

Supporting document 1

Qualitative assessment of costs and benefits – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

Executive summary

This Qualitative Assessment of Costs and Benefits (QACB) is a preliminary assessment of costs and benefits for the options proposed in the assessment summary for the 1st call for submissions for Proposal P1024 – Revisions of the Regulation of Nutritive Substances & Novel Foods in the Code.

The objective for this proposal is to reduce the health risks to consumers from potentially unsafe foods in a way that is cost-effective.

The regulatory issue to be addressed is outlined in the assessment summary. The current provisions relating to novel food and nutritive substances rely on definitions that are broad and open to interpretation. This can create uncertainty for industry and regulators.

The QACB assesses three options to address this regulatory issue:

- retain the status quo
- retain the status quo, but with amended definitions for nutritive substances and novel foods
- develop an alternative framework

FSANZ considers that the status quo is unlikely to meet the objectives of the proposal. It is the current provisions of the Code that are the source of the regulatory problem. In addition, the current requirement for premarket assessment of all novel foods and nutritive substances may not be a cost-effective way of protecting public health and safety.

Option 2, retaining the status quo with amended definitions, may improve the ability to capture all target foods for premarket assessment and enhance the ability of food enforcement agencies to enforce the relevant requirements under the Foods Acts. However, this option assumes that workable definitions could be found which adequately capture high risk foods. Previous FSANZ experience in developing definitions for these foods suggests this may not be possible. In addition, it appears not to be the most cost-effective way of protecting public health and safety in terms of novel foods and nutritive substances.

The QACB indicates that Option 3, to develop an alternative framework, has the potential to: provide greater clarity regarding which foods require pre-market assessment; ensure that the relevant foods in terms of risk are being caught; and enhance the ability of food enforcement agencies to take enforcement action when required.

In addition, by permitting manufacturers to perform pre-market assessments themselves (self-assessment) for eligible foods, Option 3 may perform better than the other options against the objective of providing a cost-effective way of protecting public health and safety in this area. The QACB's assessment of Option 3 is in the context of the elements of the draft framework developed by FSANZ, which is as an example of what could be achieved under an alternative framework.

As noted above, the QACB is a preliminary assessment of costs and benefits for P1024. A more comprehensive assessment of costs and benefits will be prepared following the 1st call for submissions. This will be in the form of a Consultation Regulation Impact Statement (RIS). The Consultation RIS will have regard to submissions received in response to the call for submissions.

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1 Background

This Qualitative Assessment of Costs and Benefits (QACB) provides a preliminary assessment of costs and benefits for the options proposed in the assessment summary for the first call for submissions on P1024. The QACB is not a regulation impact statement (RIS) for the purposes of the Council of Australian Governments (COAG) Best Practice Regulation guidelines. FSANZ will prepare a Consultation RIS to accompany the 2nd call for submissions for P1024.

1.1 Catalyst research

In 2013, FSANZ commissioned Catalyst Ltd to obtain indicative costings from businesses of the activities involved in making applications to FSANZ for permissions for nutritive substances or novel foods, and in making enquiries to the Advisory Committee on Novel Foods (ACNF). The report produced by Catalyst is included as Appendix 1 to the QACB. The findings of the report have informed this QACB.

The main findings of the Catalyst report were:

- businesses considered the cost of preparing novel food and nutritive substance applications to be substantial
- participants felt that the time taken for applications to be approved (one to two years) was too long and had cost implications for businesses
- a lack of awareness by some businesses of the Code's novel food regulations.

FSANZ requested that Catalyst Ltd survey industry participants on their costs. The survey relies on self-reported costs. The opinions and views expressed in the Catalyst report are those of the participants alone and do not represent in any way the views of FSANZ. Furthermore the consultants identified several factors which make a cost assessment difficult:

- the small number of Novel food applications
- the wide range of complexity in the applications
- the diverse nature of novel foods and avenues for commercialisation
- the variety of ways that different companies account for development and regulatory costs
- for historical applications, staff turnover precluded accurate costings for all phases.

An issue with estimating costs related to data collected to obtain approvals in multiple countries (or an ACNF opinion). In some cases, the food business in Australia did not have figures on the cost of obtaining data (as this had been done by an overseas part of the business). In other cases, the cost was known and was provided to Catalyst but the data contributed to approvals in multiple countries. Consequently, only a portion of this cost should be attributed to the Australian/New Zealand application or ACNF opinion. However, insufficient information was available to do this. Consequently, some of the estimates provided for obtaining technical and safety information are overestimates.

In spite of these caveats, the Catalyst study was useful in collecting the possible range of costs associated with bringing novel foods and nutritive substances to market. These include:

- the costs of conducting and collating research to support applications/ACNF enquiries
- the costs of preparing applications/ACNF enquiries

- while an application is being assessed, the food business cannot put the food on the market, and so is not able to earn a return on the investment they have made in developing it
- the anticipated costs of bringing a novel food or nutritive substance to market may result in some foods never being brought to market, an opportunity cost that also results in reduced consumer choice

Food businesses emphasised the challenge of organising the launch of new products with retailers when it was uncertain if and when an application would be approved.

Some food businesses also felt that the 15-month exclusivity period (available only for novel food applications) was insufficient for applicants to recoup the costs (including application costs) of bringing a new food to market.

These findings have informed the development of the options presented in the assessment summary. In particular, the graduated risk approach may make the coordination of product launches with retailers easier and enable food businesses to better capture the benefit from preparing their assessment.

1.2 Next steps in gathering cost information

FSANZ is seeking further information on the costs of the current regulatory systems for novel foods and nutritive substances, as well as for the options proposed in the assessment summary. Submitters can assist FSANZ by providing information on costs and/or by directing FSANZ to alternative information sources.

Questions:

1. 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.
2. 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.
3. How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?
4. 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.
5. (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.

6. (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced?

Following the call for submissions, FSANZ is planning to gather further information to build a better understanding of the types of costs businesses incur in bringing foods to market.

2 Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

The Act states that the protection of public health and safety is the primary objective in standards development.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the COAG Legislative and Governance Forum on Food Regulation.

The objective of this proposal is to reduce the health risks to consumers from potentially unsafe foods in a way that is cost-effective.

3 Options

The assessment summary outlines three options:

- retain the status quo
- retain the status quo, but with amended definitions for nutritive substances and novel foods
- develop an alternative framework

4 Impact analysis

4.1 Affected parties

Parties that would be potentially affected by this Proposal include:

- industry:
 - food manufacturers
 - importers
 - ingredient manufacturers/importers

- retailers
- food processors
- consumers
- government:
 - FSANZ
 - state and territory food enforcement agencies
 - Department of Agriculture (for food imported to Australia)
 - the Ministry for Primary Industries in New Zealand
 - Department of Health (Australia)
 - Ministry of Health (New Zealand)

4.2 Option 1 – Maintain the status quo

Under the status quo, P1024 would not proceed and no change would be made to the Code. The ACNF would continue to operate to provide opinions on the novel status of foods. The assessment summary contains further detail on the role of the ACNF in sections 2.3 and 3.2.

Maintaining the status quo would maintain the following issues with the current system:

- There are ambiguous terms in the definitions for nutritive substances and novel foods.
- Some substances could be considered both a nutritive substance and a novel food.
- Because of the ambiguous terms in the definitions, enforcement agencies find it difficult to determine whether an application should be made to FSANZ for a food or ingredient.
- There is the potential for substances which have not undergone pre-market assessment to cause harm to consumers if not adequately regulated or captured under other laws. The ambiguity of definitions means that food manufacturers may be unsure whether something that they consider to not be a novel food or a nutritive substance would be considered the same way by all of the relevant jurisdictions.
- The above creates uncertainty and undermines the utility of premarket assessment as a regulatory measure.
- Food businesses that ensure they do not bring to market foods that contain unapproved and potentially novel foods or nutritive substances face an uneven playing field as they must compete with other companies that bring to market foods regardless of their safety.

The objective of this proposal is to reduce the health risks to consumers from potentially unsafe foods in a way that is cost-effective.

The status quo will not achieve this objective because:

- Products deemed to require a safety assessment could potentially enter the market due to the regulatory uncertainty - which foods require premarket assessment would remain open to interpretation.

- The current provisions use one standard process for assessing the safety of novel foods and nutritive substances. This approach, with substantial data requirements for all applications, is possibly not sufficiently mindful of the cost to industry and consumers relative to risk.

4.3 Option 2 – Amended definitions

In order to ensure that the nutritive substance and novel food regulations clearly capture all foods which require the scrutiny of a safety assessment, it is likely that the revised drafting would require broader more inclusive definitions to capture a broader range of products. All substances thereafter defined as novel foods or nutritive substances would require pre-market approval through an application process. More inclusive definitions could provide greater certainty for stakeholders (including food businesses and food enforcement agencies), who would then have a clear and mutual understanding of what is captured by the definitions and what requires premarket assessment. This option assumes that workable definitions could be found which adequately capture foods with properties that warrant pre-market assessment. Previous FSANZ experience in developing definitions for these foods suggests this may not be possible.

FSANZ has investigated whether the definitions can be amended to replace the ambiguous terms with more objective terminology. However, creating effective definitions is challenging in this instance. The difficulty in amending the novel food definitions is highlighted by the outcome of the 2007 amendment to the novel food definition in Standard 1.5.1, resulting from Proposal P291 – Review of Novel Food Standard. This review produced the current definitions of ‘non-traditional food’ and ‘novel food’ in the Standard. The Proposal was subject to significant stakeholder consultation, particularly in relation to amending the definition yet it is now clear, as described above, that the amended definition of novel food is still subject to ambiguity and legal uncertainty.

Revised, broader definitions would result in a greater number of products being captured. This would be more burdensome for industry as a greater number of their products would need to go through an application process, leading to an increase in the number of applications. FSANZ considers that the cost per application would remain the same, as the application process would be the same as the status quo.

In addition, many of the products captured would be the types of foods for which the ACNF has previously provided the opinion that they do not require a pre-market approval. However, it would be likely to result in fewer foods on the market that are not established as safe (and potentially unsafe) than Option 1, and perhaps also the graduated risk approach (Option 3).

If the definitions were clear enough, this could mean that the ACNF would no longer be required. Clearer definitions would improve food businesses’ compliance with the regulations as it would be more straightforward for them, and enforcement officers, to determine which of their products are captured.

Table 1: Costs and benefits of revised definitions

Affected party	Impacts
Government	
Costs	There could be more applications, as more products or substances would be captured by the new definitions. If new definitions were clearer, the costs to regulators of dealing with enquiries would be less.

Affected party	Impacts
Benefits	Removing regulatory uncertainty can reduce the potential for unsafe food products and thereby reduce health costs to consumers and for governments. Plus lower costs from attending to incidents. If new definitions are clearer, lower enforcement costs as food businesses would be more likely to comply. There would be a lower risk of unsuccessful enforcement actions. If definitions are sufficiently clear, ACNF would no longer be required (a saving)
Industry	
Costs	Extra costs to industry in preparing novel food and nutritive substance applications, as more foods captured. Cost per application would remain the same. Opportunity costs from products not developed would increase as more products and substances captured.
Benefits	If definitions were clearer, opportunity costs from products not developed due to uncertainty would reduce (likely to be offset by the opportunity cost of products not developed because they require an application). Possibly a benefit from increased certainty regarding which products require an application.
Consumers	
Costs	Reduced availability of new products if innovation is stifled.
Benefits	Reduced potential harm from consuming unsafe products on the market.

4.4 Option 3 – Alternative framework

Submitters to the March 2012 consultation paper indicated that any new regulatory requirements should be commensurate with the likely risks to consumers posed by new foods. For this option, FSANZ considers it may be necessary to develop an alternative approach in order to improve the clarity and enforceability of the Code. FSANZ has developed a draft framework, based on a graduated approach to risk, as an example of what could be achieved under an alternative framework. The draft framework for the graduated risk approach (referred to as the graduated risk approach below) is designed to provide greater opportunity for more proportionate and streamlined assessment processes in ensuring the safety of new foods entering the marketplace in Australia and New Zealand. This approach may better manage potential risks at a lower cost than the current novel food and nutritive substance provisions.

Please see the assessment summary for more detail on the graduated risk approach. The graduated risk approach includes three main elements:

- 1 Identification of foods which do not require regulatory approval prior to market entry
 - The Code would permit the sale of new foods that meet ‘eligible food criteria’¹. The criteria would be stipulated in the Code and would reflect those foods that are considered to pose a level of risk that is negligible, well understood and/or managed by other standards in the Code or through other means.
- 2 Different pre-market assessment routes for market entry of all other foods (e.g. foods for which the risk is not known, or foods which may have a risk that requires managing through changes to the Code)

¹ FSANZ has developed a draft set of criteria for this purpose (see section 4.2.3.1 of the assessment summary and SD3 for more detail).

- Foods that do not meet the ‘eligible food criteria’ would be required to undergo a more extensive pre-market assessment before they could be supplied in the marketplace in Australia and New Zealand. The pre-market assessment would be either an industry self-assessment process (with notification to FSANZ) or the FSANZ regulatory assessment process (i.e. the current application process).
- 3 A description of data and dossier requirements to establish safety and impact on public health of new foods
- The type of information that is needed; and how it should be analysed and interpreted to determine whether a food is safe for human consumption and its potential impact on public health.

Reliance on the current definitions would not be an issue with Option 3, as the definitions for nutritive substances and novel foods would no longer be needed. Instead, the Code would focus on criteria that determine which assessment process is applied to which food. All pathways require some form of safety assessment.

A food business bringing eligible foods to market would be required to hold certain data (basic data requirements would be listed in the Code). By holding this data the business would substantiate that their eligible food is safe for consumption. Meeting these requirements would be less burdensome than going through an application process. This is because:

- the quantity of data that the food business would need to hold for an eligible food would be less than what would be needed to support an application (because pre-market approval by FSANZ is not considered necessary and the data requirements would be less)
- the food business would not need to submit an application to FSANZ and then wait for FSANZ to either approve or reject it

The graduated risk approach would improve compliance. This is because the Code would be amended to clearly identify which foods require pre-market assessment and to set out clear requirements for assessing the safety of these foods, including data requirements that must be met. This would improve the clarity and enforceability of the Code, encouraging compliance by food businesses. The legal clarity of the graduated risk approach (compared to the status quo) would make it easier for jurisdictions to take action to protect public health and safety because a food business would not be compliant with the Code if it has not followed the requirements for establishing the safety of a food.

Costs to business may be reduced compared to the status quo as some foods which currently require an application (because they are novel or a nutritive substance) would be eligible foods, and so a less burdensome process could be followed to get them to market.

In addition, by not following an application process, food businesses could potentially be able to launch eligible foods more quickly than under the status quo. This would enable them to start earning a return on their investment in new product development more quickly, likely increasing the overall return on the investment. As well as reducing time to market, the graduated risk approach would reduce uncertainty regarding when an eligible food could launch. Food businesses interviewed in the Catalyst report noted that the uncertainty regarding the time which would be taken to approve a new food made it difficult to coordinate the timing of product launches with retailers. By removing this uncertainty for eligible foods (as the food business can manage their own timelines), the graduated risk approach reduces delays further by reducing coordination challenges.

A benefit to businesses bringing a food to market either through the eligible food self-assessment option or through the industry self-assessment pathway (for non-eligible foods) is being able to better capture the benefit from preparing their self-assessment. Under the status quo, FSANZ gives public notice when an application has been accepted. This notice includes a summary of the application, giving competitors of the applicant advance notice that the applicant intends to market a particular food. If the application is approved, competitors of the applicant can ‘free-ride’ by marketing the same or similar products, without having made any investment in obtaining regulatory approval for the new product. Currently, novel food applicants can request a 15-month exclusivity period in which only their brand can use the newly approved novel food. However, food businesses interviewed in the Catalyst research expressed the view that the 15 month exclusivity period was insufficient for them to establish their product and recoup development costs.

Under the graduated risk approach, in contrast, a food business that follows the eligible food self-assessment option to bring a food to market captures the full benefit of their investment. Other food businesses wishing to bring the same food to market would need to undertake their own self-assessment, so they cannot ‘free-ride’ on the efforts of the first business that brings the food to market. This may provide an incentive to food businesses to self-assess new foods (compared to the status quo), as only food businesses that conduct their own self-assessment will be able to bring a food to market.

For a food business that follows the pre-market self-assessment (notification) pathway (for non-eligible foods), the dossier they prepare and submit to food regulators/authorities would be made publicly available (online). Unlike the current FSANZ application process, the timing of the release of the dossier would be controlled by the food business. This means they could coordinate the release of the dossier with the release of the product. Consequently, competitors would have little advance warning that the product was being released. This contrasts with the current FSANZ application process in which FSANZ gives public notice when an application has been accepted. Assessment and approval of the draft variation (or rejection) then takes approximately 3-12 months depending on the procedure under which the application is assessed².

Table 2: Costs and benefits of a graduated risk-based approach

Affected party	Impacts
Government	
Costs	Food enforcement agencies would incur costs in requesting (where there are concerns) the information held by companies with eligible foods. However, this cost may be offset by reduced costs in investigating unapproved foods than is currently the case (due to increased compliance).
Benefits	FSANZ may use somewhat fewer resources to assess applications (to the extent that some products that currently require an application would no longer need one). If the proposed system is clearer regarding which foods or ingredients are captured (and what type of assessment they need to undergo), then enforcement costs for food enforcement agencies will be reduced. Reduced potential for unsafe food products (compared to status quo), due to requirements to consider against the EFC and a clear requirement for holding a safety dossier. This would reduce potential health costs from exposed consumers. In addition the costs of dealing with incidents (such as DMAA), failed actions, and prosecutions would be reduced.

² See the FSANZ Application Handbook for more details on timelines for applications: <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>
A final decision on whether the draft variation is accepted or rejected may take longer than 3–12 months. For example, if FSANZ needs to request additional information from the applicant.

Affected party	Impacts
Industry	
Costs	Greater enforceability of the proposed system would mean higher costs to food businesses which do not currently comply with the regulations (as they would need to start complying or face enforcement action). Compared to status quo, businesses would have to do more assessment themselves and hold specified safety data to support their case.
Benefits	Many of the foods which previously went through the ACNF (and were found to not require an application) would be eligible. The information required to complete the eligible food process will be similar to the information included in a well-prepared ACNF questionnaire with accompanying information. Food businesses who have already received overseas approvals will find the graduated risk approach to be significantly cheaper than the current system. Costs would be reduced for eligible foods, as data requirements for eligible foods will be less onerous than for an application under the status quo. Less onerous processes to get to market means fewer resources tied up in the process, quicker return on investment in new product development. Also, fewer opportunity costs from products which are not launched due to the current application process. Food businesses would have a level playing field, with a higher proportion of businesses complying with the new regulations. Food businesses that bring an eligible food to market will capture the full benefit of their investment.
Consumers	
Costs	It is still possible that some 'unsafe' foods could be categorised as eligible and placed on market with inadequate safety data, posing a public health and safety risk for consumers
Benefits	(Overall) an increased range of products may be available because it is easier to get them to market. Decreased risk from potentially unsafe foods – fewer health harms.

4.5 Comparison of options

Table 3 compares the three options' performance against five criteria:

- difficulty of enforcement
- likelihood of exposure to unsafe foods
- length of process
- cost to business
- opportunity for free-riding

Each of the criteria has been worded as a negative element, and so an option which is rated as 'High' on a criterion is less desirable than an option which achieves a 'Low' or 'Medium' rating.

Table 3: Decision matrix

	Status quo	Status quo with amended definitions ³	Graduated approach
Difficulty of enforcement	High	Low	Low
Likelihood of exposure to unsafe foods	High	Low	Low
Length of process	High	High	Low-High ⁴

³ This option assumes that workable definitions could be found which adequately capture high risk foods.

⁴ This will depend on the pathway. Pre-market self-assessment (for eligible foods) will be low, pre-market self-assessment or pre-market approval (FSANZ) will be high.

	Status quo	Status quo with amended definitions ³	Graduated approach
Cost to business	Medium-high	High	Low-High ⁴
Opportunity for free-riding	High	High	Low-Medium

The table shows that the graduated risk approach performs better than the status quo against each of the criteria. Risk to consumers (likelihood of exposure to unsafe foods) is reduced; enforceability is improved; the length of the process is reduced; costs to business are lower, and the opportunity for free-riding is reduced. In contrast, the status quo with amended definitions improves enforceability and reduces risk to consumers, but at the expense of increased cost to business. In addition, the amended definitions do not address the issue of free-riding.

This QACB suggests that Option 3, the graduated risk approach, is most likely to achieve the ultimate objective of reducing the health risks to consumers from potentially unsafe foods in a way that is cost-effective.



**SURVEYING AND COSTING OF THE REGULATORY COSTS
ASSOCIATED WITH BRINGING A NEW NUTRIENT OR NOVEL
FOOD TO MARKET**

**A report for
Food Standards Australia and New Zealand
RFT NO 2012-13/19**

September 2013

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Disclaimer

This report has been prepared in accordance with the methodology in part 2. It is based on the information and opinions supplied by the companies interviewed. We have not attempted to verify the accuracy or completeness of the information and opinions and therefore we cannot accept any responsibility for the accuracy of the information and opinions from which the report has been prepared.

Executive Summary

Food Standards Australia New Zealand (FSANZ) is reviewing the provisions and processes for the addition of new nutritive and novel substances to the food supply. Any such addition requires an application to amend the Food Standards Code. The purpose of this project is to obtain indicative costings from businesses of the activities involved in these processes.

Our overall approach has been based on developing good communications with selected companies, and creating robust templates for identifying and costing activities. Applying common parametric statistical analysis to the study sample, is likely to result in misleading analysis, given the very small sample size. Therefore, a case study approach, based on consistent identification of activities and costs, was developed to provide a practical solution.

The companies have been segmented into three groups:

Group 1 companies are companies that have taken products through an application to amend the Food Standards Code or are large companies with regulatory experience in bringing products to market.

Group 2 companies have submitted an enquiry to the Advisory Committee on Novel Foods (ACNF); the enquiry may or may not have determined the product as novel.

Group 3 companies have taken products to market outside the regulatory pathway.

A key part of our methodology has used a pilot of three Group 1 companies to understand the intra-organisational system-wide activities and costs associated with bringing an application through an internal assessment, an ACNF assessment and a FSANZ assessment. The templates were agreed with FSANZ and used for the expanded study.

As a result of information gained during the interviews, we developed additional templates to capture more qualitative information. This feedback is summarized below under “Qualitative data”.

Quantitative Data

Quantitative data was obtained for Group 1 and some Group 2 companies.

It is difficult to compare costs because:

- There is a wide range of complexity in the applications;
- Where the company is a multinational, data on technical information and food safety may be generated off shore and the cost of this information is not accessible to the Australasian subsidiary;
- For historic applications, staff turnover has precluded accurate costing for all phases.

Notwithstanding these caveats, there is a wide range in the costs, from around AUD 30,000 to AUD 462,500 for taking through an application to change the Food Standards Code. Extensions to use were less at between AUD 37,000 and AUD 100,000, reflecting the reduced requirements for information.

Some companies also incurred considerable cost in developing safety information that was presented as information for an ACNF determination. Costs of between AUD 115,000 and USD 300,000 were cited. Two companies provided data for obtaining a Generally Recognised As Safe (GRAS) determination from the U.S. Food and Drug Administration (FDA): costs ranged between NZD 30,000 and NZD 70,000.

The organisations surveyed believe the application costs to amend the Foods Standard Code are substantial.

After the fact analysis of processes used and costs incurred is difficult. It is suggested that this could be addressed through developing and implementing a method for collecting the cost of compliance data, at the time of application. Some consideration could usefully be given to the methodology of cost apportionment where information is used across several jurisdictions or countries. Although it is difficult to make appropriate cost apportionment decisions, it would be incorrect under the principle of understanding the economic impact of regulation (e.g. sound analysis, informed decision making and transparency) to either exclude or fail to appropriately account for these costs.

Qualitative Data

The qualitative data provided valuable insights into company perceptions. Similar qualitative data was obtained for Group 1 and Group 2 companies. There were a diverse range of levels of experience, and these are discussed in the Results section of the report. However, there were some consistent themes and these are discussed below.

A consistent view was expressed about the timeliness of the approvals process. The respondents were almost unanimous in their desire for the timeframes for FSANZ consideration to be reduced. There are two key factors involved. Firstly, the overall elapsed time is stated to range from one to two years or longer. Secondly, the reported uncertainty over response times for steps within the overall timeline for consideration of Novel foods. Both these factors have major cost implications for applicants, which are additional to those directly related to the FSANZ process.

Generally, the window of opportunity to launch a new product is strictly defined by retailers. These windows may only open every six months for any particular product category. Failing to take advantage of these occasions creates significant “opportunity cost” and results in lost revenues and foregone profits. The uncertainty over FSANZ response times therefore has significant flow-on effects, resulting in hidden costs that are a deterrent for firms to invest in New Product Development (NPD) and significant disincentive to launch new products in Australian and New Zealand.

Overall, the ACNF process and Record of Views document was viewed as reasonable in terms of the information required and the timeframe for response, although some concerns were expressed about disparity with overseas approvals compared to FSANZ classification.

Of the companies that responded, only one product (ultimately classified as non-Novel) had a data package developed in Australia. It was emphasised that the Australian/NZ market size is small and does not justify undertaking R&D specifically to meet FSANZ requirements, for products that have already been approved by overseas jurisdictions. A number of examples were provided of overseas approval systems that were perceived as being more efficient than the FSANZ process

There was a consistent view from Group 1 companies about the difficulty and cost of getting information regarding consumer awareness/behaviour for an application to change the Food Standards Code.

Any views provided were consistent in questioning the relevance of these questions.

Overall, it was noted that few Novel foods have been approved in recent years. This may indicate that the FSANZ process is acting as a barrier to innovation or that companies are not following a regulatory pathway prior to marketing novel foods. However, it was not possible to gauge whether or not there may be a backlog of new products awaiting entry into the Australian/NZ market.

Group 3 companies were interviewed using a different set of questions to identify their understanding of their products and the FSANZ Novel Foods regime. It was our understanding that all Group 3 companies had sold Novel Foods but had taken such products to market outside the

regulatory pathway. Most products were made or formulated in Australia and New Zealand, largely using ingredients sourced from off shore. Companies had a level of awareness of a range of standards such as supplemented foods, and health claims, but expressed a low or no level of awareness of Novel Foods regulatory regime. They kept abreast of research through industry publications but did not carry out any internal research. They were cost conscious and conveyed the view that their products were not considered to have any safety risks.

It appears, therefore, that ignorance of the Novel Food regulations may be a reason for these companies not seeking regulatory approval, although subsequent cost-avoidance might be a not unanticipated response should they become aware of the requirements of the Code. However, it should be noted that only a small number of Group 3 companies were interviewed, with several turning down the invitation to engage in discussion.

1. Introduction

FSANZ is reviewing the provisions and processes for the addition of new nutritive and novel substances to the food supply. Any such addition requires an application to amend the Food Standards Code. The purpose of this project is to obtain indicative costings from businesses of the activities involved in these processes to inform the impact assessment of any proposed amendments to the current processes.

2. Methodology

2.1 Overall methodology

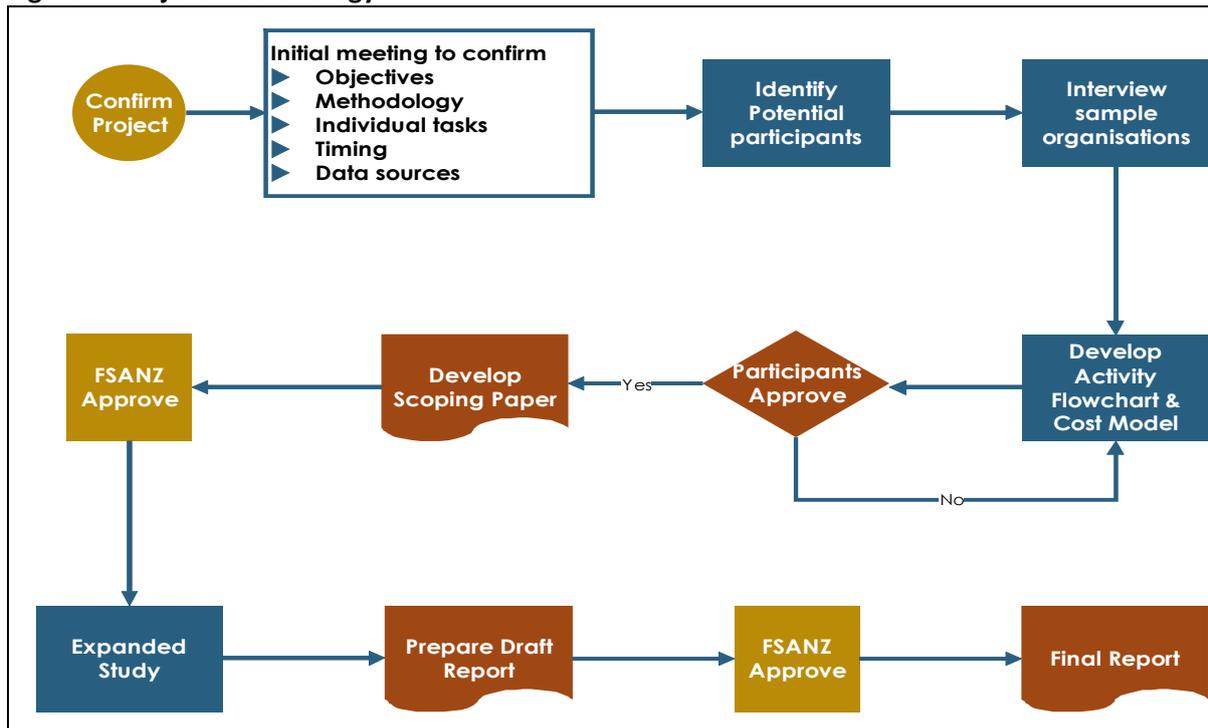
The methodology for the project has been in accordance with Annex 1 RFT No. 2012-13/19 (see Appendix 1.1).

Activity Based Costing (ABC) identifies the relationship between a business activity and all the resources needed to conduct it by assigning costs to each of these resources, thus presenting the true total expense of the entire activity (Goleman, 2006). ABC assigns cost to products, processes, activities or customers based on the resources they consume. Overhead costs are traced to a particular product, process, activity or customer rather than spread arbitrarily across all products. (O'Guin, 1991).

The subjects are companies (the population “the collection of all items of interest in a particular study” (Anderson, Sweeney, Williams, Harrison, & Rickard, 1989)) producing products in New Zealand and/or Australia that are covered by the current requirements for Novel Foods (Standard 1.5.1) and Nutritive substances (Standard 1.1.1 clause 9). Food additives, vitamins and minerals, processing aids, food produced using gene technology and irradiated foods are beyond the scope of work.

Our overall approach is shown in the figure below.

Figure 1: Project methodology



FSANZ provided the consultants with a list of organisations (the sample – a smaller collection of units from the population (Siegel, 2000)) that were involved, to varying degrees, with Novel and Nutritive substances. The contrast in size, complexity and engagement (with Novel and Nutritive substances), of the organisations in the sample was such that it was necessary to stratify them into three classes.

Group 1 companies are companies that have taken products through an application to amend the Food Standards Code or are large companies with regulatory experience in bringing products to market.

Group 2 companies have submitted an enquiry to the ACNF; the enquiry may or may not have determined the product as novel.

Group 3 companies have taken products to market outside the regulatory pathway.

Table 2 outlines the number of organisations in each class, by location. The number of organisations in each group are very small. In fact, the total sample size is so small, the organisations so varied, that they are not amenable to standard parametric statistical analysis. Simply put, the sample is not representative of the population and the data cannot be transformed into a standardised normal distribution (“one whose random variable Z always has a mean $\mu = 0$ and a standard deviation $\sigma = 1$ ” (Levine, Stephan, Krehbiel, & Berenson, 2002)).

Notwithstanding these problems, there is a wealth of qualitative data, that in the first instance, is very useful to FSANZ. To extract these data the consultants developed a series of flowcharts to graphically represent the requirements of an application to vary the code (Appendix 1.5).

A case study approach, based on developing good communications with selected companies, and creating robust templates for identifying and costing activities was adopted. This approach, based on consistent identification of activities and costs, had the advantage of providing a practical solution, to the problem of the dealing with an unrepresentative sample.

An activities template was designed to identify and categorise costs and a cost template, that reflected the flowchart, was developed to trap resource and cost information. During the interview phase, the templates were used to guide the participants through the process. After the interview phase, the costing template and flowcharts were forwarded to the participants. This ensured that the approach to each organisation was consistent and provided a coherent framework to gather the data that was available.

2.2 Methodology for pilot Group 1

FSANZ provided a list of eleven Group 1 companies. These companies would provide the best assessment of costs of approval since they would have understood the requirements of applications to the Food Standards Code and prepared the necessary data requirements.

Four companies in Group 1 were approached using the introductory letter in Appendix 1.3. Three agreed to work with us on this pilot project. Representatives of the three companies were interviewed in person to commence the engagement.

2.2.1 Confidentiality and consent form

The confidentiality and consent form, in Appendix 1.4 was provided to each participant. Signed copies are held confidentially at Catalyst offices.

2.2.2 Interviews

Three companies have been interviewed as a pilot group. The objective of this phase is to understand the intra-organisational system-wide activities and costs associated with bringing an application through an internal assessment, an ACNF assessment and a FSANZ assessment process.

The companies in the pilot study had all had experience of taking a novel food through an application to amend the Food Standards Code. Their experiences were strongly informed by the nature of the application process. Based on the interviews, the activity flow charts were developed as per Appendix 1.5. Based on these activity charts, organisations were asked to identify the costs associated with each sub activity. Companies were asked in particular to identify the following:

- External total costs where consultants were employed; and
- Where internal costs were incurred, time based costings for each person, including full company overheads.

2.2.3 Activity flow charts

An activity flow chart has been developed based on the activities required to make an application to amend the Food Standards Code (Appendix 1.5)

2.2.4 Costing template

The costing template was developed taking into account the following criteria:

- The list of tasks in total represents an appropriate description of how business is complying with the present regulation;
- Those tasks that would occur regardless of the regulatory framework will not be included, but may be identified;
- The tasks identified are readily amenable to financial analysis, or are likely to be already costed by the company; and
- Costs will remain disaggregated where possible.

The following guidance was provided on the information required (Table 1).

Table 4 Guidance provided on using the activities and costing template

Guidance on information required	
1 Internal costs	Where actual costs are available per activity please record these. Alternatively record the proxies of time estimated X personnel cost. Include and note travel costs where significant.
2 Type of internal costs	Where available record legal, technical, consumer etc. Do not record directly commercial costs e.g. product marketing.
3 Apportionment	Where a cost is incurred for purposes additional to a novel food outcome, please assess apportionment of costs, with a reason.
4 External costs	This includes actual costs of consultants or purchase of data and reports.
5 Interactions with FSANZ	Note separately costs of meetings with FSANZ, providing additional information, or resubmitting, where appropriate.
6 Direct FSANZ costs	Fee for paid application
8 More than 1 product?	Please use a separate activity costing sheet for each.
9 Time duration of the application?	When did you start and finish, in months/years.
10 Any activities not included in the activity cost sheet?	Please include, with a reason for carrying out the activity
11 Any other comments	E.g. data on opportunity costs.

The activity and costing template used is in Appendix 1.6.

2.2.5 Other considerations

Several of the pilot study participants noted that they used information prepared for other jurisdictions, and that obtaining costings for this information would be problematic, and that even if it was able to be collated, apportioning to any one application was somewhat arbitrary.

In addition to the internal costs, each company was also asked to document the cost recovery charged by FSANZ for their role in assessing the application.

2.3 Methodology for expanded study

The methodology developed above was extended to an additional six Group 1 companies. Two Group 1 companies declined to participate. Participants in the pilot and extended study are summarised as in Table 2 below by group type and location.

Table 5 Participants in pilot and extended study by group type and country

Group	Companies approached: Australia	Companies interviewed: Australia	Companies approached: New Zealand	Companies interviewed: New Zealand	Companies interviewed: Total
Group 1 pilot	3	3	0	0	3 out of 3
Group 1 expanded	6	4	2	1	5 out of 8
Group 2	3	3	5	4	7 out of 8
Group 3	4	1	5	3	4 out of 9
Total	16	11	12	8	19 out of 28

Personal contact was considered to be important in order to maximize cooperation. This was achieved. However, three companies participated via teleconference (two in Group 2 and one in Group 3). In some cases significant follow-up was required in order to identify the appropriate person in the company to engage with, and in order to obtain an appointment. (e.g. initial email sent 17 May, meeting held 25th July with at least eleven documented contacts or follow-ups in between). In other cases, repeated contact was required to obtain information.

2.3.1 Confidentiality and consent form

The confidentiality and consent form in Appendix 1.4 was provided to each participant. Signed copies are held confidentially at Catalyst offices.

2.3.2 Interviews

The activity flowcharts and costing templates were used as a first approach with the expanded set of Group 1 companies and with initial Group 2 companies. As a result of these interviews, it became apparent that a modified approach was required for the following reasons:

- New staff were in place who had not been involved in original applications, necessitating discussions at a broader level;
- In some multi-national companies, data was generated offshore, and costings were not available;
- Valuable qualitative information was available, even in the absence of quantitative information, because of changes in staff and lack of availability of information; and
- Some costs related to the FSANZ assessment processes are not readily quantifiable and represent opportunity costs due to perceived delays and other perceived inefficiencies inherent in the process.

2.3.3 Additional information for Group 1 and 2 companies

As a result of information gained during the interviews, we developed additional templates to capture more qualitative information.

The questions (as per Table 3 below) were used initially with companies. Where financial information was available, activity costings were obtained as in the activities and costing template (Appendix 1.6).

Table 6 Additional information from Group 1 and 2 companies

01	Any past experience with FSANZ and at what level?
02	Outcome of FSANZ contact
03	Any specific difficulties?
04	Any aspects of your products likely to raise special concerns?
05	Timeliness of approval process? (Any marketing implications from delays?)
06	Possible to estimate costs of undertaking each step in the process?
	If not already covered in responses above:
07	Any issues regarding process for obtaining view on whether product is a novel? (ref. Record of Views document)
08	Is the supporting research undertaken in Australia/NZ or other jurisdictions?
09	Any issues regarding sources and/or type of data required?
10	Any issues regarding ownership of/access to R&D and approval? (e.g. gaining exclusive permission)
11	Any views about F1 and F2 regarding consumer awareness/behaviour?
12	Other Issues

2.3.4 Interviews with Group 3 companies

Group 3 companies have taken products to market outside of the regulatory pathway. We identified such companies through the following ways:

- Consideration of the Record of Novel Foods to identify the kinds of products and ingredients that might be used;
- Becoming aware of foods and beverages in retail, especially in health food and sports nutrition outlets; and
- In consultation with FSANZ.

We used the questions in Table 4 as prompts for discussion. Free form discussion was pursued to understand reasons why individual activities were undertaken.

Table 7 Information sought from Group 3 companies

1.	As a company, in what ways, if any, do you consider any regulations that might apply before putting new food products on the market?
2.	Have you undertaken any formal analysis of your products and their regulatory status in New Zealand/Australia?
3.	Are you aware of any particular products or ingredients that you sell that are or might be novel?
4.	Are products approved under other regulatory regimes?
5.	Do you manufacture/formulate in New Zealand/Australia?
6.	Which countries do you mainly import product from?
7.	Do you sell in Australia/New Zealand, and what are your experiences there?
8.	Any direct experience with New Zealand/Australia regulatory requirements?
9.	Do you know what supporting research and information has been collected?
10.	Has your company incurred any costs associated with regulatory requirements for your products in New Zealand/Australia?

3. Results and Discussion

The results are shown below. Please note that we have not carried out currency conversions since many of these costs are historic, but have expressed costs in the currency provided. Neither have we adjusted for inflation.

3.1 Quantitative Data

3.1.1 Group 1 and amendment to Food Standards Code

Seven companies provided costs for applications to amend the Food Standards Code. Two companies made application for two products, although at different times. Two companies also subsequently withdrew their applications. Despite repeated contact, companies were unable to provide costing information to the level required in the activity costing template (Appendix 1.6). Therefore costs are provided at the overall section level only. For an extension to use, there is no requirement to provide data for sections B and C of the questionnaire. Costs are recorded in Table 5.

Table 8. Summary of costs for Group 1 companies who have made applications to amend the Food Standards Code

Companies*	A	B	C	D	E	F	G Extension of use	H Extension of use	I Extension of use
Section A Exclusive use of novel foods									
									2,500
Section B Technical information									
				500	20,000				
Section C Safety information									
			103 - 138,000	272,500	186,000				
Sections D-F Information on dietary exposure, nutritional and health impact and consumer understanding and behaviour									
	10, - 20,000	25- 30,000	10,000		135,000		100,000		39,000
Total									
	30,000	25- 35,000	113- 148,000	272,500 Internal costs 180,000 External costs 92,500	341,000	100,000	100,000	37,000	41,500
FSANZ application fee									
				190,000	87,000				23,000

*Companies are anonymised as A-I

All costs are in AUD. Blank cells = information not specifically provided.

There was a great contrast in the range of information that participants could provide to the project. Only two companies provided information for section B. Some safety information for section C was provided by three companies, but not by three others. Companies provided the most complete data for sections D-F, which related specifically to the Australian market. Only one company was able to provide information for all sections, and that application was the most expensive.

There was a wide range in the total cost of preparing an application (excluding the FSANZ application fee), from around AUD 30,000 to AUD 341,000. Extensions to use were less at AUD 37,000 and AUD 100,000, reflecting the reduced information requirements. The differences in costs may reflect the differences in complexity of the applications.

Both this study and a previous study undertaken by FSANZ⁵ have identified the difficulty of obtaining reliable quantitative data on the costs of preparing for and submitting a proposal for approval of a novel food. Several factors combine to make such assessment difficult:

- The small number of Novel food applications;
- The wide range of complexity in the applications;
- The diverse nature of novel foods and avenues for commercialisation;
- The variety of ways that different companies account for development and regulatory costs; and
- For historical applications, staff turnover has precluded accurate costings for all phases.

Where costs for technical information and food safety (sections B and C), are provided by three companies, the cost is significant and the average cost is AUD175,000. (One company identified that global costs for the new product were around AUD500,000, for “development costs, bioavailability studies, market / consumer research studies”, although this figure is not listed above because it was judged to be too much of a ball park estimate). In ABC, any information that is used in an application should have the costs associated with creating it assigned to the application. Where information is assigned to several applications, as maybe the case with multinational data, the costs should be apportioned accordingly. However, in practice it is difficult to make appropriate cost apportionment decisions, with a defensible rationale and particularly where robust information is not available. The costs in Table 5 for sections B and C have not been apportioned and on this basis maybe an overestimate. On the other hand, where the cost of the information for sections B and C is not accessible to the Australasian subsidiary, the true cost of those applications to amend the Food Standards Code is underestimated.

From our interviews, we consider that some of the figures provided are likely to be underestimates of the true costs to the company. Companies could easily access costs associated with third-party services (external consultants, in the main) that provided input into applications. Whereas internal time based activities are not routinely applied to specific compliance issues. In many organisations, the responsibility for compliance to Food Standards is one small area of greater compliance activities (workplace health and safety, quality, chain-of-responsibility, fatigue management, etc), and can be multi-jurisdictional. Novel food applications are a very small sub-set of compliance to Food Standards, so disaggregation to identify those required only for FSANZ activities, to this point, provides no value to the organisation. In addition, the qualitative data below refers to significant “hidden” costs (such as the opportunity costs from delayed or cancelled product launch) which are not possible to quantify.

A number of companies made some general comments in relation to this costing exercise.

⁵ 2007 P291 Novel Food Review FAR FINAL

[http://www.foodstandards.gov.au/code/proposals/Documents/P291 Novel Food Review FAR FINAL.doc](http://www.foodstandards.gov.au/code/proposals/Documents/P291_Novel_Food_Review_FAR_FINAL.doc)

Impact Analysis

- Benefit cost analysis and comparison of options, which states, in part:

FSANZ currently has limited quantitative data in relation to the impacts on the various affected parties of each of the regulatory options put forward, though some qualitative information has been made available. FSANZ has sought advice from the SDAC on the possible costs and benefits associated with each option, however, it was widely acknowledged that quantitative data is difficult to obtain due to the limited number of novel foods on the market in Australia and New Zealand. (p19)

Much of the material for sections D, E and F must be prepared specifically to meet Australian and New Zealand regulatory requirements. For instance, dietary intake and nutrition information for the Australian market must be based on Australian Dietary Intake data. By definition, this information can be difficult to obtain for “novel” foods, since such substances may not yet have consumer understanding. In addition, providing information to these sections may expose commercially confidential material and compromise marketing / innovation plans.

All these factors make after the fact analysis of processes used and costs incurred difficult. It is suggested that some, but not all, of these could be addressed through developing and implementing a method for collecting cost of compliance data, at the time of application. Some consideration could usefully be given to the methodology of cost apportionment where information is used across several jurisdictions or countries. Although it is difficult to make appropriate cost apportionment decisions, it would be incorrect under the principle of understanding the economic impact of regulation (e.g. sound analysis, informed decision making and transparency) to either exclude or fail to appropriately account for these costs.

3.1.2 ACNF determinations

Some Group 2 companies were able to produce quantitative information on the costs of getting information for an ACNF determination. These are summarised in Table 6. The remainder of the companies did not have these data.

Table 9 Summary of costs for Group 2 companies who have requested an ACNF determination

Cost and activity	
Preparing dossier and seeking advice from ACNF	
	<ul style="list-style-type: none"> ○ only involved 1-2 days ○ \$2000 ○ Minimal
Cost of safety trials information in the dossier	
	<ul style="list-style-type: none"> ○ AUD 115,000 ○ USD300,000 ○ Numerous clinical trials and scientific experiments

The costs of preparing a submission to seek an ACNF determination were not considered to be excessive. However, some companies incurred considerable cost in developing safety information that was presented as part of an ACNF determination (see Part 2 Guidance Tool for Determining Whether a Food is Novel or Not).

3.1.3 GRAS determinations and other jurisdictions

Two companies provided data for obtaining a GRAS determination from the FDA:

- Typically a panel of 4 people would cost approximately NZD30,000. Additional costs are:
 - dossier preparation, which is extremely variable depending on product,
 - a US attorney to set up the panel.
- Self-affirmation for US food applications took 9 months and cost NZD70,000.

One company also discussed their experience in seeking a complementary medicine listing under the Therapeutic Goods Administration (TGA), a process with which they are very familiar and currently have three products in train. TGA fees, consulting and literature search costs typically range from AUD 25,000 – 40,000. Management time is an additional cost.

3.2 Qualitative Data

3.2.1 Compiled responses from Groups 1 and 2

The responses gathered from one-on-one interviews are summarised below according to the questions in the template (Table 3).

Q1 Any past experience with FSANZ and at what level?

Some companies had had extensive experience with FSANZ, through applications to amend the Food Standards Code, and also had staff that served on FSANZ committees. Some companies had engaged consultants and had little direct contact with FSANZ.

Q2 Outcome of FSANZ contact

Companies reported a diversity of outcomes. Some reported Novel Foods that successfully achieved amendment of the Food Standards Code. A small number who undertook to develop an application became concerned about the cost and complexity of the approval process so that they withdrew the application. Some companies obtained advice that their proposed food was not Novel and were able to proceed to market. Others who obtained advice that their product was Novel chose not to proceed with an application.

Q3 Any specific difficulties?

The companies who had taken a Novel Food product through to an application to amend the Food Standards Code all expressed concerns about the process. The concerns related to the complexity, long timeframes and uncertainty of the FSANZ process. This view is supported by the fact that two independent consultants had differing views on the likely required resource investment and timeframe. In particular the overall definitions in the Standard and the Application Handbook lacked clarity and coherence and are not user-friendly.

Costs and delays were perceived to be out of proportion in the context of the small size of the Australian/NZ markets overall and the “niche” nature of many Novel foods within those small markets.

Some respondents had experience with the processes for listing of complementary medicines under the TGA. They reported that the process for approving Novel foods is comparable with the TGA process, despite the much more complex issues around efficacy of complementary medicines. In contrast FSANZ is primarily focussed on whether the Novel food is safe.

In addition, the TGA is moving to adopt international standards under a Common Technical Documents format. In contrast, data packages on Novel foods that have already satisfied overseas authorities require re-formatting for consideration by FSANZ. (It was not possible to investigate the TGA processes within the scope of this study)

Q4 Any aspects of your products likely to raise special concerns?

This question aimed to identify any product or market groupings that may have experienced particular difficulties or concerns. None were identified.

Q5 Timeliness of approval process? (Any marketing implications from delays?)

The respondents were almost unanimous in their desire for the timeframes for FSANZ consideration to be reduced and for a process with greater certainty about time lines to be adopted. Companies that had requested a novel food determination by the ACNF and those that applied for a code amendment expressed these concerns. They noted that the approval process lacks the rapidity of commercial imperatives.

There are two key factors involved. Firstly, the entire application process is lengthy - it can take anywhere from at least one year to more than two years - to complete. Secondly, FSANZ can be slow to respond within any given step of the process.

“Time to market” has a major bearing on achieving returns on the R&D funds already invested before the FSANZ process begins. The new product development (NPD) process is typically managed by a “stage-gate” or similar system. This encompasses several stages, of which the “development” stage is only one. The FSANZ approval process, in turn, is only part of this stage and yet the timeframes involved in the approval process exceed the total NPD for a typical food product. This makes it very difficult to effectively launch innovative products containing novel ingredients.

The market launch stage of the NPD process requires significant planning, investment and liaison with retailers (quite apart from the costs of establishing production capacity). Generally, retailers strictly define the window of opportunity to launch new products. These opportunities may only occur every six months for any particular product category, so there is a significant “opportunity cost” in missing these chances. The uncertainty over FSANZ response times therefore has significant flow-on effects, resulting in hidden costs that are a disincentive for firms to invest in NPD. Some companies noted that the lack of timeliness was more of an issue and a disincentive than the actual cost of making an application. One company suggested that a parallel approach, whereby FSANZ could review all aspects of the application concurrently, and request responses to all of the issues at that time, could improve the timeliness of the application process.

Both these factors have major cost implications for applicants, which are additional to those directly related to the FSANZ process.

Q6 Possible to estimate costs of undertaking each step in the process?

See quantitative section above, but note also comments regarding opportunity costs.

Q7 Any additional issues regarding process for obtaining view on whether product is a novel? (ACNF process and Record of Views document)

In general, companies that had applied for a Novel Food determination from the ACNF found the process and the questionnaire straightforward and reasonable in terms of the information required and the timeframe for response. This was particularly so for those that had already undertaken significant background work or were able to access information that was sourced from dossiers prepared for other markets (EU, US). One company noted that some of the queries were general in nature rather than related to safety issues. Of the companies whose product was determined to be novel, two elected not to make an application to amend the Food Standards Code. This decision was made because of the small size of the Australian and New Zealand markets relative to the perceived cost of an application, despite the fact that some of the products had already been approved in overseas jurisdictions.

In particular one respondent commented favourably about the ongoing regular contact and assistance from a FSANZ officer. This contrasted with other feedback about dealing with multiple officers during the lengthy process for applying for approval.

However, some concerns were expressed:

- One respondent prefers to use advice from consultants as this is quicker and it also avoids the proposed Novel food being listed in the public Record of Views document sooner than necessary;
- Some disparities were reported, firstly between very similar products where one is listed as Novel and the other as non-Novel and secondly some products that are approved by overseas jurisdictions are listed as Novel (i.e. not approved) by FSANZ; and
- One respondent reported significant costs in gathering the data from overseas to support an ACNF enquiry which ultimately classified the product as non-novel.

Q8 Is the supporting research undertaken in Australia/NZ or other jurisdictions?

Generally the research has been done overseas. Of the companies who responded, only one product (ultimately classified as non-Novel) had a data package developed in Australia. Other companies carried out research in EU, USA, India or multiple locations. It was emphasised that the Australian/NZ market size is small and does not justify undertaking R&D specifically to meet FSANZ requirements, for products that have already been approved by overseas jurisdictions.

A number of examples were provided of overseas approval systems that were perceived as being more efficient than the FSANZ process. One company noted that cost and time lines to obtain GRAS determination were less than FSANZ costs and time lines. Another company was of the view that Canada, Hong Kong, China and Venezuela had shorter, but equally rigorous processes.

Q9 Any issues regarding sources and/or type of data required?

This question elicited little information additional to that summarised above. However, in several instances the personnel involved in the process had since left the company and so any specific issues about data may no longer be known.

Q10 Any issues regarding ownership of/access to R&D and approval? (e.g. gaining exclusive permission)

There are some concerns about the “first-mover” risk of gaining approval for a Novel ingredient, which other parties may then use in competing products. Although a fifteen-month exclusivity option is available, this is insufficient to enable the first-mover to establish their product in order to recoup development costs (including costs of the FSANZ process).

One view was that the approved uses for Novel ingredients were unnecessarily narrow, making it difficult for innovators to develop alternative uses for the ingredient (say, a snack bar formulation when the approved use is in a drink).

Q11 Any views about requirements in the novel foods application process regarding consumer awareness/behaviour?

This question was included after the pilot studies raised it as a major issue. There was a consistent view from Group 1 companies about the difficulty and cost of getting information regarding consumer awareness/behaviour for an application to change the Food Standards Code. Any views provided were consistent in understanding the relevance of these questions.

By its nature this type of information must be obtained in Australia/New Zealand. Thus companies can reduce the cost of an application by using data from overseas, but the requirement for

information about consumer behaviour added substantial cost to all applications. One company noted that such information was generally not required in other jurisdictions.

It was noted that consumers are frequently not aware that they want a novel product until it is launched, making this type of information difficult to obtain and often unreliable.

One company commented that in effect, FSANZ are asking for a forecast of consumer response. Whilst these forecasts are possible, it is impossible to measure the quality of the forecast until after the product is launched. Econometric and marketing disciplines generally accept that “intentions” are unreliable predictors of future behaviour.

Q12 Other Issues

Overall, it was noted that few Novel foods have been introduced in recent years. This may indicate that the FSANZ process is excessively complex and acting as a barrier to innovation. It may also indicate that companies are bringing new foods to the market outside of the regulatory approval process. However, it was not possible to gauge whether or not there may be a backlog of new products awaiting entry into the Australian/NZ market. One company also noted that TGA is moving to a Common Technical Documents format, which is a set of internationally recognised standards that reduces duplication and re-formatting of data when registering in different jurisdictions. The company would be prepared to trial a streamlined process, were FSANZ to establish one.

3.2.3 Compiled responses from Group 3 companies

We identified Group 3 companies as those that had sold foods which may be considered novel, including some which market products which are not covered by the Food Standards Code (e.g. New Zealand supplemented foods). Companies were identified from internet searches and surveying retail outlets. We explained that they were operating in an innovative sector of the food industry that therefore made their opinions of value to the study. It should be noted that only a few Group 3 companies were interviewed, with several turning down the invitation to engage in discussion. The responses gathered from one-on-one interviews are summarised below according to the questions in the template (Table 4).

It is noted that Standard 2.9.4 (relating to Formulated Supplementary Sports Foods) allows certain ingredients or ingredient levels, which are not permitted to be added to other foods. This is reflected in some of the responses below.

Q1 As a company, in what ways, if any, do you consider any regulations that might apply, before putting new food products on the market?

Companies noted that they did consider regulations with respect to the products they were developing. The specific regulations depended on the products, but included the Australia New Zealand Food Code (the Code), the New Zealand Supplemented Foods Standard, TGA, and HACCP type programmes. No one identified that they were aware of the requirements for amending the Code or process for seeking approval for a Novel food or ingredient. They were clearly unaware that they were selling a product that contained a Novel product which had not been approved by FSANZ. In some cases we were interviewing a retailer rather than the formulator and there was an assumption that the formulator would manage any such issues. There was some concern expressed that other companies in the sports nutrition sector (particularly those importing from the US) were not considering the regulations.

Q2 Have you undertaken any formal analysis of your products and their regulatory status in New Zealand/Australia?

In general the response was “Yes”, through the processes in Q1 above. One company had a range of products, which fell under the Code, and the New Zealand Supplemented Food Standard. One company also tested for True to Label.

Q3 Are you aware of any particular products or ingredients that you sell that are or might be novel?

In general companies expressed a lack of awareness of Novel Foods, and no concern that their products were novel. One company was aware that a product in its range was listed in the Record of Views, but it was marketed as a supplementary food and therefore there was no issue.

Q4 Are products approved under other regulatory regimes?

Companies were either not aware, or assumed products met regulatory regimes in their country of origin, including the Supplementary Food Standard.

Q5 Do you manufacture/formulate in New Zealand/Australia?

All products were either manufactured or formulated in Australia and New Zealand. Some companies marketing US products were approached for interview but declined.

Q6 Which countries do you mainly import product from?

There was a range of responses. Proteins used in formulations were sourced from within New Zealand. Many ingredients, including amino acids and creatine, are imported from China. Other ingredients such as fruit products are sourced from around the world.

Q7 Do you sell in Australia/New Zealand, and what are your experiences there?

Australia and New Zealand are the largest markets, although product is also sold in South East Asia and the Middle East. New Zealand dietary supplements products have an advantage in Australia because of exemption from TGA.

One company expressed frustration that in their view, safety data that exists elsewhere was not acceptable for an application to amend the Food Standards Code. Such a process was also considered to be “resource hungry” and unappealing to the company.

Q8 Any direct experience with New Zealand/Australia regulatory requirements

No company had any direct experience with FSANZ.

Q9 Do you know what supporting research and information has been collected?

Companies were aware of research in the public domain and through industry publications. No company undertook any internal research.

Q10 Has your company incurred any costs associated with regulatory requirements for your products in New Zealand/Australia?

No company had incurred any costs associated with Novel Foods. Compliance costs were incurred for some regulatory programmes e.g. Food Safety. One company avoided compliance costs by not

making any health claims or statements. It was noted that some companies (who were not interviewed) register certain products with TGA but also retail certain supplements containing Novel ingredients, without gaining FSANZ approval.

Other comments

One company raised concerns about unregulated US products being widely available in the Australian sports supplement market. Such products often did not have lists of ingredients on their labels, with the risk that purchasers could exceed safety levels of certain components.

4. Conclusions

1. Large companies reported that, despite having experience with the FSANZ process and other regulatory systems, the expected costs of having a new food approved were a disincentive to taking a novel food to market.
2. Large companies reported concerns about the opportunity costs caused by the reportedly slow and uncertain process. These were often more of a concern than the direct costs of making the application.
3. Several factors combine to make it difficult to accurately assess the cost of making a submission to FSANZ to amend the Food Standards Code, especially when the enquiry is made some time after the event.
4. Even when data is available for direct compliance costs, these may underestimate the real costs, including both indirect costs and opportunity costs caused by uncertainty in the approval process. This can lead companies to delay or cancel product introductions.
5. The cost of developing a proposal to seek advice through ACNF was generally considered reasonable, whether the company was large or small.
6. However, when the ACNF advice states that a proposed food was considered to be Novel, the process entailed in obtaining approval was typically judged by small companies as being too onerous and potentially costly to pursue.
7. Companies that had sold Novel foods outside the regulatory pathway appeared to have done so through ignorance, although cost-avoidance might be a not unanticipated response to a subsequent understanding of the regulatory pathway. (Two of the companies approached, but not interviewed, are very large.) Some were highly critical of competitor companies that flouted the regulations, while being unaware that they themselves had products containing Novel ingredients.
8. Overall, the perceived high cost (direct and indirect) of a process may prove to be a sufficient barrier to innovation, especially to organisations that comply with regulations. Companies that ignore regulation are marketing unapproved novel foods and avoiding the cost of regulation. This may pose a public health issue and the avoidance of cost distorts the competitive environment.

1. Appendix

1.1 Annex 1 RFT No. 2012-13/19

Supplies

The purpose of this project is to obtain indicative costing at the activity level in relation to the regulatory costs of bringing a new nutrient or novel food to market. It is hoped that these cost will not only assist the Authority (hereafter referred to as FSANZ) to estimate the cost of the present regulatory arrangements but the cost of any new regulatory regime.

The Supplier must survey approximately twenty (20) industry participants to ascertain the cost of regulatory compliance through the various steps of the regulatory compliance process which may include:

- the internal assessment by the industry participant of whether product is safe and suitable;
- submission of an enquiry to the FSANZ Advisory Committee on Novel Foods; and
- an application to FSANZ for permission to add the product to food.

The results of the survey must be included in a report to FSANZ that will be used by FSANZ to estimate the present cost of the regulatory regime. Costs are to be estimated at the activity level where possible, as this will assist FSANZ to calculate the cost of any new regulatory regime as a number of activities are likely to be similar.

The industry participants must be surveyed in person or over the phone. Clear guidance must be given to the industry participants in relation to the sorts of costs they should be taking into account in estimating the cost of individual activities to ensure consistency in the answers. Appropriate use of activity based costing methodological approaches will be necessary to formulate and give appropriate directions.

The report must also clearly distinguish the costs that industry would incur regardless of the regulatory framework (perhaps as an appropriate risk-mitigation step in light of their civil law responsibilities).

Average costs must be calculated and all de-identified data provided in the report to FSANZ. However, if clear cost differences exist between surveyed businesses that appear to relate to the size of the business, based on standard Australian Bureau of Statistics definitions, the location of the business (Australian States or Territories or New Zealand), or other characteristics, this must be noted and multiple costs or a range of costs provided to allow more accurate costing to be undertaken by FSANZ.

The report must clearly explain the survey methodology and the directions given to industry members to assist them to estimate their costs. This includes referencing the standards, guidelines or academic papers that underpin the activity based costing approach that has been adopted to instruct industry.

The report must be provided in Word Microsoft format with data provided in Excel Microsoft format. If the cost of certain activities are not readily obtainable or estimable from the results of the survey, the Supplier must provide an appropriate methodological approach to estimate the costs and provide an estimate of those costs that FSANZ can use for in its future work. All workings of such estimates must be shown and the methodology explained and referenced. If a model is used to create these estimates, it must be provided as part of the draft and final reports.

The overall approach to undertaking the work must be based on developing good communications with selected companies, and creating robust templates for identifying and costing activities. A case study approach based on consistent identification of activities and costs can be used. The following steps must be taken by the Supplier:

1. Initial meeting with FSANZ to confirm objectives, methodology, individual tasks, timing and data sources.
2. Identify potential participants RFT No. 2012-13/19

This will involve engaging with the following groups:

- Group 1. – Sophisticated companies that have taken products successfully through to an application to amend the Food Standards Code. These companies would provide the best assessment of costs of approval since they would have prepared the necessary data requirements.
- Group 2. - Companies that have submitted an enquiry to the Advisory Committee on Novel Foods (ACNF).
- Group 3. - Companies that have taken products to market outside of the regulatory pathway. The Supplier must identify more than 20 companies, as a number will elect not to participate. The final list identified will be agreed with FSANZ.

3. Interview sample organisations and develop activity flow chart and cost model

An initial sample (up to four organisations) must be interviewed by the Supplier as a “Pilot Group”. It is envisaged that this group will be sourced exclusively from Group 1. The objective of this phase is to understand the intra-organisational system-wide activities and costs associated with bringing an application through an internal assessment, an ACNF assessment and finally, a FSANZ assessment process.

The Supplier must describe the methodology employed at each organisation. Working through an iterative process with the participants, the Supplier must ensure that the methodology employed by each organisation is mapped. Once the Supplier and the participants have reached agreement on the activity maps, the Supplier must then work with the organisations to understand the costs associated with each sub-activity. This process will enable the Supplier to develop generic templates for the extended study.

The templates must include or address the following:

- a list of the tasks that in total represents an appropriate description of how business is interacting with the present regulation;
- exclusion of those tasks that would occur regardless of the regulatory framework. These may be identified in the report;
- the tasks identified as occurring because of the regulatory framework that are readily amenable to financial analysis, or are likely to be already costed by the company;
- costs will remain disaggregated where possible;
- explanation of the reasons why individual activities are undertaken;

Where differences exist between the tasks identified in the first and third dot points these should be reported upon and the reason for the differences explained. As indicated above, where a task is not readily amenable to financial analysis the Supplier must where possible, using appropriate methodology, provide an estimate of those costs that FSANZ can use for in its future work. The methodology used to create these estimate must be fully explained in the report.

4. Scoping paper for discussion and agreement with FSANZ

It is anticipated that the Pilot Group, who are sophisticated organisations that instigated the approval process for these novel foods, will be the best source of information on the methodology (internal and FSANZ) and the costs associated with achieving approval. This information will be collated into a Scoping Document and presented to FSANZ for approval. Once FSANZ is satisfied that the Pilot Group has met the initial objectives and that the approach is feasible within the constraints contained in the RFT, the study can be expanded to include more organisations.

The scoping paper must include the methodology, costing templates, questionnaires and agreed invitation letters to participants, for discussion with FSANZ. The questionnaire must include a consent form identifying the Supplier’s responsibilities in terms of protecting company anonymity and providing feedback, and formalising the company’s agreement to participate. RFT No. 2012-13/19

5. Expanded study

The process the Supplier must follow includes:

- sending an introductory letter to food industry participant;
- making a follow up phone call to get engagement and to identify who can validate steps, and costings for these; and
- Meeting in person where possible, or by telephone.

The activity flow chart and costing model must be used in the first instance as a basis for engagement with Groups 1 and 2. With Group 3 the Supplier may take a more open approach to understand how the decision was made to proceed to market without registration. The Supplier's understanding and findings in relation to how Group 3 are making their decisions to proceed to market without registration should be detailed in the report.

6. Draft report

This must include the survey methodology directions given to industry members to assist them in estimating their costs, cost assessments for the participating organisations, and their process charts. Where costs are not readily obtainable, an appropriate methodological approach must be adopted to estimate costs, and all details must be provided.

7. Final report

This must address all comments provided and includes all changes requested by FSANZ on or to the draft report. It must include a brief summary of the feedback and comment and changes provided or requested by FSANZ to the draft report, indicating how these have been acted upon. A de-identified data base of all the survey results must be included.

Specified Personnel

Jane Lancaster

Tom Rafferty

Wymond Symes

Gerard McEvilly

1.2 Bibliography

Anderson, D. R., Sweeney, D. J., Williams, T. A., Harrison, N. J., & Rickard, J. A. (1989). *Statistics for Business and Economics* (Australian Edition ed.). Sydney, NSW, Australia: Harper & Row (Australasia) Pty Ltd.

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O'Guin, M. C. (1991). *The Complete Guide to Activity-Based Costing*. Englewood Cliffs, New Jersey, United States of America: Prentice Hall.

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1.3 Letter of approach

Dear XX

YY⁶, at Food Standards Australia New Zealand (FSANZ) gave us your contact details.

FSANZ is currently investigating the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code). As part of this project FSANZ is attempting

⁶ FSANZ officer's name redacted

to estimate the costs for industry of placing new foods and ingredients on the market. FSANZ is interested in breaking down the potential costs into activity levels, so that costs can be assigned per activity or task that may be involved in placing a new food or ingredient on the market. Based on these activity costs, FSANZ will be better able to estimate current costs. FSANZ will also be able to use these activity costs to estimate potential future cost impacts (positive and negative) on industry that may be associated with future regulatory and non-regulatory options that will be developed.

FSANZ has commissioned Catalyst to assist in liaising with industry to obtain these cost estimates. We have contacted you because of your previous experience with FSANZ through submitting an application to amend the Code, and in product development in general, particularly in relation to introducing new product(s) to the market. We are seeking your agreement to participate in this project.

The information you provide will remain confidential to Catalyst and all information supplied to FSANZ will be de-identified. I have attached a form about how we will handle information, and for providing your consent. You can either send this to me or provide to me when I meet with you. I would be happy to provide you with any further information about the project, and can call you and discuss.

Kind regards

1.4 Confidentiality and consent form

Surveying the Costing of the Regulatory Costs Associated with Bringing a New Nutrient or Novel Food to Market

Confidentiality

Your contribution will be combined with information from other companies for reporting to FSANZ. Please take a moment to read about your rights and how we (Catalyst® Ltd) will manage your information.

YOUR RIGHTS AND OUR OBLIGATIONS TO YOU

By signing below you give us permission to use the information you have provided to us in this study. We will not use this information for any other studies. We will not release your name, business name or contact details to FSANZ or any third party unless you give us permission to do so (we will ask in writing).

We aim to present the results so that you are not personally identifiable. However, once the results are analysed it may be possible by inference to identify you or your business. If this is the case we will contact you first to explain the situation and you have the choice to refuse or allow presentation of the results in this way. You can withdraw your consent to participate at any time, up until Friday 28 June, 2013. You will need to tell us by e-mail or post that you want to withdraw from the project (contact details are below). When we receive your instructions we will delete/shred all of the information you provided and will tell you this has been done.

How we will manage your information:

Any information you give to us will be transferred into a password-protected electronic document and the hard copy stored securely by Catalyst until the report has been finalised (at which point the hard copies will be shredded). Only the people who are responsible for analysing this information and writing the final report will have access to the raw electronic data.

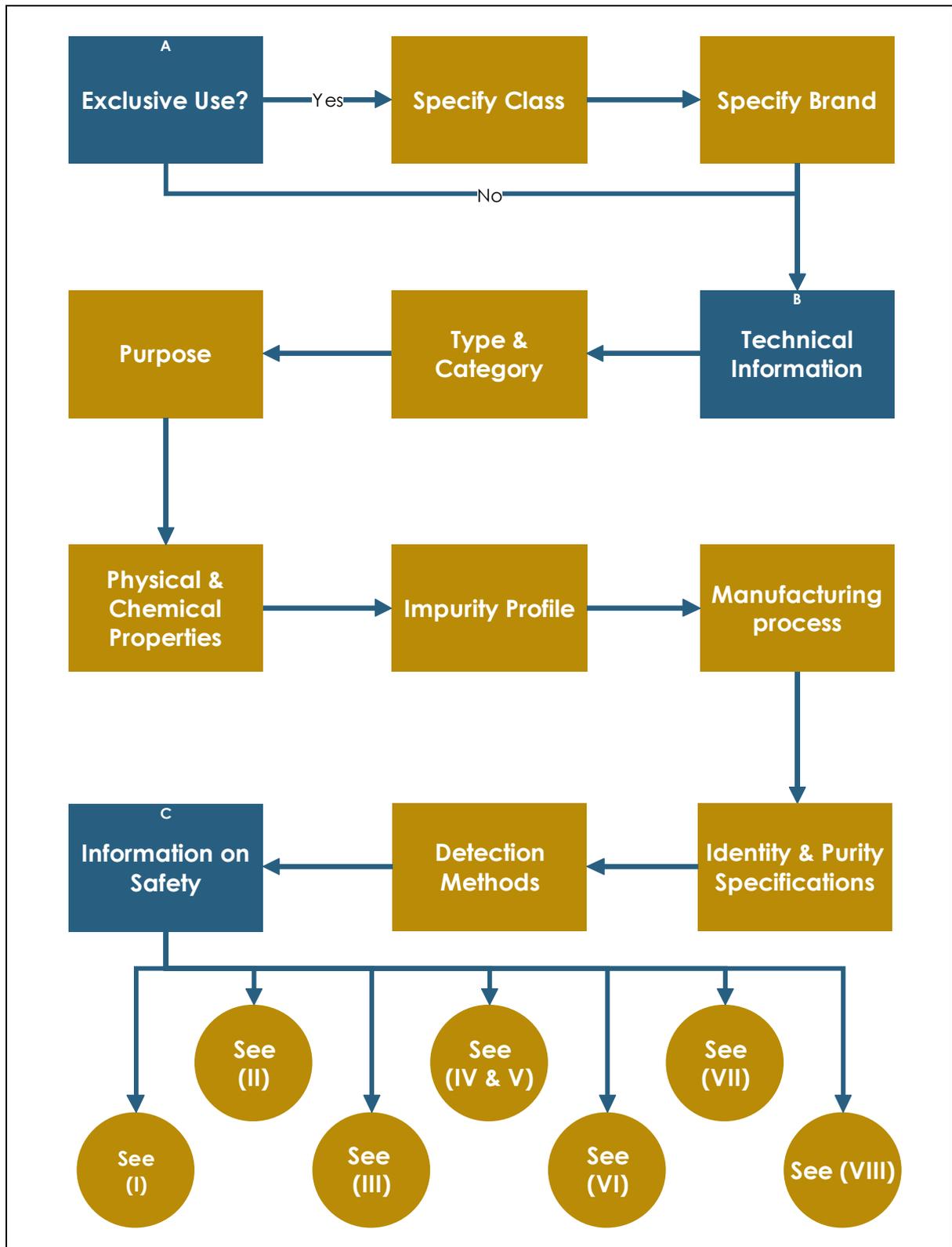
How you can contact us:
Jane Lancaster
Catalyst® Ltd
PO Box 37 228
Christchurch 8245
New Zealand
Jane.lancaster@catalystnz.co.nz
64 3 3296888

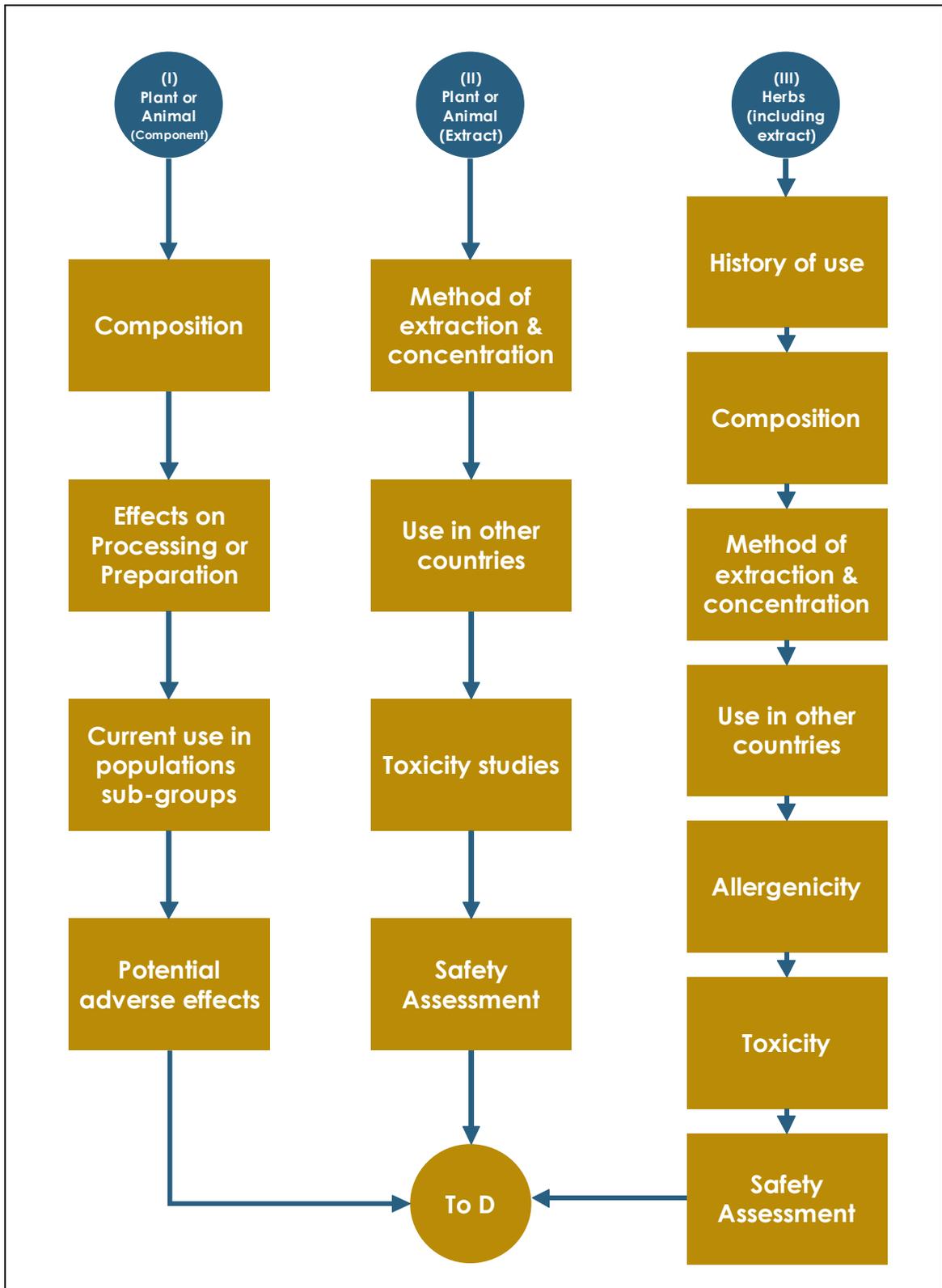
YOUR CONSENT:
By signing below I acknowledge that I am willing to participate in this study and have read and understand how my information will be managed and reported.

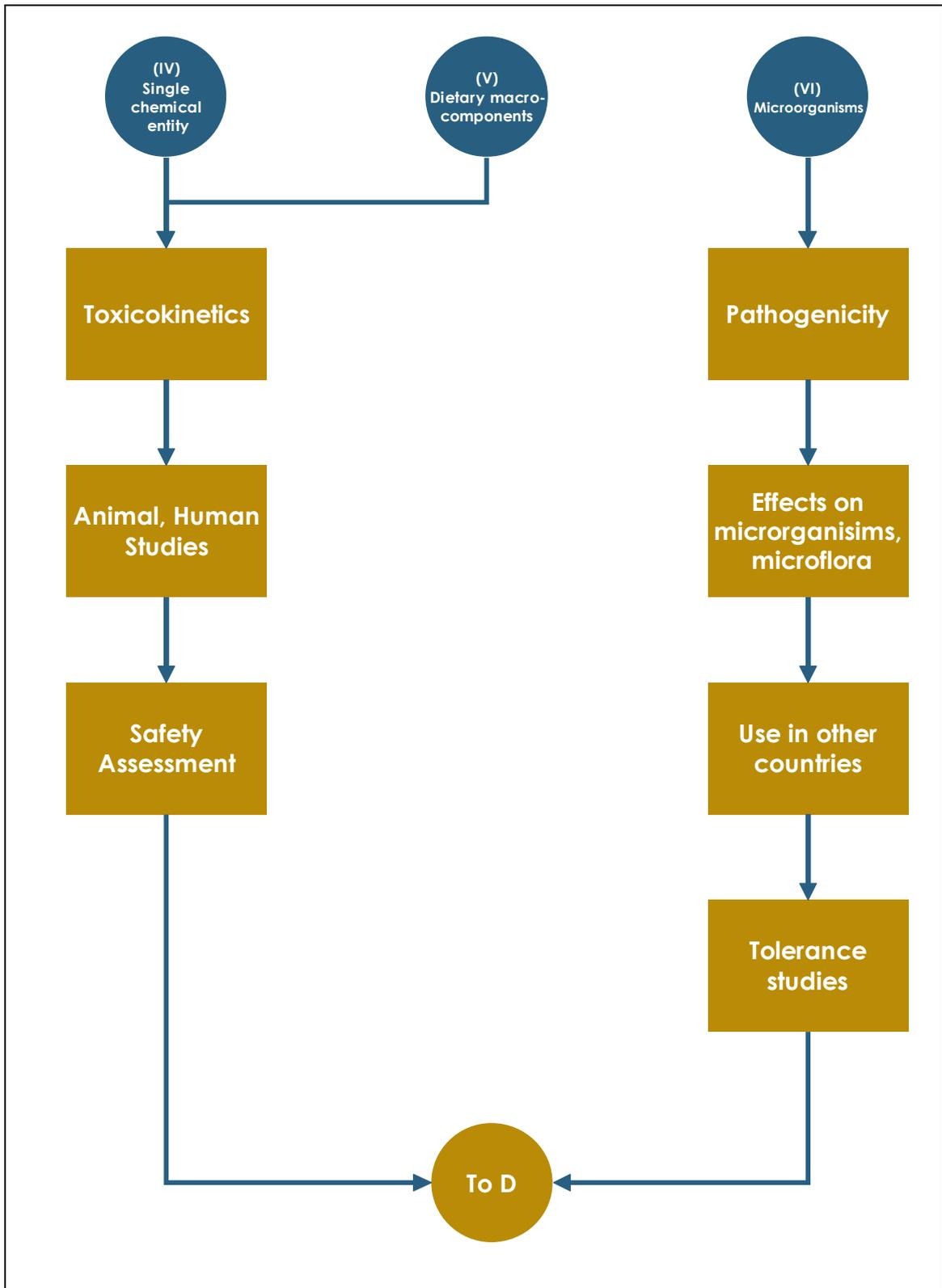
Signed: _____ Date: _____

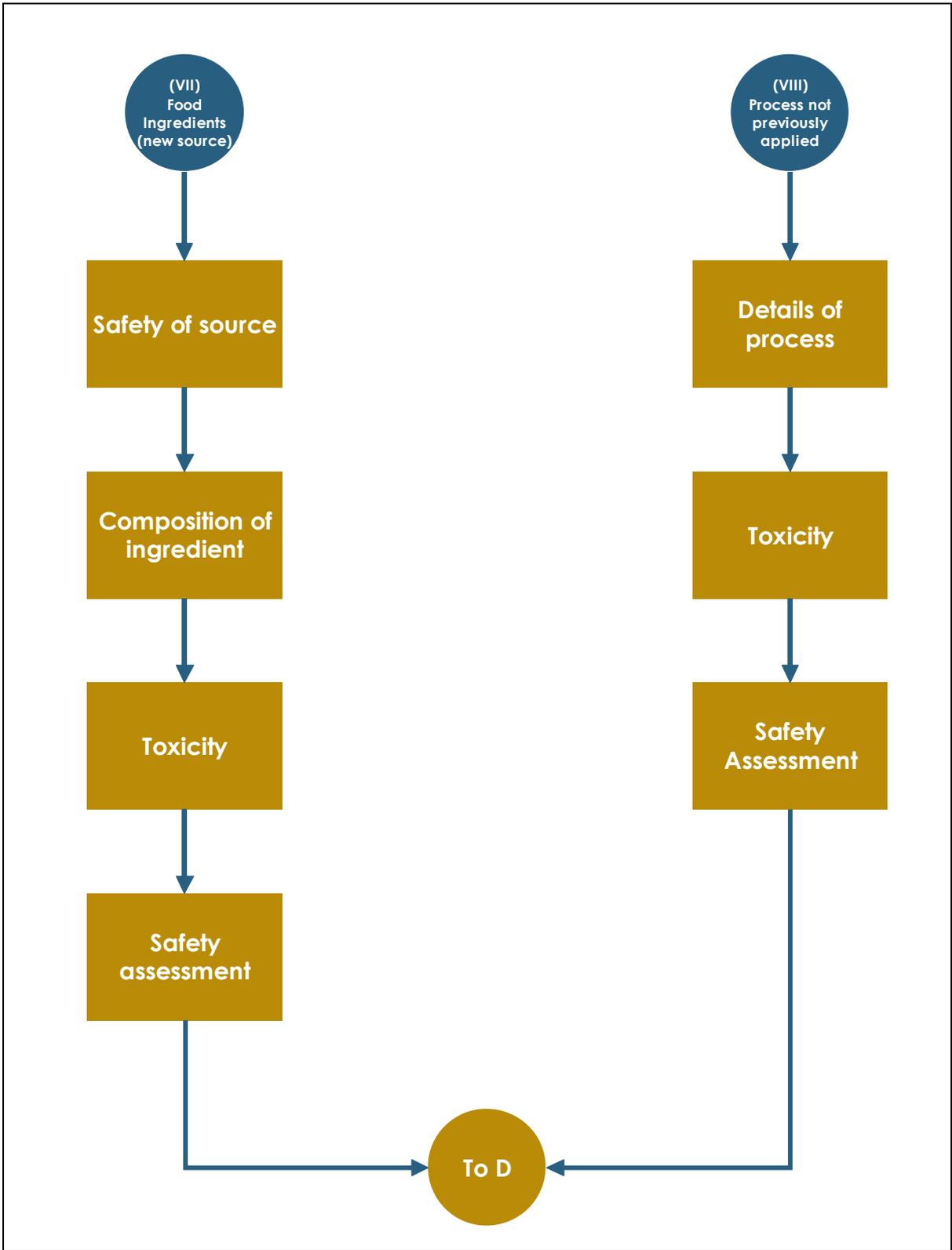
First name: _____ Last name: _____

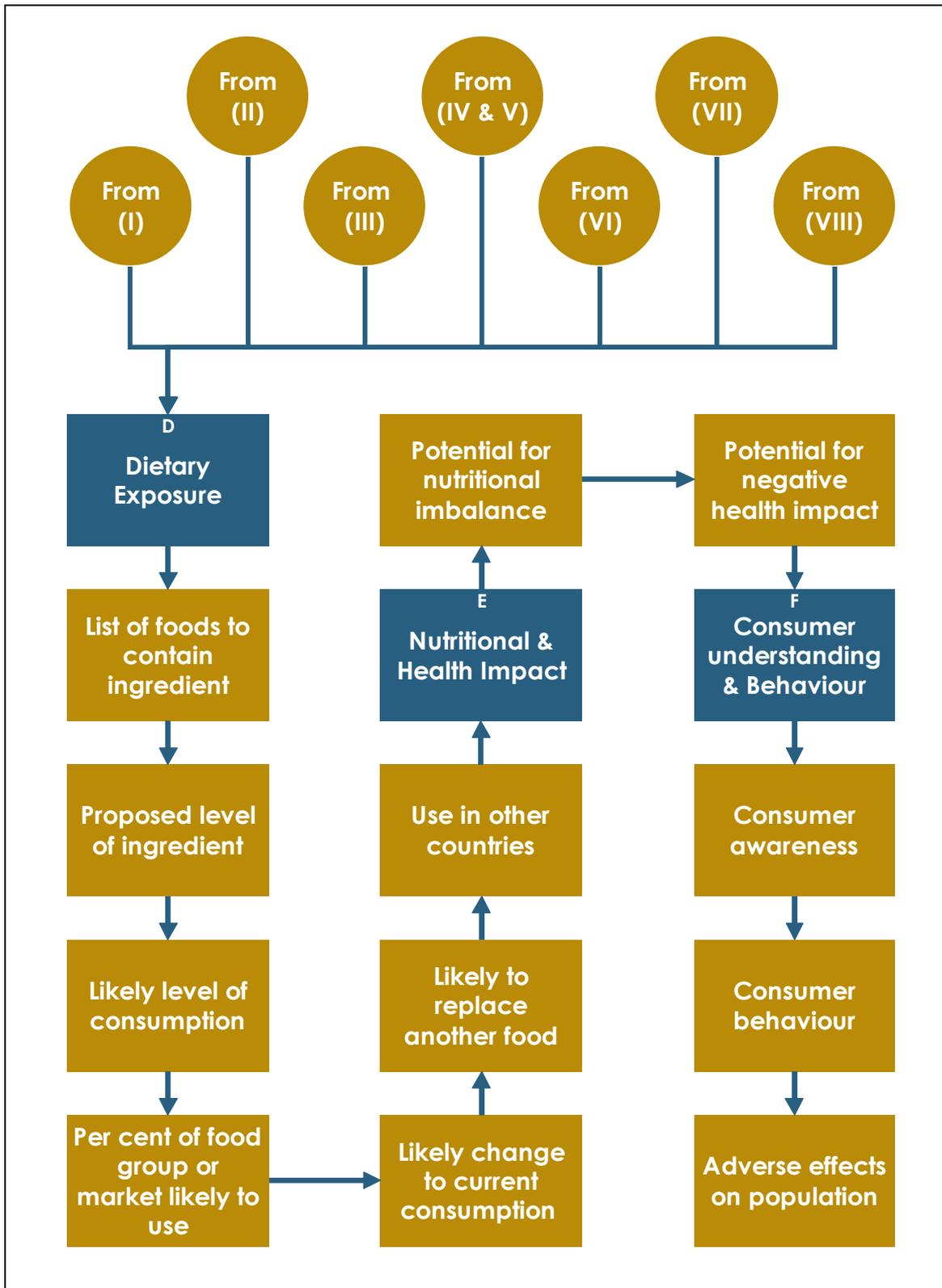
1.5 Activity flow chart











1.6 Activities and costing template

Section	Description	Resource Hrs	Cost	Comments/reason for activity
A.	Exclusive use of novel foods			
(a)	the specific class of food;			
(b)	the brand of the food.			
B.	Technical information on the novel food			
1	Information on the type of novel food			
2	Information on the purpose of adding a novel food ingredient to food			
3	Information on the physical and chemical properties of the novel food or novel food ingredient			
4	Information on the impurity profile for a typical preparation			
5	Manufacturing process for a novel food ingredient			
6	Specification for identity and purity for a novel food ingredient			
7	Analytical method for detection			
C.	Information on the safety of the novel food			
(I)	Plants or animals (or their components)			
1	Information on the composition of the novel food			
2	Information on the effects of food processing or preparation			
3	Information on the current use of this food or food component in population sub- groups or in other countries			
4	Information regarding the potential adverse effects associated with the food or its ingredients			
(II)	Plant or animal extracts			
1	Information on the method of extraction and the composition of the concentrated extract			
2	Information on the use of this plant or animal extract as a food in other countries			
3	Information on the toxicity of the extract obtained from studies conducted in animals or humans			

4	Safety assessment reports prepared by international agencies or other national government agencies			
(III)	Herbs (both non-culinary and culinary) including extracts			
1	Information on the history of use of the herb			
2	Information on the composition of the herb			
3	For a herbal extract, information on the method of extraction and the composition of the concentrated extract			
4	Information on the use of this herbal extract as a food in other countries			
5	Information regarding the potential allergenicity of the herb or herbal extract			
6	Information on the toxicity of the herb, or herbal extract, or any key constituents obtained from studies conducted in animals or humans			
7	Safety assessment reports prepared by international agencies or other national government agencies			
(IV & V)	Single chemical entities and Dietary macro-components			
1	Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites			
2	Information from studies in animals or humans that is relevant to the toxicity of the single chemical entity and, where appropriate, its degradation products and major metabolites			
3	Safety assessment reports prepared by international agencies or other national government agencies			
(VI)	Microorganisms (including probiotics)			
1	Information on potential pathogenicity			
2	Information on the effects of the microorganism on gut microflora			
3	Information on the use of this microorganism as a food in other countries			
4	Information on human toleration studies			

(VII)	Food ingredients derived from a new source			
1	Information on the safety of the source organism			
2	Information on the composition of the novel food ingredient derived from a new source			
3	Information on the toxicity of the novel food ingredient derived from the new source			
4	Safety assessment reports prepared by international agencies or other national government agencies			
(VIII)	Foods produced by a process not previously applied to food			
1	Details of the process not previously applied to food			
2	Information on the toxicity of the novel food produced by a process not previously applied to food			
3	Safety assessment reports prepared by international agencies or other national government agencies			
D.	Information on dietary exposure to the novel food			
1	A list of the foods or food groups proposed to contain the novel food ingredient			
2	The proposed level of the novel food ingredient for each food or food group			
3	For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption			
5	For foods where consumption has changed in recent years, information on likely current food consumption			
6	Data to show whether the food, or the food in which the novel food ingredient is used, is likely to replace another food from the diet, if applicable			
7	Information relating to the use of the novel food or novel food ingredient in other countries, if applicable			
E.	Information on the nutritional and			

	health impact of the novel food			
1	Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet			
2	Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact			
F.	Information related to potential impact on consumer understanding and behaviour			
1	Information to demonstrate the level of consumer awareness and understanding of the novel food or novel food ingredient			
2	Information on the actual and/or potential behaviour of consumers in response to the novel food or novel food ingredient			
3	Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)			