Evaluation of regulatory and institutional frameworks for gene editing in agriculture using CRISPR-based technologies in Latin America and the Caribbean

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Senior Research Scholar, GES Center
4 October 2022

Inter-American Development Bank

We work to improve lives in Latin America and the Caribbean. Through financial and technical support for countries working to reduce poverty and inequality, we help improve health and education, and advance infrastructure. Our aim is to achieve development in a sustainable, climate-friendly way. With a history dating back to 1959, today we are the leading source of development financing for Latin America and the Caribbean. We provide loans, grants, and technical assistance; and we conduct extensive research. We maintain a strong commitment to achieving measurable results and the highest standards of integrity, transparency, and accountability.

The IDB prioritizes social inclusion and equality; productivity and innovation; and regional economic integration in its development work across Latin America and the Caribbean. In doing so, it addresses the cross-cutting issues of gender equality and diversity; climate change and environmental sustainability; and institutional capacity and the rule of law. Learn more about the Institutional Strategy here.

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Project components

- Describe the current regulatory frameworks in the region in the 10 selected countries (Argentina, Brazil, Uruguay, Paraguay, Bolivia, Peru, Colombia, Honduras, Guatemala and Mexico).
- Document and analyze trends and changes in regulatory frameworks around gene editing in major trading partner countries (EU, US, China, Japan).
- Document the current landscape of Intellectual Property and licenses for gene editing and technical protocols
- Develop case studies on gene editing applications that are representative of the countries involved in the project and of key crops for the region, under different regulatory scenarios.
- Understand the different characteristics of process- vs. product-focused regulation of gene editing, for the future direction of public policies and the development of R&D in biotechnology in LAC. We also seek to identify potential investment priorities for the IDB in the region.
  - Stakeholder interviews
  - Case studies
  - Investment strategies

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Project Team

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Thanks also to the Ad-hoc Working Group :

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- **Brazil (Alexandre Nepomuceno)**
- **Colombia (Alfonso Alberto Rosero)**
- **Honduras (Roger Orellana)**
- **Uruguay (Alejandra Ferenczi)**

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Genome Editing in Latin America:
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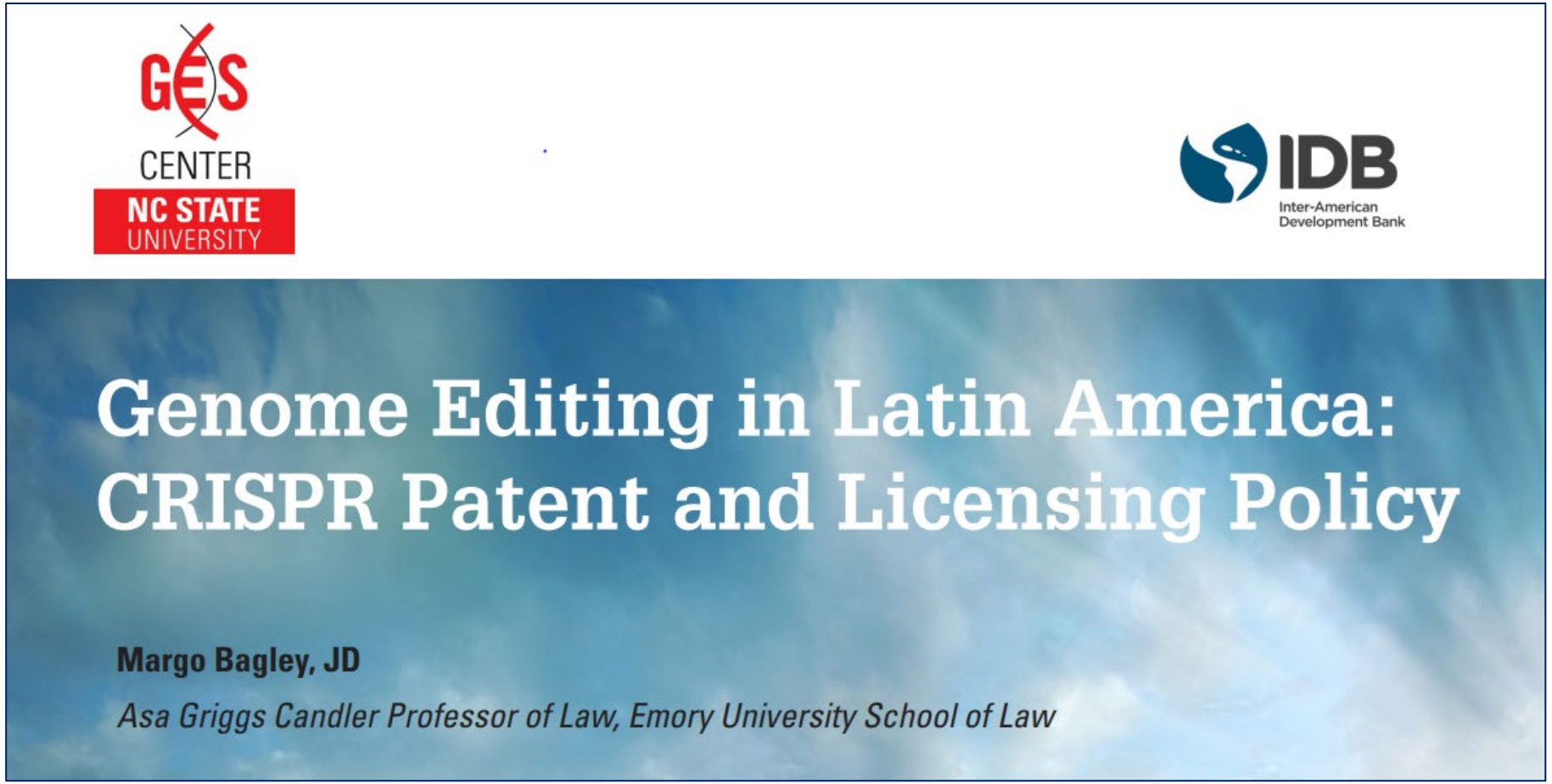
DISCUSSION PAPER Nº
IDB-DP-00877
Publication design by Patti Mulligan
go.ncsu.edu/ges-idb-crispr
JULY 2021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Genome Editing in Latin America:
CRISPR Patent and Licensing Policy
Margo Bagley, JD
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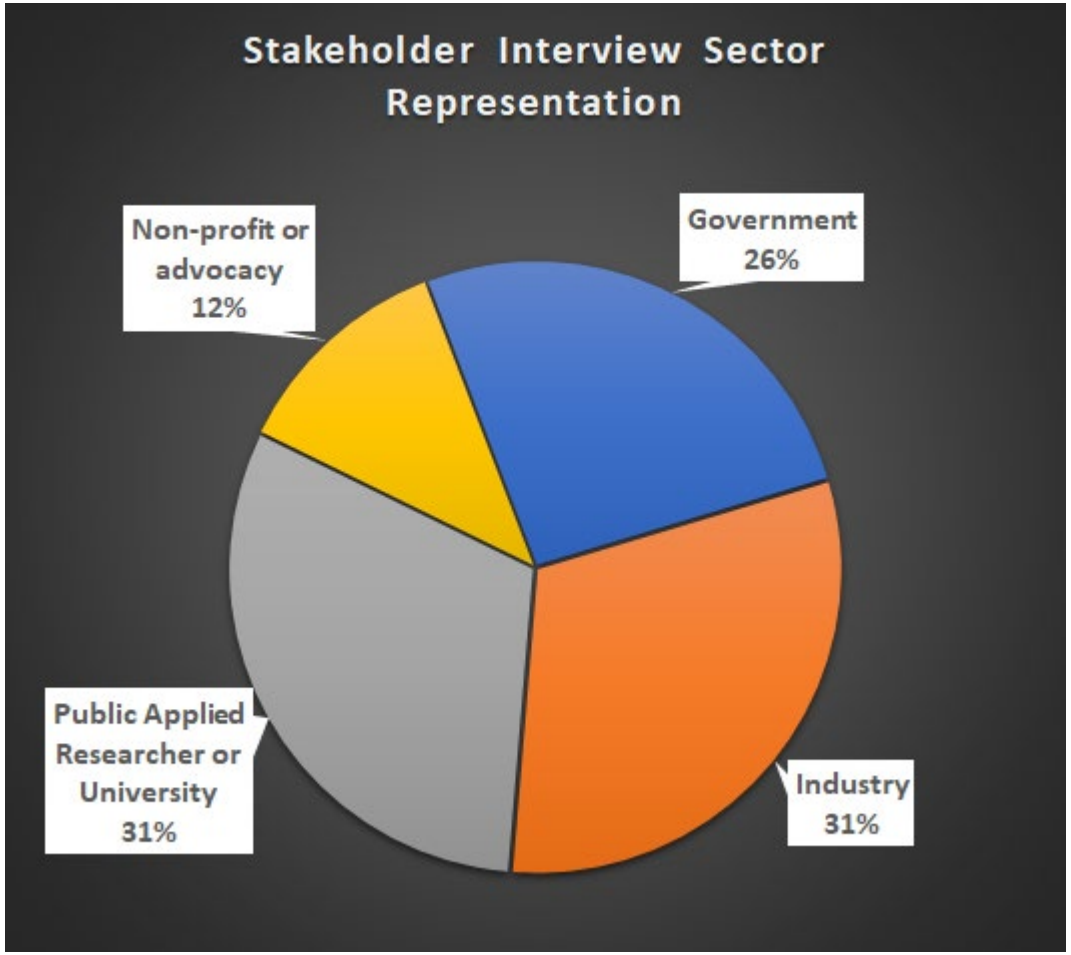
Stakeholder Interviews



- 40+ interviews conducted
- Argentina, Bolivia, Brazil, Colombia, Honduras, Mexico, Paraguay, Peru, Guatemala, Uruguay

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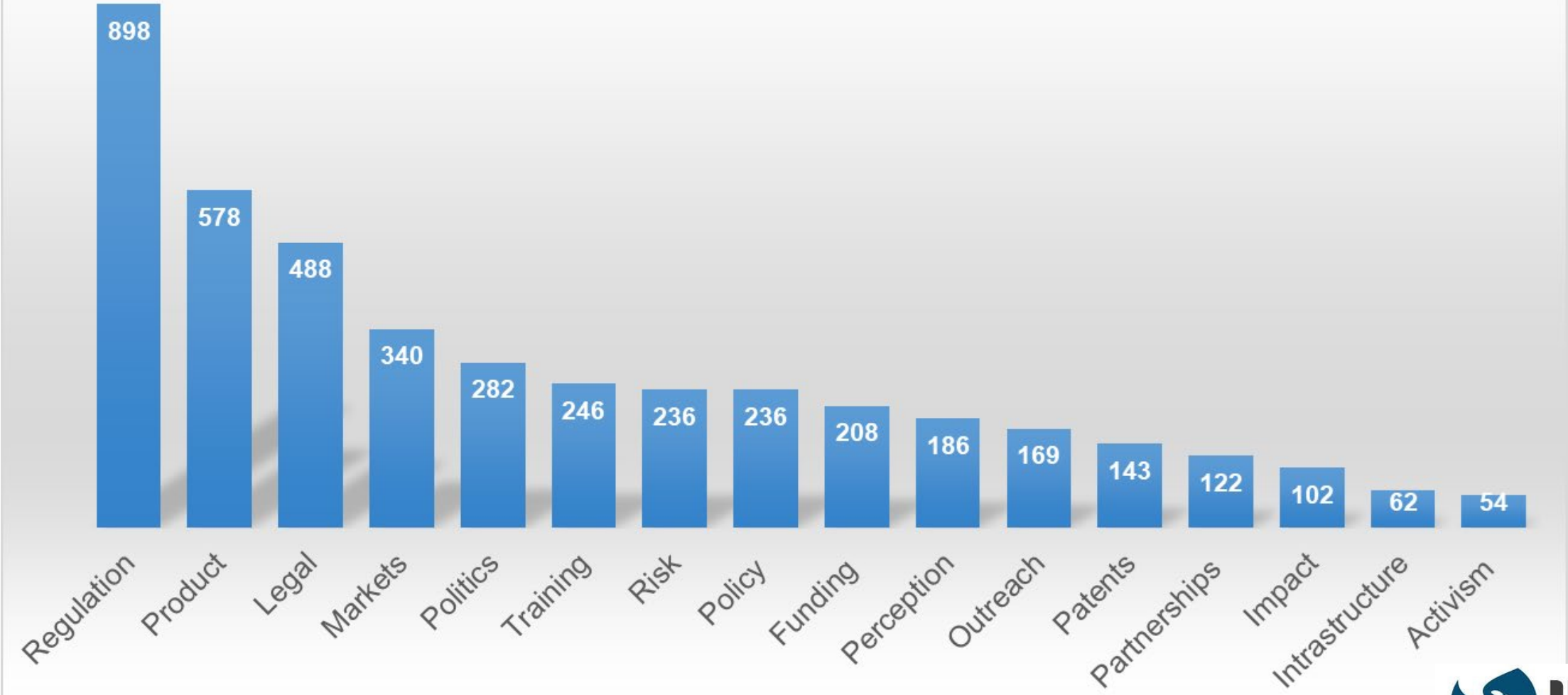
Frequency of Topics Mentioned in Interviews



Challenges

- **Regulation and legislation challenges. Need to clarify an actionable regulatory framework and harmonize with domestic and international legislation.**
- Bureaucratic limitations. Researchers struggle to obtain necessary items for their experiments and their labs. Importing them is often time consuming and not well understood by customs officials. This is critical for product developers. (Peru, Bolivia.)
- Limited partnership opportunities and career development for students. Limited opportunities to collaborate with different institutions.
- Partisanship of public officials. Biotechnology is often a partisan issue and its national support is subject to administration changes which can be disruptive to sustained innovation and development.
- **Limited public engagement. Lack of involvement of the public (few outreach activities and access to information about emerging technologies). Uncertainty and misunderstanding of community-level perception. Local opposition with support from European/International NGOs.**
- Close connection between market needs and product development. In countries that have the capacity to develop products and patents related to biotech, there is a clear influence of the market (trade) and the products down the pipeline. This represents an issue for crops that are not as attractive for the market (local).

Priorities

- Develop and enforce **flexible and harmonized regulations** that facilitate researchers' work, that respond to their needs. Avoid legal conundrums by rethinking usable and working definitions (gene edited, genome edited, etc). Allow multiple stakeholders to engage with the regulation (science, developers communities).
- Provide **training opportunities** for scientists and risk analysis experts.
- Foster **partnerships between private and public entities**, including universities, and research centers from other countries.
- Develop **education and outreach strategies** around different types of crops, valued not only by industry but also by farmers or other communities (include NGOs and local communities points of view).
- Develop platforms to facilitate **access to information about gene editing tools** as well as risk analysis/communication process to the public.

High Level Conclusions (Interviews)

- Regulation is the dimension that shapes all others.
  - Product development
  - Training
  - Capacity Building
  - Partnerships
- Many social dimensions are still poorly characterized and need more research:
  - Ex: Many regulators/product developers we interviewed believed that the activists/NGO groups were all opposition groups that are funded by EU organizations. On the ground, our research indicates that the activism is “home grown” and mostly concerned with a say in decisions that affect them and their food, with support from EU/International organizations. Not black and white opposition.

Case Studies

- Insight into the complexity and nuance of different kinds of crops in different contexts
- Different country contexts (regulatory regimes, size of economies)
- Different products responding to different needs or challenges

Maria Mercedes Roca

Estudio de caso I:

Edición génica en banano

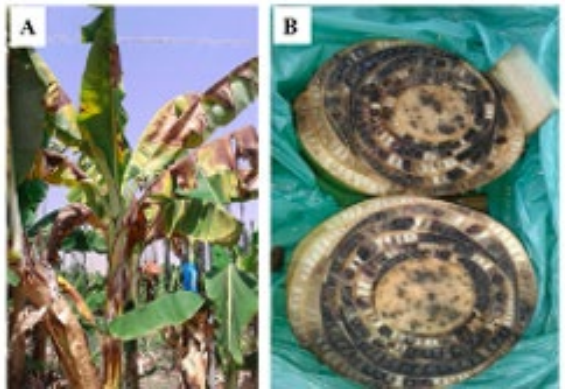
(Honduras y Guatemala)

Principales enfermedades de banano y plátano (musaseas}:

- Sigatoka del banano por *Mycosphaerella fijiensis*
- Marchitéz o Mal de Panamá por *Fusarium sp Raza Tropical 4*

Sigatoka Negra

Fusarium Raza Tropical 4



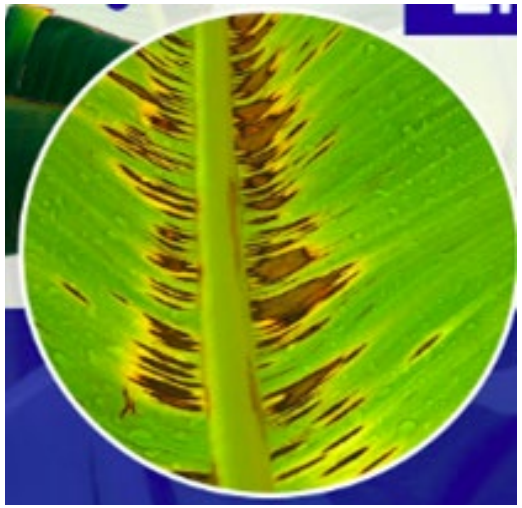
Bananas & Plantains: Food Security & Poverty Reduction

- Produced in more than 135 countries; staple crop for more than 400 million people
- Essential source of income in many developing countries
- Sigatoka and Fusarium pose serious risk

Objetivos de Desarrollo Sostenible (ODS)

Sigatoka Negra

- Most costly foliar disease: can cause up to 50% yield and 100% production loss.
- Highly virulent
- Appeared in Honduras in 1934
- Preventative measures & monitoring
- Est. cost of fungicide: $1500-2000 US/Ha/year. ~50 applications.



Fusarium oxysporum f. sp. *cubense* (TR4): Panama disease

- Soil fungus
- No effective fungicide for trees or soil
- Cavendish highly susceptible
  - Cavendish is more than 40% of world banana production, almost all of the world's exports are Cavendish
  - Conventional breeding impossible (sterile, clones)
- Transgenic, cisgenic, gene editing options all being developed

On October 1, 2020 Guatemala and Honduras opened peripheral customs that allow commercial exchange of agricultural biotechnology. On September 29, 2020 the first application for experimental stage field testing of a Black Sigatoka-resistant GMO banana was submitted to the National Committee on Biotechnology and Biosecurity (NCBB). Honduras has had biotechnology regulations and a NCBB since 1998, and as of September 2020, had more than 38,000 hectares of GE corn production, a small increase compared to 2019

https://www.fas.usda.gov/data/honduras-agricultural-biotechnology-annual-6

Estudio de Caso

Edición génica en Caña de Azúcar: Brasil y Bolivia

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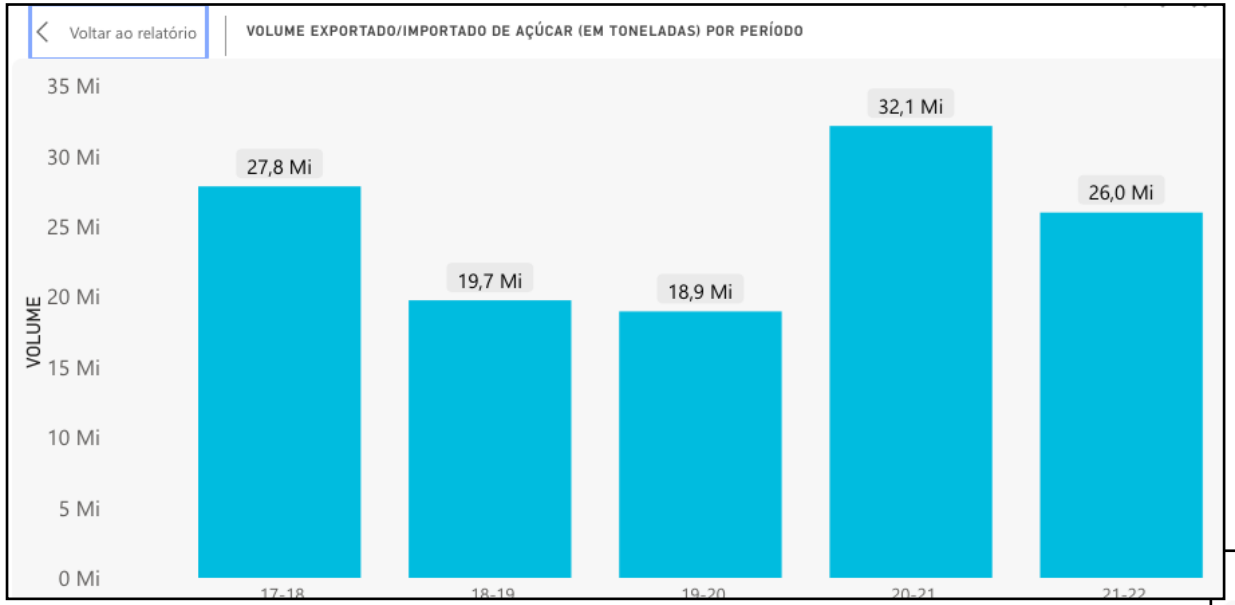
Caña de Azúcar: Importancia en Agricultura Tropical En Brasil

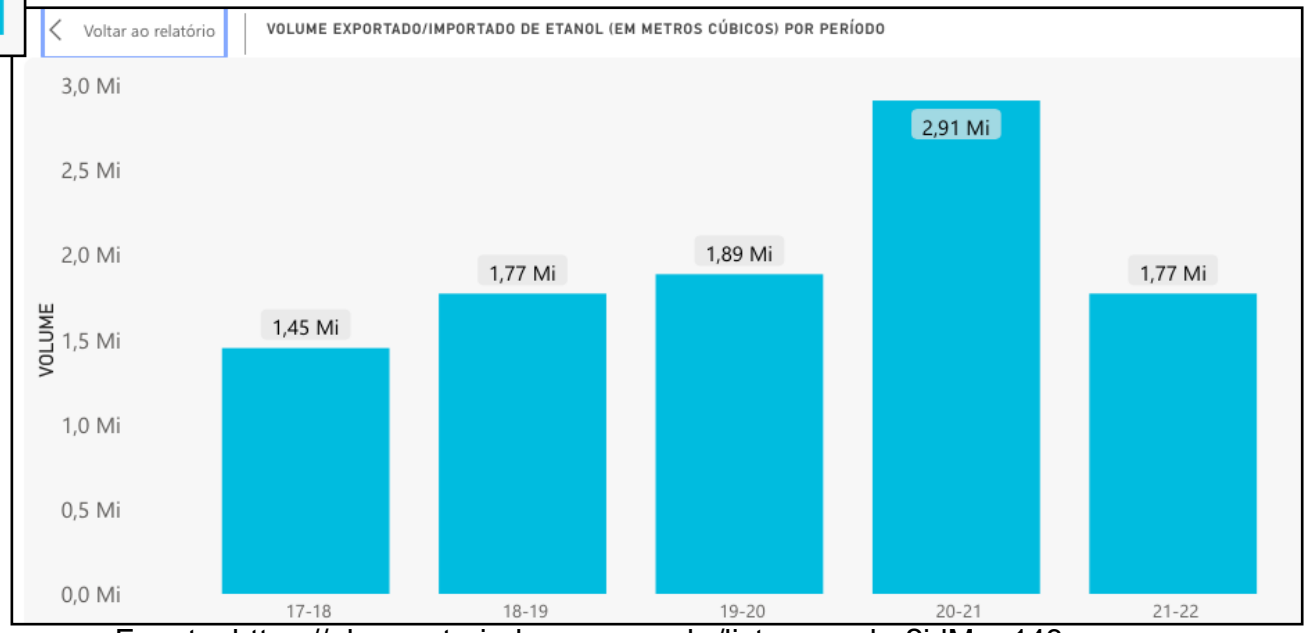


- Area total: 10Mi ha
- Producción total: 642Mi ton
- Productores: 70.000

(São Martinho, Terreaus, COFCO)

- Ingenios: 404
- Rendimiento medio: 74t/ha

Fuente: Sugar Tech (Jan-Feb 2022) 24(1):112–133



Fuente: https://observatoriodacana.com.br/listagem.php?idMn=143

Oportunidad de Caña GeD en el Sector Boliviano

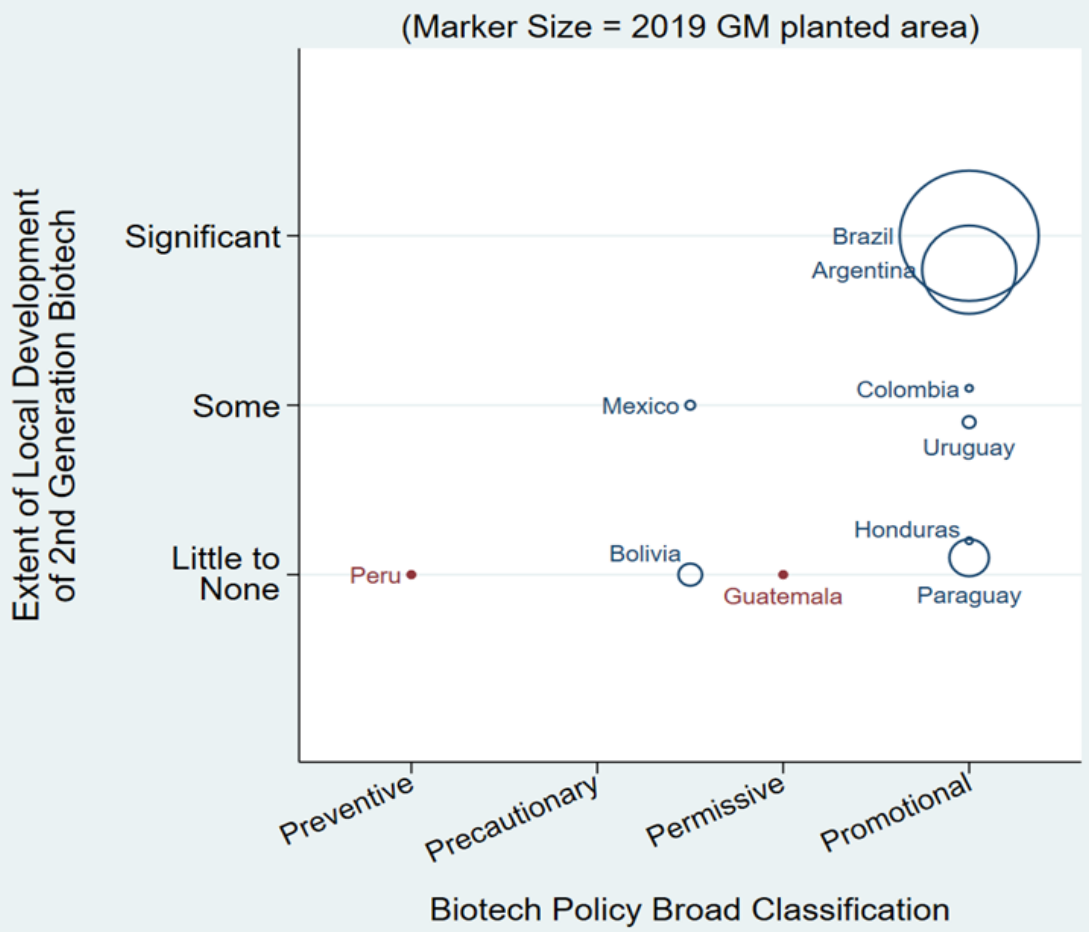
- Sector de caña de azúcar es mucho más joven y menos desarrollado
  - Bolivia (10Mi ton)
- 5 plantas (potencial de 250 Mi L etanol)
- Producción concentrada en Santa Cruz
- Centro de Investigación de Ingenio Guabira: cruzamientos de variedades Bolivia y Brasil
- Exportación de azúcar e importación de etanol

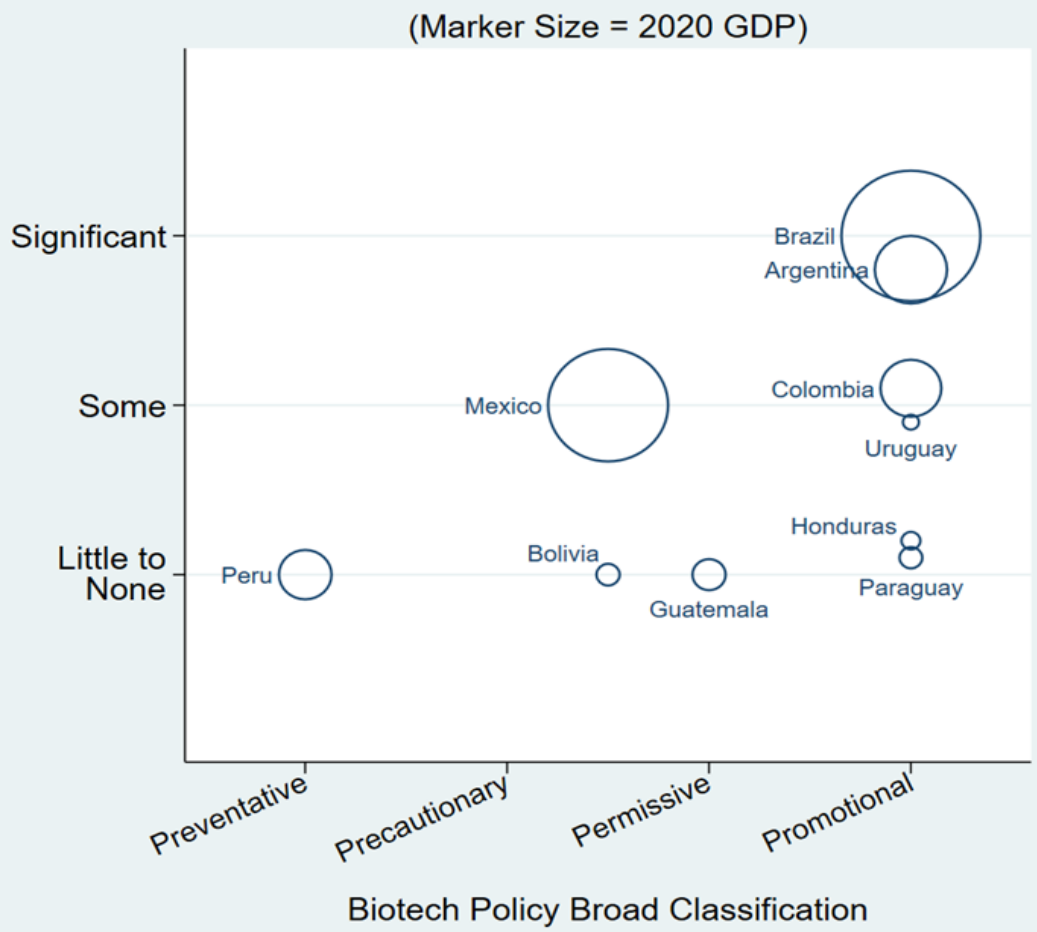
Elaborado de AEMP (2018)

Case Study Reflections

- Case study approach provides opportunity to look at an issue through transdisciplinary lenses.
- Complexity
- Surprise

Investment Recommendations: The Context





Sources: Planted Area via ISAAA; GDP via World Bank; Policy Category names via Paarlberg (2000)

Investment Recommendations

- Enhanced **cross-country collaboration** in:
  - Prior and post-consultation review procedures and disclosure protocols, tools for reducing information cost burdens
  - Expanding and coordinating **data sharing/recognition agreements** on biosafety and agronomic performance, where feasible and applicable
  - Anticipation of **licensing requirements**, optimal timelines for engagement, particularly for public entities

- Expansion of **student training** opportunities
- Consider expansion of bio-developer centers, with **support for investment recruitment**, showcasing, and facilitation of scaling up of SMEs

Concluding Thoughts 1

- Regulatory harmonization is a unifying theme.
- Sharing data across regulatory systems is of interest
- Case studies: effective for highlight complexity; gene editing/genetic engineering may not be most effective solution for key agricultural issues
- Partisanship and uncertain political climates can dramatically change biotechnology culture in countries.
- Social dimensions remain poorly characterized (NGO perspectives)

Concluding Thoughts 2

- This was a very different type of research – not just academic research but for a particular funder that's interested in investment.
- Learning curve!
- Different micro-politics: academic teams v wanting to further develop biotechnology in a region

Thank you!

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