

**Microbes for food and food
production -
Regulation in the EU and international
outlook**

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October 7, 2008, Uppsala, Sweden

General view on Microbial Food Cultures and law

- ▼ There is no world wide harmonized regulation on Microbial Food Cultures (MFC)
- ▼ Very few countries have a specific regulation covering MFC
- ▼ Reasons for regulation is normally due to a potential risk
- ▼ Risk is a function of severity as well as probability of an adverse effect
- ▼ The risk of MFC is regarded as negligible to non-existent
- ▼ From preamble of regulation: “Historically, lactobacilli and bifidobacteria associated with food have been considered to be safe. Their occurrence as normal commensals of the mammalian flora and their established safe use in a diversity of foods and supplement product worldwide supports this conclusion”

Established use in a diversity of foods



Regulatory needs at different level

MFC as traditionally used starter culture are safe

-> non big need for regulation



Probiotics are MFC with health claims

-> The use of claims are regulated



Two level of claims: a) soft, generally accepted or structure/function claim

b) disease reduction claims / significant scientific agreement claims



Strong/medical claims - indications ->

Complementary medicine -> Abridge medical application

i.e. The wording of the claim decides the level and regulatory category

What category are MFC?

- ▼ The categorization of MFC differ from country to country
 - ▶ Are they: Additive - Processing aid - Food ingredient??
 - ▶ This is an issue when the subject is on the agenda
- ▼ It is my conclusion that in EU MCF are characteristic food ingredients
 - ▶ Directive 89/107/EEC excludes characteristic ingredients of food from being food additives
 - ▶ Directive 2000/13/EC stipulate that an ingredients list is not needed for certain dairy products “provided that no other ingredient has been added other than lactic products, enzymes, microorganisms, saltare used”. This means that for a range of products it is not possible to classify MFC as processing aids since processing aids are not ingredients

Grouping according to application

- ▼ Generally the regulation of Microbial Food Cultures (MFC) can be looked at as 4 [5] subgroups:
 - ▶ Acidifier in infant formula
 - ▶ Starter cultures
 - ▶ Probiotics in food
 - ▶ Probiotics in food supplements (dietary supplements)
 - ▶ [Probiotics in pharmaceutical (medicinal) products]

The last 3 groups are special due to regulation of the use of health claims

Acidifier in infant formula

- ▼ The use of lactic acid producing bacteria in infant formula is a Codex Standard - world wide!
- ▼ The effect is acidification
- ▼ Only lactic acid bacteria producing L-lactic acid can be use, as small infant can not metabolize the D-lactic acid - risk of acidosis
- ▼ Codex does not go into the health claims
- ▼ WHO/FAO have made guidelines for probiotics and the documentation needed for health claims -> see links:
 - ▼ http://www.who.int/foodsafety/publications/fs_management/probiotics/en/index.html
 - ▼ http://www.who.int/foodsafety/publications/fs_management/probiotics2/en/index.html

Starter cultures

- ▼ Spontaneous fermentation: traditional and uncontrolled process used in food depending on microorganisms from the environment.
 - ▶ Not regulated anywhere
 - ▶ If used industrially the final product is regulated under general food laws -> It is the manufacturer's responsibility that the food is safe for the consumer.

This is as close we can come to a world wide “regulation” in the area of microbial food cultures

Industrial starter cultures, Europe:

- ▼ Microbial food cultures (MFC) with a long history of safe use are considered as traditional food ingredients
- ▼ MFC are covered by general European food law - Regulation 178/2002/EC
- ▼ MFC must be safe for their intended use
- ▼ The safety is the sole responsibility of the supplier
- ▼ MFC are legally permitted for use in human food in the EU without pre-market authorization
- ▼ With the exception of Denmark where a notification (species/strain and application) has to be performed (since 1981)

Industrial starter cultures, Europe:

- ▼ In EU the use of MFC in wine is regulated:
 - ▶ Permits the use of the genera: *Leuconostoc*, *Lactobacillus* and *Pediococcus* as well as yeast
 - ▶ Minimum 10^8 CFU/g or 10^7 CFU/ml in MFC inoculation
- ▼ Novel use of MFC is regulated in 256/97/EC
 - ▶ If a microorganism has not been consumed in a significant degree before May 15, 1997
 - ▶ [additives are out side the NFR - this is another argument why MFC cannot be additives]

Ongoing dispute in EU regarding category

- ▼ Cultures have protective properties. Can be used on meat to prevent growth of pathogens.
- ▼ This is a specific technological use, say SCFCAH and MS December 2006
Need for different **criteria** and adoption to present EU regulation:
- ▼ Cultures added at the beginning (starter in cheese, fermented milk, dry sausage) = traditional use
- ▼ Cultures used during manufacture (cheese ripening and surface cultures) = traditional use
- ▼ Cultures used with no technological effect (probiotics) = traditional use
- ▼ Cultures used for a specific technological effect (act as a preservative) = additive (as the additive category “preservatives” is regulated)

The use of bioprotective cultures

- ▼ Bioprotection with the use of microbial food cultures is not new. The original and primary purpose of fermenting food was to achieve a preservation effect
- ▼ On an average 50% of all MFC (inclusive yeast for wine, beer and bread) produce bacteriocins. This have always been a natural part of plain fermented food
- ▼ Food safety can not be the reason for this issue
- ▼ The MFC used are from the same pool of microorganisms
- ▼ The content of cultures in the final food can not be distinguee from one type of production to the other
- ▼ If it is a consumer information issue, the present regulation can cover this
- ▼ MFC being food ingredients, mean that they shall be on the ingredient list of the final product
- ▼ Avoid names in Latin - Create a common name for MFC like “cultures”

The potential negative consequences

- ▼ What are the consequences of the drafted criteria for culture when used on current and under development applications?
- ▼ Us of cultures - if considered as additives - are not able in foods with standard of identity and in organic foods
- ▼ The image of "microbial food cultures" will most likely drop if some are being additives
- ▼ What will the consequences be for the evolution of food safety?
- ▼ Will culture manufacturers invest in approvals or will the food industry have no or limited choices for those cultures?
- ▼ Will this evolution benefit consumers?

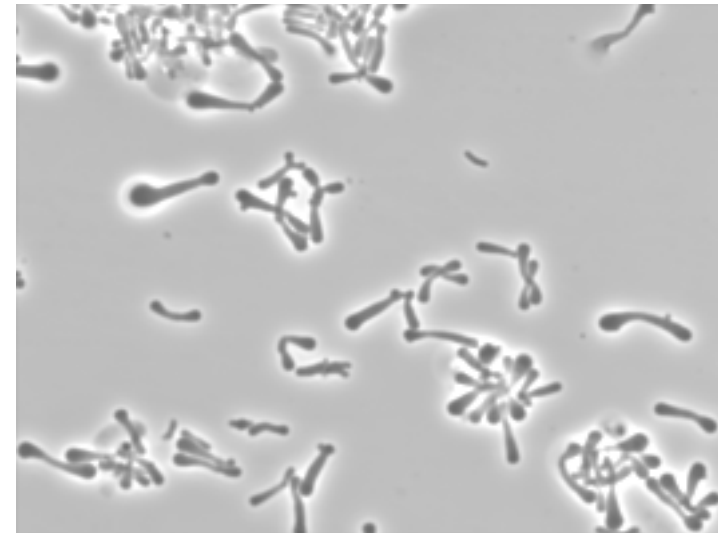
Defining Probiotics

- ▼ “Live microorganisms which when administered in adequate amounts confer a health benefit on the host”

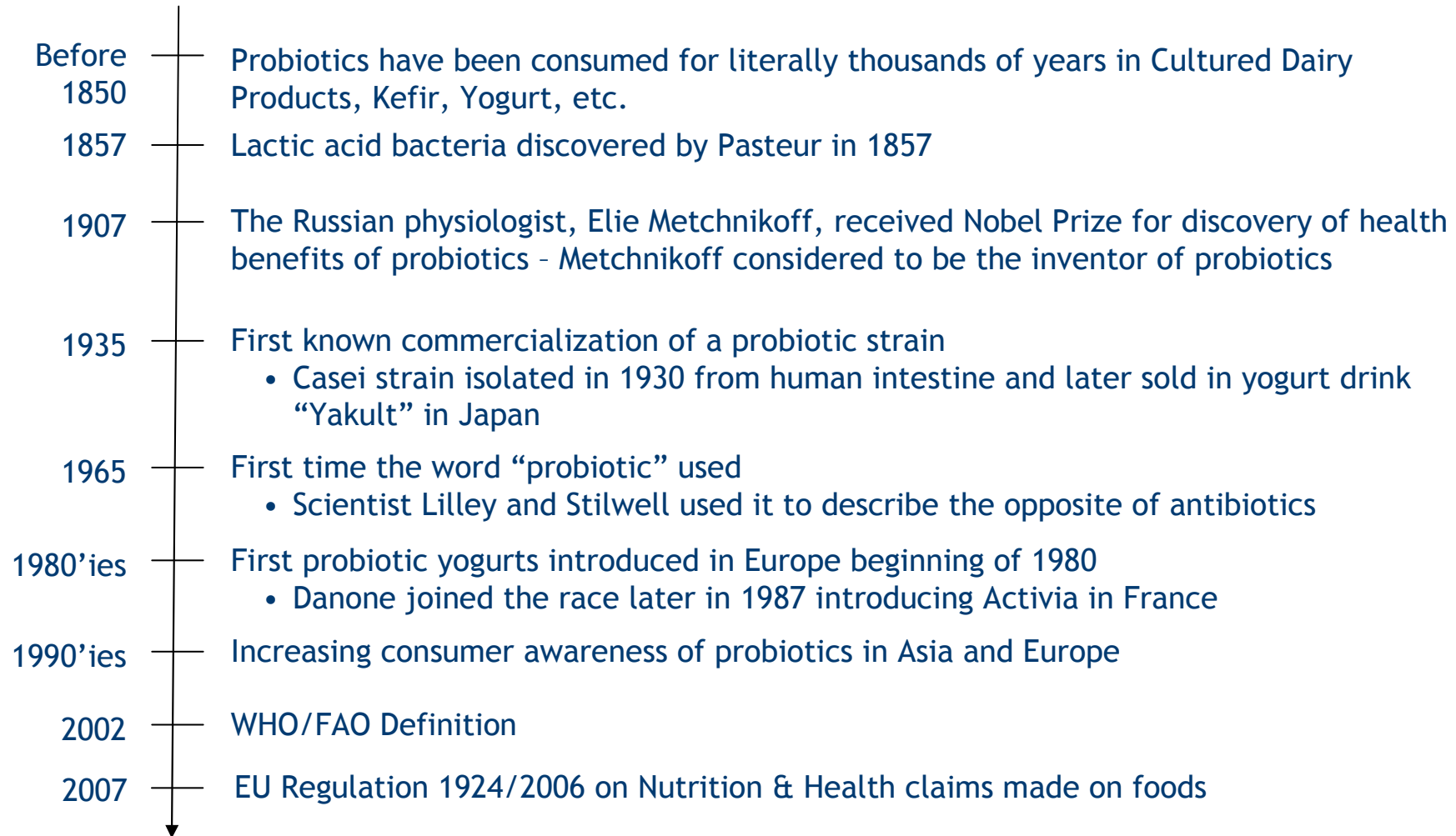
FAO / WHO 2002

Most commonly used are:

- ▶ Lactobacilli
 - ▼ Eg. *L.acidophilus*, *L.paracasei* subsp. *paracasei*,
L.rhamnosus, *L.plantarum*, *L.reuteri*
- ▶ Bifidobacteria
 - ▼ Eg. *B.animalis* subsp. *lactis*, *B.longum*, *B.infantis*
- ▶ Enterococci
- ▶ Bacillus
- ▶ Streptococcus
- ▶ *Saccharomyces boulardi*



History of probiotics



Probiotics, EU:

- ▼ The use of claims is regulated in EU from 2007 and will not be totally implemented until 2010
- ▼ Very different national rules until then with zero tolerance in Denmark to positive list of structure/function claims in Sweden and even more liberal use of language in other member states
- ▼ Claims “generally accepted in member states” (article 13) has been collected and are on its way to EFSA (European Food Safety Authorities) for assessment of efficacy
- ▼ Around 100 health claims for a selection of probiotic strains have passed “the first round”
- ▼ After an opinion from EFSA a positive list is going to be decided on by the EU Commission and the member states

Probiotics, EU: continued

- ▼ Deadline for the first positive list is January 31, 2010
- ▼ Disease reduction claims and claims for children products, called article 14 could be applied for from July 2007
- ▼ A guideline for applications was made public at the same time - it looks like the inspiration for this comes from EMEA
- ▼ The application procedure is set to 7 months - if EFSA has no questions
- ▼ In August the first 8 EFSA article 14 opinions arrived. No one on probiotics and only one was positive!
- ▼ Looking forward: new general claims (article 13.5) can be applied for and data protection up to 5 years can be asked for

Probiotics as preparations, EU:

- ▼ Regulation of health claims for food supplements is the same as for food applications
- ▼ Probiotics used before 1997 in food supplements only, is not sufficient to be “a significant food use in EU”
- ▼ Probiotics are and can be marketed as drugs, but depending of the outcome of the positive list and the wording of the claims this might change - but this is outside this area

Starter cultures, USA:

- ▼ MFC has to be GRAS substances (Generally Recognized as Safe)
- ▼ A substance with a history of common use in food before January 1, 1958 is GRAS
- ▼ Determination of GRAS status is not limited to FDA scientists
- ▼ GRAS status of a substance added to food can be based on “the views of experts qualified by scientific training and experience”
- ▼ Made on information and data generally available
- ▼ (Self) Determination shall be made on consensus of expert
- ▼ Not an FDA approval - It is the food company responsibility

Starter cultures, USA: continued

- ▼ GRAS status (determination) can be “put in the drawer”
- ▼ GRAS status can be notified to FDA - it is voluntary
- ▼ The FDA either agrees or disagrees
- ▼ A disagreement does not mean prohibition
- ▼ A food company can still use the MFC as it wishes
- ▼ Notifications and FDA reply letters are public
- ▼ See: <http://cfsan.fda.gov> for information
- ▼ Little burden on FDA - responsibility on the company
- ▼ GRAS status is for a food application
- ▼ Other uses of a GRAS substance may also be GRAS, but are not necessarily so!

Probiotics, USA:

- ▼ The use of claims is regulated
- ▼ Claims can be made as:
 - ▶ Structure/function claims: describe the role of a ingredient and how it affects the normal structure or function of the human body
 - ▼ Examples: Supports a healthy intestinal balance or Promotes immune function
 - ▶ Qualified health claims: petition for this is needed with a significant scientific evidence for the claim and information on adverse reactions
 - ▼ As of today there are no claims approve for probiotics
 - ▼ If clinical trails are performed a Master File is needed

Probiotics in preparations, USA:

- ▼ If probiotics are used as dietary supplements they are also regulated by GRAS but with another cut-of line: A substance with a history of common use in dietary supplements before 1994 is GRAS
- ▼ Claims regulation is the same as for the food applications
- ▼ Probiotics can be marketed as drugs - that is outside this presentation

Regulation of MFC in the rest of the world

- ▼ Very few countries has a specific regulation on traditional starter cultures
- ▼ Probiotic health claims - if they are regulated - tend to be regarded different for food supplements than for food applications, where the supplements in many cases are more strict and needs application and sometime is under medicinal regulation (e.g. Canada, Australia, India, Singapore, Taiwan, Egypt)
- ▼ Some countries are for the time being drafting regulation on probiotic health claims - Thailand is one of more
- ▼ The majority still have to develop regulation in this area

Svend Laulund says

▼ Thank you

▼ Questions?