

A Nutrition Claim for Probiotics? Food for thought

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Yalacta – An Introduction

- SME created in 1931
- Lactic bacteria used by consumers to manufacture homemade fermented products, yoghurts, kefir, cheese....
- Yalacta started manufacturing food supplements in 1980s
- Innovative probiotic launched in 2000
- 50% of this FS sold in France, 25% in EU and 25% outside EU
- Regulation (EC) No 1924/2006 on nutrition and health claims has discouraged innovation in the probiotic area (amongst others) and impeded business development

European Food Supplement (FS) Market

- 2000 companies
- 80% SMEs
- 600,000 jobs linked to the sector
- EU FS global market : Turnover: €13 Billion
- EU Probiotic market : FS + General Food : 5 € Billion

Probiotics – Member State Contrast

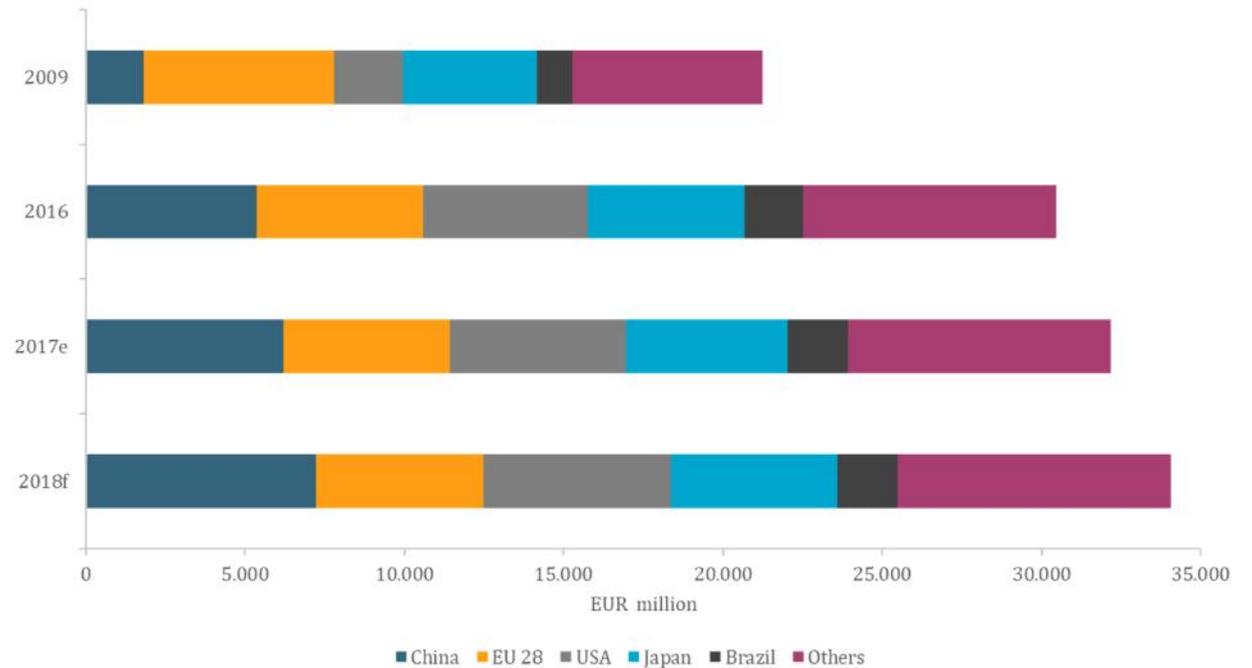
4 European countries authorize the use of the term « probiotic »:
Italy, Denmark, Czech Republic and Nederland.

KEY FACTS	ITALY	FRANCE
Population (millions)	61	67
Nutritional Claim (“Probiotic”)	Yes	No
FS Market Size (Billions €)	2.88	1.6
Probiotics FS Market Size (Billions €)	0.361	0.15

EU was the top market in 2009,

- As a consequence of the lack of clarity, EU 28 It ranks now third in probiotic yoghurt and supplement sales
- (Source: IPA Europe on Euromonitor data)

Top markets for probiotic yoghurt and supplements globally, 2009-2018



Negative Impact on the EU market and on consumers: **decline for the probiotic foods sector, while the market is growing outside Europe**

Euromonitor International estimates lost of retail value sales for the pro/prebiotic drinking yoghurt market of about EUR 500 million since 2012 in Austria, Belgium, France, Germany, Netherlands and the UK.

(Source: IPA Europe on Euromonitor Data)

Research & Development

- The Food supplements sector was one of the most innovative in the EU until 2009
- Current situation is that EFSA applies medical criteria to assesses health effects of food
- The approach of requiring that a trial shows that a substance delivers the same effect, for everyone, actually goes beyond medical review standards and is practically impossible.
- Since 2006, there has not been a single positive opinion from EFSA in relation to probiotics

Research & Development

Investment Required

- To have a 'chance' of health claim at least 2 clinical trials. 2 RCT and 1 study on the mechanism of action. Each trial costs at least € 0.5 million so minimum investment of €1.5 million
- This is clearly not affordable for SMEs – or larger companies – and entails a huge financial risk in an effort to satisfy requirements that are not even applied to medicines

For those who invest.....

- So far from 121 Article 13.5 applications submitted at an estimated cost of €60 million. 6 of those applications were successful.
- Would you invest with those odds?.....

Research & Development

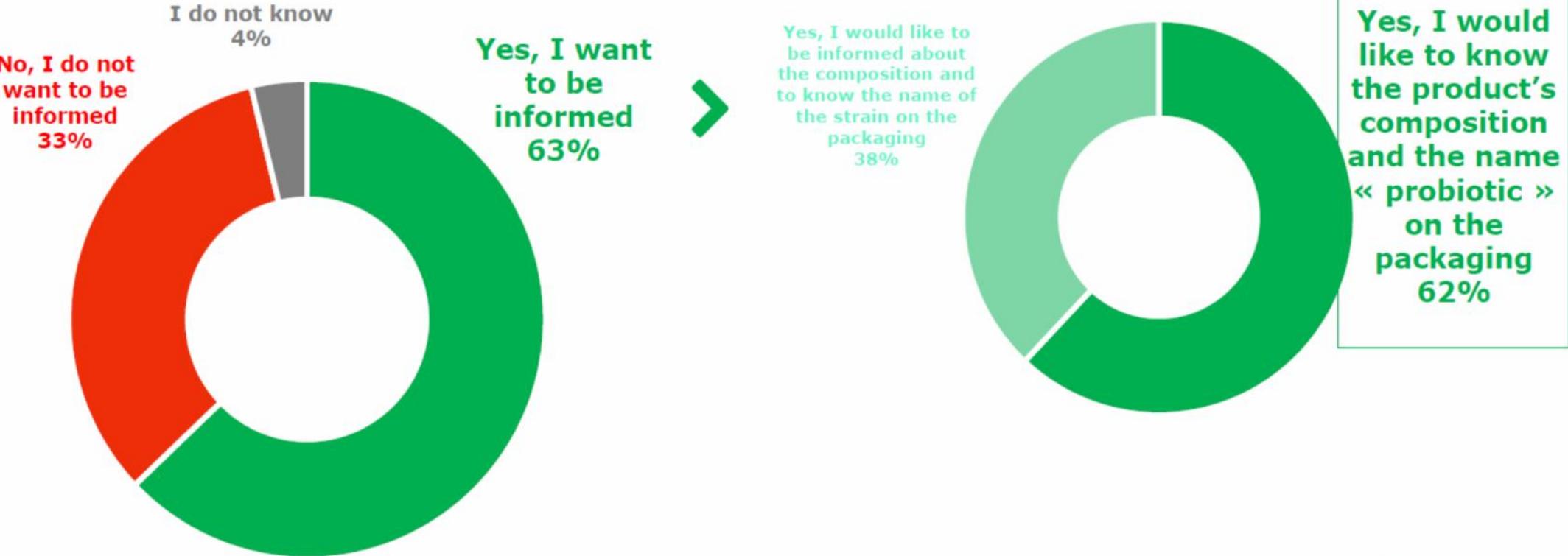
- Frequent defence of health claims regulation is that Europe has the 'highest standard'
- If so, why is this approach not being copied internationally?
- Reality is that innovation in EU is being stifled while internationally other countries are taking the lead.
- Published academic research is a good indicator of research trends
- If you consult PubMed, last 100 publications on probiotics, only 3 came from Europe – all Italian
- Research is now being driven in US, Canada, Gulf, Japan, China, Korea, South America, Russia

Consumers & Probiotics

- Key goal of regulation was to provide clear information to consumer and avoid them being misled
- What percentage of consumers will understand the following terms?
 - *Lactobacillus johnsonii*
 - *Lactobacillus rhamnosus*
 - *Saccharomyces boulardii* / *Saccharomyces cerevisiae*
- What percentage of consumer will understand the following term?
 - “Probiotic”
- Consumers remain confused and, even worse than that, they no longer have access to information on probiotics that would allow them to make informed choices.
- “Probiotic” labelling is proliferating to non-food products such as cleaning materials.

Probiotics : requested informations on a food product

Question: « Would you like to be clearly informed that a product contains probiotics and how? (One possible answer - Total of 1001 answers)



Nutrition Claim

- At present, the Commission responds to any queries for a solution to probiotics by referring to 2007 Guidance which indicates that probiotic is a health claim
- Using a document, with no legal effect that is ten years old to justify a policy approach that clearly does not work, is not acceptable
- The Commission created the problem in the way it drafted the guidance in 2007 and can fix the problem by changing the guidance.
- There is no impediment to the EC proposing a nutrition claim for probiotics because probiotics have an impact on microbiota for production of vitamins, short-chain fatty acids with nutritional impact on the body.
- It is merely a question of having a willingness to address the problem

Practical Solutions

- **Health Claims:** Genuine innovation for health claims will require adapting Article 13.5 Criteria to realistic requirements applied globally in some Member States prior to harmonisation – and adopt a grade evidence approach.
- **Nutrition Claim:** Allowing a nutrition claims for probiotic for specific widely used bacteria strains is a simple common sense approach that the Commission can take. Appropriate conditions of use can be applied to prevent misuse of the term.
- Industry is asking for the nutrition claim “**Contains probiotics**”.

Practical Solutions

- Nutrition Claim can be supported by appropriate EC or industry guidance providing criteria for:
 - Safety
 - Stability/survival
 - Concentration
- Various guidance documents already exist that can be used as a basis:
 - International Probiotic Association
 - Guidelines on probiotics and prebiotics – *Ministero della Salute (IT)* – May 2013
 - USA: Best Practice Guidance for Probiotics – Council for Responsible Nutrition
 - Santé Canada

Practical Solutions

- **The industry, represented by EHPM, IPA and EDA still support the NHCR in its objectives of achieving harmonisation, clarity and consumer protection, but there needs to be recognition for the ‘probiotic’ category as such. This requires acceptance of the distinction between what probiotics ‘are’ – the category - and what they ‘do’ – the individual health claims.**
- **Acceptance of the probiotic category as a nutrition claim would resolve the current impasse for probiotics in the EU, whilst leaving the door open for individual probiotic health claims.** It should be clearly emphasised that there are no safety concerns regarding the inclusion of recognised probiotics in foods and FS.