

Brazilian experience in submitting notifications

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Brazilian Health Regulatory Agency

Workshop on Transparency and Coordination
Sanitary and Phytosanitary Committee
World Trade Organization
Geneva,
July, 2019



ANVISA

Agência Nacional de Vigilância Sanitária

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 a 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.



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Agência Nacional de Vigilância Sanitária

Anvisa's roles and regulatory fields



Food



Cosmetics



Sanitizers



Tobacco



Pesticides



Health Service



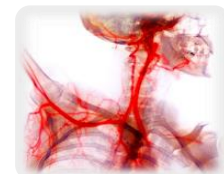
Medicines



Medical
devices



Laboratories



Blood, tissues
and organs



Pharmaco
vigilance



Health
products
Advertisement



Ports, airports
and borders
Health



International
affairs



SNVS
coordination



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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.

Predictability

Participation



Transparency



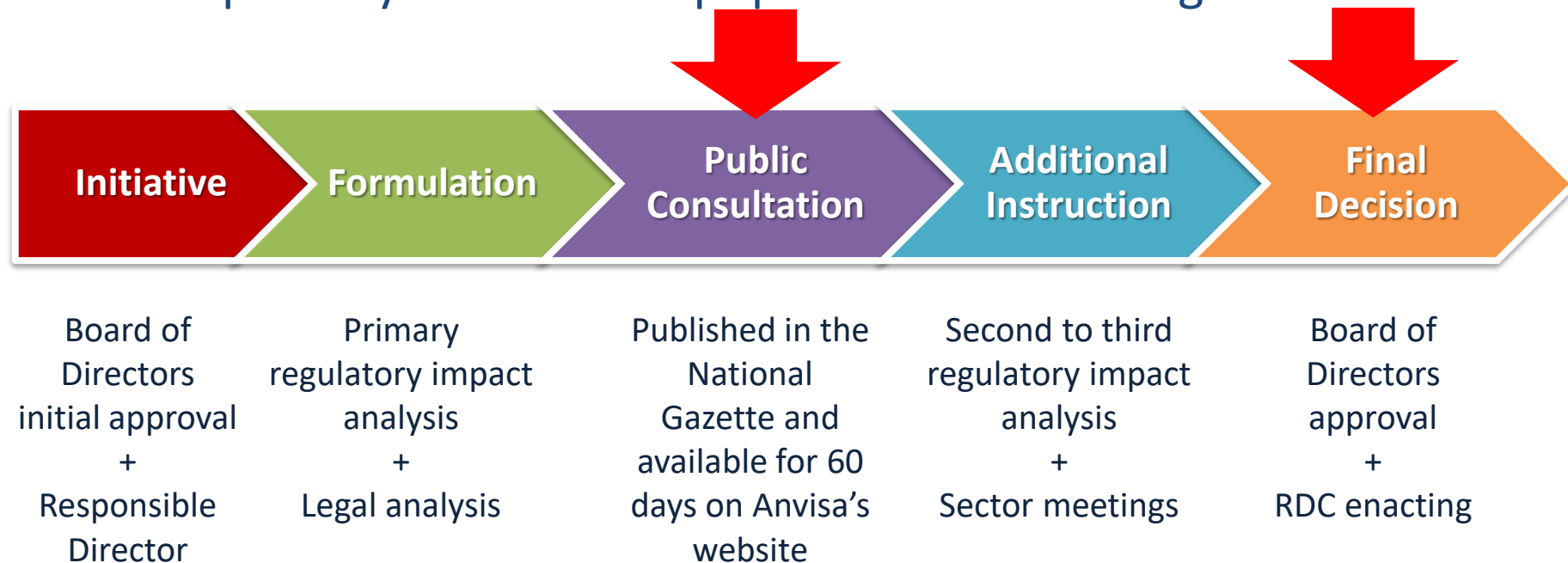
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Anvisa's Regulatory Strategies

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.

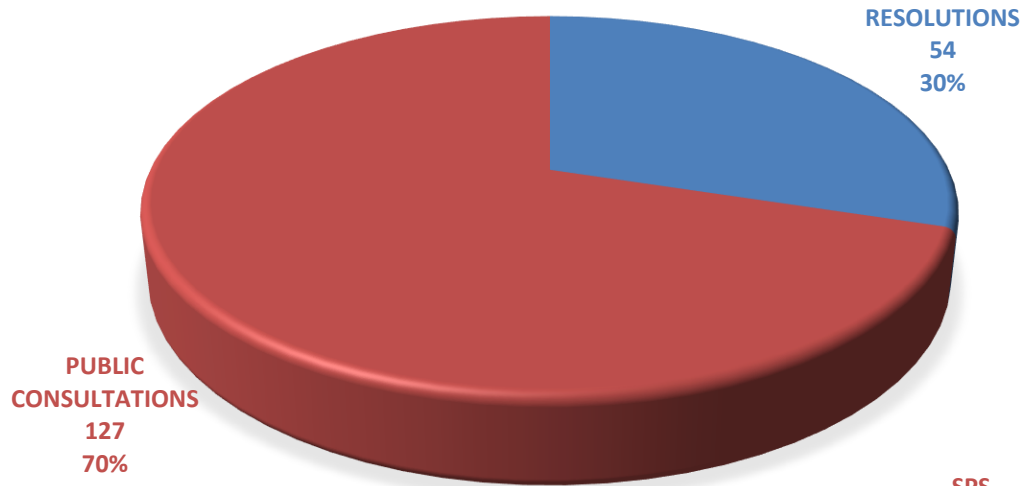


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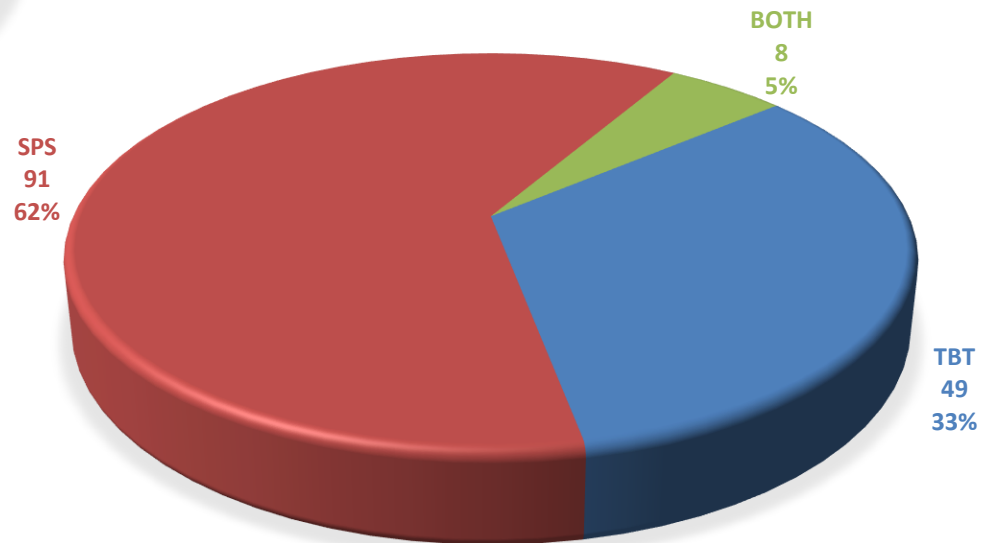
Anvisa's Notifications in 2018

PUBLICATIONS (181)



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

NOTIFICATIONS (156)

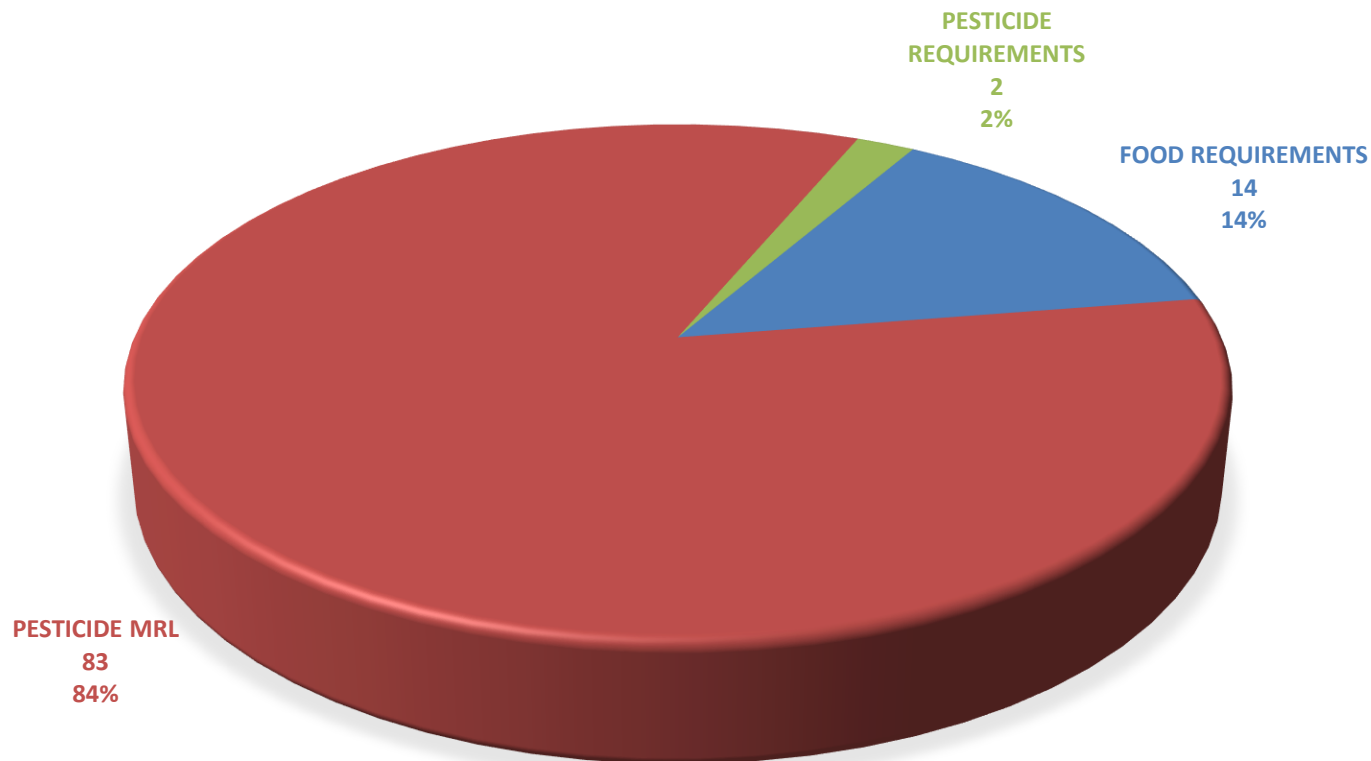


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Anvisa's Notifications in 2018

SPS NOTIFICATIONS (99)



Anvisa's Double TBT & SPS Notifications in 2018

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



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Protect health and promote innovation

THANK YOU!

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