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

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

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Note

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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[1] 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[2] (EC) No. 258/97 on novel foods[3]. 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[4], but the ESFA (Europeans 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 occurred 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.[5] These requirements may be at odds with obligations under the WTO SPS Agreement[6] 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 PhyoTrade Africa with the support of UNCTAD.[7] 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.[8] Examples of biodiversity-based and traditional foods approved by the EU NFR include *Morinda citrofilia* leaves, Tahitian noni juice and powder (products derived from the *Morinda citrofilia* plant)[9] , baobab fruit pulp, chia seeds and oil, and Allanblackia seed oil.[10] 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.[11] 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 aspects 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[12]. 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[13] that was not used for human consumption to a significant degree in the EU before 15 May 1997.[14] 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"[15] 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.[16] Primary production is defined as the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter.[17] 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).[18] 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.[19] "Compositional data[20] 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.[21]

"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)