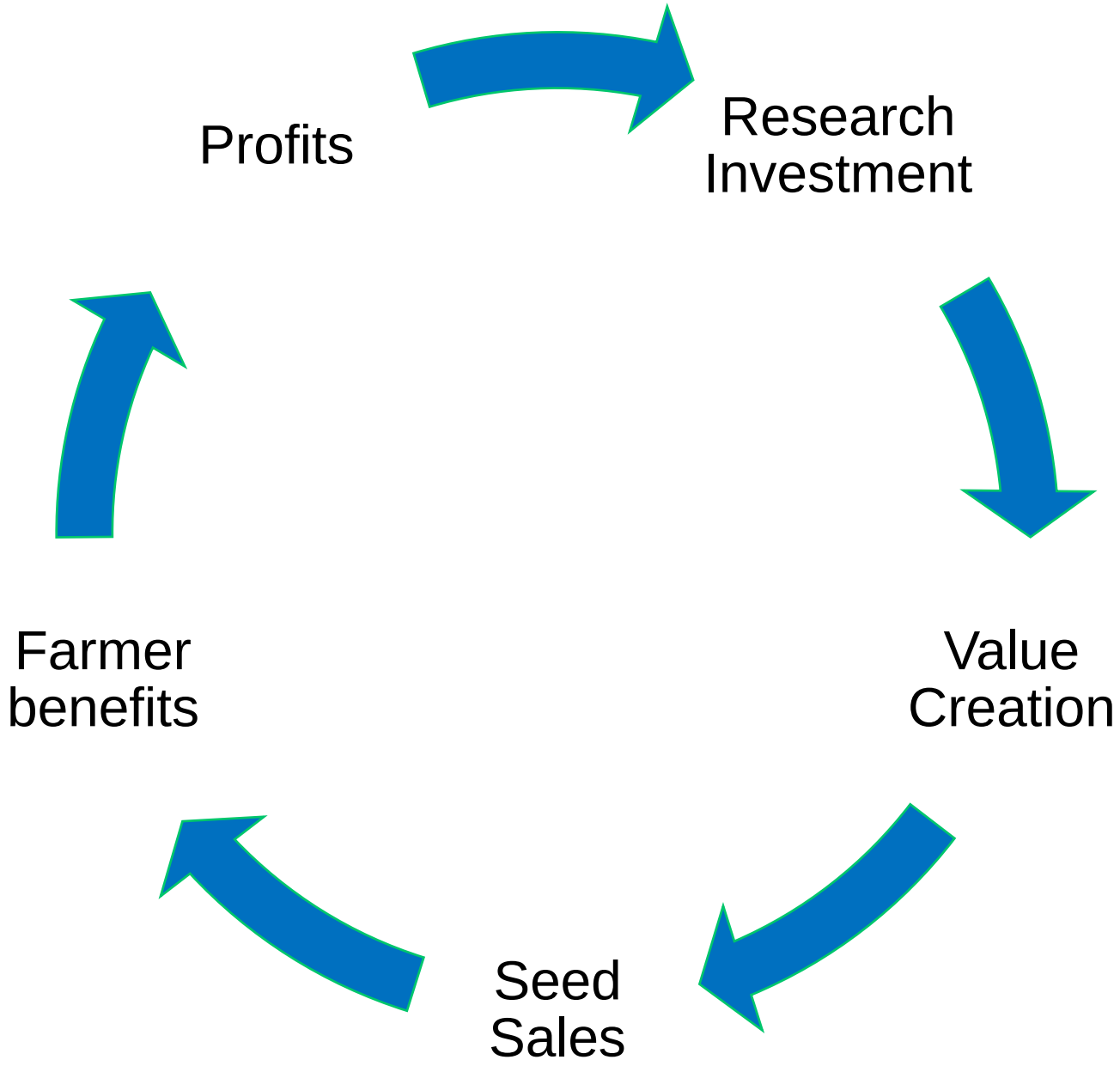
# Intellectual Property and Gene Editing
## 2 powerful tools to promote innovation

Marc Cool
Global Seed Policy Leader

# Why do Intellectual Property Rights matter?

- IP is not a goal, but an enabler to reach a goal
- The ultimate goal is to create value for farmers and society
- To do this, investments in research are needed
- An incentive for these investments is to receive a reward for the value created
- IP provides this incentive

# The Circle of Innovation



# Types of IP Protection

Trade Secrets

Contracts

Trademarks

Seed Law

Plant Breeders Rights – under UPOV91
DUS and edv, breeder and farmer exemptions

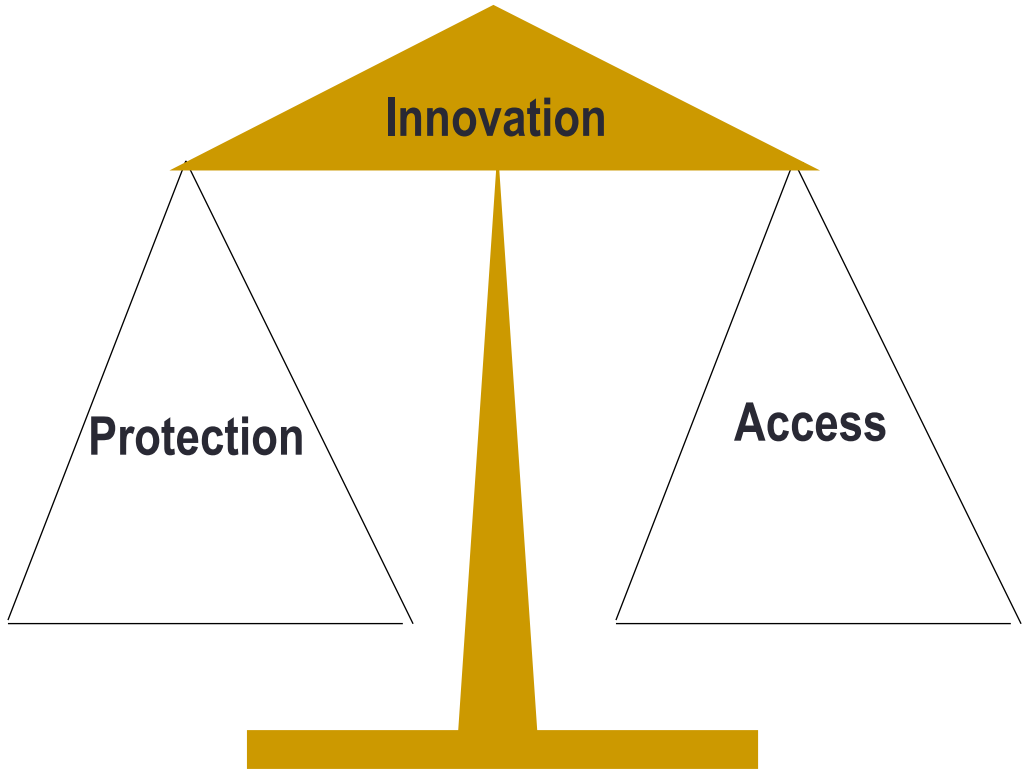
Patents (method, trait, product/variety/plant)

Coexist

Complement

Different functions

# The Balance of Protection and Access



# Regulatory status and Intellectual Property Protection

- Regulatory status and IP protection are governed by separate legislations
- These two distinct legal frameworks have different objectives:
  - The objective of regulatory frameworks is to protect human/animal health and the environment
  - The IP system is designed to stimulate innovation in all fields of technology
- Whether a product does or does not fall under a specific regulatory framework has no bearing on the IP status of such product
- Gene edited traits can be protected under the patent system – regardless of their regulatory status - provided that they meet the local patentability criteria (novelty, inventive step, industrial applicability and enabling disclosure)

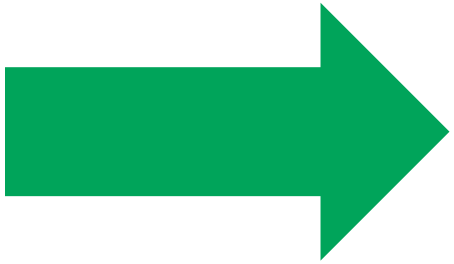
# Are methods like CRISPR accessible for breeding?

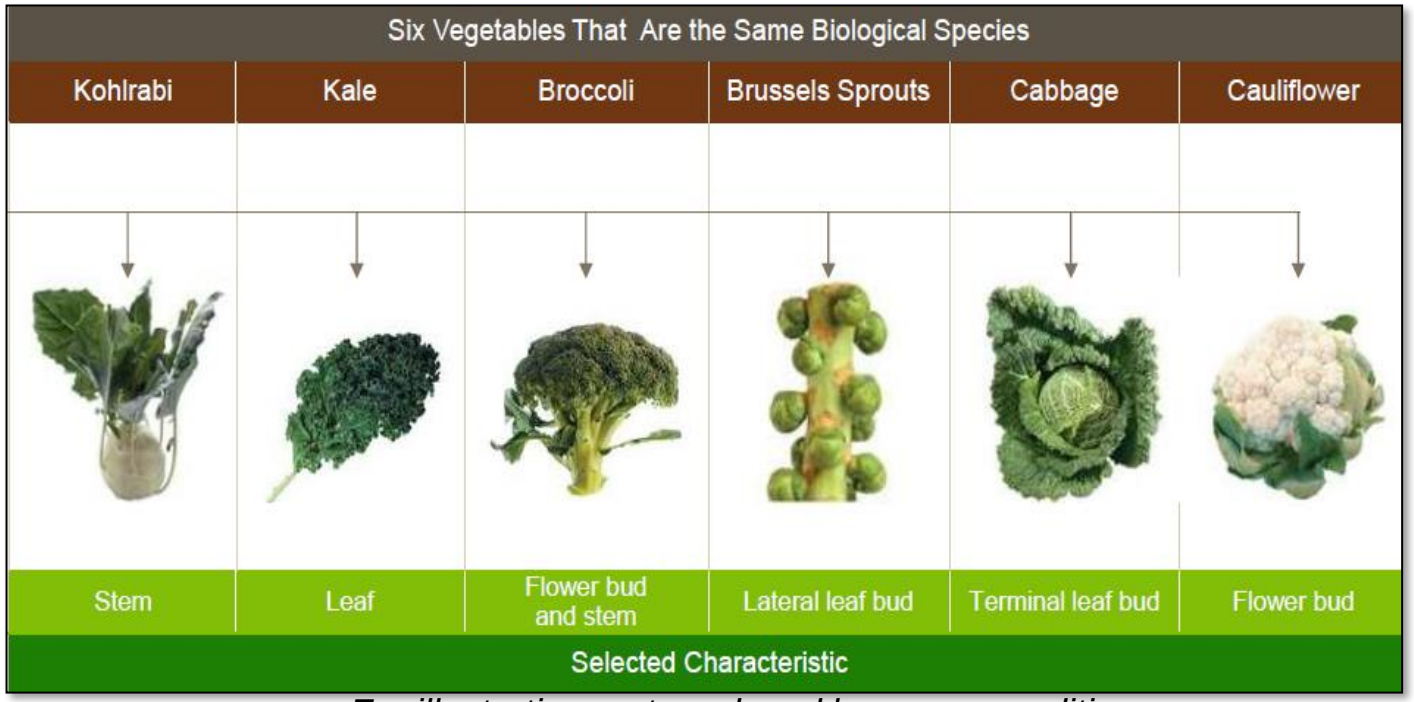
- A license may be required
- Most patent holders have out-licensing and distribution policies for medical, agricultural, and industrial applications
- For CRISPR-Cas9, the primary patent holders provide free licenses for research to academic and non-profit institutions
- Also non-exclusive, royalty-bearing, licenses to organizations that want to use CRISPR-Cas9 for commercial purposes
- Application of the technology also depends on additional technology/methodology plus enabling knowledge

# Who owns the Patents on CRISPR?

- Many of the patent holders, worldwide, are universities and research institutes
- Patent landscape for gene editing is dynamic and evolving rapidly
- Patents are not only held in the US and Europe but also Asia, particularly Korea and China
- Other methods of gene editing, like ZFN, and TALEN, have different patent application dynamics
- Updated information available on public patent databases such as the Worldwide Espacenet or Patentscope

# Plant Breeding Develops Plant Diversity




*For illustration, not produced by genome editing*

# Plant Breeding Develops Plant Diversity

## Genome Editing Allows Us to Tap Full Genomic Potential


knowledge

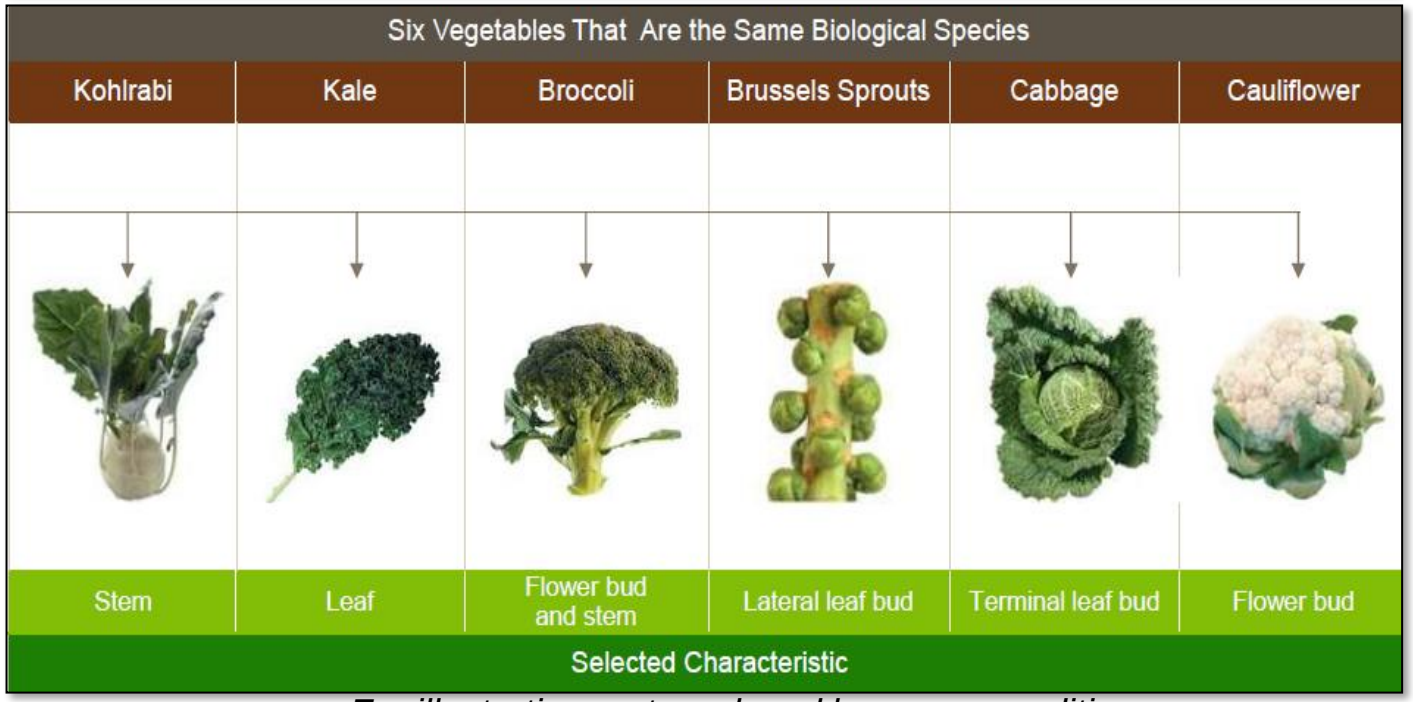
https://businessmarketingengine.com/how-growing-your-knowledge-can-grow-your-business/

**Efficiency**

tools


*Credit : Lauren Solomon, Broad Communications*

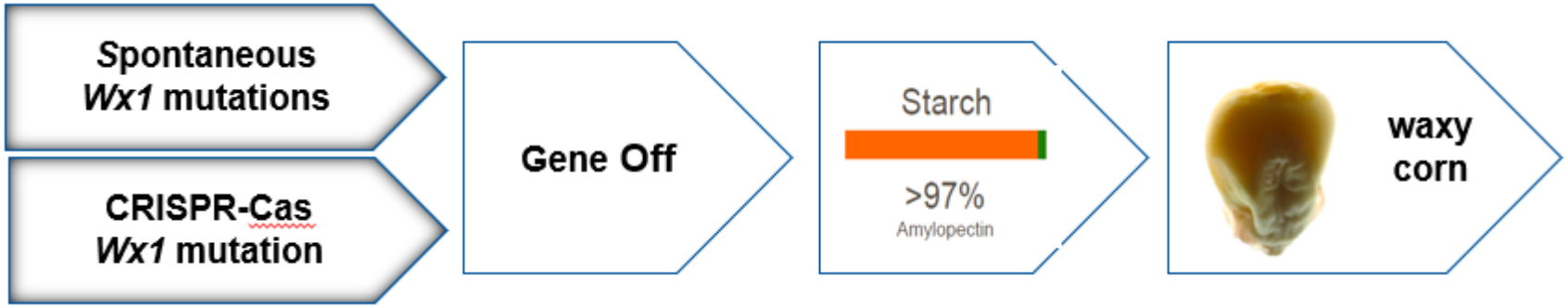
Genome editing will be the preferred method to create genetic variation




*For illustration, not produced by genome editing*

Continues the history of crop improvement through targeted breeding approach

# CRISPR waxy corn delete




- Targeted *Wx1* gene deletion directly in elite inbreds using CRISPR-Cas.
- To address time lag to introgress *wx1* mutant allele into elite germplasms and yield penalty due to linkage drag.
- Increased average yield of CRISPR waxy hybrids vs. conventional waxy hybrids.
- Several countries confirmed non-GMO/ non-regulated status.

nature biotechnology

BRIEF COMMUNICATION

https://doi.org/10.1038/s41587-020-0444-0

Check for updates

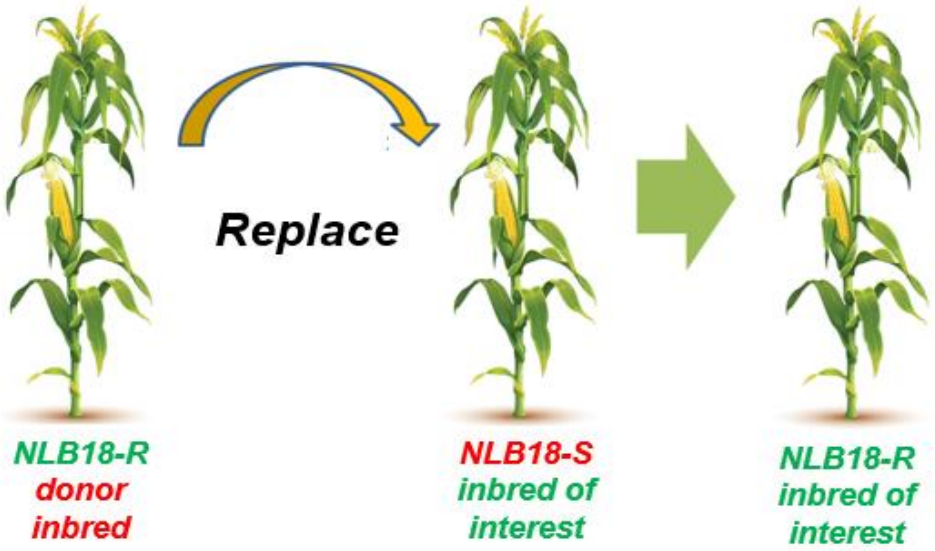
## Superior field performance of waxy corn engineered using CRISPR–Cas9

Huirong Gao[1]✉, Mark J. Gadlage[1], H. Renee Lafitte[1,2], Brian Lenderts[1], Meizhu Yang[1], Megan Schroder[1], Jeffry Farrell[1], Kay Snopek[1], Dave Peterson[1], Lanie Feigenbutz[1], Spencer Jones[1], Grace St Clair[1], Melissa Rahe[1], Nathalie Sanyour-Doyel[1], Chenna Peng[1], Lijuan Wang[1], Joshua K. Young[1], Mary Beatty[1], Brian Dahlke[1], Jan Hazebroek[1], Thomas W. Greene[1], A. Mark Cigan[1,3], N. Doane Chilcoat[1] and R. Bob Meeley[1]

[1]Research and Development, Corteva Agriscience, Johnston, IA, USA. [2]Present address: Bill & Melinda Gates foundation, Seattle, WA, USA. [3]Present address: Genus Research, DeForest, WI, USA. ✉e-mail: Huirong.gao@corteva.com

NATURE BIOTECHNOLOGY | VOL 38 | MAY 2020 | 579–581 | www.nature.com/naturebiotechnology

# Disease resistant corn edit





- **Targeted replacement** of *NLB18-sensitive* allele with *NLB18-resistant* allele using CRISPR-Cas
- At its native genomic location
- Alternative to a conventional breeding cross
- Non-GMO/not regulated status in several countries

# Corn multi disease resistance insert

**A framework for delivering cisgenic multi-disease resistance at a single genetic locus in elite corn germplasm by genome editing**

- Simplifies delivery of cisgenic disease resistance across products
- Concept: target 4 major fungal diseases- a combined solution for farmers
- Releases genetic space for breeding and facilitates product assembly
- Uses native disease-resistant alleles only, already existing in other corn germplasms (“natural occurrence”)

# Example of germplasm improvement future

Double-strand breaks

Chromosome
with pericentric inversion
unlocks recombination

nature plants

BRIEF COMMUNICATION

https://doi.org/10.1038/s41477-020-00817-6

Check for updates

## CRISPR–Cas9-mediated 75.5-Mb inversion in maize

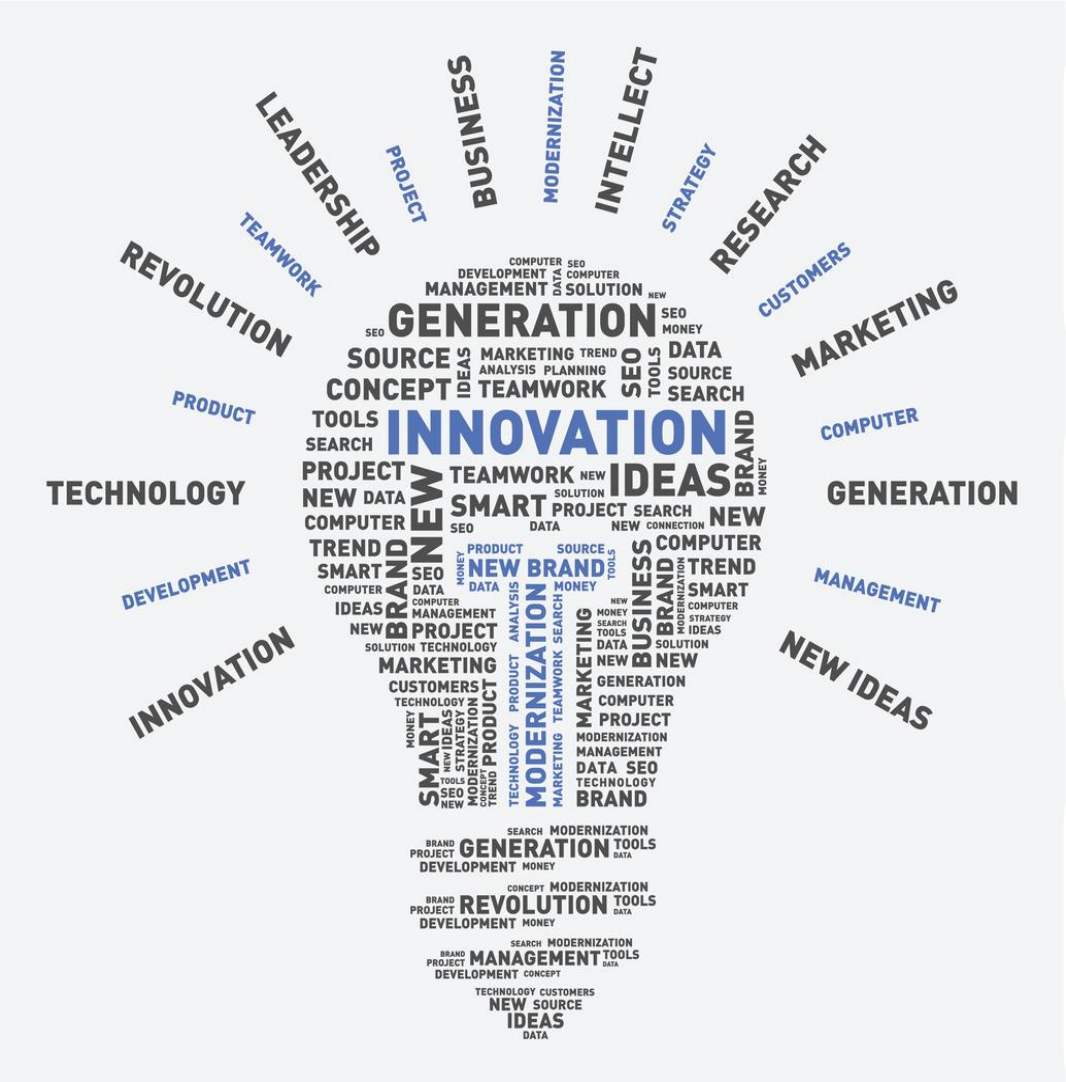
Chris Schwartz, Brian Lenderts, Lanie Feigenbutz, Pierluigi Barone, Victor Llaca, Kevin Fengler and Sergei Svitashev ✉

Corteva Agriscience, Johnston, IA, USA. ✉e-mail: sergei.svitashev@corteva.com

NATURE PLANTS | VOL 6 | DECEMBER 2020 | 1427–1431 | www.nature.com/natureplants

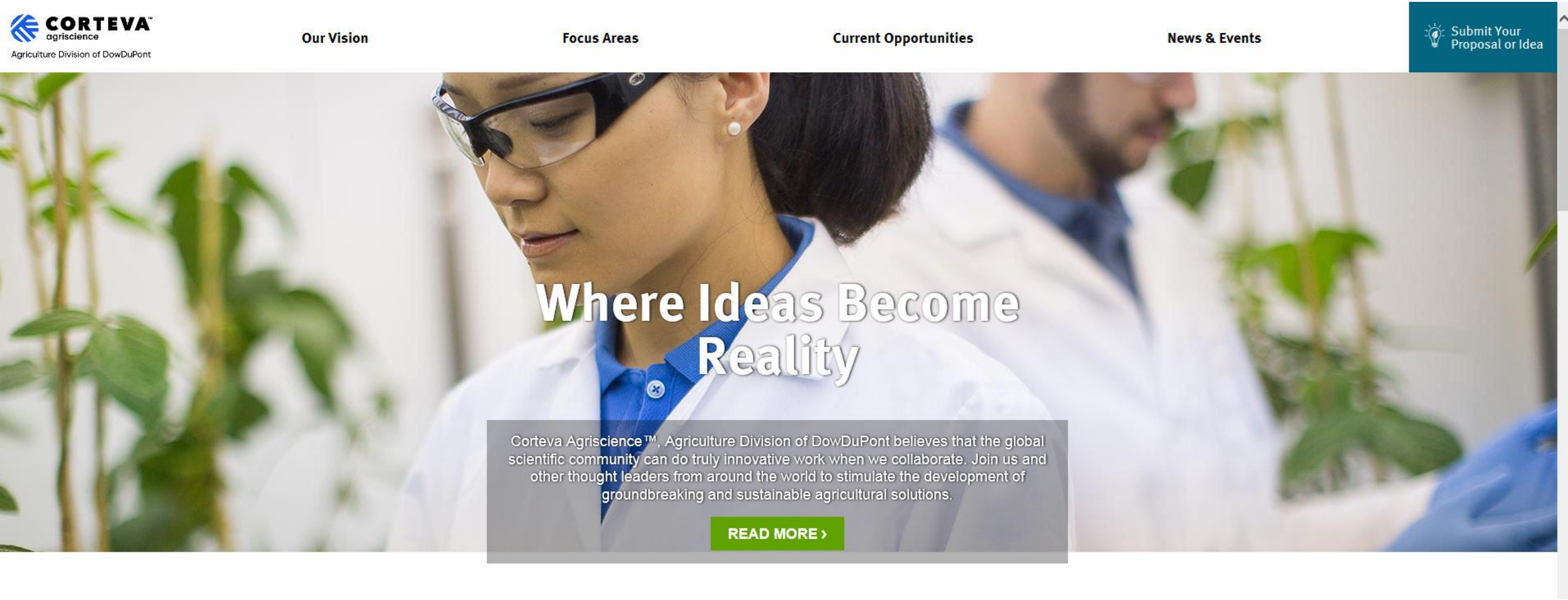
- Targeted pericentric inversion
- No deletion, edit, or insertion of DNA
- No DNA template involved in repair (NHEJ repair, as in SDN1)
- No new traits
- Chromosomal inversions are well documented to occur spontaneously in nature

# What Enables Innovation?



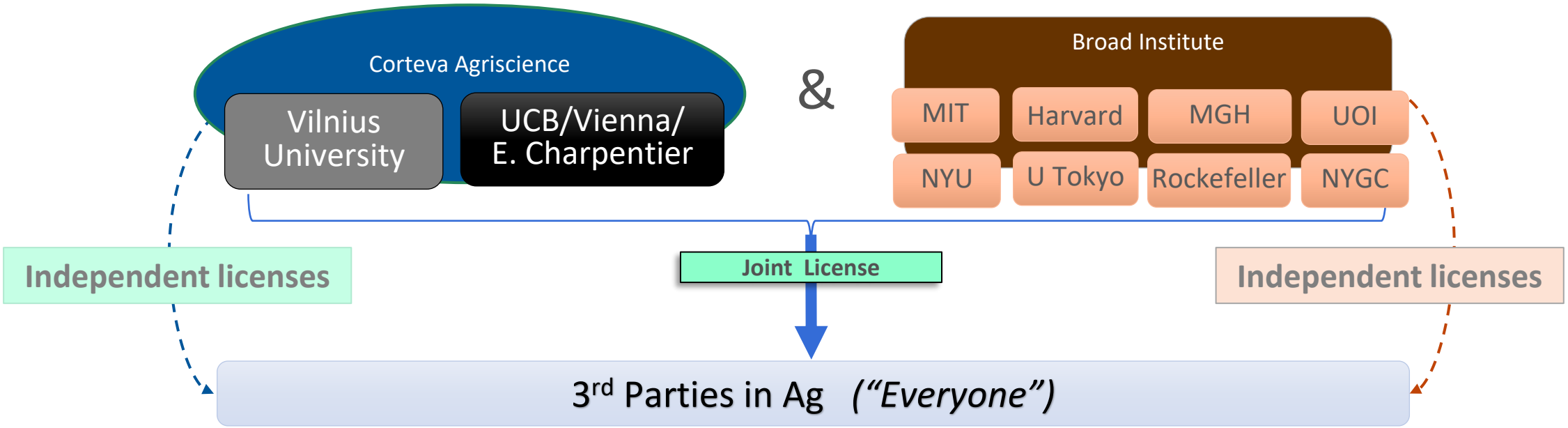

| | |
|---|---|
| Technology | • Toolbox<br>• Applications<br>• Intellectual property<br>• Collaborations |
| Policy | • Global regulatory frameworks |
| Public acceptance | • Societal value<br>• Trust<br>• Who benefits?<br>• Transparency |

# Open Innovation




openinnovation.corteva.com

# Corteva Agriscience & Broad Institute Joint Licensing Framework on CRISPR-Cas9



# Broad-Corteva CRISPR-Cas9 License Terms

- **IP Coverage:** Foundational patent families from the Broad Institute, Corteva, Vilnius University, UC Berkeley, University of Vienna and ERS Genomics

- **Non-Exclusive**

- **Royalty :** adapted to the activities chosen and the size of the licensees with proportionate terms for Not-For-Profit/Public research organizations
  - Academic research (non commercial): no license fee
  - Commercial; license fee

- **Independent Licenses:** Licensees maintain the ability to seek independent licenses from the Broad or from Corteva

- **Stewardship requirements:** no work in Tobacco/nicotine, gene drive, Terminator technology, need to steward technology and products, Herbicide Tolerance not preferred

# Corteva Philanthropic Pillar

## Examples of CRISPR collaborations: focus on smallholder farmers

Maize Lethal Necrosis

**Collaborators:** CIMMYT, KALRO, USDA-ARS

Striga-Resistant Sorghum

**Collaborators:** Kenyatta U, ISAAA AfriCenter, AATF

Improved Pearl Millet (ShelfPlus)

**Collaborators:** CIMMYT

# Argentina PBI Policy Experience: Diversification of Applicants

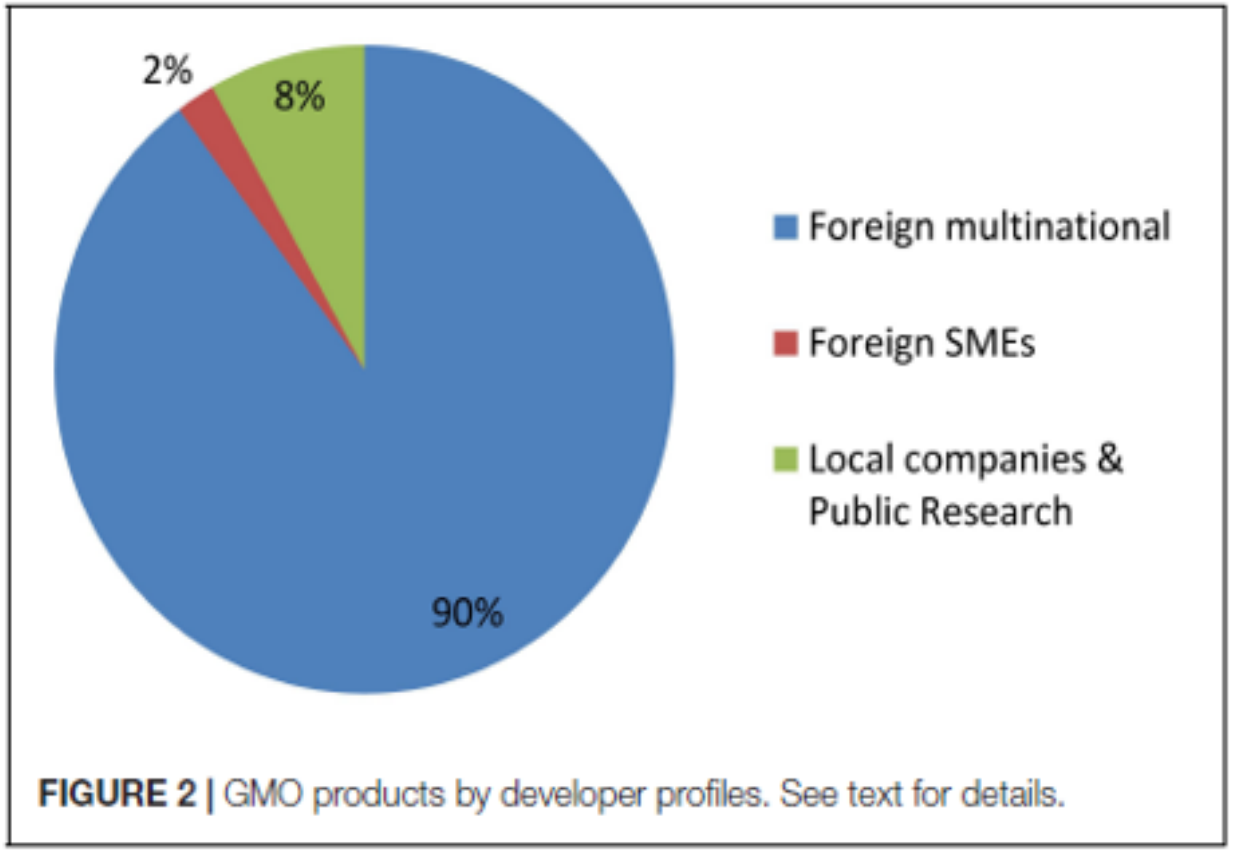



**FIGURE 2 |** GMO products by developer profiles. See text for details.

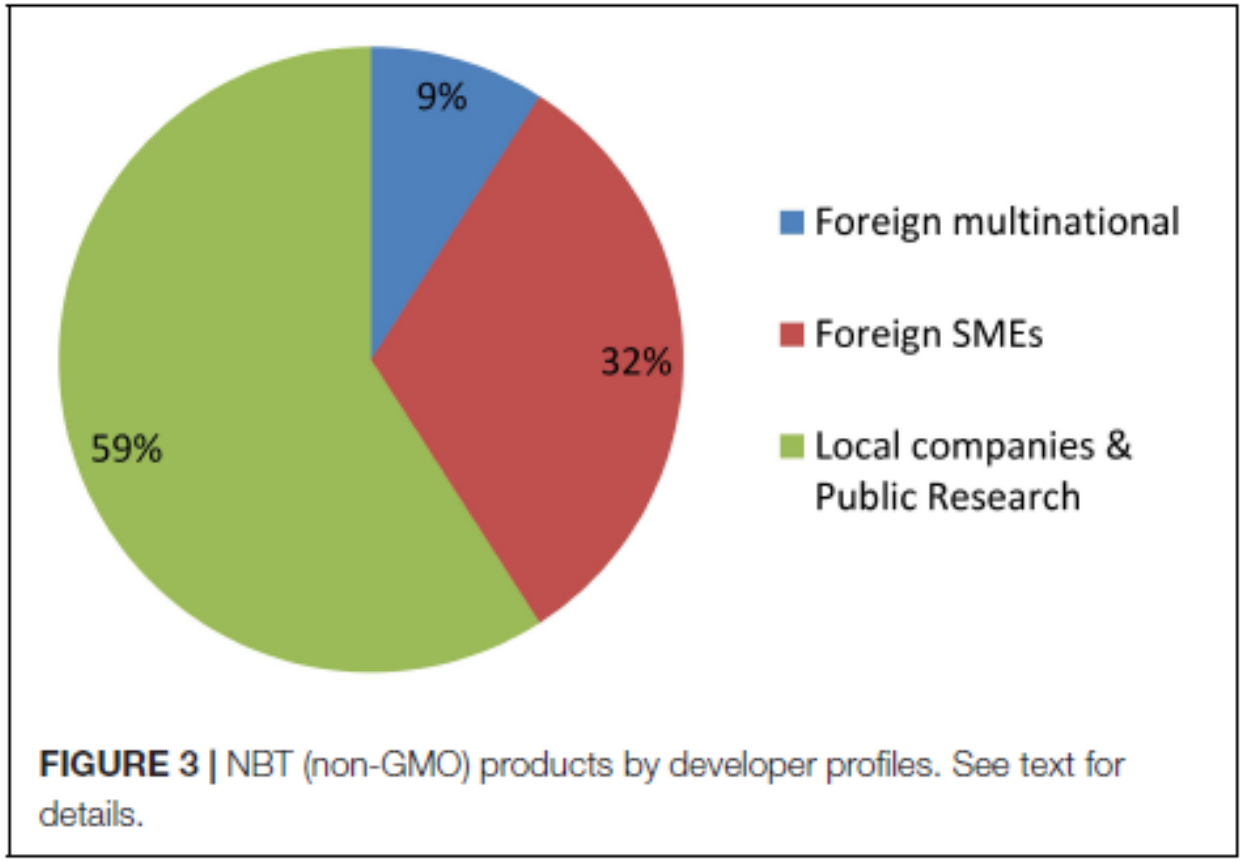



**FIGURE 3 |** NBT (non-GMO) products by developer profiles. See text for details.

*Source: A. Whelan et al. (2020) Gene editing regulation and innovation economics.* https://doi.org/10.3389/fbioe.2020.00303

# Argentina PBI Policy Experience: Diversification of Traits

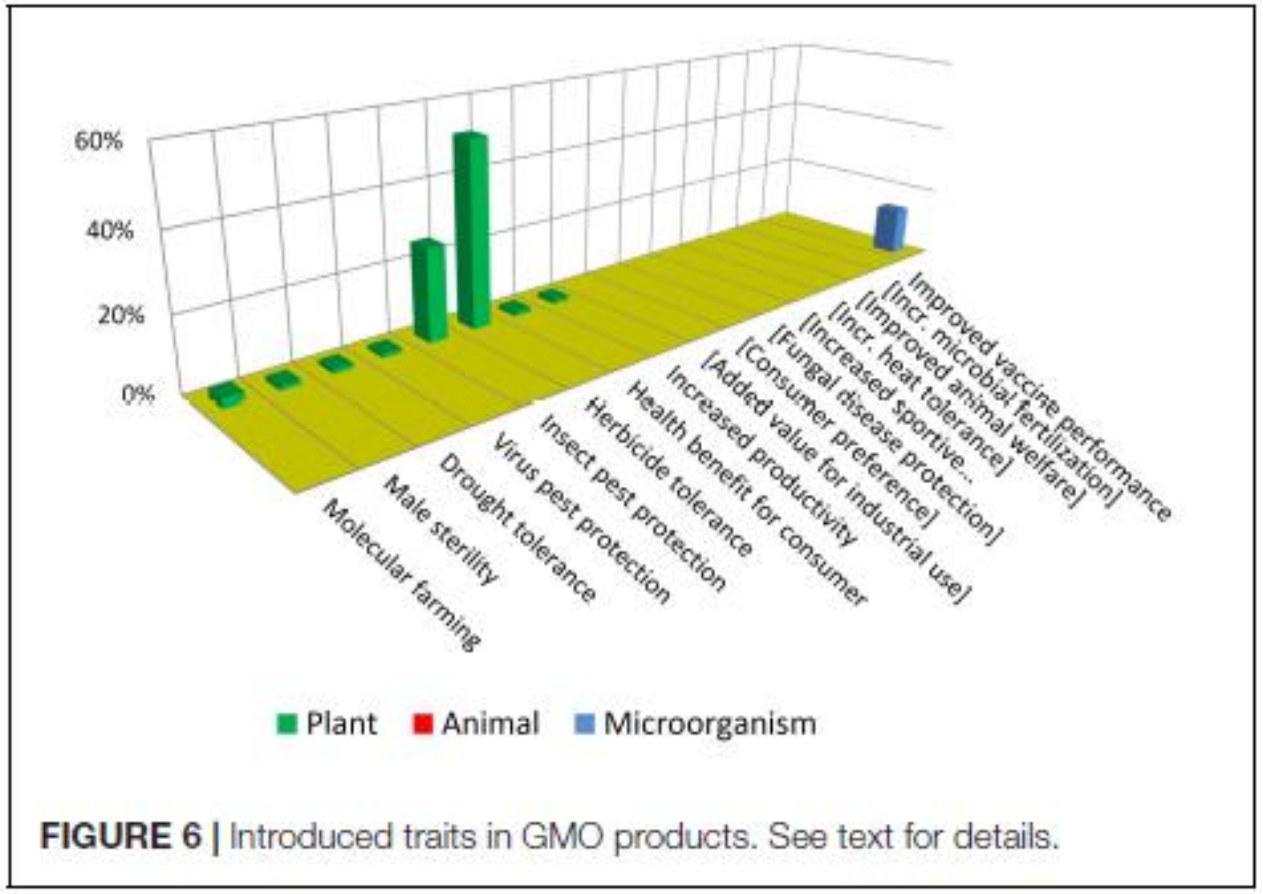



**FIGURE 6 |** Introduced traits in GMO products. See text for details.

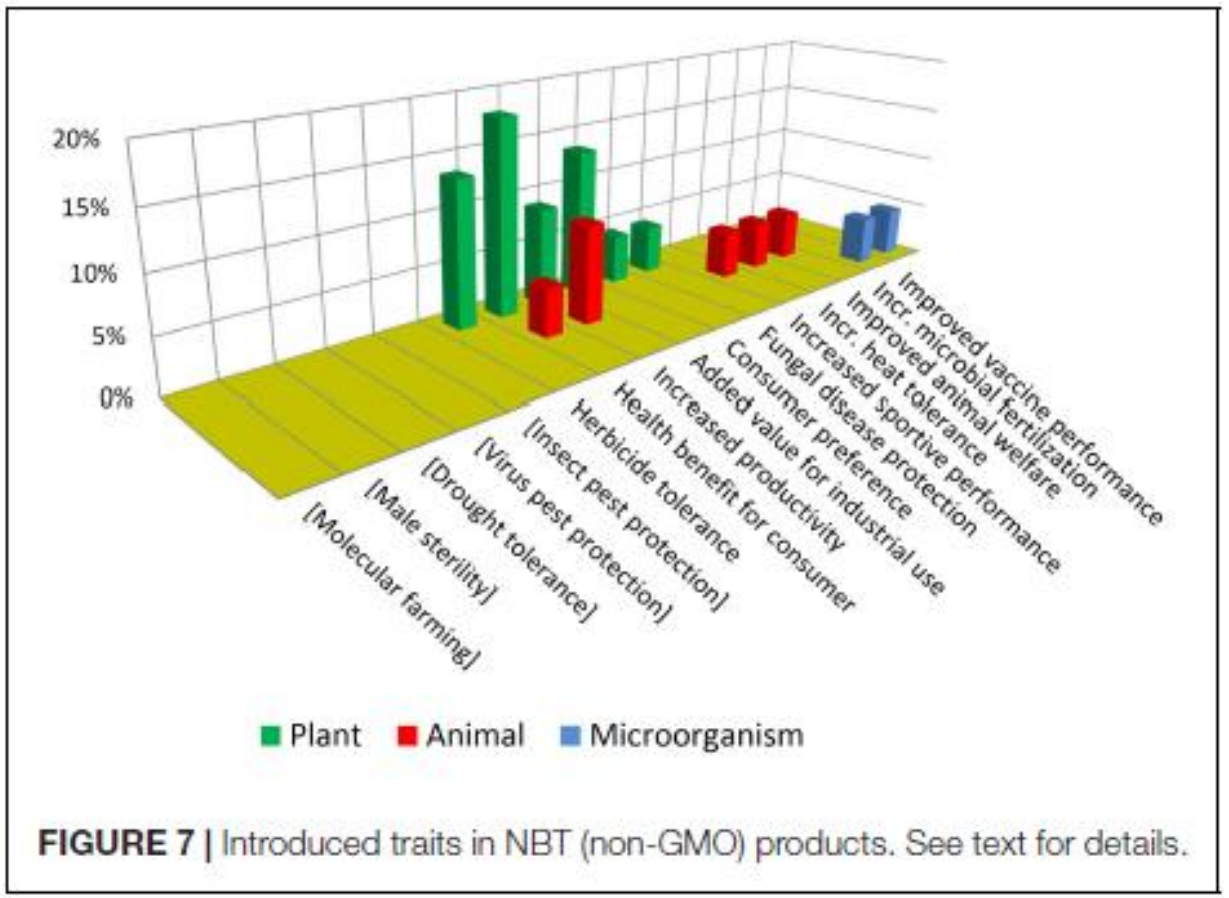



**FIGURE 7 |** Introduced traits in NBT (non-GMO) products. See text for details.

Source: *A. Whelan et al. (2020) Gene editing regulation and innovation economics.* https://doi.org/10.3389/fbioe.2020.00303

# Seed Congress of the Americas

Promoting Seed Business in the Americas

# Thank you!!

marc.cool@corteva.com