

ABOUT THE USE OF THE TERM PROBIOTIC IN EUROPE

Overview and regulatory changes – Rosanna Pecere



Overview and Regulatory Context

EU Regulatory context



- **Reg(EC) No 1924/2006 (NHCR)** on nutrition and health claims made on foods indicates 3 types of claims:
- **A general, non-specific health claim** that can be made if accompanied by a specific health claim (par. 3 art 10 of Regulation (EC) 1924/2006)
- **Nutrition claims**, if complying with the claim "contains (name of nutrient)" listed in the Regulation (EC) No 1924/2006
- **Food supplements**, the term probiotic is used as a category name to characterize the substances used in their composition, as by Article 6(3). (a) of Directive 2002/46/EC
- **Health claim**, when a with a specific health effect is claimed (subject to EFSA evaluation process)
- **Codex work**: proposal of a International probiotic guidelines (new work); will be under discussion in March 2023

Implementation and market context



- EC guidance on the implementation of Regulation 1924/2006:** it states that "contains probiotics/prebiotics" should be considered a health claim 'per se' (this guidance is non binding but still considered by the EC as the unique reference to probiotic).
- **Member States adopt several national interpretations:** the term 'probiotic' is accepted in some countries but not in others.
 - **Italy and France** have guidelines with some condition of use; the wording 'probiotics and the balance of the intestinal flora' is allowed.
 - Based on the **principle of 'mutual recognition'**, the product legally produced in a country allowing the use of the term probiotic is in free circulation in the EU (as indicated in the **Spanish** Guidelines)
 - **On the EFSA side:** they never indicated that 'probiotic' is a health claim/up to now they rejected all the request of health claim for probiotic strains

IPAEU/EDA /Danish initiatives



- **January 2022:** Denmark sent a 'call for action' letter to (supporting) member states
- **April-June 2022:** Denmark, Italy held bilateral meeting with the European Commission on several issues, including the probiotic topic
- **15th June 2022:** letter to the EU Commissioner S. Kyriakides from the Danish Minister of Agriculture on behalf of Bulgaria, Greece, Italy, Poland, Slovenia and Sweden.
- **June 2022:** Joint position IPAEU/EDA (European Dairy association) supporting the Danish initiative followed by a note with legal arguments
- **July-December 2023: 3 Responses from the European Commission/No flexibility/no openness to dialogue around the probiotic category**
- **January 2023:** France also joined the countries allowing the use of the term 'probiotic'.

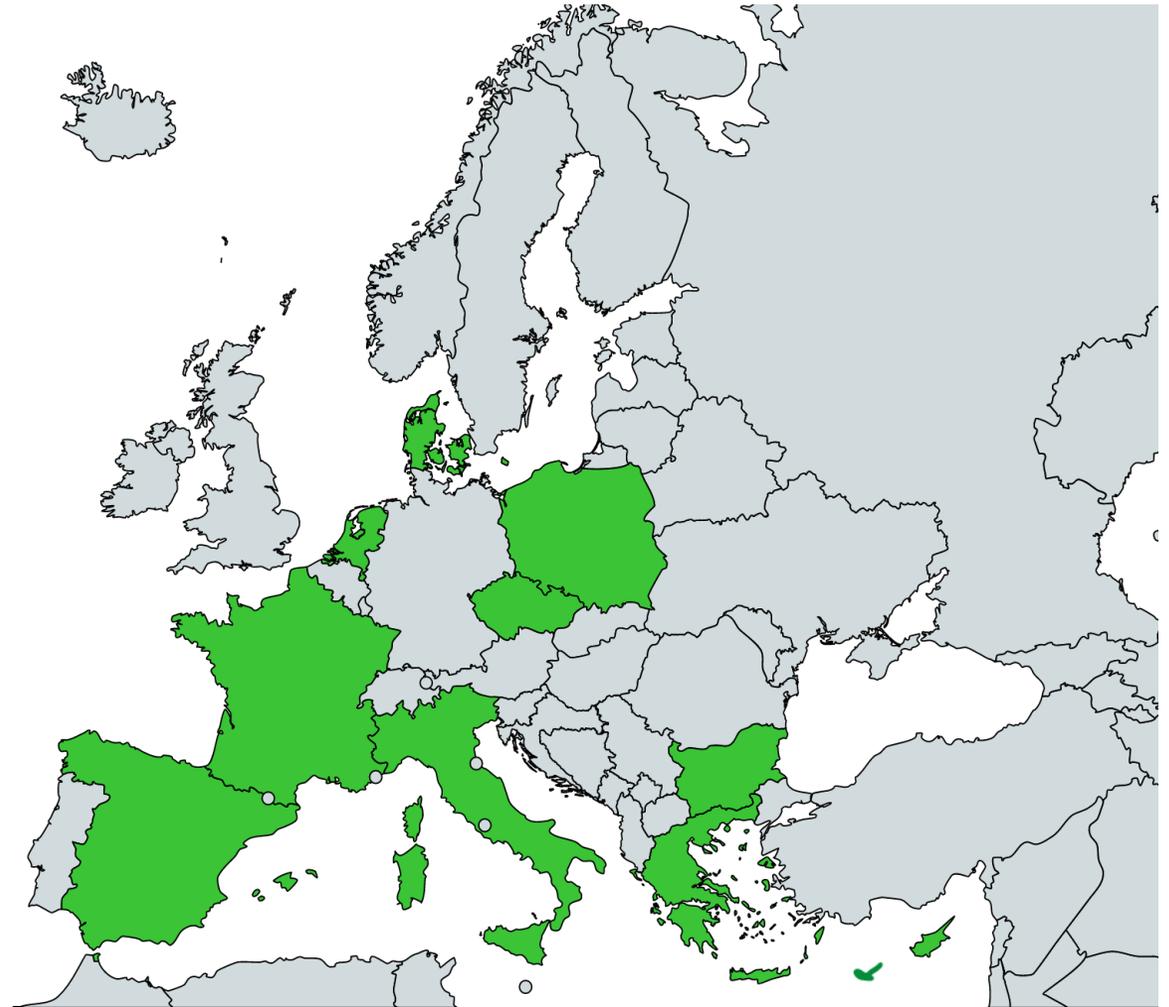
Regulatory assessment about the use of the term probiotic in foods, beverages and dietary supplements

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

- **WITH THE REFERENCE TO NUTRITIONAL /PHYSIOLOGICAL EFFECTS AND/OR**
- **AS THE NAME OF THE CATEGORY**

Bulgaria, Czech Republic, Cyprus, Denmark, Greece, Italy, Malta, The Netherlands, Poland, Spain, France.

Other European countries are considering to develop a National/European approach that can help to better identify food containing probiotic microorganisms (Romania, Sweden, Slovenia, United kingdom)



CONSUMER SURVEY –COMPLETE REPORT

30 January 2023

<https://www.ipaeurope.org/wp-content/uploads/2023/01/202211Survey-report-1.pdf>

Objectives:

- To assess people's understanding of the offer of probiotics currently on the market
- Their use of probiotic foods and food supplements in everyday life.
- What consumers would like to know more about, when it comes to probiotics.

Methodology: Survey conducted on-line by 3 GEM in 8 European countries (**Italy, Denmark, the Netherlands, Spain, Poland, Belgium, Germany and Sweden**), 8.000 interviews, 1. 000 consumers from 18 years old and + by country, representative of the general population, from several geographical areas per country ensuring a fair geographical distribution. **Gender:** about 50% women and 50% men for each country

WHO ARE THE PROBIOTICS

CONSUMERS?

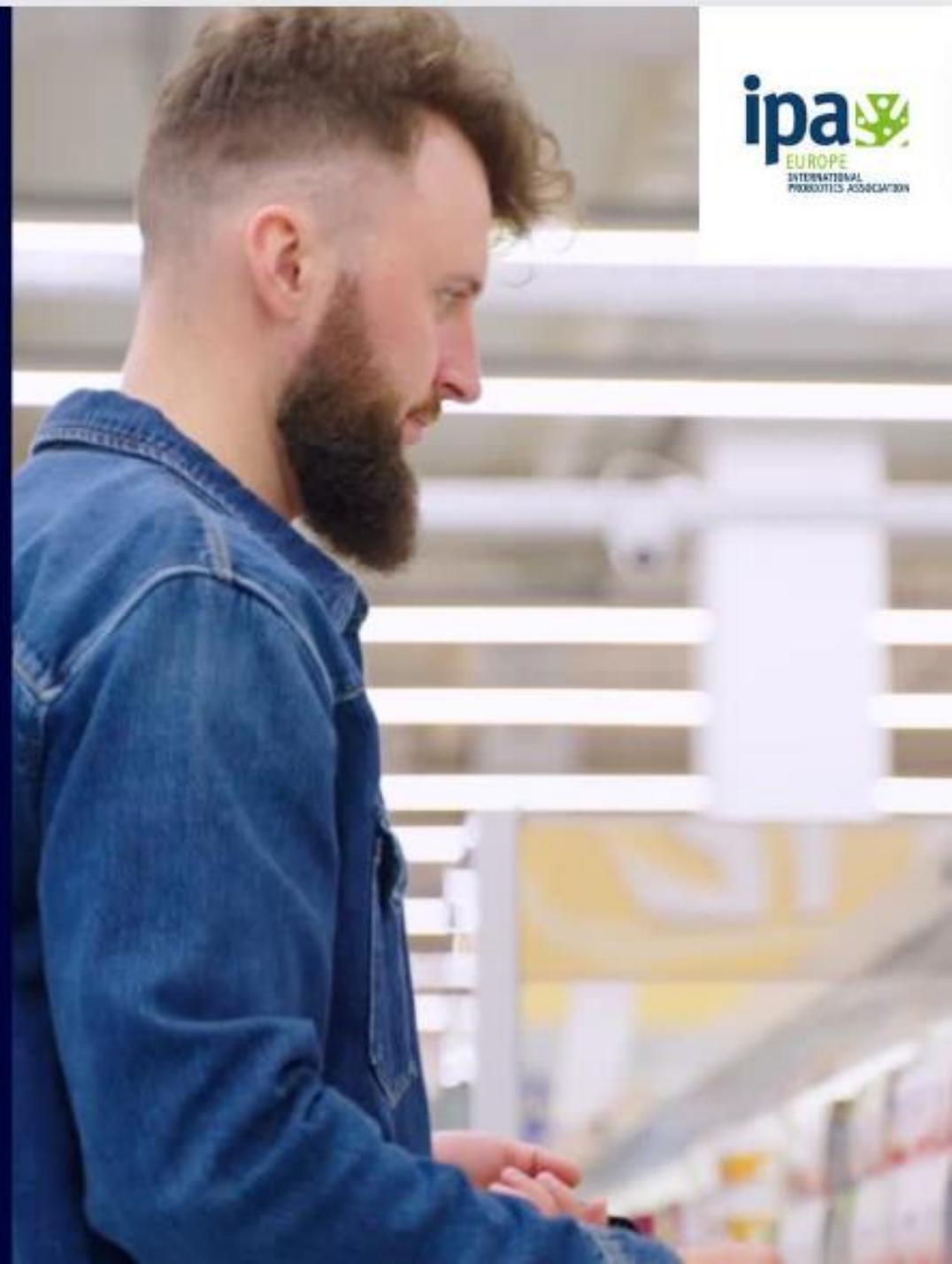


25-44



DO YOU KNOW WHAT PROBIOTICS ARE?

A consumer survey in 8 countries
shows what consumers know and what
they would like to know more about



DO YOU THINK YOU
ARE INFORMED ABOUT
PROBIOTICS IN
PRODUCTS?



NO

 69%

 62%

 51%

 60%

 59%

 57%

 54%

 45%



**WOULD YOU
LIKE TO SEE
THE TERM
PROBIOTIC ON
THE PRODUCTS?**

YES



90%



90%



83%



82%



79%



76%



76%



56%

OUTCOME

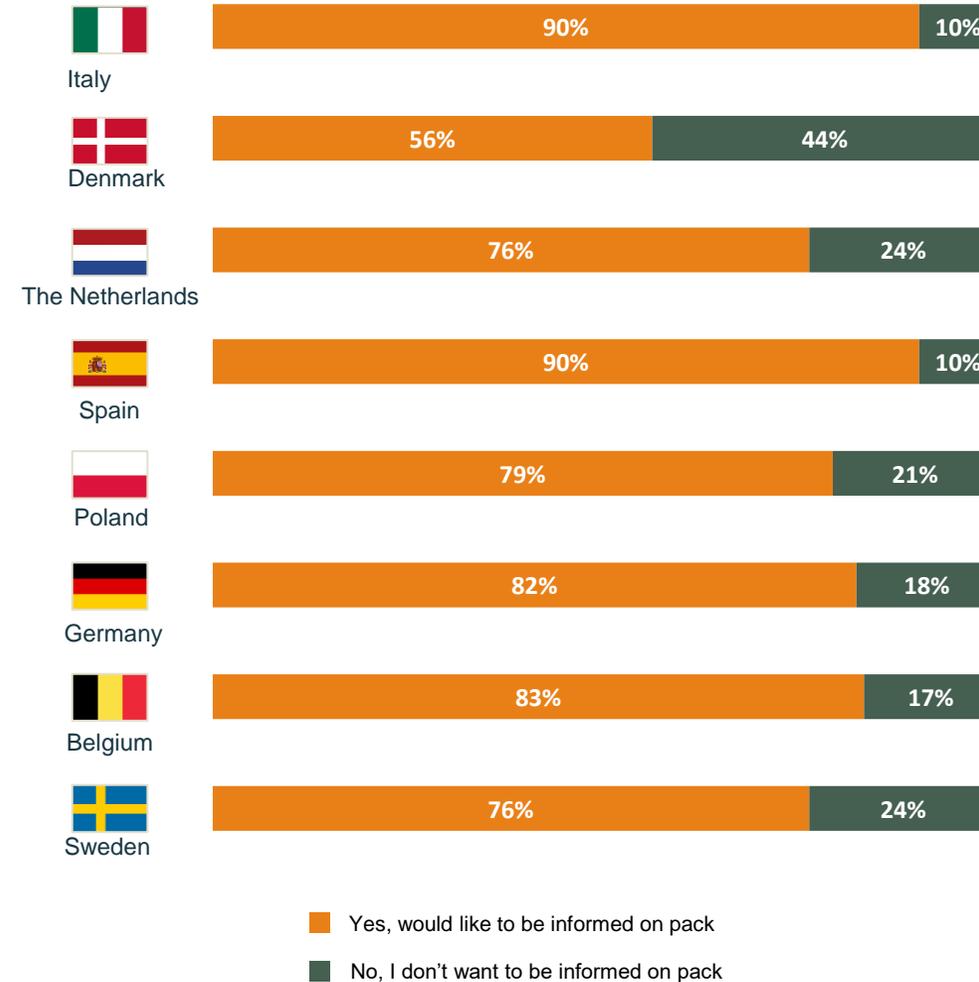
“79% of the consumers would like to know more about probiotics through, for example, food labels”

In all tested markets, consumers indicate they would like to see the term ‘probiotic’ indicated on the packaging.

The markets that feel strongest about the appearance on packaging are Italy and Spain.

► **When food and supplements with probiotics microorganisms are available in shops, would you like to see the term ‘probiotic’ indicated on the product? (e.g. in the ingredient list, on the packaging or somewhere else on the label)**

(n=1000 per country)





An unsettling national fragmentation

National pressure from member states started some years ago with the adoption of various national guidelines to allow labelling containing the term probiotics

Many Member States, including Netherlands, Poland, Spain, Italy, France, Czech Republic, Denmark, Greece, have chosen to **no longer follow the European** position indicating probiotic as health claim only

Some decided that “contains probiotics” can be used with an **authorized health claim** and other allow it on the label as the **name** of the product

The need for political pressure

- No clarity about the legal status
- No guarantee for the industry
- Need of legal endorsement in Europe

In the context of the REFIT, an expert group coordinated by the Secretary General of the EC issued a report recommending to **improve the harmonization** of the use of the term 'probiotics' to provide clarity for industry and consumers

The report also stated **the non harmonized** approach to this issue in the EU

- ***This type of pressure, combined with the national initiatives, could become enough to launch a review of the Regulation***



Fit 4Future Platform delivered 10 opinions in December 2022 Expert group

- ❑ Probiotic are included in the wider context of “Biosolutions”.
- ❑ The Platform delivers opinions to the European Commission on simplification and unnecessary cost reduction - good political value of these opinions

Opinion on ‘biosolutions’:

https://commission.europa.eu/publications/adopted-opinions-2022_en

☞ The opinion endorsed 10 specific recommendations which the Commission should take notice for simplification and better regulation, of which:

- **Suggestion 8:** Improve the harmonization of the use of the term ‘probiotics’ in the context of the health claims across the EU Member States to provide clarity for industry and consumers
- **Suggestion 9:** Develop industry guideline for food cultures as food ingredients
- **IPAEU is included in the references of the opinion**

A COMMON EUROPEAN APPROACH IS NEEDED

IPAEUROPE VIRTUAL POLICY CONFERENCE

EVENT PROGRAMME

VIRTUAL CONFERENCE

EURACTIV
EVENTS

How can better regulation strengthen the use of probiotics and health in the EU?

DATE

24th April 2023

TIME

14:00 – 15:15 CET

The use of probiotics in the EU has been increasing steadily in recent years. The World Health Organization defines probiotics as “live microorganisms which when administered in adequate amounts confer a health benefit on the host”.

According to the European Commission’s High Expert Group ‘Fit for Future Platform’, the term ‘probiotic’ is considered a health claim, because this term is deemed to include an implied health benefit. Therefore, the word ‘probiotics’ can only be used in combination with an approved authorised specific health claim. This has been contested by some stakeholders as it is broadly used all over the world.

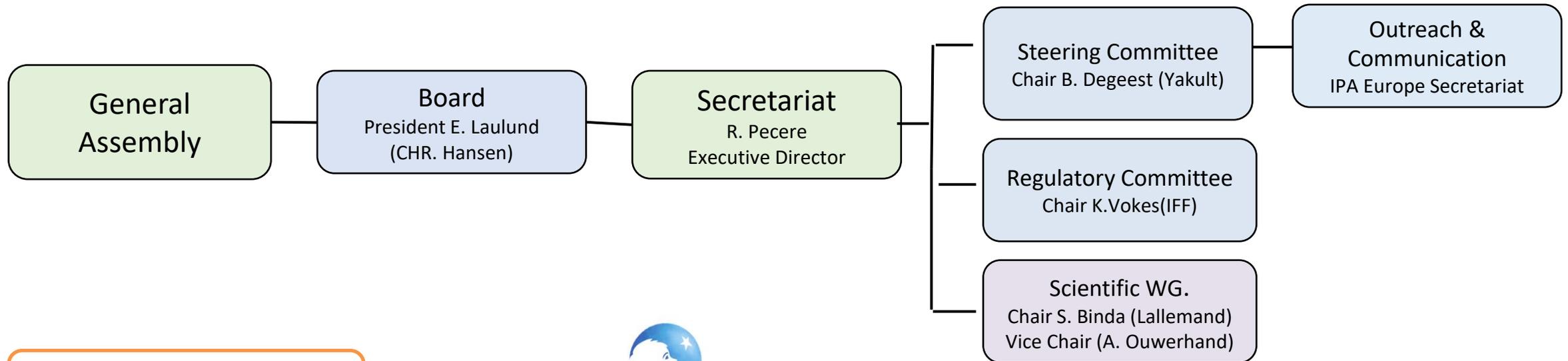
In recent years other interpretations have been developed by EU Member States, and since 2018, the situation has been changing. Some EU countries issued national guidelines allowing the use of the term, while others are now more flexible on the topic. This increased use of the term ‘probiotic’ since 2018 is reflected by the positive evolution of the probiotics market during the period 2018-2021.

Today about a third of the Member States allow the labelling of food products as ‘probiotics’. Some Member States consider that ‘probiotics’ encompass a category of nutrients to be mandatory labelled on food

INVITED SPEAKERS



IPA EU Operational structure



Steering & Regulatory Committee members



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CAN A MUTUAL SOLUTION
BE FOUND FOR
PROBIOTICS IN EUROPE?
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