Brazilian experience in submitting notifications

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Brazilian Health Regulatory Agency - Anvisa

Mission
To protect and promote the health of population, intervening in risks associated with production and use of products and services subject to health surveillance, in a coordinated and integrated action within the National Health System (SUS)

Vision
To be an institution that promotes health, citizenship and development, operating in a rapid, efficient and transparent manner, consolidating its leading role in regulation and sanitary control, both nationally and internationally.
Anvisa’s roles and regulatory fields

- Food
- Cosmetics
- Sanitizers
- Tobacco
- Pesticides
- Health Service
- Medicines
- Medical devices
- Laboratories
- Blood, tissues and organs
- Pharmaco vigilance
- Health products
- Advertisement
- Ports, airports and borders
- International affairs
- SNVS coordination
Anvisa’s Regulatory Strategies

Anvisa defines its priority regulatory issues in a quadrennial **Regulatory Agenda**.

**International partnerships** are continuously established to seek regulatory **convergence** and promote **common standards and guidances** with strategic partners.
Anvisa’s Regulatory Strategies

General health Laws allow Anvisa to establish regulations (mainly through Resolutions – RDC).

There is an approved regulatory process aiming at reaching quality and transparency both for the population and the regulated sector.

Board of Directors initial approval  
+ Responsible Director

Primary regulatory impact analysis  
+ Legal analysis

Published in the National Gazette and available for 60 days on Anvisa’s website

Second to third regulatory impact analysis  
+ Sector meetings

Board of Directors approval  
+ RDC enacting
Anvisa’s Notifications in 2018

Public Consultations (181):
- Resolutions: 54 (30%)
- Public Consultations: 127 (70%)

Notifications (156):
- TBT: 49 (33%)
- SPS: 91 (62%)
- Both: 8 (5%)

Anvisa notifies all technical regulations that may impact trade, including less trade restrictive measures and those based on international standards, going beyond what is prescribed in both Agreements.
## Anvisa’s Double TBT & SPS Notifications in 2018

<table>
<thead>
<tr>
<th>Notification ID</th>
<th>Description</th>
<th>G/SPS/N/BRA/Code</th>
<th>G/TBT/N/BRA/Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC 457/2017</td>
<td>Establishes the lists of nutrients, bioactive substances, enzymes and probiotics, limits of use, claims and supplementary labeling of food supplements</td>
<td>G/SPS/N/BRA/1350</td>
<td>G/TBT/N/BRA/781</td>
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<tr>
<td>PC 458/2017</td>
<td>Provides for categories of food and packaging exempt and with mandatory sanitary registration</td>
<td>G/SPS/N/BRA/1351</td>
<td>G/TBT/N/BRA/779</td>
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<tr>
<td>PC 484/2018</td>
<td>Establishes the criteria for the evaluation and toxicological classification of pesticides, components, related products and wooden preservatives, within ANVISA</td>
<td>G/SPS/N/BRA/1389</td>
<td>G/TBT/N/BRA/803</td>
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<tr>
<td>PC 493/2018</td>
<td>Active Ingredient T56 - TRINEXAPAC-ETHYL</td>
<td>G/SPS/N/BRA/1373</td>
<td>G/TBT/N/BRA/807</td>
</tr>
<tr>
<td>PC 529/2018</td>
<td>Active Ingredient P34 - PYRIPROXYFEN</td>
<td>G/SPS/N/BRA/1408</td>
<td>G/TBT/N/BRA/817</td>
</tr>
<tr>
<td>PC 530/2018</td>
<td>Active Ingredient B40 - BEAUVERIA BASSIANA</td>
<td>G/SPS/N/BRA/1409</td>
<td>G/TBT/N/BRA/818</td>
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<tr>
<td>PC 532/2018</td>
<td>Active Ingredient T48 - THIAMETHOXAM</td>
<td>G/SPS/N/BRA/1411</td>
<td>G/TBT/N/BRA/819</td>
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<tr>
<td>PC 535/2018</td>
<td>Active Ingredient A02 – ACEPHATE</td>
<td>G/SPS/N/BRA/1417</td>
<td>G/TBT/N/BRA/827</td>
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</tbody>
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Protect health and promote innovation

THANK YOU!

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