Nestlé Submission

Consultation Paper - Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

July 2017

Acknowledgment

Nestlé is pleased to be able to respond to the Consultation Paper on the food standard relating to nutritive substances and novel foods.

Related submissions

Nestlé has had involvement with, and supports, the comments made in the submissions of the following parties:

- Australian Food and Grocery Council (AFGC)
- New Zealand Food and Grocery Council (NZFGC)
- Infant Nutrition Council (INC)

Submission to FSANZ re Consultation Paper

Proposal P1024

July 2017

Overarching Comments on the Proposal

Rejection of the self-assessment plus notification pathway – our concerns

Objective

Nestlé believes that the intention or objective of revision of the regulation of Nutritive Substances and Novel Foods is to remove current ambiguities and uncertainties, and to facilitate innovation by adopting a risk based process for approval of these foods. As described in the first Call for Submissions (1st CFS), this would result in only those foods that have inherent and obvious risk being subject to full pre-market assessment (pathway 3) by FSANZ. Eligible foods and foods with minimal or low risk would be subject to self-assessment (and notification) risk based processes (pathways 1 and 2) undertaken by industry.

Nestlé reiterates its strong support for the 3 pathway model proposed in the 1st CFS.

Growth agenda

Both Australia and New Zealand governments have clearly articulated growth agendas, and these respective agenda include strong contributions from the primary and secondary (processed food) food industries.

It is Nestlé's position that growth can be facilitated by innovation leading to higher value products. Innovation can be enhanced by enabling rapid adoption of new foods, new substances, and new processes. Lengthy approval processes, particularly for low risk foods, along with the potential disclosure of proprietary information is likely to be counter-productive to innovation.

Rejection unfounded

Nestlé is deeply concerned that the self-assessment-notification pathway (pathway 2) has been rejected, without further industry engagement or characterisation of the issues/reasons and consideration of solutions or further alternatives. There has been little documented consideration of the consequential costs, benefits, detriments at a qualitative or quantitative level, or the potential loss of innovative capacity and flexibility.

Reasons given for the rejection of pathway 2 (refer to FSANZ executive summary in consultation paper) include:

1. The lack of centralised regulatory and scientific oversight, leading to jurisdictions being required to assess dossiers;
2. The varying level of expertise and resources leading to inconsistent outcomes across Australia and New Zealand; and

3. FSANZ resourcing constraints leading to concerns over burdening existing resources.

Question from Nestlé: Nestlé respectfully asks – 'Are these reasons based on matters of policy, principle or logic; or reasons of administration and implementation expediency?'

These specific concerns are addressed later in this paper.

Consequences

With little indication of how the 'revised' Eligible Food Criteria (EFC) might be defined or expanded, Nestlé submits that the potential or likely consequence arising from rejection of the self-assessment notification pathway is a novel food regulatory arrangement similar to that which exists today, and which is considered unsatisfactory.

There is currently little incentive to make novel food applications and the existing FSANZ processes (being a minimum of 9 months to assess the application in addition to the time required for the industry R&D process and to prepare dossiers) has the effect of slowing innovation. Suggestion of streamlining FSANZ processes is potentially helpful, but such changes have been mooted previously and progress is hampered by existing legislation and traditional regulatory practice.

*A change in the **regulatory model?***

The pace of change in the current scientific and technology environment is continuing to accelerate. 'The digital age,' as it is currently termed, along with 'big data' are challenging and overtaking existing business models. On-line retailing, personalised nutrition based on individual genomics, globalisation of media and social media are just some examples. Scientific output is accelerating – exponentially.

At a food industry level, product development and innovation, functional foods, new ingredient introductions, new business start-ups are following a similar trend. Simply put, there is an accelerating level of activity and pace of change across the board. This puts current regulatory systems, with limited resources and capped headcount at a huge disadvantage. Adaption to the new environment is required, if the existing systems are to avoid being overwhelmed. Legislative change may be required to enable the regulatory system and the food industry to keep pace and remain competitive. (See also FSANZ Act 1991 – page 7).

Food safety

Risk based food control plans are an effective response to assessing change in respect of food production. Risk based plans are replacing rule based, hands on, labour intensive inspection services with risk based (HACCP[1] type) assessments and control strategies. Risk based approaches are common throughout food manufacturing organisations being applied to end-to-end manufacturing and operations processes, and support functions such as human resources and marketing all of which can affect food safety performance.

[1] HACCP – Hazard Analysis Critical Control Point

Permissions for new foods: The current regulatory processes for approval of new foods are resource intensive and time consuming. This is justified where uncertainty is high and risk is therefore increased, but many new foods and food substances pose a low risk as well as any risks have been well researched and characterised or mitigated during development.

It is more efficient at all levels (regulatory, industry, society) to require industry to fully address low risk new foods, and for FSANZ to focus on and address those fewer high risk foods. It may be contended by some parties that all new food permissions must be controlled and if not, our health is at risk, yet equally important food safety decisions are being made successfully, daily, in thousands of businesses without centralised control.

Application beyond nutritive substances and novel foods: If a widely accepted risk based approach can be developed for regulation of nutritive substances and novel foods, then Nestlé submits that it could be applied more broadly to permissions for food additives and processing aids for example. A streamlined approach to these lower risk substances could improve regulatory efficiency, reduce industry costs and support innovation.

Alternative risk based model for regulation of nutritive substances and novel foods

Risk based food legislation is gaining momentum globally. Food safety plans are prepared by industry and reviewed by accredited and independent agencies or verifiers. Responsible food businesses, assessed as being competent, operate the food safety plans and meet the challenge of providing safe and suitable food for millions of consumers. Compliance with these food safety plans is also audited, either through internal functions or with third party auditors. Central authorities provide oversight but are not involved in day to day activities.

In respect of nutritive substances and novel foods, Nestlé contends that self-assessment with notification is still an option, utilising a 'risk based' model, similar to that in place for regulation of food safety. A risk based approach could allow food businesses assessed as competent to self-assess and notify nutritive substances and novel foods permissions through the following process:

1. A written, verified and registered *nutritive substances and novel foods control plan* prepared and operated by **businesses assessed as competent**, and verified by accredited agencies.

   The structure and procedural requirements could be similar to that required of food safety plans laid out in Part 3 of the Code and in the *Animal Products Act* 1991 and the New Zealand *Food Act* 2014, but tailored to the processes and expertise required of safety assessment for new foods and food substances. Competency could be assessed by accredited certification bodies working to a specific set of purpose-developed requirements and checklists.

In addition, key features of the process outlined in the 1st CFS could be retained:

2. Foods self-assessed as eligible (minimal risk) with documentation to be retained by the food industry.

3. Self-assessments plus notification for low risk foods undertaken by **food businesses** assessed as **competent**, with the opportunity for jurisdictions to review dossiers of concern. Review could be undertaken by an advisory body established by jurisdictions. (Refer to response under 'Part 1, The Proposal, Framework Sec 1.2.1'.)

4. Higher risk foods to be assessed by FSANZ.

5. The level of risk can be managed through clear definition of the 3 pathways and their scope.

6. Central authorities, as always, would retain their power to intervene.

Assessing food businesses as competent would give confidence that businesses would have the capability and capacity to conduct assessments to a set standard. This would reduce load on FSANZ's resources and jurisdictions, as well as help to facilitate innovation.

Businesses that could not establish competency could make applications (as is done at present) or rely upon a competent business to establish food safety on their behalf.

Response to the Consultation Paper

Overview

1. Nestlé expresses its disappointment that the 'self-assessment' notification process proposed in the 1st CFS has been removed from consideration. Nestlé supported this option as it provided an appropriate risk based process option, and provided options for speed to market for new products which would be to the ultimate advantage of the consumer.

2. Nestlé expects that in reaction to the self-assessment process being removed that expanded eligibility criteria should be considered in future work, to allow the appropriate risk based options to continue to be utilised.

3. It is difficult to comment on some of the questions for submitters without knowing the details of the Eligibility Criteria. We refer to our previous submission of March 2016 on our concerns with the definitions proposed previously.

4. The inclusion of Infant foods within the scope for this proposal is welcomed by Nestlé.

5. It is unclear whether Foods for Special Medical Purposes (covered by Standard 2.9.5 of the Code is still out of scope as is the case currently. Refer to Standard 2.9.5-3(a) and to 1.1.1-10(6)(b) and 1.1.1-10 (6)(f).

   If the intent is to include foods covered by Standard 2.9.5 into the scope for P1024, we would strongly disagree with this. FSMPs are foods designed for particular vulnerable target groups whose nutritional requirements cannot be achieved from a normal diet. Safety of use is of priority for these foods, however this is an area of medical nutrition which is growing and innovating very rapidly to provide medical nutrition options to the target group of consumers, focusing on their medical needs. The role of nutrition has changed the course of health and disease management in the past years with nutritional therapies working synergistically with medical treatments in the management of diseases and disorders. Most of the FSMP products are imported from overseas into Australia and New Zealand so restriction of use of any nutritive/novel ingredient would ultimately result in restricting access to these FSMPs.

   Exemptions from certain standards stipulated in Standard 2.9.5, one of which is Standard 1.5.1 Novel Food Standard, was initially aimed to prevent potential barriers to trade and importation from overseas. Requirement for pre-market approval of novel ingredients in FSMPs could jeopardise supply of FSMPs into Australia and New Zealand.

   The sale of such products is restricted to hospitals, pharmacies and Health Care Professionals (HCPs) (i.e. recommended for use under medical supervision) and are the subject of mandatory advisory labelling requirements. Standard 2.9.5 is consistent with relevant international regulations to minimise any barriers to the supply of these products to Australia and New Zealand. The exclusion of certain other standards and provisions in the Code to FSMP has made

the supply from overseas possible. Any changes to these conditions would have to affect consumer's access to FSMP products containing novel ingredients.

6. Some straightforward criteria should be made available to any new EFC developed in the future. For example, foods approved in other countries or having letters of no objection from recognised international jurisdictions (mutual recognition), minor changes to already approved substances, a new use for a permitted 'new' substance that has already been pre-approved by FSANZ, and foods derived from extended range of unit operations.

7. Nestlé does not support a positive list of microbiological substances being developed for any category of products.

Confidentiality/exclusivity

8. Nestlé supports retaining exclusivity (or some form of data or Intellectual Property (IP) protection) for novel foods and substances permitted by FSANZ, and recommends extending the exclusivity period to 3 years. Product development is unlikely to be completed until certainty around approval of new foods or substances has been achieved, and development could take at least 12 months after permission is given. New product launches are uncertain and a further 12 -24 months may elapse before product sales emerge from the cost intensive growth phase into maturity where returns are available.

Implementation

9. Nestlé submits that an industry support process is an essential tool in effective implementation. This new standard will be a departure from traditional regulation and while the industry may be generally supportive, it will need assistance, possibly through an ISFR working group, to support effective implementation and gain the understanding that leads to appropriate behaviours.

Part 1 – The proposal

The framework Section 1.2.1

Nestlé notes the reasons given for rejection of pathway 2, namely jurisdictions' requirement for centralised assessment (of industry self-assessments) and that FSANZ is not permitted to perform such assessments.

Nestlé also notes the issues raised in the FSANZ executive summary, namely:

1. The lack of centralised regulatory and scientific oversight, leading to jurisdictions being required to assess dossiers;
2. The varying level of expertise and resources leading to inconsistent outcomes across Australia and New Zealand; and
3. FSANZ constraints leading to concerns over-burdening existing resources.

This viewpoint assumes that all self-assessments should be reviewed and does not take in to account that centralised assessment is unlikely to be required where competent industry self-assessments occur. Nestlé submits that the jurisdictions could establish a scientific advisory body to which they could refer the few self-assessments of concern for advice, leaving jurisdictions to make the decision. If all jurisdictions were participants, this would obviate the consistency issues identified elsewhere. Consistency issues can be further addressed through setting common policy, developing common standard operating procedures and discussion to ensure definitional issues and implementation practices are resolved.

FSANZ would then be tasked with responding to applications – i.e. the higher risk new foods and food substances – which would better match FSANZ resources and capabilities.

Issues for subsequent consultation Section 1.3

The 5 issues listed under Section 1.3 are critical to how a modified version of the proposed revised standard might be built. The scope of EFC and consideration of international approvals are critical and until these issues are resolved it is difficult to provide informed comment on many of the items in this consultation paper.

Part 2 - Regulatory Framework

Table 1

FSANZ Act 1991*:* A number of alternative submitters suggested options which are set in Table 1. Many of the responses are to the effect that the *FSANZ Act* constrains or limits what can be done. These responses suggest that the *FSANZ Act* is limiting change and constraining innovation. The *FSANZ Act*, while ground-breaking legislation in 1991, is now 26 years old.

Question from Nestlé: Nestlé respectfully asks: 'Is it time for a broad review of the *FSANZ Act* considering the changes that have occurred in the general environment, and specifically the new dynamics in industry, technology, consumer behaviour and regulatory needs since 1991?'
(See also Regulatory Model page 3).

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Q1: Removal of permissions from Schedule 25:

Nestlé does **not** support removal of permissions from Schedule 25, unless a searchable list of novel or new food considerations and outcomes is provided elsewhere.

Nestlé does **not** support permissions being distributed in standards without a complete searchable list elsewhere.

Where FSANZ undertakes a regulatory process and determines that a food is not novel because it is safe, or develops a standard or adds to a standard through a specific permission, the consideration and decision should be documented and retained as an outcome of the regulatory process described in Table 1, Option 2. A record of these considerations should be retained in a searchable database.

This is a matter of efficiency, accuracy and regulatory certainty for industry.

Q2: Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards?

At present the oils derived from algae and that are listed in Schedule 25 are mostly used in foods regulated by Part 2.9 standards.

Q3: Are there other issues associated with removing permissions from Schedule 25? Please elaborate.

Nestlé does not see any other issues associated with removing permissions from Schedule 25, provided there is a record of these permissions as outlined in the answer to Question 1.

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Q 4: *Premarket approval for other substances?*

Nestlé supports the removal of the term 'nutritive substance' from the Code.

Nestlé considers there is scope to **include** other nutritive type substances in the definition of eligible food and self-assessment with notification processes, using a risk based model.

EFC definitions will prove critical here. Nestlé questions where the EFC line will be drawn with new and novel protein and lipid fractions for example. Casein as a first fraction of milk protein is acceptable, but where will sub-fractions and bio-actives derived from milk protein stand? Similarly Nestlé questions where the EFC line will be drawn for lipid fractions and carbohydrate fractions or polymers. It will be important to develop and apply risk based criteria to these questions for accuracy and regulatory certainty.

Potential to expand risk based assessments to other classes of new foods and food substances

The matter of pre-market approval for other substances such as vitamins, minerals, electrolytes raises more questions. There is a good case for reviewing the 'all require pre-market assessment' (or 100% inspection) approach and a clear opportunity for a risk based approach being applied that could improve regulatory efficiency, reduce industry costs and support innovation.

Part 3 – Other Issues

Questions page 14

Q5: Exclusivity – does exclusivity remain a requirement?

Yes, Nestlé strongly contends that exclusivity[2] (or some other form of IP protection) is still required and should in fact be extended further. Innovation has clear costs attached and returns must be received to reward the investment in innovation. Without financial returns innovation is less likely to occur, leaving business less competitive and consumers without the benefits of innovative products and technologies. A competitive industry is also favourable for exports. New product introduction requires up to three years to break-even and Nestlé strongly believes the exclusivity period should be extended to 3 years. Nestlé would support a specific cost: benefit study being undertaken on this subject. (Refer also to discussion under question 9).

Q6 and Q7: What costs (benefits) arise to the community, industry and business from exclusive permissions?

Nestlé believes that there is little **cost** to the community or the respective governments from the granting of exclusive permissions. Industry bears the cost of novel food applications – both in the R&D required to develop the ingredient, costs to comply with the requirements of the Application Handbook, and costs to have FSANZ assess the application.

Benefits can arise from the use of exclusivity – business capability improves from investment in innovation, consumers stand to gain from improved product benefits and government can benefit from use of government funded R&D (where applicable) and taxation revenue. Competitive forces can generate parallel innovation thus improving the overall capability of specific clusters or sectors and improving productivity in Australia and New Zealand.

If exclusivity permissions are **eliminated** all stakeholders stand to suffer **detriment**. Industry does not invest in innovation, consumers do not get new products and governments may lose from reduced uptake of Australian and New Zealand R&D, and reduced taxation on profits.

Q8: *Why should Australian and New Zealand food laws make Australian and New Zealand food regulators bear the onus and costs of protecting industry's intellectual property in products being sold commercially?*

Firstly, there is no data or rationale provided to indicate that the food regulators bear any substantial onus or cost of protecting IP.

Secondly, the current application process results in disclosure of proprietary IP – in part or in full. Businesses do not have a choice in this. If IP is disclosed competitors can take advantage of the IP at no cost (i.e. the free rider effect) and develop and launch competitive products in a similar timeframe, thus diminishing returns on innovation investment. Exclusivity allows companies to obtain returns from their investment. Without exclusivity

[2] In this submission, Nestlé uses the term *exclusivity* generically to refer to some form of IP protection.

investment is discouraged. This may in part explain the small number of novel food applications.

Thirdly, as part of the *FSANZ Act*, in developing or reviewing food regulatory measures and variations of food regulatory measures FSANZ must have regard to:

- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry; and
- the promotion of fair trading in food,

Exclusivity recognises the investment that industry makes in developing new and innovative foods, and supports an efficient and internationally competitive food industry.

Q9: Why are other measures (e.g. patents and innovation patents) not adequate?

(a) **Trade secrets:** Holding IP as a trade secret is possible, but the data requirements required by the Application Handbook reduce or extinguish the effectiveness of trade secrecy. Data provided under commercial-in-confidence can provide some relief, but is unlikely to be helpful, for example, where the IP is in the form of a clinical trial and its results.

(b) **Patent:** Patent protection is an option for protection of IP, but patents have limitations:

- Patents require proof of an inventive step. Not all novel foods include an 'inventive step' and the invention must be 'novel, new, inventive or innovative and must relate to a product, method, apparatus, substance or a process'. If the nutritive substance/novel food does not fall within these categories it will not be eligible to be covered by a patent. The outcome is that many 'novel' foods may not be patentable. The fact that the ingredient or product was or was not used in food before does not mean that it can be patented.

- Patents incur significant additional costs, are time consuming from an administrative viewpoint and are costly to defend. These additional costs should be voluntary and incurred to achieve a greater degree of protection and longevity of protection, rather than arising from a need to protect IP following statutory disclosure required by the FSANZ application process.

- Patents are only enforceable once the patent is certified or registered by IP Australia which can take up to 3 years to obtain. This means that any breaches of the patent cannot be acted upon until registration.

- Innovation patents do not feature in the New Zealand IP law.

- Patent filing adds cost to companies, in addition to a FSANZ application. If filing for a standard patent in New Zealand and Australia there are costs involved with patent searches, and these can cost anywhere between AUD$10,000 to AUD$20,000 and in some cases more for each country. In New Zealand there are also costs with

examination of patents, and registering patents. Further, renewal fees must also be paid throughout the life of the registration.

- The majority of costs involved in some novel food applications might be caught up in safety studies. There may be an ingredient found in nature that does not require an inventive step to commercialise it, but does need to have a safety assessment.

Nestlé notes that the European Union has addressed this situation by introducing Data Protection (not exclusive permission) for 5 years (Article 26). This means that the data to provide safety can be protected, not the novel ingredient as such. The data protection regime aims to incentivise research and development and innovation within the food industry. It protects the information and data gathered by applicants in support of their application for a novel food. As the *FSANZ Act* requires that FSANZ have regard to the promotion of consistency between domestic and international food standards, it is important to keep this in mind as a potential option.

Tension between competition and IP protection - overarching comments related to Q5-10

Much has been written on the tension between IP rights and competition law. Competition law seeks the maximisation of consumer welfare and argues that companies having unfettered IP rights can unfairly limit or diminish consumer welfare by appropriating a long term price advantage. In contrast, IP law recognises that where the investor in IP cannot reap rewards for the investment, investment is unlikely to occur, and in the long term consumer welfare suffers as a result.

It would seem that time-limited IP protection can deliver both i.e. a climate where innovation can occur and returns achieved, but with IP protection effectively time-limited so that competitors can come into the market, the innovator's pricing advantage is then eroded and consumer welfare is maximised in the medium term. Of course, those consumers who are early adopters and willing to pay for the benefit may see their individual welfare as being 'maximised' by obtaining the benefit of the innovation at a price they are willing to pay.

When IP rights are statutorily extinguished (e.g. by publication of material related to specific applications to FSANZ), then the company's ability to recover investment is likely to be diminished, with reduced innovation activity a consequence. Applying exclusivity (time-limited) can redress the balance.

Where the lack of exclusivity encourages more patent protection this may lead to unintended consequences such as delayed uptake (patents apply for 20 years, innovation patents for 8 years) of protected IP by competitors and consequently delayed consumer benefits.

Q10: What other alternatives exist to protect industry's investment in developing commercial food products (other than reliance on the Code and Australian and New Zealand food laws?)

Many companies rely on holding innovation IP within their business as trade secrets, trademarks, keeping certain active ingredients in a blend formulation as trade secret, and utilising non-disclosure agreements for third parties. If these measures are successfully

managed the technology/invention can be kept secret indefinitely and used solely by the owner of the IP. However there are risks involved with this as the information may leak to competitors. Further, statutory disclosure as required in novel food applications can negate many or all of these measures.

As noted earlier there are few companies relying on protection from the exclusivity provision in the Code, so this question could be better worded as 'Why are there so few novel food applications and exclusive permissions?'

Q11: Is the current 15 month period applied to exclusive permission sufficient?

Nestlé believes that this period is **not** sufficient and should be extended to 3 years. Investment in clinical and safety trials to create a full dossier to obtain approval means that 15 months exclusivity is not enough time to earn a return on investment. Data protection (e.g. for 5 years as done in the Novel Food regulation in Europe) gives the company opportunity to do this.

Case study:

The Net Present Value (NPV) is often used to determine the profitability of a project for a novel food application. It is the difference between the present value of cash inflows and the present value of cash outflows. NPV is used in capital budgeting to analyse the profitability of a projected investment or project.

Using this concept, a typical estimate of costs to develop a new novel food in-house, including development costs, toxicological studies, novel food approval costs as well as developing the application together with the cost of an application is AUD $1-3 million, including the investment (marketing spend and packaging design) that has to be made to establish the product in the market

Typical Nestlé modelling for an R&D project to develop a novel food in-house (considering the costs outlined in the previous paragraph), shows that a break-even point is typically reached after 3 years, and at 4 years there would be a positive cash flow, but not yet making profits over and above the original investment. This shows that at minimum 3 years is required to ensure a return on investment on a novel food. The basis of these calculations and assumptions is that there is no competitor with a similar product in the market eroding these profits and cash flow figures. This is why it is so important that a manufacturer who invests in new products and technologies can achieve a return on investment to both fund future investments which will result in more innovative products for consumers and a competitive industry in both Australia and New Zealand. An exclusivity period of minimum 3 years is required to achieve this, and 5 years is a more reasonable proposition.

In the EU, a 5 year data protection period for novel foods is in place. An applicant can protect proprietary data submitted in support of its application from use by subsequent applicants for a period of five years. When this five year period was being discussed in the EU, it was thought that this was not enough, and that 10 years would better generate a return on investment in research and development, however, it was set at 5 years, to align with the permissions in place for data protection of Health Claims in the EU.

Q12: Does the innovation activity your business undertakes typically occur in Australia or New Zealand?

Nestlé's innovation activity for novel food development generally occurs outside of Australia and New Zealand, but where new permissions are required, the cost to develop and submit an application to FSANZ is borne by the Australian and New Zealand business.

Q13: Does your business typically place new products on the market (In Australia or New Zealand) at the same time or before placing them on the market in larger overseas markets?

Nestlé generally develops novel foods for multiple markets, while recognising each market's specific requirements. A novel food that requires pre-approval will be subject to that market's requirements and timelines. Therefore the launch times in different markets can vary.

Since there are no application costs for novel foods in the EU, it is likely that a novel food may be placed on that market earlier than in Australia and New Zealand.

An EU approved novel food may be launched in the EU and other markets, but the limited exclusivity permissions and increased cost of application development in Australia and New Zealand may prevent that same novel food being launched in Australia and/ or New Zealand.

3.2 Transition Arrangements

Q14: Please indicate whether you support 'grandfathering' of foods which are available for sale in Australia and New Zealand at the time of gazettal

Nestlé considers that this is the practical approach; noting that food or food substances under current action or investigation should be excluded and, if subsequent to grandfathering, should a food or food substance be considered unsafe then it can be excluded from the Code or place on a prohibited list.

Q15: Do you consider there are categories of foods that should not be grandfathered

Nestlé supports the broad use of 'grandfathering' in this Proposal, and does not suggest any categories that should not be 'grandfathered'.

Q16: Would the proposed approach to micro-organisms present problems for your business?

(a) Nestlé supports the grandfathering of live food culture microorganisms.

(b) Nestlé supports grandfathering of lactic acid bacteria permissions in FSC 2.9.1 and 2.9.2 for both technological and nutritional purpose. This view is supported by the lack of demonstrable evidence of evidence of market failure and international recognition of inherent safety for both purposes (e.g. Codex) (noting that the Processing Aids Standard (Standard 1.3.3) covers microorganisms for technological purpose).

(c) Nestlé supports the concept of recognition of microorganisms added for a purpose other than food culturing provided they have a history of safe use.

(d) Nestlé supports the status quo of permissions for microorganisms in the vertical product standards, with the requirement of the company requiring to hold the evidence and substantiate for safety, and genetic stability of the strain.

(e) Nestlé supports the status quo of permissions for derivatives of microorganisms in the relevant horizontal standards, requiring pre-market assessment for both the derivative and source strain, as aligned with the EU Qualified Presumption of Safety (QPS).

(f) Nestlé does not support the proposal for eligible food criteria for microorganisms, where eligible microorganisms would be included on a FSANZ list. It is not clear how FSANZ would maintain a list and this would place an ongoing burden on FSANZ. Neither has risk been established.

(g) Nestlé notes the additional requirement being proposed that microorganisms be cultured to maintain genetic stability. While Nestlé agrees that a microorganism is cultured to maintain genetic stability, we consider that it would be an insurmountable task to consider and verify this at a strain level.

(h) Nestlé supports that a food business would need to be able to demonstrate that a microorganism that they intend to add to food is unambiguously identifiable, and belongs to an eligible taxonomic group listed in the Code.

Note: As already highlighted in the consultation paper, there is a "significant history of using microorganisms in foods and in the production of foods". There is been no evidence of market failure based on either technological use of a microorganism or for a nutritional purpose as a probiotic.

Nestlé considers that the main impetus for P1024 was a need for regulatory certainty predominantly for nutritive substances and novel foods, rather than a failure or safety concern relating to biologically active substances.