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
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 larynges**
National Health Surveillance Agency

Smoking causes mouth cancer and loss of teeth.

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

Smoking causes lung cancer.

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

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

Warnings are now mandatory in all tobacco ads material.

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:

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

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

(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 CIGARETTE 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.
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.
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

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Thank you!