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

**16 June 2017**
**[15–17]**

## Supporting document 1

Summary of submissions – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

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# Executive summary

Following an assessment of Proposal P1024 made under section 59 of the *Food Standards Australia New Zealand Act 1991*, FSANZ called for submissions on the outcome in December 2015. The assessment highlighted issues in relation to the regulation of nutritive substances and novel foods in the *Australia New Zealand Food Standards Code* (the Code). Arising from the assessment, FSANZ's preferred option was to develop an alternative approach to regulating nutritive substances and novel foods. The assessment documents[1] presented an alternative framework to regulating nutritive substances and novel foods.

The tables below summarise the issues raised by stakeholders as follows:

- Table 1 – List of abbreviations used in tables
- Table 2 – Overarching views on options
- Table 3 – Detailed comments on options
- Table 4 – Exclusive permissions and related issues
- Table 5 – Transitional arrangements
- Table 6 – Part 2.9 standards

[1] http://www.foodstandards.gov.au/code/proposals/Pages/P1024.aspx

**Table 1: Abbreviations used in Tables**

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| Aspen | Aspen Nutritionals Australia Pty Ltd |
| ABC | Australian Beverages Council |
| AFGC | Australian Food and Grocery Council |
| Comvita | Comvita New Zealand Ltd |
| DAA | Dietitians Association of Australia |
| Dairy | Dairy Australia |
| DCANZ | Dairy Companies Association of New Zealand |
| DGC | Dairy Goat Co-operative |
| DN | Danone Nutricia |
| FBIA | Food and Beverage Importers Association |
| Fonterra | Fonterra Co-operative Group Ltd |
| FoE | Friends of the Earth |
| Frucor | Frucor Beverages Ltd |
| GNT | GNT International BV |
| GF | Goodman Fielder Pty Ltd |
| INC | Infant Nutrition Council |
| Nestlé | Nestlé Australia Ltd |
| NSWFA | New South Wales Food Authority |
| NZFGC | New Zealand Food and Grocery Council |
| NZMPI | New Zealand Ministry for Primary Industries |
| SA | South Australia Health |
| TGB | TATA Global Beverages |
| Unilever | Unilever Australasia |
| Vic Govt | Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources |

**Table 2: Support for various regulatory options**

| Regulatory Option | Supports | Does not support | Response |
|---|---|---|---|
| **Option 1 – Status Quo** | | Aspen, ABC, AFGC, FBIA, Frucor, INC, NZFGC, TGB | For the reasons outlined in the Consultation Paper, Option 3 remains FSANZ's preferred option, subject to further consultation on the modified framework (section 2.2 of the consultation paper). |
| **Option 2 – Amend definitions** | TGB | Aspen, ABC, AFGC, NZMPI, Frucor, INC, NZFGC | |
| **Option 3 – a new framework** | Aspen, ABC, AFGC, Comvita, DAA, Dairy, DGC, DN, Fonterra, Frucor, GF, INC, Nestlé, NZFGC, TGB, Vic Govt | | |

**Table 3: Detailed comments on regulatory options**

| Issue | Raised by | Submitter comments | Response |
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| **Regulatory Option 1 – Status quo** | | | |
| **CFS Question: Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.** | | | |
| Ambiguity | Aspen, Comvita, Dairy, DN, Fonterra, Frucor, INC | The current provisions are ambiguous for both enforcement agencies and industry.<br>• This makes it difficult to determine if a food is clearly novel and requires an application to allow its use in food (Dairy, DN, Fonterra, INC).<br>• The ambiguity allows for unintended freedom to explore new ingredients without boundaries or consideration for efficacy or safety (Frucor).<br>• Global companies find that the lack of clarity in the current provisions causes costs of duplication, leading to costs of time and money. This has the potential to lead to World Trade Organization issues (DN).<br>• The current provisions may impose a risk to public health and safety due to ambiguity (Aspen). | Noted. FSANZ seeks stakeholder views on a modified framework, as described in section 2.2 of the consultation paper. |
| Pre-market restrictions | AFGC, Dairy | The current approach to mandatory premarket clearance is anti-innovation and unnecessarily restrictive. | As above |

| Issue | Raised by | Submitter comments | Response |
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| Uncertainty | Aspen, ABC, GF | The status quo creates uncertainty within the current Code provisions. | As above |
| Specific problems | INC, NZFGC | There is an absence of any mutual recognition of pre-market assessments conducted by reputable agencies overseas. | FSANZ will consider this issue further (noted in section 1.3 of consultation paper). FSANZ has had regard to pre-market assessments undertaken by overseas agencies as part of the total weight-of-evidence for all applications and proposals. |
| **CFS Question: 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.** | | | |
| Alternatives are needed to a definitions-based set of provisions | ABC, AFGC, DN, NZFGC, Vic Govt | The creation of categories of foods or substances for a particular regulatory purpose based on definitions, or undefined terms in some cases, is creating uncertainty in the marketplace.<br><br>• The uncertainty relates to whether particular foods require permission in the Code before they can be sold in Australia and New Zealand; and therefore whether the foods should be subject to pre-market assessment by FSANZ (ABC, AFGC).<br>• A broader approach to determining whether or not a product should undergo a pre-market risk assessment is required (Vic Govt).<br>• There is a level of overlap of definitions that make sections of the Code unworkable (DN, NZFGC). | Noted. See responses above.<br><br>FSANZ notes the comments on adopting a broader approach (e.g. for foods sold for technological purposes such as food additives) but considers this would broaden the scope of P0124 considerably, which may delay making amendments to address the nutritive substance and novel food issues. |

| Issue | Raised by | Submitter comments | Response |
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| Application process | ABC, Nestlé | The current 'application only' process is onerous and costly, especially if the company elects to proceed with a paid application. The existing Standard does not encourage innovation and can have a negative impact upon investment decisions. | Noted as support of Option 3.<br><br>FSANZ notes the application only process also applies to other types of foods and substances added to foods (such as food additives, processing aids, irradiated foods, foods produced using gene technology) and is not unique to novel foods and nutritive substances. The timelines for assessment of these foods is comparable to the approval processes of other jurisdictions.<br><br>FSANZ will consider possible measures to streamline the FSANZ assessment process for new foods (section 2.2.4 of consultation paper). |
| **Regulatory Option 2 – amended definitions** | | | |
| Problems with Option 2 | FBIA | Option 2 may suffice for current considerations of foods, but would constrain innovation within the terms of the new definitions and so, would not be an adequate solution to the problem. | As above |
| | NZMPI | MPI believes that new definitions alone will not achieve secondary objectives such as a framework of proportionate risk and opportunities for industry to access the market quickly and without undue regulatory burden. | As above |

| Issue | Raised by | Submitter comments | Response |
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| **Regulatory Option 3 – a new framework** | | | |
| **CFS Question: Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?** | | | |
| Supports the alternative framework, but only if modifications are made | AFGC, Fonterra, INC, Nestlé, NZFGC, NZMPI | • AFGC, Fonterra, INC and NZFGC provide a caveat to their support of option 3, stating that the option must be modified to apply to special purpose foods.<br>• NZMPI is concerned that the proposed framework for option 3 may not be viable, unless FSANZ is able to assist jurisdictions with centralised technical advice, or FSANZ provides such a service under a new model (e.g. requiring changes to the FSANZ Act and the funding model). | FSANZ has clarified how special purpose foods will be addressed (section 3.3 of consultation paper).<br><br>The comments on the viability of the framework have been addressed by removing the self-assessment notification pathway (section 2.2 of consultation paper). |
| Support all aspects of the alternative framework except the self-assessment pathway | NZMPI | NZMPI may also support a modified option 3 that includes amending the definitions, applying the EFC and FSANZ application process, but does not include the industry self-assessment pathway. | Noted, as above |
| **CFS Question: 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?** | | | |
| Yes, the draft framework is a viable option | ABC, Comvita, Dairy, DN, Frucor | • Comvita stated that it was viable except in respect to the publication of full dossiers.<br>• 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 (Dairy). | For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework (section 2.2 of the consultation paper). |

| Issue | Raised by | Submitter comments | Response |
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| No, the draft framework is not a viable option | Vic Govt | Does not support enforcement agencies being responsible for determining compliance with the EFC. A variation of option 3 could be viable. This would require exclusion of the first proposed element of the draft framework, which allows new foods that meet the EFC to go to market without regulatory approval. We advocate for FSANZ to undertake a fast-track assessment of foods meeting the EFC instead. | A requirement for all new foods to go through a FSANZ approval process, even a streamlined one, would impose a greater regulatory burden than the current process (where not all new foods require pre-approval – i.e. those not considered 'novel').<br><br>FSANZ considers an approach that requires FSANZ assessment oversight of all new foods, including those meeting the EFC, would be disproportionate to risk and may not be consistent with FSANZ' secondary objective to support a competitive food industry. FSANZ can work with jurisdictions on implementing this proposal, including provision of guidance material to assist interpretation. |
| **CFS Question: What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.** | | | |
| The proposed self-assessment pathway is not viable | NSWFA, NZMPI, SA, Vic Govt | The proposed industry self-assessment is not viable for the following reasons:<br>• Enforcement authorities do not have the technical capacity or the resources to assess dossiers used to demonstrate that foods meet gateway tests for non-eligible foods (SA, NZMPI, Vic Govt). In Victoria, that responsibility would fall to the 79 local government authorities (Vic Govt). Experience to date with the introduction of industry self-assessment for general level health claims supports this position (SA, Vic Govt). | For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework |

| Issue | Raised by | Submitter comments | Response |
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| | | • FSANZ would need to have a direct role in providing a centralised safety assessment advice to make the self-assessment pathway viable (NZMPI).<br>• The industry self-assessment is too complicated for most businesses. Most small to medium enterprises will not have the ability, capacity or resources to be able to meet this requirement (SA).<br>• It appears that a business can begin to sell a novel food following the notification of their dossier to the food regulators/authorities (NSWFA, NZMPI). This could result in retrospective enforcement as the business would not know until after sale as to whether food regulators/authorities have disagreed with the assessment (NZMPI).<br>• The *Ministerial Policy Guideline for the Fortification of Substances Other than Vitamins and Minerals* requires that the presence of a fortificant substance should not mislead the consumer as to the nutritional quality of the food. It is unclear how compliance with this policy principle would be achieved without pre-market regulatory scrutiny (NSWFA). | |
| Support for the proportionate approach to risk | DAA, Fonterra, INC | Supports the proportionate approach to risk with low risk foods being managed through pre-market self-assessment, pre-market self-assessment with notification and for those food of highest risk requiring pre-market assessment. This is a more efficient approach to managing the market entry of new food substances. | See above. |
| Conditional support | ABC | Conditional support for option 3, acknowledging that further details are required to determine viability. The current FSANZ Application and evaluation protocol can be the cause of global hesitance to enter into Australia or attempts to bypass the regulatory requirements. Option 3 shows great insight into the NPD / innovation process in the modern food and beverage industry and can address these issues. | Noted. |
| **Alternative Regulatory Options** | | | |
| Options that involve centralising assessment processes | Vic Govt, MPI | Vic Govt and NZMPI proposed similar approaches to replace the industry self-assessment with a streamlined (rapid) application process for foods that meet the EFC. This process would be centralised and conducted by FSANZ (NZMPI suggested that this could instead be a FSANZ-led committee).<br><br>• The FSANZ Act and the FSANZ *Application Handbook* would need to be amended so that FSANZ can assess eligible food criteria conformance and dossiers (NZMPI, Vic Govt). | Amendment of the FSANZ Act and other legislation remain matters for Government and are out of scope for P1024 (section 2.2 of the consultation paper). |

| Issue | Raised by | Submitter comments | Response |
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| | | • International assessments of the novel food could be used for fast tracking, as FSANZ would be able to assess the validity of these assessments (Vic Govt).<br>• A centralised assessment process would require increased resources within FSANZ, and thus additional new funding (NZMPI).<br>• The assessment could be restricted to a specified period of time (for example 30 days), after which the dossiers must be publicised and the product should be able to be sold on the market. There may not be a need for public consultation with this approach (NZMPI).<br><br>The reasons provided for this alternative approach were that it would ensure national consistency in the assessment of information and dossiers (Vic Govt), and that FSANZ is the only organisation with the level of technical knowledge and understanding of the food regulatory system to be able to undertake the work (NZMPI, Vic Govt). | Consideration of the issue of overseas assessments and approvals will be dealt with in the next stage of the Proposal. |
| | Vic Govt | Vic Govt suggested another centralised option, based on a tiered application process.<br><br>1. Fast track assessment carried out by a group similar to the FSANZ Advisory Committee on Novel Foods (ACNF) comprising FSANZ officers. The assessment would use technical information on the food (for compliance with EFC); assess whether claims made about a safe history of use could be substantiated, or whether recognised international agencies had already assessed the safety of that specific product. FSANZ would decide whether a dietary exposure assessment is required based on overseas information on safety (if available).<br>2. FSANZ makes decision on whether a full pre-market approval by FSANZ is required based on analysis of the information above and gateway tests.<br>3. These gateway tests include an assessment of:<br><br>• other assessments that may be required;<br>• other standards would need to be complied with; or<br>• any applicable policy guidelines that FSANZ should have regard to.<br><br>Foods which are determined to not require a full assessment would be listed in the Code (without further public consultation). | Noted. This is addressed above. The modified framework retains the approach of permitting foods meeting certain criteria (to be developed further) to be sold without requiring pre-market approval. |

| Issue | Raised by | Submitter comments | Response |
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| Options based on changes to the Code and/or *Application Handbook* | SA | SA proposed the following in addition to the regulatory options provided in P1024:<br><br>1. Amend the technological purposes listed in Schedule 14 to include "achieve a nutritional purpose". This would mean that nutritive substances would be considered food additives if used for a nutritional purpose. Such nutritive substances would require a risk analysis as per other food additives.<br>2. Remove Standard 1.5.1 - Novel foods<br>3. Amend Standard 1.4.4 – Prohibited and restricted plants and fungi to be an expanded list of prohibited substances that cannot be added to food<br><br>**Scenario for nutritive substance:**<br><br>If the food business intends to use the substance for a nutritive purpose they would not be allowed to use it without applying to amend the Code. If the food business intends to use the substance as a food and not with the technological function as a nutritive substance then they would be allowed to do so, but it would remain their responsibility to offer for sale a food that is safe and suitable.<br><br>**Scenario for a novel food:**<br><br>Novel Foods would no longer be regulated by a novel food standard. The decision of whether a novel food (like any other food) is safe and suitable is made by the food business, enforced by the States and Territories and decided by the courts if in dispute. | Stakeholders are generally supportive of maintaining requirements in the Code for novel foods, noting the difficulties in relying solely on safe and suitable provisions in the food acts.<br><br>Amending Standard 1.4.4, to identify substances that should be prohibited, may be reactive in nature and be a case by case proposition (e.g. relying on reports of adverse effects). Such an approach is likely to be resource intensive for government agencies (including FSANZ) and may be subject to more uncertainty than the current Code provisions. |
| | NSWFA | NSWFA requested that FSANZ explore the possibility of further developing and adding 'eligible food criteria' to the Handbook This would allow applicants to compile their own safety assessments and provide to FSANZ for review. This approach would clarify what information is required for the industry self-assessment.<br><br>As part of this suggested alternative, it may be necessary to amend the novel food standard and nutritive substances definition to ensure that processes outlined in the Handbook are followed. | See above response to Vic Govt submission. |

| Issue | Raised by | Submitter comments | Response |
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| Use overseas assessments instead of EFC to exempt novel foods from a pre-market assessment | AFGC | The AFGC proposes a three category process for assessing novel foods.<br><br>• 'Exempted" if the novel food meets certain criteria (an existing unrestricted approval from a comparable overseas economy/jurisdiction) with data to be held by manufacturer<br>• "Reported" if the novel food is not exempted and meets certain other criteria (i.e. overseas approval with restrictions), thus requiring a self-assessment analysis and data to be provided to FSANZ<br>• "Assessed" if the novel food is not exempted or reported (self-assessed), with a regulatory analysis and process required. | FSANZ will give further consideration to overseas assessments and approvals during the next stage of the proposal. |
| **Comments on EFC and self-assessment notification pathways** | | | |
| **CFS Question: What type of information do you think should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.** | | | |
| Businesses should not be holding any information | NSWFA, SA, Vic Govt | It would not be sufficient for food businesses to simply hold information. The experience provided by the self-substantiation of health claims demonstrates there needs to be a centralised body that verifies the safety of a proposed eligible food. | The foods which comply with the EFC are of low potential risk. FSANZ considers a proportionate approach is suitable for these foods. This is comparable to the current approach, where not all new foods are considered 'novel'.<br><br>The modified framework would enable jurisdictions to request the required information from industry to ensure the requirements that will be set out in the Code are met. |

| Issue | Raised by | Submitter comments | Response |
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| **CFS Question: Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?** | | | |
| Not meet EFC, but are suitable | INC, Nestlé | New foods or substances permitted elsewhere (INC, Nestlé), such as Codex, EU and US GRAS (INC). | FSANZ will give further consideration to overseas assessments and approvals during the next stage of the Proposal. |
| **CFS Question: Please provide details of how a self-assessment pathway may or may not provide benefits to industry.** | | | |
| Reduced time to market | ABC, AFGC, Dairy, Nestlé, NZMPI, TGB, Unilever | Time to market would be reduced over the current application process.<br>• The current process involves a delay while the application sits on the waiting list (if not a paid application) and is then assessed by FSANZ (ABC, AFGC, Dairy, TGB, Unilever). Would allow for a reduced time to product launch (Nestlé).<br>• NZMPI added the caveat that the reduced time would depend on whether the food regulators/authorities are able to assess dossiers without undue delay.<br>• There could also be less development time for product manufacturers if novel food suppliers already have dossier prepared (AFGC). | Noted. However, see responses above in relation to the self-assessment pathway. |
| Increase access to overseas products | ABC, Dairy, Nestlé | May encourage companies to bring food products to Australia and New Zealand that are currently available overseas, however the current application process makes it too burdensome to do so. | Addressed above. |
| Innovation | DCANZ, Frucor, Nestlé | The benefits to industry would be flexibility for innovation. | Noted. |
| Regulatory certainty | NZMPI | Regulatory certainty would result if the assessment by the regulators/authorities has a legal status. Confidentiality throughout the regulators/authorities assessment phase and possibly for a period following notification would provide a substantial commercial benefit for industry. | Noted. |
| Reduced regulatory burden | Comvita | A level of accountability for the safety of low-risk non-eligible foods will be held across industry without the undue burden of pre-market approval. Could have the potential to lift the credibility of the industry as a whole. | Noted. |

| Issue | Raised by | Submitter comments | Response |
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| Potential negatives | Nestlé, NZMPI | • Food regulators / authorities need to have the resources and expertise to assess dossiers. Resourcing and expertise issues could make it more expedient for the food business to submit an application to FSANZ (NZMPI).<br>• Potential inconsistency in implementation leading to uneven playing field (Nestlé)<br>• Uneven technical capacity across the food industry (manufacturers / ingredient suppliers) (Nestlé)<br>• Reputational risk from vested interests challenging dossiers from a non-scientific position (Nestlé)<br>• Potential loss of confidentiality or trade secrets leading to loss of opportunity to recoup R&D investment (Nestlé). | Noted. For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework (section 2.2 of the consultation paper). |
| **CFS Question: 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.** | | | |
| Does not support self-substantiation | NSWFA, NZMPI, SA, Vic Govt | The following reasons were mentioned:<br>• A self-substantiation system runs the significant risk of nationally inconsistent outcomes (NSWFA, NZMPI).<br>• Jurisdictions, whether individually or as a collective, are unlikely to have the resources or expertise to fully assess dossiers prior to publication online (NSWFA, NZMPI).<br>• There may be legal issues if an assessment is not conducted (NZMPI)<br>• Publication of a dossier on the website of an enforcement agency could be viewed as an endorsement (NZMPI)<br>• Unsure whether criteria can be developed that clearly determine whether industry can self-assess their dossier or not (NZMPI).<br>• Publication of dossiers can undermine the incentive for businesses to invest in the addition of novel or nutritive substances to foods that could be beneficial to consumers (Vic Govt). | Noted. For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework (section 2.2 of the consultation paper). |

| Issue | Raised by | Submitter comments | Response |
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| Independent review of the dossier | Fonterra | Does not consider publication of dossiers is the best approach to provide regulatory oversight and consumer confidence in the industry self-assessment pathway. Proposes an alternative self-assessment pathway, which includes an independent expert assessment to add objectivity of assessment of safety:<br><br>a. Company X develops the dossier to use as the basis for determination;<br>b. The dossier is subject to an independent expert review;<br>c. Company X holds the dossier and independent expert review on file in house; and<br>d. The dossier can be requested by food authorities if required. | FSANZ notes this is a variation on the self-assessment notification route and is similar to the US GRAS process.<br><br>For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework (section 2.2 of the consultation paper). |
| **CFS Question: 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.** | | | |
| No negative impacts identified | AFGC, INC, Nestlé, NZFGC NZMPI, SA | No. Agree that these foods are generally added for a similar purpose so can be combined.<br><br>The AFGC recommended removing the concept of nutritive substance from the Code, instead regulating specific substances of concerns, such as amino acids. | The support for combining nutritive substances and novel foods is noted.<br><br>The modified framework retains a requirement for L-amino acids to be approved via an application route (section 2.2.3.3 of the consultation paper). |
| Impact due to the definition of 'nutritive substances' | ABC, AFGC | The concept of nutritive substances could be considered to be flawed as it is duplicative, confusing, complex and uncertain. | Noted. For the reasons outlined in the Consultation Paper, Option 3 remains FSANZ's preferred option, subject to further consultation on the modified framework (section 2.2 of the consultation paper). |

**Table 4: Submitters' Comments on exclusive permissions and related issues**

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| Does not support publication of dossiers | Aspen, ABC, AFGC, Comvita, Dairy, DCANZ, DN, Fonterra, GF, Nestlé | The following comments were made in addition to expressing no support for the publication of dossiers:<br><br>• Recognises the principle that regulatory outcomes should be transparent. However there needs be a balance with information disclosure (ABC, AFGC, Comvita, GF).<br>• The 15 months exclusivity coupled with a reduced FSANZ approval process timeframe is not enough to fully offset the costs of developing intellectual property. As such, the self-assessment notification process will not provide an adequate trade-off against the publication of intellectual property (Dairy, Fonterra). Fonterra also stated that intellectual property can take decades to develop and may relate to multiple products, including products not yet on the market.<br>• Details of who should hold the data and the level of access should take account of issues such as the intellectual property of the information (DN). | FSANZ notes these comments were made in relation to the self-assessment notification route, which has been removed from the modified framework (section 2.2 of the consultation paper).<br><br>However, some of these issues are relevant to the review of exclusive permissions (covered in section 3.1 of the consultation paper) and will be further considered in that context. |
| Full publication of the industry self-assessment dossier is not viable | ABC, AFGC, Comvita, Dairy, DCANZ, Fonterra, Frucor, GF, Nestlé, NZFGC | The full publication of industry self-assessment dossiers is not viable for the following reasons:<br><br>• The current proposal to publicise the full dossier provides no intellectual property protection (Dairy, DCANZ, Fonterra, Frucor, NZFGC).<br>• Any requirement to disclose confidential information serves as a disincentive for companies to seek approval for innovative technology and even to invest in developing such technology in the first place (ABC, AFGC, GF, NZFGC)<br>• Concerns over reputational risk arising from non-science based external challenge, or attack on published self-assessments, through the national media and the free rider effect where competitors could access the published information and prepare a similar dossier at lesser cost and time. | As above. |

| Issue | Raised by | Submitter comments | Response |
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| Supports publication of dossiers | NZMPI, FoE | NZMPI supports the notification and publication of dossiers, with two caveats:<br>• Supports some form of data protection of the information published on the dossier<br>• There is enough information published to demonstrate that the dossier was assessed objectively by the self-assessor (i.e. the business) and by the food regulators/authorities. | As above. |
| Alternative dossier - a short version could be made public | Aspen, Dairy, Fonterra, Frucor, INC, NZFGC | Suggests that a summary or shortened version of this information is made public rather than the company's complete dossier.<br>• At a minimum the information that is made public would include reference to scientific evidence demonstrating the food does not pose a safety risk to human health. This would ensure confidentiality of sensitive information is protected whilst keeping the public's confidence in the safety of new foods supplied to the market (Aspen). | As above. |
| Alternative dossier - intellectual property is provided to enforcement authorities only | Aspen, Comvita, Dairy, DCANZ, DN, Nestlé, NZFGC | Commercially sensitive information should only be provided to the authorities (jurisdiction enforcement agencies), rather than included in a publicly available dossier, similar to the arrangements for health claims substantiation:<br>• NZFGC also added that it would oppose the extension of this arrangement to retailers since many retailers are also competitors (with home brands) thus resulting in a dilution of investment and innovation. | As above. |
| **CFS Question: Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.** | | | |
| Support retaining exclusive permissions in the Code for foods approved by FSANZ. | Comvita, Dairy, DN, Fonterra, Frucor, INC, Nestlé, NZMPI, SA, NZFGC | A number of these submitters also made additional comments associated with their support.<br>• NZFGC added the caveat that exclusivity should apply to notification of industry self-assessed substances.<br>• Exclusivity provides a competitive advantage for the innovative business seeking approval and enables it to recoup some of the costs associated with providing dossiers for a FSANZ safety assessment (NZMPI). | Support for the current exclusive permission arrangement is noted, as is the view these should be extended.<br><br>FSANZ is seeking further input on the review of the exclusive permission arrangement (section 3.1 of the consultation paper). |

| Issue | Raised by | Submitter comments | Response |
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| | | • The exclusivity period should be increased to align with other jurisdictions. The EU Novel Foods system offers data protection, such that evidence and proprietary data cannot be used for the benefit of another application for 5 years after the novel food has been authorised (Comvita).<br>• The provision of exclusivity may require further consideration in relation to a situation where FSANZ receives a request for pre-market approval with exclusivity for two identical (or near identical) products at the same time (Fonterra, NZFGC).<br><br>Exclusive permissions in the Code allow for clarity in interpretation and thus ease of communication, implementation and establishing compliance strategies (SA) | Currently if two applications are received for the same food, both may be granted exclusive permission (if requested). |
| Problems associated with exclusive permissions | ABC, AFGC, DN, Dairy, Nestlé | Current period of 15 months is not long enough to achieve a return on investment or for competitors to be locked out.<br>• Product development may only be finalised after novel food approval that can take up to 12 months (Nestlé). If the provision is to be retained, then the period of exclusivity must be extended to 3 years on the grounds of additional time for completing product development post-approval by FSANZ and time for new product launch (ABC, AFGC, Nestlé).<br>• Provided cost information indicating inadequacy of a 15month period (Dairy) | Noted and further input sought on this issue, as detailed above. |
| | Aspen | If exclusivity is permitted, then data protection should not be granted because having both provisions would not allow other companies to evaluate whether the authorised product is the same as one they are interested in.<br><br>Further, if exclusivity is permitted, generic authorisations should be granted over individual authorisations so when the exclusive period is over, it becomes a permissible ingredient for the industry. This will minimise regulatory burden on industry as well as on FSANZ. (FSANZ notes that this is the status quo in regards to the application of exclusive marketing provisions in the Code). | Noted. The issue of data protection is discussed in the Consultation Paper at section 3.1.3.<br><br>FSANZ notes that currently exclusive permissions revert to a generic permission for the food after the period of exclusive permission expires. |
| Opposes exclusivity | FoE | Considers this to be a form of extra-legal intellectual property not part of any current IP system. An 'innovative' combination of ingredients would not and should not be subject to this form of commercial exclusivity and nor should other 'innovations' unless they can satisfy existing IP requirements. | Noted. FSANZ is seeking further input in relation to exclusive permissions. See section 3.1 of the Consultation Paper. |

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| **CFS Question: Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods, 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?** | | | |
| Self-assessed foods should have the same level of exclusivity as applications | Aspen, INC, NZMPI | Exclusive permission should be given to businesses conducting a self-assessment in the same way as businesses that are required to apply to FSANZ for a safety assessment, as considerable resources time and funds have been invested in both scenarios.<br><br>• NZMPI supports industry having the option of submitting an application to FSANZ so that they can choose to use the application process for the benefit of the exclusive use permission.<br><br>All companies that have invested resources to a new food should not be prevented from also applying for pre-market assessment with the accompanying data and dossiers (Aspen, INC). | Noted. For the reasons outlined in the Consultation Paper, the self-assessment notification pathway has been removed from the modified framework (section 2.2 of the consultation paper). |
| The self-assessment process is only a suitable trade off if there is no public notification | AFGC, DN, Frucor, INC, Nestlé, NZFGC | If documentation and data sets for the Pre-Market Assessment by Notification Pathway are not public, then notification delivers some level of exclusivity and has the advantage of speed to market.<br><br>• There is however an issue of unintended consequence of this type of informal exclusivity, particularly with industry self-assessment, where a competitor could be 'blocked' by preparing a notification (or making an application for approval) when no intent/capacity to use the substance exists (NZFGC).<br>• INC presumes that exclusivity would not preclude applications by other parties for substances that are similar but not identical or applications for identical substances that reflect different documentation and data for delivery.<br>• Nestlé stated that if there is a disclosure of the innovators intellectual property, then the first to market advantage and managed launch timing is not a sufficient trade-off for the lack of exclusivity (Nestlé). | As above. |

| Issue | Raised by | Submitter comments | Response |
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| Benefits exist only for large companies | Aspen | If exclusive permission for a specific brand is permitted, this option will only be of benefit to large corporate companies where resources are more readily available. Smaller companies may be unnecessarily disadvantaged if 'speed to market' is the only criteria for exclusivity of new foods. | Once an exclusive permission period ends the benefit is available to all food manufacturers because the permission becomes a generic permission for the food. |

**Table 5: Submitter Comments on Transitional arrangements for existing foods in the market**

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| **CFS Question: Do you support a cut-off date? Please provide reasons for your view.** | | | |
| Supports a cut-off date | Aspen, AFGC, Comvita, Dairy, DCANZ, Frucor, Nestlé, NZFGC, NZMPI | A number of these submitters gave the following reasons for their support:<br>• The advantage of a cut-off date is that it objectively identifies and removes doubt about the foods that will be subject to the proposed new framework (AFGC, Aspen, Comvita, NZFGC).<br>• Re-defining terms like 'history of human consumption' through a cut-off date as it is the most efficient way of providing legal certainty (NZMPI).<br>• A cut-off date allows industry to work towards a deadline (Frucor) | Support for the proposed approach is noted. |
| | Fonterra, INC | Supports a cut-off date only if products under Standards 2.9.1, 2.9.2 and 2.9.5 are included. | Transitional arrangements for these standards are clarified in section 3.2 of the consultation paper. |

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| **CFS Question: Do you see a need for grandfathering provisions? Please provide reasons for your view.** | | | |
| Supports the grandfathering of provisions | Aspen, AFGC, Comvita, Dairy, DN, DCANZ, Fonterra, INC, Nestlé, NZFGC, NZMPI, Vic Govt | The following reasons were provided by submitters for their support:<br>• Will remove doubts about foods and/or ingredients that are currently available for purchase (Aspen, NZFGC).<br>• Grandfathering eliminates the regulatory burden on foods that were eligible to be put on the market at that time (Comvita).<br>• Grandfathering provides certainty (Nestlé). | Support for the proposed approach is noted. |
| The types of novel foods that should be grandfathered | DCANZ, Nestlé NZMPI | These submitters supported grandfathering provisions, but requested clarity on the types of novel foods that would or should be captured:<br>• Novel foods and nutritive substances that are currently on the market but not permitted under Schedule 25 should not be grandfathered in automatically, as some of them may not have had any pre-market assessment. FSANZ should consider a market scan of such foods (NZMPI).<br>• Need to reconsider those foods with ACNF opinions (NZMPI)<br>• Supplemented foods manufactured in compliance with the New Zealand *Food (Supplemented Food) Standard 2013* should be captured and grandfathered into the novel foods standard (DCANZ).<br>• Does grandfathering apply to truly novel substances, or new foods built from existing permitted ingredients/substances? What about new uses for foods already permitted via the red lane? What about imported foods ingredients or substances that may be used in limited quantities, will these be 'grandfathered'? (Nestlé) | Transitional arrangements for these standards are clarified in section 3.2 of the consultation paper. |
| Suggested method for grandfathering | Vic Govt | Addressed existing permissions only. The Code should include a schedule of eligible foods (including non-eligible foods that passed gateway tests). Current permissions could be moved to this list, which could have one section with GRAS status, the other with restrictions. | FSANZ considers a list of all eligible foods is unlikely to comprehensively cover all new foods. FSANZ considers the EFC pathway provides a risk proportionate approach to the risks that may be presented by new foods. |

| Issue | Raised by | Submitter comments | Response |
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| **Consideration of Microorganisms** | | | |
| | AFGC, INC | Does not support the establishment of a list of microorganisms which can be used following gazettal – there doesn't seem to be any other rationale for requiring all new micro-organisms to undergo pre-market assessment. Micro-organisms are widely used in the food and beverage sector, the population of micro-organisms is dynamic and diverse. To constrain use by a positive list is neither efficient nor practical. | Noted. FSANZ seeks input on the alternative approach outlined in the consultation paper (section 3.2.2.4). |
| | AFGC, NZFGC, Dairy, Fonterra, Nestlé | Long history of use of microorganisms in a variety of foods and there are cases where the exact composition of microorganisms is not known (e.g. starter cultures, fermentation organisms). A positive list is unlikely to cover all possibilities and will require ongoing monitoring and updating, with likely delays or lags in updating the list creating impediments to innovation. In addition, accidental omissions from a positive list may occur. | As above. |
| | DCANZ, Dairy, Fonterra, INC, NZFGC | If a positive list is included in the Code, the European Union Qualified Presumption of Safety list should be a starting point; other reference sources should also be considered. | As above. |
| | Comvita | Agrees with a list of microorganisms which do not need regulatory approval. | Noted. |
| | Comvita, Dairy, NSWFA | Requests clarification on how genetic stability will be defined and measured. | FSANZ will consider this further during the next stage of the Proposal. |

**Table 6: Submitter Comments on Part 2.9 Standards**

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| Scope of the proposal concerning special purpose foods | Aspen, AFGC, DGC, DN, Fonterra, INC, Nestlé, NZFGC | Requests the inclusion of standards in Part 2.9 within the scope of P1024. INC and DN specifically request the inclusion of Standard 2.9.1 – Infant formula products. The following reasons were provided.<br><br>• Of the eight standards in the Code that refer to 'nutritive substances', five of these standards are in Part 2.9 and three of those Standards (Standards 2.9.1, 2.9.2 and 2.9.5) are specifically excluded from the scope of Proposal P1024. It is inappropriate to develop a system for the future regulation of nutritive substances when the bulk of the application of the term is in Standards that are excluded from scope (AFGC, Fonterra, GF, INC, NZFGC).<br>• The rationale for excluding Standard 2.9.1 from P1024 is unclear and requires further consultation and consideration by FSANZ (Aspen, Nestlé). INC and NZFGC also stated that the current regulation of novel foods in relation to Standard 2.9.1 is no different to the regulation of novel foods in the general food supply.<br>• While the vulnerability of infants is a valid issue, there is no justification for not including infant formula in P1024. Also, the Ministerial Policy Guideline on the Regulation of Infant Formula Products is in line with option 3 (Aspen, INC).<br>• Concern there will be a regulatory gap if P1024 is gazetted before P1028 since provisions relating to nutritive substances and novel foods in 2.9.1 rely on the general definition of novel foods and nutritive substances. If P1024 is gazetted before P1028 then the 2.9 standards out of scope will default to the current inadequate provisions. It may take up to 2 years to progress other proposals to cover foods not covered by P1028 and P1024 (AFGC, Aspen). | FSANZ has clarified the approach to Part 2.9 standards in section 3.3 of the consultation paper. |
| | NZMPI | Notes that the proposed intent to combine the regulation of novel foods and nutritive substances does not impact on foods for special medical purposes, infant formula and infant foods because they are excluded from the scope of P1024. | As above. |
| | DGC | Concern that 2.9.3 Div 4 Formulated Supplementary Foods for Young Children is not in scope. There is an opportunity to align permissions in the Codex standards for follow-up formula for children aged 6-36 months, currently under review. | As above. |

| Issue | Raised by | Submitter comments | Response |
|---|---|---|---|
| Standard 2.9.4 | Vic Govt | Identified problems with addition of substances to formulated supplementary sports foods | Grandfathering is addressed in section 3.2 of the consultation paper. |
| How to incorporate foods regulated by Part 2.9 | Fonterra, INC | The framework proposed in Option 3 should be applied to Standard 2.9.1.<br><br>• A differentiating aspect for infant formula products could be a requirement that all safety assessment dossiers should include a focus on data that is relevant to infants as the target population group. | Noted. As above, noting that Proposal P1028 will continue to address products regulated by Standard 2.9.1. |