

The background features a dark, starry sky transitioning from deep red at the top to dark blue at the bottom. Overlaid on the left side are several semi-transparent circular gauges or dials with numerical scales and arrows. The scales range from 140 to 260. The overall aesthetic is technical and futuristic.

NEW BREEDING TECHNOLOGIES

Regulatory and Policy Perspectives

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OVERVIEW



Regulatory Triggers
and Landscape



International
Negotiation
Interfaces



Science Diplomacy



Pathways to Market



Need

- Increase of regulatory requirements not as a result of scientific assessment but due to social, legal and political constraints
- Contradiction within international law (Agreement on Sanitary and Phytosanitary Measures v. Biosafety Protocol)
- False dichotomy of nomenclature (GMO)
 - Development of genome editing technologies dictate that GMO as a workable frame for regulating plant breeding is no more valid
 - Setting regulatory bar too high enables more monopoly and reduce competition and innovation
Institutional drift leading to zero sum outcomes

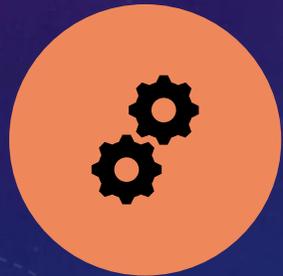
Technical Review of the Gene Technology Regulations 2001: Options for regulating new technologies



Option 1: no amendment to the GT Regulations



Option 2: regulate certain new technologies



Option 3: regulate some new technologies based on the process used



Option 4: exclude certain new technologies from regulation on the basis of the outcomes they produce

Thematic outcomes of OGTR Review

- Key themes
 - Gene editing is not GMO
 - Characteristics of the final product, not the process through which the product was created should be used as criterion for risk assessment
 - Gene editing can deliver a new Green Revolution
 - Gene editing can democratize agricultural biotechnologies
 - Gene editing should be regulated
 - Threat to organic industry/ trade due to deregulation
 - Harm to consumer choice

Policy Continuum for Regulation

Promotional

- Full patent protection
- Speedy approval
- No restriction on imports
- No labelling requirement

Permissive

- Patent/ Plant Breeder Rights
- Case-by-case screening for demonstrated risk
- GM trade based on WTO standards
- Limited labelling but no segregation for market

Precautionary

- Farmer's privilege
- Case-by-case screening also for scientific uncertainty owing to novelty of GE process
- Imports mostly restrained
- Extensive labelling requirements

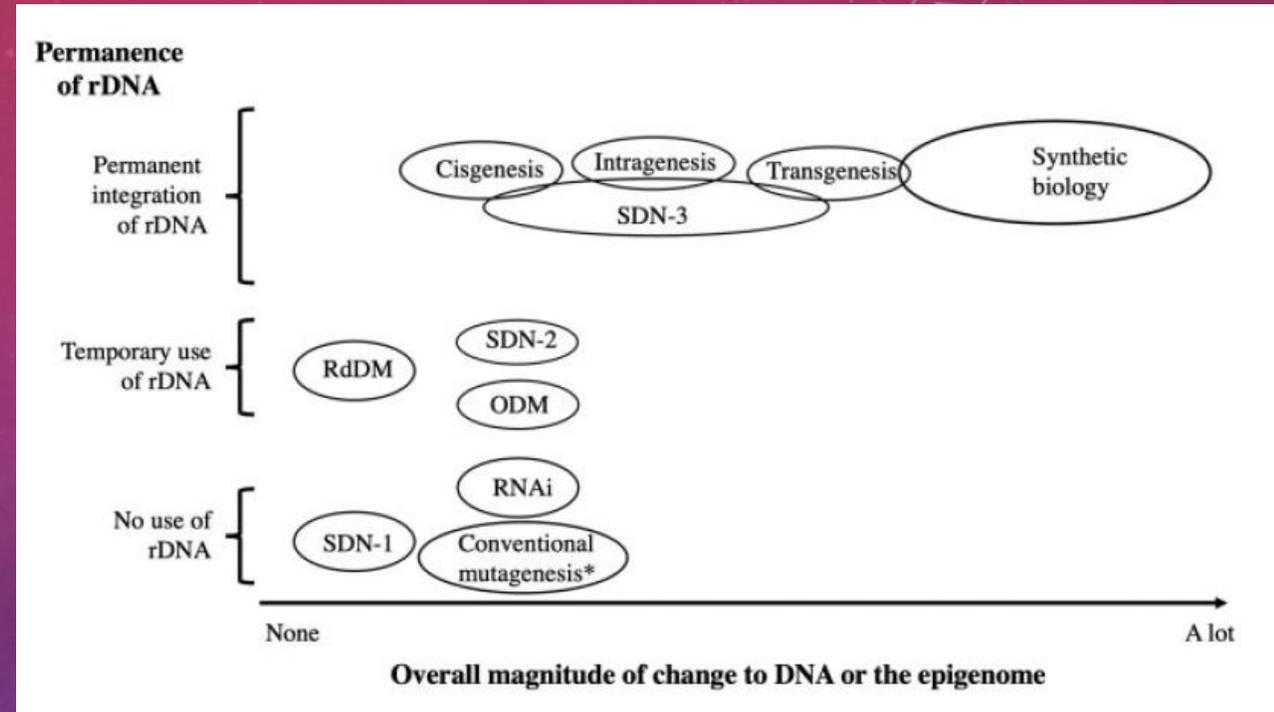
Preventive

- Restriction on IPR
- Risk assumed because of process
- GE trade blocked/ Promotion of GM free status for export premiums
- GM products banned or extensive labelling that depict GM as unsafe

(Adapted from: Migone and Howlett, 2009)

Battle of the Triggers

- Product based classification regime
- Process based classification regime
- Beyond the 'GM' binary



LEGAL FOUNDATIONS AND REGULATORY MECHANISM

Country	Major Biosafety Legislation	Regulatory Mechanism
Australia	Gene Technology Act (2000), Food Standards Australia New Zealand Act (1991)	Process Oriented
Argentina	Regulation Framework for Agricultural Biotechnology (1991)	Process Oriented
Brazil	Biosafety Law (updated 2005)	Process Oriented
Canada	Regulatory Framework for Biotechnology (1993)	Product Oriented
EU	Biosafety Directives and Regulations (1990, updated 2001/2003)	Process Oriented
Norway	Gene Technology Act (1993)	Process Oriented
South Africa	GMO Act (1997)	Process Oriented
USA	Coordinated Framework for the regulation of Biotechnology	Product Oriented
Pakistan	National Biosafety Act (2005)	Process Oriented

International Regulation of Biotechnology

Arms Control

- 1925 Geneva Protocol on the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases and of Bacteriological Methods of Warfare
- Biological and Toxin Weapons Convention (BWC)

Health and Disease Control

- International Health Regulations 2005
- International Plant Protection Convention

Environmental Protection

- Convention on Biodiversity (Cartagena Protocol on Biosafety)

Trade

- WTO
 - Sanitary and Phytosanitary Measures (SPS)
 - Trade Related Aspects of Intellectual Property Rights (TRIPS)

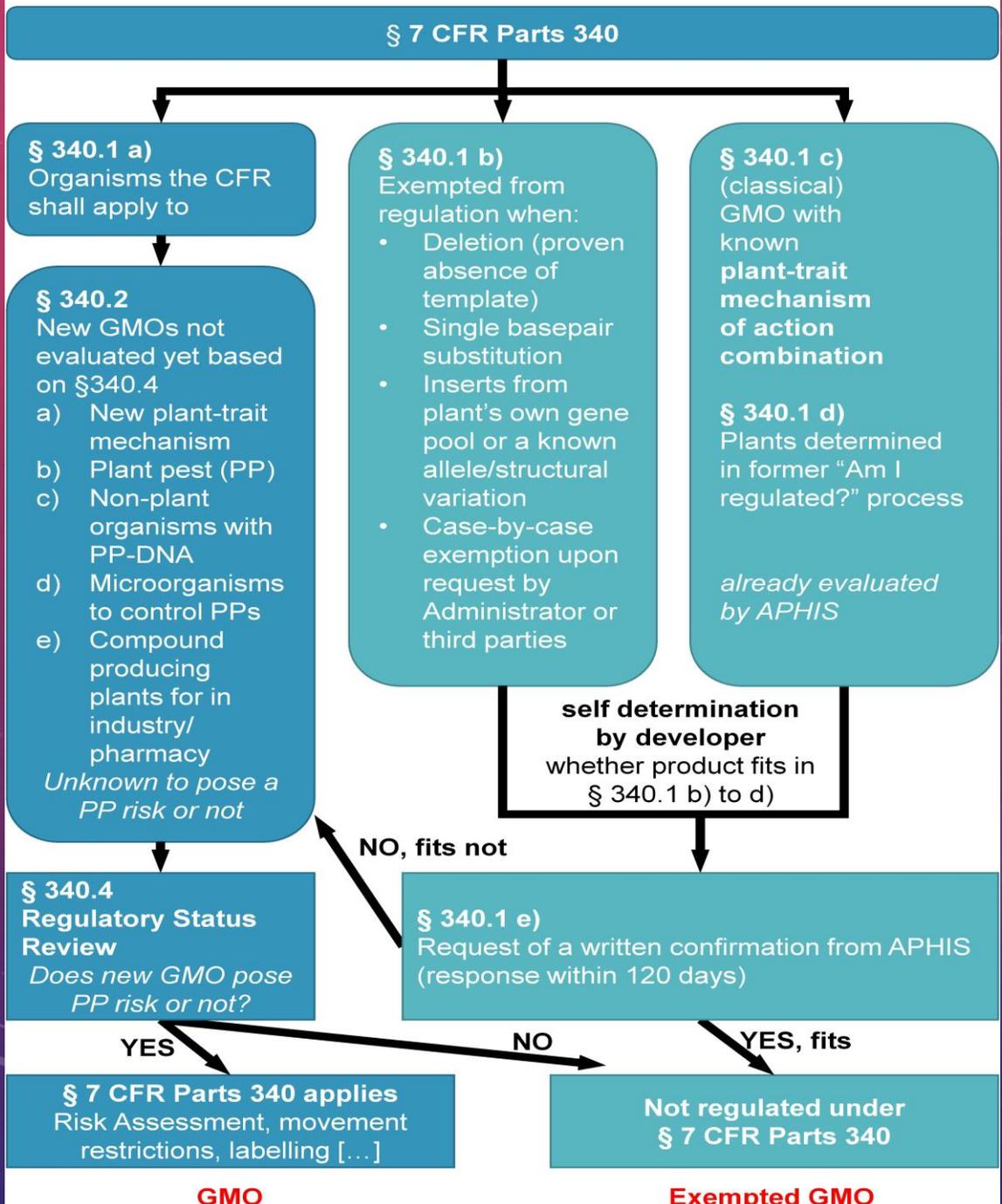
Social Impacts

- Universal Declaration on the Human Genome and Human Rights
- United Nations Declaration on Human Cloning
- Universal Declaration on Bioethics and Human Rights

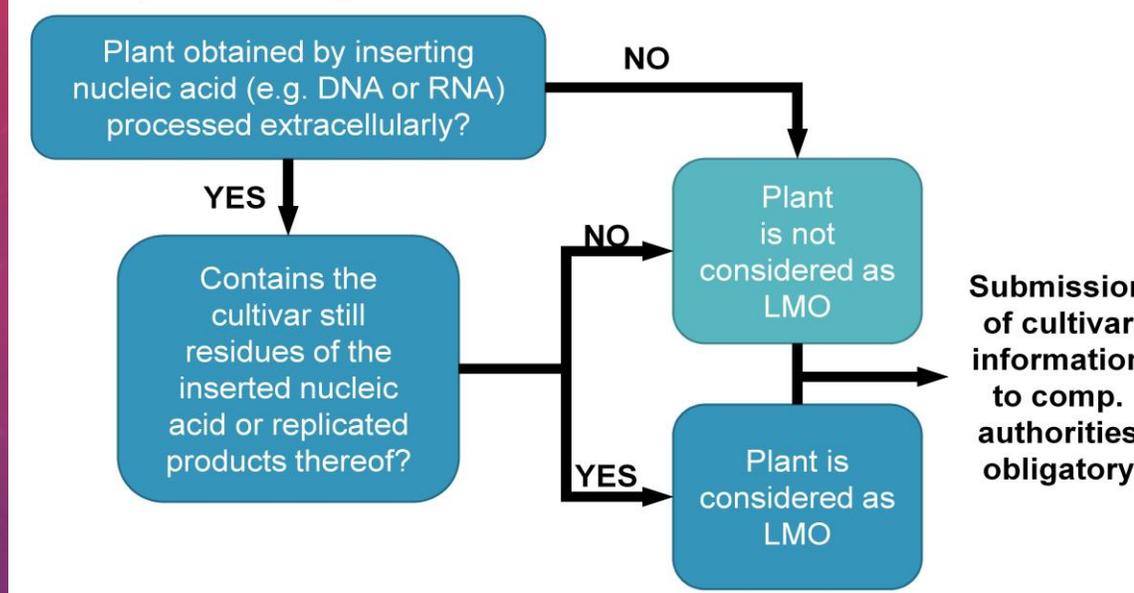
Latin America taking the lead in de-regulation of GE products

	Argentina	Chile	Brazil	Colombia	Paraguay	Honduras (together)	with) Guatemala and El Salvador
Legal Basis	Resolution 173-2015 (Ministerio de Agricultura, Ganadería y Pesca—Argentina, Argentina.gob.ar, 2015)	Consultation Procedure	Resolution 16-2018 (CTNBio, 2018)	Resolution 00029299-2018 (ICA Colombia, 2018)	Resolution 565-2019 (Ministerio de agricultura y ganaderia, 2019)	Agreement SENASA 008-2019 (SAG-SENASA, 2019)	Resolution UA 60-2019 (Customs union of El Salvador Guatemala and Honduras, 2019) and Annex: RT 65.06.01:18
Release Year	2015	2017	2018	2018	2019	2019	2019
NPBT listed	no	no	Yes	no	yes	no	no
Definition of genome editing	missing	missing	In Annex I: Oligonucleotide/Site directed mutagenesis	missing	New Breeding Techniques: CR(Y/I)SPR, TALEN, and others	New Techniques of genetic improvement (precision biotechnology)	Organisms obtained through the application of modern biotechnology
Assessment (GMO or Not?)	60 days	20 days	90 days + extended to 120 days	60 days	No information	45 days	90 days
Communication	Not public	Officially published	Officially published	Officially published	—	—	—

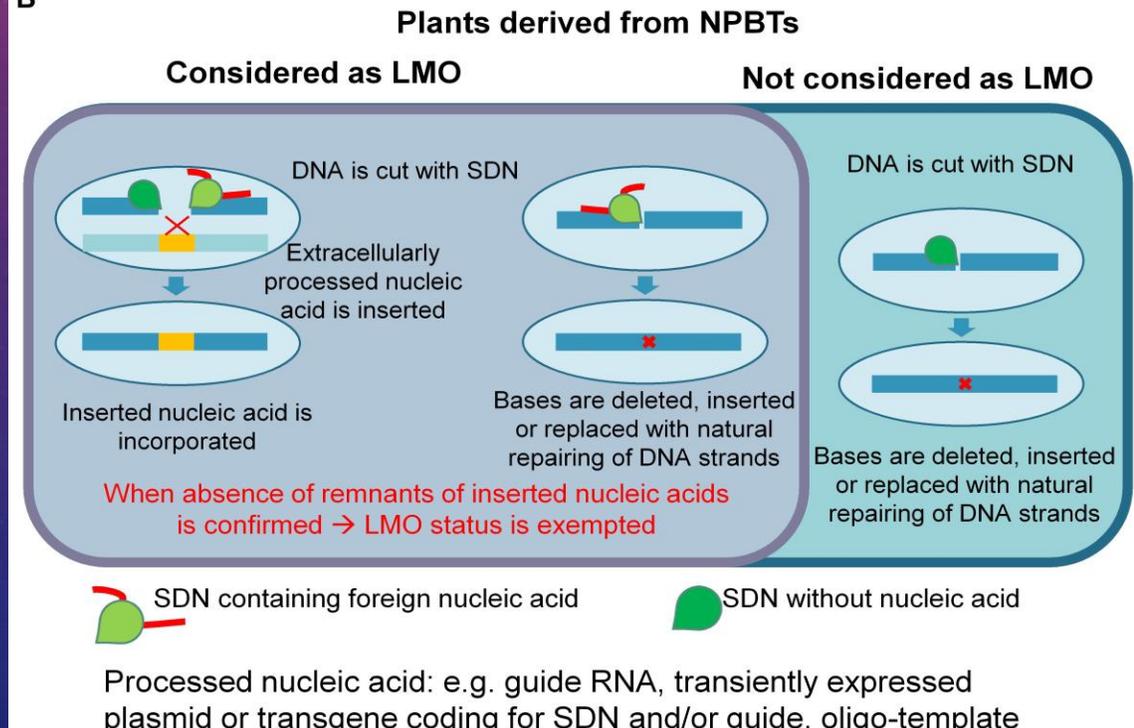
Source: Menz, J., Modrzejewski, D., Hartung, F., Wilhelm, R. and Sprink, T., 2020. Genome edited crops touch the market: a view on the global development and regulatory environment. *Frontiers in plant science*, 11.



A Japanese Cartagena Act



B



KEY ISSUES

- Institutional Drift (Technology evolving faster than regulations)
- Treaty Conflict (Trans-Atlantic Divide in Biotechnology regulation/ conflicting mandates of Cartagena Protocol v WTO SPS)
- Defining risk
 - Scientific dimension
 - Socio-economic dimension
- Convergence
 - Nano-biotechnology
 - Quantum biology
 - Bioinformatics

Problems

Resource Needs



Energy



Environment



Food



Shelter



Space



Water

Societal Needs



Disaster Resilience



Governance



Health



Learning



Prosperity



Security

Scientific
Dimension

Cross
Border/
Global

No country,
sector or
discipline
can solve
on their
own

- Science is a global enterprise
- Global problems have a scientific component, often obvious
- Science/ Scientific Method is one of the best available tools for solving societal challenges

Dimensions

The HOW of Sci Dip

Diplomacy
Advancing
Science

Science
Informing
Diplomacy

Science
Improving
Diplomacy

Community

Capacity

Leadership

Tools

The Interface to
Actualise Science
Diplomacy

Strategic

- Policy Documents

Operational

- Policy Instruments (Allocation of Funding etc)

Support

- Training
- Networking
- Capacity Building
- Consultation Platform

Incorporating Science Diplomacy for Policy Research

Science
Diplomacy
Interface for
Regulation of
NBTs



Capacity building



Developing the same
regulatory language
(harmonization)



Co-ordination between treaty
regimes

Bioeconomy v/s Biopolitics-a Geopolitical Lens

Nationalism

- Acquisition of Technologies
- Indigenous Capabilities (Civ-Mil)
- Competitive Advantage/ Power Asymmetries
- Intellectual Property Protection

Cooperation

- Technology & Knowledge Transfer
- Neoliberal market dynamics (Silicon Valley-esque approach)
- Scientific Cooperation
- Reducing the digital divide

Emerging Technologies

Multilateral Competition

- Technology denials
- Limited Scientific Cooperation
- Technological race
- Monopolisation

Multilateral Cooperation

- Norms for international cooperation
- Capacity- and confidence- building measures
- Global ethical oversight
- Equitable distribution

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THANK YOU!

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