

Global Status of Gene Edited Food Animals and their Products

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WEBSITE: <https://animalbiotech.ucdavis.edu>

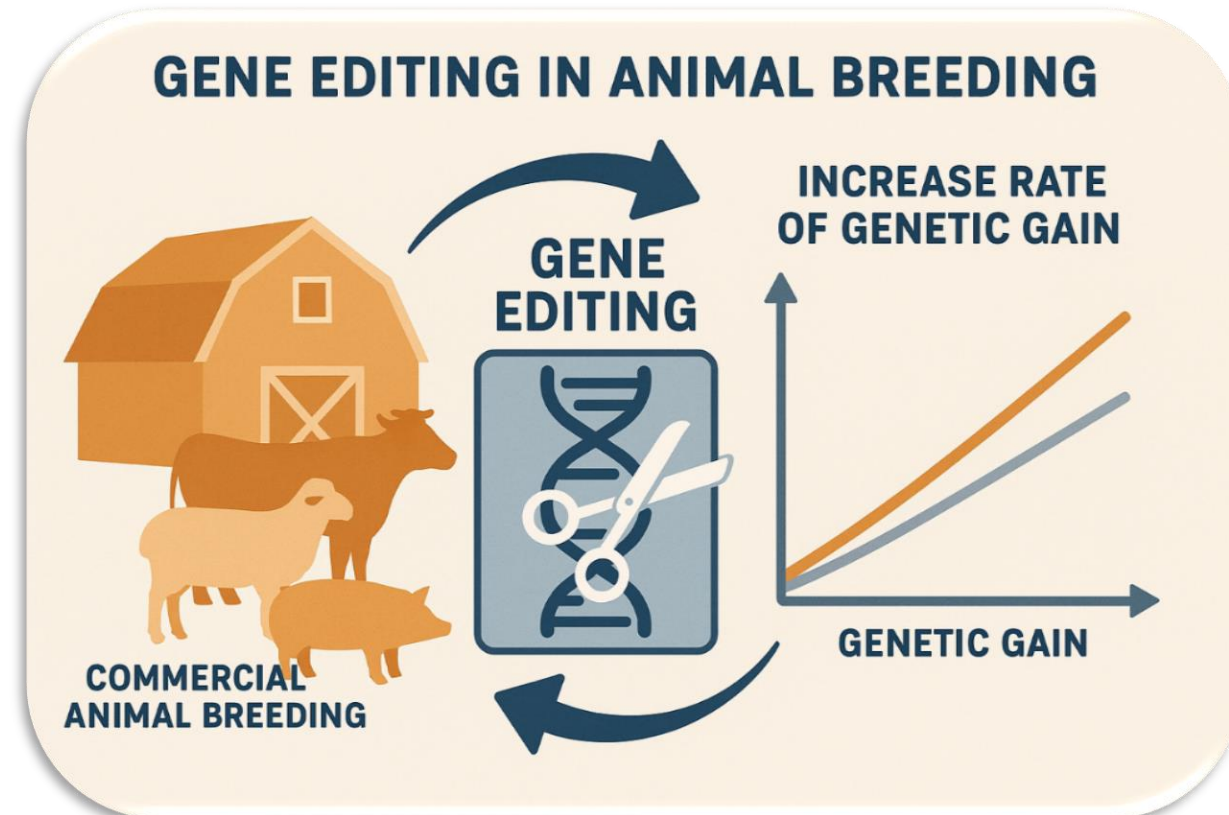
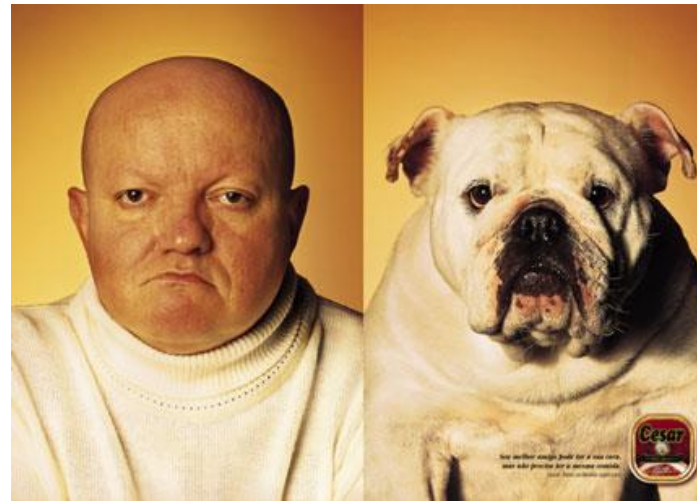


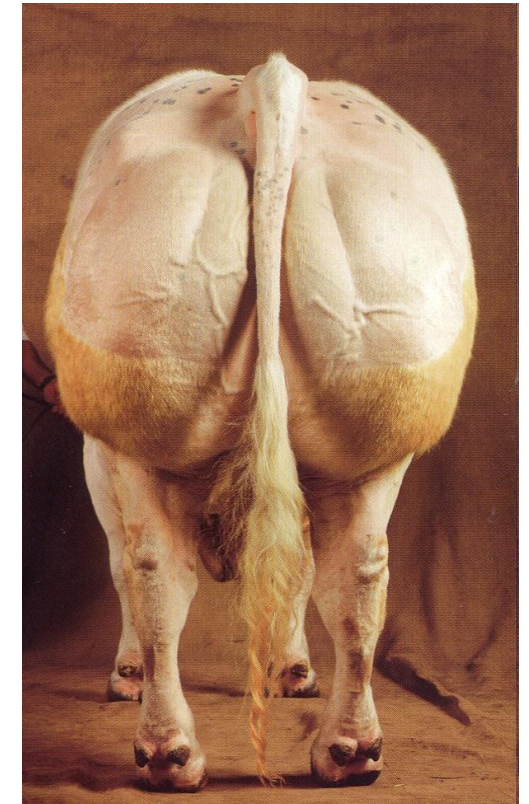
Image generated by OpenAI's DALL-E 3

Breeders have selected for desired changes to companion animal populations based on naturally-occurring variation



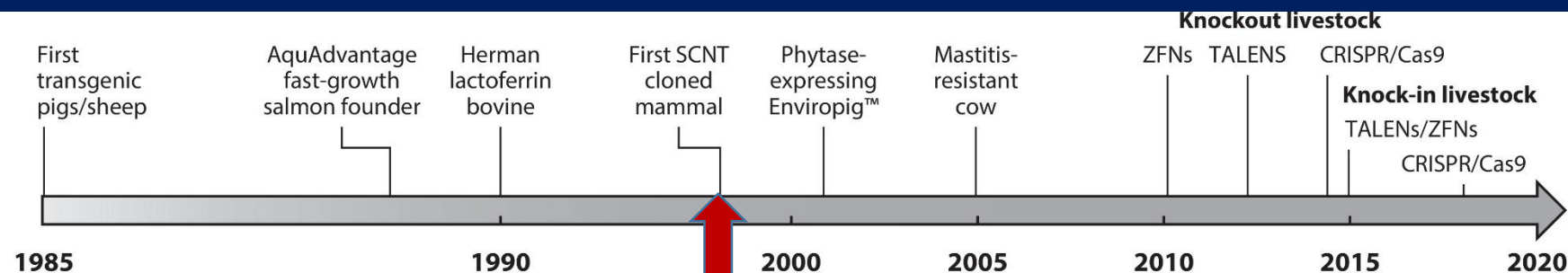
> 86.5 million genomic alterations (SNPs; Indels) between different breeds of cattle

1000 Bull Genomes Project: International consortium sequenced 2703 cattle to 11x fold coverage



Hayes, B. J. & Daetwyler, H. D. 2018. 1000 Bull Genomes Project to Map Simple and Complex Genetic Traits in Cattle: Applications and Outcomes. Annual Review of Animal Biosciences 7:1.

An abbreviated schematic history of 40+ years of biotechnology food animals for agriculture

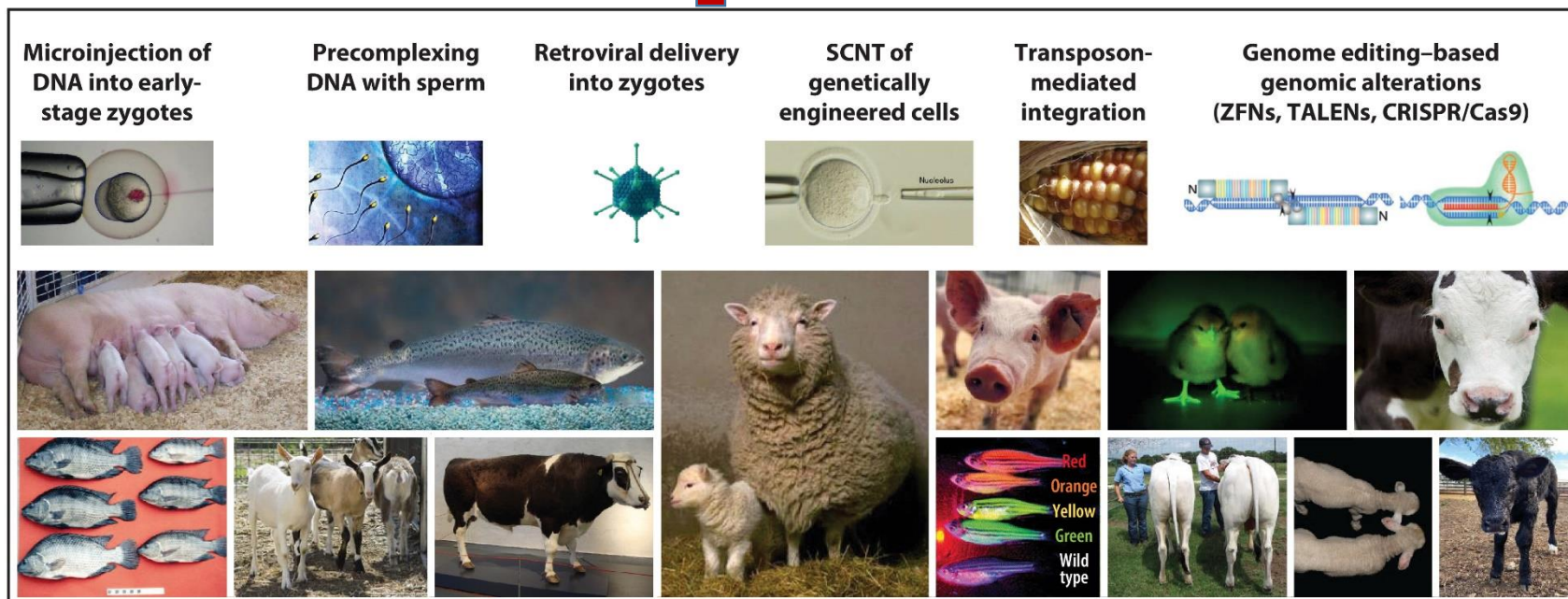


Two food-use approvals of rDNA animals globally in 40 years:

1. AquAdvantage Salmon (1991)

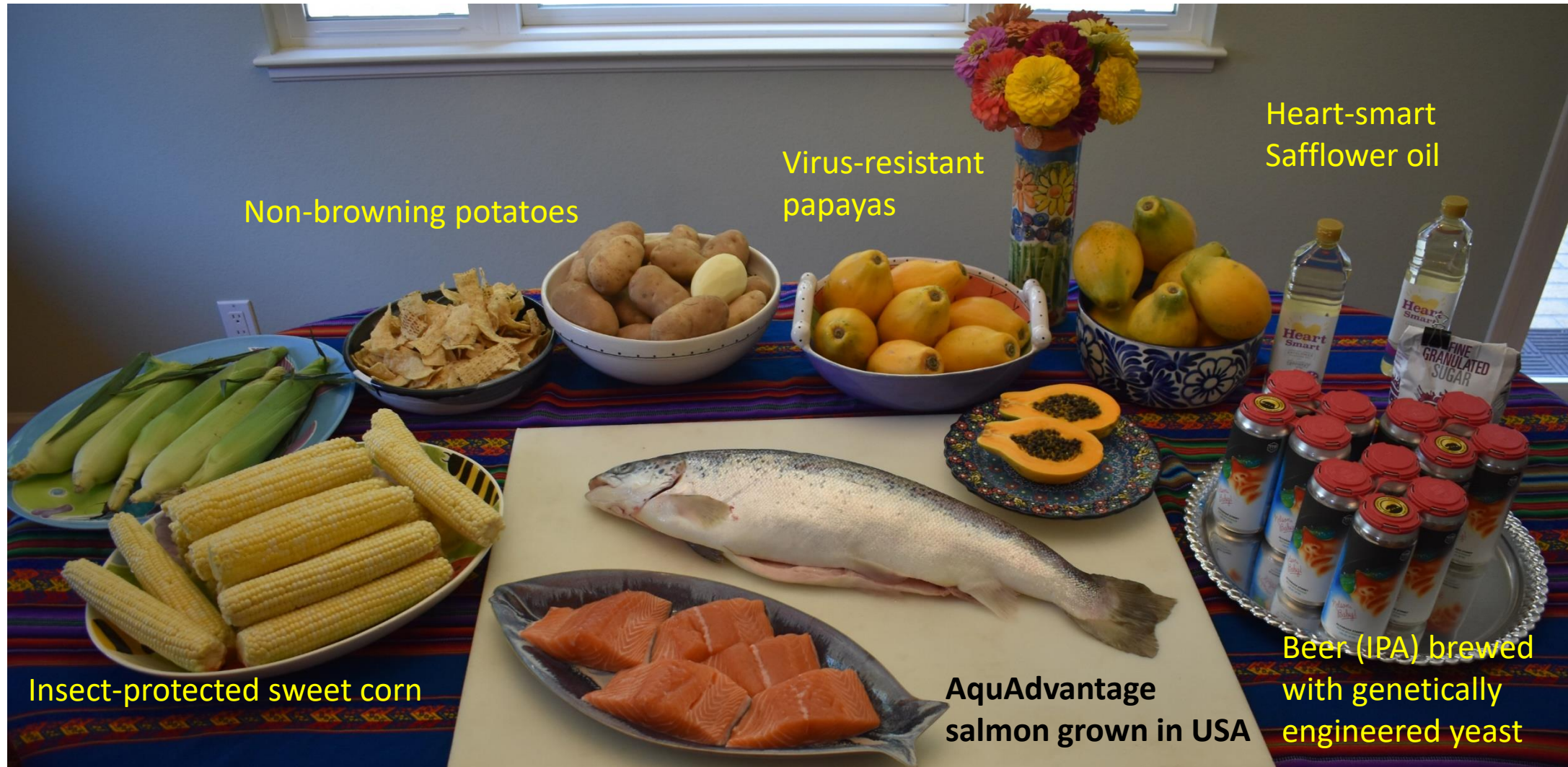


2. GalSafe Pig (2002)



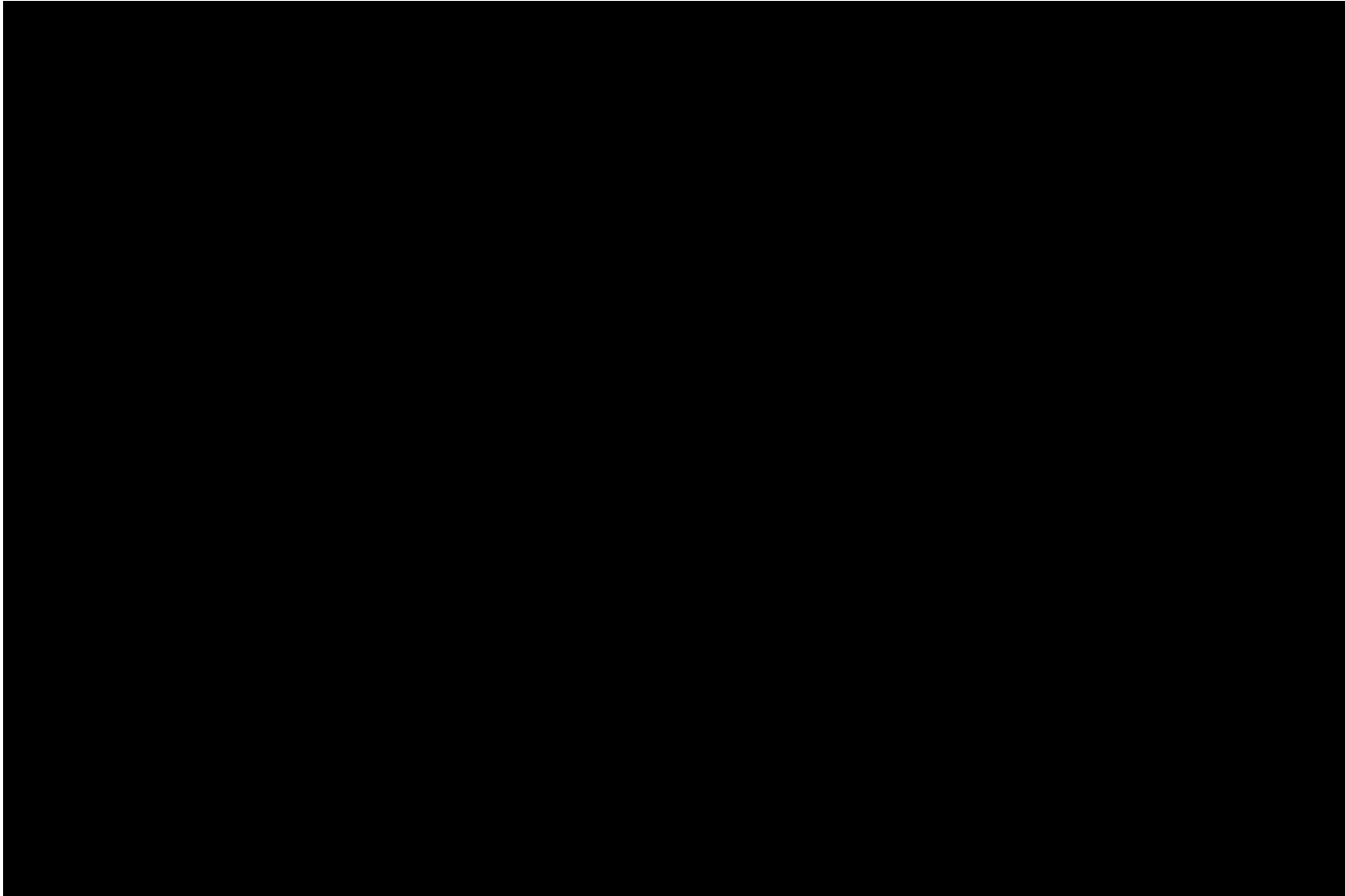
Van Eenennaam, A.L. *et al.* 2021. Genetic Engineering of Livestock: The Opportunity Cost of Regulatory Delay. *Ann Review of Animal Biosciences*.

An all-GMO meal - 2021 – at my house!

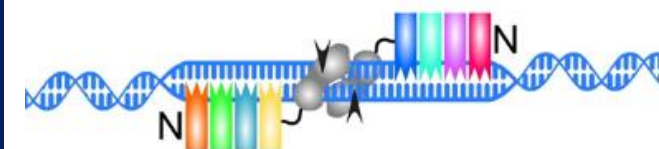


Thirty Years in the Making

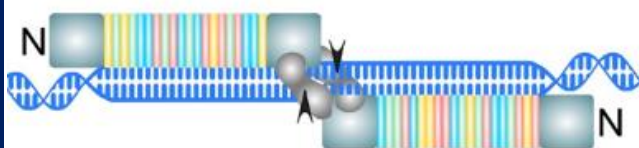
<https://www.youtube.com/watch?v=nvOnGLo0HkQ>



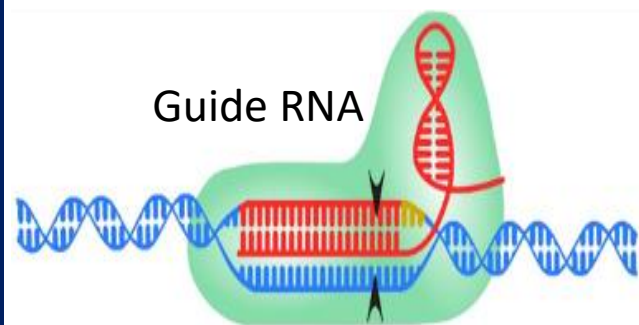
Gene editing allows the introduction of targeted double-stranded breaks in the genome



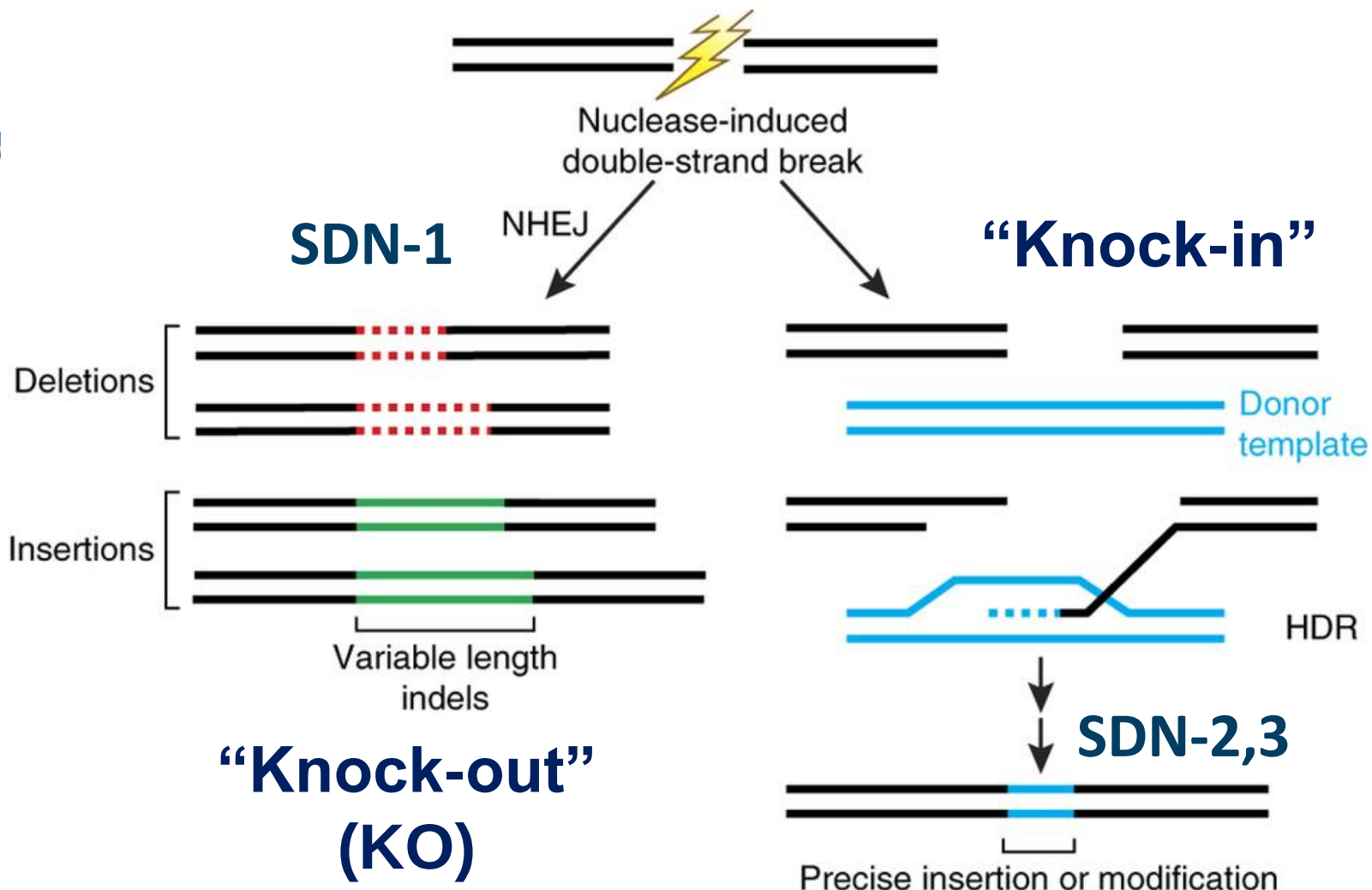
Zinc Finger Nucleases



TALENs

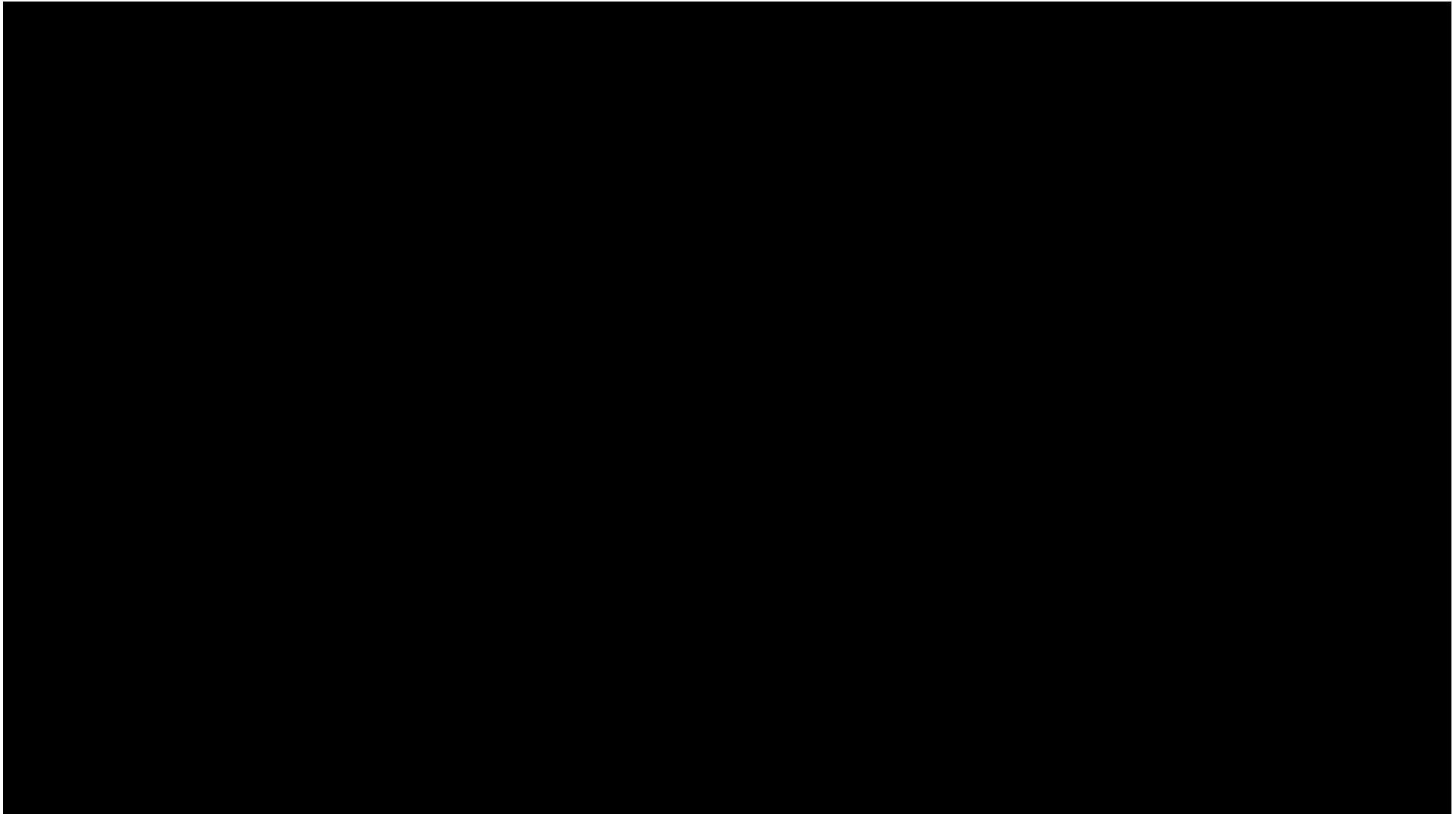


CRISPR/Cas9



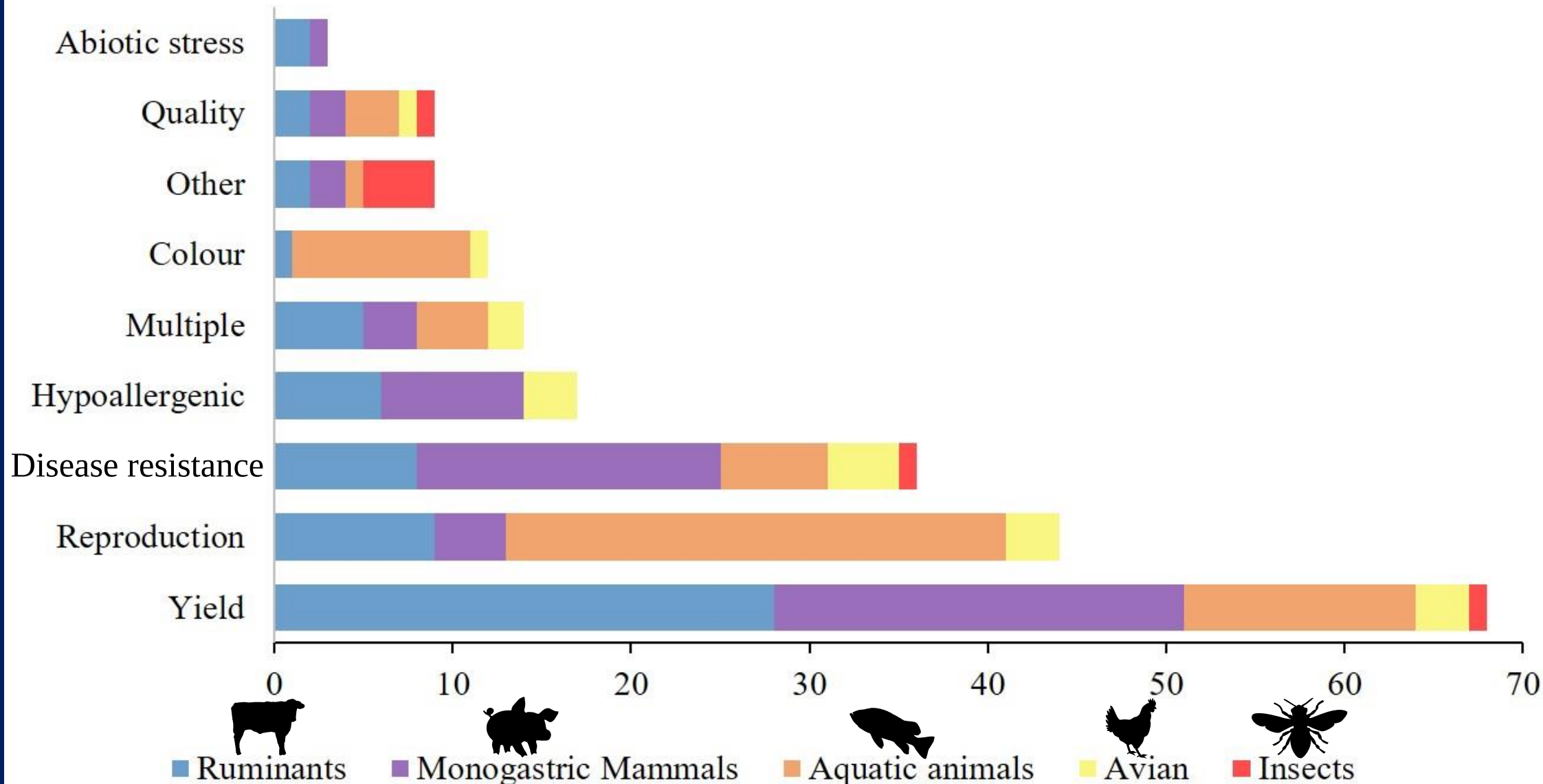
Gene editing involves introducing a double-strand break in the DNA at a targeted location in the genome

https://youtu.be/bM31E_LRszc

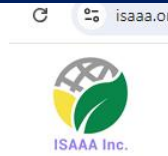




Trait targeted in animal gene editing applications



Gene-edited Animal Database



<https://www.isaaa.org/animalbiotechdatabase/default.asp>

[Programs](#) [Knowledge Center](#) [Resources](#) [Webinars](#) [GM Approval Database](#)

[Species](#) [Countries](#) [Trait](#) [Genes](#) [NGT](#) [SDN Types](#) [Institutes](#) [Editing Methods](#) [Years](#)

> > Animal Biotech Database



Gene-Edited Animals for Agricultural Applications Database

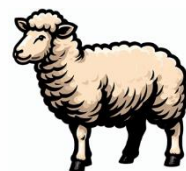
This ISAAA database compiles a list of animals developed through gene editing (also called New Breeding Techniques) for agricultural applications. The information provided in this database is based on the following scientific report:

<https://doi.org/10.2903/sp.efsa.2023.EN-8311>.

Gene-edited Animal Database

Species

- Atlantic Salmon (*Salmo salar*)
- Blunt snout sea bream (*Megalobrama amblycephala*)
- Cattle (*Bos taurus*)
- Cattle (*Bos taurus x Bos taurus indicus*)
- Channel catfish (*Ictalurus punctatus*)
- Chicken (*Gallus gallus*)
- Common Carp (*Cyprinus carpio*)
- Duck (*Anas platyrhynchos*)
- Farmed Carp (*Labeo rohita*)
- Gibel carp (*Carassius gibelio Bloch*)
- Goat (*Capra hircus*)
- Honeybee (*Apis mellifera*)
- Loach (*Paramisgurnus dabryanus*)
- Nile tilapia (*Oreochromis niloticus*)
- Olive flounder (*Paralichthys olivaceus*)
- Oyster (*Crassostrea gigas*)
- Pig (*Sus scrofa domesticus*)
- Quail (*Coturnix japonica*)
- Rabbit (*Oryctolagus cuniculus*)
- Rainbow trout (*Oncorhynchus mykiss*)
- Red sea bream (*Pagrus major*)
- Redhead cichlid (*Vieja melanura*)
- Royal farlowella (*Sturisoma panamense*)
- Sheep (*Ovis aries*)
- Silkworm (*Bombyx mori*)
- Southern Catfish (*Silurus meridionalis*)
- Sterlet (*Acipenser ruthenus*)
- Tiger pufferfish (*Takifugu rubripes*)
- White crucian carp (*Carassius auratus civieri*)
- Yellow catfish (*Pelteobagrus fulvidraco*)
- Yellow catfish (*Tachysurus fulvidraco*)



> [Animal Biotech Database](#) > [Species List](#) > Sheep (*Ovis aries*)

Undergone regulatory process: ☐ NO

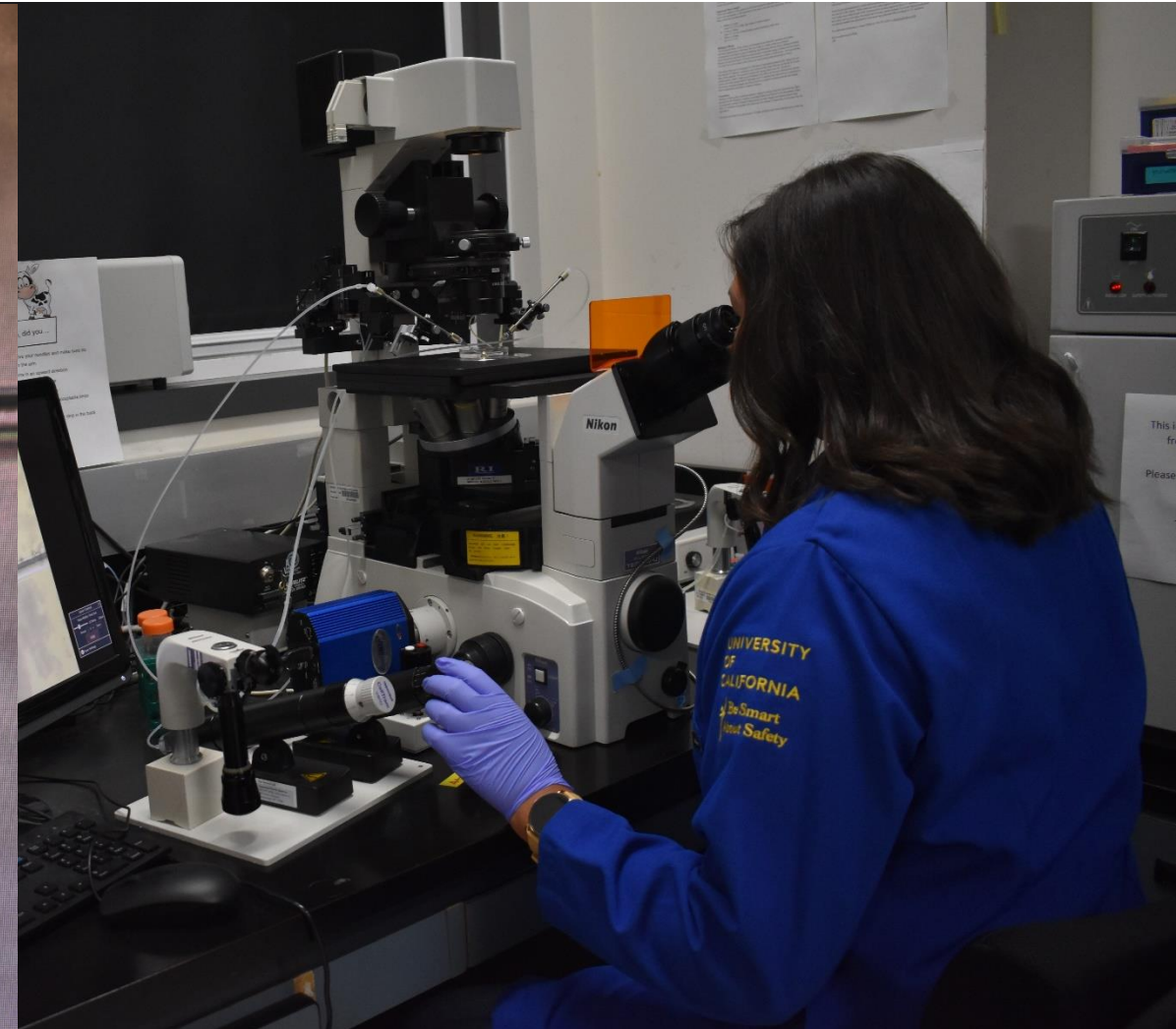
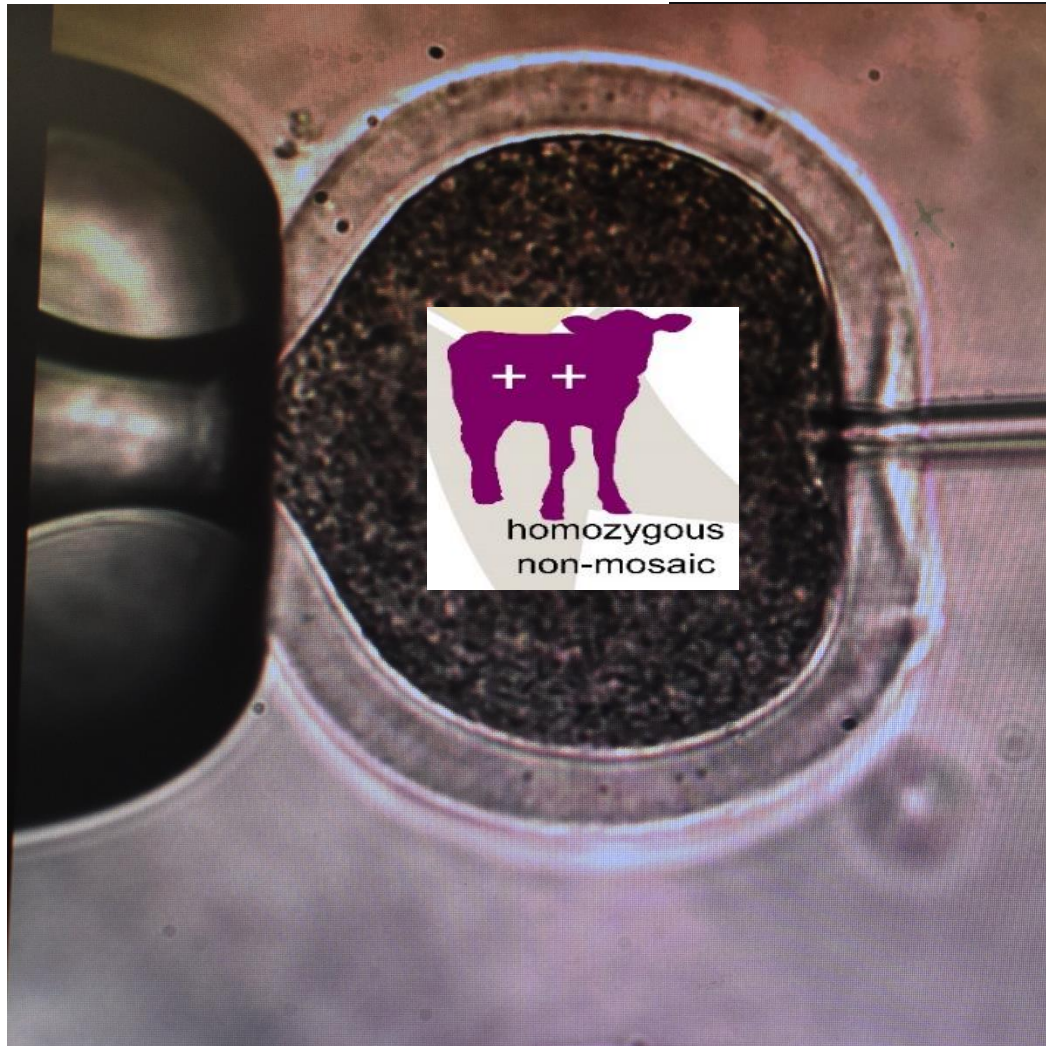
Sheep (*Ovis aries*)

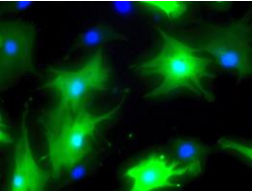
Year	Country of first Author	Species	Genes	
2023	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	New Zealand	Sheep (<i>Ovis aries</i>)	NANOS2, DAZL	View Details
2022	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	United States	Sheep (<i>Ovis aries</i>)	SOCS2, PDX1	View Details
2020	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	China	Sheep (<i>Ovis aries</i>)	BMPRI1B	View Details
	China	Sheep (<i>Ovis aries</i>)	FGF5	View Details
2019	China	Sheep (<i>Ovis aries</i>)	SOCS2	View Details
2018	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
2017	China	Sheep (<i>Ovis aries</i>)	AANAT, ASMT	View Details
	China	Sheep (<i>Ovis aries</i>)	ASIP	View Details
	China	Sheep (<i>Ovis aries</i>)	FGF5	View Details
	China	Sheep (<i>Ovis aries</i>)	FGF5	View Details
2016	China	Sheep (<i>Ovis aries</i>)	BCO2	View Details
	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	China	Sheep (<i>Ovis aries</i>)	MSTN	View Details
	China	Sheep (<i>Ovis aries</i>)	MSTN, ASIP, BCO2	View Details
2015	Uruguay	Sheep (<i>Ovis aries</i>)	MSTN	View Details
2014	United States	Sheep (<i>Ovis aries</i>)	MSTN	View Details



HOW

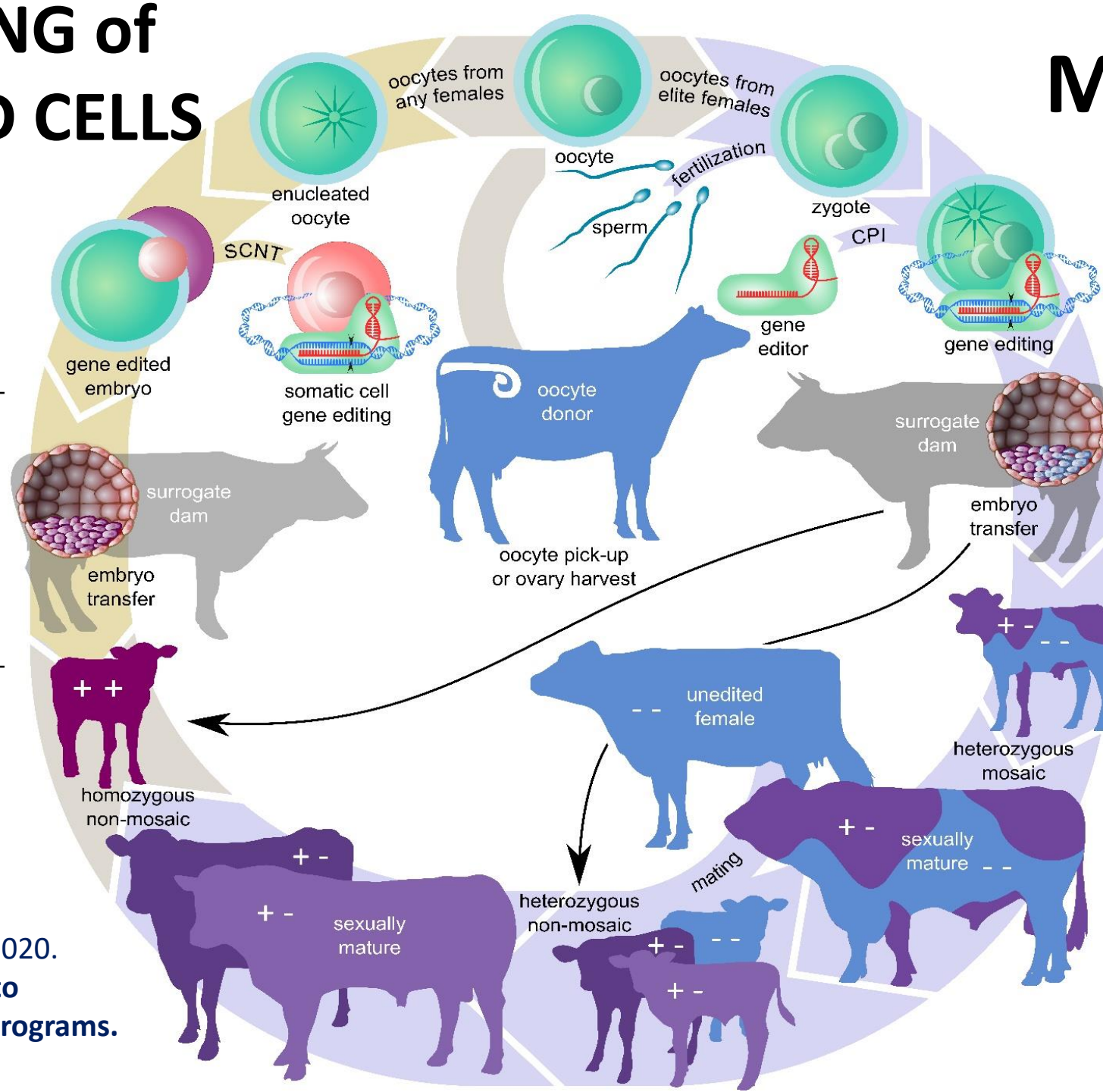
Introducing useful genetic variation into the germline of selected parents such that genetic improvement is inherited by the next generation is the ultimate goal of animal breeding.





CLONING of EDITED CELLS

MICRO- INJECTION (CPI)



Somatic Cell Nuclear Transfer (SCNT) cloning

Advantages

Germline transmission

Confirmed genotype

Higher knock-in efficiency
in somatic cells

Disadvantages

Cloning efficiency low

Use of a single cell line

Not all cell lines clone well

Cytoplasmic Injection (CPI) into embryos

Advantages

No cloning artifacts

Diversity of germplasm

High efficiency for gene
knock-outs

Disadvantages

Mosaicism

Low edited/live born

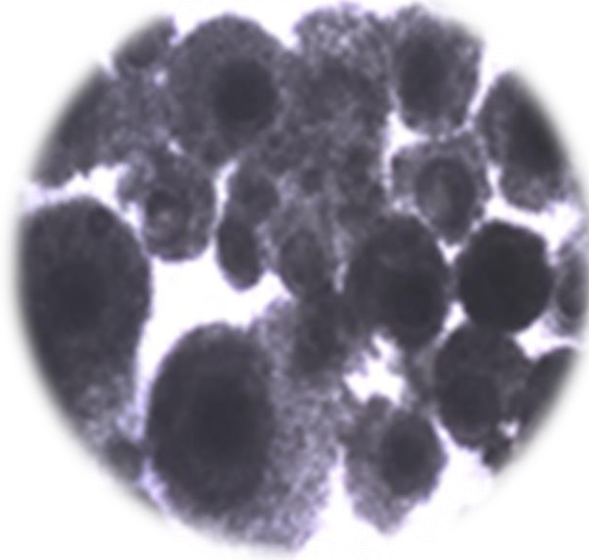
Knock-in is less efficient in
early embryos

Bishop and Van Eenennaam. 2020.
**Genome editing approaches to
augment livestock breeding programs.**
JEB doi:10.1242/jeb.207159

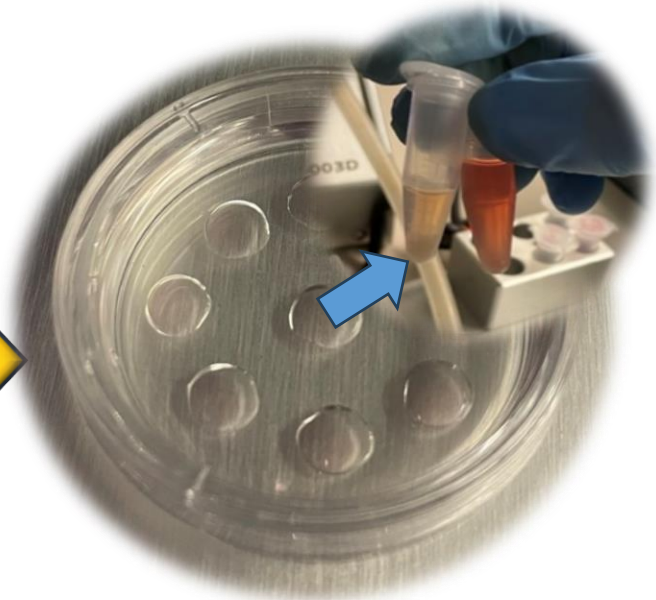
This is the “transformation pipeline” for producing genome edited embryos for Electroporation



Collect oocytes
from abattoir
harvested ovaries

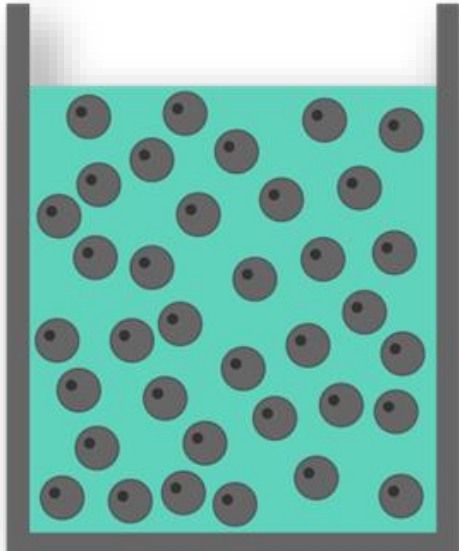


Mature
oocytes for
22-24 hours

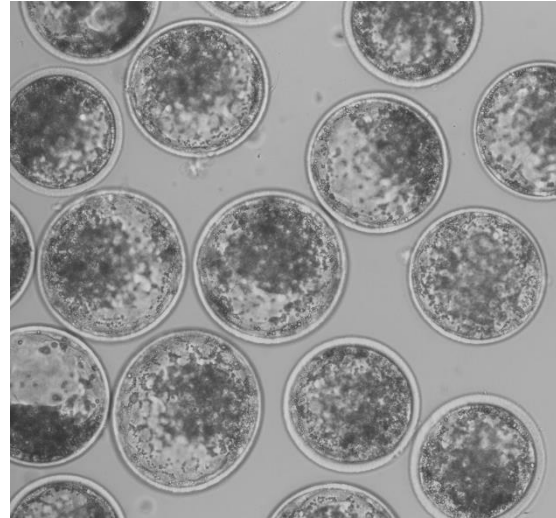
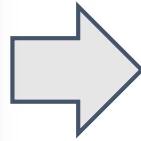


Matured oocytes
transferred to IVF
drops

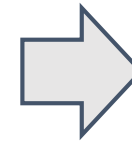
This is the “transformation pipeline” for producing genome edited sheep for surgical embryo transfer



6 hours postfertilization:
Electroporate zygotes to
introduce Cas9/CRISPR
RNP + ssODN

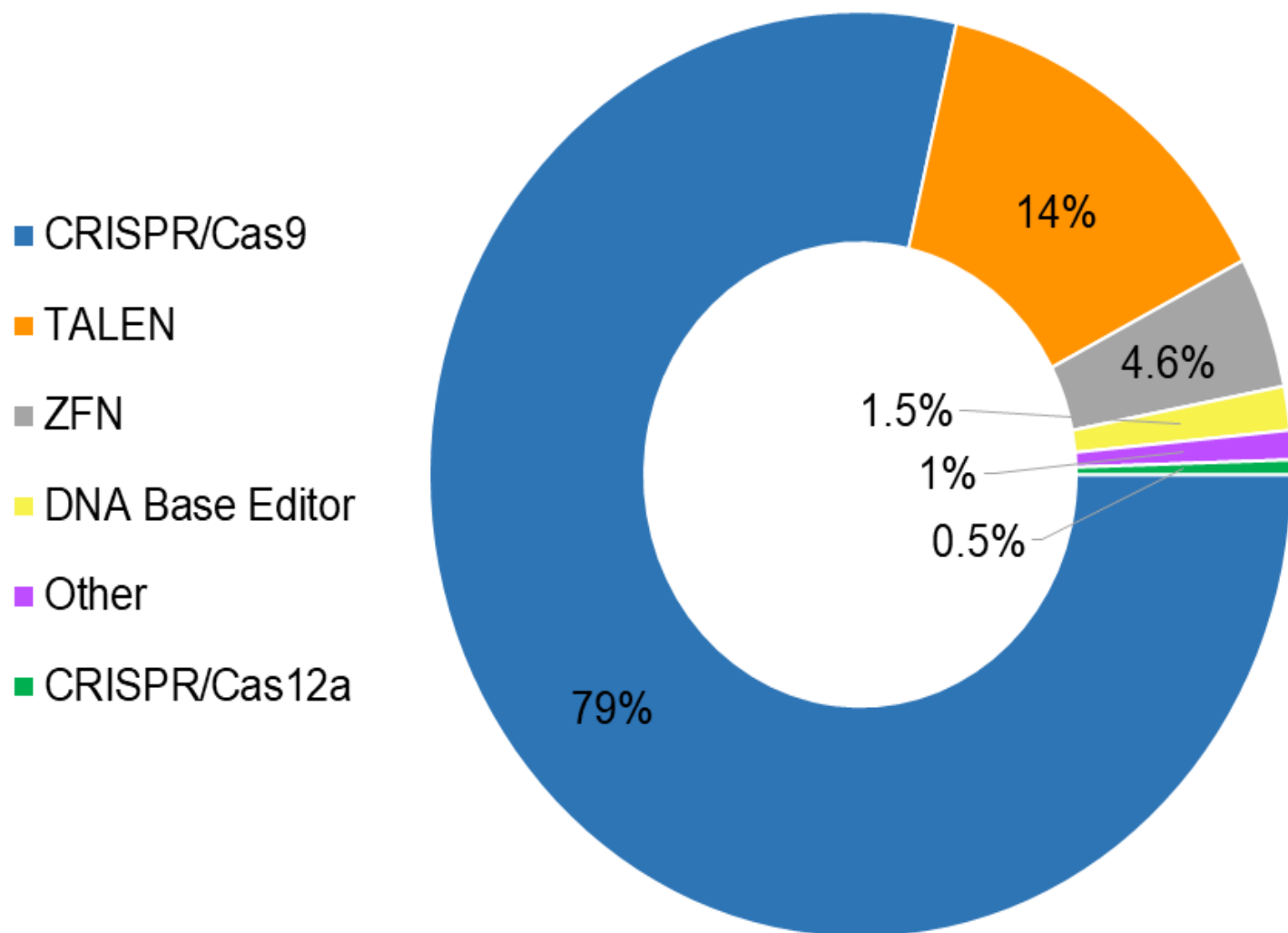


Blastocysts are cultured,
collected, and placed
into Tomcat embryo
catheter



Embryos are surgically transferred
to 8 synchronized ewes

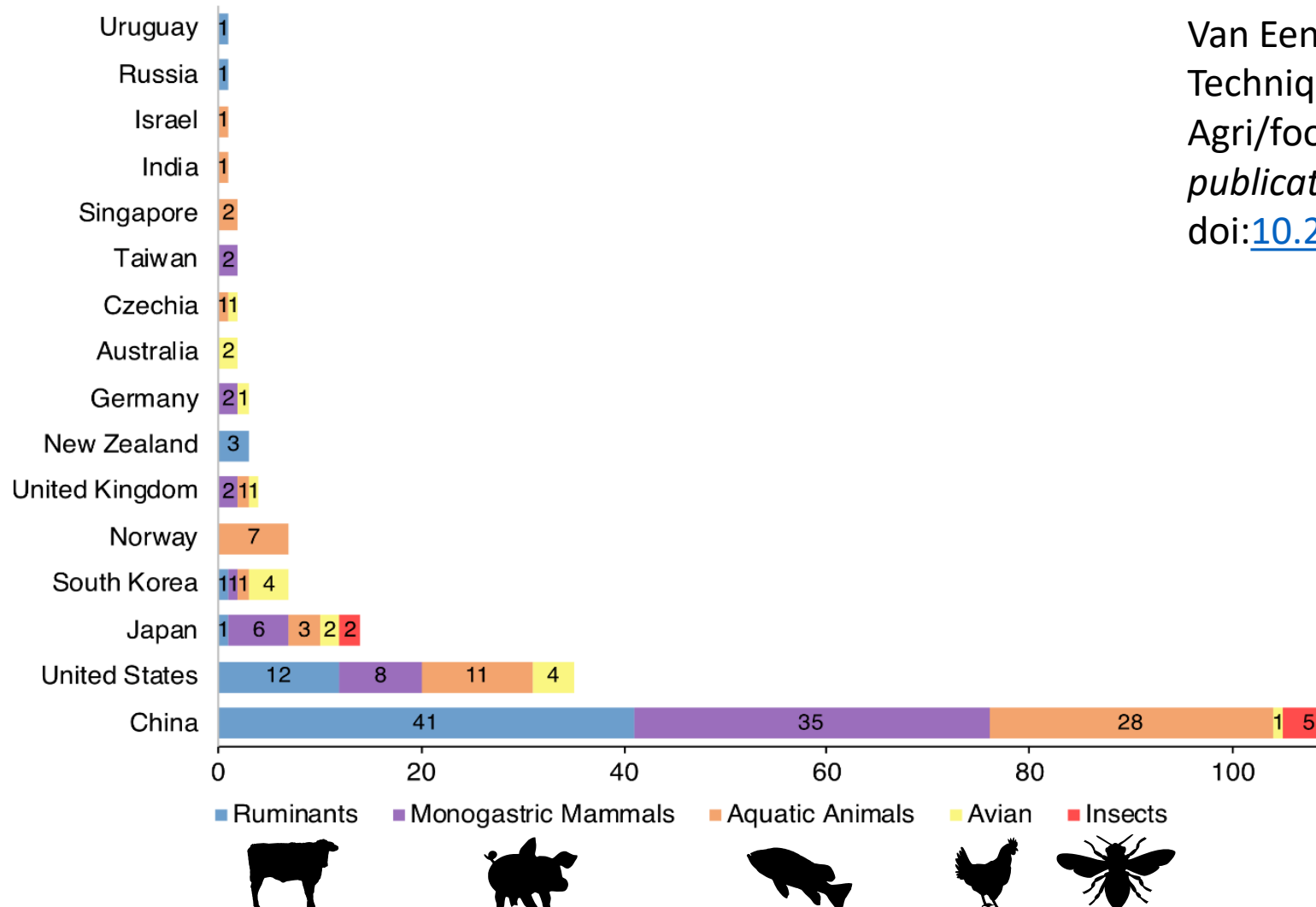
Peer-reviewed gene edited animal research papers (n=195) used CRISPR/Cas9. 61% edited embryos, 30% edited somatic cells followed by cloning, and 9% (Avian) edited primordial germ cells.



- There were 59 applications (30%) where the editing was done in cell lines followed by cloning to produce an animal, all in mammals;
- 118 publications (61%) that edited developing embryos,
- 18 “other” approaches (9%) to editing, the majority of which were publications with avian species where editing was done in primordial germ cells
- The majority ~ 75% of these applications were SDN-1 (147) aka knockouts; with 18 SDN-2, and 30 SDN-3 applications.

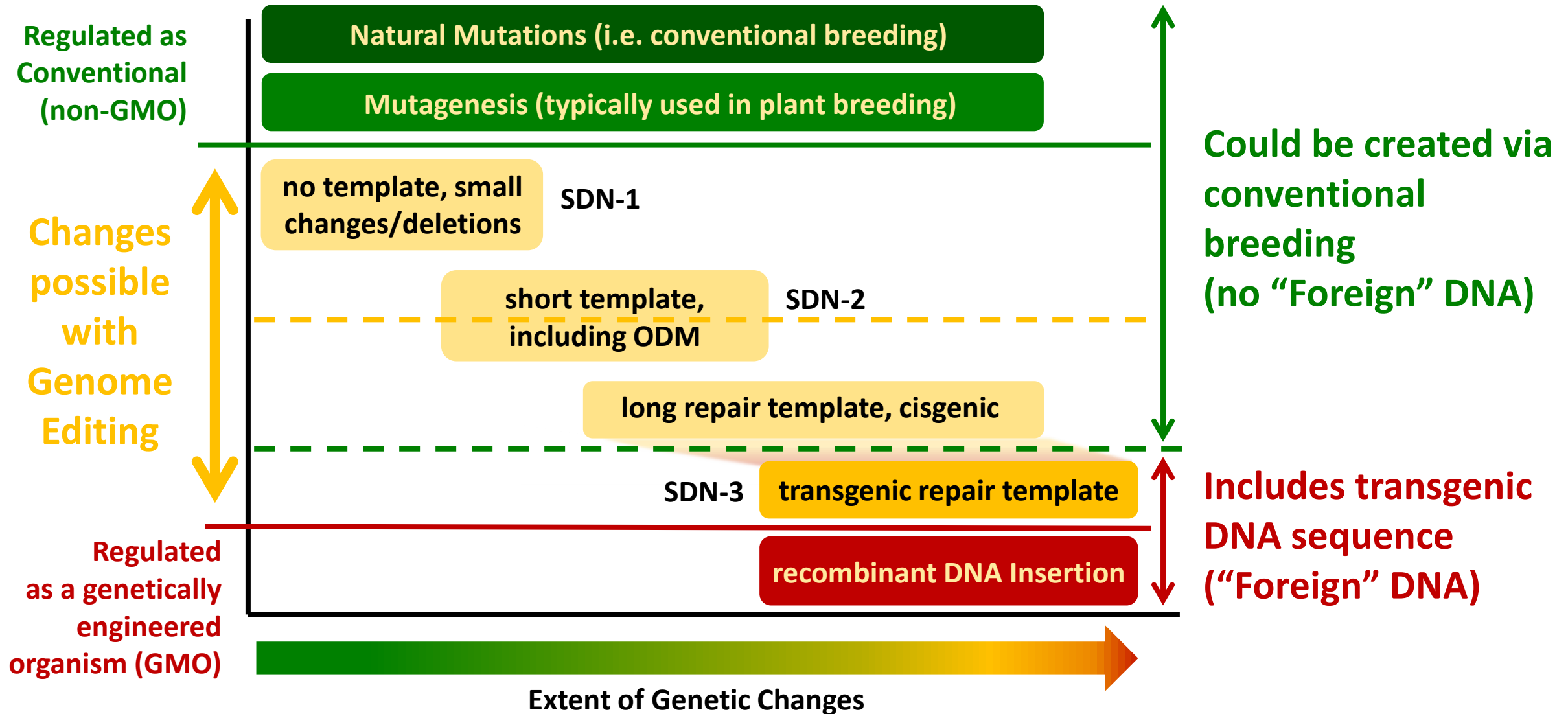


Animal category breakdown X country of peer-reviewed publications producing gene edited food animals for agriculture



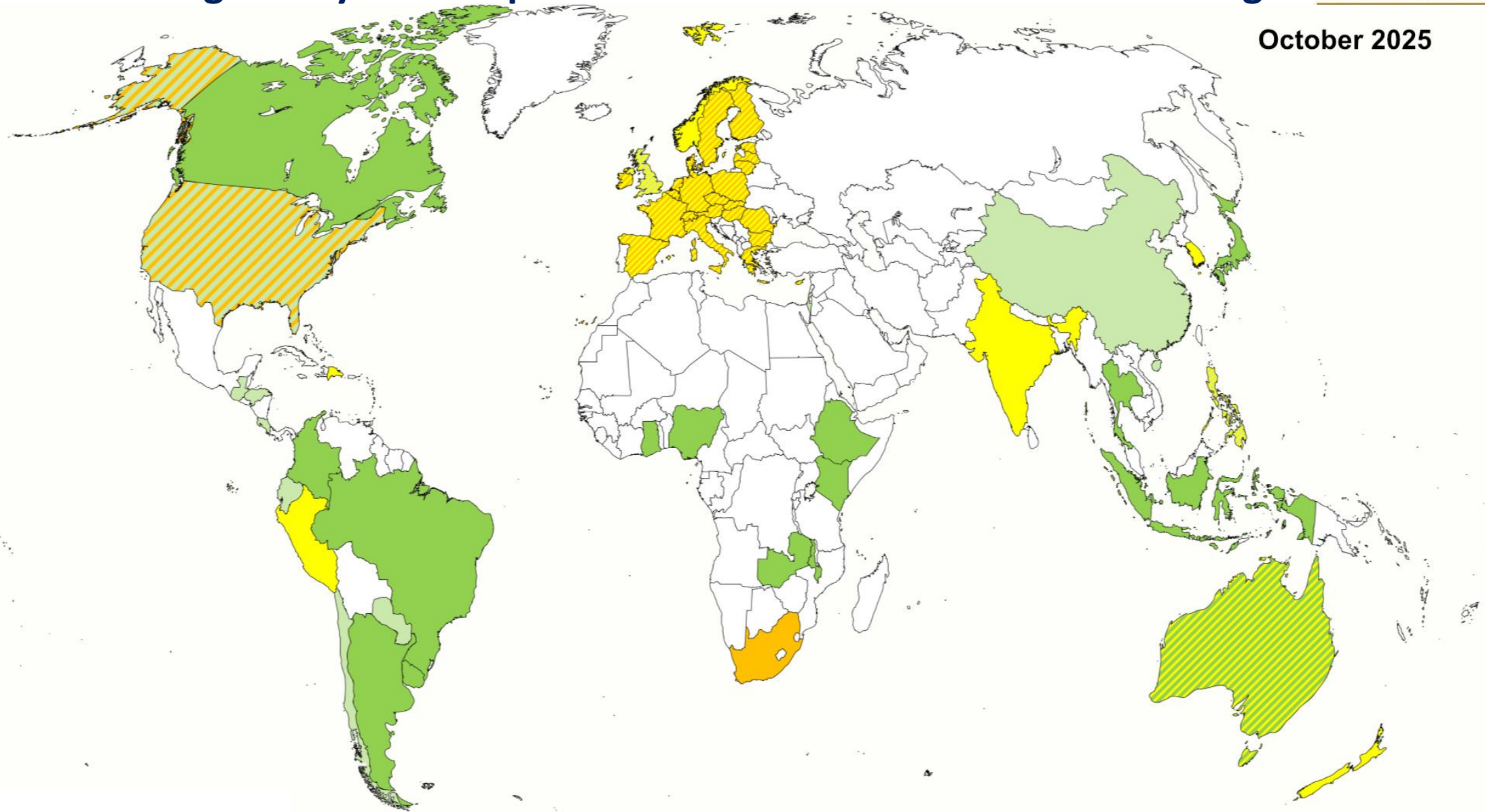
Van Eenennaam, A.L. 2023. New Genomic Techniques (NGTs) Animals and their Agri/food/feed products. *EFSA supporting publication* 2023: 20(9):EN-8311. 82 pp. doi:[10.2903/sp.efsa.2023.EN-8311](https://doi.org/10.2903/sp.efsa.2023.EN-8311)

When to Regulate as GMO?



Global Regulatory Landscape for Animal Products of Genome Editing

October 2025



■ Countries with regulatory policy with exclusions (e.g., non-GMO)

■ Countries with pending policies, regulations, or legal rulings

■ Countries with GMO only policy with no exclusions

■ Countries with regulatory policy with exclusions (plants only)



Gene edited animals that have been determined to be “non-GMO” in Argentina

Country	Common name	Trait	Gene Targeted	Year
Argentina 	Nile Tilapia	Increased yield	Myostatin	2018
	Beef cattle	Heat tolerance	Prolactin receptor	2020
	Dairy cattle	Heat tolerance/Polled	Prolactin receptor/Pc polled	2020
	Cattle	Increased yield	Myostatin	2021
	Horse	Increased speed	Myostatin	2025
	Pig	PRRS-resistance	CD-163	2025

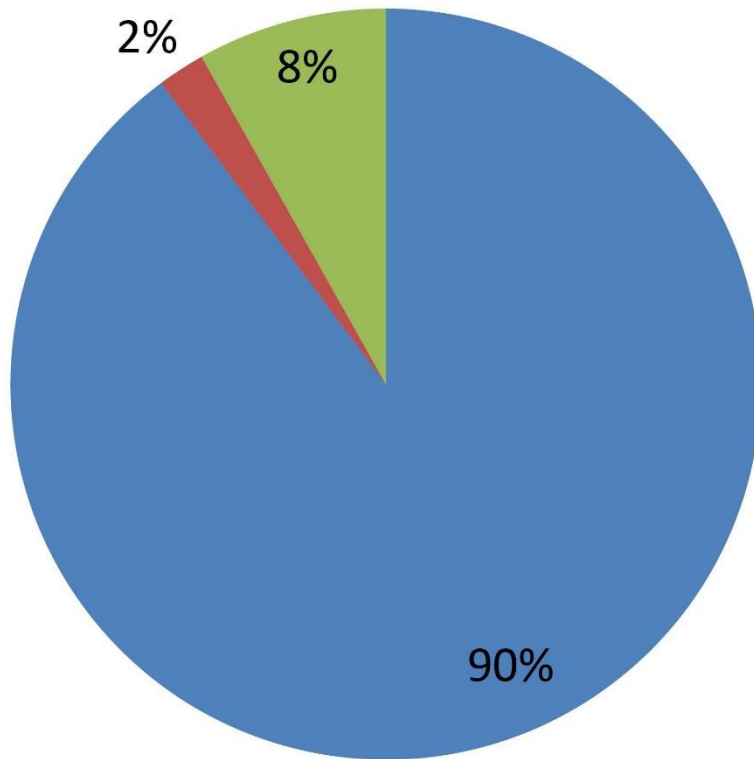


All SDN-1 examples -
no foreign DNA
sequence and as such
*“no new combination
of genetic material”*
and so considered
“non-GMO”

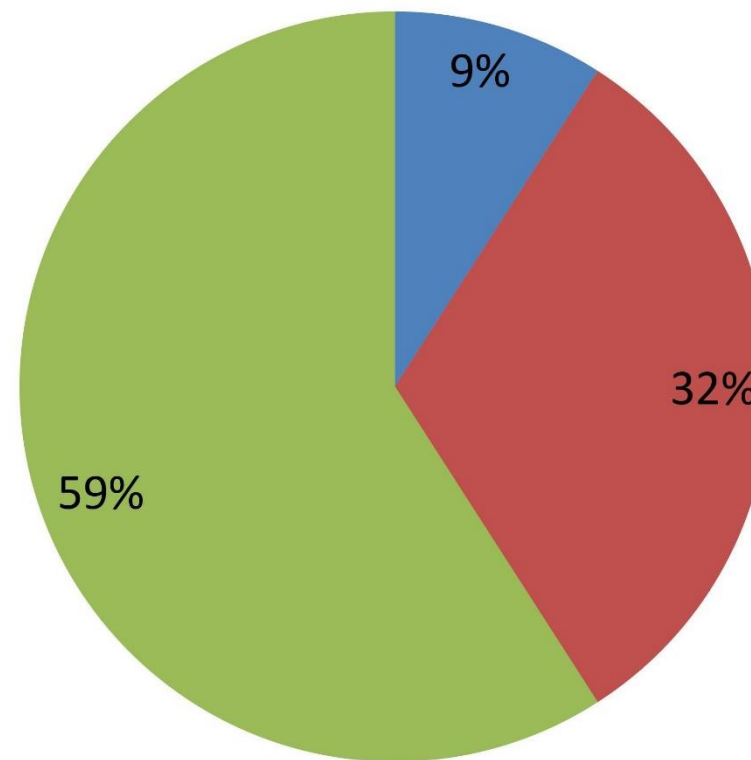
Developer profile of genetically engineered products and genome edited products in Argentina



Genetically Engineered
(GMO)



Genome Edited
(non-"GMO")



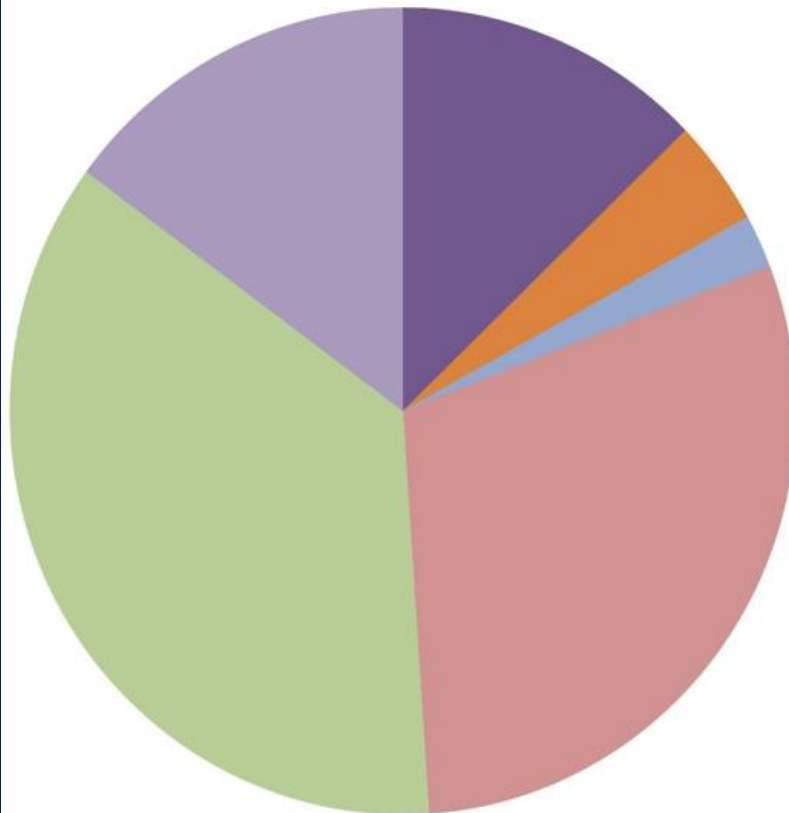
- Foreign multinational
- Foreign SMEs small & medium enterprises
- Local companies & Public Research

Developer profile of genetically engineered products and genome edited products in Argentina

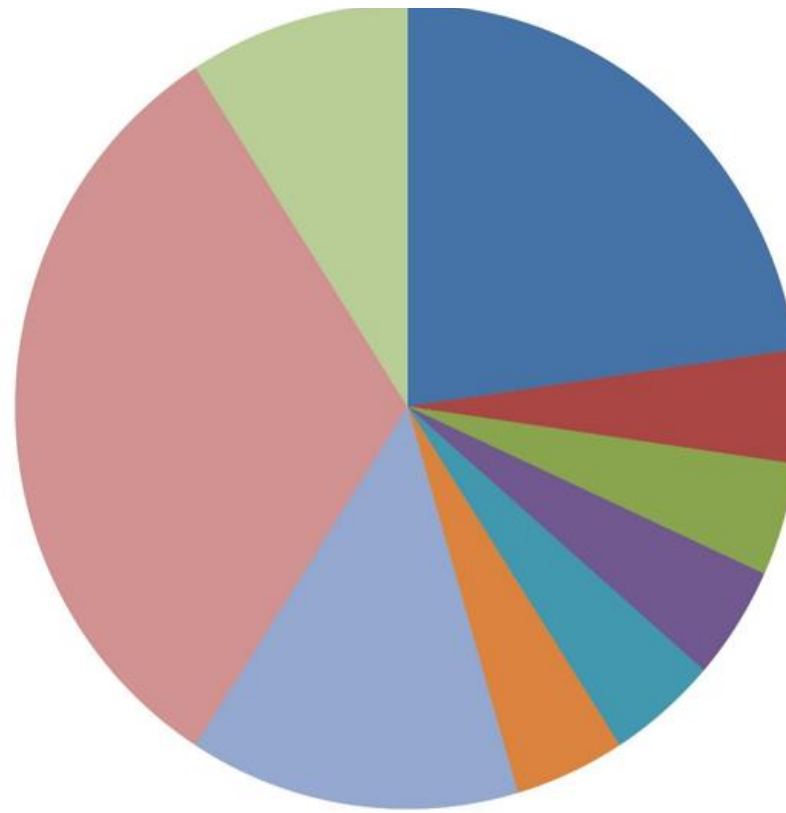
Whelan et al. (2020) Frontiers in Bioengineering and Biotechnology 8 (2020): 303.



Genetically Engineered
(GMO)



Genome Edited
(non-"GMO")



- [Farm animals]
- [Aquatic animals]
- [Bio-inputs]
- Vaccines
- [Ornamental Plants]
- Pastures
- Fruits and vegetables
- Oilseeds
- Cereals
- Fiber crops

Gene edited animals that have been determined to be “non-GMO” in Brazil

Country	Common name	Trait	Gene Targeted	Year
	Nile Tilapia	Increased yield	Myostatin	2019
	Beef cattle	Heat tolerance	Prolactin receptor	2021
	Dairy cattle	Heat tolerance	Prolactin receptor	2023
	Cattle	Increased yield	Myostatin	2021
	Pig	PRRS-resistance	CD-163	2024



Figure from Proudfoot et al. 2015 Genome edited sheep and cattle
Transgenic Research 24(1): 147-153.

Gene edited animals that have been given enforcement discretion or approval in USA

Country	Common name	Trait	Gene Targeted	Year
 USA	Beef Cattle*	Heat tolerance	Prolactin receptor	2022
	Pig	PRRS-resistance	CD-163	2025

* Enforcement Discretion

FDA Makes Low-Risk Determination for Marketing of Products from Genome-Edited Beef Cattle After Safety Review

acceligen™

March 7, 2022

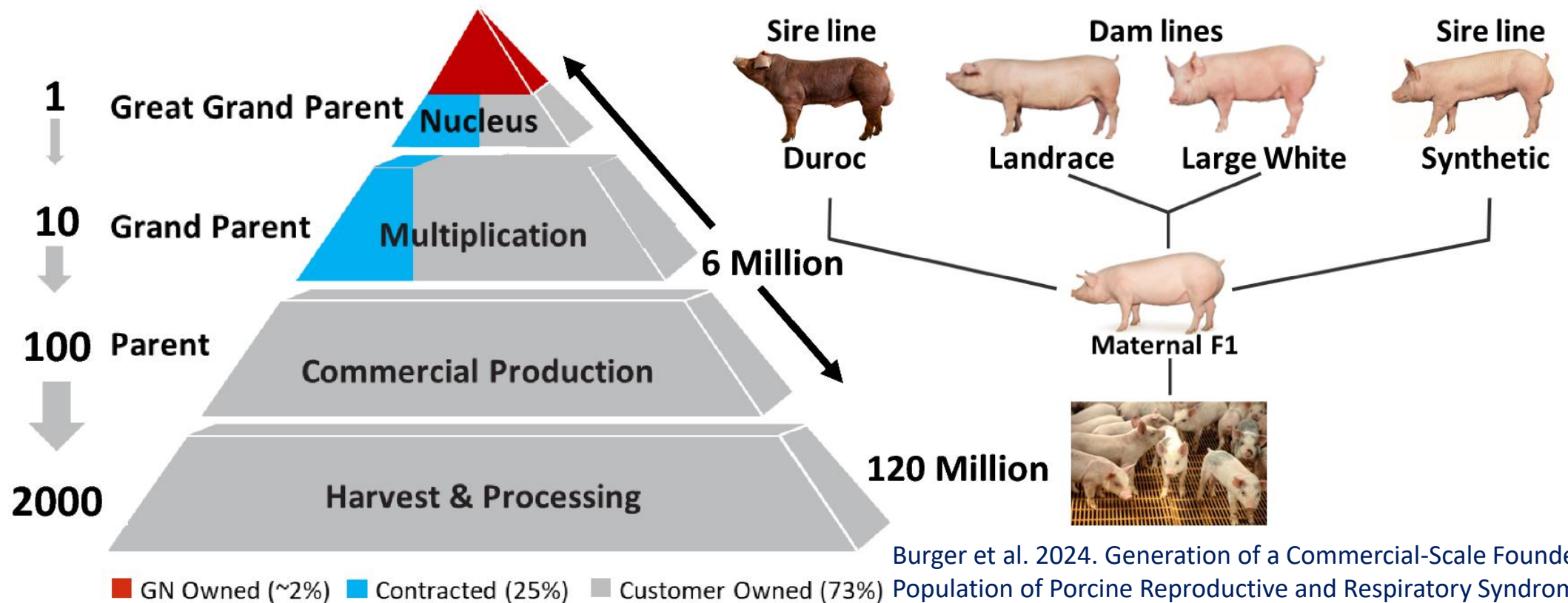


April 30, 2025



FDA approves Porcine Reproductive & Respiratory Syndrome virus resistant pigs

Pig Improvement Corporation (PIC) receives US Food and Drug Administration approval for PRRS resistant pigs **April 30, 2025**



Burger et al. 2024. Generation of a Commercial-Scale Founder Population of Porcine Reproductive and Respiratory Syndrome Virus Resistant Pigs Using CRISPR-Cas. The CRISPR Journal. 7: 12-28
Van Eenennaam ISBR 2025

SDN Type: SDN-1

Entries found: 20

<https://www.isaaa.org/animalbiotechdatabase/default.asp>

Year	Country of Determination	Species	Genes	
2025	Argentina	Horse (<i>Equus caballus</i>)	MSTN	View Details
	Argentina	Pig (<i>Sus scrofa domesticus</i>)	CD163	View Details
	Dominican Republic	Pig (<i>Sus scrofa domesticus</i>)	CD163	View Details
	United States	Pig (<i>Sus scrofa domesticus</i>)	CD163	View Details
2024	Brazil	Pig (<i>Sus scrofa domesticus</i>)	CD163	View Details
2023	Brazil	Cattle (<i>Bos taurus</i>)	PRLR	View Details
	Colombia	Pig (<i>Sus scrofa domesticus</i>)	CD163	View Details
	Japan	Olive flounder (<i>Paralichthys olivaceus</i>)	LEPR	View Details
2022	Japan	Red sea bream (<i>Pagrus major</i>)	MSTN	View Details
	Japan	Tiger pufferfish (<i>Takifugu rubripes</i>)	LEPR	View Details
	United States	Cattle (<i>Bos taurus</i>)	PRLR	View Details
2021	Argentina	Cattle (<i>Bos taurus</i> x <i>Bos taurus indicus</i>)	MSTN	View Details
	Brazil	Cattle (<i>Bos taurus</i> x <i>Bos taurus indicus</i>)	MSTN	View Details
	Brazil	Cattle (<i>Bos taurus</i>)	PRLR	View Details
	Japan	Red sea bream (<i>Pagrus major</i>)	MSTN	View Details
	Japan	Tiger pufferfish (<i>Takifugu rubripes</i>)	LEPR	View Details
2020	Argentina	Cattle (<i>Bos taurus</i>)	PRLR	View Details
	Argentina	Cattle (<i>Bos taurus</i>)	PRLR, Pc POLLED	View Details
2019	Brazil	Nile tilapia (<i>Oreochromis niloticus</i>)	MSTN	View Details
2018	Argentina	Nile tilapia (<i>Oreochromis niloticus</i>)	MSTN	View Details

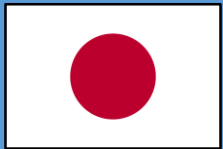
GnEd animal products that have undergone a regulatory review/low risk/approval determination

Country		Common name	Trait	Gene Targeted	Year
Argentina		Nile Tilapia	Increased yield	Myostatin	2018
		Beef cattle	Heat tolerance	Prolactin receptor	2020
		Dairy cattle	Heat tolerance/Polled	Prolactin receptor/Pc polled	2020
		Cattle	Increased yield	Myostatin	2021
		Horse	Increased speed	Myostatin	2025
		Pig	PRRS-resistance	CD-163	2025
Brazil		Nile Tilapia	Increased yield	Myostatin	2019
		Beef cattle	Heat tolerance	Prolactin receptor	2021
		Dairy cattle	Heat tolerance	Prolactin receptor	2023
		Cattle	Increased yield	Myostatin	2021
		Pig	PRRS-resistance	CD-163	2024
Colombia		Pig	PRRS-resistance	CD-163	2023
		Cattle	Heat tolerance	Prolactin receptor	2024
Dominican Republic		Pig	PRRS-resistance	CD-163	2025
Japan		Red Sea Bream	Increased yield	Myostatin	2021/2022
		Tiger Pufferfish	Faster growth	Leptin receptor	2022
		Olive Flounder	Faster growth	Leptin receptor	2023
		Tilapia	Increased yield	Myostatin	2025
USA		Beef Cattle*	Heat tolerance	Prolactin receptor	2022
		Pig	PRRS-resistance	CD-163	2025

<https://www.ISAAA.org/animalbiotechdatabase/default.asp>

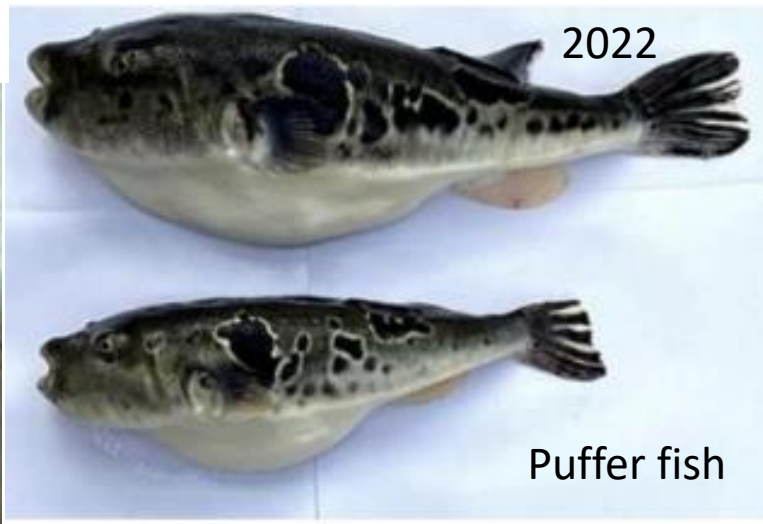


Gene edited animals that have been determined to be “non-GMO” in Japan

Country		Common name	Trait	Gene Targeted	Year
Japan		Red Sea Bream	Increased yield	Myostatin	2021/2022
		Tiger Pufferfish	Faster growth	Leptin receptor	2022
		Olive Flounder	Faster growth	Leptin receptor	2023
		Tilapia	Increased yield	Myostatin	2025



Red Sea Bream



2022

Puffer fish



2023

Flounder

“22nd Century Olive Flounder” - flounder that might be common on dinner tables in the 22nd century

<https://regional.fish/en/>

Implications & Lessons From the Introduction of Genome-Edited Food Products in Japan

Gap Between the Anticipated and Actual Public Response

The previous GM food controversies from the late 1990s, which **were driven by a number of major news companies and consumer group coalitions**, questioning their environmental and food safety risk exhorted the Japanese government to implement a mandatory legal authorization scheme for GM products. It was thus anticipated that the introduction of newer technologies would likely meet strong resistance

Given the low public acceptance of GM in Japan, it was anticipated that the societal introduction of genome editing technologies would face a degree of public controversy. A previous consumer perception survey **found more support for tight regulations of genome-editing-derived foods which were designed to reduce the risk to as close to zero as possible rather than scientifically proven regulations and technically reasonable.**

However, even though there were indeed some social actions, for instance, some groups were against the use of genome-editing; petitions were made by some consumer groups; they did not develop into a mass mobilization, and media coverage was mostly positive. After filing the notifications, there were no considerable public reactions, nor did they receive any sustained attention.

Editing as a Cherry Atop the Breeding Sundae

It will be able to introduce useful alleles without linkage drag, and potentially bring in useful novel genetic variation from other breeds



Genome Editing

Somatic cell nuclear transfer cloning

Genomic Selection

Embryo Transfer

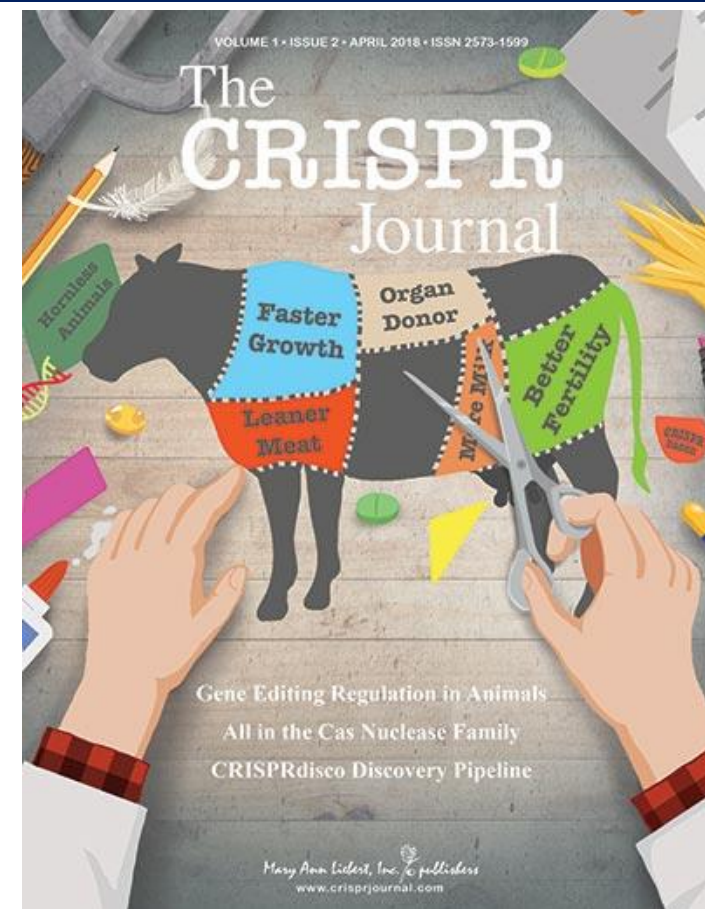
Artificial insemination

Progeny testing

Performance recording

Development of breeding goals

Association of like minded breeders



Van Eenennaam, A. L. 2018. **The Importance of a Novel Product Risk-Based Trigger for Gene-Editing Regulation in Food Animal Species.** The CRISPR Journal 1: 101-106.