PRRSV-RESISTANT PIGS

REGULATORY EXPERIENCES IN DIFFERENT COUNTRIES

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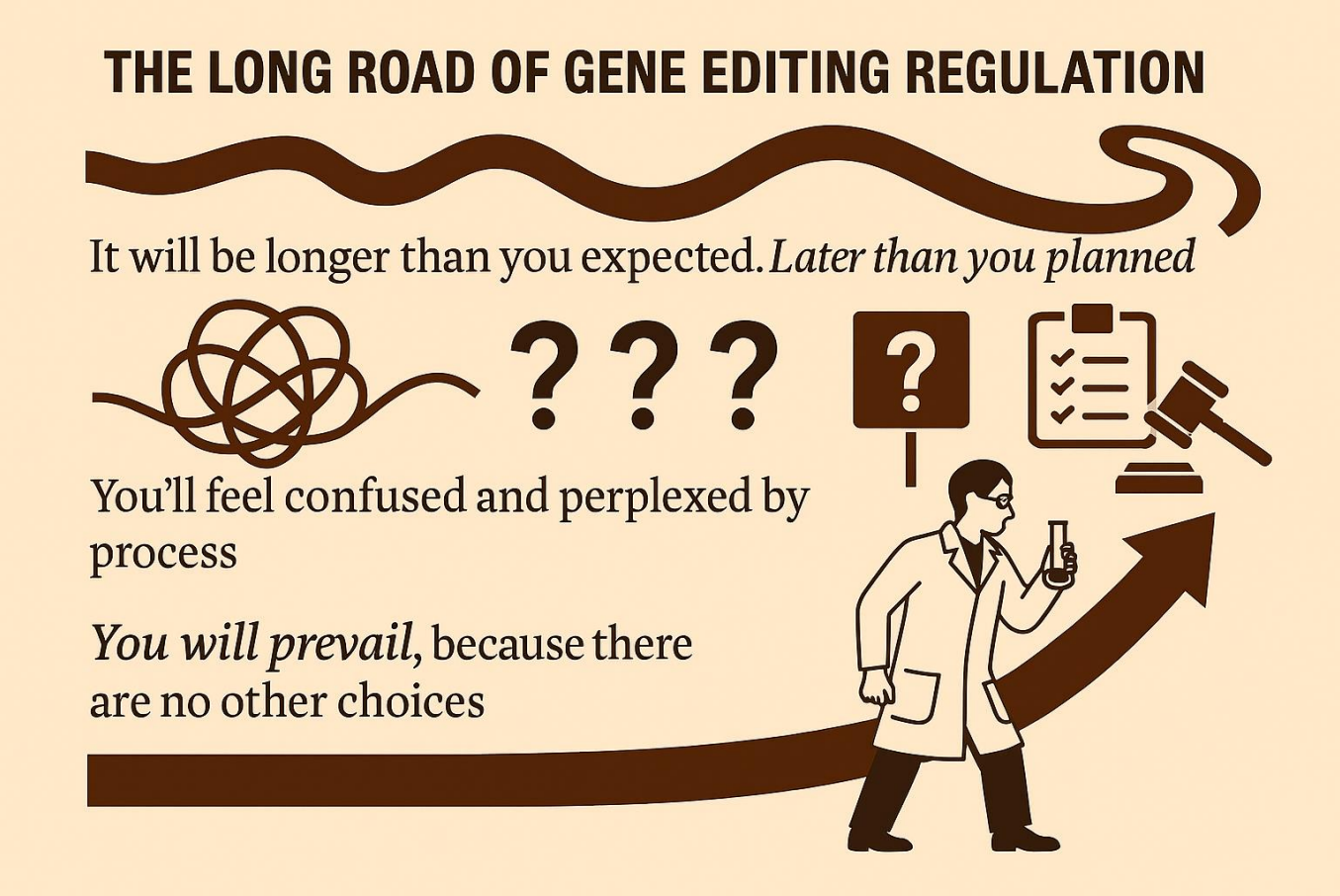
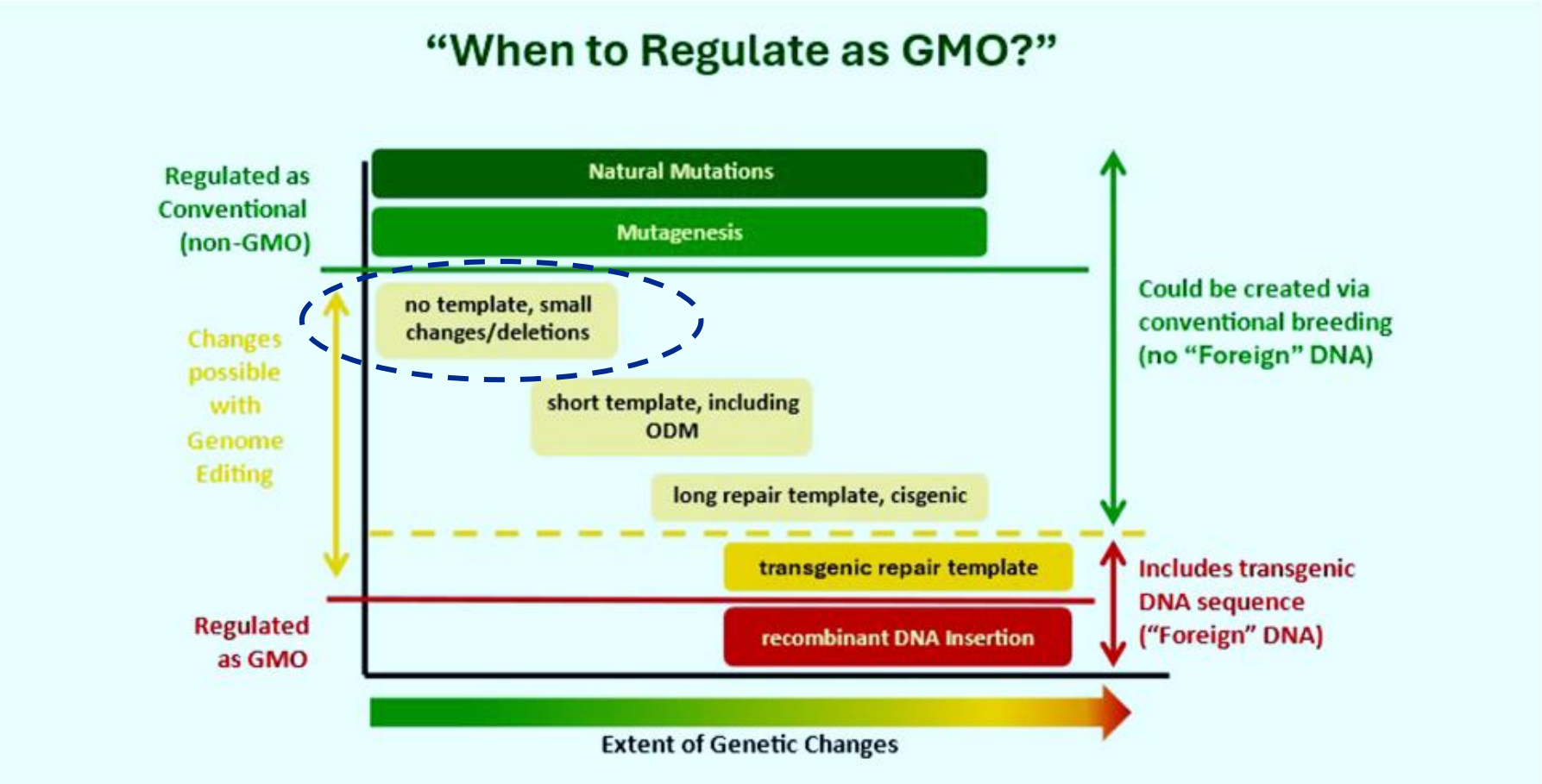
OUR ADVENTURE THROUGH GENE EDITING REGULATIONS



- No two regulatory systems are alike
  - Idiosyncratic differences among frameworks, data requirements, and individual regulators

GENE EDITING CONTINUUM



Diane Wray-Cahen at al, 2024.
https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2024.1467080/full

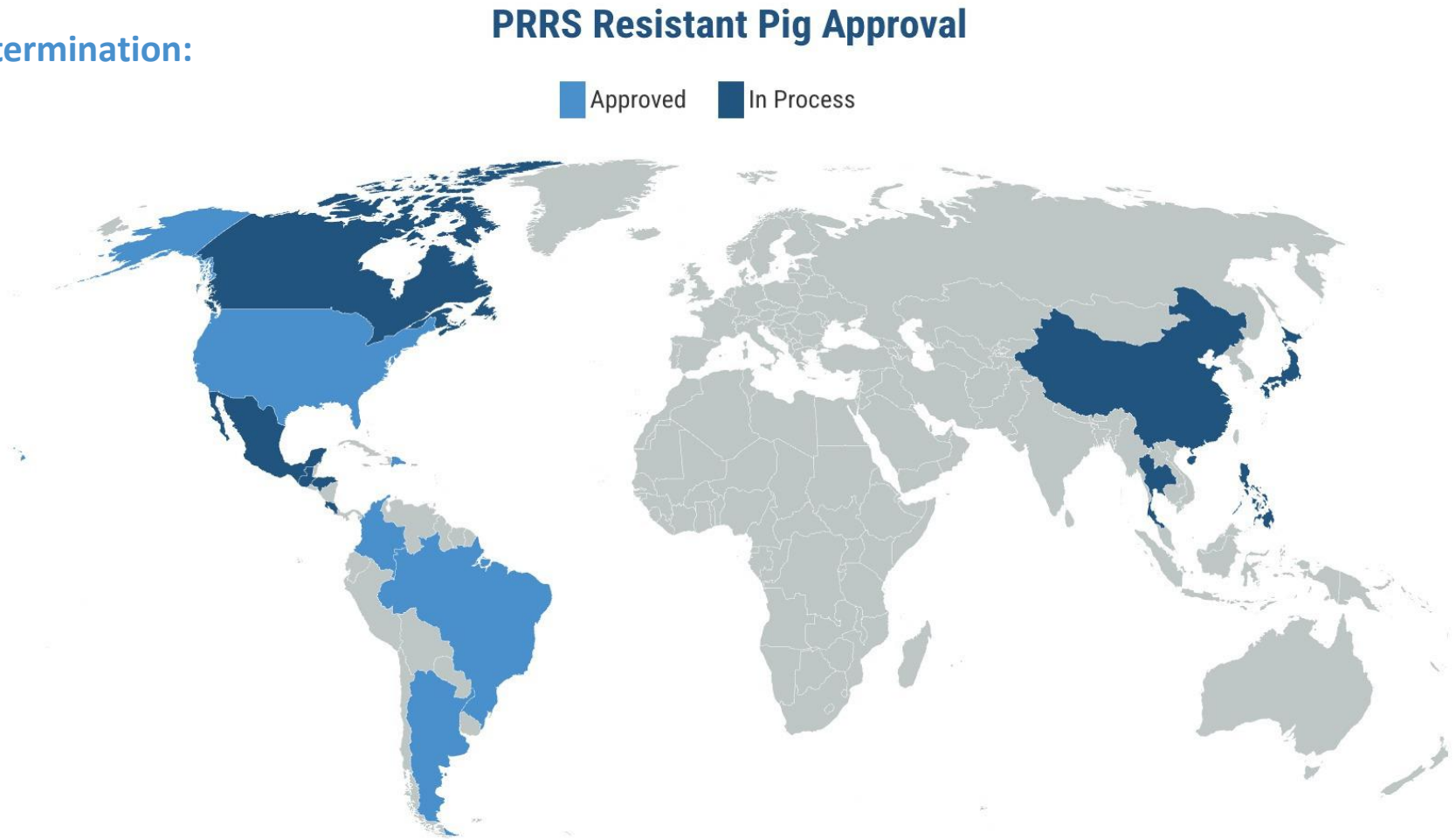
REGULATORY STRATEGY

Approved/Non-GMO Determination:

- USA
- Colombia
- Brazil
- Dominican Republic
- Argentina

In process:

- Canada
- China (via BCA)
- Costa Rica
- Guatemala
- Honduras
- Japan
- Mexico
- Philippines
- Thailand



EXAMPLE REGULATORY SYSTEMS

- US, Canada
  - US FDA regulates heritable “intentional genomic alterations” (IGAs) in animals under the animal drug provisions. The approach is the same for GMO and GE
  - Canada regulates “novel products” (products that express a new characteristic or modify an existing characteristic) regardless of the technology used (including breeding)

Evaluations are based on a complete assessment of molecular characterization data, food/feed safety, animal health, and environmental impact

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- Colombia, Brazil, Argentina, Dominican Republic, and others
  - Determination that the product is not subject to GMO law/regulations

Determination is based on molecular characterization data

- Japan
  - Hybrid: Nearly GMO-like assessment, but ends with a non-GMO determination.

Determination is based on a complete assessment of food/feed safety, animal health, and environmental impact

PROCESS

- Columbia, Brazil, DR, Argentina (et al)
  - Single agency or point of entry
  - Submission of dossier → respond to questions → determination
- Canada
  - Three agencies, three submissions (HC, CFIA, ECCC)
  - Submission → completeness review → response to questions → risk assessment → approval
- Japan
  - Three agencies, three submissions (CA, MAFF-feeds, MAFF-env)
  - Submission → completeness review → response to questions → notification phase: advisory committee determines criteria as RA continues→ determination

PROCESS (FDA)

- Investigational New Animal Drug (INAD) phase
  - Option for developers to enter CVM's Veterinary Innovation Program (VIP) – great help to the companies that are new to the gene editing FDA regulatory process
  - VIP program assists by providing intensive technical and pragmatic assistance throughout the approval process:
    - Identify the critical risk questions and get advice on a strategy for generating data
    - Review regulatory study designs before conducting the study
    - Formal and informal communication with CVM to address individual questions as they arise
    - Option for alternative data strategies
    - Dedicated review team consisting of a representative from each relevant area of expertise
    - Pre-submission review of technical sections
    - 180-day review per section with an option to stop the clock to address identified issues
  - Individual "technical section" submissions can be submitted and reviewed separately as studies progress -> Acceptance of the submission
- New Animal Drug Application (NAD) phase
  - Relatively short administrative review of all previous submissions

Genus

INFORMATION REQUIREMENTS

	COL	BRA	DR	ARG	CAN*	JPN*	USA
Molecular Characterization							
Method of creating edit	☑	☑	☑	☑	☑	☑	☑
Confirmation of intended edit	☑	☑	☑	☑	☑	☑	☑
Identification/removal of off-target edits	☑	☑	☑	☑	☑	☑	☑
No incorporation of foreign DNA	☑	☑	☑	☑	(☑)	(☑)	(☑)
Expression of RNA/protein		☑			☑	☑	☑
Phenotypic Characterization							
Toxicity/allergenicity of protein					☑	☑	☑
Meat characteristics and composition					☑	☑	☑
Animal health, growth, reproduction					☑	☑	☑
Description of production system, confinement					☑	☑	☑
Disease challenge studies						☑	☑
Environmental assmt, impacts on biodiversity					(☑)	(☑)	☑
Validated detection methodology							☑
Pre-approval inspection of production facilities							☑

*Required by one or more of three separate agencies

POST-APPROVAL OVERSIGHT

- Columbia, Brazil, DR, Argentina
  - Same as non-edited pigs
- Canada, Japan
  - TBD. Produced in specific facilities and conditions; reporting requirements?
- US
  - Continual morbidity/mortality monitoring, reporting
  - Adverse events/customer report
  - 6-12 month animal inventory/sales reporting
  - Submission of marketing and promotional materials
  - Registration, audit/inspection of production facilities/genomics lab
  - Product labeling for customers

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FEES

- FDA ADUFA Fees (FY2025)
  - Application fee (one-time): $581,735
  - Sponsor fee (annual): $137,446
  - Establishment fee (annual): $157,702
  - Product fee (annual): $10,705
- All other countries: $0

- Plus the cost of generating regulatory data, use of global regulatory consultants, etc

TIMELINES (IN GENUS'S EXPERIENCE)

Country	Time between application and approval or determination
➢ US*	5 years (depends on the developer's ability to produce all necessary data)
➢ Canada**	1.5 – 2 years (estimated)
➢ Japan**	2+ years (estimated)
➢ Brazil	6 months
➢ Colombia	3 months
➢ Dominican Republic	2 months
➢ Argentina	2 months

*Data produced for the FDA approval were resubmitted in other countries
** Additional data were requested


THANK YOU!