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ISSUE PAPER

CONCERNING THE PROPOSED AMENDMENTS TO THE EUROPEAN NOVEL FOODS REGULATION (EC) 258/97

WITH PARTICULAR REFERENCE TO

TRADITIONAL FOODS FROM DEVELOPING COUNTRIES

DEFINITIONS, CONCEPTS AND HISTORY OF SAFE FOOD USE ASSESSMENT

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Contents

A) EXECUTIVE SUMMARY 1
B) INTRODUCTION 3
1) Objectives of this Paper 3
2) Background to the current legislation 4
3) Regulation 258/97 poses Fundamental Problem for Traditional Foods 6
4) Review of the Novel Food Regulation 7
5) Methodology 8
C) THE PROPOSED AMENDMENT TO REGULATION (EC) 258/97 9
1) Requirements for Traditional Foods from Non-EU Countries 9
2) Extracts and Commentary from NFR revision 9
D) KEY TERMS AND BASIC DEFINITIONS 19
1) "Novel Food" 19
i) "Human consumption to a significant degree" 19
ii) The meaning of the term "Significant" 20
iii) The meaning of "Significant Consumption" 20
iv) Cut-off date of the 15th May, 1997 21
2) "Traditional Food from a Third Country" 21
i) Time Period for History of Use 22
ii) "Normal" or "Customary" Diet 23
iii) "Large Part of the Population of the Country" 25
3) "History of Safe Use" and the Concept of "Tradition" 26
i) Traditional Foods and Exotic Traditional Crops 27
ii) Obtained from Primary Production 28
iii) "Traditional use" 29
(a) Time-related use 29
(b) Traditional Applications 30
4) Evidence of "tradition" in the country of origin 30
i) "Traditional knowledge" 31
E) APPROACHES TAKEN BY OTHER COMPETENT AUTHORITIES 33
1) Food Standards Australia New Zealand (FSANZ) 33
i) Key Observations of the FSANZ Novel Food Standard and Procedure 33
2) Novel Food Regulations in Canada 34
i) Key Observations of the Canada Novel Foods Regulation and Procedures 34
F) HISTORY OF SAFE FOOD USE ASSESSMENT 36
1) European Food Safety Authority (EFSA) 37
2) Presumption of Safety based on Available Knowledge 38
i) Other existing knowledge 39
ii) General EU Food Law 39
iii) Other Legislation Recognizing Traditional Use 39
3) Recommendations – A Proposal for History of Safe Food Use Assessment 40
i) Step One: Identity and Traditional Food Status 41
ii) Step Two: History of Safe Food Use Assessment 43
iii) Step Three: Application Submitted to the European Commission 48
G) CONCLUSIONS 49
ANNEX I 50
Recitals to Proposal for a Revised Novel Food Regulation – Detailed Critique 50
ANNEX II 54
Articles of Proposal for a Revised Novel Food Regulation – Detailed Critique 54
ANNEX III 65
Definitions from Regulation (EC) No 178/2002 65
ANNEX IV 67
UK Food Advisory Committee Recommended Criteria for the Use of the Term 'Traditional' in Food Labelling and Advertising 67

ANNEX V 68
Risk Analysis 68
ANNEX VI 69
Schematic for QPS for Micro-Organisms 69
ANNEX VII 70
Summary of FSANZ Novel Foods Regulations 70
ANNEX VIII 75
FSANZ Standard 1.5.1 75
ANNEX IX 80
FSANZ Questionnaire 80
ANNEX X 84
FSANZ part 2 of Guidance Tool 84
ANNEX XI 85
FSANZ Record of Views (October 2009) 85
ANNEX XII 90
Health Canada Novel Food Regulations 90
ANNEX XIII 93
Health Canada Division 28 of Food and Drug Regulations 93

Acronyms

EC	European Commission
EFSA	European Food Safety Authority
FSANZ	Food Standards Australia New Zealand (*formerly, the Australia New Zealand Food Standards Authority – ANZFA*)
GM / GMO	Genetically Modified / Genetically Modified Organism
IPPC	International Plant Protection Convention
MS	Member States
NFR	EU Novel Food Regulation (EC) 258/97
UNCTAD	United Nations Conference on Trade and Development
WTO	World Trade Organisation

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A) EXECUTIVE SUMMARY

The current EU Novel Food Regulation (EC) 258/97 requires a formal authorisation and stringent food safety assessment prior to introduction into the EU market of any foods that do not have a significant consumption in the EU pre-1997. It was introduced primarily to control GM plants and their derivatives but its scope includes all "novel" foods, including those traditional in non-EU countries. Both scientific and administrative demands are considerable. Although GMOs are now subject to separate, specific legislation, no commensurate changes have been made to requirements for scientific evidence of safety of non-GM "novel" foods. Thus, traditional foods with a long history of use outside the EU are currently subject to criteria originally designed to control GMOs and, almost without exception, are denied access to the EU because they cannot show "a history of significant, safe food use in the EU, prior to May 1997".

In January, 2008, the Commission published a Proposal for a revised NFR that introduces a modified application procedure for foods which have not been traditionally sold in the EU but which have a safe history of use in non-EU countries. The Proposal has been, and continues to be, discussed within and between the Parliament, Commission and the Council / Member States. The Council reached Political Agreement in June 2009.

The text of the Regulation will, *verbatim,* be legally-binding. However, there remain a number of concepts and definitions which must be further clarified in order to establish legal certainty such that all stakeholders may benefit from consistent interpretation and uniform application of the revised legislation. Furthermore, the Proposal for a revised NFR does not include technical guidance on the safety assessment procedures themselves, which will be equally necessary to ensure consistent application of its principles.

This Issue Paper is a contribution to these discussions that (a) identifies and analyses the critical concepts, definitions and terminology within the Commission's Proposal and, where appropriate in the light of further EP and/or Council proposals, suggesting and recommending possible interpretations and ways forward that would contribute towards its consistent and uniform application and (b) analyses the technical aspects related to building a dossier and the existing guidelines that have been used, which could serve as a basis for revised recommendations for the safety assessment procedure and to provide criteria for determining the history of safe use of traditional foods.

We present a summary of the requirements of the revised NFR and, through a detailed critique of those 'recitals' and Articles that are directly relevant to traditional foods, examine the extent to which the proposal is likely to meet its objectives.

This paper identifies and discusses the uncertainty that will derive from the use of terms and concepts such as "traditional use", "history of use" and "history of safe use", "significant consumption", "customary/normal diet", "large part of the population of a country" etc. in the contexts of the geographical and political regions from which traditional foods may be expected to originate, their extended history and the criteria against which they will be assessed.

We have drawn on international texts and other EU regulations that apply similar definitions to obtain the same objectives as the NFR, such as consumer protection, public health, etc. and conclude that more precise definitions of these key terms and critical concepts are required. However, recognising that it may be difficult to develop legally precise (and concise) definitions for all aspects, we believe that, where this is not possible, our discussion and proposals will contribute towards the development of appropriate implementation guidelines to establish specific criteria that would need to be met.

In developing recommendations for a safety assessment procedure for traditional foods from third countries with a history of safe food use, the Regulations in Australia/New Zealand and Canada were compared and contrasted to the European Novel Food Regulation. Both authorities use a proportionate system to make safety assessments on foods with a history of safe use. Both authorities follow a two stage process to determine whether a safety assessment is required or whether on the basis of the information supplied there are no safety concerns.

This issue paper also reviewed a recent European Food Safety Authority (EFSA) Guidance document on the safety assessment of botanicals and botanical preparation used as food supplements. This guidance document proposes a two tiered approach depending on the available knowledge. Botanicals or botanical preparations for which an adequate body of knowledge exists could benefit from a "presumption of safety" without any need for further testing.

A similar framework is proposed for the safety assessment for Traditional Foods under the European Novel Food Regulation. Traditional foods from developing countries with a history of safe food use should benefit from a presumption of safety based on available knowledge. This principle could be applied when the available data from reliable approved sources and recognised expertise allows for the conclusion that exposure to known levels of the novel food/food ingredient has occurred for many years without reported adverse effects. The amount of information provided would be proportionate to the risk assessed in terms of the reports of adverse effect and/or the estimated levels of exposure in the EU compared to the levels of exposure in the country of origin.

Following a three step process, it is proposed that first the interested party provides evidence on the identity and traditional food status of the novel food. This evidence consists of taxonomic description, origin and evidence to support the claim that the food is a traditional food. Sources of evidence for could include scientific publications, non-scientific publications, cookbooks, books on the history of food culture. Additional information could be provided by an appropriate Competent Authority in the country and/or other countries where the Novel Food is consumed as a traditional food or other Recognised Authority or Accredited establishment.

The second step is to provide information on the history of safe food use. The interested party should provide information and data on (a) the specification and composition of the novel food and highlight any potential areas of concern (b) information about how the food is processed or needs to be processed in Europe prior to consumption (c) information on existing levels of exposure and estimated levels of exposure in Europe and (d) evidence of any reports of adverse effects on population groups.

In cases where the exposure to the traditional food in the EU is estimated to exceed the exposure in the country of origin, more authoritative evidence will be required. This could be provided by the relevant Competent Authority in country of origin and/or a recognised national or international authority. Where there are reports of adverse nutritional, allergenic and/or toxicological effects then this might also require more data/analysis depending on what data/information was already provided.

The final step would be to prepare the notification as per Article 8 of the Council Common Position.

B) INTRODUCTION

The EU Novel Food Regulation (EC) 258/97[1] was introduced in January 1997 but its scope was fundamentally amended in 2004, when GMOs and their derivatives became subject to separate, specific controls. However, no commensurate changes were made to requirements for scientific evidence of safety of non-GM "novel" foods, nor to clarify several areas where the definition of a "novel food" had been shown to be open to ambiguous interpretation.

After lengthy and comprehensive public consultations, the Commission issued a Proposal to revise the NFR in January, 2008.[2] This seeks to bring legal clarity to the definition of novel food and the scope of the Regulation by making necessary changes, updating the legislation and developing a more proportionate safety assessment for traditional food from third countries.

These proposals were considered at length by the (previous) European Parliament[3] and remain subject to formal, ongoing discussions within and between the new Parliament, Commission and the Council / Member States.

1) Objectives of this Paper

This Issue Paper aims to contribute to these ongoing, inter-institutional discussions by:

(a) identifying and analysing critical concepts, definitions and terminology within the Commission's proposed text and, where appropriate in the light of further EP and/or Council proposals, providing suggestions and recommendations on possible interpretations and ways forward that would contribute towards its consistent and uniform application;

(b) analysing the technical aspects related to building a dossier and the existing guidelines that have been used, which could serve as a basis for revised recommendations for the safety assessment procedure and provide criteria for determining the history of safe use of traditional foods.

Section C presents a summary of the requirements of the revised NFR and, through a detailed critique of those 'recitals' and Articles that are directly relevant to traditional foods, examines the extent to which the proposal is likely to meet its objectives.

Section D identifies and analyses critical concepts, definitions and terminology that require clarification within the proposed NFR text(s), and suggests and recommends possible interpretations. It draws on international texts and other EU regulations that apply similar definitions to obtain the same objectives as the NFR such as consumer protection, public health, etc., and provides information on how these concepts are treated.

Section E examines and compares the approaches taken by other global authorities such as Canada, Australia and New Zealand. It highlights, in particular, the distinctions drawn in these jurisdictions between foods with or without a prior history of consumption and the impact of such history on the safety assessment that is required.

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[1] Regulation (EC) No 258/1997 of the European Parliament and of the Council of 27 January 1997 concerning Novel foods and Novel Food Ingredients: OJ L 43, 14.2.1997 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett on http://europa.eu.int/comm/food/food/biotechnology/novelfood/index_en.htm

[2] http://ec.europa.eu/food/food/biotechnology/novelfood/COM872_novel_food_proposal_en.pdf

[3] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2008-0512+0+DOC+PDF+V0//EN

Section F analyses the technical aspects related to preparing a Dossier for a Traditional Food from a developing country and the existing guidelines that have been used. It also briefly examines the recently-published EFSA guidelines for the safety assessment of botanicals in food use and how the principles may be extrapolated in the specific case of traditional foods. This Section provides a basis for revised policy recommendations for the safety assessment procedure and to provide criteria for determining the history of safe use of traditional foods.

2) Background to the current legislation

The current NFR was introduced in January 1997 (and came into force in May 1997) in the period when commercial interest in, but more importantly consumer hostility towards, GM crops and food ingredients derived from them was rapidly gaining momentum. This was also at the time when BSE ("mad cow disease") was still a major issue in the UK and a rising concern in many other European Member States. Most importantly in any understanding of the history, purpose and requirements of the original NFR, uncertainties around the food safety aspects of BSE and, potentially GMOs, were very high on the political agenda (and the fundamental re-structuring of EU and many Member State administrative structures to separate risk assessment from risk management were still several years into the future).

The original NFR was therefore developed with the primary purpose of introducing a rigorous food safety assessment into the regime controlling the introduction of GM plants and their derivatives into the European market. Hence, also, the many references in the introductory paragraphs to the Regulation (the 'recitals') to pre-existing European legislation related to environmental release of GMOs and, as part of a "fast track" authorisation procedure, to the principles of "substantial equivalence"[4].

The Regulation applies to the placing on the market within the Community of foods and food ingredients which have not been used for human consumption to a significant degree within the Community (*prior to 15th May 1997*) **and** which fall within defined categories.

Specifically, the **original** 1997 Regulation had within its scope the following categories:

(a) foods and food ingredients containing or consisting of GMOs within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, GMOs;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (*authors' emphasis added - history of use alone is insufficient, regardless of the length of use; it is evidence of safe use that is required*.)

(f) foods and food ingredients to which has been applied a production process not currently

[4] By way of derogation from Article 3, paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4 (3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Thus, the NFR initially also covered GMOs and products derived from them, the safety requirements for which contributed to the strictness assessment procedures required for all "novel foods". Given that the principal objectives of the NFR were to protect public health (and to improve the functioning of the internal market by removing disparate national requirements and practices in this area), its basic tenet was that, unless a "novel food" (i.e. including GMOs) could be shown to be "substantially equivalent" to an existing product already available on the EU market, it should be subject to a formal authorisation procedure. This procedure implicitly requires a stringent safety assessment, for which both scientific and administrative demands are considerable.

Integral to the authorisation process has been the rigorous application, by the scientific assessment bodies, of a set of comprehensive guidelines establishing the scientific and technical requirements for the evidence necessary to support an application dossier, Recommendation 618/97[5], the scientific rationale for which was largely based on the criteria considered necessary for the safety assessment of GMOs.

However, in 2004, separate legislation on GM-derived foods and food ingredients (and corresponding animal feeds) was introduced, whereby the food safety aspects of GM-derived products are now regulated under GM-specific legislation[6] and categories (a) and (b) above were removed from the scope of the NFR.

Although all subsequent direct references to GMOs were also deleted from the original version at this time, critically, no adjustment of any kind was otherwise made to the requirements for the remaining categories of "novel" foods.

Most critically, however, no parallel changes were introduced to update the requirements for scientific evidence of safety of non-GM "novel" foods, nor to differentiate between genuinely "novel" materials (such as chemically-synthesised ingredients or highly-refined extracts of foods and food ingredients) and products which are well-recognised as foodstuffs in non-EU countries but which nevertheless have no history of food use within the EU. Consequently, the safety assessment of all non-GM "novel" foods (including those with a known history of use outside the EU) still remains effectively determined by the rigorous and stringent scientific criteria established within Recommendation 618/97.

It is important to note that the controls imposed by the NFR and its proposed revision relate only to the safety of consumption of "novel" foods and their derivatives. If there were to be any perceived concerns related to any plant health risks that might arise from the introduction, planting and cultivation of "alien" plants (or, indeed, plant pests associated with them) or that could pose a threat to native flora, separate regulatory regimes are in place to cover these, in accordance with IPPC principles. Further controls are also in place to restrict the commercial planting of crop species and varieties via Community and national permitted variety legislation.

This paper addresses only the matters covered by the NFR and, in particular, its proposed revision.

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[5] Commission Recommendation 97/618/97EC concerning the scientific aspects and the presentation of information necessary to support application for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation 258/97: OJ L 253 16.9.97.

[6] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed: OJ L 268/1, 18.10.2003: http://europa.eu.int/comm/food/food/biotechnology/gmfood/legisl_en.htm

3) Regulation 258/97 poses Fundamental Problem for Traditional Foods

Almost without exception, traditional foods from third countries have been denied access to the EU because, despite their history of use and in some cases legal status (i.e. acceptance) under other non-EU regimes, they are not considered able to demonstrate compliance with the criteria established by the "limbs" that define a "novel" food under NFR – and are therefore not able to claim exemption from its application. The following problems are particularly significant.

The NFR defines a "Novel Food" as one which has not been used for human consumption to a significant degree within the Community (*prior to 15th May 1997*) **and** which falls within one of several defined categories, i.e. to be a "novel" food, a product must fulfil both conditions.

- Traditional foods have been denied access to the EU because they are not considered able to demonstrate "a history of significant, safe food use in the EU, prior to May 1997".

- The arbitrary cut-off date (*implementation date of the Regulation*) impacts the majority of traditional foods from third countries, which have only recently sought to make their way into foreign markets, and therefore have not hitherto been considered as having a history of "significant consumption" in the (*now*) 27 EU Member States.

- The requirement to show a history of consumption in the EU prior to the cut-off date has been used as a key parameter but the wording of current sub-paragraph (e), into which traditional foods would generally fall, has also been open to varying interpretations because of the cross-referencing to "safe".

- The food categories established in the NFR do not expressly recognise or accommodate traditional foods from outside the EU. Thus, even where limited prior consumption can be shown, and although the exemption for "foods … obtained by traditional propagating or breeding practices, and having a history of safe use", could be argued to exclude traditional foodstuffs from its scope, a stringent interpretation of "safe" use has been taken to over-ride the apparent exemption.

- Furthermore, consistent application of the Regulation has been hindered by differing interpretations of key terms such as "significant degree", "generally recognised" and "substantially equivalent".

- What constitutes "a significant degree" is not defined in the Regulation and has been subject to arbitrary interpretation by the authorities, e.g. by excluding prior food supplement use, or restricting consideration of quantitative sales of products to those through general food outlets, to the exclusion of those through pharmacies.

Although applicants are able to seek advice from Commission or Member State officials, a degree of uncertainty has attached to the "novel" status of many products. If the food is viewed as not novel, it may be placed on the market and assessment under the NFR is not required. Otherwise, full assessment of the food's safety under the NFR has been required.

It is also important to note that the authorisation of a product is strictly limited to the specific subject of the application. For example, in the case of Noni juice, marketing of any other Noni products, say jam, spray-dried juice, or dried whole fruit, requires a separate authorisation. Furthermore, not only is the authorisation specific to a particular product, it is also granted solely to the applicant, meaning a competitor could not market the same product, unless he was able to present evidence of "substantial equivalence" between his and the approved product. In practice, this has restricted initial applications for approvals under the NFR to companies / organisations possessing substantial resources.

4) Review of the Novel Food Regulation

The NFR also required the Commission to review its implementation and, where appropriate, propose suitable amendments. This review was initiated through a DG SANCO Discussion Paper in July 2002[7], in which the Commission distinguished separate groups of novel foods, which it suggested might then be subject to different levels of requirements and procedures according to their categorisation and the associated risks and benefits; for example, different criteria and evidence requirements could apply to exotic traditional foods, compared with innovative products that have no such history of long term consumption in third countries:

This suggested approach is analogous to that taken in relation to complementary and conventional medicines, whereby both go through pre-market approval processes but are subject to different requirements as to the type and quantity of data they must provide.

Public responses to this consultation identified a number of problem areas, including a strong view that the NFR was being over-strictly interpreted in respect of "traditional foods", i.e. foods with a history of long term consumption in third countries, but for which it was not possible to show a significant consumption in the EU prior to the NFR cut-off date.

A previous UNCTAD / CBI paper further assessed why the Regulation presents difficulties and how these may be resolved[8], building on previous studies[9,10,11] that had also identified important concerns to be addressed in order to introduce more proportionate approaches to the evaluation of these products before they could be introduced onto the EU market.

The European Commission launched a further (online) consultation in June 2006[12], to obtain information from the general public, stakeholders and Member States in order to carry out a formal Impact Assessment on the possible policies considered for the revision of the Regulation; more than 60 stakeholder responses were received[13]. The results of the impact assessment supported the introduction, for traditional food from non-EU countries, of a procedure setting out essential criteria and guidelines, that would allow food with a history of safe food use to be subject to an adjusted safety assessment and management procedure. It was clear, however, that many stakeholders were concerned about the uncertainties, ambiguities and even contradictions that had been experienced with the definitions of the concepts on which both the current Regulations and the suggestions for its revisions had been based.

The responses also underlined the importance of a documented history of safe food use, ascertaining possible undesirable effects, and stressed the need for clear guidelines and criteria. In addition, consumers expressed concern that any different approach to traditional food from non-EU countries might result in a relaxation of safety assessments, leading to a loss of trust in novel food ingredients on the part of European consumers.

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[7] Discussion Paper: Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. DG SANCO D4, EC, July 2002. http://europa.eu.int/comm/food/food/biotechnology/novelfood/discussion_en.pdf

[8] The EU Novel Food Regulation: Discussion Paper on behalf of UNCTAD/CBI, Neville Craddock Associates, Nov 2005: http://www.biotrade.org/Events/events_docs/events-dec05-NovelfoodsCBIUNCTADpaperonEUNovelFoodRegulation.pdf

[9] Michael Hermann: The amendment of the EU Novel Food Regulation: opportunity for recognizing the special status of exotic traditional foods; Discussion paper, June 2004, International Plant Genetic Resources Institute (IPGRI) http://www.underutilized-species.org/documents/nfr/nfr_discussion_paper_june_2004.pdf

[10] Otto Mück: Trade Barrier NFR? Under-utilized Species under the European Union's Novel Food Regulation; Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, Global Facilitation Unit for Underutilized Species: October 2003 (and a related paper, April 2003). http://www.underutilized-species.org/documents/nfr/underutilized_species_nfr and http://www.underutilized-species.org/documents/nfr/Trade_barrier_nfr.doc

[11] People & Biodiversity: The EU Novel Foods Regulation – its impact on trade in biodiversity products from developing countries: http://www.underutilized-species.org/documents/nfr/gtz_novel_food_fact_sheet.pdf

[12] http://ec.europa.eu/food/food/biotechnology/novelfood/nfia_expl_doc.pdf

[13] http://ec.europa.eu/food/food/biotechnology/novelfood/resp_consult_258_97_en.htm

Finally, a formal proposal was published in January, 2008[14]. Amongst the changes proposed by the Commission is the introduction of a notification procedure for foods which have not been traditionally sold in the EU but which have a safe history of use in non-EU countries. However, the proposal currently contains a number of concepts for which further clarity of definition is required in order to establish legal certainty such that businesses, consumers and authorities may all benefit from a uniform interpretation and application of the future legislation.

In addition, the original Commission proposal has now (as of October, 2009) been debated at length by the European Parliament and Council of Ministers' Working Groups and numerous potential amendments have been discussed. Of particular note is a statement in the Report of the EP Committee on Environment, Public Health and Food Safety (the EP Lead committee) warning against "making it too difficult for third countries, often LDCs, from gaining access to our market".

5) Methodology

The authors have used the initial Commission proposal as the principal basis for this paper, but have also taken account of developments that have arisen during on-going discussions within the European Parliament and Council of Ministers.

They have also referred to the concepts in existing legislation in the EU and to similar legislation in force, primarily in Australia / New Zealand and Canada, as well as taking into account related reviews and discussion papers in the public domain.

The findings of a series of workshops and consultations, within Europe, Peru and South Africa have also been taken into account, together with valuable inputs from a number of individual international experts in this field.

Collectively, these inputs have made a significant contribution to the development of the policy recommendations included in this paper.

[14] Proposal for a Regulation of the European Parliament and of the Council on Novel Foods: COM(2007) 872 final, 14.01.2008.

C) THE PROPOSED AMENDMENT TO REGULATION (EC) 258/97

In its introduction to the proposed revision, the Commission stated its aims as being (*amongst others that are not directly relevant to this paper*) to clarify the definition of novel food and the scope of the Regulation, to develop a more adjusted safety assessment system for traditional food from third countries and to achieve legal clarity by making necessary changes and updating the legislation.

The proposal is stated to be in line with the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration.

This latter parameter is extremely important and is reflected by the proposal bearing some similarities to the risk assessment procedures in force in Australia/New Zealand and Canada. Nevertheless, the procedures by which the safety of a traditional food from a non-EU country will be assessed, and the associated definitions, need further clarification.

1) Requirements for Traditional Foods from Non-EU Countries

For "traditional food from third countries", a safety assessment and management based on "history of safe food use" is proposed. This is to be established on the basis of knowledge of the composition of the food and from experience of its use (and continued use) for at least 25 years in the customary diet of a large part of the population of a (non-EU) country. If the European Food Safety Authority is satisfied that a history of safe food use is demonstrated, an administrative procedure is proposed whereby, subject to agreement of the Commission and Member States, the novel food will be permitted to be placed on the EU market. The proposal identifies the broad requirements to be included in an application but the detailed rules remain to be developed. There is a clear political intention to allow a more proportional safety assessment and management for traditional foods but the detailed rules and criteria to be applied will be critical.

On a case-by-case basis, a specification, labelling, conditions of use and, where appropriate, a requirement of post-market monitoring for the novel food may be established.

2) Extracts and Commentary from NFR revision

This section contains selected extracts from the proposed Regulation that are relevant to Traditional Foods, incorporating suggested further amendments from a recent Council text. Comments from the authors indicate where potential uncertainties may arise and hence where clarification should be provided, ideally before the text is finalised, or within separate guidelines. The essential terms have been further analysed and possible suggestions made for their improvement or clarification in ***Section D***.

(a) General Introduction

- The proposal retains the basic concepts for "novelty" invoking a cut-off date prior to which a food must be able to demonstrate significant consumption in the EU.

- It introduces a new sub-category of "traditional food from a third country" within "novel foods" and a requirement that the traditional food must have been "obtained from primary production".

- Applications may be made by "an interested party" – a wider concept than a food business operator.

- All novel foods, including traditional foods, will be evaluated to ensure that they will not present a danger to, mislead, or be of nutritional disadvantage for the consumer.

- "Traditional food from a third country" will be subject to a new safety assessment and management procedure based on *"history of safe food use".* EFSA will verify that:
  - the history of safe food use in any third country is substantiated by the quality of data submitted by the interested party
  - the composition of the food and, where applicable, its conditions of use do not pose a health risk to EU consumers.

- The proposal formalises the existing approach whereby food supplement use is not considered to equate to "significant use" in the Community.

- A decision whether a food falls within the scope of the Regulation may be made following the EU "comitology" procedure.

- The entry of a novel food in the Community list will include a specification of the food and, where appropriate, specify the conditions of use, additional specific labelling and/or a post-market monitoring requirement.

- Products will not be permitted on the EU market unless they have been added to the list.

- Producers of novel foods will be obliged to inform the Commission of any new information which may affect the safety assessment of the novel food.

(b) Recitals to the Regulation

The intentions for the revised NFR are set out in the Recitals. Those with specific relevance for traditional foods have been identified, summarised and critiqued. Key issues are summarised below; our full critique is shown in ***Annex I***.

- Recommendation 97/618/EC[15] should become obsolete. This is very welcome, as it has, in practice, set disproportionate criteria for foods with a known history of use outside the EU.

- The criterion of absence of significant EU-27 consumption, prior to May 1997, are retained, perpetuating issues related to "significant degree" and establishing historical trade and consumption.

- The proposal falls under to the general principles and requirements of EU food law. Since 1997, EU food legislation and EU / MS administrative structures have been fundamentally updated. NFR should not duplicate requirements already established by the General Food Law. In particular, safety assessment of traditional foods must distinguish clearly between analytical and compositional parameters inherent to the product and those which may arise from poor agricultural and/or hygienic practice. The former are a legitimate parameter for the safety assessment of the food; the latter are specific to the sample/consignment concerned and (whilst of direct safety concern), responsibility for their control and legal compliance with existing food law standards must fall to the individual operator in the same way as the law requires for all current foods and ingredients.

[15] Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council: OJ L 253, 16.9.1997 pp 1-36

- Foods from third countries are "traditional" only when obtained from primary production, whether processed or unprocessed (e.g. jam, juice or purée). However, this qualification has not been fully incorporated into the Articles. The consequences are discussed in detail in ***Section D.3(ii)*** below***.***

- Implementing measures to facilitate application of the NFR will be developed.

- "Medicinal products" are outside the NFR and a MS may restrict their marketing.

- Novel foods for particular nutrition, fortification or supplement uses, will be assessed for safety under NFR, but remain subject to sector-specific rules.

- Whether a food has a significant history of prior EU consumption will be based on information submitted by operators, supported by other information available in MS. If necessary, a simple and transparent procedure involving the EC, MS and other interested will be introduced.

- Novel foods may be marketed only if safe, do not mislead and, if intended to replace another food, will not nutritionally disadvantage the consumer. "Replacing another food" is a nebulous concept, open to varying interpretation.

- Authorisations of "novel" foods must take into account "other factors" such as ethical and environmental factors and the precautionary principle.

- Criteria for evaluation of potential risks arising from novel foods are to be laid down; the assessments will be carried out by EFSA. The recently-published EFSA guidelines for safety evaluation of botanical ingredients[16] are a valuable starting point for the replacement of Recommendation 97/618.

- Traditional foods from third countries may be marketed in the EU under conditions that correspond to those for which the **history of safe food use** has been demonstrated; their safety assessment and management must take into account their history of safe food use in the third country but exclude non-food uses or uses not related to normal diets. This concept is fundamental to this paper and discussed in detail in ***Sections D.3, E and F*** below.

- Post-market monitoring requirements may be imposed, based on the safety assessment. This is a standard provision for new products introduced to the EU market.

- All novel foods are subject to the general EU labelling requirements. Approval may be qualified by specific conditions of use or labelling related to composition, nutritional value or intended use, etc. It can equally be argued that information, e.g. preparation instructions, can be used as a risk management tool to mitigate any residual doubts that might remain from the safety assessment.

- The EC will be empowered to establish criteria against which key aspects of the NFR may be determined. We believe any key criteria should be sufficiently defined in the NFR itself. If this proves impossible, the timing of guidance is critical and it should be developed before the revised NFR comes fully into effect.

[16] Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements; EFSA Journal 2009, 7(9) 1249.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902880131.htm

- MS authorities must comply with Regulation 882/2004[17] to enforce compliance with the NFR; EU food hygiene requirements[18] also apply. Compliance by operators with general food hygiene and safety rules also infers that the safety assessment of traditional foods should focus on intrinsic safety factors rather than those that may arise from poor storage and handling. It should also be noted that Regulation 882/2004 also places obligations on exporting countries' competent authorities to ensure that export products meet EU hygiene legislation.

(c) Articles of the Regulation

The following requirements are set out in the Articles of the Regulation. Those with specific relevance for traditional foods have been identified, summarised and critiqued. Article 8 is specific to traditional foods from third countries, but these are a sub-set of novel foods; thus, all articles apply to them unless they are specifically excluded. Key issues are summarised below; our full critique is shown in ***Annex II***.

- The definitions of EU General Food Law will apply; details are given in ***Annex III***. Additional definitions relevant to traditional foods will also apply; details of others, indicating the scope of the legislation are shown more fully in ***Annex II***:

  (a) **"novel food"**: food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, including traditional food from a third country.
  - Retaining the concept of "significant degree" for prior non-supplement uses risks perpetuating the problems of the current Regulation and will be discussed further in ***Section D*** below.
  - Criteria for assessing if a food meets these requirements will be adopted in accordance with a standard regulatory procedure (with parliamentary scrutiny) before the revised NFR becomes applicable.
  - Ingredients used exclusively in supplements within the EU pre-1997 will require authorisation if they are to be used in foods other than food supplements.

  (d) "traditional food from a third country" means novel food [i.e. as above], derived from primary production with a history of food use in any third country, meaning that the food in question has been and continues to be part of the ~~normal~~ customary diet for at least ~~one generation~~ 25 years in a large part of the population of the country.
  - Although Recital 6 qualifies "primary production", this critical qualification is not incorporated into the text of this Article.
  - The definition of traditional food would include plants, animals, fish and insects.
  - The definition in (d) does not address "safe" use, referring only to "history of food use". The issue of "safe food use" falls under sub-paragraph (e) below; documentary requirements are outlined in Article 8.1.
  - Interpretations of "**primary production",** "**normal/customary"** diet, and **"large part of the population of the country"** will be critical.
  - The requirement for 25 years (or an alternative period) and whether it is linked to the date of the legislation or to an application its calculation is not straightforward
  - These issues are discussed more fully in ***Sections D.2 and D.3***, below.

  (**e**) **"history of safe food use in a third country"** means that the safety of the food in question is confirmed with compositional data and from experience of use and

[17] OJ L165, 30.4.2004, p1. Corrected version: OJ L191, 28.5.2004, p1. Regulation as last amended by Council Regulation (EC) No 1791/2006; OJ L363, 20.12.2006, p1

[18] OJ L 139, 30.4.2004, p.1

continued use **for at least 25 years** in the ~~normal~~ **customary** diet of a large part of the population of a country.

- Definitions (d) and (e) overlap considerably; requiring the same period for **food use** and **safe food use** confuses the extended history of consumption of traditional foods by indigenous populations with a requirement to have established their safety, using modern scientific criteria, over the same period.
- The definitions refer to consumption by a large part of the population of "the" / "a" country, respectively. Thus, the history of use must be established in relation to the specific country, whereas the safety of use may be established in relation to consumption in any country.
- The concept of a **"large part of the population of a country"** potentially introduces numerous inconsistencies. It does not, *per se*, take into account several key issues:
  - how the **"large part"** is to be defined, particularly in relation to the statistical validity or nutritional and/or toxicological significance of the numbers involved;
  - the **"population of a country"** can range from tens of thousands to hundreds of millions of people;
  - the **"population"** of many countries is not a homogeneous group, but may comprise several ethnic and/or religious sub-populations, each with differing long-standing dietary habits and preferences;
  - these ethnic/religious groups may comprise, numerically, only a small proportion of the overall population and live in a small area (**"region"**) of a given country, yet still represent a discrete and identifiable "population"; equally, these ethnic/religious populations may be more thinly spread within a given country but be represented more widely over several countries (i.e. a wider, geographical region that shares a common cultural history);
  - the concept of "a (single) country" does not address the politically-driven changes to country boundaries that have occurred in some regions (e.g. Africa) well within the timescales of the use of traditional foods.
  - NFR must address **"regional"** consumption, whether the region is within a single country or comprises several countries or parts of countries.

- These key issues merit are discussed in detail in ***Section D.2(iii)*** below.
- Potential mechanisms to demonstrate "history of safe food use" are discussed in detail in ***Section F***.

- In accordance with basic EU food law, **business operators** must verify the NFR status of foods they intend to market; in case of doubts, the operator must consult the relevant competent authority (who may consult EC and other MS).
  - The specific provisions in Article 8 for traditional foods refer to information being provided by ***"an interested party",*** is a wider legal concept than a ***"business operator"***. This Article should be amended to reflect the distinctions and to ensure consistency.
  - It will become progressively more difficult to **prove** the use or imports of specific foods prior to 1997 (see ***Section D.1(iv)*** below).

- If necessary, the standard EU procedure will be invoked to determine if a type of food falls within the scope of NFR. This already recognises that the basic definition of a "novel food" will still result in uncertainty.

- The EC will establish and maintain a list of authorised traditional foods from third countries; only foods on this list may be placed on the market.

- General conditions are established for inclusion of all novel foods, including traditional foods, in the lists. A novel food may be included in the lists only if:

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ~~under normal consumption conditions~~;
(b) it does not mislead the consumer, ~~by the way it is presented or by its intended use~~;
(c) in the case where it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

- It is unclear why reference to normal consumption is retained only in (c); it would seem to be equally applicable to both.
- EU Food Labelling Directive forbids misleading labelling, advertising and presentation of all foods but requires that these must not mislead ***to a material degree***. This sub-paragraph should be similarly qualified.
- The concept of "replacing another food" is nebulous and may introduce discrepancies between "novel" foods and those already on the EU market that would not be subject to the same comparison or rules. Any food can be said to be replacing another food in the course of daily consumption, e.g. whether it is directly substituting one vegetable or fruit for another, or consuming one food to the exclusion of another. The difficulty inherent in this sub-clause may be illustrated by a simple example; if a fleshy fruit similar in use to melons, but of inferior vitamin content, was intended to be introduced to the EU, it could be said that nutritionally, such a fruit is "disadvantageous". Would authorization be denied, solely on this basis? That would be grotesque and surely open to challenge.

- ***Article 8*** *is the key Article specific to* ***Traditional food from a third country***

Note: the text of this article is quoted almost verbatim; some complex EU jargon has been paraphrased. Significant changes from earlier drafts are also indicated.

1. By way of derogation from the procedure laid down in article 7(1) of this Regulation, **an interested party**, [who may represent several parties], who intends to place a traditional food from a third country on the EU market […], shall submit an **application** to the EC.

The ~~notification~~ application shall include:

(a) the name and description of the food,

(b) its composition,

(c) its ~~the~~ country of origin,

(d) documented data demonstrating the history of safe food use in any ~~the~~ third country,

(e) where applicable, the conditions of use and specific labelling requirements,

(f) a summary of the content of the application ~~notification~~.

The ~~notification~~ application shall be made in accordance with the implementing rules referred to in paragraph 7 of this Article.

- The original draft Article 8.1 referred to "***a food business operator***" … shall ***notify it*** to the EC, indicating the name of the food, its composition and country of origin".
- The change from business operator to "***interested party***" more closely reflects the practicality of trade groups or wider interest groups wishing to place a traditional food on the EU market (c.f. the recent Baobab approval).
- The proposed application mechanism will require EFSA to produce its Opinion based on the data in support of a history of safe use. This Opinion will form the basis for the Commission to develop a proposal to add the food to the EU list, subject to agreement by MS (qualified majority voting) and scrutiny by Parliament.
- "Composition" is an imprecise term, capable of wide interpretation from requiring very broad details down to minutiae of scientific components. In the latter case, such details may not be readily available. Hence, it will be extremely important to ensure that a balanced, pragmatic approach is taken to the history of safe food use of the product. In

this respect, appropriate implementation guidelines will be necessary to ensure that the information demanded is proportionate to a given product, and assessed on a case-by-case basis.

- The content and scope of "documented data", where/how it is to be derived and how it is to be validated are not specified in the draft NFR but will be addressed in appropriate technical guidelines (e.g. from EFSA). We consider this in detail in ***Sections D and F***.

2. The Commission shall forward the valid application ~~notification including the demonstration of history of safe food use~~ referred to in paragraph 1 without delay to the Member States and the European Food Safety Authority.

- The EC will establish whether the application is valid – i.e. that it contains the necessary administrative and documentary information (as distinct from its scientific verification). We believe a strict time-limit should be imposed (~2 weeks) to avoid unwarranted delays to what is already an extended time-scale for the overall processing of an application from date of application to permission for marketing.

3. Within ~~four~~ six months of receipt of an application, EFSA shall give its opinion. Whenever the Authority seeks supplementary information from the interested party, it shall, after consulting the interested party, lay down a period within which this information shall be provided. The six months time limit shall be automatically extended by this additional period. The supplementary information shall be made available to the Member States and the Commission by the Authority.

- This is a highly pragmatic approach, but it must not be permitted to become a "justification" for progressively seeking more and more erudite scientific information, thereby negating the political will of the NFR to provide an accelerated mechanism for the authorisation of traditional foods. The role of technical guidelines will, again, be critical in ensuring a consistent and proportionate approach is taken.
- Provision should also be included, either in the NFR or implementing rules, to encourage direct contact between EFSA and the applicant to resolve outstanding matters.

4. In order to prepare its opinion the Authority shall verify:

(a) that the history of safe food use in any third country is substantiated by the quality of data submitted by the interested party; and

(b) that the composition of the food and, where applicable the conditions of its use, does not pose health risk to consumers in the Community.

The Authority shall forward its opinion to EC, the MS and the interested party.

- Implementing rules are to be developed for this Article (sub-paragraph 7, below); these must recognise that "safety" is not an absolute concept that can be "confirmed" by compositional data, but must require such data to be considered within an appropriate risk management framework. Where certain aspects of "compositional data" might indicate a potential risk, preparation methods and consumption patterns must be fully taken into account. Many "conventional foods" already on the EU market contain potentially unsafe components but the hazard is controlled through risk management that entails appropriate information, preparation and / or processing.

5. a) Within 3 months of EFSA giving its opinion, the EC shall submit to [MS technical working committee] a draft measure to update the list of traditional foods from third countries, taking account of the opinion of EFSA, any relevant provisions of Community Law and any other legitimate factors relevant to the matter under consideration. [This measure … shall be adopted by MS using the qualified majority voting procedure, with parliament scrutiny]. The Commission shall inform the interested party accordingly.
    - Involvement of MS is an essential democratic provision. However, based on past history of novel foods assessments, this step could remain a significant hurdle for

traditional foods; it will be essential to ensure that any objections are based on sound scientific evidence if it is not to become a purely political means to block a product from the market.

b) If the EC decides not to proceed with an update of the list of traditional foods from third countries, it shall inform the interested party and the MS accordingly, indicating the reasons for not considering the update justified.

- "Updating the list" equates to authorisation to place the traditional food on the EU market. If the food is not on the list, it may not be marketed.
- As drafted, this sub-paragraph appears to give the EC the power to reject an application, following an EFSA Opinion, advising but without consulting the MS of its decision. It would seem appropriate for a negative decision also to be subject to the same procedure as in sub-paragraph (a).

6. At any stage of the procedure the interested party may withdraw its application.

- In an earlier draft, rejection of a "notification" of a traditional food could be followed by a full novel food "application". There is no such provision in the latest Council draft. Although no explanation is given, this might infer that the level of scientific scrutiny of traditional foods ultimately expected from EFSA may be more stringent than previously envisaged.
- It is not clear whether an applicant would, if necessary, be able to opt out of the derogation provided by Article 8 and submit an application for assessment in accordance with Article 7, providing the full scientific data (and incurring the associated costs etc as per the current NFR) – as for any genuinely "novel" food.

7. Detailed rules for the implementation of this Article shall be adopted in accordance with [standard EU procedures], before the date of application of this Regulation.

- The proposed date of application has been changed in the Council text from **6** to **24 months** from its OJ publication date. Requiring the Commission to produce implementing rules within this much-extended deadline would be a seriously retrograde step, introducing a potential further 18 months delay for those parties wishing to submit an application under the new rules. The implementing rules must be established well within the implementation date to enable interested parties to begin to prepare an application as soon as possible. The previous period of **6 months** should be re-instated.

- ***Article 9*** also provides for the production of technical guidance: […] before the date of application of this Regulation the Commission shall, where appropriate, in close cooperation with EFSA and after consultation with interested parties, make available technical guidance and tools to assist interested parties, in particular food business operators and especially small and medium-sized enterprises or other interested parties in preparing and submitting applications under this Regulation.
  - We note that, since traditional foods are a sub-set of novel foods, and are not specifically excluded from this Article, it will also apply to them.
  - The comments under Article 8.7 are equally applicable to this Article. Parliament proposed that assistance should be available within **6 months** and to be publicly and easily available. This period of **6 months** should be inserted here.

- In assessing the safety of novel foods, EFSA shall in particular and where appropriate:

(a) compare, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;

- The first element (*"comparable food category"*) will be of direct relevance to the comparative assessment of traditional foods from third countries such as fruits and vegetables, since several well-known EU fruits and vegetables are known to contain potentially harmful constituents but which are managed by well-established

processing and preparation techniques (e.g. cassava, red kidney beans, rhubarb and green potatoes amongst many others). Equally, the EU and individual MS have risk management procedures in place to cover the harvesting of shellfish and fungi that might otherwise represent a serious risk to human health.

- The second element, the concept of *"intended to replace"* is nebulous and, in the absence of further clarification, has the potential to introduce considerable legal uncertainty. Any food or drink can be argued to be capable of replacing and, by extension, be "intended" to replace another; e.g. an exotic fruit or vegetable could replace a conventional food whether as a meal component or as a snack. However, in practice, the introduction of a traditional food into the EU is unlikely to be "intended to replace" another but, rather, to ***add diversity*** to diets, or ***add foods*** that are known for being high in particular nutrients, or attractive new flavours, etc.
- Sub-paragraph (a) implies that, if a traditional food is found not to be as "safe" as an existing EU food in a comparable category, this may be used as a reason either to deny authorisation or, at least, to impose post-market conditions such as additional labelling or monitoring. Intriguingly, therefore, in the event that the converse were true, and a traditional food were to be found to be SAFER or, taking into account the criteria required by Article 6(c), MORE NUTRITIOUS than a food in a similar category currently consumed in the EU, a logical and equitable conclusion would be that the pre-existing food should be withdrawn from the market or, at least, become subject to specific additional measures.
- The application of dual standards against potential imports by the EU authorities would potentially introduce WTO issues.

(b) take into account the history of safe food use.

- This sub-paragraph duplicates the specific provisions for traditional foods in Article 8.4 but, since traditional foods are not derogated from this article, risks parallel criteria being applied. It should therefore be redrafted to EXCLUDE traditional foods, thereby ensuring they are subject only to the requirements of Article 8.

We address the essential question, how to establish safe history, in ***Section F***.

- For food safety reasons and following the EFSA opinion, EC may impose product-specific post-market monitoring requirements; business operators placing the food on the Community market shall be responsible for implementing these. The producer shall forthwith inform the Commission of (a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food; (b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.
  - This Article will also apply to traditional foods; it thus appears to contradict the requirements of Article 8 whereby general obligations in respect of traditional foods are to be met by the wider concept of interested parties.
  - The principles behind this Article should therefore be re-drafted in respect of traditional foods and transferred to Article 8.

- No later than 3 years after the date of application of this Regulation and in the light of experience gained, the EC shall forward to Parliament and Council a report on [its] implementation and, in particular, of Articles 3 and 8, […], accompanied, where appropriate, by any proposals. The reports and any proposals shall be made public.
  - Traditional foods are not specifically excluded from this Article, and will therefore be covered by the Report.

- Within 24 months from the date of publication, the EC shall establish the Community list by entering novel foods authorised and/or notified under [the current NFR] in the Community list, including any existing authorisation conditions, as appropriate.

- Several traditional foods have been (e.g. Baobab and Noni derivatives) or will shortly be (e.g. Chia seed and Noni puree) authorised as "novel foods"; for consistency, they should be added to the proposed list of traditional foods under the revised NFR.
- 24 months appears extremely long for a simple administrative task (the previous draft specified 6 months). An updated list of novel food approvals is regularly published by the EC; we propose this should be adapted and formalised as the initial Community list within 3 months.
- It would also be highly beneficial for all parties for the EC to formalise and enhance the performance of the web-based "Novel Foods Catalogue", recording the discussions and status of traditional foods, food supplements, extracts etc. It should also consider adding a section on the regulatory status of selected traditional foods from third countries in other principal markets.

- This Regulation shall enter into force on [the 20th day] following [OJ publication]. Subject to paragraphs 2 and 3, it shall apply from [24 ~~six~~ months after date of publication]. Article 17 shall apply from the date of the entry into force.
  - There are minor inconsistencies in the draft concerning dates from which Article 17 will apply - 24 months from publication (Art. 17) or 24 months from entry into force (publication +20 days, Art 20).

D) KEY TERMS AND BASIC DEFINITIONS

Consistent application of the current Regulation has been hindered by different interpretations of several key terms, resulting in different interpretations as to what are considered as "Novel Foods". The proposed revision currently also contains a number of loosely-defined direct or indirect references to several key terms and concepts, even within the definition of a "novel food" itself, including therefore traditional foods from third countries.

The opportunity should therefore be taken during discussion of this revision to develop more precise definitions of these key terms to enable consistent application of the concepts. Where it proves not possible to develop a concise, legally-acceptable definition, they will need to be explained in a way that makes the concepts as clear as possible to all parties, if necessary in implementation guidelines.

Significantly, the Regulation already recognises the weakness and uncertainty of the proposed definition of "novel food" and other key concepts by providing numerous instances where uncertainties are to be resolved via standard EU administrative procedures.

Considerable uncertainty will surround interpretation of the scope and other requirements of the Regulation from the use of terms and descriptive concepts such as "history of use" and "history of safe use", "significant consumption", "customary/normal diet", "large part of the population" and even what is meant by "a country" in the context of an extended period of history in certain regions of the world from which traditional foods may be expected to originate.

More precise definitions of key terms, even within the definition of a "novel food" itself, are required to enable consistent application of the concepts and, if this proves impossible, clarification should be given in implementation guidelines.

This section explores possible ways to resolve this issue. It recognises, however, that is unlikely that legally precise (and concise) definitions for all aspects can be developed but the authors believe that their discussion of the issues may contribute towards the development of an appropriate set of criteria that would need to be met.

1) "Novel Food"

The proposal defines "novel food" as ***food*** that has not been used for ***human consumption to a significant degree*** within the Community before the 15th May, 1997.

"Food" is specifically and widely defined in EU law[19]; **Annex I** gives further details.

i) "Human consumption to a significant degree"

A number of closely-related issues derive from this concept, all contributing to the difficulties faced by potential exporters.

The proposal clarifies that the use of a food exclusively as or in a food supplement is not to be taken into account as evidence of prior consumption of that food to a "significant degree". Notwithstanding, foods with prior, exclusively food supplement use can continue to be marketed throughout EU-27 without being considered as a "novel food".

[19] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and laying down Procedures in Matters of Food Safety: OJ L31, 1.2.2002, p1

Many authorities have also linked "significance" of consumption with availability in supermarkets and general food outlets, and have taken the view that sales through pharmacies should also be discounted. The validity of these exclusions is inappropriate in EU-27, where retail sale practices and consumption patterns not only differ widely between Member States but significantly more widely than in EU-15 (i.e. the MS in 1997). In some countries, sales through pharmacies may be as much for marketing reasons as a legal necessity derived from any pharmaceutical properties, and may, in some cases, be considerable.

Food supplements are a sub-set of food under EU food law and the legality of excluding supplement use could be open to legal challenge, although to the authors' knowledge this has not been done. It is also a moot point whether refusing to accept the full range of availability of the products (i.e. legally-defined "foods"), and then using "lack of consumption of the food" as part of the argument to block imports of third country products, might also be regarded as a non-tariff barrier.

Further, any historic "general availability" of a food should also be recognised and taken into account, such as any former, local production and/or historic, traditional types of domestic consumption by any ethnic groups within any part of any of the EU-27 member states, not just sales via retail food outlets. As with consumption history in third countries, a product may have been grown / eaten in Europe many years ago but not in recent times (for economic, just as much as for safety reasons).

Countries such as Canada[20], Australia and New Zealand[21] have similar legislation on novel foods. These are explored in detail in ***Section E***.

ii) The meaning of the term "Significant"

This can be either a qualitative or quantitative term, the interpretation of which is likely to vary according to the (subjective) priorities of the user and the recipient / interpreter of the term. In its broadest use, what is "significant" to one interest may be wholly "insignificant" to another, despite the objective facts under consideration clearly being the same. On the other hand, in the case of nutritional significance outlined above, very precisely defined criteria may be set for a variety of parameters.

The use of the term in a Regulation (i.e. legally-binding, *verbatim,* text), without quantitative definition in terms of measurable parameters relevant to the specific subject, fundamentally contradicts the principles of clear and unambiguous legislation and the potential for its uniform interpretation and application.

iii) The meaning of "Significant Consumption"

The absence of a clear and precise, legal definition on which authorities and business operators must judge whether a traditional food would fall under the Novel Foods legislation remains unacceptable. The concept is ambiguous and can be interpreted as referring to either or both the quantity consumed ("quantitatively significant") or to its nutritional contribution to health ("nutritional significance").

"Significant consumption" (measured **quantitatively**) should be considered as an appropriate combination of geographical / historical availability and the quantity consumed by relevant populations over a period of time.

However, ***"significant consumption"*** (measured **nutritionally**), whether beneficial or adverse, is a different concept that may be associated with the consumption of relatively small quantities

[20] http://www.hc-sc.gc.ca/fn-an/gmf-agm/index_e.html
[21] http://www.foodstandards.gov.au/foodmatters/novelfoods/

of a food but which must also take into account other components in the diet at any point in time and the nutritional relevance of its consumption by different genetic and ethnic populations.

The **nutritional significance** must therefore be considered separately from the **quantity** of previous consumption.

The ***"significance of the consumption"*** – from an overall **food safety and nutritional** viewpoint – must recognise and encompass global consumption but, dependent upon the nature of the food, its target market/population and the anticipated volume of that consumption within the EU, may require taking into account ethnic variations between existing and potential consumers. This is one element of the risk assessment, and is not related to the numerical definition of **"significant consumption"**.

This may be a particularly relevant consideration in the case of, for example, fruits and vegetables that may be expected to be consumed in relatively large quantities at any one time both for general sustenance and even for pleasure, where food safety will be a major consideration in view of the quantities that may be consumed by any one individual.

The basic criteria for the scientific assessment of both prior and anticipated consumption must be clearly established in the proposed technical guidelines; however, they can only be applied to each application on a case-by-case basis.

iv) Cut-off date of the 15th May, 1997

It is already very difficult, and will progressively become almost impossible, for a potential importer into the EU or potential exporter to the EU to prove imports of a given product pre-1997, unless it has become widely known and consumed (e.g. aubergines, carambola, rambutan). Many exotic foods are likely to have been introduced into a new market through immigrants, by family-run businesses or SMEs that change / disappear quickly, making the documented history of these products difficult, if not impossible, to trace.

In addition, historic and precise identification of imports may be difficult since accurate official export statistics, that would allow precise identification of the products, frequently do not exist in the originating countries. Furthermore, the precise identity of the product may not appear in import statistics. By their nature (and almost by definition), "novel" foods do not have their own tariff lines, making a history of trade very hard to prove. The Harmonised Tariffs Schedule, even at the fraction level (12 digits) would not reflect the true botanical origins of exotic products which would thus likely be classified as "others" at the 6 or 8 digit level. Often, traditional fruits and vegetables are likely to have been documented under "popular" descriptions that would not necessarily have reflected the true botanical origins of the products.

However, the existence of local immigrant communities can be easily and officially demonstrated, and could form the basis of simpler measures to indicate the likely presence of "exotic" foods pre-1997. For example, if a free trade regime existed between a country and the EC and a sizeable number of immigrants from that country/region have been living in the EC for an extended period, it is likely that certain products would already have been imported, albeit with inadequate (in today's climate) documentation and would thus be excluded from the criteria of being a "novel" food.

2) "Traditional Food from a Third Country"

"Traditional food from a third country" is defined as "a Novel Food *(i.e. one that has not been used for **human consumption to a significant degree** within the Community before the 15th May,*

1997) with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least 25 years *[previously suggested as one generation]* in a large part of the population of the country".

This definition raises several issues that merit further consideration; these are discussed below:

- How is a "history of food use" to be quantified and validated?
- Is it appropriate to state a specific number of years (e.g. 25) or should another (longer) period be specified, more closely linked to the general linguistic meaning of "tradition"?
- What is meant by "the normal diet"?
- What is meant by a "large part" of the population?
- Is it appropriate to base the "large part" on the total population of a given country, or should **ethnic/cultural sub-groups** within the population also be considered?
- Is it appropriate to base the criteria only on a single country, or should **"regions" within or across more than one country** be taken into account?
- The extent and importance of existing non-EU markets to which the food is already being exported.

i) Time Period for History of Use

We believe a clear distinction should be drawn between the time scale over which a food can be shown/reliably reported to have been consumed ("history of use") and the period over which a reliable body of acceptable evidence has accumulated that can show that the food had been consumed with an acceptable degree of safety ("history of safe use").

Various proposals have been made during the development of the draft revision to NFR on how best to define / express the time periods on which the use and safety of a "traditional food" should be based. For example, consideration has been given to whether "one generation" is an appropriate period and, if so, what should comprise "one generation" or what alternatives might be considered? The EP IMCO proposed ***20 years***, the Council ***25 years*** and EP AGRI considered that the period of safe use must be "precisely defined" in order to ensure that the product is "perfectly safe" to use, and proposed a ***50-year*** period instead of the general expression 'one generation'. However, other considerations may also need to be taken into account *(see **Section D.3** below for further considerations of the concept of "tradition").*

The key questions, therefore, are the appropriate duration of the period of "traditional use" and whether the timeframe for defining it should be as concise as possible or whether it would be more appropriate to describe it (as done in Canada) as being "a number of" generations".

There is a strong argument that the concept of "traditional foods with a history of use in a non-EU country" (as is likely to be understood by the average consumer and indeed reflect linguistic constructions), when applied to foods such as fruits and vegetables, evokes an expectation that they would have a history of use spanning at least "several generations" without necessarily being able to put a fixed timescale to the precise period. A mechanism for validating this extended period of use, using recognised international historical bodies and the exporting countries' competent authorities, has been proposed previously[22] and is summarised in ***Section D.3(ii)*** below.

On the other hand, there are numerous cases where a traditional food has been used for many generations but only relatively recently have certain derivatives, such as juices and preserves, produced by conventional processing techniques become available. The development of these new products (from traditional foods), suitable for modern markets, is now a major driving force for the renewed interest in the traditional crops themselves. For example, yacon (an

[22] EU Novel Food Regulation: Discussion Paper on behalf of UNCTAD/CBI, Neville Craddock Associates, Nov 2005: http://www.biotrade.org/Events/events_docs/events-dec05-NovelfoodsCBIUNCTADpaperonEUNovelFoodRegulation.pdf

Andean root crop) has been used for millennia for fresh consumption, but the most economically promising products have only recently become available (syrup, dried slices...).

Reliable evidence of the use of the food over a more extended period would reinforce (but could not replace) the "evidence of safe use" that will have to be submitted as part of the application process. However, whilst strong evidence of 25 years of consumption would be a useful guide to safety, an application under traditional food status for a product on the basis of only 25 years of use is likely, in reality, to be subject to greater levels of scrutiny in terms of the quality of the data provided, including chemical composition and a risk assessment based thereon.

Notwithstanding the issues for determining an appropriate period of use of the product and derivatives, the Council draft text adds further complexity by referring to traditional foods as being *"derived from primary production…"*. The precise scope of this phrase is unclear, *(see discussion in **Section D.3.(iii)** below)* but, if the intention is to restrict authorisation only to the basic crop - but to exclude simply processed derivatives – this raises the WTO-related question of how such crops could then legally be permitted to be processed within the EU, yet the processed products be barred from entry to the EU, when produced using conventional food technology and in accordance with EU hygiene standards in a third country. Equally, a requirement for all derived products to be subject to individual, specific authorisation risks perpetuating the complexity of the current NFR and its perception as a barrier to trade.

A further question must also be addressed: namely whether the threshold period (e.g. 25 years) should be linked to the date of application of the Regulation (i.e. **"fixed 25 years"**) or to the date of submission of an application (i.e. **"rolling 25 years"**). The cut-off date for determining that the traditional food is subject to the revised NFR is determined by Article 3.2(a) and whether it has a history of consumption in the EU prior to May 1997. However, this is separate from the definitions of traditional use and safe history of use introduced in Articles 3.2(d) and (e), which only become fully applicable 24 months after publication of the revised regulation (say, mid-2012). Thus the "25 years" criteria pose two possibilities:

- ***"fixed 25 years"*** would set ca. mid-1987 as the cut-off date for the history of traditional foods in the third country, based on the date of application of the revised Regulation (e.g. 24 months after its publication); an alternative suggestion of a cut-off date of May 1972 (deriving from the 1997 date for being a novel food) does not appear to be consistent with the drafting of the latest text;

- ***"rolling 25 years"*** would mean that, by 2022, the initial consumption date for the "traditional" food in the third country could be more recent than the basic criterion (1997) for "novel food" in the EU – this would be illogical and does not appear to accord with the concept of "tradition";

Overall, therefore, the authors believe the short, 25-year period risks extending the scope of the use of "exotic" traditional foods too widely, but may be the appropriate period over which the evidence for the safety of their use could be established. However, in line with our commentary above on the definition "derived from primary production" and the more recent availability of processed derivatives, it would then be necessary to ensure that the use of a longer period to reflect the traditional use of the crop does not limit the scope of "traditional foods from third countries" only to those processing techniques that go back as far, thereby excluding newer, already well-recognised transformation and processing techniques from being used in the third country (but remaining available for use within the EU).

ii) "Normal" or "Customary" Diet

The EP Report defines a traditional food in relation to it having a history of food use as part of the "normal" diet for 25 years; however, the same report defines "history of safe food use" in terms of use in the "customary" diet for 30 years. Whilst there are anomalies in the time-scales

specified, consideration must be given to the question of what, in practice, comprise "normal" or "customary" diets within what may be a diverse cultural and ethnic population, spread over the very wide geographical area that may comprise the "country" in which this use must be demonstrated (in many cases, far larger than most EU Member States) and the relevance of this consumption to the EU population.

There is a linguistic distinction:

- ***"normal"*** implies a ***regularity of consumption*** of a diet that has (in some way) been defined as a standard for a typical member of a population;

- ***"customary"*** refers to the diet that itself forms **part of the custom and tradition** of a society, without inferring any degree of regularity of consumption.

This distinction may be illustrated by reference to examples of EU foods that are widely known and customary, but exceedingly rarely consumed, either because of seasonality (fungi), rarity/price (truffles), perishability ('strawberry tree'/Arbutus unedo, 'white mulberry'/Morus alba), or highly localized use (horseradish, certain vegetables). The NFR cannot require traditional foods from outside the EU to meet higher requirements in terms of "normality", regularity or "customariness" of consumption.

Many foods may already be regarded as "traditional" by the widely diverse cultures within and between the MS, but it is not necessary for a given food to be consumed frequently, or at regular short intervals, for it to be considered as a part of the "normal" diet, nor is it necessary for a food to be consumed by a representative cross-section of the whole population. Typical examples of the former would include speciality foods (and beverages) consumed periodically (and intermittently) during national and family festivals and celebrations such as birthdays and weddings; examples of the latter would include speciality foods consumed only within, but regularly by, specific religious groups or nationalities.

We are of the firm opinion that the EU Regulation must recognise not only the seasonality of many "traditional foods" but also that many may have, historically, been "harvested from the wild" and therefore their supply may itself have been subject to periodic failures and their consumption irregular. Even more importantly than periodic failures in supply, the globalization and increased uniformity of diets in the last 20-30 years, has resulted in many crop-derived foods falling out of use even though they have been significant components of local diets in the more remote past (100, 200, 1000 years ago). Reasons for the consumption decline of many traditional foods include substitution by introduced foods, excessive perishability, production costs, unawareness of nutritional value, inconvenience of use (particularly in urban contexts), and stigma as "poor people's food". To the extent to which such supply and demand constraints are overcome in modern markets and supply chains, many traditional foods have seen a significant reversal in popularity. In assessing what constitutes "normal" or "customary" consumption patterns, the EU authorities must recognise that that today's, short-term food patterns are a snapshot in time, which does not necessarily reflect the historical exposure of people to foods that may, itself, have varied dramatically.

The EU Regulation must be worded to ensure that a broad interpretation of dietary consumption by the peoples of the region where its history can be demonstrated is used.

The difficulties of establishing tangible evidence of prior consumption in the EU have been described above; additionally, as with consumption history in third countries, a product may have been grown / eaten in Europe many years ago but not in recent times (for economic, just as much as for safety reasons).

In assessing the relevance of the "history of use", it will also be necessary to take into account a realistically-assessed, likely volume and cultural distribution of the potential market for these foods within the EU population. In particular, it will be necessary to consider the extent to which the anticipated consumption patterns in the EU may be expected to reflect those of the population in the country / region of origin and whether such consumption is likely to be sporadic or part of the mainline diet of a sector of the European population. The level of evidence ("proof of safety") required should then be commensurate with the level of perceived risk, taking into account a realistic estimation of likely EU consumption patterns.

Where this realistic assessment of anticipated consumption patterns suggests these are likely (at least, initially) to be small, sporadic and restricted to a clearly identifiable sector, it may be possible to afford a proportionately greater weight to the evidence of historical use in the country of origin but to impose a clear requirement for a well-defined post-market surveillance scheme to ensure that the actual consumption patterns in the EU do indeed reflect those initially anticipated. Post-market monitoring is already envisaged under Article 11 as a potential responsibility of the business operator; its effectiveness would be highly dependent on reliable traceability systems being in place across the supply chain.

iii) "Large Part of the Population of the Country"

The concept of a *"large part of the population of a country"* potentially introduces numerous inconsistencies. It does not, per se, take into account several key issues:

- how the **"large part"** is to be defined, particularly in relation to the statistical validity or nutritional and/or toxicological significance of the numbers involved;
- the **"population of a country"** can range from tens of thousands to hundreds of millions of people;
- the **"population"** of many countries is not a homogeneous group, but may comprise several ethnic and/or religious sub-populations, each with their own differing long-standing dietary habits and preferences;
- these ethnic / religious groups may comprise, numerically, only a small proportion of the overall population and live in a small area (**"region"**) of a given country, yet still represent a discrete and identifiable "population"; equally, these ethnic / religious populations may be more thinly spread within a given country but be represented more widely over several countries (i.e. a wider, geographical region that shares a common cultural history);
- further, the concept of "a (single) country" does not address the politically-driven changes to country boundaries that have occurred in some regions (e.g. Africa) well within the timescales of the use of traditional foods.

The concept is intended to introduce a measure of the "significance" of the consumption of the traditional food as one element in assessing the value of the evidence of its history of use, and the safety of that use. However, the actual size of the population of the country of origin must also be factored into the consideration. For example, some island communities with a range of traditional foods may have a population measured in tens of thousands, for which a "large part of the population" might be regarded as 40,000 people. Conversely, India, China, Brazil and several of the emerging nations have a population of several hundred millions, where 40,000 would not event be a fraction of one percentage of the whole population. Within the Andean Community, where there is considerable interest in EU novel foods, populations range between 9.5 million (Bolivia) and 45 million (Colombia).

In many countries, the population is not a homogeneous group; rather it comprises several, potentially widely-different ethnic or cultural groups. Further consideration must therefore be given to what, for the purpose of a meaningful dietary or historical significance, is to be understood by a "large part of the population of the country" – i.e. how can or should the "large part" be defined, particularly in those cases where the total population in a given country

comprises several ethnic groups, each with their own different long-standing cultures and religions that impact on their dietary habits and preferences? For example, wide climatic and topographic diversity in a country such as Peru, which is divided into 3 mega-regions (coast, Andes, Amazon) each with numerous ethnic groups, and varying agro-ecological conditions that extend from the hot and wet tropics to sub-arctic growing conditions, results in great "compartmentalisation" of local diets and makes it impossible for a major part of the population of that country to have access to a large range of products, except those food commodities traded over large distances in the country (which is a minor fraction of all foods available). It would be inappropriate, therefore, to base the criterion on a simple arithmetical consideration of a country's total population; rather, it will be essential to take into account the individual ethnic and cultural groups and overall make-up of the population and to judge the significance of the reported consumption patterns accordingly on a case-by-case basis.

Further, it is not appropriate to restrict the criterion to a country (i.e. "the country of origin") when, in practice, the food may have been and continue to be part of the diet of ethnic and cultural groups that may reside also in neighbouring or, in the case of long-standing export markets, a wider group of countries. Consideration must also be given to "regional" consumption, whether the region may lie within a single country or comprise several countries or parts of countries with a common cultural history or, considering that consumption of a food usually relates to its presence in the wild or under cultivation, within the natural range of the crop species in question. The focus should remain on "the country of origin" but be supplemented by information obtained from the country or wider region in question.

Traditional foods are likely to originate from global regions where recent history has resulted in significant changes. The concept of "a (single) country" does not address the politically-driven changes to country boundaries that have occurred in some regions (e.g. Africa) well within the timescales of the use of traditional foods.

We therefore suggest that the criterion should be determined by the food having been, and continuing to be, a recognised part of the overall diet of a significant proportion EITHER of the total population OR of any identifiable, discrete minority population within one of the following:

- the country on which the notification is based
- an identifiable region within that country
- an identifiable region of which that country is recognised as forming a part
- the natural range of the crop species in question.

3) "History of Safe Use" and the Concept of "Tradition"

Very few "traditional foods from third countries" have been subjected to systematic toxicological and nutritional assessment in accordance with modern scientific standards, yet because of their long history of use, allied to customary preparation methods, and absence of evidence of harm, they are generally regarded as safe to eat. There is nothing unique or surprising to this; it is also the case for most of the foods regarded as traditional from within the EU, which have never been subject to the type of assessment required from the NFR.

Considerable uncertainty surrounds interpretation of the scope of the proposals in the draft Regulation as a result of the use of terms such as "history of safe use". This paper explores possible ways to resolve the issues. It recognises that it will be difficult, even unlikely, for legally precise (and concise) definitions for this class of products to be developed, but the authors believe it may be possible to develop an appropriate set of criteria to provide a clear framework within which key decisions can consistently and transparently be made.

Determination of whether a product has a ***"history of safe food use"*** is also subjective. The concept relies on the assumption that there has been a lengthy history of food use in a particular

country or culture sufficient to show that any risks are probably acceptable. However, without extensive scientific and toxicological studies, it is impossible to be certain if something is safe in the broadest sense. In the case of traditional foods, as with all foods, the goal is an "acceptable level of risk". Since it is in the nature of the parameter (history of use, rather than toxicological studies) that the modern scientific concept of "safety" has not been expressly determined, the alternative statement ***"history of use, with reasonable certainty of no harm (taking into account accepted, manageable mechanisms to avoid that harm)"*** would better reflect that "zero risk" is never achievable, but minimized risk is possible, whilst taking into appropriate account such parameters as ethnic variations between existing and potential consumers.

The need to take full account of ***"customary knowledge", "traditional"*** experience and history of safe use outside Europe is essential. The recent example of Chia seeds demonstrates this well[23].

The OECD considers "a long history of use is a reassuring and practical starting point" for evaluating the safety of a novel food[24] and describes "history of safe use" as the cumulative body of knowledge derived from the use and experience of that food, within its cultural context and conditions of use, which in practice describes its established safety profile. This profile also describes known limitations and restrictions for sensitive populations, e.g. anti-nutrients, toxicants, and allergens.

ILSI also reviewed history of safe use as applied to novel foods[25], and considered that evidence of previous human consumption of the novel food should demonstrate significant human consumption, ideally over a period of several generations by a diverse population covering a range of genetic backgrounds and age groups. ILSI also emphasised that the whole of the information must be considered together, and that history of safe use does not rely simply on specific criteria (such as the number of years of use).

Proposals for pragmatic means to establish "history of safe food use" are given in ***Section F.***

i) Traditional Foods and Exotic Traditional Crops

A wide range of natural food resources are potentially available from developing countries and, historically, several were the origins from which many of the world's agri-food crops were developed. However, the introduction to the EU of further new foods, "traditional" in their country of origin, has in effect been blocked or at best severely impeded since 1997 due to the difficult and expensive NFR requirements.

Consumption of these foods can be locally significant, but they are largely unknown outside these local regions, and often even outside their "insular" distributions within these regions. Whilst there is little formal knowledge on food composition and post-harvest processes, the wholesomeness of many of these species for consumers in their native range, often at high intake levels, is beyond doubt.

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[23] In 2003, an application for **Chia seeds** was submitted to the UK ACNFP. Their positive opinion was supported by some Member States but others presented "reasoned objections". EFSA concluded that the compositional data were insufficient to perform a full nutritional assessment; it identified uncertainties with regard to the allergenic potential; adequate toxicological information was not available and "the presence of constituents that might exert anti-nutritional or toxic effects could not initially be excluded". Therefore additional studies were required before the safety of Chia could be adequately established. In its updated Opinion in March 2009, EFSA stated: "The toxicological information on Chia seeds from animal and controlled human studies is limited. However, experience gained from previous and current use of Chia seeds for food purposes in non-EU countries can be regarded as supportive evidence to allow a positive conclusion on the safety of Chia seeds and ground whole Chia seeds under the proposed conditions of use. Based on the available data, the Panel concludes that it is unlikely that the use of Chia seeds in bread at a maximum of 5 % would have an adverse effect on public health." It is understood that a positive Decision has now been agreed between the Commission and MS but is still to be made publicly available.

[24] Organisation for Economic Co-operation and Development, Paris. OECD Observer No. 216 p. 21, 1999.

[25] Food and Chemical Toxicology 45 (2007) 2513–2525

Most of these crops are "domesticates", i.e. they have been associated with mankind for millennia and have evolved to fit human needs of cultivation and nutrition. Domestication (as opposed to mere cultivation) typically implies significant morphological changes and the development of agricultural multiplication methods, as well as selection for low levels of anti-nutritional substances (as compared with wild types), relatively high consumption levels and long experience of safe use.

A significant number of species, both from domesticated and wild sources, are closely related to - albeit taxonomically distinct from - traditional EU food sources or pertain to families (e.g. *Brassicaceae*, *Chenopodiaceae*), well-known for a variety of important vegetables.

Several foods, popularly known by a generic name may be derived from a variety of plant species. For example, "palm hearts" are produced and traded from species of different genera; certain starches, such as arrowroot starch, which can be derived from as many as four clearly distinct taxa; the generic trade name "yams" is used for a series of tropical tuber crops. If the NFR is to achieve its stated purpose, it must recognize this fundamental problem; appropriate EU assessment will depend on accurate identification of the traditional food; possible solutions are outlined in ***Part 4*** below.

ii) Obtained from Primary Production

Article 3.2(d) defines a "traditional food from a third country" as one that has been "obtained from primary production" but does not specifically define the scope of this phrase, which could be interpreted as restricting the Article 8 procedure for traditional foods only to raw, whole fruits and vegetables. With the exception of foods (largely additives or 'functional ingredients') produced by the chemical industry, ALL foods can legitimately be stated to have "been obtained (i.e. originated) from" primary production (i.e. agriculture, wild harvesting or hunting).The reasons for this wording in Article 8 are not apparent, but the consequences of a restrictive interpretation are potentially unacceptable.

Restricting authorisation ONLY to the basic crop (i.e. raw fruits, vegetables and, potentially, fish and animal species), but continuing to ban imports of simply-processed products derived from these would raise the WTO-related question of how such crops could then legally be permitted to be processed within the EU. It would be illogical, and inconsistent with WTO principles, to permit further processing of the raw products within the EU (e.g. into juices or compound foods into which the traditional food may have been included as a processed ingredient), yet to bar the equivalent processed products from entry to the EU, even when legitimately and safely produced in a third country, using the same conventional, well-recognised food processing techniques and fully in accordance with EU hygiene standards. Any exclusion of further processing of traditional foods and/or their use in products would also have to apply to the raw products after import into the EU if risks to WTO contraventions are to be avoided. This, in turn, would effectively result in minimal imports of the foods concerned and risk being seen as a non-tariff barrier.

If, however, the intention is not to ban the import of processed derivatives of traditional foods, this needs to be made clear in the Regulation.

Recital (6) of the Council Common Position (June 2009) introduces a qualification whereby "it should be clarified that foods from third countries which are novel in the Community can be considered as traditional only when they are obtained from primary production as defined[26] in Regulation 178/2002, ***whether they are processed or unprocessed (e.g. fruit, jam, fruit***

[26] Regulation 178/2002 defines "primary production" as "the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products."

juice)… ". However, although this might appear to resolve the issue, this text has not been incorporated into the legal definition of a traditional food in the Articles of the draft Regulation and the intent, scope and consequences of inserting **"originating from primary production"** must therefore be clarified.

Equally, a requirement for processed products to be subject to individual, specific authorisation risks perpetuating the complexity (and bureaucracy) of the current NFR and its perception as a barrier to trade.

As a minimum, we believe the revised NFR should encompass the following within the traditional food concept:

- whole raw fruits/vegetables; and processed foods containing them, produced using "non-novel" technologies – in the sense of NFR definitions of the term, as opposed to IP rights;
- derivatives of whole raw fruits/vegetables using "non-novel" technologies but which exclude the whole raw fruit/vegetable.

In the case of the latter, the manufacturing process might eliminate components of potential safety / toxicity concern (e.g. oil from a nut but without the protein from the nut).

iii) "Traditional use"

In language, the expression "traditional use" can apply to either ***time-related*** use or the ***nature of the application/use*** of a material, or both. These are briefly discussed in (a) and (b) below.

There is no directly applicable definition of "traditional" for the purposes of <u>general</u> EU food legislation, although the term is defined for the specific purposes of the DG Agriculture legislation on "Traditional Speciality Guaranteed" products[27] whereby it means proven usage on the Community market for a time period showing transmission between generations; this time period should be the one generally ascribed to one human generation, at least 25 years.

There is thus a potential argument that the EU must be consistent in its criteria for "tradition" for internal and external food issues, and that this period should therefore be accepted for traditional foods from 3rd countries.

The term is also defined within the Traditional Herbal Medicines Directive[28] which enables certain products that meet specified criteria to avail themselves of a simplified registration procedure. This Directive requires bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least <u>30 years</u> preceding the date of the application, including at least <u>15 years</u> within the Community.

(a) Time-related use

A comprehensive study by the UK Food Advisory Committee (FAC, 2001)[29] into the legal use, scope and understanding of the term *"traditional"* concluded that it was not possible to develop a specific definition that would be applicable in all cases to all products. Nevertheless, its commentary and findings are relevant to the consideration of history and use of "traditional" foods in 3rd countries and provide a framework within which these products could be considered. Details are in ***Annex IV***.

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[27] Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed; OJ L 93, 31.3.2006, p1

[28] Directive 2004/24 of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use; OJ L 136 p85; 30.4.2004

[29] FAC Review of the Use of the Terms Fresh, Pure, Natural etc. in Food Labelling 2001; Report No FSA/0334/0701.

The FAC examined a wide range of current applications of the term to food products and processing, and concluded that the term ***"traditional"*** should relate to the following:

- anything communicated from ancestors to descendants, generally by word only;
- things pertaining to time-honoured orthodox doctrines;
- long observed historic customs or usage;
- handed down practices that are valued by a particular culture.

FAC concluded that the concept of a 'tradition' – and hence "traditional" – must be clearly linked to the passing of a "considerable period of time". FAC felt that a suitable period was likely to be product-specific, and tentatively suggested that the period should be of the order of 2 generations / 50 years. However, in the light of other suggestions made to FAC that around 100 years might be more appropriate, it stopped short of making this a firm recommendation.

Recently-revised Canadian Guidelines require "**a number of generations**" as the basis to demonstrate a "history of safe use", although the initial consultation document proposed a more formal "3 generations / 100 years". However, it appears to us to be almost impossible to provide safety data dating back so long, particularly if it is required to be documented, although we note that in the USA, aural history is permitted as evidence for herbal remedies and, by extension, might be included in the Canadian approach.

(b) Traditional Applications

Foods or ingredients that have a history of consumption in the form of a generally-recognised food, forming part of a recognised, traditional diet among identified indigenous populations should all be regulated as "traditional foods". This would include the use of whole plants and conventionally-processed plant products as normal foods and as food ingredients in products such as juices and jams – i.e. either consumed directly as a meal or part of a meal or as a "conventional" ingredient in a component of that meal.

This use must be clearly distinguished from the use of selectively-extracted oils or dried powders etc obtained from traditional plants and consumed as food supplements in the form of pills, capsules etc, or when added as non-conventional, "functional" ingredients to a traditional food.

"Biologically active" botanical extracts and similar ingredients will be subject to specific risk assessment and safety evaluation procedures under specific EU food legislation on "Addition of Nutrients"[30]. Food supplements are also subject to their own regulatory and pre-existing food supplement use will not be impacted by the revised NFR.

4) Evidence of "tradition" in the country of origin

It will be essential to establish clearly the concept of **"traditional"** foods, and their part in the history and culture of the indigenous populations of non-EU countries. A key question is how, where and by whom, can scientific and/or historical evidence be produced that is considered valid: i.e. by applicant industry / national authority; university / research institutes; third country / EU?

In the case of plant-derived foods, this will require close collaboration between EU specialist plant breeders / taxonomists, food experts and nutritionists and their counterparts including

[30] 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: OJ L 404 30.12.2006 p26

local ethno-botanists in the appropriate 3rd countries. Potential products that could be considered for this type of collaboration were described by Mück in a 2003 GTZ paper[31].

A Working Group of the Nordic Council also examined in detail whether, and/or to what extent food plants not hitherto consumed in the EU need to undergo a full scientific safety assessment.[32] Their work also provides a valuable review of global studies of the contribution to human diets of food crops around the World and proposes a mechanism whereby food crops may be structured into a hierarchy of global, regional and local lists of recognised plant-based food sources. In the EU, the 1997 NETTOX project identified approximately 300 food plants that would be unlikely to be considered "novel"[33]. This work is being extended to cover EU-25 under the EUROFIR project[34] and should provide a most valuable contribution to the development of the materials suggested in our commentary on Article 17.

The commentary above focuses on plant-based products but similar collaboration would also be required between the corresponding specialists if consideration were to be given to traditional foods derived from animals, birds or fish species.

Ultimately, if an acceptable standard of evidence can be assembled, any risks associated with the use of traditional foods (and ingredients derived from them), should not exceed those from EU traditional foods, particularly as far as smaller intakes can be expected. A mechanism whereby the principles on which the Official Control Regulation (EC) 882/2004 is based could be extended to enable EU authorities to recognise and accept the validity of "official assurances" from competent bodies (e.g. governments / universities / museums / research institutes) in the 3rd country, relating to the "traditional" nature of a given crop and its botanical characteristics, have been described earlier[35].

Furthermore, if acceptable assurances from local experts about the food, its origins and history can be developed within an appropriate framework, it may also facilitate the protection and identification of "exotic traditional products" by virtue either of their geographic origin[36] or specific characteristics[37] and thereby further enhance the potential exports of traditional foods in a way that will be compatible with the EU's policy on aid to developing countries.

i) "Traditional knowledge"

The essential question is, effectively, "How can "traditional knowledge" and "modern science" be balanced, proportionately, to meet requirements for "scientific evidence" in safety dossiers?"

The concept of "traditional use" of a food in a non-EU country is very closely linked to that of "traditional knowledge". This is a broad concept that embraces both theoretical and/or practical understanding of an art or science, and reflects familiarity and acquaintance with facts,

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[31] Otto Mück: Trade Barrier NFR? Under-utilized Species under the European Union's Novel Food Regulation; Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, Global Facilitation Unit for Underutilized Species: October 2003 (and a related paper, April 2003): http://www.underutilized-species.org/documents/nfr/underutilized_species_nfr and http://www.underutilized-species.org/documents/nfr/Trade_barrier_nfr.doc

[32] Risk Assessment and Risk Management of Novel Plant Foods and Novel Plant Ingredients – Concepts and Principles: Nordic Working Group on Food Toxicology and Risk Evaluation, October 2005; chapter 5 and Annexes 1-3.

[33] Holm, S., 1998. NETTOX list of food plants prioritised for inclusion in a future European database. Report No.6 EU-AIR concerted action CT 94 2185: information on inherent food plant toxicants; Danish Veterinary and Food Administration, Søborg.

[34] European Food Information Resource: contract number FP6-513944, available at http://www.eurofir.net

[35] EU Novel Food Regulation: Discussion Paper on behalf of UNCTAD/CBI, Neville Craddock Associates, Nov 2005: http://www.biotrade.org/Events/events_docs/events-dec05-NovelfoodsCBIUNCTADpaperonEUNovelFoodRegulation.pdf

[36] Council Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs: OJ L 208, 24.7.1992, p 1

[37] Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs: OJ L 208 , 24.7.1992 p 9.

or a range of less-defined information, relating to habitual or commonly-used practices (i.e. in accordance with local "customs").

"Traditional knowledge" would include references to a long history of food practices and use by indigenous populations, including the traditional precautions that are integral to its safety. Thus, in addition to experimental scientific evidence, the NFR should admit traditional knowledge for food safety assessment. The combined evidence on a particular food from the ethno-botanical and anthropological literature as well as from anecdotal and folkloric sources can provide important pointers for safety assessment.

By comparison, certain of the existing approaches to determining "scientific safety" of foods in the EU (based on Recommendation 97/618/EC[38]) are not proportionate for many "traditional foods", seeming to seek "zero" or "proof of absence of" risk. As described in ***Section E*** below, a more appropriate approach would be to seek a "**reasonable certainty of no harm**", i.e. "an acceptable level of risk" for the food, based on the likely consumption patterns and precautions taken during its preparation.

Despite the very significant changes that have now been introduced into food safety legislation in the intervening 12 years, not least the separation of GM approval and control from NFR, Recommendation 97/618 continues to be applied in an extremely strict and disproportionate manner to some classes of "novel" foods for which it was not primarily intended. This results in "novel" products seemingly being assessed, inappropriately, against near-absolute parameters of "zero risk" (which does not exist) or proof of absence of risk (which mirrors the philosophical impossibility of proving a negative). In respect of "traditional foods", insufficient consideration has been given to the traditional management of known risks (e.g. selection of the parts of the food to be consumed, preparation methods and consumption patterns) that are integral to actual safety in use of the product, rather than the absolute safety of the raw material. Such risk management by the consumer is common within European culture, where many staple foods are safely consumed, despite significant risks being associated with the raw products (e.g. potatoes, red kidney beans, rhubarb, shellfish and fungi).

Throughout the life of Regulation 258/97, the authorities have emphasised that that the requirement is to demonstrate history of safe use – and that history of use alone is insufficient, regardless of the length of that use. However, there is an equally strong counter-argument that the wording, even of the current NFR, requires the applicant to demonstrate a history of safe use of the product (i.e. as consumed), not absolute safety *per se* of the raw material from which the food is prepared. It can therefore be argued that the long history of use by indigenous populations is itself strong evidence of safe use, since this very use is dependent on the management of known risks and would have been discontinued if a product were found to be disproportionately unsafe.

It is encouraging, therefore, that the Presidency text states that "Recommendation 97/618/EC should become obsolete as regards novel foods". We recommend that Recommendation 97/618 should be replaced by specific guidelines for the safety evaluation of traditional foods, focussing only on specific aspects and defining practical and proportionate mechanisms to evaluate potential risks, whilst retaining for consumers the level of safety they are entitled to expect. We further recommend that this should be done before the revised Regulation comes into force, not (as has been suggested) from its date of application some 24 months later.

Suggestions on how this might be achieved are given in ***Section F***.

[38] Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council: OJ L 253, 16.9.1997 pp 1-36

E) APPROACHES TAKEN BY OTHER COMPETENT AUTHORITIES

The Novel Food authorisation procedures implemented by the Competent Authorities in Australia & New Zealand (FSANZ) and Canada (Health Canada) are compared and contrasted to the EU Novel Food Regulation proposal.

1) Food Standards Australia New Zealand (FSANZ)

In Australia and New Zealand the sale of novel foods and novel food ingredients is regulated by Standard 1.5.1 of the Australia New Zealand Food Standards Code (see ***Annex VIII***). This standard describes the pre-market assessment requirements and includes definitions for 'non-traditional food' and 'novel food' (see also ***Annex VII*** for more details).

The requirements are based on a two step process. The first step is to assess whether the food has traditional use in Australia and New Zealand. If the food is classified as traditional then it does not require further pre-market safety assessment (see ***Annexes IX-X***)

If the food is *not traditional* then a decision is taken by FSANZ on whether that food is novel or not novel. Novel foods would need a safety assessment. Guidance Tool part 2 is used to support that assessment.

FSANZ may decide that a food or food ingredient is non-traditional but **not novel** and the basis for this view is that the available data suggests that there are no safety concerns. Hence not all non-traditional foods raise safety concerns and therefore, not all non-traditional foods are subject to the pre-market assessment requirements of the Novel Foods Standard. However, non-traditional and not novel foods can still have certain conditions of use attached.

i) Key Observations of the FSANZ Novel Food Standard and Procedure

1) A risk based approach that recognises that not all non traditional foods require a pre-market safety assessment. A non-traditional food under the FSANZ definition would (most likely) be considered as a Traditional Food from Third country under the EU Novel Foods Regulation Proposal. The FSANZ classification refers to the traditional or non traditional status in the destination market.

2) Establishes a two step procedure to decide if a food is Traditional or Non-Traditional. If Non Traditional then a decision is taken based on the evidence provided as to whether the food is Novel or Not Novel.

3) Uses a questionnaire with clear questions to elicit information about the food as part of the first step. The type of information /data required is proportionate.

4) Provides easy to read and understand guidance documents.

5) The principle upon which novel foods are permitted for sale in Australia & New Zealand is: *"there is reasonable certainty that no harm will result from the intended use of the food and... any risk management strategies are warranted to ensure the safe use of the food."* i.e. there is a presumption of safety based on the use in third countries.

6) 59 Non Traditional/Not Novel foods have been assessed as having no safety concerns identified (Record of Views: October 2009[39]) (see ***Annex XI***). This compares to 5 authorisations given by the European Union in total so far for foods that could be described

[39] http://www.foodstandards.gov.au/foodmatters/novelfoods/novelfoodrecordofvie3934.cfm

as Traditional Foods from Third countries: Noni Juice; Allanblackia seed oil; Noni Leaf Powder; Echium Oil and Baobab Fruit Pulp[40].[41]

7) Conditions of use can be specified for Non Traditional/Not Novel foods.

8) Assesses each application on a case by case basis

9) Does not establish a fixed date to establish history of human consumption but balances this against the other criteria

10) Provides an indication that food consumed for 2-3 generations in Australia is likely to be considered traditional but other factors are taken into consideration

11) The assessment process highlights the need for more information where this is required. For example, Hoodia and Ackee Fruit are non traditional foods for Australia and New Zealand but both are traditional in other parts of the world. However FSANZ has classified them as Novel Foods and therefore they would need to undergo a full safety assessment prior to a decision as to whether they can be permitted for sale.

12) Complementary to FSANZ Standard 1.5.1, FSANZ 1.4.4[42] lists the plants and fungi that (a) may not be added to food or offered for sale as food and (b) may not be used in food except as a source of flavouring substance.

2) Novel Food Regulations in Canada

The Canadian regulations on Novel Foods are contained in Division 28 of Part B of the Food and Drug Regulations (see ***Annex XIII***). The procedure is underpinned by the principle that foods that are widely consumed in other parts of the world may have adverse effects on consumers in Canada or there may be adverse effects associated to traditional methods of preparation.

The regulations also state that "*A substance may be considered to have a history of safe use as a food if it has been an ongoing part of the diet for a number of 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 Canada. The fact that a product has had a history of use according to the above definition in a jurisdiction with a similar food safety system would increase the level of confidence in the evidence presented*." The Regulation also includes a list of information that would be required (further details are given in ***Annex XII***).

i) Key Observations of the Canada Novel Foods Regulation and Procedures

1) The underlying principles for establishing risk assessment procedures for Novel Foods are that foods that are widely consumed in other parts of the world may have adverse effects on consumers in Canada or there may be adverse effects associated to traditional methods of preparation. Similarly, "foods derived from sources not previously used as human foods.....may contain toxins, contaminants and anti nutritional factors."

2) No explicit date is specified to determine when a food is classified as Novel. This is dissimilar to the 15 May 1997 date determined in the EU.

[40] 14 of the 58 FSANZ non-traditional/not novel foods are "not novel" according to the EC Novel Food Catalogue and 1 FSANZ non-traditional/not novel food is a food supplement in the EU

[41] In addition 2 positive draft Commission Decisions awaiting final adoption refer to Chia Seeds and Noni Puree. See SANCO 5566/2009 and SANCO 5794/2009

[42] Referred to as Standard 1.4.4 of the Food Standards Code (FSANZ) http://www.foodstandards.gov.au/

3) There is a single category for novel foods with 2 sub-categories for traditional food from countries outside Canada (plants, micro-organisms) as well as plants and micro-organisms having undergone novel processes or genetic modification.

4) All novel foods undergo a two stage process of notification and review. The outcome of the review determines whether a safety assessment is required or not.

5) Notifications are reviewed in a period of only 45 days.

6) Less structured guidance for the Notification step compared to the FSANZ approach.

7) Detailed guidance provided for the safety assessment procedures.

8) A wide range of evidence is allowed to demonstrate history of safe use including non-scientific publications and information from reputable authorities.

9) No specific indicators given for a period of history of safe food use. However the Guidelines refer to the need for evidence to show ongoing, frequent consumption by a cross-section of the population over several generations. This leaves a question over crops that have been neglected and under-utilised.

10) Recognises the need to assess novel foods on a case by case basis.

11) Published approved Products on the Health Canada website for Novel Foods refer to foods/ingredients that mainly have undergone genetic modification – that might have undergone a full safety assessment. There are no obvious references traditional foods from third countries.

12) The Guidelines are presented in clear English.

F) HISTORY OF SAFE FOOD USE ASSESSMENT

The knowledge to grow or collect the food and/or process it to make it safe to eat and even the knowledge about how much to eat has been learnt and passed on from generation to generation. This is the very basis of a concept of a traditional food.

"Generally considered safe" does not mean zero risk. It means that the risks are assessed and characterised, measures are put in place to manage risks where necessary and the risks are communicated. This report focuses on risk assessment and recommendations for the scientific and non-scientific data for traditional foods with a history of safe food use. Risk management and risk communications depend on the case by case risk characterisation.

This risk analysis process (see ***Annex V***) is established and applied internationally and all countries can in principle speak a common language in matters pertaining "to protect the health of the consumers and ensure fair practices in the food trade[43]" This facilitates global trade. It means that consumers can enjoy a wide variety of safe wholesome food. It also means that the risk management and risk communication procedures inform consumers about certain risks that are or maybe present in a food. At a European level, for example, such risk communications apply to foods containing known allergens such as cereals, eggs, fish, milk, nuts and seafood.

More generally, some other well established foods consumed in Europe are subject to specific storage and/or processing requirements to ensure that they are safe to eat. For example, potatoes need to be stored in dark conditions to avoid the development of a toxin, usually indicated by the presence of green discolouration. The green leafy tops of rhubarb must be removed before cooking and not consumed and foods like raw chicken must be cooked properly before eating. These are all examples of traditional European foods that are not safe to eat unless properly stored or processed before eating.

Long before the advent of formalised Risk Analysis principles advocated by global organisations such as the Codex Alimentarius Commission, global trade in foods over hundreds of years has resulted in the introduction of a wide variety of foods to other countries. For example, the potato with its origins in the Andes was introduced to Europe approximately 500 years ago. The most recent consumption data finds that the average per capita consumption in Europe exceeds the per capita consumption in Peru by 30% (source FAOSTAT). European exports of potatoes are worth US$2 billion (FAOSTAT).

[43] Article 1 of Codex Alimentarius Commission

1) European Food Safety Authority (EFSA)

In the proposed amendments to the Novel Food regulation traditional foods with a history of safe food use can follow a simplified Application procedure[44]. The data and other evidence submitted by the applicant is received by the European Commission and forwarded to European member states and the European Food Safety Authority (EFSA).

EFSA was established by Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Article 1 of this Regulation states that

> *this Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.*

This Regulation also includes, as a recital, the statement that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

Article 7 of this Regulation establishes the Precautionary principle as a part of the risk assessment:

> *In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.*
>
> *Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.*

In developing policy recommendations for a safety assessment procedure for traditional foods from third countries with a history of safe food use, reference will be made to existing EFSA guidance and opinions. Furthermore reference has also been made to the Novel Foods legislation in force in Australia & New Zealand and Canada. These policy recommendations build on the experience gained from similar novel foods legislation in force in these countries, to develop complementary approaches and seek harmonised global market access requirements.

[44] Also see page 17 and comments on change in the NF proposal from Notification to Application

2) Presumption of Safety based on Available Knowledge

The amendments proposed to the Novel Foods Regulation regarding Traditional Foods allow for a simplified procedure where the interested party[45] submits an application to the European Commission.

As part of that application the interested party needs to include documented data demonstrating the history of safe food use. This procedure moves towards a concept of a "presumption of safety based on available knowledge". The technical guidance proposed in this issue paper identifies the types of available knowledge that would be required as part of the application to demonstrate history of safe use.

The presumption of safety based on available knowledge is already recognised in other areas of work investigated by EFSA.

In September 2009, the EFSA Scientific Committee published an updated Guidance Document on Safety Assessment of Botanicals and botanical preparations intended for use as ingredients in food supplements[46]. The EFSA Scientific Committee proposes *"a general framework for safety assessment in which botanicals and botanical preparations for which an adequate body of knowledge exists could benefit from a "presumption of safety without any need for further testing".*

The guidance document describes the available knowledge that would be required to make a safety assessment for the use of botanicals used as food supplements and conclude whether there is a safety concern or not and hence whether further testing/data is required.

A similar system has been adopted by EFSA with regard to a *qualified presumption of safety* (QPS) for certain taxonomic groups[47] of micro-organisms. In work dating back to 2002 it was recognised that certain micro-organisms have a long history of apparent safe use and a tool was needed to help set priorities for risk assessment *without committing resources to extensive investigations of organisms known to be safe.*

If the defined taxonomic group did not raise safety concerns or, if safety concerns existed, but could be defined and excluded (the 'qualification'), the grouping could be granted QPS status. Thereafter, any strain of microorganism the identity of which could be unambiguously established and assigned to a QPS group would be freed from the need for further safety assessment other than satisfying any qualifications specified. (See ***Annex VI*** for a Schematic of the QPS approach for micro-organisms).

The QPS proposal was re-visited by EFSA and in an Opinion[48] adopted in November 2007 concluded *inter alia* that the introduction of a QPS system for microorganisms would meet the objectives of providing a practical tool for setting priorities and avoiding the commitment of resources to extensive investigations of organisms known not to cause concern. Updated lists of micro-organism with QPS status were also presented.

A similar framework relating to the "presumption of safety" is proposed herein for the safety assessment for Traditional Foods under the European Novel Food Regulation (proposed amendment). This safety assessment is proposed to fulfil the requirements of Article 8 (1) (d) of the Common Position of the Council of the European Union 10754/09, 17 June 2009, the documented data demonstrating the history of safe food use from any third country.

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[45] Also see page 17 and discussion on change in NF proposal from Food Business Operator to Interested party

[46] EFSA Scientific Committee; Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, on request of EFSA. EFSA Journal 2009; 7(9):1249 [19pp]

[47] Taxonomic group refers to Genus or group of related species

[48] Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. *The EFSA Journal* (2007) 587, 1-16

A presumption of safety based on available knowledge could be applied when available data from reliable approved sources and recognised expertise would permit the conclusion that exposure to known levels of the novel food/food ingredient has occurred in population groups for many years without reported adverse effects.

i) Other existing knowledge

It is worthwhile to mention that the Novel Foods regulation is complemented and supported by a range of other existing legislation that seeks to protect the consumer. For example the Medicines and Healthcare products Regulatory Agency (MHRA) has published a list of Herbs and their known uses, classified to medicinal, food, aromatherapy and cosmetic use. This provides useful additional knowledge on a history of use of particular plants[49, 50].

Referring to the body of knowledge worldwide, one other example of existing knowledge is the list of plants and fungi prohibited and restricted for use in food published by the Australia and New Zealand Food Standards Agency (FSANZ)[51].

ii) General EU Food Law

General EU food law ensures, *inter alia*, that sanitary and phytosanitary measures are in force to protect consumers from risks from pests, diseases, contaminants, toxins and additives in foods, beverages and feeds.

iii) Other Legislation Recognizing Traditional Use

Traditional Herbal Medicines Directive 2004/24/EC

This Directive illustrates principles recently introduced into EU medicines legislation to accommodate products ("traditional remedies") that parallel those considered as "traditional foods" under the proposed revision to the Novel Foods Regulation. The Directive identifies, defines and authorises a separate category of "traditional herbal medicines". Authorisation of traditional herbal medicines requires a simplified procedure. The starting point is that the medicinal product should have been in medicinal use throughout a period of at least 30 years preceding the date of application. At least 15 of the 30 years use must relate to the European Union. *The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience*[52] as long as there are no concerns with regard to the product's safety.

N.B: This Directive is not applicable to food use of "traditional foods", nor is this paper suggesting that traditional foods should fall under its scope. However, the arguments used to define "traditional" medicinal products with a history of safe use and provide a simplified authorisation procedure are relevant to the discussion of traditional foods.

[49] http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/CON009271
[50] http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/CON007544
[51] Referred to as Standard 1.4.4 of the Food Standards Code (FSANZ) http://www.foodstandards.gov.au/
[52] Directive 2004/24/EC

3) Recommendations – A Proposal for History of Safe Food Use Assessment

Article 8, paragraph 1 of the Council Common Position of 9th June 2009, describes the procedure to be followed by an Interested Party who intends to place on the European market a traditional food from a third country.

Given the need to demonstrate (1) traditional food with a history of food use and (2) history of safe food use prior to (3) the Application, a combined 3 step process is proposed:

1) The applicant prepares a "report" (using a guidance tool) on the status of the food as a traditional food with historical food use. It requires knowledge about the botanical identification of the food, expert evidence and other corroborated sources to support the claim of traditional food with a history of food use.

2) The second part is a "report" about **history of safe food use** (using a guidance tool). This includes information about how/why the food is processed, composition, specification and conditions of use. All available scientific and non-scientific evidence (both for and against food safety) should be presented. Expert evidence can be submitted by national, regional and international organisations including government, non government and private sector organisations.

3) The third step is the formal Application itself which requires, inter alia, a statement on the information relied on to conclude that the novel food has a history of safe food use and that the food composition and conditions of use do not pose a health risk to consumers, including appropriate risk management measures. This step relies on steps 1 and 2.

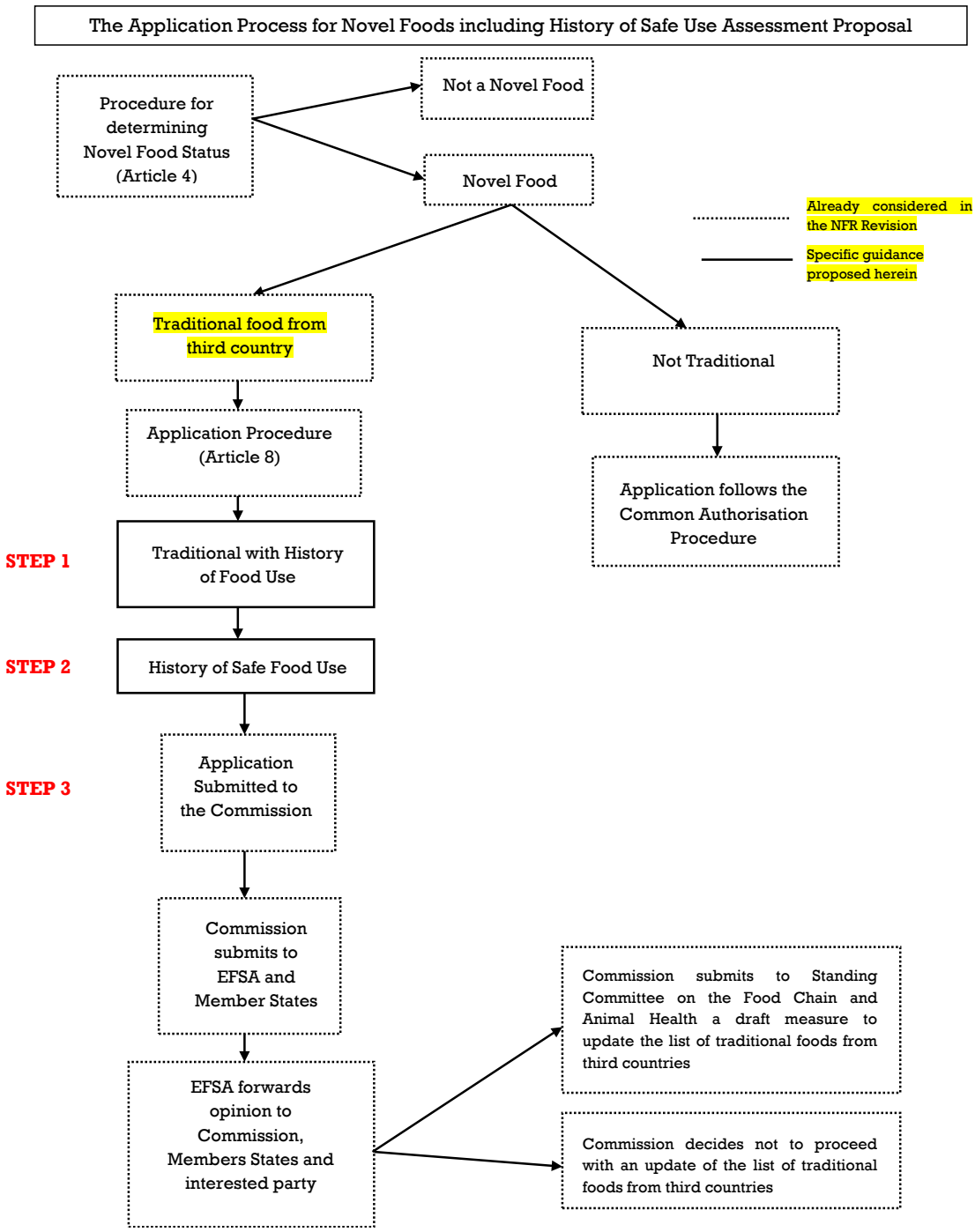
This approach respects the food traditions of third countries, opens up the European market for trade with developing countries and third countries, makes better use of scarce resources while still allowing risk managers to make informed decisions on the safety of a novel food that is a traditional food from a third country.

The flowchart below shows the steps and decisions to be taken. In step 1 the applicant provides information/data to support the claim that the food is a traditional food with a history of food use. In Step 2 the applicant provides information and data to support the claim that the food has a history of safe food use.

In the Application Procedures (Article 8 (1)) of the Council Common Position of 9th June 2009, steps1 and 2 refer to sub-section d of that paragraph.

In step 3 the applicant provides the information as required by Article 8(1) a-f, incorporating steps 1 and 2 as required by Article 8(1) d.

The dossier would be assessed according to the procedures described in the Novel Food Regulation Proposal Article 8.



i) Step One: Identity and Traditional Food Status

In the flow chart above, Step 1 requires the Applicant (interested party) to provide information/data about the identity and traditional food status of the Novel Food.

To assist the applicant with Step 1, a Guideline (Guideline I) has been developed with 6 sections. These sections concern the identity of the food, its origin, cultivation and harvesting conditions and supporting evidence to support the claim of Traditional Food. Finally the Applicant is required to confirm that the Novel Food complies with the definition of a food. The Questionnaire also includes suggested (non-exhaustive) sources of evidence that the Applicant can include. All relevant available information should be included as evidence to support the claim of Traditional Food (see also ***Chapter D.3.ii*** regarding the sources and validation of evidence.)

Step 1: Guideline I: Identity and Traditional Food Status

	Criteria	**Sources of Evidence/Comments**
I.A1	Name/Description of the Novel Food	
I.A2	The food or food ingredient is: Plant Animal Micro-organism Composite food containing novel ingredient(s) and not novel ingredients	a), b) and c) require full taxonomic description including common names, the part used as the novel food d) Requires full product description with ingredient list (see section B) and full taxonomic description of the novel food ingredient(s). Traditional Food status (section A5) refers to the use of the novel ingredient in the composite food and other uses.
I.A3	Origin	Countries, regions, populations
I.A4	Cultivation and harvesting conditions	Wild harvested or cultivated? Cultivation practices, time of harvest
I.A5	Traditional Food Status The novel food has been, and continues to be, *consumed by (as per recommendation herein) a significant proportion EITHER of the total population OR of any identifiable, discrete minority population within the country on which the application is based, or an identifiable region within that country, or an identifiable region of which that country is recognised as forming a part*, for *several generations* (to be defined as per recommended definition of traditional food from third country)	Various sources including, but not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture. Optional: Appropriate Competent Authority in third country and/or other countries where Novel Food is consumed as a traditional food and/or other Recognised Authority or Accredited establishment
I.A6	The novel food complies with the definition of a Food as per Regulation (EC)178/2002, Article 2 and Article 2 and 3 of (Proposed Amendments) Novel Food Regulation	Any reported other uses such as a traditional medicine? If the novel food has been used for medicinal purposes in any country, what is the typical use levels prescribed? How do these medicinal use levels relate to the proposed level of intake from foods? Various sources including, but not limited to, scientific publications and patents, non-scientific publications and books

ii) Step Two: History of Safe Food Use Assessment

Having completed Step One and provided evidence to support the claim that the Novel Food is a Traditional Food, the Applicant progresses to Step 2.

Step 2 requires the Applicant to provide evidence to support the claim that the Traditional Food has a History of Safe Food Use

As **recommendations** for the safety assessment of Traditional Foods with a History of Safe Food Use under the Novel Food Regulation the following framework is proposed. The framework consists of the following 5 sections:

1. Specification of the Novel Food and Processing Operations
2. Proposed Use in European Diet and Downstream Processing
3. Human Exposure to the Novel Food and Estimated Levels and patterns of Exposure in the EU
4. History of Safe Food Use

Each of the sections 1-4 has an associated Guideline. The sections are summarised in the table below:

Section	Guideline Reference	Subject	Comments
1	Guideline II.A	Specification of the Novel Food and Processing Operations	information about the specification and composition of the novel food and highlights any potential areas of concern
2	Guideline II.B	Proposed Use in European Diet and Downstream Processing	information about how the food is processed or needs to be processed in Europe prior to consumption
3	Guideline II.C	Human Exposure to the Novel Food (origin and non-origin countries/regions) and Estimated Levels and patterns of Exposure in the EU	describes existing levels of exposure and estimated levels of exposure in Europe
4	Guideline II.D	History of Safe Food Use	The culmination of evidence provided in sections (a) to (c). Furthermore in this section applicants are specifically required to present evidence on whether there are any reports of adverse effects on population groups. The greater the estimated use in the destination market the greater the weight of evidence is required. This recognises that more evidence is required if the exposure is estimated to be significantly greater in EU than the history of safe use in the country(ies) of origin.

All risk assessments need to be carried out on a case by case basis. Specific criteria are difficult to define and depend on a number of factors.

Step 2: Guideline IIA: Specification of the Novel Food and Processing Operations

	Criteria	Sources of Evidence/Comments
II.A.1	Specification	Specification of the food ingredient/food that is intended to be exported to the European Union: Dry Matter, Fat, Protein, Carbohydrate, Fibre, Ash, Fatty Acid Profile Specification should include maximum limits for undesirable substances
II.A2	Processing Operations	All operations from harvest or collection to result in final specification (above) State the plant parts that are used and any special cultivation or harvesting or traditional practises done to ensure that known toxic components do not enter food chain at this stage Mention specific processing operations carried out to ensure that toxic components or other anti-nutritional factors harmful to human health are consistently less than maximum safe permitted levels
II.A3	Food Storage and Handling	Highlight any specific handling and/or storage requirements for the novel food
II.A4	Stability/Shelf Life	Including packaging and storage conditions required to achieve the shelf life
II.A5	Ingredients List	For a composite food containing a Novel Food. Include percentages of each component (may be confidential)
II.A6	Mycotoxins and Microbiological Contaminants	Relevant to the type of food (cereals, legumes, vegetables, fruits, nuts, seeds etc)
II.A7	Heavy Metal Analysis	
II.A8	Presence of inherent toxic components in the unprocessed food	Include details of how these toxic components are reduced to safe levels/removed by processing and how this is confirmed. [This refers to the inherent toxic components in the food not those that might be present due to poor agricultural/collection practices, poor handling or other operations where quality can be managed / controlled.]
II.A9	Presence of toxic components in the Novel Food	Indicate which toxic components are present. Include details of how these toxic components are reduced to safe levels/removed before consumption. Evidence upon which this confirmed. [This refers to the inherent toxic components in the food not those that might be present due to poor agricultural/collection practices, poor handling or other operations where quality can be managed / controlled.] Also refer to section II.B

Step 2: Guideline II.B: Proposed Use in European Diet and Downstream Processing

	Criteria	Sources of Evidence/Comments
II.B1	Proposed use in European diet	Describe in detail how the Novel Food or Food Ingredient will be used, should be used or is anticipated to be used after export to European Union. Highlight any specific storage and/or handling requirements at industrial and/or domestic level.
II.B2	Further processing operations at industrial and/or domestic level in the European Union prior to consumption?	What further processing at industrial or domestic level is necessary before consumption? Give a detailed explanation why this further processing is necessary? Is it to improve palatability/nutritional value and/or to reduce toxicants to safe levels and /or other reason? Highlight any differences between these processing operations and the processing operations carried out for the traditional food in the third country.
II.B3	Differences between the processing operations carried out for the traditional food in the third country and the processing operations carried out in European Union	Evidence that these processing operations result in safe food for human consumption? Various sources including, but not limited to, scientific publications, non-scientific publications.

Step 2: Guideline II.C: Human Exposure to the Novel Food in other countries and Estimated Levels of Exposure in the EU

	Criteria	**Sources of Evidence/Comments**
II.C1	Average and maximum per capita consumption data in third country (if available).	Various sources including, but not limited to, scientific publications, non-scientific publications, Third country food use database and data from other countries where novel food is used as human food. Consideration should be given to the pattern of consumption amongst population groups as well as consumption data Appropriate Competent Authority in third country and/or other countries where Novel Food is consumed as a traditional food and/or other Recognised Authority
II.C2	The estimated average per capita exposure to European consumers	Include data to demonstrate whether exposure to European consumers is estimated to be **less than or greater than** the maximum exposure to consumers in a third country (or third countries.). N.B: There is not necessarily a single value that differentiates between "less than maximum exposure" and "greater than the maximum exposure". It may be a range of values and also depends on the degree of confidence in the values. For example, DAFNE food-use database or similar European equivalent. Consideration should be given to population groups. Exposure is not known if data is not available in third country or third countries or not available in European food use databases.

Step 2: Guideline II. D: History of Safe Food Use

<table>
<tr><td colspan="4">There is a presumption of safety based on available knowledge when available data would allow the conclusion that exposure to known levels of the novel food has occurred in the overall diet of a significant proportion EITHER of the total population OR of any identifiable, discrete minority population within the country on which the application is based, or an identifiable region within that country, or an identifiable region of which that country is recognised as forming a part for <u>several generations</u> (to be defined as per recommended definition of traditional food from third country) without reported adverse effects (adapted from EFSA Guidance Document: Safety Assessment of Botanicals (footnote 46).</td></tr>
<tr><td colspan="4">Exposure Assessment</td></tr>
<tr><td></td><td>Less than maximum per capita consumption in third country</td><td>Greater than maximum per capita consumption in third country</td><td>Not known</td></tr>
<tr><td>Claim</td><td colspan="3">Sources of Evidence</td></tr>
<tr><td>No reports of any adverse nutritional, allergenic and/or toxicological effects at existing levels of use in third country</td><td>Various sources including, but not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture, databases</td><td>Competent Authority in country of origin <u>and/or</u> at least one recognised national or international authority.

Various sources including, but not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture, databases</td><td>Competent Authority in country of origin <u>and</u> at least one recognised national or international authority

Various sources including, but not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture, databases</td></tr>
<tr><td>Known reports of adverse nutritional, allergenic and/or toxicological effects at existing level of use in third country</td><td colspan="3">Further testing and/or data may be required if there are reports of adverse effects.

A decision on the need for further testing/data depends on the nature of the reports of the adverse effects, taking into consideration the other data presented in the Notification. Post Market Monitoring (Article 11 of Proposed Amendment to the Novel Food regulation) or specific labelling (in the case of cross reactivity, for example) may provide adequate risk management whilst adopting the precautionary principle rather than a need for more scientific data (reference: EFSA Opinion on Chia (2009))[53]</td></tr>
<tr><td>Novel food listed in Directive 2007/68/EC unless specifically excluded from that list.</td><td colspan="3">Refers to list of known food allergens which must be indicated on the label of foodstuffs
Taxonomic description/Specification
Description of processing</td></tr>
</table>

[53] EFSA Journal (2009) 996, 1-26

iii) Step Three: Application Submitted to the European Commission

In Step 3 the Application, prepared by the Interested Party, is based on the information and evidence presented for steps one and two. The Application needs to include administrative data in addition to a statement, supported by the evidence that the food is safe, including risk management measures, where appropriate.

In step 3 the applicant provides the information as required by Article 8(1) a-f, incorporating steps 1 and 2 as required by Article 8(1) d.

The dossier would be assessed according to the procedures described in the Novel Food Regulation Proposal Article 8.

G) CONCLUSIONS

The Issue Paper has examined the application of the proposed Novel Foods Regulation to traditional foods from developing countries and has analysed the technical aspects related to preparing an application for a traditional food.

The use of terms and concepts in the NFR proposal such as “traditional use”, “history of use” and “history of safe use”, “significant consumption”, “customary/normal diet” and “large part of the population of a country” is discussed. Drawing on international texts and other EU regulations that apply similar definitions to obtain the same objectives as the NFR, such as consumer protection, public health, etc. we conclude that more precise definitions of these key terms and critical concepts are required. However, recognising that it may be difficult to develop legally precise (and concise) definitions for all aspects, we believe that, where this is not possible, our discussion and proposals will contribute towards the development of appropriate implementation guidelines to establish specific criteria that would need to be met.

After a review of procedures for novel food safety assessments in other countries and taking account of recent EFSA Guidance for the safety assessment of botanicals used as food supplements, a three step approach is proposed for the safety assessment of traditional foods. The approach seeks to establish the traditional food status of a novel food followed by an assessment of its history of safe food use followed by the application procedure itself. In addition to relatively simple physical, chemical and microbiological analyses, the safety assessment relies on existing sources of evidence supported where necessary with evidence provided by competent authorities and/or other recognised national or international authorities, with due consideration given to any inherent adverse effects known to be associated with the traditional food and the traditional levels of exposure compared to the predicted level of exposure in the EU. We propose that this approach is used as a basis for the revised recommendations for the safety assessment and also to provide criteria for determining the history of safe use of traditional foods.

ANNEX I

RECITALS TO PROPOSAL FOR A REVISED NOVEL FOOD REGULATION – DETAILED CRITIQUE

(b) Recitals to the Regulation

The intentions for the revised NFR are set out in the Recitals. For the purposes of this paper, those with specific relevance for traditional foods have been identified, summarised and highlighted/commented on briefly below. [*Italic text* reflects the requirements of the Articles; standard type is used for our commentary.]

- ***Recital (3)*** *Recommendation 97/618/EC[54] should become obsolete as regards novel foods.*

  This is a very welcome statement. The safety assessment of all non-GM "novel" foods (including foods with a known history of use outside the EU) has in practice been determined by the very rigorous and stringent scientific criteria set by Recommendation 97/618, originally designed specifically to assess the safety of GMOs.

- ***Recital (4)*** *maintains the dual criteria of the absence of significant consumption within the Community, prior to a cut-off date of the 15th May, 1997, and clarifies that use within the EU refers to use in the Member States independently of the date of their accession.*

  The definition of what constitutes "significant degree" and the ability to establish prior consumption were issues under the old Regulation and are discussed further below.

- ***Recital (5)*** *links the proposal to the general principles and requirements of food law, established by EU General Food Law Regulation (EC) No 178/2002; it further explains that the existing definition of novel food should be clarified and updated.*

  Since the introduction of NFR in 1997, the structure and content of EU food legislation and both EU and national administrative structures responsible for its development and enforcement have been fundamentally updated. In view of the now comprehensive scope of EU food safety legislation, it is a matter of principle that the revised NFR should not duplicate requirements already established by the General Food Law. In particular, the safety assessment must draw a clear distinction between analytical and compositional parameters of traditional foods that are inherent to the product, and those which may arise from periodic instances of poor agricultural and/or hygienic practice. The former are a legitimate parameter for the safety assessment of the food; the latter are specific to the sample / consignment concerned and (whilst of direct safety concern), responsibility for their control and legal compliance with existing food law standards must legitimately fall to the individual operator in the same way as the law requires for any current foods and ingredients.

- ***Recital (6)*** *The Council Common Position (June 2009) states:*
  - *"Furthermore, it should be clarified that foods from third countries which are novel in the Community can be considered as traditional only when they are obtained from primary production as defined* in Regulation 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should not include*

[54] Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council: OJ L 253, 16.9.1997 pp 1-36

foods produced from [non-traditional breeding techniques] … as well as foods to which a new production process is applied".

* "primary production" is "the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products."

The significance of this Recital and, in particular, uncertainties in relation to derived products and the location of their processing, within or outside their country of origin appear to have been resolved but are further discussed below.

- ***Recital (7)*** *provides for implementing measures to provide for criteria to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997.*

  Detailed references are subsequently introduced related to prior food supplement uses and are discussed below.

- ***Recital (8a)*** *provides that, where a product may fall within the definition of "medicinal product", it will fall outside the Novel Foods Regulation and a Member State may restrict its marketing.*

  This reflects the fundamental concept in EU law that a product cannot be both a food and a medicine. Food supplements are considered below.

- ***Recital (12)*** *provides that novel foods, other than vitamins and minerals, intended for particular nutritional uses, food fortification or food supplements, should be assessed for safety under this proposal, and also remain subject to existing sector-specific rules.*

- ***Recital (13)*** *The decision on whether a food has a significant history of prior EU consumption will be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. If sufficient information is not available, a simple and transparent procedure involving the Commission, Member States and any parties concerned, is to be introduced for collecting that information.*

  Although this Recital refers to the information being submitted by food business operators, in the specific traditional foods provisions in Article 8 of the Regulation reference is made to "interested parties" – a wider concept than a business operator. This Recital should therefore be amended to reflect the main text of the Regulation.

- ***Recital (14)*** *provides for novel foods to be marketed only if they are safe, do not mislead the consumer and, if intended to replace another food, do not differ from that food in a way that would be nutritionally disadvantageous for the consumer.*

  The scope of "replacing another food" has not been clarified but is a somewhat nebulous concept that is clearly open to varying interpretation. To an extent, any food can be said to be replacing another food in the course of daily consumption, e.g. substituting one vegetable or fruit for another. This is further discussed in relation to Article 6, below.

- ***Recital (15)*** *outlines the proposed centralised procedures for safety assessment and authorisation for all novel foods; a separate procedure is introduced for traditional foods. Authorisations of "novel" foods (which by definition also include traditional foods as a sub-set) are required to take into account "other factors" such as ethical and environmental factors and the precautionary principle.*

It is believed that "ethical factors" are to be targeted primarily at issues around animal cloning. Nevertheless, no clarification is given as to whether the scope of "ethical factors" extends to matters such as aiding third countries, or whether an excessively high EU "safety barrier" would fall under this aspect.

- ***Recital (16)*** *calls for criteria for evaluation of the potential risks arising from novel foods to be laid down, and for such assessments should be carried out by EFSA.*

  EFSA has recently published guidelines for the safety evaluation of botanicals and botanical preparations for use in food supplements, and indicated that the principles that have been enumerated may also be extended to cover such products when intended for use as more general food ingredients[55]. Subject to a more detailed assessment of the recent EFSA guidelines, they would appear to be a valuable starting point for the replacement of Recommendation 97/618 in respect of traditional foods.

- ***Recital (17a)*** *Traditional foods from third countries may be marketed in the EU under conditions that correspond to those for which the* ***history of safe food use*** *has been demonstrated, (and after) they are included in the list of traditional foods from third countries. The safety assessment and management of traditional food from third countries is required to take into account their history of safe food use in the third country of origin but should not include non-food uses or uses not related to normal diets.*

  The concept of history of safe food use is fundamental to this paper and is therefore discussed in detail in Sections D.3, E and F below.

- ***Recital (18)*** *provides that post-market monitoring requirements may be imposed, where appropriate and based on the conclusions of the safety assessment.*

  This is a standard provision for new products introduced to the EU market; it is not mandatory for all novel foods, and is likely to be a requirement only where there may be a small degree of uncertainty attached to the conclusions of the safety assessment.

- ***Recital (21)*** *confirms that all novel foods are subject to the general EU labelling requirements. Inclusion of a traditional food on the EU list may be qualified by specific conditions of use or labelling obligations, which may inter alia relate to any specific characteristic or property, e.g. composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population.*

  This provision has been in place for all novel foods since 1997 and it can equally be argued that this type of information, e.g. preparation instructions, can be used as a risk management tool to mitigate any residual doubts that might remain from the safety assessment.

- ***Recital (29)*** *provides for the Commission's powers, amongst others, to establish criteria by which significant prior consumption may be determined, and to clarify certain definitions, manage the list of traditional foods and adopt appropriate transitional measures.*

[55] Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements; EFSA Journal 2009, 7(9) 1249.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902880131.htm

We suggest that these fundamental criteria should be sufficiently defined in the regulation itself. However, if this proves not to be possible, the timing of any clarification guidance is critical and should be developed before the revised Regulation comes fully into effect – see Article 3.2(a) below.

- ***Recital (30)*** *indicates that Member States must follow the rules of Regulation 882/2004*[56] *to enforce compliance with the Novel Foods legislation and that EU food hygiene requirements also apply.*[57]

  (i) This makes clear that traditional foods must comply with general food hygiene and safety rules and, by implication, infers that their safety assessment should focus on intrinsic safety factors rather than those that may arise from poor storage and handling etc – see previous comments under Recital 5.

  (ii) Reference to the requirement for Member States to follow the rules of Regulation 882/2004 appears superfluous – all food enforcement bodies must follow these.

  (iii) However, Regulation 882/2004 also places obligations on exporting countries' competent authorities to ensure that export products meet EU hygiene legislation. A previous UNCTAD 2005 paper[58] suggested mechanisms whereby the principles of Regulation 882/2004 could be extended to include the validation of both scientific and non-scientific information related to traditional foods by competent authorities in the exporting country.

[56] OJ L165, 30.4.2004, p1. Corrected version: OJ L191, 28.5.2004, p1. Regulation as last amended by Council Regulation (EC) No 1791/2006; OJ L363, 20.12.2006, p1

[57] OJ L 139, 30.4.2004, p.1

[58] EU Novel Food Regulation: Discussion Paper on behalf of UNCTAD/CBI, Neville Craddock Associates, Nov 2005: http://www.biotrade.org/Events/events_docs/events-dec05-NovelfoodsCBIUNCTADpaperonEUNovelFoodRegulation.pdf

ANNEX II

ARTICLES OF PROPOSAL FOR A REVISED NOVEL FOOD REGULATION – DETAILED CRITIQUE

(c) Articles of the Regulation

The following requirements are set out in the Articles of the Regulation. Those with specific relevance for traditional foods have been identified, summarised and highlighted/commented on briefly below. [*Italic text* reflects the requirements of the Articles; standard type is used for our commentary. Where text is shown ~~*as deleted,*~~ it indicates a change between the Council political agreement and the EP position.]

Whilst Article 8 is specific to Traditional Foods from Third Countries, traditional foods are a sub-set of Novel Foods and the other articles will apply to them unless specifically excluded.

- ***Article 3***
  Definitions
  1. The definitions laid down in the General Food Law Regulation 178/2002 will apply.

  This is a standard EU legal provision; it includes a definition of "food" and is generally-applicable to all EU food legislation (see ***Annex III***).

  2. The following definitions will also apply (n.b. those relevant to traditional foods are given in full below, others are briefly summarised in light type-face to indicate the scope of the legislation into which traditional foods will fall):

  (a) "novel food": food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, <u>including</u>

  (i) food of animal origin, [… non-traditional breeding …]; and

  (ii) food of plant origin, when a novel, non-traditional breeding technique has resulted in significant changes in its composition, structure, nutritional value, etc;

  (iii) food subjected to a new production process that results in significant changes in the composition, structure, nutritional value, etc; and

  (iv) food containing or consisting of engineered nanomaterials; and

  (v) traditional food from a third country.

  Thus traditional foods are a sub-set of "novel foods" and all provisions in the Regulation will be applicable to them, <u>unless specifically excluded</u>.

  Food ingredients used exclusively in food supplements within the EU before 15 May 1997 will require authorisation under this Regulation if they are to be used in foods other than food supplements. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the EU market for the same use without being considered as novel food.

  Further criteria for assessing if a food has been used for human consumption to a significant degree within the EU before 15 May 1997, will be adopted in accordance with a standard regulatory procedure (that involves parliamentary scrutiny) before this Regulation becomes applicable.

This confirms the current interpretation of NFR whereby, where a product has an established food supplement use, any other uses of the food concerned is subject to authorisation in accordance with this Regulation. However, retention of the concept of "significant degree" for prior non-supplement use risks perpetuating the problems of the current Regulation and will be discussed further in Section D, below.

(b) defines "offspring" and (c) defines "engineered nanomaterial"

(d) "traditional food from a third country" *means novel food [i.e. as in Article 3.2(a)] other than the novel food under points (i) to (iv) of sub-paragraph (a) of this Article, derived from primary production with a history of food use in any third country, meaning that the food in question has been and continues to be part of the ~~normal~~ customary diet for at least ~~one generation~~ 25 years in a large part of the population of the country.*

(i) Recital 6 qualifies the requirement related to "primary production" but it is of concern that this critical qualification is not carried forward into the text of this Article: *"…primary production as defined* in Regulation 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should not include foods produced from [non-traditional breeding techniques] … as well as foods to which a new production process is applied".*

** "primary production" is "the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products."*

(ii) The definition of traditional food would include plants, animals, fish and insects within sub-paragraph (d).

(iii) The definition in (d) does not address the requirement for / question of "safe" use, referring only to "history of food use". The issue of the safety of this use falls under sub-paragraph (e) below, with documentary requirements outlined in Article 8.1.

(iv) Interpretation of the terms "**primary production",** "**normal/customary"** diet, and **"large part of the population of the country"** will be highly significant to the origins and history of traditional foods and are considered further in ***Section D.2***.

(v) A requirement for 25 years of food use in order for a food to qualify as "traditional" does not reflect the authors' perceptions of "traditional foods", which we believe should more accurately reflect the broader concept of "tradition", i.e. knowledge of, or use of products etc., handed down over an extended period. However, there are a number of additional factors that need to be considered, such as whether the date (whether expressed in years or in terms of "generations") from which any period will be calculated is to be fixed by the legislation or will be "rolling" (i.e. linked to the date of an application), the extent to which transformed products from primary production are to be included within the concept and the nature of any processing they have undergone. This issue is discussed more fully in Sections D.2 and D.3, below.

*(**e**) **"history of <u>safe food use</u> in a third country"** means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use **for at least 25 years** in the ~~normal~~ **customary** diet of a large part of the population of a country.*

(i) Definitions (d) and (e) overlap considerably; the purpose of this is unclear but, by requiring the same time criteria for **food use** and **safe food use**, the drafting potentially serves to confuse the extended history of consumption of traditional foods by

indigenous populations with a requirement to have established their safety, using modern scientific criteria, over the same period.

(ii) Definitions (d) and (e) refer to consumption by a large part of the population of "the" / "a" country, respectively. This clearly means that the history of use must be established in relation to the specific country, whereas the safety of use may be established in relation to its consumption in any country.

(iii) The concept of a **"large part of the population of a country"** potentially introduces numerous inconsistencies. It does not, *per se*, take into account several key issues:

- how the **"large part"** is to be defined, particularly in relation to the statistical validity or nutritional and/or toxicological significance of the numbers involved;
- the **"population of a country"** can range from tens of thousands to hundreds of millions of people;
- the **"population"** of many countries is not a homogeneous group, but may comprise several ethnic and/or religious sub-populations, each with their own differing long-standing dietary habits and preferences;
- ethnic / religious groups may comprise, numerically, only a small proportion of the overall population and live in a small area (**"region"**) of a country, yet still represent a discrete, identifiable "population"; equally, these populations may be more thinly spread within a given country but be represented more widely over several countries (i.e. a wider, geographical region that shares a common cultural history);
- further, the concept of "a (single) country" does not address the politically-driven changes to country boundaries that have occurred in some regions (e.g. Africa) well within the timescales of the use of traditional foods.

The definition must address **"regional"** consumption, whether the region is within a single country or comprises several countries or parts of countries. These key issues merit further consideration and are discussed in detail in ***Section D.2(iii)*** below.

(iv) The EP Report refers to a traditional food as a **"natural, non-engineered"** novel food having an ongoing food use of "at least **25 years** as part of the **normal** diet" and a history of safe food use of at least **30 years** in the **customary** diet" – these are clearly inconsistent and must be clarified.

(v) Furthermore, "safety" is not an absolute concept that can be "confirmed", other than within an appropriate risk management framework; even if certain aspects of "compositional data" indicate a potential risk, preparation methods and consumption patterns must be considered, c.f. many "conventional foods" already on the EU market. Potential mechanisms to demonstrate "history of safe food use" are discussed in detail in ***Section F*** of this paper.

If appropriate, the Commission may adopt further criteria to clarify the definitions under points (a)(i), (a)(ii), a(iii), (a)(iv), (d) and (e), in accordance with a standard EU regulatory procedure (that involves parliamentary scrutiny).

Article 4
Procedure for determination of novel food status

We note that, since traditional foods are a sub-set of novel foods, and are not specifically excluded from this Article, it will also apply to them.

1. Food business operators must verify the status of the food they intend to place on the Community market with respect to the scope of this Regulation.

This reflects the basic EU food law concept that the food business operator has the primary responsibility for ensuring the legality of the products which he places on the market.

2. In case of doubts, the food business operator must consult the relevant competent authority [...] on the status of this food. On request, the business operator must provide information on the extent to which the food has been consumed within the EU prior to 15 May 1997.

(i) The specific traditional foods provisions in Article 8 of the revised Regulation refer to information being provided by ***"an interested party"*** who intends to place [a traditional food] on the market. An "interested party" is defined by Regulation 1331/2008 as wider than a ***"business operator"*** but, since traditional foods are a sub-set of novel foods, there is a potential conflict between this Article and Article 8. This Article should therefore be amended to reflect the distinctions and to ensure consistency.

(ii) The expectation that a business operator will be able to **prove** the use or imports of specific foods prior to 1997 will become progressively more difficult to meet with time. Few businesses keep records for more than 12 years and, in the very near future, it will become highly unlikely that import documents will be available. This issue is discussed more fully in Section D.1(iv) below.

3. Where necessary, the competent authority may consult other competent authorities and the Commission [...], which will receive, collate, summarise and communicate the result of the consultation to the competent authorities.

4. Implementing measures for the application of paragraph 3 may be adopted in accordance with [standard] EU regulatory procedure (i.e. parliamentary scrutiny).

- ***Article 4a***
  Interpretation decisions
  Where necessary, it may be determined in accordance with the [standard EU procedure, decision period set at 3 months] whether a type of food falls within the scope of this Regulation.

  This already recognises that the basic definition of a "novel food" will still result in uncertainty. Experience of numerous "unofficial" discussions between authorities has resulted in the EU novel foods catalogue; we propose this should be further developed into a formal record of the status of the materials discussed.

- ***Article 5***
  Lists of novel foods
  1. The Commission shall maintain a Community list of authorised novel foods, other than traditional foods from third countries, (hereinafter "the Community list"), which will be published in accordance with article 2(1) of Regulation (EC) No 1331/2008 [common procedure].

  1a. The Commission shall establish and maintain a list of traditional foods from third countries, authorised [under this Regulation], which will be published in [the EU Official Journal].

2. Only novel foods, included in the Community list or in the list of traditional foods from third countries may be placed on the market.

- ***Article 5a***
  Prohibition of non-compliant novel foods
  No person shall place on the market a novel food if its use does not comply with this Regulation.

- ***Article 6***
  General conditions for inclusion of novel foods in the lists

  We note that, since traditional foods are a sub-set of novel foods, and are not specifically excluded from this Article, it will also apply to them.

  A novel food may be included in the lists only if it meets the following conditions:

  (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ~~under normal consumption conditions~~;

  It is unclear why reference to normal consumption has been deleted from this paragraph, but retained in (c) below. It would seem to be equally applicable to both. Furthermore, any food or beverage consumed to excess can be harmful.

  (b) it does not mislead the consumer, ~~by the way it is presented or by its intended use~~;

  Recital (21) confirms that the EU Food Labelling Directive will apply to novel foods; this forbids misleading labelling, advertising and presentation of all foods but requires that these must not mislead ***to a material degree***. To avoid doubt or contradiction between the legislation, this sub-paragraph should also be similarly qualified.

  (c) in the case where it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

  The concept of "replacing another food" is somewhat nebulous and risks introducing numerous and serious discrepancies between "novel" foods and those already on the market that would (presumably) not be subject to the same comparison or rules. Any food can be said to be replacing another food in the course of daily consumption, e.g. whether it is directly substituting one vegetable or fruit for another, or consuming one food to the exclusion of another.

  The difficulty inherent in this sub-clause may be illustrated by a simple example; if a fleshy fruit similar in use to melons, but of inferior vitamin content, was intended to be introduced to the EU, then it could be said that nutritionally, such a fruit is "disadvantageous". Would authorization be denied, solely on this basis? That would be grotesque.

- ***Article 8***
  Traditional food from a third country
  Note: for the purposes of this paper, the text of this article is quoted almost verbatim, as it is the key, specific Article related to traditional foods. Insertions by the author that paraphrase complex EU jargon are in [parentheses] format. Significant changes from earlier drafts are also indicated.

*1. By way of derogation from the procedure laid down in article 7(1) of this Regulation, an interested party, [*that, by definition, may represent several interested parties*], who intends to place on the Community market a traditional food from a third country […], shall submit an application to the Commission.*

The ~~notification~~ application shall include:

(a) the name and description of the food,

(b) its composition,

(c) its ~~the~~ country of origin,

(d) documented data demonstrating the history of safe food use in any ~~the~~ third country,

(e) where applicable, the conditions of use and specific labelling requirements,

(f) a summary of the content of the application ~~notification~~.

The ~~notification~~ application shall be made in accordance with the implementing rules referred to in paragraph 7 of this Article.

(i) The original draft Article 8.1 read: "A food business operator intending to place a traditional food from a third country on the market in the Community shall notify it to the Commission, indicating the name of the food, its composition and country of origin".

(ii) The change from business operator to "interested party" is beneficial and more closely reflects the practicality of trade groups or wider interest groups wishing to place a traditional food on the EU market (c.f. the recent Baobab authorisation granted to PhytoTrade Africa).

(iii) The proposed application mechanism will require EFSA to produce its Opinion based on the data in support of a history of safe use. This Opinion will form the basis for the Commission to develop a proposal to add the food to the EU list, subject to agreement by MS (qualified majority voting) and scrutiny by the Parliament. This is a more transparent and pragmatic approach for traditional foods than the previously proposed notification procedure which would have permitted MS to raise objections, even before the matter would be referred to EFSA.

(iv) "Composition" is an imprecise term, capable of wide interpretation from requiring very broad details down to minutiae of scientific components. In the latter case, such details may not be readily available. Hence, it will be extremely important to ensure that a balanced, pragmatic approach is taken to the history of safe food use of the product. In this respect, appropriate implementation guidelines will be necessary to ensure that the information demanded is proportionate to a given product, and assessed on a case-by-case basis.

(v) The content and scope of "documented data", where / how it is to be derived and how it is to be validated are not specified in the draft Regulation but will best be addressed in appropriate technical guidelines (e.g. from EFSA). We consider this in detail in ***Section F*** of this paper. In addition, a previous UNCTAD paper[59] suggested possibilities based on the concepts underlying Regulation 882/2004 on Official Controls

[59] EU Novel Food Regulation: Discussion Paper on behalf of UNCTAD/CBI, Neville Craddock Associates, Nov 2005: http://www.biotrade.org/Events/events_docs/events-dec05-Novelfoods-CBIUNCTADpaperonEUNovelFoodRegulation.pdf

and the role played by Competent Authorities in countries exporting conventional foods to the EU.

2. The Commission shall forward the valid application ~~notification including the demonstration of history of safe food use~~ referred to in paragraph 1 without delay to the Member States and the European Food Safety Authority.

The Commission will establish whether the application is valid – i.e. that it contains the necessary administrative and documentary information (as distinct from its scientific verification). A strict time-limit should be imposed (~2 weeks) to avoid unwarranted bureaucratic delays to what is already an extended time-scale for the overall processing of an application from date of application to permission for marketing.

3. Within ~~four~~ six months of receipt of an application, EFSA shall give its opinion. Whenever the Authority seeks supplementary information from the interested party, it shall, after consulting the interested party, lay down a period within which this information shall be provided. The six months time limit shall be automatically extended by this additional period. The supplementary information shall be made available to the Member States and the Commission by the Authority.

This is a highly pragmatic approach, which must not be permitted to become a "justification" for progressively seeking more and more erudite scientific information and thereby negate the political will of the regulation to provide an accelerated mechanism for the authorisation of traditional foods. The role of technical guidelines will, again, be critical in ensuring a consistent and proportionate approach is taken.

Provision should also be included, either in the regulation or implementing rules, to encourage direct contact between EFSA and the applicant to resolve outstanding matters.

4. In order to prepare its opinion the Authority shall verify:

> *(a) that the history of safe food use in any third country is substantiated by the quality of data submitted by the interested party; and*
>
> *(b) that the composition of the food and, where applicable the conditions of its use, does not pose health risk to consumers in the Community.*

The Authority shall forward its opinion to the Commission, the Member States and the interested party.

Implementing rules are to be developed for this Article (sub-paragraph 7, below); these must recognise that "safety" is not an absolute concept that can be "confirmed" by compositional data, but must require such data to be considered within an appropriate risk management framework. Where certain aspects of "compositional data" might indicate a potential risk, preparation methods and consumption patterns must be fully taken into account. Many "conventional foods" already on the EU market contain potentially unsafe components but the hazard is controlled through risk management that entails appropriate information, preparation and / or processing.

5. a) Within three months of the Authority giving its opinion, the Commission shall submit to [MS technical working committee] a draft measure to update the list of traditional foods from third countries, taking account of the opinion of EFSA, any relevant provisions of Community Law and any other legitimate factors relevant to the matter under

consideration. [This measure … shall be adopted by MS using the qualified majority voting procedure, with parliament scrutiny]. The Commission shall inform the interested party accordingly.

Involvement of MS is an essential democratic provision. However, based on past history of novel foods assessments, this step could remain a significant hurdle for traditional foods; it will therefore be essential to ensure that any objections must be based on sound scientific evidence if it is not to become a purely political means to block the product from the market.

b) If the Commission decides not to proceed with an update of the list of traditional foods from third countries, it shall inform the interested party and the MS accordingly, indicating the reasons for not considering the update justified.

"Updating the list" equates to authorisation to place the traditional food on the EU market. If the food is not on the list, it may not be marketed. As drafted, this sub-paragraph appears to give the Commission the power to reject an application, following an EFSA Opinion, advising but without consulting the MS of its decision. It would seem appropriate for a negative decision also to be subject to the same procedure as in sub-paragraph (a).

6. At any stage of the procedure the interested party may withdraw its application.

In an earlier draft, rejection of a "notification" of a traditional food could be followed by a full novel food "application"; there is no such provision in the latest Council draft. Although no explanation is given, this might infer that the level of scientific scrutiny of traditional foods ultimately expected from EFSA may be more stringent than previously envisaged.

Neither is clear whether an applicant will be able to opt out of the derogation provided under Article 8 and submit an application for assessment in accordance with Article 7, thereby providing the full scientific data (and incurring the associated costs etc as per the current NF Regulation) – as for any genuinely "novel" food.

7. Detailed rules for the implementation of this Article shall be adopted in accordance with [standard EU procedures], before the date of application of this Regulation.

The proposed date of application has been changed in the Council text from **6** to **24 months** from its OJ publication date. Requiring the Commission to produce implementing rules within this much-extended deadline is a seriously retrograde step, which introduces a potential further 18 months delay for those parties wishing to submit an application under the new rules. The implementing rules must be established well within the implementation date to enable interested parties to begin to prepare an application as soon as possible. The previous period of **6 months** should be re-instated.

- ***Article 9***
  Technical guidance

We note that, since traditional foods are a sub-set of novel foods, and are not specifically excluded from this Article, it will also apply to them.

[…] before the date of application of this Regulation the Commission shall, where appropriate, in close cooperation with EFSA and after consultation with interested parties, make available technical guidance and tools to assist interested parties, in particular food

business operators and especially small and medium-sized enterprises or other interested parties in preparing and submitting applications under this Regulation.

The comments under Article 8.7 are equally applicable to this Article. Parliament proposed that assistance should be available within **6 months** and to be publicly and easily available. This period of **6 months** should be inserted here.

- ***Article 10***
  Opinion of the Authority

We note that, since traditional foods are a sub-set of novel foods, and are not specifically excluded from this Article, it will also apply to them.

In assessing the safety of novel foods, the Authority shall in particular and where appropriate:

(a) compare, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;

(i) The first element (*"comparable food category"*) will be of direct relevance to the comparative assessment of traditional foods from third countries such as fruits and vegetables, since several well-known EU fruits and vegetables are known to contain potentially harmful constituents but which are managed by well-established processing and preparation techniques (e.g. cassava, red kidney beans, rhubarb and green potatoes amongst many others). Equally, the EU and individual MS have risk management procedures in place to cover the harvesting of shellfish and fungi that might otherwise represent a serious risk to human health.

(ii) The second element, the concept of *"intended to replace"* is nebulous and, in the absence of further clarification, has the potential to introduce considerable legal uncertainty.

To certain extent, any food or drink can be argued to be capable of replacing and, by extension, be "intended" to replace another; e.g. an exotic fruit or vegetable could replace a conventional food whether as a meal component or as a snack.

However, in practice, the introduction of a traditional food into the EU is unlikely to be "intended to replace" another but, rather, to ***add diversity*** to diets, or ***add foods*** that are known for being high in particular nutrients, or attractive new flavours, etc.

(iii) Sub-paragraph (a) implies that, if a traditional food is found not to be as "safe" as an existing EU food in a comparable category, this may be used as a reason either to deny authorisation or, at least, to impose post-market conditions such as additional labelling or monitoring. Intriguingly, therefore, in the event that the converse were true, and a traditional food were to be found to be SAFER or, taking into account the criteria required by Article 6(c), MORE NUTRITIOUS than a food in a similar category currently consumed in the EU, a logical and equitable conclusion would be that the pre-existing food should be withdrawn from the market or, at least, become subject to specific additional measures.

The application of dual standards against potential imports by the EU authorities would potentially introduce WTO issues.

(b) take into account the history of safe food use.

(i) This sub-paragraph duplicates the specific provisions for traditional foods in Article 8.4 but, since traditional foods are not derogated from this article, risks parallel criteria being applied. It should therefore be redrafted to EXCLUDE traditional foods, thereby ensuring they are subject only to the requirements of Article 8.

(ii) We address the essential question, how to establish safe history, in ***Section F***.

- ***Article 11***
  Special obligations on the food business operators

  1. The Commission may impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. The food business operators placing the food in the Community market shall be responsible for the implementation of the post-marketing requirements specified in the entry of the food concerned in the Community list of novel foods.

  2. The producer shall forthwith inform the Commission of:

  (a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;

  (b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.

  (i) Since traditional foods are a sub-set of novel foods, and are not specifically excluded, this Article will also apply to them. It thus appears to contradict the requirements of Article 8 whereby general obligations in respect of traditional foods are to be met by the wider concept of "interested parties".

  (ii) The principles behind this Article should therefore be re-drafted in respect of traditional foods and transferred to Article 8.

- ***Article 15***
  Review
  1. No later than 3 years after the date of application of this Regulation and in the light of experience gained, the Commission shall forward to Parliament and Council a report on [its] implementation and, in particular, of Articles 3 and 8, […], accompanied, where appropriate, by any proposals.

  [2 … cloned animals]

  3. The reports and any proposals shall be made public.

  Traditional foods are not specifically excluded from this Article, and will therefore be covered by the Report.

- ***Article 17***
  Establishment of the Community list
  *Within **24 months** from the date of publication the Commission shall establish the Community list by entering novel foods authorised and/or notified under [the current NFR] in the Community list, including any existing authorisation conditions, as appropriate.*

(i) Several traditional foods (e.g. Baobab and Noni derivatives) have been, or will shortly be, authorised as "novel foods" (e.g. Chia seed and Noni puree); the draft should confirm that, for consistency, they will be added to the proposed list of traditional foods under the revised regulation.

(i) 24 months appears extremely long for a simple administrative task (the previous draft specified 6 months). An unofficial list of novel food approvals is regularly updated by the Commission and we propose this should be adapted and formalised within ***3 months***.

(ii) It would also be highly beneficial for all parties for the Commission to formalise and enhance the performance of web-based "Novel Foods Catalogue", recording the discussions and status of traditional foods, food supplements, extracts etc.

(iii) The Commission should also consider adding a section on the regulatory status of selected traditional foods from third countries in other principal markets.

- ***Article 20***

Entry into force

1. This Regulation shall enter into force on [the 20th day] following [OJ publication]. Subject to paragraphs 2 and 3, it shall apply from [24 ~~six~~ months after date of publication].

2. Article 17 shall apply from the date of the entry into force.

We note minor inconsistencies in the dates from which Article 17 will apply - (24 months from publication (Art. 17) or 24 months from entry into force (publication +20 days, Art 20).

ANNEX III

DEFINITIONS FROM REGULATION (EC) NO 178/2002

Definition of 'food'
For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(a) feed;
(b) live animals unless they are prepared for placing on the market for human consumption;
(c) plants prior to harvesting;
(d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
(e) cosmetics within the meaning of Council Directive 76/768/EEC;
(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
(h) residues and contaminants.

Other definitions

For the purposes of this Regulation:

1. **'food law'** means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

2. **'food business'** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

3. **'food business operator'** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

4. **'feed'** (or **'feedingstuff'**) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

5. **'feed business'** means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

6. **'feed business operator'** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

7. **'retail'** means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food
service operations, shops, supermarket distribution centres and wholesale outlets;

8. **'placing on the market'** means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

9. **'risk'** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

10. **'risk analysis'** means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

11. **'risk assessment'** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

12. **'risk management'** means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

13. **'risk communication'** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

14. **'hazard'** means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

15. **'traceability'** means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

16. **'stages of production, processing and distribution'** means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;

17. **'primary production'** means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

18. **'final consumer'** means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

ANNEX IV

UK FOOD ADVISORY COMMITTEE RECOMMENDED CRITERIA FOR THE USE OF THE TERM 'TRADITIONAL' IN FOOD LABELLING AND ADVERTISING

Dictionary Definitions

'Traditional' can be defined as relating to the following:

- of, or pertaining to, or derived from tradition;
- communicated from ancestors to descendants, generally by word only;
- traditional customs; old-fashioned; pertaining to time-honoured orthodox doctrines;
- a custom or usage, long observed;
- handed down practices that are valued by a particular culture;

Conclusions

'Traditional' is clearly linked to the passing of time. We take the view that the 'tradition' should have existed for a considerable period of time. The term should therefore demonstrably be used to describe a recipe, fundamental formulation or processing method for a product that has existed for a significant period. The ingredients and process used should have been available, substantially unchanged, for that same period. However, the period during which this has occurred is a matter for debate and may, to some extent, be product-specific. It has been suggested that the period should be of the order of 2 generations / 50 years but, before expressing an opinion on this, we would recommend a wider consultation of all stakeholders. This consultation exercise should also include criteria for the use of "vintage", on foods other than alcoholic beverages, as this may equally have a time relationship. Pending the results of this consultation, we recommend that greater discretion should be exercised by manufacturers, and greater attention paid by Enforcement Authorities, in the use of this term.

The term 'traditional' implies more than 'original' or 'plain'. It is not a synonym for 'original' and we consider it misleading to use the term, without qualification, simply to distinguish an 'original' recipe from subsequent variants. Manufacturers and retailers must therefore pay particular attention to the use of ingredients, particularly additives, and to the use of processes that have not been used in food manufacture for the substantial period of time indicated above. They must ensure that the term does not imply a composition or production method that would not be regarded as 'traditional' by the average consumer and should consider whether the term 'original recipe' or similar may be more appropriate. In accordance with our general principles, there must be evidence to substantiate the use of the word for the particular product, vis-à-vis the foregoing, time-related guidance.

We agree with the FSC (1980) that the term is difficult to define and that its use currently does not require specific statutory control, other than by the general provisions of food law. We consider that the general provisions of the Food Safety Act 1990 and the Trade Descriptions Act 1968 provide the necessary framework controls but we would encourage a fuller recognition of these by industry and their application by Enforcement Authorities. However, in the absence of specific definitions, consistency of enforcement approach is necessary.

We recommend that further consultation should be carried out, in particular to establish whether a period of 50 years / 2 generations could practicably be applied as the basis of justification of a 'traditional' claim.

ANNEX V

RISK ANALYSIS

Risk Analysis[60] is a process consisting of three components: risk assessment, risk management and risk communication.

Risk Assessment:
A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk Management:
The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

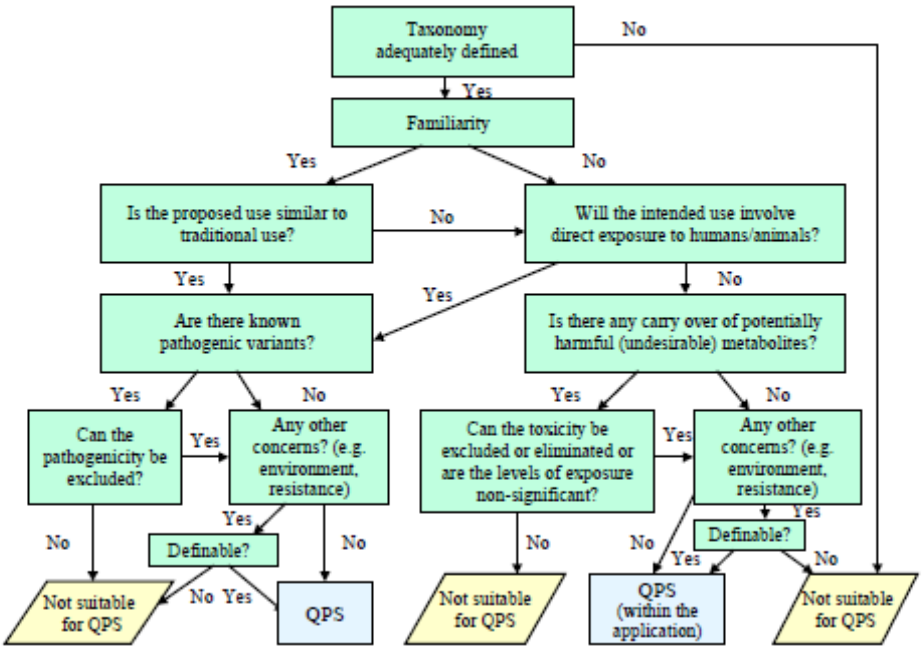
Risk Communication:
The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions

[60] Codex Alimentarius Commission Procedural Manual 18th Edition

ANNEX VI

SCHEMATIC FOR QPS FOR MICRO-ORGANISMS

Figure 1. A general scheme for the assessment of suitability for QPS status of micro-organisms.



Taken from:

On a generic approach to the safety assessment of micro-organisms used in feed/food and feed/food production

This document for public consultation has been produced by a Working Group consisting of members of the Scientific Committee on Animal Nutrition, Scientific Committee on Food and the Scientific Committee on Plants of the European Commission.

ANNEX VII
SUMMARY OF FSANZ NOVEL FOODS REGULATIONS

In Australia and New Zealand the sale of novel foods and novel food ingredients is regulated by Standard 1.5.1 of the Australia New Zealand Food Standards Code (see ***Annex VIII***). This standard describes the pre-market assessment requirements and includes definitions for 'non-traditional food' and 'novel food'.

Non-traditional food means:
a food that does not have a history of human consumption in Australia or New Zealand; or a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

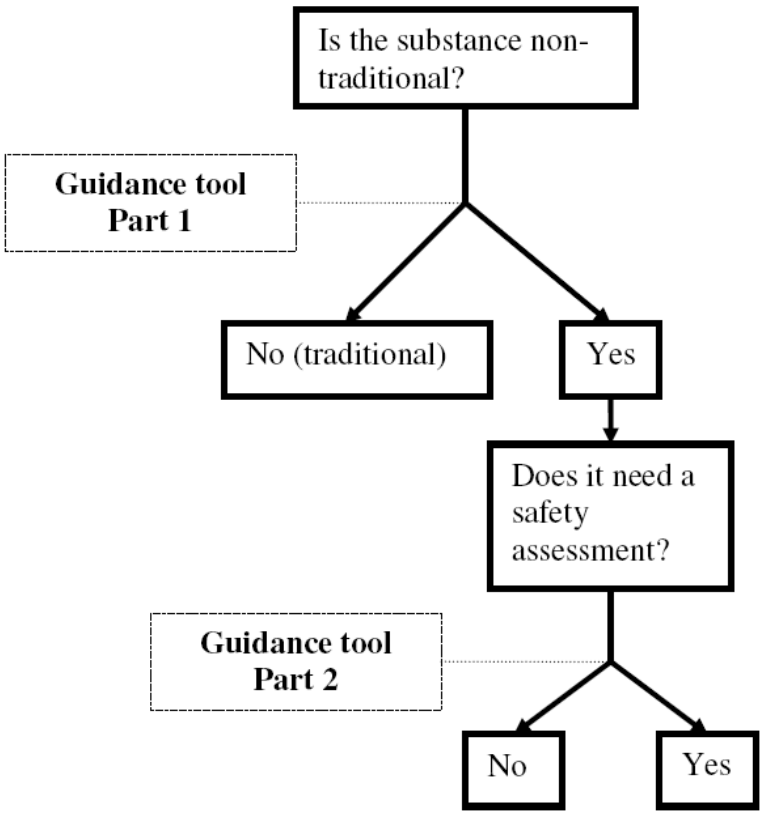
Novel food means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to:

- the potential for adverse effects in humans; or
- the composition or structure of the food; or
- the process by which the food has been prepared; or
- the source from which it is derived; or
- patterns and levels of consumption of the food; or
- any other relevant matters.

The standard includes a list of "Novel Foods" permitted for use and, where applicable, in compliance with specified conditions of use.

The requirements are based on a two step process. The first step is to assess whether the food has traditional use in Australia and New Zealand.

If the food is classified as ***traditional*** then it does not require further pre-market safety assessment.



If the food is ***not traditional*** then a decision is taken by FSANZ on whether that food needs a safety assessment. Guidance Tool part 2 is used to support that assessment.

FSANZ may decide that a food or food ingredient is ***non-traditional*** but **not novel** and the basis for this view is that the available data suggests that there are no safety concerns. Hence not all non-traditional foods raise safety concerns and therefore, not all non-traditional foods are subject to the pre-market assessment requirements of the Novel Foods Standard. However, non-traditional and not novel foods can still have certain conditions of use attached.

For example, Damiana (*Turnera diffusa or Turnera aphrodisiaca*) is Non Traditional and Not Novel when used at levels up to 100mg/100ml beverage. Above these levels a Novel Foods application is required for a safety assessment.

Another example is Yacon (*Smallanthus sonchifolius*). This food is defined by FSANZ as "not traditional and not novel". This information, and the non-traditional/novel status of other foods assessed by the FSANZ, is published in the Record of Views on the website of the Food Standards Agency of Australia and New Zealand[61].

The latest Record of Views includes 59 Non Traditional/Not Novel Foods and 54 Non-Traditional/Novel Foods[62]. (See ***Annex XI*** for full details)

Foods that are not traditional may require a safety assessment to confirm that "*there is reasonable certainty that no harm will result from the intended use of the food and ... any risk management strategies are warranted to ensure the safe use of the food*[63]."

[61] http://www.foodstandards.gov.au/foodmatters/novelfoods/index.cfm
[62] http://www.foodstandards.gov.au/foodmatters/novelfoods/novelfoodrecordofvie3934.cfm
[63] FSANZ Guidance Tool for Determining whether a food is novel or not

Applicants who intend to market a non-traditional or novel food in the Australia/New Zealand market are required to complete a Questionnaire (see ***Annex IX***). This questionnaire is designed to determine whether a food is traditional or not traditional and it is also used to determine whether a food is novel or not novel. The completed questionnaire reviewed by FSANZ using 2 Guidance Tools (see below and ***Annex X***).

The first guidance tool is used to determine whether the food is traditional or non-traditional.

If the food is non-traditional the second guidance tool is used to determine whether an assessment of public health and safety is required "*to confirm there is reasonable certainty that no harm will result from the intended use of the food and to determine whether any risk management strategies are warranted to ensure the safe use of the food*".

Foods requiring a full safety assessment that are then permitted for sale in Australia and New Zealand are published in Standard 1.5.1 (see ***Annex VIII***) together with any conditions of use.

As specified in Clause 2 of Standard 1.5.1:

"A novel food must not be sold by way of retail sale as food or for use as a food ingredient unless it is listed in column 1 of the Table to this clause and complies with the conditions of use, if any, specified in column 2." However current table does not include non-traditional not novel i.e. those foods that do not need to undergo a full safety assessment.

Guidance tool 1 essentially seeks to determine whether the food has a history of human consumption in Australia or New Zealand. FSANZ considers four areas that influence the term "history of human consumption": length of use; extent of use; quantity (level of intake) of use; and purpose or context of use. It refers to the answers given in the questionnaire.

Guidance Tool 1 for determining whether a food is novel or not, contains explanatory notes in relation to these four areas. Full details in the use of these Guidance tools are given in FSANZ *Guidance Tool for Determining whether a food is Novel or Not*[64]. An abbreviated version is presented below and shown in tabular form on page 37:

Length of use. As a general guide, 2-3 generations would be considered to be a long period of use, whereas 5 years or less would be considered a short period of use, while 10-20 years of use may be sufficient to establish history of use, depending on the three other components taken into account.

Extent of use. As a general guide, use by the general population in either Australia or New Zealand would be considered extensive use, whereas use by one sub-population group would be considered limited use. Use by a number of sub-populations in different regional areas, or use by a number of subpopulations in combination with some use by the general population may be sufficient to establish history of use, depending on the three other components taken into account.

Quantity (level of intake) of use. As a general guide, use of a food ingredient in a range of different foods at levels consistent with food macro-components would constitute a high level of intake, as would a whole food consumed on a regular basis. The use of food ingredients at low levels in a relatively small range of foods would be considered a low level of intake.

Purpose or context of use. As a general guide, food that has been consumed as a regular part of the diet would be considered to be of high relevance to food use, whereas an herb used for

[64] http://www.foodstandards.gov.au/foodmatters/novelfoods/index.cfm

medicinal purposes would be considered of low relevance to food use. A food ingredient that is extracted from a common food, but added at higher levels to a range of foods that may or may not naturally contain the component would not normally be sufficient to establish a relevant history of use as food (because the context of use is different).

Confidence in the information provided. A record of use could take various forms such as verbal accounts or interviews with traditional consumers, though written reference with information drawn from reliable sources would be the most convincing means of demonstrating use. If the Advisory Committee on Novel Foods has low confidence in the data supplied from the enquirer, the Committee can elect to supplement the data.

Overall consideration. These first four components of 'history of human consumption' are considered to be of equal importance. However, it is possible that a deficiency of (sic) (of the evidence for Ed.) a particular food in one of these components could be balanced by another component. The Committee makes recommendations as to whether a food is non-traditional or not on a case by case basis, using the best available information to inform a particular recommendation.

Non Traditional Foods

If the food is classified as Non Traditional this triggers use of **Guidance Tool 2** (see ***Annex X***). The same Questionnaire (***Annex IX***) prepared by the applicant is used by FSANZ to review the information submitted against the factors that are used to define a Novel Food, namely:

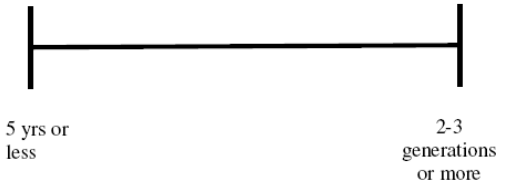
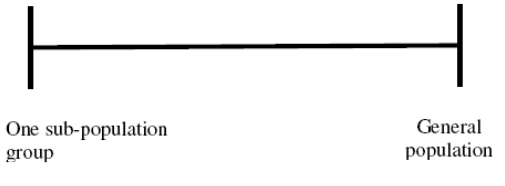
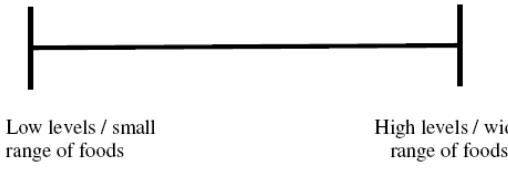
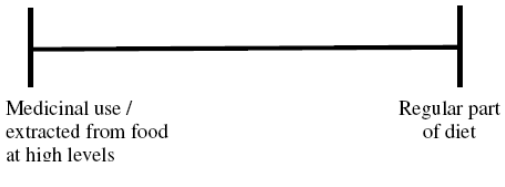
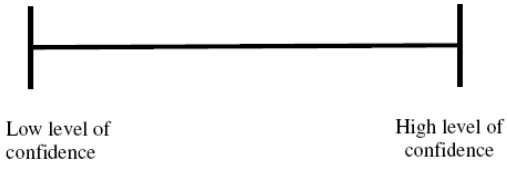
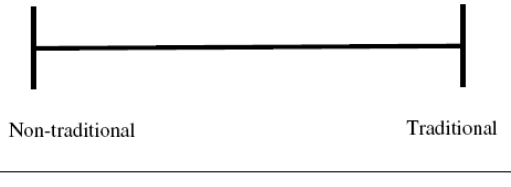
- the potential for adverse effects in humans; or
- the composition or structure of the food; or
- the process by which the food has been prepared; or
- the source from which it is derived; or
- patterns and levels of consumption of the food; or
- any other relevant matters.

Based on the information provided in the Questionnaire FSANZ makes a recommendation on whether an assessment of public health and safety is required. If the recommendation is that an assessment of public health and safety considerations is required then a novel foods application needs to be submitted to FSANZ for the assessment.

The application procedure and requirements for Novel Foods is described in The Food Standards Australia New Zealand Application Handbook[65].

[65] http://www.foodstandards.gov.au/_srcfiles/Application%20Handbook%20as%20at%205%20June%2008.pdf

TEMPLATE for Part 1 of Guidance Tool: To be used for making a recommendation as to whether a food should be considered non-traditional or not

History of human consumption	Notes	Rating
1. Length of use		
2. Extent of use		
3. Quantity of use (level of intake)		
4. Purpose or context of use		
5. Confidence in information provided		
6. Overall consideration		

ANNEX VIII
FSANZ STANDARD 1.5.1

STANDARD 1.5.1

NOVEL FOODS

Purpose

This Standard regulates the sale of novel food and novel food ingredients. This Standard prohibits the sale of these foods unless they are listed in the Table to clause 2, and comply with any special conditions of use in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, warning statements or other advice, or the need to meet specific requirements of composition or purity.

The Authority will assess the safety for human consumption of each novel food prior to its inclusion in the Table. The safety assessment will be performed in accordance with the Authority's safety assessment guidelines.

Foods produced using gene technology and foods which have been irradiated are regulated in Standards 1.5.2 and 1.5.3 respectively.

Table of Provisions

1 Definitions
2 Sale of novel foods
3 Exclusive use of novel foods

Clauses

1 Definitions

In this Standard –

non-traditional food means –

(a) a food that does not have a history of human consumption in Australia or New Zealand; or
(b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

novel food means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to -

(a) the potential for adverse effects in humans; or
(b) the composition or structure of the food; or
(c) the process by which the food has been prepared; or
(d) the source from which it is derived; or

(e) patterns and levels of consumption of the food; or
(f) any other relevant matters.

Editorial Note:

Novel food includes novel foods used as ingredients in another food.

Possible categories of novel foods are described in the Authority's guidelines. Categories of novel foods may include, but are not limited to: plants or animals and their components; plant or animal extracts; herbs, including extracts; dietary macro-components; single chemical entities; micro-organisms, including probiotics; foods produced from new sources, or by a process not previously applied to food.

2 Sale of novel foods

A novel food must not be sold by way of retail sale as food or for use as a food ingredient unless it is listed in column 1 of the Table to this clause and complies with the conditions of use, if any, specified in column 2.

Table to clause 2

Column 1	Column 2
Novel Food	**Conditions of Use**
α-cyclodextrin	The name 'alpha cyclodextrin' or 'α-cyclodextrin' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
γ-cyclodextrin	The name 'gamma cyclodextrin' or 'γ-cyclodextrin' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
Diacylglycerol oil (DAG-Oil)	The name 'Diacylglycerol oil' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
Docosahexaenoic acid (DHA) – rich dried marine micro-algae (*Schizochytrium* sp.)	
Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Schizochytrium* sp.)	
Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Ulkenia* sp.)	
Isomaltulose	

Table to clause 2 (continued)

Column 1	Column 2
Novel Food	**Conditions of Use**
Phytosterol esters	The requirements in clause 2 of Standard 1.2.3. The name 'phytosterol esters' or 'plant sterol esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to edible oil spreads – (1) according to Standard 2.4.2; and (2) where the total saturated and trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food. May only be added to breakfast cereals, not including breakfast cereal bars, if – (1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; (2) the breakfast cereal contains no more than 30g/100g of total sugars; and (3) the total phytosterol ester added is no less than 26g/kg and no more than 32g/kg. Foods to which phytosterol esters have been added may not be used as ingredients in other foods. May only be added to milk in accordance with Standard 2.5.1. May only be added to yoghurt in accordance with Standard 2.5.3.
D-Tagatose	
Tall oil phytosterols	The requirements in clause 2 of Standard 1.2.3. The name 'tall oil phytosterols' or 'plant sterols' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to edible oil spreads – (1) according to Standard 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food. May only be added to milk in accordance with Standard 2.5.1. Foods to which tall oil phytosterols have been added may not be used as ingredients in other foods.

Table to clause 2 (continued)

Column 1	Column 2
Novel Food	Conditions of Use
Trehalose	

Editorial note:

See Standard 1.3.4 – Identity and Purity for identity and purity requirements for novel foods.

3 Exclusive use of novel foods

(1) Despite clause 2, the novel food listed in column 1 of the Table to this clause may be sold as food or for use as a food ingredient for an exclusive period in the brand of food listed in column 2, in the class of food listed in column 3 and subject to the novel food complying with the conditions of use, if any, listed in column 4.

(2) The exclusive period commences on gazettal of the variation of this Standard to the Table to this clause.

(3) At the end of the exclusive period the novel food listed in column 1 of the Table to this clause, in the class of food listed in column 3 and the conditions of use, if any listed in column 4 is taken to continue as a novel food under clause 2 of this Standard.

(4) For the purpose of this clause, 'exclusive period' means the period of 15 months' exclusive use of the novel food listed in column 1 of the Table to this clause in the brand listed in column 2 and the class of food listed in column 3.

Table to clause 3

Column 1	Column 2	Column 3	Column 4
Novel Food	Brand	Class of Food	Conditions of Use

Editorial note:

Clause 3 of this Standard will be reviewed after 3 years and before 5 years from gazettal of this Standard in accordance with the request of the Ministerial Council on 4 May 2007 for review under section 113 of the *Food Standards Australia New Zealand Act 1991*.

Under subclause 3 the exclusive use permission reverts to a general permission under clause 2, after the 15-month period (exclusive period) has expired. The Table to clause 2 and the Table to clause 3 will be updated to reflect the operation of subclause 3. Note that the class of food and conditions of use, if any in the Table to clause 3 will be inserted in column 2 of the Table to clause 2.

For information purposes only, the exclusive period for the following novel foods listed in column 1 of the Table to clause 3 are as follows: **Novel food + gazettal commencement date + 15 months/end date**

ANNEX IX
FSANZ QUESTIONNAIRE

FSANZ-IN-CONFIDENCE

The following questions are to assist the Advisory Committee on Novel Foods (ACNF) in determining if a substance is likely to be considered a novel food or novel food ingredient in Australia and New Zealand. FSANZ reserves the right to ask for further information.

This communication is not to be taken as approval. You are advised to seek independent advice.

QUESTIONNAIRE to be completed by Enquirer

Product Name/Identifier	
Enquirer /Company	
Postal Address/contact details	
Telephone (include area code)	
Email	
If you are not the enquirer, please state your interest in this enquiry	
Date	
Attachments – if any please list	

Please answer <u>all</u> of the following questions. It is not sufficient to provide a 'yes' or 'no' response. You must provide justification for your answers and details of any reference material accessed in order to answer the questions.

We are unable to consider your inquiry until all questions are satisfactorily answered. We recognise that not all questions will be relevant to all enquiries. If you believe that a particular question is not applicable to your enquiry, please provide justification. FSANZ may request additional information.

1. Identity of food or food ingredient	
1.1 What is the name of the food/food ingredient?	
1.2 What are the specifications for the material?	

2. If the food is a plant or plant product, please complete the following information on botanical characterisation	
2.1 What is the common and botanical name of the plant or ingredient?	
2.2 What part of the plant is used or intended for use?	
2.3 What is the form of the final food/food ingredient? For example, does the final food product contain the plant itself, a ground up preparation such as a powder, or an extract	

3. Proposed use of the food or food ingredient	
3.1 How is the substance to be used in food?	
3.2 What type of products is the substance intended to be used in?	
3.3 At what level (or range of levels) is the ingredient intended to be used?	

4. Questions relevant to consideration of whether a food is non-traditional or not	
4.1 Does the food or food ingredient have a history of use as a food in any country? Details should be provided.	
4.2 How long has it been used as a food or food ingredient?	
4.3 Is the food or food ingredient recognised worldwide, regionally, or in isolated populations?	
4.4 Is the food or ingredient approved for use in other countries? Details should be provided (including information on current applications or petitions for approval for use in other countries).	
4.5 Is the food or food ingredient used by the general population or by a specific sub-population?	
4.6 What is the expected level of intake of the food or the substance from its use in food?	

4.7 How does the proposed level of intake compare with any traditional use as a food in any other country or region in which it has been used?	
4.8 Has the food or food ingredient been used as part of the regular diet or only at certain times (e.g. during famine or for ceremonial purposes)?	
4.9 Has the substance been used in the food context or has it been used for other purposes in addition to or instead of food use (e.g. traditional medicine)?	
4.10 If the substance has been used for medicinal purposes in any country, what are the therapeutic claims associated with its use?	
4.11 If the substance has been used for medicinal purposes in any country, what is the typical use levels prescribed?	
4.12 How do these medicinal use levels relate to the proposed level of intake from foods?	
4.13 Is the food produced by a process which has not previously been applied to food? Please include a flow process chart to describe the production method.	
4.14 Is the structure or composition of the final food or food ingredient altered because of the process by which the food has been prepared?	
4.15 Is the food or food ingredient produced from a source that in itself is not normally consumed as part of the diet?	

5. Public health and safety considerations	
5.1 Are there any known adverse effects associated with the use of the food or food ingredient in any country or region in which it has been used? Please detail the nature and extent of any such adverse effects.	
5.2 Does the food or food ingredient contain any substance known to cause adverse reaction or illness? Please detail the nature and extent of any such adverse effects	
5.3 At what levels of use have any such adverse effects been noted?	
5.4 Are any such adverse effects based on observations in humans or animal studies? Please provide copies of the referenced studies.	
5.5 What is the approximate amount present of any such substance known to cause adverse reaction or illness?	

5.6 Is any special preparation required before use? Is the food consumed raw or are there any cooking or processing steps required before the food is consumed?	
5.7 Is the structure of the substance similar to any other compound for which there are known safety concerns?	
5.8 Is the structure of the substance completely new, such that its safety for human consumption has not been established?	
5.9 If the food is a complex mix of ingredients, are there known safety concerns for any of the components? Are any of the components similar to those for which there are known safety concerns?	
5.10 If the structure or composition of the final food or food ingredient is altered because of the process by which the food has been prepared, what is the nature of any such alterations? Is the altered structure or composition likely to give rise to any safety concerns?	
5.11 If the source of the food or food ingredient is non-traditional, is the source itself known to contain undesirable substances?	
5.12 Is the source of the food or food ingredient new or uncharacterised such that its safety for human consumption has not been established?	
5.13 Does an altered pattern or level of consumption (refer to questions 4.5, 4.6, 4.10 and 4.11) give rise to any safety concerns?	
5.14 Is the expected level of intake likely to exceed levels at which there are known adverse effects?	
5.15 Is the level of intake likely to exceed any medicinal use levels?	
5.16 Is the level of use likely to exceed use in a country that it is used traditionally?	

6. Additional information	
6.1 Is there any other information that you possess and which would assist the ACNF in determining the issue? You should submit all information which is relevant even if not requested.	

ANNEX X
FSANZ PART 2 OF GUIDANCE TOOL

TEMPLATE for Part 2 of Guidance Tool: To be used for making a recommendation as to whether an assessment of public health and safety considerations is required for a non-traditional food

Matters to be considered	Explanatory notes	Evaluation
(a) The potential for adverse effects in humans	Relevant information could include: reports of adverse reactions from food use in other countries; demonstration of safe use in other countries; reports of adverse reactions from medicinal use[2]; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	
(b) The composition or structure of the food	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	
(c) The process by which the food has been prepared	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
(d) The source from which it is derived	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	
(e) Patterns and levels of consumption of the food	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	
(f) Any other relevant matters	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	

Recommendation

[2] An opinion on whether a product should be regulated as a food or a therapeutic good will have been provided (by the foods-therapeutic goods interface group) before any consideration is made by the Advisory Committee on Novel Foods. Reference to information about adverse reaction reports has been included in (a) because it is recognised that some ingredients could be used in both foods and complementary medicines (regulated as therapeutic goods). Any adverse reaction report on such an ingredient when used in a therapeutic good would raise safety concerns about its use in food and would be a trigger for requiring a public health and safety assessment for that ingredient when proposed for use in a food.

ANNEX XI
FSANZ RECORD OF VIEWS (OCTOBER 2009)

N.B: Only the Non-Traditional, Not novel foods are included below
See http://www.foodstandards.gov.au/foodmatters/novelfoods/novelfoodrecordofvie3934.cfm for full information and description

Food or food ingredient	Outcome View	Justification/Comment
Acerola (Malpighia glabra L) – frozen fruit pulp	• Non-traditional food • Not novel food	History of safe consumption in other countries. No safety concerns identified.
Agave nectar (from Agave tequilana azul)	• Non-traditional food • Not novel food	History of use as a sweet nectar in Mexico. No safety concerns identified.
Aloe vera (juice and juice concentrate)	• Non-traditional food • Not novel food	Small established market for beverages in Australia and New Zealand.
Amaranth seed (Amaranthus sp)	• Non-traditional food • Not novel food	No safety concerns identified.
Amomum tsaoko (seed)	• Non-traditional food • Not novel food	View is based on use as a spice. No safety concerns identified based on this use.
Apple polyphenol extract	• Non-traditional food • Not novel food	No safety concerns identified based on specifications provided.
Argan oil (derived from the fruit kernels of Argania spinosa)	• Non-traditional food • Not novel food	History of safe use in other countries. Chemical composition consistent with other vegetable based edible oils.
Bacillus coagulans (probiotic bacteria)	• Non-traditional food • Not novel food	Non-traditional in Australia and New Zealand, although some evidence of use in natto (Japanese fermented soybean product). No safety concerns identified.
BARLEYmax TM - Barley bred using traditional breeding techniques	• Non-traditional food • Not novel food	No safety concerns identified.
Bentonite clay	• Non-traditional food • Not novel food	No safety concerns identified at proposed levels of use.
Berries from palm fruit Açai (Euterpe oleracea) sourced from Brazil	• Non-traditional food • Not novel food	History of use in South America. No safety concerns identified.
Beta palmitin vegetable oil	• Non-traditional food • Not novel food	Use in infant formula products in overseas markets with no safety concerns identified based on this use. No concerns regarding composition.
Birds' nests (as produced by swiftlets in south-east Asia from saliva)	• Non-traditional food • Not novel food	History of safe use in Asian countries. No adverse health effects observed. No harmful substances identified. Relevant quarantine requirements exist.

Food or food ingredient	Outcome View	Justification/Comment
Boab fruit (otherwise known as boab nuts, from the Boab tree, Adansonia)	• Non-traditional food • Not novel food	Limited history of safe use in indigenous communities. No safety concerns identified. No concerns regarding composition.
Caja (Spondias mombin) – frozen puree.	• Non-traditional food • Not novel food	Non-traditional food. History of use in South America. No safety concerns identified.
Camu camu fruit (Myrciaria dubia)	• Non-traditional food • Not novel food	No safety concerns identified. No concerns regarding composition.
Cashew (Anacardium occidentale L) – frozen fruit pulp	• Non-traditional food • Not novel food	History of use in South America. No safety concerns identified. No concerns regarding composition.
Chia seed (Salvia hispanica L)	• Non-traditional food • Not novel food	No safety concerns identified.
Chinese bayberry fruit (Myrica rubra)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. No safety concerns identified.
Cocoa fruit (Theobroma ncar) – frozen puree	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. History of use as a food in South America. No indications of safety concerns.
Cocona fruit (Solanum sessiliflorum, also known as Solanum topiro)	• Non-traditional food • Not novel food	No concerns identified regarding composition or safety
Dairy mineral concentration (Lactosalt Optitaste)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand in context presented. Isolation and concentration of milk minerals and subsequent addition to other foods is not consistent with the history of consumption of dairy products. No safety concerns identified.
Damiana (Turnera diffusa or Turnera aphrodisiaca, same species) – non-culinary herb	• Non-traditional food • Not novel food when used in beverages at less than 100 mg/100 ml	No safety concerns identified at low levels of use. No application required when in beverages at less than 100 mg/100 ml.
Edible insects Zophobas morio (super mealworm), Achaeta domestica (house crickets), and Tenebrio molitor (mealworm beetle)	• Non-traditional food • Not novel food	Non-traditional in Australia and New Zealand. No safety concerns identified. Labelling of true nature of food required.
Evening primrose seed	• Non-traditional food • Not novel food	No safety concerns identified at the proposed levels of use.
Gac (juice derived from the fruit of Momordica cochinchinensis, Spreng)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. History of food use in Asia. No safety concerns identified based on composition of the fruit or the juice.
(High) α-Glucan cereals	• Non-traditional food • Not novel food	Natural variety sourced from a cereal fraction with high natural levels of α-glucan. No safety concerns identified.

Food or food ingredient	Outcome View	Justification/Comment
α-Glucan derived from barley, produced using a natural milling and separation process, potentially followed by further processing – e.g. enzymatic starch hydrolysis at elevated temperature with ethanol precipitation	• Non-traditional food • Not novel food	No safety concerns identified with the production method employed.
Goji juice derived from the goji berry (Lycium barbarum)	• Non-traditional food • Not novel food	Both the fruit and the juice are non-traditional in Australia and New Zealand. No safety concerns identified based on composition of the berry or the juice. History of food use in central Asia.
Grape pomace extract	• Non-traditional food • Not novel food	No concerns regarding composition or safety.
Grapeseed extract	• Non-traditional food • Not novel food	No concerns regarding composition or safety.
Graviola (Annona muricata L) – frozen fruit pulp	• Non-traditional food • Not novel food	Limited tradition of safe use in some population sub-groups. No concerns regarding composition or safety.
Green coffee extract (Coffea Arabica)	• Non-traditional food • Not novel food	Non-traditional use in food context. No concerns identified regarding composition or safety.
Guanabana fruit (Annona muricata L.)	• Non-traditional food • Not novel food	No concerns identified regarding composition or safety.
Kimchi (traditional Korean fermented dish)	• Non-traditional food • Not novel food	Made from some traditional ingredients, but is fermented. History of use in Korea without adverse effects.
Konjac (100% konjac in elastic, thermo-irreversible gel rather than as an additive)	• Non-traditional food • Not novel food	History of safe use in Japan and other Asian countries with no known adverse effects.
Korean supplement drink (containing lotus seeds and root (Nelumbo nucifera syn. Nelumbium speciosum), sea tangle or kelp (Laminaria japonica), jew's marrow (Corchorus olitorius))	• Non-traditional food • Not novel food	No safety concerns at the proposed low level of use of ingredients.
Kupua (Theobroma grandiflorum) – frozen puree	• Non-traditional food • Not novel food	History of use in Brazil and Peru. No indication of safety concerns.
Larch arabinogalactan (Larix occidentalis)	• Non-traditional food • Not novel food	Arabinogalactan (larch gum, 409) is approved for use as a Schedule 2 food additive in Standard 1.3.1. Non-traditional when used as a food ingredient. No safety concerns identified based on its history of safe use as a food additive.
Lithothamnium calcareum (also known as Phymatolithon calcareum or red	• Non-traditional food • Not novel food	No safety concerns identified.

Food or food ingredient	Outcome View	Justification/Comment
seaweed)		
Long neck turtle (Chelodina longicollis)	• Non-traditional food • Not novel food	Limited history of use in population sub-groups with safety concerns identified based on this use. The sale of the meat of long-neck turtles is not covered by the Code and would require permission for human consumption under State or Territory law.
Lycopene-enriched tomato extracts	• Non-traditional food • Not novel food	No safety concerns identified. Composition comparable to tomato paste products.
Maca powder (Lepidium meyenii)	• Non-traditional food • Not novel food	History of safe use in South America. No concerns regarding composition.
Mangosteen rind powder (Garcinia mangostana)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. No safety concerns identified.
Mycoprotein from Fusarium venenatum (QuornTM)	• Non-traditional food • Not novel food	Non-traditional in Australia and New Zealand, but has been widely available elsewhere for over 20 years. Reported cases of adverse events (gastrointestinal disturbance and allergy) are very rare. No safety concerns identified.
Oat fibre (powdered material prepared from oat hull)	• Non-traditional food • Not novel food	Non-traditional food because the oat hull is used to prepare insoluble dietary fibre in powdered form. The oat hull is not normally consumed as part of the diet. No safety concerns identified.
Pine bark extract	• Non-traditional food • Not novel when used as a surface treatment for cut fruit at 18 mg/L. • Other uses considered as a food additive.	Intended use will have a minimal impact due to: the small amount used on cut fruit; and the small number of products anticipated on the market. No application required when used as a surface treatment agent for cut fruit at this level. Other food uses of pine bark extract would be considered to have food additive (preservative) function and an application would be required to amend Standard 1.3.1.
Pistachia gum (for chewing) sourced from Pistachia terebinthus or Pistachia lentiscus (also known as turpentine gum and mastika gum)	• Non-traditional food • Not novel food	Non-traditional in broad community in Australia and New Zealand. Long history of use overseas (Middle East) and been available in Australia for some time.
Quinoa (grain sourced from South America)	• Non-traditional food • Not novel food	No safety concerns identified. No concerns regarding composition.

Food or food ingredient	Outcome View	Justification/Comment
Sauco fruit (Sambucus peruviana)	• Non-traditional food • Not novel food	Non-traditional in Australia and New Zealand. No concerns identified regarding composition or safety.
Schizandra (Schizandra chinensis) – non-culinary herb	• Non-traditional food • Not novel food when used in beverages at less than 100 mg/100 ml	No safety concerns identified at low levels of use. No application required when used in beverages at less than 100 mg/100 ml.
Sea buckthorn (juice derived from the berries of Hippophae rhamnoides L).	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. No safety concerns identified based on composition of the berries or the juice. History of food use in Asia and Russia and Europe.
Sheep's placenta	• Non-traditional food • Not novel food	No safety concerns identified.
Sugarcane fibres (bagasse fibre and pith fibre)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. No safety concerns identified.
Tapioca fibre	• Non-traditional food • Not novel food	Non-traditional food in form and context presented. Isolation of tapioca fibre and subsequent addition to foods that do not normally contain tapioca fibre is not consistent with its history of consumption. No safety concerns identified.
Tigernut oil and tigernut milk extract (derived from Cyperus esculentus)	• Non-traditional food • Not novel food	Non-traditional food in Australia and New Zealand. No indications of safety concerns. History of use in other countries.
Umbu (Spondias uberose) – frozen puree	• Non-traditional food • Not novel food	Non-traditional food. History of use in Brazil. No indications of safety concerns.
Yacon (Smallanthus sonchifolius)	• Non-traditional food • Not novel food	History of safe use in other countries. No concerns regarding composition.
Yuzu (Citrus Junos Siebold ex Tanaka)	• Non-traditional food • Not novel food	Tradition of safe use in Japan of the peel and oil in foods. No safety concerns identified. No concerns based on composition.

ANNEX XII
HEALTH CANADA NOVEL FOOD REGULATIONS

The following is a summary description of the Novel Food regulations in force in Canada.

The Canadian regulations on Novel Foods are contained in Division 28 of Part B of the Food and Drug Regulations (see ***Annex XIII***). The Guidelines on the Safety Assessment of Novel Foods[66] comment that "*changing consumer food preferences driven by exposure to different cultural and ethnic traditions as well as nutritional and health concerns have also resulted in the diversification of our food supply*".

The assessment of traditional foods is underpinned by the principle that foods that are not traditional in Canada may be widely consumed in other parts of the world. In some cases, adverse effects may be associated with their consumption or with the traditional methods needed to prepare the food prior to consumption.

Foods derived from sources not previously used as human foods must be evaluated for safety as they may contain toxins, contaminants and anti-nutritional factors. Conclusions from these assessments permit appropriate risk management measures to be taken.

A **novel food** is defined as

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

Within the above definition, "**major change**" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to
    (a) the composition, structure or nutritional quality of the food or its generally recognised physiological effects
    (b) the manner in which the food is metabolised in the body or
    (c) the microbiological safety, the chemical safety or the safe use of the food

Pre-Market Notification
Manufacturers or importers of novel foods are not permitted to sell or advertise for sale a novel food unless they have (a) notified the authorities of their intention to sell or advertise for sale a novel food and (b) received a written notice from the authorities that either (i) the novel food can be sold or advertised for sale or (ii) that additional information is necessary in order to assess the safety of the novel food.

[66] http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php#4.1.1

First Stage – Notification
The first stage of the procedure is to submit a Notification to the Food Directorate' Novel Food Section containing the following information:

(a) the common name under which the novel food will be sold;

(b) name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;

(c) a description of the novel food, together with
(i) information respecting its development,
(ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
(iii) details of the major change, if any,
(iv) information respecting its intended use and directions for its preparation,
(v) information respecting its history of use as a food in a country other than Canada, if applicable, and
(vi) information relied on to establish that the novel food is safe for consumption;

(d) information respecting the estimated levels of consumption by consumers of the novel food;

(e) the text of all labels to be used in connection with the novel food; and

(f) the name and title of the person who signed the notification and the date of signing.

If the information provided is not considered adequate to determine the novel food's safety, additional data supporting the safety of the food will be required. This information required, referred to as a Safety Assessment data package, will depend on a number of factors such as the nature of the food, processing methods and the intended use. Individual novel foods are assessed on a case by case basis.

Details of the procedure for submitting an application are given in the Guidelines for the Safety Assessment for Novel Foods[67]. It is not intended to detail the requirements in this report. However in certain respects it would be useful for those companies who intend to submit a Notification to review the information requirements detailed in the safety assessment guidelines and draw on relevant aspects to include in the notification.

There is no specification on the number of years that a food has had to be consumed to qualify as having a history of safe food use.

If further safety assessment is required the assessment follows a stepwise process examining factors that include:

- History of use
- Dietary exposure
- Nutritional considerations
- Toxicology considerations
- Allergenicity considerations
- Chemical considerations

[67] http://www.hc-sc.gc.ca/fn-an/gmf-agm/pol/index-eng.php

A substance may be considered to have a history of safe use as a food if it has been an ongoing part of the diet for a number of 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 Canada. The fact that a product has had a history of use according to the above definition in a jurisdiction with a similar food safety system would increase the level of confidence in the evidence presented. 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 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 Canada, including typical serving sizes and expected frequency of consumption, at both average and extremely high consumption levels.
- Analysis of the composition of the food based on randomly selected, statistically valid samples. This analysis should include proximate data as well 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 Canadian population (e.g. possible toxicants or allergens or unusually high levels of nutrients in the food source or final food product).
- Metabolism and/or gastrointestinal effects in humans.

The submission should include reliable, high quality information and reference sources. Anecdotal evidence will be given less weight than scientifically derived data. Information on the history of human exposure will be particularly important where there is traditional handling or cooking requirements for a food that is novel. This information will need to be made available to consumers in a consistent manner.

Examples of analytical tests are included and the Guidelines emphasise that special attention should be paid to the presence of compounds in the food which may have implications for the health of any groups of the Canadian population (e.g. possible toxicants or allergens or unusually high levels of nutrients in the food source or final food product).

ANNEX XIII
HEALTH CANADA DIVISION 28 OF FOOD AND DRUG REGULATIONS

Figure 1. Division 28 of Part B of the *Food and Drug Regulations*

Novel Foods

Interpretation

B.28.001. The definitions in this section apply in this Division.

"genetically modify" means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation. (modifier génétiquement)
"major change" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to
(a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;
(b) the manner in which the food is metabolized in the body; or
(c) the microbiological safety, the chemical safety or the safe use of the food. (changement majeur)
"novel food" means
(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. (aliment nouveau)

Pre-market notification

B.28.002. (1) No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food

(a) has notified the Director in writing of their intention to sell or advertise for sale the novel food; and
(b) has received a written notice from the Director under paragraph B.28.003(1)(a) or subsection B.28.003(2).

(2) A notification referred to in paragraph (1)(a) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:

(a) the common name under which the novel food will be sold;
(b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
(c) a description of the novel food, together with
(i) information respecting its development,
(ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
(iii) details of the major change, if any,
(iv) information respecting its intended use and directions for its preparation,
(v) information respecting its history of use as a food in a country other than Canada, if applicable, and
(vi) information relied on to establish that the novel food is safe for consumption;
(d) information respecting the estimated levels of consumption by consumers of the novel food;
(e) the text of all labels to be used in connection with the novel food; and
(f) the name and title of the person who signed the notification and the date of signing.

B.28.003. (1) Within 45 days after receiving a notification referred to in paragraph B.28.002(1)(a), the Director shall review the information included in the notification and

(a) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or
(b) if additional information of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.

(2) Within 90 days after receiving the additional information requested under paragraph (1)(b) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.