Nestlé Submission

1st Call for Submissions

P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

23 March 2016

Nestlé Submission

Acknowledgment

Nestlé is pleased to be able to respond to the 1st Call for Submissions (CFS) on the food standard relating to nutritive substances and novel foods. To avoid repetitive qualification, our comments are prepared from the perspective that 'option3' will proceed in some form.

Key comments

Overview

1. Nestlé supports the general direction taken and agrees that a risk based process is appropriate.
2. Companies will be undertaking a **risk analysis** activity– i.e. risk assessment, risk management and risk communication activities. This should be made clear at the outset and may help to frame the context of the proposal.
3. What are food safety hazards/risks? Intrinsic vs. extrinsic. E.g. Intrinsic – risk arising from composition i.e. protein or lipid or carbohydrate compounds or molecules, microbial content; or extrinsic e.g. foreign matter arising from harvesting; or both. Further clarification (and discussion) would be helpful.
4. Definitions: Be clear what is covered by the term new food or new substance? Is it completely new foods and substances not yet in use? Is it a new use for existing foods or substance? What will 'grandfathering' mean - will it apply to whole foods, ingredients, extracts, substances or to any use or combination of these in the food supply at that date? 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'? What are the implications if subsequently these give cause for concern?
5. How big a difference confers the title 'new substance'? E.g. a new complex carbohydrate with a higher degree of polymerisation than a previously permitted substance? A new use for a permitted microbe or enzyme? Some examples would be helpful.
6. Algae including seaweed (marine algae) and fungi are excluded from the EFC. Why? There are a number of these foods used safely. Did those algae considered to be novel by the ACNF actually show risk or were simply assessed as risky and requiring further consideration? The exclusion is not effectively justified.
7. Are edible yeasts included as one of the EFC recognised or excluded foods
8. Infant foods are out of scope for this proposal. It is not clear why this is so or how it has been justified given that if this proposal is to proceed, the regulation of nutritive substances and novel foods for infant foods will effectively default to the current less than satisfactory arrangements. It is likely that it will take up to 2 years to prepare and process another proposal to cover infant foods. Nestlé is concerned that this will delay innovation in this food category and potentially continue to leave infant foods open to the obvious concerns that catalysed this proposal.

The process/framework (option 3)

9. The list of acceptable unit operations for eligible food criteria (EFC) is limited. What criteria were used for unit operations on this list? How can these be gauged during a self-assessment process where a different unit operation is being used? There seems to be an underlying assumption that processes other than physical (e.g. separation processes using chromatography, electrophoresis, solvents) have higher risk/uncertainty. The notion that unit operations other than physical change are higher risk needs to be substantiated.
10. Some straightforward 'gateway tests' should be made available to enter the amber lane. E.g. foods approved elsewhere or having letters of no objection from recognised international jurisdictions, minor changes to already approved substances, a new use for a permitted 'new' substance that has already gone down the red lane, foods derived from extended range of unit operations e.g. enzymatic hydrolysis with approved enzymes, carbohydrates produced by polymerisation, fractionation using recognised/permitted solvents.
11. Defining pharmacological effect will be important recognising the interface between FSANZ and TGA.
12. Microbiological lists – why just a FSANZ list? Is the EU list also acceptable or is that a gateway to the amber lane? How often will the list be updated and how long is each updating process. What about enzymes – will there be a list of permitted enzymes? Are new microbes and enzymes not already on the list to go through the amber or red lane?
13. It is unclear how risk assessment arrived at the conclusion that adding substances to another food class is risky (EFC criterion 4). Is this simply intuition, or are there data to back it up? Most foods are mixture or compounds of various food, ingredients, extracts and substances and this will consign many new materials to the amber lane – perhaps unnecessarily.
14. Rules around extracts would benefit from more discussion – how do manufacturers determine what a reasonable addition rate for addition of the original foodstuff to the target food is? Is it simply application of the 'reasonable person' principle? E.g. banana 150g added to 30g of cereal, or 15g of berry fruit added to 30 g of cereal seems reasonable. As with EFC 4 – this restriction on adding back is likely to unnecessarily consign many new materials to the amber lane.

Confidentiality/exclusivity/reputational risk

15. Nestlé is not supportive of general publication of dossiers under the amber lane as it has deep concerns over reputational risk arising from non-science based external challenge, or attack on published self-assessments, through the national media. There is also deep concern over the free rider effect where competitors could access the published information and prepare a similar dossier at lesser cost and time. First mover advantage for new product launch is helpful, but not sufficient in terms of achieving commercial return on R&D investment.
    Nestlé does support jurisdictions having access to this information. Jurisdictions could then act on reasonable enquiries from interested parties.
    There should also be specific confidentiality provisions for company generated data when preparing self-assessment dossiers.
    Without these safeguards, Nestlé has concerns that there is significant business risk arising from the free rider effect and it is likely to be damaging to innovation.

There is also potential risk if a second company uses information (in part or in whole) contained in the first company's dossier and comes to an incorrect, unsafe conclusion. Would there be associated liability for the first company?

16. Nestlé supports retaining exclusivity for novel foods and substances (red lane) 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 months may elapse before product sales emerge from the cost intensive growth phase into maturity where returns are available.

The dossier

17. Graduated risk needs to be reflected in complexity of data/dossier requirements e.g. simple decision tree for low risk foods (EFC) or foods already approved in other recognised jurisdictions. It is suggested that the widely used AFGC Product Information Form (PIF) be considered in assessing eligible foods (green lane) and that the form be augmented to provide adequate information and data to meet the requirements of the Standard. Similarly, the data requirements for the amber lane should reflect that it is considering essentially low risk foods.
18. Nestlé seeks increased detail of some important process steps through providing a schedule in the standard or guidance in the application handbook e.g. weighing up, templates e.g. augmented PIF form for eligible foods (refer to guidance provided for the health claims Standard.

Implementation

19. An industry implementation working group is an essential tool in effective implementation – perhaps an ISFR group. This new standard is a departure from traditional regulation and while the industry may be generally supportive, it will need assistance to 'iron out the wrinkles' and gain the understanding that leads to appropriate behaviours.
20. It is noted that not all ingredient suppliers will have capacity to undertake assessments, and that guidance and support will be needed. Many food manufacturers rely on ingredient suppliers for technical support and their business will be affected if there is inadequate structure to support innovation.
21. Implementation issues need clarification e.g. grandfathering, transition period (support for 6-12 months) for substances in pipeline. The meaning and implications of the term grandfathering, along with others, may need to be spelled out.
22. Once a new Standard is in place, there is a case for processed foods, ingredients, substances to be deemed eligible. This is a simple matter of efficiency. It does not make sense for every food supplier to undertake self-assessment of a new but widely used new food or substance.

Related submissions

Nestlé has had involvement with and supports the comments made in 3 other submissions namely, those from:

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

Responses to questions posed by FSANZ

Refer section 3.3 (Summary of risk assessment)

Q1: How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

A1: No issues, Nestlé is fine with current definitions and arrangements noting that the ACNF is an important element of the current arrangements

Q2: Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.

A2: No

Q3: 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.

A3: Nestlé has not undertaken a novel food application recently. It is difficult to say that the current arrangements are adversely affecting our business at present, but the complexity of the current requirements are not conducive to innovating with truly novel foods or substances.

Refer section 4.2.1 (Option 1: Status quo)

Q4: Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

A4: Yes, Nestlé believes the exclusivity provision should remain and be extended to 3 years to enable fair return for investment in innovation. Introduction of novel products to the market often take some time to reach the break-even point. A 'fast follower' competitor entry after 15 months can limit returns and get a 'free rider' effect using someone else's IP. This is not a level playing field and is a disincentive to step change (high investment) innovation.

Secondly, the ACNF provides a valuable forum to provide guidance and in effect improves industry efficiency by avoiding unnecessary investment in novel food activities. The ACNF forms part of the due diligence process where companies are 'wanting to do the right thing'. We go on to suggest later that an industry-regulators forum be established should a new standard be put in place.

Q5: Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

A5: No additional problems identified.

Refer section 4.2.2 (Option 2: Amend the current definitions)

Q6: Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

A6: Nestlé understands and has no issue with the reasons for changing definitions, but has not considered new or amended definitions.

Refer section 4.2.3.1 (Identifying foods that do not require regulatory approval)

Q7: Are the EFC appropriate for identifying foods that do not need regulatory approval?

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.
A7: The general approach and logic is supported. The difference between an extract and a substance would benefit from clearer description and examples.
There are questions over the limitations placed on extracts (concentration) and substances (adding back only to same food group) when added back to foods and where there has been no specific risk identified. I.e. a risk management measure developed in the absence of an identified risk. These restrictions are likely to consign many new materials unnecessarily to the amber lane – a costly exercise.
How will FSANZ maintain the list of approved microorganisms in a timely manner? If a new microorganism is approved elsewhere, how long will it take to be placed on the FSANZ list and who will initiate that action? Is there a better way?
More discussion/description of anti-nutrients would be informative.

Q8: Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.
A8: It is possible that new plant varieties (change in bioactives) while still in the general food class or new processing technologies (heat producing acrylamide type products) should be assessed. The question is if these can be considered during the EFC assessment (green lane) or should go down the amber or red lanes. This is also interdependent with the gateway tests.

Q9: Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.
A9: The broad exclusion of algae including seaweed is not effectively justified and we question the seemingly arbitrary nature of this exclusion. Similarly with fungi – while toxic properties are recognised for some varieties, is this sufficient to place an arbitrary exclusion on fungi? Edible yeasts are not mentioned but form a significant part of the food supply at present.
Refer also to the comments in Q7 where limitations have been placed on extracts and substances when adding back to foods.

Q10: 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.
A10: *Nestlé suggests that the AFGC sponsored Product Information Form (PIF) is a good starting point for 'green lane' foods, although it may need some additional data fields.*
Primary data requirements may include: Identity of substance, history of consumption, intended use, general cultivation, harvesting and processing description, food composition data (macro and micro nutrients), microbial status and or hazards, sources of data used in the assessment (may include a literature search), eligibility criteria used and how/why decision arrived at, authorised signature.
Secondary data (it is not clear how this is triggered, but it should not be required in all instances i.e. it should be risk based) may include declaration of any potential adverse or safety effect, consideration of bioactives, anti-nutrients, toxicants, level of exposure and mitigation steps necessary.

Q11: Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?
A11: The broad exclusion of algae including seaweed is not effectively justified and we question the seemingly arbitrary nature of this exclusion. Similarly with fungi – while toxic properties are recognised for some varieties, is this sufficient to place an arbitrary exclusion on fungi? We refer to the data where 11/74 whole foods considered novel were fungi, where this data was used to support the exclusion from EFC. It is not clear how many of the 11 were assessed and found to be unsafe and resulting in specified levels of use or prohibition.
If safety is the issue – could we just 'let the science speak' and avoid exclusions.
Refer also to the comments in Q7 where limitations have been placed on extracts and substances when adding back to foods, where Nestlé considers these risk management decisions to have insufficient evidence to support the measure.

Q12: What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? See SD3 for discussion on this issue.
A12: If a food has a use as a traditional or complementary medicine (oral dosage) then if the intended level of use of the food is at similar levels at which it is traditionally used as a medicine (e.g. single dose or daily dose levels) then there is a 'reasonable potential' for the food to have a pharmacological effect. There is always going to be a grey area here for example peppermint oil has a therapeutic use but is also commonly used as a flavour and the levels of use as a flavour could be similar to the levels of use for a therapeutic use. So based on risk some things possibly should be permitted as foods at levels where they have use as a traditional medicine.

It will be a challenge to develop a clear guideline as to what could be self-assessed and what would need a FSANZ assessment. Some foods may not have a history of use as a medicine but could include substances that could have a direct pharmacological effect on the body, or be converted in the body to a substance that could have a pharmacological effect on the body. This would give them a 'reasonable potential' to have a pharmacological effect at the intended levels of consumption. For example, stimulant, sedative, hallucinogenic, toxic. Again there is a grey area because foods such as coffee, chocolate, guarana, ethanol, and others may potentially have a pharmacological effect at the intended use and are permitted as foods. So here we might be looking at what is the potential pharmacological effect at the intended level of use, what is the risk and what is the potential for people to use the ingredient / food for a therapeutic use rather than as a food.

Refer section 4.2.3.3 (Data and dossier requirements)

Q13: Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?
A13: In principle yes – but key issues remain around determining eligibility (broader rather than narrower capture) and the nature of the proposed gateway tests for the amber lane. Shifting from open to restricted publication of amber lane dossiers and providing for confidentiality of company generated research data are important matters for Nestlé.

Q14: In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft

framework do you think are viable or not viable? Please provide supporting statements for your view.
A14: Refer above answer and refer also to opening comments of submission

Q15: Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?
A15: Yes, there are a number.

- *Marine algae (seaweed) – it is not clear why these excluded. A good example e.g. lithothamnium calcaereum - also known as phymatolithon calcaerem or red seaweed – recognised as safe, but would be excluded from EFC or self-assessment.*
- *Extensions of use: Not sure how it is proposed to deal with extensions of use for substances approved by FSANZ (red lane), whether these could be considered using green or amber lanes. It may well depend whether conditions of use have been placed on the original permission – but if not, then a new application may not be warranted.*
- *New microbiological sources or new strains of an existing microbiological agent.*
- *New ingredients, extracts and substances considered for addition to Infant foods. Currently out of scope, but Nestlé is of the view that Infant Foods should be in scope.*
- *Extracts used in quantities greater than those allowed by the EFC definition (we submit that this restriction is too tight, and not supported by evidence.)*
- *Substances added to other classes of foods (we submit that this restriction is too tight, and not supported by evidence.)*
- *New foods or substances permitted elsewhere either explicitly, or by letter of no objection*

Q16: Please provide details of how a self-assessment pathway may or may not provide benefits to industry.
A16: The positive elements include: ability to capitalise on in-house expertise and improve flexibility and management of the innovation programme, better control over timing of product launch, Australia/New Zealand seen as test market for ingredient suppliers and enhancing regional innovation, potentially cost effective (but depends on final structure).
The negative elements include: potential inconsistency in implementation leading to uneven playing field, uneven technical capacity across the industry – manufacturers and ingredient suppliers – both local and imported, reputational risk from vested interests challenging dossiers from a non-scientific position, potential loss of confidentiality, IP or trade secrets leading to loss of opportunity to recoup R&D investment. Dossier complexity needs to be graduated as well. It is unclear how legitimate challenges will be resolved and illegitimate challenges rejected. There may be loss of confidence and earnings during challenges and any challenge process must be carefully constructed.

Q17: 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.
A17: Yes in terms of transparency, and exposing the information and data to scrutiny – this would be a very open process, but it may not necessarily give rise to an increase in confidence. However it is of deep concern that publication of dossiers opens up opportunity for consumers, public health advocates, academics and advocacy interests to challenge company positions and decisions from an idealistic or non-scientific position rather than a scientific one. This could lead to reputational loss

for companies, particularly if the challenging party is to go to the media. If this results in companies choosing red lane more often, then impact of a graduated risk approach is hugely diminished. One option to address this is to have the dossiers open to jurisdictions who could consider reasonable requests or challenges to the notifications.

Refer section 4.3.1 (Impact of the draft framework on current standards)

Q18: 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.
A18: Not at present

Refer section 6.2 (Exclusive permission for brand and class of food)
Q19: Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.
A19: Yes, Nestlé believes the exclusivity provision should remain and be extended to 3 years to enable fair return for investment in innovation. Product development may only be finalised after novel food approval and can take up to 12 months to do so. Introduction of novel products to the market often take some time to reach the break-even point (the market launch period is investment intensive). A 'fast follower' competitor entry after 15 months (just 3 months after the product development period concludes?) can limit returns and get a 'free rider' effect using someone else's IP. This is not a level playing field and is a disincentive to step-change innovation.

Q20: 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 (section 4.2.3)?
A20: Nestlé strongly believes that confidentiality should be afforded to company generated data (but not public domain data), when using the amber lane. In that regard, the self-assessment process as it stands is not likely to be supportive of innovation. The first to market advantage and managed launch timing is not a sufficient trade-off over disclosure of the innovators IP. While some substances may be able to be protected through patent or trademark, this is not appropriate in all cases. When the dossiers are notified and lodged, the dossiers could be placed in a secure area where only regulators could view and who could consider reasonable requests or challenges to the notifications.

Refer section 7.1 (Proposed transitional period)
Q21: Do you support a cut-off date? Please provide reasons for your view.
A21: Yes, Nestlé supports a cut-off date for certainty and including a transition period (e.g. 9 months) after gazettal to allow for completion of in-progress innovation projects that may not be concluded at the date of gazettal. (Timing can be uncertain for innovation projects).

Q22: Do you see a need for grandfathering provisions? Please provide reasons for your view.

A22: Yes, again to provide certainty. But clarity over definition of what constitutes new or novel after that date is required. Does it apply to truly novel substances, or new foods built from existing permitted ingredients/substances?

Q23: Do you see a need for a stock in trade provision? Please provide reasons for your view
A23: Possibly, this will depend largely on enforcement and implementation arrangements.

Refer section 7.2.3 (Post-market surveillance)
Q24: Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.
A24: Yes, Nestlé supports a transition period (e.g. 9 months) after gazettal to allow for completion of in-progress innovation projects that may not be concluded at the date of gazettal. (Timing can be uncertain for innovation projects).

Q25: Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?
A25: We are comfortable with this; it is not needed if grandfathering is included. It will depend largely on enforcement and implementation arrangements. If it is included, it would be helpful to give clarity as to how it applies throughout the supply chain.

Q26: Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?
A26: <u>New Zealand</u>: NZ Food and Grocery Council (NZFGC); NZ Beverages Council (NZBC) formerly NZ Juice and Beverage Association (NZJBA), National Association of Retail Grocers and Supermarkets of New Zealand (NARGON), NZ Institute of Food Science and Technology (NZIFST), Institute of Environmental Science and Research (ESR), Plant and Food Research.
<u>Australia</u>: Australian Food and Grocery Council (AFGC), Australian Chamber of Commerce and Industry (ACCI), Australian Industry Group (AIG), National Association of Retail Grocers of Australia (NARGA), Australian Beverages Council (ABC), Food and Beverage Importers Association Australia (FBIA), Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australian Institute of Food Science and Technology (AIFST).
Packaging industry bodies in New Zealand and Australia should be also considered (Packaging Council of Australia, NZ Packaging Council)

Q27: Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under Option 3?
A27: Issues are likely with ingredient suppliers, large and small catching up. Food companies will be asking for scientific information – ingredient companies must be ready to deliver. But they will likely need assistance to understand the requirements. As with health claims, some smaller companies are unlikely to be aware of the implications arising from a new standard. Nestlé suggest giving these organisations special consideration.

Seminars, workshops, guidance, and templates will be important contributors to effective implementation. (Amended AFGC PIF form for green lane would be helpful).
Do people understand that every new ingredient will have to have some assessment – i.e. move from narrow novel food thinking to broader all new foods/substances thinking?
Grandfathering definitions and arrangements will need to be very clear.

Q28: Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?
A28: We would strongly recommend that an industry-regulator working group be set up to assist with implementation. (Refer to health claims).

Refer Attachment C - Draft framework for alternative approach – Option 3

Q29: The exclusions make reference to 'reasonable potential' and 'reasonably expected'. FSANZ's intent is to capture foods that are pharmacologically active or have biological activity beyond basic nutrition at the levels they are intended to be used. Can you make suggestions in relation to how such foods might be captured to ensure they are subject to pre-market assessment?
A29: Refer answer to Q12

Q30: Why is it important for novel foods permitted in the Code to be declared 'not novel' after a certain period of time? Please explain the impacts on your business of novel food permissions remaining in the Code (as novel foods).
A30: Currently the term novel relies on the two elements i.e. non-traditional (absence of widespread and/or enduring use) and requiring a safety assessment. Once the safety assessment is completed and the food found to be safe or any issues characterised (and results published), then this element is extinguished. The remaining element of non-traditional use has a limited life once the food enters the food supply. Clearly in time both conditions for novelty will be extinguished and the food will not be novel. The one remaining issue is that of special conditions of use that may be applied following the safety assessment – there is a case for establishing some place in the Code to document these ongoing conditions of use. These conditions are easily documented for additives and processing aids, for example.
Secondly, once a new Standard is in place, there is a case for foods to be deemed eligible. This is a simple matter of efficiency. It does not make sense for every food supplier to undertake self-assessment of a new (or not so new) but widely used food or substance.

Refer SD1 (Qualitative assessment of costs and benefits)
Q31: What costs have you experienced in making novel food or nutritive substance applications (for permission in the Code) or enquiries to the ACNF under the current system? If possible, include information on size and types of costs (e.g. commissioning research, staff time spent preparing an application). If possible, indicate the costs which relate only to the Australian/New Zealand market. If this is not possible please clearly indicate these are the global costs of obtaining these data and which other regulatory authority they have been prepared for.
A31:
Nestlé has not made any novel food or nutritive substance application. The complexity of the application process for a novel food was always considered too prohibitive and unclear as to the

evidence that was required to use this pathway. In the past looking at using novel foods were predominately to make a health claim, and the complexity of making applications to include this was prohibitive.

The current novel foods system drove an inherent conservatism within the business, because we were not prepared to take the risk to self-assess a particular substance as not novel. Also, the time, cost and effort to put together an application were prohibitive.

Nestlé has made one query to the ACNF (green coffee beans) which was for both the AU and NZ market, it took roughly a month to pull together the required information, and we had 4 people working on compiling the information, but not full time. Hard to put a cost / time on this, but the direct costs could have been in the range $40-$50k.

Q32: What other costs have you experienced as a result of the current novel food and nutritive substance provisions (i.e. costs not related to applications and enquiries)? For example, costs of obtaining legal advice on whether a substance is a novel food or a nutritive substance.
A32: *Internally, Nestlé would have assessed various substances under the current provisions – this assessment would have involved the internal staff costs of 2 regulatory people and 1 – 2 legal people, as well as a product development person. We estimate looking at 10 -15 of these substances per year, and for each substance 5 people spending 2 hours of their time each. Using approximately 10 hours of assessment time per substance this would amount to approximately $30,000 per year in direct costs, assessing under the current provisions*.

Q33: How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?
A33: *(See above Q28 – cost and time are major detractors under the current provisions – 'it's all too hard'.*

Refer SD1 (Qualitative assessment of costs and benefits)
Q34: What (if any) kinds of opportunity costs have you experienced due to the time taken to assess applications? For example, missing a 'window' during which a retailer will accept new products within a particular category.
A34: Nestlé has not lodged any applications. Nestlé notes that the biggest impact may fall on ingredient suppliers as food manufacturing companies may expect suppliers to do all the work before agreeing to purchase a new material.

Q35: (For food regulators.) What types of enforcement costs does your organisation experience as a result of the current nutritive substance and novel food standards? E.g. dealing with enquiries about whether a food is novel or a nutritive substance, notifying food businesses that their food is a nutritive substance or novel food and requires pre-market assessment by FSANZ.
A35: Not applicable

Q36: (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced?
A36: Not applicable