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European Novel Food Legislation as a Restriction to Trade

Anu Lähteenmäki-Uutela

**Turku School of Economics, Finland
anu.lahteenmaki-uutela@tse.fi**



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1. Abstract

Novel foods are a category of foods that are considered possibly hazardous to public health because of the new, unfamiliar ingredients they contain. That is why they are subjected to pre-market control in the European Union and other countries. There is no international Codex¹/WTO standard on novel foods yet.

The European Novel Food Regulation applies to the placing on the EU market of foods and food ingredients which have not been used for human consumption to a significant degree within EU area. A food is novel in EU regardless of its use in third countries. This is a problem mainly to third-country producers of plant-based products. For example Chinese or Andean vegetables or berries not previously used in Europe are novel foods requiring authorization. This is the case even if they have been used by people for millennia and are considered safe. The authorization procedure is costly and time-consuming.

The Novel Food Regulation is considered a non-tariff barrier for trade. According to Hermann², current practice of the regulation has discouraged investment in supply chains, and hindered market development. There is market potential for exotic vegetables, fruit and berries. European consumers might be willing to pay for these “new” products and more variable diets. Production and export of these plant-based products would generate income for poor farmers in developing countries. In addition, this would benefit biodiversity conservation. Both the third country producers and European consumers would thus benefit from removal of hindrances on South-North trade.

There are organizations and research projects that are concerned with linking poor farmers with the market for exotic foods. Besides getting people out of poverty, these efforts aim at adding investment in biological resources, which have significant underutilized potential in many Southern countries. Questions of ethical trade are closely related: the actors are trying to build economically, socially and environmentally sustainable development. It is not understood by these organizations - or farmers - why it is so difficult to get the products onto the EU market. Of the three novel foods rejected since 1997, two were plant products (Stevia Rebaudiana and Nangai nuts). These cases show that the safety requirements for plant-based novel foods are fairly strict and lots of tests are required. The Noni case, on the other hand, shows that the requirements can indeed be fulfilled.

The current situation in practice is that many exotic foods are sold without novel food authorization. These marketers do not consider their foods novel or take the deliberate risk of getting caught and being removed from the market, because they see the novel food process as too burdensome and unpredictable. There is also an opposite trend emerging: in 2006, applications were made for several plant-based products.

The EU novel food regulation is under reconstruction. The regulation will most likely be totally rewritten with effects also on the definition of novel food. A revision of the regulation is deemed necessary in order to create a more favorable legislative environment for innovation in the food industry, and to better facilitate both internal and external trade in foodstuffs.

¹ Codex Alimentarius Commission is the international organisation creating food standards. It is part of FAO and WHO.

² Hermann 2004.

2. The Challenge of Evaluating Novel Foods

Throughout history, foods prepared and used in traditional ways have been judged safe on the basis of long-term experience. In today's risk analysis, a food is considered safe when we are reasonably certain that it will cause no harm if it is used as intended, under the anticipated conditions of consumption. Some foods are not safe in absolute terms but contain natural toxicants like solanin in potatoes.³ In these cases, safety is related to how the food is used. In the potato case, we just don't eat the green part and consider the product safe.

Foods are usually complex mixtures of macro- and micro-constituents. Foods provide energy and nutrients and have traditionally been regarded as natural, beneficial and necessary products whose safety and nutritional value need not be questioned. Regulatory approaches have focused on restricting hazards outside the food itself. This means regulating food additives, processing aids, and contaminants of natural or industrial origin. Foods as such have traditionally not been systematically subjected to nutritional or toxicological evaluation. Nutritional evaluation of foods and of diets has been performed, but such nutritional evaluations have not been used as a basis for a safety assessment of individual foods.⁴

During the 1970s, food technology developed rapidly. New products and processes were developed, especially in response to a perceived shortage of food, particularly shortage of animal protein. Methods were developed to produce protein foods from new plant and microbial sources, and to use textured plant proteins as meat analogues and extenders. Many countries had experience in evaluating safety of food additives and contaminants, but there was little experience in evaluating safety of new foods or food ingredients. It was recognised that it was inconsistent to require extensive testing for food additives but not for foods or food ingredients that might be consumed at much higher levels.⁵

Already in 1972, the Protein Advisory Group of the United Nations University (PAG/UNU) issued Guidelines for the Preclinical Testing of Novel Sources of Protein and Guidelines for the Human Testing of Supplementary Food Mixtures. This was an attempt to ensure systematic safety evaluation of novel foods that had appeared on the market, and focused on novel microbial proteins. The Guidelines were revised and re-issued by the United Nations University in 1983. The scope of the revised Guidelines was expanded to cover Preclinical Testing of Novel Sources of Food and Human Testing of Novel Foods. Novel foods were defined as *foods not previously eaten by humans*. The guidelines identified the main categories of information needed to evaluate the safety of novel foods. They also discussed some of the problems with testing novel food safety.⁶

Testing novel food safety is difficult because they are often complex mixtures of many substances, and because they are used in significant levels and to replace other foods. The usual way to test the safety of a substance in food is to feed it to laboratory animals. There is plenty of experience of doing this with additives or contaminants. Feeding studies will show the level in the diet at which animals show no adverse effects. After this, the maximum level of intake from human food is estimated to ensure that there is a large safety margin, often more than 100 times. This is possible

³ European Food Information Council EUFIC Review 04/2000.

⁴ European Commission Recommendation on Novel Foods, Annex, Part I, Chapter 3.1.

⁵ European Food Information Council EUFIC Review 04/2000.

⁶ European Food Information Council EUFIC Review 04/2000.

because the additive or contaminant can be included in animal diets at much higher levels than the anticipated level in human food.⁷

A novel food, on the other hand, is often used at significant levels and might reach for example a level of 10 per cent of a human diet. It is then impossible to feed the food to animals at 100 times higher levels. Even if it was possible to feed the food to animals at higher levels than intended for humans, and the animals would actually eat the food, the food would upset the nutritional balance of the diet. This means the diet of the animal would be worse just because the test food replaces everything else. As foods are often complex mixtures of macro- and micro-nutrients, it is difficult to determine which nutrients cause the effects in animal studies. This is why new approaches to safety assessment have been developed for novel foods. For example, a novel food is always compared to a conventional counterpart, if applicable. Starting in the beginning of 1990s, novel food regulation followed scientific development, and focused on GM food. International organisations and governments have developed guidelines particularly on assessing GM food. Not as much effort has been put in evaluating safety of traditional plants.⁸

3. European Novel Food Legislation

European Union novel food legislation was discussed and planned for years, and finally in 1997 the Novel Food Regulation⁹ came into force¹⁰. The Regulation has been applied to all foods developed or imported on the market after July 1997. GM foods were in 2002 separated from the novel food regulation and are now under their own regulation.

According to the current EU regulation¹¹ concerning novel foods, novel foods are foods that are new in the context of normal foods: “This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which *have not hitherto been used for human consumption to a significant degree within the Community...*”¹². The food (or food ingredient) must also fall under the following categories:

- It has *a new or intentionally modified primary molecular structure*.
- It consists of *micro-organisms, fungi or algae*, or is isolated from them.
- It is a food or a food ingredient consisting of/isolated from *plants* or a food ingredient isolated from *animals*, excluded foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use.
- To it has been applied *a novel production process*, where the new process gives rise to *significant changes in the composition or structure* of it, and the changes affect its *nutritional value, metabolism or level of undesirable substances*.¹³

⁷ European Food Information Council EUFIC Review 04/2000.

⁸ European Food Information Council EUFIC Review 04/2000.

⁹ Regulation (EC) No 258/97 of the European Parliament and the Council of the European Union.

¹⁰ UK and Netherlands had already by then come up with their own notification schemes and testing guidelines, which were replaced by the EU scheme.

¹¹ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

¹² Article 1(2).

¹³ Article 1(2).

This means that novel foods are foods containing components or ingredients that are not considered natural in relation to the food concerned. Two basic groups of novel foods are foods containing *new synthetic ingredients* and foods containing *new biological ingredients*. In practice, novel food applications have involved many different types of foods or ingredients. Novel plants are an important part of these. Other products include several foods with added phytosterols.¹⁴ Besides foods in food form, the novel food regulation applies also to food supplements¹⁵. Novel food applications have been made for example for food supplements using noni fruit powder, noni leaf powder, or tree lignan¹⁶.

Applications for novel food authorisation are reviewed by a competent authority in the EU member state where first sale is intended. An application must include a full dossier on the substance or process. The dossier must have the contents and format set by Commission Recommendation¹⁷. The costs of obtaining the required data are substantial and are considered prohibitive by small companies.¹⁸ Not that many applications for novel foods have been made in 10 years: there had been a total of 78 applications by July 2007. Part of these were GMOs, to which other rules currently apply.

In the application procedure, the member state performs the initial assessment, after which summaries of the application are sent to the Commission and the other 26 states¹⁹. The other states have a chance to object to the assessment, or to ask for further clarification. Many applications have also been deferred to the Scientific Committee on Food, which is under the Commission. The Commission ultimately decides whether the novel food will be authorised or not. The authorisation procedure as a whole has in practice often taken years.²⁰

There is also a simplified procedure, *the notification procedure*, for novel foods or ingredients that are considered by a national food assessment body as "*substantially equivalent*" to existing foods or food ingredients. Equivalence is evaluated as regards composition, nutritional value, metabolism, intended use, and the level of undesirable substances. By June 2007, there had been a total of 82 novel food notifications.

4. Cases of Plant-Based Novel Foods

It is noteworthy, that of the three novel foods rejected since 1997, two were exotic plant products²¹. These are *Stevia rebaudiana* Bertoni²² and Nangai nuts (*Canaria indicum* L.)²³. For example all the

¹⁴ See complete list of all the applications at: http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf.

¹⁵ Specific EU rules apply to food supplements: Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

¹⁶ Finnish Food Agency guidelines on food supplements, updated 2006, page 22-23.

¹⁷ 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.

¹⁸ Ottaway 2005, 237.

¹⁹ The European Union has 27 member states as of beginning of 2007. The last to join were Romania and Bulgaria.

²⁰ Ottaway 2005, 237.

²¹ The third novel food ingredient rejected by the Commission was Betaine. In addition, the food use of deer horn powder was rejected already in the initial assessment.

²² Commission Decision 2000/196/EC.

²³ Commission Decision 2001/17/EC.

products containing phytosterols have been authorized. There is also a good example of an exotic plant that has been authorised: the Noni fruit (*Morinda citrifolia*)²⁴. Here we discuss these three cases, mentioning also current applications for plant-based foods, and plant-based notified foods (which were considered substantially equivalent to existing foods).

4.1 Stevia Case

The Commission's Scientific Committee on Food gave its opinion²⁵ on *Stevia rebaudiana* Bertoni in June 1999. Information on the chemical composition of the plant leaves was available to the Committee. The leaves contain a complex mixture of natural sweet chemicals, the main sweet principle being stevioside.²⁶ There was data showing stevioside is not toxic. The Committee also knew the plant in question is *a traditional American natural sweetener used for centuries*. It has been added to herbal teas and other beverages.²⁷ They also knew that the plant was cultivated in several American and Asian countries, and also in Europe²⁸. Botanically, the plant was well identified²⁹. There were no particular technological processes involved, only drying.³⁰ It would thus be safe to say that using the plant in foods was not a discovery of any kind.

In Paraguay, the plant had since the 50's been *used in diabetics* to reduce blood sugar levels. The applicant had also provided results of one *animal test* proving this kind of benefits to diabetics. According to the applicant, a significant decrease in liver glycogen after 2 weeks and a significant decrease in blood glucose levels after 4 weeks was showing in the rat test. The Committee did not consider this animal test convincing, as they did not have the details of the study.³¹ The dry powder was intended to replace some of the sucrose in drinks, jams and sweets to reduce the caloric intake. Besides diabetics, the product was also considered good for obese individuals.

The Committee would have wanted more information, though. They would have liked the product to be carefully analysed, and the composition standardised, preferably with regard to stevioside. The producer should have known where the plants are cultivated, which variety of the species will be used, and what is the composition of commercial products. Also *toxicological tests* on the final products should have been helpful, even though nothing inherently toxic is present in the plant. Also *microbiological issues* should have been addressed in the application.³² The *appropriate intake* was also unclear to the Committee. There were also no studies to show the *physiological and pharmacological effects* of substituting sugar with *Stevia rebaudiana* in diabetic or obese individuals.³³ Studies on how the use of the plant might affect absorption of other food were also

²⁴ Commission Decision

²⁵ Opinion on *Stevia Rebaudiana* Bertoni plants and dried leaves. Expressed on 17 June 1999 Scientific Committee on Food. SCF/CS/NF/STEV/3 Final 17/6/1999.

²⁶ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

²⁷ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 2.

²⁸ *Stevia Rebaudiana* Bertoni was cultivated in Paraguay, Mexico, Central America, Japan, China, Malaysia, and South Korea. Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 2. In Europe it was reported to be cultivated in Spain, Belgium and the UK. In Europe, the plant was cultivated in greenhouse conditions, as it does not survive winter climate. Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

²⁹ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

³⁰ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

³¹ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 4.

³² Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

³³ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 4.

missing.³⁴ The list continuing, no investigations on the *allergenic potential* of the leaves and the powdered leaves were submitted.³⁵

The conclusion of the Committee was that there was *not enough information* available to evaluate the safety of the plant. There was no data to support safe use as food ingredients or as sucrose substitute for diabetics and obese individuals.³⁶ On the same date (17 June 1999), the Committee also gave its negative opinion on the use of stevioside as a food additive³⁷. The additive process is legally separate from the novel food process, but practically the decisions were intertwined. The outcome of the process is that Stevia plants and stevioside as a sweetener are banned in Europe. Still, they have appeared on the market³⁸.

If we look at the opinion on stevioside as a food additive, we can better understand why the application on Stevia as novel food was rejected. There have been several studies on stevioside and its metabolite steviol. Particularly steviol seems to be problematic as it has been shown to decrease fertility in male rats and to include developmental toxicity. It has been reported to cause cancer when fed at very high doses to rodents.³⁹ The actual reason for rejection was probably not lack of information as such but a hint of serious side-effects. Here the Committee resorted to the precautionary principle and decided not to take any chances.

If all of the above-mentioned tests are required before bringing a novel food on the market, it is no doubt fairly demanding. The same tests are at the moment required for biotechnological or other innovative solutions, and for simple plants. It poses challenges for a farmer if the composition of a food must be nutritionally standardised. This requirement sounds similar to quality standards of herbal medicines.

4.2 Nangai Case

Nangai nuts⁴⁰ (*Canarium indicum* Linné, kenari nuts⁴¹, ngali nuts, galip nuts, java almonds) are another example of a plant product that has been rejected as novel food in EU.

The request to market nangai nuts was made on behalf of a Vanuatu company called Pacific Nuts Ltd. The request was submitted to the French authorities in December 1998. The initial assessment report by the French competent authorities concluded that the product is safe for human consumption and could therefore be authorised. The French decision was subject to certain recommendations regarding microbiological controls, regular monitoring of aflatoxin levels and labelling requirements similar to those for nuts in general because of potential allergenic risks.⁴² This meant the French were willing to treat nangai nuts as quite harmless products, and considered normal precautions adequate.

³⁴ Opinion on Stevia rebaudiana Bertoni as a novel food, page 4.

³⁵ Opinion on Stevia rebaudiana Bertoni as a novel food, page 5.

³⁶ Opinion on Stevia rebaudiana Bertoni as a novel food, page 5.

³⁷ Opinion on Stevioside as a Sweetener, adopted on 17/6/1999. SCF/CS/ADD/EDUL/167 final.

³⁸ <http://www.food.gov.uk/news/pressreleases/2000/jun/stevioside>.

³⁹ Opinion on stevioside as a sweetener.

⁴⁰ This is what the nuts are called in Vanuatu.

⁴¹ This is what the nuts are called in Indonesia.

⁴² Scientific Committee Opinion, page 2.

However, objections were raised by four other member states. Therefore, the Scientific Committee for Food had to assess the product. They gave their opinion in March 2000, stating that *necessary data for the assessment of the safety of the product are lacking*. They said the product should not be authorised.⁴³ It was at this stage of the procedure when the applicant claimed that nangai nuts are in fact not a novel food at all. The applicant claimed that these nuts were consumed in the Netherlands to a significant degree. This claim was examined by the Dutch authorities who could not find such nuts. Nangai nuts were thus considered novel foods. The Commission decision prohibiting nangai nuts was issued in December 2000.⁴⁴ This means it took two years to assess the safety of these nuts. The opinion of the Scientific Committee⁴⁵ was based on similar facts as with the Stevia Rebaudiana Bertoni case described above. Again, *not enough tests had been completed on the plant*.

The Committee knew that the almonds were widely used in the Pacific region. The estimated consumption of ngali nuts in Western Melanesia was about 60 tonnes of almonds or about 70 g/day/person⁴⁶. No particular technology was involved, besides drying, floating, soaking and drying again. The Committee also knew that Ngali nuts are listed in the Australian tables of composition of Pacific Island Foods and that the nutrient content of the kernels had been analysed. From nutritional point of view, the Committee stated that nangai nuts are practically the same as nuts eaten in Europe.⁴⁷

The applicant had performed various tests on the nuts. They had for example tested the nuts for heavy metals and mycotoxins. The Committee would have wanted more information, though. They said not all the relevant mycotoxins were present in the studies performed. The applicant had tested the product for four different aflatoxins, but not for other mycotoxins. According to the Committee, the information on the analytical methods employed when determining the nutritional composition of the nuts was not adequate. Information on the storage conditions of the samples was insufficient. The Committee said the product does not comply with the EU hygiene standards. They were also missing toxicological assessment of the nuts and wanted information on potential genotoxicity of the nuts.⁴⁸ Also the allergy issue was mentioned: the possible allergenicity of the nuts had not been investigated.

It is interesting how the Committee ends its Opinion: “no conclusions can be drawn on the safety ... , *if the assessment procedures ... have to be followed strictly*.”⁴⁹ They were not sure if the procedures laid down in the Regulation and in the Recommendation should be strictly followed. They left the door open for the Commission to make the ultimate decision. The Commission then decided that the nuts should be prohibited based on insufficient information. The legal issue of *whether soft law should always be followed* is a general problem with European food and medicine law, which is often given by non-binding instruments. Even the drafter itself, the Scientific Committee of Food, does not know if the Recommendation was meant to be strictly followed.

Here we must agree with the French. From consumer protection point of view, nangai nuts are not known to possess any particular danger compared to other nuts. Mycotoxin levels and labelling of allergens should be separate questions from novel food evaluation, because they are addressed in

⁴³ Scientific Committee on Food. Opinion on the safety assessment of the nuts of the Ngali tree (expressed on 8 March 2000). SCF/CS/NF/DOS/5 ADD 1 REV 3 final 14/03/00.

⁴⁴ Commission Decision 2001/17/EC.

⁴⁵ Scientific Committee on Food. Opinion on the safety assessment of the nuts of the Ngali tree (expressed on 8 March 2000). SCF/CS/NF/DOS/5 ADD 1 REV 3 final 14/03/00.

⁴⁶ Scientific Committee Opinion, page 2.

⁴⁷ Scientific Committee Opinion, page 3.

⁴⁸ Scientific Committee Opinion, page 3.

⁴⁹ Scientific Committee Opinion, page 4.

other parts of European food law. This means these requirements exist even without the French authorities or the Scientific Committee particularly mentioning them. The novel food assessment should focus on the food itself with its nutritional, toxicological and allergenic properties. Hygiene rules and the levels of contaminants should be left out of the novel food assessment. These questions are answered by general food law. This means a food could be authorised, assuming that hygiene rules will also be followed and appropriate storage conditions paid attention to.

4.3 Noni Case

The application to put Noni (*Morinda citrifolia* L., Indian mulberry) juice on the market was made by a U.S. company Morinda Inc. in April 2000.⁵⁰ The request to market the product was addressed to the Belgian authorities. In the initial assessment report, the Belgians rejected the application and concluded that additional assessment was required. Perhaps they did this because they knew of the Stevia and nangai cases. The Scientific Committee gave its Opinion in December 2002⁵¹, and Commission's decision authorizing the product followed in June 2003.⁵² This time, the procedure took over three years.

The Belgian authority had rejected the application based on inadequate toxicological tests: the doses used in the original tests were too low. They would also have wanted information on the place of noni in the diet.⁵³ Member states objected noni juice for various reasons: besides toxicological and allergy studies, they focused on health claims and the medicinal nature of the product.⁵⁴ Today it is clear that the latter are according to law not part of novel food evaluation⁵⁵, but apparently the purpose of the novel food regulation was not clear a few years ago. It was not clear whether the novel food regulation was just for determining safety as such, or whether it should include assessment of the functional food properties of the food. The fact is that often the novel ingredient in a food is added because of its health effects. Now that the evaluation procedure for health claims has been created, it might be possible to combine it with the new novel food procedure so that safety and efficacy would be simultaneously evaluated by the EFSA, see below.

In the Noni case, the applicant had closely followed the Recommendation on how to structure the novel food application. He had provided the information that was asked of a non-GMO novel food. As regards compositional data, the applicant gave a typical compositional profile of the juice. He also had a Quality Assurance Policy and Procedure Manual to ensure the consistency of products. The samples used for toxicological tests were shown to be representative of commercial products.⁵⁶ The applicant had paid particular attention to finding possible toxic chemicals, and found nothing.⁵⁷

⁵⁰ The product in question was not exactly Noni fruit itself, but "Tahitian Noni" juice, a fruit juice mixture of 89 % Noni fruit (*Morinda citrifolia* L.) and 11 % common grape and blueberry juice concentrates and natural flavours.

⁵¹ Opinion of the Scientific Committee on Food on Tahitian Noni® juice (expressed on 4 December 2002). SCF/CS/NF/DOS/18 ADD 2 Final 11 December 2002.

⁵² Commission Decision 2003/426/EC of 5 June 2003 authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient (*notified under document number C(2003) 1789*).

⁵³ Scientific Committee Opinion, page 2.

⁵⁴ Scientific Committee Opinion, page 3.

⁵⁵ Health claims are regulated by: Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

⁵⁶ Scientific Committee Opinion, page 3.

⁵⁷ Plants such as *Morinda Citrifolia* were known to have chemicals called anthraquinones in their roots, and these chemicals were known to be genotoxic. It had been stated in a previous study that these chemicals did not exist in the fruit of the plant. Still, the applicant had analyzed the juice for these chemicals. Scientific Committee Opinion, page 3.

The production process did not give rise to any concerns: it was similar to all fruit juices⁵⁸. Nutritional facts were also not of any particular interest: the juice is similar to other fruit juices⁵⁹. The microbiological issues were also the same as with other fruit⁶⁰.

The history of use for Noni is interesting. The plant occurs from India through South-East Asia to Eastern Polynesia. It has a long tradition as dye plant⁶¹, as medicinal plant and as food. Virtually all parts of the plant (fruit, leaf, bark, root, flower and seed) have been used *for medicinal purposes* such as to treat cuts, inflammations, fungal infections, constipation and diarrhoea. Food use also has a long history: several studies refer to raw or cooked Noni fruit as part of the diet of aboriginal populations of Polynesia and Australia. Some studies suggest that it was eaten only in times of famine, as it tastes and smells bad.⁶² “Tahitian Noni” juice was at the time of the application already produced on a commercial scale. The applicant had marketed its “Tahitian Noni” juice in USA, Canada, Japan, Australia, Mexico, Norway and Hong Kong.⁶³

The extent of toxicological and allergy-related data is what separated the Noni application from Stevia and Nangai applications. *There was plenty of data available on Noni.* That is why it was authorised.

4.4 Applications for Other Plant-Based Foods

Besides the cases studied above, novel food applications have been made for other plant-based foods. Currently the application process goes on for:

- Whole Chia (*Salvia hispanica* L.) and Ground whole Chia,
- Vegetable oil from Inca Inchi (*Plukenetia volubilis linneo*),
- Plant Lignan from *Picea abies*,
- Baobab (*Adansonia digitata*)dried fruit pulp
- Glucosamine hydrochloride from *Aspergillus niger*,
- Refined Echium oil (*Echium plantagineum*),
- Lipid extract from *Euphausia superba*.

Applications for these products were made in 2003 - 2006. We do not try to predict here whether these foods will be authorised and when. It seems that quite many applicants have recently taken a chance with plant products, though. They seem to trust the Scientific Committee to be reasonable.

⁵⁸ Scientific Committee Opinion, page 4.

⁵⁹ Scientific Committee Opinion, page 5.

⁶⁰ By applying Good Agricultural Practices (GAP), Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP) and pasteurisation (87.7 °C for three seconds) the product was to be regarded as microbiologically safe. Scientific Committee Opinion, page 5.

⁶¹ Its root and bark have been used for colouring purposes. Scientific Committee opinion, page 4.

⁶² Scientific Committee opinion, page 4.

⁶³ Scientific Committee opinion, page 2.

4.5 Notifications of Plant-based Foods

So far (summer 2007) around 80 notifications have been made. Of these, almost half concerned noni fruit. In addition, there were notifications on prune kernel oil and argan oil. Prune kernel oil, huile d'amandon de pruneau, was notified in July 2000. Argan oil (*Argania spinosa* L.) was notified first in July 2002 and subsequently in 2005 and 2006. Among other novel foods notified are a vitamin, a fungus, a couple algae, and around 30 products with added phytosterols or phytostanols often by companies extending their cholesterol-lowering product lines.⁶⁴

It is questionable whether for example some third-country berries could be considered substantially equivalent to berries already on the European market. The probable answer is no. So far, the notification process has been used only to bring to market *the same fruit (noni)* that has already been authorized. After Noni received authorisation in 2003, it has been notified by several people and companies. It was first notified by a German Mr. Werner in November 2003. Subsequently, it has been notified by several German, French, Danish, Dutch, Finnish, Polish, Costa Rican and Dominican actors. National food agencies have repeatedly assessed the products in question to be similar to the original noni juice authorized as novel food.⁶⁵ According to the current rules, it seems that a plant must first be authorised, after which the same plant can be notified.

5. Revision of European Novel Food Legislation

The European Novel Food Regulation is at the moment under reconstruction⁶⁶. The regulation will most likely be totally rewritten with effects also on the definition of novel food. A revision of the regulation is deemed necessary in order to "reflect the fact that genetically modified food no longer falls under its scope, to create a more favourable legislative environment for *innovation* in the food industry, and to better *facilitate* both *internal and external trade* in foodstuffs"⁶⁷. Here we focus mostly on the issue of how to regulate third-country products. The Commission will also have to resolve other important issues when drafting new legislation. These include:

⁶⁴ http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf.

⁶⁵ http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf.

⁶⁶ Commission gave its discussion paper in 2002: "Discussion paper on implementation of Regulation (EC) No. 258/97 SANCO D4 July 2002". The discussion paper presented some of the issues that have emerged in relation to the regulation and it also gave future options regarding the possible revision of the regulation. About 40 stakeholders, including e.g. governments, industry, and scholars, gave their comments on the discussion paper. There was also a stakeholder meeting in January 2003. After this, a consult firm prepared a summary of stakeholder views in July 2003 in form of "Summary Report Stakeholder Submissions - Revision of the Novel Food Regulation". They also gave their recommendations on how to develop the regulation. The next step was that the Evaluation Section of the Commission prepared the "Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients". They also gave their recommendations on how to change the regulation. This was in January 2004. The "summary report" and the "evaluation report" were then summarized in "Evaluation 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 (Novel Food Regulation). Executive Summary." In June 2006, an online consultation on the revision of Novel Food Regulation (EC) N° 258/97 was launched by the Commission. Based on this, the Commission will carry out an impact assessment for a future legislative proposal. Based on the discussion paper, the stakeholder comments, the summary report, the evaluation report, the executive summary, the online consultation, and the impact assessments, novel food regulation is supposed to be revised.

⁶⁷ http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm.

- Whether to combine novel food evaluation with additive evaluation. This way all uses (additive, supplement, ingredient) could be authorised in one procedure. At the moment, it is not clear whether the novel food regulation applies to additives, flavourings, and enzymes, or whether their respective processes are enough.
- Whether to remove novel processes from the novel food regulation, and leave them under general food law. The alternative to this is to clarify the concept of “significant change”.
- Whether to continue to give authorisations as Decisions applicable only to the applicant in question, or to start to give them as Regulations applicable also to other food industry operators. The proposed compromise is that authorisations would be given as Regulations, but a period of exclusivity would be given to the applicant.

Procedural issues related to novel food authorisations have received plenty of criticism. It is very probable that novel food applications will in the future be evaluated by the European Food Safety Authority (EFSA). This has been supported by the majority of stakeholders. EFSA will have the scientific expertise to evaluate safety, leaving hopefully less room for politics and national interests. Timelines will also be set for each stage of the process, and transparency will be enhanced.

What is by many considered contradictory with the European novel food regulation is that “history of safe use” is not acknowledged if it happened outside EU. Regulating foods that are globally novel is a different issue from regulating foods that are unfamiliar to Europeans. Choosing the latter approach has made the European regulation a barrier of trade. According to the current definition of novel food, a food is novel in EU regardless of its use in third countries. This is a problem mainly to producers of plant-based products. For example Chinese or Andean vegetables or berries that have not been used in Europe are novel foods requiring authorisation, even in cases where they have been used by people for millennia and are considered safe.

The novel food regulation is, in fact, considered a non-tariff *barrier for trade*. According to Hermann⁶⁸, current practice of the regulation has discouraged investment in supply chains, and hindered market development. There might be markets in Europe for example for many different kinds of exotic vegetables, fruit and berries. European consumers might be willing to pay for these “new” products and *more variable diets*. Some of these might be so called functional foods, others might be interesting just for taste. In the other end of the supply chain, production and export of these plant-based products would generate *income for poor farmers* in developing countries. In addition, this would be good for *biodiversity* conservation. Both the third country producers and European consumers would thus benefit from removal of hindrances on South-North trade.⁶⁹

It is notable that the novel food regulation seems to work in the opposite direction as public organizations and projects seeking to assist developing countries in poverty alleviation. There are for example Swiss and Netherlands organizations and numerous research projects that are concerned with linking poor farmers with the market for exotic foods. Besides getting people out of poverty, these efforts aim at adding investment in biological resources, which have significant underutilized potential in many Southern countries. Questions of ethical trade are closely related: the actors are trying to build economically, socially and environmentally sustainable development. It is not understood by these organizations or farmers why it is so difficult to get the products in the EU market. This way there is also a humanitarian aspect to novel food legislation.

⁶⁸ Hermann 2004, 1.

⁶⁹ Hermann 2004, 1.

In 2006, the EU novel food regulation was discussed as a trade concern at the WTO⁷⁰. Concerns were raised by Peru, Ecuador, Colombia, Paraguay, the Philippines, India, Bolivia and Brazil.⁷¹ These are all countries where different plant-based products compared to Europe are used, putting these plants under the definition of ‘novel food’ in the EU. The quarrel on the definition of novel food is naturally about money. At the WTO meetings, Peru pointed to the cost involved in providing the scientific studies to back up claims of safety. These costs are unbearable to farmers or small companies. The current situation in practice is that many exotic foods are sold without novel food authorisation. The marketers do not consider their foods novel or take the deliberate risk of getting caught and being removed from the market. The novel food process is considered too burdensome and unpredictable. When a law is impossible to live by, it is not obeyed.

In the WTO meetings, Southern countries questioned the justification for giving different treatment to “products of bio-diversity” traditionally consumed outside the EU, compared to foods consumed within the EU.⁷² This different treatment is of course due to the very definition of novel food: novel foods are basically foods that have not been consumed in the EU area. There is no actual scientific ground for this kind of definition. The definition could just as well divide countries into two lists: countries where use counts, and countries where use does not count and scientific evidence on safety is required. Instead of science, the definition is in fact based on practical reasons. It is easier to gather information on familiar substances that are close to the Europeans. It would be too much work to be aware of all the foods used in the world.

The EU defends the regulation by saying that there are genuine safety concerns for products within the loose category of “products of biodiversity”.⁷³ This is of course true as plants may very well contain poisonous materials. But this reasoning does not justify how some plant products can be considered safe just based on use (use in EU), and some other plant products can not be considered safe just based on use (use outside EU).

The EU also replied that the scope of application is not limited to third countries, but affects all producers operating in the EU market. This is true, as the regulation applies to all foods marketed in the EU after 1997. Also European producers using Southern plants as raw material must go through the novel food procedure if they want to sell their product in Europe. The Southern countries never claimed the regulation is discriminatory in relation to who uses the Southern plants. They just cited the fact that Southern plants are considered novel, European plants not.

As a sign of perhaps being willing to change the definition of novel food, the EU said it welcomed examples of products approved in other markets and for which the regulation creates obstacles for development. They said this kind of information is useful in the further elaboration of the regulation.⁷⁴ The Commission has received this same message in gathering stakeholder opinions. The producers of so-called exotic food products have arguments supporting their view that either at least some of their products should not be considered novel in EU, or, alternatively, that the safety evaluation procedure including the requirements on scientific evidence should be less burdensome for these products. It is interesting to see if the Commission will resolve the issue so that both European consumers and third-country producers are satisfied. To achieve this, the Commission

⁷⁰ The March meeting and the June meeting of the SPS Committee (the WTO committee dealing with plant and animal health and food safety - sanitary and phytosanitary measures).

⁷¹ http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

⁷² http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

⁷³ http://www.wto.org/english/news_e/news06_e/sps_march06_e.htm.

⁷⁴ http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

might have to set the same standards for all foods. This means either lowering the standards for third-country foods or questioning the safety of traditional European foods.

6. Conclusions

Based on the information on the Nangai nuts case and the Stevia rebaudiani case, it is not enough that novel foods seem to be safe, based on thousands of years of use. You also have to prove it by various tests. The list of required information in the Commission Recommendation should be considered mandatory. This includes at least nutritional and toxicological information, and information on allergenic properties of the plant.

It is also noteworthy, that in the Noni case, the member state would have been stricter, and in the Nangai case, the member state would have been less strict than the Scientific Committee of the European Commission. In the current system, the member state opinion is thus not a good predictor of the final outcome of the procedure.

The European Novel Food Regulation will very likely be better in the future. The applications will possibly be evaluated by the EFSA, timelines will be set for each stage of the process, and transparency will be enhanced. The *change in the novel food definition* might affect the situation of third-country plants. The Commission is planning to clarify the concept of history of safe food use. Products having *a history of safe food use in the country of origin* might not in the future be considered novel. This would make the legal setting a bit more convenient for importers of foreign berries, fruit, vegetables etc. However, a marketer will still have to provide the evidence on safety. He will for example have to get a certificate of for example South American or Asian food safety authority saying that the product has been used for a long time without any safety issues arising. If not excluded by the new definition of novel food, is also possible that *the procedure for plant based products will be changed* to be less stringent and more affordable than for those more technological novel foods. A notification procedure might be considered suitable for plant based products.

Lastly, we should mention that European law on *traditional herbal medicines*⁷⁵ is similarly discriminatory as the European Regulation on novel foods. Traditional herbal medicines can be registered in a simplified procedure, if they have been used for at least 30 years, 15 of which in the European Community area. In this case, they can be sold based on history of use only, without the need to prove the therapeutic effect, but also without permission to mention such effect. The 2004 legislation on traditional herbal medicines is a step away from the evidence approach and a step towards ignorantly trusting what is familiar. This approach is similar to the approach taken with novel foods.

⁷⁵ Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

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