



# **NEW EUROPEAN UNION COMMISSION'S PROPOSAL ON NOVEL FOODS REGULATION (2013)**

A preliminary  
overview from the  
perspective of  
biodiversity-based  
and traditional foods



## Note

The material contained in this publication may be freely quoted or reprinted but acknowledgement is requested, together with a reference to the document number. A copy of the publication containing the quotation or reprint should be sent to the UNCTAD Secretariat, at: Palais de Nations, 1211, Geneva 10, Switzerland.

The designations employed and the presentation of the material do not imply the expression of any position whatsoever on the part of the United Nations Secretariat concerning the legal status of any country, territory, city area, or its authorities, or concerning the delimitations of its frontiers and boundaries, or regarding its economic system or degree of development.

## Acknowledgements

This publication was prepared by David Vivas Eugui, Legal Officer at the Trade, Environment, Climate Change and Sustainable Development Branch, DITC, UNCTAD. This document has benefited from substantive comments by Vanesa Ingar (Ministry of Environment of Peru), Bonapas Onguglo (UNCTAD Secretariat), Lorena Jaramillo (UNCTAD Secretariat), Katie Beckett (PhytoTrade Africa), and Eugune James, (Grenoble Graduate School of Business). The desktop formatting was done by Rafe Dent.

UNCTAD gratefully acknowledges the support of the Swiss State Secretariat for Economic Affairs (SECO) for this publication under the BioTrade Programme.

This publication, “The New EU Commission Proposal’s on Novel Foods Regulation (2013): A Preliminary Overview from the Perspective of Biodiversity-based and Traditional Products”, is a product of the BioTrade Initiative, part of the Division on International Trade Goods and Services and Commodities (DITC). It is part of a larger effort by UNCTAD to analyse trade-related issues of particular importance for developing countries.

Guillermo Valles  
Director  
Division on International Trade  
in Goods and Services, and Commodities.

UNCTAD/DITC/TED/2014/2  
UNITED NATIONS PUBLICATION  
Copyright © United Nations, 2014  
All rights reserved

---

## Contents

Note .....	ii
Acknowledgements.....	ii
Acronyms.....	iv
<b>Executive Summary .....</b>	<b>1</b>
<b>I. INTRODUCTION.....</b>	<b>1</b>
<b>II. SCOPE AND BASIC DEFINITIONS.....</b>	<b>2</b>
<b>III. SPECIFIC PROPOSED PROCEDURES FOR TRADITIONAL FOODS FROM THIRD COUNTRIES .....</b>	<b>5</b>
<b>IV. LABELLING REQUIREMENTS.....</b>	<b>6</b>
<b>V. RELEVANT TRANSITIONAL RULES UNDER THE NEW PROPOSAL .....</b>	<b>7</b>
<b>VI. POTENTIAL IMPLICATIONS FOR NATIONAL BIOTRADE PROGRAMMES AND ORGANIZATIONS .....</b>	<b>7</b>
<b>VII. SOME RECOMMENDATIONS .....</b>	<b>7</b>
Notes.....	9
References.....	9

---

## Acronyms

EC	European Commission
EPAs	Economic Partnerships Agreements
EU	European Union
ESFA	Europeans Food Safety Authority
GMOs	Genetically Modified Organisms
IGOs	International Governmental Organisations
SCFCAH	Standing Committee of Food Chain and Animal Health
SPS	Sanitary and Phytosanitary
NFR	EU regulation on novel foods
UNCTAD	United Nations Conference on Trade and Development
WTO	World Trade Organisation

---

## EXECUTIVE SUMMARY

The EU Commission has recently published a new proposal to amend its novel foods regulation in December 2013. This is the second proposal for reforming the current EU novel foods regulation (1997). It seeks to address issues related to the scope of the regulation concerning new biotechnological developments such as cloning, but more importantly to respond to concerns regarding barriers faced by traditional foods exports from developing countries. The new EU Commission proposal (2013) contains a simplified and faster procedure for market authorization of traditional foods from third countries. Although the new proposal does not address all concerns expressed by biodiversity-rich countries and BioTrade organizations over the last 15 years, it is a clear step forward in the right direction. For instance, it suggests a much better and commensurate process for the marketing approval of traditional foods and biodiversity-based products than the current status quo under the 1997 EU novel food regulation. A preliminary overview of the process suggested in the new proposal and its implications is presented in this paper.

## I. INTRODUCTION

The EU Commission has recently published a new proposal to amend their novel foods regulation (draft law). The new EU draft regulation<sup>1</sup> aims at ensuring food safety, protecting public health and securing an effective functioning of the internal EU market for food. If adopted by the EU Parliament and the Council, it would substitute the existing regulation<sup>2</sup> (EC) No. 258/97 on novel foods<sup>3</sup>. The proposed regulation seeks to introduce simpler, clearer and more efficient procedures for the commercial authorization of novel foods in the EU market. The proposed procedures will be centralized at the Community level<sup>4</sup>, but the EFSA (European Food Safety Authority) and EU members can introduce comments and objections to any application for market authorization.

**Novel foods** are currently defined as foods and food ingredients which were not consumed to a significant degree in the EU before the entry into force of the current novel foods regulation (15 May 1997).

The existing EU regulation on novel foods (NFR) has been significantly criticized over the last 15 years by a diverse set of stakeholders for applying market safety standards and evaluations to biodiversity-based products and traditional foods that are not commensurate to the level of risk posed by these products and for impeding their access to the EU market. This has oc-

curred even if the product in question has a long historical record of traditional safe use in third countries. Most of the standards contained in the EU's NFR were meant and designed to regulate the entry of products derived from transgenic technologies such as genetically modified organisms (GMOs) and not to natural products.

These concerns even reached the level of the World Trade Organisation's (WTO) Sanitary and Phytosanitary (SPS) Committee in a submission by Peru in 2011. While in its submission Peru acknowledges the importance of consumer protection and health, it indicates that because there was no significant marketing of many biodiversity-based products in the EU before 1997, and despite a long history of safe human consumption in the countries of origin, these products are treated as novel foods and subject to stringent safety and risk assessment requirements.<sup>5</sup> These requirements may be at odds with obligations under the WTO SPS Agreement<sup>6</sup> which require Members to ensure that sanitary and phytosanitary measures are not more trade-restrictive than required to achieve an appropriate level of protection.

The level of risk assessment in the novel food regulation is not commensurate with the level of risk posed by biodiversity-based and traditional products. Biodiversity-based and traditional products have a much lower risk health than any GMOs or other biotechnology-derived products as they have been consumed safely by local populations over a long period of time in the country of origin. Also biodiversity-based and traditional products are produced with inputs from



nature that existed even before humans appeared on the planet. Instead, GMOs and biotechnology-derived products have been subject to significant alterations in their genetic and/or chemical structure and have never been consumed or released in nature before, so the effects on human health or on the living environment are not known.

Moreover, according to Peru, the EU NFR is placing a heavy burden on local producers and hindering the export potential of biodiversity-based products for food consumption such as camu camu or yacon. As currently drafted EU NFR does not only affect the commercial viability of these products, but it is also inconsistent with efforts to promote sustainable use of biodiversity and even with incentives for crops shifting in the fight against illegal drug trafficking. In its submission, Peru requested the exclusion of traditional products that have a history of safe consumption in the country of origin from the scope of the EU NFR.

An illustration of the burdens and costs for obtaining market approval for novel foods in the EU is the case of baobab fruit pulp. The approval processes for this fruit pulp cost in the region of EUR 250 thousand to EUR 350 thousand for institutions such as PhytoTrade Africa with the support of UNCTAD.<sup>7</sup> The costs of filing a request to the EU do not involve a finite figure, and the costs continue after approval with follow-up work and required revisions. The process takes more than three and a half years before final approval. The complexity and length of process as well as related costs set a high regulatory bar for most biodiversity-based products, particularly if applications are being made by small and medium-sized producer organizations. This has been reflected in the fact that only a handful of applications of biodiversity-based and traditional products have been made under the EU NFR.<sup>8</sup> Examples of biodiversity-based and traditional foods approved by the EU NFR include *Morinda citrifolia* leaves, Tahitian noni juice and powder (products derived from the *Morinda citrifolia* plant)<sup>9</sup>, baobab fruit pulp, chia seeds and oil, and Allanblackia seed oil.<sup>10</sup> Inca inchi virgin oil (*Plukenetia volubilis*) has benefited from a positive option of substantial equivalence assessment with flaxseed or linseed oil by the food safety authority of Ireland.<sup>11</sup> The low number of biodiversity-based and traditional foods applications through the novel food approval contrasts with more than 130 applications for products derived from different biotechnological methods including transgenic ones.

This paper seeks to outline and introduce the key as-

pects of the new proposed regulation, EU COM (2013) 894 FINAL, published on 18 December 2013. The note also seeks to identify the main implications for BioTrade activities<sup>12</sup>. It must be understood that this is the second proposal for reform to accommodate the trade of traditional foods, so even if successful it will take a minimum of two years to become an EU regulation. To become an EU regulation, this proposal will have to be approved by both the EU Parliament and the Council. In this regard, the proposal should be taken as a positive political signal and a draft law, but not as a stable policy change at this stage.

## II. SCOPE AND BASIC DEFINITIONS

Under the new proposal, the basic definition of “novel foods” remains unchanged. This definition includes all food<sup>13</sup> that was not used for human consumption to a significant degree in the EU before 15 May 1997.<sup>14</sup> This date has been considered as somewhat arbitrary as it affects many biodiversity products unknown to date in the EU market. It is important to note that the EU novel food regulation does not apply to products for uses other than as food, such as cosmetic or medicinal uses. Thus, the same biodiversity-based product can be exported or imported for cosmetic use while it is not authorized for food consumption.

There are several key definitions in the new proposal that determine which products may be subject to a special procedural treatment under the NFR. These definitions include (a) traditional foods from third countries, (b) primary production, (c) a history of safe use in a third country and (d) experience of continuous use for at least 25 years in the customary diet of a large part of the population of a third country. There are some terms that have not been defined but could have important impacts over the potential implementation of a future NFR regulation; these terms are “traditional food processed products” and “a large part of the population”. These terms may need further legal development in order to provide certainty.

The new proposal introduces the definition for “traditional food from third countries”. It was included with the purpose of providing a separate track and facilitated procedure for these products. This definition is essential to understand which products could take this facilitated track and avoid more complex safety and risk assessments applicable to other novel foods.

UNCTAD was the first institution to put forward the need for a differential treatment for “traditional foods” and the need to use the “traditional safe use”<sup>15</sup> as the most suitable standard for assessing the risks of these products.

“Traditional foods from third countries” means a novel food, which is derived from primary production, with a history of safe use in a third country.<sup>16</sup> Primary production is defined as the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter.<sup>17</sup> It also includes hunting, fishing and the harvesting of wild products from flora and fauna. This definition excludes processed products from the scope of the regulation. This opens an important question on what happens with processed products derived from approved or non-approved novel foods. In the case of processed products that use food ingredients already approved, the logic will indicate that their commercialization should not be subject again to the novel food regulation as the risks have already been assessed and conditions for use are set. In the case of non-approved ingredients, the question remains open. However, it could be argued that the risk of processed foods is lower than that of foods from primary production as the manufacturing process might eliminate components of potential safety and toxicity concern (e.g. oil from a particular nut is retained but other proteins that may have allergenic effects may be filtered or extracted).<sup>18</sup> Clear answers regarding the status on “traditional food processed products” for the purposes of a future NFR would need to be provided in order to generate certainty among exporters and importers and to avoid the creation of additional and unnecessary barriers to processed foods from third countries.

“A history of safe use in a third country” means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a large part of the population of a third country.<sup>19</sup> “Compositional data<sup>20</sup> and relevant databases” tend to include information on the nutritional components of a food, as well as toxicological, appropriate intake levels and sometimes allergenic analysis, depending on the country. Very few “traditional foods from third countries” have been subjected to systematic nutritional and toxicological and/or allergenic assessments in accordance with modern scientific standards. However, due to their long history of use, associated with customary preparation methods and the absence

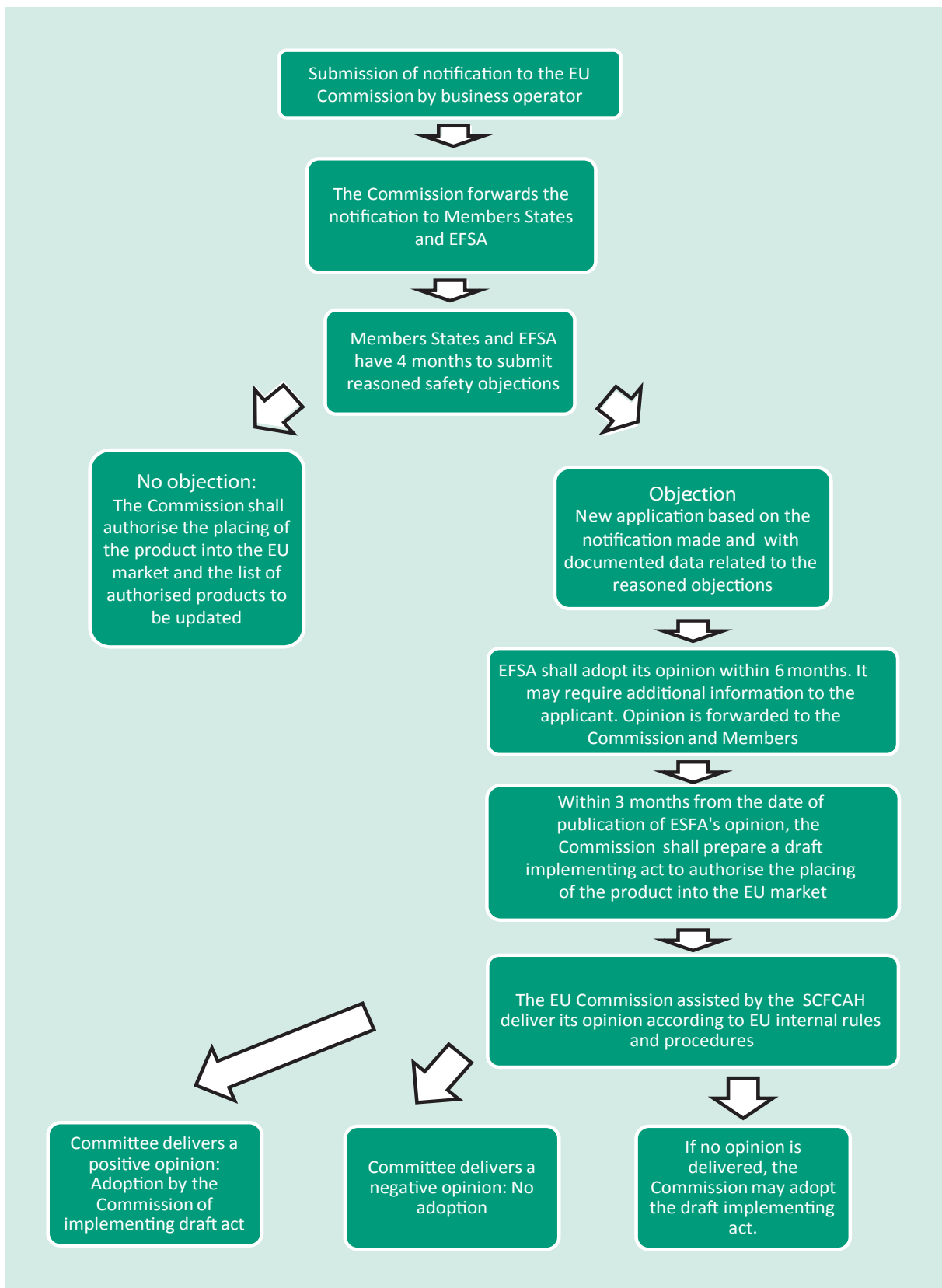
of evidence of harm, they are generally regarded as safe to eat.<sup>21</sup>

“Experience of continuous use for at least 25 years in the customary diet of a large part of the population of a third country” points toward the safe use experience by at least one generation. A period of 25 years is usually considered a good benchmark for safety and low risk. Nevertheless, the condition that the product has been part of the “customary diet of a large part of the population” may raise problems for the authorization of many biodiversity-based products. There is no definition of what a large part of the population means. It could be defined as more than 50 per cent of the total population, but less than that may also be a significant share of the population for risk assessment purposes.

While in many cases biodiversity-based products have been widely consumed, in some other cases their intake has occurred mostly within a particular region. This is particularly true in common ecosystem areas where people eat what is available. This does not mean, however, that the product has reached all national markets as traditional consumption may remain within the traditional and regional context. Whereas to have an approach on the large part of the population reduces the perception of risk, a modification in the future regulation to also cover a “region” would facilitate the approval and entry of many low volume and regionally known BioTrade products (e.g. many products of the Amazon basin or in the Namibian desert have yet not reached the national markets of other regions of South America or Southern Africa, respectively).

The definition of traditional foods from third countries introduces then a set of cumulative requirements by which both scientific data and experience are taken into consideration when defining which product will be subject to the fast-track procedure for safe food assessment. This gives an important support role for national food and sanitary authorities in third countries to provide the best available scientific evidence to support applications by food operations, exporters and importers making such an application. It also gives significant weight to recorded experience of safe use and to the absence of any negative incident in the third country which makes evidence-gathering easier. Such support in evidence-gathering will require inter-institutional coordination and capacity-building for both sanitary authorities and potential applicants so that they understand the requirements of the EU regulation as well as on the preparation of compositional data and evidence of safe use.

Figure1. Proposed EU Traditional Food Approval Process (2013)





### III. SPECIFIC PROPOSED PROCEDURES FOR TRADITIONAL FOODS FROM THIRD COUNTRIES

Procedural rules and steps have been significantly simplified under the new proposal. The main features of the proposed procedures are the following:

- There is a central procedure at the EU community level. It is initiated with a notification by the business operation seeking to place a novel food ingredient in the EU market for the first time. As mentioned above, there is space for reasoned objections and comments by ESFA and members States (within four months), but the decision for approval is taken at the EU level. National procedures and duplications will be phased out. Therefore all notifications and applications for approval will have to be submitted to the EU Commission.
- The time foreseen for the new commercial authorization procedure is of about 18 months, almost half the time that it takes today. This is a significant improvement if compared to time needed to fulfil the procedure under the current NFR, which is usually three years or more. This change could have a direct impact on the level of administrative burden and cost.
- A safety and risk management assessment for traditional foods from third countries based on a history of safe use has been created. For that purpose, the applicant has to jointly demonstrate that there has been safe use based on compositional data and experience of continued safe use for at least 25 years in the customary diet of a large part of the population of a third country.

The procedure starts with a notification by a business operator interested in placing the traditional food product from a third country into the EU market. The notification to the EU Commission must contain as a minimum, the name and description of the traditional food, its composition, the country of origin (there could be several), documented evidence and data demonstrating the history of safe use (nutritional, toxicological and allergenic) and any condition regarding use and labelling (amounts and warnings).<sup>22</sup>

While under the new proposal the data and documentation submitted to support the application for novel foods can be subject to test data protection

(the impossibility of using the data by third parties for new authorizations without the authorization of the originator of the data), this does not apply to traditional foods from third countries. In this regard, a notification/application for traditional foods is considered as a “generic” notification/application. Therefore any other exporter/importer can benefit and rely on the original data and enjoy the original marketing authorization for exporting/importing the same product.<sup>23</sup> This is a very positive feature of the new system as once a product has been authorized, there could be open competition in the EU market and other business operators and producers from third countries could export without to the need to file a new notification/application for market authorization.

After the notification is made, the Commission forwards the notification to members States and EFSA.<sup>24</sup> Members States and EFSA have four months to submit reasoned safety objections based on scientific evidence.<sup>25</sup> If there are no reasoned objections to the notification made, the Commission shall authorize the placing of the product into the EU market and the EU list of authorized products should be updated.<sup>26</sup> In such a case, the process ends and the product can be quickly placed in the EU market. This phase is perhaps the biggest advantage of the proposed process. It basically sets a positive semi-automatic response that a notification of traditional foods is in line with the NFR regulation if it fulfils the basic requirements and there is no objection by any EU member or ESFA.

If there are objections, there is a different track for the process. Objection may include health and/or ethical concerns. In such a case, there is a need to submit an application based on the notification made and with documented scientific and other data responding to the reasoned objections or comments submitted.<sup>27</sup> This information is forwarded to members and ESFA. Based on this application, EFSA shall adopt its opinion within six months.<sup>28</sup> EFSA may require additional information from the applicant.<sup>29</sup> The period of opinion may be extended if additional information is required.<sup>30</sup> The applicant may also submit additional information if the applicant considers it appropriate.<sup>31</sup> Once an opinion is taken, ESFA will forward it to the Commission and members and publish it. Within three months of the date of publication of ESFA opinion, the Commission shall prepare a draft implementing act to authorize, or not authorize, placing the product into the market.<sup>32</sup>

The Commission, assisted by the Standing Committee of Food Chain and Animal Health<sup>33</sup> (SCFCAH), shall deliver its opinion according to EU internal rules and procedures (e.g. by voting) in light of EU Regulation 182/2011. If the Committee delivers a positive opinion, the Commission will adopt the implementing draft act.<sup>34</sup> If a negative opinion is delivered by the Committee, the draft implementing act will not be adopted.<sup>35</sup> Sometimes the Committee may give no opinion. In such a situation the Commission may adopt the draft implementing act.<sup>36</sup>

To ease understanding, a simplified overview of the process is presented in the figure 1.

## IV. LABELLING REQUIREMENTS

Today, all novel foods are subject to the general requirements of the EU Directive 2000/13/EC on States related to the labelling, presentation and advertising of foodstuffs.<sup>37</sup> In this regard, the labels must indicate the food, its ingredients, quantities, special storage conditions, conditions of use, place of origin and the manufacturer.<sup>38</sup> This applies to both the current NFR and to the new proposal.

Under the new NFR proposal there are additional labelling requirements<sup>39</sup> that need to be fulfilled, once the novel food is allowed entry in the EU market, in

**Table I: Comparative features of the current NFR (1997) and new EU Commission Proposal (2013)**

	<b>Novel Food Regulation (1997)</b>	<b>New EU Commission Proposal (2013)</b>
<b>Level and phases</b>	A harmonized procedure with a mix of EU and national level phases that interact during the process. An initial national phase is followed by an assessment at the EU level, in case there are safety objections by other national authorities. Then the process comes back to the EU level for final decision and publication if the product is finally approved.	A centralized authorization system at the EU level. Members and EFSA may provide reasoned objections. Market approval is given by the EU Commission, the EU Parliament and the EU Council depending on the case (see figure 1) with effect on all EU members.
<b>Coverage of traditional foods</b>	Yes.	Yes.
<b>Special and simple procedures for traditional foods</b>	No, but there are simplified procedures when an EU member national competent authority considers that the novel food in question is substantially equivalent to an existing food or food ingredient.	Yes, especially when there are no objections by ESFA or EU members. In such a case, the process is semi-automatic. The proposed process puts the burden of the presentation of reasoned objections on ESFA and EU members.
<b>Length of the procedures</b>	Usually more than three years.	About 18 months.
<b>Data exclusivity</b>	No.	Yes, but not for notifications or applications for commercial authorization of traditional foods.
<b>Opportunity for objections</b>	Yes, plus national assessments.	Yes.
<b>Opportunity to provide additional evidence to support application</b>	Silent, only if required.	Yes, to respond to objections.
<b>Type of evidence to support safe use of traditional foods</b>	Scientific evidence available and generally recognized or based on the opinion delivered by a competent national food assessment authority.	Evidence based on compositional data and experience of continued safe use for at least 25 years in the customary diet of a large part of the population of a third country.
<b>Labelling requirements</b>	The same under both the current NFR and the new proposal as they are regulated by more general labelling rules. Additional labelling if needed is possible in both cases.	

order to inform the consumer on:

- The specification of the novel food;
- The conditions of use in order to avoid adverse effects over specific groups of the population, the exceeding intake levels and risks in case of exercise consumption;
- Any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and the intended use of the food, which renders the novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population.

## V. RELEVANT TRANSITIONAL RULES UNDER THE NEW PROPOSAL

The proposal also includes a transitional period clause by which any request for placing a novel food in the EU market submitted to a member State (meaning a national phase under current NFR procedure), (EC) No. 285/97, and for which no final decision has been taken, shall be considered as an application under the new regulation.<sup>40</sup> Such a clause will facilitate the assessment of relevant applications made but not decided before the date of entry into force of the new regulation.

## VI. POTENTIAL IMPLICATIONS FOR NATIONAL BIOTRADE PROGRAMMES AND ORGANIZATIONS

The EU novel food regulation is perhaps one of the best known examples of the non-tariff measure affecting the entry of biodiversity-based and traditional products into the EU market. The current proposal provides for a much clearer and simpler approval procedure for traditional foods than the current regulation. It also responds, to a certain extent, to concerns raised by many developing countries, international governmental organizations (IGOs) and civil society actors regarding the scope, burdensome nature, long procedures and lack of special treatment for traditional and biodiversity-based products in the current EU NFR (1997). It does not reach to the level of ambition sought by Peru in its 2011 submission to the WTO SPS Committee by which traditional products that have a history of safe consumption in the country of

origin should be excluded from the application scope of the EU NFR. Nevertheless, there are significant improvements.

The most significant improvements of the new EU proposal include a common EU procedure for NF approval, a separate fast-track procedure for traditional foods, shorter time periods, a semi-automatic approval process when there are not objections or comments, the fact that comments need to be reasoned and based on scientific evidence, the fact that composite data is complemented and supported by a history of safe use in the country of origin, the non-application of data protection rules, and the opportunity to revise application and respond to any objection or comments made. The main limitations of the new proposal are: (a) the need to obtain approval and (b) that in case there is an objection by an EU Member States, a new application, opinion and examination procedures by the ESFA and the EU's SCFCAH would apply, making the process longer. It also lacks clarity in relation to the treatment of traditional food processed products and on the scope of the terms "customary diet of a large part of the population".

The table I below compares main features of the current regulation and the new proposal.

## VII. SOME RECOMMENDATIONS

Some potential recommendations to national BioTrade programmes and BioTrade organizations involved or interested in making notifications/applications for novel foods could include the following:

1. Prepare a revised list of priority BioTrade products needing NFR approval in the EU market;
2. Undertake assessments on the capacity of national BioTrade programmes and organizations to fulfil the new EU proposal in light of the priority list of products, previous experience and national systems for the evaluation of safe use. It will be advisable to include in these assessments whether there is availability of systematic and scientific compositional and/or consumption data, and experience of traditional safe use that could be accepted under the new proposal. National sanitary authorities should be involved in these assessments in order to get their views and evaluate their level of capacity to submit and/or support the notifications/applications for the priority list of products and the potential for "substantial equivalence" with existing food products. Capacity-building could include advice to pre-

pare notifications/applications for priority products in light of safe use in light of EU standards in order to reduce the risk of opposition or rejection. UNCTAD and other BioTrade partner organizations could have a significant role in strengthening these capacities.

3. Identify options for requesting modifications and adjustments on the new EU proposal to be later submitted to the EU Commission and Parliament. This could be particularly relevant for the definition of *safe use* in order to include the consumption as part of “customary diet of a large part of the population of a **region** of the third countries or the third country”. This also applies to the clarification of the coverage and rules applicable to “traditional processed food”, so that the new proposal does not create additional uncertainty or barriers. This for example could be done through a collective exercise in the BioTrade Congress, jointly with an analysis of other non-tariff measures. Such an exercise could consider providing support to the current EU

Commission proposal with some adjustments such that its adoption by the Parliament and Council is fast-tracked. UNCTAD and other BioTrade partners and organisations will be particularly relevant in this exercise. Modification may also be necessary to enable low-cost applications and procedures for **small-scale producers**.

4. Require a technical cooperation plan for developing countries and for countries that already have economic partnerships agreements (EPAs) or preferential free trade agreements (e.g. EU–Colombia, EU–Peru, EU–South Africa) to implement current and future novel foods regulation. This for example could take the form of technical and financial support to prepare notifications and applications and gather relevant data. It could also include support to create or improve safe use data and databases, safety and risk monitoring systems and the implementation of safety measures by sanitary authorities in the country of origin.
-

## References

- EC Commission (2013). Proposal for a Regulation to the European Parliament and the Council on Novel Foods. (EC) COM (2013) 894 FINAL, 18 of December 2013.
- EU Commission (2013). *Food: Commission tables proposals on animal and novel food*. Press release, 18 of December, 2013.
- EU Directive No 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Official Journal L 109 , 06/05/2000.
- EU Regulation No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Union, L043, 14 of February 1997.
- EU Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Communities 01 of February 2002. L 31/1.
- Peru (2011). Communication regarding EU Regulation 258/97 of the European Parliament and of the Council concerning novel foods. WTO document G/SPS/GEN/1087 of the 7 of June 2011.
- UNCTAD (2009). *Definitions, concepts and history of safe use assessments*. Issue paper concerned proposed amendments to EU novel Food Regulation (EC) 258/97, with particular reference to traditional foods from developing countries. UNCTAD/DITC/BCC/2009/5.
- EU Regulation No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers of 16 February 2011. Official Journal of the European Union, L5513, 28 of February 2011.

## Notes

- 1 Proposal for a Regulation to the European Parliament and the Council on Novel Foods COM (2013) 894 FINAL of 18 December 2013. There is an older and less elaborated proposal that also sought to improve the original EU novel food regulation under the number COM (2007) 872 Final of 14 January 2008.
- 2 An EU regulation has a direct effect in the EU market. It has superiority vis-à-vis national law and can be directly applied by tribunals without the need of any national legislative or executive action.
- 3 See EC Regulation No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal L 043, 14/02/1997. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:en:HTML>.
- 4 The centralised procedure involves the Member States only when the approval is related to the traditional food from a third country (notification phase). For all applications which are not traditional foods from third countries only EFSA will evaluate the safety (section I of Chapter III of the new NF proposal, 2013).
- 5 See Communication by Peru regarding EU Regulation 258/97 of the European Parliament and of the Council concerning novel foods. WTO document G/SPS/GEN/1087 of the 7 of June 2011.
- 6 See Articles 2.2, 5.1, 5.4 and 5.6 of the WTO SPS Agreement.
- 7 From interview with Katie Becket, Phytotrader Africa.
- 8 See Applications under Regulation (EC) No. 285/97 of the EU Parliament and Council, available at [http://ec.europa.eu/food/food/biotechnology/novelfood/app\\_list\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf) (accessed 14 March 2014).
- 9 The leaves, the juice and the powder received three different applications by two different applicants. The three sets of products and derivatives were granted market authorizations at the EU level in 2000, 2003 and 2004.
- 10 See [http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm).
- 11 See [http://www.fsai.ie/uploadedFiles/Science\\_and\\_Health/Novel\\_Foods/Notifications/Inca%20Inchi%20oil%20SE%20opinion.pdf](http://www.fsai.ie/uploadedFiles/Science_and_Health/Novel_Foods/Notifications/Inca%20Inchi%20oil%20SE%20opinion.pdf).
- 12 See <http://www.BioTrade.org/aboutINTRO.asp>.
- 13 For definitions of food, food business operation and risk and for other relevant definitions, see EU Regulation 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- 14 See Article 2.2, COM (2013) 894 FINAL.
- 15 See UNCTAD (2009). *Definitions, concepts and history of safe use assessments*. Issue paper concerning the proposed amendments to the EU novel Food Regulation (EC) 258/97, with particular reference to traditional foods from developing countries. UNCTAD/DITC/BCC/2009/5.



- 16 See Article 2.2 b) and c), COM (2013) 894 FINAL.
  - 17 See Article 3.17 of the EU Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Communities 01 of February 2002. L 31/1.
  - 18 See UNCTAD (2009).
  - 19 See Article 1.2 (b) and (c), COM (2013) 894 FINAL.
  - 20 It usually includes detailed sets of information on the nutritionally important components of foods and provides values for energy and nutrients including protein, carbohydrates, fat, vitamins and minerals, as well as for other important food components. It may also include effects on humans and intended food use.
  - 21 See UNCTAD (2009).
  - 22 See Article 13, COM (2013) 894 FINAL.
  - 23 See Article 24.3, COM (2013) 894 FINAL.
  - 24 See Article 14.1 and 3 COM (2013) 894 FINAL.
  - 25 See Article 14.2, COM (2013) 894 FINAL.
  - 26 See Article 14.4, COM (2013) 894 FINAL.
  - 27 See Art. 15, COM (2013) 894 FINAL.
  - 28 See Art. 16.1, COM (2013) 894 FINAL.
  - 29 See Art. 16.4, COM (2013) 894 FINAL.
  - 30 See Art. 16.5, COM (2013) 894 FINAL.
  - 31 See Art. 16.6, COM (2013) 894 FINAL.
  - 32 See Art. 17.1, COM (2013) 894 FINAL.
  - 33 See Art. 27.1 and 27.3 COM (2013) 894 FINAL.
  - 34 See Art. 5.1 and 5.2 of the EU Regulation 182/2011 of the 16 of February 2011.
  - 35 Art. 5.3 of the EU Regulation 182/2011.
  - 36 Ibid.
  - 37 See EU Commission (2013). Press release “Food: Commission tables proposals on animal and novel food”. 18 of December, 2013.
  - 38 See Article 3 of the EU Directive No 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Official Journal L 109, 06/05/2000.
  - 39 See Art. Art. 8 COM (2013) 894 FINAL.
  - 40 See Art. 29.1. COM (2013) 894 FINAL.
-