Reply of the European Commission on a request for information from the European Ombudsman
- Complaint by M[redacted] on behalf of the International Probiotic Association – IPA Europe (IPAEU), ref. 2273/2023/AML

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

The complaint in question was put forward by M[redacted] Executive Director of the International Probiotic Association - IPA Europe (IPAEU) on behalf of IPA Europe regarding the European Commission's interpretation concerning the use of the term "probiotics" on labelling and communications within the European Union.

Live microorganisms comprise a very large group of microorganisms. The differentiation point to call some of those microorganisms "probiotics" is that they confer a health benefit to the host if administered in adequate amounts. This is reflected in the definition of probiotics by the World Health Organisation (WHO) as live microorganisms which when administered in adequate amounts confer a health benefit to the host. However, the beneficial effects of live microorganisms for the healthy population have not been proven yet. Nonetheless, consumers expect live microorganisms marketed as probiotics to confer a health benefit to them and may be inclined to favour such products and even pay a higher price, for a benefit that they will not receive.

Since the adoption of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[1] (Claims Regulation), the Commission has held the consistent interpretation that the reference to probiotics in the labelling of foods implies a health benefit and therefore it constitutes a health claim and may only be used in accordance with the conditions set by the Claims Regulation. Member States have shared the same interpretation, as evidenced by the Guidance on the implementation of the Claims Regulation[2] (hereafter: Guidance document), which was discussed and approved by the Member States. Similarly, food business operators have also considered that the reference to probiotics constitutes a health claim, as evidenced by the multitude of applications for the authorisation of health claims on probiotics, which have been also validated by Member States' competent authorities.

The Claims Regulation sets out the framework for the use of nutrition and health claims in the EU and its objective is to ensure that any nutrition or health claim made on the labelling, presentation or advertising of a food in the EU is truthful, clear and reliable.

According to the Claims Regulation, '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'.[3] The Claims Regulation provides that health claims are prohibited unless they are authorised and are only authorised for use in the EU after a scientific assessment of the highest possible standard,[4] carried out by the European Food Safety Authority (EFSA). With

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[1] 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 (OJ L 404 30.12.2006, p. 9-25)
[2] Guidance on the implementation of Regulation (EC) No 1924/2006 (2007), available at: https://food.ec.europa.eu/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf
[3] Article 2 (5) of Regulation (EC) No 1924/2006
[4] Article 10 (1) of Regulation (EC) No 1924/2006

regard to nutrition claims, the permitted nutrition claims that may be made on foods, are those listed in the Annex of the Claims Regulation. Nutrition and health claims may be used on foods placed on the EU market only if they comply with the conditions of use accompanying them as well as with the provisions of the Claims Regulation.

At the outset, it should be noted that nutrition and health claims, as regulated by the Claims Regulation, concern particular beneficial properties of food marketed to a healthy population. Recital 3 of the Claims Regulation clarifies that the Claims Regulation should complement the general principles of Regulation (EU) No 1169/2011 on the provision of food information to consumers[5] (FIC Regulation), which provides that food information shall be accurate, clear and easy to understand for the consumer and generally prohibits the use of information that would, amongst others, mislead the purchaser as to the characteristics of the food and by attributing to the food effects or properties which it does not possess.

The Guidance document which was discussed and approved by the Member States at the Standing Committee on the Food Chain and Animal Health, clarifies that a claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health: e.g.: "contains antioxidants" (the function is an antioxidant effect); "contains probiotics/prebiotics" (the reference to probiotic/prebiotic implies a health benefit). Equally, claims which refer to an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim, e.g.: "with prebiotic fibres" or "contains prebiotic fibres". [6]

Since 2008, EFSA has assessed more than 300 claims on live microorganisms and on the terms "probiotics" and "prebiotics". However, to date, the beneficial health effects of live microorganisms on a healthy population have not been established and therefore none of the submitted applications obtained a favourable opinion by EFSA. As a result, no health claim on "probiotic" and/or "prebiotic" is authorised for use on food on the EU market. The applications submitted for the authorisation of health claims on probiotics with regard to certain live microorganisms, show that food business operators, who submitted the applications, and the competent authorities of the Member States, who validated these applications and forwarded them to EFSA for scientific assessment, have consistently considered that the reference to probiotics on foods constitutes a health claim.

The Commission notes, that food business operators may at any time submit applications for authorisation of claims and inclusion to the list of permitted health claims under specific conditions. Therefore, new applications for authorisation of health claims related to the terms ''probiotics'', ''prebiotics'', based on updated scientific grounds, could be submitted for assessment by EFSA. [7]

Allowing the use of the term "probiotics" on foods, even though beneficial effect of live microorganisms contained therein has not been demonstrated, would be in conflict with the

[5] 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 (OJ L 304 22.11.2011, p. 18)

[6] See page 11 of the Guidance document.

[7] Article 16(3)(a) of Regulation (EC) No 1924/2006

provisions of the Claims Regulation, which aims to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. It would also be contrary to FIC Regulation, as it would mislead the consumers, by attributing to the foods special characteristics or beneficial effects, which they do not possess and therefore providing false information.[8]

As evidenced in the supporting documents to this reply[9], the Commission has consistently engaged with the complainant and other stakeholders, has carefully considered their arguments, and following consultation with the competent authorities of Member States has held the consistent position that allowing the use of term "probiotic" on foods, without any proof of that food having beneficial effects on human health would mislead consumers and infringe the provisions of the Claims Regulation and of the FIC Regulation. Allowing the use of term "probiotics" without proven link between the relevant substance/food and health, would not only be contrary to the EU legal framework, but could in addition in practice lead to an unjustified increase in the prices of such foods to the detriment of consumers.

II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

The complaint of the International Probiotic Association - IPA Europe (IPAEU) to the European Ombudsman concerns the European Commission's longstanding interpretation regarding the use of the term "probiotics" on labelling and communications within the European Union. The complainant wrongly considers that the Commission's responses to their numerous inquiries lack legal reasoning and are superficial.

The complainant characterises the Commission's responses to stakeholders and Member States as unsatisfactory because they do not agree with their interpretation concerning the use of the term "probiotics". The Commission's position has always been clear, in accordance with the EU law and in support of consumers' interests. It should be noted that the complainant acknowledges that the Commission has been consistent in its position.

The complainant further disputes the applicability and relevance of the Commission's Guidance document and makes false accusations stating that the Commission retains a blurry position and has not satisfactorily addressed the matter. The complainant alleges that this amounts to maladministration, an argument which is unfounded in light of the several occasions during which the Commission has provided guidance and clearly stated its position on the matter.[10]

Finally, the complainant proposes the removal or update of the Guidance document, the inclusion of the statement "contains probiotics" in the list of nutrition claims or the recognition of this statement as the descriptive name of the food. However, all these actions would be contrary to the EU legal framework and would lead to consumer confusion, for the

[8] " In order to assess the capacity of labelling to mislead, the national court must in essence take account of the presumed expectations, in light of that labelling, which an average consumer who is reasonably well informed, and reasonably observant and circumspect has, as to the origin, provenance, and quality associated with the foodstuff, the critical point being that the consumer must not be misled and must not be induced to believe, incorrectly, that the product has an origin, provenance or quality which are other than genuine" Case C 195/14, Teekanne ,ECLI:EU:C:2015:361 , par. 36, and the case-law cited therein.
https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018CJ0363

[9] See List of enclosures

[10] See List of enclosures

reasons listed below.

III. EUROPEAN OMBUDSMAN'S INQUIRY

In a letter sent on 19 December 2023 to the President of the European Commission, the European Ombudsman opened an inquiry to investigate how the Commission has replied to the complainant's concerns. In this context, the European Ombudsman is asking the Commission to explain in more detail the reasons why it considers that the 2007 guidance is up-to-date and that probiotics should systematically be considered as a health claim and not as a nutrition claim, in light of the issues raised by the complainant and other stakeholders. In doing so, the European Ombudsman is asking the Commission to explain what elements underpin this choice, other than the definition set out in the 2001 Report of a Joint Food and Agriculture Organisation (FAO)/WHO Expert Consultation on probiotics.

IV. THE REPLY OF THE EUROPEAN COMMISSION TO THE COMPLAINANT'S ARGUMENTS

The Claims Regulation was adopted on 20 December 2006, laying down harmonised rules for the use of nutrition and health claims made on foods with the aim to contribute to a high level of consumer protection as well as to ensure fair competition for the food industry. The Regulation aims to ensure that any claim made on a food label in the EU is clear, truthful and reliable, enabling consumers to make informed choices.[11]

According to Recital 15 of the Claims Regulation "it is important that claims on foods can be understood by the consumer, and it is appropriate to protect all consumers from misleading claims." Pursuant to Article 3 (general principles) of the Claims Regulation, the use of nutrition and health claims must not, among others, be false, ambiguous and misleading.

1. On the classification of probiotics as health claim

The International Probiotic Association - IPA Europe (IPAEU) is complaining about the European Commission's interpretation regarding the use of the term "probiotics" in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, within the European Union.

Although the term "probiotic" is not defined in EU legislation, the definition provided in the FAO/WHO consultation (2001) which defines probiotics as live microorganisms which when administered in adequate amounts confer a health benefit to the host is widely recognised worldwide. FAO and WHO are the relevant UN bodies for issues concerning food and health. The EU is a member of FAO and all 27 EU Member States are WHO members. The FAO/WHO definition has been widely adopted and has proven valuable to researchers and regulators and has been used by organisations and agencies such as the EFSA as well as the IPAEU[12] when referring to probiotics.

The Commission's interpretation regarding the use of this term is based on the relevant provisions of Union law, has been agreed between the Member States and acknowledged by

[11] Recital (29) of Regulation (EC) No 1924/2006
[12] https://www.ipaeurope.org/fao-wto-definition-probiotics-microorganisms/

the practices of food business operators and has been consistent since the publication of the Guidance document in 2007.

Also, the prevailing view in discussions with Member States has been to qualify the term "probiotic" as a health claim. The term "probiotic" must therefore be understood to fall within the definition of a health claim provided in the Claims Regulation, according to which 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. Foods promoted with health claims confer a positive image to consumers and may be perceived as having a nutritional, physiological or other health advantage over similar or other products not bearing such claims. It is therefore important to ensure that such claims, when made on food products are scientifically substantiated. For this reason, health claims may only be authorised for use following a scientific assessment of the highest possible standard, carried out by EFSA. Applications for authorisation of health claims should adequately and sufficiently demonstrate that the health claim is based on and substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data and by weighing the evidence.

The fact that the industry has submitted several health claims applications to prove the beneficial effect of certain live microorganisms, ultimately aiming at obtaining an authorisation for the use of the concerned health claims, shows that the industry did not question the fact that the term "probiotics" is to be considered as a health claim. At the same time, Member States have also accepted these health claim applications in the context of the preliminary "validity check" that the competent authorities of the Member States have to carry out, before forwarding any health claim application to EFSA for scientific assessment. According to 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 and specifically Article 7a, Member States are indeed responsible for the verification of the validity of applications before making them available to EFSA.

Despite the high number of applications (27) received by the Commission for the authorisation of the term "probiotics" and ''prebiotics'' as health claims, to date, none of them has obtained a favourable opinion by EFSA mainly due to the lack of established scientific evidence on their effects on human health for a healthy population but also due to insufficient characterisation, poor quality studies and undefined claims.

The majority of these claims, on live microorganisms and on the terms "probiotic" and "prebiotic", were assessed by EFSA in accordance with point (3) of Article 13 of the Claims Regulation. Between 2008-2009, 15 applications were submitted by food business operators to Member State competent authorities and 12 applications between 2010-2020.

Although the industry was initially investing in submitting applications to prove the beneficial effect of probiotics, the number of applications has considerably declined over the recent years.

The complainant erroneously alleges that according to EFSA's Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms, the term "probiotic" as such cannot be authorised as a health claim. The purpose of the EFSA Guidance is to assist applicants in preparing applications for the authorisation of health claims related to the immune system, the

gastrointestinal tract and defence against pathogenic microorganisms. It provides examples of claims evaluated favourably by EFSA to provide guidance to applicants on the scientific requirements for the substantiation of health claims in specific areas and examples of claims evaluated unfavourably by EFSA, to illustrate the shortcomings that prevented the substantiation of these claims. The guidance does not intend to provide an exhaustive list of beneficial physiological effects and studies which could be acceptable, nor to address potential health relationships and related outcome measures which have not yet been considered in the context of a particular application and it does not contradict that a live microorganism marketed as being a "probiotic" is a health claim. Food business operators have submitted and may continue to submit at any time applications for authorisation of claims on probiotics.

2. The Commission Guidance document is up-to-date and fit for purpose

Following the adoption of the Claims Regulation, a Working Group with experts from Member States was set up in order to examine a series of issues concerning its implementation, notably on the classification of claims. As a result, Member States endorsed the Guidance document on the implementation of the Claims Regulation on 14 December 2007, at the Standing Committee on the Food Chain and Animal Health. Although the Guidance document has no formal legal status, it aims in assisting interested stakeholders to better understand and apply the Claims Regulation correctly and in a uniform way.

The complainant's argument that the Guidance document is no longer fit for purpose and his proposal that it must be repealed, are unfounded considering the value and help that the Guidance has provided to date to both stakeholders and Member State competent authorities.
The Commission aims to empower consumers to make informed, healthy and sustainable food choices and therefore the correct enforcement of the currently applicable EU rules is of great importance. Any amendment of the Guidance document cannot go against the general objectives of the Claims Regulation, such as resulting in consumers being misled by unsubstantiated promotional claims on food and should not lead to the increase of food prices for consumers and distort the level playing field on the internal market. It must also be noted that the definition of a health claim and other relevant provisions within the framework of the Claims Regulation remained unchanged since the adoption of the Regulation as well as that, to date, no health claim on the term 'probiotics' has been authorised for use on food products in the EU market, therefore no need has been presented for a change in the Guidance document.

The Guidance document is therefore fit for purpose and has proven to be very useful not only for stakeholders but also for Member State competent authorities in enforcing the EU rules on claims.

Furthermore, the Commission on several occasions communicated and discussed with Member States the position that health claims on probiotics cannot be made as none has been authorised so far[13]. It is the responsibility of the Member States to ensure that the practices followed by food business operators with regard to the labelling of food products are in line with the applicable EU rules. Should this not be the case, the Member States must take appropriate measures to ensure conformity.

[13] See point 5 below.

3. Why the term "probiotic" or "contains probiotics" cannot be qualified as a nutrition claim

The complainant suggests that the term 'contains probiotics' must be included in the Annex of permitted nutrition claims with precise criteria and conditions of use.

According to the definition provided in the Claims Regulation,[14] '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 (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or

(b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain.

However, in the case of probiotics, firstly, there is no association between probiotics and nutritional qualities within the meaning of the Claims Regulation, and secondly, the particular beneficial effects of probiotics on a healthy population have not been proven. In addition, the use of a nutrition claim is permitted not only when it is listed in the Annex of the Claims Regulation and used in conformity with its accompanying conditions of use, but it must also be used in conformity with the provisions of the Claims Regulation, which provides that generally established scientific data must be in place proving the beneficial nutritional or physiological effect of the claim and to date, no such data exist for probiotics.

Therefore, the EU legal framework in force would not permit the categorisation of probiotics as nutrition claims. In discussions on the Guidance document, which was endorsed by Member States and the Commission, the term "probiotic" or "contains probiotics" has rightly not been qualified as nutrition claims for the reasons provided above.

4. On the application of Regulation (EU) No 1169/2011 (FIC Regulation)

The complainant proposes that the term "probiotics" should be recognised and allowed as the descriptive name of the product in accordance with the FIC Regulation. The complainant argues that the Commission's position in this regard negatively impacts both food business operators and consumers and creates legal uncertainly for food business operators.

Such arguments are however unfounded as both the Claims Regulation and the FIC Regulation aim to protect consumers in relation to food information by establishing the general principles, requirements and responsibilities governing food information, and in particular food labelling.

The FIC Regulation provides that food information shall be accurate, clear and easy to understand for the consumer and should not in any way be misleading. Considering that the term probiotics implies a health benefit and it is therefore by definition a health claim, it may only be used if it complies with the Claims Regulation.

According to the FIC Regulation, 'descriptive name' means a name providing a description of

[14] Article 2(2)(4) of Regulation (EC) No 1924/2006

the food, and if necessary, of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be confused[15]. Allowing the use of the term as a descriptive name, while its beneficial nutritional or physiological effect has not yet been proven, would not provide consumers with accurate and scientifically substantiated food information.

In this regard, Article 7 of the FIC Regulation on fair information practices provides that food information, including mandatory food information such as the name of ingredients, shall not be misleading, particularly as to the characteristics of the food and by attributing to the food effects or properties that it does not possess. The use of the name probiotics for different live microorganisms would be in conflict with this article, as consumers would assume that these live microorganisms have a beneficial health effect, which has not been demonstrated. In the case at hand, and in accordance with the FIC Regulation, when foods contain specific live microorganisms, their presence has to be indicated in the list of ingredients. Article 18 of FIC Regulation provides that ingredients have to be designated by their specific name, in order to ensure that consumers are appropriately informed as regards the food they consume.

A different interpretation would be contrary to the purpose and the letter of the Claims Regulation and of the FIC Regulation, as any health or nutritional claim could be used as the name of the food, without having to comply with the conditions of the Claims Regulation. For example, a food business operator could unilaterally decide that the name of its food is 'low fat yogurt', even if it contains more than 3 g of fat/100 g.

The complainant further asserts that the term probiotics is legally used on the label of food supplements as a category name to characterise the substances used in their composition, as per Article 6(3)(a) of Directive 2002/46/EC[16]. It should be noted that the Directive only prescribes the indication of either the names or the categories of nutrients or substances, or the nature of those nutrients or substances. It does not define the names of such categories but allows for the indication of the nature of nutrients or substances used in food supplements. The names of categories of nutrients or substances that characterise the product may not infringe other provisions of EU law that apply in parallel to Directive 2002/46/EC, including Article 3 of the Claims Regulation, that permits the use of health claims in the labelling, presentation and advertising of foods placed on the Union market only if they comply with its provisions. The name of the category of nutrients or substances must also comply with the provisions of the FIC Regulation, and in particular with Article 7 thereof, in particular the name of the category shall not be misleading by attributing to the food effects or properties that it does not possess.

In view of the above, probiotic cannot be considered as the name of the ingredient, or the name of the category of substances used in the manufacture of food supplements.

5. Engagement with stakeholders and Member States

The complainant is accusing the European Commission of an alleged lack of clarity and legal basis in its position as well as a lack of willingness to engage into discussions on the subject. It must be noted in this regard that the Commission has retained and reiterated its clear and

[15] Article 2(2)(p) of Regulation (EU) No 1169/2011

[16] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183 12.7.2002, p. 51)

legally grounded position concerning the use of the term probiotics on several occasions, by both replying in a timely manner to letters/questions received, as well as during meetings organised with Member State experts. In all instances, the Commission has carefully analysed the arguments brought forward by the various interlocutors, and always provided justifications supporting its position.

On 20 October 2017, a joint letter was sent from Members of the European Parliament to the First Vice-President Timmermans and Commissioner Andriukaitis with regard to promotion of innovation in food and food supplements, referring among others to the fact that at the time, there was no possibility of pre-submission meetings to be held between EFSA and applicants for assisting in the preparation of health claim applications, as well as to the possibility of permitting nutrition claims for probiotics. In his response[17] and in relation to the latter, Commissioner Andriukaitis reaffirmed the willingness of the Commission to engage in further dialogue on the matter. Concerning the pre-submission meetings, the Commissioner ensured that consideration would be given in possible changes that would assist in the improvement of the quality of studies submitted in support of an application for EU authorisation, in accordance with the General Food Law[18]. It must be noted in this regard that on 27 March 2021 Regulation (EU) 2019/1381[19] (Transparency Regulation) came into force which provides that EFSA shall, at the request of a potential applicant or notifier, provide advice on the rules applicable to, and the content required for, the application or notification, prior to its submission.

In May 2019 a presentation was given by the Commission to the Permanent Representation of Denmark to the EU on the state of play on probiotics, in which the scope of the Claims Regulation was explained and information was given with regard to the applications submitted on probiotics, the main reasons for the unfavourable EFSA opinions, as well as the initiatives from the Commission and EFSA in assisting interested stakeholders, showcasing its engagement on the matter.

In a response[20] to the joint statement sent by IPAEU and the European Dairy Association (EDA) on 29 June 2022 to Commissioner Kyriakides, the Commissioner clarified that "probiotics" are defined as live microorganisms that confer a health benefit and therefore, claims such as "contains probiotics", when made on food, are considered as health claims. None of the applications that have been submitted for the authorisation of such terms related to "probiotics" have obtained a favourable opinion by EFSA, due to the lack of sufficient scientific evidence demonstrating health benefit and as a result, health claims on "probiotics" cannot be used on foods in the EU market, as none have been authorised. This was reiterated in a reply[21] by Ms Domenech Amado, Director of Directorate A of DG SANTE, to a follow-up letter sent on 10 October 2022.

[17] Reply to: Letter from 15 MEPs on promoting innovation in food and food supplements, Ares(2017)6019904

[18] 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 (OJ L 031 1.2.2002, p. 1-24)

[19] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1-28)

[20] Reply to letter to Commissioner transmitting the joint position of IPA Europe -EDA concerning the term 'probiotic' on labelling and communication, Ares(2022)5358025

[21] Reply to: Letter from IPA Europe - Using the term 'probiotic' on labelling and communication: joint position

On 7 June 2022, a letter was sent to Commissioner Kyriakides by Mr Prehn, Minister for Food, Agriculture and Fisheries in Denmark, regarding the possibility to use the term "probiotics" to inform consumers about the presence of certain live microbial cultures contained in food. The Commission clarified once again, in its reply on 11 July 2022[22], that the term "probiotics" is considered to be a health claim in the EU and that in order to ensure that consumers receive truthful, clear and reliable information, the Claims Regulation provides that health claims may be only made on foods if they are authorised, following a scientific assessment by EFSA. Despite the number of applications for the authorisation of health claims in relation to "probiotics", none of them has obtained a favourable opinion by EFSA and therefore, for the time being, health claims on "probiotics" cannot be used in the EU market as none has been substantiated scientifically and authorised. The Commission stressed in its reply that EU rules apply equally to all products marketed in the EU, whether produced or imported, to ensure a level playing field for our industry and a high level of protection for our consumers.

The Commission reiterated its position with regard to probiotics to Member States experts during the Working Group meetings on nutrition and health claims made on foods that took place on 11 July 2022 and 17 November 2023, as well as during a meeting of the Standing Committee on Plants, Animals, Food and Feed Section General Food Law that was held on 9 February 2023[23]. The Commission explained that the use of the term is considered a health claim and it is currently prohibited to use the term probiotics in the EU market, as no health claims have been authorised so far. The Commission also explained that in cases where the labelling of food products marketed in the EU is found to not be in line with the EU rules, Member States should put in place measures to ensure their conformity with the EU rules.

The Fit for Future Platform is a high-level expert group that helps the Commission in its efforts to simplify EU laws and to reduce related unnecessary costs. The Platform issues opinions taking into account legislative density and the need to ensure existing legislation is future-proof. In its opinion on Biosolutions, adopted on 13 December 2022[24], a reference is made to the Claims Regulation and probiotics. The opinion refers to the Guidance document and to the fact that the term 'probiotic' is considered a health claim as well as to the fact that to date, none of the applications submitted for authorisation of specific health claims regarding the effect of 'probiotics', have received a favourable opinion by EFSA.

The Commission has always engaged in dialogue and exchange with all stakeholders, by replying in writing to the questions and considerations raised in the letters addressed to the Commission and sent from both the industry and the Member State competent authorities and orally during Working Group meetings and meetings of Standing Committee on Plants, Animals, Food and Feed.

V. CONCLUSION

IPA Europe -EDA, Ares(2022)8661852

[22] Ares(2022)5047632

[23] Summary report of the meeting of the Standing Committee on Plants, Animals, Food and Feed Section General Food Law, 9 February 2023: https://food.ec.europa.eu/system/files/2023-06/reg-com_gfl_20230209_sum.pdf

[24] Final opinion 2022_SBGR3_08 Biosolutions_fup.pdf (https://commission.europa.eu/system/files/2023-11/Final%20opinion%202022_SBGR3_08%20Biosolutions_fup.pdf)

The Commission's position on probiotics has remained consistent and aims at ensuring that consumers are protected and not misled by unsubstantiated health claims. In line with the applicable EU law, legal requirements and conditions need to be respected for the term to be used on foods marketed in the EU.

It has been clarified on several occasions that - should the labelling of food products marketed in the EU be found to not be in line with the EU rules - Member States must put in place measures to ensure their conformity with these rules.

The willingness of the Commission to engage in discussions with stakeholders and Member States has been repeatedly demonstrated via different channels, and its responsiveness to timely address any questions and inquiries raised on this matter, either by the industry or by the Member States, showcases its commitment in providing guidance and in clarifying the applicable legal framework. The Commission remains open for further discussion and appropriate consideration should new scientific elements be brought forward by interested parties. It welcomes the submission of new applications for the authorisation of health claims related to "probiotics" and "prebiotics", provided that they are based on solid scientific evidence in the interest of EU consumers.

For the Commission
Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

[redacted]
Director
Decision-making & Collegiality
EUROPEAN COMMISSION