

BRAZIL'S EXPERIENCE HARMONIZING WITH CODEX MRLS

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Agência Nacional de Vigilância Sanitária

BUT FIRST!

Brazil accepts imports that comply with Codex standards – even if it differs from its own established MRLs



- **Provided that the risk assessment does not indicate an unacceptable risk to Brazilian consumers**
 - **Not applicable for forbidden substances**





Anvisa

Brazilian Health
Regulatory Agency



Health Evaluation

REGULATION OF PESTICIDES IN BRAZIL



**Ecotoxicology
Evaluation**

Ibama



Brazilian Institute of
Environment and
Renewable Natural
Resources



MAPA

Ministry of Agriculture,
Livestock and Food
Supply



**Efficacy
Evaluation**



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WHAT WE DO?

PRE-MARKETING AUTHORIZATION

- Toxicological classification and evaluation
- Establishment of $\left\{ \begin{array}{l} - \text{MRL and safety intervals} \\ - \text{Modalities of application} \end{array} \right.$
- Elaboration of $\left\{ \begin{array}{l} - \text{Active ingredients monographies} \\ - \text{Technical regulations} \end{array} \right.$

POST-MARKETING AUTHORIZATION

- Post-marketing changes
- Toxicological reevaluation
- Monitoring of Pesticide Residue in Food (PARA)



ESTABLISHMENT OF MRLs

Identification of the Good Agricultural Practices

- Supervised Field Trials
- Crop, location, modality of application, quantity of applications, dose, safety interval

Residue definition

- Active ingredient, metabolites, etc.
- Which substances shall be studied in order to assess the conformity to the MRL or for risk assessment

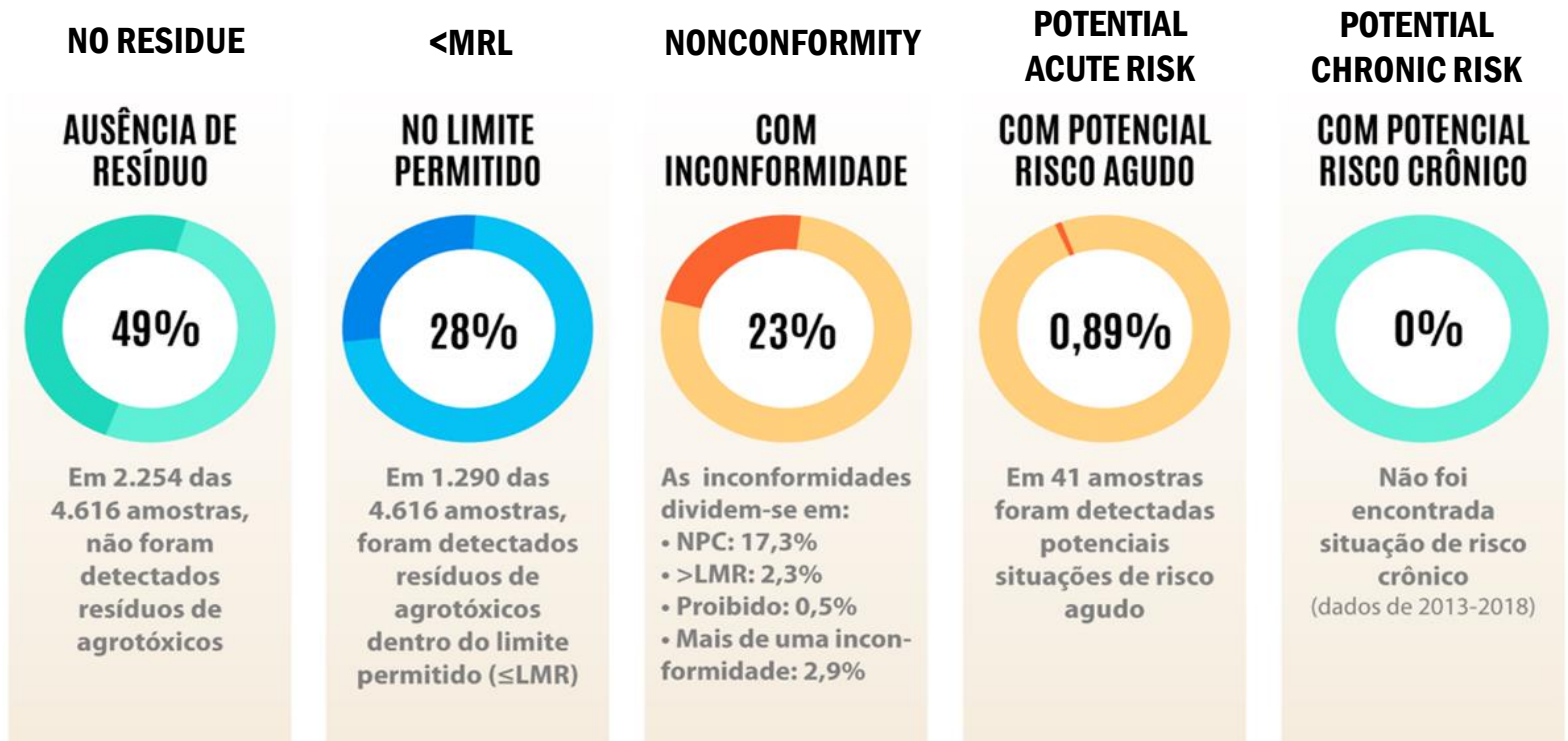
MRL Estimate

- Statistical calculation (OECD Calculator)
- MRL established for each crop (or groups of)



PESTICIDE RESIDUE IN FOOD ANALISYS PROGRAMME - PARA

- OVER 35K SAMPLES
- 28 PLANT PRODUCTS



ANVISA AND CODEX

- Anvisa is an active member of CCPR;
- Anvisa follows the same methodology for establishing MRL, according to Best Regulatory Practices, Scientific Principles and Transparency;
- Anvisa must use Brazilian consumption data (POF/IBGE);
- Supervised Field Trials must be performed in Brazil;
- If a MRL is automatically incorporated, it is not possible to enforce due to the authorized Good Agricultural Practices.





TRANSPARENCY

Brazilian MRLs are established based on scientific methodology consistent with international best practices. Countries usually set MRLs according to the Good Agricultural Practice (GAP) applicable to their region. Agricultural chemical use patterns differ between different production regions and countries as pests, diseases and environmental factors vary. This means that Brazilian MRLs for agricultural chemicals in food may differ from Codex standards. However, when a product differs from Brazilian MRLs, but is in conformity to Codex standards, it may be imported, provided that the risk assessment does not indicate an unacceptable risk to Brazilian consumers.



IN CONCLUSION...

- Brazil has a sound regulatory system in place – that considers health, environment, and good agricultural practices in its implementation;
- Brazil takes also full advantage of Codex scientific principles and Codex regulatory structure;
- Brazil complies with SPS Agreement, taking advantage of the policy space it provides, without harming harmonization principles;
- In its regulatory system, Brazil underlies SPS principles: scientific principle, transparency, risk assessment and harmonization.



Protect health and promote innovation

THANK YOU!

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