



Supporting document 4

Overview of International Regulatory Approaches – Proposal
P1024

Revision of the Regulation of Nutritive Substances & Novel
Foods

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1 Introduction

The purpose of this Supporting Document is to provide an overview and analysis of major international approaches to the regulation of novel foods/ingredients and nutritive substances. The regulatory frameworks in the European Union (EU), the United States of America (USA) and Canada are described and analysed to determine whether they, or elements of them, may be of assistance in considering potential approaches to regulating nutritive substances and novel foods in Australia and New Zealand. International approaches for the addition of vitamins and minerals to foods are noted; however the use of food additives and processing aids in foods are generally not covered in this document because they are not within the scope of Proposal P1024.

2. European Union

2.1 Novel foods and ingredients

The European Commission (EC) is currently reviewing the legislation for the authorisation and use of novel foods and novel ingredients in the EU. The following sections provide a summary of the current legislation and of the changes proposed under new legislation. The review was completed in October 2015.

2.1.1 Current legislation

The current legislation for the authorisation and use of novel foods and novel ingredients in the EU consists of two regulations:

- *Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients¹; and*
- *Commission Regulation (EC) No 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97².*

Regulation (EC) No 258/97 was adopted in 1997 and applies to *the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community*. This includes foods and food ingredients:

- with a new or intentionally modified primary molecular structure
- that consist of or are isolated from micro-organisms, fungi or algae
- that consist of or are isolated from plants and food ingredients isolated from animals
- whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.

The Regulation is not applicable to food additives, flavourings or extraction solvents.

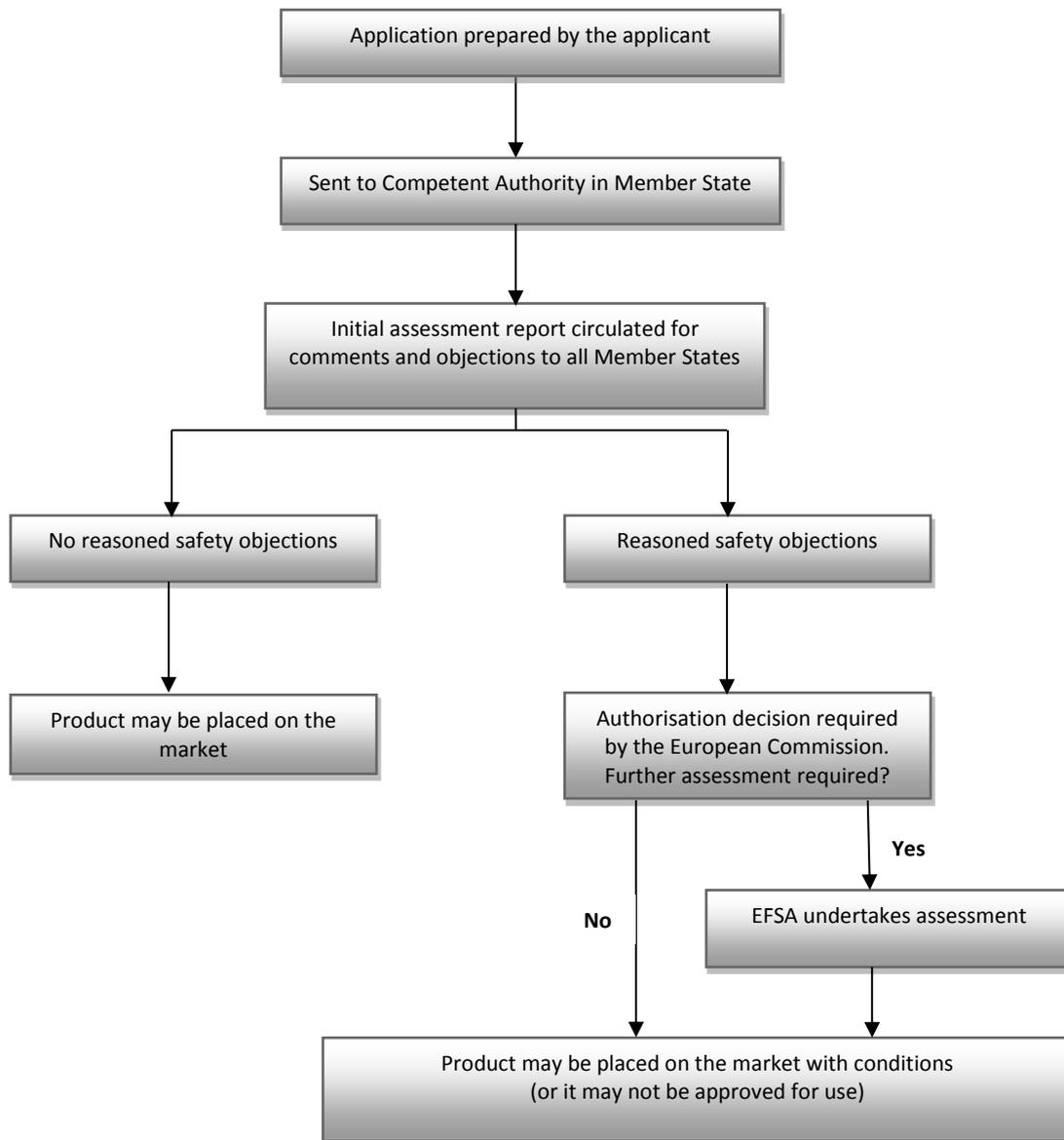
The general criteria applied to novel foods and ingredients are that they must not:

¹ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Available at: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&mod el=guichett

² Commission Regulation (EC) No 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001R1852:en:NOT>

- present a danger for the consumer
- mislead the consumer
- differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

The following premarket authorisation process is currently applied to novel foods and novel food ingredients:



The approval to market the novel food or novel food ingredient is granted to the applicant (i.e. individual authorisation). However, another applicant may notify the EC of the placing on the market of a food that is substantially equivalent to the authorised food; this notification must be substantiated by scientific evidence.

2.1.2 Proposed legislation

In December 2013, the EC adopted a proposal for a Regulation of the European Parliament and of the Council on novel foods³. It is proposed that this Regulation would replace the two existing regulations (EC No 285/97 and EC No 1852/2001). The proposal aims to ensure food safety and protection of public health, and to secure the functioning of the internal market for food, while supporting innovation for the food sector.

The same general criteria currently applied to novel foods and ingredients will be applicable to the replacement regulation: such foods and ingredients should be safe; their use should not mislead the consumer; and where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

The proposal provides a simplified procedure for the pre-market approval of novel foods and novel food ingredients. Identified key changes are:

- Centralised EU-level procedure that will separate risk assessment and risk management; all applications will be submitted to the EC directly, rather than through individual EU member states as per the current arrangements.
- The definitions (e.g. of novel food) are clarified and updated, although the 1997 cut-off date will remain⁴.
- Individual authorisations will be replaced with generic authorisations; removing the current procedure based on substantial equivalence (although individual authorisations with data protection may be granted for a period of up to five years).
- A simplified process for 'traditional foods from third countries' that is more proportionate to risk. In this case, if a history of safe food use in a third country for at least 25 years can be demonstrated by an applicant, and if member states or EFSA do not present reasoned safety objections, the food may be added to the EU list of novel foods (and can be sold on the EU market). If reasoned safety objections are presented, EFSA will conduct an assessment and the standard novel food authorisation procedure will be followed (with shorter deadlines).

It is proposed that foods intended to be used for technological purposes (e.g. additives, flavourings, extraction solvents) and genetically modified food would not fall within the scope of this Regulation. Vitamins, minerals and other substances intended to be used in food supplements or to be added to food are subject to other EC regulations (see section 2.2), and in addition would be subject to this proposed Regulation if they fall within the revised definition of novel food.

Adoption of the proposed regulation imminent..

2.1.3 Analysis of EU novel foods regulation

The inclusion of a cut-off date in the consideration of whether foods are subject to novel food regulations is not currently included in the *Australia New Zealand Food Standards Code* (the Code).

³ Proposal for a Regulation of the European Parliament and of the Council on novel foods. Available at: http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-cloning_com2013-894_final_en.pdf

⁴ The 1997 cut-off date reflects the date when Regulation (EC) No 258/97 on Novel Food and Novel Food Ingredients was adopted.

A cut-off date is an objective parameter that can provide a clear beginning point in determining whether a food or substance is subject to particular legislative requirements. However, not all foods are likely to require regulatory pre-market assessment and a cut-off date would require supporting criteria to determine which new foods should be subject to additional regulation. The EU definition of novel food does provide some additional clarification, similar to the definition of novel food in Standard 1.5.1. However, in the context of the Code, the additional clarification would need to address the problems associated with the current definition of novel food in Standard 1.5.1; that is, it would need to be unambiguous and clearly interpretable. FSANZ has investigated a cut-off date and additional clarifying criteria in its consideration of potential approaches to the regulation of nutritive substances and novel foods in Australia and New Zealand (see section 7.1 of the assessment summary).

The proposed regulation of novel foods in the EU introduces a simplified process for 'traditional foods from third countries', whereby establishing a history of safe use of a food may be sufficient to establish the safety of consumption by the food in the general population. FSANZ has considered a history of safe use as a means of establishing safety of potential novel foods and nutritive substances. However, the term 'history of consumption' in the definition of 'non-traditional food' in Standard 1.5.1 is considered to introduce a degree of ambiguity that is not acceptable in a standard in the Code, particularly without an objectively clear definition of the term (see section 2.2 of the assessment summary). FSANZ has investigated the history of safe use concept in its consideration of improving the regulation of nutritive substances and novel foods in Australia and New Zealand and considers a history of safe use of a food should be part of the supporting documentation that a food business must hold for a food that meets the eligible food criteria (see section 4.2.3 of the assessment summary and Supporting Document 2).

Another aspect of the proposed regulation that is relevant to consideration in this Proposal is the replacement of individual authorisations with generic ones. In particular, the potential for applying data protection (for up to five years) associated with authorisations is relevant to the current provision of exclusive permission for novel foods in Standard 1.5.1. FSANZ is reviewing the exclusive permission provision as part of this Proposal. The current Code provision provides permission for only a specified brand and class of novel food for a period of 15 months, after which the permission becomes generic. Further discussion of the review of the exclusive permission provision of Standard 1.5.1 is included in the assessment summary (see section 6.2).

2.2 Vitamins, minerals and certain other substances

The EC adopted Regulation EC 1925/2006 *The Addition of Vitamins and Minerals and of Certain Other Substances to Foods*⁵ in 2006. The Regulation was subsequently amended through EC regulations 1170/2009, 1161/2011 and 119/2014 to include additional vitamin and mineral substances in Annex I and II. The Regulation controls the addition of vitamins, minerals and 'other substances' to all foods except foods intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, which are regulated by Regulation (EU) No 609/2013.

The Regulation defines 'other substance' as: *a substance other than a vitamin or mineral that has a nutritional or physiological effect.*

⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1925:en:NOT>

Article 8 of the Regulation must be followed when another substance, or an ingredient containing another substance is added to foods or used in the manufacture of foods *under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.*

The Regulation adopts different approaches for the addition of vitamins and minerals to foods and the addition of other substances to foods. This proposal is not focussing on vitamin and mineral requirements in the Code, so the description of this EU regulation will focus on 'other substances'. An approach of 'permitted unless prohibited' is used for the addition of 'other substances' to foods. However, the EC may choose to evaluate a substance if it considers it may have a harmful effect on health, and list it in Annex III of the Regulation, if necessary. Annex III consists of three lists – (1) Part A – Prohibited substances, (2) Part B – Restricted substances and (3) Part C – Substances under Community scrutiny.

If a substance is put under Community scrutiny (Part C of Annex III), interested parties may at any time submit scientific data demonstrating the safety of a listed substance under the conditions of its use in a food or a category of foods and explaining the purpose of that use. Within four years of a substance being listed in Part C, the EC must decide, based on its opinion and any data provided by interested parties, to generally allow the use of the substance, or to list it in Part A or B of Annex III (i.e. prohibit or permit with conditions of use, respectively). The EC maintains a Community Register⁶ which includes information about the substances listed in Part C of Annex III and whose use is generally allowed after further evaluation. The Community Register is available to the public.

To date, only two substances have been listed in Annex III. Following a request from a Member State (Germany) under Article 8, the EC asked the European Food Safety Authority (EFSA) to undertake a safety assessment for Ephedra species (*Ephedra* spp.) and for yohimbe (*Pausinystalia yohimbe*). This assessment has now been completed and the European Commission has issued an amendment to the regulation (EU 2015/403) that adds Ephedra species in Annex III, Part A of Regulation (EC) No 1925/2006 so that its addition to foods or its use in the manufacture of foods shall be prohibited. It also includes Yohimbe (*P. yohimbe* (K. Schum.) Pierre ex Beille in Annex III, Part C of Regulation (EC) No 1925/2006, which lists substances where safety concerns have been raised but scientific uncertainty exists and will be kept under scrutiny. To monitor foods that contain added substances, individual Member States have the authority to require manufacturers/person placing the food on the market to notify them and to provide a model product label, and to also notify them on withdrawal of the product.

Article 16 of the Regulation required the EC to report to the European Parliament and Council on the effects of implementing this Regulation by 1 July 2013. The report was to address the evolution of the market in foods to which vitamins and minerals have been added, their consumption, nutrient intakes for the population and changes in dietary habits, and the addition of certain other substances, accompanied by any proposals for amendment of the Regulation. Commission Implementing Regulation (EU) No 489/2012 establishes implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006. The Commission's work on the report is still ongoing.

⁶ Community Register on the addition of vitamins and minerals and of certain other substances to foods. Available at http://ec.europa.eu/food/safety/docs/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf

2.2.1 Analysis of EU vitamin, mineral and 'other substances' regulation

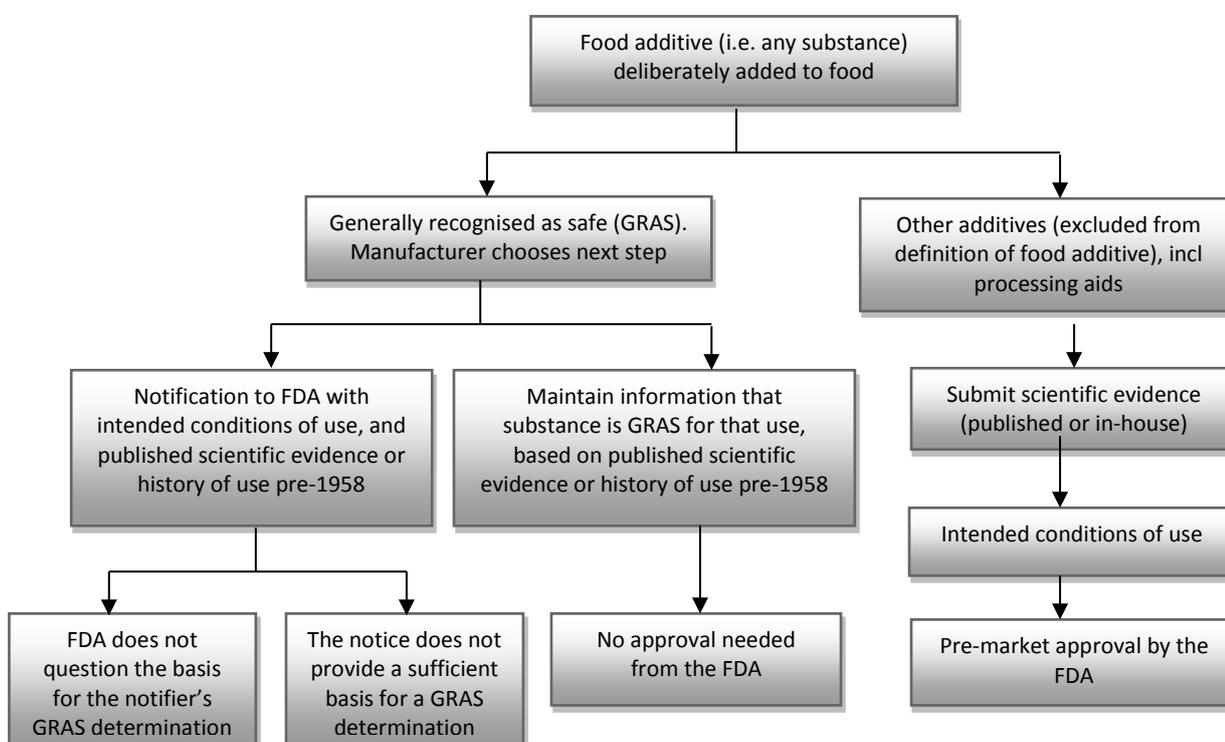
Unlike the EU approach to 'other substances', the Code currently prohibits all nutritive substances from being added to foods unless they are specifically permitted. The assessment summary examines the similarities between nutritive substances (other than vitamins and minerals) and novel foods and whether they need to be regulated separately (see section 3.2.2). The 'other substances' that have been added to Annex III by the EC appear to be similar to the type of substances/plants that are regulated in Standard 1.4.4, which includes lists of prohibited and restricted plants and fungi.

3 United States of America

In the USA, the term 'food additive' is used to describe any substance added to food. This differs from the understanding of the term in the Australian and New Zealand food regulatory regime, where a food additive is a substance added to food to achieve a technological function (such as a preservative or intense sweetener).

In the USA, any food additive intentionally added to food is subject to premarket approval by the US Food and Drug Administration (USFDA), unless the substance is generally recognised as safe (GRAS) through scientific procedures, through experience based on common use in food (dating to before 1958), or it meets one of the other exclusions from the food additive definition in section 201(s) of the *Federal Food, Drug and Cosmetic Act*. Also exempt from requiring pre-market approval are substances that the USFDA or the US Department of Agriculture (USDA) had determined safe for use in food prior to 1958 when the legislation was amended.

An overview of the process is described below:



Under the GRAS requirements, a food business must substantiate that their 'food additive' is GRAS before supplying it. The food business must show that experts would agree that the substance is GRAS under the conditions of its intended use in food – based either on scientific procedures or a history of use before 1958. Food businesses can commission a panel of experts to assess the GRAS status of a substance. A food business is not obliged to notify the FDA of its intention to market a GRAS substance; however they can do so if they wish. Upon receipt of a GRAS notification, the USFDA will provide an indication of whether the basis of the GRAS determination appears reasonable or not. While not a decision, or full assessment, by the USFDA, this response provides an indication of the quality of the GRAS assessment undertaken by the food business. These USFDA responses are publicly accessible and a list of GRAS notifications is maintained on the USFDA website.

3.1 Analysis of US GRAS system

FSANZ does not have the legislative power to perform a similar function to the USFDA in relation to responding to notifications of industry self-assessment of safety of substances. FSANZ can only undertake assessments upon receipt of an application from industry to amend the Code and the assessment process is subject to public consultation and FSANZ Board and Ministerial approval before the Code can be amended and a product can be marketed. FSANZ is also not able to maintain a register in the same way that the USFDA assesses and provides an indication of whether the agency has any questions about the outcomes of GRAS notifications. Any such list published outside of the Code would not have legislative underpinning in Australia and New Zealand. For example, the current list of recommendations from the FSANZ Advisory Committee on Novel Foods (ACNF) is published on the FSANZ website. However, this list is provided for information purposes only; it does not have any legal effect because it is not part of the Code.

The concept of the food industry being able to self-assess the safety of foods and food ingredients by a GRAS-like process is something that FSANZ has investigated in considering potential improvements to the regulation of nutritive substances and novel foods. Some published reviews of the GRAS system, noting that industry does not have to notify the USFDA of a GRAS determination, have expressed concern about the lack of transparency associated with these assessments of safety that result in an industry GRAS determination without the oversight of the USFDA⁷. The alternative regulatory approach developed by FSANZ and presented in the assessment summary (section 4.2.3) proposes industry self-assessment of safety for new foods: eligible foods that are known to be low risk; and non-eligible foods that may have an unknown or uncertain level of risk that requires additional assessment. FSANZ has proposed assessment requirements that would need to be met by industry before supplying eligible and non-eligible foods, with the more detailed assessments required for non-eligible foods being published and therefore publicly available and reviewable by food enforcement agencies (subject to any commercial in confidence allowances).

Although a food additive may have GRAS status, the USFDA may at any time prohibit its use or conduct further studies to determine its safety if new evidence suggests that a product already in use may be unsafe or if consumption levels have changed. FSANZ and other food regulatory agencies in Australia and New Zealand can take post-market action to prohibit foods or remove foods from the market (such as a FSANZ proposal to prohibit a food or place limits on the presence of a component in foods, food recalls or food enforcement agencies taking action on the basis of a food business supplying an unsafe or unsuitable food (relying on Food Act provisions)).

⁷ Such as the PEW Charitable Trusts' *Fixing the Oversight of Chemicals Added to our Food*: <http://www.pewtrusts.org/en/research-and-analysis/reports/2013/11/07/fixing-the-oversight-of-chemicals-added-to-our-food>

However, there are issues associated with the effectiveness or timeliness of these measures, particularly reliance on Food Act safe and suitable provisions, as described in section 3.1 of the assessment summary.

4 Canada

In Canada, any foods sold must meet the requirements of the *Food and Drugs Act*⁸ and the *Food and Drug Regulations*⁹.

4.1 Novel foods

Part B, Division 28 of the *Food and Drug Regulations* regulates novel foods. The regulations define 'novel food' as:

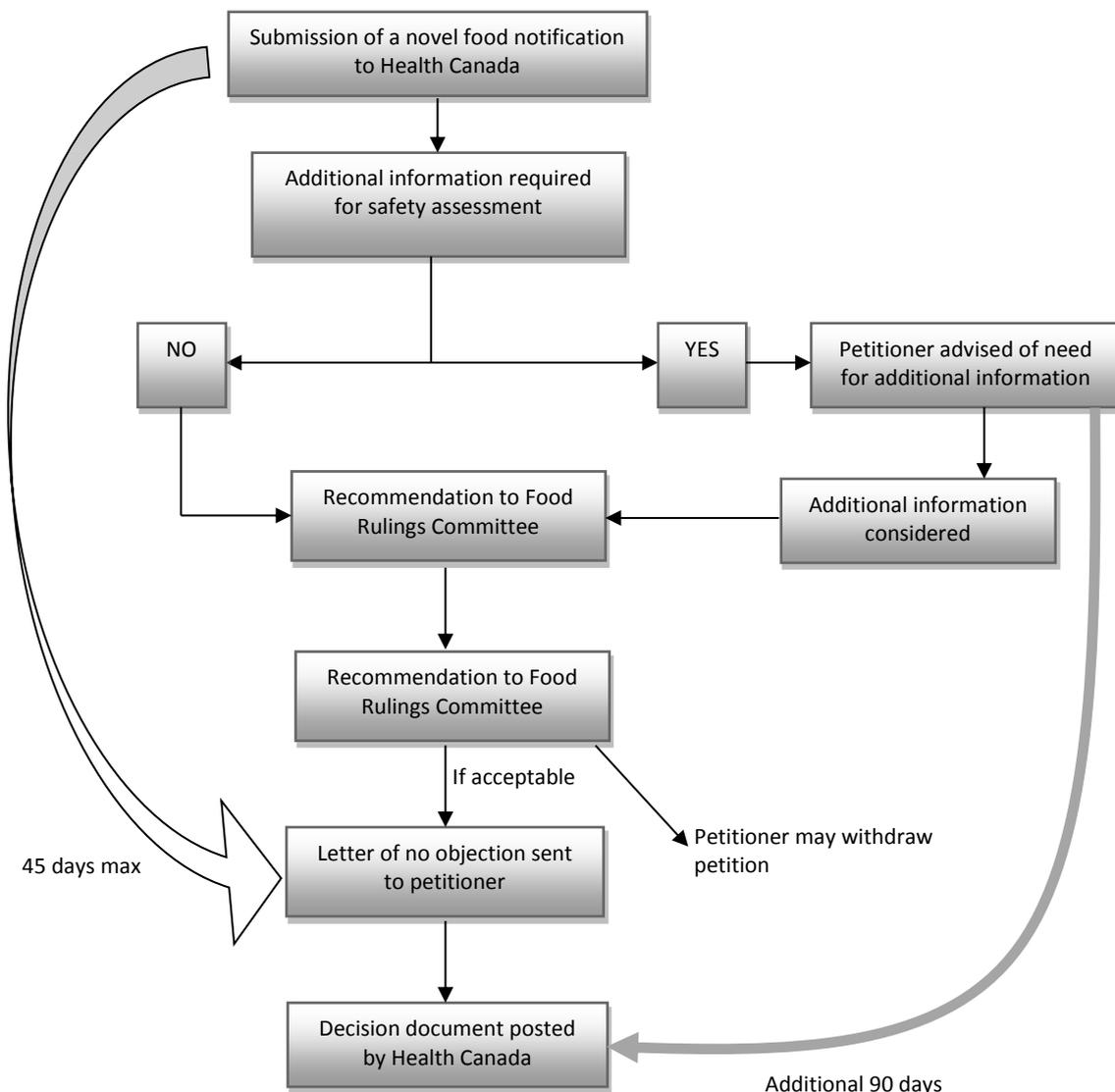
- (a) a substance, including a microorganism, that does not have a history of safe use as a food;
- (b) a food that has been manufactured, prepared, preserved or packaged by a process that:
 - (i) has not been previously applied to that food, and
 - (ii) causes the food to undergo a major change; and
- (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that:
 - (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

Therefore, the Canadian 'novel food' requirements apply to both novel and nutritive substances as regulated in the Food Standards Code.

Health Canada assesses the safety of all genetically-modified and other novel foods proposed for sale in Canada. Companies are required to submit detailed scientific data for review and approval by Health Canada, before such foods can be sold. The process (B28.002) requires the manufacturer to notify the Director in writing of their intention to sell or advertise for sale the novel food; and receive a written notice from the Director. An overview of the process is described below:

⁸ Canada's Food and Drug Act. Available at: <http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html>

⁹ Canada's Food and Drug Regulations. Available at: <http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C%20c.%20870/>



4.1.1 Analysis of Canadian novel food regulation

The Canadian novel food regulation shares some commonalities with the Code’s novel food standard (novel foods are prohibited and defined) and with the US GRAS notification system (notification to Health Canada and letter of no objection to petitioner (if acceptable)). However, FSANZ’s assessment process is subject to public consultation and is a transparent process that results in either a change to the Code (if a novel food is approved) or not (if a novel food is rejected or application is withdrawn). The Canadian and US systems do not result in a legal decision, but are rather an indication that a petitioner’s submission appears reasonable. FSANZ does not currently have the legislated capability of following a similar notification and ‘no objection’ approach. FSANZ must assess submissions (applications) it receives and propose that the Code is amended or not, depending on the outcome of the assessment.

Health Canada has developed ‘Guidelines for the Safety Assessment of Novel Foods’¹⁰ which includes consideration of a history of safe use of a food in another country as part of the evidence to support the safety of a novel food.

¹⁰ <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php#a4.1.1.1>

The guidelines set out the type of information that would be needed to support a claim that a product has a history of safe use. FSANZ has proposed, in the graduated risk approach presented in section 4.2.3 of the assessment summary that a history of safe use of a food can be part of the evidence of safety of eligible foods that industry must hold. The Health Canada guidelines have been noted as an example of the type of information that industry would need to hold to demonstrate a history of safe use.

4.2 Vitamins, minerals and amino acids

Part D, Division 3 of the *Food and Drug Regulations* regulates the addition of vitamins, minerals and amino acids to foods. The addition of these substances to foods is prohibited unless permitted. Permissions are specific to the substance and food type (e.g. breakfast cereals, flour). This is similar to the current regulation of nutritive substances in the Code.

5 Summary

The EU, USA and Canada have broadly similar approaches to Australia and New Zealand in the regulation of new or novel foods, insofar as some form of pre-market safety assessment is required before these foods can be sold to consumers. However, the identification of these foods, the form of pre-market assessment, the level of regulatory oversight and the legislated powers of regulators does vary between countries. FSANZ has highlighted aspects from the international approaches that may be of assistance in improving the regulation of novel foods and nutritive substances in Australia and New Zealand. In particular, FSANZ has utilised the following aspects in developing the alternative graduated risk approach presented in section 4.2.3 of the assessment summary:

- A cut-off date (EU, USA) can provide an objective parameter to assist in identifying new foods and substances that require pre-market assessment.
- Industry self-assessment of safety can provide a more streamlined process for industry in relation to the time it takes to get a new product into the market (USA, Canada), although the levels of transparency and regulatory oversight are important considerations to take into account.
- A demonstrated history of safe use of a food in other markets can provide a level of confidence in the assessment of safety of new or novel foods (EU, Canada).
- The proposed EU novel food regulation suggests an approach that results in generic approvals of novel foods can achieve a level of protection for industry derived safety data that differs from the current exclusive permission provision in Standard 1.5.1.