

Response to

**P1024 Revision of the Regulation of  
Nutritive Substances & Novel Foods**

**Consultation Paper – 16 June 2017**

Prepared by Dairy Australia on  
behalf of the Australian Dairy Industry

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# P1024 Revision of the Regulation of Nutritive Substances & Novel Foods

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### The Australian Dairy Industry

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

The Australian dairy industry:

- The third largest regional industry in Australia, after grains and beef, and makes a significant economic contribution to regional economies.
- Present in every state across Australia, with dairy farming activity close to major metropolitan areas to ensure reliable, year-round fresh drinking milk for local consumption.
- As of August 2016, the industry directly employed almost 44,000 people across Australia both in farming and processing, predominantly in regional areas.
- In 2015/16, produced some 9,679 million litres of milk with a farm gate value of approximately \$A4.3 billion, much of which is returned directly into local regional economies.
- This production was processed into some 2.5 billion litres of drinking milk, and with some further processing made 344,000 tonnes of cheese, 119,000 tonnes of butter and 322,000 tonnes of various milk powders.

Since de-regulation, the processing and manufacture of non-beverage products has become more concentrated in Victoria and Tasmania. These two states accounted for the majority of Australia's dairy exports, which were valued at almost \$A3 billion in 2015/16.

Underpinning Dairy Australia's policy and regulatory, public health, nutrition science, and dietetic expertise is commitment to evidence-based public health policy and food regulation. Our role is to provide expertise and evaluate, proposals in light of the most current relevant evidence, in the context of sound regulatory and policy development principles.

Dairy Australia welcomes the opportunity to present this submission in response to the June 2017 Consultation Paper, P1024 Revision of the Regulation of Nutritive Substances and Novel Foods.

### Overview of Comments

1. Dairy Australia acknowledges the significant amount of work already undertaken in the revision of the regulation of Nutritive Substances and Novel Foods. It also acknowledges the broad, often divergent views expressed by various stakeholders in response to the initial Call for Submissions in December 2015. As such, Dairy Australia welcomes the opportunity for further consultation on key issues of P1024.
2. Section 1.3 of The Consultation Paper identifies further issues not addressed in the Consultation Paper which will be dealt with in a subsequent call for submissions. Dairy Australia welcomes the opportunity to comment on these issues and encourages this to be done by way of an additional consultation paper, prior to any development of draft regulation of Nutritive Substances and Novel Foods.

3. It is not possible to give unqualified support for the modified framework presented, in the absence of clarity of how the Eligible Food Criteria concept will operate, and potentially impact, support for innovation.
4. Dairy Australia is disappointed to see the removal of the self-assessment pathway in the modified pathway and whilst recognising the identified difficulties with this option, encourages continuing work to find a solution where such an option could be included.
5. In general, proposed grandfathering approaches to transition arrangements for currently marketed foods are supported, provided the approach applies to both foods and ingredients.

## **General Comments**

### **Issues for subsequent consultation**

Dairy Australia notes that the Consultation Paper identifies a number of specific issues that are pertinent to the proposal, require further consultation. Many of these issues are focussed on the concept of Eligible Food Criteria, and as this is such an integral element in the proposed framework, it is essential that this, and the other issues identified (data requirements for Eligible foods, consideration of overseas approvals) are afforded the necessary opportunity for comment by interested stakeholders. Given the fundamental role that these issues contribute to the proposed framework, we encourage the opportunity to comment on these issues should be done by way of a subsequent Consultation Paper, prior to the development and Call for Submission on any draft regulation of Nutritive Substances and Novel Foods.

In addition to the issues identified for subsequent consultation, Dairy Australia would encourage further consideration of modifications to the proposed framework which allow greater support for innovation. Removal of the self-assessment pathway from the framework with no further opportunity for discussion on this mechanism, removes the opportunity to further resolve a process which may both encourage innovation whilst also meeting the needs of those charged with enforcement and approval. Whilst we recognise that many of the options presented in the Call for Submission in December 2015 can only be resolved via amendment to the FSANZ Act, we feel this requires further examination and that removal of the self-assessment pathway simply removes this issues from further consideration – both a missed opportunity and potentially a further delay in progressing a real solution to this complex issue. Such a mechanism may also form the basis for addressing similar challenges in other areas such as Health Claims.

### **Regulatory Framework – Proposed approach**

Dairy Australia is unable to offer unqualified support for the proposed framework as presented in the Consultation Paper. The proposed modified pathway has significant reliance on elements which have not yet been clarified. In particular the issue of Eligible Food Criteria essentially provides the only possible option for pursuit of innovation, however how this may function remains unclear and is yet to be consulted on. Without this clarity, it is not possible to fully assess how the proposed framework will function, and indeed how this will encourage innovation in the dairy sector.

### **The concept of novel food in the modified framework**

- **Existing permissions for novel foods**

Dairy Australia supports the proposed approach in the Consultation Paper.

- **Consideration of nutritive and related substances**

We do not consider there are nutritive substances in addition to vitamins and minerals, electrolytes and L-amino acids which should automatically be subject to pre-market approval by FSANZ.

Dairy Australia is supportive of the proposed approach which offers consistency for both nutritive substances and novel foods. It is however noted that the under the proposed modified framework, consideration of the requirement for a pre-market assessment for new nutritive substances will be made against the Eligible Food Criteria, the details of which are yet to be fully considered. So our support must be seen in the context that it is dependent on full understanding and support for the Eligible Food Criteria, which will not be confirmed until the opportunity for further consultation on this issue is presented.

- **Amended data requirements for applications**

Dairy Australia is supportive of the proposal to consider possible amendments to the FSANZ Application Handbook, to streamline the assessment process by amending the data requirements for applications. We would encourage such a review to be focussed on food safety and to set requirements proportional to risk.

- **Summary of modified framework**

As already mentioned in this submission, Dairy Australia is disappointed to see the removal of the self-assessment pathway in the modified framework. We feel this is the pathway most likely to facilitate and encourage innovation and strongly encourage that work continue to determine a way such an option could be included in the framework.

We acknowledge the concerns raised by enforcement agencies but would encourage the option to remain, to permit further discussion and exploration of a mutually acceptable solution. In the absence of the self-assessment pathway, the proposed modified framework cannot be fully supported without further clarification of the conditions encapsulated by the Eligible Food Criteria concept.

At the point at which any proposed legislation is put forward for a cost benefit evaluation, it may well be worth including the concept of a self-assessment pathway (even if it is not legislatively possible) as it would still provide a more realistic reflection of overall costs and benefits of the legislation, by providing

## **Review of exclusive permissions**

Dairy Australia strongly supports the retention of exclusivity provisions and welcomes further discussion on the content of these. In our response to the Call For Submissions in December 2015, we stated:

1. ***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.*

The Consultation Paper provides reference to public interest in the information and detail contained in applications. Whilst this interest is valid, it does not warrant any reduction in the protection of intellectual property of applicants such that any lessening of the exclusive permissions would serve to further discourage innovation. Whilst the paper also makes reference to a relatively low incidence of applicants choosing to use the exclusive permissions provisions, it is possible that this reflects existing concerns that

the period for exclusivity is insufficient to support the cost recovery of bringing innovation to market as stated above.

#### **Transition arrangements for currently marketed foods**

- **Grandfathering**

Dairy Australia supports the principle of “grandfathering” food products “on the market” at the time of gazettal as this is the most practical approach and offers no compromise to food safety. In describing the products which would be covered by any grandfathering statement, it is important to ensure the language includes both food products and food ingredients, and that with respect to ingredients, they will be considered “on the market” or supplied if they are available for sale in either Australia or New Zealand at the time of gazettal. Food products and food ingredients that previously have been sold in the Australia and/or New Zealand markets with a safe history of use, that may not be available for sale at the time of gazettal should also be included in the products to be grandfathered.

- **Microorganisms**

The current approach to the use of microorganisms in the food standards code as outlined in the Consultation Paper recognise the inherent safety of fermentation and flavour cultures. The microorganisms and the processes and methods for selection have a history of safe use. Based on this, there appears to be no food safety based justification for changing the approach to how their use is addressed in the code.

The proposed approach as described in the Consultation Paper is not completely clear.

If it is deemed that microorganisms are to be included in the revision of Nutritive Substances and Novel Foods, then Dairy Australia would support grandfathering of microorganisms that have been intentionally added to foods or ingredients that have been manufactured or sold on Australia or New Zealand at the time of gazettal.

Dairy Australia does not support the inclusion of a positive list of microorganisms in the Standard.

Whilst the microorganism may be grandfathered, manufacturers using them will retain the responsibility for ensuring that they are suitable and have a history of safe use.

#### **Part 2.9 Standards – scope and timing**

Dairy Australia acknowledges that FSANZ recognises the concerns raised by a number of stakeholders in the Call for Submissions December 2015 consultation round. We encourage that the framework applied to Infant Formula should align with that which will apply to general foods, albeit with reference to the increased vulnerability of the infant consumer.