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## NEW LEGAL REQUIREMENTS REGARDING THE PLACING OF NOVEL FOODS ON THE EUROPEAN UNION MARKET

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### ABSTRACT

*The new regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 applies the placing of novel foods on the market within the European Union. Novel food is defined as food that has not been consumed to any significant degree in the EU before May 1997, when the first novel food legislation entered into force. It was necessary to revise the novel food legislation because the current rules date back almost 20 years. Since then, technological developments and scientific advice have evolved considerably. Therefore, to reduce the current length (3 and a half years on average) for the authorisation procedure, EU rules needed to be updated. This new novel food Regulation that has been agreed today aims to improve conditions so that businesses can more easily bring new and innovative food to the EU market, while still maintaining a high level of food safety for European consumers. The authorization of these kind of foods follows few clear steps explained in the regulation for novel foods. It is very clearly stipulated that traditional food from a third country fall under this new regulation. Therefore, Member States, including Romania, have to respect all requirements set out regarding this Regulation.*

**Keywords:** novel foods, food safety, consumers, European Union

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### 1. INTRODUCTION

In the year 1967, World Health Organization defined health as “a physical, mental and social condition and not just the absence of illness or infirmity”. Therefore, a particular role is played by both the food and the diet of the individual throughout his life in order to maintain health (Burton, 1988). That is why the medical world, but also the governmental and /or non-governmental, national and /or international bodies such as the World Health Organization, the European Commission, the Food and Agriculture Organization, the United Nations Development Program, UNICEF, etc, are concerned more and more for the consumption of safe and healthy food among the population, this aspect being a major component of what is called "healthy lifestyle"( WHO European Region Food and Nutrition Action Plan 2014 – 2020).

In this context, for the free movement of safe and healthy food products on the European market, in order to ensure a high level of

protection of human health and consumers' interests and for the effective functioning of the internal market, an important role lies in the drafting and implementation of legislation The European Union in the field (FAO/WHO Pan-European Conference on Food Safety and Quality, 2002). This is generally applicable to food, but also includes novel foods introduced on the EU market, as well as novel foods imported from third countries, from outside the European area (Regulation No EU 2283, 2015), (Regulation EC No. 178, 2002).

Until now, the placing on the European Union market of novel foods and food ingredients has been made in compliance with the requirements of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients in food law, in general (Regulation EC No. 178, 2002).

As the legislation needed to be updated in the light of scientific and technological developments in this area, in 2008 the European Commission proposed for the first

time the proposal to amend the EC Regulation no. 258/97 (Belliste, 1998), (Costin,1999). This first attempt to amend the mentioned regulation was rejected by the European Parliament because of a particularly sensitive point regarding the inclusion of food from cloned animals as novel foods. That is why the subject was resumed in 2013 with the revision of the first proposal, this time ending with the approval of the respective act, namely Regulation no. 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. (EC) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 with effect from 1<sup>st</sup> of January 2018. Until that date, the requirements of Regulation No. 258/97 apply.

## 2. “NOVEL FOOD” CONCEPT

It is important to note that the definition of “novel food” has not changed compared to the one set out in the previous regulation, the distinction being that in the current regulation this definition has been supplemented by other categories of food (EFSA Scientific Colloquium Summary Report, 2009), (Regulation No EU 2283, 2015). In the definition of the novel food, the most important element is that the food was not consumed significantly by the population of the European Union before the first date of the legislation in this field, respectively 15<sup>th</sup> of May 1997. This date remains as a landmark, without taking into account the date of accession of the various countries to the European Union.

In the novel food category, the following types of foods are included: foods with structural or intrinsic modifications, foods obtained from plants or animals or from different parts thereof, from mushrooms or algae, from minerals or from manufactured nanomaterials, foods obtained by processes other than known (Regulation No EU 2283, 2015). In other words, novel foods refer to new food sources or newly developed or innovative foods, food

produced using new technologies and production processes, and food traditionally consumed in third countries outside the European Union (CHANCE Project, 2014), (Climate Change, Food and Nutrition Security Implications, 2010).

The following examples of novel foods can be given (Brochure d'information sur les Nouveaux Aliments, Réglementation et procédures, 2017), ([www.europa.novelfoods](http://www.europa.novelfoods); [www.efsa.europa.eu](http://www.efsa.europa.eu)):

- milk and bread treated with ultraviolet radiation;
- refined seed oil of *Buglossoides arvensis*;
- D-tagatoza;
- oil with high content of DHA and EPA extracted from the *Schizochytrium* microalgae;
- Beta-glucans extracted from yeast;
- heat treated and fermented milk products with *Bacteroides xylanisolvens* (DSM 23964);
- plant products: rapeseed proteins; juice from *Morinda citrifolia* fruit; Chia seeds; Dry baobab fruit, etc

The procedure for authorization or notification of novel foods is done according to the steps described very clearly in the Regulation, starting with the submission of the application by the applicant and ending with authorization by the European Commission. Throughout the process, the European Food Safety Authority and the Member States of the European Union play a very important role (Regulation No EU 2283, 2015). Sometimes it is very difficult to have a very clear demarcation between novel foods, food supplements, foods for special medical purposes, foods for athletes, regular food or even medicines, and for this reason the so-called "border products" (Ghidul privind informarea consumatorilor cu privire la produsele alimentare, Romalimenta – ANPC, 2013).

The novel food regulation does not apply to the following categories of foods that are specifically regulated: genetically modified foods regulated by Regulation (EC) (EC) No 1829/2003, food enzymes, by Regulation (EC) 1332/2008, food additives by Regulation (EC) No. 1333/2008, food flavorings by Regulation (EC) No. 1334/2008 and extraction solvents

used or intended for use in the manufacture of food and food ingredients by Directive 2009/32 / EC (Regulation No EU 2283, 2015).

### 3. IMPACT ON THE PUBLIC HEALTH

Application of the requirements of Regulation No. 2283/2015 on novel foods at European Union level and, of course, at Romanian level, has the main aim to ensure the effective functioning of the internal market and in the same time to protect the health and consumer interests (Climate Change, Food and Nutrition Security Implications, 2010), (WHO European Region Food and Nutrition Action Plan 2014 – 2020). When a novel food is placed on the European market, it must comply with certain mandatory marketing requirements: be safe, not to mislead the consumer and not present disadvantages of consumption. The food safety can be guaranteed only by fulfilling all these requirements (EFSA Scientific Colloquium Summary Report, 2009).

In order to demonstrate that novel food which will be authorized is safe, the scientifically documented studies showing that there is no allergenic, toxicological, chemical or microbiological contamination risk on the consumer's health must be provided (Brochure d'information sur les Nouveaux Aliments, 2017). In order not to mislead the consumer, the novel food should be appropriately labeled, according to the general labeling requirements of foods but also to the specific requirements for the product, if applicable (European Food Information Council, 2012), (Regulation EU No 1169, 2011). In order to prove that there are no disadvantages of consumption, well-documented scientific arguments must be provided in order to demonstrate that it is not nutritionally disadvantageous to the basic food or which it intends to replace, but it would even have benefits (eg. increased intake of polyunsaturated fatty acids, increased intake of vitamin D3, lower allergenic risk, etc) (EFSA Scientific Colloquium Summary Report, 2009). The careful analysis of the steps to be taken to authorize the placing on the market of such foods, it is clear that the European Commission

is directly responsible for this process, but also the authorities of the Member States of the European Union must actively participate beginning with setting the possible novel food status of the product concerned and finishing the sanctions that may be applied if the provisions of this Regulation are not complied with (Regulation No EU 2283, 2015).

Therefore, the authorization of novel foods at European level guarantees food safety by complying with the requirements described above. On the contrary, the placing on the market of these categories of food without authorization has a high risk to the consumer's health in the last situation, the Member States being obliged to take the necessary measures

### 4. CONCLUSIONS

The new regulation has made the following improvements to the previous legislation on novel foods (Guidance for Industry Use of Nanomaterials in Food for Animals, of Nanotechnology, 2015), (Regulation No EU 2283, 2015):

1. The procedure for authorizing the placing on the market of novel foods has been optimized and centralized, including generic authorization;
2. The European Food Safety Authority (EFSA) will conduct food safety assessments following consultation with the European Commission;
3. A new EU list of novel foods will establish starting with January 1, 2018;
4. The efficiency and transparency of the whole process of placing these foods on the market will be improved;
5. The safety assessment will be faster and more proportionate for traditional food from third countries and with a history of safe food use.
6. New technologies and innovations in food production will be encouraged.

Taking into account the above, Romania, as a Member State of the European Union, must apply it too the provisions of this regulation at the national level by involving all relevant

actors in this process: manufacturers and processors, operators, authorities, etc.

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