

# Current Legislation of Probiotic Products



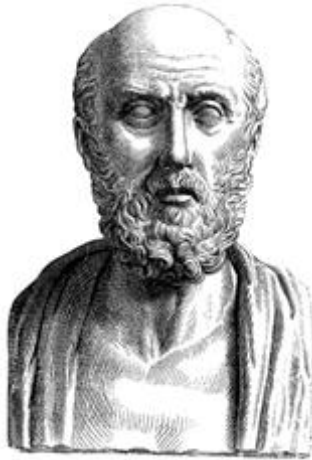
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# Outline

- ❖ A little history – the scientific foundations for probiotics
- ❖ The Japanese Functional Foods Model – a success story?
- ❖ International efforts to elaborate a common and sound scientific basis
- ❖ The United States – a major challenge
- ❖ The Canadian approach to probiotics and health claims
- ❖ China –an opportunity but also a challenge
- ❖ Some Conclusions and Future Prospects



The Father of (Western) Medicine  
**Hippocrates of Kos (c. 460 – c. 377 BC)**  
*“Let food be thy medicine and medicine be thy food”*

# Probiotics from traditional to modern

## ❖ Fermented Milks have been consumed from the earliest days of dairy farming – c. 6,000 B.C.

- Traditional fermented milks come in many forms
  - e.g. in the Mediterranean Basin, Near East and Asia (Ayrán (TK), Laban/Labneh, Doogh (IR), Lassi (IN) etc.
  - In Europe Kefir, Kumys/Koumiss, Bulgarian milk, Stragisto, Sour buttermilk etc.



## ❖ Modern times

- Yogurt (plain and flavoured), Yogurt with added probiotic cultures, Acidophilus milk, Probiotic drinks (not all milk based)

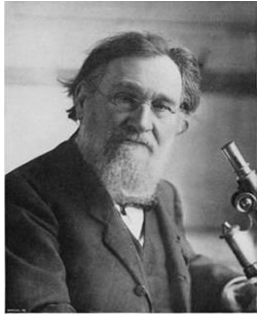


## ❖ Probiotic supplements

- as tablets, capsules, sachets etc.



# The Scientific Foundations and Founders



The founding father of probiotics

**Ilya (Élie) Mechnikoff (1845 – 1916)**

- Born near Kharkov, Ukraine
- He became interested in the study of microorganisms and especially their roles in the immune system
- 1888 – joined the Institut Pasteur in Paris
- 1908 – shared the Nobel Prize for Physiology Medicine with Paul Erlich for their work in the field of immunology
- 1908 - The Prolongation of Life: Optimistic Studies which proposed that the longevity of Bulgarian peasant farmers was related to their ingestion of fermented milk products.
- 2007 – the IDF instituted the Élie Metchnikoff Prize in three categories: Microbiology, Biotechnology and Nutrition and Health.



**Stamen Grigorov (1878 – 1945)**

- Born in the village of Studen Izvor, Tran Region, Bulgaria
- 1905, aged 27, working in the laboratory of Professor Masole in Geneva, he identified the microorganism in yogurt, which he called *Bacterium bulgaricum*
- Prof. Masole wrote to Mechnikoff telling him of his assistants findings.
- Metchnikoff invited Grigorov to visit the Institut Pasteur where he read a paper on the lactobacillus he discovered.
- Soon after Coendi and Mikelson, assistants to Mechnikoff, named the microorganism *Bacillus bulgaricus* (Grigoroff) in his honour.
- This is the microorganism is now called *Lactobacillus delbrueckii* subsp. *bulgaricus*
- 1906 - Grigorov published a scientific report “The Anti-tuberculosis vaccine”, which detailed his application of Penicillium fungi for the treatment of tuberculosis



## Alfred Nissle (1874 – 1965)

- Born in Köpenick district in the south-east of Berlin.
- 1912 – joined the Institute of Hygiene of the University of Freiburg .
- From 1915 to 1938 - he was head of the Institute for Infectious Diseases in Freiburg.
- 1917 – he isolated a strain of non-pathogenic *E. coli* (*E. coli* Nissle 1917) from the faeces of a WW1 soldier who did not develop enterocolitis during a severe outbreak of shigellosis.
- He used the strain to treat intestinal diseases such as shigellosis and salmonellosis with a considerable amount of success.
- *E. coli* strain Nissle 1917 (EcN) has many features in common with the probiotic lactic acid bacteria but was the first non-LAB probiotic identified



## Henry Tissier

- A French-born paediatrician, he was contemporary of Mechnikoff at the Institut Pasteur.
- 1899 – he observed that the stools of breast fed children contained Y- or bifid-shaped rods – these became known as the genus *Bifidobacterium*.
- 1906 – he published a paper where he reported the stools of young children with diarrhoea were characterised by low numbers of these bifid-shaped bacteria, while those of healthy children had high numbers of such organisms. He suggested the possibility of administering such bacteria to ill children.



### Leo Rettger (1874 – 1954)

- Born in Huntington, Indiana on 17 March 1874
- Taught at Yale University from 1902-1942.
- Was Professor of Bacteriology there and became the first US proponent of probiotics.
- 1920 – he showed *Lactobacillus bulgaricus* could not survive in the human intestine - this seemed to contradict Metchinikoff's theory and the idea of the benefits of fermented food waned.
- 1935 - Rettger published a paper that identified that certain strains of *Lactobacillus acidophilus* were very active, when introduced to the human digestive tract.
- Tests were carried out and it was found to be helpful in relieving chronic constipation



### Minoru Shirota (1899 – 1982)

- Born in Inadani, a village in Western Nagano, Japan
- 1921 - He chose to study medicine in Kyoto Univ. when a number of children died in his village due to infectious diseases and malnutrition.
- Inspired by Mechnikoff, he sought to develop a stronger strain of lactic acid bacteria which would help destroy the harmful bacteria living in the intestines, and thus improve and maintain human health.
- 1930 - he succeed in culturing a strain of lactic acid bacteria, *Lactobacillus casei* strain *shirota*
- 1935 – he succeeded in incorporating this strain into a drink he called Yakult.
- 1964 - Yakult expanded to markets outside Japan and is now sold in 35 countries worldwide

# The history of the term Probiotic

- ❖ There seems to be general agreement that the term **Probiotic** was first used in a **1965** paper entitled: Probiotics: Growth-Promoting Factors Produced by Microorganisms  
*Daniel M. Lilly and Rosalie H. Stillwell* of the Department of Biology, St. John's University, Jamaica, NY in Science (1965),**147**, Issue 3659, pp. 747-748
  - However, in this paper the term was used, in a different context, to describe substances secreted by one organism which stimulate the growth of another (symbiotic?)
- ❖ The term probiotic was used as it conveyed the opposite intent of the term antibiotic.
- ❖ It was not until **1974** that the term probiotic was actually used to describe a feed or food supplement by R.B. Parker, who defined it as *“organisms and substances which contribute to intestinal microbial balance”* – but this includes what we now call prebiotics
- ❖ In **1989**, Roy Fuller, an expert in gut microecology at the AFRC (Agriculture and Food Research Council), which was then based here in Reading University, modified Parker’s definition to: *“live microbial feed supplement which beneficially affects the host animal by improving its intestinal microbial balance”*
- ❖ In **2002** a Working Group of an FAO/WHO Expert Consultation proposed the following definition:- *Live micro-organisms that when administered in adequate amounts confer a health benefit on the host*  
This though now widely accepted, at least in the scientific community, has not been adopted into any international standard (at least to date).
- ❖ In **2014** a similar panel of scientific experts organised by the International Scientific Association for Probiotics and Prebiotics (ISAPP) agreed that the 2002 FAO/WHO definition for probiotics was still relevant, but advised a minor grammatical correction as follows  
*“Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host”*



# The Japanese Functional Foods Model – a success story?

## WHY?

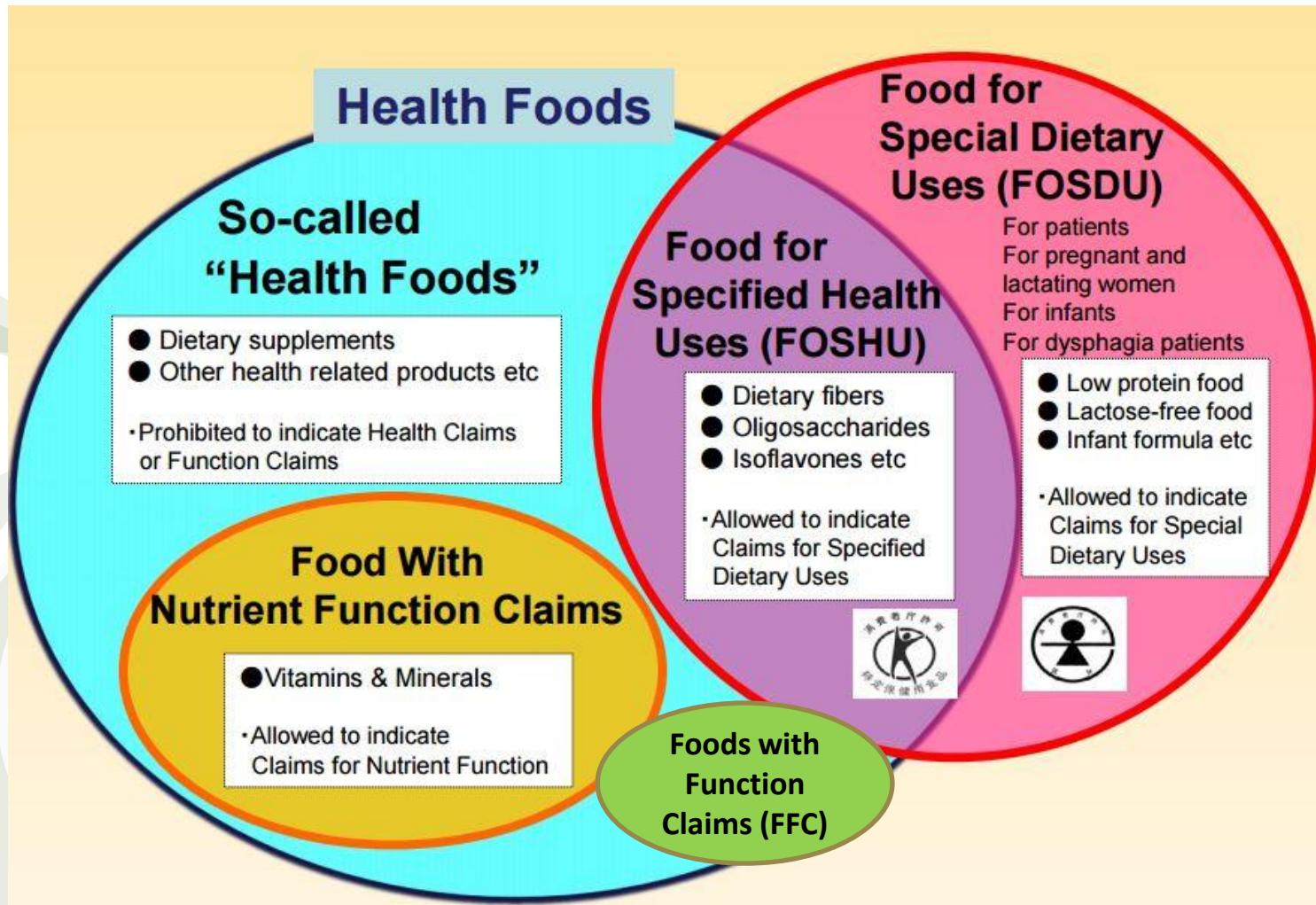
- ❖ Post WW2 severe malnutrition among certain groups led to
  - Introduction of schools lunch programmes
  - Allowing the addition of certain nutrients to staple foods e.g. bread and rice
- ❖ Concerns arose about an aging population and the consequential burden on state finances in the future

# Chronology of Legislation and Structures Japan

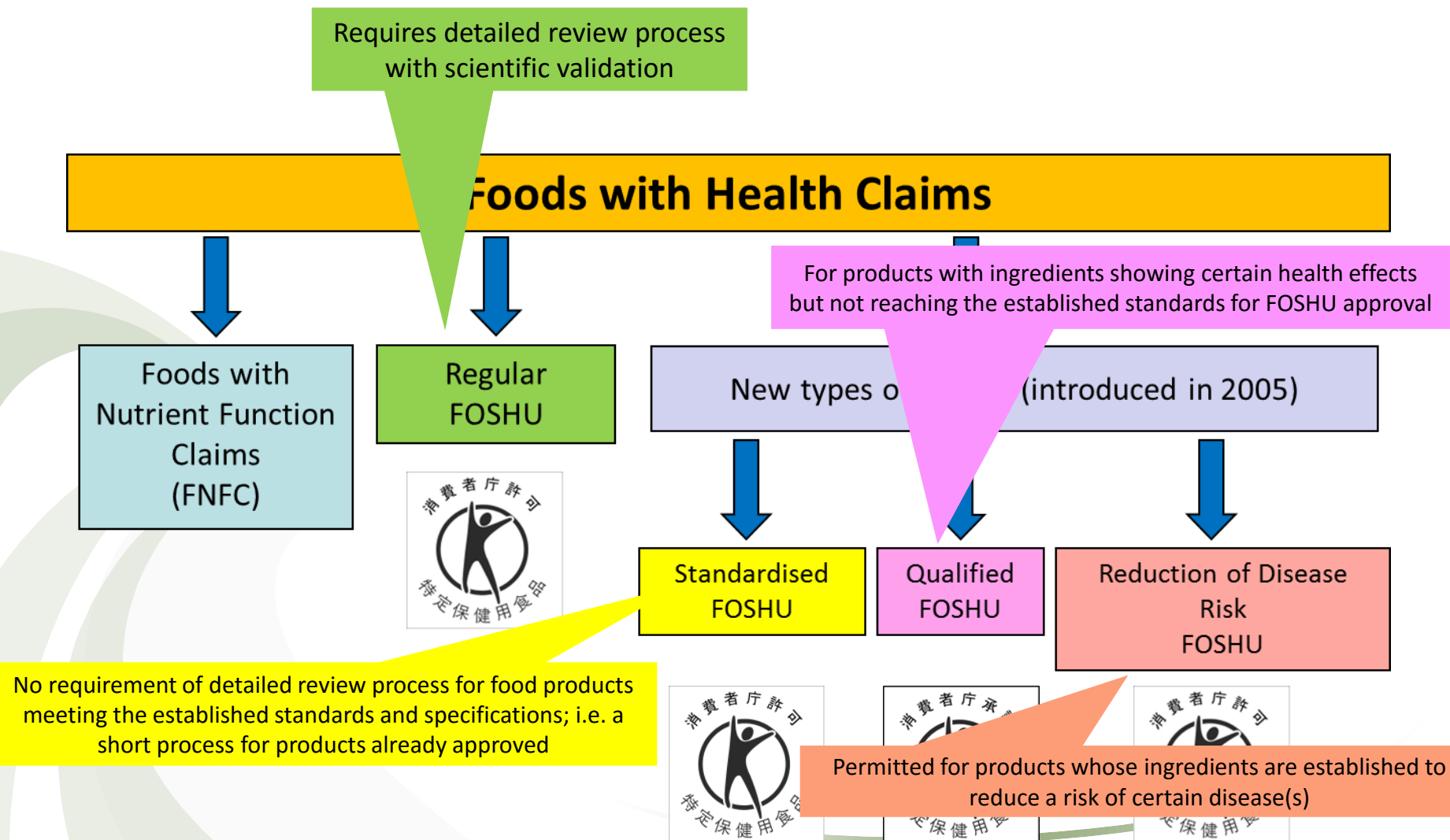
- 1952 – Nutrition Improvement Law created a category of foods for special dietary uses
- 1984 – From analysis of food nutrition surveys by the Ministry of Education, Science and Culture, 3 main functions of food were identified:
  - ❑ Nutritive value;
  - ❑ Organoleptic appeal;
  - ❑ Physiological features; e.g.
    - ✓ Regulation of bodily function
    - ✓ Disease prevention
    - ✓ Recovery promotion
    - ✓ Good health
    - ✓ Out of the latter grew the concept of **functional food** and lead to the setting up of a **Functional Foods Forum**
- The Ministry of Health and Welfare promoted functional food and the food industry was keen to make such products that could make health claims

- **1989** – More comprehensive guidelines were established for the appropriate labelling on health food; this allowed manufacturers of functional foods to make health claims
- **1991** – the Nutrition Improvement Law was further amended and the term functional food was replaced by foods for specific health uses (FOSHU); it listed 5 categories:-
  - ✓ Milk Powder for pregnant and lactating women
  - ✓ Infant Formula
  - ✓ Food for dysphagia patients (those difficulty in chewing and swallowing, usually the elderly)
  - ✓ Food for medical patients; and
  - ✓ Foods for special dietary uses (FOSHU)
- **2001** - A new regulation system for food with nutrient function claims (FNFC) was introduced.
- **2005** - Standardised FOSHU, Qualified FOSHU and Disease Reduction Risk FOSHU were also added.
- **2009** – The Consumer Affairs Agency (CAA) was established and given responsibility for the Japanese food labelling system, including those provisions covering FOSHU.
- **2015** – A new category of Foods with Function Claims was introduced in order to make more products available, clearly labelled with certain nutritional or health functions, and to enable consumers to make more informed choices

# The Health Food Market in Japan



# Categories of foods with health claims Japan



# Structure following the 2015 change

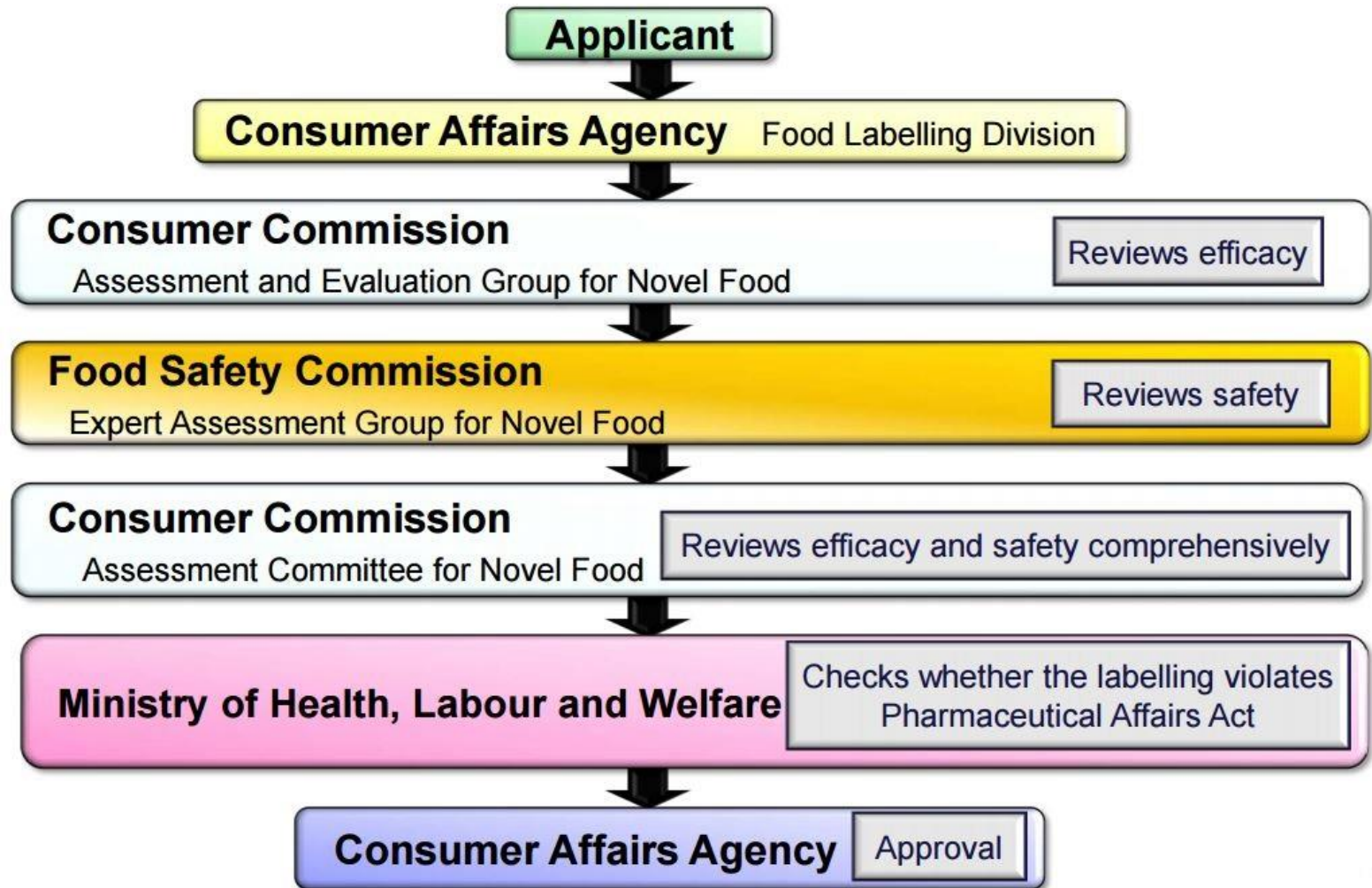


# Features of the (new) category of Foods with Function Claims

- ❖ There is no safety assessment or evaluation of functionality by government
- ❖ The food operators can use functional claims on their own responsibility.
- ❖ Prior notification must be given to the Consumer Affairs Agency (60 days before launch)
- ❖ The notification number appears on the packaging.
- ❖ Information of each product (scientific data etc.) can be seen on the website of the CAA. (any revisions/modifications of the text are also clearly shown).
- ❖ According to the website of the CAA, there are 225 notifications up to late March 2016.
- ❖ Some claims made are quite strong.

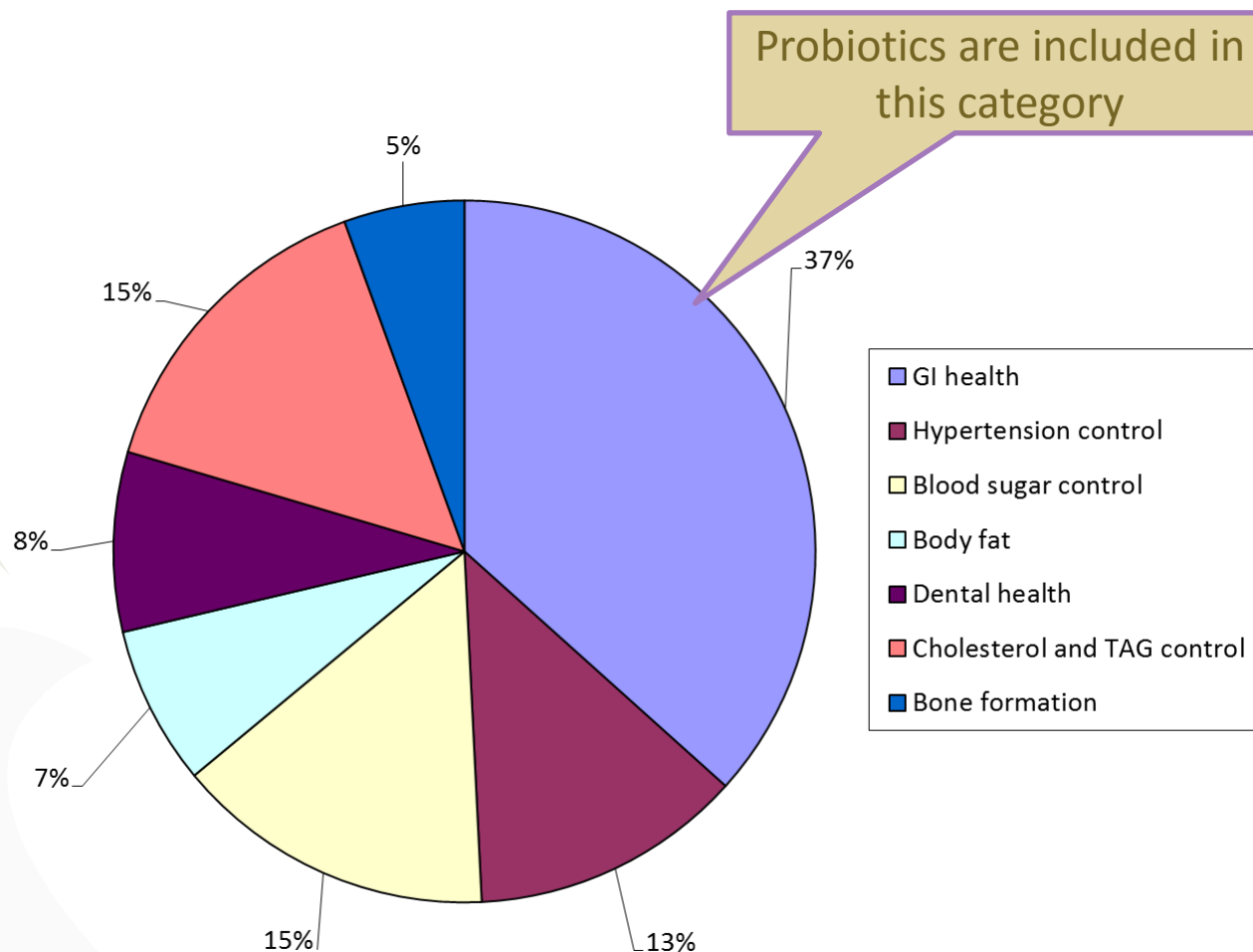


# FOSHU Approval Process Flow Chart



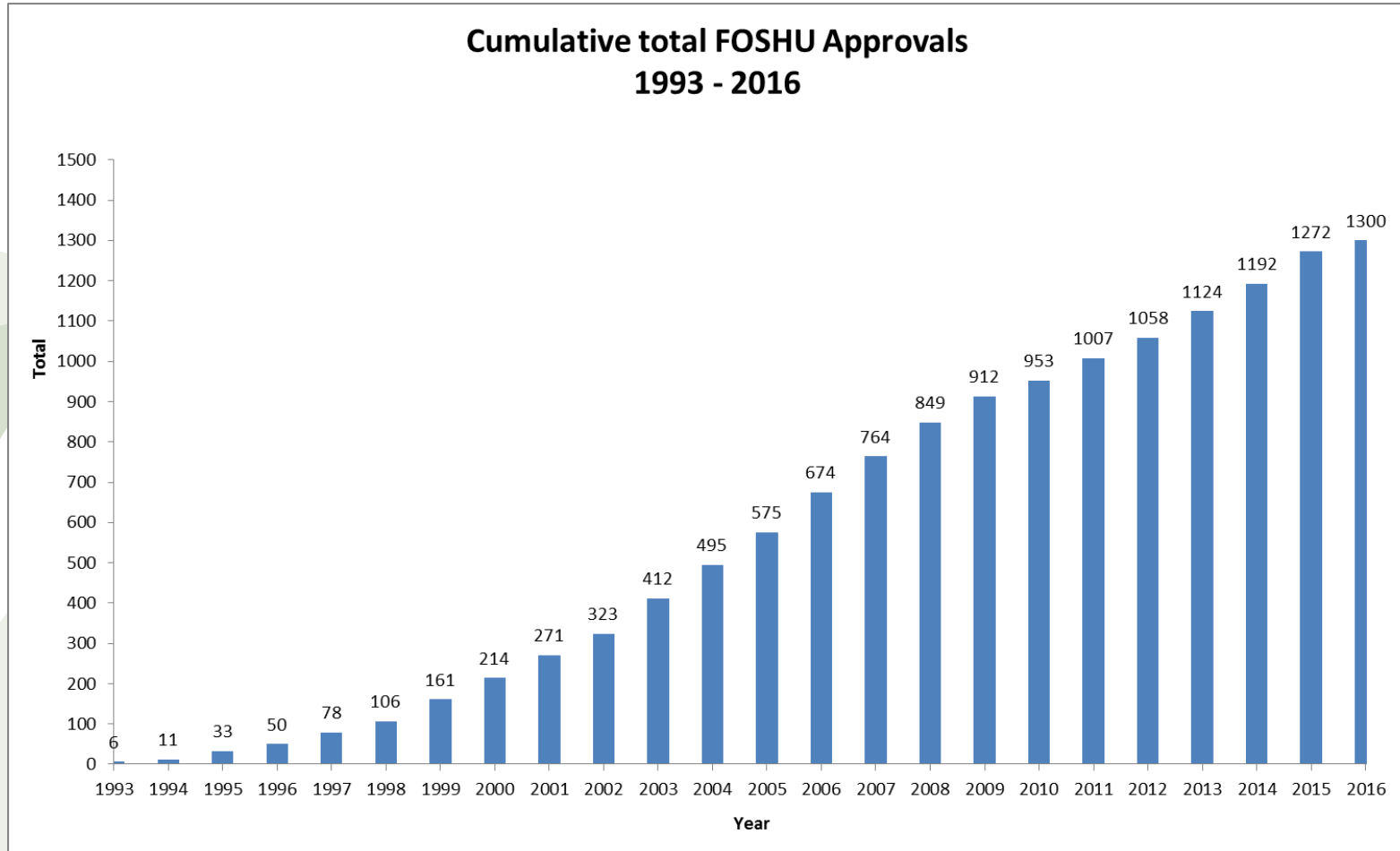


# FOSHU products by health use category



Source: CAA Japan 2011

# Growth of FOSHU Approvals



Compiled from data obtained from the site of the CAA Japan to 3 March 2016

# Some probiotic products Japan



Due to the effects of the Yakult strain (*Lactobacillus casei* strain Shirota), which can reach the intestine alive. Yakult maintains the intestine in good health by increasing beneficial bacteria, decreasing harmful bacteria and by improving the intestinal environment



This product contains GABA and is suitable for those who with slightly elevated blood pressure

Yakult Pretio



Due to the effects of *Bifidobacterium longum* BB536 which reach the intestine alive, the bifido bacteria in the intestines increase and it improves the intestinal environment and regulates the intestinal/tummy (ONAKA) conditions.



Morinaga Milk  
Bifidus BB536 Yogurt



Morinaga Caldas Milk



Due to the effects of *Bifidobacterium longum* BB536 which reach the intestine alive, the bifido bacteria in the intestines increase and it improves the intestinal environment and regulates the intestinal/tummy (ONAKA) conditions



This product contains Bifidobacteria BB 536. It has been reported that Bifido acteria BB 536 improves the intestinal environment and regulate the intestinal/tummy (ONAKA) condition

Notification of Food with Function Claim (FCC)

Morinaga  
bifidus BB536 supplement tablets



Lactic acid bacteria  
which fight against risks

Meiji  
Probio Yogurt Drink LG21

Due to the effects of Lactobacillus GG, which can reach the intestine alive, this product increases beneficial bacteria and decreases harmful bacteria. It improves the intestinal environment and regulates the tummy (ONAKA) conditions.



Takanashi Yogurt  
Onaka-He-GG

Lactic acid bacteria  
which fight against risks



Meiji  
Probio Yogurt LG21



### On the Label

- Gasseri strain SP yoghurt which decreases visceral fat.
- A 46 /Food with a function claim : notification number A48  
This product contains Gasseri strain SP and therefore it has the function of decreasing visceral fat.
- This product is notified to the Secretary General of the Consumer Affairs Agency that the food business operation will mention on its own responsibility on the label that special functional effect can be expected. However, unlike FOSHU, the product was not individually assessed by the Secretary General of the CAA
- No Fat (0), No sugars used

Megumi Gasseri strain SP yoghurt



### Notification of Food with Function Claim (FCC)

This product contains *Lactobacillus gasseri* strain SP. It has been reported that Gasseri strain SP has the function of decreasing visceral fat. .

Megumi Gasseri strain SP yoghurt drink

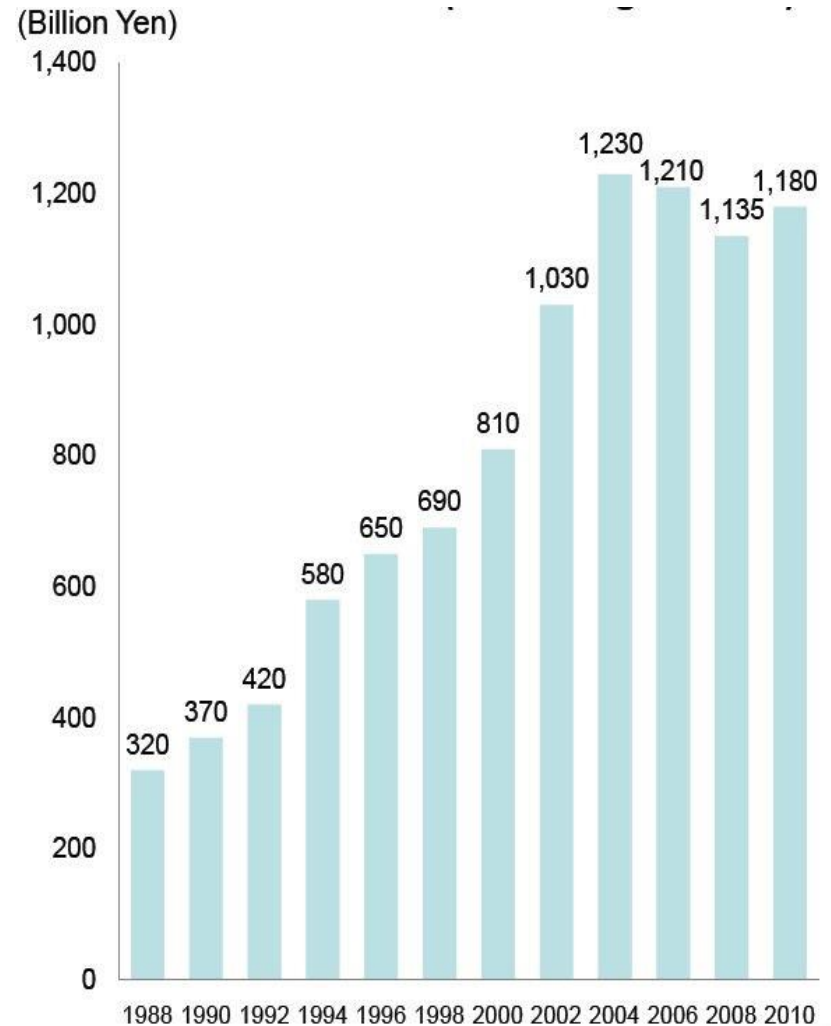
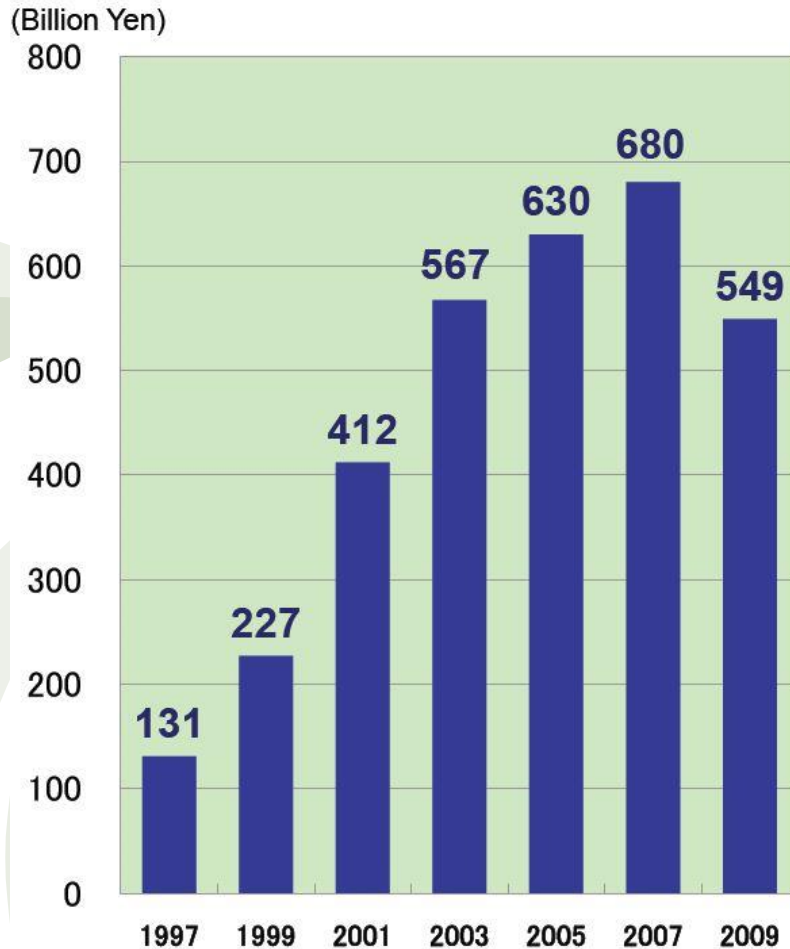


Yakult Sofhul  
Smooth texture yoghurt

Due to the effects of the Yakult strain (*Lactobacillus casei* strain Shirota), which can reach the intestine alive. Yakult maintains the intestine in good health by increasing beneficial bacteria, decreasing harmful bacteria and by improving the intestinal environment

# Share of the Japanese Health Food Market

## FOSHU v non-FOSHU



Source: CAA Japan 2011

# Features of the Japanese Model

## For FOSHU

A proactive approach based on perceived need

Government endorsed and supported

A Voluntary system

Approval given for individual products

Health claim wording is approved

Approval based on demonstrated and documented scientific safety and efficacy

Approved products can use the FOSHU logo on label

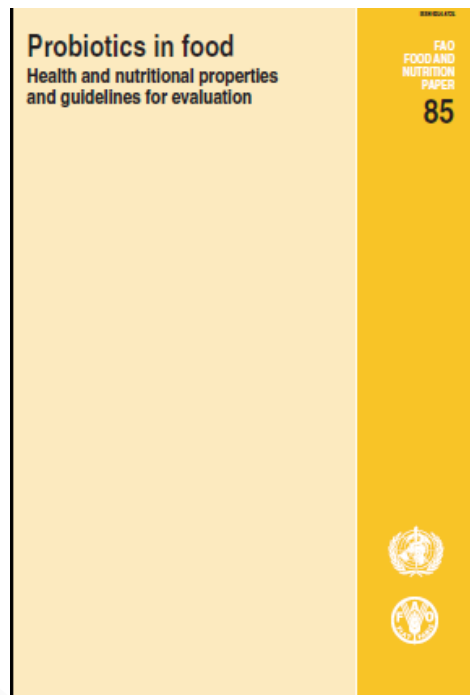
# Japanese Model – is it a success?

- ❖ Given the number approved, and the value of the market for FOSHU – probably a qualified YES
- ❖ However:-
  - It is expensive to obtain approval both in terms of cost and time especially for SME's
    - ❑ Some companies estimated to have spent more than £750K and waited more than 3 years for approval (USDA Gain Report 8/3/2015)
  - There remains a large market for “So-called” Health Foods outside the system
  - It is not known how many approved FOSHU products are still on the market.
  - It remains to be seen what the effect of the new Foods with Function Claims (FFC) category will have on approved foods
    - The market size for financial year 2015 (Apr 2015 - Mar 2016) was ¥30.3bn.
    - Estimates for financial year 2016 (Apr 2016 - Mar 2017) is ~ ¥70bn
    - Estimates for FOSHU market for financial year 2016 predict a decline of ~¥3bn as companies switch priorities from FOSHU to FFC foods



# International efforts to elaborate a common and sound scientific basis

- 2001 (Cordoba, AR) – An FAO/WHO Expert Consultation on:- Probiotics in food Health and nutritional properties and guidelines for evaluation



# Outcomes of the Expert Group

- ❖ Drafted Guidelines for the evaluation of probiotics in food
- ❖ 11 experts from 10 countries attended
- ❖ They evaluated the latest information on
  - Scientific evidence available on probiotics as functional foods;
  - Food safety aspects of probiotics;
  - Methodologies to assess such aspects.
- ❖ In addition to scientific recommendations they made recommendations pertaining to regulatory matters including
  - That to be termed a probiotic, the M/O must be able to confer defined health benefits to consumers in the product as marketed;
  - That GMP must be applied in manufacture and labelling;
  - That the regulatory status should be established at international level;
  - That a regulatory framework be established to include efficacy, safety, food labelling, claims and to prevent fraud;
  - That qualifying probiotics should be allowed to describe properly validated benefits (health claims);
  - That surveillance systems should be established to identify any adverse effects and monitor the long-term health benefits of their consumption

➤ **1992** (London, ON, CA) – A Working Group of the FAO/WHO Expert Consultation established to draft Guidelines for the Evaluation of Probiotics in Food :-

- ☐ Concluded probiotic effects are strain-specific;
- ☐ Elaborated the definition of probiotics as outlined earlier
- ☐ Recommended that adoption of their Guidelines, as contained in their report, should be a pre-requisite for calling a strain a probiotic

- ❖ The conclusions and recommendations of these groups are those of the participants and do not imply any opinion on them by the organisers of the Expert Consultation (FAO & WHO)
- ❖ It is also recognised that the participants were all scientists and not legislators
- ❖ Nonetheless, the conclusions appear to have been well received generally – their subsequent adoption is another matter

# CODEX Standards and Guidelines

- **1971 (Rev. 1991) – Codex General Guidelines on the Use of Claims**
- **2007 - Codex Guidelines on the Use of Nutrition and Health Claims**
- **2009 – Recommendations on the Use and Substantiation of Health Claims** adopted and now included in the 2007 Guidelines
- ❖ **NOTE: Codex does not evaluate health claims** – the guidelines are intended for individual governments to facilitate their evaluation of health claims made by industry  
They also should provide a reference in preparing dossiers aimed at substantiating such claims.

# Codex General Guidelines on the Use of Claims

## Prohibit

Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are:

- (a) in accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines.
- or,
- (b) in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

# Codex Guidelines on the Use of Nutrition and Health Claims

## Defines

**Health claim** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

**Reduction of disease risk claims** – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

### Examples:

“A healthful diet low in nutrient or substance A may reduce the risk of disease D.

Food X is low in nutrient or substance A.”

“A healthful diet rich in nutrient or substance A may reduce the risk of disease D.

Food X is high in nutrient or substance A.”

# Codex Guidelines on the Use of Nutrition and Health Claims

Focus on criteria to be used for substantiation and for systematic review of relevant scientific evidence such as:

- ❖ Health claims should primarily be based on evidence provided by well-designed human intervention studies
- ❖ Recognise that human observational studies per se are not necessarily sufficient alone but they may contribute to the totality of the evidence
- ❖ Data from *ex vivo* or *in vitro* animal model studies are not regarded as sufficient but may be used to provide additional supportive information
- ❖ The totality of the evidence should be identified and reviewed
- ❖ Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the claimed health effect
- ❖ Substantiation can take into account specific situations or alternate processes
- ❖ Some health claims, e.g. those involving a relationship between a food category and a health effect, may be substantially based on observational studies
- ❖ Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used

# Codex Standard for Fermented Milks

- Adopted in **2003** – replacing 2 earlier yogurt standards
  - Revised **2008** – to include *Drinks based on Fermented Milk*
- Specified min. level of starter cultures =  $1 \times 10^7$  cfu/g (or ml)
- Allowed the use of other safe and suitable M/Os
- Allowed the labelling of the presence of specific M/Os, but specified a min. level for such cultures =  $1 \times 10^6$  cfu/g (or ml)
- Did not use or reference the term probiotic
- Regional standards for certain fermented milks being considered (doogh, labneh) and others may follow.
  - The current draft of the standard for doogh does include “probiotic provisions”



# US Regulatory Implications

- ❖ Probiotics are regulated differently depending on the intended use
- ❖ Regulations for claims are dictated differently for:

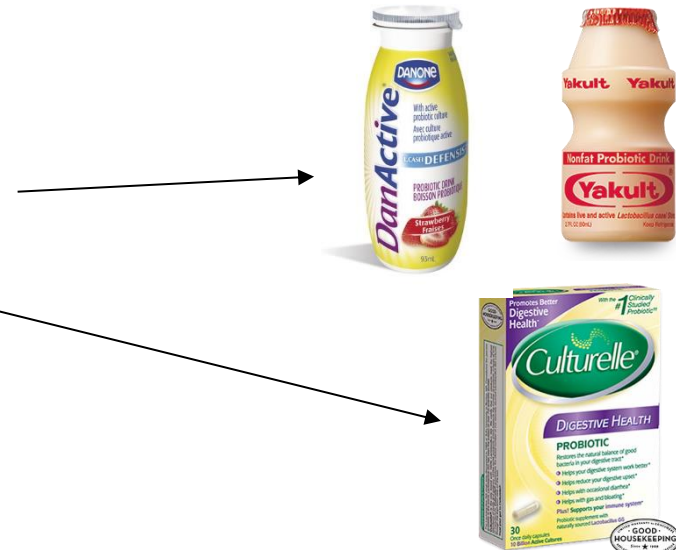
- **Conventional Foods**

- Dietary Supplements

- Medical Foods

- Drugs

- Animal Feed Additives



# US Regulatory Implications

## ➤ Intended Use

- ✓ Nature of claims made

## ➤ Formulation

- ✓ Capsules and pills

## ➤ Route of administration

- ✓ Orally for foods & supplements

## ➤ Target Consumers

- ✓ Foods intended for general public

## ➤ Safety

- ☐ Food - GRAS or approved food additive

- ✓ DS - NDI New dietary Ingredient notification (1994)



# US Types of Food Labelling Claims

Type of Claim	FDA standard	Example
Nutrient Content	FDA Clearance	"Contains calcium" "Good source of calcium"
Health Claims	FDA Clearance	"May reduce the risk of osteoporosis"
Structure/function	Accurate & Substantiated	"Helps build strong bones and teeth"
Dietary Guidance	Accurate & Substantiated	"Diets rich in dairy foods, fruits and vegetables reduce the risk of some chronic diseases"

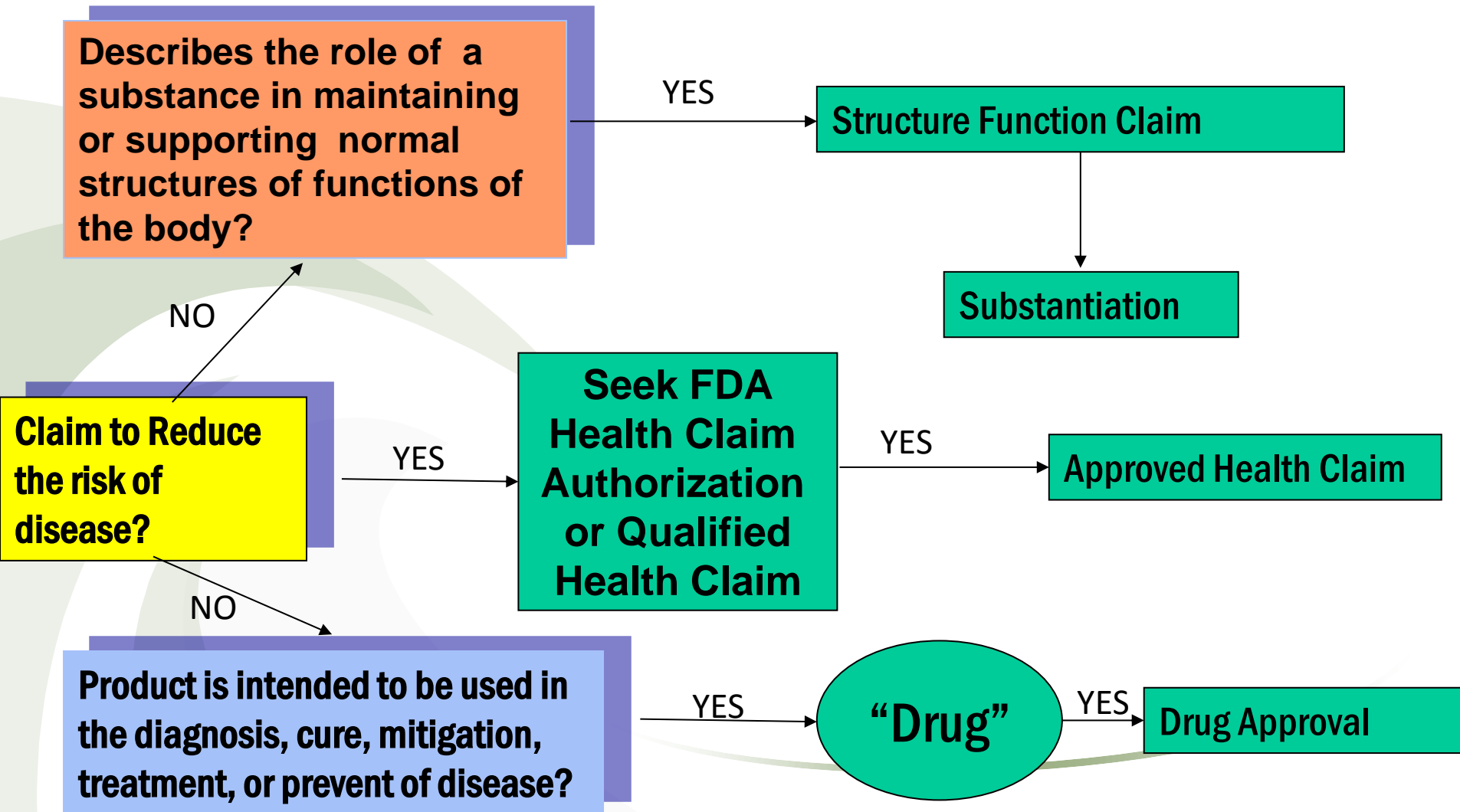
# Health Claims in US

- ❖ Reduction of risk of disease claims
  - Statements that describe the relationship between a substance and a disease in the labelling of foods, including dietary supplements
    - ✓ Reviewed and authorized by FDA based of "significant scientific agreement" or
    - ✓ Appropriately qualified - where quality and strength of scientific evidence is inconclusive
    - ✓ Authoritative government body
    - ✓ No authorizations for probiotics

\*3g of soluble fiber daily from oatmeal, in a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.



# Structure/ Function, Health, and Disease Claim Distinction



# US Regulatory Challenge for Probiotics

Conveying the benefits of a food or dietary supplement containing probiotic organisms to avoid wording claims in a manner that would be viewed by FDA as unauthorized health or drug claim.

# Legal Challenges to probiotic claims in US



## The Complaints were

1. Dannon's advertisements for DanActive conveyed to consumers that drinking the product reduces the likelihood of getting a cold or flu
2. In a TV for Activia yogurt, an actress lounging on a couch tells viewers that many people suffer from irregularity, and that *"our busy lives sometimes force us to eat the wrong things at the wrong time."* She reassures viewers that Activia can help.

## OUTCOME

Dannon had to cease using these health claims

# Yet another Class Action in the US

**FOOD**  
navigator-usa.com

## Yakult USA confident of "eventual and ultimate vindication" in probiotics class action



By Elaine Watson+ 

27-Aug-2015

Last updated on 27-Aug-2015 at 17:06 GMT



### *Torrent v. Yakult U.S.A., Inc.*

Plaintiff, Nate Torrent, alleged that Yakult violated California's Unfair Competition Law (UCL) by deceptively claiming that its probiotic beverages containing the *Lactobacillus casei* Shirota microorganism help balance the digestive system and maintain overall health



# But all challenges do not result in a loss

## Stand Down! Court Rejects Yakult Yogurt False Advertising Class for Lack of Standing

**Blog** Private Surgeon General Class Action Defender

Morrison & Foerster LLP

USA | January 19 2016

### Outcome:

The Court found that the sole named plaintiff lacked Article III standing to seek injunctive relief on behalf of the putative class because he failed to allege or offer evidence of a sufficient likelihood of future harm.

Even on a second challenge

## Class Cert Denial Redux: Plaintiff's "Manufactured" Standing Falls Short in Yakult Yogurt Action

Morrison & Foerster LLP

USA | April 1 2016

### Outcome:

The same Judge ruling that his newly alleged intent to buy Yakult in the future was nothing more than a barely disguised attempt to manufacture standing

# Claims of products on US Market



Enrich your day with a delicious, creamy Activia lowfat yogurt. Rich in flavor and made with our exclusive probiotic yogurt culture, Bifidus Regularis® (*Bifidobacterium lactis* DN-173 010), Activia will please your taste buds and your tummy.\* Available in seven great flavors.



DanActive helps support your immune system when consumed regularly as part of a balanced diet and healthy lifestyle.



Yakult is a probiotic drink. It contains billions of live and active "good bacteria." Your digestive system naturally contains trillions of bacteria -- some are helpful, some are harmful. When you drink Yakult daily, it makes it difficult for the bad bacteria to take over. Yakult also gives you more of the good bacteria that may help balance your digestive system.



## Probiotics

Probiotics support digestive health and immunity so that your body is strong on its own and can proactively fight off infection and help prevent disease.

## Bifidobacterium BB12®

There is a unique strain of the probiotic Bifidobacterium BB-12® in every cup of La Yogurt Probiotic. This special strain works with the rest of your body to help maintain balanced microflora, support immunity and support digestive health.

# So What is the future for Probiotics in US?

Probiotic Foods

or

Probiotics as Supplements  
(in tablets, sachets, capsules)



Mary Ellen Sanders – a leading US Food Microbiologist and proponent of probiotics



A non-profit public research management corporation whose mission is to lead and deliver best research and science-based educational programs towards innovative and sustainable California and U.S. dairy industry

## How FDA's Actions Are Guaranteeing Research on Probiotic Foods is Not Conducted in the USA

October 13, 2012

By Mary Ellen Sanders , Dairy & Food Culture Technologies

## “Probiotics: Achieving a Better Regulatory Fit”

July 24, 2014

By Mary Ellen Sanders , Dairy & Food Culture Technologies

## Definition of Probiotics: 12 Years Later

June 10, 2014

By Mary Ellen Sanders , Dairy & Food Culture Technologies



# The Canadian approach to probiotics and health claims



- **1998** - HC published a **Policy Paper on Nutraceuticals /Functional Foods and Health Claims on Foods**
- **2002** – HC produced an **Interim Guidance** document that outlined standards of evidence for evaluating foods with health claims
- **2003** – The **Canadian Food and Drug Regulations** were amended to introduce the first series of authorised health claims
- **2009** – HC updated the Interim Guidance replacing it with a **Guidance Document for Preparing a Submission for Food Health Claims**
  - ❖ HC posted a guidance document **The Use of Probiotic Microorganisms in Food**
  - ❖ HC published a new guidance document **Classification of Products at the Food-Natural Health Product Interface: Products in Food Format**

# Categories of Food Claims - Canada

## Nutrition Claims

### Nutrient Content Claims

Describe the quantity of energy or nutrient e.g. "low", "high", "light", "source", etc.

### Nutrient Function Claims

"Calcium aids in the formation and maintenance of bones and teeth."

## Health Claims

### General Health Claims

"Canada's Food Guide recommends eating at least one dark green and one orange vegetable each day."

### Function Claims

"Consumption of 1 cup of green tea helps to protect blood lipids from oxidation."

### Disease Reduction and Therapeutic Claims

Disease Reduction Claims

Disease Reduction Claims

Non-Strain Specific Probiotic Claims?

No strain Specific Claims approved to date

Strain Specific Probiotic Claims?



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### Health Claims

Health Canada recognizes that the foods we eat can affect our health in different ways. Some food labels contain statements about the beneficial effects of certain foods on a person's health, such as "*a healthy diet low in saturated and trans fat may reduce the risk of heart disease*". This type of statement is an example of a health claim.

A health claim is any representation in labelling or advertising that states, suggests, or implies that a relationship exists between consumption of a food or an ingredient in the food and a person's health.

**Function claims** are health claims that describe the physiological effects of foods or food constituents on normal functions or biological activities of the body associated with health or performance.

**Therapeutic claims** are claims that would bring a food into the definition of a drug or a natural health product (drug claims). These are claims about the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans, or restoring or correcting organic functions in humans, or modifying organic functions in humans. Products that carry such claims are considered to be represented for "therapeutic use".



# Probiotic Health Claims in Canada

- A probiotic health claim can consist of one of the following examples:
  - Use of the term "probiotics" and similar terms or representations;
  - Use of words such as "with beneficial probiotic cultures"; or
  - "contains bacteria that are essential to a healthy system"; and
  - Use of the Latin name of a microbial species modified to suggest a health benefit.
- A probiotic health claim can be presented in either text or graphic, on food labels or in advertisements to suggest that a food confers a health benefit.
- **Non-strain specific probiotic claims** are allowed
- **Strain specific probiotic claims** are allowed – but none have been approved to date

# Canada - Eligible Genus/Species to make a non-species specific health claim

Eligible bacterial species <sup>2</sup>	Acceptable Non-Strain-Specific Probiotic Claims for Food
Latin name (acceptable nomenclature <sup>3</sup> ) and synonym where applicable	
<i>Bifidobacterium adolescentis</i>	<ol style="list-style-type: none"><li>1. Probiotic that naturally forms part of the gut flora. (§)</li><li>2. Provides live microorganisms that naturally form part of the gut flora. (§)</li><li>3. Probiotic that contributes to healthy gut flora. (§)</li><li>4. Provides live microorganisms that contribute to healthy gut flora. (§)</li></ol>
<i>Bifidobacterium animalis</i> subsp. <i>animalis</i>	
<i>Bifidobacterium animalis</i> subsp. <i>lactis</i> -synonym: <i>B. lactis</i>	
<i>Bifidobacterium bifidum</i>	
<i>Bifidobacterium breve</i>	
<i>Bifidobacterium longum</i> subsp. <i>infantis</i> comb. nov. (*)	
<i>Bifidobacterium longum</i> subsp. <i>longum</i> subsp. nov. (*)	
<i>Lactobacillus acidophilus</i>	
<i>Lactobacillus casei</i>	
<i>Lactobacillus fermentum</i>	
<i>Lactobacillus gasseri</i>	
<i>Lactobacillus johnsonii</i>	
<i>Lactobacillus paracasei</i>	
<i>Lactobacillus plantarum</i>	
<i>Lactobacillus rhamnosus</i>	
<i>Lactobacillus salivarius</i>	
<p>(*) In product labelling, <i>Bifidobacterium longum</i> subsp. <i>infantis</i> and <i>Bifidobacterium longum</i> subsp. <i>longum</i> would be considered acceptable nomenclature.</p> <p>(§) The word "gut" may be replaced by the expression "digestive tract" in these claims.</p>	

A serving of stated size of a product should contain a minimum level of  $1.0 \times 10^9$  cfu of one of the eligible microorganism(s) that is(are) the subject of the claim

# Summary of Canadian Health Claim Requirements

Type of Claim	Pre-Market Approval	Scientific Substantiation
<b>All Health Claims</b> <ul style="list-style-type: none"> <li>Any representation in labelling or in advertising that states, suggests, or implies that a relationship exists between consumption of a food, or an ingredient in the food, and health</li> <li>Applies to symbols, graphics, logos, trademarks or seals of approval as well as words</li> </ul>	<ul style="list-style-type: none"> <li>Follow the <i>Canadian Food Health Claim Roadmap</i> for a logical approach to regulatory considerations en route to using claims</li> </ul>	<ul style="list-style-type: none"> <li>All claims must be supported by scientific evidence in a systematic, comprehensive and transparent manner</li> </ul>
<b>Nutrient Function Claims</b> <ul style="list-style-type: none"> <li>Describe well-established roles of energy or nutrients that are essential for maintenance of good health or for normal growth and development</li> </ul>	<ul style="list-style-type: none"> <li>Pre-market notification is not required for accepted nutrient function claims listed in <a href="#">GFLA* Chapter 8</a> (section 8.6)</li> </ul>	<ul style="list-style-type: none"> <li>New nutrient function claims will be considered only for nutrients with established recommended intakes and if the function reflects consensus among authoritative scientific bodies</li> </ul>
<b>General Health Claims</b> <ul style="list-style-type: none"> <li>Broad statements on healthy eating patterns or dietary guidance</li> <li>Do not refer to a health effect, disease, or health condition</li> </ul>	<ul style="list-style-type: none"> <li>Pre-market notification is not normally required</li> <li>Statements that imply "healthy choice" or the use of a logo or symbol are subject to review and must not be false, misleading or deceptive</li> </ul>	<ul style="list-style-type: none"> <li>Consult <a href="#">GFLA* Chapter 8</a> (sections 8.8–8.15)</li> </ul>
<b>Function Claims</b> <ul style="list-style-type: none"> <li>Link the consumption of a food or a food constituent with normal body functions or biological activities</li> <li>Based on the role that the food or food constituent plays when consumed at levels consistent with normal dietary patterns</li> </ul>	<ul style="list-style-type: none"> <li>A list of acceptable function claims and conditions for use is maintained in <a href="#">GFLA* Chapter 8</a> (section 8.5)</li> <li>Pre-market notification is recommended for new function claims</li> <li>Evidence should be available upon request</li> </ul>	<ul style="list-style-type: none"> <li>Claims must be supported by acceptable standards of evidence</li> <li>Claims should clearly state a specific and scientifically supported physiological effect associated with good health or performance</li> <li>Consult <a href="#">Guidance Documents for Preparing Health Claim Submissions</a></li> </ul>
<b>Disease Risk Reduction and Therapeutic Claims</b> <ul style="list-style-type: none"> <li>Link a food, food constituent, or dietary characteristic to a reduced risk of developing a diet-related disease or condition (e.g. heart disease) or highlight a therapeutic effect, including restoring, correcting, or modifying body functions (e.g. lowering cholesterol)</li> <li>Food must contribute to a healthy dietary pattern</li> <li>The health effect is based on food's normal use as part of the diet</li> </ul>	<ul style="list-style-type: none"> <li>A list of claims reviewed by Health Canada for scientific validity is published on Health Canada's <a href="#">Health Claim Assessments</a> web page</li> <li>Conditions of use and prescribed wording apply</li> <li>If a claim associates a food as a treatment, preventative or cure for any of the diseases referred to in <a href="#">Schedule A of the FDA</a>, then a regulatory amendment is needed prior to use</li> <li>If the claim is not subject to Schedule A, then a regulatory amendment may not be required before the claim can be used</li> </ul>	<ul style="list-style-type: none"> <li>Consult <a href="#">Guidance Documents for Preparing Health Claim Submissions</a></li> <li>Submissions for new claims must characterize the food and the health effect, substantiate claim validity, demonstrate feasibility of consumption of effective dose, and propose claim wording</li> </ul>

\*GFLA = CFIA's *Guide to Food Labelling and Advertising*

Source: Health Canada (2012)

# Examples from the Canadian Market

Find out how Activia can help you



The infographic features a yellow stick figure with a drop above its head. Text on the left states: 'up to **66%** of the **GENERAL POPULATION EXPERIENCES** these minor digestive issues frequently as part of the usual physiological digestive process\*.' A central yellow balloon contains the text 'BLOATING GAS DISCOMFORT RUMBLING'. Below this, a calendar icon shows 'FOR 2 WEEKS'. To the right, a white bowl with '2x' inside is followed by 'WHEN CONSUMED **TWICE\*** PER DAY'. At the bottom, it says 'AS A PART OF A **BALANCED DIET AND HEALTHY LIFESTYLE**' with a small apple icon. A smiling mouth made of stars is at the bottom right.

**ACTIVIA**  
MAY REDUCE THE FREQUENCY  
OF MINOR DIGESTIVE  
ISSUES

BLOATING  
GAS  
DISCOMFORT  
RUMBLING

FOR  
**2**  
WEEKS

AS A PART OF A  
**BALANCED  
DIET AND HEALTHY  
LIFESTYLE**

WHEN  
CONSUMED  
**TWICE\*** PER DAY

**2x**

\*Omnibus Study, Ipsos, 2013

\*2x 100g



Every bite of food you eat has an impact on your digestive system. Activia's exclusive probiotic BL Regularis culture survives gastric acids and enzymes. It reaches your intestinal tract alive, active and in great numbers. Friendly bacteria present in the large intestine, contained in Activia, help digest our food and produce certain vitamins, help to make conditions unfavourable for some harmful bacteria.

## Friendly bacteria

DanActive contains 3 different cultures: *Streptococcus thermophilus*, *Lactobacillus bulgaricus*, and *Lactobacillus casei*, a probiotic culture that contributes to healthy gut flora.

## Vitamin D

Vitamin D helps build strong bones. By choosing a yogurt made with vitamin d fortified milk, you can contribute to your daily intake of this vitamin. Not a bad way to start the day!

## Calcium

Whatever your age, calcium aids in the formation and maintenance of bones. DanActive is source of calcium.





# China – an opportunity but also a challenge

- ❖ Traditional Chinese Medicine (TCM) has a long-documented history – back to the Western Zhou Dynasty => 1046 - 771 BC.
- ❖ The term **Medicinal Food** is first found in the literature of the Han Dynasty => 206 BC - 220 AD
- **Early 1980's** – saw the development of Healthy (Functional) Foods, some of which claimed to improve health and remedy certain diseases or conditions
- By **1991** the China Market estimated as £3bn – but there were concerns as regards
  - Identity
  - Efficacy
  - Possibly Food Safety

This led to the necessity to establish evaluation and assessment procedures and for regulatory control and monitoring
- **1995 - Food Hygiene Law** of the P. R. China – the basic food law legislation
- **1996** –Ministry of Health Regulation set **Administrative Provisions for Health Foods**

- **2005** – Interim Regulations for the Control of Health Foods
- **From 2008 onwards** – Regulation(s) on the Inspection and Administration of Health Food
- **2009** – The Food Hygiene Law was replaced by **Food Safety Law**  
revisions of this law are ongoing
- **2009 - Regulation on the Implementation for the Food Safety Law**
- **2012** – The CFDA issued **Requirements on and a Guide to the Naming of Health Foods**
- **2016** – CFDA issued provisions for **Health Food Registration and Filing**

# China Food and Drug Administration (CFDA)



- ❖ CFDA (sometimes the abbreviation SFDA is used) got its current name in **2003** with added supervision and administration functions in **food** and cosmetics
- ❖ In **2008**, its responsibilities underwent 2 major changes.
  - Its responsibility of coordinating food safety and investigating major food safety incidents was transferred to the MOH.
  - It took over MOH's responsibility of supervising food safety e.g. food hygiene licensing, the catering sector etc., as well as overseeing **health food** and cosmetics.
- ❖ It is now responsible for protecting public health by assuring the safety, efficacy, and security of drugs, biological products, medical devices, food supply (**including Health Foods**) and cosmetics
- ❖ As a direct part of the State Council, CFDA has regulatory and legal enforcement functions in the supervision the above fields

# Main Provisions for Administration of Health Food

## ❖ Definition of Health Foods

Food products that claim specific health functions and have been approved according to Regulations

## ❖ Scope:

The product is suitable for a specific population to consume, assists with regulating different body functions, and is not intended to cure disease

## ❖ Nutrient supplements, specifically including vitamins and minerals designed to supplement people's diet, are regulated by the health food regulations



# 27 Health Food Categories in China

Enhancing immunity

Accelerating lactating

Assisting blood sugar reduction

Assisting blood lipids reduction

Improvement of growth and development

Enhancing anoxia tolerance

Assisting irradiation hazard protection

Increasing bone density

Eliminating acne

Improving skin moisture (water content)

Anti-oxidation

Improving nutritional anaemia

Facilitating digestion

Co-protection of chemical liver damage

Slimming (weight loss)

Sleep improvement

Maintain regularity & relieve constipation

Alleviating physical fatigue

Assisting blood pressure reduction

Assisting memory improvement

Alleviating visual fatigue

Eliminating skin chloasma

Improving skin oil content

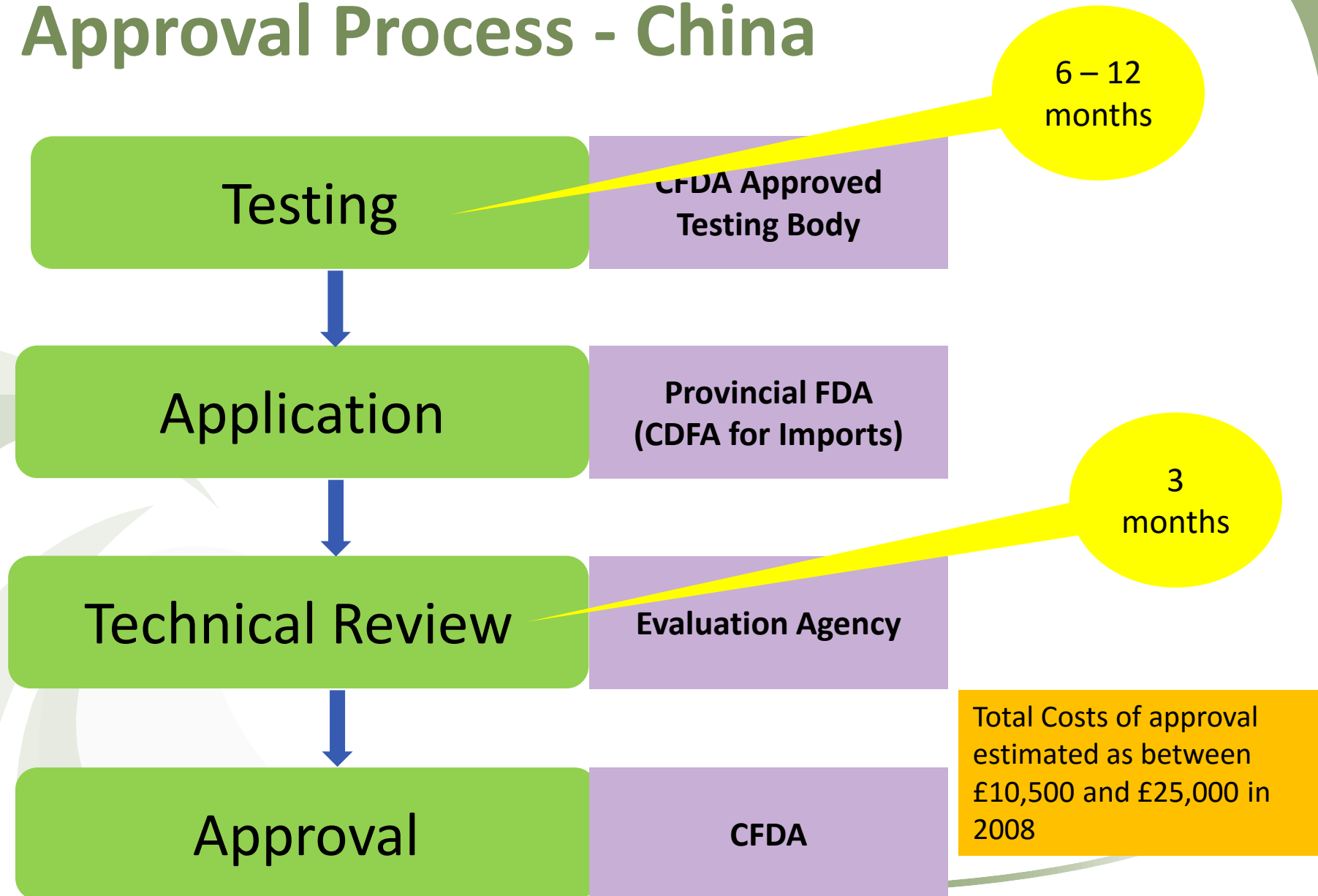
Help release lead from the body

Clear the pharynx (throat)

Adjusting intestinal bacterial flora

Assisting the protection of gastric mucous membrane

# Approval Process - China



# Main Tests and Evaluations

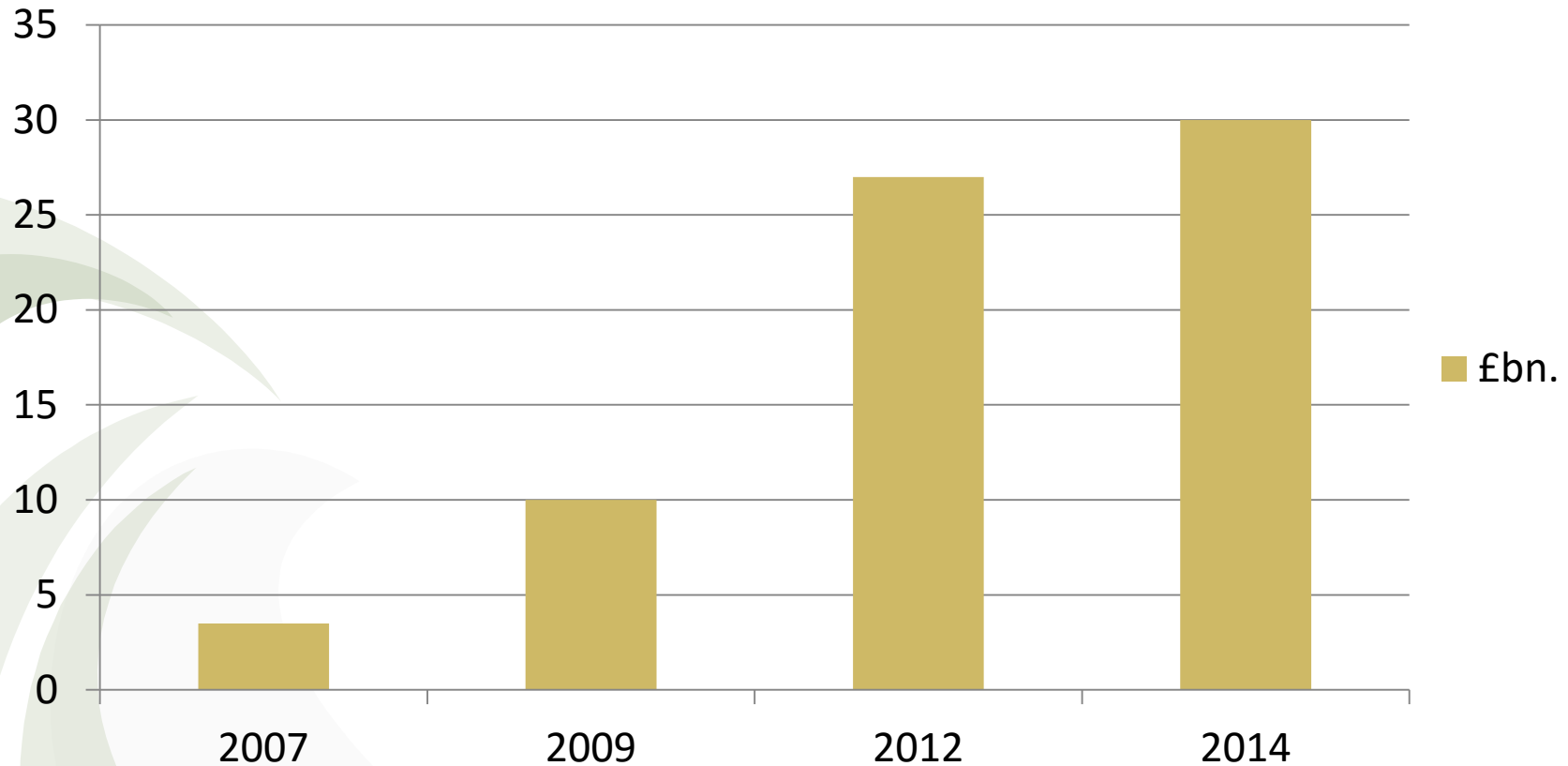
- ❖ Toxicological, physical and chemical, microbiological and quality stability
- ❖ Functional evaluation - Scientific substantiation is the key for efficacy claims
  - ❑ Depending on the category the type of trials required may be
    - ✓ Animal (n = 7) e.g. increasing bone density, or enhancement of the immune system:
    - ✓ Human (n = 4) e.g. eliminating skin cloasma (melasma);or
    - ✓ Both Animal and Human trials (n=15) e.g. adjusting intestinal bacterial flora
- ❖ Quantitative test of level of active/marker ingredients
- ❖ Tests of nutrient content

# Technical Review - Key issues

- **Safety:** focusing on novel ingredients/raw materials and formula
- **Efficacy confirmation:** scientific substantiation, including functional tests ·
- **Quality control:** contents of active/marker ingredients and product standards - challenges of complex and diverse factors affecting stability and consistency
- **Quantitative assessment:** safety usage/relationship between dosage and efficacy
- **Assessment of formulation/combination:** challenges of scientific evidence, interaction, etc.

# Market size 2007 to 2014 (£bn.)

£bn.



# Market size 2007 to 2014

## Product approval numbers and top categories

- ❖ Between **1996 and mid-2007**, approx. **8,200** health food products were approved by the Ministry of Health and the CFDA – at the end of that period it was estimated only about 30% of the approved products were still on the market

Source: Hong Kong Trade Development Council (HKTDC), 2015

- ❖ As of **mid-July 2015**, the CFDA had approved a total of **15,802** health food products
  - ❖ Of these **95%** (n=15,063) were **made in China** and **5%** (n=739) were **imported**
  - ❖ It is estimated that functional foods account for about 65%, with nutritional supplements accounting for the remaining 35%
  - ❖ No figures are available for the number of these products that are still on the market there.
- ❖ Top Categories were regulating the immune system, alleviating physical fatigue, anti-ageing (likely involving multiple categories) and assisting blood lipids reduction

Source: Hong Kong Trade Development Council (HKTDC), 2015

# Some Conclusions and Future Prospects

- The scientific basis for the benefits of probiotics have been recognised for over 100 years but the regulatory status has not evolved at the same rate as the science
- Though all regulatory systems we have looked at use scientific validation for health claims the outcomes differ
  - This is likely due to different levels or standards for approval being applied
- Probiotic related claims fare better in Japan and China than in the US and the EU - well they could hardly fare worse!
- Canada recognises 17 probiotic species; permits specified non-strain health claims; and allow strain specific claims – though none of the latter are approved – at least as yet
- Will the future for probiotics be in foods or sold as supplements – this is likely to be decided for individual markets
- In the markets of developed countries, leading probiotic brands may continue to grow
- What will happen in developing markets? How will new products be promoted?
- In countries where regulatory challenges are greatest, will the use of scientific conferences aimed at health professionals substitute/replace claims in labelling and advertising?

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**Yakult**



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While I have used information and material supplied by these colleagues, the opinions, views and conclusions expressed are mine alone and do not purport to be theirs





**Thank you for your kind attention**

**Any Questions?**

**But not too difficult please!**