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INVESTIGATION OF A NUTRITIONALLY BALANCED ANIMAL PROTEIN-BASED FOOD SUPPLEMENT "OMARIDIN"

Final project report

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MTEP work group

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Introduction

In Lithuania, the State food and veterinary service (hereinafter – SFVS) is responsible for the safety, monitoring and regulatory compliance of food and food supplements. The European Commission (EC) is responsible for legal regulation in the member states of the European Union. European food safety authority (EFSA) is responsible for providing science-based opinions to the EC for the development of the legal framework. To ascertain whether a product developed complies with the legal requirements, it is necessary to check the consistency of the documents, advisory guidelines and other sources of information issued by these organisations. Although most of the regulatory documents in the member countries overlap, before exporting a product to any country it is recommended to contact the food safety authority of specific target country to ask for clarification whether the country has any additional regulations defined for the specific imported product. This step is necessary because member countries have the right to regulate more strictly the production, entry and conditions of sale of products. Country-specific requirements can be provided by the country's food safety authorities, which are listed in Annex 1.

All EU member countries have a permanent EFSA National Focal Point (NFP). The authorities listed in Annex 1 can be contacted if you have any questions or need assistance, advice on the legal regulation of a particular product in other countries, or the contact details of the NFP in a particular country.

The composition of the product under analysis, commercially known as OMARIDIN, is given in Table 1, which is based on the product description provided in certificate along with product samples for analysis. According to the data provided, the object of this study is dietary supplement, including high amounts of protein, some vitamins and other microelements. It is important to note that the specification provided by the customer for OMARIDIN does not contain the list of ingredients that are required for the marketing of dietary supplements in Lithuania or in any other European Union country. The requirements for the information on the label are further discussed in the section "Labelling requirements". According to information provided in product certificate, analysis was based on these keywords: proteins, dietary proteins, milk proteins. Since laboratory test showed, that product had less than 1 colony forming unit of yeast in one gram of substance, yeast as a part of this supplement was not discussed.

Definitions of foods and food supplements

Food includes all products of plant, animal and mineral origin, whether grown, processed or manufactured, intended for human consumption and meeting the requirements for that product as laid down in national or EU regulations. Nutrition and health claims may be made on foods provided they comply with regulatory requirements. Nutrition and health claims must comply with the requirements of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods.

Food supplements are a type of food. They are intended to supplement the normal diet and, alone or in combination with other substances, are concentrated sources of nutrients or other substances having a nutritional or physiological effect. Food supplements are placed on the market in dosage forms such as capsules, lozenges, pills, tablets and other similar forms, as well as in powder sachets, ampoules, drop bottles and other similar forms of liquids and powders intended to be consumed in small dosage quantities.

Lithuanian and EU legislation prohibits claims of therapeutic and preventive properties of food supplements (or the ingredients they contain) in advertising, except where such claims are approved by the European Commission. Although supplements are classified as foodstuffs, they are intended only to supplement the normal diet and should not be used as a food substitute. The conditions for placing food supplements on the market also differ substantially. Food supplements, like some other specialised foodstuffs, are subject to pre-market notification.

The microbiological safety of the product must be ensured in accordance with the requirements of (EC) No 2073/2005. Before notification process to prove chemical composition and ensured antimicrobial safety laboratory tests must be done according to regulations provided in "On the approval of the description of the procedure for notification and evaluation of food supplements places on the market in the republic of Lithuania" [15].

Online trading of food and food supplements

The information provided by the SFVS indicates that those who sell or offer to buy food online,

i.e. sell food to consumers without physical contact, are also responsible for the correct provision of food information to consumers and are subject to food law.

It should be noted that as of 1 May 2019, before selling food to a consumer online, the seller of food must also indicate his/her number as a registered and/or approved food business operator, for example:

- "food business operator approval certificate number 999999999" or;

- 'food business operator's pat. 999999999' or;
- 'Food business operator registration number 999999999' or;
- etc.

Please note that the above mandatory information must be provided in advertisements placed on social networks or advertising portals next to the food for sale, or on the website, in the shop next to the contact details, company details or in another prominent position visible to consumers.

Territorial departments of the SFVS register food business operators in accordance with the Description of Procedures for Approval and Registration of Food Business Operators, approved by the Order of the Director of the State Food and Veterinary Service No B1-527 of 15 October 2008 "On the Approval of the Requirements for the Approval and Registration of Food Business Operators" (hereafter referred to as the "Description") [5].

A food business operator shall be registered and included in the list of food business operators maintained by the SFVS by the territorial department of the SFVS according to the actual location of the food business operator's activities or intended activities. Only quality, safe and properly labelled foodstuffs may be marketed.

It should be noted that natural or legal persons who trade in food products via the internet are also considered to be food business operators, even though they do not have direct contact with the food (the consumer chooses the food based on the information provided on the internet). For such food business operators, it is sufficient to register as set out in point 25 of the Description [5]. In this case, the code of the economic activity according to Annex 1, "List of codes of economic activities of food business operators", point 2, line 12 of the Description must be 47.91 "Sale by mail order or online".

If the trader has direct contact with food in his/her activities (production, storage, packing, packaging, dispatching, etc.), it is necessary to register these additional activities and to have suitable premises for carrying out these activities.

It should be noted that food labelling laws prohibit the provision of misleading information about food, and the mandatory information must be provided to consumers in advance, i.e. before the food is purchased. This information should be provided on the website, social network or media page where the food is marketed. Where this is not possible, mandatory food information may be provided by other appropriate means, i.e. by providing the consumer with a clear indication of where to find the mandatory information, without the consumer having to incur additional costs or fees to obtain the information. The mandatory labelling information

must be available in Lithuanian (if the product is marketed in Lithuania). It must be accurate, clear, do not include any ambiguities and easily understandable to any age or educational background consumers.

In accordance with Regulation (EU) No 1169/2011 not only on the labelling or packaging of the food product presented to the consumer, but also on the website, must provide detailed information on the product marketed: the exact name of the food product, the list of ingredients (and, where appropriate, their quantities), highlighting or otherwise indicating the substances or products causing allergy or intolerance, the net quantity, the name of the entity responsible for providing the information (e.g., the name and address of the person responsible for providing the information (e.g. the manufacturer), any special conditions of use or storage, instructions for use, including the country or place of origin. For more details on the information required on the label and a model label, see the section "Labelling requirements". Only best- before dates are not mandatory - consumers will only see this information when they receive the specific product. However, as in the case of traditional trade, there is an obligation to market foods that have not passed their expiry date.

It should also be kept in mind when proposing the online marketing of food products that health claims are prohibited unless they comply with the general requirements of Chapter II and the specific requirements of Chapter IV of Regulation No 1924/2006, and are permitted under this Regulation and are included in the lists of permitted claims provided for in Articles 13 and 14. Nutrition and health claims used shall be substantiated and substantiated by generally accepted scientific evidence.

Requirements for the marketing of food supplements

Entities supplying (manufacturing, importing, selling, etc.) food supplements to the market of the Republic of Lithuania must have a food handling permit issued by the territorial unit of the SFVS, as specified in the Description of the Procedure for Approval and Registration of Food Handling Entities, approved by the Order of the Director of the State Food and Veterinary Service of October 15, 2008, No. B1-527 „On the approval and registration of food business operators “ a food business operator authorised to handle food shall be entered in the list of food business operators.

Without this authorisation, food handling activities are prohibited. Detailed information on the registration of food business operators is publicly available and can be found on the official website of the SFVS [6].

Food supplements placed on the market in the Republic of Lithuania must be notified, i.e. notified to the SFVS in the manner set out in the “Description of the Procedure for Notification

and Assessment of Food Supplements Placed on the Market in the Republic of Lithuania”, Nr. B1-275, approved by the Director of the State Food and Veterinary Service in 2016 [15]. Then they are included in the list of notified food supplements, which is made publicly available on the website of the SFVS [7]. The placing on the market of non-notified food supplements in the Republic of Lithuania is prohibited. Detailed information on notification and the necessary documentation is available on the website of the SFVS [8]. Since exact composition of OMARIDIN was not provided, only partial information in example of label was filled and provided in chapter “Labelling requirements”. The term “novel food” referred to in point 5 of Annex 3, in accordance with Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council of novel foods should be verified according to the materials used and the characteristics of the production process.

Nutrition and health claims

“Nutrition claim” means any claim stating, implying or suggesting that a food has particular nutritional benefits due to:

- energy value (calorific value) provided, provided at a reduced or increased rate or not provided;
- the amount of nutrients or other substances which it contains is reduced or increased; or does not contain.

Nutrition claims are only permitted if they are listed in the Annex to Regulation (EC) No 1924/2006 as last amended by Regulation (EU) No 1047/2012 (see Annex 2 of the report for the condensed information).

A health claim is any claim about the relationship between a food and health. The EC allows a wide range of health claims as long as they are based on scientific evidence and are easily understood by consumers. EFSA is responsible for assessing the scientific evidence supporting health claims.

EFSA provides types of health claims [3]:

- Functional health claims (or Article 13 claims) relating to the growth, development and functions of the body; relating to psychological and behavioural functions; relating to slimming or weight control.
- Risk reduction claims (or Article 14(1)(a) claims) concerning the reduction of a risk factor for the development of a disease.

- Claims on child development (Article 14(1)(b) claims).

Manufacturers and importers are allowed to advertise the nutritional and/or health benefits of their food products provided that:

- these benefits are scientifically proven,
- EU rules on labelling, presentation and advertising are respected. Nutrition and health claims cannot:
 - be false, ambiguous or misleading,
 - cast doubt on the safety or nutritional adequacy of other foods,
 - encourage or tolerate excessive consumption of the food,
 - claim or imply that a balanced diet alone cannot provide adequate nutrients,
 - to make claims that would create fear among consumers.

Manufacturers and importers must hold and, on request from national authorities, provide scientific documentation to support the product claim. In most cases, laboratory tests carried out by independent laboratories are used to determine whether a product complies with the requirements, and test reports issued as evidence.

Under EU law, certain nutrition claims are allowed if:

- you can prove that your product meets the official definition,
- the product meets the conditions for making a nutrition claim.

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods allows 28 different nutrition claims. The claims to be used and their requirements are set out in Annex 2 and the section Regulatory nutrition and health claims applicable to OMARIDIN contains the nutrition and health claims that are appropriate for the product under analysis.

The EU Register of Nutrition and Health Claims [4] provides a regularly updated list of authorised and unauthorised health claims. Food business operators operating in the EU may use authorised health claims only if they comply with specific and general requirements. National authorities monitor the use of claims through inspections and legislation. In Lithuania, this is the responsibility of the SFVS, in other countries it is the responsibility of the authorities listed in Annex 1.

Health claims that are not included in the lists should not be used. Any food business operator may use approved health claims provided that the conditions of use and any applicable restrictions are respected. Health claims should only be made for the nutrient, ingredient used, food or food category for which they have been approved and not for the food in which they are contained.

Some flexibility in the wording of a claim is possible, provided that it is intended to help the consumer to understand the claim, taking into account factors such as linguistic and cultural differences and the target population. The adapted wording should have the same meaning for the consumer as the claim approved in the EU Register.

Regulatory compliant nutrition and health claims applicable to the product OMARIDIN

The first table represent the nutritional comparison of the product OMARIDIN. First column shows the quantities based on the quality certificate provided by the manufacturer, second column shows the results of the tests carried out in July-August 2023 in the laboratories of Hamilton Sekargas and the KTU food institute.

Table 1. OMARIDIN nutritional composition

Substance	Unit of measure	Specified in certificate	Results from laboratory tests 2023
Lysin	Mass %	2.1421	1.80
Methionine	Mass %	0.8237	0.88
Alanine	Mass %	Not indicated	1.34
Threonine	Mass %	1.7097	1.73
Tryptophane	Mass %	Not indicated	0.00
Tyrosine	Mass %	0.9291	1.81
Serine	Mass %	1.8208	2.14
Cystine	Mass %	1.1877	0.73
Asparagine	Mass %	2.8072	0.00
Arginine	Mass %	1.1243	1.04
Valine	Mass %	1.5205	2.02
Glutamic Acid	Mass %	5.7885	8.11
Aspartic Acid	Mass %	Not indicated	3.24
Glycine	Mass %	5.0765	0.74
Histidine	Mass %	1.0708	0.92
Isoleucine	Mass %	1.1651	1.92

Leucine	Mass %	2.4877	3.67
Proline	Mass %	2.7955	4.32
Phenylalanine	Mass %	1.0823	1.85
Vitamin A	mg/100g	0.02	0.01
Vitamin D ₃	mg/100g	0.07	1.36 µg/100 g or 54 TV/100 g
Vitamin E	mg/100g	<0.2	25.8 µg/100 g or 0 TV/100 g
Vitamin B ₂ (riboflavin)	mg/100g	1.4	1.9
Vitamin B ₆ (pyridoxine)	mg/100g	<0.2	0.08
Crude fiber	Mass %	0.3	3.7
Soluble fiber	Mass %	Not indicated	2.7
Insoluble fiber	Mass %	Not indicated	1.0
Phosphorus	Mass %	1.22	1.37
Nitrogen amount	Mass %		6.3
Protein	Mass %	40.00	39.4
Fats, of which:	Mass %	2.04	2.5
Saturated fatty acids	Mass %	Not indicated	1.68
Monounsaturated fatty acids	Mass %	Not indicated	0.7
Polyunsaturated fatty acids	Mass %	Not indicated	0.07
<i>Trans</i> fatty acids	Mass %	Not indicated	0.05
Omega-3 fatty acids	Mass %	Not indicated	0.01
Omega-6 fatty acids	Mass %	Not indicated	0.06
Omega-9 fatty acids	Mass %	Not indicated	0.03
Calcium	mg/100g	1377	1148.41
Copper	mg/100g	0.04	0.11
Iron	mg/100g	0.57	23.00
Selenium	mg/100g	0.04	0.013
Zinc	mg/100g	5.3	5.36
Magnesium	mg/100g	117	103.39
Potassium	mg/100g	1574	1741.38
Sodium	mg/100g	425	683.24
Vitamin B ₁ (Thiamin)	mg/100g	0.2	0.11
Number of yeasts	CFU/g	Not indicated	<1.0 × 10 ¹

As referred in product certificate, daily dose sums up to 14 grams, ingested twice a day as a portion of 7 grams. Table 2 represent all nutritional analytes, re-counted to represent amounts in one daily dose.

Table 2. OMARIDIN nutritional composition in one portion

Substance	Unit	per 100 grams	per daily portion (14 grams)
Lysin	g	1.8	0.25
Methionine	g	0.88	0.12
Alanine	g	1.34	0.19
Threonine	g	1.73	0.24
Tryptophane	g	0	0.00
Tyrosine	g	1.81	0.25
Serine	g	2.14	0.30
Cystine	g	0.73	0.10
Asparagine	g	0	0.00
Arginine	g	1.04	0.15
Valine	g	2.02	0.28
Glutamic Acid	g	8.11	1.14
Aspartic Acid	g	3.24	0.45
Glycine	g	0.74	0.10
Histidine	g	0.92	0.13
Isoleucine	g	1.92	0.27
Leucine	g	3.67	0.51
Proline	g	4.32	0.60
Phenylalanine	g	1.85	0.26
Vitamin A	mg	0.01	0.00
Vitamin D ₃	µg	1.36	0.19
Vitamin E	µg	25.8	3.61
Vitamin B ₂ (riboflavin)	mg	1.9	0.27
Vitamin B ₆ (pyridoxine)	mg	0.08	0.01
Crude fiber	g	3.7	0.52
Soluble fiber	g	2.7	0.38
Insoluble fiber	g	1	0.14
Phosphorus	g	1.37	0.19
Nitrogen amount	g	6.3	0.88
Protein	g	39.4	5.52
Fats, of which:	g	2.5	0.35
Saturated fatty acids	g	1.68	0.24
Monounsaturated fatty acids	g	0.7	0.10
Polyunsaturated fatty acids	g	0.07	0.01
<i>Trans</i> fatty acids	g	0.05	0.01
Omega-3 fatty acids	g	0.01	0.00
Omega-6 fatty acids	g	0.06	0.01
Omega-9 fatty acids	g	0.03	0.00
Calcium	mg	1148.41	160.78
Copper	mg	0.11	0.02

Iron	mg	23.00	3.22
Selenium	mg	0.013	0.00
Zinc	mg	5.36	0.75
Magnesium	mg	103.39	14.47
Potassium	mg	1741.38	243.79
Sodium	mg	683.24	95.65
Vitamin B ₁ (Thiamin)	mg	0.11	0.02

Since extensive chemical composition and active ingredient forms are not known in the product and if found vitamins and minerals occur naturally or were introduced in any other form, there is no possibility to objectively decide, whether any health-related claims can be applicable to product. To indicate whether vitamins and minerals in product provide adequate levels, each value must meet requirements under the Annex to (EU) No 1169/2011 or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

The search for authorised health claims shall be carried out in accordance with the publicly available "Claims Manual" of the SFVS [2]. Regulation (EU) Nr.432/2012 annexes provide information about permitted health claims.

Additionally, European Union Register of Health Claims that could be found at EFSA (*European food safety authority*) portal [3, 4] was scanned to check whether any additional health claims can be used for OMARIDIN and the authorised possible claims are given in table

3. It is important to notice, that these claims can be used under certain conditions and without extensive knowledge about product, its ingredients and manufacturing process any conclusions on applicable claims must not be done.

Table 3. Examples of health claims that potentially could be applicable to OMARIDIN according to EU Register of Health Claims

Substance	Unique ID	Claim	Conditions of use of the claims	Health relationship
Vitamin D ₃	POL-HC-6268	Calcium and vitamin D are needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of calcium and vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Not indicated
	POL-HC-6202	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium and 20 µg of vitamin D from all sources. For food supplements with added calcium and vitamin D the claim may be used only for those targeting women 50 years and older	
	POL-HC-6270	Vitamin D is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of Vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
	POL-HC-6219	Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older.	The claim may be used only for food supplements which provide at least 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 20 µg of vitamin D from all sources. For food supplements with added vitamin D the claim may be used only for those targeting men and women 60 years and older	
	POL-HC-6515	Vitamin D contributes to normal absorption/utilisation of calcium and phosphorus	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations
	POL-HC-6516	Vitamin D contributes to normal blood calcium levels	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF	absorption and utilisation of calcium and

			VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	phosphorus and maintenance of normal blood calcium concentrations
	POL-HC-6517	Vitamin D contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bones and teeth
	POL-HC-6518	Vitamin D contributes to the maintenance of normal muscle function	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Normal muscle function
	POL-HC-6519	Vitamin D contributes to the maintenance of normal teeth	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bones and teeth
	POL-HC-6520	Vitamin D contributes to the normal function of the immune system	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Normal function of immune system and inflammation response
	POL-HC-6521	Vitamin D has a role in the process of cell division	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	cell division
	POL-HC-8483	Vitamin D contributes to the normal function of the immune system in children.	The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
Vitamin B ₂ (riboflavin)	POL-HC-6450	Riboflavin contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal energy-yielding metabolism
	POL-HC-6451	Riboflavin contributes to normal functioning of the nervous system	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of the normal function of the nervous system

	POL-HC-6452	Riboflavin contributes to the maintenance of normal mucous membranes	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal skin and mucous membranes
	POL-HC-6453	Riboflavin contributes to the maintenance of normal red blood cells	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal red blood cells
	POL-HC-6454	Riboflavin contributes to the maintenance of normal skin	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal skin and mucous membranes
	POL-HC-6455	Riboflavin contributes to the maintenance of normal vision	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal vision
	POL-HC-6456	Riboflavin contributes to the normal metabolism of iron	The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal metabolism of iron
Phosphorus	POL-HC-6271	Phosphorus is needed for the normal growth and development of bone in children	The claim can be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation 1924/2006	
	POL-HC-6438	Phosphorus contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	energy-yielding metabolism
	POL-HC-6439	Phosphorus contributes to normal function of cell membranes	The claim may be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	function of cell membranes
	POL-HC-6440	Phosphorus contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bone and teeth
	POL-HC-6441	Phosphorus contributes to the maintenance of normal teeth	The claim may be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF	maintenance of bone and teeth

			VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
Protein	POL-HC-6274	Protein is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.	
	POL-HC-6446	Protein contributes to a growth in muscle mass	The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.	growth or maintenance of muscle mass
	POL-HC-6448	Protein contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal bones
Calcium	POL-HC-6269	Calcium is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
	POL-HC-6340	Calcium contributes to normal blood clotting	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	blood coagulation
	POL-HC-6341	Calcium contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	energy-yielding metabolism
	POL-HC-6342	Calcium contributes to normal muscle function	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	muscle function and neurotransmission
	POL-HC-6343	Calcium contributes to normal neurotransmission	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	muscle function and neurotransmission
	POL-HC-6344	Calcium contributes to the normal function of digestive enzymes	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	function of digestive enzymes
	POL-HC-6345	Calcium has a role in the process of cell division and specialisation	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF	regulation of cell division and differentiation

			VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
	POL-HC-6346	Calcium is needed for the maintenance of normal bones	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal bones and teeth
	POL-HC-6347	Calcium is needed for the maintenance of normal teeth	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal bones and teeth
Calcium and vitamin D	POL-HC-6268	Calcium and vitamin D are needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of calcium and vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
Iron	POL-HC-6273	Iron contributes to normal cognitive development of children	The claim can be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006	
	POL-HC-6390	Iron contributes to normal cognitive function	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	cognitive function
	POL-HC-6391	Iron contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal energy-yielding metabolism
	POL-HC-6392	Iron contributes to normal formation of red blood cells and haemoglobin	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	formation of red blood cells and haemoglobin
	POL-HC-6393	Iron contributes to normal oxygen transport in the body	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	oxygen transport
	POL-HC-6396	Iron has a role in the process of cell division	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	cell division

	POL-HC-6394	Iron contributes to the normal function of the immune system	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	function of the immune system
	POL-HC-6395	Iron contributes to the reduction of tiredness and fatigue	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	reduction of tiredness and fatigue
Selenium	POL-HC-6460	Selenium contributes to normal spermatogenesis	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	spermatogenesis
	POL-HC-6461	Selenium contributes to the maintenance of normal hair	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal hair
	POL-HC-6462	Selenium contributes to the maintenance of normal nails	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal nails
	POL-HC-6463	Selenium contributes to the normal function of the immune system	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of the normal function of the immune system
	POL-HC-6464	Selenium contributes to the normal thyroid function	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	thyroid function
Zinc	POL-HC-6546	Zinc contributes to the protection of cells from oxidative stress	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	protection of DNA, proteins and lipids from oxidative damage
	POL-HC-6547	Zinc has a role in the process of cell division	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	DNA synthesis and cell division
	POL-HC-6530	Zinc contributes to normal DNA synthesis	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF	DNA synthesis and cell division

		VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	
POL-HC-6531	Zinc contributes to normal acid-base metabolism	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	acid-base metabolism
POL-HC-6532	Zinc contributes to normal carbohydrate metabolism	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal carbohydrate metabolism
POL-HC-6533	Zinc contributes to normal cognitive function	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	cognitive function
POL-HC-6534	Zinc contributes to normal fertility and reproduction	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	fertility and reproduction
POL-HC-6535	Zinc contributes to normal macronutrient metabolism	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal macronutrient metabolism
POL-HC-6536	Zinc contributes to normal metabolism of fatty acids	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal serum testosterone concentrations
POL-HC-6537	Zinc contributes to normal metabolism of vitamin A	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	vitamin A metabolism
POL-HC-6538	Zinc contributes to normal protein synthesis	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	contribution to normal protein synthesis
POL-HC-6539	Zinc contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bones

	POL-HC-6540	Zinc contributes to the maintenance of normal hair	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal hair
	POL-HC-6541	Zinc contributes to the maintenance of normal nails	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal nails
	POL-HC-6542	Zinc contributes to the maintenance of normal skin	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal skin
	POL-HC-6543	Zinc contributes to the maintenance of normal testosterone levels in the blood	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	fertility and reproduction
	POL-HC-6544	Zinc contributes to the maintenance of normal vision	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of vision
	POL-HC-6545	Zinc contributes to the normal function of the immune system	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	function of the immune system
Magnesium	POL-HC-6401	Magnesium contributes to a reduction of tiredness and fatigue	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Reduction of tiredness and fatigue
	POL-HC-6402	Magnesium contributes to electrolyte balance	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	electrolyte balance
	POL-HC-6403	Magnesium contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	energy-yielding metabolism

	POL-HC-6404	Magnesium contributes to normal functioning of the nervous system	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	neurotransmission and muscle contraction including heart muscle
	POL-HC-6405	Magnesium contributes to normal muscle function	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	neurotransmission and muscle contraction including heart muscle
	POL-HC-6406	Magnesium contributes to normal protein synthesis	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	protein synthesis
	POL-HC-6407	Magnesium contributes to normal psychological function	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Contribution to normal psychological functions
	POL-HC-6408	Magnesium contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bones
	POL-HC-6409	Magnesium contributes to the maintenance of normal teeth	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of teeth
	POL-HC-6410	Magnesium has a role in the process of cell division	The claim may be used only for food which is at least a source of magnesium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	cell division
Potassium	POL-HC-6443	Potassium contributes to normal functioning of the nervous system	The claim may be used only for food which is at least a source of potassium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Muscular and neurological function
	POL-HC-6444	Potassium contributes to normal muscle function	The claim may be used only for food which is at least a source of potassium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Muscular and neurological function

	POL-HC-6445	Potassium contributes to the maintenance of normal blood pressure	The claim may be used only for food which is at least a source of potassium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Blood pressure
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Labelling requirements

The SFVS is responsible for monitoring and notifying food supplements in Lithuania. According to the explanations provided by the SFVS [1], it is stated that the labelling must comply with the requirements set out in the Lithuanian hygiene standards HN 119:2014 "Labelling of foodstuffs" and HN 17:2010 "Food supplements". The information (both written and pictorial) provided on the label or accompanying information material (website, additional packaging) must not be misleading. For example, if a product cannot be attributed a weight- reducing effect according to the regulatory documents, the phrase or the visual information suggesting this, such as persons with scales, measuring tapes, etc., must not be used.

The use of a health claim shall only be permitted if accompanied by the following information on the labelling, presentation and advertising of the product:

- a claim stating the importance of a balanced diet and a healthy lifestyle,
- the amount and method of consumption of the food necessary to achieve the beneficial effects claimed (for example, '30 g of walnuts per day will increase the elasticity of blood vessels'),
- in certain cases, a claim for persons who should avoid the consumption of the food (e.g. 'Not suitable for pregnant and lactating women'),
- a warning about products that may pose a health risk if consumed in excess.

The labelling of food supplements placed on the market in the Republic of Lithuania must comply with the requirements of the legal acts governing the labelling of food and food supplements. The website of the SFVS makes publicly available detailed information on the labelling requirements for food and food supplements, with links to the applicable legal regulations [10].

A model label for the product OMARIDIN shall be drawn up on the basis of the model food supplement label provided by the SFVS. The nutritional reference values must be calculated according to the requirements of (EU) No 1169/2011 [11].

Table 6. Example of correct label for product OMARIDIN.

Food supplement **OMARIDIN**

7 portions

Net quantity: 100 g (1 portion = 1 table spoon, 7 g)

Ingredients: Here all ingredients must be mentioned and ranked from most abundant to least.

	Per 100 grams:	Per 1 portion (7 g)	RDV* 1 portion, %
Energy value			
Fats, from which:			
Saturated fatty acids			
Monounsaturated fatty acids			
Polyunsaturated fatty acids			
Carbohydrates, from which:			
sugars			
Crude fiber			
Protein			
Vitamin or element			

RDV* - reference daily value

Usage: For adults, take 1 portion of the product, 2 times a day. Do not directly swallow, let product slowly melt in mouth.

This food supplement contributes to maintain normal teeth, nervous system and blood function. (*here producer can mention all applicable health benefits*).

A varied and balanced diet and a healthy lifestyle are important.

Do not exceed the recommended dose.

The food supplement should not be used as a substitute for food.

Keep out of the reach of children.

Storage conditions: store in a dark place, at a temperature not exceeding +25°C.

Manufacturer: Indicate the exact name and address of the manufacturer

Distributor: The exact name and address of the distributor shall be provided

Batch: see on the packaging (*The batch does not have to be indicated in online resources, but must be labelled on the end-user packaging*)

Best before: where the date indicates a day (e.g. 30-06-2016) or **Best before (end):** otherwise (e.g. 06-2016).

Suggestions for product improvement

Since data, provided in product certificate and in latest laboratory test protocols for some substances show significant changes (for example, tyrosine (changed from 0,9 to 1,8 mass %), asparagine (from 2,8 to 0,0 mass %) glutamic acid (from 5,8 to 8,1 mass %), glycine (from 5,1 to 0,7 mass %), proline (from 2,8 to 4,3 mass %), crude fibre (from 0,3 to 3,7 mass %), iron (from 0,57 to 2300 mg/100 g) it is recommended to repeat tests on newly made batch and compare them to test ran with product produced in 2021 and 2023. These differences might indicate changes during storage (which might raise product stability concerns), inhomogeneous batch (with great differences between separate packages). It is also possible to develop the product by improving its quality, focusing on the specific function of the additive, identifying specific active ingredients.

Additionally, test to identify all amino acids and free amino acids and full composition of fatty acids, present in the product, was done and protocols of these trials will be provided as separate annexes with this report. Additional analysis should be used for further product improvement.

Literature list

1. <https://vmvt.lt/maisto-sauga/verslui/zenklinimas-ir-reklama/maisto-produktu-zenklinimas>
2. https://vmvt.lt/sites/default/files/atmintine_del_teiginiu_2022-02-08.pdf
3. https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/nutrition-claims_en
4. <https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register>
5. <https://e-seimas.lrs.lt/portal/legalActEditions/lt/TAD/TAIS.329396?faces-redirect=true>
6. <https://vmvt.lt/maisto-sauga/verslui/dokumentai-pradedant-veikla/maisto-tvarkymo-subjekto-registravimas>
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12. https://europa.eu/youreurope/business/product-requirements/food-labelling/health-nutrition-claims/index_lt.htm
13. <https://open.efsa.europa.eu/questions?search=plantago+ovata>
14. https://ec.europa.eu/food/food-feed-portal/backend/claims/files/claims_pending.pdf
15. <https://www.e-tar.lt/portal/lt/legalAct/bf979470836311e3a89fd7598ca5c9ab/asr>

Annex 1. EFSA national food safety authorities belonging to the network of EFSA focal points

COUNTRY	REPRESENTATIVE FOOD SAFETY AUTHORITY
AUSTRIA	Austrian Agency for Health and Food Safety (AGES)
BELGIUM	Federal Public Service (FPS) Health Food Chain Safety and Environment
BULGARIA	Risk Assessment Center on Food Chain – Bulgarian Food Safety Agency
CROATIA	Croatian Food Agency (HAH)
CYPRUS	Ministry of Health – The State General Laboratory
CZECH REPUBLIC	Czech Agriculture and Food Inspection Authority (SZPI, CAFIA)
DENMARK	National Food Institute
ESTONIA	Ministry of Agriculture – Food Safety Department
FINLAND	Finnish Food Authority (Ruokavirasto)
FRANCE	French Agency for Food, Environmental and Occupational Health Safety (ANSES)

GERMANY	Federal Institute for Risk Assessment (BfR)
GREECE	Hellenic Food Authority (ΕΦΕΤ, EFET)
HUNGARY	National Food Chain Safety Office (Nébih/NFCSO)
ICELAND	The Icelandic Food and Veterinary Authority (MAST)
IRELAND	Food Safety Authority of Ireland (FSAI)
ITALY	Istituto Superiore di Sanità (ISS)
LATVIA	Institute of Food Safety, Animal Health and Environment “BIOR”
LITHUANIA	State Food and Veterinary Service (SFVS)
LUXEMBOURG	Ministry of Agriculture, Ministry of Health
MALTA	Malta Competition and Consumer Affairs Authority
NETHERLANDS	Netherlands Food and Consumer Product Safety Authority (NVWA)
NORWAY	Norwegian Scientific Committee for Food and Environment (VKM)
POLAND	State Sanitary Inspection (PIS) – primary focal point; Veterinary Inspection (IW) – accessory focal point
PORTUGAL	Economic and Food Safety Authority (ASAE)
ROMANIA	National Sanitary Veterinary and Food Safety Authority

SLOVAKIA

Ministry of Agriculture and Rural Development

SLOVENIA

Ministry of Agriculture, Forestry and Food

SPAIN

Spanish Agency for Food Safety and Nutrition (AESAN)

SWEDEN

Swedish National Food Agency

Annex 2. Nutrition and health claims made on foods

(EC) NR. 1924/2006 (p. 28-31)

LOW ENERGY	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
ENERGY-REDUCED	A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
ENERGY-FREE	A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
LOW-FAT	A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).
FAT-FREE	A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.
LOW-SATURATED FAT	A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in

	the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.
SATURATED FAT-FREE	A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.
LOW SUGAR	A claim that a food is low in sugar, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g of sugar per 100 g for solids or 2,5 g of sugar per 100 ml for liquids.
SUGAR-FREE	A claim that a food is sugar-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugar per 100 g or 100 ml.
WITH NO ADDED SUGAR	A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.
LOW SODIUM/SALT	A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.
VERY LOW SODIUM/SALT	A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of

	sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.
SODIUM-FREE or SALT-FREE	A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g.
NO ADDED SODIUM/SALT	A claim stating that sodium/salt has not been added to a food and any claim likely to have the same meaning for the consumer may only be made where the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.
SOURCE OF FIBRE	A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.
HIGH FIBRE	A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.
SOURCE OF PROTEIN	A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.
HIGH PROTEIN	A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 % of the energy value of the food is provided by protein.
SOURCE OF (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)	A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive

	90/496/EEC or an amount provided for by derogations granted according to Article 7 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
HIGH (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)	A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of (NAME OF VITAMIN/S) and/or (NAME OF MINERAL/S)'.
CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)	A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.
INCREASED (NAME OF THE NUTRIENT)	A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30 % compared to a similar product.
REDUCED (NAME OF THE NUTRIENT)	A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a similar product, except for micronutrients where a 10 % difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.
LIGHT/LITE	A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term 'reduced'; the

	claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.
NATURALLY/NATURAL	Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.
SOURCE OF OMEGA-3 FATTY ACIDS	A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.
HIGH OMEGA-3 FATTY ACIDS	A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.
HIGH MONOUNSATURATED FAT	A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20 % of energy of the product.
HIGH POLYUNSATURATED FAT	A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.

HIGH UNSATURATED FAT	A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 70 % of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20 % of energy of the product.
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