

The EU Novel Foods Regulation –

its impact on trade in biodiversity products from developing countries



Fruits of *Canarium indicum* (photo: C. Elevitch)

What is “Novel Food”?

The NFR regulates the placing of “novel foods” in EU member states to protect public health by ensuring food safety. It calls for anyone wishing to place a food product on the EU market to first evaluate whether the food is “novel” and then to present evidence that it is safe. **Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997.** 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.

The regulation (258/97) principally addresses food safety concerns in the context of foods derived from, or containing, genetically modified organisms (GMOs), with “new molecular structure” or those derived from novel production processes. The categories established in the regulation do not expressly recognize or accommodate traditional foods from outside the EU, and yet according to article 1.2.[e] “food and food ingredients consisting of or isolated from plants and food ingredients isolated from animals” may be novel foods, except for those “obtained by traditional propagating or breeding practices, and having a history of safe use”. Thus, the regulation appears to exclude traditional foodstuffs, but the wording is unclear (How does one prove a history of safe use?) and contradicts current interpretations and practice under the NFR.

The challenge

Most of the world’s food is derived from just a few crops. Rice, wheat and maize supply roughly three-quarters of the world’s food energy. In total more than 95% of all food energy and protein comes from just 30 species. This obscures the rich diversity of edible plant species, particularly in the tropical latitudes of developing countries. These foods have been consumed for millennia, but mostly in their native range. In recent years the prospects for commercializing “neglected” and “underutilized” species beyond national or regional borders have improved. Demands for more diverse and nutritious diets, grown in accordance with verified social and ecological standards, are on the increase, particularly in developed countries. Therefore, official development assistance agencies support the efforts of developing countries to promote trade and investment in biological resources, with the aim of contributing to sustainable development and biodiversity conservation. Several organizations, such as BMZ/GTZ (through Public Private Partnerships and other programs), SIPPO (Swiss Import Promotion Program), CBI (Center for the Promotion of Imports from Developing Countries, Netherlands) and the UNCTAD Biotrade Initiative, seek to link cash-poor but diversity-rich communities with emerging international markets for exotic foods.

Unfortunately, potential traders in foods that are exotic in developed countries but nevertheless traditional in their region of origin, face considerable challenges in accessing the European market legally. The EU Novel Foods Regulation (NFR) (Regulation No. 258/97) adopted in 1997, in efforts to harmonize consumer protection within the EU and to confront food safety concerns, is an obstacle to marketing such exotic foods. ▶



Global
Facilitation
Unit
for Underutilized
Species



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Canarium indicum, a commonly cultivated tree of the Pacific (photo: B. Evans)



Nangai nuts. In natural populations of Nangai (*Canarium indicum*) there is tremendous variation in size and shape of nuts, as well as quality of the edible kernel. (photo: B. Evans)

- ▶ If a food product or ingredient is identified as *novel*, it must go through a safety assessment procedure to gain access to the EU market. This places a high burden of proof on those bringing traditional food products from the South to the EU market, the costs of which are usually beyond the possibilities of small-scale producers and exporters in developing countries. Europeans are fortunate to have introduced products like potatoes and coffee long before 1997; today both would almost certainly be rejected by the NFR.

Discouraging experiences

Those who followed the rules have experienced a lengthy and expensive process with an uncertain outcome. Even investigating whether an exotic traditional food product is “novel” or not to the European Community may involve considerable time and effort. When an application is accepted, the average time taken to reach a final decision has been 18-24 months.

Some exotic traditional plant products have been denied access to the EU market for lack of what country authorities regard as sufficient food safety evidence despite their long history of safe use in other parts of the world. One is ***Stevia rebaudiana***, a shrub first cultivated in Brazil and Paraguay. The plant has been known for centuries by the native Guarani Indians for the sweet taste of its leaves. Today Stevioside, a white crystalline powder, is extracted from *Stevia* leaves, and both Stevioside and *Stevia* are widely used as a natural, non-calorific

sweetener, particularly in Brazil, China, Japan and South Korea. In 1998 a request was made for *Stevia* plants and dried leaves to be marketed in the EU as a novel food under the NFR. The EC Scientific Committee on Food concluded in June 1999 that the information submitted on the plant products was insufficient with regard to specification and standardization of the commercial product and contained no scientific safety studies. The fact that *Stevia* has long been used in the above-mentioned countries was not taken into account.

Another case concerns **Nangai nuts**, harvested from *Canarium indicum*, a commonly cultivated tree native to the Pacific. The nuts are already exported as gourmet products to Australia, Japan and Hawaii. Access to the EU market was denied because the information submitted for safety assessment was considered incomplete.

Maca (*Lepidium meyenii*), a root crop from Peru, where it was enjoyed centuries ago by the Incas, appeared as a “non-authorized novel food” in the weekly “Rapid Alert System for Food and Feed”. This instrument assists authorities in rejecting incriminated foods at the EU’s external borders or removing such foods from the market.

By November 2003, only one exotic plant product had been authorized as a novel food; the juice of the **noni fruit** (*Morinda citrifolia*), which is marketed by a large US-based company that was able to supply the extensive food safety evidence needed.

The authorization is limited to noni *juice*; any other noni product (e.g. jam, spray-dried juice, dried whole fruit) would require a separate application. Moreover, authorization is specific to the applicant. A competitor cannot market noni juice, unless evidence has been presented of substantial equivalence.

Not surprisingly, potential importers are increasingly reluctant to invest in the supply chain for such foods.

Changing the current situation

The upcoming amendment of the Novel Foods Regulation (Regulation No. 258/97) provides an opportunity for change. In July 2002 the European Commission's Health and Consumer Protection Directorate General (SANCO D4) published a Discussion Paper that presents some of the major issues that have emerged in relation to the implementation of the NFR. **Comments and suggestions are still invited.** The review is limited to non-GM novel foods, as since April 2004 the authorization and traceability of GM food and feed is covered by a separate regulation. With the new GM food and feed regulation, issues have become somewhat disentangled and the prospects have improved that the long-awaited amendment of the NFR can be realized in 2005.

A joint initiative by the Global Facilitation Unit for Underutilized Species (GFU), the International Plant Genetic Resources Institute (IPGRI), and the Deutsche Gesellschaft für technische Zusammenarbeit (GTZ) is raising awareness and campaigning for an amendment of the regulation so that exotic traditional foods can access the EU market more easily. The issue was brought to the attention of the German Ministry for Economic Cooperation and Development (BMZ) and the German Ministry of Consumer Protection, Food and Agriculture (BMVEL) highlighting the inconsistency between development policies and consumer protection within the EU. The group developed a pro-

posal containing suggestions of how the interests of developing countries could be better taken into account:

- ◆ Exotic traditional foods should be recognized as a separate novel food category so that different requirements can be set for them.
- ◆ There is a need to develop simplified safety assessments for traditional exotic foods. The NFR should admit evidence from ethnobotanical and anthropological literature as well as from anecdotes and folklore. Toxicity, allergenicity or clinical studies should only be required where reasonable doubts as to food safety are justified. 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.
- ◆ Exotic traditional foods should remain in the public domain and no private entity should be granted privileged access to the EU market for authorized products, as happened in the case of noni fruit juice.
- ◆ It would be desirable if both the commercial companies and the non-profit or public sector institutions with no intent of placing the product on the market themselves could make an application in order to open up the EU market to assist beneficiaries such as poor farmers.
- ◆ Wherever possible a generic admission should be granted for a range of products from the same species (e.g. for pasteurized juice, frozen pulp, jam, ice-cream and related products from one fruit).

These recommendations are currently being scrutinized from a legal point of view by BMVEL, the competent national authority for the implementation of the regulation in Germany, and will be fed into the EU-working group on Novel Food currently reviewing the regulation.



Maca (*Lepidium meyenii*), a native Andean crop (photo: M. Hermann)

Roles for the research and development community

Legitimate food safety concerns regarding exotic traditional foods will not disappear. Even an amended NFR will require documentation on nutrition, composition and other aspects that is currently not available for most traditional and under-researched foods. Research and development activities that promote exotic foods must increasingly accommodate food safety concerns and consider this need in project design, product development and trade promotion. Awareness raising is still needed among those fostering the development of biodiversity products for niche markets.

Further information:

Global Facilitation Unit for Underutilized Species

http://www.underutilized-species.org/the_latest/archive/pop_up/eu_nfr.html

M. Hermann (2004): The Amendment of the EU Novel Food Regulation: Opportunity to recognize the special status of exotic traditional foods. Discussion Paper. IPGRI.

http://www.underutilized-species.org/documents/nfr/nfr_discussion_paper_june_2004.pdf

EC Novel Foods Webpage

http://europa.eu.int/comm/food/food/biotechnology/novelfood/index_en.htm

EC SANCO D4 (2002): 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. European Commission.

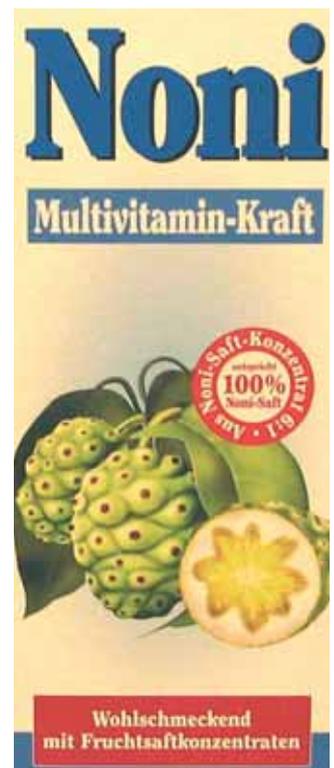
http://europa.eu.int/comm/food/food/biotechnology/novelfood/discussion_en.pdf

Article "An unintended barrier to EU markets"

<http://www.new-agri.co.uk/04-6/focuson/focuson5.html>

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, and nutritional assessments (food intake levels considered safe) for both human and animal use.

Developed and developing countries should discuss together the risks of marketing new exotic foods, assess different approaches of dealing with "novel" foods, and harmonize their regulations.



Demands for healthy biodiversity products are on the increase, particularly in developed countries.

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- arouse interest in the topic of conservation and sustainable use of biodiversity,
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- explain new terms and concepts in the thematic area of biodiversity,
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