



*Overview of the U.S. and
global regulatory policy
landscape for genome edited
plants*

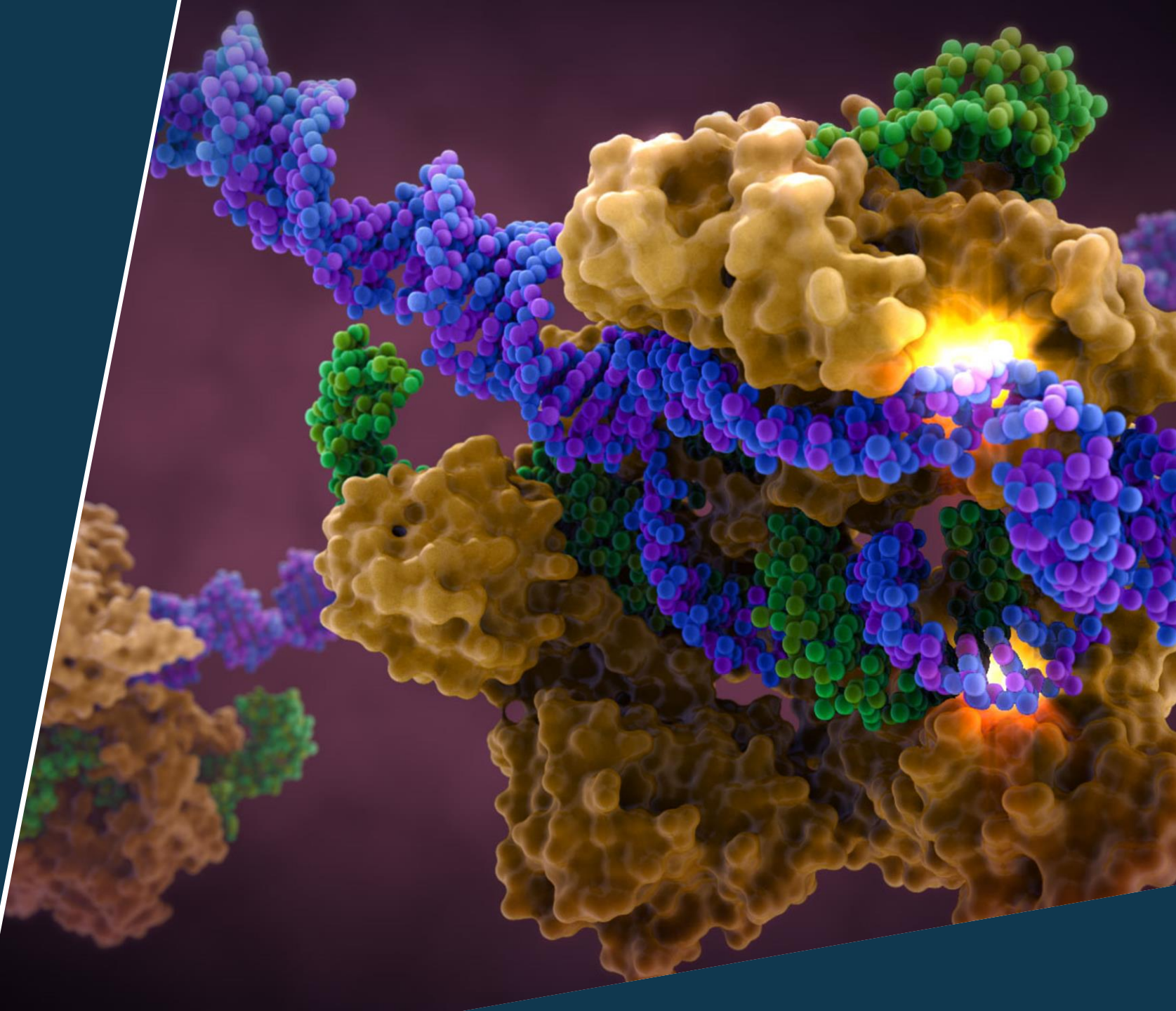


**Analytical Excellence through Industry
Collaboration (AEIC) meeting**

April 17th, 2024

Miguel Vega-Sanchez, Head of Regulatory
Affairs Cross Crop Strategy

Lieselot Bertho, Regulatory Policy Manager



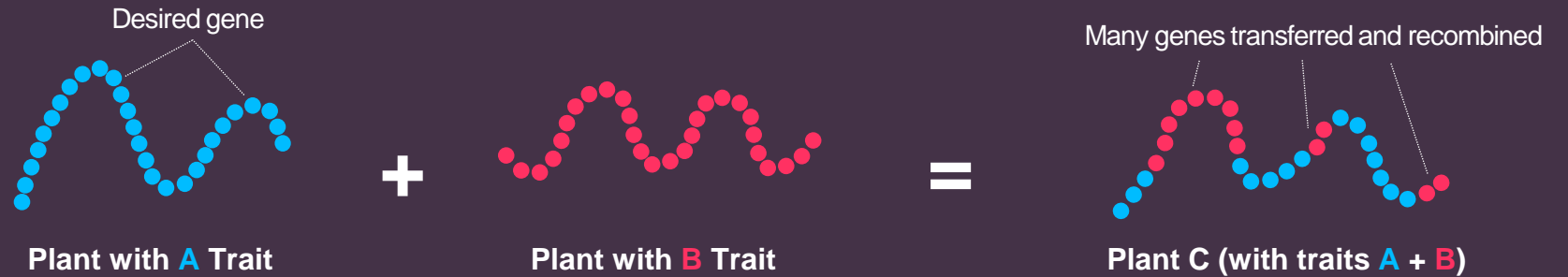


Plant science is constantly evolving

The efficiency and accuracy with which plant traits can be improved is increasing



Beginning in 10,000 BC:
Plant Breeding



Beginning in the 1990s:
Genome Editing



Beginning in the 1970s:
GMOs





Bayer prioritizing open innovation, transparency and sustainability on genome editing

- // Leverage **partnerships and investment to accelerate the best solutions for ag** through combined expertise and IP
- // **Genomics expertise, discovery capabilities across R&D platforms, regulatory experience, and the ability to work across the healthcare, food and agriculture industries** uniquely positions Bayer
- // **Engaging widely across stakeholder groups to find common ground**; building new collaborations to address previously unmet needs for ag and society

Strategic investments



Pairwise Plants

Co-founder and minority shareholder; multi-million collaboration and exclusive licensing agreement for work in row crops



CoverCress

BGV - Leveraging breeding and gene editing to convert **pennycress** into a winter cover crop used as oil feedstock and animal feed



Field trials ongoing

Partnerships & collaborations

Global alliance against TR4 fungus in bananas

Collaborators include consumer brands, NGOs, farmers and academia working to find genetic, crop protection and infrastructure solutions for banana growers



University of Wisconsin

Bayer has enabled a crop improvement center with transformation technology to further corn and soy editing in academia



D. Danforth Plant Science Center

Tool discovery, product advising



University of Freiburg

Editing target discovery



Licensing & Technology Access

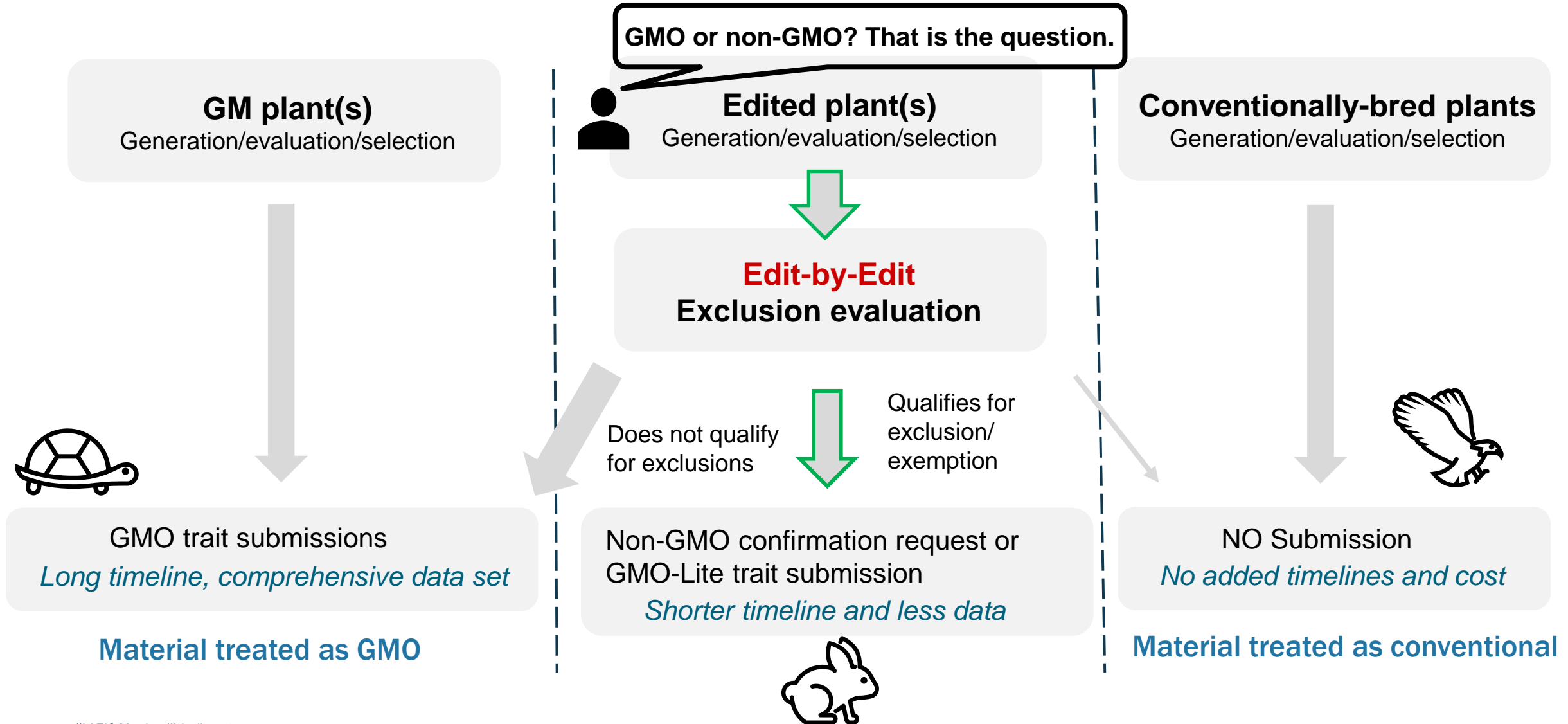


Grants4Ag Testing4Ag





A main challenge in the genome editing regulatory landscape is the diversity in exemption criteria

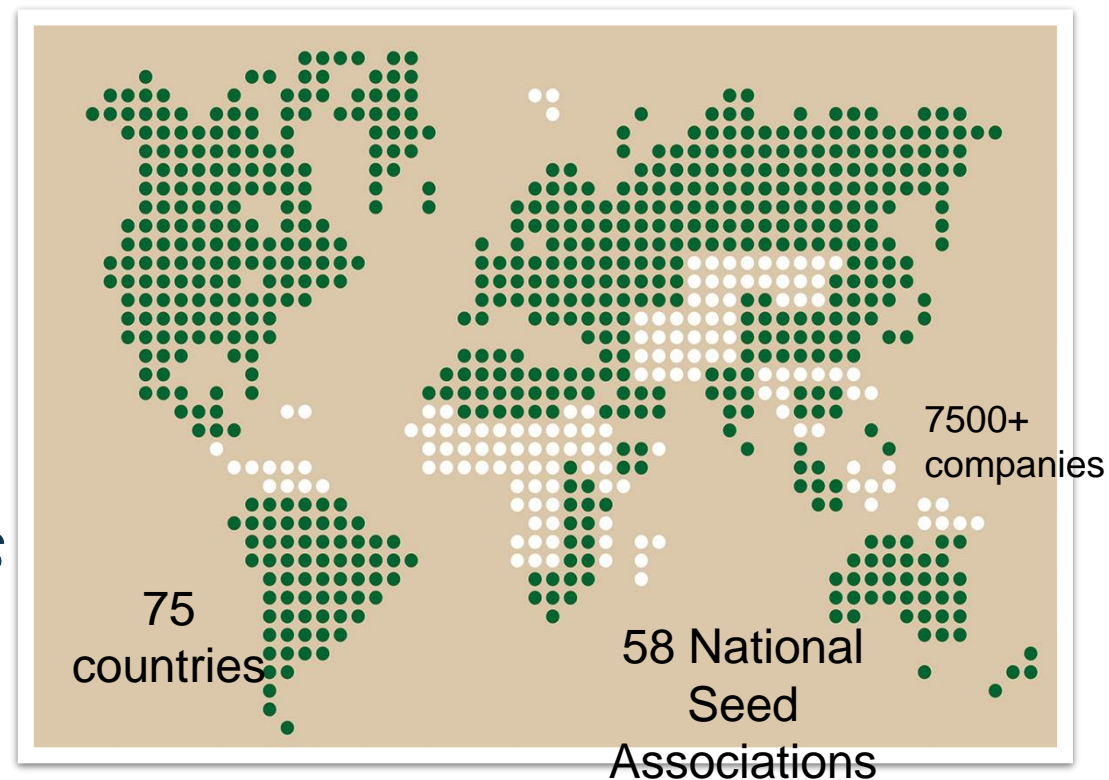




Should genome edited plants be regulated as GMOs?

Underlying Principle

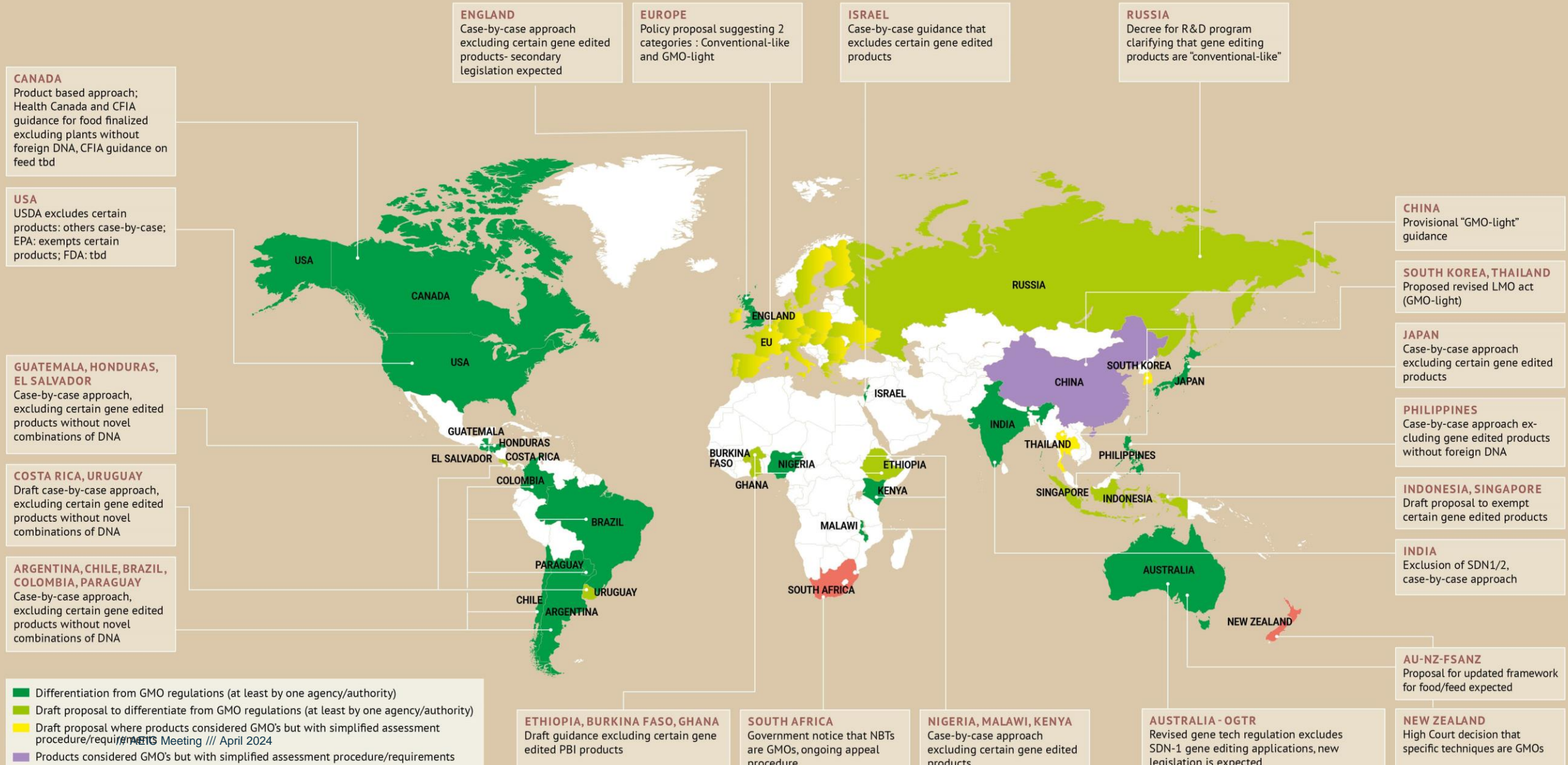
*“Plant varieties developed through the latest breeding methods **should not be differentially regulated** if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods or can be found in nature.*



Like products should be treated the same under the law



Enabling Regulatory Policy





International Policy: General Observations

// **Positives:**

- // Growing alignment in recognizing that not all gene edited plants should be treated as GMOs (e.g., no foreign DNA in final product, conventional-like).
- // Case-by-case consultation process.
- // Many countries allow for consultation at early-stage development (at product conception stage).
- // Regional harmonization are underway (e.g., Central and South America).

// **Challenges remain:**

- // Differences in information required for review.
- // Differences in timelines for review.
- // Lack of experience with more complex edits.
- // Edit by edit review (GMO model).



Three agencies can have oversight of GM and genome edited plants in the U.S.

USDA

All Plants

Is it safe to grow?

- Shipping
 - Field testing
- Permits
Notifications (pre-'21)

- Determination of non-regulated status

Plant Protection Act

FDA

Food, Feed

Is it safe to eat?

- Food and Feed safety consultation

Food Drug Cosmetic Act

EPA

'Pesticidal' substances

Is it safe for the environment?

- Plant-Incorporated Protectants (PIPs)
 - >10 acre Field Testing
 - Tolerance Exemption (allowed in food)

- PIP Registrations
- PIP renewals

**FIFRA
Food Drug Cosmetic Act**

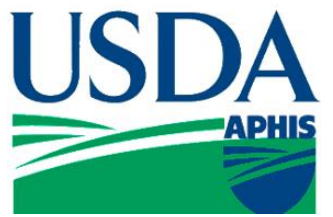
Example:
Bt corn

precommercial

commercial



Three U.S. agencies – three different approaches



Proposed rule: June 2019
Final rule: May 2020



Voluntary notification process

“Conventional like” Exemptions

- Currently three categories of modifications
- Proposed five additional categories

The types of plants that qualify for these exemptions can also be created through conventional breeding

Plant-Trait-Mode of Action Exemptions: reviewed and determined to be not regulated

Regulatory Status Review: for products that are not exempted



Proposed rule: Oct 2020
Final rule: May 2023



Notification or/and confirmation process

Exemptions [PIPs created through genetic engineering from a sexually compatible plant
Loss of function PIPs

PIPs developed through genome editing pose no greater risk than similar PIPs created through conventional breeding that have been exempt since 2001.



Public notice: Jan 2017
Final Guidance: Feb 2024



Voluntarily processes for developers to inform FDA

Premarket review is not necessary

Long history of safe food from new plant varieties developed through the plant breeding process, genome editing as plant breeding method with greater control and can produce foods with same characteristics as compared to foods from older methods



ASTA actively engaged in U.S. policy developments



EPA TURNS BACK THE CLOCK ON INNOVATION
On May 25, 2023

EPA Turns Back the Clock on Innovation

Alexandria, VA—May 25, 2023—The following statement is released on behalf of American Seed Trade Association (ASTA) President U.S. Environmental Protection Agency's (EPA) announcement today of its [final rule](#) on Plant Incorporated Protectants (PIPs).

"EPA's publication of its final rule on Plant Incorporated Protectants (PIPs) is a disappointing blow to plant breeders, public and private varieties to U.S. farmers and producers. Rather than improving and modernizing the U.S. biotechnology regulatory system, as called for in the new rule adds bureaucratic layers of red tape for the development of improved plant varieties created using innovative plant breeding techniques even though the agency views those products as posing no greater risk than their conventional counterparts.

"The competitiveness of the U.S. seed industry, and agriculture as a whole, rely on domestic and global policy alignment. At the dawn of interagency alignment under the U.S. Coordinated Framework, in essence negating much of the regulatory streamlining enabled by recent revisions to its Part 340 regulations.

"Internationally, EPA is handing a strategic advantage to foreign seed development and will delay U.S. farmers' access to improved seed varieties of the world. The rule is out of step with a growing list of international regulatory authorities that have used a science-based rational approach to support commercialization of innovative products. Notably, Canada, the U.S.' top trading partner for seeds, very recently announced a new rule for plant breeding innovation. In contrast to EPA's rule, the updated Canadian policy focuses on the characteristic of the product, and not the process of its development."

FEDERAL REGISTER
The Daily Journal of the United States Government

Notice

Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions

A Notice by the Animal and Plant Health Inspection Service on 11/15/2023

PUBLISHED DOCUMENT Start Printed Page 78285

AGENCY:
Animal and Plant Health Inspection Service, USDA.

ACTION:
Notice.

SUMMARY:
We are advising the public that we are proposing to add five new types of genetic modifications a plant can contain and be exempt from the regulations for the movement of organisms modified or produced through genetic engineering because such modifications could otherwise be achieved through conventional breeding methods. First, we propose any diploid or autopolyploid plant with any combination of loss of function modifications (i.e., a modification that eliminates a gene's function) in one to all alleles of a single genetic locus, or any

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
11/15/2023

Agencies:
Department of Agriculture
Animal and Plant Health Inspection Service

Dates:
We will consider all comments that we receive on or before December 15, 2023.

Comments Close:
12/15/2023

Document Type:
Notice

Document Citation:
88 FR 78285

Session Details

Name: Innovation in Plant Breeding Subcommittee (Closed to media)

Date & Time: Sunday, January 28, 2024, 2:00 PM - 3:30 PM

Location Name: Steinbeck III (Monterey Conference Center)

Description: This is a meeting for members of the Innovation in Plant Breeding Working Group. Working group members will review and discuss priority issues and activities pertaining to developments in international and national regulatory policies for products of plant breeding innovations, such as genome editing. If you would like to request participation, contact fchou@betterseed.org.

Program Description: PBI Subcommittee Agenda_DRAFT.docx

Speakers:
[Nastasia Bodnar - NSCEB](#)
[Christopher Holdgreve - Global Stewardship Group](#)
[Barrie McMahon - U.S. Food and Drug Administration - US Food and Drug Administration](#)
[Jessica Mahalingappa - USDA BRS](#)
[Hebke Striegel - U.S. Environmental Protection Agency - US Environmental Protection Agency](#)

Close



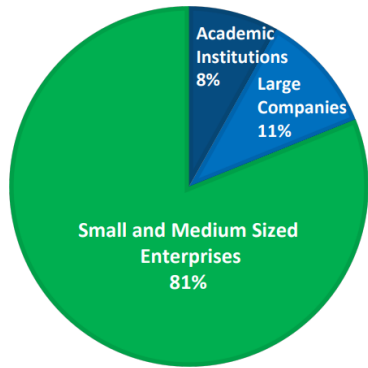
Despite global complexities crop genome edited products are commercially available in niche markets

Developer profile

Type of traits

U.S. (USDA)

Products confirmed exempt from regulation*



Herbicide, Insect, and Disease Resistance Traits



Product Quality Traits



Agronomic Property Traits



Other



/// AFIC Meeting // April 2024

Total of **69 confirmed exemptions** for genome edited plants

CR Number	Requestor	Plant	Scientific Name	Trait	Exemption Category	Response Date	Confirmation Request	Confirmation Response
23-209-02r	Inari Agriculture, Inc.	Com	Zea mays	Altered Yield Characteristics	(b)(1)	8/31/2023	View Document	View Document
23-208-01r	CoverCress Inc.	Pennyross	Thlaspi arvense	Altered Seed Composition	(b)(1)	8/31/2023	View Document	View Document
23-174-01r	CoverCress Inc.	Pennyross	Thlaspi arvense	Altered Seed Composition	(b)(1)	8/31/2023	View Document	View Document
23-114-01r	Redd Plants Corporation	Tomato	Solanum lycopersicum	Altered Fruit Characteristics	(b)(1)	8/8/2023	View Document	View Document
23-142-01r	CoverCress Inc.	Pennyross	Thlaspi arvense	Altered Seed Composition	(b)(1)	8/28/2023	View Document	View Document
23-142-02r	CoverCress Inc.	Pennyross	Thlaspi arvense	Altered Seed Composition	(b)(1)	8/28/2023	View Document	View Document
23-072-08r	Pairwise Plant Services, Inc.	Blackberry	Rubus L. subgenus Rubus	CR	(b)(1)	6/12/2023	View Document	View Document
23-072-07r	Pairwise Plant Services, Inc.	Blackberry	Rubus L. subgenus Rubus	CR	(b)(1)	6/12/2023	View Document	View Document
23-072-06r	Pairwise Plant Services, Inc.	Blackberry	Rubus L. subgenus Rubus	CR	(b)(1)	6/12/2023	View Document	View Document

(Status: April 2024)

Determination of regulatory status does not equal commercial availability

1 commercial genome edited plant product on US market, 1 in Japan



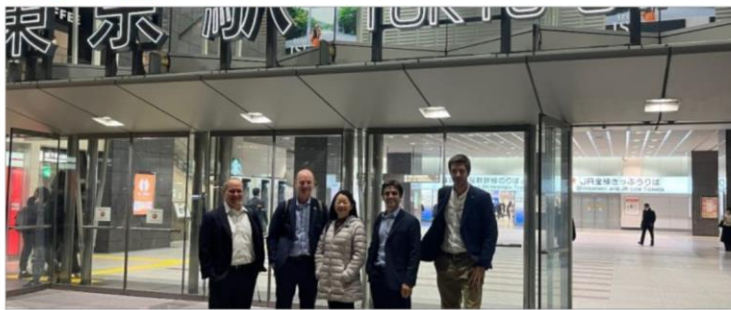
sanatechseed
For Tomorrow's Children and Earth

This product is brought you by Gene Editing.
NOTIFICATION SUBMITTED AS GENE EDITED PRODUCT.



ASTA international engagement in key markets for US seed - partnering with global and local seed associations

[International - ASTA - \(betterseed.org\)](https://www.betterseed.org)




ASTA LEADS TRIP FOR SEED INDUSTRY EXECUTIVES TO JAPAN
On February 23, 2024

Alexandria, VA—February 23, 2024—The American Seed Trade Association (ASTA) convened member company executives from leading seed companies for a weeklong trip to Japan. The group, led by Dr. Fan-Li Chou, ASTA's Senior Vice President, Scientific Affairs and Policy, included representatives from GDM, J.R. Simplot Company, and Pairwise, and packed in several days of intense and productive engagement with government and industry partners, with the goal of supporting ongoing bilateral collaboration with our Japanese counterparts. During the trip, the executives participated in a technical seminar at the U.S. Embassy in Japan and a webinar hosted by the Network for Breeding by Genome Editing on the use of genome editing in plant breeding to support both a healthy planet and...

"The meetings deepened the collaboration between the U.S. and Japanese seed industries and our public sector partners. Our conversations highlighted how genome editing integrated into plant breeding programs develops solutions to challenges facing agriculture and food systems," said Dr. Chou. "Meetings in Japan, and in our ongoing advocacy across the United States and with our global partners, ASTA continues to advocate for pre-innovations that ensure sustained public and private sector investments in agriculture sciences and support the use of all breeding tools, including genome breeding to bring improved varieties to market."

"Japan's commitment to pioneering innovations, coupled with the government's unwavering support for the development of innovation-friendly..."



16th ISBR SYMPOSIUM
ST. LOUIS, MO • USA
30 April - 4 May • 2023

UNION STATION HOTEL

ASTA ATTENDS ISF MID-TERM MEETINGS
On November 15, 2023

From October 30 – November 3, an ASTA delegation attended the mid-term meetings of the International Seed Federation (ISF) in Athens, Greece. During the meetings, ASTA met with representatives of seed companies, national seed associations, and regional seed associations from six continents to shape regulatory and policy alignment on key issues facing the seed industry. Topics of discussion focused on intellectual property, biotechnology, and phytosanitary policies, principles for combating seed theft and promoting agricultural sustainability, and building capacity of governments in emerging markets to expand business opportunities for seed companies.



ASTA ATTENDS 2023 ASIAN SEED CONGRESS
On December 21, 2023

In November, ASTA joined over 1,300 representatives from nearly 40 countries at the 2023 Asian Seed Congress, the largest seed industry event in Asia. ASTA's Senior Director, International Programs and Policy, Sam Crowell presented on the launch of ASTA's updated Policy...

ASTA PARTICIPATES IN APEC 2023
On August 23, 2023

American Seed Trade Association, ASTA, Biotechnology, Plant Breeding Innovation, Seed, Seed Industry

ASTA was proud to support the United States' Asia-Pacific Economic Cooperation (APEC) conference held earlier this month in Seattle. The conference featured a Policy Dialog for Agricultural Biotechnology (HLPDAB) and Policy Partnership for Food Security (PPFS).

In its presentation, ASTA provided recommendations to APEC economies on how to facilitate global seed trade, including through modernizing regulatory alignment on phytosanitary, biotechnology, and intellectual property measures.

PLANT BREEDING INNOVATION REGULATORY LANDSCAPE IN THE AMERICAS

Plant Breeding Roundtable
China Seed Congress
March 18, 2024

Fan-Li Chou
flchou@betterseed.org
American Seed Trade Association
www.betterseed.org



www.betterseed.org



Aligned and coordinated policies amongst different agencies in Canada

Canada's PBI Regulatory Space



Health Canada and CFIA both issued rationale that conclude:

- Targeted editing of a plant's own DNA poses the same level of risk as conventional plant breeding
- The end-product should be regulated, not the method of production



- Foreign DNA in final product
- Health Canada:
 - New or increased allergens or toxins
 - Impacts on key nutrients composition
 - Change in the food use of the plant
- CFIA (environment):
 - Herbicide Tolerance (focussed on stewardship)
 - Does “not foresee” any other endpoints that would require premarket safety assessment
- CFIA (feed) **NOT YET FINALIZED**
 - The guidance, as drafted, is workable by industry
 - There are opportunities to provide further clarification and refine through the consultation



Canadian transparency initiatives for genome edited crops

Government-led Processes

Health Canada introduced the voluntary Transparency Initiative (TI) specifically for gene-edited plant products:

- that do not meet the definition of a novel food
- for which no novelty determination has been sought from Health Canada

List of non-novel products of plant breeding for food use

Date	Product Name	Plant	Plant developer	Technology	Characteristic(s)	Mechanism(s) of Action	Food Use(s)	Earliest Entry to Market Date
2023-10-20	RTM1 Rice	Rice (<i>Oryza sativa</i>)	RiceTec, Inc.	Conventional breeding; classic mutagenesis	Herbicide tolerance	Mutation in a gene encoding a spatacsin-like protein	Whole rice and rice-derived ingredients	2026
2023-05-09	AXigen® Wheat	Wheat (<i>Triticum aestivum</i> L.)	Limagrain Cereal Seeds, LLC	Conventional breeding; classic mutagenesis	Herbicide tolerance	Mutation in a gene encoding an acetyl CoA carboxylase (aACCase) involved in lipid biosynthesis	For use as wheat flour	2024
2023-03-20	YM-ALS-205	Yellow mustard (<i>Sinapis alba</i>)	Agriculture and Agri-Food Canada (AAFC)	Conventional breeding; classic mutagenesis	Herbicide tolerance	Mutation in a gene encoding an acetolactate synthase (ALS) involved in amino acid synthesis	Condiment mustard usage	2028
2023-03-07	GT22, GT23, GT24, GT28, GT29, GT30	Mustard greens (<i>Brassica juncea</i>)	Pairwise Plant Services, Inc.	Gene editing - CRISPR/Cas12a	Reduced pungency to improve flavour	Deletions, insertions, and/or inversions in a gene encoding a myrosinase enzyme involved in the breakdown of glucosinolates	Leafy greens food usage	2023

Industry-led Processes

Canadian Variety Transparency Database

This database is part of a broader, seed industry-led effort to provide varietal level transparency.

In accordance to the Health Canada Transparency Initiative, where a variety has been developed using gene editing technology and does not meet the definition of a "novel food", "Required" will appear under "Health Canada Notification" column of the database. More information on these varieties can be found on the [non-novel list](#).

Varietal data is obtained from the records of the Canadian Food Inspection Agency (CFIA) and Seeds Canada members and partners.

You can download the database by clicking below or search using the search box below.

If you have any questions, please contact us at info@seeds-canada.ca.

Download Database

Search...

Any Crop

Any Status

Any Notification

CLEAR

Variety Reg. #	Variety	Crop	Canadian Representative	Status	Health Canada
6121	BINSCARTH	Barley, (Forage Type), six-row, spring	WAGON WHEEL SEED CORP. (ROGER & WARREN KAEDING)	National Registration	Not required
6301	CORCY	Barley, (Forage Type), six-row, spring	LA COOP FEDÉRÉE	National Registration	Not required
4805	SOMMERVILLE	Barley, (Forage Type), six-row, spring	THOMPSONS LIMITED	National Registration	Not required
5146	WESTFORD	Barley, (Forage Type), six-row, spring	NUTRIEN AG SOLUTIONS INC.	National Registration	Not required
5296	ACRANGER	Barley, (Forage Type), six-row, spring	OFFICE OF INTELLECTUAL PROPERTY AND COMMERCIALIZATION (AAFC)	National Registration	Not required
5423	DILLON	Barley, (Forage Type), six-row, spring	NUTRIEN AG SOLUTIONS INC.	National Registration	Not required

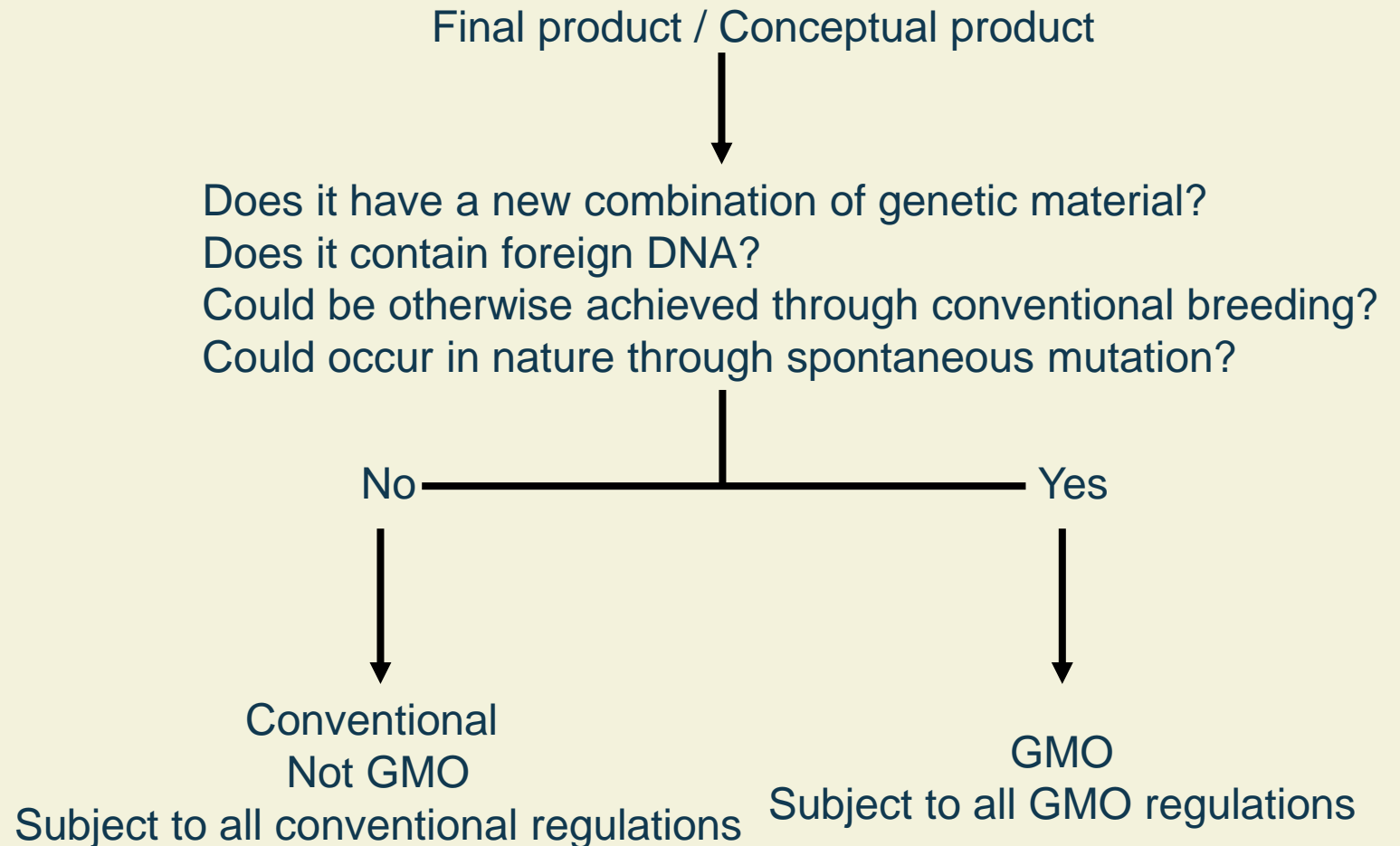


Harmonized approach by many countries in Latin America

General Observations:

- // Many national laws include definition of “GMO” that is based on the “LMO” definition in the Cartagena Protocol on Biosafety
- // LMO definition: *possesses a novel combination of genetic material obtained through the use of modern biotechnology*
- // Case by Case Consultative Process
- // It’s not a risk assessment rather a confirmation of regulatory status

General Consultative Process:





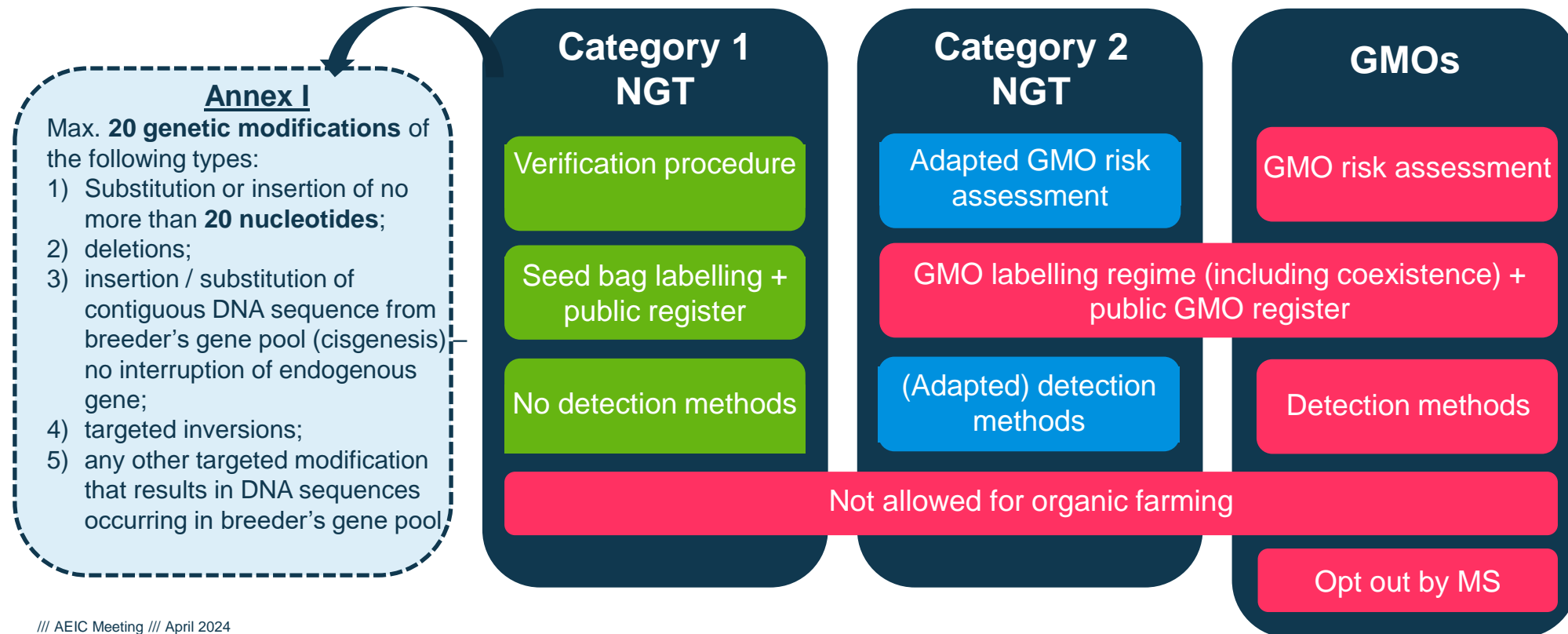
The European Commission proposes distinction between two types of NGT plants

// Proposal covers deliberate release and placing on the market of NGT plants and derived products.

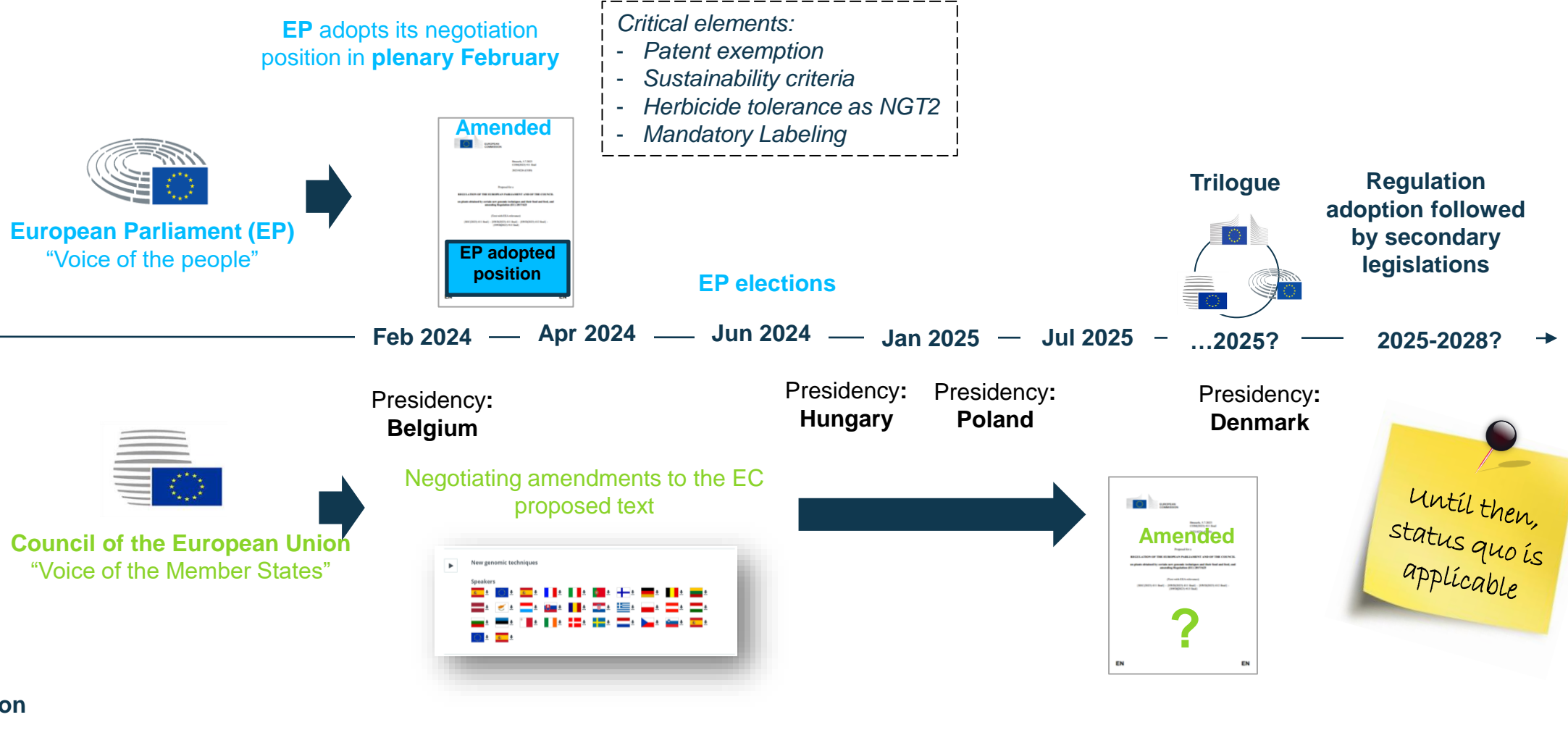
// Proposed distinction between:

// Category 1 (“conventional-like”) → meet specific criteria, subject to verification process.

// Category 2 → all other NGT plants that do not meet specific criteria, subject to “GMO-like” authorization process.



The road towards a final EU regulation is long and unpredictable

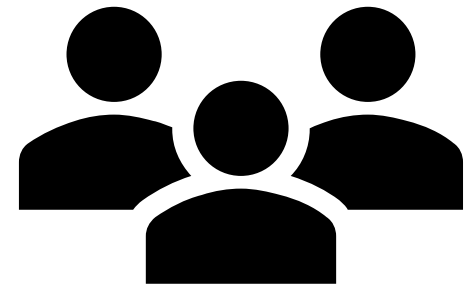




Common theme across regulatory policies around the globe

Edits are considered exempt/excluded/as-safe-as conventional if the edit

“Can be generated through conventional breeding”





“Editing to Breed” is where genome editing can make the highest impact to drive innovation and advance agriculture

Science Bulletin 69 (2024) 281–284

Contents lists available at ScienceDirect

Science Bulletin

journal homepage: www.elsevier.com/locate/scib

News & Views

Unlocking crop diversity: Enhancing variations through genome editing

Jinpeng Zou ^{a,1}, Yong Huang ^{a,1}, Caixia Gao ^{b,c,*}, Kejian Wang ^{a,d,*}

^aState Key Laboratory of Rice Biology and Breeding, China National Rice Research Institute, Chinese Academy of Agricultural Sciences, Fuzhou, China

^bNew Cornerstone Science Laboratory, Center for Genome Editing, Institute of Genetics and Developmental Biology, Chinese Academy of Agricultural Sciences, Beijing, China

^cCollege of Advanced Agricultural Sciences, University of Chinese Academy of Sciences, Beijing 100049, China

^dHainan Yazhou Bay Seed Laboratory, Sanya 572025, China

https://doi.org/10.1093/plcell/koac243

THE PLANT CELL

BREEDIT: a multiplex genome editing strategy improve complex quantitative traits in maize

Christian Damian Lorenzo ^{1,2}, Kevin Debray ^{1,2}, Denia Herwegh ^{1,2}, Ward Develte ^{1,2}, Lennert Impens ^{1,2}, Dries Schaumont ³, Wout Vandeputte ^{1,2}, Stijn Aesaert ^{1,2}, Griet Coussens ^{1,2}, Yara De Boe ^{1,2}, Kirin Demuyck ^{1,2}, Tom Van Hautegeem ¹, Laurens Pauwels ^{1,2}, Thomas B. Jacobs ^{1,2}, Tom Ruttink ³, Hilde Nelissen ^{1,2} and Dirk Inzé ^{1,2,*†}

Large-Scale Biology

1 Center for Plant Systems Biology, VIB, B-9052 Gent, Belgium
 2 Department of Plant Biotechnology and Bioinformatics, Ghent University, B-9052 Gent, Belgium
 3 Flanders Research Institute for Agriculture, Fisheries and Food (ILVO), B-9820 Merelbeke, Belgium

Investing in CRISPR for Crops of the Future: What We Heard at World Agri-Tech

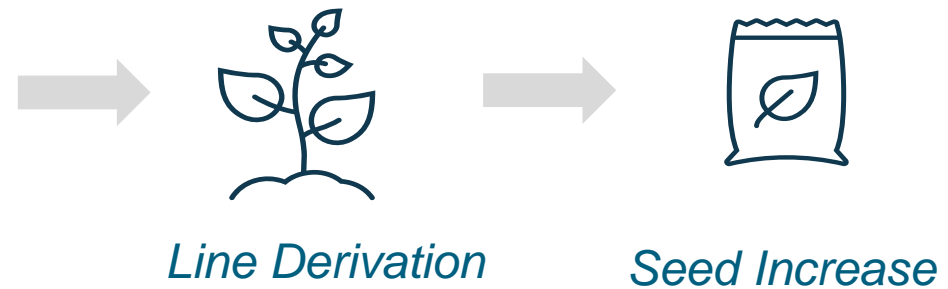
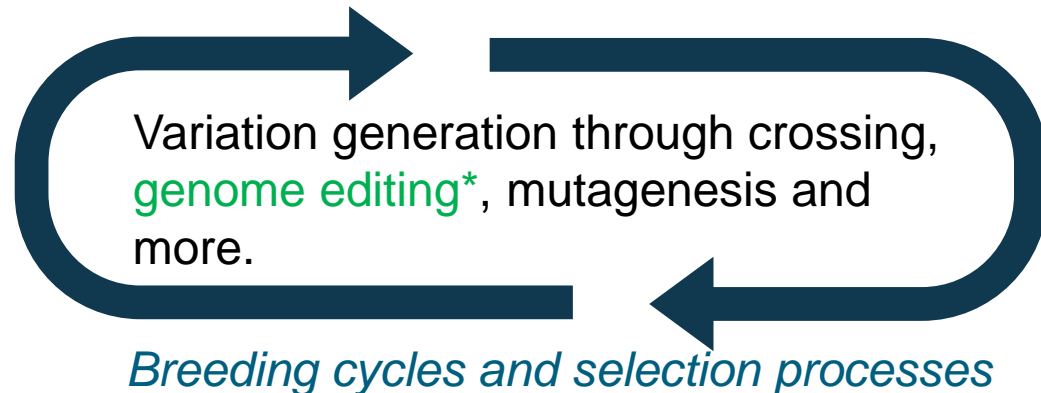
Madeleine Baerg | March 27, 2024 | Featured - Global, Seed World U.S.

“One cross, you can introduce the trait into any elite varieties or hybrids you would like,” said Wu.

Perhaps the largest opportunity ahead for CRISPR is how gene editing can be applied to complex traits where you need complex, multiple gene modifications or pathways.

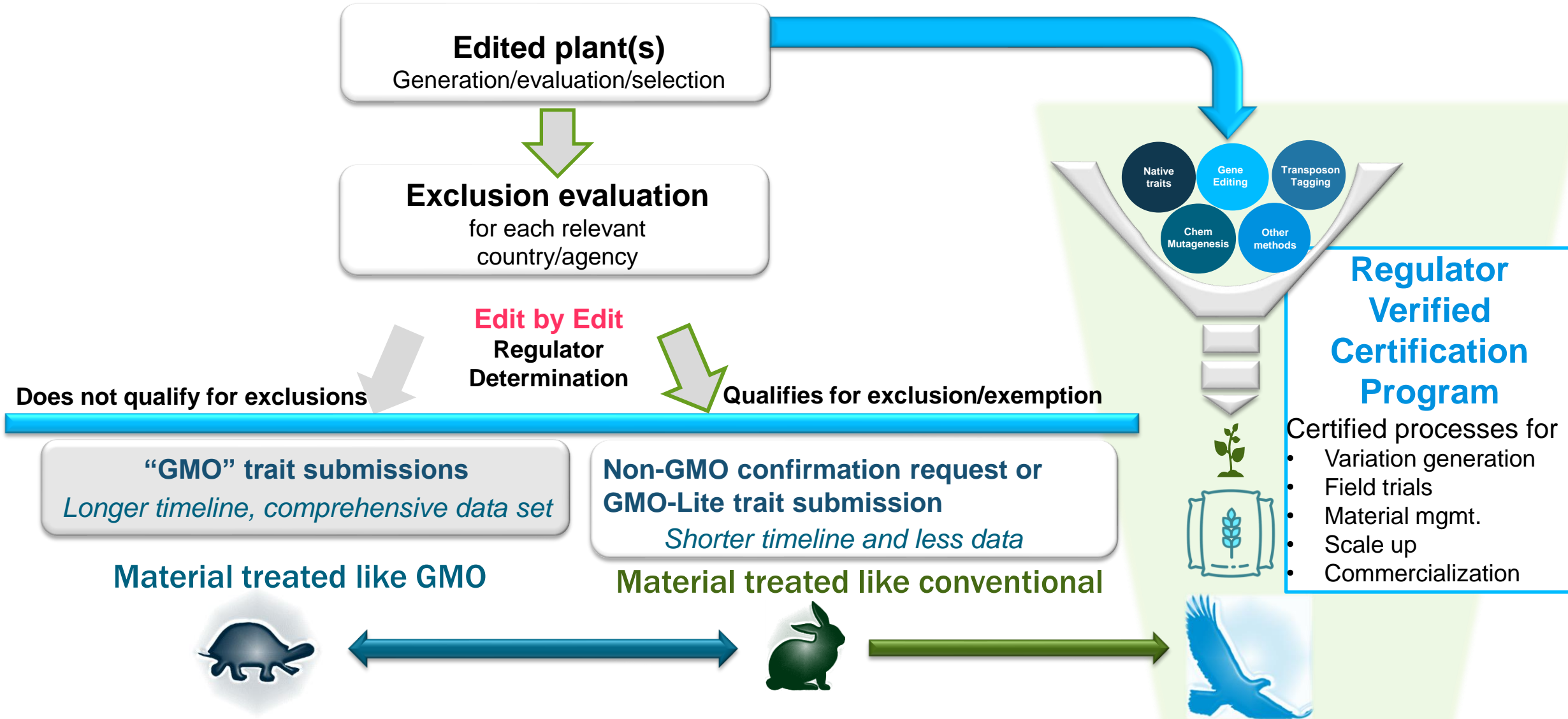
“This can happen today; we see the opportunity and the potential,” Wu said. “With gene editing in combination with machine learning, now even artificial intelligence, we can now create designed genetic variations. The variations can give you outcomes with high predictability and today we see examples demonstrating that. So, this opportunity is going to be huge.”

The next stage for CRISPR is likely to be its most exciting, and its opportunity to make its biggest impact on the market.





VISION: From product-to-product assessment to certified processes for genome edits





Key messages:

[Innovation and Policy - ASTA - \(betterseed.org\)](https://betterseed.org)

- // Regulatory modernization process is not short, nor straight, nor easy.
- // Key for success:
 - // Regulators open to looking at scientific opinion and eager to develop science-based regulation.
 - // Government, private sector, public sector committed to co-development, partnership and open dialogue.
- // Evidence of success:
 - // Alignment among regions.
 - // Domestic developers, more diversity in types of plant species.
- // Preparing for the future:
 - // Sustained government, private sector, public sector engagement to ensure regulatory approach is flexible to accommodate scientific progress.
 - // International engagement: government to government, and private sector.



Thank
you

Follow Bayer on: [Twitter](#) /// [Facebook](#) /// [Instagram](#) /// [LinkedIn](#) /// [YouTube](#)

