Nutrition and health claims on foods in the EU legislation

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Abstract

The main aim of the EU food legislation is health protection of consumers. The key regulations, Regulation 1169/2011 on food information to consumers and regulation on nutrition and health claims are intended to ensure that consumers have sufficient information about the quality of the food product. That is why there is an effort by the EU to constantly improve food legislation in order to provide consumers with information in an acceptable and useful form. Currently the nutrient profiles and botanical health claims are in the focus of the EU Commission. However, this increases the requirements on food producers, in particular on the packaging of the product, which must fit even more information in a reasonably large font, and on the environment, as the amount of waste produced increases with increasing packaging area. The paper deals with the selected legal arrangements related to the health and nutrition claims on the food in EU food legislation in the context of judgments of the Court of Justice of the EU and point out the actual questions in relation to them.

Keywords: *food, EU food legislation, consumer, health claims, nutrition claims.*

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1. Introduction

One of the key themes of the European Union is consumer protection and food security.[3] We live in an era of profound transformation, and some of the most important concerns of the moment, in addition to the challenge of providing sustainable food sources for the world's population, are the increase in consumer confidence that the products they use are quality and the existence the possibility of following the route they have taken before reaching the final consumer[4]. In EU legislation, we find a large body of legislation dedicated to the protection of the rights, legal interests, health and lives of consumers in the internal market. One of the main and common tools for protecting consumers is to provide information to consumers so that they can make rational choices. The correct understanding of consumers' food labeling knowledge and perceptions is a prerequisite to develop and

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[3] Schwarcz et al., 2021; Takáč, Palšová, 2021.
[4] Georgescu, B., Onete, C.B., Pleșea, D.A., Chița, S.D., and Sava, Ș., 2022.

implement coherent and appropriate food safety policies[5]. It is also the most important tool for protecting health of consumers in the food market, mainly when the attributes of food are not visible. Healthy food has gained relevance amongst consumers.[6] In such cases the EU law maker tries to reduce information asymmetry between food producers and consumers by the adequate food labelling rules.[7] The key ones are regulation 1169/2011 on food information to consumers[8] and regulation on nutrition and health claims.[9] They are intended to ensure that consumers have sufficient relevant information about the quality of the food product. The first regulation regulates also the duties of food producers what kind of information they have to provide to consumers, in what form and style of writing or where this information should be presented, e.g. in front of package (FoP) or back of the package (BoP). There is usually a problem how to print all these information in a given form on the food packages.[10] The second regulation is based on voluntarily principle; however, claims are very favourite marketing tool of food producers,[11] in spite of the fact that the use of claims usually needs an advice of experts for food legislation. Claims are usually based on scientific evidence, but in Europe specifically, nutrition and health claims need to be authorised prior to their usage on the market.[12] The paper is focused on the current status of the legal regulation in the EU for health and nutrition claims on the food packages. In spite of the nutrition and health claims regulation and Commission authorisation procedure, it is quite difficult to decide which health and nutrition claims are permitted or forbidden or do not fall within the scope of the regulation. Moreover, there are still some questions which are not prepared (e.g. nutrient profiles) or authorised (e.g. botanical health claims) by EU Commission. Judgements of the Court of the Justice of the EU (hereinafter as ECJ) are important source for interpretation of the rules including in this regulation but there are only few judgement in relation to the claims.

2. The relations of the regulation on claims to other relevant EU legal acts

The Regulation 1924/2006 should be read in the context of the other relevant EU legislation and implementing and delegated acts issued by the EU Commission.

[5] Petrescu, D.C., Petrescu-Mag, R.M., Bran, F. and Rădulescu, C.V., 2018.
[6] Santeramo et al., 2018; Díaz et al., 2020.
[7] Van Trijp, 2009.
[8] Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004.
[9] 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.
[10] Lazíková, Rumanovská, 2021.
[11] E.g. Tarabella et al., 2021; Wansink, 2003; Kozup et al., 2003.
[12] De Boer, Bast, 2015.

It was created a complicated network of various EU legal acts regardless on the national legal regulations of the member states.

2.1 Nutrition declaration versus nutrition and health claims

Regulation 1169/2011 on the food information is the basic legal regulation on the food information provided on the food packages. The mandatory requirements are stipulated in the article 9 of this regulation. There are twelve particulars and the last one is nutrition declaration. According to the article 30 of this regulation the mandatory nutrition declaration shall include energy value and the amounts of fat, saturates, carbohydrates, sugars, protein and salt. These mandatory requirements may be supplemented with an indication of the amounts of mono-unsaturates, polyunsaturates, polyols, starch, fibre, any of the vitamins or minerals listed in Annex XIII which includes daily reference intakes for vitamins and minerals.[13] All information must be expressed per 100g or per 100ml. The declaration must be presented in a legible tabular format on the packaging. Where space does not permit it, the information may be presented in linear format. This nutrition declarations are usually provided on the back of packaging and have to be mandatory presented from 13 December 2016. During two years period (from the application of the regulations 13 December 2014 up to 13 December 2016) the nutrition declarations were only voluntarily.

Nutrition declaration needs to be distinguished from nutrition claims which are still voluntarily and are regulated by the special EU legal regulation. The Regulation 1924/2006 of nutrition and health claims (hereinafter as Regulation 1924/2006) should ensure the effective functioning of the internal market and providing a high level of consumer protection as well.[14] The Regulation 1924/2006 includes article 4 according to which the nutrient profiles for foods shall be established by the Commission. In 2008, EFSA adopted a scientific opinion on the setting of nutrient profiles,[15] and the Commission started to consult the Member States. However, the work on nutrient profiles was eventually postponed given the high controversy of the topic.[16] Nowadays, there is actual issues front-of-packing nutrition labelling. It is simplified nutrition declaration on the front of food packaging that should help consumers to choose healthier food. The EU Commission started 12-week (from 13 December 2021 to 7 March 2022) open public consultation to consult all citizens and stakeholders via online portal.[17] The consultation will help to collect data on the main obstacles relate to the food labelling areas and the main

[13] Vitamin A, D, E, K, C, B1, B2, B3 (niacin), B5 (Pantothenic acid), B6, B7 (Biotin or Vitamin H), B9 (Folic acid), B12, K, Chloride, Ca, P, Mg, Fe, Zn, Cu, Mn, Fluoride, Se, Cr, Mo, Iodine.
[14] Regulation (EC) No. 1924/2006.
[15] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.644.
[16] https://ec.europa.eu/food/system/files/2020-05/labelling_nutrition-claims_swd_2020-95_part-1.pdf.
[17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-pro vided -to-consumers/public-consultation_en.

possible ways to overcome these obstacles.[18] Even though nutrient profiling and front-of-pack nutrition labelling may seem like two separate topics in food policy, the increased attention for front-of-pack nutrition labelling has stimulated the discussion on nutrient profiling and labelling of healthy foods.[19] To prevent claims being made on foods with a less healthy profile, nutrient profiles should specify threshold amounts of saturated fat, sodium and sugar present in any product bearing a nutrition or health claim, and thus the composition of a food will be critical in determining whether it is eligible to carry a claim.[20] It would be a relevant tool to discriminate the nutritional quality of products within and across relevant food groups in different European countries, with consistency with nutritional recommendations.[21] Foods bearing health-related claims are considered slightly healthier.[22] However, the health and nutrition claims are focused on the effect of particular nutrients on human health; but do not reflect the common effect of all nutrients and substances in the food. Therefore, the development of nutrient profiles should considered all necessary food nutrients and substances and the use of health and nutrition claims would be able only on the foods with the higher nutrition profile to receive the main objectives of the regulation 1924/2006 as declared in the article 1 to providing the high level of consumer health protection.

2.2 Claims versus trademarks

The interaction between Regulation 1924/2006 and EU legislation related to the trademarks[23] is mentioned in the article 1(3) of the Regulation 1924/2006: *A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation*. The transitional measures in the article 28 of the Regulation 1924/2006 stipulated an exemption: *Products bearing trademarks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.* The EU law maker provided a long transition period, but actually from 19 January 2022, only foods with trademarks which are fully compliant with the Regulation 1924/2006 may be used on the EU internal market. It means, all trademarks evocated a nutrition or health claim regardless on the date of their

[18] More informations are available at the website https://ec.europa.eu/food/safety/labelling-and-nutrition/food-information-consumers-legislation/nutrition-labelling_en.
[19] De Boer, 2021.
[20] Buttriss, Benelam, 2010.
[21] Dréano-Trécant et al., 2020.
[22] Hieke et al., 2016.
[23] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark; Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trademarks.

registration, should be accompanied by a relevant nutrition or health claims which are in harmony with the Regulation 1924/2006 from 19 January 2022.

In spite of the large judgements of the EU in the field of trademark, there are very few judgments related to the trademark in context of nutrition and health claims. It could be caused not only by the long time transitional period but it is more probably that nutrition and health claims are not favourite signs as trademark because the transitional period was not applied on the trademarks registered after 31 December 2004. The ECJ decided the question whether the first sentence of Article 28(2) of Regulation No. 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a product bearing a trademark was marketed as a medicinal product before 1 January 2005 and subsequently, although having the same characteristics and bearing the same trademark, is marketed as a food stuff after that date. Nelsons Company had marketed preparations made from flowers as medical products in Germany before 1 January 2005 and labelled with the European Union mark "RESCUE" registered for medicinal products. In 2007, Nelsons also registered "RESCUE" as a European Union mark for foodstuffs. In 2008, a German court held that medical products of Nelsons Company are not medicinal products but are foodstuffs. Therefore, Nelsons Company began marketing the products as foodstuffs; however, it was not accompanied by any change to them. Furthermore, the German court decided that "RESCUE TROPFEN" and "RESCUE NIGHT SPRAY" are health claims within the meaning of Regulation 1924/2006 and that "RESCUE" constitutes a trade mark within the meaning of Article 28(2) of this regulation. However, there was a question if the particular article is applied also on this situation when the EU trademark was registered for foodstuffs after 1 January 2005 in spite of the fact that the products were not changed but only reclassified form medical products to foodstuffs. The ECJ had to prejudice the question if the foodstuff classified before 1 January 2005 as medical products can be considered as foodstuff also before this date. According to Article 2 of Regulation No. 178/2002 with the context of Article 2(1)(a) of Regulation 1924/2006 the definition of food does not cover medicinal products. Therefore, a product cannot be both, foodstuff and medicinal product as well. In spite of this legal rule, the ECJ took into consideration that this product is objectively foodstuff before 1 January 2005 as well as after its administrated reclassification because the product itself was not changed. Therefore, it must be classified as products within the meaning of Article 28(2) of Regulation 1924/2006. *Having regard to the wording of that provision, 'existing' must be understood as meaning that those products had, already before that date, to have the same substantive characteristics and bear the same trade mark or brand name. It is clear from the order for reference that such is the case in the main proceedings...Article 28(2), first sentence, of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, while having the same physical characteristics and*

bearing the same trade mark or brand name, as a foodstuff prior to that date.[24] It means that objective character of a product is important to consider of the particular product falls within the scope of the Regulation 1924/2006. Therefore, there should ask a question if all products registered as medical products are really medical products and not foodstuffs objectively and so they should be in harmony with the Regulation 1924/2006. This fact does not improve legal certainty of food producers on the EU internal market.

2.3 Claims under the Regulation 1924/2006 *vs.* claims under the special legal acts

According to the 1(5) of the Regulation 1924/2006 *this regulation shall apply without prejudice to the following provisions:*

(a) Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses;

(b) Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters;

(c) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption;

(d) Directive 2002/46/EC.

2.3.1 Council Directive 89/398/EEC

Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses concerned foodstuffs for particular nutritional uses for categories of persons whose digestive processes or metabolism are disturbed, for categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs, and for infants or young children in good health. This directive was replaced by the new one, Directive 2009/39/EC of the European parliament and of the Council on foodstuffs intended for particular nutritional uses. However, the categories of persons covered by the directive have not been changed. In 2013, the directive was replaced by the Regulation (EU) no. 609/2013 of the European parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) no. 41/2009 and (EC) no. 953/2009. This regulation has cancelled not only the main Directive 2009/39 but also directives relating to foodstuffs for particular nutritional uses. However, while Directives 2009/39/EC, 92/52/EC and Regulation 41/2009 were repealed with effect from 20

[24] C-177/15, points 47 and 48.

July 2016, Regulation (EC) no. 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC should be repealed *from the date of application of the delegated acts referred to in Article 11(1).*[25] Of it, there is still valid Regulation no. 953/2009 up to 26 October 2022 when Commission Delegated Regulation (EU) 2017/1798 shall apply. The Directives 96/8/EC and 2006/125/EC were not replaced therefore the date of their validity is not stipulated and the last one, Directive 2006/141/EC was replaced by the Commission Delegated Regulation (EU) 2016/127. Therefore, the article 1(5)(a) of the Regulation 1924/2006 should include the regulation 609/2013 in the context of existing and still valid Directives 96/8/EC and 2006/125/EC and Regulation no. 953/2009 up to 26 October 2022. These legal acts are special legal acts which regulates claims in the special cases when the Regulation 1924/2006 is not applied or in the alternative when the special acts do not stipulate otherwise.

The reason of adoption of a new Regulation 609/2013 is explained in the preamble of this regulation. *An increasing number of foodstuffs are currently marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in that Directive. Food regulated under that Directive differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups...there is therefore a need to eliminate differences in interpretation by simplifying the regulatory environment.*[26] In contrary to the previous directives,[27] Regulation 1924/2006 *should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or delegated acts adopted pursuant to this Regulation*[28] and the definitions of nutrition and health claim are defined within the meaning of Article 2(2) of Regulation 1924/2006. Moreover, *in order to eliminate any potential confusion within group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, such statements should be regulated solely under Regulation (EC) No. 1924/2006 and comply with requirements set out in that Regulation*.[29]

2.3.2 Council Directive 80/777/EEC

Council Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters

[25] Article 22 of the regulation EU no 609/2013 of the European parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009.
[26] Point 10 of the preamble of the Regulation EU no. 609/2013.
[27] Directive 89/398/EEC and Directive 2009/39/EC.
[28] Point 28 of the preamble of the Regulation EU no. 609/2013.
[29] Point 43 of the preamble of the regulation EU no. 609/2013.

was replaced by the Directive 2009/54/EC of the European parliament and of the Council on the exploitation and marketing of natural mineral waters. This Directive concerns waters extracted from the ground of a Member State and recognised by the responsible authority of that Member State as natural mineral waters satisfying the provisions of Annex I as well as waters extracted from the ground of a third country, imported into the EU and recognised as natural mineral waters by the responsible authority of a Member State. However, this Directive shall not apply to waters which are medicinal products and natural mineral waters used at source for curative purposes in thermal or hydro mineral establishments.

In Directive 2009/54/EC, there is not mentioned the relation to the Regulation 1924/2006; however the Annex of the Regulation 1924/2006 includes the nutrition claim "very low sodium/salt" which "*shall not be used for natural mineral waters and other waters*."

The labelling of natural mineral waters is regulated by the Directive 2009/54/EC and its annexes and by general rules of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs when article 7 – 10 of the Directive 2009/54/EC does not stipulate otherwise. However, the directive 2000/13/EC was cancelled by the Regulation 1169/2011 which excludes its application on the mineral water within the meaning of the Directive 2009/54/EC. It means that Regulation no. 1924/2006 shall not apply on mineral waters at all.

2.3.3 Council directive 98/83/EC and 2002/46/EC and other relevant legal acts

Council Directive 98/83/EC on the quality of water intended for human consumption shall be to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. The directive imposes an obligation to the Member States to ensure that consumers are adequately and appropriately informed of the quality of water intended for human consumption, of any derogations granted by the Member States and of any remedial action taken by the competent authorities. The Regulation 1924/2006 will be not applied in the cases of water for human needs at all.

Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements concerns food supplements marketed as foodstuffs and presented as such. Food supplements *means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients* (vitamins, minerals) *or other substances with a nutritional or physiological effect, alone or in combination...*[30] Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements. Annex I includes all vitamins and minerals as the Annex XIII of the Regulation 1169/2011 mentioned above; however, the Directive 2002/46/EC includes Sodium, Boron and Silicon as minerals which are

[30] Article 2 a) of the Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.

missing in the Annex XIII of the Regulation 1169/2011. Article 6 of the Directive 2002/46/EC stipulates the special rules for labelling of food supplements and the Regulation 1169/2011 will be used as general legal rules for labelling of food supplements when Directive 2000/13/EC was cancelled. The Regulation 1924/2006 shall not apply on the food supplements according to last sentence of the article 7 of the Regulation 1924/2006 because *in the case of food supplements, the nutrition information shall be provided in accordance with Article 8 of Directive 2002/46/EC*.

On the other hand, food enriched with vitamins, minerals and certain other substances,[31] food additives,[32] and novel foods[33] may bear a statement indicating nutrition or health claims under the conditions laid down in Regulation 1924/2006. They are not explicitly excluded from the scope of the Regulation 1924/2006. Any application for a claim relating to an enriched food, a novel food and food additives has been submitted separately and in accordance with the Regulation 1924/2006. The regulations of an enriched food, a novel food and food additives provides the requirements for mandatory labelling, however mandatory statements required by EU law are not considered as health or nutrition claims and do not fall in the scope of the Regulation 1924/2006, which is related only claims on a voluntary basis.

3. Nutrition and health claims

The nutrition and health claims are voluntarily on the one hand but a very important marketing tool on the other hand. That is the reason why the food producers do not hesitate to use claims in spite of the fact of complicated legislation and the strict requirements stipulated in the Regulation 1924/2006.

According to the article 2 the regulation applies *to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer*; however this regulation applies also *in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers*. Then a question arose at the ECJ if that communication addressed not to the final consumer, but exclusively to health professionals, fall within the scope of that regulation. The final consumer is defined according to the Regulation 178/2002[34] as the ultimate consumer of a foodstuff that will not use the food as part of any food business operation or activity. The ECJ confirmed that article 1(2) of Regulation 1924/2006 *must be interpreted as meaning that nutrition or health claims made in a commercial communication on a*

[31] Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

[32] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of on food additives.

[33] Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

[34] Article 13 (18) of the regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

food which is intended to be delivered as such to the final consumer, if that communication is addressed not to the final consumer, but exclusively to health professionals, falls within the scope of that regulation.[35] The ECJ justified its decision by two most important points. First, that communication between the food business operators and the health professionals covers principally the final consumer, in order that that consumer acquires the food which is the subject of that communication, following the recommendations given by those professionals.[36] It means, the Regulation 1924/2006 will apply in such situation when the health professionals are only sales intermediary of food products between food producers and final consumers. Second, we could not wait that the health professionals will be able to correct all misleading claims because health professionals cannot be regarded as being in a position to permanently have all specialized and up-to-date scientific knowledge necessary to evaluate each food and the nutrition or health claims used in the labelling, the presentation or advertising of those foods.[37]

According to the article 2 (2) claim *means any message or representation, which is not mandatory under EU law or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics*. The particular characteristics can include a food with particular beneficial nutritional properties due to the nutrients it contains or there is a relationship between a food and health. According to the Regulation 1924/2006 we can recognize two main categories of food claims such as nutrition and health claims.

Regardless a category of claims they shall fulfil the general principles in article 3 of the Regulation 1924/2006. The general principles include principles such as the claims shall not be false (the claims is false also if it is correct but incomplete),[38] ambiguous or misleading; give rise to doubt about the safety and/or the nutritional adequacy of other foods; encourage or condone excess consumption of a food; state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general; or refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations. At the same time, the rules stipulated in the Regulation 1169/2011 on the provision of food information to consumers [39] and the Directive 2006/114/ES on misleading and comparative advertising[40] should be respected.

Moreover, there are or there could be stipulate some categories of food for which the claims are prohibited or restricted at all. According to the article 4(3) of the Regulation 1924/2006 the health claims are prohibited for beverages containing

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[35] C-19/15.
[36] Point 35, C-19/15.
[37] Point 43, C-19/15.
[38] C-544/10, Point 51.
[39] Regulation (EU) No. 1169/2011.
[40] Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.

more than 1.2 % by volume of alcohol and nutrition claims are restricted to the claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content for beverages containing more than 1.2 % by volume of alcohol. The ECJ justified the article 4 (3) of this regulation as follows: *However, in a case such as that in the main proceedings, even if the claim at issue can be regarded as being substantively inherently correct in that it indicates reduced acidity levels, the fact remains that it is incomplete. The claim highlights a certain quality that facilitates digestion, but is silent as to the fact that, regardless of a sound digestion, the dangers inherent in the consumption of alcoholic beverages are not in any way removed, or even limited. Thus, the European Union legislature was fully entitled to take the view that claims such as that at issue in the main proceedings are ambiguous or even misleading where they relate to an alcoholic beverage. By highlighting only the easy digestion of the wine concerned, the claim at issue is likely to encourage its consumption and, ultimately, to increase the risks for consumers' health inherent in the immoderate consumption of any alcoholic beverage. Consequently, the prohibition of such claims is warranted in the light of the requirement to ensure a high level of health protection for consumers.*[41] Any other prohibition or restriction of claims on the food has to be adopted by Commission according to the Regulation 182/2011.[42] Currently, they are no others implementing legal acts prohibiting or restricting the claims on the any kinds of food.

However, there is one exemption related to the general principles of claims. According to the article 1(4) of the Regulation 1924/2006 *for generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, a derogation from paragraph 3 designed to amend non-essential elements of this Regulation by supplementing it may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), on application by the food business operators concerned*. It was adopted Commission Regulation (EU) No. 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations) which includes application procedure for use of generic descriptors in its Annex. Applications for a term to be used as generic descriptor may be submitted by food business operators to the national competent authority of a recipient Member State. A valid application should be transmitted to the Commission and to all Member States and Member States concerned by the application shall provide the Commission with their opinions thereon. Following receipt of the opinions of Member States the Commission may initiate the procedure of approval of the generic descriptor. The generic descriptors can imply a relationship between the foods bearing these terms and health. However, if the evidence is provided that these terms have been traditionally used in particular

[41] C-544/10, point 51 and 52.

[42] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (the regulation 1924/2006 refers to the decision 1999/468/ES but it was replaced by the regulation 182/2011).

countries and the term has neither been used in these countries with the aim to indicate a health effect of this class of food nor is understood by an average consumer as claiming a health effect of this class of food. According to the Commission Regulation (EU) 2019/343 providing derogations from Article 1(3) of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors, mainly its Annex includes generic descriptor and Member States where the exemption is valid, e. g. Halsbonbon (throat praline) in Germany or Hustenstopper (cough stopper) in Austria.

Moreover, the food claims shall fulfil not only general conditions that are common for both main categories of food claims but also specific conditions that are stipulated in the chapter III of the Regulation 1924/2006 for nutrition claims and chapter IV of the Regulation 1924/2006 for health claims.

The general conditions enable to use correctness of a claim has been shown by generally accepted scientific evidence that a content of a food has a beneficial nutritional or physiological effect as established. However, there is important not only an occurrence of a particular nutrient or substance in a food but also its quantity and form to receive the declared effect. Therefore, the nutrient or other substance has to be contained in the food in a significant quantity (or in a reduced quantity or is not present) that will produce the declared nutritional or physiological effect. The relationship between quantity of a nutrient or other substance and the mentioned nutritional or physiological effect is in harmony with the EU legislation or if missing in harmony with the generally accepted scientific evidence. And a nutrient or other substance is in a form that is available to be used by the body. Moreover, there is important also the fact that the nutritional or physiological effect can be received only if the certain quantity of a particular food is consumed. If there is not probable that a consumer is able to eat a sufficient quantity of food the claims is not permitted. The quantity of the product is stipulated by the EU legislation or if missing, by generally accepted scientific evidence. One of the key elements of the general conditions is generally accepted scientific evidence. According the ECJ generally accepted scientific evidence means that such evidence should not be limited to beliefs, hearsay derived from popular wisdom, or the observations or experiences of persons outside the scientific community but should be based on objective and scientific evidence and that, in particular, and there should be sufficient scientific agreement as to the benefits of the substances. In addition, claims must be scientifically substantiated by taking into account the totality of the available scientific data and by weighing the evidence.[43] On the other hand article 5(1) and 6 (2) of Regulation 1924/2006 do not impose a requirement to a food operators to produce its own evidence and prepare scientific studies itself or by the appropriate institutions, however, they require a food business operator to be able to justify the health claim it uses.[44]

[43] C-363/19, point 46- 47.
[44] C-363/19, point 49-50.

Second, the general conditions include a requirement that the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim. The Regulation 1924/2006 does not define the average consumer. In article 2(1)(a) the definition of final consumer of the Regulation 178/2002 shall apply. According to this definition, *final consumer means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.*[45] According to the ECJ an average consumer is reasonably well informed and reasonably attentive and circumspect to understand the link between general health claims and a health claim appearing on the list of implementing legislation by the Commission.[46] We believe that this requirement can only be achieved through adequate nutrition education of consumers, which should already be emphasized in primary and high schools.

Third, nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions. If the food is not intended for direct consumption but is intended to be prepared by cooking (e.g. pasta), mixing other ingredients (e.g. cereals may be mixed with water, milk, yoghurt), then the use of a health or nutritional claim with food preparation should be considered. First, it must be ensured that the requirements of the claim are met by the final food obtained by preparing the food according to the manufacturer's instructions, and the consumer should be informed that the claim is only valid for such food processing (e.g. low-energy powder can be mixed with water, juice, milk, while the drink will remain low-energy probably only if it is mixed with water). Second, a claim can be used if the various kinds of food processing do not have an effect on the effect of the claim. It means if the food can provide the effects of the claim regardless of its further processing (e.g. enough fibre is consumed by the consumer regardless of whether the cereals are eaten with milk, yoghurt or other ingredients).

3.1 Nutrition claims

Nutrition claims are the first main category of food claims. According to the article 2(2) of the Regulation 1924/2006 nutrition claim *means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to (a) the energy (calorific value) it provides; provides at a reduced or increased rate; or does not provide; and/or (b) the nutrients or other substances it contains; contains in reduced or increased proportions; or does not contain*. According to this definition there are three types of nutrition claims. The nutrition claims that describe the level of a nutrient contained in a food (e.g. high fibre or source of protein) are called nutrition content claims. The nutrition claims that compare the nutrient levels or energy values of two or more foods (e.g. energy reduced, light yogurt or increased

[45] Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[46] C-524/18, point 40.

fibre) are called nutrition comparative claims. The nutrition claims that an ingredient has not been added to a food in spite of the fact that it is normally presents in this kind of food are called non-addition nutrition claims (e.g. sugar free).

Nutrition claims shall only be permitted if they are listed in the Annex of the Regulation 1924/2006 and are in conformity with the conditions set out in this regulation. In the original text of the regulation there were only 24 nutrition claims. In 2010, there were added five other nutrition claims related to omega-3 fatty acids and unsaturated fat. In 2012, there was added one more nutrition claim "no added sodium/salt". In spite of the list of nutrition claims, the legal uncertainty in some cases still remains due to ambiguous character some of them, e.g. "contains [name of the nutrient or other substance]." It may only be made where the product complies with all the applicable provisions of the Regulation 1924/2006, in particular article 5 defined the general conditions mentioned above. Moreover, there is usually very difficult to classify those claims as nutrition or health claims. If the claims "contains nutrient or substance" indicate a nutritional or physiological effect, the claim is classified as health claims; otherwise, it is a nutrition claims according to the Annex of the regulation 1924/2006. According to the EU guidance the claim "contains lutein" is the nutrition claims but the claim "contains antioxidants" is the health claim.[47] There is only ambiguous border between both categories of claims.

One of the categories of the nutrition claims are comparative nutrition claims. According to the article 9 of the Regulation 1924/2006 *comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands*. The comparative nutrition claims *may only be made between foods of the same category, taking into consideration a range of foods of that category.* Moreover, *the difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.* The quantitative difference of nutrients or energy is expressed in percentage or absolute value refereeing to the same amount of food, e.g. 50% less fat or 30% more fibre. The more difficult question is related to the food category taking into account all the food products in a particular category, e.g. milks, yogurts, breads; however the comparison between various dairy products should be forbidden, e.g. milk and butter. It means the category dairy product is too broad as a food category. Product being compared should therefore be foods belonging to a group of foods that are similar in terms of nutritional content.[48] Moreover, to not mislead the consumer, it should be avoided the use an indication that, although being equivalent to 30% of a specific nutrient, concerns a food category irrelevant for the consumption of that specific nutrient (e.g. the indication "reduced in fats" as applied to bread).[49]

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[47] Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health, https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf.

[48] Ibid.

[49] Silano, Silano, 2020.

3.2 Health claims

The second category of food claims are created by health claims. According to the article 2(2) of the Regulation 1924/2006 health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. In comparison to the nutrition claims, there is no legal definition in the Regulation 1924/2006. The ECJ judgement brings some more characteristics of the health claims. The ECJ decided the case of vine containing more than 1.2 % by volume of alcohol of a German vine producer for which the health claims are forbidden but the labels on the necks of the vine bottles bear the inscription "easily digestible" considered by the German authority as a health claim. The ECJ justified that *the concept of a health claim must cover not only a relationship implying an improvement in health as a result of the consumption of a food, but also any relationship which implies the absence or reduction of effects that are adverse or harmful to health and which would otherwise accompany or follow such consumption, and, therefore, the mere preservation of a good state of health despite that potentially harmful consumption. Moreover, the concept of a health claim is deemed to refer not only to the effects of the consumption – in a specific instance – of a precise quantity of a food which is likely, normally, to have only temporary or fleeting effects, but also to those of the repeated, regular, even frequent consumption of such a food, the effects of which are, by contrast, not necessarily only temporary and fleeting*[50]*. It is established that, by indicating a nutritional, physiological or any other health advantage over similar products, claims promoting the foods on which they appear guide the choices made by consumers. Those choices directly influence the total selected intake of individual nutrients or other substances, thereby warranting the restrictions imposed by that regulation in relation to the use of those claims.*[51]

The special conditions of health claims are stipulated in the Chapter IV. According to the article 10(1) of the Regulation 1924/2006 only health claims included in the lists of authorised claims are permitted.[52]

A health claim can be made on the 'labelling' which can mean more than just the label, since it encompasses all the information to the consumer about the food which it accompanies or refers to.[53] The health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

- *a statement indicating the importance of a varied and balanced diet and a healthy lifestyle*. Consumers should understand that consumption of this food is only part of a varied and balanced diet and not eaten excessively in order to achieve

[50] C-544/10, point 35 and 36.
[51] C-544/10, point 37.
[52] https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search.
[53] 2013/63/EU: Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council.

healthy outcomes declared in the health claims.

- *the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect*. Consumers should be informed of how much of the food is required and how it should be consumed during the day to obtain the effect declared in the health claims. However, the health claims should not *encourage or condone excess consumption of a food* (article 3 of the Regulation 1924/2006 as one of the general principles).
- *where appropriate, a statement addressed to persons who should avoid using the food* (e.g. people with a particular diseases, usually various allergies on a particular food element).
- *an appropriate warning for products that are likely to present a health risk if consumed to excess* (e.g. hypervitaminosis if the food is enriched by vitamins).

Moreover, the article 10(3) of Regulation 1924/2006 establishes an exemption from the above mentioned specific conditions that only health claims from the list of authorised claims are permitted. According to the article 10(3) *reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14*. Article 10(3) makes a distinction between the specific health claim included in the lists of authorised claims and, the general health claim referring to general, non-specific benefits and accompanying by a specific health claim from the lists of authorised claims. A general health claims are on the one hand more helpful to consumer because the consumers understand better the health claims (e.g. "for good function of heart"); on the other hand there is a higher risk that such claims could be misinterpreted by the consumers. Therefore, the article 10(3) requires accompanying general health claims by a specific health claim from the lists of authorised health claims. It means, the specific authorised health claim should be made 'next to' or 'following' general health statement.[54] The ECJ added that *the visual dimension of the requirement of 'accompanying', within the meaning of Article 10(3) of Regulation No. 1924/2006, should be understood as referring to the immediate perception by the average consumer*, *reasonably well informed and reasonably attentive and circumspect, of a direct visual link between the reference to general, non-specific health benefits and the specific health claim, which requires, in principle, spatial proximity or immediate vicinity between the reference and the claim. However, in the particular case where the specific health claims do not appear in their entirety on the same side of the packaging as the reference which they are intended to substantiate due to their large size or length, it should be considered that the requirement for a direct visual link could be satisfied, exceptionally, by means of an explicit reference, such as an asterisk, where that ensures, in a manner that is clear and perfectly comprehensible to the consumer, that, in spatial terms, the content of the health claims and the reference match*.[55] But Article 10(3) of Regulation No. 1924/2006 *is not satisfied*

[54] Ibid.
[55] C-524/18, point 47-48.

where the packaging of a food supplement contains a reference to general, non-specific health benefits of a nutrient or food on the front of the packaging, whereas the specific health claim intended to accompany it appears only on the back of that packaging and there is no clear reference, such as an asterisk, between the two.[56] Moreover, the accompanying the general health claims by the specific health claims from the list of authorised health claims fulfil also the general conditions valid for all nutrition and health claims and it is justification by scientific evidence. The ECJ justified that references to general health claims must be justified by scientific evidence but it suffices for such references to be accompanied by specific health claims.[57] The article 12 of Regulation 1924/2006, which establishes the restrictions on the use of health claims, affirms that those referring to recommendations of individual doctors or associations and/or the rate or amount of weight loss will not be authorized, as well as those suggesting that health could be affected if the product in question is not consumed.[58]

There are two main categories of health claims. The first one is related to the reduction of disease risk and children's development and health and the second one is related to the function claims.

3.2.1 Reduction of disease risk claims

The first category of health claims is related to the health claims made on foods referring to the reduction of disease risk (article 14(1)(a) of the Regulation 1924/2006) and claims referring to children's development and health (article 14(1)(b) of the Regulation 1924/2006). There are two subcategories of these health claims.

Claims referring to children's development and health covered health claims related to the children and young people. There is missing the single definition of children under the EU law. The definition of children varies depending on the legal issues. A child is generally considered to be less than 18 years old.[59] It is usually the age when reaching the end of their growth. However, the EU law includes the definition of infants and young children according to the Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC. The article 2 of this directive infants means children under the age of 12 months and young children means children aged between one and three years. Infants and young children are sub groups of children as referred to in Article 14(1)(b) of the Regulation 1924/2006.[60] Only the claims referring to children are considered as health claims under the article 14(1)(b); however the claims referring

[56] C-524/18, point 50.
[57] see C-524/18, point 59.
[58] Díaz et al., 2020.
[59] www.unicef.org.
[60] Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health, https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf.

to children and other categories of adults (e.g. pregnant women) are considered usually as function health claims.

Reduction of disease risk claim is defined by the article 2(2) of the Regulation 1924/2006 and *means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease*. In this connection, the ECJ decided *that in order to be considered a 'reduction of disease risk claim' within the meaning of that provision, a health claim need not necessarily expressly state that the consumption of a category of food, a food or one of its constituents 'significantly' reduces a risk factor in the development of a human disease*.[61] On the other hand, human diseases are usually affected by more than one factor therefore the claims are related of reduction of diseases risk not of prevention of it. Therefore article 14(2) of the Regulation 1924/2006 stipulates that the labelling of the health claims *shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect*. The presentation of risk reduction claims must ensure that consumers do not take these claims as diseases prevention (e. g. "food" have been shown to lower/reduce "some negative elements in a human body" but not "food" prevents "some human diseases").

In respect of claims relating to reduction of disease risk and claims referring to children's development and health, only those authorised by the Commission, under the conditions laid down in the Regulation 1924/2006, may be used on the food packages. The EU Commission issues Regulation (EC) No. 983/2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health. It includes a list of the permitted health claims made on foods and all necessary conditions for the use of those claims as well as rejected health claims. Currently, there are 14 permitted health claims by the article 14(1)(a) (e.g. *Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease)* and 13 permitted health claims by the Article 14 (1)(b) (e.g. *Essential fatty acids are needed for normal growth and development of children*). However, there is not consolidated text of this regulation, so the individual claims should be looked for in its separate amendments. The Commission received 41 application of health claims related to applications for reduction of disease risk claims by the Article 14(1)(a) of Regulation 1924/2006, and 57 application were related to applications for health claims referring to children's development and health by the Article 14(1)(b) of Regulation 1924/2006.[62] The Commission rejected most of health claim applications (e.g. *three portions of dairy food every day, as part of a balanced diet, may help promote a healthy body weight during childhood and adolescence* – for dairy products or *Help to support the learning ability* - for docosahexaenoic Acid (DHA) and eeicosapentaenoic acid (EPA), etc.).

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[61] C-299/12.

[62] https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home; the above mentioned data includes also the new claims which were not considered up to 31.12.2021.

3.2.2 Function claims

The second category of health claims is function claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. The border line between function claims and the previous ones consists in the reduction of disease risk and claims mentioned above consists in stating, suggesting or implying reduction of a disease, e.g. lowers or reduced a risk factor is a reduction of disease risk claim but maintenance a vital function or care for health is a function claim.

There are also two subcategories. The first one is based on article 13(1) of the Regulation 1924/2006 called function claims based on generally accepted scientific evidence. The second one is based on article 13(5) of the Regulation 1924/2006 called function claims based on newly developed scientific evidence. Currently, there are 229 permitted health claims by the article 13(1) (e.g. *Biotin contributes to normal functioning of the nervous system)* and 13 permitted health claims by the Article 13(5) (e.g. *Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow).* The Commission received 2104 application of health claims according to the article 13(1) of Regulation 1924/2006, and 162 applications according to the article 13(5) of Regulation 1924/2006.[63] The Commission rejected more application than were authorised, mainly application on botanical health claims due to a non-adequate characterisation of the botanical preparations or to the non-demonstrated correlations between the use in humans of the botanical preparation and the beneficial health effects asserted.[64] The list of permitted health claims are issued in the Commission Regulation (EU) No. 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. The food producers have to use only the permitted health claims allowed by this Commission regulation. It includes a list of permitted health claims made on foods and all necessary conditions for the use of those claims. There are currently more than 260 health claims describe or refer to:

- the role of a nutrient or other substance in growth, development and the functions of the body;
- psychological and behavioural functions; or
- slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.[65]

If the effect is commonly known, generally accepted scientific evidence is sufficient proof (function claims based on article 13(1) of the Regulation 1924/2006). If the claim refers to an effect not commonly attributed to an ingredient

[63] https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home; including the new ones which were not considered up to 31.12.2021

[64] Silano, Silano, 2020.

[65] Without prejudice to Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

of the food, the claim shall be substantiated by sufficient scientific proof, including human studies[66] (function claims based on article 13(5) of the Regulation 1924/2006). Any additions of claims to the list of health claims based on newly developed scientific evidence shall be adopted following the procedure laid down in Article 18 of the Regulation 1924/2006 described below.

4. Authorisation of health claims

The health claims include in the Commission Regulations (no. 432/2012 related to the function claims and no. 983/2009 related to the reduction of diseases risk claims) are based on the on generally accepted or newly developed scientific evidences. Developing the scientific evidences enables to add, modify or revoke a health claims. The procedure is stipulated in the article 15 -19 of the Regulation 1924/2006 and in the Commission Regulation (EC) No. 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No. 1924/2006. The Commission regulation establishes implementing rules for two types of applications.

First one is related to the *applications for authorisation, submitted in accordance with Article 15 of Regulation no. 1924/2006*. There are the health claims regulated by the article 14(1)(a) and 14(1)(b).

Second one is related to the *applications for the inclusion of a claim in the list provided for in article 13(3) submitted in accordance with article 18 of Regulation 1924/2006.* There are the health claims regulated by the article 13(5).

The health claims regulated by the article 13(1) based on generally accepted scientific evidence are adopted in accordance with the Regulation no. 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

The authorisation procedures consist usually in four steps: (1) scientific research conducted or compiled by industry; (2) submission to Member States authority; (3) Opinion of European Food Safety Authority (EFSA) on scientific research; and (4) Decision based on scientific opinion and other considerations.[67] The procedure for authorisation of health claims is started by submission of application. The application includes the name and address of the applicant; the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics; a copy of all relevant studies, which is available to demonstrate that the health claim complies with the criteria in this regulation 1924/2006; where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification; a copy of other scientific studies which are relevant to that health claim; a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use; and a summary of the

[66] Mejborn, 2007.
[67] De Boer, 2021.

application. The Annex of the Commission regulation 983/2009 includes more detailed elements of the application.

The application shall be sent to the national competent authority of a particular Member State. The national competent authority has no power to make any decision of the application. It is only delivery body between applicant and the EFSA because it shall only acknowledge receipt of an application in writing within 14 days of its receipt, inform without delay the EFSA and make the application and any supplementary information supplied by the applicant available to the EFSA. After the delivery of application to the EFSA, it informs without delay the other Member States and the Commission of the application and shall make the application and any supplementary information available to them. Moreover, the EFSA makes the summary of the application available to the public.

The EFSA has a time limit of five months from the date of receipt of a valid application in giving its opinion. The date is able to be prolonged up to two months[68] following the date of receipt of the requested supplementary information submitted by the applicant. The EFSA verifies that the health claim is substantiated by scientific evidence and that the wording of the health claim complies with the criteria laid down in the Regulation 1924/2006. The EFSA answers the question whether the health claim applied for properly expresses a cause to effect relationship between the consumption of a category of food, a food or one of its components and the beneficial physiological effect stated.[69] For health claims of article 13(1) generally accepted scientific evidence such as consensus documents or workshop statements can be sufficient; however health claims of article 13(5) or article 14 need to be more extensive, specific and to contain detailed information to support the causal relationship between consuming the ingredient and relevant health outcomes, as established by appropriate measurement methods.[70] However, the scientific risk assessment carried out by EFSA alone cannot provide all the information on which a decision should be based and other legitimate factors should be taken into account, too.[71] It is a role of Commission. Therefore, EFSA forwards its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based. The next step belongs to the Commission. Within two months after receiving the opinion of the EFSA, the Commission prepare a draft decision and submits it to the Standing Committee on the Food Chain and Animal Health.

The Commission takes into account not only the opinion of the EFSA, though scientific substantiation is the major cornerstone on which authorisation for the use of health claims will be granted,[72] but also any relevant provisions of EU law

[68] Only one month if the claims is related to the article 13 (5) of the regulation 1924/2006 (article 18(3) of the regulation 1924/2006).
[69] T-100/15, point 39.
[70] De Boer, 2021.
[71] T-100/15, point 40.
[72] Lalor, Wall, 2011.

and other legitimate factors relevant to the matter under consideration.[73] While it is the case that scientific justification should be the main aspect to be taken into account for the use of nutrition and health claims, the fact nonetheless remains that that regulation does not provide that claims are to be rejected on non-scientific grounds only rarely and exceptionally; however, the Commission must take all three factors into account.[74] Therefore the draft decision is not always in accordance with the opinion of the EFSA, however in such case the Commission has to provide an explanation for the differences, e.g. in spite of the fact that EFSA concluded that a cause and effect relationship has been established between the consumption of glucose and contribution to energy-yielding metabolism, Commission found that health claim is inconsistent with generally accepted nutrition and health principles. It argued that the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advance, national and international authorities inform the consumer that their intake should be reduced. Therefore, such a health claim does not comply with article 3(a) of the Regulation 1924/2006 which foresees that the use of claims should not be ambiguous or misleading. Furthermore, additional statements or warnings would not be sufficient to alleviate the confusion of the consumer, and consequently the claim should not be authorised.[75] The General Court[76] and the Court o the Justice[77] confirmed the Commission decision. The courts agreed with the Commission that the grant of a nutrition or health claim confers a positive image on the foods and it cannot be concluded that that image would not encourage the consumption of those products.[78] Even if the average consumer who is reasonably well informed and reasonably observant and circumspect to whom the applicant refers, knew that he must not consume too much sugar, he might therefore be induced to consume more sugar by reason of the health claims.[79] Moreover, the health claims do not comply with article 3(a) of the Regulation 1924/2006 because they are incomplete when *highlighting a certain quality of such a kind as to enhance energy-yielding metabolism, but are silent as to the fact that, irrespective of the proper functioning of the energy-yielding metabolism, dangers inherent in the consumption of more sugar are neither ruled out nor limited. By highlighting only the beneficial effects for energy-yielding metabolism, the health claims at issue are likely to encourage consumption of sugars and, in fact, to increase the risks for consumer health inherent in the excessive consumption of sugars. In the light of the foregoing, it must be considered that the health claims at issue are incomplete and therefore ambiguous and misleading, even though the information provided is correct*.[80]

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[73] And after having consulted the Member States if the claims is related to the article 13 (5) of the regulation 1924/2006 (article 18(4) of the regulation 1924/2006).
[74] T-100/15, point 84.
[75] T-100/15, point 13.
[76] T-100/15.
[77] C-296/16 P.
[78] T-100/15, point 55.
[79] T-100/15, point 60.
[80] T-100/15, point 68.

A positive EFSA decision does not yet guarantee that the Commission will authorize the use of a health claim. On the contrary, a negative opinion of EFSA leads to the rejection of the application for its use on the grounds of non-compliance with Article 5 and 6 of Regulation 1924/2006. Moreover, there are still more than 2000 applications related to the claims on botanical substances for which finalisation are still pending.[81] The Regulation 1924/2006 should regulate health claims on food products containing botanical preparations. However, most such claims were rejected by the EFSA, so it was decided to put these claims on hold. It means, the transitional measures under Article 28 of the Tegulation 1924/2006 are used under the responsibility of food business operators, provided that they comply with the other provisions of the Regulation 1924/2006 and with EU and national provisions applicable to them.[82] It is questionable whether consumers, who are faced with these different types of claims, can clearly distinguish these non-reviewed claims from the claims that have been scrutinised upon their scientific merit.[83] On the one hand, the average consumer is required to be able to distinguish between permitted claims and claims on hold, on the other hand, the consumer should be thoroughly informed about the importance of a varied and balanced diet and a healthy lifestyle (article 10(2)(a) of the Regulation 1924/2006), or what benefits and risks are associated with the consumption of a particular food (e.g. the claim that highlights and certain quality sound digestion, but the dangers inherent in the consumption of alcoholic beverages are not in any way removed, or even limited). We believe that information on the need and varied and balanced diet and a healthy lifestyle is such a basic knowledge that consumers have from elementary education that there is no need to inform the consumer with a special label on food packaging, where there is already such a large amount of mandatory required data, less and less transparent to the consumer. The average consumer also thinks that the statement 'easily digestible' on an alcoholic beverage does not mean that it eliminates the risk associated with consuming alcoholic beverages, especially when he has information on the packaging about the amount of alcohol in the product. It follows that the criteria of the direct consumer should be clearly defined for the purposes of this Regulation. It is irrational, on the one hand, to inform the consumer of the basic knowledge which unnecessarily takes up space on the packaging of the food and, on the other hand, to require him to make a professional assessment of some of that information, e.g. the ability to distinguish the usefulness and harmfulness of each type of fat from the packaging, whether to assess whether the amount of sugars in the product is low or high, or even whether it is a health claim based on scientific knowledge or just a claim on hold. However, it follows from the above mentioned that the basic objective of Regulation 1924/2006, which is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection (Article 1 (1) of the Regulation 1924/2006), is lost.

[81] https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/resources/docs/claims_pending.pdf
[82] Christodoulou, 2018.
[83] De Boer, 2021.

Any draft decision to amend the lists of permitted health claims includes the name and address of the applicant; the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics; a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use; and where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

A final decision on the application is adopted by the procedure referred to in Regulation 182/2011.[84] The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the Official Journal of the European Union. Health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, however only if they are not restricted for use due to protection of proprietary data. At the applicant's request for the protection of proprietary data, the Commission proposes to restrict the use of the claim in favour of the applicant for a period of five years. After this period of five years, the claim becomes a generic health claim and for other products for which the conditions of use are fulfilled this claim may be used.[85] The Commission have established and maintained a Register of nutrition and health claims made on food,[86] which includes the nutrition claims and the conditions applying to them; the authorised health claims and the conditions applying to them; and a list of rejected health claims and the reasons for their rejection. Health claims authorised on the basis of proprietary data are recorded in a separate Annex to the Register together with the date of authorisation and the name of the original applicant that was granted authorisation; the fact that the Commission authorised the health claim on the basis of proprietary data and restricted use; and the fact that the health claim is authorised for a limited duration.

5. Conclusion

The regulations of an enriched food, a novel food and food additives provides the requirements for mandatory labelling, however mandatory statements required by EU law are not considered as health or nutrition claims and do not fall in the scope of the Regulation 1924/2006, which is related only claims on a voluntary basis. The nutrition and health claims on foods are an important tool for health protection of consumers. The actual legal Regulation 1924/2006 is quite complicated in relation to other legal acts and some of the rules are too ambiguous or vague. There are only few judgements of the ECJ to interpret and apply the particular legal rules of this regulation. Moreover, there are still open the questions related to the nutrient profiles and botanical claims.

[84] Regulation (EU) No. 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[85] De Boer, 2021.

[86] https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search.

A decision needs to be made whether botanical claims on foods should be assessed similarly to other food products, or whether a separate category needs to be developed for (botanical) claims based on traditional use evidence.[87] If the scientific studies are missing, there could be considered the authorisation procedure which do not ask so strict scientific evidence when botanical elements are not able to harm the consumer health and in the worst cases will be no effect on their health.

Currently the nutrient profiles are in the focus of the EU Commission. Many studies[88] try to prove that front-of-pack nutrition labelling is one of the best tools for consumer health protection. However, there is a fear of the oversimplifying, discrimination and penalisation of some foods when warning consumers what should not be eaten based only on particular nutrients. Moreover, many consumer food choices are habitual and based on simplified ways of decision-making, and health will often not be the only and not the main motive for their choices.[89]

In addition, there is no quite clear who is an average consumer. On the one hand, the consumers should be informed on basic knowledge (e.g. information on the importance of a varied and balanced diet and a healthy lifestyle on the package of foods; or information that the dangers inherent in the consumption of alcoholic beverages are not in any way removed, or even limited when the beverage package includes title 'easily digestible'), on the other hand, the consumers should make a professional assessment of some of that information (e.g. the ability to distinguish the usefulness and harmfulness of each type of fats from the packaging, or if the amount of sugars in the product is low or high, or even whether it is a health claim based on scientific knowledge or just a claim on hold). In addition, the regulation itself states in Article 5(2) that the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects expressed in the claim. We recommend that the elementary knowledge should be a subject of the education in the elementary and high schools. The nutrition education in the schools and nutrition courses for adults is the most important tool for consumer protection.[90] Knowledge is a key influence on how claims are perceived.[91] Then the elementary knowledge does not need to take up space on the packaging of the food and it could also help to reduce amount of waste from the food packages. Otherwise, the basic objective of Regulation 1924/2006 ensuring the effective functioning of the internal market and providing a high level of consumer protection is being lost. On the other hand, the current legislation increases the requirements on knowledge of food producers, in particular on the packaging of the product, which must fit even more information in a reasonably large font, and on the environment, as the amount of waste produced increases with increasing packaging area.

[87] De Boer, 2021.
[88] Emrich, 2017; Mendoza et al., 2018, Julia et al., 2016.
[89] Grunert, 2017.
[90] Tarabella, Burchi, 2012; Ames, 2005.
[91] Benson et al., 2019; Annunziata, Mariani, 2019.

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Bibliography

I. Doctrine

1. Ames, B.N. 2005. *Increasing longevity by tuning up metabolism*. In: EMBO reports, 2005, 6, 20-24.
2. Annunziata, A., Mariani, A. 2019. *Do Consumers Care about Nutrition and Health Claims? Some Evidence from Italy*. In: Nutrients 2019, 11, 2735; doi:10.3390/nu11112735.
3. Benson, T. et al. 2019. *Are the Claims to Blame? A Qualitative Study to Understand the Effects of Nutrition and Health Claims on Perceptions and Consumption of Food*. In: Nutrients 2019, 11, 2058; doi:10.3390/nu11092058.
4. Buttriss, J.L., Benelam, B. 2010. *Nutrition and health claims: the role of food composition data*. In: European Journal of Clinical Nutrition, 2010, 64, 8–13.
5. Christodoulou, M. 2018. *Study supporting the evaluation of: a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations, and of b) the general regulatory framework for their use in foods. Final Report: Executive summary and abstract.* Brussels, EU Commission, 2018. Available at: https://op.europa.eu/en/publication-detail/-/publication/f129e13a-99b7-11ea-aac4-01aa75ed71a1/language-en.
6. De Boer, A. 2021. *Fifteen Years of Regulating Nutrition and Health Claims in Europe: The Past, the Present and the Future*. In: Nutrients, 2021, 13, 1725. https://doi.org/10.3390/nu13051725.
7. De Boer, A., Bast, A. 2015. *International legislation on nutrition and health claims*. In: Food Policy, 2015, 55, 61-70.
8. Díaz, L. D. et al. 2020. *An international regulatory review of food health-related claims in functional food products labeling*. In: Journal of Functional Foods, 2020, 68 (2020) 103896.
9. Dréano-Trécant, L. et al. 2020. *Performance of the Front-of-Pack Nutrition Label Nutri-Score to Discriminate the Nutritional Quality of Foods Products: A Comparative Study across 8 European Countries*. In: Nutrients 2020, 12, 1303; doi:10.3390/nu12051303.
10. Emrich, T. E. 2017. *Traffic-light labels could reduce population intakes of calories, total fat, saturated fat, and sodium.* In PLoS ONE, 2017, 12(2): e0171188. doi:10.1371/journal.pone.0171188.
11. Georgescu, B., Onete, C.B., Pleșea, D.A., Chița, S.D., and Sava, Ș., 2022. *Consumer Attitude Towards the Use of Blockchain Technology. Study on the Implementation of the "Green Deal" Strategy for Organic Foods.* Amfiteatru Economic, 24(60), 380, 379-394.

12. Grunert, K.G. 2017. *The health trend.* In: Grunert, K.G., Ed. Consumer Trends and New Product Opportunities in the Food Sector. Wageningen Academic Publishers, 2017, 236 ps. ISBN 978-90-8686-307-5.
13. Hieke, S. et al. 2016. *The role of health-related claims and health-related symbols in consumer behaviour: The CLYMBOL project*. In: Agro Food Industry Hi Tech, 2016, 27(3), 26-29.
14. Julia, Ch. et al. 2016. *Impact of the front-of-pack 5-colour nutrition label (5-CNL) on the nutritional quality of purchases: an experimental study.* In: International Journal of Behavioral Nutrition and Physical Activity, 2016, 13, 101, DOI 10.1186/s12966-016-0416-4.
15. Kozup, J.C. et al. 2003. *Making healthful food choices: the influence of health claims and nutrition information on consumers' evaluations of packaged food products and restaurant menu items*. In: Journal of Marketing, 2003, 67 (5), 19-34.
16. Lalor, F., Wall, P. G. 2011. *Health claims regulations Comparison between USA, Japan and European Union*. In: British Food Journal, 2011, 113(2), 298-313.
17. Lazíková, J., Rumanovská, Ľ. 2021. *Food Labelling to protect consumers.* In: Quality Soil as a Pathway to Healthy Food in the EU, Nitra: SPU, 2021. 90-103 s. ISBN 978-80-552-2403-9.
18. Mejborn, H. 2007. *Health Claims on foods and food supplements. Existing practice in Nordic and Baltic countries*. National Food Institute, Technical University of Denmark, 2007. ISBN 978-87-92158-13-0.
19. Mendoza, R. et al. 2018. *Modifications in the Consumption of Energy, Sugar, and Saturated Fat among the Mexican Adult Population: Simulation of the Effect When Replacing Processed Foods that Comply with a Front of Package Labeling System*. In: Nutrients 2018, 10, 101. https://doi.org/10.3390/nu10010101.
20. Petrescu, D.C., Petrescu-Mag, R.M., Bran, F. and Rădulescu, C.V., 2018. *Consumer Food Security and Labeling Intervention on Food Products through Public Policies in Romania*. Amfiteatru Economic, 20(47), 99, 99-115.
21. Santeramo, F.G. et al. 2018. *Emerging trends in European food, diets and food industry*. In: Food Res. Int. 2018, 104, 39–47.
22. Schwarcz, P. et al. 2021. *Poľnohospodárska politika Európskej únie. /Agricultural Policy of the EU/.* Nitra, Slovak University of Agriculture, 2021. 86 ps. ISBN 978-80-552-2455-8.
23. Silano, M, Silano V. 2020. *Ensuring Food Safety in the European Union*. CRC Press, 2020. 264 ps. ISBN 9781000198133.
24. Takáč, I.; Palšová, L. 2021. *Ako napísať a implementovať úspešný projekt v rámci výziev Spoločnej poľnohospodárskej politiky - manuál. /How to write and implement a succesful project in the framework of CAP*/. Nitra, Slovak University of Agriculture, 2021. 133 ps. ISBN 978-80-552-2357-5.
25. Tarabella, A. et al. 2021. *The effects of advertisements on consumer choices and health: A content analysis of health claims in Italian magazines.* In: British Food Journal, 2021, 123 (8), 2785-2804.
26. Tarabella, A., Burchi, B. 2012. *The role of nutrition and health claims in consumers' perception. Creating educational paths to resolve information asymmetries caused by promotion and marketing activities regarding foodstuffs.* In: Procedia. Social and Behavioral Sciences, 2012, 46, 2173-2177.
27. Van Trijp, H.C.M. 2009. *Consumer understanding and nutritional communication: Key issues in the context of the new EU legislation*. In: Eur. J. Nutr. 2009, 48, 41-48.

28. Wansink, B. 2003. *Using laddering to understand and leverage a brand's equity*. In: Qualitative Market Research: An International Journal, 2003, 6 (2), 111-118.

II. List of cited legal documents

1. Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004.
2. 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.
3. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.
4. Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
5. Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark.
6. Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks.
7. Regulation EU no 609/2013 of the European parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009.
8. Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.
9. Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.
10. Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001.
11. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
12. Regulation (EU) No. 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.
13. 2013/63/EU: Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.
14. Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health, https://ec.europa.eu/food/system/ files/2016-10/labelling_nutrition _claim_reg-2006-124_guidance_en.pdf.

15. Commission Staff Working Document Evaluation of The Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods {SWD(2020) 96 final}. Available at https://ec. europa.eu/food/system/files/2020-05/labelling_nutrition-claims_swd_ 2020-95_part-1.pdf.
16. European Commission. Food labelling - revision of rules on information provided to consumers. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-provided-to-consumers/public-consultation_en.
17. European Commission. Nutrition labelling. Available at: https://ec.europa.eu/ food/safety/labelling-and-nutrition/food-information-consumers-legislation/nutrition-labelling_en.
18. European Commission. EU Register of Health Claims. Available at: https://ec.europa.eu/food/safety/labelling_ nutrition/claims/register/public/?event=register.home.
19. EFSA. The Setting of Nutrient Profiles for Foods Bearing Nutrition and Health Claims Pursuant to Article 4 of the Regulation (Ec) ° No 1924/2006 Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies (Request N° Efsa-Q-2007-058). Available at: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.20 08.644.

III. List of ECJ judgments

1. C-544/10: Judgment of the Court (Third Chamber), 6 September 2012 *Deutsches Weintor eG v Land Rheinland-Pfalz*.
2. C-299/12: Judgment of the Court (Ninth Chamber), 18 July 2013 *Green — Swan Pharmaceuticals CR, a.s. v Státní zemědělská a potravinářská inspekce, ústřední inspektorát.*
3. C-19/15: Judgment of the Court (Third Chamber) of 14 July 2016 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*.
4. C-177/15: Judgment of the Court (Third Chamber) of 23 November 2016 *Nelsons GmbH v Ayonnax Nutripharm GmbH and Bachblütentreff Ltd.*
5. C-524/18: Judgment of the Court (Second Chamber) of 30 January 2020 *Dr. Willmar Schwabe GmbH & Co.KG v Queisser Pharma GmbH & Co. KG.*
6. C-363/19: Judgment of the Court (Tenth Chamber) of 10 September 2020 *Konsumentombudsmannen v Mezina AB.*
7. T-100/15: Judgment of the General Court (Fifth Chamber) of 16 March 2016 *Dextro Energy GmbH & Co. KG v European Commission.*