

The Rise and Fall (and rise?) of Probiotics: The effects of Health Claim Regulations on probiotics in Europe.

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Contents

1. IPA Europe
2. In Europe, where do we stand?
3. Probiotic Foods in the EU
4. The source of the problem: the 2007 interpretation
5. The proposed solution to the probiotic impasse
6. Ways forward

1. IPA Europe

- **IPA Europe** is the European Chapter of IPA, the *International Probiotics Association*; it was established in Brussels in 2015.
- **Mission:** IPA Europe, *the European voice for probiotics*, advocates for a well-defined status for probiotics in Europe that aims to properly inform the consumer and thus increase awareness of the benefits of probiotics.
- The **members of IPA Europe** are companies directly engaged in the manufacture of probiotic cultures or probiotic containing foods, supplements, nutritionals or therapeutic products: Chr. Hansen, Danone, DuPont, IPA, Lallemand, Lesaffre, Probi and Yakult. At global level, IPA counts some 60 members.



**THE
EUROPEAN
VOICE OF
PROBIOTICS**

ipaeurope.org

2. In Europe, in 2016, where do we stand?

A lot of customers worry when purchasing ALL N
shampoos, bath & shower gels that they won't get
LATHER because no chemicals are used
We have found a way to get a really good foam in
and still our products are 100% natural with the ad
of a PROBIOTIC!

WC Net BIOigiene Gel

WC Net BIOigiene Gel

Dall'incontro tra l'efficacia pulente di WC Net e la biotecnologia nasce WC NET BIOigiene, il primo pulitore liquido con agenti probiotici.

I probiotici, agenti 100% naturali, creando un biofilm, aiutano a proteggere il WC dall'insediamento dei batteri. Dopo la pulizia, l'azione di igiene e protezione dei probiotici continua per 7 giorni.

Istruzioni d'uso

Spruzzare abbondante prodotto per 20 minuti

Precauzioni d'uso

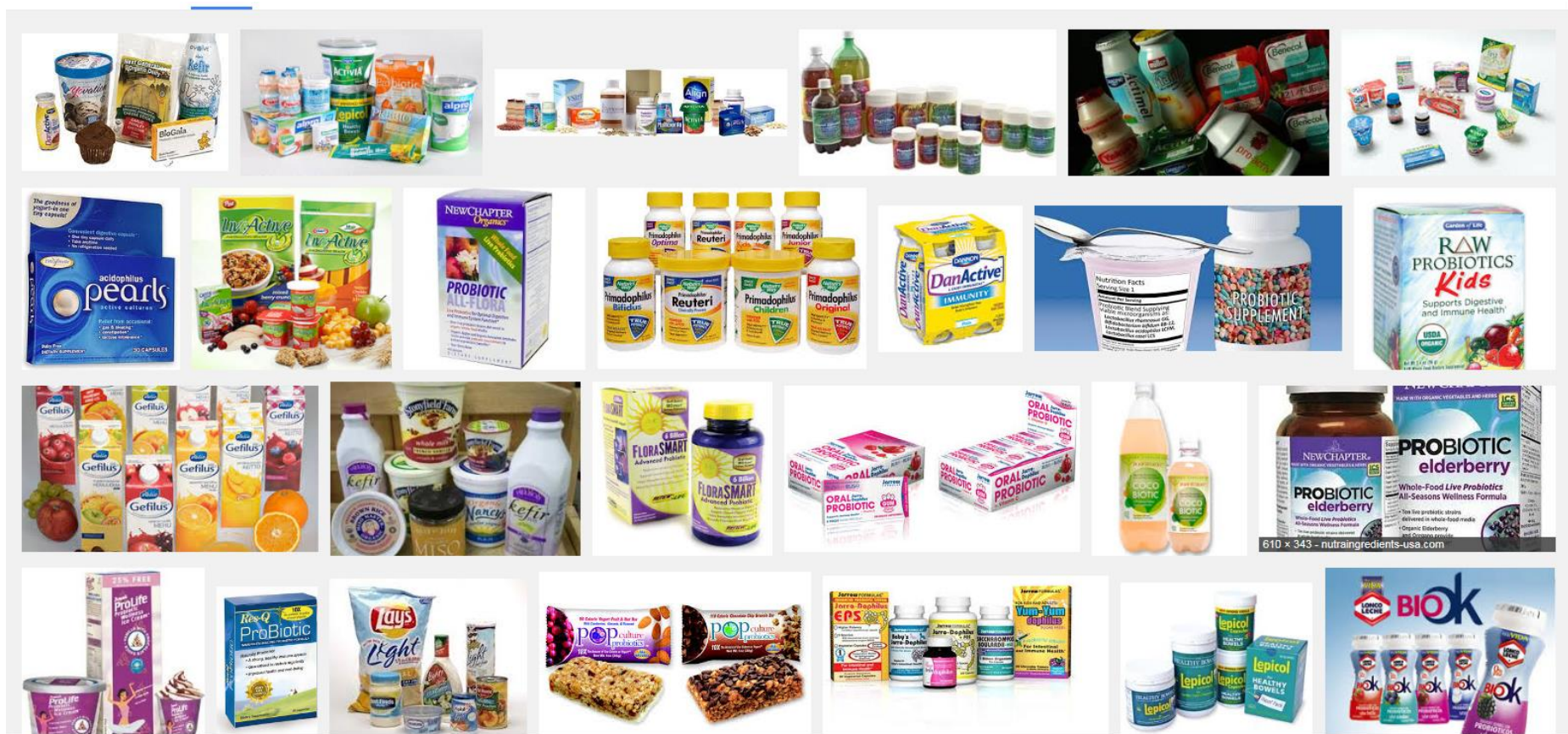
Non usare su marmo e superfici cromate.

asciugare il

metallo smaltato o



2. In Europe, where do we stand?



2. In Europe, where do we stand?

	Feed	Food	Pharma
Classification	Additive	Ingredient	Active Pharmaceutical Ingredient (API)
Health Claims	Yes - EFSA	No - EFSA	-
Guidelines - EU	Yes	No Only Italy	
Guidelines - WW		FAO/WHO	WGO
Use of the term "probiotic"	Yes	No	Yes

- In the EU, there is no EU-wide **legal framework defining** probiotic micro-organisms or the probiotic food category.
- There is no harmonised EU legal framework establishing the **conditions for a strain to be considered as probiotic** or a **positive list of individual strains / species** which have a probiotic status.
- By contrast, **probiotics in feed** benefit from a comprehensive status as zootechnical – or feed – additives, with a positive list of identified strains and clear *conditions of use*.

3. Probiotic Foods in the EU

- The FAO/WHO definition "**live microorganisms which when administered in adequate amounts confer a health benefit on the host**", that was agreed in 2001 at international level by the *Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria* is THE reference adopted by administrative and scientific bodies in several Member States.
- At *national level*, the only comprehensive guidelines for probiotics in food are the **Italian Guidelines on Probiotics**, revised in 2013, which govern the use of the claim *favorisce l'equilibrio della flora intestinale* (enhances the balance of gut flora) in food and food supplements containing probiotic microorganisms (bacteria and/or yeasts) traditionally used to balance gut flora, **provided certain conditions as to their characterization, identification, amount and safety are met**.

3. Probiotic Foods in the EU

- In the EU, Probiotic foods, mainly fermented milks and supplements, are submitted to the *General Food Law*.
- **Communication on the nutritional & health effects** of probiotics is subject to the *Nutrition & Health Claims Regulation 1924/2006 (NHCR)*:
 - ✓ This regulation is the legal framework used by food business operators when they want to **highlight the particular beneficial effects of their products - in relation to health and nutrition - on the product label or in its advertising**.
 - ✓ NHCR applies to **nutrition claims** (such as "low fat", "high fibre") and to **health claims** (such as "Vitamin D is needed for the normal growth and development of bone in children").

3. Probiotic Foods in the EU

- ✓ The objective of the NHCR is to ensure that **any claim** made on a food's labelling, presentation or advertising in the European Union is clear, accurate and **based on scientific evidence (EFSA)**.
 - ✓ This not only **protects consumers**, but also **promotes innovation and ensures fair competition**. The rules ensure the free circulation of foods bearing claims, as any food company may use the same claims on its products anywhere in the European Union.
- ☞ *In Europe, since the entry into force of the Claims Regulation, at the end of 2012, the probiotic food industry faces a double problem:*

3. Probiotic Foods in the EU

Scientific level - EFSA:
*no authorised health claim on
probiotics in food*

- In the EU, Probiotics is one of the categories of foods that have been the most negatively affected by the NHCR: of the more than 400 applications submitted to EFSA, **no probiotic claim has received a positive assessment.**

Political level (Member States & COM):
*the de facto ban of the use of the term
probiotic in food*

- The expression "*contains probiotics*" is interpreted by the European Commission and Member States as a **health claim**.
- Consequently, **use of the term "probiotic"** in the labelling and advertising of food products **is no longer permitted in the European Union...** and this, even though not one single health claim is made!

3. Probiotic in the EU: the 2007 interpretation

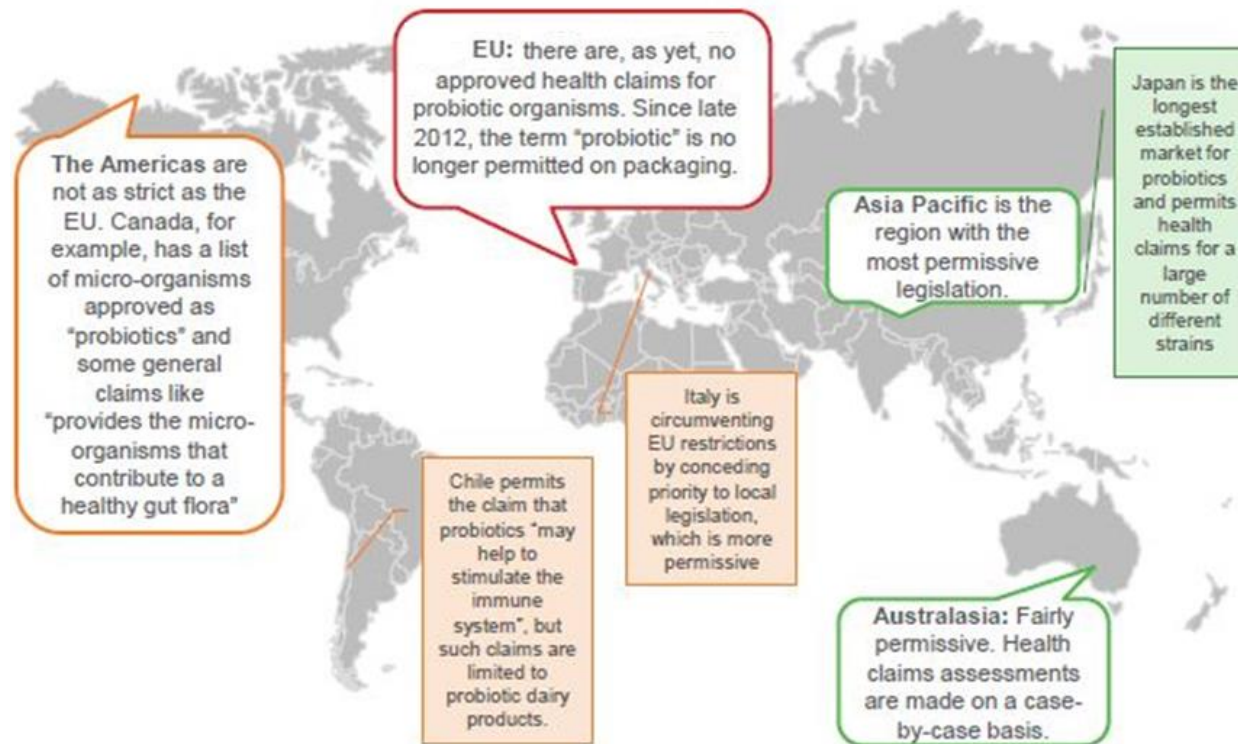
- *Guidance on the implementation of Regulation N° 1924/2006 on Nutrition and Health Claims made on Foods, dated 14 December 2007:* on the basis of the assumption that **the average European consumer perceives the term probiotic as *implying a health benefit***, the European Commission and the Member States interpreted the expression "contains probiotics" as a **health claim**.
- This means that, in principle, commercial use of the term "probiotic" for foods and supplements **would *require a health claim authorisation***.

3. Probiotic in the EU: the vicious circle

- ⇒ Yet, the term "probiotic" *per se* **cannot be authorised as a health claim** since it has been acknowledged by scientific experts and authorities - including EFSA - that probiotic effects are *strain specific*.
- ⇒ In addition, the expression "contains probiotics" **lacks any description of a bodily function**, which is a **requirement** for health claims.
- ☞ **As the term "probiotic" as such cannot be authorised as a health claim, the 2007 interpretation led to the current *de facto* ban of the term probiotic in the EU.**

4. Impact of the *de facto* ban

➤ Regulation



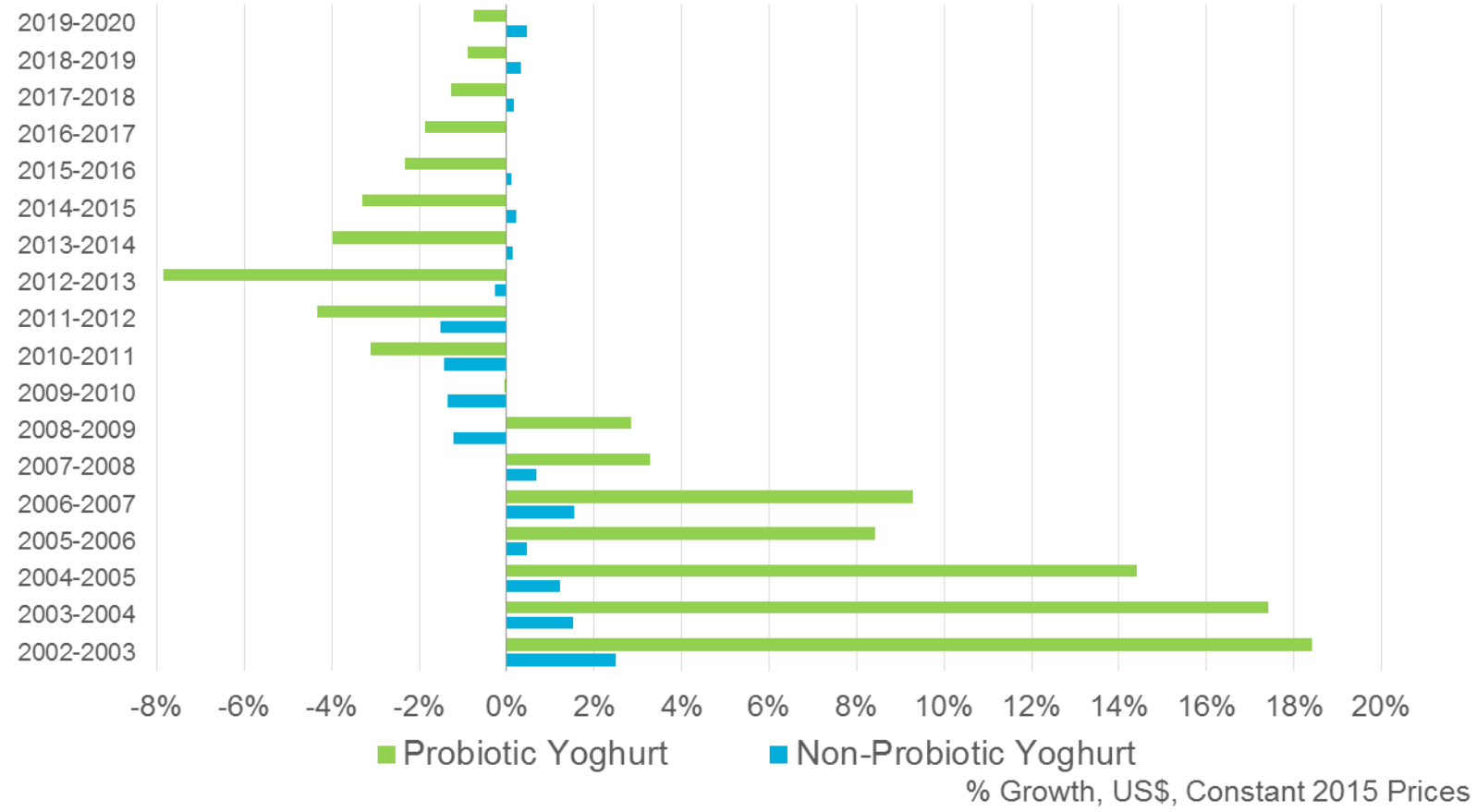
- The EU remains in an **isolated position** compared to other regions of the world, where public authorities consider probiotics as an *ad hoc* category of ingredients and acknowledge their particularities.

4. Impact of the *de facto* ban > Market

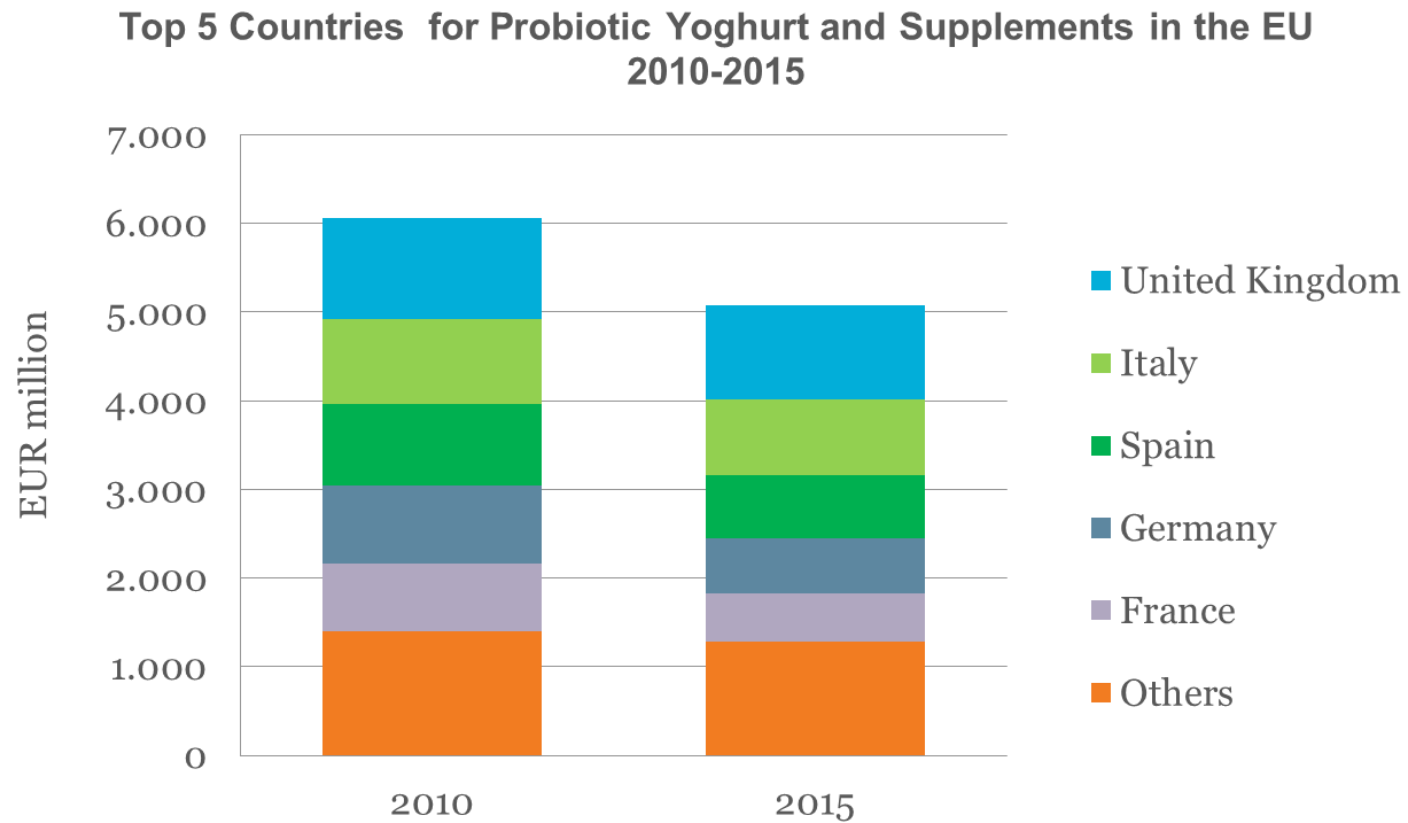
- After a decade of 5% annual growth for the *probiotic foods* sector, the decline is of about -8% in 2013 in EU while the market is growing outside of Europe: 7% growth in USA, 7% Latin America, 4% Middle East, 11% Asia (Euromonitor).
- **Probiotic Yoghurt EU:** 9% decline expected between 2013-2018 meaning -2% annual growth in the EU versus 34% Global growth (Euromonitor).
- According to Euromonitor, the "probiotic health claims ban" to cost up to **EUR 1.5 billion in lost revenue by 2020.**
- Euromonitor estimates that the ban has already cost the pro/prebiotic drinking yoghurt market over **EUR 500 million** in lost retail value sales since 2012 in Austria, Belgium, France, Germany, Netherlands and the UK.
- Between 2015 and 2020 this market stands to lose a further **EUR 1 billion** in retail value as a direct result of the restrictive regulatory environment.

Probiotics – the driving force of yoghurt in the EU

EU 20: Probiotic versus Non-Probiotic Yoghurt Annual Growth 2002-2020

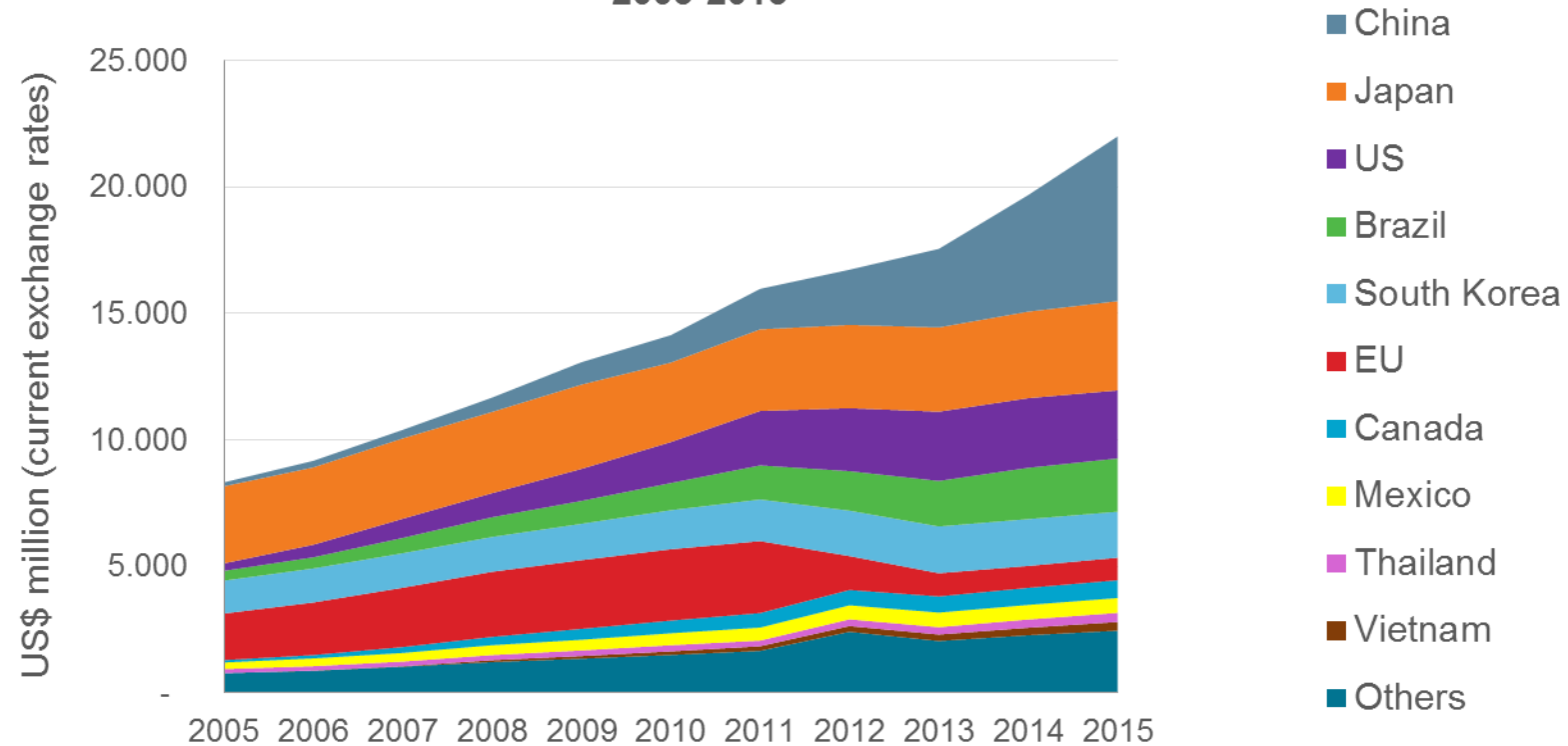


Top 5 countries in the EU



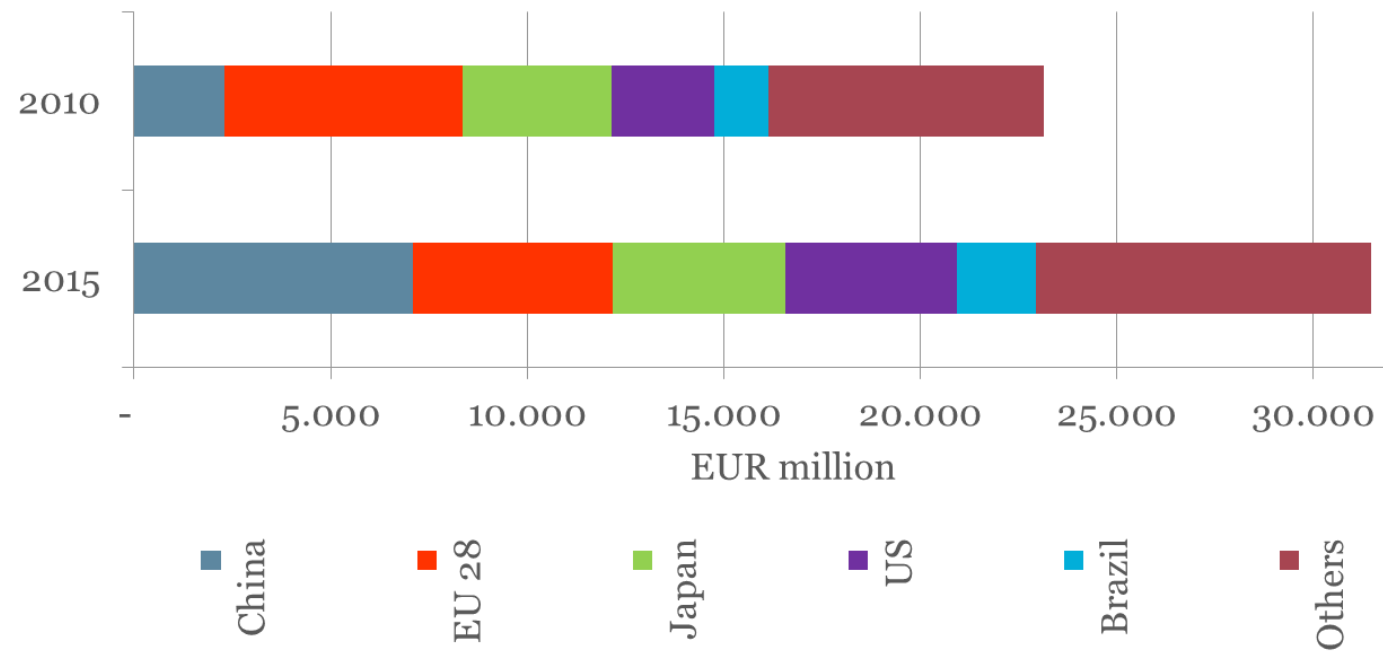
Digestive wellness platform erodes in the EU and explodes in China

Digestive Health Positioned Pro/Pre Biotic Yoghurt, Leading Markets 2005-2015



Top markets for probiotics globally

Top Markets for Probiotic Yoghurt and Supplements Globally 2010-2015

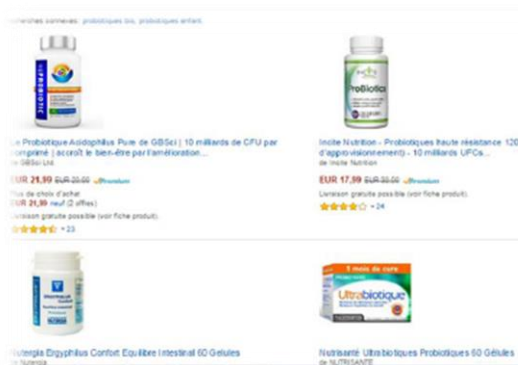


4. Impact of the *de facto* ban

➤ Consumers



- The ban compromises the right of the consumer to be properly informed about the probiotic content of any food or food supplement.
- *Furthermore this restriction has created confusion around the use of the term "probiotics" which is still allowed to be used for non-food products without any pre-requisite or minimum scientific substantiation.*



4. Impact of the *de facto* ban ➤ R&D in the EU



Research on probiotics in EU

Top 12 nations – papers retrieved by using « probiotics» and «humans» keywords

TOP COUNTRIES 2008		TOP COUNTRIES 2010		TOP COUNTRIES 2012		TOP COUNTRIES 2014	
USA	162	USA	767	USA	1243	USA	1243
Italy	88	Italy	383	Italy	635	Italy	635
Finland	68	United Kingdom	317	United Kingdom	465	United Kingdom	465
United Kingdom	61	Germany	275	Canada	371	Canada	371
Germany	58	France	236	Germany	370	Germany	370
France	56	Finland	224	France	332	France	332
Canada	39	Canada	220	Finland	298	Finland	298
Japan	38	Japan	195	Japan	284	Japan	284
Spain	37	Spain	155	China	273	China	273
Australia	32	Netherlands	146	Spain	258	Spain	258
Netherlands	32	Australia	125	Netherlands	225	Netherlands	225
Belgium	30	Belgium	113	Australia	206	Australia	206

701 papers
EU 62%

1087 papers
EU 66%

1785 papers
EU 49%

4960 papers
EU 52%

- The ban has also had a negative effect on research and innovation, which is slowing down in the EU.

4. Impact of the *de facto* ban > Internal Market

- **Discrimination against the probiotic industry:** Substances such as Omega 3, lycopene or fibres also *implying per se a health benefit* for the average consumer remain undisputed nutrition claims.
- In the absence of a common approach regarding the understanding and use of probiotics as ingredients in the EU there is a fragmentation of the EU internal market.
- *Some Member States:*
 - ✓ no longer permit the simple mention of the Latin names of individual probiotic strains at the front of pack,
 - ✓ prohibit the use of the term "live" on the packaging
 - ✓ consider that the term "probiotic" is not a health claim
 - ✓ consider that the term "probiotic" is a nutrition claim

5. The proposed solution: back to the basics!

- Over the last three years, the probiotic sector, with support from certain Member States, has made sustained efforts to propose solutions to put an end to the *de facto* ban of the term probiotic in Europe.
 - Recently, some Member States strongly advocate for the search of a **harmonised European solution**.
- ⇒ *Despite these initiatives, there is still no workable solution for the probiotic sector.*

5. The proposed solution: back to the basics

- The 2007 interpretation of "probiotic" as a health claim contradicts the initial intent of the European Commission, which cited probiotics as an example of other substances with a nutritional or physiological effect *to be covered by **nutrition claims** such as "Contains [name of the nutrient or other substance]"!!*
- The mere *association* by consumers of a term with *health* cannot convert a named ingredient into a health claim.
- As defined by the NHCR, **all nutrition claims imply a beneficial effect.**

⇒ "contains probiotics" clearly meets the definition of **nutrition claim**.

Solution: *Is the expression "contains probiotics" a health claim or a nutrition claim?*

Health Claim

Any claim that states, suggests or implies that **a relationship exists** between a food category, **a food** or one of its constituents and **health**.

The claim "contains (...)" may be a health claim instead of a nutrition claim, **if the name of the substance describes a bodily function.**

Nutrition claim

Any claim which states, suggests or implies that a food has **particular beneficial nutritional properties** due to the nutrients or other substances it contains.

- ⇒ **All nutrition claims imply a beneficial effect by definition (Art 2 and 5 NHCR).**
- ⇒ **Non beneficial nutrition claims are not covered by the scope of NHCR!**

Consumers may associate the word "probiotic" with "health", as it is the case for the words "vitamins", "fibre" or "protein".

Solution: *Is the expression "contains probiotics" a health claim or a nutrition claim?*

Health Claim

Any claim that states, suggests or implies that a **relationship exists** between a food category, a food or one of its constituents and **health**.

Nutrition claim

Any claim which states, suggests or implies that a food has **particular beneficial nutritional properties** due to the nutrients or other substances it contains.

Contains "probiotics" – as **generic denomination** of a category of ingredient, with no mention of a particular health effect, is a **nutrition claim**

Use of the name of an **individual probiotic strain** making a link with a specific health effect is a **health claim**

5. The proposed solution: back to the basics

- Claiming the nutritional or physiological effect of probiotics should be allowed **without any specific authorisation**, provided that the conditions established by the Claims Regulation to the claim "Contains [name of nutrient or other substance]" are respected, in particular:
 - The nutrition claim only highlights *that the food product contains probiotics*.
 - Operators are able to provide evidence upon request of the beneficial nutritional or physiological effect of probiotics, as established by generally accepted scientific evidence.
 - No direct reference is made to functional effect, to a function of the body, to psychological and behavioural functions, to slimming or weight-control, to a reduction of disease risk or to children's development and health.
- Opting for such a solution **does not change the fact that a specific health benefit for a specific probiotic strain can only be claimed after assessment and approval of the claim by EFSA**, and the necessary authorisation procedure.

6. Ways forward

Use of the term probiotic in the marketing of food:

- The principles of "better regulation", growth and innovation are promoted by the Juncker Commission. The harmful consequences of the 2007 interpretation for probiotic foods are leading the Commission to envisage legal solution for probiotics that are in line with these principles.
- Some Member States, at the initiative of Denmark and the UK, are working on alternatives and advocate for a European harmonised solution for probiotics.
- The probiotic industry urges the Commission and Member States to reconsider their interpretation of "contains probiotics" as a health claim and to revert to the initial position of the Commission that "contains probiotics" is a nutrition claim. **The 2007 guidance document should be revised to reflect this.**

As a conclusion, what future do we want for probiotics in Europe?

Some reflexion elements:

- To develop a pragmatic, European harmonised approach for probiotics that would respond to a real need, protect the consumer and support innovation.
- To use common sense and implement solutions that have already worked in other parts of the world... Like in Italy, Canada or Argentina.
- To improve dialogue with EFSA and find constructive solutions.
- In short, to put regulation in line with real life...



Thank you

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