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

Interim Progress Update

December 2, 2021

IDB
Inter-American Development Bank

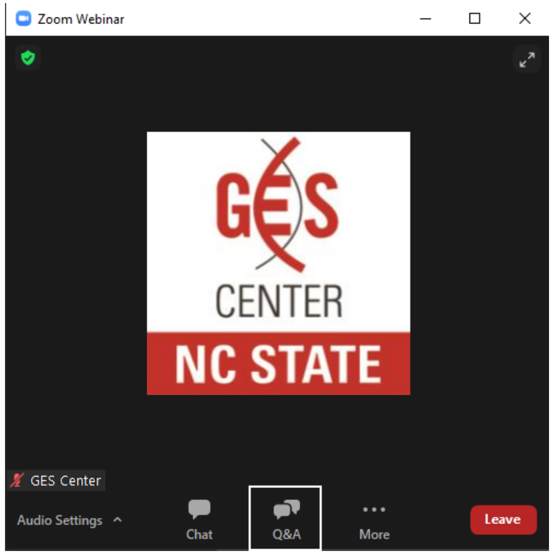
Tradução simultânea

- A reunião será realizada principalmente em espanhol.
- Há tradução simultânea para inglês, espanhol e português.
- Para os participantes do Brasil tirar dúvidas durante a reunião, recomendamos:
  - Escrever a pergunta em português no chat do aplicativo Zoom.
  - Se for possível, pedir a palavra e fazer as perguntas em inglês ou espanhol.
- Para ouvir as traduções:
  - Nos controles de sua reunião/webinar (Zoom), clique em Interpretação
  - **Clique no idioma que deseja ouvir, observando o idioma de origem necessário para a apresentação (inglês ou espanhol para os que falam português)**
  - (Opcional) Para ouvir apenas o idioma interpretado, clique em Silenciar o áudio original.

Traducción simultánea

- La reunión se desarrollará principalmente en español
- Hay traducción simultánea para inglés, español y portugués
- Para escuchar las traducciones:
  - **En los controles de su reunión/webinar, haga clic en Interpretación**
  - Haga clic en el idioma que desea escuchar.
  - (Opcional) Para escuchar sólo el idioma interpretado, haga clic en Silenciar el audio original.

Preguntas y respuestas en el seminario Web - Guia para los asistentes



- De manera predeterminada, los asistentes ingresan en modo “mira y escucha” (solo los ponentes pueden compartir audio o video)
- Desplácese hasta la opción “Preguntas y Respuestas” en la parte baja de la pantalla.
- “Preguntas y Respuestas” permite realizar preguntas a los ponentes.
- Los ponentes decidirán qué preguntas responder usando el micrófono y que preguntas serán respondidas en “Preguntas y Respuestas”
- Zoom dispone de una opción “Chat” en la que los asistentes pueden hacer comentarios. Sin embargo todas las preguntas deben hacerse en “Preguntas y Respuestas”.

IDB
Inter-American Development Bank

Project Presentation

Pedro Martel

Division Chief Environment,
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Inter-American Development Bank

Project Presentation

Michael S. Jones, PhD
Assistant Professor of Economics,
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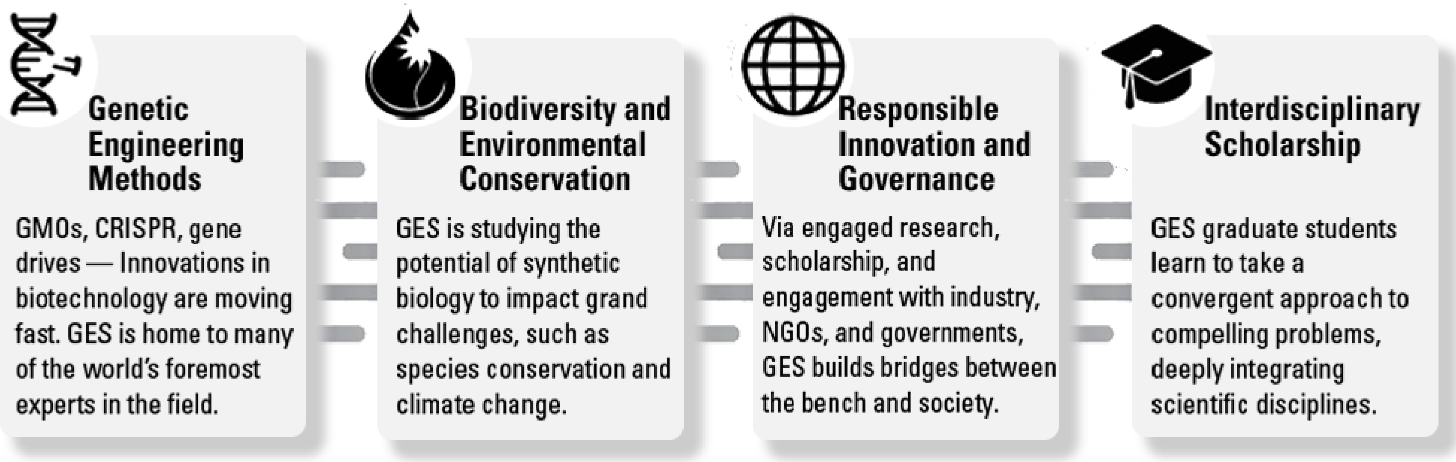
About the GES Center

The Genetic Engineering and Society (GES) Center serves as an international hub of interdisciplinary research, engaged scholarship and inclusive dialogues surrounding opportunities and challenges associated with genetic engineering and society.

- Positioned at the nexus of science and technology, the social sciences and humanities
- Experts in the technical, ethical, and societal dimensions of biotechnology



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Integrating scientific knowledge & diverse public values in shaping the futures of biotechnology.

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Project components

- Develop a baseline on national and international public policies on agricultural biotechnology in LAC.

- Consider the implications of the regulatory contexts of the CBD/Cartagena Protocol, EU, US, Japan, and China on public policies related to agricultural biotechnology (or only agriculture) in LAC

- 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.

- 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.

Project components

Base 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

Additional components (under development)

- Stakeholder interviews
- Case studies
- Investment strategies

NC STATE UNIVERSITY

Project Team

GES CENTER

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IDB
Inter-American Development Bank

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Thanks also to the Ad-hoc Working Group :

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

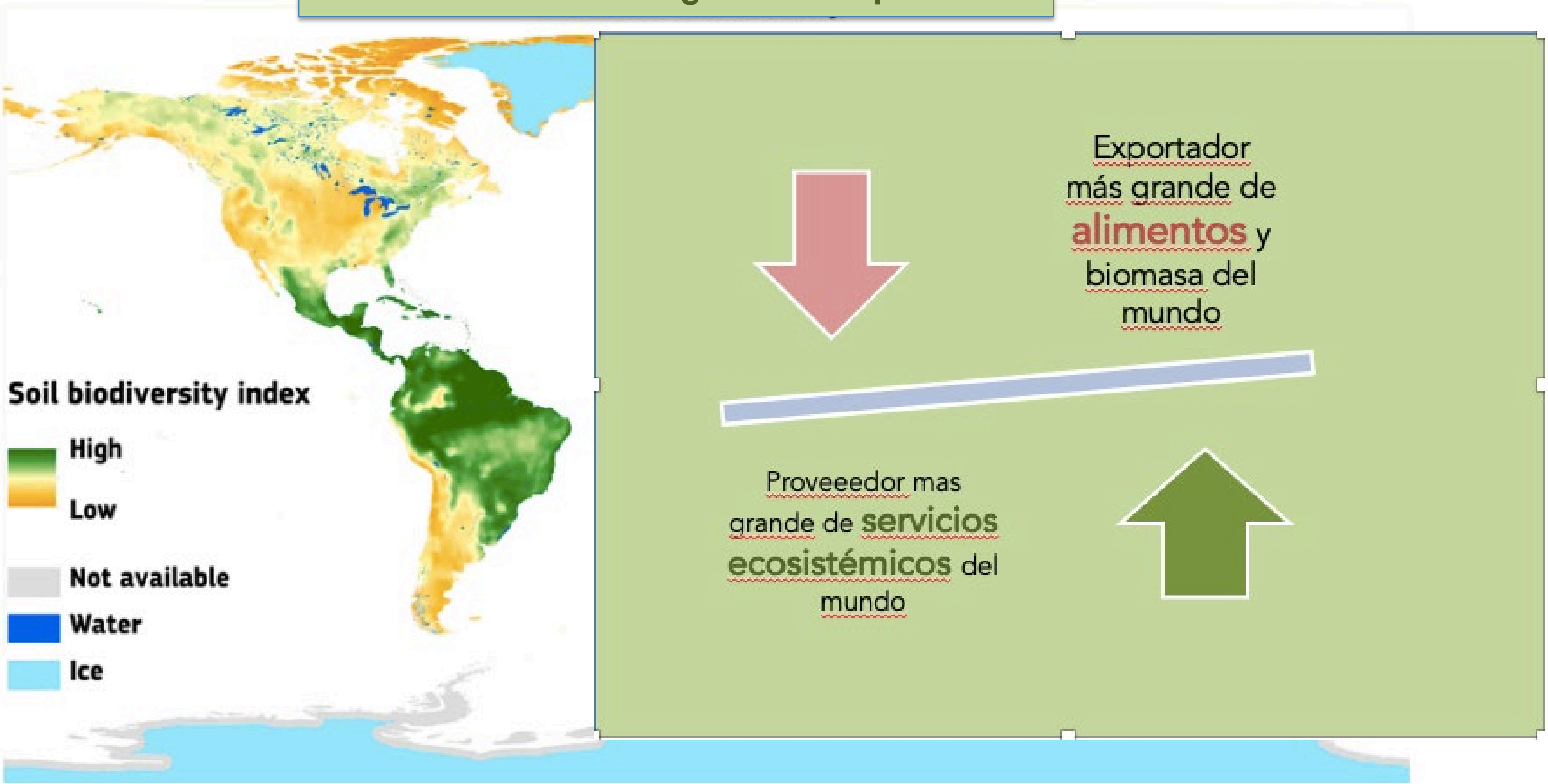
GES CENTER

Tecnologías para el mejoramiento de precisión

Maria Mercedes Roca
Directora Ejecutiva
Bioscience Thinktank

Inter-American Development Bank

Most biodiverse region on the planet

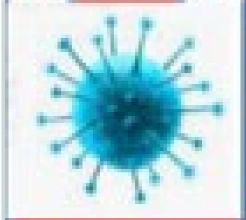


Source: Orgiazzi et al. (2016).

Tecnologías disruptivas para la industria agroalimentaria

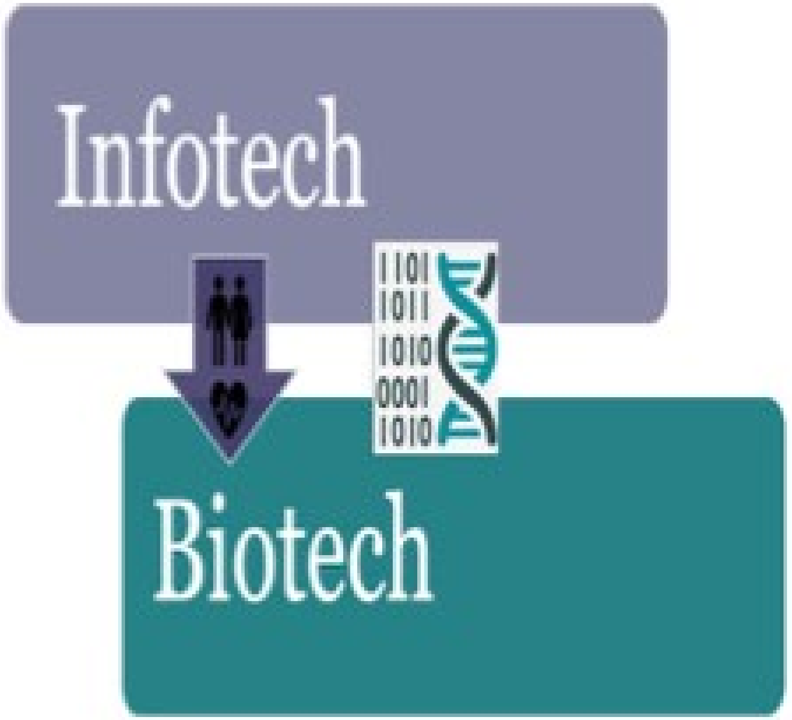
- **Tecnologias digitales** : Bioinformática, Inteligencia Artificial

- **CRISPR:** Edición génica de humanos, animales y plantas



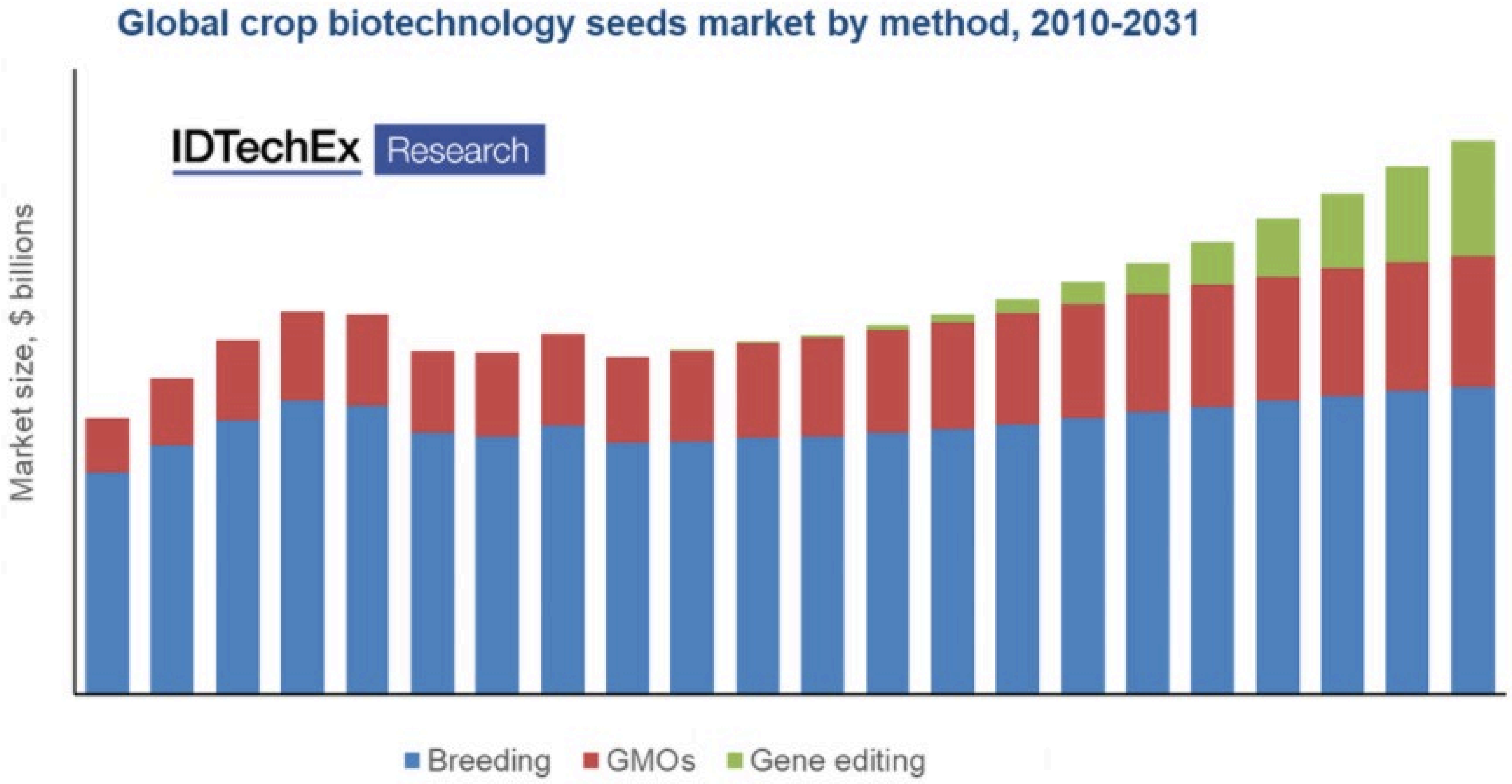
- **Microbiomas** : de humanos, animals y suelos/plantas (mejorados por biología sintética)

Technologías de **mRNA** & **virus**



Hoy podemos leer, escribir, diseñar y sintetizar el ADN de cualquier organismo, como lo hacemos con el código binario de computadoras

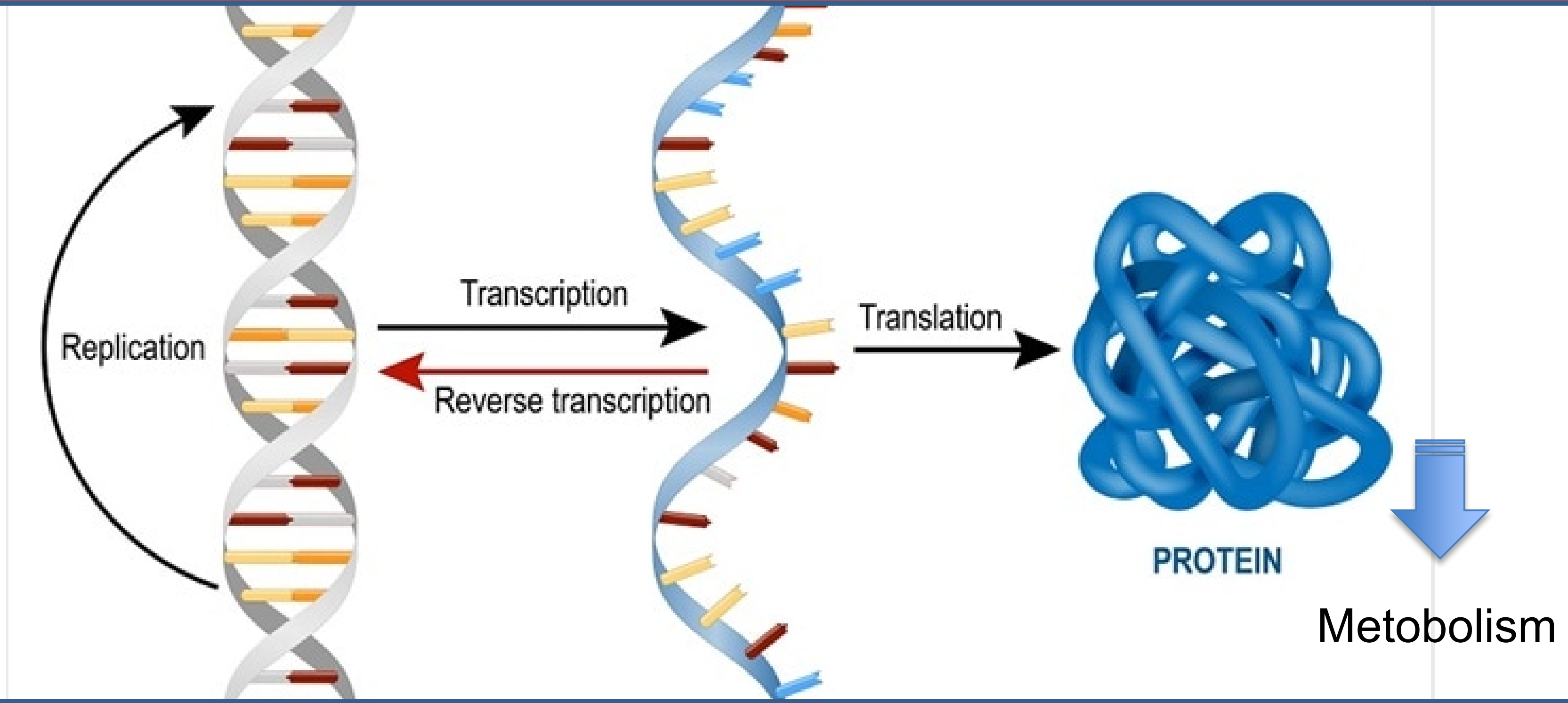
The market for genetic engineering in agriculture will reach $42 billion by 2030



Fuente: Michael Dent. IDTechEx, 2021

The Central Dogma of Biology and BioRevolution

DNA → mRNA → Proteina

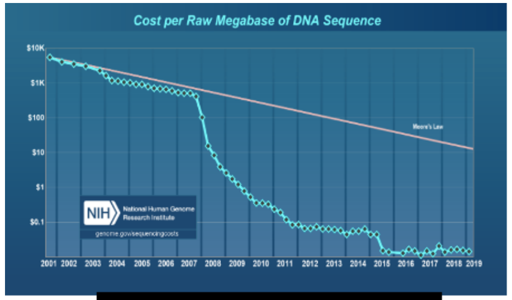


"-omic" Sciences

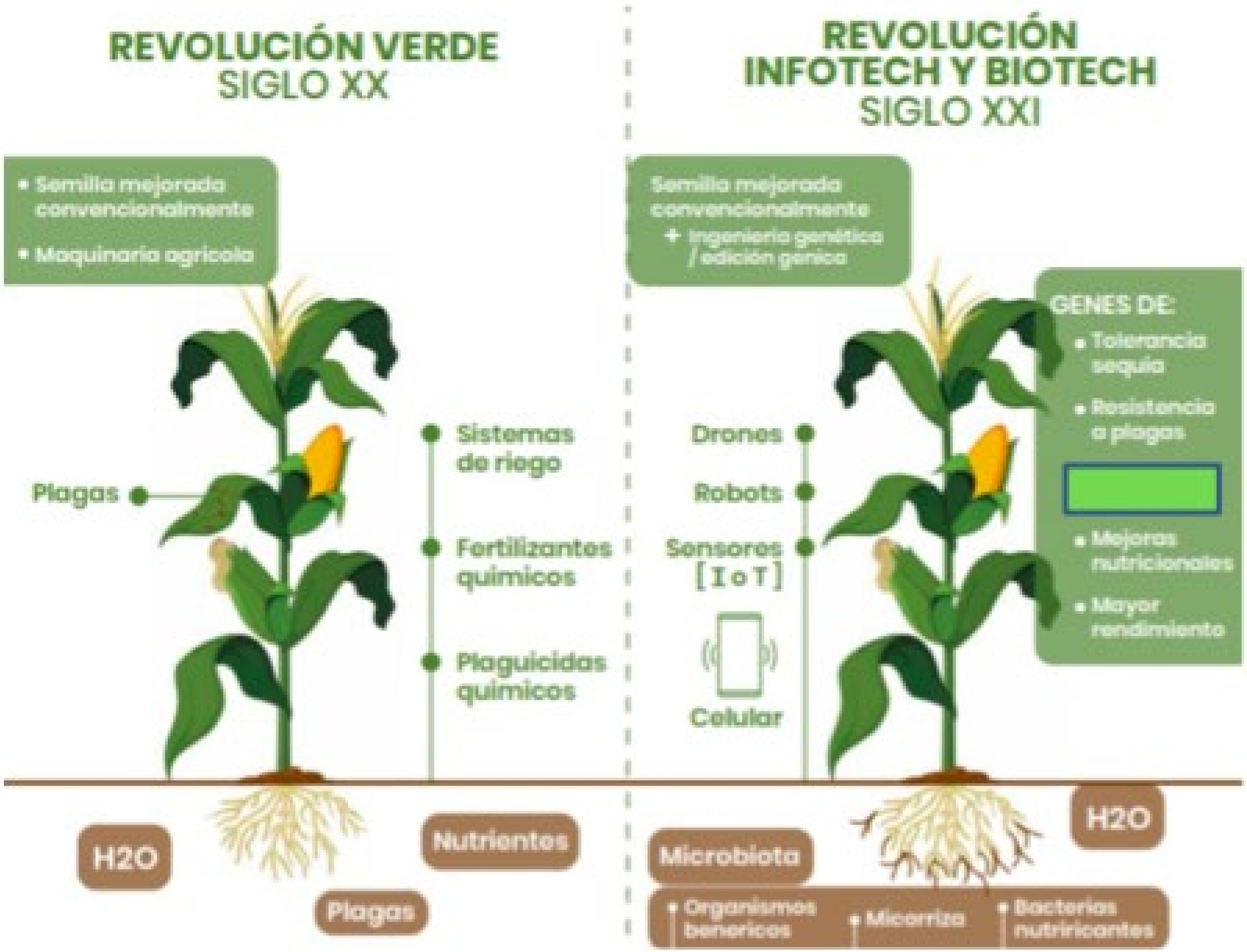
Pan-omics

- Genomics
- Epigenomics
- Transcriptomics
- Proteomics
- Metabolomics
- Phenomics (phenotype)

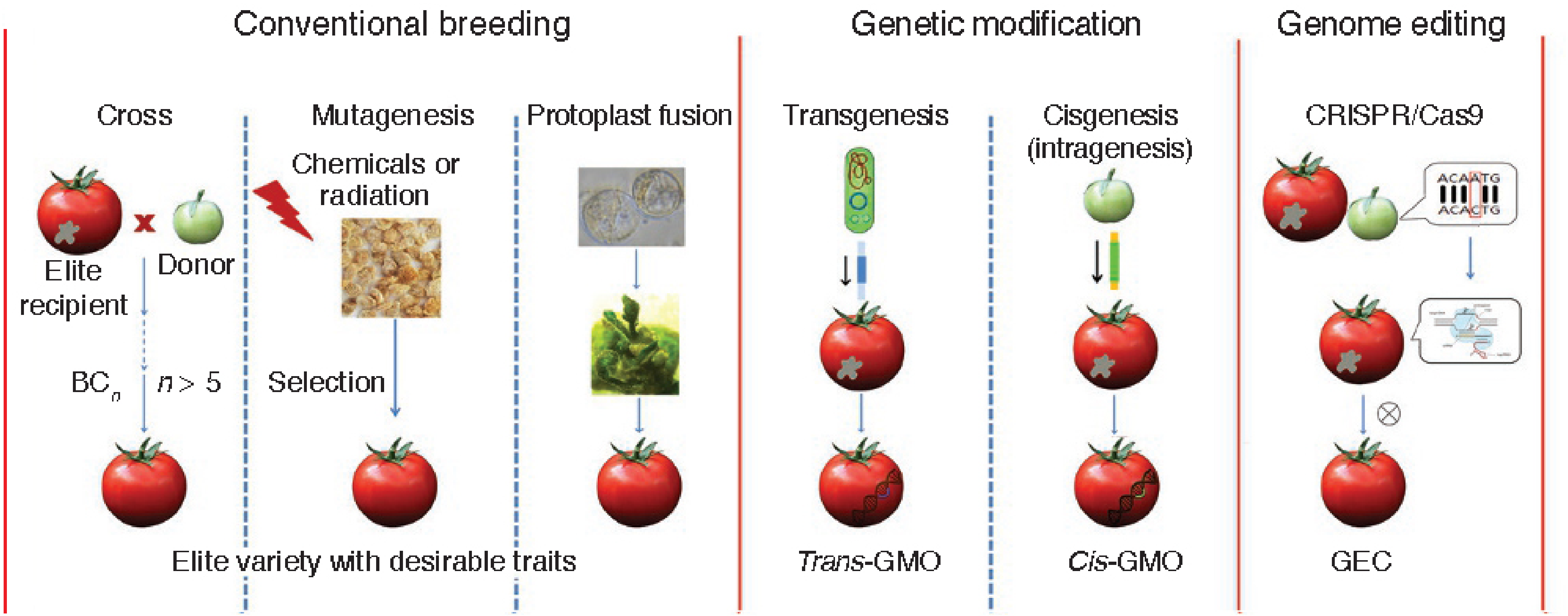
Advances in life sciences can transform economies and societies, helping to address global challenges such as pandemics, food production, biomaterials, and climate change.



NIH National Human Genome Research Institute


REVOLUCIÓN VERDE
SIGLO XX
Semilla mejorada convencionalmente
Maquinaria agricola
Plagas
Sistemas de riego
Fertilizantes quimicos
Plaguicidas quimicos
H2O
Plagas
Nutrientes
REVOLUCIÓN INFOTECH Y BIOTECH
SIGLO XXI
Semilla mejorada convencionalmente
+ Ingenieria genética / edición genica
GENES DE:
Tolerancia sequia
Resistencia a plagas
Mejoras nutricionales
Mayor rendimiento
Drones
Robots
Sensores [I o T]
Celular
H2O
Microbiota
Organismos benericos
Micorriza
Bacterias nutriricantes

Plant Improvement Technologies



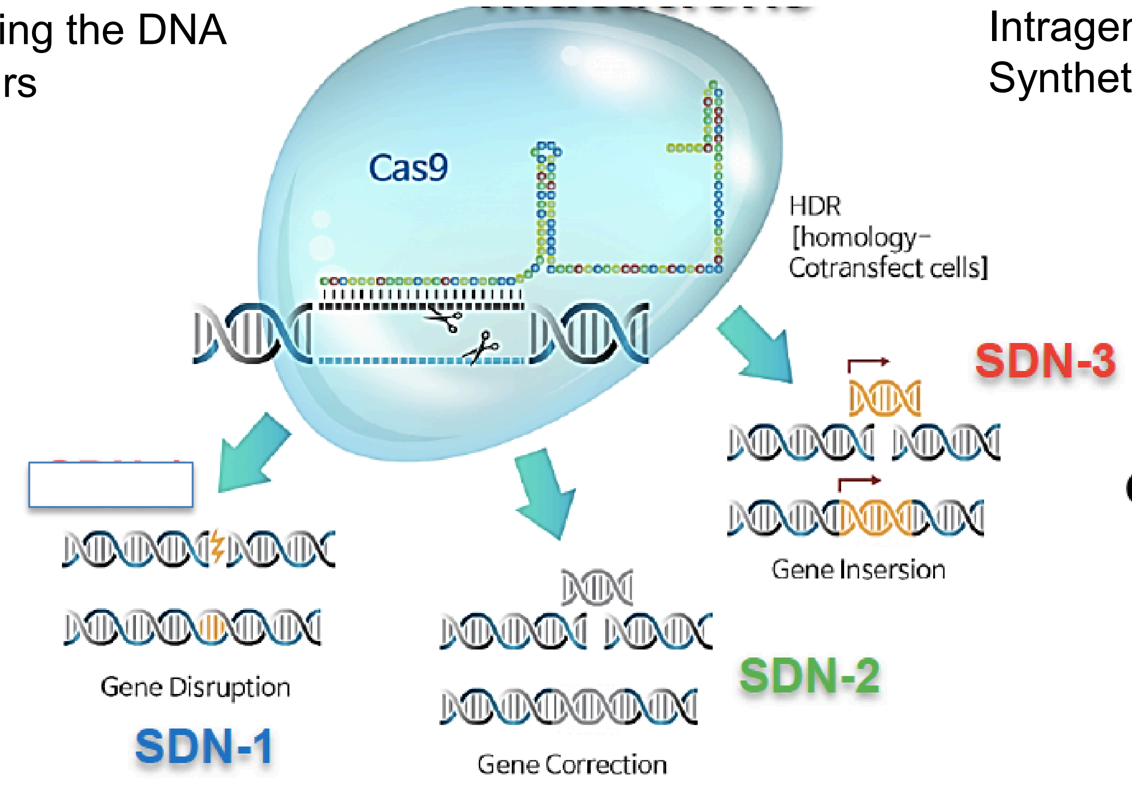
CRISPR gene editing using SDNs

– Or molecular scissors – to knock out, fix, or insert a gene

SDN-1: Genetic disruption.
No edits to the DNA

SDN-2: Editing the DNA
to make repairs

SDN-3 : Insertion of new DNA:
- Transgene
- Cisgene
- Intragene
- Synthetic gene



SDN: Site Directed Nuclease

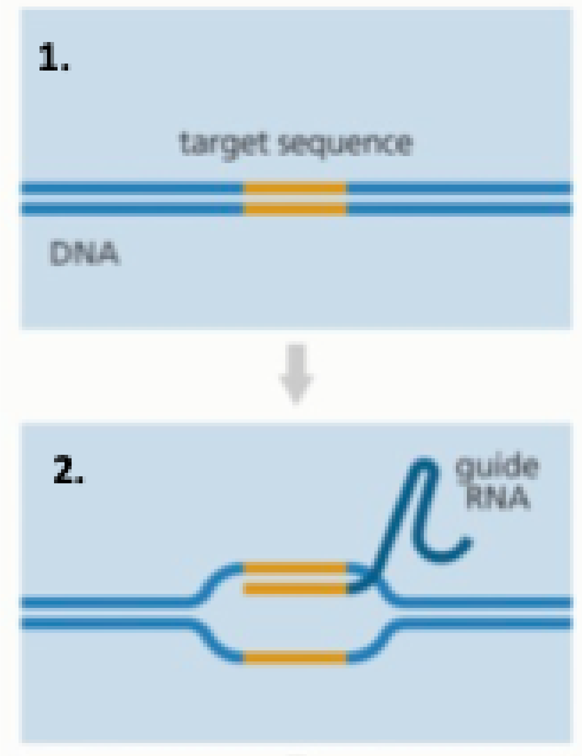
CRISPR

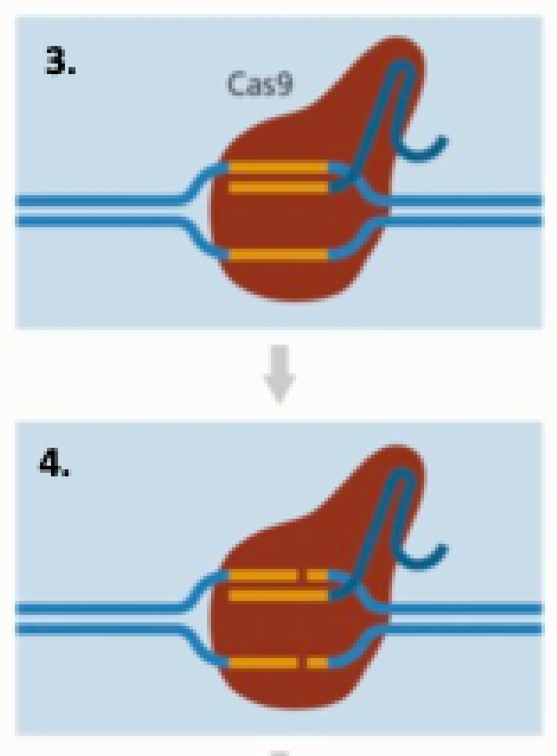
Three requirements
for plant improvement:

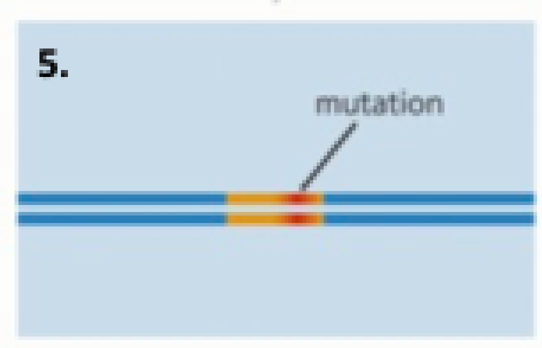
1. Panomic information (computational strategies with Artificial Intelligence)
2. Tools transformation (CRISPR)
3. Protocols regeneration (tissue culture)

El sistema CRISPR funciona con endonucleases: tijeras moleculares que cortan el ADN (Cas9; Cas12a y otras)

La enzima CAS-9 se acopla al gRNA



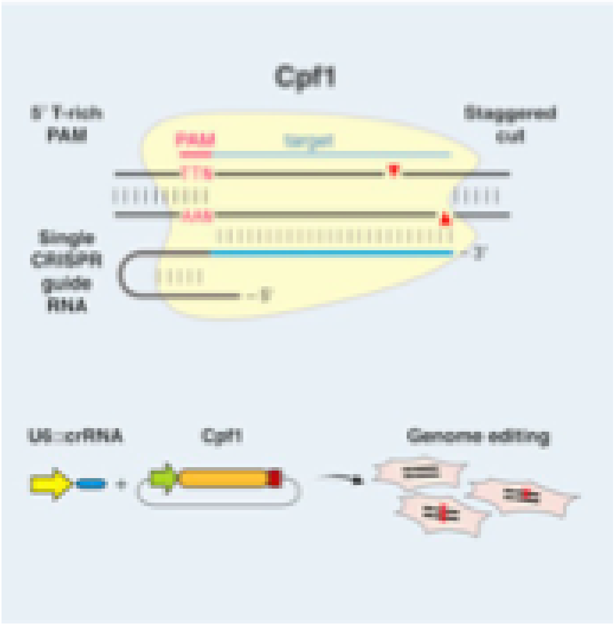




El ARN guia (gRNA) se acopla a la secuencia meta

La enzima CAS-9 corta ambas hebras del ADN

El corte es reparado induciendo una mutación



Cpf1 → Cas12a

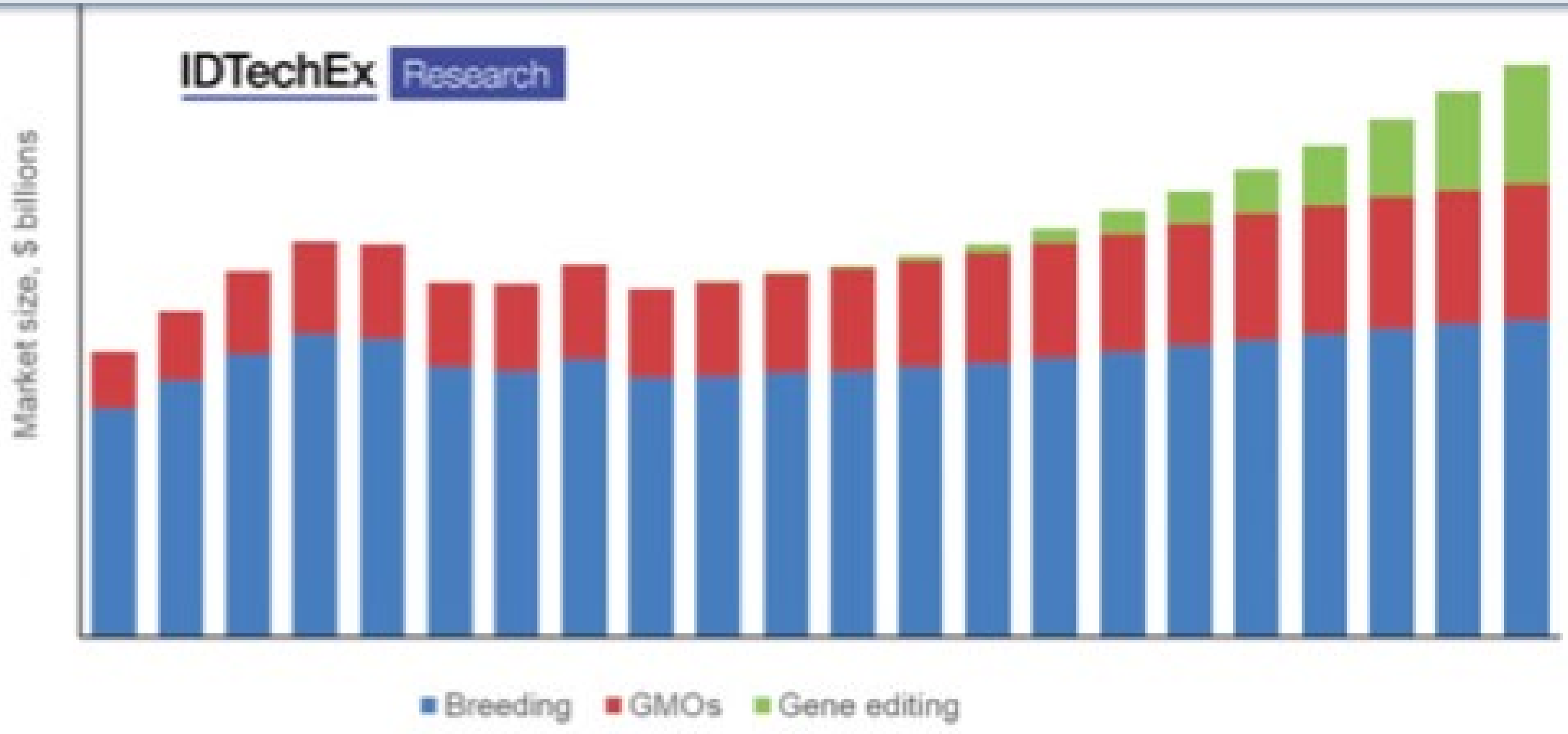
Fuente: Genome Research Limited

Mejoramiento convencional vs. edición génica. vs. transgénesis

	Mejoramiento convencional	Mejoramiento por edición génica	Modificación por transgénis
Tiempo (para nueva variedad)	10 años	2-5 años	10-12 años
Enfoque	Aleatorio (prueba & error)	Preciso	Semi-preciso (inserción aleatoria)
Costo	$ 10 M	$0.5 – 5 M	$20 -50 M
Desperdicio	> 95%	< 10%	10-50 %
ADN foráneo en producto	No	No (SDN-1 & 2) Si (SDN-3)	Si
Cambios no intencionados	Alto	Bajo	Bajo
Incremento en rendimiento	Incremental (1% p.a)	"Breakthrough" posible (>20%)	No directamente (protección del cultivo)

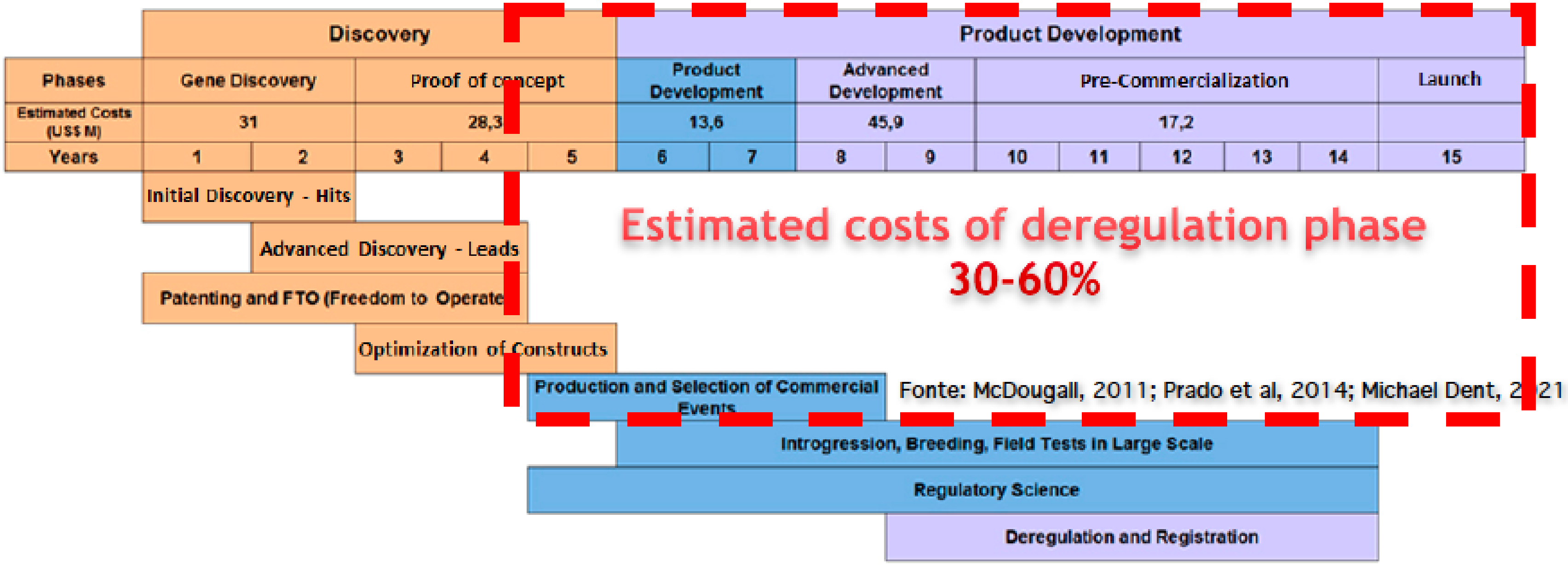
The market for genetic engineering in agriculture will reach $42 billion by 2030

El mercado de semillas mejoradas con biotecnología por métoods, 2021-2030



Fuente: Michael Dent. IDTechEx, 2021

Cost of Bringing a Biotech Crop to Market



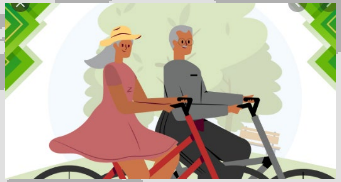
Estimated Costs: U$136 million

Estimated Costs of Deregulation Phase: U$35 million

It can take ~12-20 years from discovering a gene(s) and placing a GM Commercial Variety in the Market

La demografía de la discordia: cambios en la población 2050

Distribution by region



-1%

Populations grow, shrink and diversify… all at the same time

4%

Europe influences public agri-food policies including biotechnology in developing countries

41%

49%

7%

What could affect the future of agri-food systems in LAC?

Drivers: trends and "disruptors"

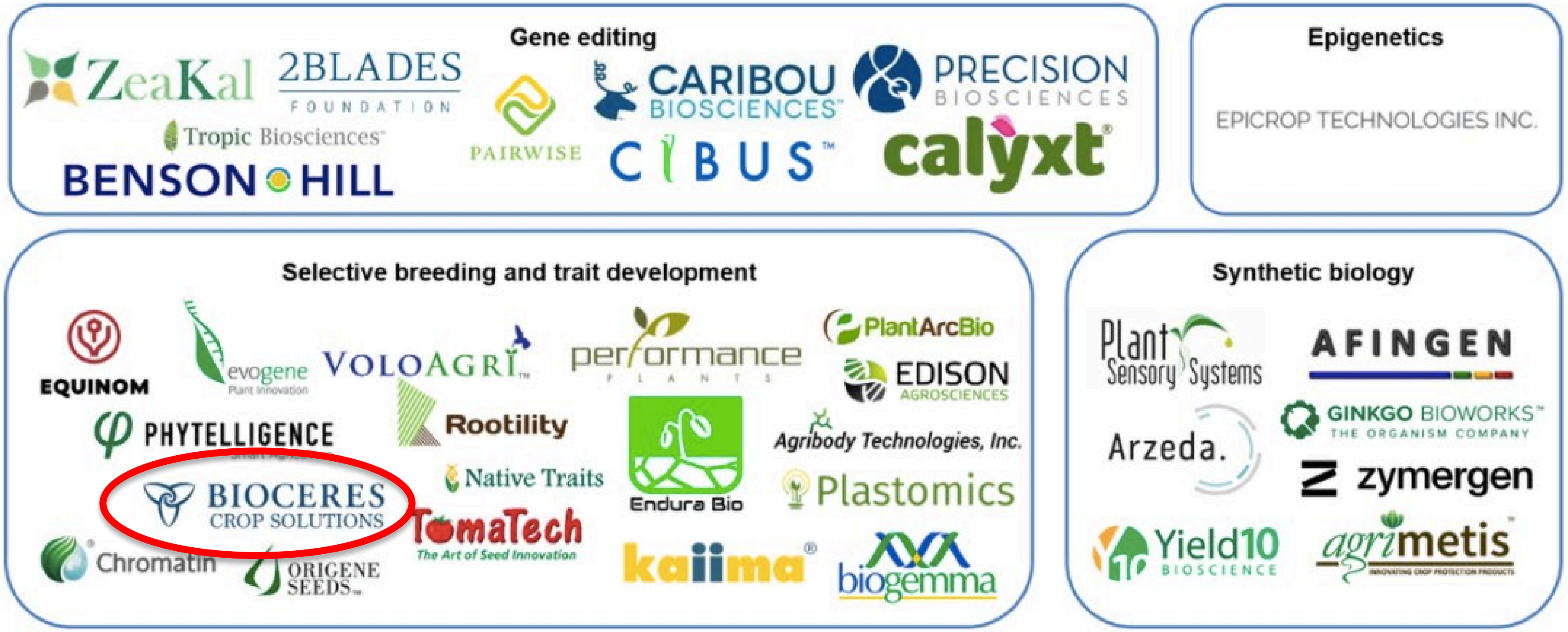
Trends: slow and relatively predictable forces. They allow advanced strategic actions

Population growth, urbanization, decarbonization, nationalist protectionism technology - digitization, consumer preferences, **activism and fake -news**

Disruptors:
Sudden, unexpected forces

Pandemics, natural disasters, radical changes in government, radical policy changes (decarbonization, non-agrochemicals), social and commercial conflicts, **breakthroughs in technologies**

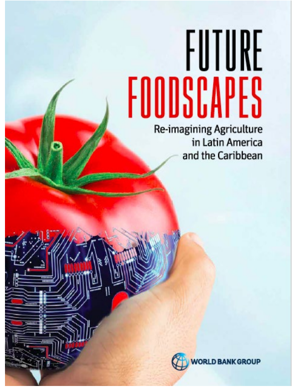
The crop biotechnology start-up landscape



The crop biotechnology start-up landscape. Source: IDTechEx

Bibliography

2020

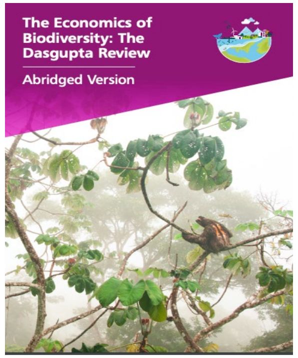


Future Foodscapes: Re-imagining Agriculture in Latin America and the Caribbean
https://www.worldbank.org/en/region/lac/brief/future-foodscapes-re-imagining-agriculture-in-latin-america-and-the-caribbean

2020

The Bio Revolution: Innovations transforming economies, societies, and our lives
https://www.mckinsey.com/industries/life-sciences/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives

2021



The Economics of Biodiversity: The Dasgupta Review
https://www.gov.uk/government/publications/final-report-the-economics-of-biodiversity-the-dasgupta-review

Genome Editing in Latin America: CRISPR Patent and Licensing Policy

Margo Bagley, JD

Asa Griggs Candler
Professor of Law,
Emory University School of Law

CRISPR PATENT AND LICENSING POLICY

- **Purpose of IP Policy Brief:**
  - Provide overview of CRISPR plant agriculture patent landscape in relevant countries
  - Identify and describe key licensing protocols for LAC companies and institutes interested in engaging in CRISPR plant agricultural research

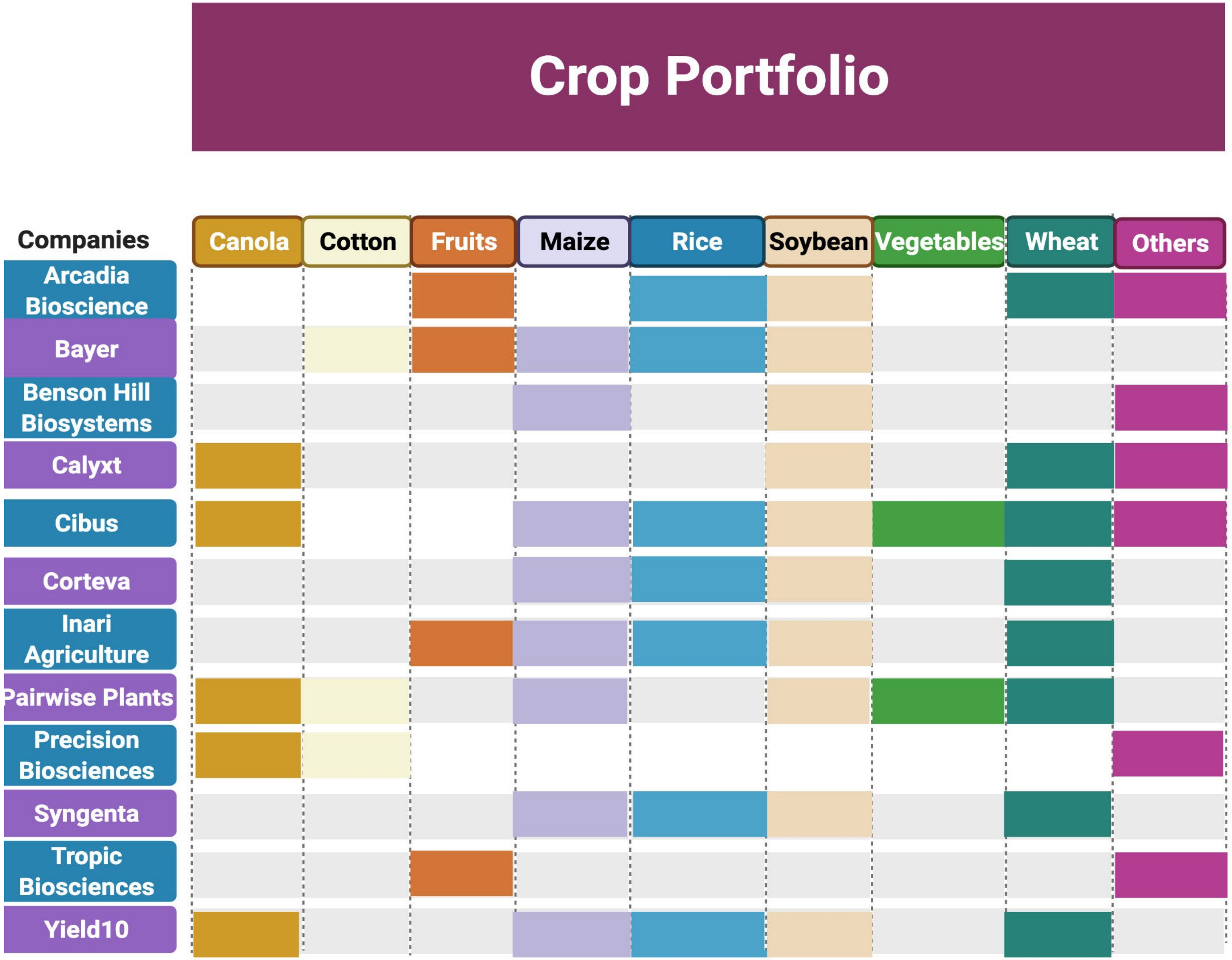
CRISPR PATENT FILINGS

Genome editing with CRISPR-Cas9 has revolutionized agricultural research by reducing the time it takes to develop an improved trait by half from 8-12 years down to 4-6 years.

CRISPR PATENT AND LICENSING POLICY

The relative ease of use, efficiency, and flexibility of the system has resulted in its use in a wide variety of crops to develop several traits of interest, including higher yields, herbicide resistance, drought tolerance, disease resistance, faster growth, and more.

- Some crops in which CRISPR-Cas9 technologies are being employed (others include barley, cucumber, lettuce, potato, sorghum, sunflowers, camelina, and tobacco)



CRISPR PATENT FILINGS

- With such a promising field there are a lot of competing and overlapping patents
  - This creates licensing and freedom to operate concerns
  - Has led to several different alternatives like CRISPR-Cas 12 a & b, 13, 14, and CRISPR-Cms1 for genome editing
- Cas9 remains the most widely used

CRISPR PATENT AND LICENSING POLICY

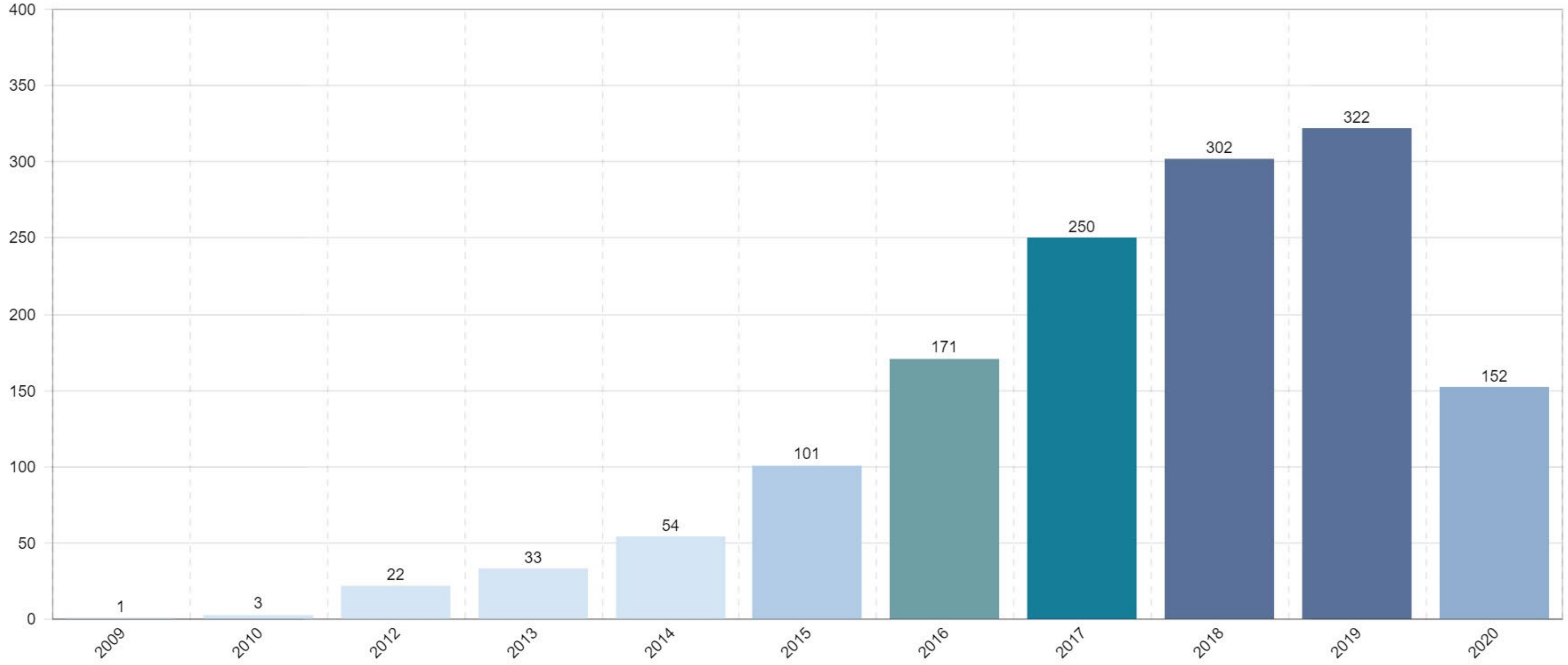
- Patents grant a ~20-year right to exclude others from doing certain things with a claimed invention, namely:
  - Making
  - Using
  - Selling
  - Offering to sell
  - Importing
- These rights are territorial, and must be sought in every country/region protection is desired
- Inventions are assessed for novelty, inventive step, adequate description, and subject matter eligibility.
- Now to the patent landscape…

CRISPR PATENT AND LICENSING POLICY

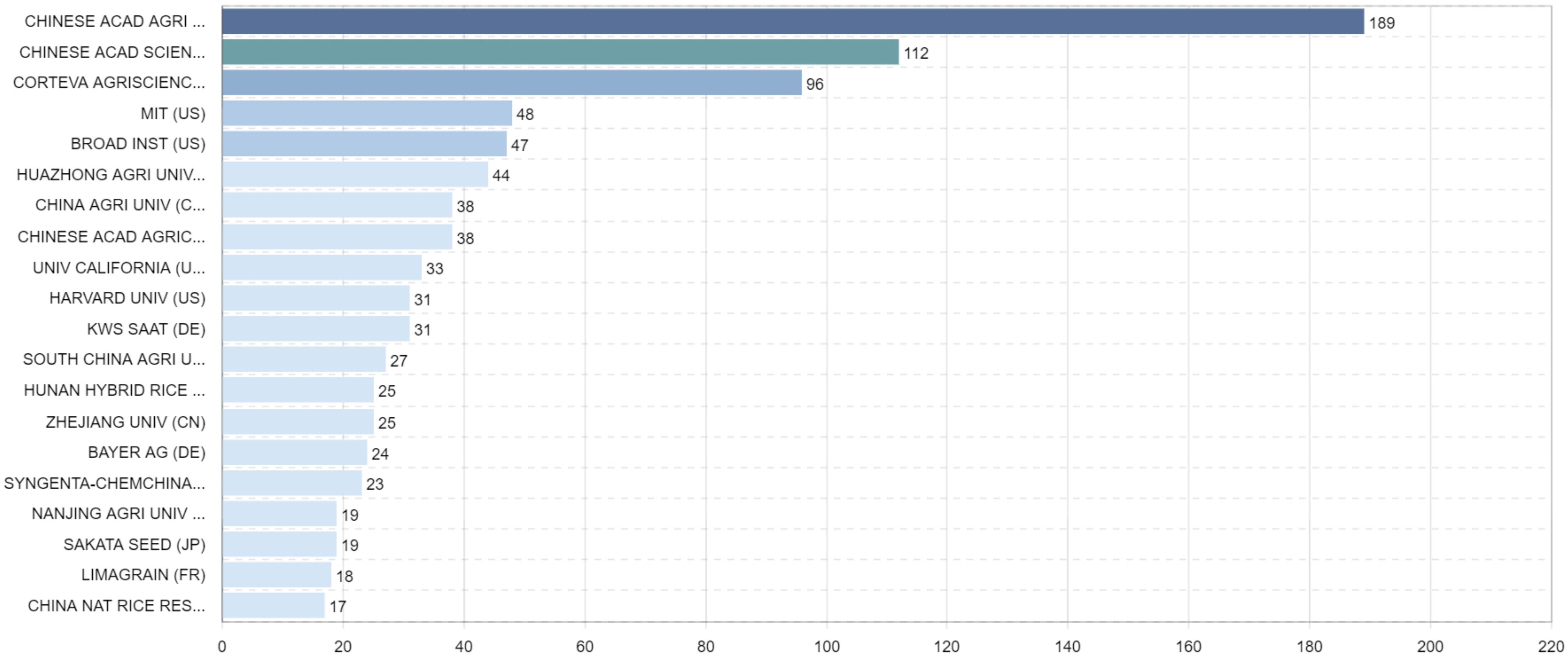
- There were **8100** CRISPR patent families worldwide as of January 30, 2021, of which **1400** relate to plant agriculture
  - A "patent family" encompasses all patent filings in different countries for one invention. For example, one patent family could have one individual patent filing in Argentina, another one in Brazil, another in Mexico, etc.
  - "Patent filings" are published patents and patent applications.
- Because some of these published documents are still applications, they may never actually issue as patents.

Published Patents Applications and Patents

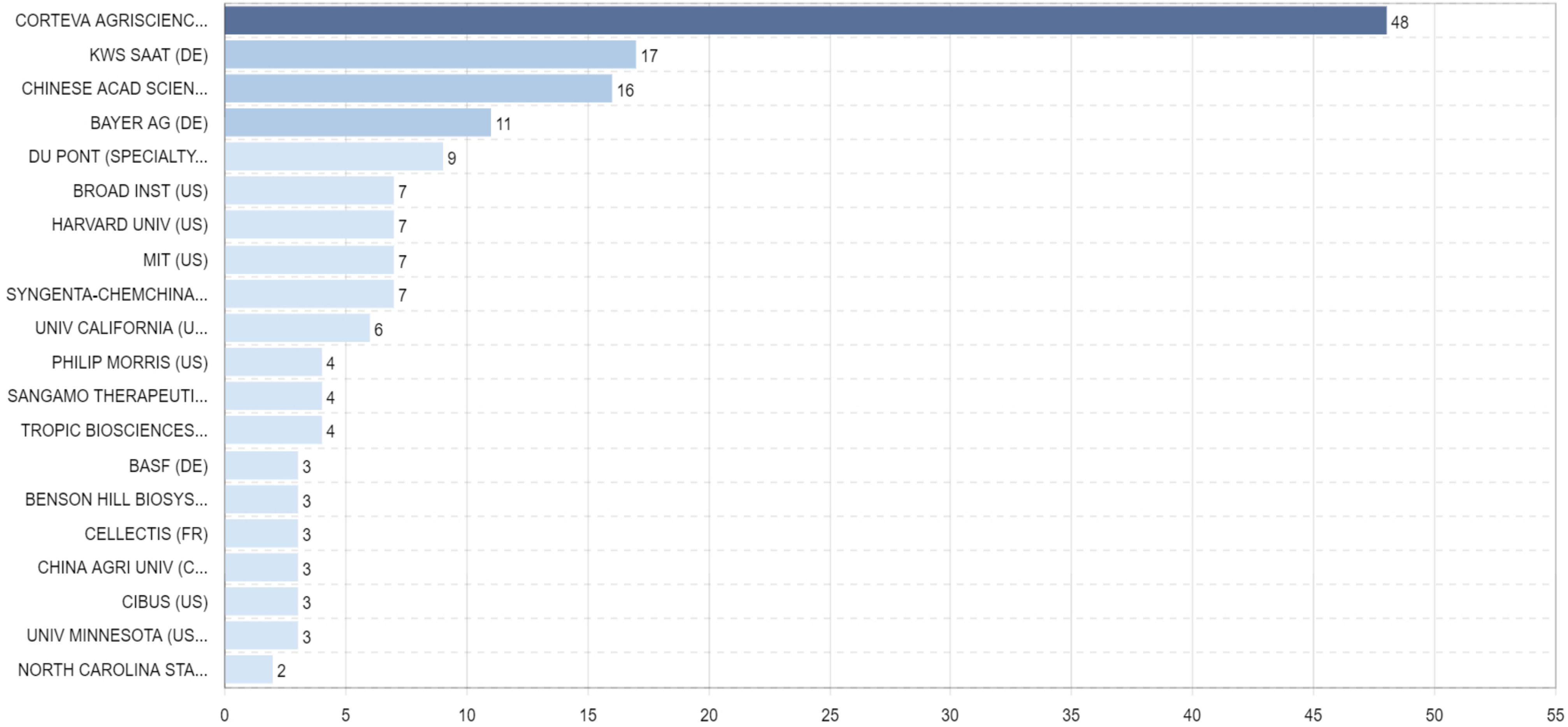
- There are more than 1400 patent families worldwide, comprising numerous published patents and patent applications covering the use of CRISPR tools in plant agriculture and the number of filings have been increasing over time



Top 20 Filers of CRISPR Plant Agriculture Published Patents and Patent Applications Worldwide

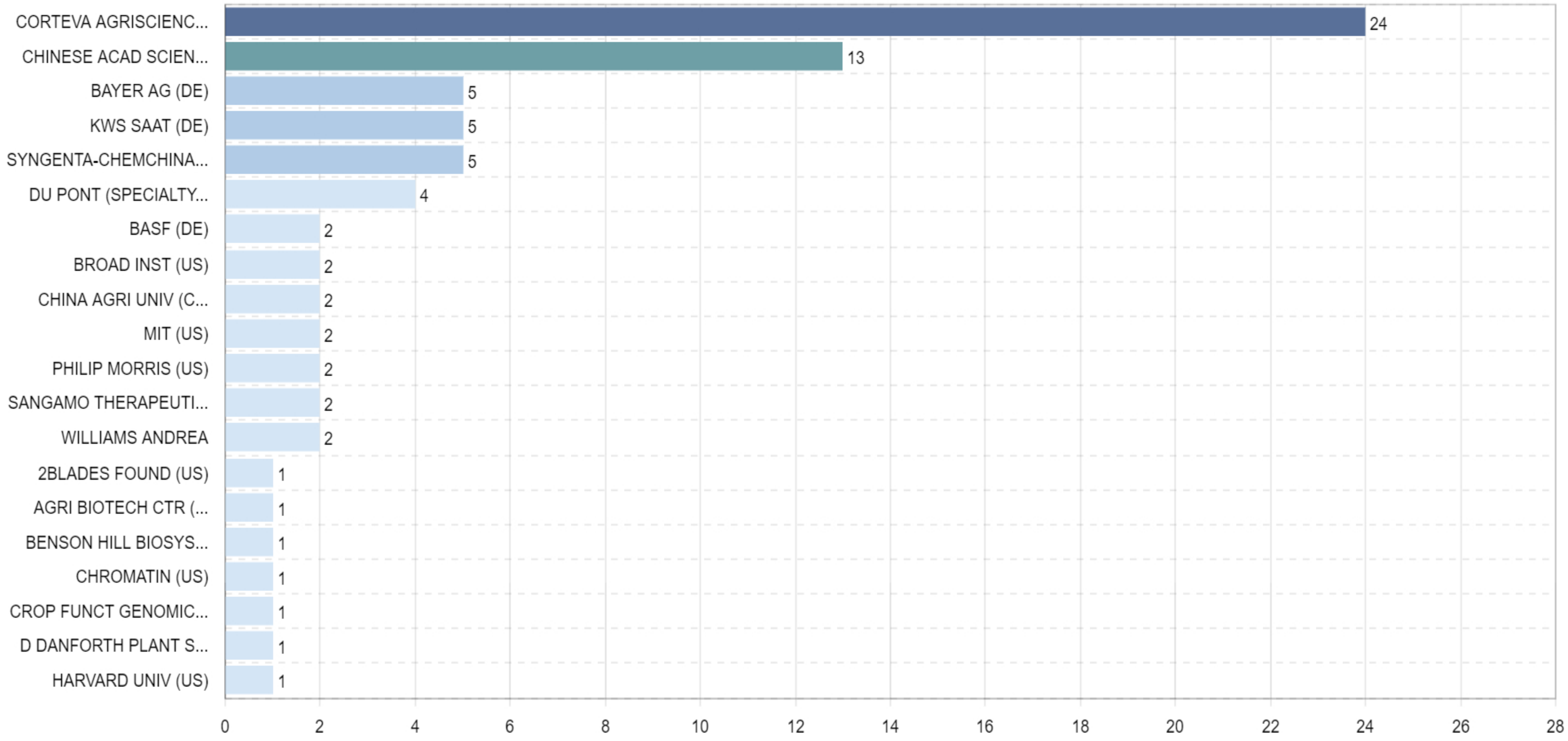


Top 20 Plant Agriculture Filers in Latin American Countries of Interest
(175 patent families)

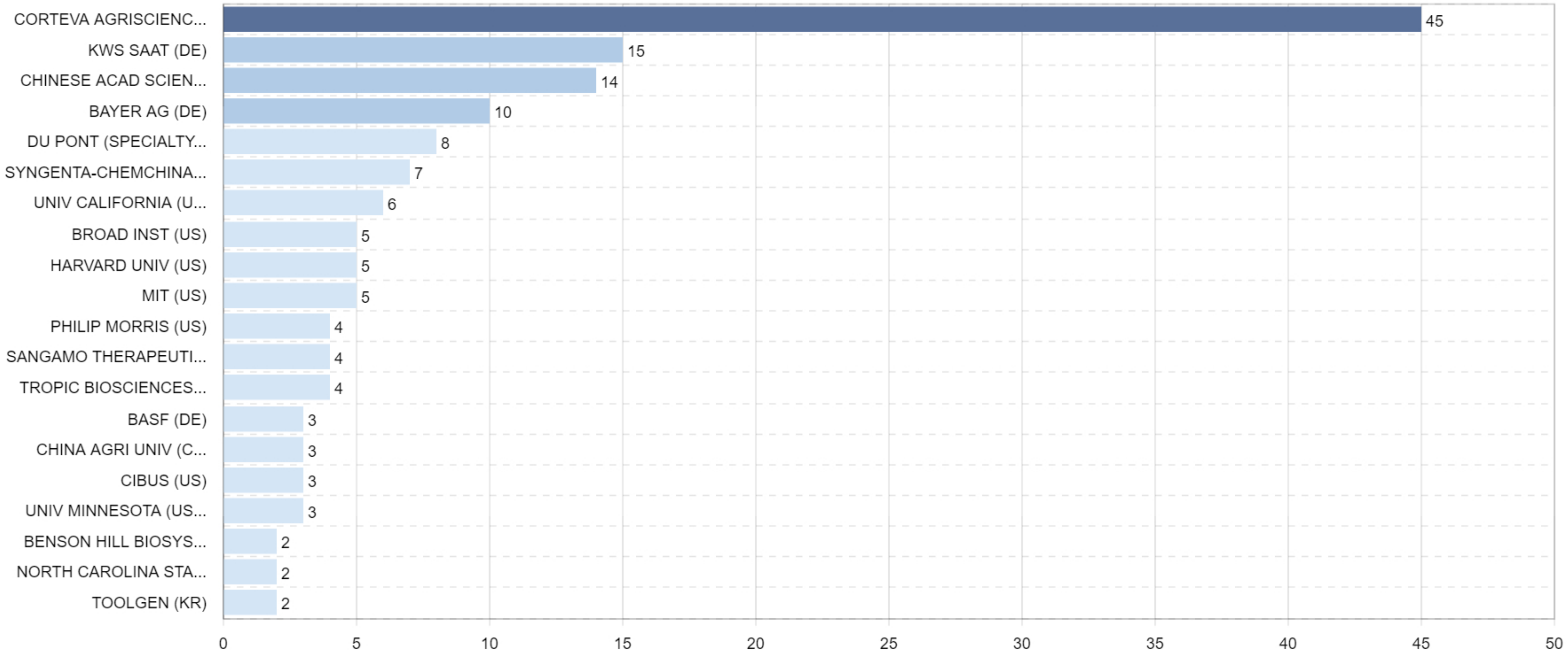


Top CRISPR Plant Agriculture Patent Filers in Argentina

(65 patent families)

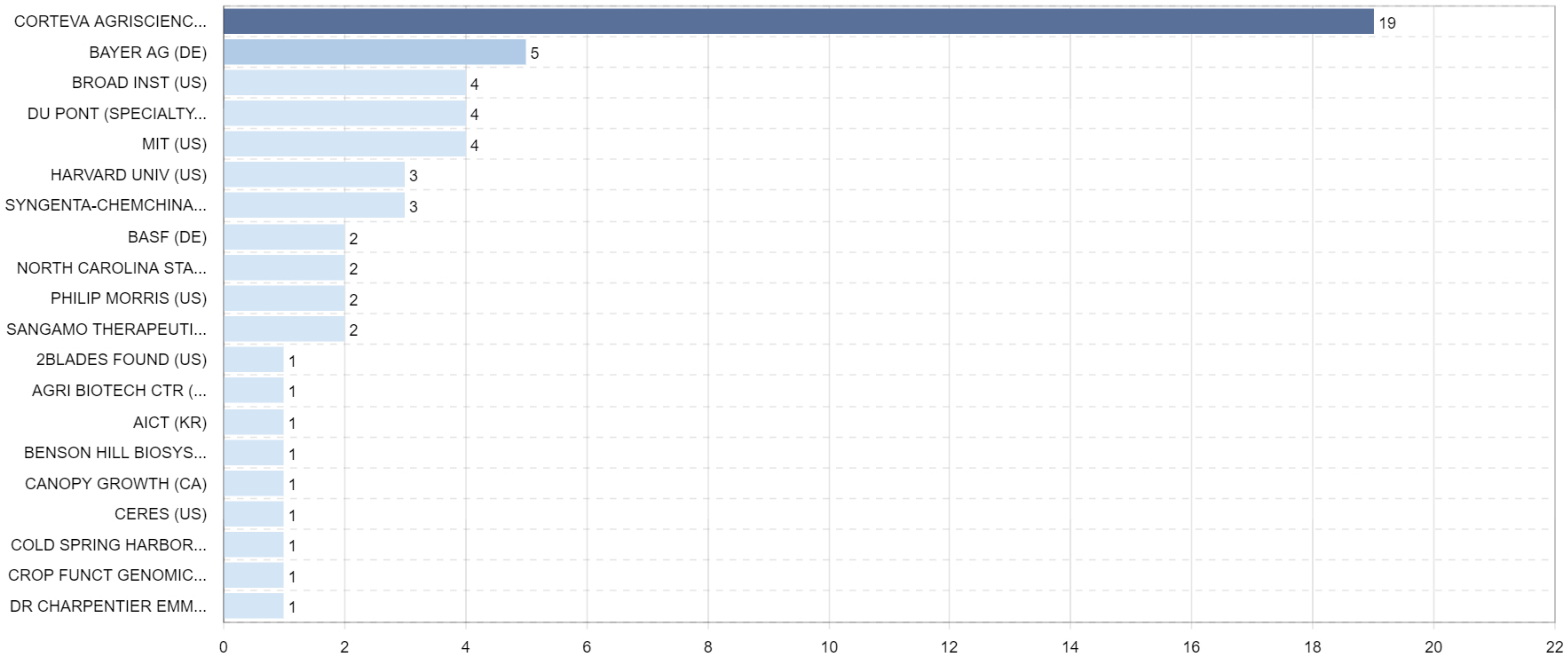


Top CRISPR Plant Agriculture Patent Filers in Brazil (155 patent families)



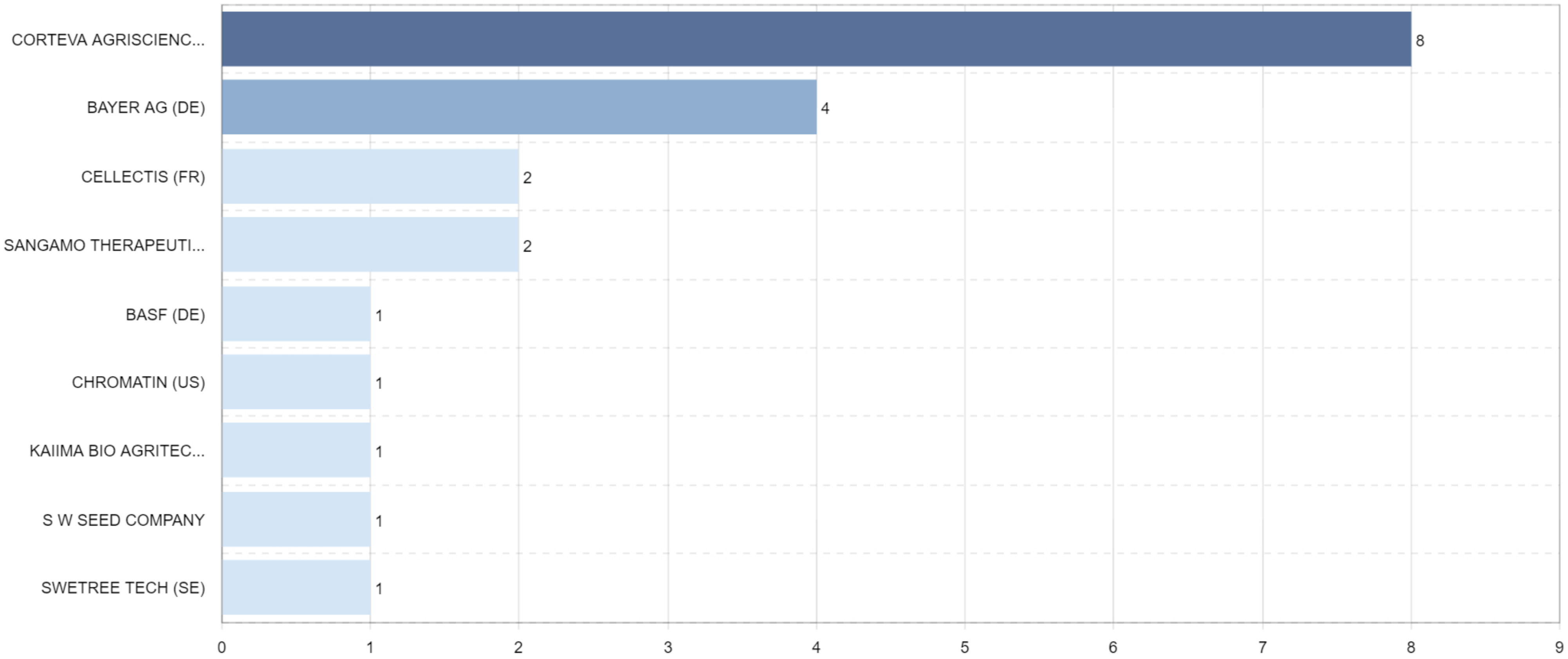
Top CRISPR Plant Agriculture Patent Filers in Mexico

(51 patent families)



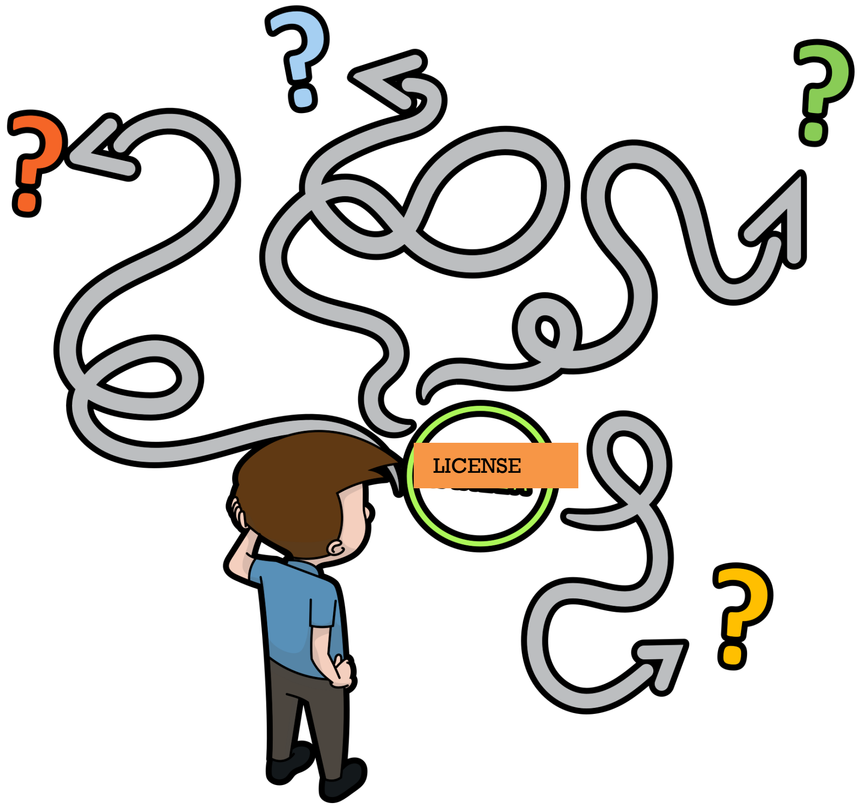
Top CRISPR Plant Agriculture Patent Filers in Uruguay

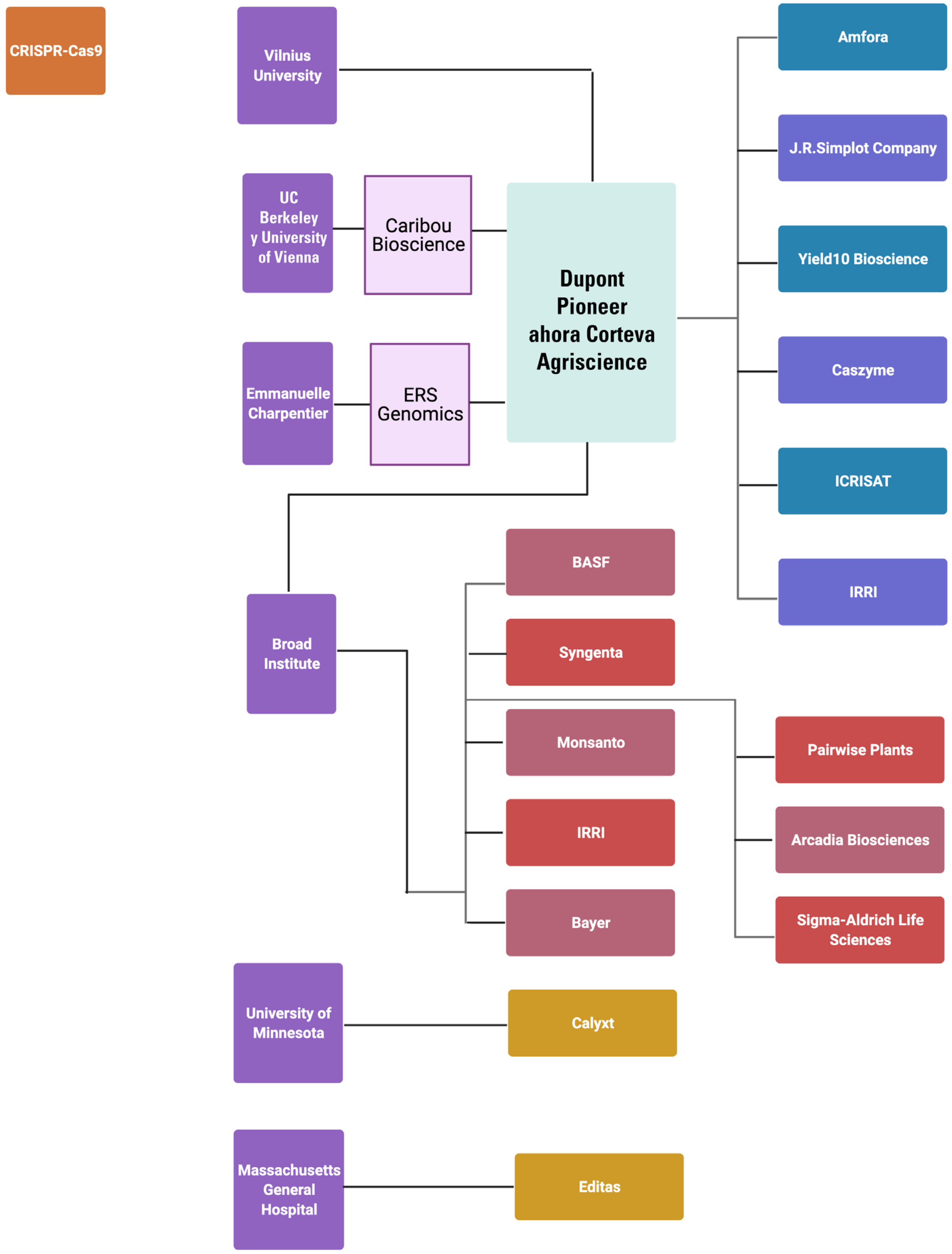
(17 patent families)



CRISPR Patent Licensing Protocols

- The landscape is extremely complex, likely impossible to know all the possible patent owners one might need to seek a license from.





Reported CRISPR-Cas9 Licenses in Plant Agriculture

Can offer a single license bundle (to a suite of CRISPR-Cas9 patents)

Five types of licenses:

Internal only R&D; (may be advantages to seeking this early)	Commercial seeds and crop trait products;	Commercial license for other (non-livestock) agricultural products;	License to provide CRISPR-Cas9 services; and	No-cost academic research license.

CRISPR-Cas9 and Cas12a & b: The Broad Institute

- Whether through the Broad Institute or Corteva, there are limitations on potential licensee uses:
  - Cannot use to:
    - Enable gene drives;
    - Create terminator seeds; or
    - Produce tobacco products for human consumption.

CRISPR-Cms1 (CRISPR 3.0): Benson Hill Biosystems

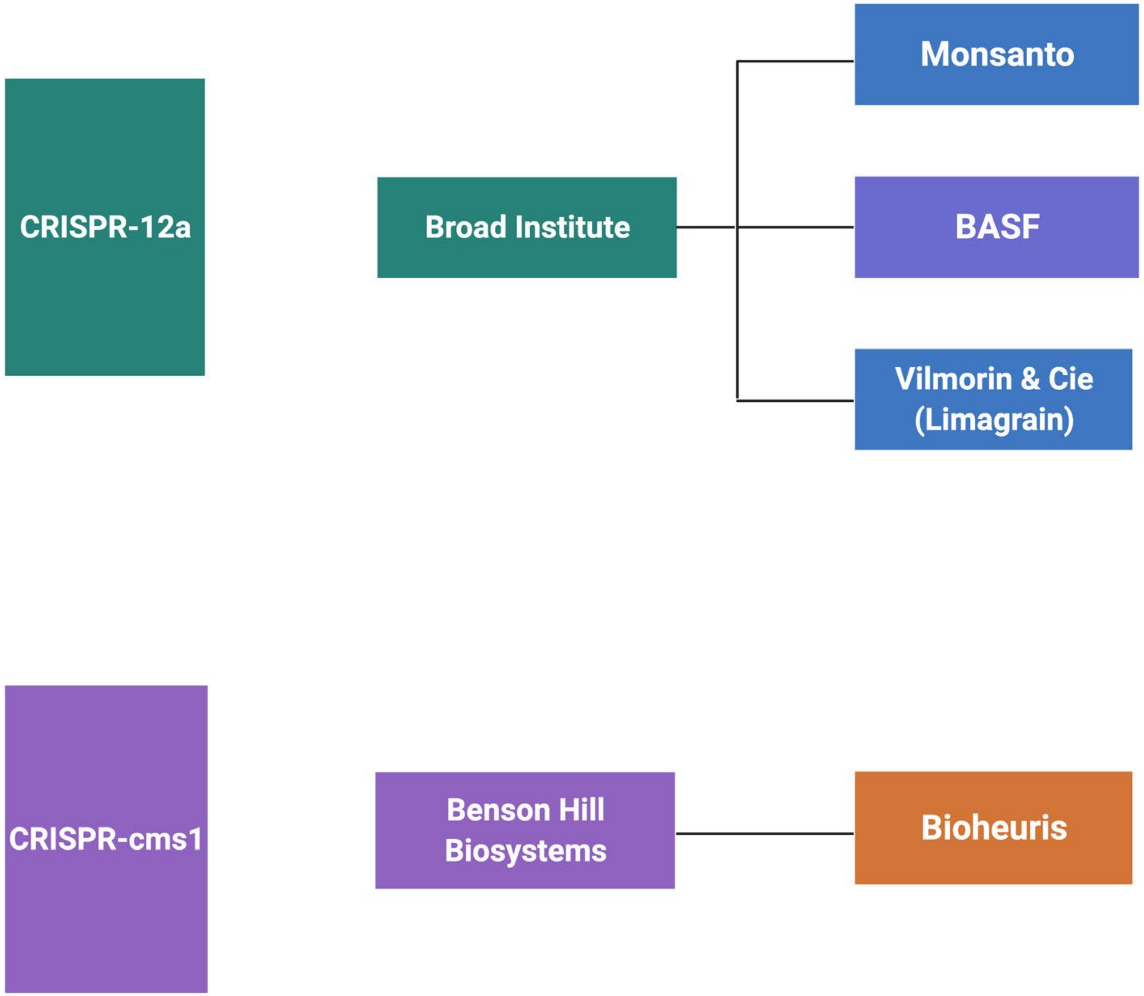
- May be able to offer lower cost licenses and greater clarity regarding patent rights.
- Agreements are individually negotiated.

Nuclease	Type	in planta activity	Microbial activity	Mammalian Cells	in vitro activity	IP Status
Sm	Cms1	Yes	Yes	In Progress	In Progress	Issued Patent
Su	Cms1	Yes	In Progress	In Progress	In Progress	Issued Patent
Ob	Cms1	Yes	In Progress	In Progress	In Progress	Issued Patent
Mi	Cms1	Yes	In Progress	In Progress	In Progress	Issued Patent

CRISPR-Cms1 (CRISPR 3.0): Benson Hill Biosystems

- Positioned as the most cost-effective alternative.
- These Cms1 proteins are 10-15% identical to Cas9 at the amino acid level.
  - This smaller size allows for more compact system for precision genome editing.

Reported CRISPR-12a and CRISPR-Cms1 Licenses in Plant Agriculture



Conclusion

Entities seeking to commercialize products using CRISPR/Cas9 should consider obtaining research licenses with Corteva in early stages to possibly obtain more favorable commercial licensing terms.

None of the CRISPR licensors provides licensees with freedom to operate opinions or any guarantee that a license from them will be enough to avoid infringement. It thus is up to the individual licensee to continue to assess the patent landscape and determine whether licenses from other entities may be required.

Development in gene editing in Brazil and at EMBRAPA

Alexandre Nepomuceno, Ph.D.
General Head
Brazilian Soybean Research Center –
Embrapa Soja

***See separate slide deck**

Current international and LAC regulatory structures for gene-editing

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Genome Editing in Latin America: Regional Regulatory Overview

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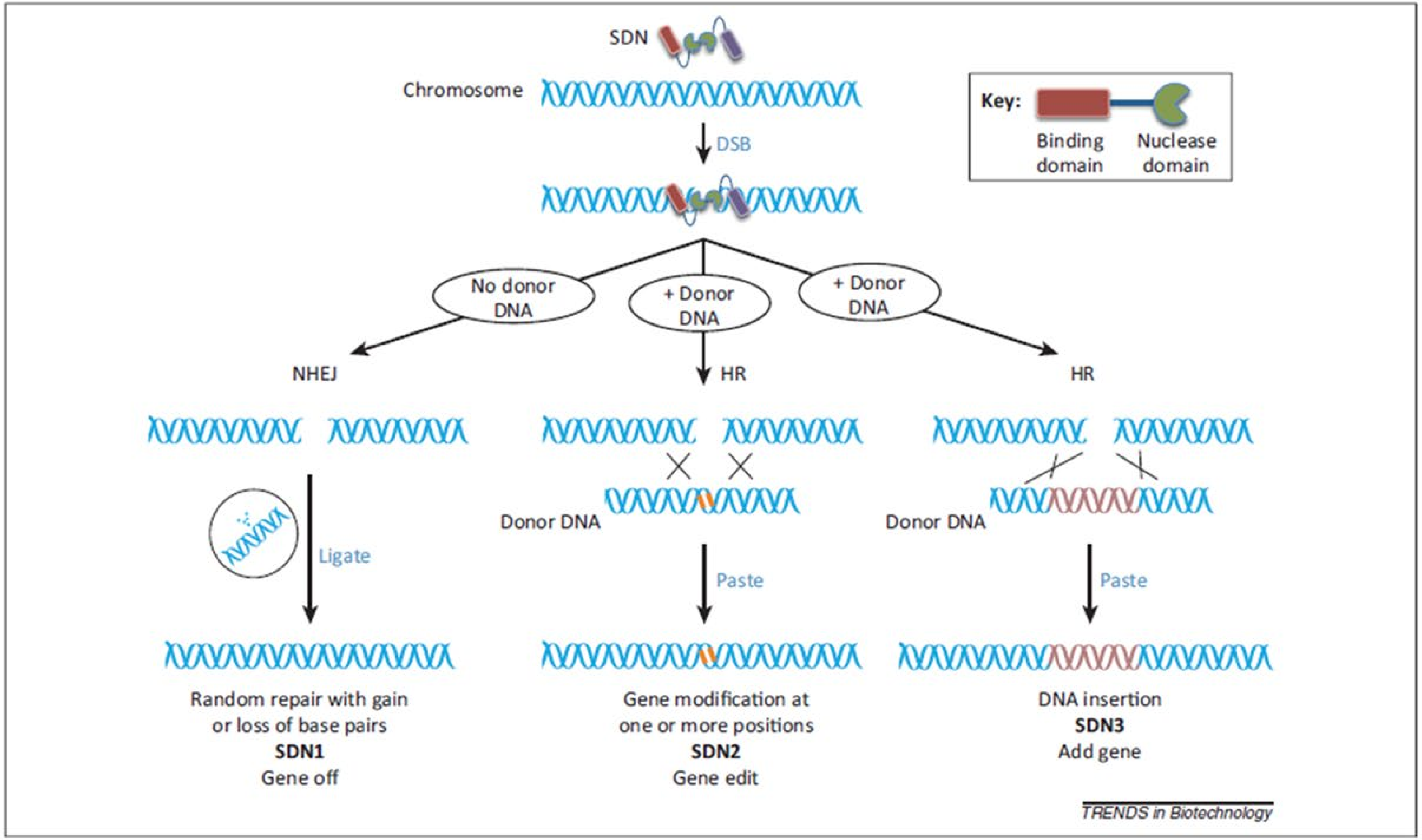
Current LAC & International regulatory structures for gene editing

- "Living Modified Organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" [Cartagena Protocol]

- Point of regulatory investigation: whether certain gene-edited or genome-edited (GED) crops possess a **novel combination** of genetic material and/or contain **transgenes** in the final product to fall within the LMO definition

- Gene editing is not a singular technology or technique; it refers most often to a set of techniques that enable the manipulation of a genome with greater precision than previous iterations of genetic engineering.

Gene Editing
Genome Editing
(GED)



SDN 1 **SDN 2** **SDN 3**

Podevin et al. 2013

Important for Regulation

Findings: Current LAC regulatory structures for gene editing

- Several nations in the LAC region appear to be coalescing around a particular viewpoint on gene editing as it relates to LMOs or GMOs, with some leading the world with a clearly defined framework for evaluating gene edited crops. Many GED products will not be regulated as LMOS or first-generation GMOs, although they are evaluated on a case-by-case basis.
  - Argentina was the first in the region with Brazil, Chile, Colombia, Paraguay, Honduras and Guatemala following.
  - Certain gene edited products are not considered LMOs or like first-generation GMOs (do not possess a novel combination of genetic material or do not contain transgenes) if SDN coding genes and DNA repair templates are backcrossed out of the plant after incorporation of the edit.
    - Mostly SDN1 (site-directed nuclease), SDN2 and ODM are not generally considered GMO, although there is evaluation on a case-by-case basis.
  - Other gene edited techniques and their products are likely to be considered GMOs
    - SDN3 – involves a template guided repair of a DSB using a sequence donor typically containing an entire gene **which allows the introduction of the gene (transgene)** or genetic element at the target site. Could also be entire cisgene, coming from same species, in some cases.

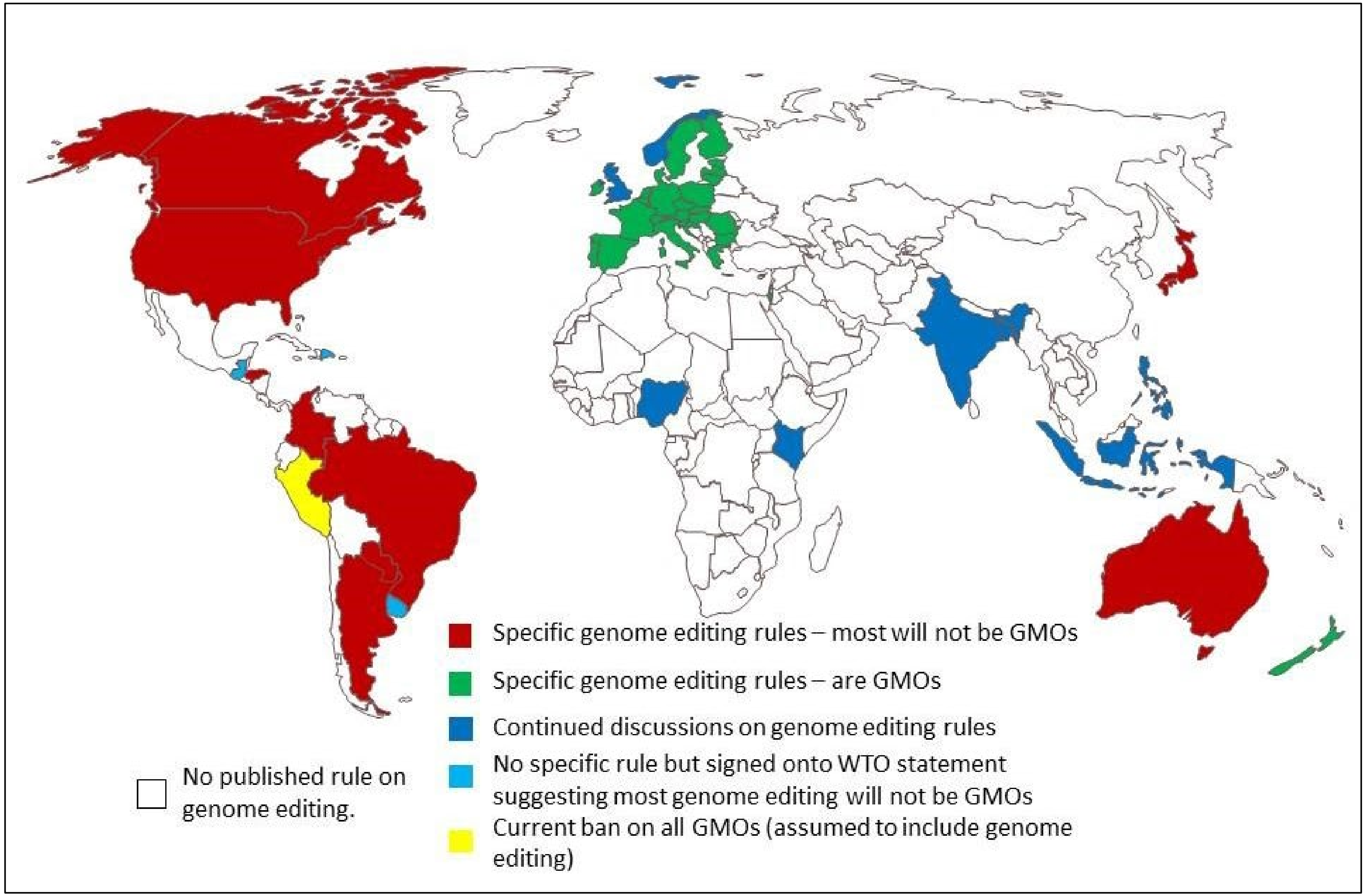


Figure 3. Global Status of genome editing legislation. Updated and adapted from (Schmidt, Belisle, and Frommer 2020). As of February 2021. In countries with genome editing rules; most SDN-1 and SDN-2 will not be GMOs see Table 1.

Overview of Gene edited crop oversight in select LAC countries

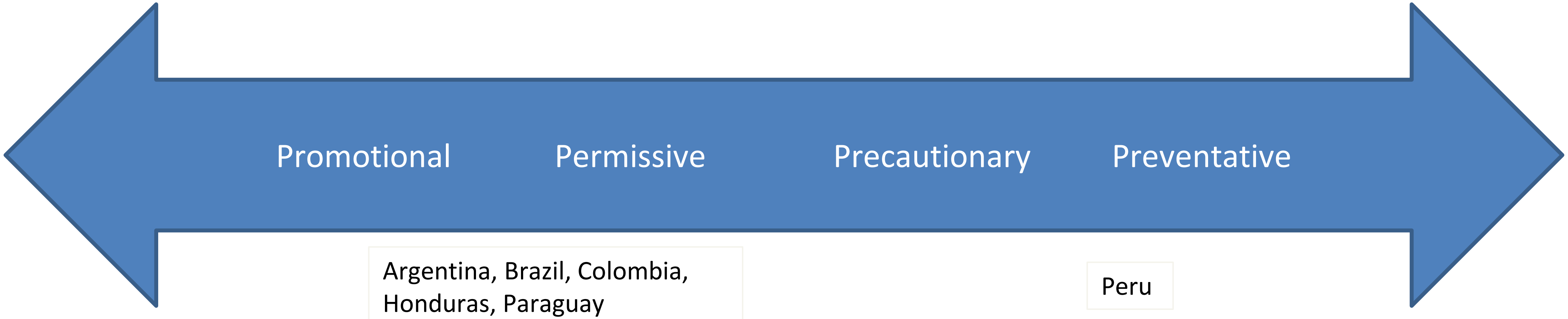
Country	Party to Cartagena Protocol on Biosafety	GMO regulation	Genome editing specific regulations	Signature to WTO precision biotech statement (See Box 1.)
Argentina	No	Yes	Yes—2015	Yes
Bolivia	Yes	Yes	No	No
Brazil	Yes	Yes	Yes—2018	Yes
Colombia	Yes	Yes	Yes—2018	No
Honduras	Yes	Yes	Yes—2019	Yes
Mexico	Yes	Yes	No	No
Paraguay	Yes	Yes	Yes—2019	Yes
Peru	Yes	Yes (current ban on all GMOs)	No	No
Uruguay	Yes	Yes	No	Yes

Table 2. Overview of Gene edited crop oversight in select LAC countries.

Draft Cross-comparison of GED Formal Regulatory Approach

Below, nations are placed on the spectrum primarily according to the regulatory capture of GED as 1st generation transgenic GMOs or not.

Note: Countries in same category below may differ in their institutional structure, whether a specific law or regulation for GMOs exists (or older product-based laws & regulations are used), whether they are parties to CBD, and whether they require GM food labeling



Argentina, Brazil, Colombia, Honduras, Paraguay (potentially Uruguay)

Peru

?
Mexico, Bolivia

US, Australia, Canada, Japan

EU

National similarities and differences in regulatory systems Beyond whether GEDs are GMOs or not

(As discussed in discussion paper)

- Is there a specific law for GMOs versus reliance on existing product-based laws?

- What is the institutional structure for regulatory decision-making?
  - Multiple agencies versus Single lead agency
  - External, expert commissions or advisory groups with some input to decision-making
  - Places for public and stakeholder input in decision making
  - Most have some consultation process for review (by external commission or government body) prior to exemption (unlike U.S.)

- Are certain SDN methods specified as exempt from being considered GMOs in regulations or not?

- Are there mandatory GM food labeling laws and regulations?
  - How might they apply to GED crops?

Example comparison: Argentina vs. Brazil for GED crops

- Argentina uses its general laws for environment, food, plant and animal health to oversee GM and GED crops
  - Brazil has a specific National Biosafety Law for GMOs (11,105/2005)

- Like Argentina's resolution 173/2015, Brazil's RN 16/2018 establishes the requirements for a consultation on whether a GED product is exempt from the nation's GMO regulatory framework or not.
  - Argentina's Resolution 173/15 sets forth procedure to determine whether a GED crop would be subject to pre-existing GMO regulations according to the key criteria of "novel combination of genetic material" (definition of LMO under CPB)
  - Brazil has similar regulations for consultation procedures, Normative Resolution 16/2018, but its GMO law focuses on "use of recombinant DNA molecules"(definition of GMO under its biosafety law)
  - Brazil also as a specific, non-exhaustive list of the types of genome editing methods that would likely lead to a product not being considered a GMO in an Annex to its GED resolution

- Both countries have biosafety advisory group processes with experts from different agencies or institutions who examine GEDs on a case-by-case basis under the above resolutions
  - Argentina's CONABIA (60 days to determination)
  - Brazil's CTNBio (90-120 days to determination)

- Brazil has ratified CBD/CPB, whereas Argentina has not
  - How will this affect future policy on GEDs in the two countries if decisions under the CPB are made about GEDs in the future?

Example Comparison	Argentina	Brazil
Regulatory Frameworks	Uses its general laws for environment, food, plant, and animal health to oversee GM & GED crops	National Biosafety Law specific to GMOs (11, 105/2005)
Establishes requirements for consultation: is GED exempt from GMO regulatory framework?	Resolution 173/2015	Normative Resolution 16/2018:
Regulatory definitions for GED = GMO determinations	Determinations based on definitions of LMO under CPB: “novel combination of genetic material.”	Determination based on definition of GMO from Biosafety Law: “use of recombinant DNA molecules.” +Annex language also includes specific, non-exhaustive list of methods that would likely lead to a product NOT being considered a GMO
Biosafety advisory groups: experts from different agencies & institutions who examine GEDs on a case-by-case basis	CONABIA (60 days to determination)	CTNBio (90-120 days to determination)
Ratification of the CBD/CPB?	No	Yes

How will this affect future policy on GEDs in the two countries if decisions under the CPB are made about GEDs in the future?

International Negotiations

- The UN will discuss the development of a post-2020 global framework towards the vision 2050 on biodiversity: living in harmony with nature.
  - Target 16 says: By 2030, establish and implement measures to prevent, manage or control potential adverse impacts of biotechnology on biodiversity and human health reducing these impacts by [X].

- Gene editing has not been a direct focus of discussions within the Convention on Biological Diversity (CBD) and its Cartagena Protocol (CPB).
  - The CBD has instead been focusing on “synthetic biology” since 2010;
    - SBSTTA (Subsidiary Body On Scientific, Technical And Technological Advice) considered synthetic biology and risk assessment for LMOs (focusing on gene drives and GM fish) at June 2021 meeting Gene editing was first mentioned in the 2019 synthetic biology AHTEG report as a new technological development in synthetic biology

- Neither the CBD nor CPB has formally clarified whether products of gene editing fall under the definition of an LMO or not, although CPB definition of LMO as “novel combination of genetic material” used in LACs for GMO classification with regard to GEDs (e.g. Argentina)

Findings: International Negotiations

- While many countries in the LAC region appear to be coalescing around a similar interpretation of how genome editing will be governed that is consistent with the CPB definition of LMO and;

- Most countries in the region are signatories to the Convention on Biological Diversity and the Cartagena Protocol;
  - How this will impact future negotiations on GED in the Convention on Biological Diversity and the Cartagena Protocol is unclear when other regions in the world (European Union) and other countries within the LAC region, have taken different positions?

- Questions to examine moving forward:
  - Will the disputes concerning GEDs occur mainly through the WTO given that the U.S and Argentina, two of the biggest growers of GED and GMO, are not parties to the CPB?
  - Will individual countries, groups of countries, or regions continue to move ahead of the processes happening within international bodies?

Regulation of Genetically Modified Crops within the Framework of the Customs Union of Honduras and Guatemala)

Roger Orellana
President. Committee for Agricultural Biotechnology and Biosafety (CNBBA). Honduras, Central América
SENASA-SAG

***See separate slide deck**

Stakeholder Interview Progress Update

María Mercedes Roca &

Mike Jones

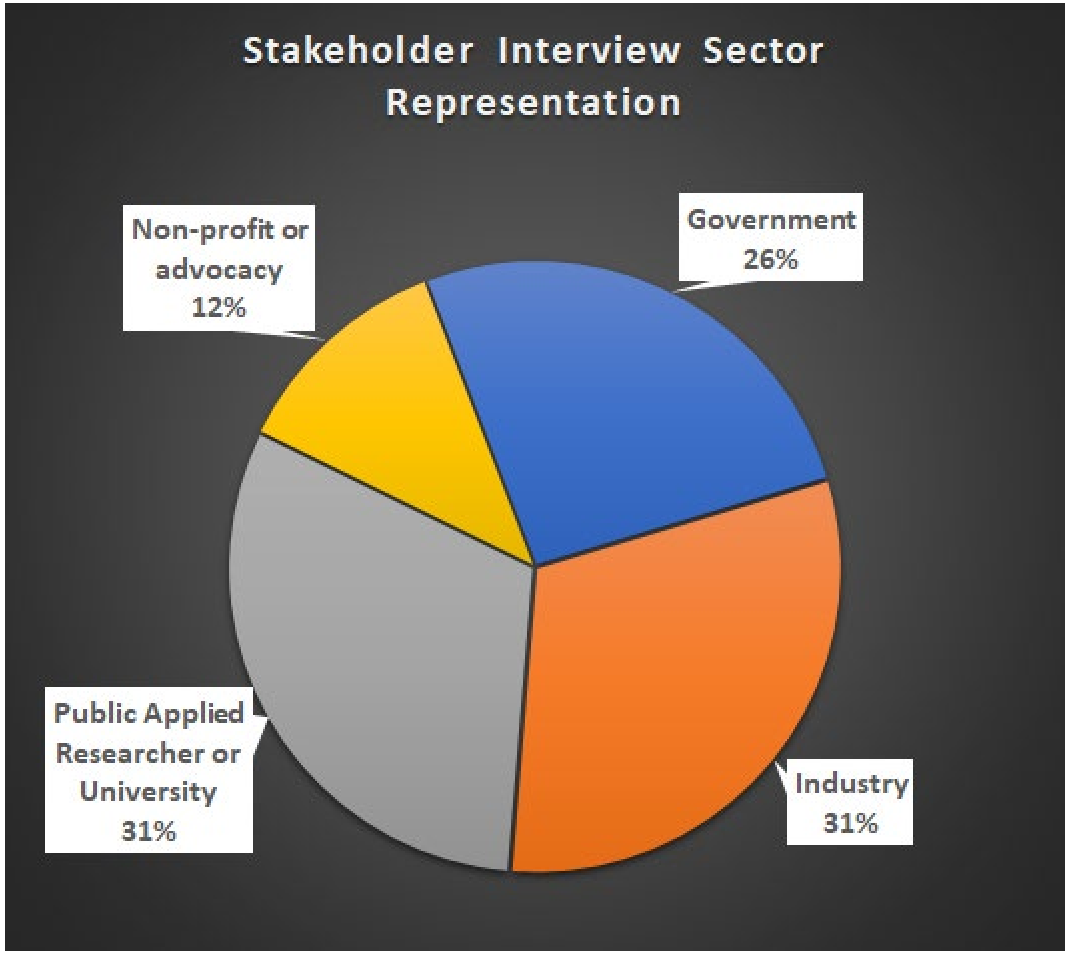
Project Team

Stakeholder Interviews

- Representative countries of the different regions (Southern Cone, Andean and Central America) were chosen for an in-depth analysis of the different regulatory frameworks.
- Leaders from the agricultural biotechnology sector from governments (regulators), academia (including researchers, consultants and students) and industry were identified and interviewed. We still hope to incorporate producers and other individuals as we move forward.
- Studied were the priorities, challenges, uncertainties, and key issues of the gene-edited products in development, as well as the respective regulatory frameworks. Also considered were the main benefits, risks, and the types of risk analysis being used.

Interview progress update

- 38 interviews conducted
- Relatively larger number of interviews in Brazil
- Coverage in Argentina, Bolivia, Colombia, Honduras, Mexico, Paraguay, Peru, and Guatemala



Interview progress update

Three broad categories of data:

1. ***Policy***: regulation, politics, bureaucracy, internal and external economic policy
2. ***Research***: local product development, training, equipment, reagents and infrastructure
3. ***Public***: public perception and outreach

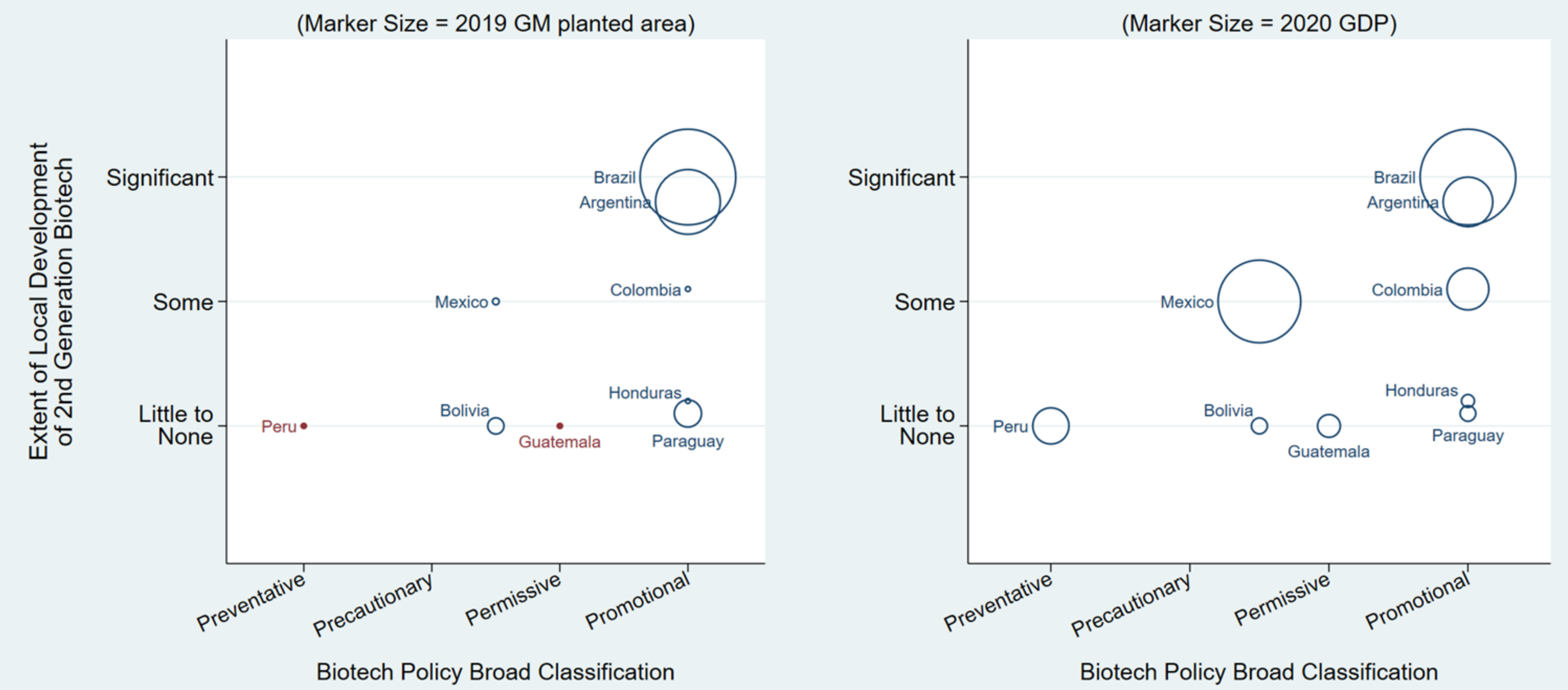
Authoritative Bodies for Biotechnology

	Argentina	Bolivia	Brazil	Colombia	Guatemala	Honduras	Mexico	Paraguay	Peru
Ministry of Agriculture has more influence than Ministry of Environment									
Ministry of Environment has more influence than Ministry of Agriculture									
Shared authority and rotation									

Local Development of 2nd Gen. Biotech.

	Argentina	Bolivia	Brazil	Colombia	Guatemala	Honduras	Mexico	Paraguay	Peru
Significant Development of 2nd Gen Biotech from Local Public and/or Private Sector									
Some Development of 2nd Gen Biotech from Local and/or Private Sector									
Little or no Development of 2nd Gen Biotech from Local Public and/or Private Sector									Moratorium

Agricultural Biotechnology Policy Tendencies and Extent of Local Technology Development



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

Groups supporting biotech research

Brasil, Argentina, Colombia, Guatemala, Honduras, México, Paraguay, Bolivia, Peru	
EMBRAPA (Brasil) Universidad de Campinas & Universidad de Minas Gerais (Brasil) Instituto de Agronomía (Brasil) Grupo Don Mario (Argentina & Brazil) CIAT (Colombia) IICA (Guatemala, Honduras, Colombia, Argentina) Dole Company (Honduras) Compañía Nacional de Chocolates (Colombia) Universidad del Valle & University of San Carlos (Guatemala) CONABIA (Argentina) ILSI (Argentina)	IICA (Panama, Bolivia) AquaBounty Technologies (Panama) Indigo Ag (Paraguay) Instituto Paraguayo de Tecnología Agraria (Paraguay) Universidad Nacional de Asunción (Paraguay) INIAF (Bolivia) ANAPO (Bolivia) Universidad Católica (Bolivia) UNESCO scholarships (Bolivia) CIP - Centro Internacional de la Papa (Peru)

Stakeholder Interviews: Next Steps

1. **Thematic Content Analysis** (NVivo QDA software)
    1. Using IDB priorities, code for specific issues
    2. Provide empirical decision support for issues that are important to IDB's investment inquiries.
2. **Network Analysis** (Gephi Platform)
    1. Identify networks of collaborators across the region
    2. Provide empirical decision support for IDB to identify emerging innovation networks

Case Study Selection Update

Katie Barnhill-Dilling &
Mike Jones
Project Team

Case Study Goals

- To provide tangible illustration of the consequences of various potential policy directions

- To select the most illustrative examples of the potential for CRISPR-based technologies to develop products which could have quite different impacts in various economic, environmental, and regulatory contexts.

- From previous interviews, identify two (2) varieties (existing or anticipated) of plants or livestock, developed through gene editing, for intensive research as a case study

Case Study Parameters: Country-Level

Dimension	Diversity sought in comparison
Level of Infrastructure in Country	More versus less developed
Biotechnology Policy Environment	Have determined (at least) gene-edited SDN-1,2, not to fall under broader GMO (transgenic) equivalent regulatory scrutiny
Geographic Region	Inclusion of at least one country in Central America and/or Caribbean, Andean Region, and Southern Cone

Case Study Parameters: Product-Level

Dimension	Diversity sought in comparison
Transformation	All products sought to be non-transgenic gene-edited products developed through modern biotechnology, preferably falling under SDN-1 and SDN-2 classification
Stage of Product in Development	Some variation within: ● Proposed and completely hypothetical ● Transformation made, approaching experimental phase ● Experimental Phase ● Safety Testing Phase ● Final Testing before commercial release ● Commercially released At least one product to be non-hypothetical and already through some type of regulatory review process

Case Study Parameters: Product-Level

Dimension	Diversity sought in comparison
Developer Details	Private versus Public entity Regional versus Outside developer
Primary Market Nature for Product	Cash versus Staple
Primary Grower Profile	Small, Medium, Large, multinational corporation, or clear mix

Case Study Candidate 1: Gene-edited Banana

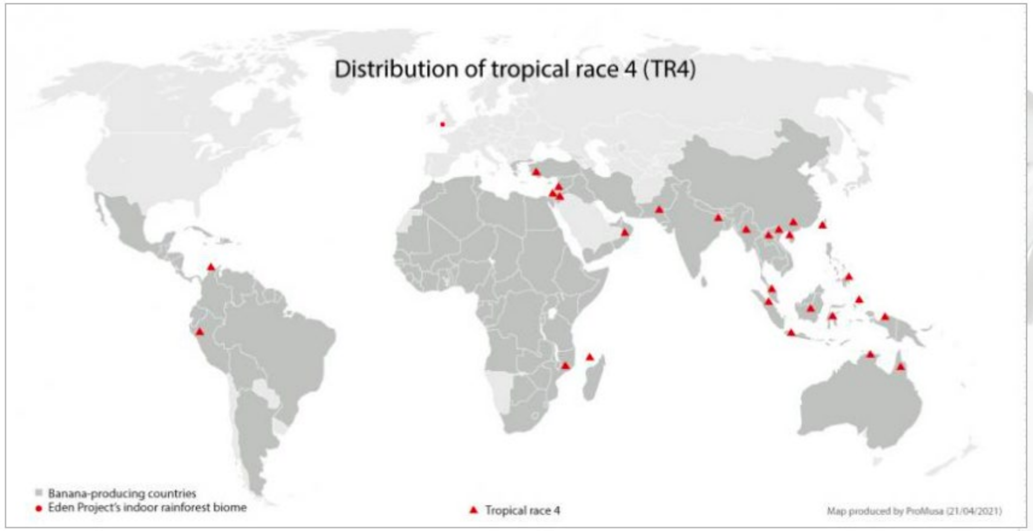
Source: FAO

- Existing and Hypothetical Products
- Sigatoka resistance
- Panama disease (Fusarium TR4) resistance
- Country focus: Honduras and Guatemala
- Developer: Tropic BioSciences (UK)

NEWS | 24 September 2019

CRISPR might be the banana's only hope against a deadly fungus

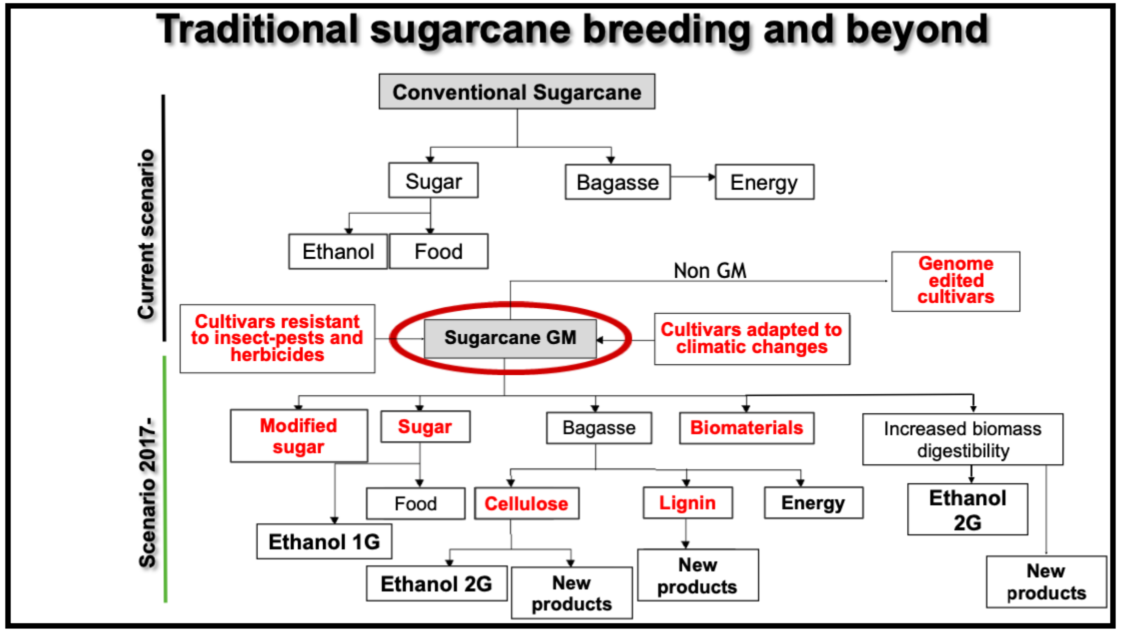
Researchers are using the gene-editing tool to boost the fruit's defences and prevent the extinction of a major commercial variety.



Source: ProMusa

Case Study Candidate 2: Gene-edited Sugar Cane

- Existing Products
- Biomass digestion and sucrose accumulation
- Country focus: Brazil and Bolivia
- Developer: Embrapa (Brazil)



Source: Dr. Hugo Molinari Embrapa

Stakeholder Interview and Case Study Question and Answer

- Questions submitted through portal and selected to address

Thank you for your participation!

- Project team
- IDB

Please send questions or comments to us at:
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