

Regulatory Roundtable

The Brazilian Experience

Better Foods for Better Health

Les Pensières, April 8th 2016

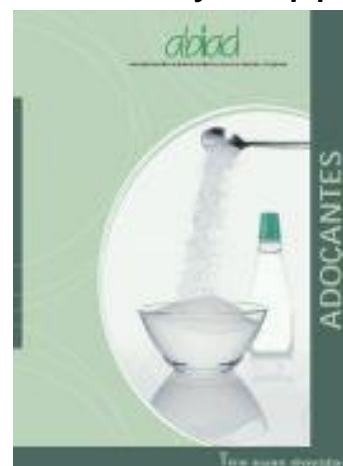
Carlos Eduardo Gouvêa

ABIAD



Associação Brasileira da Indústria de Alimentos para Fins Especiais e Congêneres

- Association founded in 1986, with more than 45 members with a clear focus on Special Purpose Food Products, being their representative before:
 - ANVISA
 - Ministry of Health
 - Ministry of Agriculture
 - INMETRO
 - Congress
- Geographical scope: Brazil, but also active in international fora
- Affiliated to IADSA – International Alliance of Dietary Supplement Associations
- **Working Groups:**
 - WG Supplements,
 - WG Enteral Nutritional
 - WG Infant Nutrition
 - WG Sweeteners / Diet & Light
 - WG Functional Foods
 - WG Sports Nutrition

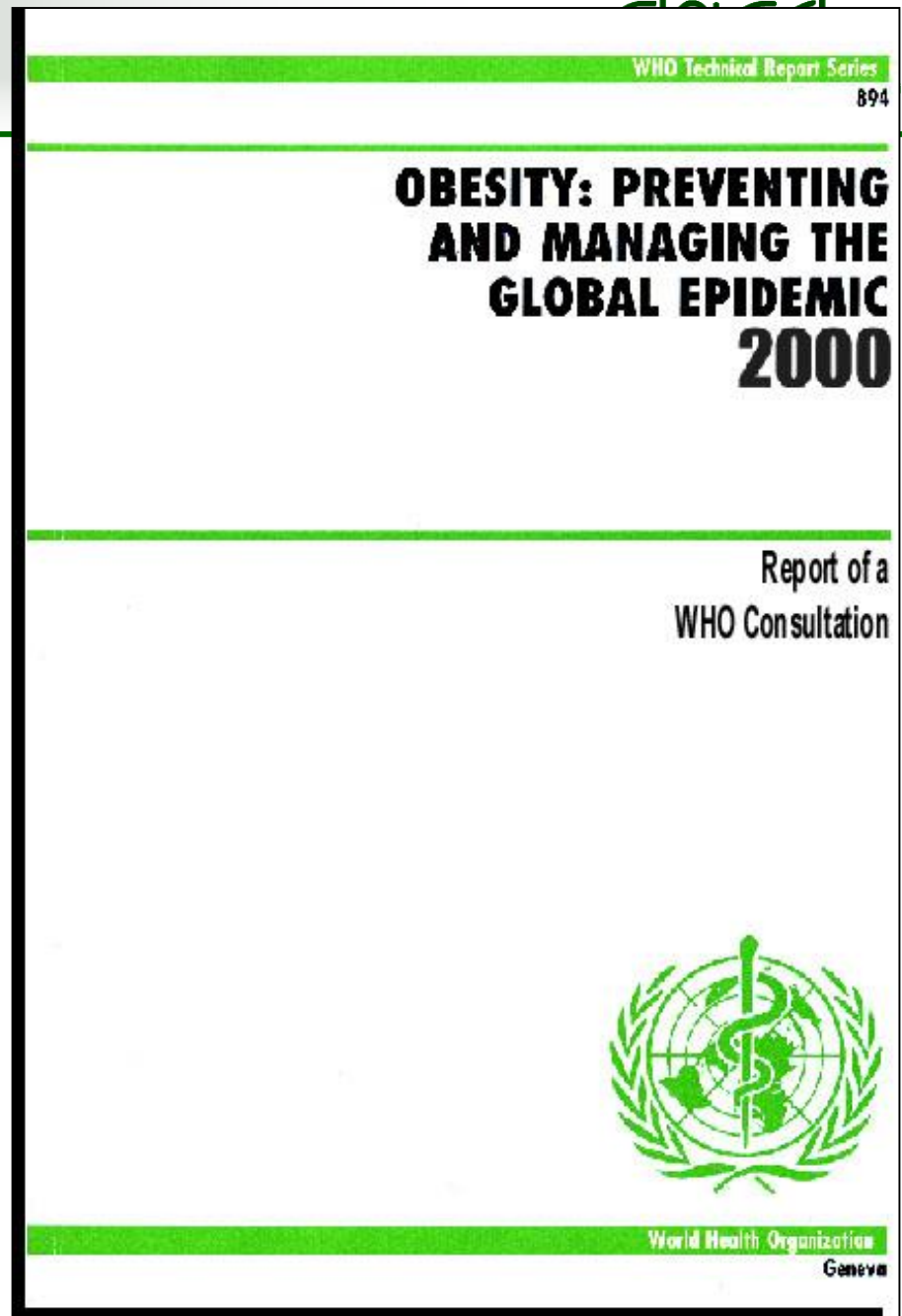


GLOBAL HEALTH RISKS

Mortality and burden of disease attributable to selected major risks

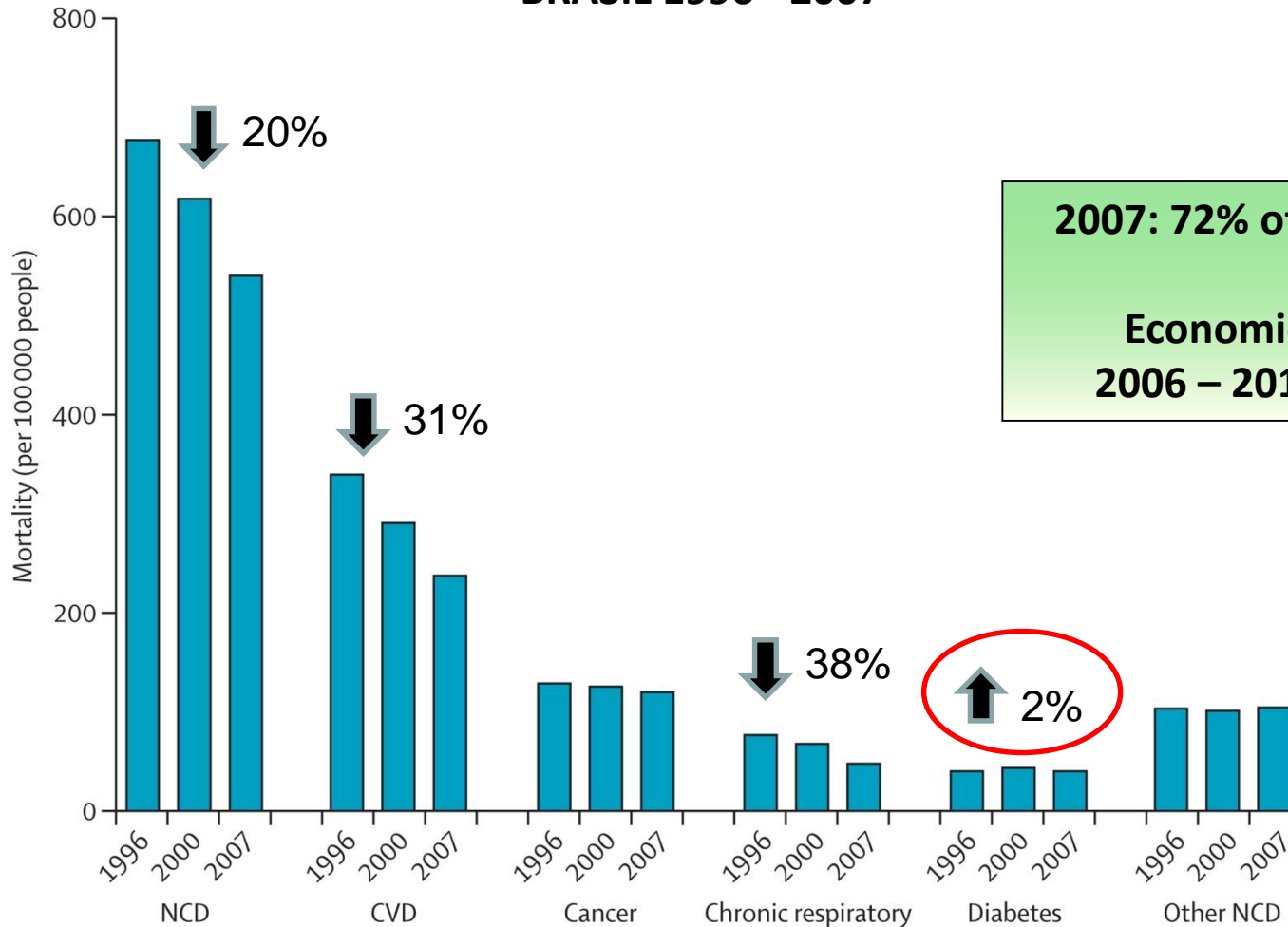


Obesity:
becoming a serious
local issue!



Evolution of Mortality x NTCD*

BRASIL 1996 - 2007



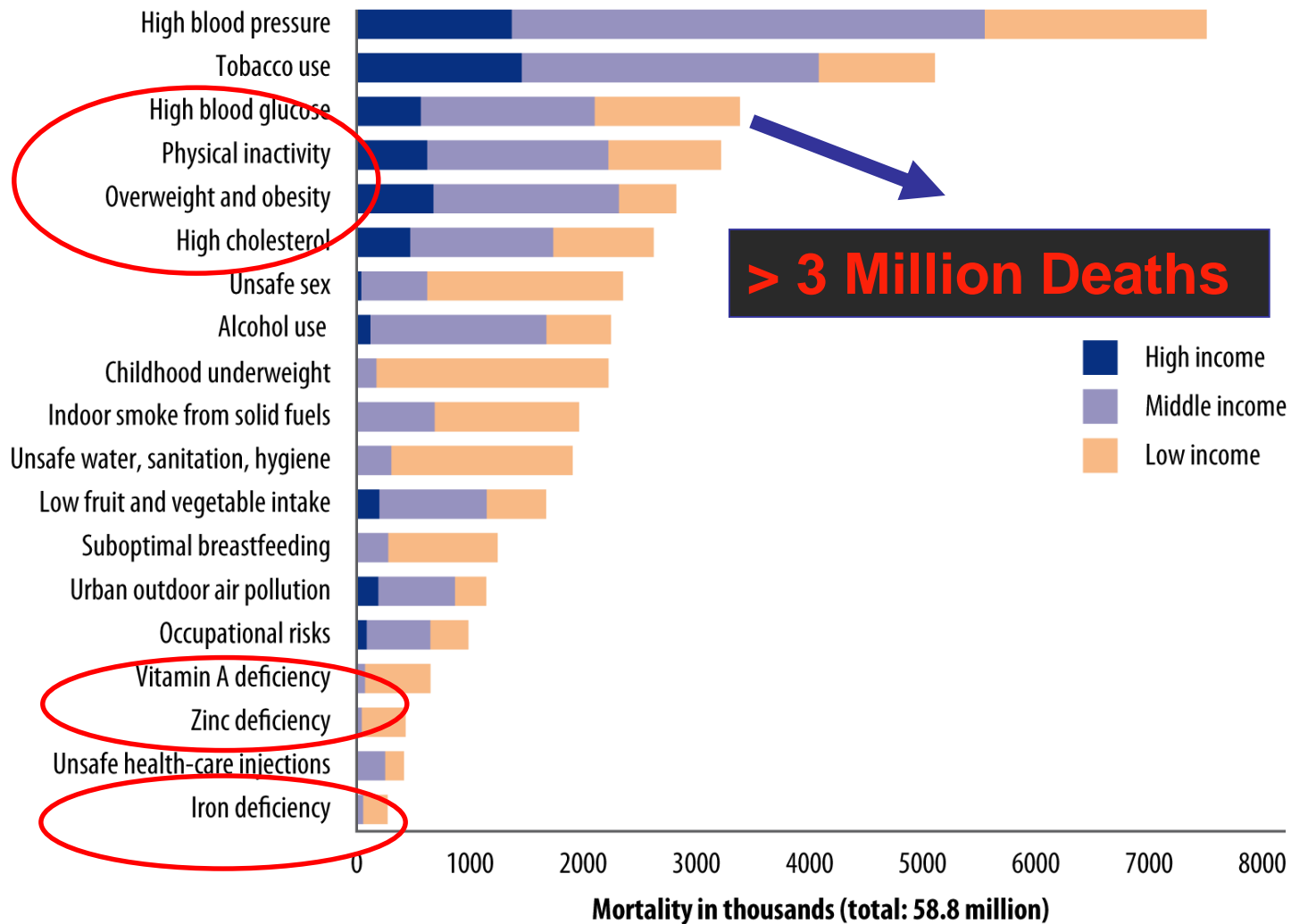
2007: 72% of the deaths = NTCD

Economic Loss (estimate)
2006 – 2015 US\$ 4,18 billion

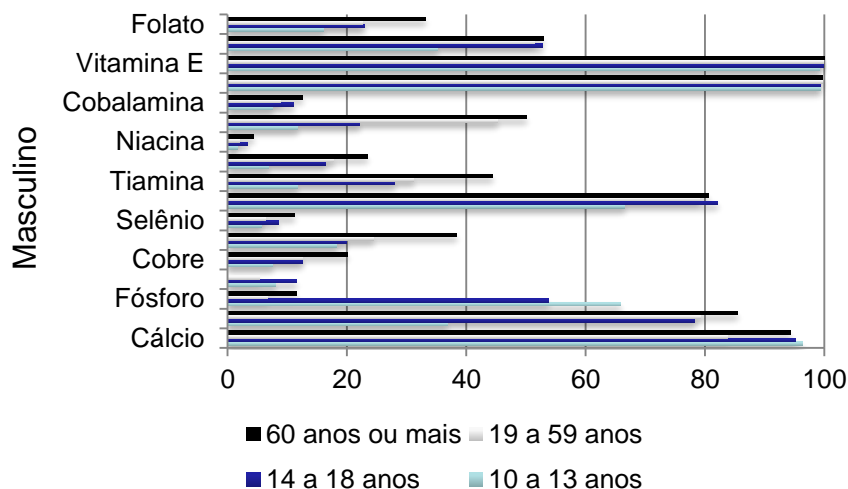
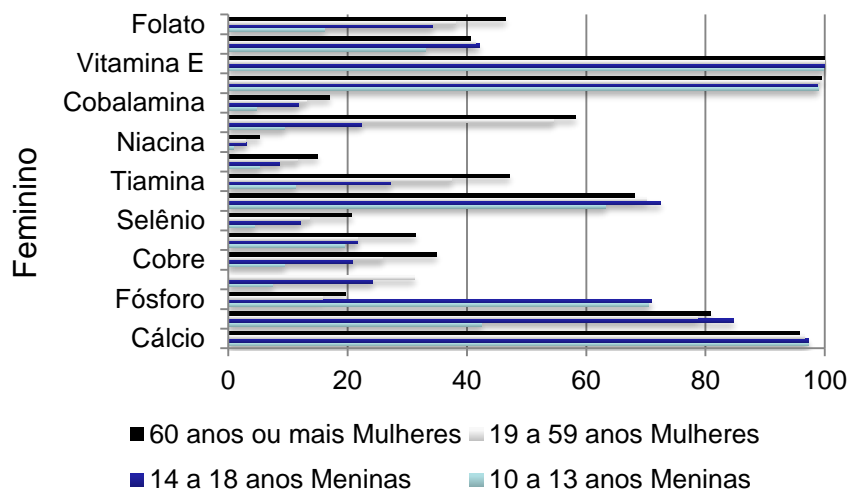
Source: Schmidt, MI; Duncan, BB; Silva, GA; Menezes, AM; Monteiro, CA; Barreto, SM; Chor, D; Menezes, PR. **Chronic non-communicable diseases in Brazil: burden and current challenges.** The Lancet, Vol 377: 1949-1961 (2011).

* Non Transmissible Chronic Diseases

Deaths related to 19 main factors, according to income level



Prevalence of **INADEQUATE** consumption of Micronutrients (%)



- Increase in the indexes of overweight and obesity;
- **Inadequate intake of micronutrients**, specially, Vitamins A, C, D, E, Calcium, Phosphorus and Magnesium;
- Inadequate intake of sugars, sodium, saturated fats and fibers
- **Low consumption of fruits and vegetables**

Summary: POF

SOURCE: IBGE, 2010. Pesquisa de orçamentos familiares, 2008 – 2009. (Survey on Family Budgets. Analysis of personal food consumption)



ANVISA

The National Agency of Sanitary Surveillance

THE ROLE OF REGULATION



ANVISA

Agência Nacional de Vigilância Sanitária

Boas Práticas Regulatórias



Complexity and Areas of Scope



Foods



Cosmetics



Sanitizing



Tobacco



Toxicology



Healthcare Services



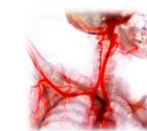
Drugs



Medical Devices



Laboratórios



Blood, Tissues and Organs



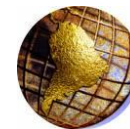
Post Market Surveillance



Advertising Monitoring



Ports, Airports and Borders



International



Coordination of the Natl Surveillance System

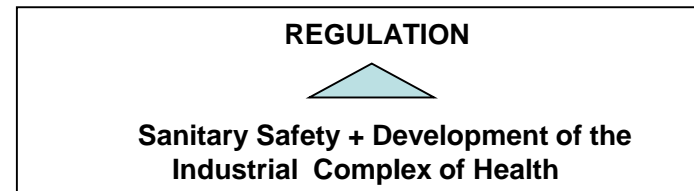
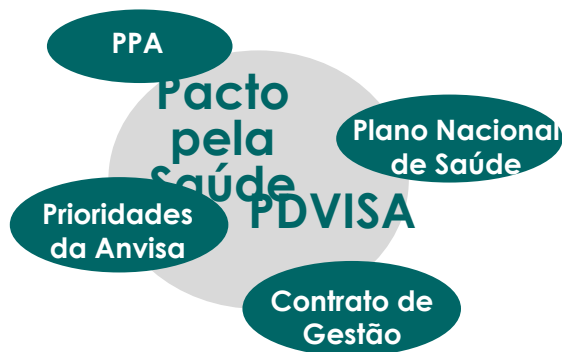


Boas Práticas Regulatórias



Strategic Alignment with Public Policies

- **Regulatory Policy** (PRO-REG: Program of Strengthening of Institutional Capacity for the Management of Regulation, coordinated by Civil House of the Presidency of the Republic)
- **Program More Health** (action of increasing the predictability of sanitary regulation within the Brazilian Healthcare System - SUS)



The ANVISA regulation must conciliate the objectives of health protection and social and economic development of the country

Anvisa competencies:



Actions of sanitary surveillance are related to the safety and quality of industrialized products



DECRETO-LEI N. 986/69

REGULAMENTOS TÉCNICOS DE IDENTIDADE E QUALIDADE
TEMAS HORIZONTAIS

Alimentos para atletas	Procedimentos de registro e dispensa da obrigatoriedade Rotulagem Geral de Alimentos Rotulagem Nutricional de Alimentos Informação Nutricional Complementar Embalagem e materiais em contato com alimentos Contaminantes Matérias Macroscópicas e Microscópicas Microbiologia de Alimentos Aditivos Alimentares e Coadjuvantes de Tecnologia Boas Práticas de Fabricação Recall Avaliação de segurança Publicidade e propaganda
Água Mineral e Nat. / envasadas/ Gelo / adici. de Sais	
Alimentos para fins especiais - geral	
Alimentos para controle de peso	
Alimentos para gestantes e nutrízes	
Alimentos para Nutrição Enteral	
Alimentos para atletas	
Alimentos à base de cereais para alim. infantil	
Alimentos de trans. p/ lact. e ccas. de 1.a infância	
Alimentos com aleg. prop. funcional e/ ou Saúde	
Fórmulas infantis	
Café, Cevada, Chá, Enva-Mate e Produtos Solúveis	
Chocolate e Produtos de Cacau	
Especiarias, Temperos e Molhos	
Balas, bombons e gomas de mascar	
Gelados Comestíveis e Prep. para Gelados Comestíveis	
Novos Alimentos e/ ou Ingredientes	
Mist. p/ o preparo de alim. e Alim. prontos p/ o cons.	
Óleos vegetais, gorduras vegetais e creme vegetal	
Produtos de cereais, amidos, farinhas e farelos	
Produtos protéicos de origem vegetal	
Produtos protéicos de origem vegetal	
Produtos de vegetais, s de frutas e cogumelos	
Palmito em conserva	
Sal	
Sal hipossódico/Sucedâneos do Sal	
Suplemento vitamínico ou mineral	

PRODUCT REGISTRATION - ANVISA



Agência Nacional
de Vigilância Sanitária



"Notification"
- Communication of
Beginning of
Production / Import

**Registration
(5 years)**
- Published at the
Official Gazette

PRODUCT REGISTRATION - ANVISA

Food Products to be necessarily registered

(Annex II - RDC 27/10)

- ✓ Food with Health/Functional Claim
- ✓ Novel Foods
- ✓ Infant Food
- ✓ Enteral Nutrition
- ✓ Packaging / New Technologies
- ✓ Bioactive Substances and Isolated Probiotic with Functional Claim



PRODUCT REGISTRATION - ANVISA

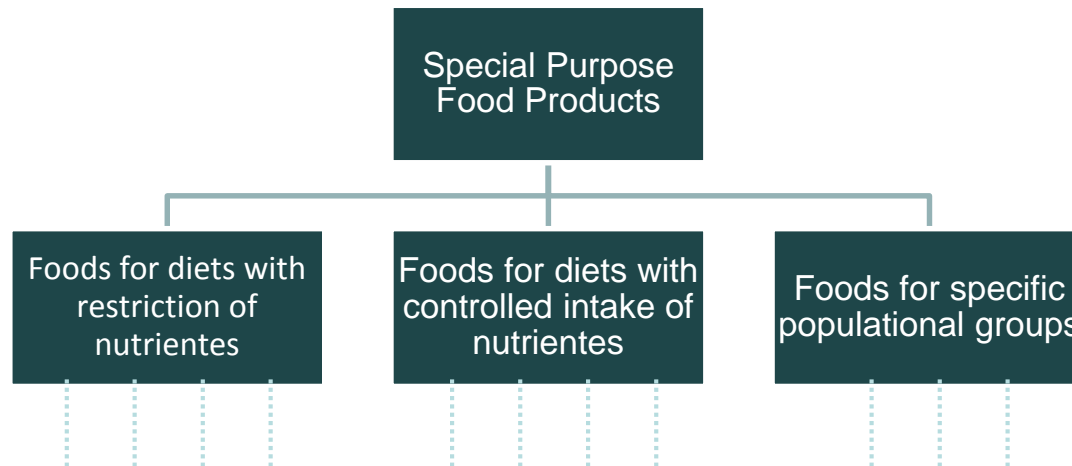
Food Products which are not subject to registration (Annex I - RDC 27/10)

- ✓ Sports Nutrition
- ✓ Vitamin and/or Mineral Supplements
- ✓ Biscuits, candies, gums, chocolates
- ✓ Food Additives
- ✓ Foods for Weight Control
- ✓ Foods for diets with restriction of nutrients
- ✓ Foods for pregnant women and nursing mothers
- ✓

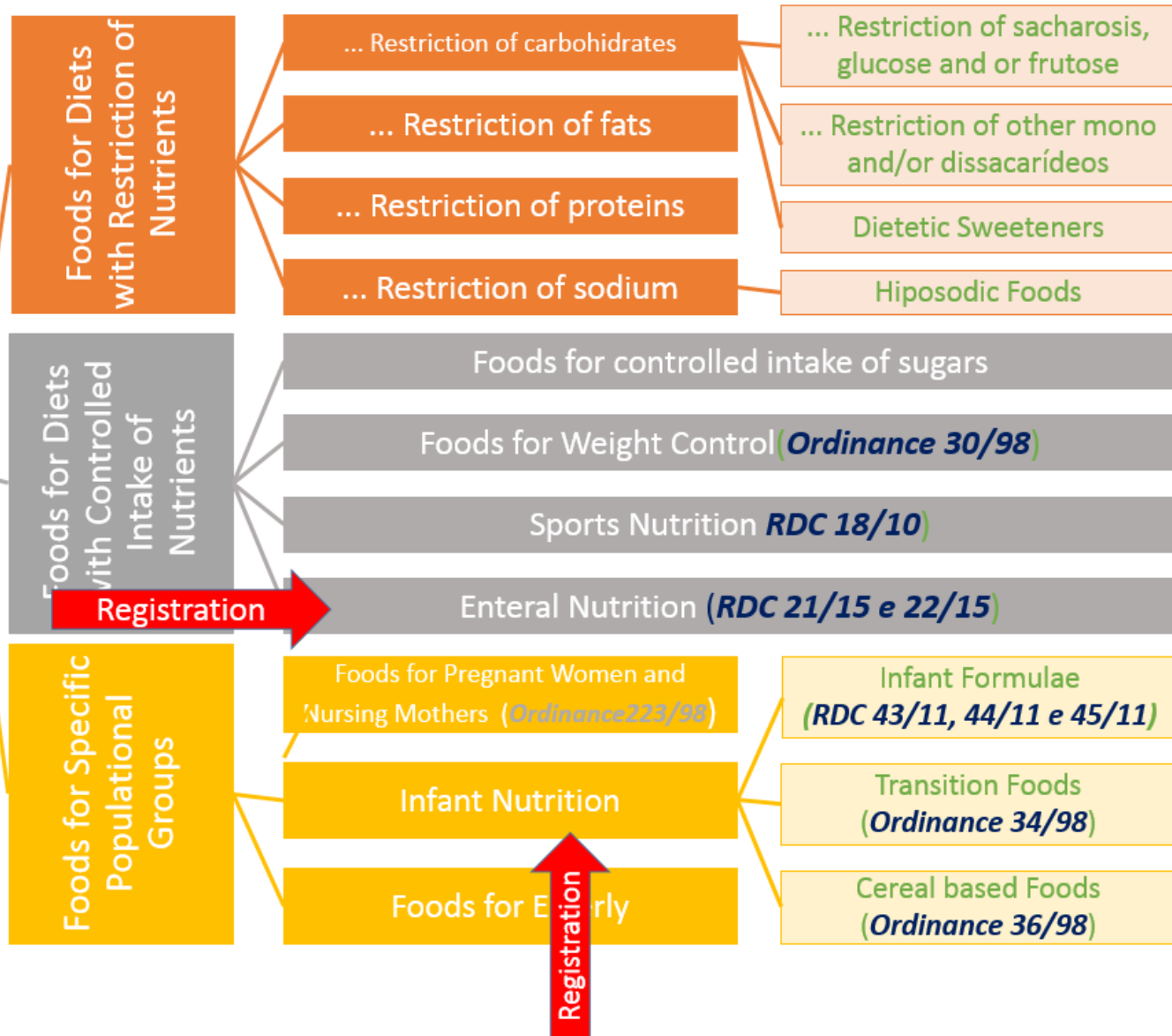


Regulation for Special Purpose Food Products

The Ordinance SVS/MS # 29/98 is a complex technical rule that forms the basic Brazilian regulatory structure of the foods elaborated to comply with the needs of people in specific physiological or metabolic conditions (Special Purpose Food Products).



Special Purpose Food Products
Ordinance 29/98



Information of the Functional Claims

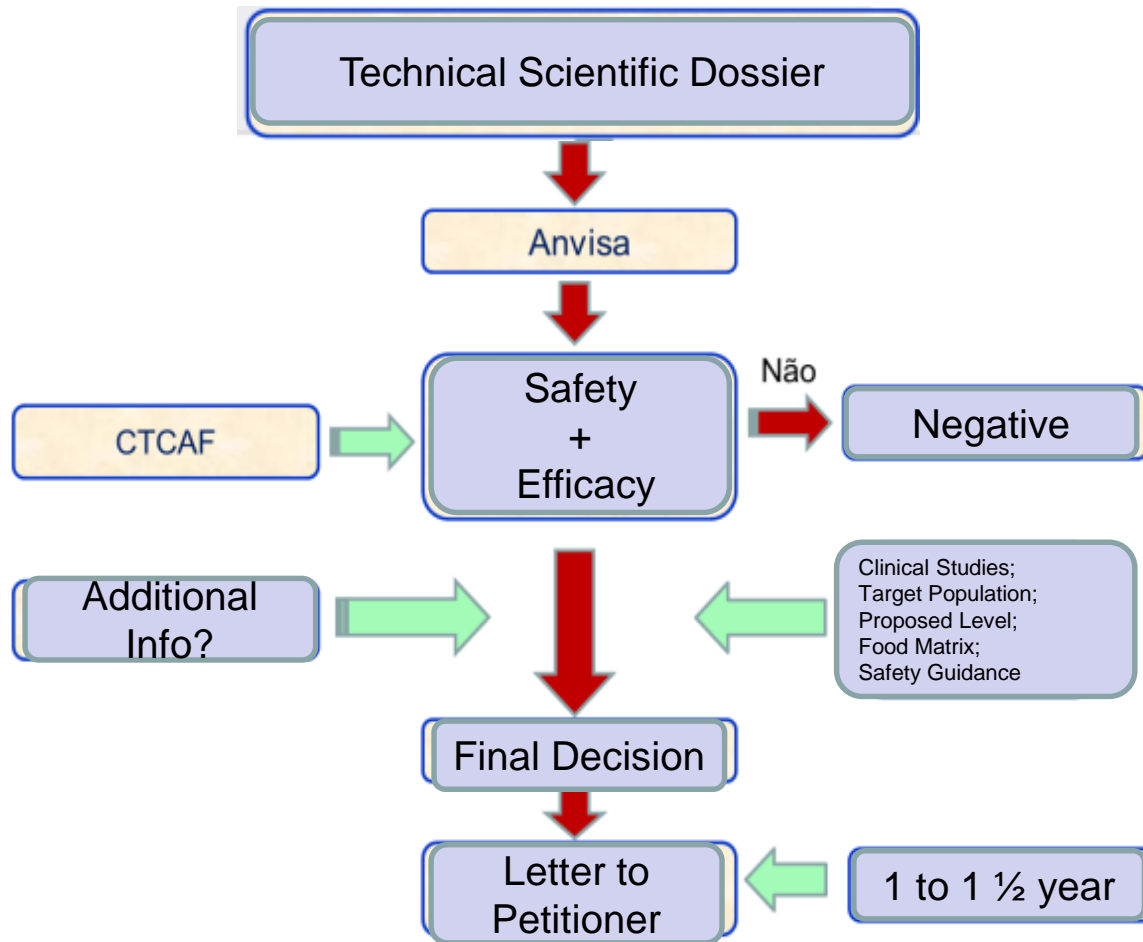
- In accordance with the Resolution 19/99:

“Any information or functional and/or health property of a food, conveyed by any communication means, can not be different in its meaning from the one approved to be part of its label/packaging.”

Guide for Evidence of Safety of Foods and Ingredients

- February/2013
(<http://portal.anvisa.gov.br>)
- Result of over a decade of experience
- Support by CTCAF (Technical-Scientific Committee on Assessment in Functional and Novel Foods)
- Improve guidance for the industry
- Improve the quality of processes
- Allow a quicker and more transparent evaluation





Positive List of Nutrients and Non-Nutrients with standardized claims and requirements

- Fatty Acids
 - EPA / DHA
- Carotenoids
 - Licopeno
 - Lutein
 - Zeaxantine
- Soy Protein
- Probiotics*
- Prebiotics (Fibers)
 - Food Fibers
 - Beta Glucan (in oat bran, oat flakes and oat flour)
 - Resistent Dextrin
 - FOS
 - Guar Gum
 - Inulin
 - Lactulose
 - Polydextrose
 - Psyllium
 - Chitosan
 - Phytosterols
 - Polyols



Source:

<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Alimentos/Assuntos+de+Interesse/Alimentos+Com+Alegacoes+de+Propriedades+Funcionais+e+ou+de+Saude/Avaliacao+de+seguranca+e+comprovacao+de+eficacia>

Example of Claim

FRUTOOLIGOSACHARIDE – FOS

Claim

“The Fructooligosacharides – FOS (prebiotic) contribute for the equilibrium of the intestinal flora. Its consumption must be associated to a balanced nutrition and healthy life habits”.

Specific Requirements

This claim can be used if the recommendation of daily consumption of the product ready to be used supplies a minimum of 5 g of FOS. The portion should supply at least 2,5 g of FOS.

At the nutritional table it must be declared the quantity of “fructooligosacharides (FOS)”, below food fibers.

The use of the ingredient should not go over 30 g in the daily recommendation of the product ready to use, as per indication of the manufacturer.

When presented isolated in capsules, tablets, pills, powder and similar presentations, it has to contain on the product label the following information, properly highlighted:

“The consumption of this product must be made together with the ingestion of liquids”.

Probiotics

In the case of Probiotics, the functional property or health claims must be proposed by the company and it will be assessed, case by case, taking into consideration the definitions and principles established in Resolution # 18/99.

Specific Requirements:

To prove the safety and efficacy of the products, it must be presented at least, the following information:

1. Characterization of the micro-organism

- Identification of gender, species and strain. The nomenclature should be aligned with the International Code of Bacteria Nomenclature.
- Information about the deposit of the micro-organism strain in a culture bank internationally known.
- Origin and way it was obtained, including the information if the micro-organism is GMO
- Production of toxins and bacteriocines.

2. Profile of resistance to antimicrobials and information about the genetic basis of antimicrobial resistance, according to the methodology described by EFSA

3. Determination of haemolytic activity for the species with haemolytic potential

4. Studies available in the literature that describe the adverse effects observed with the specific strain (e.g.: case reports)

5. Demonstrations of efficacy

6. Viability

De: Alimentos [mailto:alimentos@anvisa.gov.br]
Enviada em: quarta-feira, 6 de abril de 2016 09:09
Para: Tatiana da Costa Raposo Pires
Assunto: ENC: ABIAD / Ofício 127-2016 ANVISA / Probióticos

Prezada Tatiana,

Desde fevereiro deste ano, a GGALI tem adotado diversas medidas visando a organização, harmonização e transparência dos procedimentos de análise de processos de probióticos.

Paralelamente, estamos buscando aprofundar nossos conhecimentos e elaborar um protocolo (ou Guia) que estabeleça mais detalhadamente as informações que devem ser apresentadas pelo setor produtivo para submissão das petições à Anvisa.

Nossa intenção é iniciar com mais intensidade a elaboração desse protocolo no mês de maio, portanto, será um bom período para que as Associações apresentem esse material.

Atenciosamente,

Thalita Antony de Souza Lima

Gerente-Geral de Alimentos

Agência Nacional de Vigilância Sanitária – ANVISA

[\(61\) 3462-6514/4194](tel:(61)3462-6514/4194)

Política Nacional de Alimentação e Nutrição e o setor industrial

Eduardo A. F. Nilson
Coordenação-Geral de Alimentação e Nutrição
Ministério da Saúde

Discussões atuais:

- **Agenda prioritária da CGAN:** promoção da alimentação saudável.
- **Revisão da PNAN:** reforço à vigilância sanitária, promoção da alimentação saudável, à nutrição na atenção à saúde e à segurança alimentar e nutricional.
- **Plano de Enfrentamento das Doenças Crônicas Não-Transmissíveis:** Vigilância (Sisvan, inquéritos e pesquisas), Promoção da Saúde e Atenção à Saúde.
- **Câmara Setorial de Alimentos (Anvisa e MS):** Boas Práticas Nutricionais, educação para o consumo, promoção da alimentação saudável .
- **Negociações com setor industrial:** reformulação de produtos (melhoria do perfil nutricional: sódio, gorduras e açúcar).





The future is in our hands...

abiad

Associação Brasileira da Indústria de Alimentos para Fins Especiais e Congêneres

Obrigado!

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www.abiad.org.br