

From Science to the Regulation of Food Safety in Latin America **Brazil**



Background on Food Safety Approvals

- Approvals and Maximum Limits (MRLs) established considering:
 - FAO/WHO expert group assessments and Codex Alimentarius recommendations
 - International legislation from other countries

BUT

Brazil has differences in:

- Climatic conditions
- Production methods
- Occurrence data
- Dietary habits

Evolution of Risk Assessment in Brazil

Codex Alimentarius discussions emphasized the Importance of scientific evidence and risk assessment

Training opportunities in risk assessment

Challenge: Limited availability of specialized human resources

Risk assessment from FAO/WHO expert group should reflect:

Brazilian occurrence data and National consumption patterns

Submission of country occurrence data (mainly contaminants) in food to the Global Environment Monitoring System (GEMS) and consumption data



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Risk Assessment

**MRL:Veterinary Drugs,
Pesticides, Food
Additives, Processing
Aids, Packaging Materials**

**ML: contaminants
Novel Ingredients and
Novel Foods**

Inspections and
Monitoring Programs

MAPA

Products registration
(veterinary drugs and
pesticides)

Product/ Commodities
Standards

GMP, Inspections, y
fiscalización,
Certification, Monitoring
Programs

CONTAMINANTS

RISK CHARACTERIZATION AND ESTABLISHMENT OF MAXIMUM LIMITS

OCCURRENCE DATA

- CALL FOR DATA
- MONITORING PROGRAMS

CONSUMPTION DATA

EXPOSURE ASSESSMENT

HEALTH-BASED
GUIDANCE VALUES
JECFA, EFSA, etc

RISK CHARACTERIZATION VS REJECTION RATE

Adoption of Codex Limits, when available

**Approval of Food Additives,
Processing Aids, Food contact
materials, pesticides,
veterinary drugs, novel
ingredients and novel foods**

Approval of substances/ingredients:

- Request by the interested party
- Alignment with Codex
- Review of the assessment by Anvisa initiative

RELIANCE

Decisions based on scientific evidence

Safety

Toxicological
package
Exposure

It depends on the
characteristics of
the substances
and the method of
production

Purpose of Use

Efficacy
Technological need
Benefit

PESTICIDES

RDC 294/2019- Provides criteria for toxicological evaluation and classification

RDC 4/2012- criteria for carrying out pesticide residue studies for the purpose of pesticide registration in Brazil

Guide No. 13- Submission Guide for the Company's Technical Evaluation Report

Food regulation

RDC 868/2024- Basic guidelines for food risk and safety assessment

RDC 839/2023- Safety evaluation and authorization for novel foods and novel ingredients

Guia 23/2019- Guide for Evaluation of Food and Ingredient Safety

RDC 778/2023- Food additives and processing aids

Guide 43/2020- Procedures for Requests for Inclusion and Extension of Use of Food Additives and Processing Aids in Brazilian Legislation

RDC 730/2022- Risk assessment of veterinary drugs, the maximum residue limits (MRLs) in food of animal origin, and the analytical methods for the purpose of compliance assessment.

BIBLIOTECA DE ALIMENTOS

[AnvisaLegis](#)



