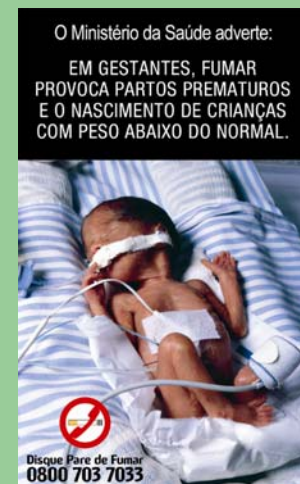
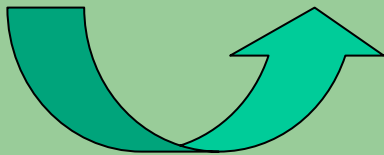


# BRAZILIAN EXPERIENCE ON PACKAGE WARNINGS AND LABELING REGULATION



To initiate the regulation and controlling of the tobacco products, a **Regulatory Agency** became essential in this process, with **legal power** to evaluate, regulate and control these products.

In 1999 the **National Health Surveillance Agency – ANVISA** was created by **Law 9782**



**ANVISA** is a special federal entity with:

- ✓ Financial independence
- ✓ Independent work and administrative ruling
- ✓ Stability of its Directors
- ✓ Police Power

**Main aim:** to promote people's health protection by sanitary surveillance and control of services and products subjected to health surveillance, for example:



Ports, Airports and International borders



Drugs and medical devices



Food



Sanitizers, cleaners



Tobacco products

ANVISA is the Brazilian federal entity with legal competence to regulate tobacco products, including its packs, packages and ads.

The Control and Sanitary Fiscal measures can be performed by:

- **ANVISA**
- State, Federal District and Municipal Sanitary Surveillance Centers (**VISAS**)

## ANVISA's Regulations of Packages and Ads

The regulations that have been adopted are in accordance with WHO FCTC article 11

***Packaging and labelling of tobacco products***

*(a tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive .... These may include terms such as “**low tar**”, “**light**”, “**ultra-light**”, or “**mild**”;*

***Brazil was the first country in the world to ban misleading descriptors such as light, ultra-light, mild, etc.***

The first regulation on packs and ads was published in 2001:

### 1. Board Directory Resolution RDC 46/2001:

Banned the **use of the terms** “light”, “mild”, “low tar” and others on the packages of cigarettes sold in the country.



### 2. Board Directory Resolution RDC 14/2003:

Banned the use of sentences like “**only for adults**”, which was replaced by:

Prohibits sales to persons under eighteen  
Federal Law 8069/1990.

## WHO FCTC article 11 continuation:

*(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry **health warnings** describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:*

*(i) shall be approved by the competent national authority,*

*(ii) shall be rotating,*

*(iii) shall be large, clear, visible and legible,*

*(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,*

*(v) may be in the form of or include pictures or pictograms.*

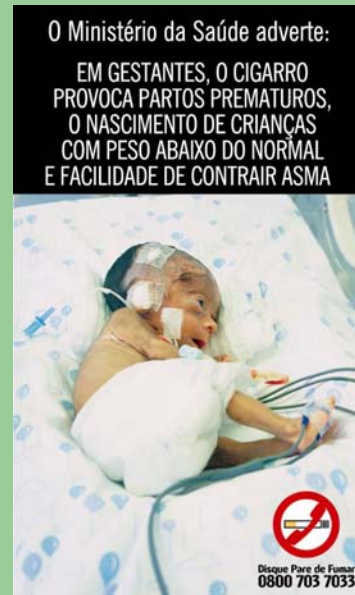
The item (b) from WHO FCTC has already been regulated:

### 3. Board Directory Resolution RDC 104/2001:

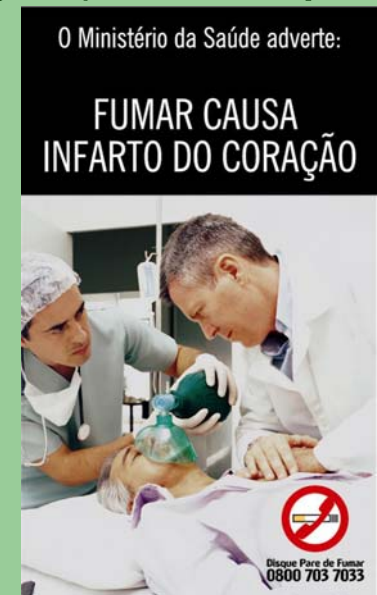
Mandated the insertion of images and warning on the packs, that must cover 100 % of one of the largest surfaces on each tobacco product and shall be rotating (10 images). Examples:



Smoking  
causes lung  
cancer



In pregnant women, cigarette  
leads to premature delivery,  
children with birth weight  
below normal and prone to  
asthma



Smoking causes  
heart attack

## 4. Board Directory Resolution RDC 335/2003:

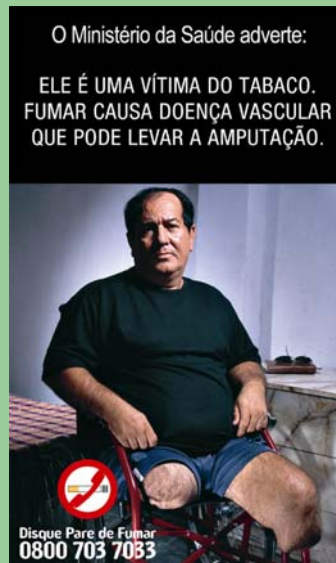
a) Exchanged the images, for increasing the effectiveness of the measures. More aggressive printed images were obtained from real patients.



This necrosis was caused by tobacco consumption



Smoking causes sexual impotence



He is a victim of tobacco. Smoking causes vascular disease that may lead to amputation



Smoking causes spontaneous abortion



Smoking causes cancer in the larynxes

O Ministério da Saúde adverte:  
**FUMAR CAUSA  
CÂNCER DE BOCA E PERDA  
DOS DENTES.**



Disque Pare de Fumar  
0800 703 7033

Smoking causes  
mouth cancer and  
loss of teeth

O Ministério da Saúde adverte:  
**CRIANÇAS QUE CONVIVEM  
COM FUMANTES TÊM  
MAIS ASMA, PNEUMONIA,  
SINUSITE E ALERGIA.**



Disque Pare de Fumar  
0800 703 7033

Children living  
with smokers have  
more asthma,  
pneumonia,  
sinusitis and  
allergy

O Ministério da Saúde adverte:  
**FUMAR CAUSA  
CÂNCER DE PULMÃO.**



Disque Pare de Fumar  
0800 703 7033

Smoking causes  
lung cancer

O Ministério da Saúde adverte:  
**EM GESTANTES, FUMAR  
PROVOCA PARTOS PREMATUROS  
E O NASCIMENTO DE CRIANÇAS  
COM PESO ABAIXO DO NORMAL.**



Disque Pare de Fumar  
0800 703 7033

Smoking during  
pregnancy  
causes  
premature birth  
and the birth of  
babies with low  
birth weight

O Ministério da Saúde adverte:  
**AO FUMAR VOCÊ INALA  
ARSÊNICO E NAFTALINA,  
TAMBÉM USADOS CONTRA  
RATOS E BARATAS.**

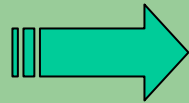


Disque Pare de Fumar  
0800 703 7033

When smoking,  
you inhale arsenic  
and naphthalene,  
also used against  
rats and  
cockroaches

In accordance with item “a” from FCTC the RDC 335 also:

b) **Forbids** the use of Tar, Nicotine and Carbon Monoxide contents **associated with the brand name** (considering that can cause misleading).



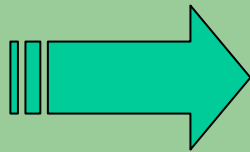
c) Determines the **replacement of the TNCO levels** on the pack by the following warning (printing of TNCO levels is optional):

This product contains more than **4.700** toxic substances and nicotine, which causes physical and psychological addiction.  
There are no safe limits for the use of such substances.

## 5. Board Directory Resolution RDC 302/2002:

Bans sales of food and packages which **simulate** tobacco products.

This measure aims to reduce tobacco products promotion, mainly towards children and adolescents.



## 6. Board Directory Resolution RDC 15/2003:

- Bans on-line sales and ads (taking into account that there is no effective means to avoid the access of children and teenagers to the Internet pages content):

Ads are prohibited in:

- Newspapers and magazines;

- Internet (National broadcasting);

- National cultural events.

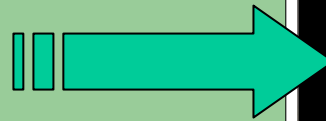


The screenshot shows a web browser window displaying the Charutaria Brasil website. The browser title is "Charutaria Brasil - Microsoft Internet Explorer". The website has a navigation menu with links: "home", "quem somos", "carrinho", "informações", "links", "sugestões", "cigar news", "charuto por ocasião", "saiba mais", "serviços", "compras". The main content area features a search bar, a "Busca" button, and a "OK" button. A large red box with the word "PROHIBITED" in yellow text is overlaid on a product advertisement for "La Paz Mini Wilde Cigarilhos". The advertisement shows a pack of cigars and lists the price as "De R\$11,00 por apenas R\$ 9,00". To the right, there is a "Cigar News" section with a list of articles: "Coluna da Márcia", "Conservando Charuto", "Nova Marca de Cubano", "Charutos Suaves, Médios e Fortes", "A Arte de Elaborar um Charuto - Fase 4", "A Arte de Elaborar um Charuto - Fase 3", and "A Arte de Elaborar". The website footer includes the "Internet" logo.

## 7. Board Directory Resolution RDC 335/2003:

Warnings are now mandatory in all tobacco ads material.

**Warning  
Compulsory**



**FACILITE O TROCO.**

Colabore em excesso.  
Fume com moder

Uma questão de ser Free.

ESTE PRODUTO CONTEM MAIS DE 4.700 SUBSTÂNCIAS TÓXICAS, E NICOTINA QUE CAUSA DEPENDÊNCIA FÍSICA OU PSÍQUICA. NÃO EXISTEM NÍVEIS SEGUROS PARA CONSUMO DESTAS SUBSTÂNCIAS.

O Ministério da Saúde adverte:  
**FUMAR CAUSA IMPOTÊNCIA SEXUAL**

MODELO

Smoking Part of Fumar  
0800 703 7033

**Tobacco advertising is restricted  
to points of sales.**

## To enforce the regulations, ANVISA has been:

- ✓ **Monitoring labelling of cigarette packs;**
- ✓ **Punishing tobacco companies because of infraction of the law;**
- ✓ **Punishing the press media because of inappropriate publicity;**
- ✓ **Ordering the registration of all packs of tobacco brands sold in the country;**

But some tobacco companies made opposition to current ANVISA's regulation and legislation

- **Tobacco companies** were against the use of **black color** in the warnings and pictures established by law 9294/96 (the black color is associated to controlled drug packs). For 2 years after the publication of RDC 104/2001, companies continued to use the same colors from the pack, not black, reducing the perception of the warning. The measure is currently enforced.



➤ **Inserts and Onserts:** Souza Cruz, a BAT subsidiary, used adhesives (onserts) and cards (inserts), both with the same size from the images, with brand advertisement, to be used over the image.

ONSERT is a miniature adhesive glued under the cellophane wrapper on the SOFT pack, that contains information about the changes on the brand name and the product:

Front side

Back side



**(translation)** Soon, your Derby will change its King Size, Mild and Light versions. Now, besides the different yields, the traditional colors of Derby will remind the consumer on the difference among them:

**Red – for people that prefer a stronger taste**

**Blue – for people that wish softness**

**Silver – light taste, the lightest of the family**

The names were changed, but your Derby is still the same, with the same quality, leadership and taste that has pleased Brazil.

Red, Blue and Silver.  
Now, this is the way  
you ask for Derby.

INSERT is a miniature brochure included inside BOX pack, that contains information about the changes on packs and brand name, and the product.

Front side

Back side



(translation)  
**BLUE**  
 Pleasure and softness in a new modern and innovating package. This is Hollywood Blue, a light version of Hollywood.



Front side

Back side



Front side

Back side

(translation)  
**FREE**  
 changed its clothes.

**Such strategy was considered a severe infraction of the law, since it has communication or publicity campaign purposes, and as being a tentative of hiding the health warnings.**

**Tobacco ads are restricted to point sales (in the case presented the ad is going out with the product).**

## **ANNUAL FEE FOR KEEPING RECORD OF CIGARRETE BRANDS**

**Law 9782 defined the Annual Fee for record of each brand**

**Cost: R\$ 100.000,00 per brand**

**The value was defined under the same law, based upon the costs of regulation, control and fiscal activities**

**However, some industries have been depositing the value under due process by means of judicial measure.**

## CONCLUSION

Early results obtained by countries' smoking control confirm the impact of educational and legislative measures taken:

- 1- **Decrease of 32 % (1989) to 19% (2003)** in the number of consumers in the country;
- 2- The images and warnings released on the packages have been a **very effective tool** to motivate stop smoking.

## CONCLUSION (cont.)

3- After printing the images in cigarette packs the number of phone calls to “Brazilian Governmental **Quit line**”, increased more than 100% (more than 300% in the beginning);

*Brazil was the first country in the world to use cigarette packs labelling to promote a “Quit Line” –  
Disque pare de fumar*

4- The photos and the warnings on the cigarette packs are serving of inspiration to Thailand, Australia, Singapore and 25 countries of EU to formulate packaging and labelling policies.

The creation of a regulatory agency represented a landmark in control actions for reduction of tobacco use, as the Agency is empowered to formulate rules, discipline the use, the commercialization and the advertisement of tobacco products.

All regulations are available in Portuguese,  
Spanish and English

at

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

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**Thank you!**