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The impact of the European Novel Food Regulation on trade and food innovation based on traditional plant foods from developing countries

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ABSTRACT

The stringent food safety assessment for novel foods required by the European Union's Novel Food Regulation (NFR) places a high burden of proof on those bringing traditional food products to the EU market not consumed in the EU prior 1997. The regulation has emerged as a non-tariff trade barrier for heritage foods from developing countries that are viewed as "exotic" from the EU perspective. We show how the regulation has discouraged investment in supply chains and market development, and how this negatively affects income generation and rural poverty alleviation in developing countries. Focusing on plant-derived foods, this paper proposes to recognize traditional exotic foods in current EU law as a food category *sui generis* with food safety evidence requirements being proportionate to the risks they may pose. We argue that development activities promoting export food chains must increasingly accommodate legitimate food safety concerns about neglected food species in project design and seek to generate data to enhance regulatory acceptance in target markets.

Introduction

Global inventories of food crops (Uphof, 1968; Kunkel, 1984) list astonishingly high numbers of edible plants, typically exceeding several thousand species that are either cultivated or collected from the wild. A more recent compilation of useful plants in Peru (Brack Egg, 1999) recognizes 782 edible species for this country alone. Each edible plant species itself may be the source of a multitude of foods, depending on intra-specific or varietal diversity, the use versatility of the species' edible parts, cultural preferences and post-harvesting procedures (drying, curing, fermentation, extraction of particular constituents, etc.), that typically have co-evolved with particular plant varieties suited for such procedures.

World-wide, this food diversity has come under threat from the globalization and standardization of food production and is giving increasingly way to simplified diets, a process referred to as "nutrition transition". It is characterized by the replacement of dietary diversity with a limited number of high-energy plant and animal sources, particular refined carbohydrates and fats (Johns and Eyzaguirre, 2006). There is growing evidence suggesting the association of the nutrition transition with the rise of non-communicable diseases such as diabetes, cardiovascular disease, obesity and cancer, even in poor countries (reviewed in Johns, 2007).

It is an often stated fact that humankind's nutrition is now largely relying on two dozen crops, with rice, wheat and maize alone contributing some 60% of caloric intake (Eyzaguirre et al., 1999). The production of these global crops takes place under economies of scale; it uses high yielding varieties, continually improved agronomical efficiencies and post-harvest technologies, resulting in the availability of inexpensive foodstuffs. This has eroded the competitiveness of minor or heritage crops, leading to concerns that some of these will be pushed into mere subsistence uses or even extinction owing to under-use in agricultural systems and markets.

This situation is particularly severe in the tropics where rich biological, environmental and human diversity has produced a plethora of plant foods. Much of this food diversity in the tropics has been used for millennia, yet either the species delivering these foods or the foods themselves present a variety of supply and demand constraints that further exacerbate their low competitiveness vis-à-vis global crops (Fujisaka et al., 2006). Supply constraints include narrow environmental adaptation (e.g. day-length sensitivities to the development of economic plant parts), long crop duration, low seed replication rates as well as badly functioning value chains. The more important demand constraints may involve inconvenience of use and low palatability, highly competitive substitutes, ignorance of uses and nutritional benefits, or the image as poor peoples' food.

However, recent years have seen encouraging examples of traditional plant foods re-gaining ground in production systems and markets, such as 'minor millets' in India, Andean grains (Bioversity, 2007), African leafy vegetables (Irungu, 2007) and Andean roots and tubers (Hermann and Heller, 1997). Typically,

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the removal of demand constraints in the context of urban consumption has been of critical importance to the expansion of crop areas and the re-integration of derived foods in diets.

Much of the renewed consumer interest in heritage crops has been stimulated by the discovery and promotion of nutritional or other commercially relevant food attributes, and the development of convenience products for urban consumption. Domestic markets in producer countries are generally recognized as the most obvious target for marketing traditional foods, because market access barriers are less pronounced and supply chain management less complex than in external markets. However, new demand for traditional foods from the tropics often arises from consumers in high-income countries, for reasons explained further below. This presents the poor but food-diverse developing countries with opportunities for foreign exchange income and poverty alleviation of rural producers.

This paper concerns the access of "exotic traditional" food species to the EU market, which provides bright prospects for their commercial use, often in up-market niches paying premiums for specific product attributes. However, perceived food safety concerns in the North, especially those embodied by the European Novel Food Regulation (NFR) (EU Regulation 258/97) are increasingly getting in the way of South–North food chains.

This paper first examines the relevance of trade in traditional foods for development. It then describes the implementation of the NFR since its inception in 1997, and how it has inhibited the placing on the market of exotic traditional foods in the EU. We argue that the NFR has emerged as a non-tariff trade barrier, which: (1) discourages investment in export supply chains, (2) hinders food innovation from tropical agrobiodiversity, and (3) curtails income opportunities for poor producing countries.

Recognizing that the food safety of EU consumers cannot be compromised, we propose amendments to EU food law to make it consistent with the EU's international obligations dealing with trade and development. We conclude by suggesting that there is a need for increased investments in the scientific documentation of food safety evidence of traditional foods, which needs greater attention in the design of trade promotion policies and development projects.

Academic and peer-reviewed literature on the focus of this paper is extremely scarce. Therefore the paper relies to an unusual extent on grey literature, internet-based documents, press releases and personal communications of the author with actors of firms trading in traditional foods.

New income opportunities for poor countries from traditional food products

Several factors are behind the rising interest in diverse foods from the developing world. Demographic change, especially aging and immigrant populations, have lead to a previously unseen demand for new health, functional and ethnic food. The desire for dietary diversification and consumer unease about industrial production methods as well as rejection of genetically engineered food sources further motivates the search for new ingredients from sources that are perceived as less "artificial". Moreover, fierce competition in the food market forces companies to differentiate, and add value to, their products through novel ingredients and flavors.

Many of the traditional food species of the developing countries meet the changing needs of developed country markets. Marketable attributes of these foods include particular nutritional value (high contents of vitamins or functional nutrients, the absence of known allergens such as gluten, etc.), aesthetic appeal, and the sourcing from environmentally sustainable and ethically managed production systems (often certified as 'organic' or 'fair trade' produce).

Table 1 presents the attributes of an arbitrarily chosen selection of promising food species from Andean South-America, a region known to contain many useful but underutilized foods.

Table 1
Edible minor plant species from Andean South America not yet widely traded internationally.

Common and scientific name	Family	Uses in human nutrition	Salient properties of commercial interest	Status relative to Novel Food Regulation[a]
Arracacha (*Arracacia xanthorrhiza*)	Apiaceae (Umbelliferae)	Edible root, staple food in Colombia and Ecuador	Unique flavor, low syneresis starch	Not listed
Mashua (*Tropaeolum tuberosum*)	Tropaeolaceae	Edible root, widely used in Andes	Piquant flavor, rich in mustard oils	Not listed
Oca (*Oxalis tuberosa*)	Oxalidaceae	Edible tuber, widely eaten in the Andes	Colored, visually attractive tubers, specialty "potatoes"	Not subject to NFR
Maca (*Lepidium meyenii*)	Brassicaceae (Cruciferae)	Traditional tonic, Peru	High antioxidant content	Not subject to NFR
Yacon (*Smallanthus sonchifolius*)	Asteraceae (Compositae)	Edible root, eaten raw	High in fructans, recognized for gut health (Geyer et al., 2008)	Requires authorization under NFR
Cañihua (*Chenopodium pallidicaule*)	Chenopodiaceae	Andean grain	Exceptionally high in iron content, balanced protein, substitute for gluten containing cereals	Not listed
Camu camu (*Myrciaria dubia*)	Myrtaceae	Amazonian fruit, mostly collected wild	Exceptionally high in Vit C content, novel flavour	Only authorized for food supplements
Lucuma (*Lucuma obovata*)	Sapotaceae	Fruit from sub-tropical valleys	Fruit pulp for gourmet market	Not subject to NFR
Andean Elderberry (*Sambucus nigra* var. *peruviana*)	Caprifoliaceae	Temperate fruit, and medicinal tea from flowers	Fruit for gourmet market, superior to European Elderberry	Not listed
Lulo (*Solanum quitoense*)	Solanaceae	Edible domesticated fruit	The connoisseur's "most delicious fruit of the Americas"	Not subject to NFR
Ungurahua (*Jessenia bataua*)	Arecaceae (Palmae)	Amazonian tree with fruits yielding edible oil	Nutritionally balanced fatty acid composition of oil	Requires authorization under NFR
Peach palm (*Bactris gasipaes*)	Arecaceae (Palmae)	Amazonian tree with edible fruits	Nutrient-rich fruits	Requires authorization under NFR
Cupuaçu (*Theobroma grandiflorum*)	Malvaceae	Edible fruit	Fruit pulp for gourmet market, novel flavor	Not subject to NFR

NFR = EU Novel Food Regulation.
[a] Status as per Novel Food Catalogue, URL: http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm (accessed 20 December 2008).

Their consumption can be locally significant, but they are largely unknown outside South America, often even outside their "insular" distributions. Overlooked by food science, there is little formal knowledge on food composition and post-harvest processes.

Interestingly, several of the world's cuisines and cooking traditions are becoming more widely known. Peru's cuisine, an amalgam of European, Asian and native Peruvian traditions has been celebrated in recent years for its unique dishes. To the extent to which traditional cuisines have come to the forefront of international attention (as a backlash to ever more uniform diets) traditional foods and food ingredients have been seen much increased demand on international markets.

Species shown in Table 1 represent different groups of edible species. Most are domesticated, meaning they have been associated with humankind for millennia and have evolved to fit human needs of cultivation and nutrition. Domestication (as opposed to mere cultivation of wild-type plants) typically implies significant morphological changes and the development of agricultural multiplication methods, as well as the selection for low levels of anti-nutritional substances (as compared with wild types), relatively high consumption levels and long experience of safe food use (Harlan, 1975).

The relevance of trade in traditional exotic foods to development and poverty alleviation

Trade in products derived from sustainably managed biodiversity can contribute to development as recognized by the Eighth Conference of the Parties of the Convention on Biological Diversity[1]. Trade in dietary supplements, many of which are derived from traditional food crops and herbal remedies, is now exceeding US$ 20 billion and has been growing strongly in recent years (Gruenwald and Galizia, 2005). The proliferation of specialized and international trade fairs in recent years such as *Health Ingredients* and *Ethnic Specialty Food* (Paris), *Vitafoods* (Geneva) and *Biofach* (Nuremberg, Germany) further testifies to the growing commercial interest in 'exotic' traditional foods.

In recognition of this development, many donors and national authorities are committed to trade promotion. Aid donors, notably CBI, BMZ-GTZ and SIPPO, assist developing countries to promote trade and investment in biological resources, with the aim of contributing to poverty alleviation and biodiversity conservation. For example, UNCTAD's Biotrade initiative seeks to facilitate access of biodiversity products from developing countries to international markets. In pursuing this goal Biotrade's regional programs Biocomercio (Andes) and Bolsa Amazonia (Amazonian countries) place much emphasis on building equitable and environmentally sustainable supply chains that originate in poor, but diversity-rich communities. Numerous development and research projects are concerned with the goal of linking poor farmers, the originators and custodians of agricultural biodiversity, with the emerging market for exotic food species.

It is beyond the scope of this paper to assess to what extent the rural poor actually benefit from raised export chains. However, marketing companies increasingly embrace fair trade principles and link with poor farmers, who benefit in terms of contract farming, higher prices and/or purchase guarantees. Poor small farmers can take advantage of such opportunities, particularly where they have privileged access to indigenous cultivars and specific agro-ecological production niches and where the production of such crops does not involve economies of scale that will make large-scale farming more competitive.

[1] http://www.cbd.int/decisions/cop8.

The EU Novel Food Regulation

Procedures and implementation since 1997

In this section we describe the European Novel Food Regulation (NFR[2]), a directive that requires food safety assessments of traditional foods (viewed as novel from a European perspective) for pre-market approval. Its stated objective is to protect public health by ensuring food safety. The NFR has been in force since 1997. It arbitrarily defines novel food as food or food ingredients that were not used for human consumption to a significant degree[3] within the EU before 15 May 1997. By definition this would concern the majority of exotic traditional foods, for they are only recently beginning to make their way into EU markets.

The following four novel food categories fall within the scope of the NFR:

- foods and food ingredients with a new or intentionally modified primary molecular structure
- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae
- 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 with a history of safe use
- foods and food ingredients to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances

These categories do not expressly recognize or accommodate traditional foods from outside the EU. By exempting "foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use" the regulation appears to exclude traditional foodstuffs, but the wording is unclear and, as we will see, is at odds with current interpretations and the application of the NFR.

The NFR calls for anyone wishing to place a food product on the EU market to first evaluate whether the food was used prior 1997 and to present evidence to support the case. If the food in question can be shown *to have been used* within the EU before 15 May 1997, it is viewed as *not novel*, and it may be placed on the market. An assessment under the NFR is then not required. If market presence for the food can not be demonstrated for the time before 15 May 1997, it is viewed as *novel*, and an assessment of the food's safety under the NFR is required. (Prior use as a supplement does not count towards this consideration.) A corresponding application can be accepted by the competent authority of any member state.

Once submitted to the relevant member state authority, the application takes its course in a process in which the commission, all member states, and advisory bodies intervene at various stages and iterations. Essentially, the competent national food assessment body will issue an initial safety assessment report. The Commission then forwards this initial report to all member states. Article 6(4) of the NFR requires any reasoned objections of member states to the marketing of the product to be laid down within a 60-day

[2] Regulation (EC) No. 258/97 of the European Parliament and of the council of 27 January 1997 concerning novel foods and food ingredients. Available from http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1997/R/01997R0258-20040418-en.pdf (accessed 27 December 2008).

[3] What constitutes "a significant degree" is not specified and is subject to interpretation. Applicants may seek advice on these matters from commission officers or member states.

period. If objections are raised in accordance with this provision, the European Food Safety Authority (EFSA) will be consulted, which typically charges panels of specialists to define the evidence requirements applicants need to present and that will eventually assess the validity of such evidence. This process scrutinizes the novel food against the objectives of the NFR, which is to ensure that it neither presents a danger for the consumer nor that its consumption is nutritionally disadvantageous. The applicant may be required to present specific data with regard to food composition, suggested intake levels, toxicological assessments and allergenic potential, to support the application. It is common that such evidence is questioned by EFSA panels, and both the panels as well as member states may demand further additional food safety evidence.

The extent of food safety evidence requirements mandated by the NFR and a commission recommendation[4] on the scientific standards required for generating the evidence, suggests that EU legislators were guided by concerns surrounding the food safety of genetically modified organisms (GMOs). Indeed, the original NFR text included foods derived from or containing GMOs. With the approval of a separate food safety regulation for GMOs in 2003[5], these were excluded from the NFR, but the recommendation was not revised as it should have been.

Implementation of the Novel Food Regulation from 1997 to 2008

By December 2008, EU commission decisions had been made in relation to 37 novel foods[6]. Thirty four decisions authorized the placing on the market of novel foods, most of which are genuine food innovations (30) such as the use of novel molecules, extracts from micro-organisms, modified oils and others. Four authorizations concerned traditional food species, namely noni (fruits and leaves), allanbackia seeds and dehydrated Baobab fruit pulp (see Table 2). Noni fruits were authorized 2003, while the other three authorizations were issued in 2008, that is 11 years after the NFR came into force. Of the three applications denied market access, two involve exotic traditional foods that are considered safe for human consumption and are commercially used outside the EU (*Stevia rebaudiana* and *Canarium indicum*).

Authorized applications

Noni juice and leaves

By 2003, only one traditional food product had been authorized as novel food, namely the juice of the noni fruit (*Morinda citrifolia*), produced by Morinda Inc., a large US-based company with operations in several other countries. Noni is widely used in Polynesia as a traditional food and folk medicine. In the initial assessment, the company's application was rejected, based on a series of specific objections raised by member states. Only after the company had produced extensive food safety evidence from compositional, toxicological and allergenicity studies and clarified suggested intake level (30 mL per day), did the EU grant authorization in June 2003.

It is important to note, that this specific authorization was limited to the juice supplied by Morinda Inc. The placing on the market of any other noni-derived products, say jam, the spray-dried juice, or the dehydrated fruit, would require a separate authorization.

As a matter of fact, in November 2004, an additional NFR application for the use of leaves of the noni plant for consumption as herbal tea was submitted on behalf of Morinda Inc. Four years later, in December 2008, Commission Decision 2008/985 authorized Morinda Inc. to place noni leaves on the EU market as novel food ingredient[7]. The company had complied with the required presentation of extensive data regarding the food safety of noni tea including compositional data of noni leaves prior and after roasting (in relation to the intended processing), studies of acute toxicity in rats, and various state-of-the-art tests for gene mutation using bacterial and mammalian cells[8]. The assessment panel abstained from insisting on allergenicity test (as was the case with the NFR application of nangai nuts – see "denied applications of traditional foods under the NFR") noting "the current limitations to assess and to predict allergenicity of foods. . ..and was aware of the difficulties to use data from animal models for prediction of allergenicity in humans".

Both noni-related authorizations were addressed to Morinda Inc. as the applicant (as required under the NFR) and granted the company a unique market position – at least momentarily after the authorization– as the sole supplier of noni juice on the EU market. This infuriated a host of smaller companies with total annual sales probably under Morinda's research budget, and that could not afford the research to obtain authorization for their own noni products. However, the NFR permits the option of a simplified procedure to demonstrate 'substantial equivalence'. The procedure requires the company's application dossier to lay out how the novel food or novel food ingredient is substantially equivalent to an existing food or food ingredient in regard to its composition, production and intended use. In contrast to the complexities of a full application under the NFR, the evidence requirements for substantial equivalence are much reduced, and the process has typically taken only a few months to complete. A favorable opinion from the competent authority of a member state in relation to claimed substantial equivalence is sufficient for authorization and is communicated by national authorities.

As of July 2009, 48 companies have successfully demonstrated the 'substantial equivalence' of their noni juice product to the one offered by Morinda Inc. and have thus effectively been authorized to market it. These companies consist of considerably smaller operations as compared with Morinda Inc. Thirty three of the companies are based in EU countries (Austria, Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Spain, Poland, United Kingdom), while seven are from Polynesian countries, three from the USA, three from Central America and the Caribbean, one from New Zealand and Switzerland, each[9]. This geographic spread of companies is clear evidence of the international commercial interest in noni.

Baobab fruit pulp

In 2008, the EU Commission authorized the NFR application for the dried fruit pulp of baobab on the EU market, submitted two years earlier by Phytotrade on behalf the consortium's 55 members drawn from eight Southern African countries, including small producer groups, private sector companies, non-governmental organizations, research and government organizations. Baobab

[4] 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No. 258/97 of the European Parliament and of the Council. Available from http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg = EN&numdoc = 31997H0618&model = guichett. (accessed 28 December 2008).

[5] Regulation (EC) 1829/2003 on genetically modified food and feed.

[6] http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm (accessed 28 December 2008).

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri = OJ:L:2008:352:0046:0047:EN:PDF.

[8] Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the European Commission on the safety of leaves from Morinda citrifolia L. The EFSA Journal (2008) 769, 1-17. URL: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902043844.htm (accessed 30 December 2008).

[9] Notifications pursuant to article 5 of regulation (EC) No. 258/97 (April 2007). http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf#page = 68 (accessed 10 August 2009).

Table 2
Promising minor crops challenged by EU Regulation 258/97.

Common and scientific name	Description and uses	Attributes of commercial interest	Status of use and trade	Product application under NFR	Food safety assessment under NFR	Authorization status, year of EU decision	Time between initial application and EU Commission authorization
Nangai nuts (*Canarium* spp.)	Several tree species in East Asia/Pacific with edible seeds; archaeological evidence for use dating back 8000 years BP	Almond-sized kernels for gourmet market	Traded regionally and internationally	Dried seed kernels	Submitted compositional and toxicology data deemed incomplete; product allergenicity not investigated	Application refused, 2000	n.a.
Stevia (*Stevia rebaudiana*)	Herb from South America, cultivated world-wide; foliage used by Guarani people for centuries	Non-caloric sweetener	Dried foliage and extract traded internationally	Dried leaves	Toxicity data deemed unsatisfactory to dispel food safety concerns; insufficient standardization of commercial product	Application refused, 2000	n.a.
Maca (*Lepidium meyenii*)	Ancient root crop from Peru with documented food use since 16th century; closely related to a number of European Brassicaceae	Traditional tonic, Mounting evidence for pharmacological effects on endurance and spermatogenesis	Dried roots and extracts traded internationally, particularly in US and Asia; much informal and Internet marketing in EU	No application	n.a.	NFR status not clear until 2007; some EU member states prohibiting commercialization, confiscations, since 2008 listed in NFC as not subjected to NFR	n.a.
Noni (*Morinda citrifolia*) Fruit use	Polynesian tree with edible fruits; Long tradition as famine food and folk medicine of aboriginal people	Health-promoting attributes	Noni juice traded internationally and available on EU market after NFR came into force; Commercialization temporarily suspended, after novel food status became evident	Fruit Juice	In 2002, favorable opinion issued by EU Scientific Committee, based on assessment of extensive toxicity and allergenicity data	Authorized as novel food ingredient in 2003	37 months
Noni (*Morinda citrifolia* Leaf use	See above	Health-promoting attributes	Noni leaves not traditionally used	Leaves for use in infusion	Submitted evidence included extensive compositional data, acute toxicity in rats, gene mutation tests in bacterial and mammalian cells	Authorized as novel food ingredient in 2008	49 months
Baobab (*Adansonia digitata*)	Tree from Southern Africa, fruits and leaves widely eaten	Dried fruit pulp has high contents of vitamin C, iron, soluble dietary fibre. Potential as functional ingredient in food and beverages	Important source of food and medicine in savannas, since ancient times (Gruenwald and Galizia, 2005)	Dried fruit pulp	Extensive literature survey of history of safe use and composition. Submitted new data on microbiological contamination, specific toxins	Authorized as novel food ingredient in 2008	23 months
Allanblackia (*Allanbackia* spp.)	Rainforest tree from tropical Africa. Seed oil used as food and for soap manufacture; medicinal use of leaves and bark	Unique fatty acid composition of seed oil; use as hardstock in yellow spreads and margarines	Mostly local subsistence use; little regional trade	Seed oil	Compositional data, in particular fatty acids; Oil stability; Bacterial genotoxicity tests; subchronic toxicity in rats	Authorized as novel food ingredient in 2008	46 months

NFR, EU Novel Food Regulation; NFC, EU Novel Food Catalogue; n.a., not applicable.

(*Adansonia digitata*) is a large tree found mainly in South Africa, Botswana, Namibia, Mozambique and Zimbabwe. The tree produces large fruits that dry out during maturity and contain a powdery white pulp high in minerals, vitamin C and dietary fiber. Conveniently extracted and traded at a wholesale price of approximately €35/kg the dried pulp has potential for use as a func-

tional ingredient in smoothies, cereal bars, confectionary and related products. A market study on baobab (Gruenwald and Galizia, 2005) suggests a multi-million dollar market, with benefits accruing potentially to many thousands of poor rural producers, who gather the fruits and sell them to local processors.

In their application to the UK's national authority, the Food Standards Agency (FSA)[10], Phytotrade presented an extensive literature survey on baobab, including evidence on the widespread use of baobab in Africa and Asia, compositional and toxicological data, as well as the results of laboratory studies commissioned by Phytotrade to verify the freedom of baobab pulp of particular toxins. The initial opinion by an independent panel of scientists appointed by FSA noted the absence of 'classical toxicological analyses" in the application, but accepted Phytotrade's reasoning that the family Malvaceae (to which baobab belongs) and the related Bombacaceae are not known for the presence of toxic or allergenic constituents[11]. However, the panel recommended that Phytotrade should carry out analyses for aflatoxin, a request derived from a perception that the fruits would be "lying around" in adverse conditions that would permit mould growth. The data produced by the applicant were within EU limits for dried fruit and the panel accepted reassurances by Phytotrade that it would carry out routine quality control tests for aflatoxins. The application was then forwarded to the Commision and subsequently distributed to all member states which did not raise food safety concerns. In June 2008, the Commission authorized baobab dried pulp as a Novel Food, a decision directed to Phytotrade. No notifications of substantial equivalence of baobab pulp as described above for noni juice have come forward as yet.

Allanblackia

With almost four years elapsing between application and authorization, and the additional complication of the Commission having to deal with objections from member states after issuance of the initial opinion by the German national authority, the case of allanblackia seed oil required a greater degree of food safety evidence and presumably also greater financial resources for regulatory approval as compared with baobab fruit pulp. This application was presented by Unilever, a firm with a research and development budget of over $800 million. Unilever submitted the application in the context of the Novella Africa Partnership[12], a "textbook" public–private partnership involving overseas development donors, the World Agroforestry Centre, the World Conservation Union (IUCN), NGOs, local communities and the private sector. Motivated by the lesser ecological footprint of allanblackia oil vis-à-vis its substitutes (e.g. palm, oil) and recognizing the commercial potential of allanblackia seed oil in the global food market, this partnership seeks to assist allanblackia producers in five Sub-Saharan countries with improving supply and market access. Partnership activities are aimed at identifying superior planting materials, improved crop management and post-harvest techniques as well as overcoming market access barriers, with the ultimate goal of improving the income of poor allanblackia producers. Unilever committed to supporting the smallholder production base, and purchase guarantees for the raw material, and assumed responsibility for regulatory approval.

The applicant submitted data concerning expected intake levels, presence of contaminants, fatty acids composition, as well as a various toxicity laboratory tests. The initial assessment by the German authority was positive recommending authorization, but subsequently, an additional EFSA opinion was commissioned to deal with a range of reasoned objections made by several member states. Concerns included inter alia: (1) doubts as to the representativeness of tested samples in light of the large diversity of Allanblackia species used for the production of seed oil, (2) suitability for frying, (3) allergenicity and toxicity concerns, and (4) diverging interpretations of submitted food safety evidence. However, the EFSA opinion eventually cleared these concerns and Unilever was authorized in 2008 to market allanblackia oil in the EU. No notifications of substantial equivalence of allanblackia pulp as described above for noni juice have come forward as yet.

Denied applications of traditional foods under the NFR

In 2000, the European Commission refused to accept Stevia or stevioside as a novel food, based on a report of the EU Commission's Scientific Committee on Food questioning the documentation submitted by the applicant, as insufficient toxicity and carcinogenicity data[13]. Stevia is a plant of the Compositae family that is native to Brazil and Paraguay, and is traditionally used there as herbal tea. Both the Stevia plant, its extracts, and its compound stevioside have been used for several years as a sweetener in South America, Asia (notably Japan), and in different countries of the EU prior to the EU's ban. In Brazil, Korea and Japan Stevia leaves, stevioside and highly refined extracts are officially used as a low-calorie sweetener[14]. In the USA, powdered Stevia leaves and refined extracts from the leaves have been used as a dietary supplement since 1995. Quite obviously, these countries draw different conclusions from the comparatively extensive food science literature on Stevia upon which the EU's decision was partially based.

The other case concerns the edible nuts of *C. indicum*, which was refused market admission in 2000. Known as nangai, these nuts come from a commonly cultivated tree of East Asia and the Pacific, traded regionally and known to be used by humans since several thousand years (Thompson and Evans, 2004; Nevenimo et al., 2007). The applicant, a small French company was sourcing the almond-sized nuts from women producers and processors in Vanuatu, and intended to use them in up-market gourmet products. The initial assessment report in 1999 by the French competent authorities concluded that the product is safe for human consumption and could therefore be authorized. This initial assessment report met with objections on the part of several member states, which made an additional assessment necessary. In March 2000, the EU Scientific Committee for Food adopted an opinion, which deemed submitted compositional and toxicology data incomplete and observed that the product allergenicity had not been investigated[15]. Since the applicant failed to produce verifiable evidence for the claim that nangai nuts had been consumed in the Netherlands to a significant degree before the NFR entered into force, and in view of the – from the EU perspective - insufficient food safety evidence, nangai nuts have since then been considered as novel food, and in the absence of an approved food safety assessment under the NFR are banned from the community's market.

[10] Baobab Dried Fruit Pulp – An application for Novel Foods Approval in the EU as a food ingredient. URL: http://www.food.gov.uk/multimedia/pdfs/baobabapplicationfinal.pdf (accessed 15 December 2008).

[11] Initial opinion on an application under the Novel Foods Regulation for baobab dried fruit pulp as a food ingredient. FSA. 2007. URL: http://www.food.gov.uk/multimedia/pdfs/baobabinitialopinion.pdf (accessed 15 December 2008).

[12] Novella Africa Partnership. URL: http://www.allanblackia.info (accessed 15 December 2008).

[13] Opinion on stevioside as a sweetener. European Commission, Scientific Committee on Food. 1999, 7 p. URL http://ec.europa.eu/food/fs/sc/scf/out34_en.pdf (accessed 30 December 2008).

[14] European Stevia Center http://bio.kuleuven.be/biofys/ESC/English/ESC.htm (accessed 20 December 2008).

[15] 2001/17/EC: Commission Decision of 19 December 2000 on refusing the placing on the market of "Nangai nuts ("as a novel food or novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council (notified under document number C(2000) 3888). http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg = EN&numdoc = 32001D0017&model = guichett (accessed 21 December 2008).

Other traditional foods challenged by the NFR

In addition to the two denied applications, several other traditional foods have been challenged by the NFR over the years or have been identified as falling under the regulation's remit. Some of these are listed in Table 1.

It is important to realize that the NFR requires anyone marketing a food in the EU to be prepared to demonstrate its status under the legislation, a task inherently difficult to perform in a community of 27 countries. It requires proof that the food in question was on the EU market prior 15 May 1997, in at least one country. Moreover, in the absence of clear and unambiguous guidelines, member states seem to disagree about the criteria to be taken into account for the determination of the novelty status (see below the cases of maca and oca). Since 2008, the EU Commision's website features a Novel Food Catalogue, which provides the NFR status of some exotic species[16], to assist applicants decide whether a product: (1) has been on the market before May 1997, (2) is authorized only as a food supplement, (3) has not been on the market prior 1997 and therefore needs community authorization, or (4) has uncertain status. Unfortunately, this list has not been available until recently, and with its small number of species/products is of limited value.

Given the absence of comprehensive and reliable information as to the status of traditional foods vis-à-vis the NFR, it is not surprising that some importers and distributors of exotic traditional foods have indeed chosen to ignore the NFR in the hope that their marketing of exotic foods in niches will go unnoticed by regulatory bodies. This is particularly so, when companies become aware of the NFR after investments in supply management and marketing have been effected that they are reluctant to abandon. Others are uncertain about the novel food status of a particular product, and prefer to assume it is not novel.

However, an increasing number of traditional food products has eventually been recognized as falling under the jurisdiction of the NFR and is continually removed from the market. The continued, yet infrequent, presence of unauthorized or even incriminated traditional exotic foods in several countries of the EU therefore is not a contradiction to the view of this paper of the NFR as a potential threat to trade but rather consequence of legal uncertainties and divergent implementation in different countries.

Particularly confusing is the implementation of the NFR in regard to the edible root maca (*Lepidium meyenii*), a cruciferous crop endemic to the Central Peruvian Andes. Official Peruvian export statistics reveal for 1996 maca shipments worth some US$ 5000 going to Italy and Spain. Peruvian maca shipments to EU countries had grown to a total free-on-board value of US$ 113 000 by 2002 but subsequently dropped sharply (Hermann and Bernet, 2009). In January 2003, the Belgian authority issued a statement that maca had been on the market in Belgium before 1997 and should therefore not be considered a novel food. In May 2003, however, maca appeared as a "non-authorized novel food" (along with a variety of chemically and microbiologically contaminated food items) in the weekly published "Rapid Alert System for Food and Feed" a newly created instrument to assist authorities with the rejection of incriminated foods at the EU's external borders or with the removal of such foods from the market. Based on this list, the Netherlands seized a maca consignment in August 2003 but returned it to the importer after receiving the above-mentioned Peruvian export statistics. However, as of December 2008, after years of uncertainty and confusion over differing practices of the NFR in EU member countries with regard to this species, maca has been listed in the EU commissions Novel Food Catalogue as a species not restricted by the NFR.

The practice of the NFR has varied from country to country and can be remarkably "relaxed". Thus, a UK importer of specialty vegetables seeking clarification as to the food status of oca (*Oxalis tuberosa*, see Table 1), was informed in 2001 by the Food Standards Agency, the UK competent authority, that oca was unlikely to fall within the remit of the NFR. The UK authority appears to have relied in their assessment on texts in three garden books, supplied by the company, where cursory mention is made of the occasional presence of oca in European gardens since the early nineteenth century, evidence deemed by the authority as of a "somewhat anecdotal" nature but sufficient to let the company import oca for fresh consumption (under the trade name "chioca").

Discussion

Adverse impact of the Novel Food Regulation on trade in biodiversity products

The average time taken from acceptance of an application to market authorization by the EU Commission has taken an average of 39 months for the traditional food products shown in Table 2. Companies will usually not disclose the costs of producing food safety evidence required for successful applications, but according to a press report[17] Phytotrade expended more than £150,000 on the baobab application. It would seem this represents rather the lower margin of costs if using the amount of experimental evidence generated for particular applications as a proxy for costs.

The two declined NFR applications as well as the above-described cases of foods challenged by the NFR have been widely observed by developed country exporters, European importers and distributors of specialty foods. The costs, complexity, length and uncertain outcomes of NFR procedures have led to uncertainties about the likelihood of successful applications and discouraged firms of the sector to file applications. This situation was clearly expressed by private sector participants of a workshop on the revision of the NFR in Brussels in 2005, also attended by developed country representatives, researchers and EU lawmakers[18] .

No matter how favorably exotic traditional foods are viewed in relation to market potential, companies shy away from the investment and (often futile) efforts of registering them properly through the NFR. This is evident from surveys conducted by the author from 2001 to 2003 as an exhibitor of traditional foods on international trade fairs (unpublished) and through interaction with specific firms exploring traditional Andean foods for market potential. For example, Prolucuma, a Peruvian association of producers of the lucuma fruit (see Table 1), identified great interest in their products from European processors in that period, but corresponding purchase contracts did not materialize, when uncertainties about the status of lucuma vis-à-vis de NFR became apparent (Mr. Bederski, personal communication).

Chances of EU market authorization for the majority of exotic food species are currently nil, unless extensive data allowing stringent food safety assessment are available. Larger corporations or consortia, such as those involved in the management of successful applications of noni, baobab and allanblackia have research budgets to tackle this task, but such investments are rarely justified in view of the still embryonic market size and the fact that

[16] Novel Food Catalogue. URL http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm (accessed 20 December 2008).

[17] http://www.independent.co.uk/news/world/africa/the-tree-of-life-and-its-superfruit-869737.html.

[18] Workshop on the revision of the Novel Food Regulation; Views and experiences regarding traditional foods. Proceedings UNCTAD-CBI workshop NFR, Brussels, 1 December 2005. http://www.biotrade.org/Events/events_docs/events-dec05-novelfoodsagenda.PDF (accessed 20 December 2008).

authorizations are restricted to specific products. On the other hand, the NFR curtails the entrepreneurial initiative of small and medium-sized companies, who typically have the agility and pioneering spirit to develop niche products but cannot afford the research to gain regulatory acceptance.

It could be argued that the low number of NFR applications concerning traditional foods indicates very limited commercial interest and contradicts the thesis of this paper of the NFR as an emerging trade barrier. However, the high number of notifications of substantial equivalence by small companies in the wake of the authorization of noni juice (see "noni juice and leaves") clearly demonstrates significant interest in marketing this product that would have remained hidden if the authorization had not come forward. While the authorization was initially limited to Morinda Inc. it eventually had the effect of opening the market for a range of suppliers of the product. Notifications of substantial equivalence have not been published for baobab and allanblackia, most likely because these authorizations have only recently come in force.

In conclusion, the NFR has emerged as a serious, albeit unintended, non-tariff trade barrier to imports from the developing world into the EU, perhaps the most attractive market for exotic traditional foods. A description of market access of novel food in countries outside the EU is beyond the scope of this paper, but the fact that many of the foods challenged by the NFR are legally available for food uses in Canada, Japan, Switzerland and USA suggests that regulations in these countries is less stringent than the European NFR. There is also a tendency of traders and exporters of re-directing their marketing strategies to these markets preferentially.

Organizations promoting trade in biodiversity products and aid donors have expressed concerns that the NFR is in conflict with their objectives, especially with policies aimed at investment in the sustainable use of biological resources in support of poverty alleviation (see Lebot, 2006, on kava). Developing country governments and international organizations such as UNCTAD have come to view the NFR as inconsistent with EU obligations in international agreements, particularly those in relation with the WTO SPS agreements (Mr. Escobedo, personal communication).

Need for the recognition of exotic traditional foods as a food category sui generis

The NFR currently provides a single regulatory framework to extend the safety assessment strategies for GMO foods (originally included in the NFR) and other kinds of innovative foods, such as those derived from novel processes and molecules, to traditional foods. There is only cursory mention in the NFR and complementary legal EU texts of exotic traditional foods, as if they were almost immaterial to the subject matter of the regulation. As shown in previous sections, exotic traditional foods consist of a vast variety of food items and are of growing importance to poor country economies and to the diet diversification desired by EU consumers.

In light of the diverse nature of novel foods it is unreasonable to subject them all to a single safety assessment as currently practiced under the NFR. We argue the need for establishing a separate novel food category for exotic traditional foods as opposed to innovative products with no history of long-term consumption outside the EU.

Evidence requirements for traditional exotic foods

Evidence requirements for traditional exotic foods need to be proportionate to risks and take into account the history of safe use in the country of origin. The NFR places a high burden of proof on the innocuousness of products generally regarded as safe (GRAS) outside the EU. Applicants are required to present extensive data with regard to composition, nutritional considerations, intake levels, toxicology and allergenic potential, which even in the case of vastly better researched major European foods would be hard to come by. Had the potato not been introduced to Europe in the 16th century, would it be possible to obtain an EU authorization as novel food today, given this food's potentially high glycoalcoloid levels?

The scientific requirements for exotic traditional foods should be proportionate to the potential risks they pose, and not exceed those required for accepted European traditional foods, particularly as far smaller intakes can be expected (see also Craddock, 2005).

Safety assessments do currently not consider the history of safe use of exotic traditional foods outside the EU, for example preparation methods and consumption patterns that have evolved over centuries. In addition to experimental scientific evidence, the NFR should therefore admit traditional knowledge for food safety assessment. The combined evidence on a particular food from the ethnobotanical and anthropological literature as well as from anecdotal and folkloric sources can provide important pointers for safety assessment.

The scientific criteria for the safety of traditional foods as required by the NFR "reflect the approach taken towards GM-derived products, seemingly to establish 'zero risk' or 'proof of absence' of risk" (Craddock, 2005). Toxicity, allergenicity or clinical studies should only be required where reasonable doubts as to food safety are justified In a similar vein, the SPS agreements require WTO members to justify food safety standards that exceed those of the Codex Alimentarius or of the exporting country on scientific grounds.

The need for enhanced scientific documentation of traditional foods

Food safety concerns in regard of exotic traditional foods will not go away. Even if the evidence requirements in the EU were to be aligned with practices in other developed countries' novel food legislations, exporters will require nutritional, compositional and other documentation. However, scientific documentation of the innocuousness of many traditional exotic foods even if they have a long history of safe use is typically non-existent or deemed insufficient by regulators, owing to the lack of peer-reviewed research publications, or lack of data from certified laboratories. The research and development community must address this gap of knowledge in project design and product development and trade promotion activities. Too many promotional activities, such as those surrounding Stevia for export, have been going on with an almost exclusive supply-oriented emphasis on production, whereas little if any investment of the public sector was aimed at food safety issues.

Traditional uses and the knowledge of local peoples from the country exporting traditional products has provided important pointers for the identification of functional attributes of traditional foods in commercial exploitation (see Table 2). However, such indigenous knowledge has not been recognized as evidence in the evaluation of novel product applications. It is only through its substantiation by scientific methods in formal experiments that traditional knowledge is validated in the course of an application.

There is a need to develop dossiers for exotic traditional foods, which compile the available knowledge and identify gaps. Issues that need to be addressed 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, nutritional assessments (food intake levels considered safe) for both human and animal use. Such knowledge constitutes a public good that needs to be generated by public–private partnerships, where private sector co-investment is key to ensuring the commercial relevance of procedures and outcomes.

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