

# **Strengthening Regulatory Capacity –**

**Risk factors for noncommunicable diseases (PAHO / WHO)**



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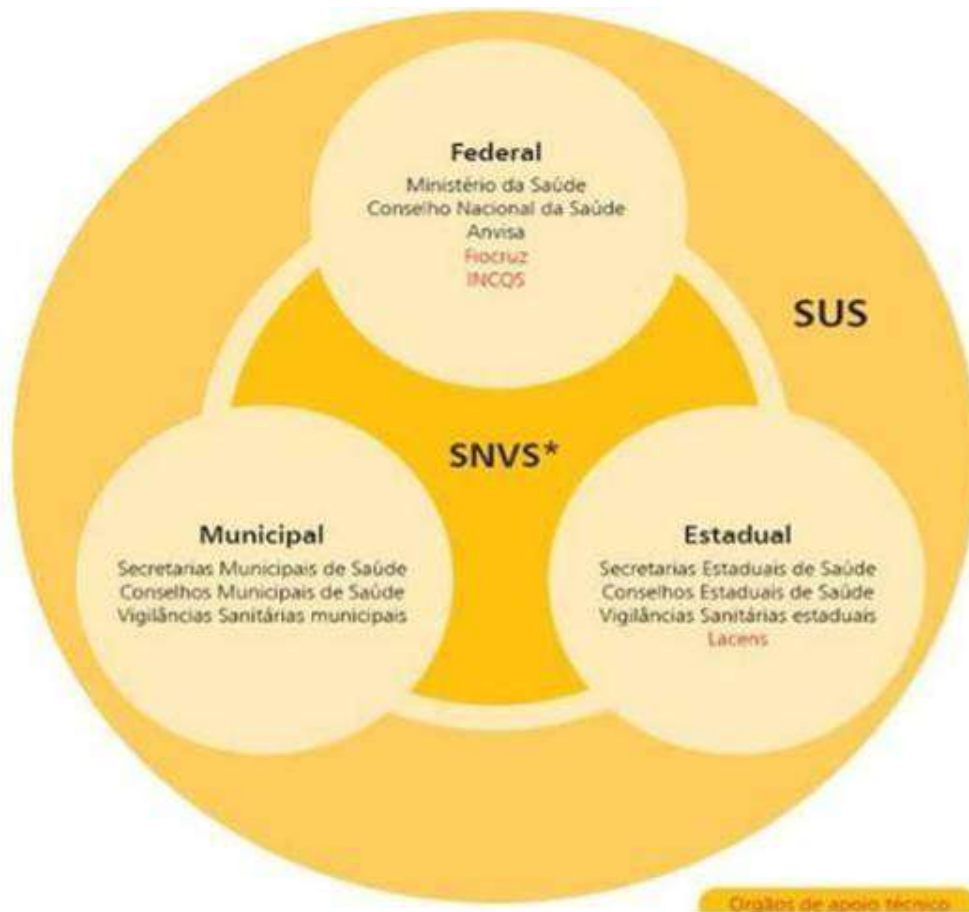
**Washington – November 2014**



**Agência Nacional  
de Vigilância Sanitária**

**[www.anvisa.gov.br](http://www.anvisa.gov.br)**

# ANVISA



- First Regulatory Agency of the social area in Brazil - created by Law No. 9,782, of January 26, 1999;
- Governmental regulatory body with independency under special regime, liaison to the Ministry of Health;
- Coordinator of the National Health Surveillance System;
- Performance goals agreed with the Ministry of Health and regulated under the Management Agreement;
- Presence in all States and Federal District: 83 Posts of Health Surveillance in Brazil.
- Staff: More than 3000 workers

# **Regulation in ANVISA**

# The Regulatory Process

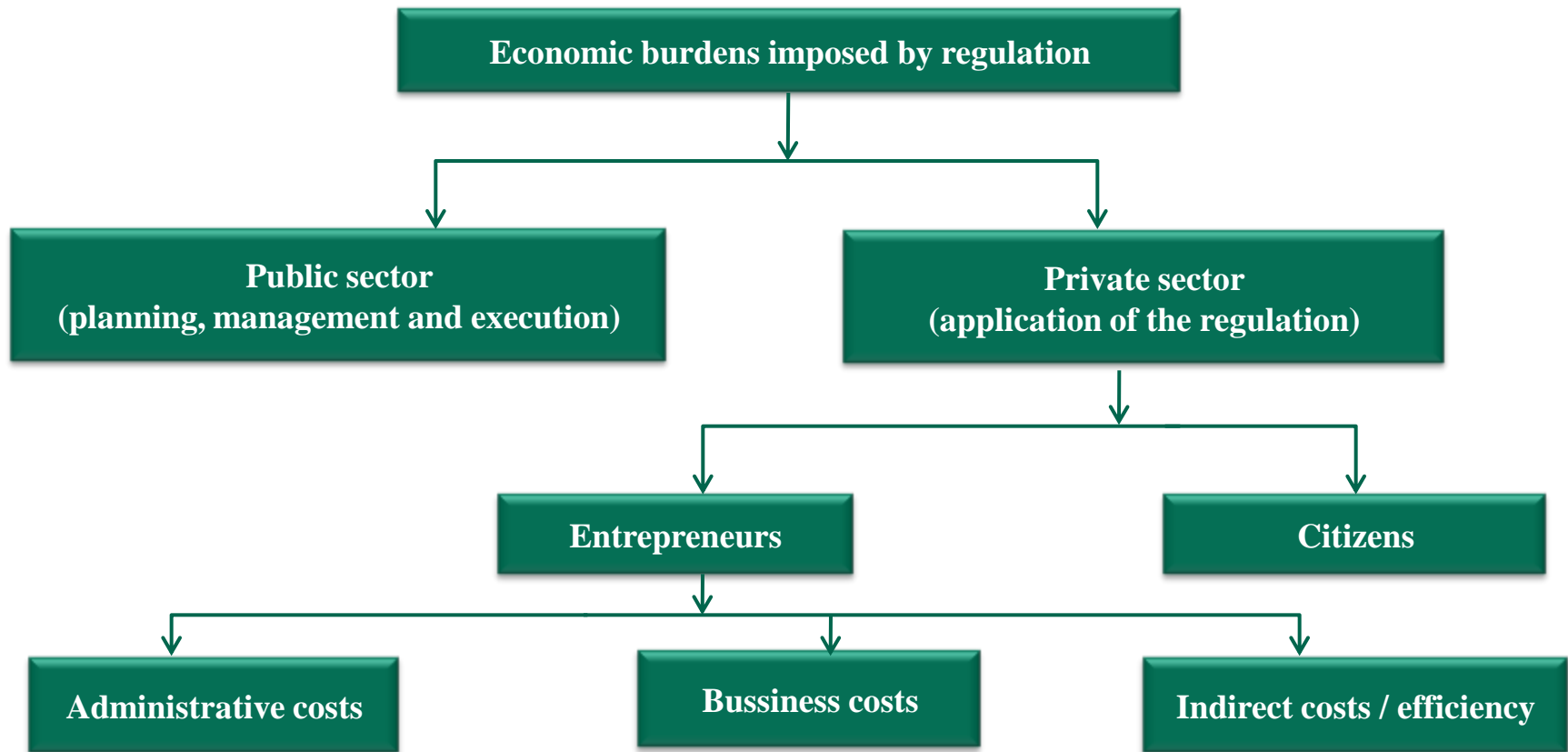
- In the field of health monitoring, regulation can be understood as the mode of state intervention to prevent possible damage or health risks to the population.
- Acts through the regulation, registration and authorization, control, monitoring and surveillance of the relations of production and consumption of goods and services related to health.
- Thus, sanitary regulation contributes to the proper functioning of the market, eliminating its flaws, giving increased predictability, transparency and stability to the regulatory process and actions in the field of activity of the Agency in order to provide a safe environment for the population and conducive to social and economic development of the country.

# **Strengthening of the ANVISA Regulation**

- Improving the regulatory activity thus permeates the improvement of regulation and consequent enhancement of the existing relations between the Agency process, society and the productive sector in the performance of this award, as well as with other actors SNVS, organs and institutions of power public in the various spheres of government.
- ANVISA has developed several initiatives aimed at improving the quality of health regulation, establishing processes and procedures best suited to the challenges associated with the current context of economic and social development of the country.
- Moreover, it has also sought the betterment of social participation channels and the implementation of tools and practices that provide greater transparency and improved management of regulation, such as Regulatory Agenda, the public consultation mechanisms and the Regulatory Impact Analysis (AIR).

# Regulatory Macroprocess

## Nature of regulatory costs



# Regulatory Macroprocess

## Examples of regulatory costs

### Consumers

- Prices, variety, availability, quality
- Security and risk, damage
- Access to information

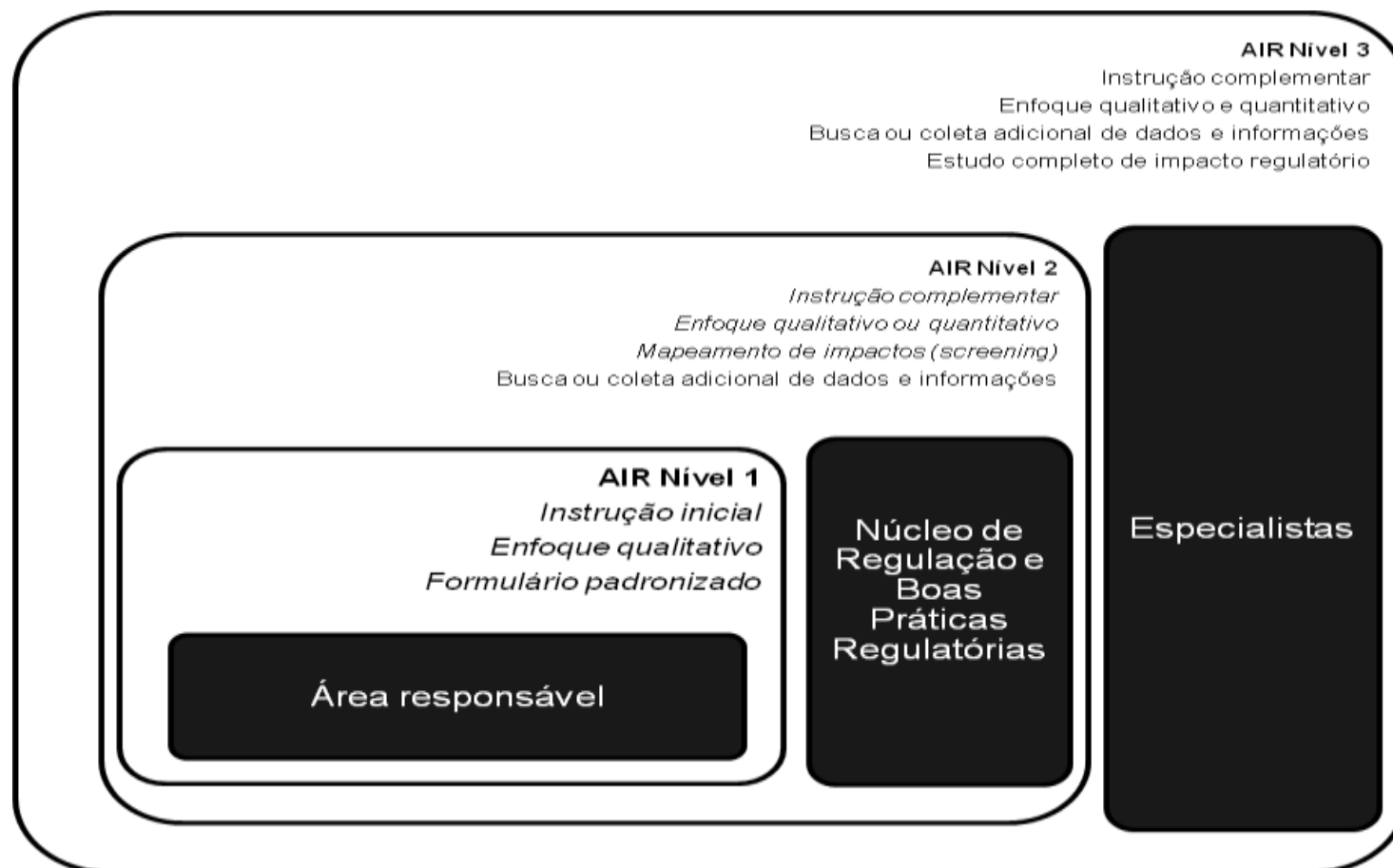
### Government

- Administrative costs
- Maintenance
- Supervision

### Business community

- Operational and production costs
- Perception of risk
- Access to funding
- Innovation

# Regulatory Macroprocess



# Instruments of accountability, transparency and participation in ANVISA

- Social control of SUS
- **Management contract**
- Management report
- ANVISA Advisory Council
- Ombudsman
- Public hearings of Congress
- Activity Report of the National Congress
- Partnerships with Consumer Protection
- **Regulatory agenda**
- Sectoral Chambers
- **Public Consultations**
- **Public Hearings**
- Forums Health Surveillance
- Charter of Services to Citizens
- Access to information on the Internet
- Call Center 0800
- Public meetings of the board

# ANVISAs Good Regulatory Practice

## Instruments used:

Guide to Good Regulatory Practice;

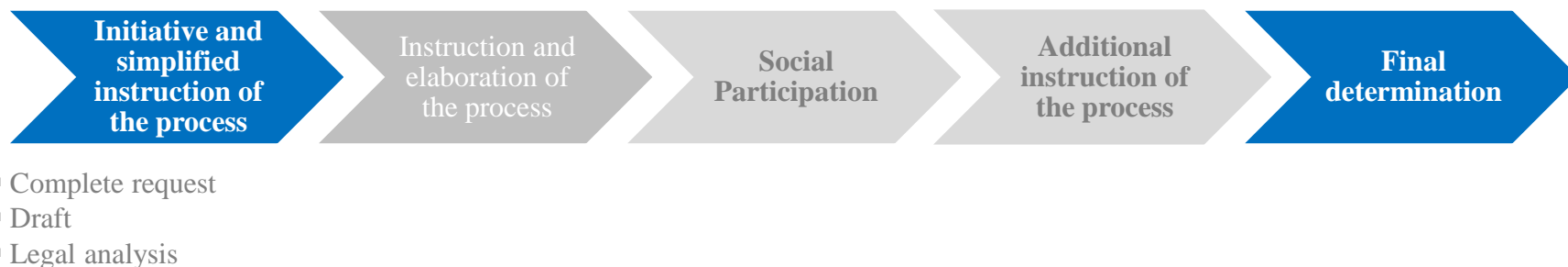
- Regulatory Agenda;
- Publication of Regulatory Initiative;
- Regulatory Impact Analysis (RIA);
- Openness of decision making.

# Stages of the regulatory process in ANVISA

## ORDINARY WORKFLOW



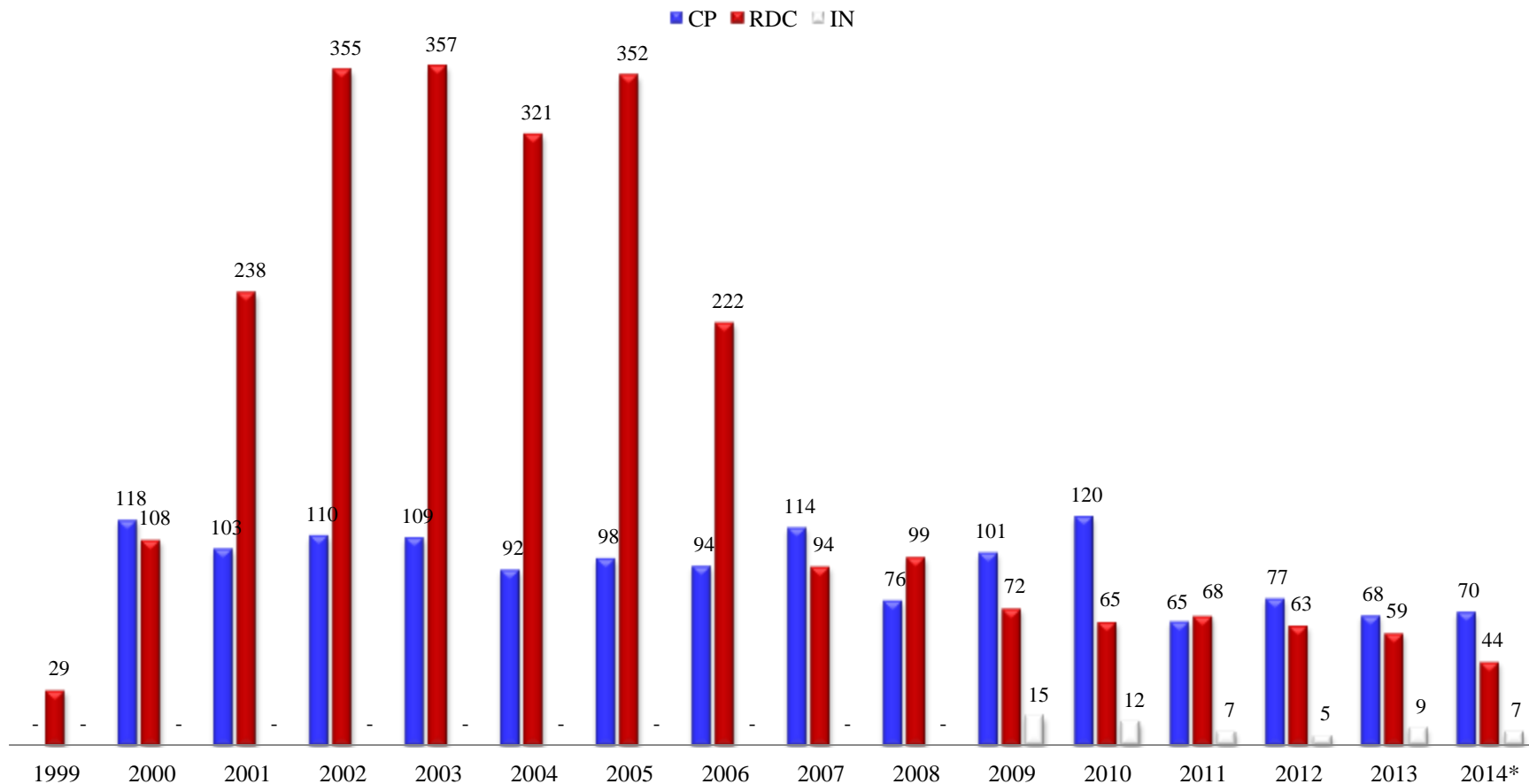
## SPECIAL WORKFLOW



# Public consultation process in ANVISA

- The Public Consultation:
- ✓ It is one of the main stages in the regulatory process conducted by ANVISA.
- ✓ The main purpose is to obtain elements and information from society for the decision-making process in the Agency.
- ✓ Allows the elaboration of normative acts in a democratic and transparent manner favoring the whole society.
- ✓ With the implementation of the **Program for Improvement of the Regulatory Process** (RMP), there was the standardization of procedures for consultation, in addition to establishing routines and mechanisms to encourage participation and to provide answers to society.

## Public consultations (CP), Collegiate Board Resolutions (RDC) and normative instructions (IN) issued by ANVISA, by year (1999-2014 \*)



# Public Hearings

- The regulatory process may be preceded by a public hearing, depending on the specific situation and the relevance of the topic. A public hearing is compulsory in case of a Act proposition issued by the Agency.
- Among the goals of the Public Hearing, the most relevant are:
  - ✓ Collect inputs, expertise and information for decision making.
  - ✓ Provide economic agents, consumers and users the opportunity to clarify or reinforce opinions and suggestions
  - ✓ Identify in the broadest possible manner, all relevant aspects of the subject matter of the Public Hearing
  - ✓ Give publicity, transparency and legitimacy to ANVISA regulations.

# ANVISAs website

<http://portal.anvisa.gov.br>

Email: [gggreg@anvisa.gov.br](mailto:gggreg@anvisa.gov.br)

BRASIL Acesso à Informação #CancerDeBomDia #OuvindoRosa2014 Participe

ANVISA Agência Nacional de Vigilância Sanitária English / Português

INÍCIO A AGENCIA SALA DE IMPRENSA SERVIÇOS ALIMENTOS INFANTIL REGULAÇÃO EDUCAÇÃO E PESQUISA CRIAÇÃO / PROFISSIONAL DE SAÚDE SETOR REGULADO

**Proteção à Saúde**

- Agrrotóxicos e Toxicologia
- Alimentos
- Cosméticos
- Derivados do Tabaco
- Insarvos Farmacêuticos
- Laboratórios
- Medicamentos
- Partos, Amparos e Fronteiras
- Produtos para a Saúde
- Saneantes
- Sangue, Tecidos e Órgãos
- Serviços de Saúde

**Pós - Comercialização / Pós - Uso**

- Vigipós
- Fiscalização
- Câmara de Regulação de Mercado de Medicamentos - CMED
- Tecnovigilância
- Hemovigilância
- Farmacovigilância
- Dados Qualitativos

**Destaque**

Anvisa prioriza análise de novos medicamentos para hepatite C. Tendo em vista as solicitações de informações recebidas pela Anvisa sobre o procedimento de avaliação de novas terapias para o tratamento da hepatite C no Brasil, a Agência informa que está avaliando novas moléculas para o tratamento das hepatites virais.

**Consulta Produtos**

Tire suas dúvidas sobre produtos e empresas. [ACESSAR AQUI](#)

**Notificação - Notivisa**

Relata aqui problemas encontrados no uso dos produtos sob vigilância sanitária. [ACESSAR AQUI](#)

**3ª PESQUISA DE SATISFAÇÃO DO USUÁRIO OUVIDORIA A-T-E-N-D-E**

**Talidomida**  
Ajuda, informação e orientação

**CURSO DE MANIPULADORES DE ALIMENTOS JÁ DISPONÍVEL**

**Acesso à Informação**

**Petição aguardando análise**

**DESCONTINUAÇÃO DE MEDICAMENTOS**

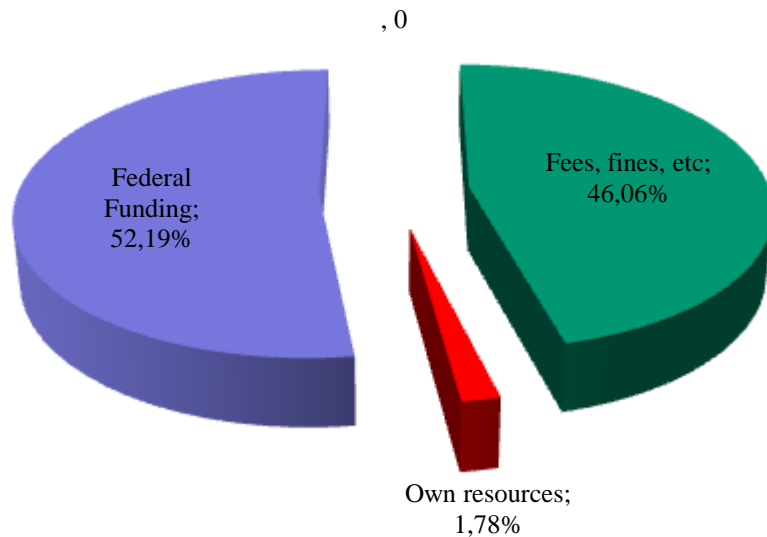
**twitter**

**RASTREABILIDADE**

# Financing and budget

# ANVISAs activities financing and budget sources

The Ministry of Health presents the Agency revenue sources to be used in each Budget Action. These sources are from the exercise of police power (fees, fines, etc), federal funding and own financial resources:



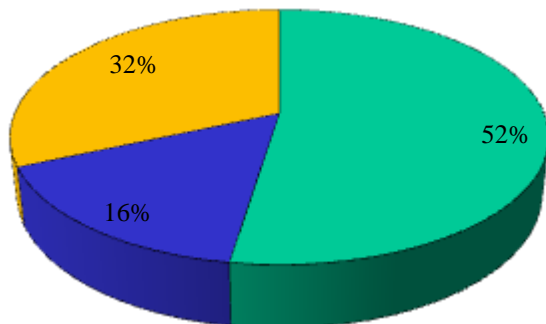
Fees, fines, etc.	46,06%
Own resources	1,78%
Federal funding	52,19%

# ANVISAs activities financing and budget sources

ANVISA who coordinates the National System of Sanitary Surveillance -SNVS promotes financial transfers to States and Municipalities:

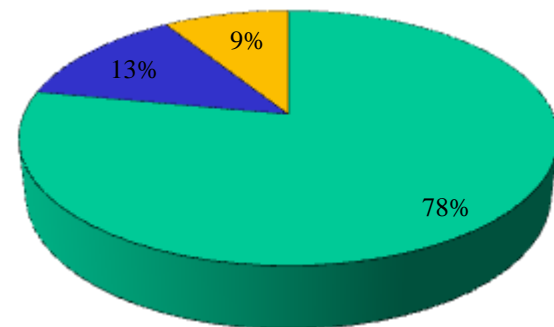
## Transfer of Treasure Funds

■ Anvisa ■ Estados ■ Município



## Transfer of Fees and Fines

■ Anvisa ■ Estados ■ Município



States - 26 and 1 Federal District  
Municipalities- 5570

# **Risk factors for noncommunicable diseases**

**Consumption of foods with high amounts of sodium  
and sugar**

# **Brazilian initiatives on the consumption of foods with high amounts of Sodium and Sugar**

- **Action plan for coping with Chronic Non-Communicable Diseases** (2011-2022), coordinated by the Ministry of Health (MS):

**Result:** Elaboration of Reference for Nutritional Guidelines for Good Practice, Good Practice Guide for French Bread Nutrition and Good Practice Guide to Nutritional Collective Restaurants.

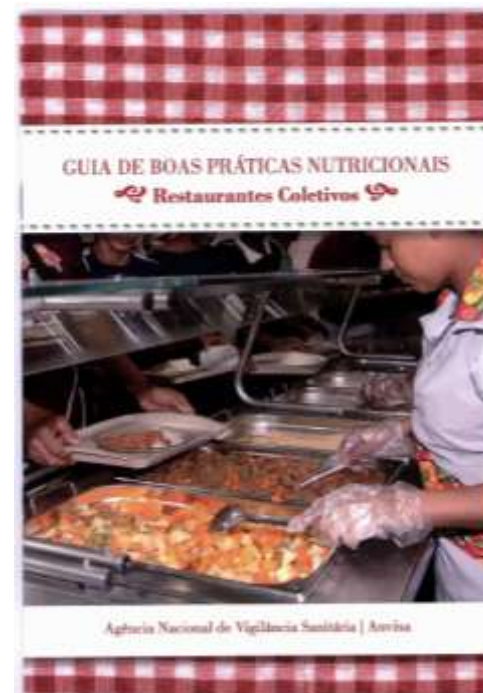
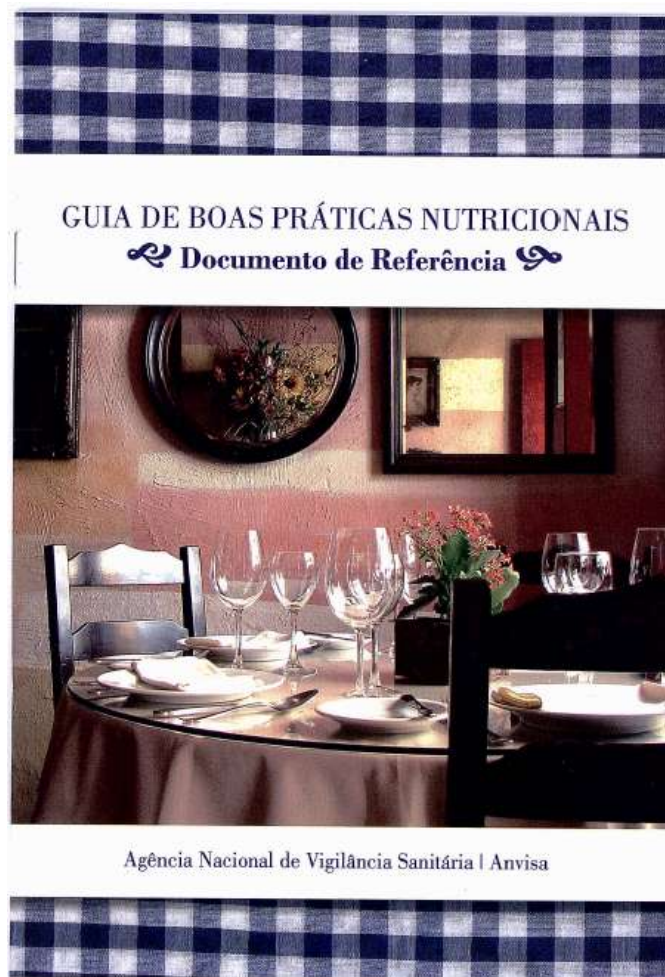
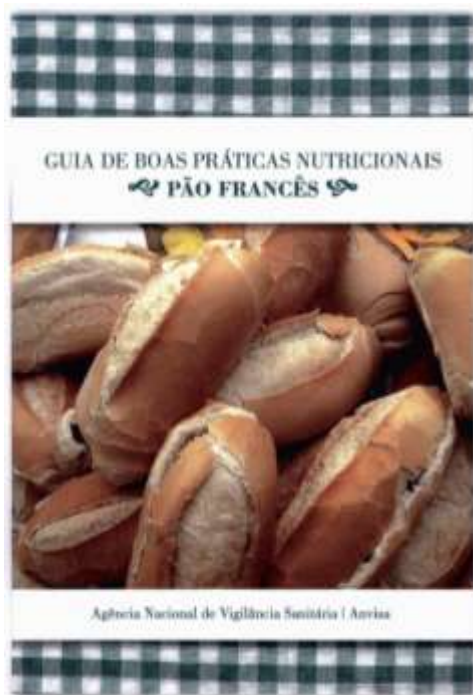
- **National Plan for Food Security and Nutrition** (Plansan- 2012-2015), Coordinated by MS and Ministry of Social Development and Fight Against Hunger (MDS):

**As a product:** Promote the monitoring of sodium, sugar and fat levels in processes food, in 50% of the Brazilian states.

- **Multiyear Plan**– PPA (2012-2015):

**As one of the goals:** Communicate to society the risks associated with the consumption of food, based on the results of food monitoring programs, it was analyzed for sodium content in categories of processed foods. (Published Technical Reports)

# Good Practice Nutrition Guides



# Brazilian initiatives on the consumption of foods with high amounts of Sodium and Sugar

- **Sectoral Plan for Prevention and Control of Obesity:** guidance on lifestyle and healthy feeding habits for the Brazilian population, coordinated by the Interministerial Council of Food and Nutrition Security - CAISAN MDS.

## Activities inside ANVISA's jurisdiction:

- Mercosur Proposition for inclusion of mandatory statement of the amount of sugar in nutrition labeling;
- Promote the monitoring of sodium, sugar and fat levels in processed food, in 50% of the Brazilian states and
- Develop communication strategies on the risks associated with the consumption of foods high in sugar, fat and salt.

# Monitoring results of the reduction of sodium in food

- **Removal of 1,295 tons of salt by 2012**

## Perspective:

- **1,859 tons by the end of 2014**
- **28.562 tons by 2020**



# Brazilian initiatives on the consumption of foods with high amounts of Sodium and Sugar

- **National Strategy for Reducing Sodium Amounts in Processed Foods**, coordinated by MS and ANVISA:

Subgroups were created in ANVISA's Sectorial Chamber for Food:

- Subgroup #1: Commitment Agreement signed between the MS, Anvisa and Brazilian entities related to the food industry, in order to establish national goals to reduce the sodium content in processed foods in Brazil and perform monitoring of such products in the market;
- Subgroup #2: In a joint effort by ANVISA, MS, University of Brasília (UNB) and the productive sector were published: **Reference Document for Good Nutritional Practices (BPN), Good Practice Guide on Nutrition (BPN) for Fresh Bread and the Good Practice Guide on Nutrition (BPN) for Collective Restaurants**;
- Subgroup #3: Communication and Disclosure to Consumer. These activities were coordinated by ANVISA and the Brazilian Association of Supermarkets (Abrás), with representatives of the General Coordination of Food and Nutrition, Ministry of Health (CGAN / MS), civil society, scientific community and the productive sector to permit execution of the **Campaign to Reduce Consumption of Salt for the supermarket chain**.

# **Anvisa and NCDs in Brazil**

## **The role of the regulatory agency**



# TOBACCO REGULATION

- 1977 - Federal Act 6.437 – sanitary infractions.
- 1999 – Federal Act 9.782 – a new era in tobacco control in Brazil is set. Paradigm shift that the legal control of tobacco products would not be possible in Brazil.

article 8, §1, X

*To regulate, control, monitor and inspect all products that involve risk to health, among them “cigarettes, small cigars, cigars and any other product, whether or not, derived from tobacco”.*

- 2000 – Establishment of the tobacco product control dept. - mandate and authority to regulate tobacco products

# **TOBACCO REGULATION**

- Anvisa's proposed tobacco products rules and regulations are made through public consultations advertised in the media and in Anvisa's website.
- Authority is granted for enforcement, for establishing binding norms and rules under existing laws, for imposing penalties to those who violate tobacco law, whether it is regarding advertising, sales, public or workplace smoking regulations, tobacco product packaging and labeling, and tobacco products registration.

# TOBACCO FEDERAL REGULATION

- 1996 - Federal Act 9.294 - restricts the use and the advertising of tobacco products in compliance with the Federal Constitution (Paragraph 4 – Article 220 - CF/88) (altered by Federal Acts 10.167/00, 10.702/00 e **12.546/2011**).
- 1996 Federal Decree 2.018 – regulates Federal Law 9294/1996 (Altered by **Decree 8262/14**) – 100% smoke free environments and total ban of advertising in PoS .
- 2004- Portaria do MS nº 1.035 – expands access to approach and treatment of tabagism for basic attention and medium complexity network of SUS.
- 2007 – Lei nº 11.488 – Requires cigarette manufactures to install an equipment for production counting that allow control and tracking in the country.

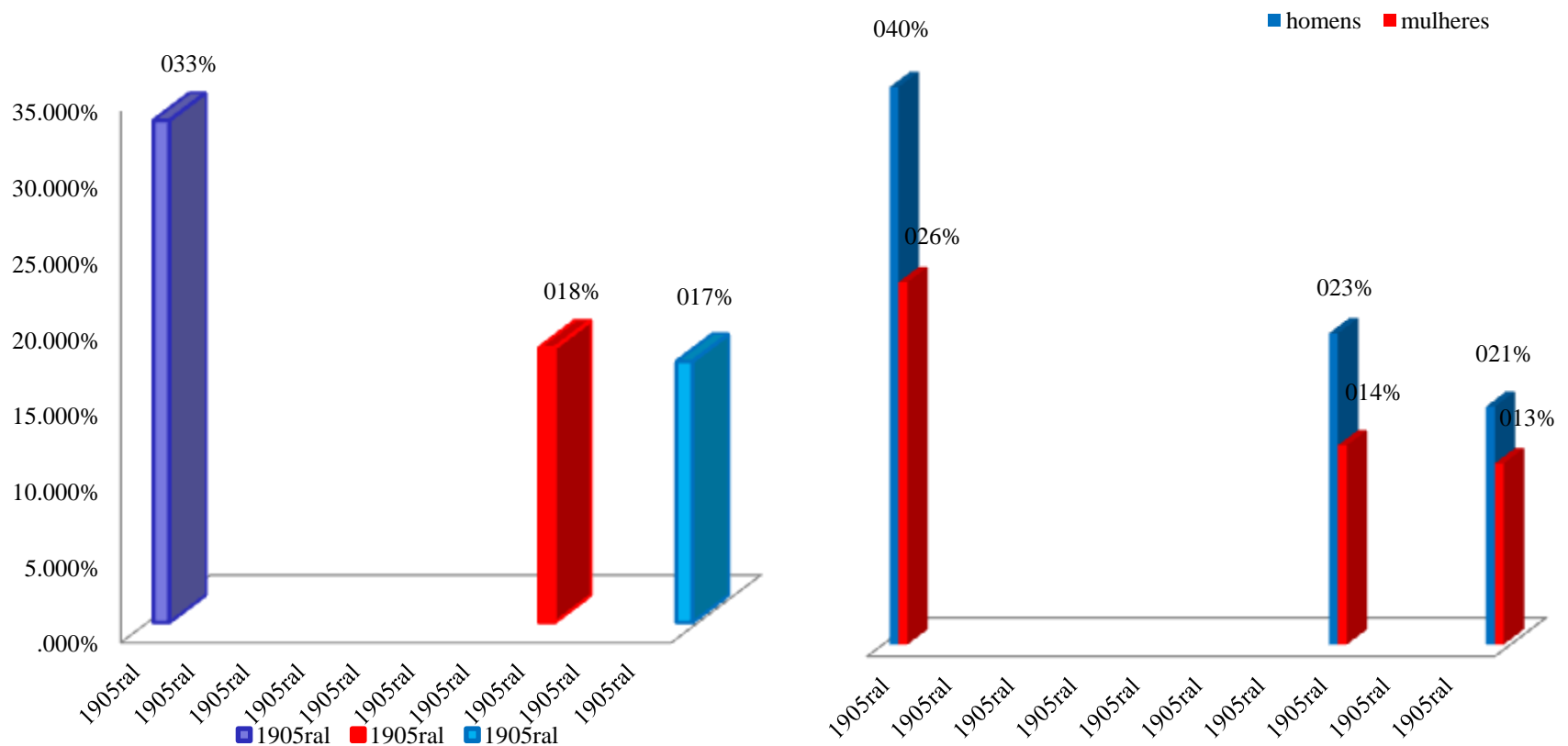


## RESULTS

- World's first country to ban misleading descriptors such as *light*, *mild* etc ...
- Second country in the world to adopt health warnings (pictorials)
- The first country in the world to ban the commercialization of electronic smoking devices (ENDS and ENNDS)
- World's first country to ban additives (including menthol)
- ANVISA collaborates with WHO on the subject of tobacco control (including tobacco laboratory - TobLabNet)
- Key facilitator of FCTC's Working Groups to articles 5.3, 8, 9 & 10 (current) and 11

# RESULTS

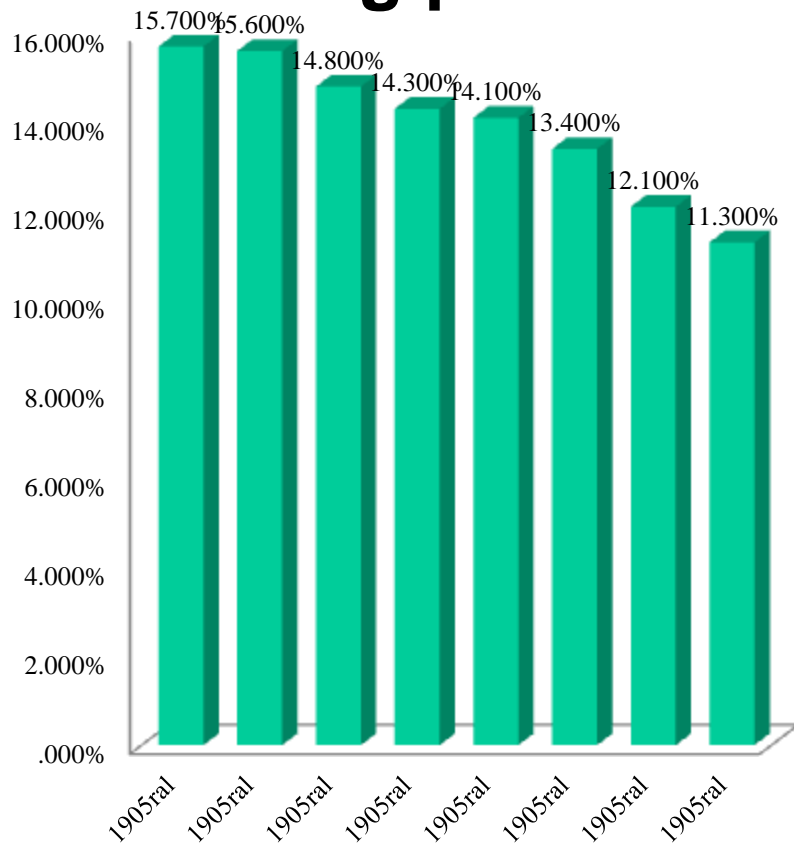
## ✓ Smoking prevalence in Brazil (%):



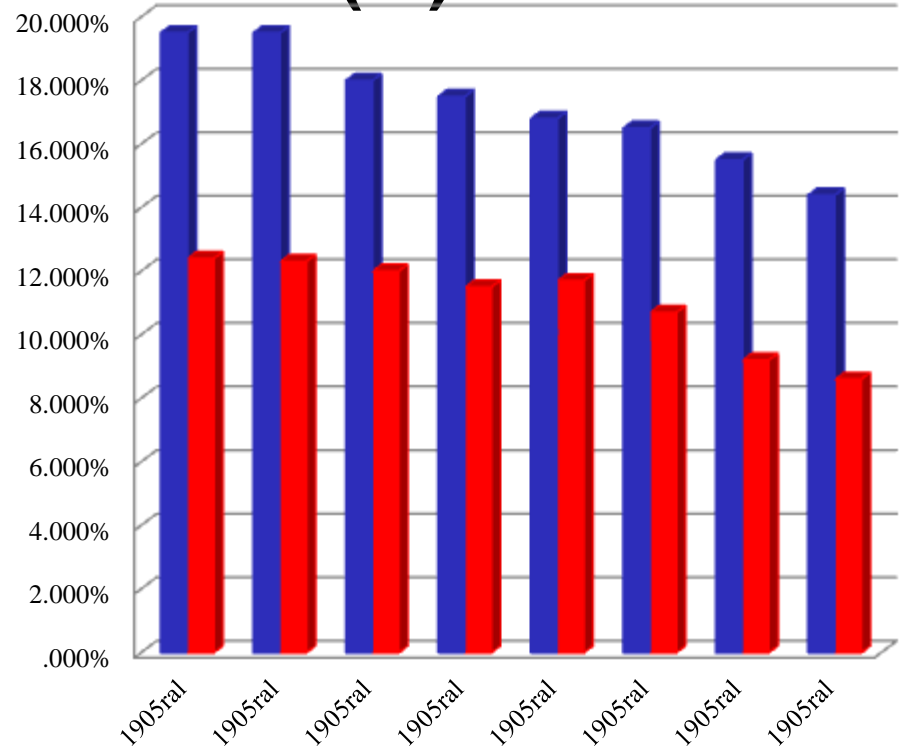
IBGE, 2008

# RESULTS

## ✓ Smoking prevalence in Brazil (%):



■ Prevalência de fumantes



	1995ral	1995ral	1995ral	1995ral	1995ral	1995ral	1995ral	1995ral
■ homens	19.500%	19.500%	18.000%	17.500%	16.800%	16.500%	15.500%	14.400%
■ mulheres	12.400%	12.300%	12.000%	11.500%	11.700%	10.700%	9.200%	8.600%

## Challenges

- Expand regulatory convergence in the Americas region;
- Consolidate the program for reduction of sodium and sugar amounts in processed food as a way to minimize risks of non-communicable diseases;
- Strengthening the Quadro Convention for Tobacco Control.

# THANK YOU

# OBRIGADO

**Diretoria de Coordenação e Articulação do Sistema Nacional de Vigilância Sanitária**

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