LATAM Regulatory Changes: Preparing for 2024 and Beyond

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About the Speaker

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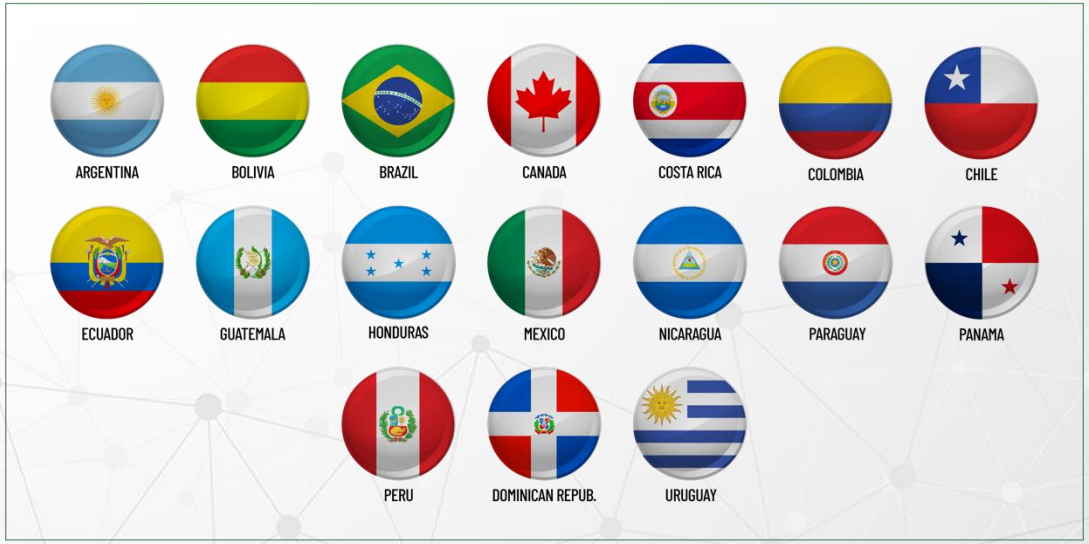
SMARTTOX
Specialized Consulting on Regulatory Toxicology



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MEXICO

- **Highly Hazardous Pesticides (HHP)**
  - Intrinsic properties of a chemical, and not just the risk or level of exposure, would play a crucial role in determining whether its use
  - Regulatory agencies are also considering the possibility of introducing a risk assessment
  - Global trend toward incorporating more rigorous risk assessment
    - This approach aims to evaluate both the potential hazards of a substance and the likelihood of exposure to determine the actual risk it poses to human health and the environment
  - This hazard-based approaches offers a more nuanced framework for decision-making
  - Initatives of Cofepris to ban highly hazardous pesticides (HHP), as part of a broader strategy to promote sustainable agriculture and protect biodiversity
    - The 50% decrease in glyphosate imports in 2023 highlights Mexico's ongoing push to phase out the herbicide, which has been linked to health risks and environmental damage

MEXICO

❖ **Phase-out of Glyphosate**

- In November 2023, the EU extended the approval for glyphosate use for an additional 10 years, until December 15, 2033, while maintaining certain conditions and restrictions on the ingredient during that timeframe.
- This decision, following extensive debate, influences global markets and policies all over the world.
- Planned to be banned in January, 2024
  - Postponed to March, 2024
  - Postponed again to April 2024
  - **Postponed again to 2027, due to lack of viable alternatives and concerns over food production and safety**

BRAZIL

Project of Law - Bioinputs (Substitute to PL 658)

- **Registration of establishment for commercial purposes**
  - Required by the federal agricultural defense body
- **Product Registration**
  - Mandatory its registration (Bioinputs and bioinput inoculants)
  - May be required an efficacy and viability technical-scientific report (Brazilian body legally recognized / CRO)
  - Risk Assessment attested by National Technical Biosafety Commission (CTNBio) for genetically modified organisms (GMO)
  - Bioinput inoculants registration gives permission to: commercial or research purposes, self-use, or formulate products
    - Personal use are exempt of registration, but in this case its commercialization is prohibited
    - No prior registration will be required for the Bioinput registration by the same registration holder

BRAZIL

❖ **Product Registration (cont.)**

- Bioinputs registration may use simplified administrative registration procedure when there are similar products already registered in Brazil
- The federal agricultural defense body may consult other government bodies, to obtain technical-scientific subsidies for the registration process regarding new products intended for phytosanitary control
  - Only will be used if these research and development bodies brings no prejudice to confidentiality and conflict of interest
- Are exempt of registration:
  - Bioinputs produced exclusively for self use;
  - Semiochemical products exclusively for mechanical action
  - Insects monitoring baits which AI is from biological and/or residual food fermetation
- **Obs.: Federal body may establish law risk products by a specific normative.**

BRAZIL

❖ **Self Use Production**

- Exemption of registration, following the Good Practices instructions
- Can be exempt of registration in a simplified manner by the federal body
- Can produce individually, or by association, consortium, cooperatives, etc. (commercialization prohibited)
- Transportation autorized between facilities from the same economic group, association, consirtium, coopertaive, etc
  - Cargo needs to be documented indicating product details, destiny, and production site, except in the same property
- A qualified tecnical responsable may be requested in the production facility
- Exempt of enviromental licences, since the facility attens the local regulation (law 12.651, 2012)

BRAZIL

- **Commercial Production**
  - The registration owners can define revalidation, rework and reprocessing procedures for their on products
  - Bioimputs produced only for exportation purposes are exempt of registration
    - Company needs to inform the federal agricultural body the product and amount to be exported
- **Bioinputs National Incentive**
  - The Executive Branch of Brazil may use financial mechanisms, including tax and fiscal mechanisms, to encourage research, development, production, use and commercialization of bio-inputs for use in agricultural, livestock, aquaculture and forestry production
  - Encourage research, development and experimentation of bio-inputs with a focus on promoting the bioeconomy and socio-biodiversity
  - Federal, state, district and municipal public authorities will be able to create public policies and develop fiscal and tax mechanisms that encourage and facilitate the production and use of bio-inputs

ARGENTINA

Resolution SENASA 694/2024

- **Recognition of equivalence of technical grade active substances**
  - Registration granted in the competent authorities of the countries listed below:
    - United States
    - Mexico
    - European Union
    - United Kingdom
    - Australia
    - New Zealand
    - Brazil
  - Only will be recognized in those cases in which the active substance grade technical to be registered comes from the same manufacturing establishment and has the same minimum or higher purity as that registered in other countries

ARGENTINA

- **Requirents to attend the resolution**
  - Submit the data required in the Chapter 7 - Resolution No. 350 of August 30, 1999
  - Registration Certificate issued by another country, describing name of the active substance technical grade, the minimum purity expressed in PERCENTAGE WEIGHT BY WEIGHT (% w/w), the name and address of the establishment synthesizer
- **Post - Registration**
  - SENASA may carry out post-registration inspections of the active substance equivalent technical grade
    - If found some inconsistencies in the documantation submitted and the analyzes carried out by the oficial body, when requesting its registration by equivalence of the active substance for the plant in question, SENASA will request the corresponding correction (Chapter V of Law No. 27.233)
    - If found some inconsistencies between the declared information and the analyzes carried out on the oficial body, SENASA will cancel the registration (Chapter V of Law No. 27.233)

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THANK YOU!

Questions?

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