



The European Novel Foods Regulation

The Case of Exotic Novel Foods

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Summary

The global food production is only based on a few plant and animal species. Approximately 30 out of about 7.000 food plant species supply 95 % of human food energy needs. There is a big potential for exotic novel foods, especially to high-income markets like the European Union. However, food-exporting businesses in developing countries face many challenges with regards to food safety and quality requirements. One example is the European Novel Foods Regulation. It was developed to regulate Genetic Modified Organisms, but exotic novel foods from third countries also became subject to this regulation.

After the Novel Foods Regulation was adopted in 1997 it has been subject to much criticism, especially with regards to exotic novel foods from developing countries. This research evaluates the significance of European food legislation on food-exporting businesses in developing countries, in the case of exotic novel food. Food-exporting businesses from Latin American and African countries were interviewed in addition to experts on the area.

The interviews carried out among the food-exporting businesses indicated that most of the exporters were not acquainted with the Novel Foods Regulation. The food-exporting businesses explained that they faced other problems graver than European food legislation. However, the few food-exporting businesses that were affected by the Novel Foods Regulation experienced severe problems. The authorisation procedure was seen as the main obstacle. The experts who were interviewed regarding the same subject reviled the same information.

The European Commission published a proposal for a New Novel Foods Regulation in January 2008. There were high expectations to this proposal, especially with regards to traditional and exotic novel foods from developing countries. The author along with the majority of the experts believes that the New Novel Foods Regulation will be an improvement for food-exporting businesses in developing countries. As a consequence, the author's main recommendation is: the food-exporting businesses should wait until the New Novel Foods Regulation is implemented before they put applications forward. Until the New Novel Foods Regulation is adopted markets outside the European Union should be considered as an alternative.

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List of Abbreviations

BTFP - BioTrade Facilitation Programme

CAFAB - Competent Authority Food Assessment Body/NFs Working Group

CBI - The Centre for the Promotion of Imports from developing countries

DC - Developing Countries

EC - European Commission

EFSA - European Food Safety Authority

EU - European Union

FEB - Food Exporting Business

FSA - UK Food Standards Agency

GFL - General Food Law

GFU- The Global Facilitation Unit for Underutilized Species

GMO - Genetically Modified Organisms

GTZ - The German Gesellschaft für Technische Zusammenarbeit

IPGRI - International Plant Genetic Research Institute

LDC - Least Developed Countries

NF - Novel Food

NFR - Novel Food Regulation

NNFR - New Novel Food Regulation

NTB - Non-Tariff Barriers

MS - Member State

SCF - former Scientific Committee for Food of Europe

SPS Agreement - Sanitary and Phytosanitary Measures Agreement

UNCTAD - United Nations Conference on Trade and Development

UNCTAD's BTI - BioTrade Initiative

WTO - World Trade Organisation

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1. Introduction

1. Background

Through the 1990s there was a significant growth in international trade in high-value agricultural and food products, such as fruit, vegetables, dairy and poultry products. Changing consumer tastes, advances in production, transport and other supply-chain technologies, and the progressive liberalization of conventional trade barriers, stimulated this expansion. As a consequence of this trend the share of high-value products in the agricultural and food exports in DCs also increased with products such as fresh and processed fruits and vegetables, fish, meat and spices. This export as a whole accounts for more than 50 percent of developing country agricultural and food exports.¹

Today DCs face different challenges than the challenges they have historically faced in commodity markets that have been governed by price and quality grades. Nowadays, markets for high-value agricultural and food products are increasingly driven by quality-based competition with the associated food safety and quality requirements codified in public and private standards.²

In 2006, the EU's imports of fresh fruit accounted for €19 billion value, which is an increase of 20 % since 2002. Import volumes increased by 16 % over the same period, reaching 25 million tonnes. As for imports from DCs, they were substantial with a value of at €7.1 billion and a volume 9.8 million tonnes in 2006.

In the same year, the EU imports of fresh vegetables amounted to 11.5 million tonnes with a value of €10.7 billion. €1.2 billion and 1.2 million tonnes were from DCs, which is a much less significant than for fruit imports.³

In the early 1990s, the mad cow disease sent a shock wave through the EU's internal market. This crisis and other food scares that followed soon after brought to light many shortcomings in the existing body of European food law⁴. Political pressure increased, particularly with questions related to dioxin contamination in animal feed and EU-wide concerns over the use of GMOs in foods. As a result of these concerns, the NFR⁵ was enacted on 27 January 1997 and came into force on 15 May 1997.

An example that can shed light on the high levels of food safety standards in the EU is the example of the implementation of the aflatoxin standard.

Aflatoxins are a group of structurally related toxic compounds that contaminate certain foods and result in the production of acute liver carcinogens. These are substances that can produce liver cancer in the human body. Aflatoxins are particularly prevalent in stored agricultural crops, such as peanuts. The toxic compound has been identified in corn and corn products, groundnuts and groundnut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts.⁶

In 1997 the EC proposed a uniform standard for total aflatoxins, setting the acceptable level of the contaminant in food products. This standard is tighter than the standards implemented

¹ Henson & Jaffee, 2006:593-594.

² Henson & Jaffee, 2004 in Henson and Jaffee, 2006:594.

³ CBI Market Survey: The fresh fruit and vegetable market in the EU, 2008:2-3

⁴ Meulen, van der et al., 2008:229.

⁵ Regulation (EC) No 258/97 of the European Parliament and the Council of the European Union of 27 January 1997 concerning Novel Foods and Novel Food Ingredients (OJ No L 43, 14.2.1997).

⁶ Otsuki et al., 2001:498

in most member countries⁷. The research conducted by Otsuki et al. (2001) is a good example of the effect EU food regulations have on DCs. The authors describe how the new aflatoxin standard in the EU impacts African exports of cereals, dried fruits and nuts to Europe. The authors state: *'the new EU standard, which would reduce health risk by approximately 1.4 deaths per billion a year, will decrease these African exports by 64% or US\$ 670 million, in contrast to regulation set through an international standard'*.⁸

This gives an example of how high EU technical and regulatory standards have vast impacts on trade from DCs. In this research the impact of EU food regulations will be approached from another angle, namely through the NFR.

2. Problem Definition

The global food production is only based on a few plant and animal species. Only 30 out of roughly 7.000 food plant species supply 95 % of human food energy needs. About 50 % of the world's food dry weight is derived from four cereals: rice and wheat, maize and barley. Potatoes, cassava and other roots and tubers contribute less than 10 %. Alongside these foods there are species of regional importance grown by traditional farmers, which have lost their former importance for human consumption.⁹ These are frequently seen as NFs in the European market. Examples of such foods include many exotic fruits and vegetables such as Stevia, Baobab and Ngali nuts. There are naturally other NFs of non-plant origin, such as Lamas, Yaks and Buffaloes. However, in this research the focus will be on NFs from plant origin.

The NFR came into force in May 1997, as described above. The rationale behind the NFR was to protect public health and to improve the functioning of the internal market within the EU. It was adopted at a time when the introduction of GMOs into the European market was a topic of grave concern. GMOs are now regulated under a separate, specific legislation¹⁰ but still all non-GM NFs remain effectively subject to the strict scientific analysis that was originally designed for GMOs. Foods that exist and which have been used for generations in other parts of the world are considered novel in the EU. This creates a barrier to trade and hinders the possibility for many DCs to export.¹¹

UNCTAD's BTI, CBI, GTZ, GFU and IPRGI promote the exports of NF products as a potential for income generation to promote sustainable development and fight poverty alleviation in DCs¹².

BioTrade products include natural foods and ingredients from DCs, which are deemed "exotic" and thus "new" under this EU legislation. The barrier of exporting these exotic traditional foods to Europe undermines the development objectives of both the exporting DCs and the EU MS according to UNCTAD's BTI¹³. Furthermore, they restrict innovation on the part of EU companies and diet diversification on the part of EU consumers. The Neville Craddock Associates state: *'the NFR seeks to protect public health and to improve the functioning of the internal market by imposing a formal authorization procedure. This implicitly requires a stringent safety assessment for which the scientific and administrative*

⁷ p:500

⁸ p:495

⁹ Mück, 2003:4

¹⁰ EC No. 1829/2003

http://eur-lex.europa.eu/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf

¹¹ Neville Craddock Associates, 2005: 1-2

¹² Neville Craddock Associates, 2005:1

¹³ Novel Foods. BioTrade Initiative. Consulted 20.02.08

demands are considerable, potentially lengthy and expensive. They place a heavy and, arguably, disproportionate burden on potential suppliers from developing countries and EU importers by introducing considerable investment costs in order to overcome the perceived trade barriers'.¹⁴

Michael Hermann working at the IPGRI explains: *'the regulation has emerged as a non-tariff barrier for trade in food items that are often derived from under-utilized crops and are viewed as "exotic" from the EU perspective.'* *'Current practice of the regulation has discouraged investment in supply chains, and particularly in market development. Research and development agencies concerned with neglected crops and poverty alleviation are still to recognize the potential threat, which the regulation poses to income generation in developing countries and poor farmers' livelihoods.'*¹⁵

Knudsen et al. (2008) state: *'in the on-going general climatic and demographic changes, the need for alternative crops to meet these conditions may only be encountered through the introduction and utilisation of NF crops and varieties of NF crops selected from this extant crop biodiversity*¹⁶.

The EC acknowledged the problems and as a starting point they launched a Discussion Paper in 2002 with possible solutions to the Regulation¹⁷. Stakeholders were invited to comment on the paper and forward their suggestions.

On 14 January 2008 a proposal for amending the Regulation was published (NNFR). It has been adopted to improve the access of new and innovative foods to the EU market, while still maintaining a high level of consumer protection. Under the draft Regulation, NFs would be subject to a simpler and more efficient authorisation procedure. In addition special provisions are made for traditional foods, which have not been sold in the EU before, but have a history of safe use in third countries.

The consequence of the situation presented above for people and organizations involved in promotion and trading of NFs are obvious according to Mück (2003), namely more administration, costs and possible exclusion of certain products from the EU markets. However, these consequences are most severe for rural populations who may see a chance in exporting products for a special price market.¹⁸

This leads to the research objective presented in the following section.

3. Research Objective

The aim of this research is to evaluate the significance of EU food legislation on food-exporting businesses in developing countries, in the case of exotic NF. By examining the current situation regarding this matter, the influence of the NFR on DCs will be established. Further, recommendations for the legislature, FEBs and development agencies will be made based on these findings, namely to facilitate FEBs in DCs.

¹⁴ Neville Craddock Associates, 2005:4

¹⁵ Novel Foods. BioTrade Initiative.

¹⁶ p:1684

¹⁷ Commission Services Discussion Paper, 2002.

¹⁸ p:13

4. Research Questions

Main question:

What is the impact of EU food legislation on food exporting businesses from developing countries in the case of exotic NF?

Sub questions:

1. Which impact has EU food legislation on FEBs in developing countries?
2. Which impact has the NFR had on food exporting businesses in developing countries?
3. Which evidence is needed to establish novelty?
4. To what extent does the proposed NNFR provide an adequate framework for solving the problems experienced by food exporting businesses in developing countries?

5. Justification of Methods

This research is primarily based on a literature study. To complement the literature study, semi-structured interviews will be conducted of FEBs and experts by telephone. This implies an approach of the research question from three different angles: the literature study, interviews of FEBs and experts. By applying these different approaches hands-on knowledge will be obtained.

6. Thesis Framework

This thesis contains 10 chapters in total. Chapter 2 introduces the reader to developing countries and food legislation. Chapter three presents literature on how European food law has developed with special emphasis on the NFR. The impact of the NFR is introduced in chapter 4. Further, in the following chapter specific NF cases are presented to gain further understanding of how the NFR is applied in practice. The NNFR is presented in chapter 6. The methodology used for the empirical part of this research is explained in chapter 7 and the results from the data analysis in chapter 8. These chapters will be followed by the discussion in chapter 9. The final chapter will present the conclusions and recommendations from the research.

2. Developing Countries and Food Safety Regulation

1. Food Regulations and Standards

Governments regulate food sectors extensively; these regulations have their place in a wider legal framework within each country. General legal provisions are important to ensure safe food with a certain quality. Nevertheless, the need for specific regulatory measures to support the general requirements is widely accepted.¹⁹

Looking at the economic rationale of food safety regulations, the justification for some governments to intervene in the market fall roughly into two categories:

1. Achieving provision of public good:

If regulations enhance the efficiency of the food sector they can be seen as economically beneficial. The benefits are weighed against the possible costs the regulations might cause.

2. Facilitating production and exchange through various means of lowering transactions and information costs:

Regulations can improve the functioning of the market when information about health or aspects linked to quality is unknown or distributed unbalanced between the producer and the consumer.

These explanations are especially significant when market failures are associated with the production, processing, distribution and consumption of food products. Further, the spread of animal and plant diseases, outbreaks of food-borne illnesses, distribution of misleading food labels, or use of production practices that do not reflect current norms may indicate the necessity for regulatory instruments.²⁰

Even if regulations fall within the two categories mentioned above and place a legitimate restriction on trade, food regulations are increasingly at the centre of trade disputes. On the global food system the incidence of risk or available market information can vary across countries. This can lead costs to exceed the benefits of a regulation in one country but not in another. According to Josling et al. (2004) possibly the most significant problem for the global food system is that both the inflexibility of regulations and the provision of farm support and protection policies tend to increase among wealthier countries, which complicates the political economy regarding food regulation²¹.

The following section will take a closer look at which impacts food regulations in developed countries have on exports from DCs.

2. Food Regulation and Developing Countries

At the beginning of this century the value of international trade exceeded US\$ 400 billion per annum and accounted for in the region of 500 million tons of food products. Since then the trade share has also grown for DCs but still they remain mainly exporters of primary products and importers of processed food.²²

¹⁹ Josling, et al. 2002:13.

²⁰ Josling, et al. 2002:14-15.

²¹ Josling, et al. 2002:16.

²² Ramaswamy & Viswanathan, 2007:123.

Higher awareness and concern to protect human, animal and plant health among the developed countries have developed safety standards that often overrule existing international standards. According to Ramaswamy and Viswanathan (2007) lowered tariff barriers seem to be replaced by non-tariff barriers based on protective safety matters.

Henson and Jaffee (2006) state that *'there is a widespread presumption that food safety standards are used as a protectionist tool, providing 'scientific' justifications for prohibiting imports of agricultural and food products or discriminating against imports by applying and/or more rigorous regulatory enforced standards than on domestic suppliers'*²³.

Further, these concerns have been intensified as traditional barriers to trade have been reduced through multilateral trade negotiations and preferential trading arrangements, the latter at least for the least-developed countries (LDC).

In the worst case, food safety standards can exclude exports from an entire country. The reasons for this can be an acute food safety hazard in a sector or systems. Further, the inspection and control of a product may be inadequate to the importing country. However, it is more common that food safety standards act to prevent or exclude only parts of a country's export sector. The effects of stringent standards are observed among smaller and more marginal agribusiness firms and producers. Problems they face may be linked to weak food safety controls, other market supply or demand-side challenges or difficulty raising enough capital to upgrade to the standards required.²⁴

The common concern regarding the lack of administrative, technical and scientific capacities hinders many DC to comply with strict food safety standards (public or private)²⁵. Wilson and Abiola (2003) argue that these institutional weaknesses and costs of compliance to food regulations contribute to further marginalisation of smaller and/or poorer countries and weaker economic players²⁶.

A market survey published in 2008, by the CBI explains the opportunities and threats for exporters of fruit and vegetables from DCs to the EU. A few of the opportunities and threats are listed below.²⁷ This market survey gives an indication of what exporters in DCs are up against.

Opportunities:

- Increasing demand for convenient, ready-to-eat products.
- Growing demand for tropical fruits and new products.
- Growing demand for organic, fair-trade and sustainable products.
- Increasing income, changing food habits and growing consumption levels in new EU member countries.

Threats:

- Stagnating/declining consumption and changing eating habits of fruit and vegetables in old EU countries ('the battle for stomach share').
- High demand for top quality in the old EU MSs and, increasingly, in the east European countries.

²³ Henson & Jaffee, 2006:599

²⁴ *ibid.*

²⁵ Henson et al., 2000. In: Henson & Jaffee, 2008:551

²⁶ In: Henson and Jaffee, 2008:552

²⁷ p:10

- Certification requirements for fresh fruit and vegetables (GlobalGAP, formerly EurepGAP) and for processed fruit and vegetables (GMP/HACCP/BRC), which involve serious managerial and technical efforts and high costs. These are strictly required to gain access to northwestern European countries and, increasingly, in the southern and western European countries.
- Fluctuating prices and production volumes of fruit and vegetables due to fluctuating supply.
- Relatively weak competitive position of DC suppliers due to higher transport costs.

3. An alternative perspective

The perspectives presented above portray a rather negative view of the challenges DC face. Henson and Jaffee (2008) introduce alternative perspectives on the trade effects of food safety. One suggestion is that DC can embrace the potential opportunities provided by evolving food safety standards and utilise these opportunities to their competitive advantage. This perspective views public and private standards as an important bridge between increasingly demanding consumer requirements and the participation of international suppliers. Further, the authors imply that food safety standards provide a “common language” in the supply chain. By complying with these standards and regulations, transaction costs will be reduced and consumers’ confidence for food product safety will improve.²⁸

The second point is linked to the costs of complying with food safety regulations. They state that it may be a powerful incentive to modernise the export supply chain in DCs. It can stimulate capacity building within the public sector and the adoption of “good practices” may create spillover effects into domestic food safety systems, which further will benefit the local population and domestic producers. However, Henson and Jaffe (2008) underline that it is important to note that there will always be winners and losers. Nevertheless, this view portrays that by acting in accordance with the standards it can provide the basis for more sustainable and profitable agricultural and food exports in the long run.²⁹

The authors conclude with the notion that for future research more emphasis should be put on programmes of technical assistance and support. The rationale behind this is to be able to learn more about strategic responses to food safety standards for DCs.³⁰

Henson and Jaffee (2008) introduce an alternative perspective as described above. Nevertheless, barriers to trade with regards to food have serious implications for many DCs especially with regards to NTBs to trade. This will be elaborated further in the next section.

4. Non-Tariff Barriers to Trade

In the simplest fashion NTBs mean the totality of instruments, other than custom duties, which restrict international trade³¹. Examples of NTBs are anti-dumping measures, new technical standards applied to imports, new safety regulations, changed sanitary requirements, or more exacting procedures for import licensing and customs clearance³².

As tariff barriers came down the NTBs have multiplied in the recent decades. Stiglitz (2000) does not find this surprising. He states: *‘after all, the political forces that give rise to high tariffs do not disappear once tariffs are brought down’ ‘Rather, they must seek protection*

²⁸ Henson and Jaffee, 2008:552.

²⁹ p:552

³⁰ p:566

³¹ Hillman, 1996: 2.

³² UNCTAD, 2005

*through other channels.*³³ The major problems with these NTBs are that they are much harder to assess and quantify than tariffs.

Lupien (2002) explains in spite of the many national and international steps that have been taken to promote free and fair international food trade, many tariff and NTBs to trade still remain. He explains that these barriers are particularly harmful to DCs that are trying to improve national economies and access to food.³⁴

The impact that NTBs have on trade is difficult to calculate. Nevertheless, it is clear that NTBs are especially damaging to exports from DCs and particularly from LCDs. An estimate made by UNCTAD from 2002 shows that NTBs affected 40% of the exports of LDCs. The increased use of NTBs has placed costly burdens on firms, especially from DC, which struggle to meet technical, health or administrative requirements for their export. All in all NTBs affect supply capacities, export competitiveness and market access in DC.³⁵

The previous chapters have served as an opening to the problems DCs have face with regards to food regulation and NTBs to trade. The example regarding the aflatoxin standard underlined the high levels of food safety standards in the EU and the impact they have on DCs. Another example regarding the same subject is the NFR, which is the main focus of this research. The following chapters will introduce the development of EU food law, the NFR and the discussions that have followed from its implementation.

³³ p:446

³⁴ p:404

³⁵ UNCTAD, 2005

3. The EC Novel Foods Regulation and Food Exporting Businesses in Developing Countries

To understand the development of the NFR and probable future development, section one will give a short history of the development of food law within the EU. This will be described in three periods. Section two will give a short introduction to the initiation of the NFR and section three presents an analysis of the regulation. The final section introduces the revision of the NFR.

1. The European Union and the beginning of Food Law

Period 1. (1957-1986): The EU was established in 1957 and through this establishment certain rules were adopted for agricultural products under the EU's Common Agricultural Policy (CAP). The Treaty of Rome establishing the European Economic Community (EEC) initiated the creation of the Common Market, through the adoption of legislation. However, the Treaty did not grant EU institutions any specific power to adopt food legislation. The envisaged harmonisation process slowed down at the beginning of the 1980s and in 1985 MS governments' placed new political emphasis on establishing a new single Internal Market within the Union. This meant that goods, services people and capital could move freely.³⁶

During the 1970s there were big developments within food technology. Countries had at that time already experience in evaluating the safety of food additives and contaminants, but there was little experience in evaluating the safety of NFs and novel ingredients.

In 1972 the Protein Advisory Group of the United Nations (PAG/UNU) issued Guidelines for the Preclinical Testing of Novel Sources of Protein and Guidelines for the Human Testing of Supplementary Food Mixtures, with a focus on novel microbial proteins. These guidelines were revised in 1983 and they identified the main categories needed to evaluate the safety of NFs as well as some of the problems with testing their safety. NFs were defined as '*foods not previously eaten by humans*'.

The UK Government introduced a notification scheme for NFs in 1984 that supplemented general safety provisions in food law. They were the first government to introduce specific provisions to NFs and were followed by a regulation in the Netherlands for protein food ingredients.³⁷

Period 2. (1987-1992): Within this period a large number of legislations were developed to eliminate obstacles to cross border trade within the EU by harmonising most divergent national laws. The completion of the single Internal Market was achieved in 1992 when the MS granted further powers to EU institutions, particularly in areas regarding consumer protection and public health.³⁸

It became clear in the early 1990s that development in gene technology would be important for food supply. International organisations and regulatory agencies in individual countries began developing guidelines for assessing the safety of foods derived from GMOs.³⁹

Period 3. (1993-today): In the early 1990s, the mad cow disease sent a shock wave through the Internal Market. This crisis and other food scares that followed soon after, brought to light

³⁶ Will & Guenther, 2007:63.

³⁷ EUFIC Review 04/2000.

³⁸ Will & Guenther, 2007:63.

³⁹ EUFIC Review 04/2000.

many shortcomings in the existing body of European food law⁴⁰. Political pressure increased, particularly with questions related to dioxin contamination in animal feed and EU-wide concerns over the use of GMOs in foods. As a result, the NFR was enacted on 27 January 1997 and came into force on 15 May 1997.

Food safety concerns and problems went from being a MS concern to the main topic of the EC's agenda. A fundamental restructuring and harmonisation of the MS's food regulation was desperately needed, leading to the publishing of the White Paper on Food Safety⁴¹ in January 2000.⁴² The focus of the White Paper was to review food legislation in order to make it more coherent, comprehensive and to strengthen enforcement. As a scientific point of reference for whole of the EU, the EC supported the establishment of a new European Food Safety Authority (EFSA)⁴³, which could contribute to a high level of consumer health protection⁴⁴.

In 2003 GMOs were separated from the NFR and are now regulated under Regulation (EC) No 1829/2003.

2. The Initiation of the Novel Food Regulation

The first draft proposal of the NFR was discussed in the Food Advisory Committee on 5-6 June 1990 with stakeholders from industry, commerce, agricultural sector, consumers. Already at this point industry and commerce were worried about the possible bureaucratic burden the NFR may develop. The need to clearly identify the safety question was taken into consideration and was made clear *by* clarifying the scope of the proposal and *by* establishing a decision tree, which lead to three different procedures⁴⁵. The requirements of these procedures were relevant to the absence or the need for safety clearance. After these revisions had been made an informal meeting was held with the stakeholders involved to further explain the modified text. The stakeholders appeared to be satisfied with the modified provisions and accepted that where "NFs" were being imported the appropriate procedures would have to be followed.⁴⁶

The EC made a proposal on the basis of Article 100a of the Treaty, having regard to the opinion of the Economic and Social Committee and in cooperation with the European Parliament would adopt this regulation⁴⁷.

A Regulation was seen as the most appropriate instrument for the assessment of NFs and NF ingredients because:

- The constraining legal nature of the proposed rules, which would only leave a small discretionary margin to the national legislators.
- To ensure a uniform implementation of the rules from the start.

⁴⁰ Meulen, van der et al., 2008:229.

⁴¹ COM (1999) 719.def. Unlike a Green Paper that is intended mostly as a basis for public discussion. A White Paper contains concrete policy intentions.

⁴² Will & Guenther, 2007:63.

⁴³ Established in Article 22 of Regulation (EC) No 178/2002.

⁴⁴ Meulen, van der et al., 2008:244.

⁴⁵ No further action needed, notification and authorisation.

⁴⁶ Commission Proposal for a Council Regulation (EEC) on Novel Foods and Novel Food ingredients. Official Journal No. C190. 29.7.1992:20.

⁴⁷ Commission Proposal for a Council Regulation (EEC) on Novel Foods and Novel Food ingredients. Official Journal No. C190. 29.7.1992:6.

- It would reduce the implementation period of the new system since no national act was required to make it applicable. This was crucial to achieve the Internal Market by the end of 1992.⁴⁸

3. Analysis of the current Novel Food Regulation

3.1 Objective

The main objectives of the NFR are:

- to protect the functioning of the market within the Community
- to protect public health

Consistent with these objectives the regulation establishes a Community system for the pre-market approval of NFs and NF ingredients.

Within the NFR there is a single cut-off date, namely the 15 May 1997. After this date NFs require approval based on a safety assessment before they can be placed on the European market. This will harmonize the different legislations in the individual MS and provide the public with a positive assurance of safety.⁴⁹

3.2 What is a Novel Food?

The NFR defines NF as “*foods and food ingredients that were not used for human consumption to a significant degree within the Community before 15 May 1997*”. Further, these foods and food ingredients must fall within certain categories, that is to say they must be food and food ingredients;

- *with a new or intentionally new primary molecular structure; or*
- *consisting of, or isolated from, micro-organisms, fungi or algae; or*
- *consisting of or isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use; or*
- *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 food or food ingredient, which affects its nutritional value, metabolic effect or level of undesirable substances.*⁵⁰

The definition of ‘human consumption to a significant degree’ in Article 1(2) has been interpreted as a food having been *generally available* within the Community. This means that if a food was available for instance in pharmacies within the Community it would not represent evidence of use for human consumption to a significant degree. A food available on the other hand in general food stores would constitute evidence enough⁵¹.

3.3 Procedure

3.3.1 Establishing Novelty

The procedure begins with a potential applicant considering if the product in question is novel and gathering information to support their case. The person responsible for placing the

⁴⁸ Commission Proposal for a Council Regulation (EEC) on Novel Foods and Novel Food ingredients. Official Journal No. C190. 29.7.1992:5.

⁴⁹ Commission Services Discussion Paper, 2002:1

⁵⁰ Article 1(2)

⁵¹ Commission Services Discussion Paper, 2002:2

product on the market has to submit a request to the MS where the product will be placed on the market for the first time. At the same time, a copy of the request has to be forwarded to the Commission⁵².

If there is uncertainty about the novelty of a product the EC and other MS can be consulted. The NFs Working Group⁵³ (CAFAB) is generally consulted if there are reservations. This group consists of experts from the different MS and an officer from the EC chairs it. Their undertaking is to facilitate the co-ordinated implementation of the NFR.

If the food is viewed as novel, an application to assess the food under the NFR can commence with the relevant MS. If the food in question is *not* novel the MS will not accept the application and the food may be placed on the market as long as it complies with other legislation at a MS and European Community level.⁵⁴

3.3.2 Criteria for placing the food on the Community Market

The basic criteria for an authorisation are that NF must not;

- present a danger for the consumer; or
- mislead the consumer; or
- differ from food ingredients that they are intended to replace to an extent that their normal consumption would be nutritionally disadvantageous to the consumer.⁵⁵

3.3.3 Principal Procedure

The NFR lays down a harmonized procedure for the authorisation of NFs and NF ingredients inside the Community. It commences with an initial assessment, but may proceed to a Community decision⁵⁶ under certain situations. Further, some products may only require a simplified procedure.

As stated above the principal procedure begins with an initial assessment. Prior to the assessment a request has been submitted to a MS with a copy to the EC⁵⁷. This request must contain specific information as stated in Article 6(1) in the Regulation;

- a copy of studies and other material available to demonstrate that the food and food ingredient complies with the criteria laid down in Article 3(1);
- an appropriate proposal for the presentation and labelling of the food and food ingredient in accordance with Article 8;
- and a summary of the dossier.

After the MS has accepted the request, they ensure that the initial assessment is conducted as laid down and portrayed in Article 6(2). After the MS has notified the application, the Commission forwards a summary to the other MS along with the name of the assessment body that will conduct the initial assessment report. This report should be finished within

⁵² Article 4(1)

⁵³ The Novel Foods Working Group is also known as the Competent Authority Food Assessment Body (CAFAB).

⁵⁴ Commission Services Discussion Paper, 2002:3-4.

⁵⁵ Article 3(1)

⁵⁶ In the NFR it is referred to as the “authorisation decision”, see Article 7(1). Commission Services Discussion Paper, 2002:5

⁵⁷ Article 4(1)

three months, as stated in the Commissions published recommendations⁵⁸. The report makes recommendations in respect of;

- the conditions of use of the NF;
- the designation of the NF;
- the specification of the NF; and
- specific labelling requirements⁵⁹.

Finally, it must state if the food in question needs additional assessment in accordance with Article 7(1).

If the report requires additional assessment or the assessment body is not able to reach a positive conclusion regarding the NF, a *Community decision* in respect of authorisation is required⁶⁰. The Community decision, which means the "Comitology" procedure, set out in Article 13 of the NFR, is engaged by referring the matter to the Standing Committee on the Food Chain and Animal Health⁶¹ (SCFCAH).⁶²

Within 60 days of circulation of the report the EC and the MS can make comments or objections with regards to marketing, the presentation or the labelling of the NF⁶³. Objections from the MS triggers a Community decision regarding the authorisation, while comments on the other hand do not.

If a Community decision is not required, the food can be placed on the market within the European Community.

3.3.4 Simplified Procedure

The simplified procedure applies to NFs, which are considered to be 'substantial equivalent' to existing foods or food ingredients as regards to composition, nutritional value, metabolism, intended use and undesirable substances contained, and that;⁶⁴

- consists of or are isolated from micro-organisms, fungi or algae; or
- are foods or food ingredients that consists of or are isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use⁶⁵.

These NFs only require notification⁶⁶. The company can submit a notification to the EC that the food or food ingredient will be placed on the European Community market, after obtaining an opinion on equivalence from an EU MS. Included in the notification is the

⁵⁸ 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.

⁵⁹ Commission Services Discussion Paper, 2002:5-6.

⁶⁰ Commission Services Discussion Paper, 2002:6

⁶¹ The SCFCAH was established following the adoption of Regulation (EC) 178/2002.

⁶² Commission Services Discussion Paper, 2002:6

⁶³ Article 6(4)

⁶⁴ Article 3(4)

⁶⁵ According to the EC, the concept 'history of use' by itself is insufficient regardless of the length of use; it is the evidence of safe use that is required. Commission Services Discussion Paper, 2002:6.

⁶⁶ Article 3(4)

material, which establishes substantial equivalence⁶⁷. The labelling requirements for provisions of Article 8 still apply.⁶⁸

There are two possible justifications for establishing ‘substantial equivalence’. First, the food can be considered substantial equivalent to an existing food on the basis of available and generally recognised scientific evidence. Second, it can be based on the opinion of a competent food assessment body⁶⁹.

4. Revision of the European Novel Foods Regulation

By Regulation 1829/2003 GMO’s were detached from the current NFR. As stated by the EC; *‘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 industry, and to better facilitate both internal and external trade in foodstuffs’*⁷⁰.

Article 14 of the NFR requires that no later than five years from the date of its entry into force the EC has to forward a report of the implementation of the regulation to the European Parliament and the Council.

In 2002 a discussion paper was launched as a basis for discussion of the experiences gained by the different stakeholders involved with the NFR since its implementation in 1997. Further consultations were carried out when the Commission conducted an Interactive Policy Making consultation (online) with the general public. The EC received feedback from various stakeholders such as food industry, consumers, third countries, national and EU authorities and international organisations. The results from this impact assessment were scrutinised by experts from the MS, from different Commission Directorate-Generals’ represented in the Inter-Service Group and from other relevant stakeholder groups in the working group of the DGSANCO Advisory Group on the Food Chain and Animal and Plant Health and the European Commission Impact Assessment Board (IAB).⁷¹

The main issues regarding the NFR put forward by the interested parties from 2002 until 2007 were:⁷²

1. Adjusted safety assessment and management for traditional food from third countries and newly developed innovative food. In the NFR there is a uniform criterion for the safety assessment of all foods, but the requirements in the NFR are not always proportional to the potential risks. This has led to disproportionate costs and has been perceived as an unjustified barrier to trade by certain third countries.
2. The safety assessment and authorisation procedure has proved to be time-consuming and has imposed a high administrative burden. One of the reasons is that the applications are assessed twice; first an initial risk assessment is carried out by a MS’s competent assessment body and then circulated to the other MS. If there are objections

⁶⁷ Article 5

⁶⁸ Commission Services Discussion paper, 2002:7

⁶⁹ Article 3(4). In: Commission Services Discussion paper, 2002: 8

⁷⁰ European Commission: Novel Foods - Review of Regulation (EC) 258/97.

⁷¹ Summary Impact Assessment for a Regulation replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food ingredients, 2008:2.

⁷² Summary Impact Assessment for a Regulation replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food ingredients, 2008:3-10.

it will be assessed again for a second time at EU level. In practice this has happened most frequently.

3. In the NFR the authorisation decision is linked to the applicant. This makes it necessary to have an additional administrative notification procedure (simplified procedure). The current system is held in high regard by industry, but for food that has already been notified it has caused manifold work.
4. The interested parties also put forward a submission for application of several food uses. At present the separate applications for different food uses has lead to repetitive work and an additional administrative burden for the stakeholders. Allowing applicants to apply for an approval by a single application covering NF and food uses regulated under various frameworks could have positive impacts on for instance trade from third countries.
5. The stakeholders underlined the need for legal clarifications and updating in the NFR. For example the lack of clarity of concepts such as 'to a significant degree' and 'history of safe food use' has been troublesome especially for exporters in third countries. Clear guidelines were requested to leave less room for interpretation for the regulators.

4. The Impact of the Novel Food Regulation

This chapter will describe various practical experiences and view points put forward by different organisations and stakeholders affected by the NFR.

1. The Authorisation Procedure

The first point stressed by the stakeholders as described in chapter 3.5, is the problem regarding the uniform criteria for the safety assessment of all NFs. This has especially been a problem for traditional food from third countries as put forward by Neville Craddock Associates in a discussion paper from 2005, prepared for UNCTAD and CBI in cooperation with GTZ, GFU and IPGRI⁷³.

Today countries such as Canada and Australia/New Zealand as well as the EU have regulations for NF. These countries have different definitions for what constitutes a NF but what the regulations do have in common is the requirement for a pre-market safety assessment for NFs⁷⁴. The prerequisite for doing a safety assessment is the recognition of the food item being novel within a regulatory framework, which means that the definition of a NF is very important⁷⁵.

As described in chapter 3.4.3 those who are interested in placing a NF on the market have to submit an application to the competent authority of the MS where the product is first to be placed. After the initial risk assessment is conducted (by the competent authority in the MS) the information is sent to the other MS. If there are objections it will be assessed again at EU level. As noted in the second point put forward by the stakeholders: this has proven to be very time-consuming and led to a high administrative burden.

2. Commission Recommendation

How the required safety assessment of the NFs should be performed was given to the scientific community. This question was addressed in a Commission Recommendation of July 1997 (97/618/EC). The scientific aspects and information needed to support an application was presented in this recommendation, included those derived from GMOs.⁷⁶

UNCTAD's BTI is one of the organisations that have been critical to the EC NFR and the Commission Recommendations. In the Discussion Paper from 2005 described in the previous section they find the Recommendation 97/618 to be *'applied in an extremely strict and disproportionate manner to some classes of "novel" foods for which it was not primarily intended'*. Further, they state: *'in respect of "exotic" traditional foods, insufficient consideration appears to be given to the traditional management of known risks (e.g. preparation methods and consumption patterns) that are integral to actual safety in use of the product, rather than the absolute safety of the raw material'*.

According to the authors: *'this results in "novel" products seemingly being assessed, inappropriately, against near absolute parameters of "zero risk" (which does not exist) or proof of absence of risk (which mirrors the philosophical impossibility of proving a negative)...'*⁷⁷.

⁷³ The EU Novel Foods Regulation Impact on the Potential Export of Exotic Traditional Foods to the EU: Suggestions for Revision. November 2005.

⁷⁴ Only the EU definition will be discussed in this research.

⁷⁵ Knudsen, I. et al., 2005:24

⁷⁶ Knudsen, I. et al., 2005:26

⁷⁷ Neville Craddock Associates, 2005:7-8.

3. Disproportionate costs

In addition to the difficulties experienced with the safety assessment the stakeholders further put forward the disproportionate costs linked to the assessment. Ottaway (2005) describes the costs of obtaining the required data are substantial and considered prohibitive by small companies⁷⁸.

The juice from the Noni fruit (*Morinda citrifolia*) is one of the few traditional products that has been authorised as a NF. Morinda Inc., which is a large US based company, filed the application. The application was rejected in the initial assessment based on series of specific observations raised by MS. But after extensive food safety evidence from compositional, toxicological and allergenicity studies and clarified suggested intake level⁷⁹ was presented, the EU granted authorisation in June 2003.

Because Morinda Inc. is a large company with a big research budget Hermann (2004) implies that the company can afford the costs linked to the extensive research needed⁸⁰. In other words they can ‘afford’ the disproportionate costs linked to such an application.

On the other hand, considering the same case again, Lähteenmäki-Uutela (2007) explains that the applicant (Morinda Inc.) closely followed the recommendations on how to structure the application and provided the information that was asked by a non-GMO NF. She suggests that the extent of toxicological and allergy-related data was what separated the Noni application from other cases. Further, she states: ‘*There was plenty of data available on Noni*’. ‘*That is why it was authorised*’⁸¹.

4. Time

Furthermore, the interested parties described the authorisation procedure to be time-consuming and increasing the administrative burden. As described by Ottaway (2005), the authorisation procedure as a whole has in practice taken years⁸². Since May 1997 up to March 2007 there have been 61 full applications, the Genetically Modified foods are not included in this number. Only a few applications are related to “exotic” food products, such as the Noni fruit mentioned above. Of the 61 applications, 26 of these applications remain under review, 22 have been authorised, five refused authorisation and eight withdrawn by the applicant. Of the 22 that were authorised, UK was the competent body for six, while the others were spread among the Netherlands, Belgium, Finland, France and Germany.⁸³

Regarding the time to authorise a NF/ingredient, it has on average taken 35 months, within a range of 16-60 months⁸⁴. In Table 1, three examples of novel products and the time in took to authorise them are visualised.

⁷⁸ Ottaway, 2005: 237.

⁷⁹ 30 ml per day.

⁸⁰ p:4

⁸¹ Lähteenmäki-Uutela, 2007:9-10.

⁸² Ottaway, 2005:237.

⁸³ Brookes, 2007:17.

⁸⁴ Brookes, 2007:17-18.

Table 1 Time taken to authorise a Novel Food.

| Company | Product/ingredient | Time taken to authorise (months) | Date applied for authorisation | Date authorisation granted |
|----------------|---|---|---------------------------------------|-----------------------------------|
| Morinda Inc. | Noni juice | 26 | 22-04-2000 | 12-06-2003 |
| Unilever | Phytosterols in yellow fat spreads | 26 | 22-05-1998 | 24-07-2000 |
| ADM | Phytosterols & phytostanols in various products | 28 | 02-11-2001 | 31-03-2004 |

Source 1: Brookes, 2007:18

As noted by Hermann (2004) by October 2002, EU commission decisions had been made in relation to eight NFs⁸⁵. Six of the products represent innovations or derivatives of existing products. An example of the latter (phytosterols) can be seen in Table 1. Hermann along with Lähteenmäki-Uutela (2007)⁸⁶, find it noteworthy that two of the NFs that were denied market access were exotic plant products. These are *Stevia rebaudiana Bertoni* and Ngali nuts (*Canaria indicum L.*). While all the products containing phytosterols have been authorised⁸⁷.

5. The Simplified Notification Procedure

A simplified notification procedure is permitted for NFs that fall under to categories of Article 3(4) in the NFR as described in section 4.3.4:

- consists of or are isolated from micro-organisms, fungi or algae; or
- are foods or food ingredients that consist of or are isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a **history of safe use**⁸⁸.

Further, these NF have to be **substantial equivalent** to existing foods or food ingredients.

As described in point five by the interested parties in the discussion paper launched by the EC there is a need for clarification of certain concepts. The concepts in bold above and the concept '**human consumption to a significant degree**' in *Article 1(2)* have caused numerous discussions by parties involved. The latter concept is very important because it helps to establish if the food is indeed novel⁸⁹.

The Neville Craddock Associates Discussion Paper describes some of the problems regarding the concepts mentioned above:⁹⁰

- **Significant:** it is a qualitative term and the interpretation will vary according to the priorities of the user and the recipient/interpreter of the term. Its use in the NFR, without a quantitative definition contradicts the principles of a clear legislation.

⁸⁵ p:3

⁸⁶ p:5

⁸⁷ Hermann, 2004:3.

⁸⁸ Article 3(4)

⁸⁹ See Chapter 4.2 for definition of Novel Food.

⁹⁰ 2005:5-7.

- **Human consumption to a significant degree:** “significant” have been linked with availability in supermarkets and general food outlets, and not e.g. sales through pharmacies. The concept of availability should also include historic, local production and/or old traditional types of domestic consumptions. Further, it is currently impossible for a potential importer to prove imports of a given product before 1997, unless it is widely known and consumed. Identification of imports of the products may also be difficult because accurate official export statistics frequently do not exist in the originating countries.
- **History of safe use:** this is a subjective concept. It relies on a lengthy history of food use in a particular country or culture sufficient to show that any risks are probably acceptable. This is impossible without scientific and toxicological studies.
- **Substantial equivalent:** this concept represents a range of interpretations that lead to lack of legal precision, which again leads to imprecise requirements for an evaluation of the scientific evidence needed to see if a novel product is proportionate to any realistic risk. The concept has been used in the strictest sense removing any possible comparison of relative safety of similar products in the EU. The use of this concept for third country foods have been almost impossible due to the inflexible use of the concept “equivalence” against which comparisons could be made.

6. Consequences of the Authorisation Decision

Points three and four put forward by the stakeholders are concerned with the authorisation decision being linked to the applicant and the requirement for separate applications for different food uses of the same product.

Because the authorisation is product specific, the company cannot place for instance Noni jam on the market when it was only authorised for juice, this would require a separate authorisation. In addition, the application is directed to the applicant. This gives the producer a unique market position until a competitor can provide evidence of substantial equivalence⁹¹. Morinda Inc. and their Noni juice is a good example of this issue.

7. Novel Foods Regulation as a Non-Tariff Barrier to Trade

Fresh food products are more likely to cause concern than for instance manufactured products. This can be explained by the fact that fresh foods are shipped and consumed in fresh form, meaning, all points in the food chain can influence food safety and quality⁹². While manufactured or processed food, have widely accepted standards and may not worsen during shipping and handling. In addition, fresh commodities are subject to increasing scrutiny and regulations in DC, as the understanding of hazards increase. Unnevehr (2000) suggests that the outcome of these aspects *‘may be a potential barrier to the development of fresh product exports from less developed countries’*⁹³.

In December 2005 UNCTAD and its BioTrade Initiative along with CBI organised a workshop on the EU NFR. Different stakeholders⁹⁴ perceived the NFR to be a NTB to trade.⁹⁵ This is also supported by Hermann (2004): *‘the regulation has emerged as a non-tariff barrier for trade in food items that are often derived from under-utilized crops and are*

⁹¹ Hermann, 2004:4.

⁹² Zepp et al., 1998. In: Unnevehr, 2000:232.

⁹³ p:232

⁹⁴ Developing countries, developing countries exporters, European importers.

⁹⁵ Final proceedings UNCTAD-CBI workshop NFR 1 December 2005.

*viewed as "exotic" from the EU perspective'. 'Current practice of the regulation has discouraged investment in supply chains, and particularly in market development. Research and development agencies concerned with neglected crops and poverty alleviation are still to recognize the potential threat, which the regulation poses to income generation in developing countries and poor farmers' livelihoods'*⁹⁶.

Because the EU is a member of the WTO the NFR has to be confirmative with the SPS Agreement⁹⁷. This research will not put focus on the WTO and EU's obligations to its agreements. However, the literature presented below explains how the NFR is seen as an unjustified barrier to trade or a NTB to trade as stated by Hermann (2004).

In March 2006 representatives of Peru's private sector received a letter from the EC identifying Yacon (*Smallanthus sonchifolius*) as a NF. In an SPS Committee communication from April 2006 they expressed their concerns regarding the NFR. Further, Peru was concerned that the implementation of the NFR directly affects the trade in exotic traditional products from the country's mega-diversity and as a consequence blocking their entry to the European market. They also refer to a similar incident happening in 2000 when shipments of dehydrated Lucuma (*Lucuma obovata*) that had regularly entered through the ports in Italy and Portugal was detained and denied entry through the port of Valencia, Spain because it was a new food ingredient and had to comply with the NFR.⁹⁸

Peru claims that the NFR is an unjustified barrier to trade. As stated in the communication: '... exotic traditional products have suffered discrimination merely because they were not significantly marketed in Europe prior to a totally arbitrary date (May 1997), although these products have a long history of safe human consumption in their countries of origin'⁹⁹. Further: '*at the inconsistency in the application of the NFR with the principles and obligations set forth in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, in particular Articles 2.2, 5.1, 5.4 and 5.6 and Annex C of the Agreement, and at the implications of this legislation for the joint efforts of the European Communities and Peru to facilitate sustainable trade*'¹⁰⁰.

In the following SPS Committee meetings in 2006 and 2007 the NFR was brought forward as a concern by other DCs, especially countries from the Andean community but also from African countries.

The EC expressed their understanding for the countries concerns and the problems experienced with the NFR. However, no promises were made except that their concerns were taken under consideration for the revision of the NFR, which would be published sometime late in 2007.

⁹⁶BioTrade Initiative. Novel Foods.

⁹⁷For more information please see: Sanitary and Phytosanitary Measures: Introduction. Understanding the WTO Agreement on Sanitary and Phytosanitary Measures, May 1998. Accessed 19.05.09.
http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

⁹⁸G/SPS/GEN/681. 5 April 2006:1

⁹⁹G/SPS/GEN/681. 5 April 2006:2

¹⁰⁰ibid.

5. Specific Novel Food Cases

Since the NFR was implemented several applications have been made with regards to technical inventions and exotic NFs¹⁰¹. In this chapter specific NF cases will be presented with regards to the latter group. The objective behind the presentation of these cases is to illustrate the divergence of evidence used to support their cases. First, the Goji berry represents a case of non-novelty; second the Baobab fruit describes the case of a successful application and finally, the Stevia case, which has caused many heated discussions among MS, scientists and applicants.

1. Goji Berry Case

The NF Catalogue is a list of products where MSs and the EC exchange information whether specific products are subject to the NFR. The document is the result of the continuing discussions within CAFAB¹⁰².

The catalogue states the Goji berry was on the market before 15 May 1997, which, means it is not subject to the NFR¹⁰³, however the case is interesting from several aspects, which will be described below.

Goji berries are small red fruits obtained from the plant *Lycium barabrum*, a vine that grows in China, Tibet and other parts of Asia.

The status of Goji berries as NF was first raised in 2004. At that time none of the Competent Authorities in the EU MS were aware of a significant history of consumption, except as use in food supplements.

The problem was that the use of a food and/or food ingredient as a food supplement was not considered to be significant human consumption within the meaning of the NFR.

A company asking whether the NFR did not apply to the Goji berries approached the UK Food Standards Agency (FSA) in August 2006. This same company presented figures from Chinese exports of the berry during 2000-2005, selling to a number of EU countries. The authorities in these countries still regarded the berry as novel. In February 2007, the FSA wrote to interested parties and published the request for information on their web page.¹⁰⁴

The FSA received more than 70 responses, but as it is stated in the report: *‘the NFR does not define what constitutes “human consumption to a significant degree”, which is a central criterion for establishing whether a food falls within the scope of the regulation’... ‘In the Agencies view, and consistent with advice from the European Commission, significant consumption would be demonstrated by evidence of sale to the general public in a range of locations, and in non-trivial amounts*¹⁰⁵.

One interesting response indicated that the name ‘Goji berry’ is a relatively new invention and that the plant and berry are also known as: Chinese wolfberry, matrimony wine, Chinese boxthorn, red medlar and the Duke of Argyll’s Tea Tree. It was even suggested that the name ‘Goji’ was originally applied to the species *L. chinensis* and should not be used for *L.*

¹⁰¹ See: The Novel Foods Catalogue, published by the European Commission.

¹⁰² The Novel Foods Catalogue, published by the European Commission.

¹⁰³ http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod_search/index.cfm?action=mod_search_details&seqfce=168 Accessed 15.02.09

¹⁰⁴ Goji Berries, 2007:1-2.

¹⁰⁵ Goji Berries, 2007:3.

*barbarum*¹⁰⁶. Nevertheless, the FSA states in the report that: ‘it appears that ‘Goji’ is widely understood in the UK to refer to the later species and that is how it is used in this report’¹⁰⁷.

Looking at the evidence provided on consumption of the Goji berries in the UK/EU a number of different data was provided.¹⁰⁸

1.1 Cultivation of *L. barbarum* in the UK

The existence of the plant *L. barbarum* in hedgerows and gardens in the UK does not mean that the fruit has been grown and consumed to any significant extent.

1.2 Import data

A number of respondents provided figures of export from China to the UK and other EU countries. The same information was also provided by the Chinese authorities along with re-export of Goji berries from Hong Kong. Comparable import data does not exist in the UK because imports of dried fruits are not categorised at this level. Even if the quantities imported from China were low in relation to the UK, more significant amounts arrived in the UK from Hong Kong having been grown in China or other Asian countries.

1.3 Ethnic markets and restaurants in the UK

Information provided by Chinese outlets, and their customers, provides strong evidence that the berries were marketed in numerous locations in the UK and consumed as such. Standard practice is to dispose of commercial records after six to seven years making it difficult to provide exact evidence. As a result, there was no information on quantities and therefore not possible to comment on how significant this consumption was.

1.4 Whole Goji berries sold or used as food ingredients

The Health Food Manufacturers Association (HFMA) provided a page from a company’s catalogue dated back to 1995, but with only a total sale of 48kg from January 1991 to May 1997. The HFMA provided records indicating that the berries were sold during 1996 (280kg in 500g units). An article in Health Eating Magazine in November 1994 was provided including a number of traditional Chinese recipes, which calls for the use of ‘wolfberry fruit’, and ‘Lycium berries’. Since a mainstream magazine would be unlikely to publish recipes that rely on ingredients that cannot be reasonably easily obtained by its readers it provides supporting evidence of the use in 1994.

1.5 Extracts and infusions of Goji berries

Documentary evidence was provided of the supply of more than 25 tonnes of extracts used in various soft or alcoholic drinks during 1996-1997 imported from Hong Kong. However, this cannot be taken as a history of consumption of whole berries, which will contain other components than in extracts and infusions.

1.6 Sale of Goji berries in other EU Member States

There were reports of sale in Germany and the Netherlands before 1997. Further, attention was drawn to an official decree issued in Belgium in August 1997 on a list of herbal products authorised in foodstuffs. Because the FSA is not responsible for the implementation of the NFR in other MS they passed the information they received to the equivalent authorities in the

¹⁰⁶ Goji Berries, 2007:4.

¹⁰⁷ *ibid.*

¹⁰⁸ Goji Berries, 2007:4 -13.

relevant MS. The MS confirmed that in their opinion it does not provide evidence of a significant history of consumption.

1.7 Legal issues

Some respondents suggested that the Goji berries are not subject to the NFR. The arguments put forward were:

- Paragraph 2(e) of Article 1 defines one category of NF as ‘foods ... consisting of or isolated from ... plants ... except for foods ... obtained by traditional propagating or breeding practices and having a history of safe food use’.
Because the berries are a result of traditional breeding, and have a history of safe use in countries where they are grown, they should be excluded from the scope of the NFR. The FSA stated that this exclusion had to be read together with the opening of Article 1(2), which states that it is talking about consumption within the EU, as was the case for Noni juice.
- There is no legal basis for differentiating between the use of ingredients in food supplements and their use as, or in, other foods. Because they were accepted as a supplement prior to 1997 they fall outside the scope of the NFR. The FSA draws on the position of the Standing Committee on the Food Chain and Animal Health in February 2005 regarding ingredients that have a history of use only in food supplements. They are empowered by Article 1(3) of the NFR to decide, whether a particular type of NF or ingredient falls within its scope.

1.8 Other information

One respondent provided data on quantities of berries exported from China to Hong Kong, when Hong Kong was a British colony. The FSA explained that even if this could be assumed, it would not affect the position under the NFR as Hong Kong is not, and never has been a part of the European Community.

Another respondent reported that a Chinese exporter of the berries had received organic certification in 2006 from a German certifying body. However, this does not prove that there is a history of consumption before May 1997.

Information suggesting that if the berries needed an authorisation it would have a significant impact on small stakeholders based in UK trading these berries and that this should be taken into account. The FSA did not see this as relevant considering the status of Goji berries under the NFR.

1.9 Concluding remarks

None of the individual pieces of information provide incontrovertible proof of a substantial history of consumption, but the overall picture is sufficient to indicate that the berries were consumed to a significant degree in the UK before May 1997, which means the requirements of the NFR does not apply according to the FSA.

The evidence received by the FSA was varied as described above. Nonetheless, the **combination** of the evidence made the FSA conclude that the Goji berry is not under the requirements of the NFR.

2. Baobab Case

PhytoTrade Africa put the baobab fruit pulp application forward on 9 August 2006 to the FSA¹⁰⁹. The Advisory Committee on NFs and Processes (hereafter Committee) reviewed the application on behalf of the FSA¹¹⁰. PhytoTrade Africa is a trade association that represents individual companies in Africa that would like to export baobab and other African products to the EU market. It acts as an umbrella organisation and operates a Pre Qualified Supplier (PQS) system, which assesses and maintains members' standards to ensure consistency with regards to production and quality¹¹¹.

Baobab dried fruit pulp is derived from the fruit of the baobab tree (*Adansonia digitata*), Bombacaceae family. It is also known as the 'upside down tree' and produces large green or brownish fruits, which are characteristically iridescent. The tree grows primarily in South Africa, Botswana, Namibia, Mozambique and Zimbabwe but is also found in India, Sri Lanka, Malaysia, China and Jamaica.¹¹²

2.1 History of traditional use

The applicant underlined that fruit pulp is unprocessed and has a long history of traditional use in Africa. Therefore, the applicant considers that the history of use provides adequate reassurance about the safety of the product. As a consequence, reducing the need for conventional safety studies which are normally required in a NF assessment as described by the FSA.¹¹³

To support the claim of a long history of traditional use the applicant highlighted a number of publications indicating that the fruit pulp has an extensive history of consumption among indigenous Africans. In addition, two questionnaires were presented as proof of current use in Africa. One of the questionnaires was completed by 15 experts, representing nutritionists and botanists from Africa, the EU and the USA with knowledge of African diets and food crops. Further, a literature review conducted by PhytoTrade Africa indicated consumption of baobab fruit in India and other *Adansonia* species with a history of consumption in Australia.

The Committee accepted this information.¹¹⁴

2.2 Production and harvesting process

With regards to the production process the Committee was satisfied with the proposed process, which is a simple, exclusively mechanical process. The Committee asked for additional information about shelf life where the applicant provided additional analytical data to show that the levels of Vitamin C and other key nutrients remained stable over time. No specific indication for shelf life was presented but concluded that the data described above demonstrated that dried Baobab fruit pulp is stable over the time period examined. Further data regarding the PQS system was also supplied as a response to the Committee's concerns about the rigour of the system.

The physical nature of the fruit resembles a coconut in hardness, which provides some reassurance that damage leading to possible environmental and microbiological contamination will be minimal.¹¹⁵

¹⁰⁹ <http://www.food.gov.uk/multimedia/pdfs/baobabapplicationfinal.pdf>

¹¹⁰ The Committee is a non-statutory, independent body of scientific experts that advises the Food Standards Agency on any matters relating to NFs (including genetically modified foods) and novel processes (including food irradiation).

¹¹¹ Initial Opinion: Baobab Dried Fruit Pulp, 2007:2.

¹¹² *ibid.*

¹¹³ *ibid.*

¹¹⁴ Initial Opinion: Baobab Dried Fruit Pulp, 2007:5-6.

¹¹⁵ Initial Opinion: Baobab Dried Fruit Pulp, 2007:3-4.

2.3 Nutritional information

The Committee accepted the nutritional profile, which was consistent with other fruits. The applicant highlighted that the ingredient has a range of potential nutritional benefits such as high levels of ascorbic acid and several B Vitamins. With regards to anticipated intake, no reasons for concern were found.¹¹⁶

2.4 Toxicological and allergenic concerns

The information provided was not typical to other NF applications with regards to e.g. toxicology. One *in vivo* study in rodents from 1994 was presented. The test material was from a different source to PhytoTrade's product. However, in this specific case the MSs were reassured that the NF was a simple fruit preparation and that it is an integral part of the traditional diet in a large geographical area in Africa.

After the publication of the application dossier, a MS put a forward comment related to yeast/moulds and mycotoxins. This was followed up with an additional mycotoxin analysis, which indicated that the product would not be contaminated. The hard outer shell as explained in section 2.2 would offer protection against fungi before harvesting.

With regards to allergenicity, no reports have been found of such in the Malvaceae family, which is closely related to the Bombacaceae family.

A study published in 2001 on the irritant effects of baobab fruit pulp on human volunteers was used as evidence that the fruit is 'non-irritant'.¹¹⁷

2.5 Concluding remarks

The Committee underlined that this application is different to other foods previously subject to a NF assessment that was regularly consumed outside the EU. The Committee states that with regards to other cases: 'there was either a specific safety concern or the food was of limited palatability and was consumed as a natural remedy rather than a staple part of the diet'.¹¹⁸

As with the Goji berry case the long history of traditional use was seen as very important to the Committee and the MS authorities. However, multiple tests with regards to nutrition, toxicology and allergenicity were conducted. It seems like the combination of these factors led to an approval of the application. If there had been import data of the product prior to 1997, an authorisation may not have been necessary.

3. Stevia Case

An application for *Stevia rebaudiana* Bertoni (plant and dried leaves) was first filed on the 7 November 1997, just after the NFR had been implemented. A Belgian assessment body carried out the initial assessment¹¹⁹.

The indigenous Guany natives have used the plant for centuries as a traditional sweetener because the plant yields a sweet extract containing various glycosides. It is still cultivated in Paraguay, Mexico, Central America, Japan, China, Malaysia, and South Korea.¹²⁰

¹¹⁶ Initial Opinion: Baobab Dried Fruit Pulp, 2007:5-6.

¹¹⁷ Initial Opinion: Baobab Dried Fruit Pulp, 2007:7-8.

¹¹⁸ Initial Opinion: Baobab Dried Fruit Pulp, 2007:9.

¹¹⁹ List of Applications under Regulation (EC) N° 258/97 of the European Parliament and of the Council.

Updated 13.05.09.

¹²⁰ Scientific Committee on Food. Opinion on *Stevia Rebaudiana bertoni* plants and dried leaves. Expressed on 17 June 1999:2-3.

The EC's Scientific Committee on Food (SCF) carried out an additional assessment and they gave their opinion in June 1999. The following conclusion was given by the SCF: *'the information submitted on the plant products was insufficient with regard to specification and standardisation of the commercial product and contains no safety studies ... The only toxicological data submitted are essentially concerned with the stevioside component of the plant product ... No appropriate data were presented to enable the safety of the commercial plant product to be evaluated.'*¹²¹

3.1 History of use

According to Geuns (2008) Stevia has a history of safe use in different countries in the EU before 1997 and the introduction of the NFR. In 1942 there were experimental Stevia fields in the UK and in 1984 in d'Adesky, the Belgium government authorised the sale of crude Stevia extracts in Belgium. Five years later, in 1989, 9.28 tonne of dry Stevia leaves were imported in Belgium, and there are reports of sales in the Netherlands, Belgium, Switzerland, Germany and the UK during 1989 to 1997. Stevia was also on the positive list of authorised herbs in Belgium before 1997.¹²²

3.2 Data presented by the applicant

With regards to the chemical composition, the plant contains a complex mixture of natural sweet chemicals the main one being stevioside.

No inherent toxic components were described but as the opinion states: *'no analytical evidence for their absence has been supplied'*. They further declare that: *'no microbiological specification has been supplied'*¹²³.

Lähteenmäki-Uutela (2007) describes that the SCF knew that the plant was a traditional natural sweetener used for centuries for different beverages. Further, they also knew that the plant was cultivated in several American and Asian countries and also in Europe as mentioned in 3.1 and well defined botanically. Data from different tests were presented the SCF but they did not find them convincing because they did not have the details of the study.¹²⁴

One test provided results from an animal test (feeding study in rats) showing promising results if used in diabetics to reduce blood sugar level. The plant has been used for this purpose in Paraguay since the 1950s. But the SCF still decided that: *'there are no satisfactory data to support the safe use of these products as ingredients of food or as sucrose substitute for diabetics or obese individuals'*¹²⁵.

The toxicological data submitted by the applicant concerned crude or purified extracts or pure stevioside. The SCF did not see the use of these studies as relevant because: *'they did not enable determination of the precise specification and origin of the source material used for these extracts they are irrelevant for the assessment of the safety of the leaves and powdered leaf products'*. The only study presented to the SCF where the plant was used, was in the animal study described above, which they did not approve of. Further, no investigations on the allergenic potential of the leaves and the powdered leaves were submitted.¹²⁶

¹²¹ Scientific Committee on Food. Opinion on Stevia Rebaudiana bertonii plants and dried leaves. Expressed on 17 June 1999:5.

¹²² p:1

¹²³ Scientific Committee on Food. Opinion on Stevia Rebaudiana bertonii plants and dried leaves. Expressed on 17 June 1999:2.

¹²⁴ p:6

¹²⁵ Scientific Committee on Food. Opinion on Stevia Rebaudiana bertonii plants and dried leaves. Expressed on 17 June 1999:4.

¹²⁶ Scientific Committee on Food. Opinion on Stevia Rebaudiana bertonii plants and dried leaves. Expressed on 17 June 1999:3-4.

3.3 Stevioside as a food additive

Lähtenmäki-Uutela (2007) suggests that by looking at the opinion on stevioside as a food additive one can better understand why the application on Stevia as a NF was rejected. The opinion on stevioside as a sweetener was given on the same date as Stevia, namely 17 June 1999¹²⁷.

Several studies have been conducted on stevioside and its metabolite steviol. Steviol has shown to decrease fertility in male rats and to include developmental toxicity. When fed in high doses to rodents studies have shown that it causes cancer. *'It is this 'hint of serious side-effects that made the Committee to reject the application and not the lack of information'* as stated by Lähtenmäki-Uutela (2007). As a result, the SCF resorted to the precautionary principle and decided not to take any chances¹²⁸.

3.4 Concluding remarks

The data presented above describe a history of use before 1997 in the EU and centuries of use in third countries. Further, information was also offered on current cultivation in several third countries. With regards to toxicological data and allergenic potential the SCF indicated that the applicant used irrelevant and unclear scientific studies. Lähtenmäki-Uutela (2007) suggests that the application was refused due to *'hint of serious side effects'* for the Stevia application as sweetener.

As described in the beginning of this chapter the reason for presenting these cases was to demonstrate the difference in evidence among them. It becomes clear from these examples that the question of novelty and which evidence is considered legitimate to establish novelty or non-novelty, is a very complicated matter. This makes the matter very complex for both the assessment bodies and the applicants. To get a better understanding of these problems the experts were asked questions regarding these problems in order to try and understand the different decisions made. Their answers will be presented in chapter 8.

¹²⁷ Scientific Committee on Food. Opinion on Stevioside as a sweetener. Adopted on 17/06/1999. SCF/CS/ADD/EDUL/167 final.

¹²⁸ p:7

6. The Proposal

After years of consultation and discussion with different stakeholders regarding the current NFR, the Commission finally presented a proposal 14 January 2008 (hereafter NNFR)¹²⁹. The expectations from this proposal were many and the parties involved anticipated big changes. In the following sections an analysis of the proposal will be presented.

1. The Objective

The explanatory memorandum explain the objectives of the proposal, which is to:

- ensure food safety
- protect human health
- secure the functioning of the internal market for food

To be able to achieve this the proposal aims to:

- streamline the authorisation procedure
- develop an adjusted safety assessment system for traditional food from third countries
- clarify the definition of NF
- improve the efficiency, transparency and application of the authorisation system
- advance the legal clarity by updating the legislation
- empower consumers by informing them about food

Further, according to the Explanatory Memorandum the proposal is consistent with other policies and objectives of the EU such as the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy.¹³⁰

2. Choice of instrument

A regulation was chosen as the instrument because the area of NFs is harmonised in the EU. Using for instance a code of good practice or a guideline would not give sufficient protection of consumer's health and also lack legal certainty. Additionally, the safe use of NF depends on pre-market safety evaluations and often on permitted conditions of use.¹³¹

3. The Procedure

3.1 Determining Novelty

Article 3(2)(a) defines NFs:

(a) "NF" means:

(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;

The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being

¹²⁹ Proposal for a Regulation of the European Parliament and of the Council on Novel Foods and amending Regulation (EC) No XXX/XXXX [common procedure], COM(2007) 872 final.

¹³⁰ NNFR, Explanatory Memorandum pp:2-3.

¹³¹ NNFR, Explanatory Memorandum p:6.

considered as NF. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997; and

(iii) food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.

Article 4(1)¹³² regards the collection of information regarding the use of a food for human consumption:

The Commission may collect information from the Member States and/or from food business operators to determine to what extent a food has been used for human consumption within the Community before 15 May 1997.

3.2 Requirements and inclusion in the Community list of Novel Foods

The Commission as explained in the proposal will develop a list that will contain all the authorised NFs.

As stated in Article 5¹³³, only NFs included in the *Community list* of NFs may be placed on the market. This article implies a generic authorisation procedure, which means that everybody can place the same product on the market as long as it complies with the following conditions laid down in Article 6¹³⁴:

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

Article 7¹³⁵ sets the decisive factors for the content of the Community list.

1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure].

2. The entry of a NF in the Community list shall include a specification of the food, and, where appropriate, specify the conditions of use, additional specific labelling

¹³² Article 4(1)

¹³³ Article 5

¹³⁴ Article 6

¹³⁵ Article 7

requirements to inform the final consumer and/or a post-market monitoring requirement.

3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a NF, *other than traditional food from third countries*, shall be decided in accordance with the regulatory procedure referred to in Article 14(2)¹³⁶ in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12¹³⁷.

This means that traditional food from third countries will deviate from the updating of the Community list, which is intended for other NFs.

Two authorisation procedures have been projected in the proposal. The first one is aimed at *traditional food from third countries* and the second is known as Regulation (EC) No [Common Procedure]. This Common Procedure aims to establish a common authorisation procedure for food additives, food enzymes, food flavourings and on the basis of the NNFR also to NFs.

For traditional food from third countries, a safety assessment and management based on history of safe food use in the country of origin shall be introduced as stated in *Article 8*¹³⁸ of the proposed NFR.

Before examining *Article 8*, the definitions of “traditional food from a third country” and “history of safe food use” will be given.

*Article 3(b)*¹³⁹

"traditional food from a third country" means NF with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least one generation in a large part of the population of the country;

*Article 3(c)*¹⁴⁰

"history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use in the normal diet of a large part of the population of a country.

Going back to *Article 8(1)*, it states:

A food business operator intending to place a traditional food from a third country on the market in the Community shall notify it to the Commission, indicating the name of the food, its composition and country of origin.

¹³⁶ Article 14

¹³⁷ Article 12

¹³⁸ Article 8

¹³⁹ Article 3(b)

¹⁴⁰ Article 3(c)

The notification shall be accompanied by documented data demonstrating the history of safe food use in the third country.

All applications for the approval of NF shall be submitted to the Commission and then directed to EFSA, which will carry out the safety evaluations. The Standing Committee on the Food Chain and Animal Health (SCFCAH) will also assist the Commission¹⁴¹.

Within *four* months of the notification a MS and the Authority (EFSA) may inform the Commission that they have safety objections based on scientific evidence regarding the food in question¹⁴².

If the history of safe food use in the country of origin has been demonstrated, and MS and EFSA do not present safety objections, based on scientific evidence, the food can be placed on the market on basis of a notification of the food business operator intending to market the food after *five* months of the notification¹⁴³.

If there are objections, the food shall not be placed on the market in the Community and *Articles 5 to 7* shall apply. With regards to the notification referred to in *paragraph 1*, it shall be considered as an application to the [*Common Procedure*]¹⁴⁴.

The Commission shall also publish a list of traditional foods from third countries which can be placed on the market that are in line with *paragraph 4 of Article 8*¹⁴⁵.

Further, *Article 10*, in assessing the safety of NFs, the Authority shall:

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

(b) take into account for traditional food from a third country, the history of safe food use.

3.3 Technical Guidance

In addition, the proposal incorporate an article about technical guidance, namely *Article 9*:

The Commission shall, where appropriate, in close cooperation with the Authority, make available technical guidance and tools to assist food business operators and especially small and medium-sized enterprises in preparing and submitting applications under this Regulation.

4. Central Aspects

The possible improvements for exporters in DCs laid down in the NNFR will be discussed in chapter 9. Nevertheless, a few central aspects will be put forward in this section to summarize some of the most significant points.

¹⁴¹ Explanatory Memorandum, p:7.

¹⁴² Article 8(3)

¹⁴³ Article 8(4)

¹⁴⁴ Article 8(3)

¹⁴⁵ Article 8(5)

- Main definition and cut off date have been sustained
- Two authorisation procedures have been projected; one aimed for traditional food from third countries and the second known as Regulation (EC) No [*Common Procedure*]
- Authorisation process will be centralised
- A list of authorised NFs will be developed which will be generic
- The concept history of safe food use has been introduced in association with traditional food from third countries
- Time wise, the application procedure has been reduced

7. Methodology

The previous chapters have introduced literature with regards to the impact of the NFR on DCs, the analysis of the NFR and three NF cases. These chapters are the starting points of the empirical research, which leads us to the methodology. The following chapter will present the methods that were used to develop the questionnaires, collect the data and finally, how the data was analysed.

1. The research area and sampling

The main focus was set on Africa and the countries in Latin and Central America. This decision was based on information from the literature review. It describes that development organisations and agencies operating in Latin America and Africa have reported problems acquainted with the NFR¹⁴⁶. It became evident that it was important to talk to those who have to deal with the NFR on a daily basis namely the FEBs. As a consequence: the area of research became FEBs from DC.

The companies' contact details were obtained through countries' export promotion web pages and non-governmental organisations promoting exports from DCs. Further, during the authors' internship at UNCTAD's BTI, contacts were gathered.

The sample includes FEBs from; Ecuador, Colombia, Peru, Bolivia, Costa Rica, El Salvador, Nicaragua, Chile, Mexico, Kenya, Uganda, Ghana, Zambia, Zimbabwe, Senegal, Ethiopia, Mali, Egypt, India and Vietnam.

2. Food Exporting Businesses

The semi-structured questionnaire for the phone interviews was based on the literature review. Southwold (2002) explains several advantages of semi-structured interviews. The three most relevant aspects for this research will be described here. First, the informant can express himself in his own terms, second, the interviewer can make follow-up questions on leads that come up during the conversation, and third, the data is comparable because the same topics were covered with each informant.¹⁴⁷ According to Bernard (1998) the most common form of structured interviewing is the questionnaire. This form was also used for this research as explained above¹⁴⁸.

The questionnaire was divided in two main sections, namely questions about the NFR and the NNFR. This was done to gain knowledge about the NFR and to see if the FEBs were acquainted with the NNFR. Within these two sections, questions related to both the NFR and the NNFR were asked. The questions were linked to familiarity, procedure, enforcement, assistance, and general export experience to the EU, strategies for export and specific experiences with regards to NF exports. The complete list of questions can be found in Annex I.

The interviews contained both open and closed questions in order to leave room for personal views and comments on the different topics.

When the interviewee was approached a brief explanation about the topic of research was given. The duration of the interviews was between 10 and 20 minutes.

¹⁴⁶ See e.g. Neville Craddock Associates, 2005.

¹⁴⁷ p:9

¹⁴⁸ p:88. In: Southwold, 2002: 9.

If the informant was not acquainted with the NFR he/she was still asked about their general experiences with exporting to the EU.

3. Data collection

At the outset of the research the gathering of data was done by phone¹⁴⁹ and recorded¹⁵⁰. It proved to be difficult to get hold of FEBs by phone. As an attempt to gather supplementary data, a questionnaire was developed and sent by email to approximately 150 exporters of fruit and vegetables in Asia, Latin America and Africa. This questionnaire was similar to the one developed for the semi-structured interview.

Even if many FEBs were contacted the response rate remained low. First, the companies may not know the NFR or be affected by it. Second, finding the time to answer questionnaires is not of high priority to the company because there is no incentive to do so. Third, many of the emails were also undelivered. This can be because the company was not in business anymore or the company had forgotten to update their contact information on the respective web pages. Fourth, the language aspect; the emails were only sent in English and Spanish. As for the questionnaire, it was only developed in English. The response rate would most likely have been higher if it had been translated into Spanish and French and other languages spoken in the countries in question. When calling the companies in Latin and Central America the language issue became very evident for the author. As for the questionnaire and undelivered emails, there were similar problems for the phone interviews, namely numbers out of order and bad connections

The data was collected between October 2008 and February 2009. Six informants were interviewed by phone and six questionnaires were received by email.

4. Expert Interviews

Experts are integrated into the research not as a single case but as representing a group. The interpretation of these interviews mainly aims at analysing and comparing the content of the expert knowledge.¹⁵¹ An interview guide is very important when interviewing experts to avoid unproductive presentations¹⁵².

Snowball sampling was used as the starting point of building the pool of informants. Contacts from the author's internship with UNCTAD's BTI started the process of data gathering. These contacts put the author in touch with other relevant informants.

A potential drawback with the snowball technique as explained by Taylor & Bogdan (1998) is that it can limit the diversity of ones informants¹⁵³. To be able to avoid this limitation experts were identified in public institutions and, private institutions and organisations. Because the area of experts working with novel traditional products unknown to the EU is still a 'niche' area compared to experts of 'real' NFs¹⁵⁴ the author believes that this specific sample presents a valid picture of the situation. The number of experts interviewed by phone was 10 and one via email.

The questionnaire for the expert interviews was developed the same way as for the FEBs, namely based on the literature review. The expert questionnaire was also divided in two main

¹⁴⁹ Skype.

¹⁵⁰ Recording program: Pamela for Skype.

¹⁵¹ Flick, 2006:165.

¹⁵² Mauser and Nagel, 2002. In: Flick, 2006:165, 206-207.

¹⁵³ p:93

¹⁵⁴ e.g. produced with new technology.

sections, questions related to the NFR and questions related to NNFR. The questionnaire can be found in Annex II.

The duration of the interviews was between 30 and 60 minutes.

5. Analysis

After the interviews were conducted they were transcribed and the informants were given the opportunity to review them¹⁵⁵. This gave the respondents the chance to add additional information and correct the interview. Because some of the calls were long distance the connection was sometimes poor, therefore the review also gave the opening to correct misunderstandings. Finally, the reconsideration gives the possibility to quote the informants in the final text.

Coding is a way of developing and refining interpretations of the data. As Taylor and Bogdan (1998) describe, the coding process involves bringing together and analysing data bearing on the major themes, ideas, concepts, interpretations and propositions.¹⁵⁶ The data was coded by using the categories from the questionnaire as explained in chapter 7.2 and 7.4. By using the categories as “headings” the transcribed data was filed under the applicable category. Data, that matched several categories, was filed under each relevant heading. The coding was conducted in an excel sheet, which made it easier to add the relevant information¹⁵⁷. While the coding was conducted, adding and redefining some of the categories specified the scheme even further.

Flick (2006) explains that different types of coding aim at consequent breakdown of text. However, a problem with this method is the potential endlessness of options for coding and comparisons¹⁵⁸. In this research the options for coding have been kept limited, namely to the categories mentioned from the questionnaires.

6. Validation

Matters of leading and miss interpretation are known criticism of survey data¹⁵⁹. Non-sampling errors can have an effect on the reliability and validity of the resulting information. The interviewers background can influence the informant’s views. An error when asking questions by emphasising different aspects for each informant is a frequent problem. Further, errors, which occur because the informant does not understand the idea of the research, can influence the informants’ replies¹⁶⁰.

Additionally some questions are difficult to ask by telephone due to their complexity. If the informant misses one single word the question may become incoherent. Besides, the interviewer does not have visual cues to see if there has been a misunderstanding.¹⁶¹

To overcome these limitations the respondents were given the opportunity to review their interview.

While the data cannot portray replicability and reliability due to the limited number of respondents, it can say something about the impact of the NFR in practice. This gives the

¹⁵⁵ This was done both by the exporters and the experts.

¹⁵⁶ pp:150-151

¹⁵⁷ The analysis could also have been conducted by qualitative data analysis software like Atlas/ti or Nudist Compared. However, because the amount of data was practicable (about 60 pages) the author made the decision to do it manually.

¹⁵⁸ p:306

¹⁵⁹ Southwold, 2002:12-15

¹⁶⁰ Southwold, 2002:13-14.

¹⁶¹ Judd et al., 1991:221-222

possibility to determine which factors are important for the different stakeholders and if these aspects have been addressed in the NNFR.

8. Empirical Data

In the following chapters the analysis will be presented, first from the FEBs' point of view and second from the experts'.

1. Food Exporting Businesses

1.1 General Findings

The twelve informants are from seven different countries: Ghana, Uganda, Egypt, Ecuador, Peru, Bolivia and Columbia. These exporters produce a variety of fruit and vegetables, grain, seed and vanilla. All but two are currently exporting to one or several EU countries. A producer from Columbia is at the start phase of exporting to Spain and has sent samples with positive feedback. Because it is likely that this producer will soon export to the EU, the results have been used in the analysis. The second producer, from Bolivia, has sent samples to the EU, which means he will be familiar with the requirements of exporting to the EU, and therefore is included in the analysis.

1.2 Awareness Novel Foods Regulation

This section tries to explain why some of the FEBs were acquainted with the NFR and some were not.

The four informants acquainted with the NFR receive assistance from different organisations promoting exports from DCs informing them about developments in the area of food legislation. This can suggest that it is more likely that they know the NFR because they are involved with a development agency. However, the two other informants interviewed by phone are also linked to development agencies and they do not know the NFR.

Even if all the informants were linked to a development agency informing and updating them about food legislation in the EU it could not fully explain why they are not all acquainted with the regulation in question. A possible explanation to why they are unaware of the NFR can be explained by the observation that the majority of the informants export products that are not novel to the European market and have a history of export.

One can also look at this from another perspective. It could be that the exporters fall into the demand of the European market. As long as there is a demand for their product, the incentive to start exporting 'new' or innovative products is not there. Brookes (2007) describes the economic impact assessment of the way in which the EU NFs regulatory approval procedures affect the EU food sector. One of the impacts he notes is that the current NF approval mechanism encourages companies to be followers to the market rather than innovators. The followers of the market experience lower costs and risk than NF innovators.¹⁶²

Even if this impact assessment was conducted among the European food sector, it may also help to understand why companies outside the EU decide to follow the flow of the market.

Further, the transaction costs to go from one production to another, having to adapt to for instance different regulations and production methods, may be too high for the exporters to risk entering a new market segment.

Blind et al. (2004) conducted a survey among European Companies regarding the role of regulation for innovation. They explain that regulations have a strong negative impact on costs for the development and the introduction of new products and services. Especially regulations related to health and safety aspects, the quality and services and the question about

¹⁶² p:6

liability. They also found large consensus that approval procedures such as in the NFR are both too costly and long.¹⁶³

These findings can offer an additional explanation to why most of the exporters in this research did not have problems with the NFR. It can be that for them as well as European companies, the impact of regulations on costs for the development and the introduction of new products and services are too high.

Although only a few of the informants were acquainted with the NFR, there are two interesting findings linked to the awareness of the regulation in question. One of the informants from Columbia realised that he had several products, which are considered novel, such as Borojò (*Boroja sorbibilis Cuatrinioi*), Noni and Nopal (*Opuntia ficus*) after answering the questionnaire. As described above he is the informant who is in the start phase of exporting to Spain. Even if he has several products in his portfolio that are novel, he has had no problems with the samples he sent.

The second interesting finding in this regard was from an informant situated in Ghana. He is only acquainted with the NFR and in the process of getting products authorised. He explained that he did not have to deal with the problems because he was only supplying the raw botanicals and the manufacturer dealt with the problems with the NFR.

Two of the informants knew the NFR in detail. The first is from Peru, and the regulation has caused big problems for his company. The second is located in Uganda, he was asked to check if the product he wanted to export was novel.

The informant from Ecuador was familiar with the regulation through his involvement with a development agency. The final informant who was acquainted with the NFR is the producer from Ghana mentioned above.

As for the questionnaire informants none of them had heard about the NFR.

1.3 Awareness New Novel Foods Regulation

The previous section described the FEBs' awareness with regards to the NFR. This section has the same objective but with the NNFR.

As for the NNFR only one informant knew this regulation, this was the informant from Peru. He did not know it in detail but knew that there were made some changes with regards to the authorisation procedure and traditional foods. He believes that the proposal will be better than the NFR with regards to the application procedure, which in his opinion will make it easier to export.

As for the concept 'history of safe food use' he has mixed feelings. He thinks that the concept is key to food safety, but could be misused for political matters. In his opinion, food regulations should be more practical. He explains further, *'I think most of the traditional foods that have been domesticated and eaten for centuries.'* *'This is something the proposed regulation should consider because this is already proof enough, rather than a laboratory.'* *'You can test a new food in a laboratory, but you cannot see what will happen in one or two generations from now.'*

Why were the informants not acquainted with the NNFR? First of all not even half of the respondents knew the NFR, which makes the probability of being familiar with the NNFR low. This can be based on the rationale that they do not produce any NFs and therefore not

¹⁶³ p: VI

experienced any difficulties with the NFR, meaning: the need to keep updated on the development of the regulation has not been necessary. Further, the legislation was recently published and the informants may not have come across it yet through for instance development agencies.

1.4 Information Access

In the following sections the problems perceived by the FEBs regarding the NFR will be explained by the data gathered.

The sections 8.1.2 and 8.2.3 have explained the producers' familiarity with the NFR. All the companies, familiar and unfamiliar with the NFR were asked if they found it easy to locate information needed to export to the EU and in addition where they acquired it. This was done to obtain a general understanding of how FEBs in DCs go about to gather knowledge about EU food legislation.

All the informants from the phone interviews except one explained that they used the Internet to access information. Those who are members or linked up to a development agency said they use the agency's web pages¹⁶⁴ and newsletters, which are sent to them by email. Two informants said that they would even contact the agencies/organisations in person if they had problems.

From the questionnaires only one informant, from Columbia, found it difficult to find the information required to export to the EU.

He describes his experience:

'When we decided that we wanted to start exporting to the EU, it was NOT easy for us to find the information we needed to do so (e.g. different requirements regarding hygiene etc)'. 'We had to invest many hours exploring the WEB, then many hours analysing the information we found, then many hours looking for the application to our product portfolio'.

The reason behind his difficulties could be linked to his current status as a new exporter to the European market. As for the exporters linked to an agency, gathering information did not seem like a major obstacle. This can be said both for the informants who were acquainted with the NFR and those who were not.

1.5 Export Experience

1.5.1 The Novel Food Regulation

The informant from Ghana has not been impacted by the NFR 'personally' because he supplies the raw material. However, he knows that his manufacturer has experienced several difficulties. The informant explains that he has supplied three products, which have gone through the authorisation procedure.

He explains: *'one product (Ximenia americana) has been delayed for over ten years, this was for a German manufacturer'.*

He understands this delay to be because: *'many tests have to be conducted because the product will be consumed'.*

One of the informants from Uganda explains that he encountered the NFR when he was trying to develop a product (Mesquite) for exports to the EU. His company was asked to check if the product had been imported into the EU before and if it now falls under the NFR. He considers

¹⁶⁴ For instance; CBI, IPPN, ITC, PhytoTrade Africa and CORPEI.

the regulation clear but: *'... I have the impression that it is a tool to keep other products out of the EU.'*

He explains further, that he discovered that the majority of the applications made under the NFR relate to very big companies that produce genetically modified products. As he states: *'they are apparently the "main client"'*.

When asked about the authorisation procedure, he believes that it would be expensive for his company and it could have been a reason not to go through with the application. However, he clarifies that the main reasons for dropping the process was related to local problems in the area (tribal conflicts) and they could not get the funding they wanted.

The informant from Peru has had severe problems with the NFR. He explains that the first time his company came across the regulation was when they sent some kilos of Maca (*Lepidium meyenii*) to a client in the Netherlands. *'What followed was that the Dutch Food Authorities confiscated the Maca and claimed it was a NF.'* Further, at that moment his company was involved with the CBI. He illustrates: *'they were helping us to export Maca to the EU. It was a big issue because a Dutch government institution was promoting the Maca and another was stopping it, a big contradiction'*.

The CBI brought the issue to the general prosecutor in The Hague. *'We sent a lot of statistical information, that before 1997 some countries and citizens of the EU were buying Maca.'* At the end it was stated that the EU should not consider Maca as a NF and therefore Maca could be imported to the Netherlands and my Maca was released.'

After this incidence he explains that: *'the CBI has played a very important role for us in trying to modify the NFR even after this'*.

The same informant has a similar experience with another product, namely Yacon. *'We had a big business plan for Yacon, but could not go ahead due to the NFR.'* *'We started a relationship three years ago with a company in Austria and they wanted to invest in Yacon, but they found out that it was a NF and they withdrew from the investment.'* *'I imagine the authorities told him that the Yacon could be confiscated.'*

In spite of that, he states: *'we are exporting [Yacon] in low quantities to England as an organic product also to Germany'*. *'To Germany it is exported as conventional product.'* *'But our clients are warning us that our products might be stopped at any moment because somebody could raise the issue of NF.'* *'Even if the product has been cultivated in Holland for the last six years on an organic farm'*. *'The problem seems to start when we try to sell it in big quantities.'*

Their product Yacon syrup has been introduced to the biggest organic supermarket in the USA (Wholefood). He believes that the EU is missing out on a very good product: *'many products are kept off the market due to this regulation, which could be very good for the European consumers'*.

He explains that through the Instituto Peruano de Productos Naturales (IPPN) with help from a German NGO (GTZ) and Swiss founding they are finishing an application for Yacon powder. They will send the application to the UK, this coming January¹⁶⁵. Further, he states: *'behind this application is nearly two years of preparing papers and doing research and \$60.000'*. *'This could not have been done without the Swiss founding and the German NGO.'*

¹⁶⁵ 2009

His company also exports organic Lucuma, which he sees as a promising product, to the UK in small quantities.

The informant believes that bureaucracy is the main problem with the current authorisation procedure [NFR]. But also those certain food industries from the USA and Europe do not want to expand their range in traditional foods. He believes that the authorisation procedure should be as short as possible: *'as I said before: it has stopped the exports of so many traditional Andean foods'*.

1.5.2 General experiences

In this section the general bearings the producers have experienced when exporting to the EU will be described.

Nine of the informants did not find it hard to comply to EU food legislations and procedures, while three said they had encountered problems.

The informant from Egypt, who exports peaches, strawberries and grapes mainly to the UK and the Netherlands, is certified for EurepGap (now GlobalGAP) and a member of the CBI. He states: *'as long as the parties comply with the EU regulations, it is a straight forward business deal'*.

Shipping and packaging costs are much bigger problems for an informant from Uganda than complying with regulations. He states: *'a major obstacle is that Uganda is a landlocked country, therefore cost of freight is very high'*.

He exports Shea butter and has sent samples for analysis of sunflower cooking oil to the EU; he is also a member of the CBI.

Faye et al. (2004) explain that landlocked countries not only face the challenges of distance but also challenges that result from a dependence on passage through a sovereign transit country. This means that the exports must pass this country in order to access international shipping markets. This problem is a particular obstacle for DCs.¹⁶⁶

It is estimated that for land-locked African countries a drop of 10 percent in transport costs increases the volume of international trade by as much as 25 percent¹⁶⁷.

The informant from Ghana explains that he exports to China in addition to the EU. It is easier for him to access the European market than China. He claims that this has mainly to do with the fact that China is further away from Africa than Europe. This makes it harder to maintain the quality of the product when it is exported in containers.

His main concern regarding export is linked to quantity. He is not able to export enough and the regulation aspect is not a concern for him.

The informant from Ecuador has just started exporting to the EU. He believes that because they comply with international standards they do not have many problems with regards to food regulation. His main concern regarding exports is finding an opening in the market. His company exports mainly passion fruit purée to the Netherlands, Spain and the USA. He is a member of CBI.

¹⁶⁶ p:32

¹⁶⁷ Limañ and Venables, 1999. In: Ruijs et al. 2004:220

Turning our attention to two informants from Uganda and their experiences, they elucidate that their export problems have more to do with their region or company.

The first informant believes that the troubles he has come across have less to do with the EU, but the region from where they export.

Issues like logistics and finances would still be problematic if they were exporting to the USA. He says: *'its not a specific problem related to the EU'*. His company is certified organic and as a result he explains that *'we don't have too many problems with for instance EurepGAP, standards and so on'*. *'Because organic is a standard of EurepGAP'*. *'This is very useful for us'*.

A recent problem for his company was the 'certificate of origin'. Because parts of their products come from a neighbouring country and its shipped together and that causes a lot of problems. He believes that: *'there is a lot of bureaucracy and people probably do not stick to the rules but the Europeans want it so we do for them, as they want to see it'*.

The other informant from Uganda sees the non-tariff barriers as the main constrains when exporting to the EU. With this he means getting directly to the buyers and avoiding the middlemen. He does not think that it is harder to export to the EU then other countries, but because the EU is not a single country it means that all the individual countries in the EU have different restrictions.

He believes that the problem lies with them and it would be easier for his company if they had someone stationed in Europe to look for buyers and to work closely with them. As he states: *'one needs "on site representation" in the market to follow up these leads'*.

They currently export vanilla to France but since the fall in prices it has been difficult. At the moment they are looking for a market for fresh and dried fruits. He is also a member of CBI.

As explained in the previous chapter the informant from Peru had experienced the impact of the NFR. After being asked if he found that it was generally easier to export to non-EU countries he proclaimed that his company did not have any problems with the USA and that they import many types of fruit. The few problems they had experienced were linked to quality. They have had no problems with Australia and Canada. As for Japan they had some problems, he explains: *'because they are very careful with importing fruits'*.

A producer from Uganda states that he has 10 years experience in exporting to the EU and the problem is: *'the ever changing food safety regulations which involve very high investments in order to comply'*. Another informant, also from Uganda, explains that his experience includes opaque regulations and excessive paper trails, which leads to high costs.

1.5.3 Burden of Proof

As for the burden of proof, six producers stated clearly who they think is responsible, namely the producers. Some of the statements were: *'the exporter, since it is the one being involved with the export process'* and *'I do think that we as export companies have to have the responsibility to hold proof of safe food...'* *'As an example, we are ISO 9001 certified company, so we do have registers of our food safety.'*

... would have to be the company who wants to enter the specific product on the market... I have to comply with everything (e.g. regulation) and that cost, has to be the cost of entering your market'.

'Not much choice, the person who is trying to sell the product.' *'It is logic'*.

The informant from Columbia states: *'if the "authorisation procedure" is clear enough for both exporters and authority, the burden of proof "for safety" should bear the exporter'*.

Two informants have a different view. The first, from Bolivia thinks that it should be a special organisation for this, who knows specifically the aspects related to foods and its types, qualities and markets. While the second, believes that for LDC exporters, the main EU importer should bear the burden, as they are more able to deal with the EU authorities and absorb the costs.

1.5.4 Strategies

When the informants were asked about which strategies they apply to deal with problems related to the NFR, different statements were given.

The informant from Peru who had experienced severe difficulties due to the NFR explained that exporting low quantities of the NF was the company's main strategy to work around the NFR. As for the informant from Ghana, who was acquainted with the impact of the NFR but did not have to deal with it personally, his strategy was to cultivate a plantation to be able to meet the demand of his product. As described before, his manufacturer dealt with the problems linked to the regulation.

With regards to the other informants who had not dealt with the regulation in question, maintaining quality was an important strategy.

What was interesting to note was that six of the informants were certified organic and two are in the process of being certified and one partly organic. As an informant from Uganda describes: *'... because we are certified organic we have as a result not too many problems with for instance the EurepGAP, standards and so on ... this is very useful for us'*. Another informant explains that it is easier to export when the product is certified.

A different informant from Uganda, which is in the process of being certified describes: *'our advantage in Europe can be organic farming, but organic certification is expensive for most companies'*.

Private standards such as different organic certification labels can help exporters reach new markets. However, the differences between standards and certification systems can act as a non-tariff barrier for the exporters. Martinez and Bañados (2004) explain that changes in EU certification legislation have resulted in an access barrier for many DCs. Organic products from third countries can only be marked as organic if they are equivalent to the certification systems in the EU. If they are considered 'non-equivalent' special import permits have to be obtained from the competent EU authorities providing that the products are in accordance with EU organic production and inspection system standards.¹⁶⁸

¹⁶⁸ p:2

2. Expert Interviews: The Novel Foods Regulation

2.1 General Perceptions

Through its BTI, UNCTAD works with partners in DCs to promote trade in biodiversity products and services. These countries' increasing need for hands-on assistance in export promotion has led to the creation of a special trade promotion programme: the BioTrade Facilitation Programme (BTFP) for biodiversity products and services¹⁶⁹. Former programme manager of the BTFP Mr. Rik Kutsch Lojenga, explains that UNCTAD's BTI started working with the NFR in 2003. He describes that they were supporting companies to export products that derive from the diversity, which is unique to their countries. The products they were working with were well known in their countries but novel to the European market and as a consequence they could not export their products to the EU.

He says: *'first of all we could not understand why it was there, it did not seem very logical or fair' 'We were frustrated because we had put down a lot of effort with these companies and due to the NFR we were not able to export the products.'*

Mr. Eduardo Escobedo, economic affairs officer at UNCTAD's BTI is currently working on the NF issue. He says: *'this regulation was created for completely other reasons than the traditional foods, namely GMOs'. 'Because of lack of knowledge and lack of importance in terms of trade, traditional foods were included in the basket as any other GMO or new technology to transform food.'*

He further states: *'now that the GMOs are regulated under their own legislation then it becomes even more evident that there is need for revision'*.

Mrs. Lucia Espinosa, is the director of the commercial office at the Ecuadorian Export and Investment Promotion Corporation (CORPEI) in Belgium and in France. CORPEI provides support to export products from Ecuador and works to attract foreign investment to the country. Mrs. Espinosa finds the legislation illogical. She states: *'it is terrible we cannot export anything'*. She believes that the legislation was developed for GMOs and not fruit and vegetables from third countries.

Prof. Jan M. C. Geuns a founder of the European Stevia Association (EUSTAS) and head of the laboratory of functional biology at the University of Leuven, Belgium has been involved with the NFR since 1997. He explains that the initiation of the NFR started as a suggestion to have a good label for food quality but in the end they decided to make a regulation of it. He states: *'I see it as just an addition to the General Food Law (GFL) and we do not need it'*.

Ms. Ana Vilorio works at the Ministry of Health in the Netherlands; she is a diplomat in veterinary medicine. This past year she has been in charge of the NFs dossier, especially working on the discussions on the NNFR. When Ms. Vilorio was asked if the NFR was developed for GMOs and not traditional NF she explains: *'yes, we can even say that it is a kind of an "incidental" regulation'. 'It was meant in the very beginning specially to regulate GMOs because GMOs were new to the EU.' 'GMOs needed a specific risk assessment and a specific regulation.'*

'Since the GMO's have a specific EU-regulation from 2003, a logical question at that moment was if a specific legislation on NFs was still needed and in which form'. 'It was decided to keep specific EU-legislation on NFs.'

¹⁶⁹ BioTrade Facilitation Programme. A BioTrade Initiative. UNCTAD/ITC. 'Promoting sustainable use of biodiversity through trade'.

‘However, we are talking about a regulation that has a very specific date as starting point (15 may 1997) and in 20 years it could be strange to work on the basis of this date’.

When asked if she believes it is necessary to control traditional NF when the GFL is in place, she answered: *‘I believe it was to control everything that was novel and the need to make a risk assessment’.* *‘The question is if the GFL is enough?’*

Mr. Ludo Vischer working at Dutch Ministry of Agriculture, Nature and Food Quality believes that the NFR has forced especially industry to provide more information in the framework of evaluation of new products. Further, this has stimulated awareness and has also forced policy makers and scientists to reflect on what they actually want to know. He believes this is also very positive with regards to safety because you can be more science based on those subjects with the general public.

Dr. Clemens M.A. van Rossum is employed at the NFs Unit of the Medicines Evaluation Board in the Netherlands and is a CAFAB member for the Netherlands. He explains that the idea behind the legislation was that there would be food entering the market which would be so different from foods already known in Europe that it would be good to have a safety assessment before they would be available to the general public.

DI. Klaus Riediger works at the Austrian Agency for Health and Food Safety (AGES); he is also a CAFAB member for Austria. He explains that the NFR was founded especially for GMOs. At that time, the regulation was very important to create the same “measurement” for safety within the EU.

The CAFAB members were asked how they believe that the NFR has contributed to the safety of the European market.

Dr. van Rossum explains that it is difficult for him to say something about this, because: *‘they only see the products for which an assessment is done’.* He underlines: *‘it is impossible to state what would have happened and to say which products would have been on the market had the regulation not been in place’.* Nevertheless, he thinks there are other issues of safety, which are beyond the NFR. Mr. Riediger states: *‘some relatively unknown products might have been on the market “legally” before the NFR but in my opinion when you don’t have experience with a novel product it is good to have this regulation’.* Mr. Riediger emphasizes this by explaining about a poisoning incident they had in Austria a few months ago with the kemiri nut (*Aleurites moluccanus*) due to lack of labelling. He states: *‘In this aspect I think it is important that we have the NFR as a form of European database’.*

2.2 The Novel Foods Regulation in a Broader Trade Perspective

To understand the problems related to the NFR it is necessary to comprehend the regulation in a broader trade perspective.

When the experts were asked how they would weigh the NFR compared to other problems FEBs in DCs encounter, there was a common understanding that if working with traditional foods from third countries it did have a big impact.

Ms. Ariane van Beuzekom is responsible for updating the CBI members about EU market access requirements. She states: *‘the NFR is a big problem but it is only for a few products, only for the “relevant” products’.* *‘It is a problem for a minor part of our program.’*

Mr. Escobedo working at UNCTAD states that in general terms for traditional food, he believes that if the trade volume is low and the expected growth is limited the overall impact on DCs in trade for these types of food is very limited. However, he underlines the

importance of the matter when these cases are linked with the producers of these types of food. *'They are the poorest types of communities and in many times the most isolated.'* *'It has a key impact on the most vulnerable percentages of the population.'* According to Mr. Escobedo the development link is very important. Their concern is not only that the NFR hampers trade with traditional foods but also hampers the development spillovers this trade could have, specifically with regards to sustainable use and conservation of biodiversity.

Mrs. Lidwine Dellaert is a consultant for the Dutch senior expert program (PUM). They assist small and medium sized companies in DCs and in Eastern European countries. Mrs. Dellaert shares Mr. Escobedo's concern with regards to sustainable use and conservation of biodiversity. She says: *'... European foods like e.g. asparagus or grapes for wine for export increase.'* *'The numbers of varieties grown is decreasing and I think that is very sad.'* *'This is also a pity worldwide because everything gets more uniform.'*

Mr. Hermann thinks because of the as yet small size of the sector [NFs] the importance of the NFR is minor compared to fruits and vegetables, or commodities (cacao, coffee, etc.). However, he believes that the NFR is becoming a serious impediment for food innovation based on developing country products.

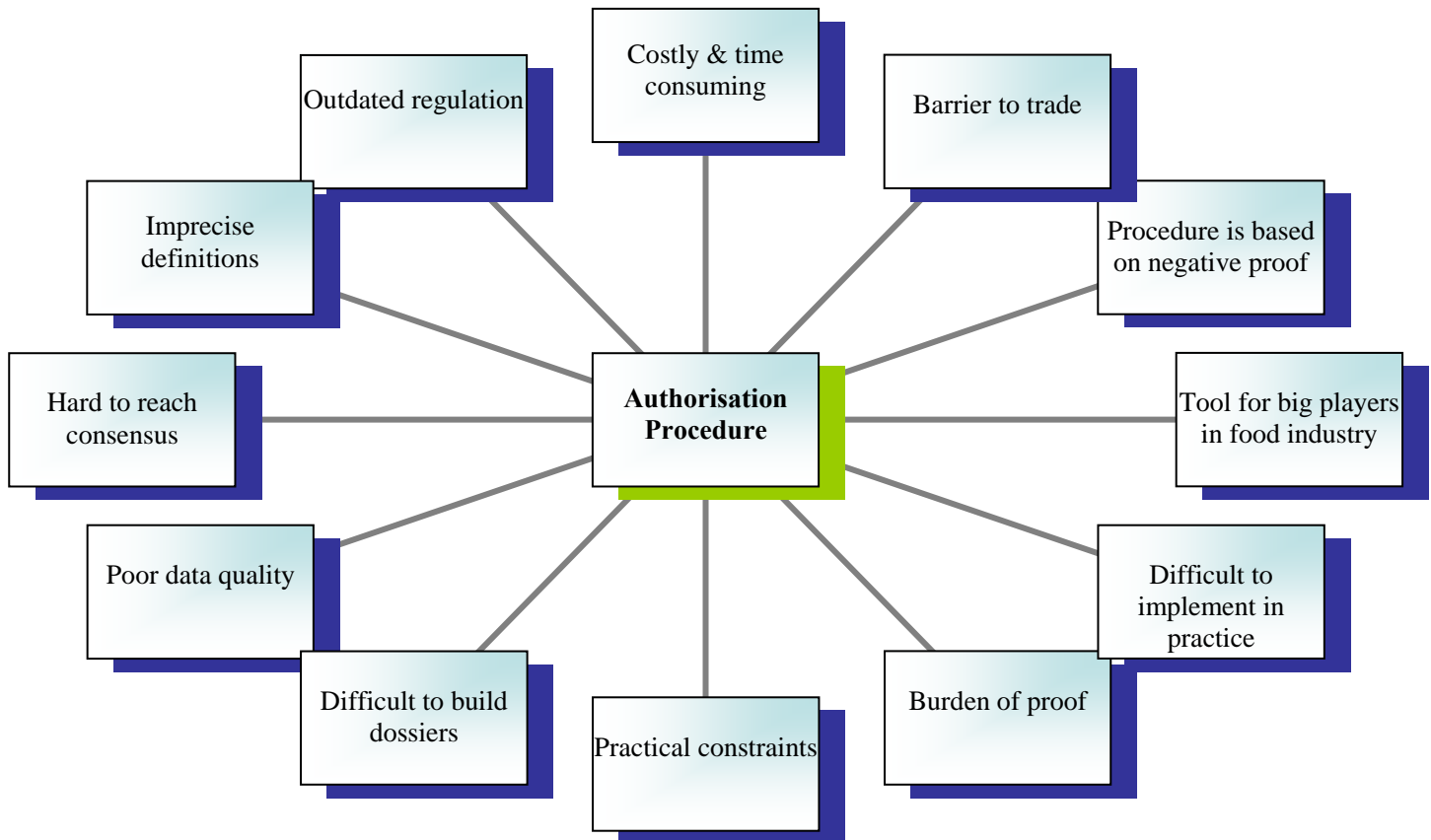
Mrs. Espinosa explains that the market for these exotic products coming from Ecuador is very important for the small companies. *'We are not talking about products that will be the next "apple" or "orange".'* *'We are talking about products being exported of a total of maybe two tonnes a year.'* *'It is also important for the development of biodiversity of different regions of Ecuador.'* *'We were working with UNCTAD on this subject and nothing has come out of these programmes due to the NFR.'*

Chapter 3 and 4 presented stakeholder perspectives and impacts of the NFR, where the authorisation procedure was seen as a major hinder to export. In the following sections we will take a detailed look at how the experts perceive the authorisation procedure.

2.3 Authorisation Procedure

The figure below, illustrates central aspects stated by the experts with regards to the procedure. The aspects will be elaborated in further detail in the following sections.

Figur 1 Novel Food Regulation Authorisation Procedure



2.3.1 Costly and Time Consuming

As explained in chapter 4, the main concern among the stakeholders was that the authorisation procedure is seen as expensive and time consuming.

Ms. van Beuzekom sees the authorisation procedure as a bottleneck for both the exporters and the MS. She further explains that the exporters use a lot of time to make the dossiers and the requirements for making them are not very clear.

Mrs. Espinosa from CORPEI thinks that the procedure is expensive. She says: *'it is very expensive to go through with the risk assessment and only the biggest companies can do that, which means that the product only stays in the hands of very big companies'*. *'For small and medium sized companies it is impossible.'*

Mr. Kutsch Lojenga links the expensive and lengthy procedure to the novelty criterion. He says it is expensive and time consuming to run the research to establish novelty. In addition it takes a long time to get feedback from the Commission regarding the novelty of the product.

Prof. Geuns explains that he attended the 2nd International Fresenius Conference on "NF" in Cologne, Germany, 2008. At the conference he was informed that an application costs on

average €3 million and only 25% is authorised. He states: *'as only 1 out of 4 is successful, the "mean total cost" for 1 approved application is 3x4=12 million euro!*

He describes further: *'the European Commission (EC) states that everybody can apply, but it becomes clear from these numbers that it is not possible for smaller companies both in the EU and in developing countries to apply'. 'It is pure hypocrisy from the EC.'*

When analysing the economic impact of the NFs approval procedures on the EU food sector Brookes (2007) found that the common costs with meeting regulatory requirements were between €0.3 million and €4 million. In addition comes the considerable additional time taken to authorise NFs in the EU which adds an extra of €0.3 million to €0.75 million per application.¹⁷⁰

Mr. Hermann states: *'...smaller companies are often more innovative, and will go after small market niches, but when faced with the requirements of the NFR, they simply don't have the means to deal with it'*.

Mrs. Dellaert came across the NFR when she worked as a consultant for the Pro-Lucuma association in Peru¹⁷¹. She also thinks that the procedure is time consuming. She states: *'it takes a long time because you have to prove that it [the product] is not bad and a lot of information is needed'. 'It is very different when the authorities have to prove that it is bad.'* *'With this regulation it is the other way around, you have to prove that it is healthy.'*

As described in the introduction to this section along with the statements presented above, the matter of time and expenses is clearly a problem.

When the CAFAB members were asked about the differences between the MS assessment bodies interesting answers were given which shed light on the matter in question.

Dr. van Rossum explains that there are differences between the assessment bodies because there are no harmonized rules for costs for example. He explains that it has changed in the Netherlands where it was free until two years ago. He states: *'we have become a very expensive MS to process an authorisation'*. The reason behind the increased costs is that a fee was implemented due to the structure in the Dutch governmental system, whereas in their agency, in principal they should get the funds from the companies they do assessments for.

When confronted with the question if there are differences for instance between the Dutch and the British assessment bodies he explains: *'in a way there are but there are also similarities. Both countries have a long history of assessing NFs. I believe the UK was first in establishing the committee, but also in the Netherlands before the NFR there was an expert committee in place advising the ministry of health on NFs'*.

The duration of the overall assessment period is 90 days for an initial assessment, nevertheless, he states: *'one has to bear in mind that every time there is a question the time will stop'*. Further: *'there might also be practical constraints, for instance if a small assessment body is faced with ten assessments at the same time, there will be no way they can process it within the given time'*.

¹⁷⁰ p:4

¹⁷¹ Peruvian Farmers Association established in 1999 with the objective to join individual efforts of production, processing and commercialization with the formation of the Peruvian Lucuma. Accessed 25.01.09.
<http://www.prolucuma.com/Main.asp?T=3145>

Mr. Riediger explains that with regards to time, there are often problems with the dossiers they receive from the applicants. The dossiers are often incomplete and some companies are not able to prepare enough data for a risk assessment. He uses the case of Stevia as an example: *'the problem was that the current NFR is very strict and you need a lot of data and for Stevia it was not sufficient'*.

2.3.2 The question of novelty.

When the experts were asked about using novelty as the criterion for the 'the right of entry' to the procedure and how they perceive the novelty concept the statements reveal that the idea of novelty is seen as problematic. Knudsen et al. (2008) state: *'the main difficulties experienced so far in relation to novel plant foods in EU relate to defining the borders of the regulation ("what is novel?")...'*¹⁷².

Mr. Kutsch Lojenga understands the concept of novelty the way the EC defines it, but personally he does not find that novel. He believes that there is a problem with the definition of novelty: *'it is an arbitrary cut-off date'*.

Mr. Escobedo on the other hand believes that novelty is the only criteria they could use and refers to other similar regulations in the world where they use the same criteria regarding novelty¹⁷³. However, his criticism is not regards to novelty but how it is defined. He explains: *'setting a random date to define novelty I see as a very inadequate way of defining novelty'*. In addition he appraises the fact that there is no movement in terms of time, he elucidates: *'which means that something produced in 2000 will still be novel in 60 years time'*. He refers to other similar regulations in for instance Canada; where they speak of novelty being 50 years but the difference is that there they use a moving date. Mr. Escobedo justifies this by explaining that right now this would be 1958 and next year 1959 and so on, he personally believes that this is a better way of doing it.

In addition to the comments above he also points out that by using this specific definition the food consumed within the EU will be fairly limited. As he describes, outside the EU there are traditional foods, which have been eaten for millennia, and he finds it strange to classify those as novel. He thinks that: *'the definition of novelty should go further and not be used for the traditional foods but for foods that have been produced from new types of technology'*.

Ms. van Beuzekom explains that the CBI conveyed to the EC a long time ago that they should let other legislations do the work such as the GFL and the labelling Directive. These legislations will make sure that the novel product will be safe on the European market. For instance by adding information about the product on the labelling, as she states: *'there is already a sufficient labelling legislation in use and there is no need for the NFR as an extra legislation'*.

Mrs. Dellaert points to the fact that food processing industries or the traders that import goods are responsible for the health safety of the goods. As she states: *'and that should be enough; I think it is over regulated this way'*. She thinks the safety of the food should not be in the regulation but within the processing industry or the traders. *'They should be responsible for the placing of healthy foods on the market'*.

She finds it strange that with the NFR it is easy to import a "new food variety" within accepted food species; however it is very difficult to import a widely used food crop in another culture. She gives the example of the kiwi: *'originally Kiwi's are green and yellow'*

¹⁷² p:1683.

¹⁷³ E.g. Australia/New Zealand and Canada

kiwi was not known at all'. 'However, under the regulations is very easy to import a yellow kiwi because the green kiwi was already imported'. 'And no proof is requested that the yellow kiwi is healthy'.

Ms. van Beuzekom also refers to the Kiwi: *'it should be up to the consumers if they want to buy it' [the product]. 'Its like for instance with the Kiwi, you don't buy it if you have an allergy, this does not mean that the product should not be imported into the EU'.*

Knudsen et al. (2008) put forward an argument for not being too restrictive in the regulation of fruits and vegetables. In contrast to for instance food additives, as long as the new products are in their original shape as fruits and vegetables usually are very visible for the consumers. The consumers can then on the basis of the available information make an informed choice of their own.¹⁷⁴

When Mr. Vischer was asked if he thought that only additional labelling could be enough for traditional foods with a history of safe food use he explains that it is of course a political question. He states: *'many people think that the answers to certain problems are to be found in regulations'. 'That is not necessarily my personal opinion'. 'One cannot deny that on a national level but also on EU level until recently the answer to a problem was to improve the regulation.'*

When the CAFAB members were asked if they could mention cases where it was unclear if the product was novel they both stated that there were many such cases.

Dr. van Rossum refers to the NF catalogue on the EC web pages¹⁷⁵. He explains that the reason behind the catalogue was that there were many discussions over some products. This meant that there was a need to publish a final result from the NF working group with the legal constraints, which were attached to them.

He further describes that there are products that are being discussed which there are no consensus yet and not all of them are on the web page. The reason why it is hard to reach consensus is linked to different aspects according to Dr. van Rossum. *'There is no such thing as a register of foods being marketed in a given MS'. 'In the legal system, it is up to the companies to make sure they comply with all the legal requirements attached to operating in the food area'. 'The big companies will have their own specialists in this field, but smaller companies have to find another way to comply'. 'Regarding the NFs legislation, such companies may approach the authorities more often with a question regarding the status of their product, often without being able to supply enough facts to support a clear decision'.*

Second, in other cases he exclaims, *'a question on the novelty of a product may hide the question if that product is considered as a food at all' (or e.g. as a medicine). 'This is something the MSs opinions may differ on, making it difficult to decide on the novelty status'.* He states: *'in contrast, if a company provides clear evidence, the process may not be difficult at all: if MS A doubts if a food is novel, and the company convinces the authorities in MS B that the product was legitimately marketed and consumed there, MS B will communicate that to the other MSs'.*

As Dr. van Rossum states: *'there is no such thing as a register of foods being marketed in a given MS'.* The EU research project NETTOX identified 307 food plants in the human diet in the 15 MS of the European Community in 1998. The idea behind the list was to include as a

¹⁷⁴ p:1695.

¹⁷⁵ The Novel Food Catalogue, published by the European Commission.

start at least all major plants (and mushrooms) used for human consumption in Europe.¹⁷⁶ This list has recently been revised and edible plant parts have been added in the EU project EUROFIR¹⁷⁷. Another list is the Food and Agriculture Organisation (FAO) list of global plant food production. According to Knudsen et al. (2008) these lists give a good starting point for identification and evaluation of fruits and vegetables as sources for NFs at the global, regional and local level of regulation. Nevertheless, the authors stress that to become more useful and fitted for the evaluation of history of use, such lists should be based on individual plant species with their scientific names and include information on the plant part(s) normally used for consumption. In addition, recommendations for preparations and cooking procedures would also be very valuable.¹⁷⁸ To build up an international net of global, regional, local and ethnobotanical lists of traditional food plants would serve as a guide to the decision on novelty at the first step and to enable the safety assessment at the second step as said by Knudsen et al. (2008)¹⁷⁹.

In Mr. Riediger's opinion the main problem with novelty is for instance with products such as the Amla also known as the Indian Gooseberry (*Emblica officinalis*) used in chutney in the UK. This product is traditionally used in India and Pakistan, but it is dealt with as a NF in the EU¹⁸⁰. He explains that this is also the case for the Goji berry. At first the UK Food Safety Authority assumed that the Goji berry was a NF, but Hong Kong and a few other countries could bring documents forward to establish that it is not a NF¹⁸¹.

As stated by Mr. Riediger: *'the "problem" is that it is getting more common to use food from India or other countries'*. As a consequence, he thinks it is very important to know how to prepare these products. The problem that follows according to him is that they may be considered medicinal. Nevertheless, he states: *'I am not sure if they should be dealt with as NFs, it might be better if they were dealt with through the general food and feed law or medicinal law if they were consumed prior the 15 may 1997 by the not European population in the EC like it is for Amla'*.

The views presented above paints a picture of how the concept of novelty and its criteria as 'the right to entry' is perceived by a few of the experts. In the following section the two CAFAB members will give insight into how a product is evaluated as novel in practise.

Dr. van Rossum refers to how novelty is defined in the NFR. When asked what he thinks about using novelty as the criterion for "the right of entry" to the procedure, he thinks this is a question for the lawmakers. He believes that the basic idea behind the novelty concept is quite simple but in practice it is all about interpretation. He states: *'the date is easy to interpret but the regulation states that we should look at if there was a significant consumption within the EU before that date'*.

The other CAFAB member Mr. Riediger, explains that at AGES they use different methods when judging if a food is novel or not. He states: *'in Austria, many questions related to NFs are within the food supplement sector'*. *'We had something called Verzehrprodukte they are something like food supplements.'* *'There was a database for these products from about 1975 to 2001. This is a good record of information for evaluation of products'*.

¹⁷⁶ Knudsen et al., 2008:1685.

¹⁷⁷ Pilegaard et al., 2007. In: Knudsen et al., 2008:1684.

¹⁷⁸ pp:1686-1687.

¹⁷⁹ p:1697.

¹⁸⁰ See: Novel Food catalogue-Details. *Emblica officinalis*.

¹⁸¹ See chapter 5.1 for more information.

They also use information if it was sold or not on the Austrian market. However, he explains that this is naturally not enough. Experiences and records from for instance universities, ministry of agriculture, and the ministry of health are used and seen as very useful. He states: *'it is very complicated to evaluate the NF status of a food but I believe it will be better with the proposed regulation'*. *'Many times it is hard to give an answer on a scientific basis, which is of course a big problem'*.

Mr. Riediger was asked if he found it difficult to follow the recommendations set by the Commission. He is of the opinion that there is too much room for interpretation within the recommendations. He believes that it would be better if the NFR would only deal with foods that are really novel. *'I don't understand why we cannot be honest and say that this product (traditional) is not novel (maybe for a European) and then do a safety assessment instead or create better labelling'*. However, he underlines that he is not against the NFR because he has experience with food that has caused serious poisoning and especially for new compounds the NFR is essential.

The Ngali Case can shed light on the issue of interpretation and the Commissions Recommendations. The Ngali nut was rejected as a NF in the EU in 2000. An application was sent to the French authorities in 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 were willing to treat the Ngali nuts as harmless products taking the necessary precautions as for other nuts. Other MS made objections and the Scientific Committee for Food had to assess the product¹⁸². The committee stated: *'the information submitted on the Ngali nuts is incomplete with regard to the analytical procedures employed for determining their nutritional composition and the extent of natural variation of the data submitted'*¹⁸³.

It took two years to assess the safety of the nuts; the European Commission decision prohibiting the nuts was issued in December 2004¹⁸⁴. Lähteenmäki-Uutela (2007) explains the opinion of the Scientific Committee was based on similar facts as the Stevia case¹⁸⁵. As for both the cases, the data was insufficient. With regards to the Ngali nut the possible allergenicity of Ngali nuts had not been investigated and no adequate toxicological data were available to the Committee¹⁸⁶.

What is particularly interesting with the Ngali case, also noted by Lähteenmäki-Uutela (2007) is the Committee's conclusion: *'no conclusions can be drawn on the safety from the consumer health's point of view of Ngali nuts, if the assessment procedures laid down in Regulation 258/97, Article 6.1 and in the guidelines developed by the SCF for the evaluation of the safety of NFs have to be followed strictly'*.¹⁸⁷

The SCF was not certain if the Recommendations should be followed strictly or not, leaving the door open for the EC to deny the authorisation based on insufficient information.

¹⁸² Lähteenmäki-Uutela, 2007: 7-8.

¹⁸³ Scientific Committee on Food. Opinion on the safety assessment of the nuts of the Ngali tree. Expressed on March 8 2000:4.

¹⁸⁴ 2001/17/EC: Commission Decision of 19 December 2000 on refusing the placing on the market of 'Nangai nuts (*Canarium indicum* L.)' as a Novel Food or Novel Food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

¹⁸⁵ See chapter 5.3

¹⁸⁶ Scientific Committee on Food. Opinion on the safety assessment of the nuts of the Ngali tree. Expressed on March 8 2000:4.

¹⁸⁷ Ibid.

Lähteenmäki-Uutela (2007) brings up the legal issue of whether soft law should always be followed. She sees it as a general problem with European food and medicine law, where non-binding instruments are often used. She explains further that even the drafter of the Recommendations, namely the Scientific Committee of Food does not know how to follow the instructions.¹⁸⁸

2.3.3 Dossier Problems

When asked, if it often occurs that dossiers are incomplete Mr. van Rossum expressed that it happens quite a lot. However, he does not see this as strange. He states: *‘we have a wide range of products that should fit in the regulation because it is not a regulation on e.g. sweeteners, which clearly defines the product group’*. He proceeds: *‘Novelty is the only issue so it can be either the exotic fruit on the one hand and a completely new synthetic ingredient on the other hand of the spectrum’*.

Dr. van Rossum understands that it can be difficult for companies to build up their safety dossier. He refers to the Commission Recommendation from 1997 that addresses this question, but as he exclaims: *‘it still leaves a lot of room for interpretation’*.

When Dr. van Rossum was asked if for instance exotic fruits were in a single group would make it easier to assess the product, he states: *‘I hope that not too much emphasis is given to the types of product in the recast of the regulation’*.

He refers to his past experiences with the NFR and problems with the categories in the regulation. He states: *‘a product might not “fit” in one of the categories’*. *‘I think it would be better if the regulation would describe novelty in more general terms, and would be supplemented by guidance documents on requirements for the safety assessment of different types of products’*.

As stated by Ms. van Beuzekom at the beginning of section 2.3, she sees the authorisation process as a bottleneck for both the exporters and the MS. She also underlines as Dr. van Rossum and Mr. Riediger have done, that the exporters have to use a lot of time making the dossiers and that the requirements are not very clear. Further, she explains that many exporters do not export to the EU because they do not know how to make the dossiers. In addition, she explains that many MSs do not know what to do with the dossiers as well.

From experience Ms. van Beuzekom reveals that MSs like the UK and the Netherlands are used to handle the dossiers. She got complains from producers in Latin America who send their dossiers to Spain. She explains that the authorities there do not know how to handle the dossiers. Ms. van Beuzekom thinks that a central way of assessing the dossiers would be more efficient. As for the costs of the authorisation procedure, she finds it very unfair that the MS have different costs.

The discussion on novelty is linked to the concept ‘human consumption to a significant degree’ as it is also defined in the NFR¹⁸⁹. The perspectives related to this concept will be discussed in the following section.

2.3.4 The meaning of significant degree

As described in section 3.4.2 the definition of “*human consumption to a significant degree*” has been interpreted as a food having been *generally available* within the Community. This

¹⁸⁸ p:8

¹⁸⁹ Article 1(2)

means that if a food was available for instance in pharmacies within the European Community it would not represent evidence of use for human consumption to a significant degree. A food available on the other hand in general food stores would constitute evidence enough¹⁹⁰.

The Neville Craddock Associates discussion paper put forward the need for clarification regarding the concept presented in this section as described in chapter 4.5¹⁹¹. To understand how this concept is used in practice the CAFAB members were asked which criteria are employed to establish 'human consumption to a significant degree'.

Dr. van Rossum explains that for food that have been consumed before 1997 the situation seems simple because it is the company that has to prove that it was consumed in Europe before that date. Further, Companies may seek confirmation from the MSs involved and sometimes there will be a discussion between different MSs.

In spite of this he states: *'there is not a formal decision making machine, there is an informal scene of MSs operation together under the chair of the European Commission in the NF Working Group'*. He describes that when there are doubts about the consumption this is the means to settle this issue. If one MS is convinced that the information is correct, there is usually no problem with the other MSs. Moreover, *'if e.g. France says a food in question was on their market it is a given fact for us, it means that the product is not novel'*. Dr. van Rossum says that it is all about significant use. He refers to discussions in the past about number of kg imported into the EU and if this could be classified as significant history of consumption.

He explains further that they have had difficulties in interpreting whether or not there was a significant use before a certain date. In addition there were discussions on whether the use of a supplement was significant use or medical use.

Because there is no a system for formal decisions within the NFR Mr. van Rossum states: *'so it is really up to the companies to decide whether their product is a NF'*. This is because the starting point is the obligation for companies to comply with all relevant legislation. He explains: *'if you're planning to sell a food, you should consider if this would be a NF in the EU'. 'If so, you should file a safety dossier for authorisation or notification'. 'So only products would have to be discussed regarding their status if there is doubt about the significant history of consumption within the EU'. 'A company would start this discussion by contacting a member state where the previous consumption would have taken place'. 'However, the company itself should supply the evidence for their case.'* *'And we can only help to interpret the legislation as it is'*.

Mr. Riediger explains that you would need a lot of information from trade records to establish 'human consumption to a significant degree'. As an example he describes that they could maybe get information from the chamber of economics (Wirtschaftskammer), and if things are sometimes unclear he states: *'you just have to trust the information given to you'*.

He further adds that there is often the problem with significant amounts, because they were only sold in e.g. Chinese or Indian shops. According to him it is getting more and more trendy to cook exotic food products and these are changes one should be aware of. He states: *'dealing with every product through the NFR is too much in my opinion'. 'It could be dealt with, lets say traditional foods used in our countries, which have been used for many years only by small groups of the population and have to be checked for safety issues also by using knowledge from other MS'*.

¹⁹⁰ Commission Services Discussion paper, 2002: 2.

¹⁹¹ 2005:5-7.

2.3.5 Burden of Proof

According to the CAFAB members providing the information for the risk assessment is laid down in the NFR and is also in line with the GFL.

Mr. van Rossum states: *'I think they are the only ones that are in place to give the information on their products.'* *'They are responsible for what they are doing and if you are in no position of providing the information you should not be selling food.'*

Mr. Riediger explains: *'If we don't have any data about the food in question it becomes very difficult for the risk management in the MS, not only regarding the risk assessment.'* *'There would be too many questions to answer.'*

Mr. Escobedo and Mr. Kutsch Lojenga believe that asking businesses to provide the information is against international trade rules (WTO). Mr. Escobedo states: *'it should normally be the EU possibly through EFSA that needs to conduct a risk assessment study.'* *'Then the EU should ask the businesses to comply in relation to the results of the risks assessment study. This is how the SPS agreement dictates how it should work.'*

Nevertheless, they believe there is a practical side to the matter as Mr. Escobedo explains: *'in practical terms you risk the fact that the EC might be over loaded with work and risk that it could take several years before the application would be authorised.'*

They both think that the businesses should provide the information as long as it does not cause big difficulties and costs.

Mrs. Dellaert believes that as far as traditional food is concerned it depends what proof is requested. She explains that if for instance a country has statistics for over more than the last 15 years over the production and consumption of the crop, and this is accepted as proof, then the burden is limited. However, if there are no statistics she thinks that the EU should support the investigation of data needed for proof. On the other hand Mrs. Dellaert thinks it is different when it concerns real NFs. On that matter she is of the opinion that the firm developing and producing the food should bear the burden.

The following chapter will present strategies that the experts were aware of that the FEBs apply to overcome the problems linked to the NFR. These strategies will be complemented with examples.

2.4 Strategies

Mr. Escobedo from UNCTAD and Ms. van Beuzekom from the CBI explain that they have experience with companies that group together to meet the investment cost of the NFR. Escobedo gives the Baobab case as an example. A business association led the application process and now the authorisation sits with this association and not with one operator¹⁹². Another example is the Yakon in Peru; different stakeholders are brought together and trying to apply together as a country rather than a business.

However, individually Ms. van Beuzekom thinks the FEBs stop exporting the product, and start exporting something else in stead. This is also supported by Prof. Geuns. He explains that about three or four years ago he was invited to Paraguay where he had to explain what was required for the NFR. However, they told him it was so expensive that it was impossible for them to go through with an application.

¹⁹² See chapter 5.2.

The CAFAB member, Mr. Riedger supports the idea that it would be better if not just one small company would file an application, but rather a country or region. Still, he states: *‘for the current regulation I might tell small companies that they have no chance, if it really is a NF’*.

A strategy used by the FEBs was to export unauthorised foods as described in chapter 8, section 1.5.4. Mrs. Espinosa working at CORPEI does not support this strategy. She states: *‘I would not suggest Ecuadorian companies to try and export products that are not authorised’*. The strategy or assistance that CORPEI applies is to try and help the smaller companies by for instance gathering information for European authorities about different products exported from Ecuador.

Mrs. Dellaert explains that she knows that companies export NFs to the fresh market in small quantities to the European market. This is a strategy that works well as long as the quantity is low. As an example she refers to the product Lucuma from Peru. She explains further that the large processing industries which are also more controlled by inspection services and so on, are generally not interested in importing foods that cannot be proven to have been imported before. She mentions Noni as an example of a novel product that has gone through the authorisation process. However, she states: *‘but there is a lot of money behind the Tahiti Noni industry’*.

Mr. Michael Hermann from the International Plant Genetic Resources Institute (IPRG) also supports this. He states: *‘big companies such as Unilever or Moringa Inc. have the financial and human resources to deal with the NFR’*.

Another example is given by Prof. Geuns; he explains that Cargill, Coca Cola spent about 10 million dollars to get an authorisation on Steviol glycoside in the USA.

Figure 2 below, describes the development of exports of Lucuma to the EU and also to the USA from 2000 until 2006.

Table 2 Export Development of Lucuma pr. destination in \$US FOB, from December 2000 to December 2006

| Destination | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | Total |
|---------------|----------|----------|-----------|-----------|-----------|-----------|-----------|------------|
| United States | 5 727,98 | 6 008,12 | 18 947,05 | 28 935,57 | 38 600,62 | 71 736,76 | 96 401,66 | 266 357,76 |
| France | | | 1 288,65 | 31 942,07 | 12 085,97 | 720,61 | 16 219,99 | 62 257,29 |
| Spain | | 226,40 | | 1 006,25 | 2 402,60 | 585,00 | 3 347,86 | 7 568,11 |
| Italia | 1 191,24 | 253,36 | 1 368,33 | 1 775,30 | 2 364,67 | 4 147,77 | 2 573,28 | 13 673,95 |
| Germany | | 49,55 | 848,72 | 11 866,58 | 312,00 | 1 377,61 | 30,25 | 14 484,71 |
| UK | | | 15,00 | | 57,00 | 121,60 | 8 225,80 | 8 419,40 |

Source 2: Mrs. Lidwine Dellaert

The table clearly indicates exports of Lucuma to several European countries. As can be seen from the table export to the European countries do not have a constant growth as for the Lucuma exported to the USA, where the fruit is not a NF.

Mrs. Dellaert explains that the Peruvian government tried to lift the ban on the product by negotiating with the European authorities, and also by trying to persuade the Spanish and Italian government to provide the information that Lucuma had been imported into their countries in big quantities already before 1997. However, the Spanish and Italian government were not able to prove it.

It is interesting to see from the table that Italy has imported Lucuma for thousands of dollars since 2000. It seems likely that this product would also have been on the market before 1997.

As for the farmers association Mrs. Dellaert assisted, they decided not to go through with the authorisation procedure because they did not have the budget to do so. She advised the association to continue to export to the USA and Australia and in addition to focus more on increasing their markets in Latin America. She sees this as a more profitable solution instead of spending their money proving that the product is safe.

Four of the other experts are aware of unauthorised NFs are exported to the European market in small quantities. Mr. Escobedo has made an important observation with regards to foods being imported into Switzerland. These foods pass through the EU and some of the products are left there. He states: *'because Switzerland has different types of regulation in regards to these types of food'* [food which are seen as novel within the EU].

This chapter has described different strategies used by FEBs when faced with the NFR as told by the experts. The example of Lucuma gave an indication of unauthorised NFs exported to the European market. In the following section other examples of NFs will be explained to underline the problems experienced with the authorisation procedure.

2.5 Novel Food Cases

2.5.1 Exotic products from Ecuador

Mrs. Espinosa working at CORPEI gives several examples of products from Ecuador, which are considered novel in the EU.

She refers to the fruit Arazá (*Eugenia Stipitata*). She explains that the product was accepted by a big company in Germany, but could not be approved due to the NFR.

An Ecuadorian company wanted to produce Arazá juice (concentrated juice) but had to start producing other juices due to the NFR. She says she contacted a laboratory in Belgium to conduct a risk analysis for Arazá. She states: *'when I talked to the director of the laboratory to ask for the price to conduct the risk assessment, he laughed at me'*. *'They thought it was very funny that we had to do a risk assessment for a product that is consumed on a regular basis in Ecuador'*. They could not go through with the assessment¹⁹³ because it would cost about €100 000.

They also experienced problems with the product Babaco (*Carisa pentagona*) in Spain. The Babaco was one of the ingredients in cans with mixed cocktail fruits. Mr. Espinosa explains that several cases were destroyed in Spain because they contained the fruit and the authorities said it was a NF. She states: *'it took me more than six months to convince the Spanish authorities that Babaco was exported to the EU before 1997'*. *'I sent them for instance many invoices from 1989 and 1992 to 1994.'* *'These were small quantities; 200-300 kg pr. month but Spain did not want to accept it'*.

She went to the EC and said this was not fair from a trade point of view. Further, the German authority told her that she should apply to them. *'I asked them to help me to prove that Babaco was on the German market before 1997'*. *'I sent publications to Spain from a big German company who was importing Babaco'*. The quantity of imported Babaco is now much bigger, about one tonne per year, but as she says: *'it will always be a small market'*.

¹⁹³ Feed concentrated juice to rats

Another product namely, Tamarillos (*Solanum betaceum*) was exported to Spain. The product was already on the Spanish market, but three of their consignments were destroyed. She describes that one was about 50 kg and another around 100 kg, which came by air. *'We proved that this product was sold in Madrid coming from Columbia'. 'And also here it took us a long time to convince them, we have had many problems with Spain'*. She explains that for instance Germany is much more open to new products.

She believes that because the products come in such small amounts it is hard to prove that they have entered the market. *'We don't have a specific nomenclature for these products; they come as "the others"'*. As soon as the proposed legislation goes through, CORPEI will send a list of at least 20 fruits for approval.

When asked how the NFR impacts FEBs in Ecuador she explains that CORPEI has encouraged Ecuadorian companies to develop new products for exports because the market is saturated with bananas. She exclaims: *'there are many consumers, which are originally from Latin America who would love to buy the products from their home country, such as Tamarillos'. 'Take for instance Physalis (Physalis peruviana) which can be found in every supermarket, but who buys them?' 'The people who know them such as immigrants.'* *'You don't eat them because they are bad for your health, you just don't know them.'*

2.5.2 Stevia

The Stevia case was introduced in chapter 5.3. Prof. Geuns explains that Stevia has not been authorised yet, he states: *'it is a crime against humanity, because it is the safest sweetener I know'*.

He explains that European companies are very interested in Stevia because *'they know it is the best compound'*. Prof. Geuns believes it is the lobbying from European sugar industries and synthetic sweetener industries, which work against the approval of Stevia. He believes that the former scientific committee for food has made many errors in the opinion on Stevioside. *'There is not one serious scientific paper that proves that Stevia or Steviol glycoside is harmful.'*

Table 3 explains some of the “errors” made by the former SCF (before the foundation of EFSA) with regards to their opinion on Stevioside as sweetener¹⁹⁴. According to Geuns (2008) there are big discrepancies between *the opinion* and the scientific facts, which can be seen below.

¹⁹⁴ Scientific Committee on Food. Opinion on Stevioside as a sweetener. Adopted on 17/06/1999. SCF/CS/ADD/EDUL/167 final.

Table 3 "Errors" made by the SCF for food of EU in their opinion on stevioside as sweetener

| Erronous claims in the opinion of the SC | Facts from the scientific literature |
|---|---|
| <p>- p.3, line 17: Degradation of stevioside by various digestive enzymes from the gastrointestinal tract (8 = Hutapea et al., 1997)</p> <p>- p. 4, line 36: effects on male reproductive system, and p.4, line 43: used as a male contraceptive.</p> <p>- p.4, line 44, and 4, line 45, A target organ toxicity directed to the male reproductive system</p> | <p>- The authors of ref. 8 have proven that these enzymes did not degrade stevioside</p> <p>- In the cited "Indian story" it were the women who drank the tea.</p> <p>- stevia extracts were given to the female rats and it is said that <u>the males were never in contact with the stevia extracts!</u> Moreover, the results of Planas and Kuc (1968) were refuted by Shiotsu (1996)</p> |

Source 3: Geuns (2008)

The author believes that faulty opinions like those presented above undermine the credibility of EU institutions and EC decisions¹⁹⁵.

He thinks that the NF procedure is based on negative proof; *'this cannot be done in science'. 'This opens the possibility to ask "a thousand additional questions" and this is what happens.'* Prof. Geuns explains that they were asked by the German authorities to study the stability of Stevia leaves. *'In a leaf there are thousands of compounds, so what should we measure?'* *'Because it is not specified what they are looking for they can just continue and continue to ask question in this way.'*

He says he could prove that about 164 million people are consuming Stevia every day world wide, *'but for them it seems not sufficient'* *'much of the required research is not necessary!'* *'It should be looked at case by case.'* He refers to what is stated by Knudsen et al. (2008). The authors note that the lack of regulatory and scientific consensus on the type of safety data needed to perform the safety assessment is one of the main difficulties experienced with the NFR¹⁹⁶.

Prof. Geuns believes there is too much room for interpretation because everything is based on negative proof. With regards to Stevia there have been many stories regarding effects on male fertility, *'but it is all based on a lie because the former scientific committee did not seem to know the difference between male and female animals.'* *'I do not believe that scientists can do this, so something else is going on and this is corruption in my opinion.'*

He thinks the best thing that could happen is that the NFR disappears. Further, he believes this regulation has been created by the food industry. *'For me it is more a question about patents and intellectual property and protecting the market.'* *'In my eyes the NFR has nothing to do with safety. If the food laws in EU have something to do with safety they should forbid the use of sugar and fructose.'* *'I see it as a crime because fructose directly induces insulin resistance so you are creating diabetics instead of curing them.'*

¹⁹⁵ 2008:2

¹⁹⁶ p:1683

3. Expert Interviews: The New Novel Foods Regulation

This chapter portrays the findings related to the NNFR. First, the general perceptions will be presented, second, aspects linked to the authorisation procedure will be described, and finally opinions regarding the concept ‘history of safe food use’ will be illustrated.

3.1 General Perceptions

The experts found it very positive that traditional food from third countries was in a separate category. In addition, they were pleased with the centralised authorisation procedure. Nevertheless, there were still some critical points regarding the proposal.

Mr. Escobedo described three negative aspects with the proposal. First, the uncertainty in regards to the application, second, the lack of clarity regarding key concepts, such as the history of safe use. The final aspect regards intellectual property and how that would work in regards to traditional foods. He states: *‘I see it personally as a contradiction, trying to put intellectual property on traditional foods is trying to privatise what is the public domain’*.

Mr. Kutsch Lojenga expressed concerns regarding which information would be required for the assessment and who would make the final decision.

Further, he was also apprehensive with the fact that an approval is still needed. He refers to PhytoTrade Africa that got Baobab approved. Because they have the authorisation this makes PhytoTrade the ones that have to make sure that all their suppliers meet the specifications of the product, because they have approved baobab specifications. He states: *‘this means that every time they export something from Africa, a batch analysis has to be conducted by a laboratory, this is quite expensive’*. Further: *‘PhytoTrade needs to be sure that their members always comply with the right specification’*. *‘This is quite difficult to comply with.’*

Mrs. Dellaert is also concerned with the administration the NNFR will impose on the exporters. She was not very happy with the proposal due to this.

Mrs. Espinosa finds the proposal very interesting and she explains that the EC took most of their recommendations into consideration. She also sees it as is very positive that traditional foods have been listed specifically. She states: *‘we may have to send all the information about the fruit and maybe the composition of the fruit in question but it is not a risk assessment that has to be conducted’*. *‘I think the proposal as it has been presented could be very good for the Latin American countries.’* Nevertheless, she believes that certain aspects of the NNFR could have been explained better. At CORPEI they thought the proposal would be published and accepted at the end of this year¹⁹⁷, *‘but unfortunately the discussions are continuing’*.

Mrs. Espinosa finds it very hard to understanding the current situation. *‘It is not a market problem, not a safety problem, but something else’*. *‘I do not understand’*. Further: *‘it could have been a political problem if we were talking about thousands of tonnes of a product’*. *‘Then it could have been an issue of trade protection, but it is not going to be in such big quantities.’* *‘They said they were worried about the safety aspects with regards to e.g. allergic or pregnant women but that does not mean that they can forbid everybody to eat a specific fruit?’*

‘We export these fruits to USA and Japan and they have no problems with them.’ *‘And it is very difficult to get to the Japanese market.’* *‘So you see the products are not just eaten in Ecuador they are also consumed safely in other countries.’*

‘We were so pleased with the NF proposal, the European Commission did a very good job and now it seems that all our work is lost.’

¹⁹⁷ 2008.

Ms. van Beuzekom says *'it is still a draft so many things are still unclear'*. She is concerned about possible problems related to the definitions in the NNFR. *'How will they be defined and by whom?' 'If the definitions are vague it might be an advantage, namely flexibility, but it can also be a disadvantage because you do not know what the EC wants.'* *'Even so, I am convinced that it will be better than the current regulation.'*

Dr. van Rossum explains that it will be very important to define what exactly will be assessed. *'We are talking about how an assessment of these types of products will take place.'* *'But still, rather than starting from scratch where you have to prove that it is as safe as other foods we have known for a long time, the question here would be to prove that it is safely being consumed for a certain time within a large part of the population outside of the EU.'* *'All depends on how these general principles are applied in practice.'*

In the next section specific opinions regarding the NNFR authorisation procedure will be presented.

3.2 Authorisation Procedure

The positive side with regards to the authorisation procedure according to Mr. Kutsch Lojenga is that there is a clear recognition of traditional products in DCs and they will receive different treatment.

However, on the negative side as he underlines, *'there is just less criteria or information required to approve the products'*. *'But the legislation does not specify exactly which information is required and who will take the decision'*. *'It is my personal understanding that it is EFSA, which will make the decision, and they may still require additional information'*.

Mrs. van Beuzekom also has her concerns with regards to EFSA. She says: *'it may also be positive that EFSA will do the assessments because it might be more efficient'*. *'But I am not sure how EFSA specifically will deal with the authorisations'*. *'They are very technical in their work and this worries me'*.

Ms. Viloría explains that in the case of traditional food from third countries EFSA will go through the dossiers and form an opinion on the history of safe food use of the product. She underlines that it is not a complete risk assessment, as is the case for the remaining NFs under the scope. Ms. Viloría states: *'the clue is if the business can prove that the food has been used in a safe way'*. *'Further, they will look and see of course if there are no health concerns based on the information sent by the applicant'*.

Ms. Viloría was asked if she perceives EFSA as being too technical as well, she explains that during the discussions in the past some of the MS wanted to keep the right to assess the information themselves. The EC and other MS were in favour of making a central procedure. This would provide for a more harmonized and efficient procedure. *'If we take a look at the framework of food safety, EFSA is our central authority.'* *'You are right, normally they are very technical.'* *'This is one of the uncertainties with regards to the proposal'*. *'I believe they have to learn how to deal with this kind of information, but naturally I have no doubts they are capable to do so.'* *'The EC might have the experience to take this role but I believe not the capacity.'* *'At least they did not want to take this role.'* *'The central assessment was made trying to guarantee harmonization on this procedure.'* *'I think it is very important that the Commission works together with EFSA on this matter. Further, it is very important to have clear guidelines.'*

When the CAFAB members Mr. Riediger and Mr. van Rossum were asked what they thought about the authorisation procedure, Mr. Riediger said: *'yes, it is better than the current regulation for novel traditional foods'. 'The safety assessment is too strict for these products in the current regulation; they only had a chance if they had a big company behind them for the application process'. 'But it really depends on the way the products will be evaluated and I hope it can be done on an easy way for safe traditional NFs'.*

Dr. van Rossum believes that an improvement can only be judged after it has been working for some time, *'but I think that the basic concept of harmonising the assessment more is a good thing'. 'I also think that all the MS have shown with this new system they want to have a central role of the European Food Safety Authority'.*

3.2.1 Defining novelty

The date 15 May 1997 was upheld in the NNFR, although stakeholders have found it to be illogical. When Mr. Riediger was asked why he thought this date was also used as point of reference in the NNFR he stated: *'if you don't still use this date you can throw the regulation away.' 'If you would change the date, it would make things very unclear and uncertain.'* *'Everything that has been done before would not be usable. If the use of this specific date is a good thing is another discussion.'*

Dr. van Rossum explains that there were discussions from a legal perspective if it was the right thing to continue using the date. *'I think that the argumentation was that if it was not used before this date then it would have been a NF, and even if it was on the market between 1997 and now this history would have been illegal, it would have been difficult to use that history now to say that it is safe.'* *'I can imagine that a product that might have seemed novel at one time after 1997 which were still marketed, and were not harmful and not prohibited, you could have a story there, saying we have data now showing that its safe, but even so, if you have this data you should put it in a dossier and still file the dossier.'* *'This is the whole difference again between whether it is novel or safe.'*

As for the concept 'significant degree' which is stated in the NF definition, Ms. Viloría explains that they are currently working on a paper trying to define the concept. *'In my personal opinion, the concept applies for all the definitions under the regulation and especially for NFs that are produced within the EU.'*

'In the current regulation [NFR] it also applies for traditional products.' *'The proposed revised regulation [NNFR] has a specific definition for traditional food from a third country which is mainly based on the demonstration of a history of safe use for this products in the country of origin.'*

Article 7 sets the decisive factors for the content of the Community list as described in chapter 7.3.2. This means that traditional food from third countries will deviate from the updating of the Community list, which is intended for other NFs. This positions the fact there is a generic application procedure for traditional food from third countries.

The experts were asked if they found that this procedure would make it easier for the FEBs in DCs. Some of the statements given will be presented in the next section.

3.2.2 Generic Application

Ms. Viloría believes that the shift from specific to generic application is an improvement *'because generic applications mean less administrative burdens'*. However, she also

underlines that: *'at the same time the introduction of generic applications leads also to discussions on issues as data protection and level of specification regarding the authorized food'*.

Mr. Escobedo shares this concern. He believes it really depends on the application process. *'If the application process is very costly and time consuming then you would be hampering innovation if you would not be giving the authorisation to the applicant, which means you would have less incentive to apply'*. *'In general terms I am in favour of the generic applications but the regulation needs to address key issues to continue the incentives for businesses, communities or groups to apply'*.

However, he states: *'I think from a development perspective it is very positive. For many of the cases regarding traditional foods it's the local community that produce these products so that the right should not be given to one producer'*.

Mr. Kutsch Lojenga is not sure if it is an improvement. *'It depends on the costs that will be involved in getting the product approved.'* *'If the costs linked to the approval will not be too high then, I think it will be a big improvement.'* *'But if the costs will still be relatively high (€100 000 - 200 000) to develop the dossier, then I am not sure if it is an improvement.'*

As described earlier in the research the definitions and concepts used in the NFR has been subject of much criticism. The subsequent section will present the experts' understanding and views of the concepts and definitions presented in the NNFR.

3.3 History of Safe Food Use

Few foods have been subject to toxicological studies, nevertheless foods are generally considered safe to eat. Many traditional foods are considered safe even if the food may contain antinutrients, toxins and/or allergens. As long as appropriate care is taken during development, production, processing, storage, handling and preparation they are considered safe. The knowledge required to manage the risks associated with traditional foods has been acquired in the course of their long history of safe use.¹⁹⁸

Constable et al. (2007) explain that the concept 'history of safe food use' is widely used around the world as a cornerstone of the safety evaluation of NF. Even so, the concept has *per se* seldom been defined.¹⁹⁹

The NNFR introduces the concept 'history of safe food use' in relation to 'traditional food from a third country'²⁰⁰. These concepts give rise to many uncertainties with regards to interpretation.

The experts were consulted on two matters with regards to the concept 'history of safe food use'. First, they were asked to explain how they value the concept and second, how they think it will be defined and interpreted. Their understandings will be presented in the next section.

The experts clearly pointed out that the concept 'history of safe food use' would be a very important aspect in the NNFR. However, they were concerned with the definition of the concept and how it would be applied in practice, which has been a problem with other concepts in the NFR.

¹⁹⁸ Constable et al., 2007:1-2.

¹⁹⁹ p:2

²⁰⁰ Article 3(2)(b)and (c)

Mr. Kutsch Lojenga believes it is a big step forwards that this concept has been included but: *'it depends on how you define the history of safe food use'*. He explains: *'because just the history of use is not enough, you also need to prove that the food use has been safe'*. *'How are you going to prove this?'* *'Is history one generation, two generations or longer or shorter, is it in a small part of the country, big part of the country, what kind of population, what makes it significant and so on'*. *'And how will this be implemented?'* His worry is that: *'EFSA has to check this and if they start to develop all kinds of rules and regulation for the interpretation of the history of safe food use'*. *'It means that it can still result in quite heavy dossiers'*.

Mr. Kutsch Lojenga is also concerned about the fact that traditional food is not separated from the history of safe food use. *'If it were just traditional food from a third country it would have been easy.'*

Ms. van Beuzekom sees it as an important and powerful element. *'It states that the products are safe, an advantage for the producers'*. *'An the longer it has been in use, the better, it then shows that it is a normal food product.'*

Mr. Vischer understands the concept to be *'nothing more or less than normal import conditions'*. *'I think this regulation is not there to prevent international trade but to regulate it.'* *'To be able to know what you are importing and what you can expect from these products.'* *'From this reasoning there is no more behind it then that we want to be sure that we have safe food.'*

Ms. Vioria says there are two things you have to differentiate between when looking at the question of 'history of safe food use'. She states: *'you have products, which are new and produced within the EU and those that are traditional foods from outside the Union and thus new in the EU-market.'* Further: *'The specific category for traditional foods was created within the revised proposal on NF trying to minimize the possible trade barriers of course within a food safety framework.'*

3.3.1 Valid data

Article 3 (2)(c) in the NNFR states that ... *'the safety of the food in question is confirmed with **compositional data** and from experience of use and continued use in the normal diet of a large part of the population of the country.'*

When Ms. Vioria was asked which data would be accepted as 'valid' she explained that examples of data which should be included in the dossier of traditional food from a third country are: *'clear description of the food, name, composition, country of origin, data has to prove that it has been used in a safe way for a certain amount of years'*. *'If applicable, also the conditions of use for instance if it needs to be cooked and also if the consumer needs to be informed how it should be used safely'*. *'This should be put also on the label of the product.'*

As for the NNFR guidelines, she elaborates that they have not been developed yet.

Nevertheless, she believes that when the guidelines are in place there will be definitely less room for interpretation. *'I think the positive thing is that there is a simplified procedure especially for traditional foods.'* *'We have tried to describe a very clear procedure, but you are right the question regarding which data is needed is difficult to state.'* *'I think we need to try and define it in the most practical manner possible.'*

With regards to analysing data linked to traditional food and safe use, Mr. Riediger explains that for instance the data the applicants provide may not be from a recognised laboratory in Europe. He further describes that foods are very complicated to evaluate with regards to the whole plant. *'To conduct the risk assessment of such a food is really not easy.'* Constable et al. (2007) and Knudsen et al. (2008) also support this view. While there exist well established paradigms for safety assessment of isolated and extracted plant products like e.g. sugars and fats, there are no commonly accepted international approaches to assess the safety of complex foods like fruits, vegetables and other plant parts derived from novel sources²⁰¹.

Mr. Riediger further explains that: *'if one has good information of safe use from a third country it is very important data, but the problem is that people are "not the same people"'. 'For example if you compare the Japanese people with the Europeans, the Japanese eat a lot of Iodine (from fish and algae products) and it is not a problem for them, this cannot be done by Europeans.'* *'Discussions like these and topics like allergenicity are problematic topics.'* Constable et al. (2007) also support this. The authors state: *'the history of use of the traditional food may also indicate certain food safety concerns (e.g. allergenicity). 'Thus "history of safe use" does not necessarily equate to absolute safety, rather, it provides a benchmark indicating a level of safety that, subject to appropriate risk management procedures (e.g. labelling or cooking advice), is regarded as acceptable by consumers of the traditional food.'*²⁰²

In addition, Mr. Riediger states: *'When you don't have data of allergens (which is often the case for developing countries) it is a problem.'* *'This can be a big issue for establishing food safety.'* *'And this can naturally hinder many traditional products from entering the market.'* *'But personally I do not think it is ok to treat some of these products as poisonous plants.'* *'In the NF Working Group we discussed the concept "history of safe food use and we are still working on it.'* *'It is a very important question.'*

When Dr. van Rossum was asked how the concept 'history of safe food use' would be defined in the NNFR, he says that: *'we have some idea and I can say we have stressed this point when we have talked to our colleagues at the Ministry of Health. He underlines, from a personal view, that he thinks it is very important to have a European dimension of the implementation of the concepts. 'We would not really want to have all the MSs to have their own opinion without going through a process where you come to a final European idea whether or not the regulation is applicable.'* *'How this will be put in the legislation is an issue for the negotiations.'*

He further states: *'you can write down what a NF is, but just by changing a definition will not make the questions go away'. 'It is all about the implementation.'*

As explained above Article 3 (2)(c) in the NNFR explains what the 'history of food use' means. The definition also states: *'... experience of use and continued use in the normal diet of a large part of the population of the country.'*

Dr. van Rossum believes that the basic idea behind using these concepts are good, *'because you can imagine that there would be subgroups consuming the strangest kind of product that you could not see as a normal food'. 'The whole idea is to stress this idea of proportionality for food that are widely consumed, for which there are real evidence that it does not produce any harm.'* *'You are measuring a system in a completely different type of the world with your own concepts of food safety.'*

²⁰¹ Knudsen et al., 2008:1681.

²⁰² p:3

Ms. Vitoria thinks that the EC chose the concept 'normal diet' in the NNFR because this implies a large use of the food within the population and at the same time gives that the use of the food, a common use is in the country of origin: 'traditionally consumed'.

She further explains that with regards to 'at least one generation': *'we are at this moment talking about 25 years'*. *'It is very difficult to define these concepts.'* *'Why was the period set at 25 years? I don't know exactly, I think has to do with definition of one generation accepted in other guidelines or law.'*

9. Discussion

1. Impact of EU Food legislation on FEBs in Developing Countries

The majority of the FEBs did not find it hard to fulfil the requirements of EU food legislation and described other problems as graver. The obstacles they mentioned were shipping and packaging costs, maintaining quality during export and maintaining quality in general, regional problems in specific areas (e.g. political conflicts), certificate of origin, finding an opening in the market for their products, avoiding middlemen, finances, logistics and being a landlocked country.

When the data was analysed the author was surprised not to find more statements and comments like the ones presented below. For instance, a producer from Uganda with 10 years of experience with exporting to the EU states: *'the problem is the ever-changing food safety regulations, which involve very high investments, in order to comply'*. Another informant, also from Uganda, states that his experience includes opaque regulations and excessive paper trails, which lead to high costs.

The market survey conducted by CBI presented in chapter 2.2 pointed out the opportunities and threats for exporters of fruit and vegetables from DCs to the EU.

One of the points mentioned under threats is the GlobalGAP (former EurepGAP) and its certification requirements, which according to the survey involve serious managerial and technical efforts and high costs.

In this research the FEBs gave another viewpoint. According to the informants, to be certified under GlobalGAP made it easier to export to the EU. Possible difficulties with being certified under GlobalGAP were not mentioned by the informants.

It also appeared that it was easier to export to the EU if they were certified as organic. This was the case for organic certification under the EurepGAP as well for other types of organic certification. One of the informants from Uganda describe that being organic certified is a very good strategy for his company.

What is interesting to note is that the FEBs found organic certification to be an advantage in reaching the EU market and not a NTB to trade as mentioned by Martinez and Bañados (2004). This was an unexpected result. Even if the number of informants was low and a generalisation cannot be based on these findings, the fact that this was not information sought after makes it unbiased. In other words, the informants gave these answers without being asked if organic certification was a strategy for them. An informant from Uganda states: *'... because we are certified organic we have as a result not too many problems with for instance the EurepGAP, standards and so on ... this is very useful for us'*.

The market survey conducted by the CBI can support this statement, namely the growing demand for organic, fair-trade and sustainable products.

The FEBs further mentioned shipping and packaging costs as well as being a landlocked country as obstacles to export. This is supported by the market survey that makes it clear that higher transport costs give the DC suppliers a relatively weak competitive position.

In addition, the FEBs mentioned quality in various forms as a perceived problem. Not surprisingly, this is also mentioned in the CBI market survey. The high demand for top quality is growing in the old EU MSs and increases in the east European countries. As a result maintaining good quality is used as a strategy by the FEBs.

Why the majority of informants did not find the EU food legislation too difficult to deal with is difficult to elaborate upon without further follow-up questions to the informants.

Nevertheless, because they see the problems mentioned at the beginning of this chapter as much graver, it seems that complying with regulation comes second.

As described in chapter 8.1 most of the informants were connected to a development agency and were able to obtain the information they needed on how to comply with regulations through them. This can imply two things. First, the sample is biased. It can indicate that because they are linked to a developing agency they have a bigger ‘chance’ of successfully complying with regulations. Second, it can imply that exporters linked to development agency find it easier to fulfil the terms of EU food regulation as a consequence of their involvement with an agency. If this were so, it would be very interesting to conduct a research about the issue in question by comparing exporters from DCs who are linked to an agency with those who are not. Henson and Jaffee (2008) as described in chapter 2.3 suggest something analogous. They state that for future research further emphasis should be put on programmes of technical assistance and support. The rationale behind this is to be able to learn more about strategic responses to food safety standards for DC.

As for the experts experience with DC and food export to the EU, Mr. Escobedo explains that if you are dealing with food products that are familiar to the European market that have not become a political issue *‘I think entry to the market is one of the easiest with regards to the other major markets in the world’*.

However he states that: *‘if you look at more political sensitive products like bananas and coffee the scenario changes, especially if your product is not well known in Europe, then you have a set of obstacles linked not only to borders, but also in terms of knowledge, how to consume the products, labelling, and marketing requirements’*. *‘If you are in one of these “extremes” (well known and political or unknown products) you have problems entering the European market.’*

The data presented above indicates that FEBs in DC face bigger challenges than European food regulation. On the other hand the example of European aflatoxin standard presented in the introduction paints a clear picture of the inflexibility of food safety standards in the EU. The sample in this research can only indicate practical experiences and not an overall understanding. Nevertheless, the data presented along with the literature indicates a very complex picture of food export from DC to the EU.

2. The Impact of the Novel Foods Regulation on FEBs in Developing Countries

The author was surprised to find that very few exporters knew the NFR and the problems it has caused for DC as for instance noted in the discussion paper by the Neville Craddock Associates. In chapter 8.1 the author suggested explanations to why the FEBs were not acquainted with the NFR and why it was an obstacle to few of the FEBs.

The first explanation suggests that it is because they do not produce any foods that are novel to the European Community. The second explanation proposes a more interesting approach, the FEBs fall into the demand of the European market. Mrs. Dellaert sheds light on this implication. She explains that production of European foods like asparagus or grapes for wine for export increase, and traditional varieties decrease. This has also an impact on the conservation of biodiversity as put forward by Mr. Escobedo.

As long as there is a demand for their product, the incentive to start exporting ‘new’ or innovative products are not there. As described by Brookes (2007) the current NF approval mechanism encourages companies to be followers to the market rather than innovators.

In addition, Blind et al. (2004) found large consensus that approval procedures such as in the NFR are both too costly and long which creates a negative environment for innovation. This means that there is little incentive to go through with a NF application. If a FEB would want

to proceed with an application it would most likely be full stop. Because of the costs linked to NF applications only companies like Morinda Inc. can meet the expenses as described by Mr. Hermann. As Henson and Jaffee (2006) illustrate, it is more common that food safety standards act to prevent or exclude only parts of a country's export sector. However, as the authors state: *'in the worst case, food safety standards can exclude exports from an entire country'*, which is the case of traditional NFs from outside the EU.

The general result from this research indicates that the NFR has not had a major impact on FEBs in DC. As Ms. van Beuzekom working at the CBI explained, the NFR is a problem only for a minor part of their program. Nevertheless, for the FEBs that try and have tried to export NFs to the EU the problems have been serious.

For UNCTAD's BTI and their BTFP the NFR had serious consequences because they were not able to export the products they had invested time and money in. This situation was the same for CORPEI as Mrs. Espinosa explained in her interview. The exporters from Ecuador, which CORPEI represents, were not able to export any of their products due to the NFR. She refers to several incidents with the Spanish authorities where they had confinements destroyed because the authorities said the fruits were NFs. It is interesting to note that while CORPEI has experienced difficulties with the Spanish authorities regarding products that appeared not to be novel, one of the FEBs reported that he had in fact not had any problems with the same authorities even if he tried to export products that are seen as novel in the European Community. Mrs. van Beuzekom explained that she got complains from producers in Latin America who send their dossiers to Spain. Further, she described that the authorities in Spain do not know how to handle the NF authorisation dossiers.

Peru has also experienced problems with the Spanish authorities. In 2000 shipments of dehydrated Lucuma that had regularly entered through the ports in Italy and Portugal was detained and denied entry through the port of Valencia, Spain as explained in chapter 4.7.

The author has no concrete answer to why there have been so many negative incidents with the Spanish authorities. It can be that it is just a coincidence. However, it is a surprising result that the Spanish authorities was mentioned as a problematic authority in several of the interviews.

An interesting outcome of the interview with Mr. Escobedo working at UNCTAD was his concern with the damage the NFR does to development spillovers. According to him the development link is very important with regards to this specific regulation. Because the NFs often come from the poorest types of communities the NFR has impacts on these rural communities. This is supported by Mrs. Espinosa who underlined the importance of export for small and rural companies in Ecuador. As described in chapter 2.2 Wilson and Abiola (2003) argue that the cost of compliance to food regulations contribute to further marginalisation of smaller and/or poorer countries and weaker economic players, which emphasizes the point made by Mr. Escobedo.

The author believes that other EU legislations than the NFR have the same impact on development spillovers. A good example is the case of aflatoxins as explained earlier in the research. Nevertheless, it is perhaps easier to deal with such a standard or other standards linked to for instance EurepGAP. Because if the product in question is seen as novel within the European Community, at this point there is not much FEBs in DC can do. The CAFAB member Mr. Riediger also supports this, he states: *'for the current regulation I might tell small companies that they have no chance, if it really is a NF'*.

Another development link with regards to the NFR was the informant from Peru. He was exporting Maca to the Netherlands. While one Dutch institution was helping him export Maca another was preventing it. This is probably not the first contradiction with regards to development funding and EU food regulation and technical assistance. Luckily for this exporter he got assistance from the CBI and was able to put forward statistical information that the product in question was on the European market before 1997. As the exporter states: *'the CBI has played a very important role for us in trying to modify the NFR even after this'*. The author is sure that other FEBs do not have the same support and ability to put relevant data forward.

With the impact of the NFR, which strategies have the FEBs created to deal with these challenges? The simplest strategy and maybe the most efficient would be to start producing and exporting something else which is not seen as novel within the European Community. Namely, fall into the demand of the European market as described in the first section of the discussion. Ms. van Beuzekom from the CBI believes that individually, this is what the FEBs do. They stop exporting the NF and start exporting something else. Prof. Geuns also supported this.

However, it was reported through the interviews by both FEBs and the experts that unauthorised NFs are exported in small amounts to the European market. As the informant from Peru explained, it can only be done in small amounts because in bigger scale the risk of being caught will naturally be bigger. Mrs. Dellaert explained that the large processing industries which are more controlled by for instance inspection services are generally not interested in importing foods that cannot be proven to have been imported before. To export unauthorised NFs is in the author's opinion not a very favourable solution to the problems linked to the NFR for FEBs in DC. Mrs. Espinosa does not support this strategy and has not suggested that the Ecuadorian FEBs take advantage of this situation. Nevertheless, it is a strategy that works for some FEBs and the author can understand why they wish to take the risks related to it.

Mrs. Dellaert worked with the Peruvian farmers association Pro-Lucuma as described in chapter 8.2.4. The association could not go through with the authorisation procedure because it was too expensive. The strategy Mrs. Dellaert advised Pro-Lucuma to conduct was to focus on other markets than the EU. She also explained that the Peruvian government tried to lift the ban on the product by negotiating with different European authorities, with no success. Conversely, at the time of writing the author received news from Mrs. Dellaert regarding Lucuma as a NF within the EU. She was very pleased to mediate that the competent French authorities have declared that they have records of imports of the fruit from Peru, which was accepted as sufficient evidence by the EC. Mrs. Dellaert sees this as a big step forward for a large introduction of Lucuma to the European Market.

To be able to deal with the costs linked to the authorisation procedure a few of the experts suggested that several FEBs could group together and send a common application to share the costs. They referred to the Baobab application as explained in chapter 5.2. This seems to be a good strategy. The author believes that the strategy will prove to be very useful in the NNFR because as it seems now that the authorisation procedure will be simpler for traditional foods from third countries as explained in chapter 6.

3. Establishing Novelty

The question of novelty has proven to be very difficult. In this research, chapter 5 introduced the reader to which evidence is needed to establish novelty through three specific cases. The

author finds it surprising that in the Goji berry case none of the individual pieces of information provided unarguable proof of a substantial history of consumption, but rather the combination of evidence made the FSA conclude that Goji berries were not novel to the European market. While in the Stevia case the combination of evidence was not seen as enough to establish that the product was not novel to the EU. It appears that the amount of Stevia on the European market was of bigger quantities than for Goji berries, but the author believes this was overlooked because of questions linked to toxicology and allergenicity or the *'hint of serious side effects'* as Lähteenmäki-Uutela (2007) puts it.

Prof. Geuns has worked with Stevia for many years and has tried to persuade the EC to allow Stevia into the European market. Table 3 shows the mistakes the SCF made with regards to Stevia as a sweetener according to Prof. Geuns. It is rather disturbing if such errors have indeed been made as he states. As Knudsen et al. (2008) point out as well; the lack of regulatory and scientific consensus on the type of safety data needed to perform the safety assessment is one of the main difficulties experienced with the NFR.

This can be seen in coherence with whether soft law should always be followed as stated by Lähteenmäki-Uutela (2007). She explains that it is a general problem with European food and medicine law, where non-binding instruments are often used. There was an overall agreement with the experts that the Commissions Recommendations gave too much room for interpretation leading to the lack of regulatory and scientific consensus as Knudsen et al. (2008) indicates. As Mr. Riediger stated: *'Many times it is hard to give an answer on a scientific basis, which is of course a big problem'*.

'Human consumption to a significant degree' is one of the concepts, which have been subject to criticism by the involved stakeholders. An interesting observation with regards to this issue was noted in the interview with Mrs. Espinosa. She explained that the NFs only arrive in small amounts to the EU. This is because they are usually just meant for instance for certain ethnic markets. They only arrive in small quantities and do not have specific nomenclature but come as "the others" as she states. This makes it hard to prove that they in fact have entered the market. A similar problem was portrayed with the Goji berry case and the relevant commercial records. Because standard practice is to dispose of commercial records after six to seven years it makes it difficult to provide exact evidence. As a result, there was no information on quantities and therefore not possible to comment on how significant the consumption was in the information received from Chinese outlets. The author believes that similar cases will appear in the future where significant consumption may have been established but FEBs will come across the problems mentioned in the Goji berry case and by Mrs. Espinosa.

The third case presented in chapter 5 was the Baobab. It is a very interesting case as evidence of history of safe use outside the EU was taken into account in the application. The history of use provided a reassurance of the safety of the product and conventional safety studies was not seen as necessary. However, multiple tests with regards to nutrition, toxicology and allergenicity were conducted. This example brings optimism with regards to traditional foods from third countries especially with regards to the NNFR.

The burden of proof has been discussed earlier in this research. As stated by Mrs. Dellaert: *'it [authorisation procedure] takes a long time because you have to prove that it [the product] is not bad and a lot of information is needed'*. *'It is very different when the authorities have to prove that it is bad.'* *'With this regulation [NFR] it is the other way around, you have to prove that it is healthy.'*

The burden of proof has fallen on the FEBs in this case, which is seen as an unjustified barrier to trade according to Peru (as described in chapter 4.7) and other Latin American and African countries. It is also supported by most of the experts in theory, however as for instance Mr. Escobedo explains: *'in practical terms you risk the fact that the EC might be over loaded with work and risk that it could take several years before the application would be authorised'*.

The author agrees to this opinion as long as providing the evidence does not cause big obstacles and costs for the FEBs. Even if it is indeed more practical that the FEBs bring the evidence forward, the issue becomes complicated when the fitness for human consumption of a product that is novel to the EU is tested on the record of use inside the European market. This matter does not have very little scientific justification, if any at all. However, this is a discussion, which would require further investigation into the WTO SPS Agreement, which is not the main focus in this research. Nevertheless, it is indeed important and the author is sure that it will be further discussed in SPS Committee Meetings in the future.

The FEBs, which were not acquainted with the NFR, were asked about the burden of proof. What the author found unexpected during the interviews with the FEBs regarding this matter was that they also believed that they should have main responsibility. It was expected to find more negative statements with regards to the burden of proof, but this was not the case. A possible explanation could be that the FEBs have other obstacles that are seen as graver, which was explained in section one in this chapter. It is important to note that this was for FEBs, which had not faced problems with the NFR.

In the next section the NNFR will be discussed to see if it will be a better framework to deal with the difficulties experienced by the FEBs.

4. The NNFR as an adequate framework for solving the problems experienced by FEBs in developing countries

As described in chapter 8.1 only one of the FEBs knew about the NNFR and not in great detail. This limits the research because the FEBs viewpoints are very important to be able to understand if the NNFR will help solve some of the issues they have experienced with the NFR. Nevertheless, the informant that was aware of the NNFR referred to the concepts *'traditional foods from third countries'* and *'history of safe use'* as a very positive development. This was the general opinion among the experts as well. This outlook was an expected outcome of this research because stakeholders involved in the discussions around the NNFR stressed their inclusion and the separate authorisation procedure for traditional foods from third countries.

Mrs. Espinosa believes it will be an improvement for the FEBs in Latin America, especially because the authorisation procedure is not a major risk assessment. However, as the other stakeholders she is waiting for the final NNFR to be published. She also supports the centralised assessment, which will be conducted by EFSA. Both Mr. Kutsch Lojenga and Ms. van Beuzekom are worried about how EFSA will manage the application, as they are very technical people. This is also the opinion of the author. However, as Ms. Viloría explains, the EC may have more experience than EFSA in this matter, but not the capacity. She further underlines the importance of cooperation between EFSA and the EC along with clear guidelines.

Without comprehensible guidelines the author believes that there will be problems similar to those experienced with the NFR. The NFR guidelines were developed for GMOs that suggest a probability of better and clearer guidelines for the NNFR. Even so, the guidelines are of concern to the experts as well. As described above and in chapter 8.3, they are positive to the NNFR but nothing will be clear before the concepts have been defined in further detail, like for instance *'history of safe food use'*. Mr. Kutsch Lojenga's concern is that the *'history of*

safe food use’ is not separated from *‘traditional foods from third countries’*. The author sees this as a concern as well because even if traditional foods have been included the burden of proof linked to the history of safe use may prove to be substantial to the FEBs.

Taking a closer look at the history of safe food use, Constable et al. (2007) explain that the concept *‘history of safe food use’* is widely used around the world as a cornerstone of the safety evaluation of NF. Despite that, the concept has *per se* seldom been defined. This argument emphasizes the uncertainty among the experts of how the concept history of safe use will be interpreted. Mr. Riediger underlined that: *‘good information of safe use from a third country is very important data’*. However, he stressed the point that people are different (Europeans vs. Japanese) and traditional food may affect people differently, for instance with regards to allergenicity. The author does not see this as a substantial argument and refers to Knudsen et al. (2008). The authors describe that in contrast to for instance food additives, as long as the new products are in their original shape as fruits and vegetables usually are very visible for the consumers. The consumers can then on the basis of the available information make an informed choice of their own.

Certain choices should be left to the consumer if not one will end up with many cases like the Stevia. According to Prof. Geuns 164 million people use Stevia on a daily basis, which the author believes gives clear indications of history of safe use. But as Mr. Riediger explains: *‘When you don’t have data of allergens (which is often the case for developing countries) it is a problem.’ ‘This can be a big issue for establishing food safety.’ ‘And this can naturally hinder many traditional products from entering the market.’*

Further, in the NNFR there has been a shift from specific to generic applications. This is seen as an improvement especially with regards to less administrative burdens as explained by Ms. Viloría. However, as underlined by her and Mr. Escobedo, it further leads to discussions of data protection. As Mr. Escobedo explains, it may hamper innovation but from a development perspective it is very positive. The author also believes the right should not be given to just one producer. This would hinder development spillovers as described earlier in this chapter. The shift to generic applications should decrease the time it takes to authorise the NF. This has been one of the big disapprovals with regards to the NFR among all the stakeholders.

Within the NNFR many of the viewpoints put forward by the stakeholders working with traditional foods from DCs have been taken into account. Nevertheless, the definition of novelty has been sustained including the date; this did not come as a surprise to the author. As underlined by Mr. Escobedo in section 8.2, this may prove to be difficult in the future. He states: *‘...something produced in 2000 will still be novel in 60 years time’*.

As the NNFR appears now, it will help to solve some of the problems experienced by FEBs in DC. However, as underlined by the experts, one has to wait for the guidelines. In the end it all comes down to implementation in practice and that can only be observed after the NNFR have been adopted.

Ms. Viloría is working at the Dutch Ministry of Health and is currently working on the NNFR. She explains that the presidency of the Council is at the moment from the Czech Republic. They are busy with the negotiations with the Parliament, Commission and the rest of the Council and naturally the MS.

The first negotiation meeting was held on 10 of February. After this there were some open discussion points, especially on foods originated from cloned animals but also about foods originating from third countries. There has been a lot of discussion especially between the Commission and the MS to be able to get a procedure that everyone can agree to. She does

not see it as a big discussion point with the Parliament. With regards to traditional foods from third countries they are currently discussing specific definitions, for instance regarding “one generation”. Ms. Vilorio further explains: *‘with regards to the procedure we have more or less got a compromise’. ‘Which means a kind of ‘reduced’ common authorisation procedure, with a final decision through the Commitology procedure’. ‘The presidency of the Council is currently trying to get a political agreement before the summer’. ‘I am very excited to see if it will be successful’.*

10. Conclusions and Recommendations

This research has examined the impact and the significance of EU food legislation on food-exporting businesses in DCs, in the case of exotic NF.

10.1 Conclusions

Through interviews with FEBs and experts regarding the impact of the NFR it can be concluded that the significance of this regulation is limited in general. It appeared that few of the FEBs were acquainted with the NFR and saw other problems not linked to European food legislation as graver. However, for those FEBs who had to comply with the NFR explained that the regulation had a big impact on their business. This was also the opinion of the experts.

A handful of the experts believed that the NFR is an addition to the GFL and not required. This is also the opinion of the author. As the NFR was originally created for GMOs as explained by Ms. Viloría, the author believes that the GFL would be able to maintain the safety of the European Market and for the consumers with regards to traditional foods from a third country. Unfortunately this is not the opinion of the EC. This means that FEBs in DC will be met with an additional modus operandi in addition to other EU food legislation. This will create a hostile environment for innovation among FEBs in DC. As Mrs. Espinosa explained, CORPEI advised the Ecuadorian farmers to be innovative with regards to new products. This was recommended because the market is saturated with bananas. Due to the NFR it has proven to be impossible for them.

The world is becoming more like a melting pot and people move across continents bringing new tastes and cooking cultures with them. This will bring new challenges for food safety in the EU. Mr. Riediger pointed out that it is getting more and more trendy to cook exotic food products and these are changes one should be aware of. If every exotic NF that enters the European market or which is found in an ethnic shop, needs to go through the NNFR, the author believes that this will be very demanding of the EFSA and the MSs.

Nevertheless, it appears that a regulation for traditional NFs from third countries is here to stay, but hopefully in a better version, namely the NNFR. The resolution to this matter will be answered when the NNFR and its guidelines are implemented within the EU.

10.2 Limitations

- The biggest limitation of this research is the low number of informants. At the beginning of this research the author thought it would not be a problem to gather informants, however as described in the methods' chapter it proved to be somewhat difficult. This was especially the case with regards to FEBs who were acquainted with the NFR. As a result, statistical analysis was not possible making it difficult to compose common conclusions regarding the situation in general. It would for instance have been interesting to see if there was a difference in opinion between the African and Latin American FEBs. Nevertheless, the information gathered from the experts in combination with the FEBs has established interesting observations and hands-on knowledge.
- An economic analysis of the impact if the NFR on FEBs in DC would have given more magnitude to the research, but as Mr. Kutsch Lojenga explained it is very difficult to get concrete figures because this is trade that has never been banned but trade that never takes off, which only indicates potential.

- A further limitation is the NNFR and its guidelines. The author expected that these documents would have been published by the time of writing. As this is not the case, it is difficult to conduct an adequate analysis to understand if this regulation will provide an adequate framework for solving the problems the FEBs have experienced. In other words, we have to wait until the NNFR is implemented to be able to see the results.

10.3 Recommendations

For the legislature:

- The definitions of the concepts ‘human consumption to a significant degree’, ‘history of safe food use’ and ‘traditional food from a third country’ should be described as exact as possible in the guidelines for the NNFR. However, it is just as important to define them in a practical manner, which will make it easier for the FEBs to create the dossiers and for EFSA to evaluate them.
- The European Commission should continue their work with the NETTOX list and recognize and include the FAO list.

For the FEBs:

- As it appears at the moment, the NNFR will be an improvement for the FEBs. Therefore, the author proposes that the FEBs wait until the NNFR is implemented before they put applications forward. Until the NNFR is adopted, markets outside the EU should be considered as an alternative.
- The author suggests that the FEBs in DC should group together and file common applications to share the costs when filing applications for the NNFR.
- This research indicates that the FEBs who are connected to a development agency manage to keep updated with European food legislation in a constructive manner. Consequently, FEBs, which are not linked up to such an agency, should embrace this strategy.

For development agencies:

- Give further technical assistance to FEBs during the development of NF dossiers when the NNFR is adopted.
- Develop a practical handbook along the lines of the guidelines developed for the NNFR. By developing it in cooperation with the EC it would be of great assistance to the FEBs.
- Further research should be conducted on which strategic responses DCs apply to adapt to EU food safety legislation *and* how development agencies can best act upon these approaches to assist FEBs.

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Annex I: Questionnaire Food Exporting Businesses

Novel Foods Regulation (NFR):

Familiarity:

1. Have you ever come across/heard about the NFR? **If yes**, please continue with question **2** till **18**, **if not** please go to question **19**.
2. How did you come across this regulation?
3. Why did you consider your product a Novel Food?

Procedure:

4. What do you think about the current authorisation procedure?
5. Do you consider the current NFR clear?
6. If you have questions about the NFR where can you get help/information?
7. Do you understand what a Novel Food is?

Experiences:

8. Which exact impacts of the regulation has your company experienced?
9. What are your experiences with exporting to non-EU countries?

Strategies:

10. Which strategies does your company use to deal with the current regulation?

New Novel Foods Regulation:

11. Do you know the proposed new NFR?
12. Is it an improvement, please explain?

Novelty:

13. How do you understand history of safe food use?
14. How do you understand traditional food?

Procedure:

15. Do you think that the proposed regulation will make it easier for your company to export to the EU, please explain?
16. How long should an authorisation procedure take in your view, please explain?

Enforcement:

17. Who should bear the “burden of proof” for safety in your view, please explain?

Strategies:

18. How will your strategies change if the proposed regulation is implemented?

Export issues:

19. What is your experience with exporting to the EU?
20. Do you face problems when exporting to the EU? If yes, please explain.

Food Safety:

21. How long should an authorisation procedure take in your view (please explain)?
22. Who should bear the “burden of proof” for safety in your view (please explain)?

Annex II: Questionnaire Experts

Novel Foods Regulation (NFR):

Familiarity:

1. What is your background/expertise?
2. When did you start working with the NFR?
3. What are your experiences regarding developing countries and food exports to the EU?
4. What are the specific problems?
5. How would you weigh the NFR compared to other problems food exporting businesses in developing countries encounter?

Procedure:

6. What are the positive and negative sides of the regulation?
7. What do you think about using novelty as the criteria to the right of entry to the procedure?
8. What do you think about the current authorisation procedure?

Strategies:

9. Which strategies are you aware of that companies apply when confronted with the regulation? Do many companies do this?
10. Do you have information regarding unauthorised Novel Food exported into the EU?

New Novel Foods Regulation (NNFR):

11. Which positive and negative sided does the NNFR have?
12. Could something have been better?

Novelty:

13. How do you value the importance of the concept history of safe food use in the NNFR?
14. How do you value the importance of the concept traditional food in the NNFR?

Procedure:

15. Do you think the NNFR's authorisation process is an improvement?
16. Do you think the shift from specific to generic applications in the NNFR is an improvement?

Enforcement:

17. Do you think it is reasonable that businesses should provide the information for the risk assessment? (Who should bear the "burden of proof" for safety in your view?)

Strategies:

18. Do you think that the proposed regulation will make it easier for food exporting businesses in developing countries to export to the EU?