The EU Novel Food Regulation

Impact on the Potential Export of Exotic Traditional Foods to the EU: Suggestions for Revision

Discussion paper

prepared for UNCTAD and CBI

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BioTrade Facilitation Programme (BTFP)

UNCTAD

Through it's BIOTRADE Initiative, the United Nations Conference on Trade and Development (UNCTAD) works with partners in developing countries to promote trade in biodiversity products and services. These countries' increasing need for hands-on assistance in export promotion has led to the creation of a special trade promotion programme: the BioTrade Facilitation Programme (BTFP) for biodiversity products and services.

The following organisations are partners in the BTFP: the International Trade Centre (ITC), the Dutch Centre for the Promotion of Imports from developing countries (CBI), the Swiss Import Promotion Programme (SIPPO), the BioTrade National Programmes, PhytoTrade Africa, among others.

This programme is an official partnership of the World Summit on Sustainable Development (WSSD), and counts with the financial support of the Governments of Switzerland and the Netherlands. More information can be obtained at www.biotrade.org

CBI

The Centre for the Promotion of Imports from developing countries (CBI) was established in 1971 and is an agency of the Ministry of Foreign Affairs. CBI's main objective is to contribute to the economic development of developing countries in Africa, Asia, the Caribbean, Central and South America, Mediterranean and the Pacific. To fulfil this mission, CBI aims at sustainable strengthening the competitiveness of companies on the EU market. For CBI social values and compliance with the relevant environmental as well as health and safety requirements are an integral part of its activities.

CBI offers several products to assist companies to prepare for the EU market; market information, export development programmes, business support organization development programmes, training programmes and company matching. CBI serves three target groups: exporters and business support organizations in developing countries and importers in the EU and operates in a wide variety of non-traditional sectors. In all its products CBI focuses on the EU market offering 5 core competencies (1) market knowledge, (2) product and production improvement, (3) quality control, (4) export marketing and management, and (5) market entry. For disciplines beyond these core competencies, CBI cooperates with various other specialized organizations. More information can be obtained at www.cbi.nl

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Executive Summary

Abstract

A wide range of traditional food resources are potentially available from third countries but their introduction to the EU faces considerable hurdles as a result of strict interpretations of the EU Novel Food Regulation (NFR). The Commission recognised this and proposed possible solutions in its own Discussion Paper in 2002. This paper builds on the merits of the Commission's suggestions and explores further options for change from the perspective of developing countries, based on the premise that traditional foods with a long history of human consumption should be considered separately from truly "innovative" products such as novel additives and food chemicals.

The paper examines the difficulties presented to potential exporters by the NFR and develops proposals whereby traditional foods undergo a central notification and evaluation procedure, supported by EFSA risk assessment only when valid and reasonable doubts about safety are identified. The methods used would be obliged to take into account the wider global recognition afforded to these foods, be proportionate to any potential risks envisaged and not disproportionately prevent access to the EU market.

The paper addresses associated marketing rights, proposing generic mechanisms for approvals of traditional foods and food classes and concludes that the introduction and development of a separate category for non-EU traditional foods should be progressed.

Summary

A wide range of traditional foods potentially available from developing countries is being denied access to the EU by over-strict interpretation of the NFR, which fails to differentiate fails between genuinely new foods that have not been consumed anywhere before, and foods that are merely new to Europe and are only "novel" due to an arbitrary cut-off date in legislation that was not intended directly for them. Equally, these "exotic" foods are denied exemption from the notification procedure because they do not have "a history of significant, safe food use in the EU, prior to May 1997". They must therefore undergo a stringent, formal EU safety assessment and pre-market authorisation, for which scientific and administrative demands are considerable, potentially lengthy and expensive, and place a heavy and disproportionate burden on potential exporters.

The scientific criteria for the safety of traditional foods reflect the approach taken towards GM-derived products, seemingly to establish "zero risk" or "proof of absence" of risk. However, the long history of use of traditional foods by indigenous populations in their country of origin is itself evidence of their safe use, since this would have ceased if they had been found to be disproportionately unsafe. In practice, safe preparation methods and consumption patterns have evolved accordingly. It is thus inappropriate only to apply absolute scientific parameters to the safety assessment of traditional foods without also taking fully into account traditional precautions that are an integral part of their safe preparation and use.

Consistent application of the Regulation has been hindered by differing interpretations of key terms such as "significant degree", "generally recognised" and "substantially

equivalent". Measurement of "significant" prior consumption has been taken as sales through general food outlets and has excluded sales through pharmacies. This is inappropriate in EU-25, where sales patterns vary widely and sales through pharmacies may be considerable. It is also necessary to clarify whether "significant consumption" refers to the quantity consumed or to its nutritional relevance. The absence of a legal definition on which to base comparative safety (more specifically, potential risks) of traditional foods against other foods already on the market has resulted in it being very difficult for applicants to meet the authorities' perception of "generally recognised" scientific evidence to show a product is "substantially equivalent" and, consequently, all foods "notified" to date have relied upon opinions of competent food assessment bodies rather than the judgment of the applicant. More precise definitions of key terms within the regulation, and a more pragmatic definition of a "novel food" are required and, if this proves impossible, clarification should be given in implementation guidelines.

The very restrictive regime for novel foods was introduced at the height of the BSE crisis and in the face of the imminent introduction of genetically modified food crops. However, NFR no longer applies to GM products and all aspects of the EU food safety regime have recently been fundamentally overhauled. The comprehensive scope of current EU food safety legislation, and the responsibilities that it defines for businesses and control authorities, mean that NFR now contributes only a small part towards guaranteeing overall consumer safety and the application of its original, GM-driven strict procedures to traditional foods is no longer appropriate. Planned new controls on herbal extracts added to foods for functional purposes will further diminish its role. Thus NFR can, and should, be revised to include a separate category for traditional foods without reducing consumer safety, yet at the same time facilitating trade in accordance with the EU's international obligations and responsibilities.

An alternative, streamlined central procedure should be introduced for a new, separate category of "traditional non-EU foods". A proportionate, cost-effective approach should be taken, reflecting that there is no such thing as "zero risk". It should require evaluation to be proportionate to any realistic, potential risk associated with their introduction, recognise potential compensatory benefits and ensure that they are regulated (or not) accordingly. This process could be based on an initial notification to the Commission, complemented with a proportionate pre-market evaluation and require detailed scientific assessment only in cases where there might be valid doubts about food safety aspects. This detailed scientific evaluation would also be performed at Community level by EFSA.

The approach should take full account of the global history and consumption patterns of the product, and customary knowledge related to its existing food use and traditional preparation. Full consideration must be given to scientific assessments and other relevant evidence, available globally (such as US panels, Canada, FSANZ, Japan etc). The level of evidence ("proof") required should be commensurate with the level of perceived risk, taking particular account of realistic estimates of likely EU consumption patterns. This will provide an estimate of the chance / level of any potential risk and will identify the type and depth of additional evidence (if any) that may be required to establish an acceptable level of safety or justify any restrictions on the availability of the product.

Concerns expressed in some quarters about the validity of 3rd country data used to support novel food applications could be resolved by adapting the principles in Regulation 882/2004 on Official Controls. The range of "guarantees" required from

national authorities for technical purposes could be extended to include similar "guarantees" from recognised non-administrative sources (such as universities, national and regional Institutes and global organisations) as an essential element of acceptable evidence and assurances relating to the safe history of traditional, national products. The Official Control Regulation also recognises that EU requirements must be technically and economically feasible and, therefore, provides for technical assistance to 3rd countries. This may provide a model for future developments in respect of the NFR.

In respect of risk management, there should be no pre-determined requirements for labelling or post-market monitoring. Any specific labelling provisions should be adopted only on a case-by-case basis to inform consumers of any significant requirements, such as storage or preparation, where these might be necessary to ensure safe consumption of the food. Post-market monitoring should only be considered in very specific cases, e.g. to monitor actual availability and consumption where the risk assessment determined that a low level of consumption was safe but higher levels might be a potential cause for concern in defined sectors.

The current regulation potentially may result in an effective "monopoly" being granted to a single company for the use of a traditional, naturally-occurring food. This appears to be in conflict with the spirit of international law, which provides that no natural substance can acquire intellectual property protection. This outcome could be mitigated by extending authorisations to cover broader, generic categories in a way that allows the natural resource to remain available for all developing countries operators.

Whilst the EU rightly regards food safety as one of its highest priorities, its laws and their application must be consistent with its global commitments to trade, development and aid. Where the demands exceed safety levels acceptable in the country of origin or in international standards, they must be justified. This does not appear to be the case with NFR and the stringent demands that it implicitly makes for the prior safety assessment of traditional foods. The applicant must prove his product meets (higher) EU standards whereas, arguably, it is the EU's responsibility to prove that the products concerned are unsafe – a reversal of the current balance of proof. Also, in practice, the applicant cannot rely on the most important evidence (i.e. safe food use over many years) but instead must produce detailed scientific evidence. The criteria for determining scientific "safety" (in practice virtual absence of risk) appear excessively and even prohibitively strict when applied to foods already available outside the EU, to the point where the implementation of NFR may run counter to WTO rules, creating a *de facto* non-tariff trade barrier and consequently impeding the economic development of sectors and countries concerned.

1. Introduction

The EU Novel Food Regulation EC 258/97[1] came into force in May 1997. Its principal objectives are to protect public health and to improve the functioning of the internal market. Unless a "novel food" can be shown to be "substantially equivalent" to an existing product already available on the EU market, NFR imposes a formal authorisation procedure which implicitly requires a stringent safety assessment. The scientific and administrative demands are considerable.

However, NFR also requires the Commission to review its implementation and, where appropriate, propose suitable amendments. This review was initiated in July 2002[2].

Responses identified several problem areas. In particular, there is a strong view that the Regulation has been over-strictly interpreted in respect of "exotic traditional foods" - foods with a long history of consumption in third countries, but not able to show a significant consumption in the EU market. Usually these "exotic foods" are grown or produced in developing countries by resource-poor producers and small traders.

Several international and regional organizations are promoting "biotrade" – sustainable biodiversity-based trade - to promote trade in these traditional food and food ingredients for poverty alleviation and sustainable development, in support of the principles of the Convention on Biological Diversity and trade and development objectives defined at the World Summit on Sustainable Development. The UN Conference on Trade and Development (UNCTAD) hosts the BioTrade Facilitation Programme[3], with partners including the Netherlands-based Centre for the Promotion of Imports from developing countries[4] (CBI), the Swiss Import Promotion Programme[5] (SIPPO), German Technical Cooperation[6] (GTZ), the Global Facilitation Unit for Underutilized Species[7] (GFU) and International Plant and Genetic Resources Institute[8] (IPGRI), plus regional and national biotrade groups in Africa, South America and Asia.

Through their work with exporters, these groups have experienced that NFR, as currently applied, is in direct conflict with their aims and is preventing small-scale farmers and communities in developing countries from using their rich botanical heritage to improve their economic situation. The requirements to produce extensive scientific dossiers - to prove safety beyond doubt - place a heavy burden on producers and exporters, and in many cases are far beyond their means. Frequently, the minor crops from which these foods are produced have been largely neglected by modern science,

[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] 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

[3] Bio-Trade Programmes exist or are being developed in: Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Paraguay, Peru, Uganda and Venezuela. PhytoTrade Africa is active in Botswana, Malawi, Namibia, South Africa, Zambia, and Zimbabwe. http://bio-trade.org/btfp.htm

[4] Centre for the Promotion of Imports from developing countries: http://www.cbi.nl

[5] Swiss Import Promotion Programme: http://www.sippo.ch

[6] German Technical Cooperation: http://www.gtz.de

[7] Global Facilitation Unit for Underutilized Species: http://www.cbi.nl/show.php http://www.underutilized-species.org/the_latest/archive/pop_up/eu_nfr.html

[8] International Plant and Genetic Resources Institute: http://www.ipgri.cgiar.org/index.htm

so the required data does not exist in formally documented records but only in the customary traditions and knowledge of the local communities.

UNCTAD and its partners believe NFR may, *de facto*, create a non-tariff trade barrier against these products, consequently impeding the economic development of the sectors and countries concerned and, therefore, strongly supports amendment of NFR to facilitate biotrade in safe food products.

Previous studies[9],[10],[11] have 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:

- Can "exotic traditional crops / foods" be defined (legally) as a category?
- What is "traditional use" and how might it be defined?
- How can "customary knowledge" and "modern science" be balanced, proportionately, to meet requirements for "scientific evidence" in safety dossiers?
- How, where and by whom, can "scientific evidence" be produced that is considered valid: i.e. by applicant industry / national authority; university / research institutes; third country / EU?
- More cost-effective administrative and scientific assessment procedures for submitting and evaluating applications are required, which need to be economically and technically feasible for exporters from developing countries.
- Are generic applications / authorisations feasible for some categories of products?

[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

2. Objectives

This paper seeks to answer these questions and concerns from the perspective of developing countries and their supporting agencies.

The DG SANCO Discussion Paper[2] already recognised the difficulties faced by potential exporters of exotic traditional foods and made positive suggestions towards resolving these. This paper therefore also builds on DG SANCO's suggestions by further assessing why the regulation presents difficulties and how these may be resolved.

The paper explores the possibility of creating a distinct category of "exotic traditional foods" so that they may be considered separately from novel chemical entities and additives etc, and can either be regulated as such within a revised Novel Food Regulation or, potentially, under their own specific legislation.

It seeks to define, in particular, an alternative, proportionate food safety assessment that more fully recognises the history of "exotic traditional foods" and their likely role in the European diet, and that does not hinder exporters from developing countries more than necessary, whilst still delivering an adequate level of consumer safety. It is intended that such a scheme should be less complex than that currently applied, scientifically and legally acceptable to EFSA and the European Commission, respectively, whilst being economically and technically feasible for exporters from developing countries. In particular, a clear distinction is sought between the scientific risk assessment and aspects of risk management such as labelling and post-market monitoring. The revised scheme should also be accompanied by clear guidelines on the structure and content of any food safety dossiers that may be shown to be necessary.

Integral to a simplified scheme is the need to define a legal mechanism whereby the EU can accept evidence and assurances from, or on behalf of, the exporting countries. The paper, therefore, seeks to establish a process for recognition of relevant traditions, based on information from recognised local or global institutions.

Developing countries have a strong interest in exploring new markets to boost trade and provide social and economic benefits. In many cases, these initiatives are actively and financially supported by the European Commission, individual Member States and international agencies but are, in practice, seriously impeded by the technical barriers established as a consequence of the Novel Food Regulation. This paper therefore aims to ensure that economic and other development aid can be brought to fruition by reducing these barriers to proportionate and cost-effective levels by exploring the possibility of generic admissions, as opposed to individual approvals, where these are related to commercial marketing rights applied to traditional foods and knowledge.[5]

The over-riding objective throughout the paper is to ensure that a revised NFR should represent a proportionate and cost-effective approach to any potential risk that traditional foods might pose.

The paper does NOT address any animal feed, plant health or environmental issues that may arise from the import of these products or their by-products.

3. Background to Current Concerns

3.1 Current Scope

Regulation 258/97 is interpreted to encompass "Exotic traditional foods". The exemption provided for plants and plant products obtained by traditional methods is not granted, even when these products have a history of safe use, solely on the basis that this experience of safety is derived from consumption outside the EU.

The Novel Food Regulation ("NFR") specifies that two conditions must be met for foods and food ingredients to be considered as "Novel" and to be approved for sale in the EU:

- they have not been used for human consumption to a "significant degree" within the Community (prior to 15th May 1997), and
- they fall within a sub-category of foods defined as "*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*".

Accordingly, to be a "novel" food, a product must fulfil both conditions. These have been interpreted to encompass "exotic traditional foods".

The NFR seeks "to protect public health and to improve the functioning of the internal market" by imposing a formal authorisation procedure. This implicitly requires a stringent safety assessment for which the scientific and administrative demands are considerable, potentially lengthy and expensive. They place a heavy and, arguably, disproportionate burden on potential suppliers from developing countries and EU importers by introducing considerable investment costs in order to overcome the perceived trade barriers.

Initially, the NFR also covered Genetically Modified Organisms (GMOs) and products derived from them, the safety requirements for which contributed to the strictness of the required assessment procedures. These products are now regulated under separate, specific legislation[12] but, in practice, all non-GM novel foods remain effectively subject to the rigorous and stringent scientific scrutiny that was originally designed for GMOs.

Although the legal exemption for products obtained by traditional propagating or breeding practices remain in place, the key issue is the linked requirement "***and*** *having a history of safe food use*" and the way this is assessed in practice.

This all-encompassing approach is particularly relevant for plants and plant products which are customarily obtained in countries outside the EU, using traditional methods of propagation or cultivation, but which cannot be proved to have been used for human consumption within the EU "to a significant degree" (even though it is likely that they have been imported and consumed by ethnic populations for many years). In addition, having been deemed "novel" (in the EU) solely because of an arbitrary cut-off date imposed by legislation (whose prime purpose was not specifically designed with these products in mind), the EU scientific assessment has then not accepted "a history of safe food use" in their country of origin. For example, Nangai nuts and Stevia were rejected;

[12] 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

comprehensive scientific evidence was required for Noni juice before it was accepted. Argan Oil was only accepted following the rejection of objections from several Member States. In all these cases, objections were against the lack of data, on the one hand, to show the absence of potentially harmful components and/or metabolites and, on the other, the presence of contaminants that should more appropriately be judged on a case-by-case basis against individual consignments of products at import – i.e. not intrinsic properties of the product, rather a result of poor product handling. In the case of Chia seeds (given a somewhat negative Opinion by EFSA[13] and now awaiting a Decision from the Commission), little if any credit seems to have been given to potential beneficial properties of the nutrients such as *ω*-3 fatty acids, focussing instead on the uncertainty with regard to potential allergenicity and the conclusion that "the presence of constituents which might exert anti-nutritional or toxic effects cannot be excluded".

The Commission recognised the difficulties faced by traditional products in its 2002 discussion paper (paragraph 3.3.1) and proposed Options to resolve them. We see particular merit in the Commission's Option 2 and have explored a further development of this by considering the involvement and recognition of 3rd country national authorities and laboratories that will become necessary under the new EU legislation on Official Control procedures in respect of food imports from third countries[14].

3.2 Adverse Consequences of Imprecise Definitions

Consistent application of the Regulation has been hindered by different interpretations of several key terms, resulting in different interpretations as to what are considered as "Novel Foods". More precise definitions and consistent application of the concepts are required and, if this proves impossible, clarification should be given in implementation guidelines.

3.2(a) "Significant"

This a qualitative term, the interpretation of which will vary according to the (subjective) priorities of the user and the recipient / interpreter of the term. What is "significant" to one interest may be wholly "insignificant" to another, despite the objective facts under consideration clearly being the same. Its use 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 its potential for uniform interpretation and application.

3.2(b) "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.

Many authorities have linked "significance" with availability in supermarkets and general food outlets, and do not accept sales through pharmacies. This approach is not appropriate in EU-25, where retail practice differs more widely than in EU-15. In some countries, sales through pharmacies may be as much for marketing reasons as a legal necessity derived from any pharmaceutical properties, and may be considerable.

[13] http://www.efsa.eu.int/science/nda/nda_opinions/1205_en.html

[14] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; OJ L 191 28.5.2004 p1: http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_191/l_19120040528en00010052.pdf

"General availability" should also include historic, local production and/or old traditional types of domestic consumption, not just sales via retail food outlets, and must now encompass all 25 Member States.

It is a moot point whether refusing to accept the full range of availability of the products, and then using "lack of consumption" as part of the argument to block imports of third country products, might also be regarded as a non-tariff barrier.

Furthermore, it is currently almost impossible for a potential importer into 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 history of these products difficult 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 and nor, therefore, would the precise identity of the product appear in import statistics.

However, the existence of the 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. As an example, if a free trade regime existed between a country and the EC and a sizeable number of immigrants from that country/region are living in the EC, it is likely that the product would already have been imported and could be excluded from "novel" food criteria.

"Significant consumption" (measured **numerically)** should be considered as an appropriate combination of both geographical / historical availability and volume of consumption. The ***"significance of the consumption"*** – from a **food safety and nutritional** relevance viewpoint – is a different concept which should also recognise and encompass global consumption but, dependent upon the nature of the food and its target market / population, 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".

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, 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"*** would better reflect that "no risk" is unachievable, but minimized risk is possible.

The difficulties of establishing tangible evidence of prior consumption in the EU have been described above; or 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). The need to take full account of ***"customary knowledge", "traditional"*** experience and history of safe use outside Europe is considered further in Section 4.

3.2(c) "Substantial" and "substantially" are terms representing a range of interpretations relating to comparisons. "Substantially" can, linguistically, mean anything between "broadly the same" (i.e. indicating a relative lack of precision) and "virtually identical" according to the context in which it is used. Similarly, the concept of ***"equivalence"*** lacks legal precision. Thus, when these terms are used together, the combined lack of precise legal meaning (and/or lack of clear interpretive guidelines for the assessors) leads to imprecise requirements for, and evaluation of, the scientific evidence needed to ensure that an assessment of the safety (or more specifically, potential risk) of novel products is proportionate to any realistic risk associated with their potential EU consumption. This uncertainty, combined with zealous application of the "precautionary principle" has led to the scientific assessors applying the most stringent criteria and contributed to the over-strictness of the present regime, in particular by removing any possible comparison of relative safety against similar, existing foods in those cases where there is no directly "equivalent" conventional food in European culture.

Thus, in practice, the current fast-track "notification" procedure, based on a "novel" food being "substantially equivalent" to another, existing product has been largely unavailable for the initial introduction and evaluation of 3rd country foods, since the assessors have felt it to be impossible to accommodate any flexibility to the "equivalence" against which safety comparisons could be made. However, the principle is now being applied to subsequent notifications of Noni juice, following the initial approval granted to Morinda Inc., and currently over 25 "notifications" for equivalent products have been accepted.

3.3 SCF 1996 Opinion and Commission Recommendation 97/618

The Opinion[15] of the former SCF provided the framework for evaluations of all novel foods (Recommendation 97/618[16]), including those derived from GM technology, and introduced an extremely cautious approach towards the "novelty" in the EU. This was understandable at the time. In 1997, all parties were extremely sensitive to the consequences of BSE and other food safety "scares", which had seriously affected the credibility both of scientists involved in food safety and of the assessment and regulatory processes. When faced with the introduction of foods from GM crops, an extremely cautious approach was adopted. At this time, the Food Safety White Paper[17] was still 3 years into the future and much of today's food safety legislation was either not in place on a pan-EU basis or had not been updated for many years.

Despite the very significant changes that have now been introduced into food safety legislation in the intervening 8 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. In respect of "exotic" traditional foods, insufficient consideration appears to be given to the traditional management of known risks (e.g. preparation methods and

[15] SCF Opinion on the Assessment of Novel Foods, Parts I - III, 7.6.96: SCF Reports, 39th series, pp33 – 70.

[16] 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.

[17] White Paper on Food Safety COM (1999) 719 final: Brussels, 12 January 2000 http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf

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 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). 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) as with Chia, above.

There is a perception that the introduction of transparency to all aspects of assessment and regulation has led many individuals involved to act as if they feel obliged to protect both their personal and professional positions from potential "blame" in the event of any future (currently unpredictable) crisis.

3.4 The Notification Procedure and Traditional Use

A simplified, "notification" procedure is permitted for "novel" foods which meet certain criteria and have a history of safe use, if they are considered to be "substantially equivalent" to existing products. The lack of legal certainty in these concepts, described more fully above, is implicitly recognised in the NFR by providing for arbitration if it is disputed whether a "novel" food is "substantially equivalent". Nevertheless, it has proved difficult for applicants to persuade authorities that their product is "substantially equivalent" and, consequently, all "notifications" have relied upon opinions of a national assessment body rather than the judgment of the applicant.

It is always emphasised that the requirement is to demonstrate safe use – and that history of use alone is insufficient, regardless of the length of that use. There is an equally strong counter-argument that the wording of NFR requires a history of safe USE of the product, not absolute safety *per se* of the raw material. **The long history of use by indigenous populations is itself 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.**

3.5 Strengthening of EU Consumer Protection Legislation since 1997

EU food safety legislation has been significantly revised and strengthened since the NFR was introduced. It comprises comprehensive food safety, import and marketing controls, with defined, legal responsibilities to ensure that safety is delivered throughout the food supply chain. Much of the legislation is of general application and applies to any business or 3rd country wishing to trade in "exotic traditional foods" as well as to the individual, traded products themselves. In addition, Regulation 882/2004 on Official Controls introduces procedures that will be very relevant to future controls of these foods (section 3.5(c) and Annex II).

Compliance with specific safety parameters (detailed in numerous secondary statutes) is thus an ongoing legal responsibility for all food businesses, independent of the "novelty" or otherwise of their products. It is neither necessary nor appropriate for initial safety assessments of non-GM "novel" foods to include potential contamination (such as heavy metals and micro-organisms) during harvesting, production, transport and storage. The "novel" food assessment should focus on naturally-occurring parameters that are inherent to the novel food and, if potential toxicological concerns are identified, these

must be assessed in conjunction with the scientific basis of the traditional methods used to manage and control the safety of the food prior to consumption.

Thus, the NFR now contributes only a small part towards guaranteeing overall consumer safety and the severe demands, restrictions and prohibitions imposed on "novel" foods from outside the EU have become wholly disproportionate.

The key legislation is indicated below.

3.5(a) General Food Law - Regulation 178/2002[18]

This "umbrella" statute for all legislation relating to food safety makes the **business operator** legally responsible for ensuring that he places only safe and legal products on the market. This fundamental requirement was not in place when the NFR was introduced.

3.5(b) General Food Hygiene - Regulation 852/2004[19]

This recently-overhauled Regulation defines extensive hygienic practices at all stages of the production and supply chain. All foods imported into the EU must have been produced and handled in a way that complies with Community, or equivalent, hygiene standards. Because of legal links with Regulation 882/2004, many of its requirements will, *de facto*, have to be operated by 3rd country businesses as an integral part of the EU's acceptance of those countries as exporters.

3.5(c) Official Controls - Regulation 882/2004[20]

With effect from January 2006, considerably stricter EU requirements for imports of plant-derived materials will be introduced, which will be of particular importance to countries potentially wishing to export "exotic traditional products". The EU will require formal "guarantees" from 3rd country that all export products meet EU, or equivalent internationally recognised, standards of food safety. These "guarantees" must be based on effective, impartial legislative and administrative structures, and scientific results derived from officially-approved laboratories equipped and operated in accordance with internationally recognised and audited standards. Fuller details are given in **Annex II**.

3.5(d) Food Fortification - Proposed Regulation[21]

This proposal will ultimately be extremely relevant for traditional botanical products, as uses of their derivatives are likely to fall under the "herbal extracts" category. EFSA will evaluate the addition to foods of various plants and herbal extracts, whose consumption

[18] Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 L 31, 1.2.2002 p1

[19] Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs: OJ L 226, 25.6.2004 p3

[20] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; OJ L 191 28.5.2004 p1

[21] Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods: 2003/0262 (COD).

may represent an identified risk to consumers, and either to allow general use or, if there are any safety doubts, assign products to one of three restricted categories:

- Prohibited substances (absolute);
- Restricted substances: food use is only permitted under defined conditions;
- Substances "under Community scrutiny": where the initial evaluation identifies a possibility of harmful effects but uncertainty exists, EFSA will carry out further safety evaluation and decide whether to allow general or restricted use or to prohibit it, as appropriate.

The mechanisms for the compilation, submission and consideration of the scientific data have yet to be established but may provide a model for traditional exotic products.

3.5(e) Labelling - Directive 2000/13[22]

Comprehensive labelling legislation requires the name or, where this may not be understood by a consumer, a full description of the nature of a food to appear clearly on the label. Instructions necessary for the safe storage and preparation of the product are mandatory. Thus, consumers who may not be familiar with a particular product are already protected.

The use of medicinal claims on foods is prohibited and the framework for health / nutrition claims is in the final stages of development. This will control marketing aspects of traditional products and the efficacy of claims made for them. Such assessments should not form part of the novel food evaluation, *per se*, which should focus on the safety of the product (see section 6.2(e) below).

3.5(f) Traditional Herbal Remedies - Directive 2004/24[23]

[N.B. This Directive is not applicable to food use of "exotic traditional foods", nor is this paper suggesting in any way that these products should fall under its scope. However, the arguments used to define and derogate "traditional" products with a history of safe use from full regulatory controls are very relevant to the discussion of traditional foods.]

This Directive illustrates principles recently introduced into EU medicines legislation to accommodate products that parallel those considered for food use in this paper. It identifies, defines and authorises a separate category of "traditional herbal medicines" that, although lacking sufficient, formal, scientific proof of their properties, nevertheless demonstrate well-established use with recognised efficacy and an acceptable level of safety. These may be marketed following a special, simplified registration procedure without being subject to the full medicines licensing process.

3.5(g) Other plant etc protection measures

Comprehensive EU legislation on plant health / disease protection exists, reflecting international requirements under the International Plant Protection Convention (IPPC), under which any potential threat against EU plant pests and diseases from third

[22] Directive 2000/13 of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer: OJ L 109 6.05.2001.

[23] 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

countries would be regulated. This potentially over-rides all the legislation above, and unless the plant and animal disease status of the country concerned is acceptable to the EU, then no imports of plant / animal products, respectively, would be authorised, regardless of other considerations.

3.6 Global Agreements on Trade and Safety Matters

The EU rightly regards food safety as one of its highest priorities but controls must, nevertheless, be applied within its global commitments to trade, development and aid. Two elements are of particular importance: the founding Treaty of the EU itself and the WTO SPS Agreement.

The Treaty (Articles 177, 178) requires Community policy and its implementation to foster sustainable economic and social development of developing countries, (particularly the most disadvantaged) and their smooth and gradual integration into the world economy.

Under WTO rules, where EU consumer protection laws conflict with the level of safety acceptable in the country of origin, or exceed those established in international standards, then it must justify its position. This does not appear to be the case with NFR, under which the applicant must prove his product meets the (higher) EU perceptions of safety whereas, arguably, the balance of proof should be reversed, and the EU required to prove that the products concerned will be unsafe for consumption.

Although the SPS Agreement fully recognizes the legitimate interest of countries in setting up rules to protect food safety and animal and plant health (and, in fact, allows countries to give these objectives priority over trade, provided there is a demonstrable scientific basis for their food safety and health requirements[24]) it also provides that, in doing so, they have to take into account the objective of minimizing negative trade effects (Article 5.4). Of particular relevance to traditional foods from 3rd countries is the obligation to avoid unjustifiable distinctions in the levels of protection the EU considers to be appropriate in different situations, if such distinctions result in discrimination or disguised restrictions on international trade (Article 5.5).

It can also be argued that denying traditional foods access to a simple notification procedure contravenes the principle of proportionality, since all “novel” foods are subject to the same main procedure. This potentially constitutes discrimination, since situations that are totally different are being treated in exactly the same way.

The Agreement also permits the adoption of provisional measures as a precautionary step where the scientific evidence is insufficient. However, the emphasis is on provisional, and the necessary evidence must be sought within a defined time-scale.

Recognising that some restrictions may be scientifically justified but difficult for the exporting country to meet, Article 9.2 introduces the possibility of aid being provided.[25]

[24] More specifically, the Agreement covers measures adopted by countries to protect human or animal life from food-borne risks; human health from animal- or plant-carried diseases; animal and plants from pests and diseases; and the territory of a country from the entry, establishment, or spread of pests.

[25] SPS Agreement, Article 9.2: “where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved”.

Organisations involved in developing trade from developing countries[3] believe that the practical implementation of NFR may be creating a non-tariff trade barrier and consequently impeding the economic development of the sectors and countries concerned. Nevertheless, to date there have been no formal complaints lodged against NFR, although this may be a consequence of the costs involved in pursuing a complaint compared with the commercial value of initial, potential trade in a given traditional food.

3.7 Monopoly Rights to Natural Products

NFR, in practice, has resulted in single company applications, and the first applicant being granted an effective "monopoly" for a natural food. The time taken, to date, to progress applications results in the potential for this "monopoly" to last for a considerable period unless a second applicant is able, very quickly, to demonstrate that his product is "substantially equivalent" to the original authorisation. This practical consequence of NFR appears to contradict the principles of international law whereby no natural substance can acquire intellectual property protection (considered further in **Section 6**).

4. The Concept of Tradition and "History of Safe Use"

As discussed in Section 3.2, considerable uncertainty surrounds interpretation of the scope of the Regulation as a result of the use of terms such as "history of use". The following section explores possible ways to resolve the issue. It is unlikely that a legally precise (and concise) definition for this class of products can be developed but a set of criteria to be met is developed. The use of these as the basis of the information to support an application to market a traditional food is described in **Section 7**.

4.1 "Exotic Traditional Foods"

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 crops, "traditional" in their country of origin, is effectively blocked or at best disproportionately difficult and expensive. A revised NFR should treat these products as a separate novel food category and should exempt foods which have a history of safe use, wherever this may be.

Collaboration between EU specialist plant breeders / taxonomists, food experts and nutritionists and their counterparts in the appropriate 3rd countries will be essential to establish clearly the concept of **"traditional",** when used in the context of products that are part of the history and culture of the indigenous population of developing countries. This would also facilitate potential "generic approvals" for such products.

If assurances from local experts are developed within an appropriate framework, it will facilitate the protection and identification of "exotic traditional products" by virtue either of their geographic origin[26] or specific characteristics[27]. Potential products that could be considered for this type of collaboration were described in an earlier GTZ paper[6].

A Working Group of the Nordic Council has recently examined in further detail whether, and/or to what extent food plants not hitherto consumed in the EU need to undergo scientific safety assessment.[28] The Nordic paper 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 has already identified approximately 300 food plants that would be unlikely to be considered "novel"[29]. This work is due to be expanded to cover EU-25 under a new EUROFIR project.[30]

[26] 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

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

[28] 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.

[29] Holm, S., 1998. NETTOX list of food plants prioritised for inclusion in a future European database. Report no.6 (of 9). EU-AIR concerted action CT 94 2185, information on inherent food plant toxicants. Danish Veterinary and Food Administration, Søborg.

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

The principles on which the Official Control Regulation (882/2004) is based could be extended to enable the EU authorities to accept "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. Several aspects of this approach are explored in this paper and the detailed requirements summarised in **Annex II**.

4.2 "Traditional use"

There is no directly applicable definition of "traditional" for the purposes of EU food legislation, although the term has recently been defined within the Traditional Herbal Medicines Directive[31] enabling products that meet the criteria to avail themselves of a simplified registration procedure. In language, the expression "traditional use" can apply to either / both time-related aspects of use or the nature of the use of the material itself.

4.2.1 Time-related use

A detailed study by the UK Food Advisory Committee (FAC, 2001) 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[32]. 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 the exotic products from developing countries can clearly be considered.

The FAC examined a wide range of current applications of the term to food products and processing. Recognised uses of 'traditional' included it being related 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", and the food, food ingredients and processes used for their preparation should have been available, substantially unchanged, for that same period. FAC felt that a suitable period was likely, to some extent, to be product-specific, and suggested 2 generations / 50 years. But recommended that, whatever the period there must be clear and reliable evidence to substantiate the use of the word for the particular product.

Revised Guidelines currently under discussion in Canada[33] are suggesting 3 generations / 100 years should form the basis of a "history of safe use" (section 5.1(a)(iii)).

4.2.2 Traditional Applications

[31] 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

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

[33] http://www.inspection.gc.ca/english/plaveg/bio/gatconsult/consulrevise.shtml

There is a clear difference in public perception between the use of plants and plant products as conventional foods and food ingredients – i.e. either consumed directly as a meal or meal component or as a "conventional" ingredient in a component of that meal – and the use of dried, powdered extracts etc of a plant consumed as food supplements in the form of pills, capsules etc, or when added as non-conventional ingredients to a traditional food. The latter will become subject to specific legislation in the near future, thus permitting foods and ingredients consumed as foods to be regulated as such, with the concept of "novelty" being restricted only to those cases where there is no accepted (global or regional) history of food use.

In this way, foods or ingredients that form part of a normal daily diet and have a history of consumption in the generally-recognised form of a normal food can be regulated as conventional "foods" and be subject to a regime for "novelty" in only very exceptional circumstances.

Food supplements, such as "biologically active" herbal and other such ingredients will become subject to risk assessment and safety evaluation under the forthcoming EU legislation on "Addition of Nutrients". They should not be subject to parallel safety assessments under different, "novel foods" legislation.

However, where herbal extracts etc, with a history of use in supplements, are to be more widely used as ingredients in normal foods, the extent to which this prior use is acceptable evidence of a significant consumption or history of safe use, should be judged on a case-by-case basis.

4.2.3 Definitions related to tradition

The following could form the basis for legal definitions, but in practice it is likely that individual product decisions would need to be made on a case-by-case basis, determined against the evidence submitted in support of an application (**Section 7**).

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.

The ***"tradition"*** should have existed for a considerable period. The raw materials, derived foods and the processes used to obtain them should have been available, substantially unchanged, for the same period which should represent several generations within the culture concerned.

"Customary knowledge" reflects familiarity and acquaintance with facts, or a range of less-defined information, relating to habitual or commonly used practices (i.e. in accordance with local "customs"). It is, thus, a broad concept that embraces both theoretical and /or practical understanding of an art or science.

It 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.

5. Balance of Scientific Evidence and Customary Knowledge

Summary

The existing approaches to determining scientific "safety" of foods in the EU are not proportionate for many of these products, seeming to seek "zero" or "proof of absence of" risk. 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. Recommendation 97/618 should be amended to include a section relevant to 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. A Qualified Presumption of Safety (QPS) approach to the safety of plant species should be explored further.

A centralised procedure should be introduced to determine any realistic, potential risk and the appropriate level of regulation (if any). "Notification" is appropriate for foods that have no prior Community use but are considered safe on the basis of reliable 3rd country assurances. Notification would be directly to the Commission, supported by validated information on prior 3rd country food use and customary knowledge. A proportionate pre-market evaluation (Commission, aided by Member States) would identify the level of any potential risk and hence the nature of additional evidence (if any) required to establish an acceptable level of safety or justify any restrictions on the product. Only where insufficient evidence is available to establish an appropriate level of safety, should a focussed scientific risk assessment be requested from EFSA. The level of evidence ("proof of safety") required should be commensurate with the level of perceived risk, taking into account a realistic estimation of likely EU consumption patterns (**Annex I**).

The validity of 3rd country data used to support notifications could be ensured by adapting and extending the principles in Regulation 882/2004 on Official Controls to cover assurances from 3rd countries in respect of the history, preparation and use of traditional products. These should be derived from officially-recognised non-administrative sources (such as national authorities, universities, national and regional Institutes and global organisations).

Products that cannot show the necessary evidence should remain subject to the full novel foods assessment procedure.

5.1. Customary Knowledge and Modern Science

5.1(a) Proportionality

Examples of alternative, more proportionate approaches exist in Canada[34], (in the final stages of revision[35],[36]), Australia/New Zealand[37] (also under review[38]) and the original scheme operated in the UK, prior to the introduction of controls focused on GM foods[39].

[34] http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/nvvli_e.pdf
[35] http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/consultation/consultation_guidelines-directives_e.pdf
[36] http://www.inspection.gc.ca/english/plaveg/bio/gatconsult/consulrevise.shtml
[37] http://www.foodstandards.gov.au/_srcfiles/fsc_1_5_1_Novel_Foods_v78.pdf
[38] http://www.foodstandards.gov.au/_srcfiles/DAR_P291%20Novel%20Food.pdf

These countries provide examples on which a proportionate revised EU regulatory framework for traditional foods could be based.

5.1.(a)(i) United Kingdom

The UK has a long experience of risk assessments of various non-GM novel foods (e.g. Quorn, quinoa, lupin flour, passion fruit seed oil and others) and the parallel management of these via the Food Advisory Committee[40]. The elements of the former UK ACNFP scheme relevant to traditional crops are shown in **Annex III**.

5.1(a)(ii) Australia/New Zealand

Australia/New Zealand define a "novel" food in terms of the level of knowledge and understanding which exists in their population regarding the potential safety risk posed by these foods, rather than characterising the food in terms of physical or technological properties[41]. This approach allows the scientific risk assessment to focus on those foods for which the risk is unknown or uncertain:

- **non-traditional food** means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

- **novel food** means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account:
    - the composition or structure of the product; or
    - levels of undesirable substances in the product; or
    - known potential for adverse effects in humans; or
    - traditional preparation and cooking methods; or
    - patterns and levels of consumption of the product.

Two guidance documents are available (updated in June and Oct 2005, respectively):

- "Format for applying to amend the Code: Novel Foods" - includes a template for use when making an application for novel food authorisation[42]
- "Guidelines to assist in applying to amend the Code: Novel Foods" - details the operation of the standard, likely categories of novel foods, a decision tree for determining "novelty", and information requirements[43].

For "non-traditional foods", two steps are potentially necessary: firstly, to assess the novelty of the food, including identification of any potential hazards and, secondly, to assess the safety of the novel food. A safety assessment of "non-traditional foods" is undertaken where there is "insufficient knowledge in the broad community to enable safe use". An assessment of the level of knowledge about the safe use of a non-traditional food in the broad community is made in determining novelty.

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[39] Guidelines on the Assessment of Novel Foods and Processes: Department of Health Report RHSS 38, 1991; ISBN 0 11 321336 0.
[40] http://www.food.gov.uk/science/ouradvisors/novelfood/acnfpannreps
[41] http://www.foodstandards.gov.au/_srcfiles/fsc_1_5_1_Novel_Foods_v78.pdf
[42] http://www.foodstandards.gov.au/_srcfiles/Application%20format%20%20Novel%20foods%20June%20051.pdf
[43] http://www.foodstandards.gov.au/_srcfiles/Novel%20Food%20Guidelines%20%20October%202005.pdf

The guidelines also include a category "foods that have not traditionally formed part of the diet in the broad community in ANZ, such as foods from other parts of the world, traditional indigenous foods consumed by specific groups in the community, or new foods produced from traditional breeding techniques". The guidelines also state: "only those new foods where there is some evidence of potential adverse effects would be considered novel".

5.1(a)(iii) Canada

Novel foods must undergo a pre-market safety assessment. The relevant part of the definition of a "novel food" is: *"a substance that does not have a history of safe use as a food"*. The Canadian regulations require a pre-market notification to the federal health department, followed by firstly, a determination that the product is novel and, secondly, the safety assessment. The content of the notification and the administrative mechanisms for its progression are specified.

Guidelines for the pre-market assessment are currently being revised[44],[45] to clarify required safety data but, *inter alia*, recognise non-Canadian prior history of safe use: *"… 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 guidelines also outline the types of data needed to support a "history of safe use" and provide a valuable basis on which the EU could accommodate traditional foods within its own legislation (**Section 7**).

Canada requires supporting evidence from "reliable, high quality information and reference sources", stating that "anecdotal evidence" will carry less weight than scientifically derived data. Specific reference is made to the importance of information on the history of human exposure where traditional handling or cooking requirements exist, and the need for this to be made available to consumers.

5.1(b) Precautionary approach[46]

The political background to the EU's very strict, precautionary approach to food safety, deriving from BSE and other crises, has been described in section 3.3. However, an essential prerequisite for the legitimate use of precaution is that it must be proportionate to the matter under consideration and justifiable in respect of specific local circumstances. It should not be used as the basis for excessively stringent measures.

Nevertheless, NFR presents hurdles to potential importers that are not proportionate to the risks that traditional foods may pose relative to their history of use and their likely (initially limited) consumption in the EU, were they to be more widely approved.

This ultra-cautious approach is particularly restrictive in the case of ethnic minority immigrants from the 3rd countries where the traditional crops that are the focus of this paper originate. It is likely that many of the traditional foods would be consumed almost

[44] http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/consultation/consultation_guidelines-directives_e.pdf
[45] http://www.inspection.gc.ca/english/plaveg/bio/gatconsult/consulrevise.shtml
[46] The term precautionary approach is deliberately used here to distinguish this discussion from the formal, and internationally divisive "precautionary principle".

entirely by ethnic populations that are familiar with the character of the foods concerned and will be fully cognisant of the precautions necessary to avoid any inherent risks. These populations are therefore being deprived of access to their cultural foods on the disproportionate basis of a perceived need for the EU to protect the vast majority of its citizens against a very small risk to which they are most unlikely to be exposed.

Whilst the extensive scientific demands to "prove the safety" of traditional foods may be politically expedient in the EU, their impact on 3rd countries should be mitigated by introducing a legal commitment for the Commission to provide financial or other technical aid to potential exporting countries, as has been done in Regulation 882/2004, or via the international commitments given by other Directorates General, e.g. to respect Article 9.2 of the SPS Agreement.

5.2 Derivation of Scientific Evidence

5.2(a) General

The authenticity and validity of any evidence provided in respect of safety evaluations of "novel foods" is critical both technically and politically and must, therefore, be derived from recognised and reputable sources.

Previously-expressed concerns on how "independence" of organisations and "validity" of data can be guaranteed, and the extent to which government, university, medical and / or industrial laboratories can be considered acceptable, can be resolved by extending the principles established by Official Control Regulation 882/2004 into a revised NFR and requiring any scientific evidence in support of novel food safety to be derived from an appropriate medical / laboratory facility, officially accredited in accordance with internationally-recognised procedures in respect of the subject in question. "Accredited" establishments may be located anywhere in the world. This principle could be extended to require non-scientific evidence (e.g. history and traditional use of products) to originate from a national / regional centre of excellence, similarly validated as competent by an appropriate national / international authority (e.g. Food Control Ministry / FAO).

Currently, there is no formal EU Guidance to assist applicants to compile relevant safety dossiers for traditional foods. This should be developed, as has been done for other, genuinely "innovative" food categories such as GMOs and refined chemicals.

5.2(b) Revisions needed to Recommendation 97/618

Since the original NFR was introduced in 1997, the risk assessment and risk management functions have been separated between EFSA and the Commission. Consequently, the revised NFR can only set a framework to establish categories of products for which EFSA may need to performed detailed safety assessments. Existing requirements for the safety assessment, defining the nature of the scientific data needed to support applications for different categories of novel foods, are set out in Recommendation 1997/618 via a "decision tree" process. The technical details were largely driven by consideration of foods derived from GM origins and have to a considerable extent now been superseded by the introduction of separate GM legislation. EFSA has already published an updated "Guidance Document on Risk

Assessment of GM plants and derived foods".[47] Recommendation 97/618 can, and should therefore now be updated / replaced by parallel "Guidelines on Risk Assessment of non-GM novel foods" in order to introduce more proportionate requirements for traditional 3rd country foods. The Canadian draft Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Micro-organisms[48] provides a useful and comprehensive overview of likely requirements.

5.2(c) Scope and focus of data

Evaluations should start with an assessment by the Commission, assisted by MS, of the global history and customary knowledge of the food, its traditional preparation methods and consumption patterns. If significant gaps or uncertainty in safety knowledge are identified, these should be considered in conjunction with a realistic estimation of likely EU consumption patterns to provide an estimate of the chance / level of any potential risk and to identify the type and depth of additional evidence (if any) required to establish an acceptable level of safety or justify any restrictions on the availability of the product.

Experiences with applications for Chia, Nangai / Ngali nuts, Noni and Stevia suggest a disproportionate focus, seeking virtually absolute rather than comparative safety against familiar products which may present a far greater overall risk – e.g. sesame seeds or other nuts. Such comparisons would result in a more proportionate assessment. (Nangai nuts are already exported as gourmet products to Australia, Japan and Hawaii.)

Attention has also focussed on contaminants which are not inherent in the product but reflect inadequate hygienic handling and storage. Management of these is an essential and integral part of food trade and falls within the framework of EU legal controls applied to all foods. Such parameters should not therefore form part of the formal assessment of the "novel" food, which should be focussed on the intrinsic properties of the food itself.

5.2(d) Presentation of data

Notwithstanding the evidence that is required for supporting dossiers, they need to be presented professionally, in a standard format, if they are to receive timely attention. EU Guidance for the generation and presentation of data for the "notification" procedure should therefore be developed, in parallel with more comprehensive requirements for the technical data necessary for a full safety assessment. The UK and NL authorities have already developed guidelines for the submission of data to show that a food is "substantially equivalent" (**Annex IV**). These could form the basis of a wider-ranging document. Again, where it is not immediately possible for a 3rd country to meet EU requirements, technical and / or financial assistance should be provided.

5.2(e) Qualified Presumption of Safety (QPS)

This new concept, targeted initially towards food safety of micro-organisms and products derived from them[49] appears capable of extension to higher plant

[47] Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed; EFSA Journal (2004) 99, pp 1- 94.

[48] http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/consultation/consultation_guidelines-directives_e.pdf

[49] Opinion of the Scientific Committee: A generic approach to the safety assessment of microorganisms used in food/feed (Request No EFSA-Q-2004-021) (adopted 15.4.2005). Available at: http://www.efsa.eu.int/science/sc_commitee/sc_opinions/972/sc_opinion_ej226_qps_en1.pdf

materials and merits further examination by appropriate plant and food safety specialists.

QPS derives from a recognition that approaches to safety assessment of micro-organisms, deliberately used in the food chain, differ considerably according to the applicable legal framework. Central to the concept is the adoption of a system, similar to the USA GRAS (Generally Recognized as Safe), but modified to take account of EU regulatory practices and to recognise that issues of importance in Europe would not necessarily influence a GRAS listing. Fuller details of QPS are given in **Annex V**.

QPS recognises prior knowledge (however gained) and offers a possible route to a harmonised approach, without introducing unnecessary measures where there have been no great concerns about safety but, at the same time, allowing new concerns to be addressed. Currently, QPS is being considered for selected groups of micro-organisms, whereby future applications involving a strain falling within a "QPS group" would not need further safety assessment, other than to address any specific requirements that had been previously identified for that group as a "qualification" to its safety.

Establishing QPS status for micro-organisms rests on four pillars, from which its principles could relatively easily be developed to apply to plant-based food materials along the following lines:

- **Taxonomy:** the taxonomic level or grouping;
- **Body of knowledge:** whether sufficient is known about the organisms to reach a decision on their safety;
- **Toxicity:** whether the group contains known toxic members and, if so, whether sufficient is known about their toxigenic potential to exclude them;
- **End use:** whether toxic elements of the plants enter the food chain, whether they are used to produce other products and what precautions are taken to eliminate toxins.

Foods not considered suitable for QPS would remain subject to a full safety assessment.

Significantly, independently of this UNCTAD/CBI initiative, the Nordic Group[28] also evaluated the QPS concept and derived a definition of *History of safe use:*

> "… a term for the *qualified presumption of safety* [of a food], where there is evidence for its safety from compositional data and from experience as an ongoing part of the diet for a number of generations in a large, genetically diverse population. This QPS applies to a defined context of use (conditions of use, such as part of the plant used and required processing) and allows for minor population predispositions such as intolerance and allergenicity."

This approach reflects the FSANZ/Canadian, rather than current EU practices and, recognising that absolute consumer safety is impossible to achieve, it importantly limits comprehensive risk assessment and the corresponding evidence requirements to "problematic" species.

The concept merits further consideration within the NFR review process.

6. Proposed Administrative Procedures

A decision-tree summarising the proposed mechanism is given in Annex I.

A mechanism for identifying exotic traditional foods and the information that should comprise a supporting dossier is described fully in Section 7, below.

6.1 Background

The legal and practical difficulties that effectively prevent applicants from benefiting from the simplified procedure have been fully described above. The consequent, "full" assessment procedure is scientifically rigorous but, when applied to traditional foods, the data requested has been shown to be disproportionate and difficult for 3rd countries to meet. There have also been widely divergent views as to what constitutes necessary and reliable evidence, resulting on occasion in conflicting opinions as to the safety or otherwise of the product for which authorisation is being sought[50].

The Commission proposed and discussed Options to revise the administrative aspects of both types of approval procedures[2]. Fears that information from 3rd countries may not be sufficiently robust for EU purposes are not necessarily justified and could easily be met by adapting the systems, necessary to verify export food safety controls, to include additional recognised bodies to ensure that applications/ information from 3rd countries meet internationally-acceptable criteria.

The Commission also proposed (Option 2) that "exotic traditional foods" could become a separate category, subject to specific requirements and procedures. This positive suggestion would allow the development of a robust, reliable assessment of these foods in a cost-effective and proportionate way that will provide consumers with the level of safety that they are entitled to expect. Business operators also require procedures (whatever mechanism is in place) and documentary requirements to be clearly-defined, transparent and proportionate. Where information, such as scientific dossiers, must be provided in a defined format, and this is difficult for a 3rd country to achieve, technical training and/or financial aid should be made available (c.f. WTO and other EU legislation).

6.2 Potential for Central Assessment of Applications

The NFR was introduced before the creation of EFSA and the procedures prescribed reflect the systems of that time; hence, the multiple involvement of Member States in the scientific assessment of applications. Although time limits are specified, few applications have been determined quickly, as most have been subject to requests for further information and/or conflicting views between Member States (e.g. Chia took 28 months).

A more streamlined alternative is required for traditional foods. All evaluations should be performed at Community level, whereby the Commission (assisted by Member States)

[50] 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 has concluded that the compositional data were insufficient to perform a full nutritional assessment; there are uncertainties with regard to the allergenic potential; adequate toxicological information is not available and "the presence of constituents that might exert anti-nutritional or toxic effects cannot be excluded. Therefore additional studies are required before the safety of Chia can be established.

determines the risk management strategy on the basis of existing global knowledge of these foods, seeking additional scientific support from EFSA only if/when necessary.

The procedure below is consistent with a management approach that requires regulatory controls to be commensurate with the risk, whilst respecting the principle that all food must be safe for its intended consumption ("fit for purpose"). It would reduce the workload of the competent EU bodies, while paying sufficient regard to consumer protection, and restore legal certainty for businesses. It would result in a more rapid, consistent scientific consideration of applications and would also mirror the procedures in place for other scientific decisions within the Community.

6.2(a) Modus operandi - overview

The precise administrative route for filing a notification / application (i.e. to a Member State or directly to the Commission) is relatively insignificant but, in principle, should be directly to the Commission to remove one step from the current process. The central application would also avoid the previous, sometimes arbitrary, selection of a Member State to be the first EU market for the food. Whichever route is used, the submission and all relevant material must continue to be made available to all MS as rapidly as possible (in regulatory terms "immediately").

If the Commission or any MS has valid reasons, i.e. "reasoned objections" to doubt the safety of a product, and these are considered valid by the Novel Foods WG and / or Standing Committee (by Qualified Majority Voting if necessary), the notification should then progress to a centralised scientific risk assessment by EFSA, briefed to focus either on specific factors or for a general safety assessment.

A negative assessment by EFSA, having taken into account ALL aspects of the proposed use of the product, should generally lead to rejection of the application. However, a revised NFR must contain a legal obligation for the final Decision (Commission / Standing Committee) to take account of the Community's ***global obligations*** towards 3rd countries in respect of development and trade facilitation. It should also be clear precisely how the views of the Directorates General are to be considered and "weighted" where food safety is only one of the parameters.

The possible option of an application direct to EFSA should be discounted on two grounds: firstly, in many cases, a "notification" supported by appropriate evidence will suffice; secondly, EFSA's role is scientific assessment, rather than administration. Its expertise should be used accordingly.

6.2(b) Preliminary advice/opinion

A preliminary, voluntary step should be introduced into the legislation as a formal option (reflecting current practice in Member States), whereby a potential applicant could seek initial advice on whether a product falls within the scope of the Regulation, whether the evidence available is sufficient (particularly with respect to history of safe use, etc) and, if not, what additional information might be required, based on the framework guidelines proposed elsewhere in this paper. The task could be formalised within the SCFCAH and its sub-group structures, if necessary with assistance from Member State experts who already have extensive experience in this field.

This would permit applicants to determine whether it is cost-effective for them to proceed, without committing to prior collation of expensive data.

If it is decided that a product does not fall within the revised NFR (and, hence can be marketed freely), this should be recorded on a public "Register". This approach should also include retrospective consideration of some products whose legal status has been / is uncertain. The role of a Register is developed further in section 6.2(g).

6.2(c) Notification procedure (to Commission)

The Commission Discussion paper considered the simplified procedure and suggested three possible Options for a revised mechanism. Option 1 postulated that safety could be determined through 3rd country evidence or processes but was discounted on the basis that some parties in the EU would consider such evidence reliable. As stated above, this need not be the case if a validation mechanism can be developed.

Option 2, whereby "traditional" foods become a separate category, subjected to specific requirements and procedures, would present a proportionate approach and enable the appropriate type and level of scientific evidence to be sought, as needed.

Where there is a significant history of safe use in a third country, a **prior notification procedure** is appropriate. Foods derived from traditional propagation or cultivation methods (but with no evidence of prior Community consumption) should be notified directly to the Commission by, or on behalf of the initial distributor before being marketed within the EU. It is not necessary for notifications to be made via a member state "post-box" (section 6.2(a)).

There should be defined, short periods in which to raise an objection. If there are no objections or if there is no reason to doubt the product's safety, the notifying party would be permitted to market the product in the Community. For example, NFR could state:

> *"Within [say, 30] days of receiving a notification, the Commission must review the information included in the notification and*
>
> *(a) if the information establishes that the novel food is safe for its intended consumption, inform the notifier, in writing, accordingly; or*
>
> *(b) if additional information is considered necessary to assess the safety of the novel food, request it (in writing) from the notifier.*
>
> *Within [say, 45] days after receiving the requested additional information, the Commission must assess it and, if it establishes that the food is safe for its intended consumption, advise the notifier (in writing) that it may be placed on the market."*

At all times during these periods, the notifier should have a legal right to active participation, to support and/or clarify his submission as necessary in direct response to any questions or doubts that may be raised.

6.2(d) Risk assessment process (EFSA)

In the event that the notification is not considered to demonstrate a level of safety proportionate to the intended consumption, the relevant areas of uncertainty should form the basis of a referral brief to EFSA (as is already done for many other food safety

evaluations - e.g. GM Food and Feed, Flavourings, Pesticides, Food Contact Materials etc). *[It is recognised that EFSA acts independently of DG Sanco when performing risk assessments. The comments in this section are therefore intended to help the Commission in its consideration of possible mechanisms for referring traditional foods to EFSA for assessment.]*

EFSA should be briefed to provide scientific advice (an Opinion) in respect of specific safety aspects of the "novel" food, taking fully into account its intended pattern of consumption, and the science that underlies precautions known to be taken during its traditional preparation prior to consumption. [The Opinion could lead to a requirement for specific labelling instructions as an integral condition of being granted marketing authorisation (Commission decision as part of risk management).]

The revised NFR must place EFSA under a clear legal obligation to take into account all relevant evidence relating to the history of safe use, with the level and type of evidence required being commensurate with (i.e. proportionate to) the level of perceived risk. In particular, recognising the specific nature of the history and consumption of "traditional foods", full consideration must be given to 3rd country scientific evidence and assessments (such as US panels, Canada, FSANZ, Japan etc) and to global data (such as that from FAO and similar programmes). Since the assessment will need to take account of the intended consumption of each individual product, it will not be possible to establish a single set of criteria for such assessments and each product will have to be considered on a specific, case-by-case basis.

In order to provide the risk managers (i.e. the Commission and Member States) with an appropriate basis for comparison, the assessment should consider the types and level of risk associated with conventional foods with which the "novel" food and its intended consumption might realistically be compared (if any), and the measures routinely taken during preparation to minimise these and enable the food to be safely consumed. Examples where this appears not to have been done could include the negative approaches taken by EFSA towards Nangai nuts and, very recently, Chia seeds as compared to other nuts and Sesame seeds, respectively, which are freely available on the EU market (but now subject to allergen labelling provisions[51]).

Risk management must remain separate from the scientific assessment, for the Commission / MS to decide, and is considered in section 6.2(h) below.

A suggested decision-tree summarising the proposed scheme is given in **Annex I**.

Pre-determined time limits should also be set for the EFSA assessment. If necessary, the revised NFR should allow Member States' experts to provide additional resource, in the form of "sub-contractors", in order to ensure the timescales are met.

The applicant should have a legal right to support and/or clarify his application as necessary throughout the EFSA assessment process, in direct response to any questions or doubts that may be raised.

[51] Directive 2003/89/EC and 2005/26 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs: http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/fl_com2003-89_en.pdf as amended by http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_075/l_07520050322en00330034.pdf

6.2(e) Health claims, "Novel" foods and Traditional herbal remedies

Many exotic traditional foods, and particularly extracts and preparations derived from them, are frequently attributed with, and even positively promoted on the basis of, claimed "medicinal" and similar properties. However, a clear legal distinction must be made between the approval of the inherent safety of a food product and any optional claims that an operator may wish to make for it.

Such "health claims" should not, themselves, be considered under the Novel Food admission procedure, which should focus entirely on the SAFETY of the product as a normal dietary component. If any operator subsequently wishes to apply such claims to a product, after its safety has been assessed and authorisation for marketing as a food given under the NFR, the legality and validity of these claims should be assessed under existing food labelling (or medicines) provisions or the forthcoming EU Health Claims legislation (when this comes into effect). In this way, other businesses who wish to sell the novel product without such claims (direct or implied) will remain free to do so.

On the other hand, however, if an initial application includes a specific reference to the intended marketing of the product being dependent on its "long-standing health-related benefits", then it is likely that it will fall under existing EU medicines legislation, the recently introduced Traditional Herbal Remedies Directive or the forthcoming Herbal Extracts legislation and the efficacy of the product and the validity of the claim will need to be evaluated under one of these, accordingly.

6.2(f) Risk assessment outcomes

The assessment outlined above will essentially lead to one of three scenarios:

i) "Safe"

The whole product (e.g. plant) or those parts intended to be consumed may be determined as being "safe", if necessary taking into account specific precautions during preparation. In either case, the "traditional" food can be regarded as wholesome, and toxicologically and nutritionally acceptable for use in the overall diet either in its own right or in a manner comparable to, or as a replacement of, any counterpart that may be identifiable, and treated accordingly.

ii) "Generally Safe" except for one or more identified parameters

The "traditional" product may be considered to be "generally safe", but with the exception of one or more identified elements that require further assessment. This does not automatically imply that it is "unsafe". It indicates that these parameters must be further assessed before a final decision can be made. The situation becomes more complex, the less the knowledge and experience of the product, or as the product becomes less similar to established products or, even, has no counterpart against which it may be compared.

Thus, no general rules can be set and the data required for each product must be considered individually (i.e. on a case-by-case basis).

iii) No experience

Where there is little or no scientific information available (and if the "traditional" food cannot be compared to any extent with an existing product), it is likely to require a more extensive EU safety assessment, based on current mechanisms. However, where there is a history of use in 3rd countries, without documented science, the emphasis should be on balancing anticipated potential risks against envisaged patterns of consumption.

6.2(g) Transparency and public consultation

Active involvement of the public and transparency in decision-making processes is now an established Community practice and can be expected to form part of a revised NF procedure, although a balance between "provision of information" and "consultation" must be maintained. Where an assessment has focussed on highly specific food safety aspects, public "consultation" may be counter-productive by instilling doubt and undermining the credibility of EFSA scientific advice.

However, in cases where the "novelty" of a food is in effect determined solely by its lack of EU history (i.e. its geographical origin) or the arbitrary cut-off date imposed by the legislation, publication of a summary of the applicant's dossier and an initial assessment report is sufficient to satisfy the "information" needs of the public and may be beneficial for all parties.

The procedure followed by the UK ACNFP[52] currently works well and could be considered as a model.

6.2(h) Decisions under the Novel Food Regulation.

Products authorised via a "notification" (i.e. based on their widespread, non-EU acceptability) should be permitted to remain freely on the market (subject to normal food laws) unless valid, new evidence doubting their safety becomes available (globally).

Where a product has been authorised following a specific assessment by EFSA (as opposed to an accepted notification) the initial approval should be limited to [*say, 10*] years, to be followed by review. This will permit an evaluation of Community consumption patterns to be carried out and, if necessary, any additional scientific issues to be identified and addressed. If this review is satisfactory, the product should no longer be considered "novel" and become subject only to normal food safety rules.

At all times, and regardless of the type of authorisation, the standard national safeguard / Community evaluation procedures would apply.

The revised NFR should introduce a public register of all approvals, whether granted via a notification or following full assessment. For transparency and operator certainty, the register should also include those products assigned "non-novel" status as described in section 6.2(a). Where the approval falls within a "generic" category outlined below (section 8), this would permit all operators to identify and market the food.

[52] http://www.food.gov.uk/science/ouradvisors/novelfood/assess/assess-uk/acnfpassessments/

6.2(i) Risk management

Risk management should be under the responsibility of the Commission, assisted by the Member States, and be addressed separately from the scientific assessment (EFSA). Where necessary, appropriate decisions should be taken through the Standing Committee procedure.

Risk management options in respect of traditional foods are likely, in practice, to be related to either product-specific labelling requirements and / or the possible need to monitor the on-going availability and consumption of an individual product in the market.

The revised NFR should NOT contain any pre-determined, automatic requirements for ***labelling***. However, specific provisions may need to be adopted, on a case-by-case basis, but ONLY where it is considered necessary to inform consumers of significant requirements for individual foods, such as storage or preparation, where these might be required to ensure safe consumption. In extreme cases, wording for specific requirements may need to be closely defined and form a condition of approval, where it is essential to convey a precise message/warning, e.g. restrictions on the consumption of the product, as is already required for a number of existing, conventional EU foods.

In some cases, e.g. where a novel food may introduce a low (but acceptable) risk for specific groups (such as allergenicity) but is considered to be of no concern to the average consumer, it may be appropriate to require a system to be in place to ensure that medical practitioners are aware of the introduction of the product into the market.

Similarly, ***post-market monitoring*** should only be considered in very specific cases, e.g. to monitor actual availability and consumption where the risk assessment determined that a low level of consumption was safe but higher levels might be a potential cause for concern in defined sectors. Results of post-market monitoring would form part of the 10-year review outlined in section 6.2(h).

7. Criteria for the Evaluation of "Exotic Traditional Foods"

It is unlikely that a concise, legally precise definition for this class of products can be developed but a number of criteria and a series of related issues are proposed below to serve as a basis for further input from relevant specialists and stakeholders. In particular, terms in square brackets should be legally defined (Sections 3 and 4, above).

7.1 General Criteria – origin of foods

There must be acceptable, validated and verifiable evidence that the food and the plant or animal from which it is derived meets the following criteria:

- the plant or animal [suitably defined (section 7.2(a)] has extended history of growth / production in a 3rd country or readily-identifiable geographic region; but
  - has not been grown, reared or produced in [*significant*] quantities in the EU
- the food product has a history of consumption extending over a [*significant period*] amongst the native population of that 3rd country or region; but
  - does not have any history of [*significant consumption*] in the EU market;
- the food belongs to a normal diet and its history of use reflects consumption in a form generally-recognised as a normal food or food ingredient;
- the food should have been obtained by [*"conventional"*] processes such as water extraction, drying, fermentation, cooking, salting etc;
- plant-derived foods must comprise or be produced from plants [e.g. *fruits, vegetables, seeds, fruits, nuts, leaves and tubers or other parts*] that occur naturally or are derived from [*traditional propagation**] and
  - obtained by harvesting from the wild state; or
  - agricultural cultivation that is traditional in the 3rd country or region;
- animal-derived foods must comprise or be derived from [*species*] that are indigenous to, and occur naturally in the 3rd country or region. They may have been farmed or wild-caught. (*N.B "animal" includes animals, birds and fish.*)

*[* - it remains to be established whether (and how) it is feasible (or necessary) to distinguish between traditional crops and modified variants obtained, for example, by (non-GM) techniques such as accelerated breeding. Information in respect of the products of specialist commercial breeding programmes needs to be investigated further by EU and international specialists, in order to propose scientifically sound distinctions between "conventional" "traditional" crops and those resulting from "accelerated" commercial development.]*

The [*food source*] and the specific derivatives must NOT appear on relevant proscribed lists of controlled narcotic substances, such as those developed under the various International Conventions on Narcotic Substances.

Limited usage or short term exposure is not adequate to prove a history of safe use.

Proof that the food source, or food product, has no prior history in the EU (i.e. that the product must be subject to NFR requirements) is the responsibility of the authorities.

7.2 Evidence required

The "notification" submitted to the Commission should include validated and verifiable supporting evidence to demonstrate how the food product(s) meet the General Criteria

indicated in Section 7.1, above. In addition, and as appropriate to the nature of the food, the submission should also include:

7.2(a) evidence of history and tradition

- full and precise description of the plant (or animal) from which the food has been derived; a taxonomic and/or legal description, in accordance with [*recognised international practices*][53],[54]; (e.g. kingdom, division or phylum, class, order, family, genus, species, subspecies, common name, etc);
- geographical origin and distribution of the food source(s) and/or food product(s)
  - evidence that it is / they are indigenous to the 3rd country or region;
- cultural history of the wild plant, cultivated crop, animal/fish/bird (as appropriate)
  - general cultural aspects of the local tradition and relevant "folk-lore"; and
- food use history and traditions
  - evidence of frequent and ongoing consumption over several generations
  - handling from harvesting through storage, preparation methods and consumption frequency and quantity patterns
  - a particular focus on treatments considered necessary to ensure the safe consumption of the product; techniques and justifications
  - scientific justification in support of the safety of traditional preparation methods
  - any possible adverse effects recorded in its country of origin or elsewhere;
- the commercial status of the derivative and its production in the country of origin.

7.2(b) details of proposed product

- description of product
  - derivation from the source material (e.g. whole, natural parts or extracts)
  - method(s) by which it has been harvested, reared, produced, prepared, preserved, packaged and stored;
  - details of any major changes incurred during processing;
- the name under which the food will be sold;
- anticipated EU consumption patterns
  - sales volumes
  - proposed geographical markets
  - any special target consumer groups (children, elderly, immigrant etc)
  - anticipated per capita consumption (frequency, quantity - typical and ranges)
- if appropriate, information about the possible displacement of existing foods and any nutritional impact of such displacement;
- a statement of intended uses; and
- an indication, where necessary, of proposed consumer information describing
  - precautions to be taken during storage and preparation, prior to consumption
  - any groups for whom the product may be unsuitable or for whom restrictions may be prudent.

[53] International Code of Botanical Nomenclature (St Louis Code); Regnum Vegetabile 138: Koeltz Scientific Books, Königstein; ISBN 3-904144-22-7: http://www.bgbm.fu-berlin.de/iapt/nomenclature/code/SaintLouis/0000St.Luistitle.htm
[54] International Plant Names Index: http://www.ipni.org/index.html

7.2(c) availability in non-EU countries[55]

- details of any authorisations granted by a non-EU country
  - conditions applicable to any such approvals, if any, and
  - details of any decision to refuse to grant approval, and the reasons;
- countries where the product is currently marketed where no formal approval process is applicable.

7.2(d) general requirement

Where a food may be a combination of ingredients, the information must in all cases relate to the final product and, as far as reasonably practical, each individual ingredient.

Evidence on the traditional use of the product must be sufficient to show that its safety is plausible on the basis of long-standing use and experience; in particular, that the product is not likely to be harmful taking into account the likely pattern of consumption and any specified preparation conditions (i.e. an "acceptable level of safety" within the meaning of Regulation 178/2002). Taxonomic position and relatedness of novel food sources to widely used species (within and beyond the EU) should provide important hints for appropriate safety assessments. Reliable evidence should be admitted from ethnobotanical and anthropological literature as well as from anecdotes and folklore, and from scientific and non-scientific publications. Where appropriate, the evidence should include affidavits or affirmations of a similar status from independent, reputable authorities on the history and use of the food and, in particular, how they know the information is valid. It may also include non-scientific data originating from national / regional centres of excellence, validated as competent by the national authority responsible for food export control (as discussed in section 5.2(a)).

If available, or readily feasible, the notification dossier should also include, for example:

- evidence from recognised food control laboratories that the product, prepared in accordance with recommended, traditional methods, complies with quality standards in relevant EU legislation or other International Standards (Codex etc);

- a bibliographic review of safety data together with an expert report and, if specifically requested, data necessary for assessing the safety of the product;

- evidence appropriate to the nature and anticipated (extreme range) consumption of the product, that it does not inherently contain significant levels of potentially harmful substances. This might include proximate data, amino acid and fatty acid profiles, mineral / trace mineral and vitamin composition, and any anti-nutrients and bioactive phytochemicals of particular interest.

Additional toxicity, allergenicity or clinical studies on humans or animals should only be required where reasonable doubts as to food safety justified them.

[55] Whilst "novelty" of the product in the EU is an important criterion for determining the extent to which the product will need to be assessed, availability and consumption of the product in a jurisdiction with a similar food safety system would be an important consideration with respect to the evaluation of the product, its manufacture and consumption.

8. Generic applications and approvals

The current mechanism, whereby authorisation is granted to a single business operator in respect of a single, natural resource is not appropriate in all cases. The potential for a range of types of national / regional generic approvals should be considered, either for a given product and its derivatives or for groups of food plants on a wider botanical basis. There are advantages and disadvantages to all options, which should therefore be considered on a case-by-case basis. In particular, close co-operation between specialists will be necessary to determine scientific bases for plant groupings, and to develop sound distinctions between "conventional" indigenous crops and more recent, commercial developments.

8.1 Overview

The "non-innovative" traditional foods (so-called "products of biodiversity") are fundamentally different from the other categories of "innovative" novel products (such as foods from previously unused, non-food sources, new food additives, or foods obtained through novel processes) currently regulated under the NFR. They have existed, naturally, for a long time and are in the public domain at origin. This fundamental difference is a strong argument for treating these "biodiversity products" as a separate entity under EU food legislation, either by excluding them from the scope of a revised NFR, or through the development of their own, distinct legislation.

It has been of concern to many 3rd country operators that the NFR is believed to have the potential to generate an effective "monopoly" to a single company for the use of an indigenous, natural food. This appeared to be the case following the approval for Noni juice granted to Morinda Inc.[56] However, this "protective monopoly" proved to be short-lived and has been followed by over 25 accepted "substantial equivalence" notifications[57] (with a further notification in the pipeline at the time of drafting this report).

Nevertheless, such "monopoly protection" (if it did materialise) would appear to be in conflict with the spirit of international intellectual property rules, which provide that no natural substance can acquire such protection. By substantiating the safety of traditional foods to the EU authorities, the applicant can be granted exclusive marketing rights, when in fact all that has been shown is that the product is edible – a fact that may be well known outside the EU! This is not legitimate since it is, in effect, an appropriation of indigenous knowledge in disguise; traditional foods should remain in the public domain and no private entity should be granted privileged access to the EU market for these products.

This potential outcome might be mitigated by extending applications to cover generic categories in a way that allows naturally-occurring plant resources to remain available for all operators. However, this approach could result in a dilemma for both regulators and businesses.

[56] Commission Decision 2003/426/EC authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council: OJ L 144, 12.6.2003 p12.

[57] Notifications pursuant to Article 5 of Regulation 258/97 of the European Parliament and of the Council as at September 2005: http://europa.eu.int/comm/food/food/biotechnology/novelfood/index_en.htm

Where a notification/application to market a traditional food leads to a formal risk assessment, even if the evidence requirements are much reduced, it would be proportionate and equitable for the legislation to provide some form of ”compensatory reward” (commercial protection) for the applicant's development of the necessary evidence / dossiers. Conversely, if an application for a traditional food were to result in automatic and general availability of the product for all traders, applicants may, in effect, have no incentive to bring traditional foods to the EU market.

The Commission Discussion Paper (2002) considered whether a Decision under NFR should generally be addressed to an individual applicant or granted on a wider basis but did not specifically address “exotic traditional foods”.

8.2 Generic versus Specific applications / authorisations

In the case of exotic traditional foods derived directly from indigenous species, it is pertinent to consider whether novel food approval can legitimately, “ethically” and scientifically be granted to a single company or should be “generic” (using the term in the sense of both “available to all”, “covering several derivatives/presentations of a given food” and “covering a range of botanically/scientifically related indigenous materials”). There are thus different aspects to consider, where the concept of generic approval may relate to:

- different products derived from one plant or plant family[58];
- general authorisation to export a given product from the country concerned, regardless of the supplier / manufacturer;
- EU importers that import the same product from suppliers in different countries.

8.2(i) Different products from the same plant

It may be scientifically justified to seek approval for a traditional food and its derivatives (e.g. extracts, powders, juices) or products containing them (e.g. jams or ice-cream) on a broad basis, subject to one major caveat. It would be essential to show that none of the envisaged (or likely) derivatives was produced in a way that would concentrate any potentially harmful constituent to a level at which it would be reasonable to assume that the food would become “unsafe”. Experience shows, however, that EFSA has been very reluctant to give positive Opinions in relation to any foods, and particularly ingredients derived from “sensitive” origins, where there might be a latent or potential food safety issue but for which a definitive (and consistently met) specification is not available.

8.2(ii) Different products from related groups of plants

It may be scientifically justified to seek approval for a traditional food on a broader biological/botanical basis, providing it is possible to establish an adequate degree of concurrence between the plants / plant “groups”, their availability and history etc, and appropriate knowledge of their chemical composition / toxicological properties etc. The group, collectively, would need to meet the necessary criteria to be considered

[58] 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).

"substantially equivalent" to each other and / or to a recognised product, or it must pass the rigorous, full safety assessment. All plants in the group would be required to meet the necessary safety parameters. A parallel can be drawn with the QPS approach to micro-organisms (section 5.2(e) and **Annex V**) and further development of this concept will require close collaboration between appropriate, international plant specialists.

8.3(iii) Single application / multiple suppliers

"Generic" approval (a single application covering multiple suppliers of the same food) requires consideration of a combination of factors, ranging from ethical to commercial, according to the nature, origins and history of the crop and / or its derivatives, including:

- is the application for an indigenous crop – cultivated or wild harvest;
- how widespread is the geographical distribution;
- what is its food history – local, global, timescales etc;
- has any form of commercial plant breeding been undertaken;
- does it relate to a simple derivative from the crop, i.e. natural parts or ingredients derived by a simple process such as water extraction, drying, fermentation etc;
- are the products and processes generic and public, or do they represent commercial intellectual property;
- what is the commercial status of the derivative and its production;
- how is the product to be traded?

In the case of a traditional, indigenous crop and natural parts such as seeds, fruits, nuts, leaves and tubers, it may be difficult to justify (ethically) any approval that represents intellectual property protection and which will generate benefits for a single company, regardless of whether they were the original applicant. *[A grey area exists in respect of the products of specialist commercial breeding programmes, which would need to be considered further by EU and third country specialists, in order to propose scientifically sound distinctions between "conventional" indigenous crops and those resulting from "accelerated" commercial development.]*

8.2(iv) Single company or national/regional authorisation

The NFR specifies that "persons" (without further qualification) may submit applications for approvals. Some have questioned the scope of this requirement but, legally, it would describe the wider concept of "natural and legal persons" and would normally include any national or state governmental department or institution (subject to minor variations according to the legal systems in an individual country). Although, to date, no 3rd country national government has applied for novel food clearance, any problems would seem to be easily rectified.

Currently, if a company applies for EU novel food approval for an indigenous crop/food, this potentially grants the company IP rights over a national resource, albeit this may be only for as long as it takes for further applications for the same food to be submitted.

In the event that it is confirmed that a national government (or similar broad-based organisation) is entitled to apply, it would then become a matter of "internal, national politics" whether the exporting country would wish the commercial rights of one of its indigenous materials to be assigned to a single business, or whether it would wish to

intervene and seek a generic national (or, conceivably, regional) approval and open up access to the EU market for a wider range of local beneficiaries.

The feasibility of generic national/regional approvals may also be facilitated by the consequences of the new EU Official Control Regulation (section 3.5(c) and **Annex II**):

- any business operating within the jurisdiction and control of the food authorities within a 3rd country that has provided the EU with acceptable "guarantees" about their food control systems will be entitled to export any plant-based food products (providing the individual food is legally acceptable within the EU);
- any business wishing to export from a 3rd country that has not met the EU criteria would need to work closely with its national authorities to ensure that the necessary (i.e. EU-acceptable) national control systems were put in place;
- it will no longer be possible for an individual business to establish private schemes for direct exports to another EU business, unless the 3rd country itself meets the EU criteria.

Thus, exporting countries will have to be aware of the commercial activities of all companies within their jurisdiction and of any trade that it may consider prejudicial to its national/regional interests. The relevant information will therefore be available, should it wish to intervene in respect of commercial IP rights over a traditional resource.

An alternative route to protect traditional, indigenous species from commercial "privatisation" would be for the EU to introduce a legal regime (or to seek agreement under one of the global treaties, e.g. the Convention on Biological Diversity) whereby any approval granted in response to a corporate application for a natural, indigenous crop and its simple derivatives would, legally and automatically, be accessible to all suppliers of the crop concerned in the country / region of origin. It would then become a commercial decision for the company to decide, before making an individual application, whether its commercial position was sufficiently strong to benefit from generic approval (which would entitle its competitors to the same trading opportunities) or whether to seek assistance from the national government, from the outset, in obtaining generic novel food authorisation for the country as a whole. Nevertheless, many businesses may be expected to take the opposite course and seek a period of data protection, in order to recoup the costs of developing expensive, supporting dossiers.

8.3 Legal representation for application

Currently, an applicant may be a natural or legal person under public or private law who has a legal representative in the EC. It has been suggested that requests may be submitted by any interested party, irrespective of whether or not he has a legal representative in the EC. Whilst this may be superficially attractive, practical experience suggests that the present mechanism has advantages in respect of ease and speed of contact between applicant and the assessing authority.

In the case of countries wishing to make a generic application in relation to an indigenous crop, it would seem feasible for such an application to be submitted through an embassy / consulate acting as the representation of that country in the EU.

9. Economic and technical feasibility for third countries

9.1 Background

The general objective of EU food law is to protect human life and health, and provide consumers with a high degree of protection. These objectives must be achieved with due consideration for existing or planned international standards (see section 3.6 on WTO/SPS rules). It is essential therefore that the science on which the controls are based can withstand peer review and challenge. This is the responsibility of EFSA.

In addition, the EU has a responsibility to contribute to the development of international food standards. Its credibility must not be prejudiced by rejecting products that may be considered acceptably safe in 3rd countries, unless there are very strong scientific reasons to do so.

The revised NFR must therefore strike a careful balance. It must not, and must be seen not to, compromise genuine food safety and EU consumer perceptions of it, yet it must also respect the EU's obligations towards 3rd countries. In this respect, DG SANCO is the "appointed guardian" of Community food safety (acting on scientific input from EFSA) and cannot be expected, without very strong scientific justification, to relax the principles underpinning its controls in this area.

However, the respective DGs for Trade, Development and External Relations have a significant political and economic role in ensuring that 3rd countries are not disproportionately affected by its actions and must also, therefore, be fully integrated into the approval process for traditional 3rd country foods seeking access to the EU markets.

9.2 Revision to NFR

The review of the NFR should address practical and appropriate changes to the mechanisms used to assess the inherent safety (and through specific risk management procedures), consumer acceptability and safe use of "exotic traditional foods", rather than to changes in absolute levels of safety themselves. Although neither a revised NFR nor DG Sanco can (or should) directly influence the high level of scientific scrutiny applied by EFSA to any given question referred to it, both the revised NFR and DG Sanco, when applying it, must mitigate the practical and financial impacts (in particular on developing countries) of the current, extremely rigorous approach.

It is recognised that legitimate food safety concerns regarding some traditional foods will arise in the future and that an amended NFR is still likely to require documentation on aspects that are currently not available for most traditional and under-researched foods. There will be a need to develop dossiers for exotic traditional foods, which compile the available knowledge and identify gaps. Areas will include history of use (origins, domestication, cultivation), composition and compositional changes due to post-harvest conditions and processing, evidence for the presence of functional nutrients, evidence for the presence or absence of anti-nutritional or toxic factors, and nutritional assessments (food intake levels considered safe) for both human and animal use.

However, the cost of producing a full technical dossier can be prohibitive for a 3rd country operator. The revised NFR must therefore ensure that administrative demands are the

minimum commensurate with meeting the necessary scientific rigour. The legislation must also be drafted in a way that clearly requires a proportionate approach to be taken towards risk, and DG Sanco should ensure that this is done by formulating appropriate briefs to EFSA when seeking Opinions related to 3rd country traditional foods. The Commission – i.e. all relevant DGs - must then ensure that the widest range of scientific, economic and other information has been taken into account when developing the risk management policies for these products.

Equally, the global R&D activities seeking to foster the development of traditional foods and biodiversity products for niche markets must increasingly become aware of the need to accommodate food safety concerns in their projects and promotions. There is a clear need for the EU and developing countries to discuss the benefits and risks of marketing traditional foods and to assess different approaches of dealing with them.

In all these respects, the Commission must take into account the EU's responsibilities towards 3rd countries and, where individual developing countries need technical assistance to meet the EU requirements, this should be made available. A variety of mechanisms already exist.

The Official Control Regulation recognises that EU requirements must be technically and economically feasible and provides for a range of technical assistance to help 3rd countries to meet them. This may provide a model for future NFR developments.

Technical support could be linked with the SPS trade-related assistance sector in DG TRADE. As part of the its response to commitments within the Doha Development Agenda, and Article 9 of the SPS Agreement, EC has a budget to provide specific, targeted technical assistance to developing countries to enable them to reach the required level of food safety to be able to export their products to the EU.

The TRADE.COM initiative launched in 2004 should be explored as a potential source of assistance towards meeting technical demands for scientific and other dossiers related to potential exports of exotic traditional crops and their derivatives.

There is an active programme of trade / aid cooperation with the Andean Community, which should be considered as a possible means of assistance when any future novel food applications are being considered.

The underlying principles for these budgets indicate clearly the willingness of the Commission to assist less well resourced countries to meet EU requirements and to facilitate trade.

10. Conclusions and Recommendations

CR1: a sizeable range of potentially valuable traditional foods is denied access to the EU market. Their "safety" is being assessed against excessively and prohibitively strict criteria, out of proportion to any potential risks. Insufficient consideration is given to the products' global history of use or to comparisons with other foods for which certain risks are known to exist, but are safely managed. The likely pattern of consumption and the traditional precautions that have evolved as an integral part of their safe use must be taken fully into account when justifying restrictions.

CR2: the "fast-track" notification process or the exemption for plant products obtained by traditional methods are not granted, on the basis that experience of safe use has been derived outside the EU. The concept of "substantial equivalence" does not recognise that there may be no "equivalent" in European culture. This geographic restriction is not justified. Traditional foods that can show a history of safe consumption, wherever this may be, should be subject to a simple "notification" procedure and only be referred to a fuller, focussed scientific assessment if specific, valid safety doubts are raised.

CR3: different interpretations of several key terms contribute to over-strict interpretation. Clear definitions and consistent application of all concepts are needed; if this proves difficult, clarification should be given in EU implementation guidelines.

CR4: Recognition of the separate category of 3rd country traditional foods would permit the introduction of a proportionate pre-market evaluation procedure. A precise, legal definition may be difficult to develop and is most likely to entail the product falling within a set of broad criteria (**section 7**). Collaboration between technical specialists will permit these concepts to be developed, separate from other genuinely "novel" foods. An alternative is to refine and extend the food plant lists currently under international development.

CR5: All evaluations should be performed at Community level. "Notification" is appropriate for foods that have no prior Community use but are considered safe on the basis of reliable 3rd country scientific assurances. Where insufficient evidence is available to establish an appropriate level of safety, a focussed scientific risk assessment should be performed by EFSA.

The legislation should require the level of scientific proof of safety to be commensurate with the perceived risk, taking into account anticipated EU consumption patterns and all globally-available, relevant evidence and assessments. The principles in the Official Controls Regulation could be extended to cover assurances from 3rd countries in respect of the history, preparation and use of traditional products.

Recommendation 97/618 should be replaced by new assessment guidelines, focussing only on specific aspects relevant to traditional foods and defining practical and proportionate mechanisms to evaluate potential risks, whilst retaining for consumers the level of safety they are entitled to expect. A QPS approach to the safety of plant species should be explored further.

CR6: Following the recent, significant strengthening of EU food safety controls and the separation of GM legislation, NFR now contributes only a small part towards guaranteeing overall consumer safety. Assessment of traditional novel foods should focus on their intrinsic properties, with microbiological or chemical contamination being controlled as an integral part of food trade.

The Food Fortication proposal will soon become relevant, regulating the use of many traditional herbal extracts and further reducing the role of NFR in this area.

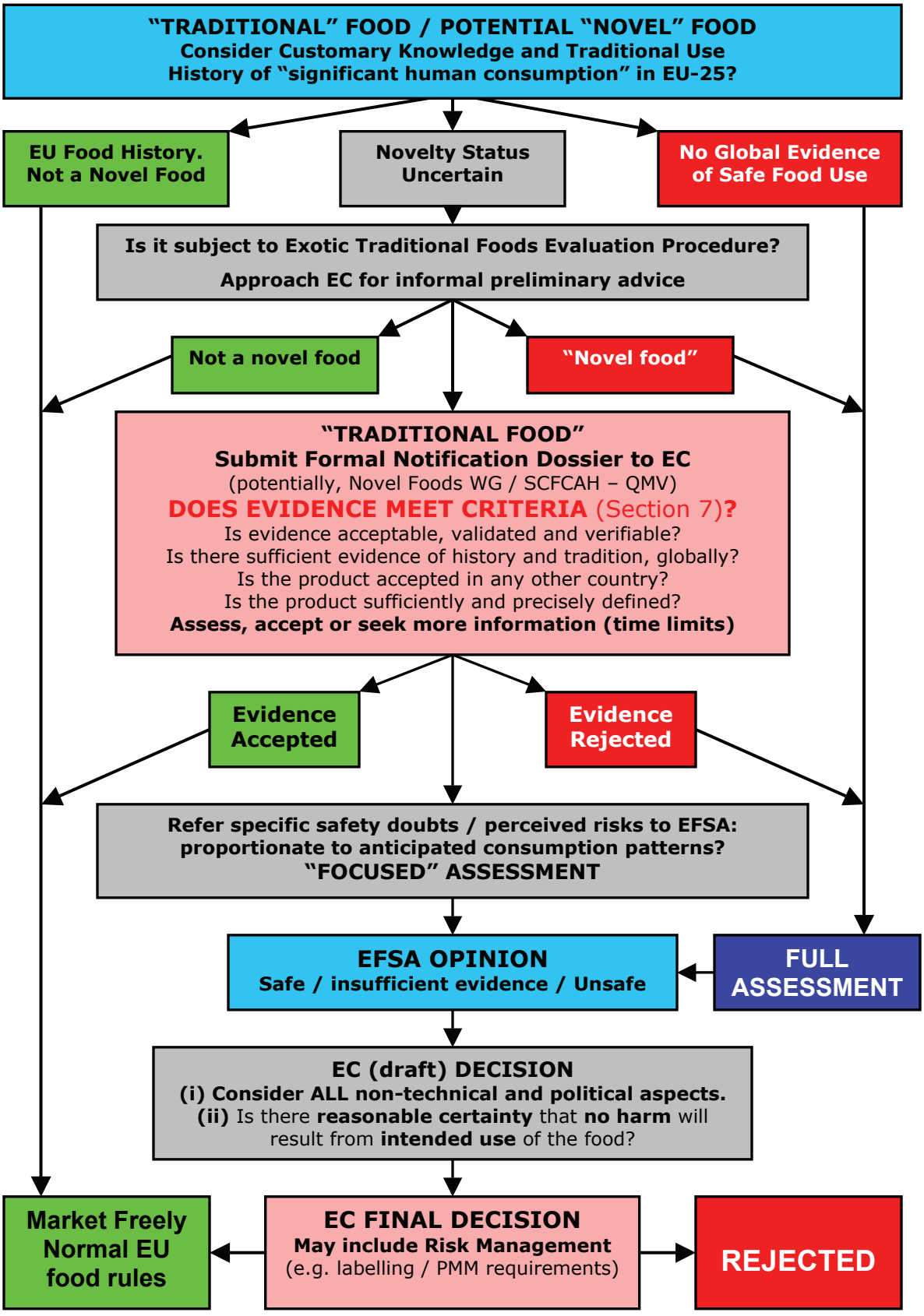
CR7: Risk management Decisions should be determined following current procedures. Additional labelling should only be prescribed in exceptional circumstances, where it is necessary to provide specific information for clearly identified consumer groups. Post-market monitoring should not be a general requirement, but limited to cases where the risk assessment determined that a low level of consumption was safe but higher levels might be a potential cause for concern in defined sectors. All decisions should be placed on a public "register".

CR8: The current mechanism, whereby authorisation is granted to a single business operator in respect of a natural resource is not appropriate in all cases. The potential for National / regional generic approvals should be considered, either for a given product and its derivatives or on a wider botanical basis for all plants possessing similar properties within an identifiable group. Co-operation between specialists will be necessary to determine scientific bases for these potential groupings, and to develop sound distinctions between "conventional" indigenous crops and more recent, commercial developments.

CR9: The practical implementation of the Regulation runs counter to WTO rules and appears to risk creating a non-tariff trade barrier against traditional, 3rd country products, and impeding the economic development of sectors and countries concerned. Future control must respect the EU's global obligations, without compromising genuine food safety or consumer perceptions of it. Where demands are such that individual developing countries may need technical assistance to meet them, the impact should be mitigated by introducing a commitment to provide financial or other technical aid to potential exporting countries, as has been done in Regulation 882/2004, or via the international commitments given by DG Trade and other Directorates-General.

ANNEX I

TRADITIONAL FOODS AUTHORISATION PROCESS



ANNEX II

Impact of Regulation 882/2004[59] on Third Countries

This Annex is provided to demonstrate the extent to which a potential exporting 3rd country will need to have in place comprehensive Official Control structures and procedures in order to satisfy EU import requirements, and to illustrate how these principles could easily be extended to encompass the provision of evidence from 3rd countries in support of traditional foods.

By demonstrating the depth and complexity of the EU scrutiny to which 3rd countries will be exposed, it can be seen that an extension to cover assurances about the origins and authenticity of information supplied by them relating to the history and knowledge of traditional foods would ensure that they would have to be similarly rigorous and capable of withstanding detailed examination.

It must be noted, in addition, that no business will be authorised to export any food products to the EU unless the country has provided satisfactory "guarantees" in respect of its administrative food control structures and their operation, and these have been validated as acceptable by FVO (see Equivalence of Guarantees section below).

This Regulation will apply to all 3rd Countries wishing to export food products to the EU and comes into effect on the 1st January, 2006. It obliges the Commission to request 3rd countries to provide comprehensive, accurate and up-to-date information on the general organisation and management of their sanitary control systems, specifically:

- sanitary or phyto-sanitary regulations (adopted or proposed);
- control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures in place;
- risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phyto-sanitary protection;
- follow-up to recommendations made as a result of previous FVO inspection visits.

Information requested by the Commission will need to be proportionate to the nature of any risks posed by the products but may take account of the "specific situation and structure" of the 3rd Country and the nature of the products. (This concept has not been defined.) The information may also relate to:

- results of national controls on products for export to the Community;
- important changes to the structure and functioning of relevant control systems, in particular to meet EU requirements or recommendations.

Guidelines will be formulated on how to collate and present this information, but if a 3rd Country does not provide the information or if the information is inadequate, specific import conditions may be imposed.

The Regulation also provides for Commission experts (from FVO etc.) to perform Official Controls in 3rd Countries to verify, on the basis of the information provided, compliance or "equivalence" of 3rd Country legislation and systems with Community food, feed, and animal health law, paying particular attention to:

- legislation in place;

[59] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; OJ L 191 28.5.2004 p1

- organisation of the competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;
- training and competence of staff in the performance of official controls;
- resources, including diagnostic facilities, available to competent authorities;
- existence and operation of documented control procedures and control systems based on priorities;
- where applicable, the situation regarding plant health, animal health and zoonoses, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal and plant diseases;
- extent and operation of official controls on imports of animals, plants and their products;
- assurances which can be given regarding compliance with, or equivalence to, Community requirements.

The frequency of inspection visits / audits to a particular country will be determined by a wide range of factors, including risk assessment of the products and the volume and nature of imports; information received as a result of Commission and MS controls; information from EFSA, WHO/FAO, Codex and other internationally-recognised bodies etc; evidence of emerging food safety issues that might result in imported products presenting health risks and the need to investigate or respond to emergency situations.

If a serious risk is identified, any necessary emergency measures must be applied immediately in accordance with Regulation 178/2002 or with the safeguard provisions contained in specific Community legislation.

EQUIVALENCE OF GUARANTEES

Third Countries will be permitted to export products to the EU only if their competent authorities provide "appropriate guarantees" or if inspection visits verify compliance or equivalence with EU food legislation. Although the wide-ranging scope of aspects that need to be considered is given in the Regulation, there is no indication of the objective assessments that will have to be made. Nevertheless, since "equivalence" and "equivalent" are defined as the capability of different systems to meet the same objectives as Community legislation, the requirements specified for Member States' control systems and personnel can serve as a base-line against which 3rd Countries' systems are likely to be compared. Full details are given in the Annexes to the Regulation, but the summary below outlines the breadth and depth of scrutiny that will be applied:

- Official controls must enable verification of, or enforce compliance with, national and Community food law;
- Official controls must be carried out regularly, on a risk basis and at an appropriate frequency; they should take account of the business operators' past records of compliance, the reliability of any checks that he may already have carried out, and any information that might indicate non-compliance;
- Official controls should generally be carried out without prior warning, at any stage of production, processing and distribution, and in accordance with written procedures; legal procedures must be in place to enable relevant access to premises and documentation. Prior warning is not excluded and may be essential where a detailed audit is to be carried out, to ensure that the necessary personnel and supporting documents are readily available;
- Competent authorities must meet operational criteria that guarantee their efficiency, effectiveness and impartiality. Staff must have received adequate training to enable them to undertake their duties competently, and they must be free from any conflict of interest; they must respect professional confidences;

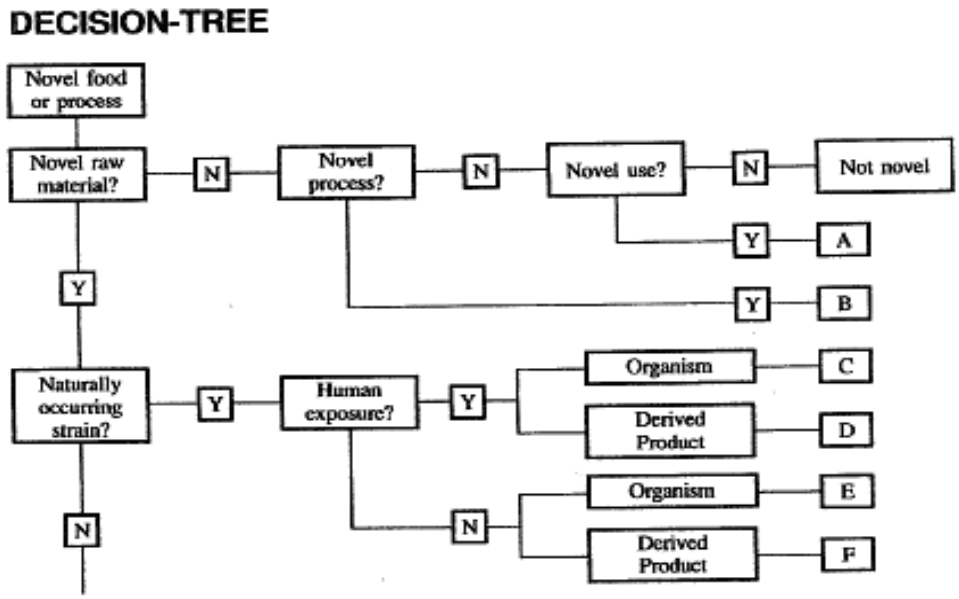
- Specific control tasks may be delegated to an independent body, but only under strict conditions; these independent bodies must be impartial and possess the legal powers necessary to carry out their tasks; there must be systems in place to ensure adequate co-ordination between all relevant control bodies;
- There must be access to an adequate laboratory capacity using appropriate, properly maintained facilities and equipment with a sufficient number of suitably qualified and experienced staff;
- Methods of sampling and analysis must be validated in accordance with internationally-accepted protocols such as CEN / ISO / IUPAC, including those based on performance criteria, and be carried out by laboratories accredited for that purpose;
- When non-compliance is identified, appropriate measures must be taken; measures and sanctions must be effective, dissuasive and proportionate;
- Contingency plans must be formulated, setting out measures to be implemented in case of food emergencies, and reviewed as appropriate;
- Where official controls require action by more than one Member State, or by 3rd Countries, competent authorities must afford each other administrative assistance.

In order for the Commission to verify that checks are being carried out to support "guarantees", the systems will need to be auditable by FVO (i.e. appropriate, validated records will be needed). A greater emphasis will be placed on formal accreditation of laboratories and control systems by independent, internationally-recognised bodies. Where official controls are carried out on a regional basis, or are delegated to other third parties, co-ordination will also be needed.

A Community framework for the development and operation of EU Member State control systems will be developed, reflecting existing best practices and based on agreed criteria for their performance. Community guidelines and training programmes will be developed, which will be open to 3rd countries.

ANNEX III

DECISION TREE (according to UK ACNFP original procedure)



Key to Decision Tree

Exit Point	Information Requirements
A	V
B	III, IV, V, VIII
C	I, II, III, V, IV
D	I, II, III, IV, V, VI
E	I, III, V, VI, VIII, IX
F	I, III, IV, V, VI, VIII, IX

I. —Instructions for use
II. —Evidence of previous human exposure
III. —Intake/extent of use
IV. —Technical details of processing and product specification
V. —Nutritional studies
VI. —History of organism
VII. —Characterisation of derived strain
VIII. —Toxicological assessment
IX. —Human studies

ANNEX IV

A. UK ACNFP

Guidelines for the Presentation of Data to Show that a Novel Food / Ingredient Is "Substantially Equivalent" to an Existing Counterpart

Introduction

The Novel Food Regulation 258/97 provides a simplified, "notification" route for manufacturers to introduce certain novel products. This procedure is only available for:

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

that must be shown to be "substantially equivalent" to an existing food / ingredient as regards:

- composition,
- nutritional value,
- metabolism,
- intended use and
- level of undesirable substances contained.

This may be done on the basis of

- scientific evidence available and generally recognised, or
- an opinion delivered by a Member State designated competent body.

In practice, however, experience has shown that each notification requires a suitable opinion from a Member State competent authority that confirms that the product meets these criteria.

The following is suggested guidance on the data that should be submitted with a request for such an Opinion from a Competent Authority.

Contents of the application dossier

The dossier should contain basic administrative information, technical data to address each of the criteria above and any other relevant information on the novel product.

(a) Administration

name of the applicant; contact information (postal / e-mail addresses, telephone and fax); name of the novel food or food ingredient; date of the application.

(b) Composition

The application should contain a specification of the novel product, including

- information on the source organism
- methods used for preparation of the novel product
- the composition of the final product
- maximum limits for the presence of known or potential contaminants.

Comparisons should be drawn with only one existing product, which should be described in the same level of detail.

Compositional analyses should be reported for a number of representative batches of each product. *[If in doubt, advice should be sought, at an early stage on the range of analyses that should be carried out for each specific product.]*
If the applicant is not the manufacturer of the novel product, the application should indicate the intended supplier(s).

The novel and existing products should be derived from the same or very similar species, grown and harvested under similar conditions. A monitoring programme may be required in order to provide ongoing assurance that the approved sources continue to yield appropriate product. This requirement may be relaxed if the products are refined extracts that contain only a limited number of defined chemical components, as defined by a detailed specification.

The proposed novel product should not contain significant levels of substances that are not present in the existing counterpart. In the event of utilisation of related but different species, culture or harvesting practices, the application should include results of a detailed search designed to elucidate presence or otherwise of substances that may be involved. *[It should be noted that the presence of such substances requires a fuller evaluation that is not compatible with the simplified procedure.]*

(c) Nutritional value / (d) Metabolism
If the composition of the product does not differ from its existing counterpart, it is unlikely that there will be significant differences in its nutritional value or metabolism. Nevertheless, the applicant should consider this possibility and provide results of any relevant studies. These might include the results of stability tests to show that the novel product does not degenerate during storage or use, or bioavailability studies.

(e) Intended use
The application should describe the uses of the existing product and explain which of those are relevant to the novel product. This may include use in food supplements, use as a food / ingredient in a list of specified food categories. The levels of use should be specified.
Where the application covers use in food supplements, it should include information on the recommended dosage of the new and existing products.
In general, applications cannot include new uses, particularly if they are likely to result in consumption of the product by a wider range of the population or at higher levels, compared with the existing product.
In particular, the novel product cannot be assessed as "substantially equivalent" if it is intended for use as an ingredient in foods and the existing counterpart is only consumed in the form of food supplements.

(f) Level of undesirable substances
The application should consider the potential presence of undesirable substances, such as environmental contaminants, mycotoxins, naturally occurring toxins and anti-nutrients, and undesirable microorganisms.
Evidence should be provided that the levels of these substances are comparable between the new and existing products. *[It may also be necessary to distinguish between contaminants that are inherent to the product and those that arise from environmental origins – the latter will fall under the responsibility of the business to control.]*
Analytical data that are provided should be for a number of representative batches of the new and existing products and may be required on an ongoing basis.
The new product should obviously comply with existing EU legislation on contaminants, pesticides etc. *[Unless the contaminant is an intrinsic component of the novel product, this requirement should arguably fall to the business to resolve under general food law provisions.]*

(g) Other relevant data
The application should also include any other relevant data on the novel product, including the reports of any safety studies that have been conducted on it.
It should also include a proposal for labelling, to demonstrate that consumers will be adequately informed of the nature of the novel ingredient, its intended use and any restrictions that may need to be respected.

B. NL Commissie VNV

What data must the dossier contain to be able to assess substantial equivalence with an existing product?

Information on history of the source, human exposure and toxicology: it may in principle be sufficient to refer to the existing product (e.g. an already approved 'novel' food or 'old' food).

The dossier must contain the following data:

- product specification: a good description of the composition of the foodstuff or food ingredient. It must be shown that it is a consistent product, based on compositional analyses of several production batches
- source identification:
    - it must be shown that the product is from the same species as the previously authorised novel food or the 'old food'
    - if the source differs at the level of the species or if is there even less affinity, market authorisation cannot be granted by the notification procedure unless it concerns an extensively refined product that consists almost exclusively of one, or a very limited number of chemical compounds.
    - if the final material comes from another variety within the same species, then a precise description of the source must be supplied with all relevant information concerning safety issues (e.g. secondary plant substances, potential allergens)
- Description of the production process, including quality assurance (e.g. GMP)
- Level of undesirable substances: naturally-occurring toxicants and potentially introduced contaminants, including microorganisms
- Intended use; description of the intended application(s): the applicant must also indicate the expected quantity that will be consumed daily
- Nutritional value, metabolism: it may be sufficient to refer to the already approved `novel food ' or the `old food ', if the product has a similar composition

ANNEX V

Qualified Presumption of Safety (QPS)

This Annex reproduces the discussion document prepared by a working group of the European Commission DG Health and Consumer Protection (June 2003) which outlines the principle of QPS as originally proposed for micro-organisms. This proposal was favourably received[60] following discussion at the EFSA second Scientific Colloquium in December 2004 and is considered to represent a valid starting point for the development of potential generic safety assessment mechanisms for traditional plant foods.

Discussion of the concept derived from a recognition that approaches to the safety assessment of micro-organisms deliberately used in the food chain differed considerably depending on any legislation applicable. Central to the concept is the adoption of a system, similar to the GRAS (Generally Recognized As Safe) definition used in the USA, but modified to take account of the different regulatory practices in Europe. This is necessary since issues of importance in Europe would not necessarily influence a GRAS listing. It is intended to provide a mechanism to recognise and give weight to prior knowledge (whether gained through formal investigation or by experience of use).

It is considered to be a possible route to harmonisation without introducing unnecessary measures where there have been no great concerns about safety but, at the same time, allowing any new safety concerns to be addressed. It is intended to offer a process that could be incorporated into guidelines for pragmatic use.

This proposes a concept of Qualified Presumption of Safety (QPS), applicable to selected groups of micro-organisms. Future applications involving a strain of micro-organism falling within a QPS group would be freed from the need for further safety assessment, other than any specific requirements introduced as a qualification.

Establishing QPS status rests on four pillars:

- **Taxonomy:** the taxonomic level or grouping for which QPS is sought;
- **Body of knowledge:** whether sufficient is known about the proposed group of organisms to reach a decision on their safety;
- **Pathogenicity:** whether the grouping considered for QPS contains known pathogens. If so, whether sufficient is known about their virulence determinants or toxigenic potential to exclude pathogenic strains;
- **End use:** whether viable organisms enter the food chain or whether they are used to produce other products.

Microorganisms not considered suitable for QPS would remain subject to a full safety assessment.

Although not specifically addressed, it would seem that the basic principles might be capable of extension to higher plant materials, although the distinctive nature of certain exotic traditional species would need to be further addressed.

EFSA has concluded that QPS could provide a generic assessment system that could be applied, without compromising on safety, to all requests received by EFSA for the safety assessments of food-use microorganisms. Its use would make more transparent and aid the consistency of

[60] Opinion of the Scientific Committee: A generic approach to the safety assessment of microorganisms used in food/feed (Request No EFSA-Q-2004-021) (adopted 15.4.2005). Available at: http://www.efsa.eu.int/science/sc_commitee/sc_opinions/972/sc_opinion_ej226_qps_en1.pdf

approach, and make better use of assessment resources by focussing on those organisms that present the greatest risks or uncertainties.

However, consideration would need to be given to product-specific data and how this could be accommodated within a generic assessment system. This is referred to as the Qualified Presumption of Safety (QPS).

Implicit in the current absence of any formal requirement for a safety assessment is the recognition that there has been a history of presumed safe use.

It was therefore proposed to introduce the concept of Qualified Presumption of Safety, (QPS), presumption being defined as "an assumption based on reasonable evidence" and qualified to allow certain restrictions to apply. This designation would, after due consideration, be applied to selected groups of microorganisms, freeing any future applications involving a strain of micro-organism falling within a QPS group from the need for further safety assessment, other than any qualification specified.

QPS status would be determined in advance of any specific safety assessment and products/processes involving organisms not considered suitable for QPS would not be excluded but would remain subject to a full safety assessment.

Taxonomy versus identity

The starting point for establishing suitability for QPS status is the grouping of microorganisms for which QPS status is sought. This is best expressed as a recognised taxonomic unit (e.g. genus) but could be based on other groupings provided that these are recognisable and can be adequately defined (e.g. hetero-fermentative lactobacilli). To be of greatest value as an assessment tool, QPS should be sought at the highest taxonomic level that is practicably possible by using the mechanism of "qualification" to exclude undesirable strains.

Establishing identity is a pre-requisite for Notification. If the micro-organism(s) cannot be related via existing or historic nomenclature to a taxonomic group with QPS status, then a full safety assessment is required. This is most likely to occur when an isolate identified to the genus level cannot be assigned to an existing species/sub-species or when the species is a newly recognised taxonomic unit. Notifiers should also be encouraged to use the most up-todate methodologies for identification and to use the most recent nomenclature.

Reclassification of a micro-organism does not imply automatic loss of QPS status. The identity of an isolate depends upon determining its biological activity and this will not change when an isolate becomes reclassified. Reclassification involves assigning different weightings to features, rather than altering the fundamental features themselves. Furthermore, the process of reclassification of a micro-organism will add to the body of knowledge relating to that organism, strengthening the QPS safety assessment.

Many industrial strains of microorganisms will be the product of a programme of selection/mutagenesis designed to improve the phenotype for a particular purpose. In the majority of cases cryptic mutation or selection for the same use (e.g. increased phage resistance or over-production of an enzyme) will not affect identity. Use of recombinant technology for strain improvement is the subject of separate existing legislation. However, if the parental strain belonged to a taxonomic group with QPS status, this would allow the safety assessment to focus only on the intended change and its consequences.

Body of knowledge (Familiarity)

The term "familiarity" was used in the QPS document to encompass practical experience of the use of the organism(s) including its history of use for particular purposes and any body of literature on the biology of the taxonomic unit seeking QPS status. This term proved confusing on

consultation and is better replaced with the term “body of knowledge” to cover all sources of information which may be used to judge to safety (see Figure 1).

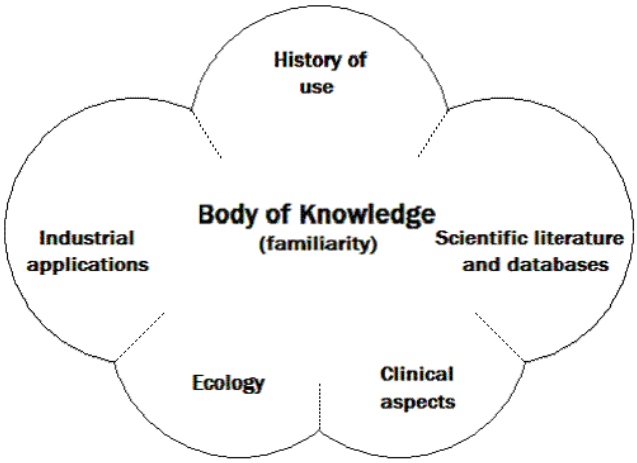


Figure 1. Sources of knowledge forming a body of knowledge on a particular group of microorganisms

The body of knowledge of the group of organisms seeking QPS must be sufficient to provide adequate assurance that any potential to produce adverse effects in humans, livestock or the wider environment is understood and predictable. Whether the existing data are sufficient should be determined by an expert group established for this purpose and should be based on a weight of evidence approach. While this will not guarantee absolute safety, for QPS status to be granted there should be “reasonable certainty of no harm”.

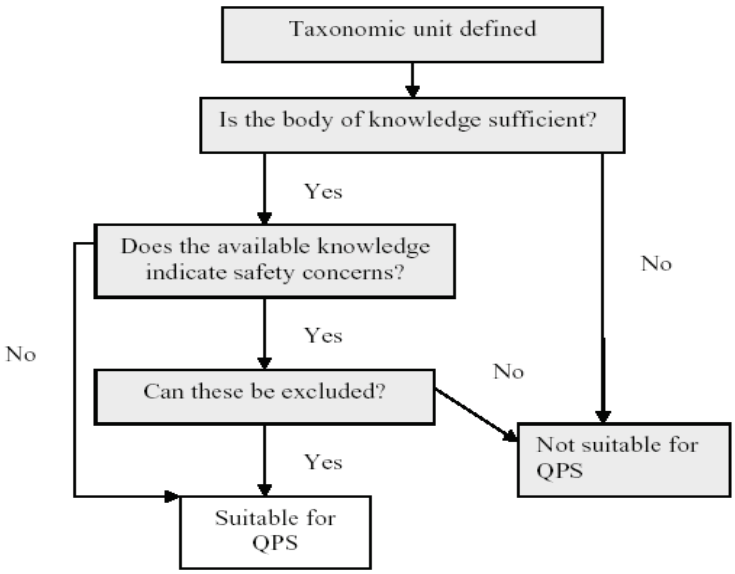


Figure 2. A generalised scheme for assessing the suitability for QPS status of microorganisms.

Conclusions

QPS as a concept could provide a generic approval system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food chain. Its introduction would make more transparent approach across the EFSA panels. It would aid the consistency of assessment and make better use of resources by focussing on those organisms which present the greatest risks or uncertainties.

To become a tool for safety assessment within EFSA, QPS status would, initially at least, have to be established in advance of and independent of applications of Notifiers. Initially, this might centre on the more commonly notified genera. Consideration of relatively few fungal and bacterial genera would capture a large majority of applications.

The body of knowledge about the organisms for which QPS is sought must be sufficient to provide adequate assurance that any potential to produce adverse effects in humans, livestock or the wider environment is understood and predictable. Judgement as to whether the existing data are sufficient needs to be determined by an expert group established for this purpose and should be based on a weight of evidence approach.

Unlike the US GRAS system, the decision whether or not to award QPS status should remain with the risk assessors.

Further consideration needs to be given to product specific data and how these can be considered within a generic assessment system.

There should be no implication that microorganisms considered unsuitable for QPS status are less fitted for introduction into the food chain. The distinction between QPS/non-QPS should only be the need for a full safety assessment in the latter case.