

NOVEL FOODS IN NORTH MACEDONIA: REGULATION, ROLE, AND PERSPECTIVES OF FOOD OBTAINED WITH INNOVATIVE TECHNOLOGIES

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Abstract

The evolution of the dietary habits of populations opens new opportunities for food operators who, in recent years have been interested in developing new products but also in enriching available products with new ingredients. Food or food ingredients obtained with innovative technologies and food that had not been consumed to a significant degree by humans before 15 May 1997 are considered novel food. For easier use and characterization, novel foods have been categorized into several groups. A key aspect of its approval and marketing is for it to be safe and not to pose a risk to human health, not to mislead consumers, all of which is confirmed by relevant scientific evidence. The regulation and approval of novel foods in Europe after 2018 must comply with EU Regulation 2015/2283, which regulates the manner of its authorization and presentation. According to EFSA, the number of applications for novel foods has increased with the setting of the new regulation. Any novel food that is approved is placed on the Union's list of authorized novel food (Commission Implementing Regulation (EU) 2017/2470). The Register of approved foods and food ingredients produced with innovative technologies in the Republic of North Macedonia has so far numbered 560 food or novel food ingredients. Assessing the value and importance of novel food in the modern food industry, this paper will review the approved novel food in the Republic of North Macedonia, its presence, and its role in obtaining as new innovative foodstuffs. This paper shall also make it possible to inform consumers, food operators, the academic community, and the food industry about the prospects of novel foods when creating innovative products with increased nutritional and/or functional characteristics.

Keywords: novel foods, North Macedonia, food ingredients, innovative technologies, innovative products, food safety

1. Introduction

Promoting a healthy diet has contributed to increasing the production of new food products or improving the characteristics of existing products. Although there is an increase in the number of people adhering to healthy diet habits, there are certain difficulties in getting consumers to accept a novel product, especially if the changes relate to certain sensory characteristics, which makes it more difficult to change their eating habits. Thus Florack et al., 2021, noted that consumers notice the different attributes between the classic product and the new product, i.e., the healthier alternative is more negatively evaluated, while more shared attributes are considered a positive thing. In this context, food operators have a major challenge in finding an alternative, i.e., it is very challenging to develop a new product that would be easily accepted by consumers. For example, food futures develop new products with an incorporated new ingredient, which are similar but are not identical to existing foods (e.g., reduced meat or plant-based burgers). In recent times, companies are developing plant-origin meat substitutes and developing meat-free products to keep consumers consuming the desired type of food, while still practicing healthy diets (Khillar, 2021). In other distant countries, insects have been used as a traditional food for many years. In recent years, these traditional foods from third countries have been considered in the European Union (EU) as "novel" food, i.e., certain insects and their products such as insect

powder or insect proteins have been reviewed by food authorities such as European Food Safety Authority (EFSA) and some of them are already approved as safe food products, especially because of the nutritional properties of these products (Finardi & Derrien, 2016).

1.1. Categorization of Novel Food: With the introduction of the term novel food into European Union regulations, products from this category of food begin to be recognized as such, and if we look at the whole picture it shows a significant increase in innovative products or new food products, which the food operators put on the market and are available to consumers and are categorized as a novel food. Food and food ingredients that had not been consumed to a significant degree by humans in the EU before 15 May 1997 are defined as novel food in the Republic of North Macedonia this type of food is known as food produced by innovative technologies (Rulebook, 2020). Novel food can be newly developed, innovative food, food produced using new technologies and production processes, as well as food that is or has been traditionally eaten outside of the EU. Because of its better classification, its categorization was made, and these are the following categories of novel food:

- food or food ingredients with a new or intentionally modified molecular structure, which has not been used as food in the Republic of North Macedonia so far.
- food and food ingredients consisting of, isolated from, or produced from microorganisms, fungi, or algae.
- food or food ingredients consisting of, isolated from, or produced from material of mineral origin.
- food or food ingredients consisting of, isolated from, or produced from plants or their parts, except when the food has a history of safe food use and is consists of, isolated from or produced from a plant or a variety of the same species obtained by: - traditional propagating practices which have been used for food production; or - non-traditional propagating practices which have not been used for food production so far, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- food or food ingredients consisting of, isolated from, or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use in the Republic of North Macedonia.
- food or food ingredients consisting of, isolated from, or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi, or algae;
- food or food ingredients resulting from a production process not used for food production within the Republic of North Macedonia so far, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism, or level of undesirable substances.
- food or food ingredients consisting of engineered nanomaterials, with a history of safe use in the Republic of North Macedonia.
- vitamins, minerals, and other substances intended for use in dietary supplements, in enriched foods, or foods of special nutritional use, when: - a production process not used for food production before has been applied, or they contain or consist of engineered nanomaterials, with a history of safe use in the Republic of North Macedonia.
- food or food ingredients used exclusively in food supplements so far and which will now be used in another type of food but use in dietary supplements is not considered a history of safe use of food or ingredients.

These categories may be supplemented with other food and food ingredients following a procedure carried out by the European Commission authorizing the Commission to act on matters relating to food safety and veterinary policy (Rulebook, 2020).

1.2. Novel food in the European Union: Novel food in the European Union was regulated by regulation (EU) 258/97, but the application of this regulation has established that there is a need to supplement and simplify the procedure for approving, considering scientific achievements and European law, and today it is regulated by the new regulation (EU) 2015/2283 of the European Parliament and the Council on Novel Food. This regulation complements categories or introduces new groups of novel foods, according to scientific and technological development, but the biggest change is due to the procedure for approving novel food (Haber & Aurich, 2018). European Union member states have been key players in assessing the safety of novel foods, while EFSA today plays a central role in assessing the safety risk of novel food when approving any novel food by the European Commission. Under the old regulation, applicants submitted their applications to the responsible authorities in the member states, and today the central address for approval is the European Commission. European Commission has requested the European Food Safety Authority (EFSA) to develop scientific and technical guidelines for the preparation and presentation of applications for authorization of novel foods, which would be a common format for attaching information to be presented, to assist food operators in preparing a well-structured application followed by a technical dossier for proving food safety. The guide will aim to facilitate access to information and scientific data in applications so that EFSA can conduct its risk assessment with an evaluation that it will provide in its scientific opinion effectively and consistently. The EFSA thus provides the type and quality of information needed to evaluate whether food is safe or not, by the proposed terms of use (Turck et al., 2016). Data need to be submitted to assess the safety of novel food, which is one of the most significant conditions before it is approved and released for sale. That is, these are data relating to the description of the novel food, the production process applied, composition data, specification, proposed purpose, level of use, and the intended intake of novel foods. The manufacturing process applied to the production of novel foods (e.g. chemical synthesis, enzymatic catalysis, fermentation or isolation from a natural source, etc.) should be described in sufficient detail to be able to provide information, evaluate bioavailability, nutritional value, and safety, as well as information on potential by-products, impurities, and contaminants (Turck et al., 2016). If a new production process has been applied, i.e. a process that was not used for food production in the European Union before 15 May 1997, it is necessary to characterize the new aspects of the process. Furthermore, the applicant should also consider the history of use of the novel food or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information, and the possibility of causing allergic reactions. If the food is isolated or produced from a plant, animal, or microbiological source, it is necessary to describe the entire process of how the raw material is converted into an ingredient or a preparation intended for a new innovative product or food product, for example, whether any heat treatment, fractionation, extraction, distillation, fractionation, purification, etc. have been applied.

In the case of complex mixtures (extracts, or protein hydrolysates) and whole foods (e.g., meat, milk, fruit, seeds), i.e. where all ingredients cannot be completely chemically characterized, qualitative and quantitative characterization of the main ingredients should be performed, while for those components that are unidentified it should be indicated but their quantity should be much smaller.

If potential health hazards are identified, for example, based on its composition, production process, its history of use or there are results from animal or human studies, this should be discussed and the expected intake of the novel food, as well as the population for which it is intended, should be considered. According to the above, we can emphasize that the novel food should be safe and based on the available scientific evidence should not pose a risk to human health. Along with the adoption of the new regulation, the European Commission also adopted the „Union list of authorized novel foods (Commission Implementing Regulation (EU) 2017/2470). The list of approved novel foods, which in addition to the old regulations for approved novel foods, is supplemented with the new "novel" foods according to the regulation 2015/2283, is updated by adding, subtracting, or changing the specifications, conditions of use or specific requirements, or post-market

monitoring requirements. All participants benefit from this List and Novel foods catalog in the marketing and approval of novel foods, and this includes applicants, food operators, food authorities as well as consumers.

1.3. Novel food in the Republic of North Macedonia: In the Republic of North Macedonia, novel foods are foods produced by innovative technologies (Rulebook, 2020). The national legislation is fully harmonized with the EU legislation in this area. Its categorization is consistent with the categorization in the European Union. Something characteristic of a novel food is that it should be safe, not mislead the consumer and if it is applied to replace another food, it should not differ from that food in such a way that its usual consumption would be disadvantageous for the consumer, especially when it comes to nutritional aspects.

In the Republic of North Macedonia, each approved novel food is entered in the Register of approved food and food ingredients prepared by the Department for food produced with innovative technologies, food with ionizing radiation, and other types of foods within the New Food Technologies Department of the Food and Veterinary Agency. The Register of approved products from the group of food and food ingredients produced with innovative technologies in the Republic of North Macedonia counts 560, for the period from 2014 to the beginning of 2022 (fig. 1) (Register of novel foods, 2022).

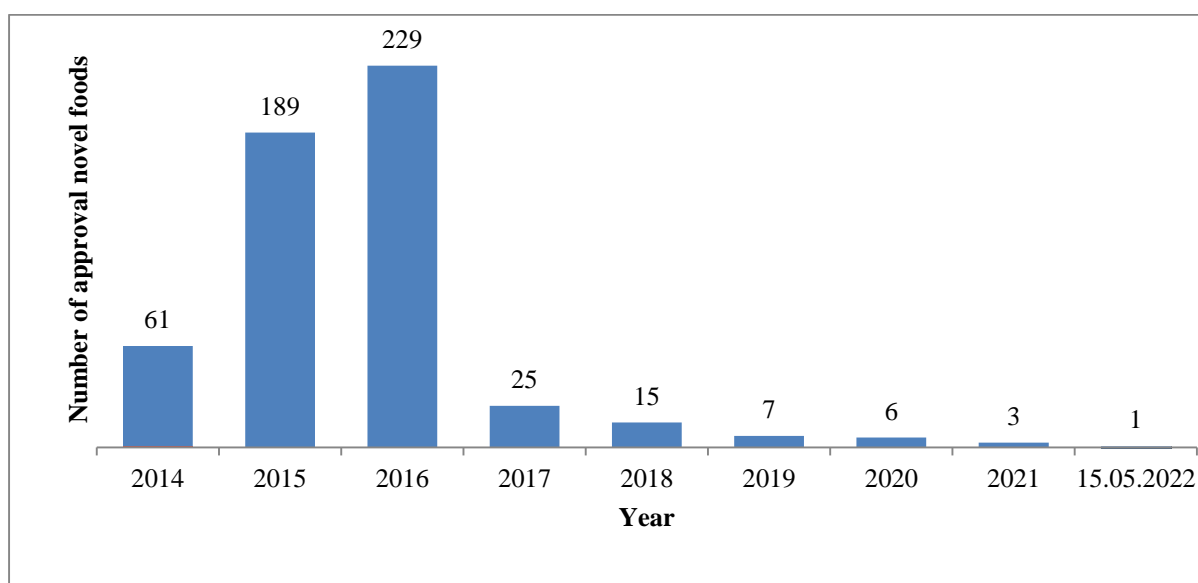


Fig1. Number of approved products from the group of novel foods and ingredients of novel foods in the Republic of North Macedonia (2014-2022) (Register of novel foods, 2022)

There are 21 808 establishments and food operators operating in the Republic of North Macedonia (Register of facilities and operators, 2022). Food operators, before placing food or food ingredient on the market in the Republic of North Macedonia, need to check whether such food or food ingredient is in compliance with the Regulations and is on the Register of approved food and food ingredients produced with innovative technologies, approved by the European Commission for marketing in the Member States of the European Union and the European Catalogue of food produced with innovative technologies and published by the Food and Veterinary Agency.

If food operators are unsure whether a particular food, they intend to put into circulation, is under the regulations or whether has been approved, they should receive confirmatory information from the Food and Veterinary Agency (Rulebook, 2021). The applicant or food operator shall apply and submit it to the Food and Veterinary Agency. The Commission makes a food safety assessment which, according to the offered data, determines whether the food is safe as the food from a comparable category of food that has already been

marketed in the Republic of North Macedonia, the composition does not pose a risk to human health, as well as if the food is intended for replacement of other food, whether it differs and would be adverse from a nutritional point of view. The Commission also carries out a safety assessment if it concerns traditional food from a third country, i.e. whether there is a history of safe use in that third country and the same conditions as for any food. Approval for marketing a food product and food ingredients produced with innovative technologies shall be granted for a period of 10 years and may be renewed. Table 2 gives selected groups of novel foods that have already been approved by the Republic of North Macedonia and have been marketed.

Table 2. Novel food approved in the Republic of North Macedonia (Register of novel food, 2022)

Ingredient Name	Product Type
Krill oil (<i>Euphasia superb</i>)	Dietary supplements (capsules)
Sweet anise (<i>Foeniculum vulgare</i>)	Dietary supplements (instant tea)
Quinoa (<i>Chenopodium quinoa</i>)	Galettes, dietary supplements (syrup, potion), flour, pasta
Dried goji berry fruits (<i>Lycium barbarum</i>)	Dried fruits
Cold squeezed pomegranate seed oil (<i>Punica Granatum</i>)	Oil
Shiitake mushroom powder (<i>Lentinula edodes</i>)	Dietary supplements
Flaxseed (<i>Linum usitatissimum</i>)	Bread, crackers
Black seed (<i>Nigella sativa</i>)	Oil, bread, dietary supplements
Pine bark (<i>Pinus pinaster</i>)	Beverage
Reishi Mushroom Extract (<i>Ganoderma lucidum</i>)	Dietary supplements (capsules)
Dried cranberry (<i>Vaccinium macrocarpon</i>), dried goji berries (<i>Lycium barbarum</i>), dried blueberries (<i>Vaccinium myrtillus</i>)	Muesli, bar tile
Organic lucuma (<i>Pouteria lukuma</i>)	Protein supplement (dietary supplement)
Chia seed (<i>Salvia hispanica</i>) (3.5%) and black seed (<i>Nigella sativa</i>) (3.5%)	Biscuits
Flax seed (<i>Linum ussitium</i>), chia seed (<i>Salvia Hispanic</i>), spirulina (<i>Artrospira platensis</i>)	Bar (sweet)
Noni (<i>Morinda citrifolia</i>)	Dietary supplements (extract)
Isomaltulose	Cookies, biscuits
Chia Seed & Quinoa Flakes	Instant mixture for the preparation of oatmeal, granola

2. Role and Perspectives of selected Novel food

This section will provide an overview of selected approved novel food products or food ingredients as required by the European Commission and approved by the EFSA Panel on Nutrition, Novel Foods, and Food Allergens (NDA).

2.1. Pea and rice protein fermented by Shitake (*Lentinula edodes*): mycelia is a mixture of fermented pea and rice protein concentrate with shiitake micelles (65 % and 35 %, respectively). The main ingredient is a protein ($\geq 75\%$ dry weight) which is easily digestible and provides enough essential amino acids. It is used as a food

ingredient in certain food categories for the general population, however, caution should be exercised against the possible occurrence of allergic reactions in people sensitive to rice, peas, and shiitake mushrooms (Turck et al., 2022a).

2.2. *Dried coffee husk (Cascara) from Coffea arabica L.*: contains skin (exocarp), the pulp (mesocarp), mucilage (pectin), parchment (endocarp), and a part of the silver skin of the coffee fruit, and consists mainly of digestible carbohydrates, dietary fiber, and water. This product is safe if it is stable throughout its shelf life, and if caffeine-free drinks are prepared that will not exceed the permissible amount of 150 mg/L for children, pregnant women, or nursing mothers, and a maximum permissible concentration of 600 mg/L caffeine for the rest of the population (Turck et al., 2022b).

2.3. *Mung bean protein*: as a novel food (NF) is extracted from seeds of the plant *Vigna radiata*. It is used as a food ingredient added to a protein product, for the general population. The main ingredients are protein (~85%), fat (3–4%), and moisture (3–5.5%). This NF contains a protein that is easily digestible and provides enough multiple essential amino acids, but also organic amounts of sulfur-containing amino acids. The maximum estimated intake is 758 and 260 mg/kg body weight per day for children and adults, respectively (Turck et al., 2021a).

2.4. *Frozen and prepared formulations from whole house crickets (Acheta domesticus)*, can be applied in three formulations: frozen, dried, and ground. The main components are proteins, fats, and fibers (chitin) in the dried form, and water, proteins, fats, and fibers (chitin) in the frozen form. It can be applied as a snack or as a food ingredient in several foods applicable to the general population (Turck et al., 2021b).

2.5. *Frozen and dried formulations from whole yellow mealworm (Tenebrio Molitor larva)*. The term yellow food worm refers to the larval form of the insect species *Tenebrio Molitor*. The NF comprises the frozen and frozen prepared formulations of the yellow mealworm, whole or in the form of powder, for the general population. The frozen formulation consists mainly of water, crude protein, and fat until the freeze-prepared formulations of crude protein, fat, digestible carbohydrates, and fiber (chitin). It is used as whole frozen or whole dried insects, or in the form of powder, added as an ingredient in various foods such as cereal bars, pasta, meat imitates, and bakery products (Turck et al., 2021c).

2.6. *Cetylated Fatty Acids* is administered as a dietary supplement and a safe daily intake is 1.6 g per day for adults. This product is a mixture of acetylated myristic acid and acetylated oleic acid synthesized from cetyl alcohol, myristic acid, and oleic acid, and to a lesser extent, other acetylated fatty acids and other compounds from olive oil (Turck et al., 2021d).

2.7. *UV-treated baker's yeast* containing up to 3.5 million IU of vitamin D/100 g is safe under the proposed conditions of use for yeast-leavened bread, rolls and fine bakery wares, and food supplements. Its application as a Novel Food has been extended, but it is emphasized that care should be taken in children from the age of 4-10, not to exceed the content of vitamin D given that potential exposure from other supplements and foods containing vitamin D is possible (Turck et al., 2021e).

2.8. *Oil from Schizochytrium limacine* (Strain FCC-3204) for use in infant formula and follow-on formula is an oil obtained from *Schizochytrium* sp. single-celled algae and the species FCC-3204, belonging to the species *Schizochytrium limacine*. As a novel food, it is used in milk formulas for infants and milk formulas. It

represents an oil rich in docosahexaenoic acid (DHA) derived from microalgae. The level of use is from 20-50 mg/100 kcal (Turck et al., 2021f).

2.9. *Rapeseed powder from Brassica rapa L. and Brassica napus L.* is produced from a variety of seeds with low sorption of erucic acid and reduced content of glucosinolates, with a new production process applied. It is used as an ingredient added to several food products, intended for a general population over 1 year of age. The maximum estimated intake of the NF is 18-21 g/day in adolescents, adults, and the elderly (corresponding to 0.35, 0.23, and 0.25 g/kg body weight (BW) per day, respectively (Turck et al., 2020a).

2.10. *Vitamin D2 mushroom powder.* The NF is an ingredient produced from *Agaricus bisporus* mushrooms that have been exposed to ultraviolet (UV) light to induce the conversion of provitamin D2 (ergosterol) to vitamin D2 (ergocalciferol). The NF contains concentrations of vitamin D provided by vitamin D2 in the ranges of 1.000-1.300 µg/g. It is added to various types of food and beverages, including food for special medical purposes and dietary supplements. The target population is the general population, except for dietary supplements, for which the target population is individuals older than seven months (Turck et al., 2020b).

2.11. *Egg membrane hydrolysate.* The NF is a water-soluble hydrolysate of egg membrane, produced by alkaline treatment of the thin layer lining the shells of chicken eggs. The main constituents of the NF are elastin, collagen, and glycosaminoglycans. The NF is proposed to be used as a food supplement for adults, at a maximum daily amount of 450 mg. The target population for the NF is the general adult population (Turck et al., 2018)

2.12. *Cranberry extract powder.* The NF contains about 55-60% proanthocyanidins (PACs). Cranberry extract powder is produced from cranberry juice concentrate through an ethanolic extraction using an adsorptive resin column to retain the phenolic components. The NF is intended to be added to beverages and yogurts to provide 80 mg PACs per serving. The target population is the adult general population (Turck et al., 2017).

2.13. *UV-treated milk* the novel food is cow's milk (whole, semi-skimmed, or skimmed) to which treatment with ultraviolet (UV) radiation is applied after pasteurization to extend the shelf life of the milk. This treatment results in an increase in vitamin D3 concentrations. The target group is the general population with the exclusion of infants (up to 1 year of age) (Bresson et al., 2016).

2.14. *UV-treated bread.* The NF is bread to which treatment with UV radiation is applied after baking to convert ergosterol, which is present in bread because of yeast fermentation, to vitamin D2. Vitamin D2 content of 0.75-3 µg/100 g in the UV-treated bread, 1-5 g/100 g of yeast in the dough, and the data from batch testing do not give rise to safety concerns. Even if it is conservatively assumed that all consumed bread is UV-treated and contains the maximum proposed amount of 3 µg vitamin D2/100 g, it is highly unlikely that tolerable upper intake levels for vitamin D, established by EFSA for various age groups, will be exceeded (Agostoni et al., 2015).

The specified novel food products or ingredients, because of their characteristics, have a major role in obtaining innovative products, therefore, the food industry and food operators will benefit if they incorporate them into new products.

3. Innovative products with novel food and ingredients

Since the approval of novel foods was regulated and its categorization expanded, the food industry has marketed several innovative products and certain industries are developing new products. According to Jankuloska et al., 2020, it is necessary for the food industry to monitor consumer needs and, by applying scientific achievements in the world, introduce new innovative technologies for obtaining a functional product. In this section, several innovative products will be mentioned to see the role of the novel food in obtaining an innovative product and the perspective of the novel food in creating a new product with functional or improved nutritional characteristics.

The food industry has released yellow fat spreads containing phytosterol esters. The recommended intake is 2-3 servings per day from the range of foods containing phytosterol esters which is equivalent to a daily intake of 2-3g free phytosterol. The currently available phytosterol-fortified products in the market include yellow fat spreads (fat content from 32-63%), yogurt (natural, vanilla, toffee, and various fruit flavored), semi-skimmed milk, chicken balls, chicken gratin (a chicken dish with potatoes and cream), sausages, salads (potato and beetroot), mayonnaise, cereal bars (chocolate chip, raisin nut, and apricot), and soft cream cheeses (natural, garlic and herbs). Commercially, phytosterols are currently contained in bars (Australia, England), vegetable oils (Japan, Israel), orange juice, mayonnaises (Australia), milk (England, Australia, and Argentina), yogurt (Australia, England), yogurt drinks, soy milk, meat and soups (Finland), and green teas (Korea) (Berger, Jones & Abumweis 2004).

Quinoa biscuits containing 60 g quinoa flour/100 g have been shown to have a positive effect on reducing the risk of cardiovascular disease in adults when consumed over 4 weeks. Consumption of novel quinoa biscuits produced small but favorable changes in body weight, body mass index (BMI), and circulating cholesterol concentrations (Pourshahidi et al., 2020).

Chia seed as a novel food is incorporated into food products and improves physical-chemical, sensory, and nutritional characteristics. According to Rendon-Villalobos et al., 2012, the incorporation of chia seeds into tortillas reduces the rate of enzymatic hydrolysis of starch and glycemic index. Chia seeds added to bakery products increase the concentration of proteins, unsaturated fatty acids, antioxidants, and dietary fibers (Iglesias-Puig & Haros, 2013; Segura-Campos et al., 2013), in wheat bread increases its antioxidant, texture, color, and sensory properties (Sayed-Ahmad et al., 2018), while the rubber present in the seeds can retain water (Segura-Campos et al., 2014). Similarly, the use of 10% chia flour in gluten-free bread increases lipid, protein, and dietary fiber levels compared to white gluten-free bread (Sandri et al., 2017). Chia seed oil is also commercially exploited due to its rich content of essential fatty acids, such as alpha-linolenic acid (omega-3 or n-3) and alpha-linolenic acid (omega-6 or n-6) (Mohd Ali et al., 2012) and plays an emulsifier and stabilizer role (Segura-Campos et al., 2014).

4. Conclusions

To contribute to healthier populations, whereby consumers would have greater opportunities when choosing food, in the countries of the world as well as in the Republic of North Macedonia, novel foods have been introduced and regulated. Despite the good regulation of novel foods in the Republic of North Macedonia, however, the interest of food operators in obtaining innovative products in which novel foods ingredients would be incorporated should be stimulated, by presenting the opportunities for obtaining new products and the benefits they would receive from such a product. With such scientific research and understanding of the perspectives of all categories of novel foods, it will help the food industry and all concerned authorities to expand their established business models and encourage them to further develop innovative products with improved characteristics.

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