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

Supporting document 2

Assessment of Risks and Safety Data Requirements for New Foods – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

---

Executive summary

FSANZ is considering a range of different options for the regulation of nutritive substances and novel foods. The purpose of this document is to describe how those options might be applied while ensuring that safety of the food supply is maintained, and what data requirements would be likely to apply to the different options. In this supporting document, specific areas of risk including microbiological risk, toxicological risk, and nutritional risk are discussed.

The draft framework for a graduated risk approach is predicated on the assumption that foods can be graded or grouped according to the extent to which they can be predicted to be of low risk and therefore safe to market.

Foods that meet specified Eligible Food Criteria (EFC), and may therefore be marketed following *self-assessment,* are those that are unlikely to pose any health concerns. This document addresses the data that a manufacturer would be expected to hold in order to show that the food meets the EFC and is safe for human consumption.

The general principles and considerations for establishing safety of foods that do not meet the EFC are then presented, followed by the data requirements that would determine whether pre-market *self-assessment with notification* by the manufacturer would be appropriate or whether a full assessment by FSANZ by the current application process, with consequent change to permissions given in the Code, would be required.

The existing application process is the appropriate pathway to market for foods which may represent risk to specific subpopulations and therefore require risk management measures, as well as for particular classes of foods for which risk cannot be predicted without full assessment e.g. particulate, nanoscale novel foods or microorganisms not listed in the Code as eligible foods.

Table of Contents

Contents

1 Introduction

As part of this Proposal, FSANZ is considering a range of different options for the regulation of novel foods. The preferred option is to consider an alternative approach to the regulation of novel foods, involving different pathways of pre-market assessment, and section 4.2.3 of the assessment summary provides details of a possible framework to implement a graduated risk approach. The purpose of this document is to describe how different pathways to market for novel foods might be applied while ensuring that safety of the food supply is maintained, and what data requirements would apply to the different pathways.

FSANZ recognizes that some nutritive substances and novel foods have a low likelihood of toxicity or anti-nutritive effects, and that it is possible to delineate some of the characteristics of these foods. Therefore, FSANZ proposes to include in the Code specific eligible food criteria (EFC). Foods that meet any of the EFC are considered to be potentially safe, and would not require pre-market approval by FSANZ before they can be sold in Australia and New Zealand. However, the company placing those foods on the market would be expected to hold appropriate data to show that the foods meet the EFC and are safe for consumption.

Foods that do not meet the EFC, but which meet specified requirements, such that the safety (low risk) can be predicted with a reasonable degree of confidence, would be eligible for self-assessment by the company manufacturing those foods. The company would be required to notify food regulators/authorities of the intent to market the novel food, and submit a dossier of data supporting the claim that the food meets the specified safety requirements. The dossier would be made available to the public by being published online after submission. No change to the Code will be made for these foods.

Foods that do not meet any of the EFC, and do not meet the requirements for self-assessment, will require pre-market assessment by FSANZ before they can be sold as food in Australia and New Zealand. These are foods for which safety cannot be determined without a full assessment.

2 Safety of Eligible Foods

This section outlines the range of issues which need to be considered to ensure the safety of eligible foods. It is essential that the marketing company needs to hold the appropriate data to support the safety of foods that meet the Eligible Foods Criteria (EFC). The EFC shown here is also given in SD3:

Eligible Food Criteria

1. Microorganisms are eligible if they are listed in the Standard (in the Code) and are cultured to maintain genetic stability.

2. Animal food commodities and plant commodities that are described in the list of food classes, except for plants listed in Schedule 1 of Standard 1.4.4.

3. Animal and plant commodities that have been enzymatically modified, physically fractionated, fermented (using microorganisms that meet criterion 1), and/or physically processed (including chopping, cutting, peeling, grinding, squeezing, pressing, steeping, infusion, distillation, filtering and dehydration) subject to criteria 4 and 5.

4. Extracts are eligible if they are prepared from foods described in criteria 2 and 3 when added to processed foods where the total concentration of the naturally occurring and added components in the extract is no higher than that present as if the source

commodity or a product described in criterion 3 were used as an ingredient.

5. Substances are eligible if they are obtained from animal commodities when added to processed animal commodities from the same food class, or if they are obtained from plant commodities when added to processed plant commodities from the same food class provided that the concentration of the total of the naturally occurring and added substance is within the natural range in that food class.

Criterion 1 applies to microbiological safety and it is proposed that FSANZ will develop a list of microorganisms with a known history of safe use to harmonise risk assessment and focus the need for pre-market approval on the biological agents with the greatest risks or uncertainties.

Criterion 2 permits animal and crop commodities ('primary foods') to be sold without pre-market assessment by FSANZ, provided they are not prohibited under Standard 1.4.4 of the Code. It should be noted that the list of food groups from which such primary foods may be sourced does not include fungi or algae, including seaweeds. FSANZ considers that novel fungi and novel algae do not meet the EFC. Consequently, novel fungi and novel algae could only reach the market via self-assessment with notification or via the existing application process.

Criterion 3 covers the processing of primary foods by processes that are not considered to increase risk if carried out under good hygiene and manufacturing practices.

Criteria 4 and 5 of the EFC are intended to prevent the over-addition of naturally occurring substances. It should be noted that Criteria 4 and 5, as currently drafted, allow the potential for increased dietary exposure, which could create safety issues for those parts of the traditional Australian/New Zealand diet that already have a narrow margin of safety.

2.1 Evidence for Establishing Microbiological Safety of Eligible Foods

To be eligible for inclusion on the proposed list of eligible microorganisms, the taxonomic unit to be assessed needs to be established and be based on valid nomenclature and taxonomy. Any changes in nomenclature and taxonomy over time would be taken into consideration and any reclassification should be considered when assessing the evidence.

To satisfy the requirements of Eligible Food Criterion 1, a food business would need to be able to demonstrate that a microorganism that they intend to add to food is unambiguously identifiable, belongs to an eligible taxonomic group listed in the Code and is cultured to maintain genetic stability. It is proposed that novel strains of an eligible microorganism will not require further risk assessments if any minimum requirements or qualifications are met. For example, a minimum requirement may be an absence of toxigenic activity or absence of acquired antimicrobial resistance genes.

FSANZ considers that individual strains belonging to a taxonomic unit not listed as an eligible food in the Code may be low risk but this cannot be ascertained from the existing knowledge of the taxonomic unit to which it belongs. Consequently, novel strains of microorganisms not listed in the Code could only reach the market after a full risk assessment is completed by FSANZ to determine their safety.

2.2 Evidence for Establishing the Toxicological Safety of Eligible Foods

All whole foods meet the EFC, not just those traditionally part of the Australian/New Zealand diet, provided that they are not novel fungi, novel algae, or in the list of prohibited plants and fungi in Standard 1.4.4 of the Code. However, it is not reasonable to assume that all poisons that may be found in plants or animals are already known, particularly those which may exert a chronic or carcinogenic effect. Therefore some 'history of safe use' must be built into the EFC for whole foods that are not already part of the traditional Australian/New Zealand diet. Foods are currently considered to be 'non-traditional' if there is a lack of history of safe consumption in Australia or New Zealand, but the term 'a history of human consumption' is used in the standard, and 'non-traditional' is not defined in the Code.

It is likely to be necessary to specify a date for the identification of foods that are a traditional part of the diet in Australia and New Zealand, so that all foods present in the diet prior to that date are considered traditional and are therefore eligible for marketing without a safety assessment. This eligibility should also extend to macronutrients extracted from those traditional foods, even if the extraction method postdates the traditional food date. For example, milk proteins extracted by a new method would still be considered to be a traditional part of the Australian and New Zealand diet because whole milk and dairy products are traditional parts of the Australian and New Zealand diet. For safety reasons, this eligibility should apply only to macronutrients.

For the safety of consumers, FSANZ considers that it is essential that the manufacturer or importer compiles and retains a dossier of appropriate data to justify the claim that there is a history of human consumption, although not necessarily a history of human consumption in Australia or New Zealand.

Health Canada, which administers the *Food and Drugs Act* (R.S.C., 1985, c. F-27) has addressed the question of what data requirements should be required to support a history of traditional use of a food in other countries. Health Canada's data requirements provide a good indication of the data requirements that might reasonably be expected to support a claim of 'history of safe use'.

Adoption of data requirements equivalent to those specified by Health Canada would mean that a substance would be considered to have a history of safe use as a food if it has been an ongoing part of the diet for at least three generations in a large, genetically diverse human population where it has been used in ways and at levels that are similar to those expected or intended in Australia and New Zealand. A history covering three generations is considered the minimum to cover all potential toxicities including those affecting germ cells.

The following information would be needed to support a claim that a product has a history of safe use:

- Historical evidence indicating ongoing, frequent consumption by a cross-section of the population where it has been used over several (at least three) generations. This evidence may be derived from various sources including, but not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture, and/or affidavits from two or more independent, reputable authorities that include well-documented accounts of the way the food is used and how they know it has the history it does. Limited usage or short term exposure would not be adequate to demonstrate a history of safe use.

- A declaration of any possible adverse effects linked to the food documented in its country of origin and/or a country where there is a high degree of consumption.

- A description of the standard methods of commercial and/or domestic processing and preparation for consumption.

- A description of how the food is cultivated or (if from wild sources) harvested.

- Amounts of the food that people are likely to consume in Australia and New Zealand, including typical serving sizes and expected frequency of consumption, at both average and high consumption levels.

- Analysis of the composition of the food based on randomly selected, statistically valid samples. This analysis may include information such as amino acid profile, fatty acid profile, mineral and trace mineral composition and vitamin composition, as well as any nutrients, anti-nutrients and bioactive phytochemicals known to be of particular interest in the product. The analysis should pay special attention to the presence of compounds in the food which may have implications for the health of any groups of the Australian and/or New Zealand population (e.g. possible toxicants or allergens or unusually high levels of nutrients in the food source or final food product).

- Data indicating metabolism and/or gastrointestinal effects in humans.

The dossier would be expected to include reliable, high quality information and reference sources. Anecdotal evidence such as testimonials would be considered unsuitable as evidence on their own, and would be given less weight than scientifically derived data. Information on the history of human exposure would be particularly important where there are traditional requirements for the processing, preparation or cooking of the food. This information on handling or cooking requirements would need to be made available to consumers in a consistent manner. The level of confidence in the evidence presented would be increased if the product had a history of use according to the above definition in a jurisdiction with a similar food safety system to that existing in Australia and New Zealand.

2.3 Evidence for Establishing Nutritional Safety of Eligible Foods

The dossier should include a consideration of the possible presence of anti-nutritional factors (anti-nutrients) in the novel food, extract or substance. Anti-nutritional factors are compounds or substances that act to reduce nutrient intake, digestion, absorption and utilization and may produce other adverse effects. They include*, inter alia*, toxic amino acids, saponins, cyanogenic glycosides, tannins, phytic acid, gossypol, oxalates, goitrogens, lectins (e.g. phytohaemagglutinins), protease inhibitors (eg antitrypsin), chlorogenic acid and amylase inhibitors. The level or concentration of these anti-nutrients vary with the species of plant and the cultivar, and may be altered by post-harvest treatments (processing methods).

The ‘history of safe use’ criteria specified in the previous section could offer some protection against anti-nutritional effects.

3 Risks Associated with Non-eligible Foods

Risk is assessed by consideration of both exposure and hazard. For food and food ingredients, exposure is the quantity and frequency of consumption. In the case of toxicological and nutritional risks associated with food, a hazard is the adverse toxic or nutritional effects of a constituent. Thus, a food/food ingredient may be considered to be low-risk because a low level of consumption is predicted, and/or because constituents pose low

intrinsic hazard.

3.1 Principles for Establishing Safety

This section reviews the principles for establishing food safety through consideration of the general microbiological, toxicological, or nutritional risks that new non-eligible foods might present to consumers.

3.1.1 Principles for Establishing Microbiological Safety

The exclusion of a particular microorganism from the eligible food list does not necessarily imply risk associated with its use. Individual strains may be safe but this cannot be ascertained from the existing knowledge of the taxonomic unit to which it belongs. In the case of microbiological risk, the microbial agent is itself the potential hazard and exposure may result in an acute or chronic adverse health effect. Examples include infections causing severe systemic disease, gastrointestinal illness, hepatitis, reactive arthritis, or tooth decay. Microbial ingredients may pose a risk of pathogenicity in consumers through infection or inappropriate colonisation after consumption, or via the production of toxins or other metabolites in the food matrix or at the site of infection or colonisation. In the case of bacteria, risk may also be associated with the carriage of mobile genetic elements containing antimicrobial resistance and/or virulence genes.

The aim of this part of the assessment is to establish that a microbe that does not satisfy the requirements of being listed as an eligible food does not cause an adverse health effect or does not carry genetic elements that could confer antimicrobial resistance (AMR) or virulence determinants to other microbes. In establishing the safety of a microbial ingredient, the overarching principles are that the microorganism to be assessed must be unambiguously identifiable and sufficient data and information exists to demonstrate safety.

The starting point for assessing safety is defining the taxonomic unit (genus, species and strain) using valid nomenclature (both existing and historical nomenclature) for which the taxonomy is well described. The name and classification of taxonomic units may change over time and for a safety assessment to be effectively undertaken, the microorganism being assessed must be unambiguously identifiable and previous naming conventions distinguishable. Further still, the microorganism must have unique identifying characteristics (e.g. genetic or biochemical) such that it can be distinguished from related but distinct taxonomic units not considered in the assessment.

The principle of being identifiable is interlinked with the ability to demonstrate that the microorganism being assessed can be stably maintained through repeated culture and maintains genomic and phenotypic stability in the food matrix, the host and the environment.

Once the identity has been established, the safety of a microorganism may be assessed through (i) a demonstrable history of safe use in food and, (ii) an exploration of associations with disease or the production of toxins or metabolites (such as antimicrobials) that could lead to adverse health outcomes. This also entails the identification of known virulence determinants and AMR genes within the genome. For bacteria, the presence of mobile genetic elements that could enable transmission of virulence determinants and AMR genes via bacterial mating to other bacteria must be considered in the assessment.

There will be a requirement to define what is considered ‘sufficient evidence’ to arrive at a decision on the safety of a taxonomic unit. ‘Sufficient evidence’ encompasses the identification of evidence (search terms and databases), the type of evidence that is deemed acceptable (inclusion and exclusion criteria) and the quantity, quality and diversity of evidence.

3.1.2 Principles for Establishing Toxicological Safety

Toxicological safety can be established through the provision of relevant information and evidence showing that the food or food component does not present a food safety risk when consumed as intended. Under most circumstances, this would involve a detailed knowledge of the key constituents in the food/food component including substances that could have an impact on safety, for example the presence of natural toxicants, anti-nutrients (see next section), and possible contaminants, including those that could be formed during processing.

The presence of natural toxicants in plant-based foods can sometimes be mitigated through selection of appropriate cultivars, or post-harvest processing or refining steps that reduce the levels in the final food product. It is also necessary to demonstrate that any possible contaminants arising from the production or processing of the food/food ingredient would pose a negligible food safety risk. The form must also be taken into account for many non-nutrient chemicals, for example organic arsenic versus inorganic arsenic.

For non-eligible foods that contain some minor constituents of toxicological concern, evidence is required to demonstrate that these do not occur in the final food in amounts that would pose a food safety risk in the general population or in target consumers. This could be demonstrated through the provision of appropriate toxicity studies and information on anticipated dietary exposures.

For most novel foods, it is likely that some *in vivo* dietary studies in animals will be required. However, a full suite of traditional toxicity studies is not necessarily required for all novel foods or food constituents. For example, if there is no evidence of genotoxicity, and no evidence of toxicity in acute and 90-day subchronic rodent studies, it is unlikely that a 104-week carcinogenicity study would be required. Similarly, if there is evidence available to show that absorption of a novel food/constituent from the gastrointestinal tract is negligible, and it does not interfere with absorption of other nutrients, it would be considered unlikely to cause developmental or reproductive toxicity. Evidence of a plausible biological mechanism associated with consumption of the food/constituent and any apparent adverse effect(s) is also considered in the totality of evidence.

In certain cases, potential allergenicity could be considered an additional safety risk for some consumers, for example where the novel food ingredient is obtained from a known allergenic source or is chemically related to a class of known allergens, or has on the basis of previous use been associated with allergies in humans.

3.1.3 Principles for Establishing Nutritional Safety

In principle, the aim of this part of the assessment is to establish that the food or food component does not have an adverse effect on the nutritional quality of the diet as a whole. In practical terms, this would entail consideration of the major constituents in the food/food component, with a particular focus on any natural toxicants or anti-nutrients normally present in the food. As described above, a potential food safety risk posed by the presence of natural toxicants can be addressed through the provision of relevant information on toxicity in animals or preferably humans if available, and likely levels of exposure.

The presence of anti-nutritional factors, such as trypsin inhibitors, in the novel food can have an impact on normal digestion and the absorption of nutrients from food. It is necessary to demonstrate that the novel food would not have an adverse impact on the diet by interfering with the bioavailability of nutrients in other foods consumed at the same time.

A knowledge of the composition of the food including the levels of key nutrients such as vitamins and minerals, also allows consideration of estimated total dietary intakes of a

specific vitamin or minerals in the context of anticipated or foreseeable consumption levels. Some, but not all nutrients also have adverse effects when intake is excessive, usually over a long time frame. Therefore for nutrients, identifying a safety concern primarily involves good quality evidence preferably in humans. A wide range of data may be examined including epidemiological, clinical and other studies relating to physiological and biochemical effects and response.

Bioconversion might be an important consideration in some cases. If bioconversion from another compound occurs, then both the form of the chemical present in the food and its precursor(s) need to be included in an exposure assessment. For example, a dietary intake assessment of vitamin A would include beta-carotene and retinol.

3.1.4 Principles for Establishing Safety of Products of Nanotechnology

Particulate, nanoscale materials that are new to the food supply will be subject to toxicological evaluation as outlined in the Application Handbook. In responding to the potential applications of nanotechnologies to foods, the primary toxicological concern is not the size of the material *per se*, but whether materials are likely to exhibit physico-chemical and/or biological novelty[1]:

a) Nanoscale materials that undergo dissolution in water or oil in the final food, or in the gastrointestinal tract do not pose unique risks which require them to be considered as a separate category to other new foods

b) Conversely, nanoscale or microscale materials that are insoluble in water and oil and are non-biodegradable, particularly those that may not be readily excreted, may require additional regulatory scrutiny due to their particulate nature.

The toxicity of soluble materials (in a) above) will be mainly attributable to the constituent ions and monomers, so these materials will be assessed according to a conventional risk assessment pathway. Changing the particle size of soluble materials may alter the pharmacokinetics of the material because nanoparticles can be expected to dissolve in biological media more quickly and (theoretically) to a greater extent than larger particles of the same material. An increased rate of dissolution has the potential to alter blood and tissue concentrations of the material constituent ions or monomers, which may impact the safety of the material. However, for most foods listed in the EFC a change in dissolution rate would not be expected to significantly change the toxicity of the food.

For materials that remain particulate in nature (in b) above) in food and the gastrointestinal tract, there is a possibility that the use of nanotechnologies could alter the physico-chemical properties of the material, and this may impact on the biological activity/toxicity of the compound. While the current risk assessment paradigm and toxicological tests are considered generally sufficient to assess the safety of insoluble nanoparticles, it is acknowledged that amendments may be necessary over time, as the sophistication of nanotechnologies increases. It is also generally considered that additional or different testing methods are required to characterise the physico-chemical properties of these materials - compared to conventional small molecules.

[1] Regulation of Nanotechnologies in Food in Australia and New Zealand By Nick Fletcher and Andrew Bartholomaeus. Available at: http://www.intechopen.com/journals/international_food_risk_analysis_journal/regulation_of_nanotechnologies_in_food_in_australia_and_new_zealand.

3.2 Data Requirements for Establishing Safety

Adoption of the proposed system of graduated risk assessment is predicated on the assumption that foods can be graded or grouped according to the extent to which they can be predicted to be safe. The self-assessment pathway by which foods may be placed on the market if they meet the EFC is appropriate for foods which are known to be of low risk. The pre-market self-assessment with notification pathway to market is appropriate for foods which can be predicted, with reasonable confidence, to be of low risk. The pathway of full assessment by FSANZ is required for those foods for which the likelihood of an adverse safety outcome cannot be confidently predicted without a full assessment. Assessment by FSANZ is also the appropriate pathway to market for foods which may represent a potential risk to specific subpopulations and therefore require a pre-market approval involving a risk assessment and subsequent risk management measures.

This section addresses the information that would be required to delineate whether a food that does not meet the EFC could be placed on the market via self-assessment with notification or would require a full assessment by FSANZ.

3.2.1 Data Requirements for Microbiological Safety

The data requirements for establishing microbiological safety of non-eligible foods will be the same as those for establishing microbiological safety of eligible foods and guided by the "Principles for Establishing Microbiological Safety". The risk assessment for novel non-eligible microorganisms will consider the following:

i. establishing the identity of the taxonomic unit
ii. assessment of evidence of the taxonomic unit with regard to history of use, clinical aspects, industrial use and other factors deemed applicable
iii. assessment of possible pathogenicity and safety concerns
iv. end use.

3.2.2 Data Requirements for Toxicological Safety

For foods/substances requiring some toxicological assessment, the following data would be considered appropriate on a case-by-case basis. For foods for which such data are not considered relevant, an explanation should be included.

- Composition of the novel food: key constituents, major components such as amino acids and fatty acids, quantitatively more minor constituents such as vitamins and minerals, natural toxicants and anti-nutrients, and contaminants[2]
- The toxicokinetics (absorption, distribution, metabolism, and excretion) of novel components not present in other foods, or previously consumed in limited amounts or in limited circumstances
- *In vitro* assessment for genotoxicity
- Animal studies including:
  - Acute toxicity
  - Subchronic toxicity
  - Chronic toxicity/carcinogenicity
  - Developmental and reproductive toxicity
  - Systems-specific toxicity studies as indicated

[2] In cases where particle size is important to achieving the technological function or may relate to a difference in toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.

- Human studies including human toleration studies
- Studies on potential allergenicity *In vitro* digestibility.

Depending on the extent of the toxicity database available a novel food may be reasonably predicted to be of low toxicological risk if the data indicate the following:

(a) No positive or equivocal findings on genotoxicity screening
(b) Toxicokinetics data that demonstrate negligible absorption, and/or dietary modelling that demonstrates negligible or minimal exposure
(c) No treatment-related findings on a 90-day subchronic toxicity study, including endocrine endpoints, in laboratory animals.

As far as toxicological risk is concerned, novel foods could be eligible for self-assessment with notification provided that the data requirements (a) to (c) above, together with evidence of human toleration and of lack of allergenic potential, are included in the dossier.

3.2.3 Data Requirements for Nutritional Safety

Identifying potential nutritional issues must consider both food safety and health aspects for all population groups. The nutritional safety assessment should follow a case-by-case approach taking into account values set nationally or internationally for upper levels of intake of specific nutrients, in order to assess the public health implications of potentially exceeding these levels. In addition, a novel food particularly of plant origin, may contain more than one chemical form of a nutrient, with some not fully characterised from a nutrition perspective. In these cases, information would be required on the levels of such nutrients in food and their bioavailability. Several definitions exist for nutrient bioavailability, but broadly it refers to the proportion of a nutrient that is absorbed from the diet and used for normal body functions.

An initial step of bioavailability can be investigated using *in vitro* methods to assess extent of release of a substance from plant tissues during digestive processes. However, human studies are likely to provide more relevant information about whether the nutrient is bioavailable. In some cases, it may be sufficient to demonstrate an established history of safe use, provided that the patterns of consumption are similar to those already established.

The dossier should include information on the possible presence of anti-nutritional factors (anti-nutrients) in the novel food. Anti-nutritional factors are compounds or substances that act to reduce nutrient intake, digestion, absorption and utilization and may produce other adverse effects. They include, *inter alia*, toxic amino acids, saponins, cyanogenic glycosides, tannins, phytic acid, gossypol, oxalates, goitrogens, lectins (e.g. phytohaemagglutinin), protease inhibitors (e.g. antitrypsin), chlorogenic acid and amylase inhibitors. The nature and amounts of anti-nutrients present in plant-based foods can vary not only with the plant species, but also with the cultivar, geographical location and conditions in which it is grown. Anti-nutrient levels can also be altered by post-harvest treatments (processing methods). Information on the degree of removal or destruction of anti-nutritional factors during processing or refining to produce the final food/ingredient would be relevant to the assessment.

3.2.4 Data Requirements for Products of Nanotechnology

The data requirements for establishing the safety of particulate, nanoscale novel foods will be the same as those outlined under “Data Requirements for Toxicological Safety” (section 3.2.2). At present, the risk arising from these foods is not fully predictable and therefore will, for the foreseeable future, require a full assessment via the existing Application process.