the export market. However under the current provisions the costs and time required to meet regulatory requirements and complete premarket assessment can outweigh the benefits of releasing a novel food in the domestic market. For example recaldent was not released into the Australian food supply and was limited to one export market where the regulatory framework was more amenable to assessment and approval for use, resulting in overall significant opportunity cost both domestically and internationally.

**Questions**:

Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

It is appropriate that FSANZ assess the safety of high risk Novel Food and Novel Nutritive Substances on behalf of consumers, and in conjunction with the ANCF establishes an appropriate regulatory framework of oversight for pathways for 'Self-Assessment' to achieve similar outcomes.

The ANCF forms a critical part of the framework managing Novel foods. Similar expert bodies are an integral feature of international jurisdictions e.g. the UK, Canada. The ANCF is somewhat different to other similar bodies in the lack of legal status and current available expertise, which pose some issues. However a review against similar bodies overseas could be undertaken to inform the revision of the role, authority and expertise composition to increase the effectiveness of the committee.

Dairy Australia agrees that the key problems are those which have been highlighted in the report and FSANZ has done a good job of bringing them together. In evaluating regulatory approaches in other markets, key markets for our dairy products that have well developed regulatory frameworks for Novel Foods such as Japan are overlooked. It is advantageous to the food industry that the regulations in all potential markets, and not just the English-speaking world be reviewed for lessons to be learnt and recognition for decisions made be given.

**Questions:**

Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

Dairy Australia **supports amending the definition for** 'novel food' and removing 'used as a nutritive substance' on the basis that other standards within the code manage any 'nutritive' aspects of a food/ingredient.

The key issue this Standard is addressing is safety including for 'nutritive substances', as opposed to efficacy or any nutritional contribution.

To ensure definitions provide greater clarity with respect to what is considered novel and what is not, care must be taken not to exchange one set of ambiguous terms for another equally ambiguous.

- For example, other terms mentioned in the Proposal such as 'safe food', 'normally consumed' and 'tradition of consumption' will require clear descriptions.

- Guidance on definitions such as examples, will need to be included collaboratively developed guidance material to support stakeholders interpret and apply the definitions in their use of the standard.

The graduated risk approach is presented as an example of an approach that could work in the context of the existing legislative requirements of the food regulatory system in Australia and New Zealand. FSANZ has presented detail on identifying foods that require regulatory approval while presenting principles of alternative assessment processes for these foods. FSANZ is presenting this approach to encourage discussion among stakeholders on potential alternatives that will improve the regulation of nutritive substances and novel foods. FSANZ encourages stakeholders to provide submissions in response to this assessment summary, which will be used to inform a decision in relation to the preparation of a draft variation to the Code and a second call for submissions.

Dairy Australia is very supportive of a risk based, proportionate approach that is outcomes focussed and welcomes any proposal that is consistent with the approach of identifying:

- Novel and not novel i.e. eligible foods
- Including self-assessment for low risk novel foods, and
- Requiring application for only the highest risk.

In developing and outcomes focussed risk based framework and pathways it is important to consider

- Viability in respect to costs and benefits.
- Criteria to determine pathways and meet requirements must be sufficiently clear

**Eligible Food Criteria - General**

There are significant issues for dairy foods and dairy derived ingredients with the Eligible Food Criteria as currently proposed. Particularly in regards to:

- Microorganisms
- Extracts
- New processes, including specifically enzymatic processing

These issues are further detailed in response to the questions regarding the EFC.

**The Self Assessment – General**

If an **assessment is approved in another country** with a reputable safety assessment process, then this decision should be considered for expedited assessment for Australia and New Zealand.

**The Self Assessment – Microbiological Safety**

The criteria in the Proposal are reasonable for those **microorganisms** which might be **deliberately added** to foods provided it is expanded to include other reliable sources of information and the positive list is readily updated.

**The Self Assessment – Toxicological Safety**

**Dairy Australia supports the notion that there are traditional foods and non-traditional foods and that traditional foods are safe or have adequate controls around them**. Specifying a date for the identification of foods that are a traditional part of the diet in Australia and New Zealand and therefore do not need a safety assessment, would need to be consistent with other requirements if this were to be implemented. Eligibility should extend to components extracted from traditional foods, even if the extraction method postdates the traditional food date, including not only whole milk but also dairy products more broadly.

In judging the safety of the food, Canada is prepared to take into consideration foods consumed in other countries, as is the EU, with qualifications.

It is important for Australia and New Zealand that food from other countries be able to be assessed against the history in those countries as many have been brought into Australia with the various waves of migrants. When the food supply in the source country is similar to that of Australia and New Zealand and/or the safety data is readily available this should be recognised in support of the safety assessment of the food.

If there is little history of human consumption, and therefore little or no history of any adverse effects, then the food should be the subject of an Application (or an assessment by FSANZ) rather than a 'Self-Assessment'. With little evidence from history, expert opinion of metabolic and similar studies would be necessary.

**The Self Assessment – Nutritional Safety**

The self-assessment should investigate whether there is any apparent pharmacological/metabolic effects (other than normal nutrition) exhibited by the food, and this should be available from the history. If there is little history of consumption available, then the food will need expert analysis and evaluation of anti-nutrients via an Application.

In the case where there may be known safety related upper limits of consumption (for example as are set for some nutrients), but no other safety concerns, a dietary exposure assessment could be untaken as one of the levels of self-assessment.

**The Self Assessment – Reporting**

Confidentiality would be one of the key reasons for doing a 'Self-Assessment'. This applies not only to what the food is that is being developed and keeping this from the public domain as long as possible, but also to the details of the assessment work. Given the 15 months exclusivity and the time the completion and approval of an application to FSANZ does not fully offset costs of development, a level of confidentiality of self-assessment, offers a lower risk of competitors using the data of others to release their own equivalent product. This then enables the self-assessment pathway to support speed to market, with a higher chance of exclusivity for a significant period of time, whilst allowing regulatory resources to focus on high risk foods.

The criteria regarding format and mandatory information to be included in a publicly available notification will need to be developed in targeted consultation with all key stakeholders represented.

If there are any health safety concerns with the food which were documented during the investigation, then these may be able to be managed by appropriate warning labels, etc. Subsequently, any risk management that requires changes to other standards within the Food Standards Code will require applications to FSANZ to make the requisite changes.

**Step 4: Pre-market safety assessment via application to FSANZ**

An Application is required if there is little history on which to base a decision, or if any adverse reports are uncovered during literature searches. This enables more expertise to be called on (via the ACNF) for the evaluation of the data and for mitigation of any issues to be initiated via other Standards should that be deemed to be appropriate.

An Application that meets the requirements of the Application Handbook is also obviously necessary if the food/ingredient fails at any of the previous stages and subsequently deemed a high risk novel food.

**ANCF**

A body such as the ACNF to refer to, could provide another resource of appropriate expertise alternative to FSANZ.

There is still a requirement for a body such as the ANCF, however a review of role and composition against similar bodies overseas to identify what is required to gain the greatest benefit from the body within the Australian New Zealand Novel Foods framework.

As has been mentioned above, some export markets require a food to be approved for use in the source country before they will accept it into their country. The ability to access the expertise of a body such as the ANCF provides an avenue to provide reassurance that compliance has been met by both industry and jurisdictions, mitigating potential for dispute

The Code would list the EFC and include a provision that novel foods that meet any of the EFC can be sold in Australia and New Zealand without being subject to regulatory pre-market assessment requirements in the Code.

The Code would also include record keeping requirements that food businesses would need to meet to support the safety of an eligible food that is supplied for sale. Failure to hold these records would mean a food business would be supplying a food in contravention of the Code's requirements.

The challenge with this requirement is the clarity around the concept of a novel food and resolving the issues currently posed by the proposed EFC. As can be seen from the ACNF data, many foods have been submitted to determine whether they are novel or not.

Businesses may need to document their opinions as to whether the food is traditional or not in order to ensure they comply, however any criteria for record keeping would need to be developed in consultation with all key stakeholders represented.

**Questions:**

Are the EFC appropriate for identifying foods that do not need regulatory approval?

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.

Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

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.

Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?

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.

Dairy Australia supports the inclusion of "mammalian milk products" in the EFC, however we are very concerned regarding a number of aspects of the EFC as proposed in the consultation documents.

The proposals for EFC2, EFC3, and EFC4 are not consistent with appropriately managing currently produced dairy ingredients

- If rennet is considered an eligible enzyme, then all products using rennet would be produced using the criteria listed in processing techniques listed in SD3 table 3, page 8, which would then exclude them through EFC2
- In the lactoferrin example, SD3 p23, dried sweet whey is 'simply processed', however it will have undergone physical fractionation, thermal processing, mixing, enzymatic processing, filtration, evaporation and drying
- Subsequently there is confusion over what from a regulatory perspective is 'simply processed' commodity, extract or substance
- Issues are further compounded by the lack of clarity in relation to appropriate 'source food' or 'food class' for an extract or substance
- To use milk as the only point of comparison for concentration is not viable. By better defining 'simply processed food' in a more workable way, this may provide a more appropriate point of comparison.

It is critical that these issues are resolved to ensure the long history of safe consumption of dairy foods and dairy derived ingredients is recognised and able to be referenced as a point of comparison for concentration.

Dairy Australia invites further targeted consultation with the dairy industry to work through these issues with the view to identify a viable solution.

Microorganisms

Limiting the starters to the EFSA list will result in several commonly used starters being absent from the list. Dairy Australia suggests that the criteria should include lists from **EFSA and other reputable food safety authorities** along with published lists of microorganisms with a long history of safe use.

The Dairy Industry is concerned about the criteria for microorganisms would put a lot of traditional European cheese and a significant amount of cheese manufactured in Australia and New Zealand into the category of potentially needing pre-market assessment if they were to be judged against these criteria. This presumably is not the intention.

Commonly used microorganisms which are not on the list include:

- Staphylococcus carnosus and S. xylosis (used in most white mould and other specialty cheeses, salamis, etc)
- Penicillium (white mould cheese)
- Geotricum (white mould cheese)
- Entercoccus (salamis and other foods)

Generally, using "positive" lists such as that of acceptable microorganisms is problematic on the following basis:

- Frequently overlook key items which should be included, especially in the early days of implementation. Subsequently there needs to be a quick, non-penalty, non-onerous means of having the lists updated once regulated.
- There are many cases where the microorganism make-up may not be known. Sourdough cultures are typically mixtures of wild cultures that produce the desired outcome and are consequently not fully characterised.

Extracts

From a dairy perspective, milk has been part of the diet in many countries for a long time. The various components of milk have been used in many different ways. It has been separated, partitioned, ultrafiltered and dried. Various fractions have been converted to cheeses, spreads, yoghurts, drinks, powders (e.g. skim, whey protein concentrate), etc. and these fractions have been used with many other foods. These are all concentrates of the original milk, and as described above, should be considered to be traditional under eligible food criteria.

As currently proposed there is confusion in relation to how **processes or a combination** thereof are considered acceptable. It is expected that the following processes are acceptable as the extracted material is essentially the same as in the parent material except that it has been separated and dried even though it has had to go through a number of steps. Examples are:

- Lactoferrin is isolated from sweet whey by physical fractionation, thermal processing, mixing, enzymatic processing, filtration, evaporation and drying.
- Whole milk powder is made from milk by physical separation, thermal processing, mixing, crystallisation with added lactose, evaporation and drying.

There is a high level of concern about the restriction in the use of extracts into products only at a percentage similar to what would have been present in the final food had the original food been added to the product. What is currently proposed raises challenges that result in what seems to be an unintended exclusion of many dairy and dairy derived ingredients from being considered eligible.

The daily consumption of many foods varies widely, and the natural variation of extractable material can also vary wildly. We therefore recommend that the **addition of extracts to a level as if the original food was added is restrictive**, particularly where there has been no issue of safety with the parent food.

As an example of the difficulty of understanding the reference for adding back the extract, consider the following: whey protein concentrate is essentially a concentrate of the protein with the fat left in. It would not be appropriate to limit addition at the same solids level as if milk, or dried milk were added.

Ricotta cheese is made from the same whey, and this is a traditional food, so could arguably be considered a reference, and hence whey protein concentrate can be used at any level. Milk may be unique in the way that it is converted into so many different commodities, but by clarifying the criteria with milk and its derivatives in mind, the most appropriate set of criteria may be obtained.

New Processes

The Dairy Industry appreciates the suggestion in the discussion of the EFT that "milk proteins extracted by a new method would be considered to be a traditional part of the Australian and New Zealand diet" and therefore not subject to a safety assessment. In a broader sense regarding the approach to new processes. New processing techniques may be implemented for many reasons, and in a number of cases the nature and subsequently the safety of the food is not altered.

It would be expected that the consideration of the use of any new process by a manufacturer would include what effect the process had on the composition/structure of the food. In the case where no substantive change occurs, it would be unreasonable to expect that the food is automatically excluded from EFC and requires a pre-market assessment.

Enzymatic Processing

EFC2 (Enzymes): The current proposal to exclude enzymatic processing from processing techniques that would meet criterion 2 inadvertently excludes many commonly produced and consumed dairy foods and dairy derived ingredients. This exclusion also clearly discriminates against products where enzymes are added as opposed to foods where enzymes are produced by micro-organisms in the food. For example:

- Applying the current proposal, all whey protein ingredients (including the sweet whey powder example used in the lactoferrin example in SD3) would have required an application to FSANZ for pre-market assessment.
- A more appropriate approach would be, not to make a blanket exclusion based on processing method. Suggested workable options include a CODEX style approach (e.g. general cheese standard) allowing for the use of safe and suitable enzymes. Safe and suitable enzymes however may be better managed via permissions within the processing aids standard, rather than within the novel foods standard.

Information requirements

It is difficult to try to define the type of information food businesses should hold to support the safety of eligible foods for a number of reasons. Collaboratively developed **good guidance material is required** to help understand the quantity, quality and scope, all of which need to be assessed for relevance.

Summary EFC issues

The Eligible foods criteria as drafted in the current proposal raises considerable issues for dairy foods and dairy derived ingredients.

Some of the **issues around the EFC** that still need to be addressed are as follows:

- As has been mentioned above, **safety is not well defined** and this would need to be addressed before anyone could be held to account for it.
- **The ability to use information from overseas decisions** (not just those from the EU, Canada and the US) including the justification for those decisions.
- Elements of the 'self-substantiation' process for health claims should be explored for applicability to P1024, including for determining EFC.
- Significant issues remain to be addressed in relation to microbes, enzymes, extracts, substances and concentrates, and processing methods.

**Dairy Australia invites targeted consultation with FSANZ regarding the dairy industry concerns, with a view to find a mutually acceptable resolution prior to drafting the revised proposal.**

**Questions:**

Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?

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 do you think are viable or not viable? Please provide supporting statements for your view.

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

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

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.

In principle, Dairy Australia is supportive of option 3 (introducing a risk-based regime with industry self-assessment pathways). As noted earlier, there are elements of the Proposal that require further work before full support can be given.

Success in realising benefits over cost will depend on whether new regulations can be revised to provide:

- clarity regarding conformance with the Eligible Foods pathway,
- suitable gateway criteria for each level
- protection of IP under the industry self-assessment pathway, and
- clarity over the evidence required to support these assessments.

Building confidence can be done through providing good guidance material for businesses and enforcement authorities, perhaps similar to that for self-substantiated health claims. This guidance should include how to utilise decisions made in overseas jurisdictions and how that decision relates to the Australian context. The guidance provided by Health Canada is quite clear and describes how to decide what the relevant information for a decision will be, but it does not give any clear decision points.

With respect to protecting public health and safety, **the risks with the new framework are no different to the current process**. Companies are required to hold information on the safety of foods and ingredients regardless of which pathway they fall under. Those items which are more likely to be of concern will still need to go through the formal review process with FSANZ. In the Proposal as presented is not clear that foods for which the data is scarce or are implicated in minor health issues can still be put to a formal review via an Application. This needs to be addressed.

Assuming the EFC are revised to provide greater certainty over their application to dairy products, there is the potential for the alternative approach to be of benefit in expediting new products to market in that field. As mentioned above, the criteria for safety and the extent documentation required on this topic are not defined and this level of detail is required before an appropriate assessment may be made of the impact on the dairy industry.

**The dairy industry has concerns about the publication of full dossiers**. Particularly with respect to confidential information and information gathered at expense to a particular manufacturer which other manufacturers then have free access to and the ability to utilise. The issue of other manufacturers picking up the information include, **safety and efficacy may be product specific** due to the combination of factors and not just relate to a single substance. This raises safety issues if indiscriminate access to full dossiers is permitted.

Further issues arise regarding the manner in which highly technical information within full dossiers if presented may be misinterpreted by lay people raising unwarranted concerns.

The dairy industry supports a notification and a summary of key findings only, including the specific products contain the novel food, which is exclusive to the manufacturer making the notification. Notification and publication of summary information should be sufficient to provide oversight of the novel foods. Should jurisdictions have any concerns once a novel food is notified, they should be able to call for all of the assessment to be provided to the ACNF for review.

**Questions:**

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.

There is a blurring between novel foods and nutritive substances. The primary difference is that nutritive substances that may be novel are associated with a health effect, whereby efficacy would need to be assessed if health claims are intended. Both require a safety check separate from any efficacy assessment. The requirements should be similar for all foods and food components, including vitamins and minerals, or any other nutritive substance.

It is not just vitamins and minerals which are also subject of another standard. Additives, nutritive substances via Health Claims, etc. are also dealt with under other Standards as well. These other Standards require safety assessment, but they also require efficacy assessment also. For example, Tonalin is a CLA synthetically produced from plant oils and is a nutritive substance - the novel food assessment process that prohibited its use in Australia was based on adverse metabolic health effects, not efficacy issues. The EFC would clearly require something like Tonalin to go through an Application. This ingredient would have gone through the same safety assessment process as a first step if it was considered under the additives regulations.

**Questions:**

Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Can you identify any issues that may arise if exclusive permissions 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)?

Exclusive permission is required if novel foods are going to be facilitated into the market place to compensate businesses for the expense of obtaining all the information required for that permission. Launching a Novel Food is a very expensive exercise and is not easy to achieve, no matter whether it is a paid application or not. Benefits must significantly outweigh costs of development and bringing a product to market.

Examples of some of the expenses incurred include:

- Literature searches and preparation of submission $50,000
- Trials to support claims – a minimum of $100,000 each. (It is also becoming more difficult and therefore more expensive to find someone who is prepared to carry out the trials). Complex trials have been quoted at upwards of $1mill.
- Application to FSANZ $25,000 - $150,000
- Marketing to explain the novelty and allay concerns because of novelty $50,000 - $500,000 (this is extra to the normal marketing budget to support a new product)

Cost recovery of a Novel Food application is not easy. The new food has to have a high profit margin, which may be a problem if the market is competitive. Based on the costs above an average cost might be $400,000. To just cover the costs of the regulatory aspects alone, the $400,000 is extra profit that the product needs to generate over the products it is displacing. The 15 month exclusivity period is necessary to support the Application but it is still far too short. In most cases companies would prefer to test this product in overseas markets where the volume of sales is higher before bringing it to Australia.

**Consistency of enforcement across jurisdictions will be important**. With self-assessment, there is always the risk that the jurisdiction would require the company to make an Application, and this incurring all the costs mentioned above. As can be seen, the direct cost of the application is only part of the cost incurred, and even with the self-assessment it is still a major challenge to bring a novel food to the marketplace. As with self-substantiated health claims, industry should be encouraged to work with the authorities, be they the local jurisdiction or FSANZ to ensure the level of rigour is appropriate.

Self-assessment, provided the commercially sensitive details are not required to be published, can provide a level of exclusivity which will go part way at least to compensating the company for its investment.

As stated above, exclusivity in the Australian market can only go part way towards covering the costs involved because of the small size of the market.

**Questions:**

Do you support a cut-off date? Please provide reasons for your view.

Do you see a need for grandfathering provisions? Please provide reasons for your view.

Do you see a need for a stock in trade provision? Please provide reasons for your view.

Dairy Australia supports a cut-off date and grandfathering provisions are necessary to prevent a hiatus around any foods which might fall under the new definitions.

**Questions:**

Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.

Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?

Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?

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?

Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?

Dairy Australia offers no opinions on these questions at this point. We will provide further comment once the final details of the regulations and structures around them have been agreed.

**SUMMARY:**

Dairy Australia

- Supports the introduction of a tiered approach to approval of novel foods and substances.
- Contends there is no value in separation of novel foods and substances with respect to this Standard
- Strongly recommends further engagement and review to resolve identified issues with the proposed EFC.
- Recommends utilisation of novel foods approved in other countries with recognised authoritative review systems.
- Recommends including related regulatory systems in countries which are major trading partners, e.g. Japan.
- Recommends review to improve the role and retaining of the ACNF or similar body to facilitate resolution of issues around Novel Foods.
- Recommends reviewing the requirements for organisms including expanding the list of authorities which produce lists of acceptable organisms.
- Notes that 'Applications' and 'Self-Assessments' are difficult and expensive and require support through direct and indirect exclusivity

**Dairy Australia invites further targeted consultation prior to drafting, to work through the issues in the proposal identified for dairy foods within this submission**