

USE OF THE TERM PROBIOTIC

A EUROPEAN OVERVIEW

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THE CONTEXT

The interest in the consumption of **'probiotics'** in food, beverages and dietary supplements continues to grow, as both consumers and the industry look for **'microbiome-friendly'** foods

Currently, the **NHCR** is applied differently, depending on the interpretations of the Member States' authorities, but also on the typology of probiotic food products

A more consistent approach should be developed in the EU on the use of the term **'probiotic'**, providing useful guidance for stakeholders and consumers

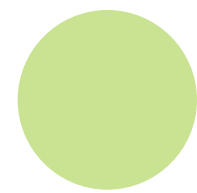
Fostering the harmonisation and conditions for use of the term **'probiotic'** in food, beverages and dietary supplements is a necessary step in the interest of European consumers and for a better functioning of the European Market



PROBIOTICS FOOD AND FOOD SUPPLEMENTS

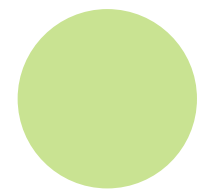
USES OF THE TERM PROBIOTIC WITHIN THE CURRENT EU NHCR FRAMEWORK

Probiotic as **nutrition claim** ?

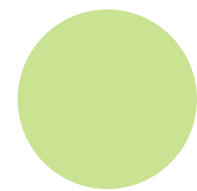


It can be, if in the naming of the substance, or category of substances, there is only factual information, complying with the conditions for the use of the claim "contains (name of nutrient or other substance)" in the NHCR n° 1924/2006

Probiotic as **health claim** ?



It can be, 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 ⇒ EFSA process of evaluation ⇒ positive evaluation ⇒ EC Approval of the specific health claim



Probiotic" as a **general, non-specific health claim** that can be made if accompanied by a specific health claim (par. 3 art 10 of NHCR n° 1924/2006)

USE OF THE TERM PROBIOTIC IN FOODS, BEVERAGES AND DIETARY SUPPLEMENTS

EUROPE AT A GLANCE

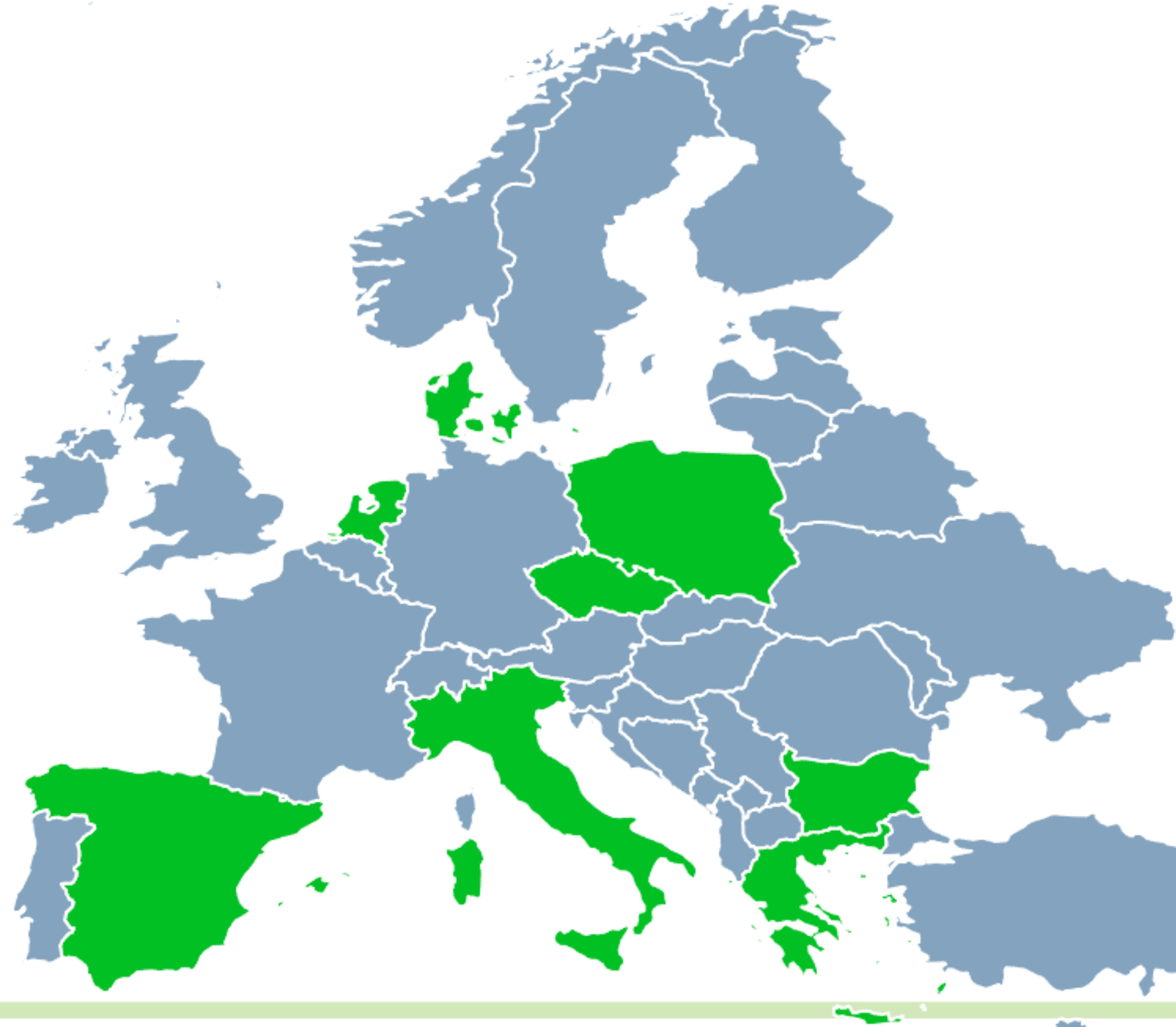
**THE COUNTRIES IN GREEN
ALLOW THE TERM PROBIOTIC
ON LABELS**

**•WITH THE REFERENCE TO NUTRITIONAL
/PHYSIOLOGICAL EFFECTS**

OR

•AS THE NAME OF THE CATEGORY

**Bulgaria, Czech Republic, Denmark,
Greece, Italy, Malta, The Netherlands,
Poland, Spain**

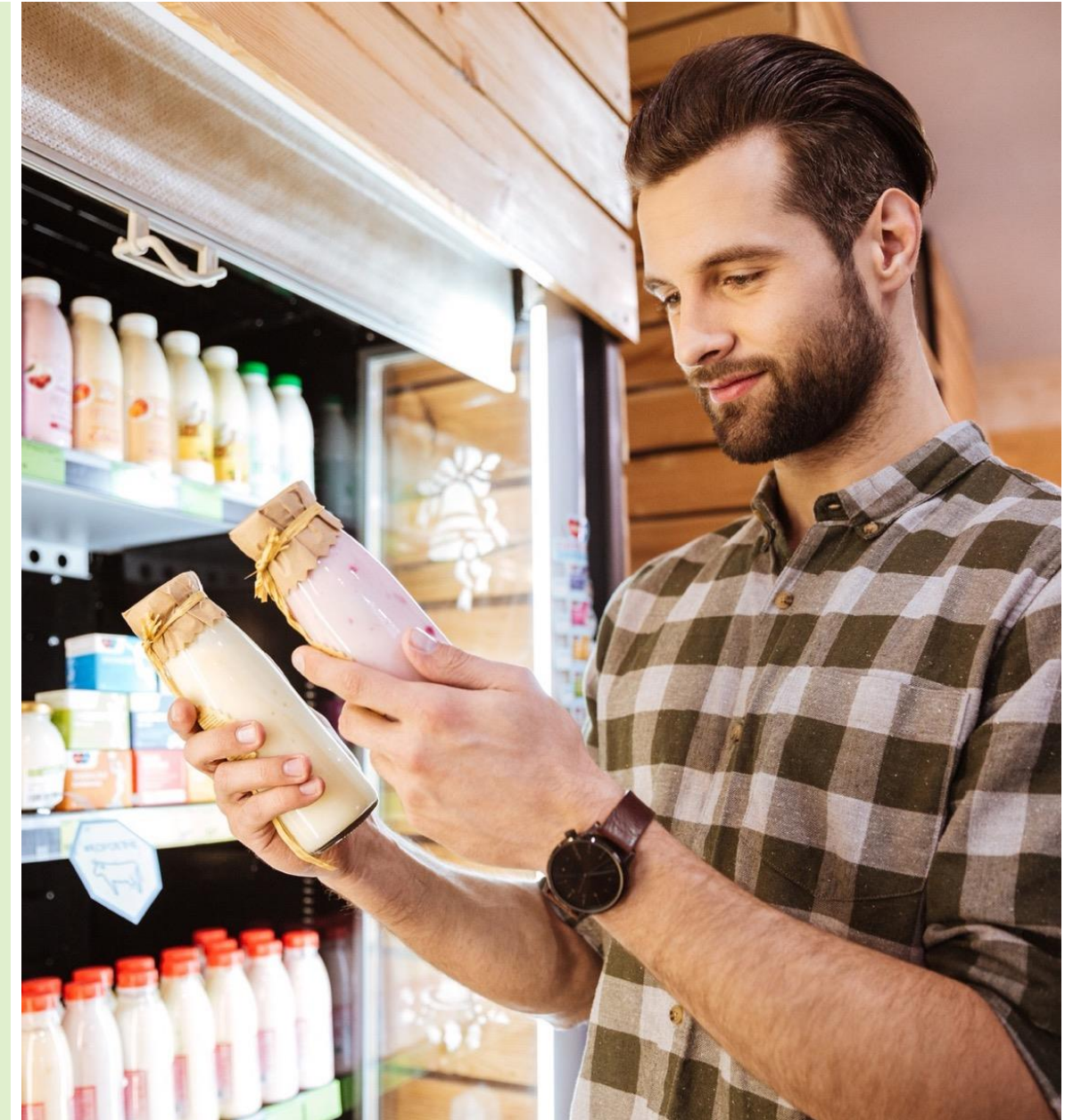


A EUROPEAN SOLUTION IS NEEDED FOR LABELLING FOODS WITH THE TERM “PROBIOTIC”

EC INTERPRETATION OF PROBIOTIC AS HEALTH CLAIM ONLY

For a decade the probiotic sector has requested an adjustment to the regulatory framework in the EU for probiotics in food and food supplements

The lack of a harmonized regulatory framework and lack of clarity on the definition of the term “probiotics” at EU level has led individual Member States to adopt national guidelines to allow labelling with the term probiotics.



USE OF THE TERM PROBIOTIC IN EUROPE

- REFERENCE TO NUTRITIONAL/PHYSIOLOGICAL EFFECTS
- USE OF THE TERM "PROBIOTIC" AS A CATEGORY

Two main approaches are used:

- The wording "Contains probiotics" can be used if specific conditions are fulfilled (Close to the "contain" approach of Reg (EC) N. 1924/2006, Art 5)
- Use of the term probiotic on the label as the name of a category

- **Bulgaria** (on a *case by case* base)
- **Czech** (National Recommendation)
- **Denmark** (National rule of May 2021 for food supplements)
- **Greece** (National rule of May 2021 for food supplements; market practice for food)
- **Italy** (National Guidelines)
- **Malta**
- **Poland**
- **The Netherlands** (Nutrition and Health Claims Handbook of NVWA of March 2021)
- **Spain** (National Q&A of October 2020 for food and food supplements)

USE OF THE TERM "PROBIOTIC" AS A NON-SPECIFIC HEALTH CLAIM THAT CAN BE USED WITH THE AUTHORISED HEALTH CLAIM

- Some European Countries issued National Q&A indicating that the term probiotic can be used with an authorised health claim(*). (Reg (EC) N. 1924/2006, Article 10.3 applies)
- Opportunities for dialogue with some MSs Authorities for **setting criteria to qualify the probiotic category** with conditions of use for probiotic foods and food supplements

National Q&A using the reference to the only approved health claim :

- **France, Spain, United Kingdom**

In practice, the reference is also used in the following countries:

- **Belgium, the Netherlands, Portugal.**

(*) the only authorised health claim is "live cultures of yoghurt improve lactose digestion".

COUNTRIES FOLLOWING THE EC INTERPRETATION OF THE USE OF THE TERM AS HEALTH CLAIM ONLY.

THE USE OF THE TERM "PROBIOTIC" IS THEREFORE NOT ALLOWED

- European Countries following the EC Guidance of 2007 which provides information on how to implement the NHCR (not legally binding but still an EC reference)
- Opportunities for dialogue with some MSs Authorities for **setting criteria to qualify the probiotic category**, with conditions of use for probiotic foods and food supplements

- **Germany** (but despite the official position, the term is used on the label of supplements with a specific/authorised health claim e.g vit. D)
- Not used in **Latvia, Lithuania, Slovakia, Slovenia, Sweden, Ireland.**

NUTRITIONAL/PHYSIOLOGICAL EFFECTS

(Close to the “contain” approach of Reg (EC) N. 1924/2006, Art 5)



BULGARIA



CZECH REPUBLIC

Manual for Food Business Operators for food labelling according to EU regulations published on 2018:

http://eagri.cz/public/web/file/593400/Pri_rucka_k_oznacovani_podle_predpisu_EU_2018.pdf



ITALY

The Guidelines of the Ministry of Health are neither a health claim or a nutrition claim, but it can be considered as a factual statement. Italian Guidelines on probiotics and prebiotics revised in March 2018

English version:

http://www.salute.gov.it/imgs/C_17_publicazioni_1016_ulterioriallegati_ulterioreallegato_0_alleg.pdf

OTHER COUNTRIES USING THE TERM



GREECE

National Medicines Agency notification on May 2021: the term 'Probiotics' is accepted for food supplements only for the nutritional table, with the contained microorganisms (qualitative and quantitative). [Εθνικός Οργανισμός Φαρμάκων - Ανακοινώσεις για λοιπά προϊόντα \(eof.gr\)](https://www.eof.gr/medias/Default3.aspx?lang=en)



POLAND



MALTA

USE OF THE TERM PROBIOTIC ON THE LABEL AS A CATEGORY

USE OF THE TERM PROBIOTIC ON THE LABEL NATIONAL Q&A

THE NETHERLANDS

The Nutrition and Health Claims Handbook of NVWA published on March 2021 indicates that the term “probiotics” can be used on food and on food supplements on the label and in mandatory information to identify the categories of micronutrients or substances that characterize the product (see on page 35, and footnote 2).

<https://www.nvwa.nl/documenten/consument/eten-dinken-roken/etikettering/publicaties/handboek-voedings--en-gezondheidsclaims>

This confirms the indication of the 2018 Guidance of the self-regulatory body KOAG/KAG on NHCR



DENMARK

National rule published in May 2021 stating that the term probiotic can be used on the label of the products as a mandatory category term for food supplements.

<https://www.foedevarestyrelsen.dk/Foedevarer/Kosttilskud/Sider/Kosttilskud.aspx>



SPAIN

The Spanish Q&A refers to the Mutual Recognition Principle (MRP *), and mentions infant formulae and follow-on formulae, food supplements marketed in Spain.

The term probiotic can be used also on the food and food supplements produced in Spain.

http://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/Probioticos_alimentos.pdf

English version:

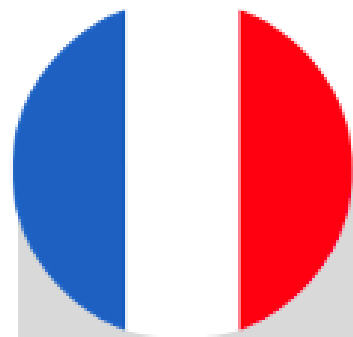
<https://www.ipaeurope.org/wp-content/uploads/2020/11/202010-QA-Spain-Engl.pdf>

(*) MRP stating that, in absence of EU harmonisation, the products legally marketed in others EU Countries can circulate on the European Market

USE OF THE TERM "PROBIOTIC" AS A NON-SPECIFIC HEALTH CLAIM AND WITH THE AUTHORISED HEALTH CLAIM

(REG (EC) N.1924/2006, ARTICLE 10.3)

NATIONAL Q&A USING THE REFERENCE TO THE ONLY AUTHORISED HEALTH CLAIM



FRANCE

DGCCRF Q&A (end of April 2020),
Q25:

<https://www.economie.gouv.fr/dgccrf/Consommation/Etiquetage-des-produits/Allegations-nutritionnelles-et-de-sante>



SPAIN

The Spanish Q&A refers in the text to the only authorized health claim:
http://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/Probioticos_alimentos.pdf

English version

<https://www.ipaeurope.org/wp-content/uploads/2020/11/202010-QA-Spain-Engl.pdf>



UNITED KINGDOM

UK claim guidance still applies:

<https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods>

(Updated on May 2013) Q7. "probiotic and prebiotic fiber" refer to a function in the body and are therefore defined as health claims and will need to be authorized via Article 13.

'Probiotic' could at the very least be considered a general, non-specific health claim (as referred to in Article 10(3) of the Regulation) and so will, in due course, have to be accompanied by a specific authorized health claim.

COUNTRIES FOLLOWING THE EC INTERPRETATION OF THE USE OF THE TERM AS HEALTH CLAIM ONLY

THE USE OF THE TERM PROBIOTIC IS THEREFORE NOT ALLOWED



GERMANY

Despite the official position, GE authorities receive the notifications of labels for supplements mentioning e.g “probiotics and vit D” on the label; these products are on the German market.



SWEDEN

The NHCR Guidance from the Swedish Food agency website

<https://kontrollwiki.livsmedelsverket.se/artikel/473/narings-och-halsopastaenden-begrepp>



LATVIA



LITHUANIA



SLOVAKIA



IRELAND

IRL Q&A the name of the bacteria can be indicated in the list of ingredients but the use of the term probiotic is not allowed.

Food safety Authority of Ireland

https://www.fsai.ie/science_and_health/nutrition_and_health_claims.html

For information on the use of the term 'probiotic' : FAQ on Probiotic Health Claims



SLOVENIA

In November 2018, the Slovenian authorities (UVHVVR) issued a statement that the word "probiotic" is a health claim.

A COMMON EU SOLUTION IS NEEDED FOR LABELLING OF FOODS WITH THE TERM “PROBIOTICS”

- Europe does not have a clear or harmonized regulatory framework on probiotics, and therefore decisions may be made on them by individual Member States.
- The current lack of harmonisation may go against the Mutual Recognition Principle, laid down in the Treaty on European Union
- Given that adjacent markets already using the term “probiotic”, the position it held until now by the EC may be detrimental for the industry, market and consumers.
- A more flexible approach does not imply the authorization of a health claim for probiotics



A COMMON EU SOLUTION IS NEEDED FOR LABELLING OF FOODS WITH THE TERM “PROBIOTICS”



It is time for the EC to re-open a discussion and initiate a dialogue to set rules on the use of the word “probiotic” in Europe when the information is merely factual and does not describe a specific effect.



In this context IPA Europe welcomes the initiative of the Danish Authorities to reach out to European partners, in order to open the discussion for a more harmonised approach for probiotic food and food supplements in Europe.

THE IPA EUROPE KEY MESSAGES FOR A BETTER EUROPEAN FRAMEWORK FOR PROBIOTIC FOOD

- 1 Implement precise criteria and conditions to frame the term 'probiotic'
- 2 A graded approach where, depending on the characteristic of the product, the appropriate rule applies within the EU regulatory framework
- 3 A clear labelling environment for probiotics across Europe
- 4 A harmonized and holistic approach which is in line with the EC Farm to Fork Strategy objectives



A HOLISTIC APPROACH TO PROBIOTICS IN THE EU FOR INFORMED CONSUMERS AND A SUSTAINABLE FOOD INDUSTRY

- PROBIOTIC KEY FACTS AND FIGURES
- OPENING WORDS BY THE PRESIDENT, ESSEN LAULUND
- ENGAGING TO DEVELOP BETTER INFORMATION FOR THE USE OF THE TERM 'PROBIOTIC'
- LOOKING AT THE REQUIREMENTS FOR A CATEGORY OF PROBIOTIC FOOD AND FOOD SUPPLEMENTS
- IPA EUROPE & VOLUNTARY ENGAGEMENT

**Thank you the IPA Europe Regulatory Committee
for the contribution to this presentation.**

THANK YOU FOR YOUR ATTENTION

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