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THE AMBIGUOUS CATEGORIZATION OF RISK CONCERNING THE TRADITIONAL FOREIGN PRODUCTS *

Marlen LEON GUZMAN¹

Summary. Introduction: The inconsistency of risk definition. I. The inconsistency of the amendment regarding the European Food Law. A. The categorisation represented by the TTCP. A) The TTCP as a certain risk. B) The TTCP considered as an uncertain risk and the application of the precautionary principle. II. The inconsistency of the NF regulation in relation to the equivalence requirements for imported products. A) The inconsistency concerning the safety of "Traditional products" in the European Food Law. B) Equivalent sanitary conditions of imports from the third countries in the European Food Law. Conclusion.

Abstract

The last project of modification of the regulation on new foods contained a categorization of the risk, which included traditional non-European products. This categorization established the characteristics of what was defined as "new food". In particular, reference was made to the requisite of counting with a "sure use history" of the product. The product's sure use history should be documented and proven. This situation could affect the marketing of food products, the ancestral consumption of which in Latin American, African, Asian, or any other non-European country is not proved "objectively", and in many cases is not documented. These are foods that form part of the culture of the people themselves, which consumption has been taught from generation to generation and transmitted in many cases by means of oral tradition. The documentation of the history of sure use of a product has as purpose the evaluation of the risk to categorize it, as established in the principle of risk analysis. Nevertheless, have traditional European products been subjected to these evaluations? Which criterion permits the establishing that one traditional European product is surer than a non-European product? Why do we part from the assumption of uncertain risk of non-European traditional products? Even if the project of modification of the Novel Food Regulation is filed, the following depth discussion continues in force: if the European food legislation establishes the principle of equivalence for imported products, why are the requisites for placing a product in the market not the same for traditional non-European and European products? If traditional European products are not considered within the Novel Food Regulation as products with an uncertain risk, why is it considered that traditional non-European products do.

This paper covers these questions analyzing two elements: I. The categorization of the risk of traditional products, and II. The inconsistency of the Novel Food Regulation in the face of the principle of equivalence of imported products foreseen in By-Laws CE 178/2002.

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Introduction: The risk definition

Starting from the risk definition, a foodstuff can be recognized as a safe or a risky product. The question is if every traditional third country food product should be considered as a risky one? The appreciation of the risk represented by an “exotic” product coming from a third country depends of its safety categorisation on the European sanitary level. The proposed amendment of the Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients that was “archived”, wasn’t clear about which is the category of the risk associate to traditional food from thirds countries (TTCP).

Two possible interpretations about the risk concerning these products were possible. In one hand, if the European authorities consider the risk associated to the traditional products as a “certain risk”, the upcoming regulation could be interpreted as establishing a presumption about the safety of this kind of products. In this way, the procedure contained in the proposal would be based in one prudential approach and prior authorisation will confirm not the scientific evidence by a risk analysis procedure but empirical evidence of the safety of these products. In others words, this confirmation will be not a risk analysis in terms of the general food law regulation.

Nevertheless, according to this interpretation, reasoned safety objections based on scientific evidence, could justify the refusal to place into the market one product. In that case, the safety of the traditional third country product shall be proved by scientific evidence. Consequently, as regard of risk analysis principle, a risk evaluation of each traditional third country product should be done (concerning the general application of novel food regulation, see Van der Meulen, Van der Velde, 2008).

From this point of view, the risk associated to these products cannot be longer considered as a “certain” risk. It means that NF regulation consider, in fact, this risk as an “uncertain one”. This categorisation gets third countries products under a precautionary approach. Therefore, food operators shall prove the safety of these products, filling all the requirements to be included in the Community list of novel foods. In conclusion, the TTCP will be considered an “uncertain risk products” as is the case of the current NF regulation.²

In this regulation the place into the market of TTCP’s is submitted to a prior safety authorization if they: 1) “have not hitherto been used for human consumption to a significant degree in the Community” and 2) “has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value,

²“2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories (...) (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances”. Regulation (EC) 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 P. 0001 – 0006.



metabolism or level of undesirable substances". The classification of the TTCP on the general category of novel food could have important effects in trade, because it could represent a barrier for the TTCP's presenting these characteristics.

For this reason, Colombia, Ecuador and Peru³, supported by other South American and African countries, are claiming in the SPS Committee forum that the NF regulation it's a clear obstacle to trade⁴. Only some "exotics" products have been approved and placed into the European Market⁵ in accordance with this procedure.

This is the case of the noni juice which authorization as novel food ingredient was approved in 2003⁶, after 37 months of procedure⁷. The use of leaves procedure takes 49 months⁸ and the authorization procedure to place in the market the puree and concentrate takes 48 months⁹. The exportation of other products, as the dehydrated *lúcuma* meal and *yacon*¹⁰, exportation has been stopped as consequence of the implementation of the Novel food regulation. In these cases, to obtain an authorization under the NFR was (sic) "A complex and very costly registration process which includes providing scientific information on the safety of the product...

³ In this sense, see Organización Mundial del Comercio, G/SPS/GEN/733, 18 de octubre de 2006. (06-5037). Comité de Medidas Sanitarias y Fitosanitarias. Declaración del Perú sobre el Reglamento 258/97 de las Comunidades Europeas. Organización Mundial del Comercio G/SPS/GEN/713, 12 de julio de 2006. Comité de Medidas Sanitarias y Fitosanitarias. Declaración del Perú sobre el Reglamento 258/97 de Las Comunidades Europeas. Declaración del Perú en la reunión celebrada los días 27 y 28 de junio de 2006. Organización Mundial del Comercio, G/SPS/GEN/714, 12 de julio de 2006. Comité de Medidas Sanitarias y Fitosanitarias. Declaración del Ecuador sobre el reglamento 258/97 de las Comunidades Europeas. Declaración del Ecuador en la reunión celebrada los días 27 y 28 de junio de 2006. Organización Mundial del Comercio, G/SPS/GEN/735, 18 de octubre de 2006, Comité de Medidas Sanitarias y Fitosanitarias. Declaración de Colombia respecto al Reglamento 258/97 de las Comunidades Europeas declaración de Colombia en la reunión celebrada los días 11 y 12 de octubre de 2006.

⁴ See the report by the WTO Secretariat "*Activities of the SPS Committee and other relevant WTO activities since January 2006*" (Codex Document CAC/29 INF/5, April 2006).

⁵ World Trade Organization, G/SPS/GEN/699, 8 June 2006, Committee on Sanitary and Phytosanitary Measures. Reply of the European Communities to the Communication from Peru concerning Regulation 258/97 on Novel Foods, Communication from the European Communities, §14.

⁶ Commission Decision of 5 June 2003 authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. 2003/426/EC. L 144/12. OJEC 12.6.2003.

⁷ Hermann, M. The impact of the European Novel Food Regulation on trade and food innovation based on traditional plants foods from developing countries. *Food Policy*, n° 34, 2009, 499-507, spec. 503. In same way see, Moorhead A. (2007) Missing the market. How exotic food are being barred from the NFR. Joint paper prepared by the UNCTAD, CBI, GTZ, GFU and IPGRI. Craddock N. (2005). The EU novel food regulation. Impact on the potential export of exotic traditional foods to the EU: Suggestions for revision. <http://www.biotrade.org/BTFP/btftp-novelfoods.htm>. Mück O (2003). Underutilized plant and animal species and the EU Novel Food Regulation. An overview of potentials and constraints. Available in http://www.underutilized-species.org/documents/nfr/underutilized_species_nfr.doc. Mück O. (2003) Trade Barrier NFR? Underutilized species under the European Union's Novel Food Regulation.

⁸ Commission Decision 2008/985/EC of 15 December 2008 authorising the placing on the market of leaves of *Morinda citrifolia* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. See too, *supra* 5.

⁹ Commission Decision of 21 April 2010 authorising the placing on the market of puree and concentrate of the fruits of *Morinda citrifolia* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. 23.4.2010 OJEU L 102/49.

¹⁰ Concerning the properties of *Lucuma* and *yacon* see, Hermann (H), The amendment of the EU Novel Food Regulation: Opportunity for recognizing the special status of exotic traditional foods. Discussion paper: International Plant Genetic Resources Institute (IPGRI), June 2004, Annex 1: Edible minor plant species from Andean South America not yet widely traded internationally, p.10. Craddock, N., 2005.



involving clinical studies that call for significant investments for each product to be registered, and would take three to five years to complete"¹¹. The safety information on foreign products is an important element that retards or blocks the authorization procedure¹².

This information is often insufficient to establish the safety of the product according to the EC member States or the European Food Safety Agency (EFSA) opinions. This is the case for example, of the *Stevia rebaudiana*. The *Stevia rebaudiana* is a plant well known for centuries by the native Guarani Indians for the sweet taste of its leaves¹³ and first cultivated in Brazil and Paraguay¹⁴. At the present time, the *Stevioside*, a white crystalline powder, is extracted from *Stevia* leaves and both *Stevioside* and *Stevia*, are widely used as natural non-calorific sweeteners particularly in Brazil, Costa Rica, China, Japan, and South Korea.

In 1998, a request was made for *Stevia* plants and their dried leaves to be marketed in the EU as a novel food under the NFR. The EC Scientific Committee on Food concluded in June 1999¹⁵ that the information submitted on the plant products was insufficient with regards to specification and standardization of the commercial product and there were no scientific safety studies in the dossier. Consequently, the authorization was not granted¹⁶. In April 2010 "considering all the data available, the Panel of the European Food Safety Authority (EFSA) concluded that steviol glycosides covered by the proposed specifications are not carcinogenic, genotoxic or associated with any reproductive/developmental toxicity." But the conclusion of the EFSA doesn't mean that the authorization to place it in the market is granted. The Commission under the framework shall approve its placement in the market by the current NF regulation. This case shows how the availability of sufficient or available scientific information is the main condition for the authorization procedure.

Taking into account this kind of experiences, the proposed amendment establishes important reforms. In order to recognize the differences between the TTCP from the "technological products" and promote the potential interest trade of the first ones¹⁷, the proposed amendment defines a prior safety evaluation and authorization procedure based on a demonstration of their "history of safe use".

The dossier presented by the third country demand shall have to prove the "history of safe use" of the product. If a Member state or the European Food Safety Agency have justified objections (based on scientific evidence) about its "safety", the product shall not be placed in the market. In that case, the traditional foodstuff is submitted to the standard procedure. In this procedure three conditions shall be demonstrated on

¹¹ World Trade Organization, G/SPS/GEN/699, 8 June 2006, Committee on Sanitary and Phytosanitary Measures. Reply of the European Communities to the Communication from Peru concerning Regulation 258/97 on Novel Foods, Communication from the European Communities, §2.

¹² Hermann, M. *Supra* n° 6, spec. 504.

¹³ The EU Novel Foods Regulation. Its impact on trade in biodiversity products from developing countries. Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH Sector project, People and Biodiversity in Rural Areas⁴ (Unit 4411) Postfach 5180, 65726 Eschborn, Germany, p.2.

¹⁴ Hermann, M. *Supra* n°6, spec. 503.

¹⁵ Scientific Committee on Food CS/ADD/EDUL/167 final 17 June 1999. Opinion on Stevioside as a sweetener (adopted on 17/6/99), p. 6. Scientific Committee on Food CS/NF/STEV/3 Final 17 June 1999. Opinion on *Stevia Rebaudiana* Bertoni plants and leaves, p. 5.

¹⁶ Décision de la Commission du 22 février 2000 relative au refus d'autorisation de mise sur le marché de «*Stevia rebaudiana* Bertoni: plantes et feuilles séchées» en tant que nouvel aliment ou nouvel ingrédient alimentaire conformément au règlement (CE) no 258/97 du Parlement européen et du Conseil. Journal officiel des Communautés européennes 8.3.2000 L 61/14 FR.

¹⁷ The EU Novel Food Regulation. Impact on the potential export of exotic traditional foods to the EU: Suggestions for revision. Discussion paper prepared for UNCTAD and CBI, in cooperation with GTZ, GFU and IPGRI. 60 p. http://www.biobtrade.org/Events/events_docs/events-dec05-Novelfoods-CBIUNCTADpaperonEUNovelFoodRegulation.pdf (accessed 2.12.08).



the basis of the scientific evidence available: 1) that the NF “does not pose a safety concern to health of the consumer under normal consumption conditions”; 2) that it does not mislead the consumer, by the way it is presented or by its intended use”; and 3) that “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”. In this standard procedure the risk evaluation is a requirement, because the scientific evidence is necessary to demonstrate the above-mentioned conditions.

Then, the proposed amendment will establish two different procedures to approve the placement in the market of the TTCP. However, these two procedures are based on two different classifications of the risk represented by TTCP: as an uncertain risk or as the certain risk. These two classifications imply the application of two different general principles that are going to define the procedure of authorisation for placement in the market.

The risk categorisation of the TTCP is inconsistent regarding the European Food Law. It could be analyzed from two perspectives: the categorisation of the risk represented by the TTCP and the application to the equivalence requirement for imported products.

I. The categorisation of the risk represented by the TTCP

The European food law establishes the framework for food production, the transformation and the commercialisation in the common market. The Regulation (EC) N°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 (General Food Law Regulation, GFL) settles the bases of the food safety requirements that food operators and authorities have to ensure.

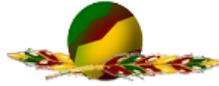
The GFL principles state the food safety approach of the European Union. In particular, the risk analysis and the precautionary principle define the European risk policy. According to these principles, procedures are established to determine the risk and manage it.

The definition of the nature of the risks represented by the TTCP is settled by the application of both principles: the risk analysis principle and the precautionary principle. The risk analysis principle has as objective the developing of the scientific evidence on food safety. Regarding the risk analysis principle, all food law measures shall be based on risk analysis. This way, all sanitary measures shall be justified with scientific evidence to demonstrate, in one hand the pertinence of the measure in relation to the risk and, on the other hand, that it isn't an arbitrary measure. Consequently, this principle is applied when it is possible to obtain “relevant” or “sufficient” scientific information concerning the risk.

Otherwise, the precautionary principle is applied when “in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists”¹⁸. In that case, “the provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.”¹⁹ Under this principle, some measures can be settled to avoid the negative effects caused by a risk on which we don't have “relevant” or “sufficient” scientific information.

¹⁸ Article 7,§1. REGULATION (EC) 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, JOEC, 1/2/2002, L31/1.

¹⁹ Hermann, M. *Supra* n°6..



If it is a certain risk, the risk analysis principle is applied. If it isn't, the precautionary principle shall be applied. The categorisation of the risk represented by the TTCP determines the application of one of these principles, and therefore, the type of authorisation procedure to place the foodstuff into the market.

a) The TTCP as a "certain risk"

The special procedure settled in the reform takes into account the differences between the TTCP's and others food products considered also "novel foods". From a categorisation risk perspective, the TTCP represents "certain" risks. A risk is considered as "certain" when their causes and effects are commonly well known and its way to be managed has been clearly determined.

The categorisation of the traditional food coming from third countries as a certain risk implies a procedural treatment different from the prior authorisation procedure. This different treatment is based in a prudential approach of risk. This approach's goal is to prevent the possible prejudicial effects of the dangers represented by the risk. Taking into account the general knowledge about the certain risk, management measures are well determined.

From a prudential approach, management measures aren't the object of a risk evaluation. The risk evaluation is only applied when it is necessary to identify the hazard identification, its characterisation, and the exposure assessment because the available information doesn't come from a scientific based process²⁰. Management measures result from risk analysis, specifically from the risk management step, which is defined as "the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options"²¹. In other words, management measures are the result of a risk management process, but aren't the result of a risk assessment process. Management measures are taken in an advanced and different risk analysis phase.

In accordance with the prudential principle, management measures are identified. Third countries products could be submitted to the same treatment as European products, based on the fact that they both represent the same kind of risk: a certain risk. In other words, the TTCP's would be approved without a prior authorisation procedure, applying the general safety conditions established in the GFL regulation for third country products. The TTCP wouldn't be submitted at the risk analysis procedure.

The exceptional procedure contained in the proposed amendment search is to prove the "history of safe use" of TTCP's. This upcoming regulation apparently introduces an exception to the general principle of risk analysis. But, is the "history of safe use" assimilated to scientific information or information derived from a scientific process? Is the "history of safe" a disguised risk analysis? If not, how to prove the history of safe use? Would the history of safe use take the place of risk analysis? Is it a simplified risk assessment?

The history of safe use means, according at the proposed amendment, "the safety of the food in question is confirmed with the compositional data and experience of use and continued use in the normal diet of a large part of the population of a country". This definition establishes two different elements to determine the safety of the product. First, it's settled as an objective element: the compositional data, second, it defines four subjective elements: 1) experience, 2) continued use, 3) normal diet and 4) use by a large part of the

²⁰ Article 3,§ 11. REGULATION (EC) 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, JOEC, 1/2/2002, L31/1.

²¹ Article 3,§ 12. REGULATION (EC) 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, JOEC, 1/2/2002, L31/1.



population of a country. The objective element is clear and their interpretation is restrictive, but each one of the subjective elements could be of a large range of interpretations.

What does experience of use mean? It's a formal or an empirical experience of use? Is it a documented experience in time or is it an empirical experience present in the society as a simple collective knowledge? How to prove the empirical knowledge transmitted by oral traditions or undocumented? Could the empirical experience be discharged by safety scientific evidence presented by the Authority or a Member?

In other words, for how long does a product have to be used to consider of "continued use"? What does "normal diet" mean? How much is a "large part of the population"? The scope of these elements is not defined in the proposed amendment. Arbitrary interpretations could be made if the "history of safe use" is understood as a simplified risk assessment, or if it's a substitute for risk analysis, or also if the TTCP are considered an "uncertain" risk in the absence of scientific proofs of safety. Therefore, management measures could be excluded and risk analysis results could be insufficient giving place to the application of the precautionary principle.

b) The TTCP considered as an uncertain risk and the application of the precautionary principle

The precautionary principle defines the procedural treatment of uncertain risks in the European Community. "Uncertain risks" are defined as those "concerns particular instance of suspected possible hazards those are usually associated with complex causalities, large-scale, long term and trans-border processes, and which are usually difficult to control" (Van Asselt, Vos, Rooijackers 2008). Uncertain risks are defined too as "a range of indexes and hypothesis not scientific validated yet but that permit release the release of an alert, [as...] the relation of heterogeneous information's [...] that permit progressively to limit the uncertainty". (Lascoumes, Callon, Barthe 2001; see in same way, Lorvellec, Collart Dutilleul 2002, Collart Dutilleul, Delebecque 2007; Godard, Henry, Lagadec, Michel-Kerjan 2002; León-Guzmán, 2010). These definitions show two different elements of uncertain risks: the first one describes principally the causes; the second one focuses on the measures that could be taken. In others words, we can see that the principle of precaution is a procedural principle that permits that the uncertain risk may yet be treated within a rational framework of decision-making devoid of direct interaction (see Vos, 2008) that takes in account, the causes of risk and the possible management measures.

From the precautionary principle point of view, the TTCP could be considered as an "uncertain risk" in a double sense. First, the information about their safety is not, in some many cases, available. Second, frequently the safety information isn't "formal" scientific information. Then, the safety of TTCP's could be the object of arbitrary interpretations.

These interpretations could be oriented in at least two senses. Primarily, the "history of safe use" and the "experience of use and continued use in the normal diet of a large part of the population of a country" couldn't be scientific information to prove the safety of the product. Secondly, if the objection of the Authority or the Member states suggests that the "experience of use" is composed of social elements, some ambiguity about the safety of these products could be exposed.

The "history of safe use" and the "experience of use and continued use in the normal diet of a large part of the population of a country" couldn't be considered as scientific evidence. First, it isn't the result of a methodical procedure. It's empirical evidence resulting from the people experience. Second, the available information could be qualitatively limited. Consequently, if the Authority or the Member State's objections could be justified in scientific evidence, the empirical evidence presented by third countries could be considered as incomplete, irrelevant or informal information. This is not a hypothetical consideration, this



kind of situation was evidenced in the cases of the *Stevia Baraudiana*²² and the *Nangai Nuts*²³ when, the authorisation was refused because safety evidence was considered as insufficient according to the EU authorities.

The TTCP couldn't be considered as a "novel food". This categorisation was created for regulated specific products as the GMO's and other technological developments that justified the application of a risk assessment. The TTCP category derives from common and traditional procedures of production. The population of the third countries has identified their dangers and their risk management. For these products the application of the precautionary principle could be unreasonable, disproportional and extremely restrictive. The authorisation to place into the market could be reduced to: 1) the prior information of the use, 2) the risk management conditions and 3) the respect of the general safety conditions defined by the European Food Law. These requirements would be consistent with the principle of equivalence of the Food Law Regulation.

II. The inconsistency of the NF regulation in relation to the equivalence requirements for imported products

The inconsistency of the NF regulation in relation to the equivalence requirements for imported products is determined by two elements: the inconsistency concerning the safety of "Traditional products" and the application of equivalent sanitary conditions of imports from third countries.

The World Trade Organisation Agreement on Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement) settled the equivalence principle. This Agreement states in the article 4.1: "Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own or those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection." This Principle is recognition of the differences between the sanitary protection levels and an instrument of governance risk in the international trade. The equivalence principle permits the recognition of the legitimacy of diverse risk approaches (Hathaway, 1999).

The GFL Regulation includes this principle of equivalence in the relations with third countries. This regulation says, in the article 11, that "Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein." This principle, presented as a "general obligation of food trade", looks for a balance between the European food safety requirements and conditions established to the third countries products, as a way to avoid unreasonable obstacles for the international trade.

The equivalence is both substantive and procedural. It's a substantive equivalence because it concerns the objective of the sanitary measure: it shall be assuring the product safety. It's also a procedural equivalence because it establishes consistency between the requirements for similar products, similar risks and then, similar safety conditions. By the application of this "principle of equivalence" the TTCP products should have the "equivalent" treatment as the one given to the European traditional products.

²² Commission Decision 2000/196/EC (OJ L61, p14, 08/03/2000) of 22 February 2000 refusing the placing on the market of *Stevia rebaudiana* Bertoni: plants and dried leaves as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

²³ Commission Decision 2001/17/EC (OJ L4, p35, 09/01/2001) 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. See too, Hermann, M. *Supra* n°6.



a) The inconsistency concerning the safety of “Traditional products” in the European Food Law

European traditional products have a different treatment in the European Food Law. European traditional products are subject of a safety presumption and this is not the case of the TTCP's. For the last ones, in spite of the safety presumption established in the NF regulation, the authorisation procedure settles the requirement of a risk assessment and the burden of proof about safety suggest that they are really seen as “risky products”. This treatment is inconsistent with the principle of equivalence of the European food law because of a special safety regime that is only accorded to European traditional products.

In 2002, the European Food Law was deeply reformed, and a general framework to define and enforce of the food safety was established. General Food Law Regulation EC N° 178/2002, settles the bases of this reform, which was completed by the Hygiene Package and the Official Controls Package. The Hygiene Package establishes the general hygiene requirements, as a way to guarantee a basic level of food safety. The Official Controls Package states the organisation of official systems of safety controls at communitarian and national levels.

The experiences of the application of the Hygiene Package reveal the need of some “flexibility” to contribute to the development of the European market. For ETP some requirements settled by the Hygiene Package were very hard or impossible to fulfil. So, the EFL regulation settles the possibility of some derogation to the hygiene regulation if it is necessary to facilitate the food safety implementation. In this way, article 13, paragraphs 2 and 3 settles say that: “Derogations from Annexes I and II may be granted, in particular, in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation. [3] Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II. 4. (a) The national measures referred to in paragraph 3 shall have the objective: (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; ...” In the same sense, article 10.2 and 10.4.a) I of the Regulation EC 853/2004²⁴ and article 17.2 and 17.4.a)i of the EC Regulation 854/2004²⁵ grant this flexibility in the application of hygiene requirements to the ETP.

These derogations applied for the traditional products should comply with at least one of three conditions: (a) historically recognised as traditional products; (b) manufactured according to registered technical references of the traditional processes, or according to traditional production methods; or (c) protected as traditional food products by the communitarian, national, regional or local law²⁶. The last condition is illustrated by the traditional specialities guaranteed (TSGs), registered under EC Regulation N° 509/2006 or the protected designations of origin (PDOs) and the protected geographical indications (PGIs) produced in a traditional way under EC Regulation N° 510/2006.

This regime of derogation is based on the ETP safety presumption. Following the interpretation of the Commission about hygiene provisions, “In the Member States, food may be manufactured in accordance with longstanding traditions that have proven their safety although not always fully in line with certain technical requirements of the Regulation. The Regulation recognises the need for maintaining these traditional

²⁴ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs. OJ 30.4.2004 L 139/55.

²⁵ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. OJ L 139, 30.4.2004.

²⁶ European Commission. *Commission Staff Working Document on the Understanding of certain provisions on flexibility provided in the Hygiene Package Frequently Asked Questions Guidelines for food business operators*. Brussels, 12.8.2010 SEC (2010) 985 final. p. 5.



production method's that are proof of the cultural diversity of Europe, and provides therefore for the flexibility needed by food businesses. There is no intention in the context of this document to proceed to the making of an inventory of the traditional methods of production in the Member States. It is up to the competent authorities to take the necessary initiatives or act on possible requests from food businesses for flexibility."²⁷ This interpretation establishes a safety presumption of the ETP. This presumption is based on the "proof of safety" resulting from the experience of the traditional consumption in Europe. The ETP are considered safe products, they aren't submitted to a specific risk evaluation to be placed in the market.

This situation has two procedural effects. First, the European traditional products are authorised without special requirements. They aren't subject of a risk analysis because their safety is "proved" by traditional and common consumption by one part of the European population. Second, beyond this safety presumption, a special treatment is established as regard of the general hygiene requirements it permits the derogation of common safety conditions.

Compared to this situation the TTCP are in disadvantage, despite that they have in general the same characters as the European Traditional products (with exception of the TSG's, PDO's and PGI's regime). The Traditional products from third countries are defined as novel food taking into account: (a) a history of safe use in a third country; (b) the use has been and continues to be part of the normal diet for a least one generation in a large part of the population of the country. According to the interpretation of the DG Sanco, the European traditional products are: (a) recognised historically as traditional products, or (b) manufactured according to a registered technical reference to the traditional process, or according to traditional production methods, or (c) protected as traditional food products by EU, national, regional or local law²⁸.

Both of these definitions contain the "traditional" characteristic that permits to establish the conceptual similarity between the ETP and the TTCP. Two elements can be derived from this condition: the relevance of history and the transmission²⁹ that settle the equivalence of these two categories of products from a qualitative and a quantitative point of view.

From a quantitative point of view, the equivalence between the two types of traditional products is determined by the time that proves their use. It's generally accorded in one generation, in others words, 25 years. The NF amendment regulation establishes this temporal condition as a minimal reference: "a novel food 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 *a least* one generation in a large part of the population country". For the ETP case this condition is implicitly accepted for the most of them but explicitly establish one subcategory: the TSG. The TSG must demonstrate a specific period of proven use, at least 25 years. In both cases, the temporal condition permits to prove the historical relevance and the knowledge transmission and so, the traditional character.

From a qualitative perspective, the "recognition historically as traditional products" character of the ETP and the "history of safe use in a third country" and the continued use in a "part of normal diet for a least one generation in a large part of the population of the country" of TTCP permit to demonstrate at the same time, the historic relevance and the transmission of the knowledge of this kind of foods. For the ETP the recognition historically of traditional products proves the knowledge concerning the production and consumption by part of the people's common memory. This knowledge is permanent because of their transmission still from one generation to another.

²⁷ European Commission Health & Consumers Directorate-General. *Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of foodstuffs*. Brussels, 16 February 2009 EN SANCO/1731/2008 Rev. 6, p. 11, §5.2.

²⁸ European Commission. *Commission Staff Working Document on the Understanding of certain provisions on flexibility provided in the Hygiene Package Frequently Asked Questions Guidelines for food business operators*, Brussels, 12.8.2010 SEC(2010) 985 final. p. 5.

²⁹ See in this sense, BERARD L., MARCHENAY P. (1995). *Lieux, temps et preuves : La construction sociale des produits de terroir*, Revue Terrain, n°24, p 153 – 164.



For example, the TSG states the “traditional” character as the “proven usage on the Community market for a time period showing transmission between generations; time period that should be the one generally ascribed to one human generation, at least 25 years”. More generally, other characters as the “historical recognition as traditional products” or the “manufacturing according to registered technical references to the traditional process, or according to traditional production methods” prove the historic relevance and the knowledge transmission as qualitative elements of the traditional character. It corresponds to what was defined by the European Commission in its interpretation concerning the safety derogations for the ETP.

The same qualitative character is present in the definition of traditional third countries products. The NF amendment settles that is a “novel food 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 a least one generation in a large parte of the population country”. The historical relevance is integrated in this definition by the requirement of a “history of safe use” concerning the use continuous in the “normal” diet for a minimal period of time. The transmission character is present by the continuity of the consumption by a part of a population, which implies an intergenerational knowledge communication.

The knowledge transmission and the historical relevance are the common elements that characterize the ETP and the TTCP. From qualitative and quantitative points of view, they are similar kinds of products. The historical relevance use and the transmission knowledge also permit, in both cases, to prove their safety. A safety proved by the risk information that is transmitted by people, as part of the continuous learning procedure of production or consumption. The risk information is transmitted as part of this process. From an objective perspective, the historical relevance and the transmission knowledge don’t permit to establish a relevant safety distinction between the ETP and the TTCP. Both kinds of products are in fact equivalents from a food safety perspective. Consequently, they should have an equivalent authorisation procedure.

b) Equivalent sanitary conditions of imports from the third countries in the European Food Law

The principle of equivalence has been introduced in the article 11 of the GFL Regulation. This rule is that: “Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.” According to this provision, this principle implies two conditions: 1) foreign products shall comply with the European food law requirements and 2) European authorities shall evaluate the conditions of foreign products to determine if they could be considered as equivalents, with regards to the European sanitary objectives. In others words, “an importing country must be satisfied that imports meet its legitimate food safety requirements, and the regulatory authority concerned must reach judgements about the effectiveness of sanitary measures undertaken in the exporting country”³⁰ (Hathaway, 1999). In that way, the TTCP can be submitted to this equivalence evaluation if they respect the same sanitary conditions settled for the ETP.

The principle of equivalence settles some consistency between the requirements for the European and the foreign products. The requirements for the imports must be “at least equivalent” with the ones settled by the European food law for the European products. Under this principle, products of the same nature shall respect the same sanitary conditions.

The TTCP and the ETP have the same nature and, consequently, they shall respect the same sanitary requirements. They are both “traditional products”. The traditional character of these two types of them is

³⁰ Hathaway. S. (1999). *The principle of equivalence*. Food Control 10, 261-265, specif. 261. In same way, León-Guzmán M. (2004). *Análisis de riesgos y su aplicación en el comercio internacional de alimentos*. San José: IJSA, speciif. 69-86.



similar in nature; an equal commercial treatment in the European Market must be the consequence. The similarly safety requirement shall be applied in accordance with the principle of equivalence.

The principle of equivalence is an element of governance in the European Food Law because of it permits to reaffirm the consistency of the European risk management system, and then, with the risk analysis approach. (Houghton, J. et al, 2008). This consistency works from internal and external market points of view. From an internal market perspective, it preserves the European sanitary level and protects it from potential risks presented by the foreign products. This protection is consistent with the objective of the European Union, to avoid the exposure at risk of the importation of non-safe products. It's a clear measure of risk governance taken by the European authorities. From the international trade point of view, the equivalence is a governance element because of it permits the recognition of differences between the legislations of different countries but respecting the European sanitary objectives. It settles reasonability in the definition and consideration of sanitary measures.

Nevertheless, the NF amendment seems to forget this principle of equivalence or recognition in detriment of the NF trade, and particularly, the TTCP. This situation could be inconsistent with the European Union Trade Policy and the Bilateral and multilateral trade systems.

Conclusion

The inconsistency of the Novel Food Regulation with the principle of equivalence applicable to imported products shows how the analysis of the risk of a product is a determining element of the coherent and consistent application of the EFL.

On the one hand, the classification of traditional products as products representing a certain or an uncertain risk, determines the measures of handling or of precaution applicable. When the traditional product of a third country is considered within the first category, the measures of risk control do not represent greater difficulty, since they are genetically foreseen either generically or specifically by the legislation. On the other hand is the case in which the risk that TTCP represent is considered uncertain. The ambiguous, and up until now, arbitrary principle of precaution would be applied. Summarizing, the classification of the risk that these products represent will define their sanitary states and the handling measures to be applied.

Nevertheless, under this perspective, TTCP have – or would have – a particular regime. This regime lacks basis if the principle of equivalence is applied. In accordance therewith, products imported from third countries could benefit from the application of equivalent criteria, both in the definition of risk and in the establishment of the requests of entrance and marketing. The analysis exposed showed the inconsistency of the Novel Food Regulation in the face of the principle of equivalence of products imported established in by Laws CE 178/2002, inconsistency that is grounded in an almost arbitrary categorization of the risk of European and third country traditional products.



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