



Global and Local Perspectives in the Regulatory Frameworks for New Breeding Techniques in Crops , March 6, 2025



A Global Perspective on Regulating Crops Developed through New Breeding Technologies

Michael G. K. Jones

Professor of Agricultural Biotechnology - Crop Biotechnology Research Group, Food Futures Institute,

Foundation Director, WA State Agricultural Biotechnology Centre and Centre for Crop and Food Innovation, Murdoch University, Perth, W. Australia



State Agricultural
Biotechnology Centre
WESTERN AUSTRALIA

MU **Murdoch
University**

Centre for
Crop and Food
Innovation

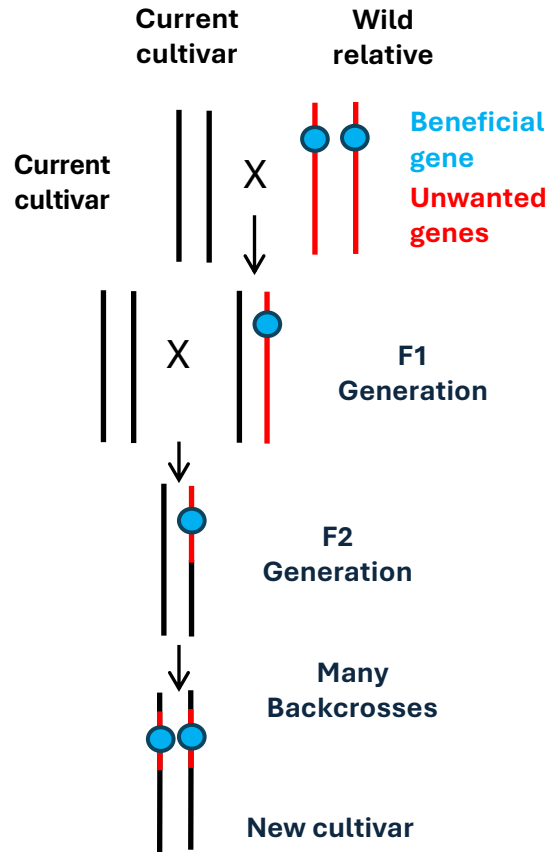


What does the term New Breeding Techniques/Technologies (NBTs) include?

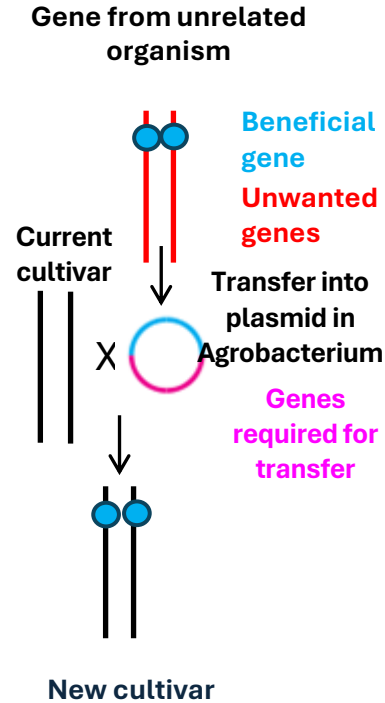
- NBTs encompass a variety of methods that modify the DNA of plants to introduce desired traits
- They can include genetically modified plants (GMOs)
- With time, the term NBT has become more restricted to techniques of gene (or genome) editing
- Gene-edited plants may or may not be GMOs, depending on whether introduced DNA is present, and if so, its origin
- Presence of unrelated DNA means the plant is a GMO, no external DNA, or introduction of DNA from the same gene-pool, may not be classified as a GMO, depending on the jurisdiction

CONVENTIONAL AND NEW BREEDING TECHNOLOGIES

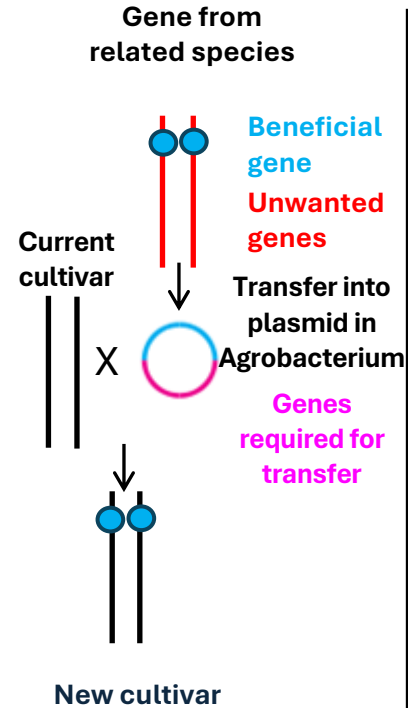
Conventional breeding



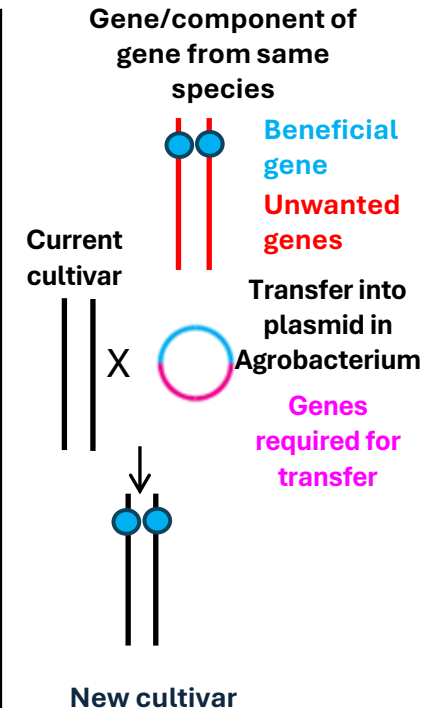
Transgenesis



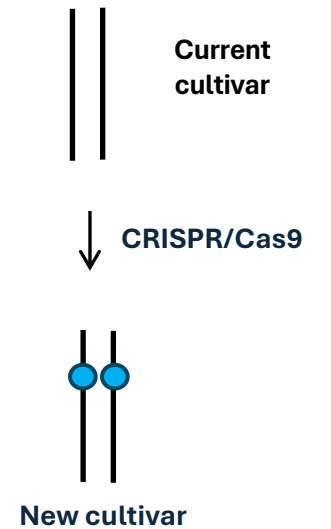
Cisgenesis



Intragenesis



Gene-editing (SDN-1)

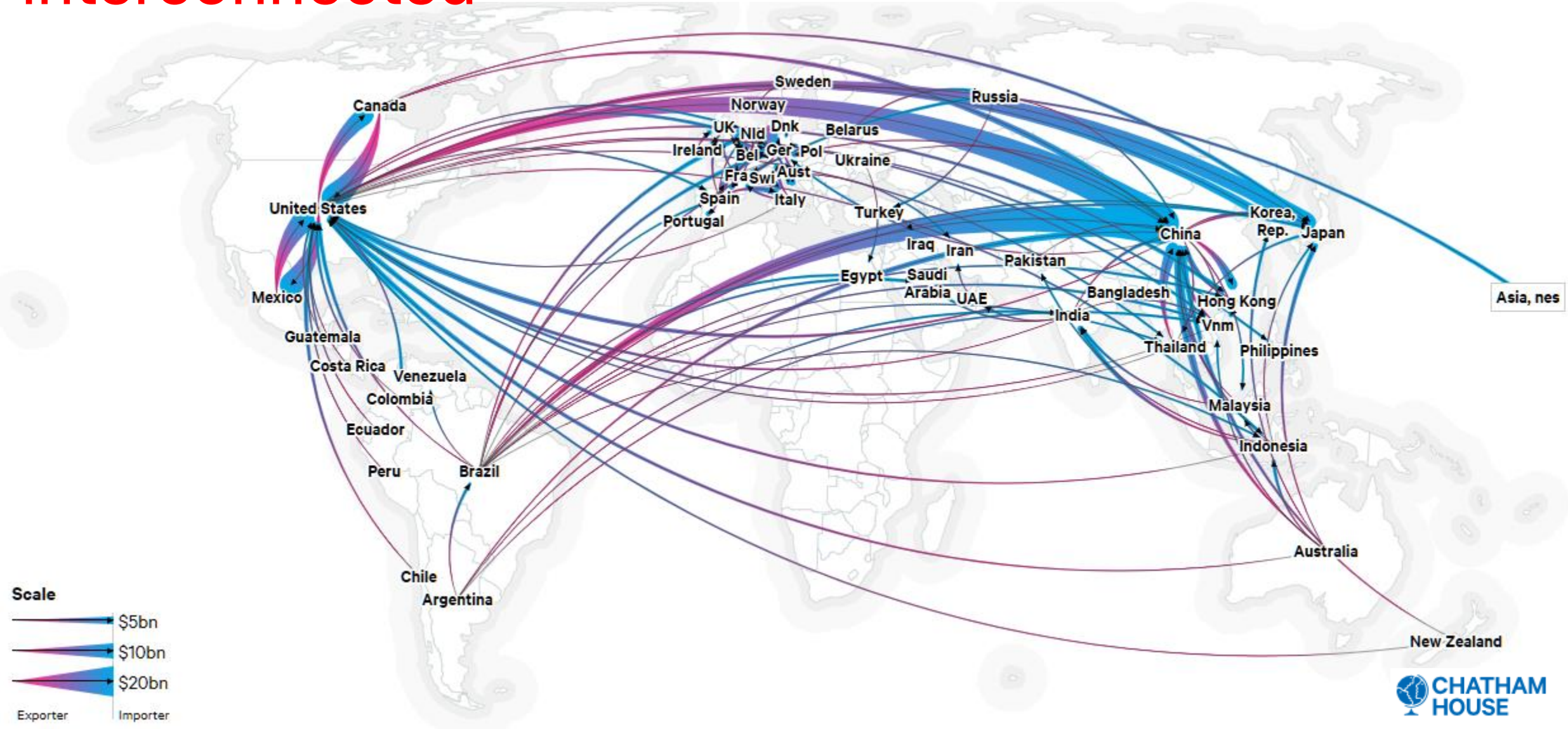


Genetically modified (GM) or Biotech Crops Gene-edited (GEd) crops

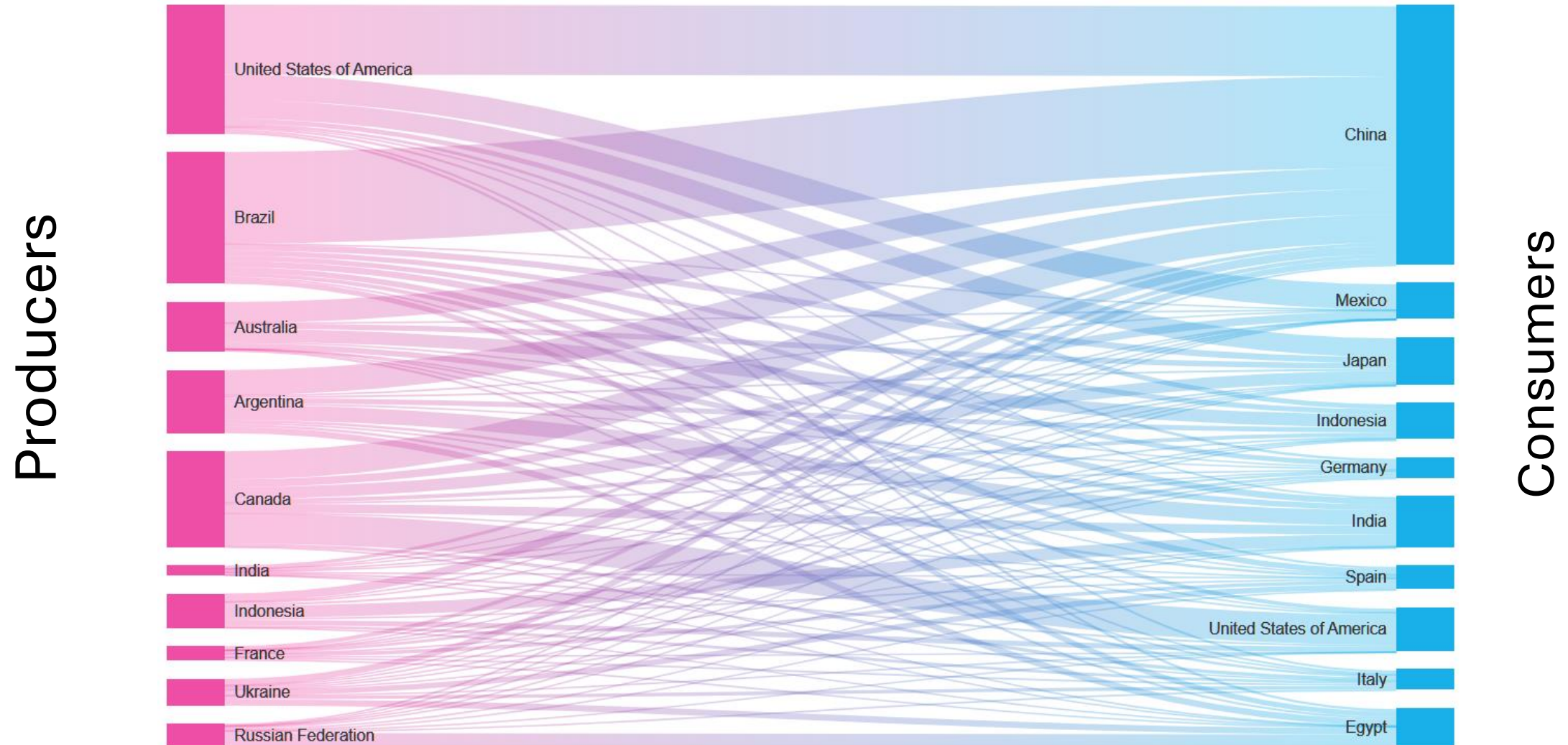
Why are the definitions of GMOs and Gene Edited (GEed) produce so important?

- Because we have an opportunity to separate GMOs and GEed produce
- This difference will increasingly enable trade in world GEed produce
- Alignment or harmonisation of international regulations is vital before producers and consumers can gain the full benefit of new technologies of Gene Editing

The global food system is highly complex and interconnected



Non-livestock agriculture, trade between top ten producers and consumers



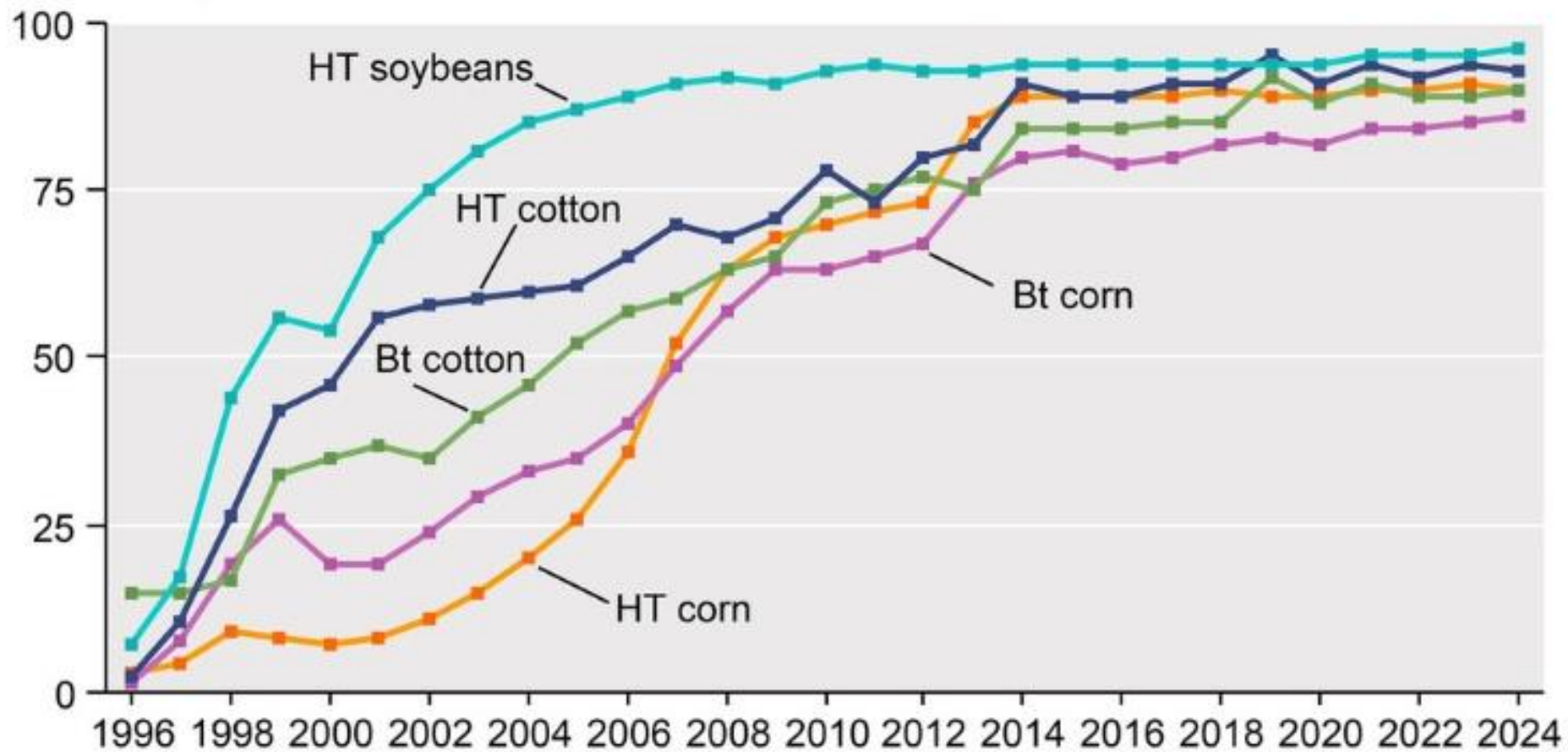
Agricultural Biotechnology (Agri-Bio)

There are major scientific advances in

- **Genomics** – the complete genomic sequences of all major crops are now available
- **Genes** that underlie agricultural traits can be identified
- **New ways** of combining genes and speeding up breeding
- **Genetically Modified** (GM) crops
- **Gene-Edited** (GE) crops

In 2024, >90% of U.S. maize, cotton, and soybean crops were GM varieties

Percentage of area grown





Bt brinjal in Bangladesh

- Four varieties of insect resistant Bt brinjal grown in Bangladesh, now adopted by 27,000 farmers
- Farmers report a 3-fold increase in yield at half the production costs of non-Bt brinjal

Reduced pesticides, herbicides; improved quality for consumers

Left: Bt cotton, right wild type cotton, no
insecticide application(GM), 99.5% uptake



Roundup Ready (RR) herbicide
tolerant canola



High
anthocyanin
purple
tomatoes

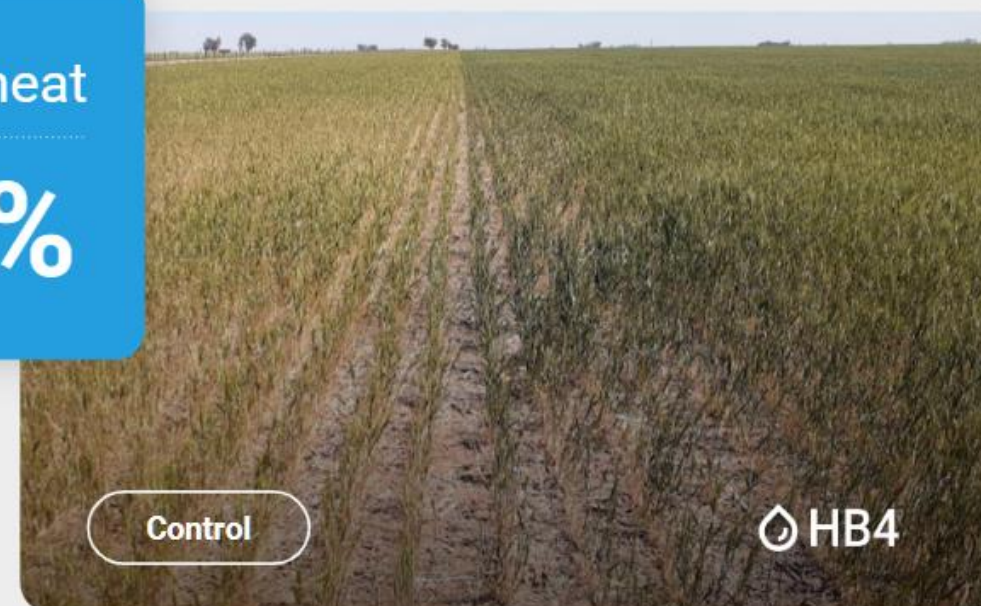
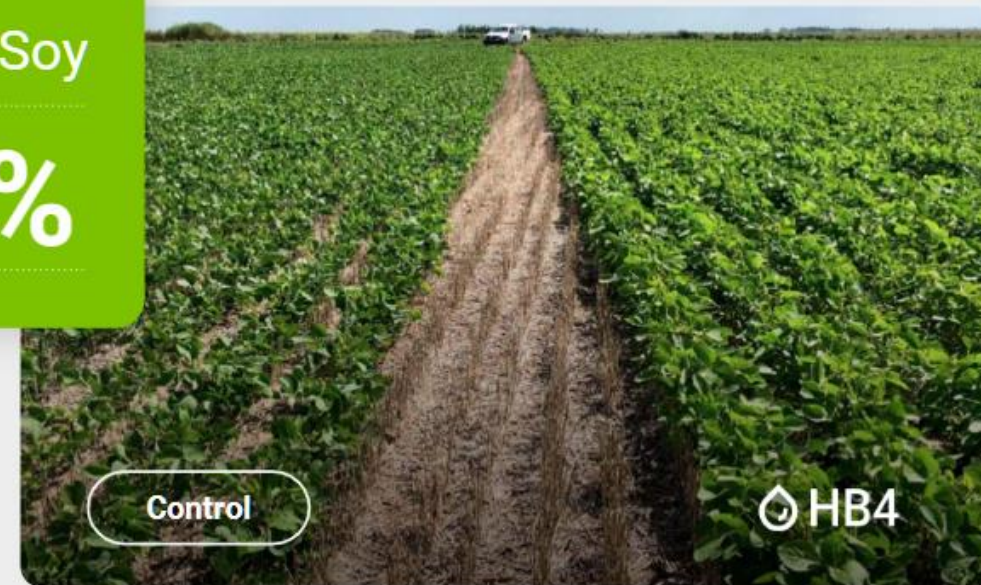


Bioceres Crop Solutions

Drought tolerant wheat
and soybean

The **HB4** technology

The only available technology for drought
tolerance in soy-wheat cropping systems



HB4 wheat
introgressed into WA
germplasm



Countries approving GM crop cultivation (1996 - 2024)

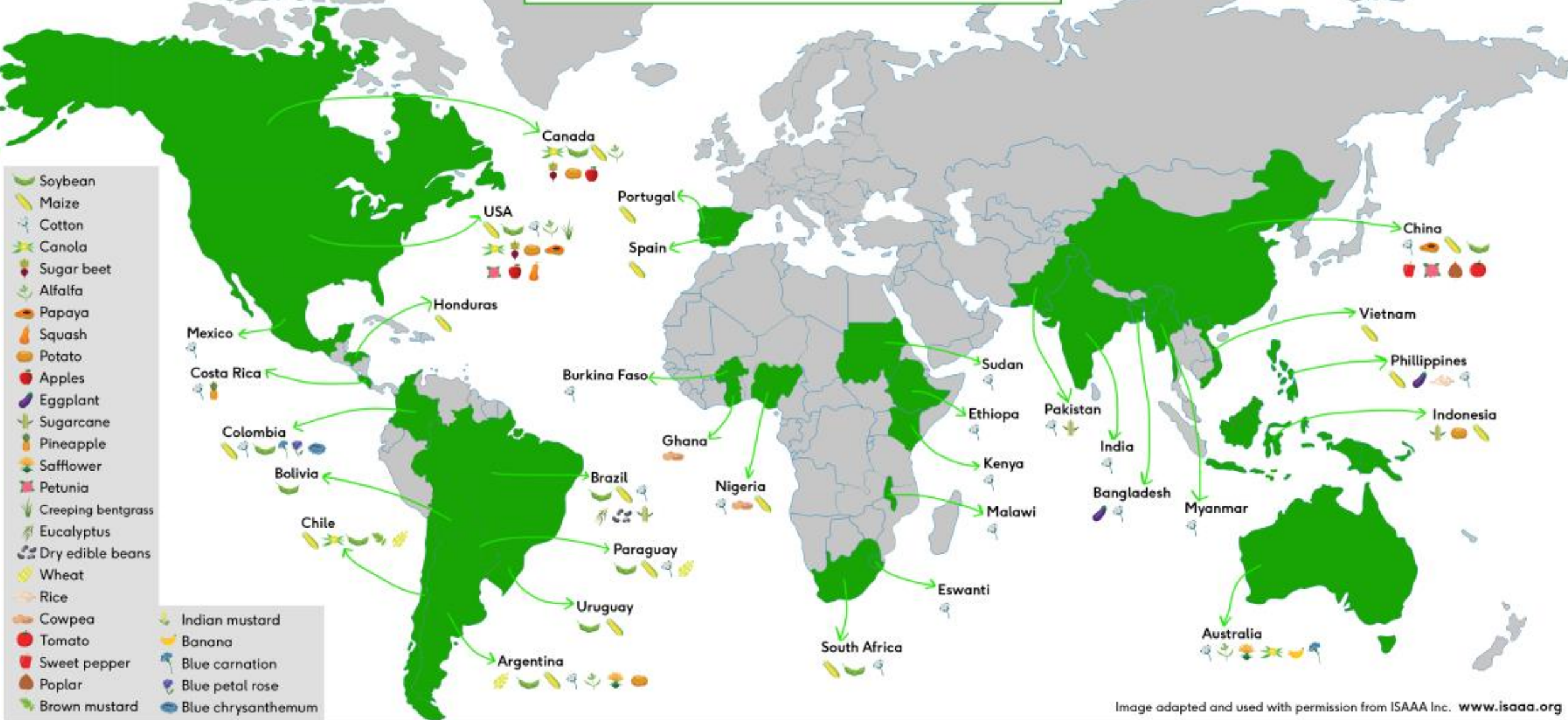
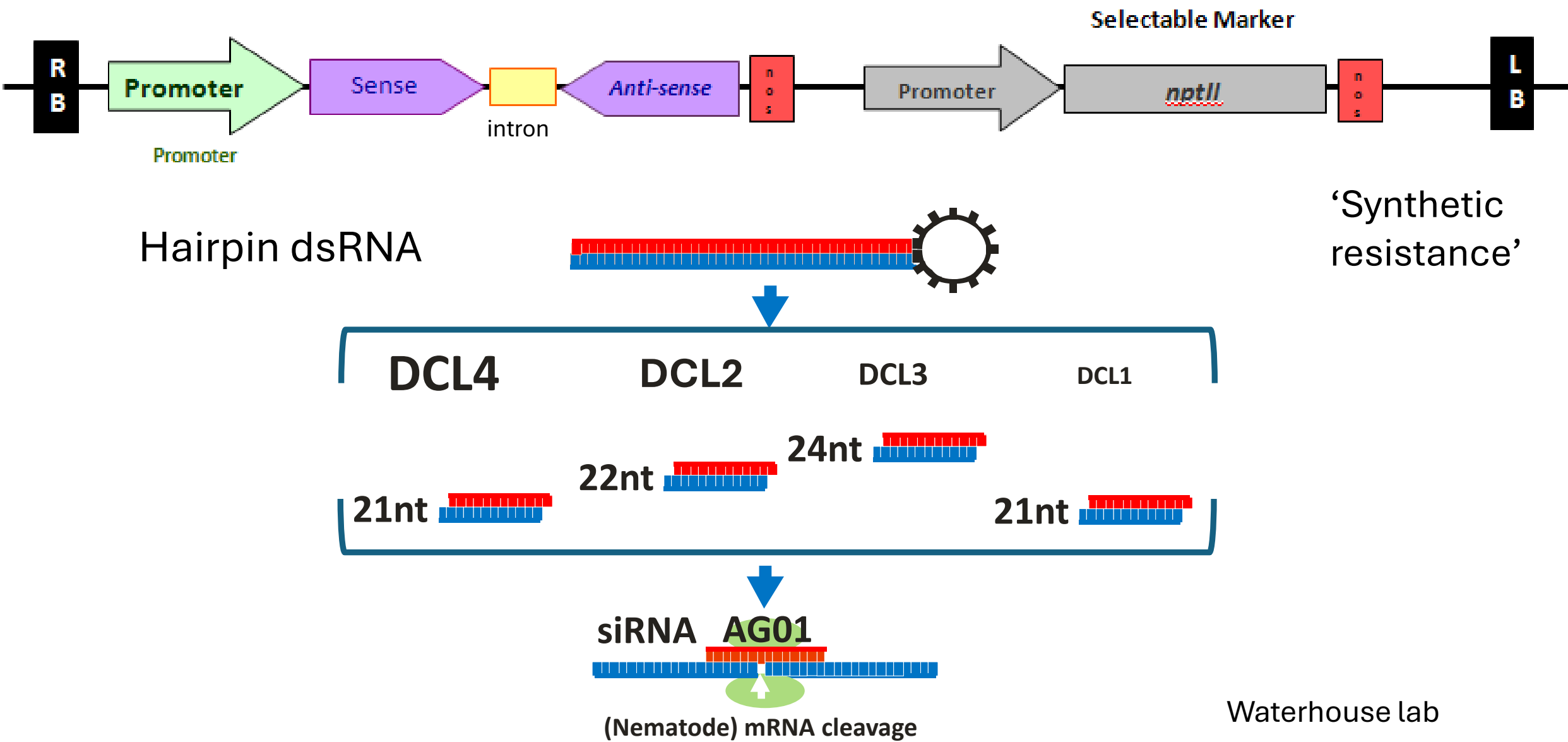
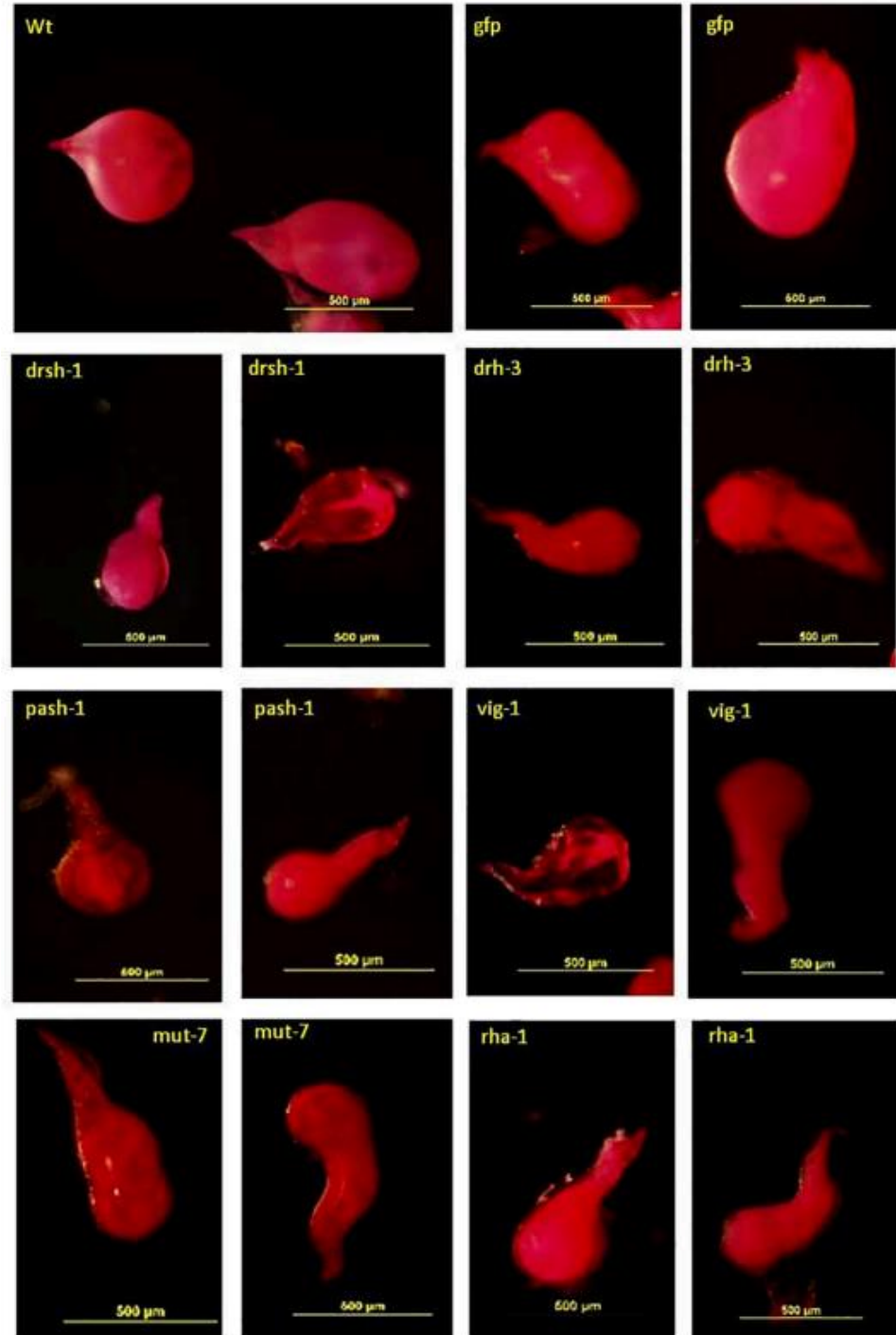
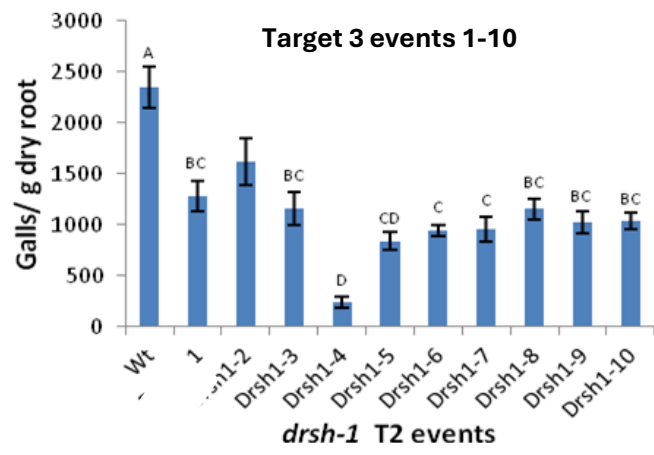
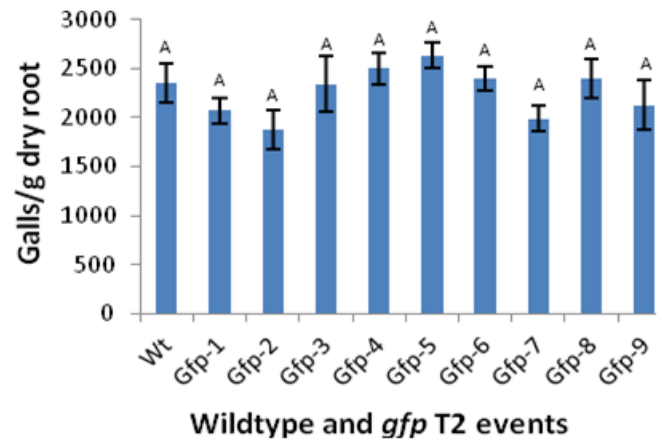


Image adapted and used with permission from ISAAA Inc. www.isaaa.org

Gene silencing- RNAi constructs to silence vital nematode genes via transgenic plants

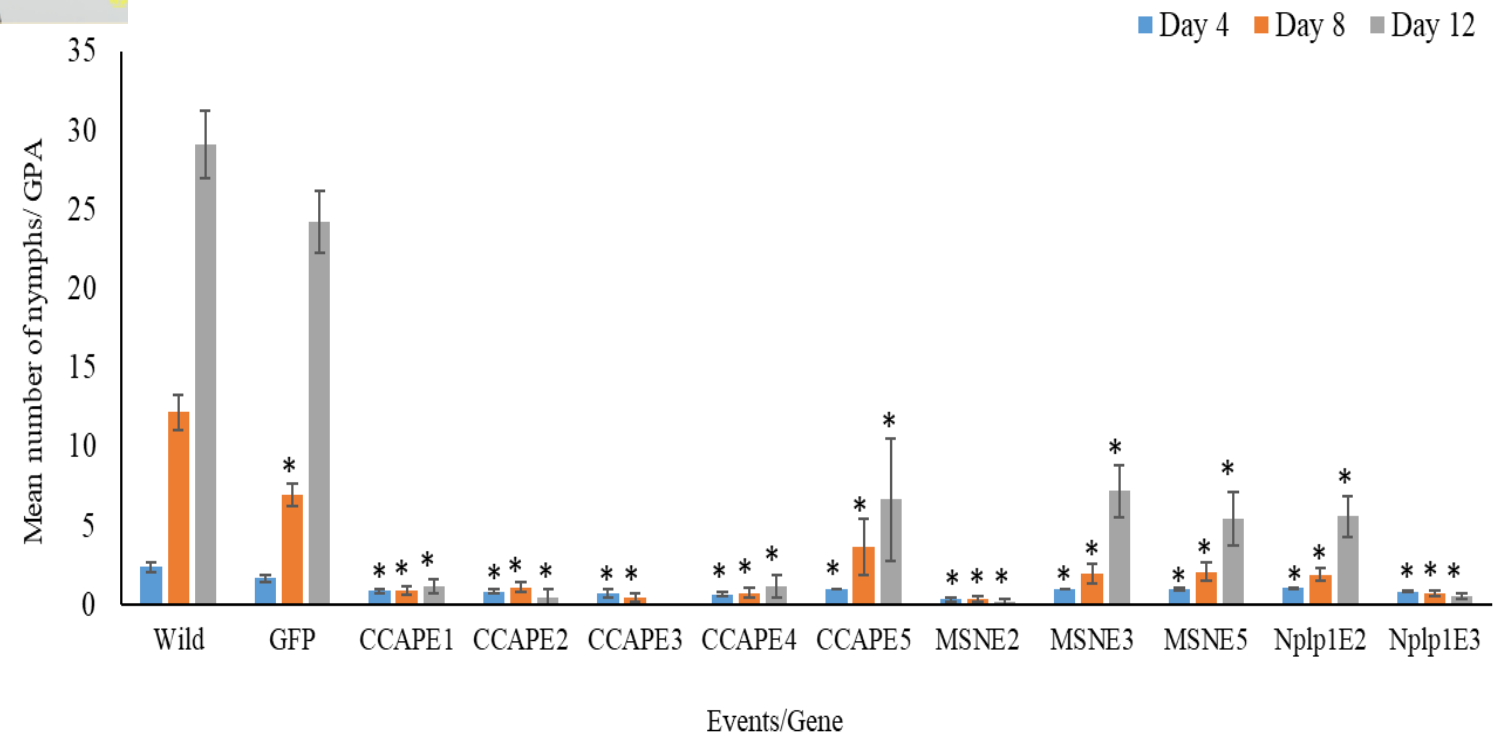


Malformed *M. incognita* females from Arabidopsis plants expressing dsRNA, up to 89% reduction in infestation



Plant-aphid interactions

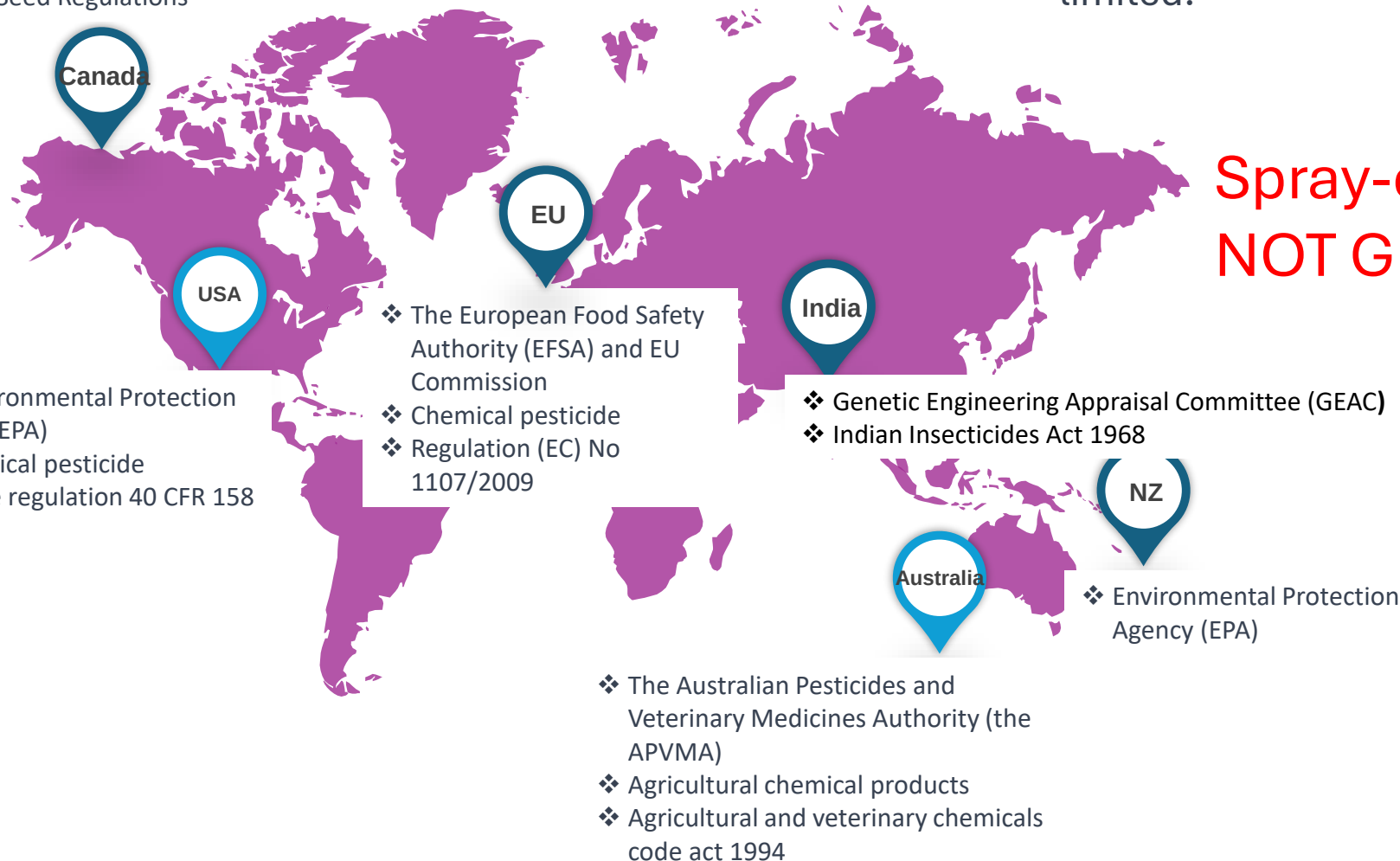
- RNAi - based resistance to the Green Peach Aphid (GPA)



Regulatory landscape for spray-on RNAi – biopesticide (2024)

- ❖ Pest Management Regulatory Agency (PMRA)
- ❖ Plant Protection Act 1990, Plant Protection Regulations, Seeds Act 1985 and Seed Regulations

China and Japan have many publications related to RNAi technology, but their legislative and regulatory status for this technology is limited.



**Spray-on dsRNA (SIGS)
NOT GM in Australia**

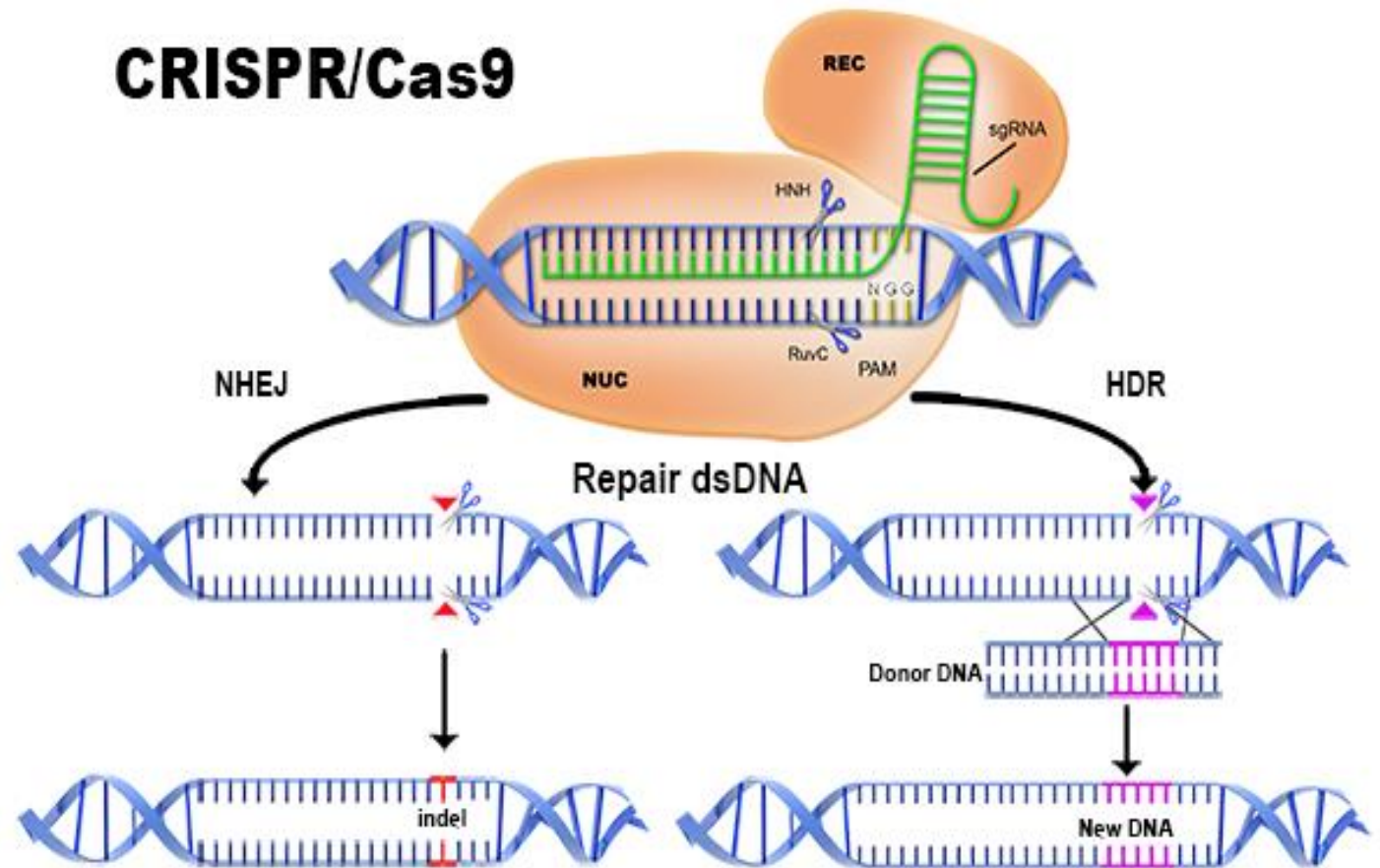
New Breeding Technologies – Gene Editing (GEd)

CRISPR-Cas9 targeted double-strand DNA break

SDN-1 – non-homologous end joining (NHEJ) - natural repair mechanism, small nucleotide deletions, additions or substitutions

SDN-2 – in the presence of an oligonucleotide template, homologous end joining (HEJ or HDR) can occur, to insert one or more bases at the break site

SDN-3 – as for SDN-2, but with a longer DNA insert, e.g. up to a full gene expression cassette



(Source: <http://www.labgene.ch/img/cms/AATI/crispr-dual-editing-method.png>).

The power of SDN-1 GEd for crop improvement

- GEd of all six MLO alleles in hexaploid wheat confers **resistance to powdery mildew** (Wang et al, 2016, Nature Biotech)

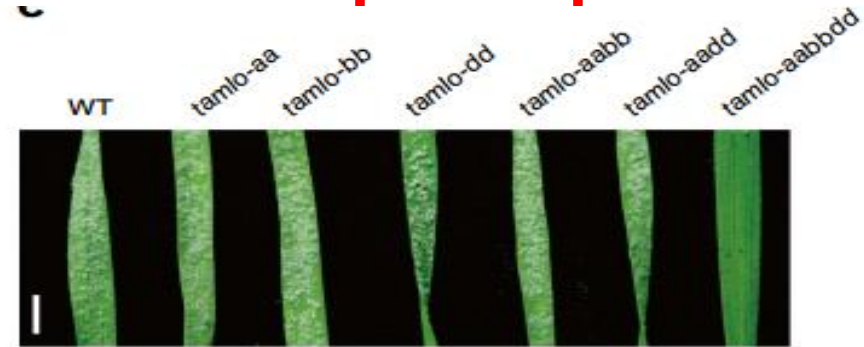
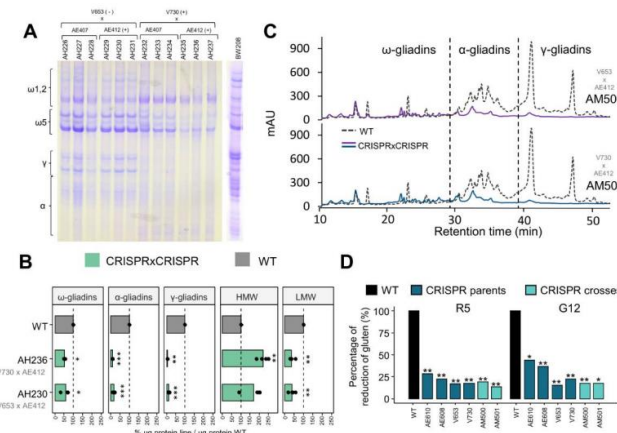


Figure 6

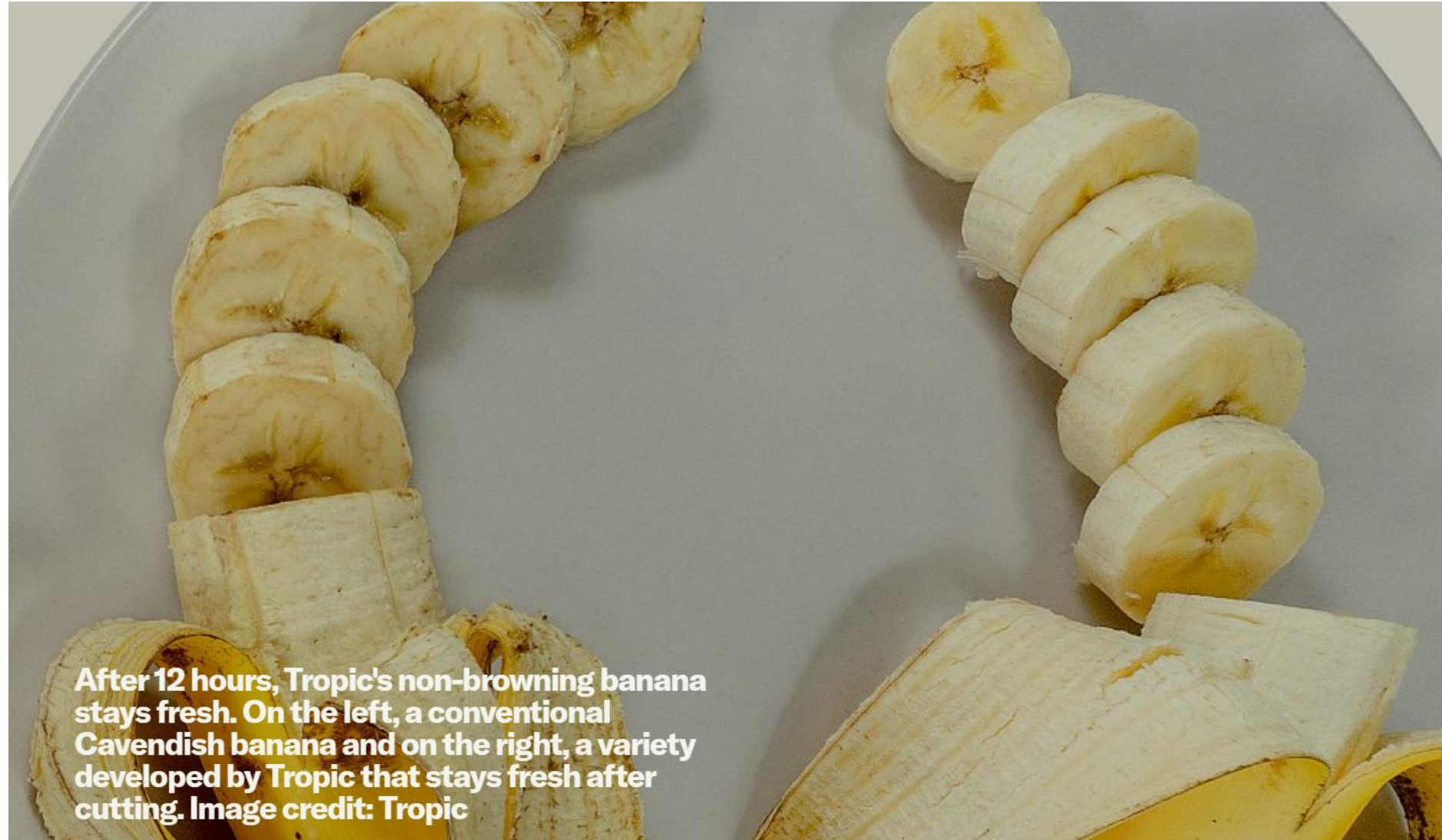
- Multiplex GEd of gamma and omega gliadins for allergen-free wheat - **97.7% reduction in wheat allergens**, Sánchez-León et al (2024) J. Exp. Bot.



Tropic to launch non-browning GEd bananas in March 2025, extended shelf-life bananas by end of 2025

GEd of PPO and ethylene synthesis

GEiGS vs Fusarium wilt TR4



Gene editing toolkit

Sequence deletion/insertion (SDN-1, 2, 3) including allele replacement

DNA free editing – Cas9 plus guide RNA (RNPs)

Base editing (BE_d)

Prime editing (PE_d)

Gene segment deletion

Gene expression changes

Epigenetic changes

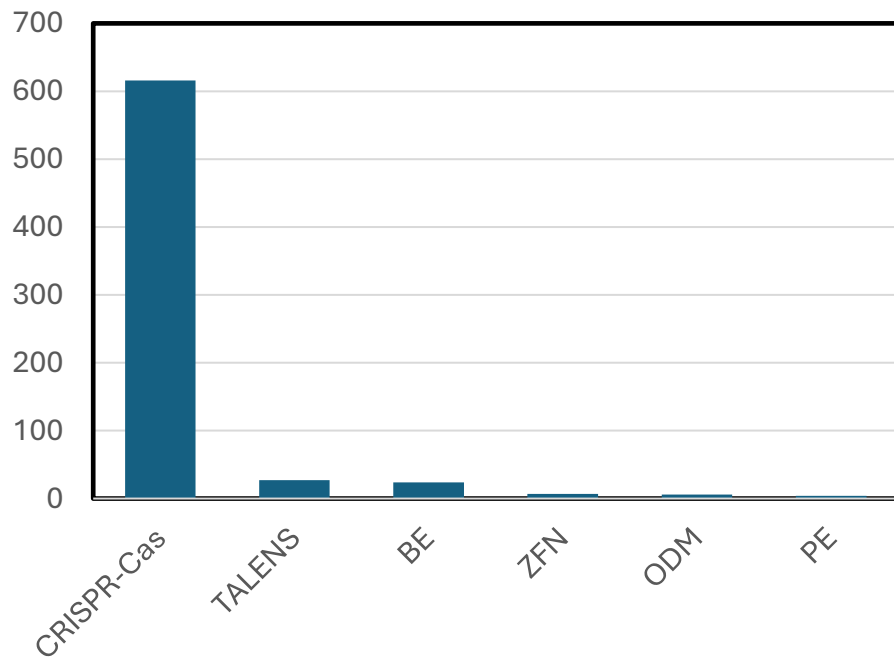
SDN Application	Targeted to a specific genome location?	Use of repair template? Origin of the repair template	Type of targeted sequence change(s)
SDN-0	YES Epigenetic change defined by nuclease specificity	NO	Epigenetic changes only , (<u>e.g.</u> transcriptional control)
SDN-1	YES Defined by nuclease specificity	NO	Edit(s) (Spontaneous mutations: deletions, substitutions, addition of bases)
SDN-2	YES Defined by nuclease specificity	YES Species own gene pool only	Edit(s) (Predefined mutations, sequence optimisation, allele replacement)
SDN-3	YES Defined by nuclease specificity	YES Any source, including species own gene pool only	Insertions (Addition of sequence at the targeted location in the genome)

What's in a name? Differentiating GM and GEd

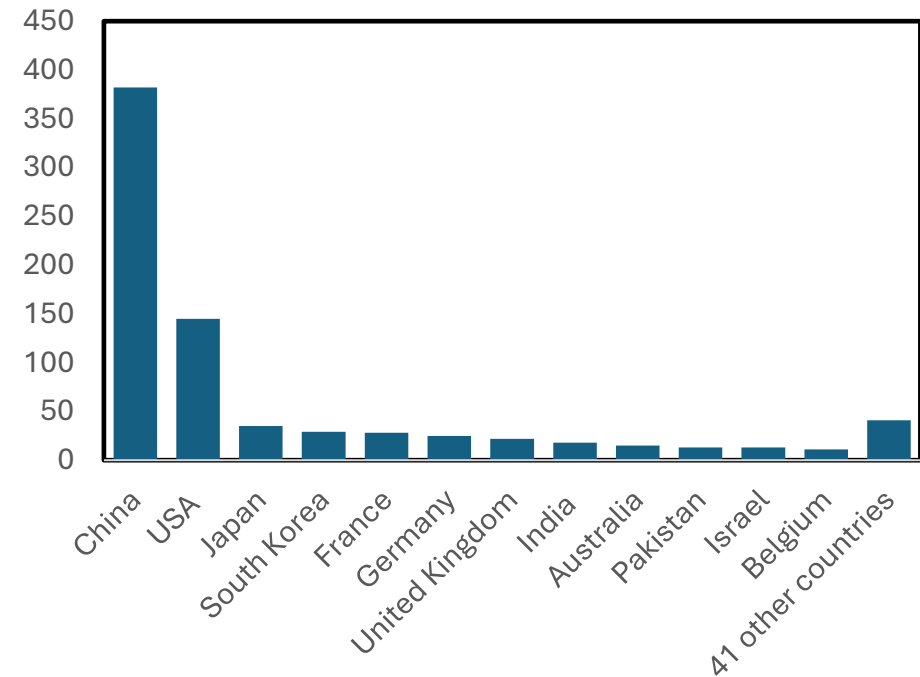
– terminology is important

- How a technology is described is **critical**
- Imprecise 'academic' terminology will be picked up and used by the anti-Gene Technology lobby
- **GM/GMO/LMO/GE/Biotech** – introduce genetic material from an **unrelated organism**
- **NBTs/Genome editing/Gene Editing/GEd/Precision Breeding** – **no genetic material introduced, or from the same gene pool**
- **Please do not use GE for Gene Editing!** This adds to public confusion! The minimum is GEd... or GnEd

GE_d techniques used, countries using GE_d



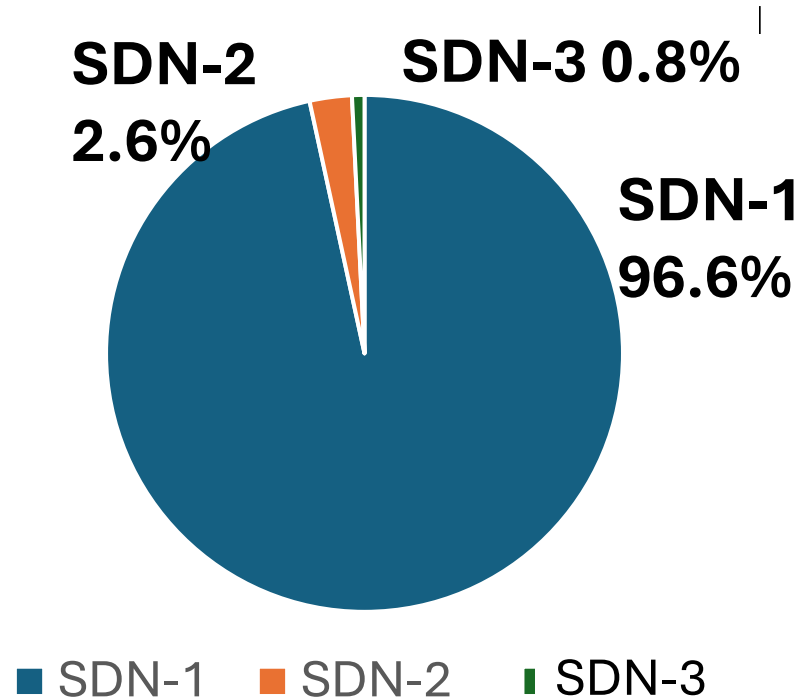
GE_d methods used



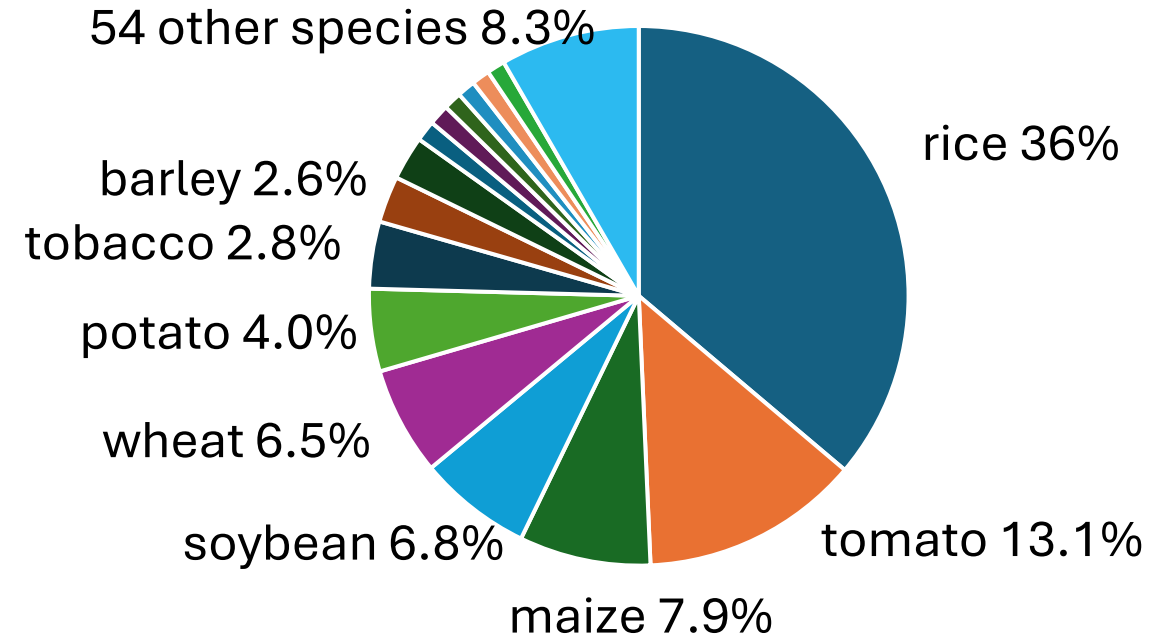
Countries where GE_d work done

SDN method used

(SDN = Site Directed Nuclease)



Crop species edited – percentage of total reports



Rice 234	Tomato 85	Maize 51
Soybean 44	Wheat 42	Canola 32
Potato 26	tobacco 18	Barley 17
Watermelon 8	Poplar 8	grapevine 7

Australia is a food exporting nation

- 60% of the world's population, >\$4.3 billion people
- 95% of wheat from Western Australia is exported
- Australian exports (\$billion)
 - wheat \$4.6 b
 - barley \$1.6 b
 - canola \$1.56b
 - horticulture 77% (of total to Asia)



Some considerations for delivering GEd crops

- Differing definitions of SDN-2
- Absence of external DNA
- Possibility of off-target edits
- Unintentional low-level presence of edited seeds

Absence of external DNA

Once a successful edit (from a plasmid supplying the editing machinery as T-DNA) has been identified, selfed, and selected for **null segregants** for the TDNA

- Could there be any **residual external DNA**?
- What tests are reasonable?
 - **sequence the site of editing**
 - **Quantitative PCR** to show absence of backbone T-DNA
 - check sequences at the site of editing to show **no new short ORFs** are present

Off-target edits – must be viewed in context

- Spontaneous mutations occur naturally (10^{-7} – 10^{-8} per site/generation)
- Pan-genome sequencing reveals many sequence differences in a species
- There are >3,200 crop varieties generated through mutagenesis
- Somaclonal variation can be a major source of mutations
- Off-target edits can be minimised by choice or gRNA
- History of safe consumption of plant foods with many mutations, regardless of origin
- An off-target edit resulting in an undesirable phenotype will normally be eliminated in subsequent crop breeding
- Is there any biological significance for food crops?

Project to enable trade in GEd produce



- Forward looking - to enable Australian grains and horticultural industries to be first-movers in applying new breeding technologies to crop improvement
- Provide information on new science/technologies, and on the policies and regulations that relate to them both in Australia and with our trading partners
- To help promote international harmonisation/alignment of regulations and reduce barriers to trade – Science Diplomacy

National and international workshops/webinars

International Trade in Crops with New Breeding Technologies: The Australian Perspective

June 11, 2021
2:00 PM Philippines (GMT +8)
Via Zoom

LIVESTREAMING AT: isaaa.org

FREE REGISTRATION HERE: isaaa.org

SPEAKERS:

 PROF. MICHAEL JONES Professor, Murdoch University; Foundation Director, Western Australia State Agricultural Biotechnology Center	 MR. MUHAMMAD ADEEL Career Diplomat, PhD Scholar, WA State Agriculture Biotechnology Center, Australia	 MS. LUCY BARRAGH Manager, Crop Biotechnology Policy CropLife Australia
 PROF. DR. MOHD FAIZ FOONG BIN ABDULLAH Chair, Genetic Modification Advisory Committee (GMAC), Malaysia	 DR. REYNANTE L. ORDONIO Senior Science Research Specialist/Scientist I Project Leader, Golden Rice Project Philippine Rice Research Institute	 DR. BAMBANG PRASETYA Chairman Indonesian Biosafety Committee of Genetically Engineered Products

A VIRTUAL WORKSHOP

The Biotech Game: A negotiation simulation of Science Diplomacy

About the virtual workshop
Participate in a negotiation simulation involving Science Diplomacy on the regulation of gene-edited crop plants based on the Cartagena Protocol on Biosafety

Who:

- Early career researchers
- Undergraduates and post-graduates
- Scientists
- Policymakers
- Industry players

Prof. Michael Jones
Professor, Murdoch University;
Foundation Director, Western
Australia State Agricultural
Biotechnology Center

Muhammad Adeel
Career Diplomat,
PhD Scholar, WA State
Agriculture Biotechnology
Center, Australia

26 August 2021
2:00pm Singapore

Register at
<https://bit.ly/BiotechGame2021>

ASCA 2021

4TH ASIAN SHORT COURSE ON AGRIBIOTECHNOLOGY, BIOSAFETY REGULATION, AND COMMUNICATION

November 23-26, 2021
2:00-5:00PM Manila Via ZOOM
from ISAAA SEAsiaCenter
Philippines

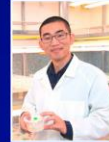
Policy Consideration For Gene editing : The Asian & Australian Perspective

23rd – 25th August 2022
West Point 1&2

A discussion evening at CERI on:

GENE EDITING AND CROP BREEDING: A GUIDE TO INTERNATIONAL TRADE

July 26th, Tuesday 5:30 - 7.30pm, panel including:

				
Prof Michael Jones	Dr Muhammad Adeel	Dr Linda Kennaugh	Dr Dini Ganesalingam	Dr Yang Han

CERI **MU Murdoch University** **LIFE SCIENCES WA**





ASCA7 2024

**7th Asian Short Course on Agribiotechnology,
Biosafety Regulation, and Communication**

September 2 – 6, 2024 | Maruay Garden Hotel | Bangkok, Thailand



Numerous regional training workshops,
meetings, conferences e.g.:

Thailand: Dec. 2023 (APAARI), Sept 2024
(ISAAA, ASCA, APSA, CropLife Asia etc)

India: 2016, 2022, 2023, 2024

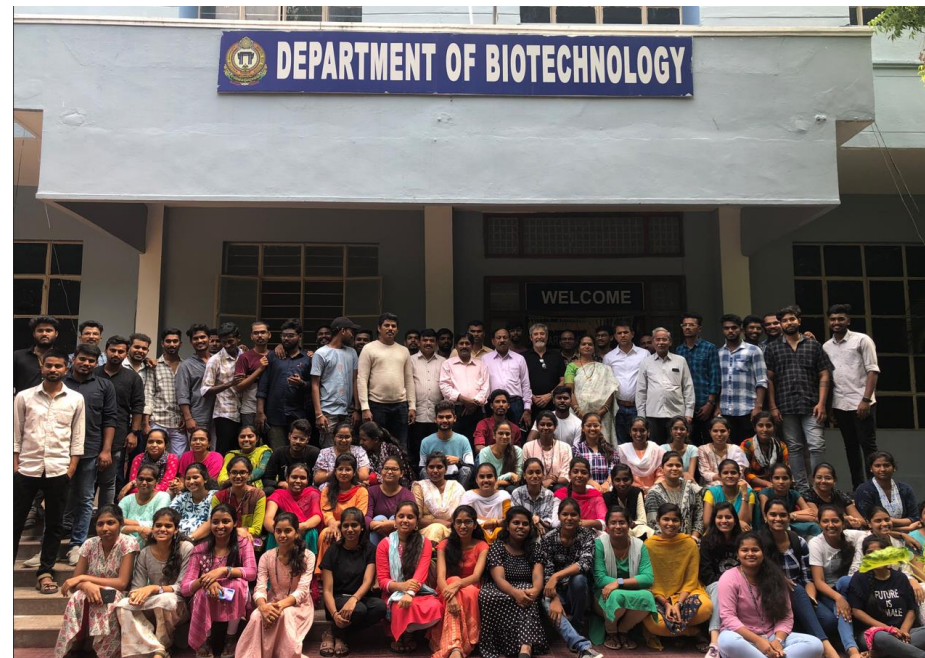
Malaysia: 2022

Indonesia: 2023 (ASCA6)

Mauritius: 2023, 2024

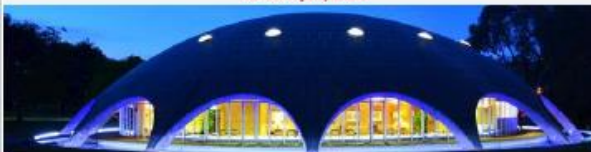
Philippines: 2022 (ASCA5)

Turkey: 2022



DG, Dept of Ag, Thailand

An International Conference on
Gene-Edited Crops: Enabling Future
Commercialisation and Trade
The Shine Dome, Canberra
26-27 April, 2023



Conference Organisers



Conference Sponsors



Project supporting partners



PASE-NBT Conference on Gene-Editing
26th-27th April 2023
The Shine Dome, Canberra, ACT, Australia



Day 1 – Wednesday 26th April 2023

09.00 – 10.00 Registration and coffee

Introduction

10.00 – 10.05	Welcome address	Professor Michael Jones, Foundation Director, WA State Agricultural Biotechnology Centre, Murdoch University (MU), Perth
10.05 – 10.15	Opening address	Dr Misha Schubert, Chief Executive Officer, Science & Technology Australia (STA)
10.15 – 10.45	Science of GEd	

Session 1.

Moderator: Dr Rhodora Romero-Aldemita, Executive Director, ISAAA Inc.

10.45 – 11.15	An overview of gene-editing platforms	Professor Peter Waterhouse, ARC Laureate Fellow, Queensland University of Technology (QUT)
11.15 – 11.30	Morning tea and Group photograph	
11.30 – 11.50	Gene-editing of cereals	Dr Steve Jobling, Senior Research Scientist, CSIRO
11.50 – 12.10	Gene-editing of horticultural plants particularly bananas	Professor James Dale, AC, FTSE, Distinguished Professor, Queensland University of Technology (QUT)
12.10 – 12.30	Progress towards socially responsible climate resilient future crops	Professor Barry Pogson, ARC Laureate Fellow, Australian National University (ANU)

12.30 – 13.00 Lunch

13.00 – 14.00	Short presentations by ECRs	Dr Sadia Iqbal, Murdoch University Dr Nijat Imin, University of Western Sydney Dr Neelam Gogoi, Australian National University
	• Gene-editing of potato for better human health	
	• The knife is sharpened, but where is the meat: What genes should we edit?	
	• Nanotechnology for accelerating gene-editing in crops	

Round Table/Panel Discussion – The Science of Gene-Editing

14.00 – 15.10	Dr Steve Jobling (CSIRO) Professor Peter Waterhouse (QUT) Professor James Dale (QUT)	Professor Barry Pogson (ANU) Professor Channa Prakash (Tuskegee University)
---------------	--	--

15.10 – 15.25 Afternoon tea

Session 2.

15.25 – 15.45	Regulation of GEd	
15.45 – 16.05	The regulation of gene-edited food in Australia and New Zealand	Dr Shai Joseph, Senior Regulatory Scientist, FSANZ
16.05 – 16.25	The regulation of gene-editing technology in the UK and Europe	Professor Huw Jones, IBERS, Aberystwyth University, UK
16.25 – 16.45	The regulation of gene-editing technology in South-East Asia	Dr Gabriel Romero, Exec Director, Philippines Seed Industry Association
16.45 – 17.00	Q&A, Synthesis and close	Professor Michael Jones

17.00 – 19.30 Reception and drinks in the Shine Dome - sponsored by Murdoch University



PASE-NBT Conference on Gene-Editing
26th-27th April 2023
The Shine Dome, Canberra, ACT, Australia



Day 2 – Thursday 27th April 2023

The Regulation of Gene-Editing in Crop Plants – Moderator: Mr Muhammad Adeel

08.50 – 09.00	Recap of the previous day	Professor Michael Jones
09.00 – 09.20	The regulation of gene-edited produce in Argentina/South America	Dr Martin Lema (Online), National University of Quilmes, Argentina
09.20 – 09.40	Opportunities and challenges for bringing gene-edited produce to market	Dr Nicole Juba, Associate Director, Regulatory, Pairwise (Online)
09.40 – 10.00	A proposal for a revised regulatory scheme for food, fibre and feed in Australia – a personal view	Dr Bob Redden, RIR Agriculture Consultants
10.00 – 10.20	The need for enabling and future-proofed regulatory policies for gene-edited products	Mr Osman Mewett, Global Regulatory Policy Manager, BASF

10.20 – 10.35 Morning tea sponsored by Corteva Agriscience

Session 3. Intellectual Property and Licensing of Gene-Edited Produce – Moderator: Panfilo de Guzman

10.35 – 10.55	IP and Licensing	
10.55 – 11.15		Dr Barbara, Senior Patent Consultant, Wray, Kwock, Corteva Agriscience, USA (Online)
11.15 – 11.35	acceptance of gene-edited products	Dr Mirac Cool, Corteva Agriscience, USA (Online)

Session 4. Industry Perspectives on Gene-Editing for Crops – Moderator: Kristine Tome, ISAAA Inc.

11.35 – 11.50	Industry perspectives	
11.50 – 12.05		Dr Craig McCormick, OAM, Creative Director, ThinkOutsideThe Box, www.thinkoutsidethe.com.au
12.05 – 12.20		Dr Mahaletchumy Arujanan, Global Coordinator, ISAAA BioTrust; Executive Director, MABIC
12.20 – 12.35	The horticultural industry perspective on genetic improvement	Dr Wino Rajandran, Head of Production R&D, Horticulture Innovation Australia
12.35 – 12.55	The opportunity cost of using or not using gene-editing	Professor Stuart Smyth, Research Chair in Agri-Food Innovation, University of Saskatchewan, Canada (Online)

12.55 – 13.30

Session 5.

13.30 – 13.50	Public acceptance	
13.50 – 14.10	Modelling public acceptance based on what we learned from attitudes to GM	Dr Craig McCormick, OAM, Creative Director, ThinkOutsideThe Box, www.thinkoutsidethe.com.au
14.10 – 14.30	The role of science communication - communicating regulations	Dr Mahaletchumy Arujanan, Global Coordinator, ISAAA BioTrust; Executive Director, MABIC
14.30 – 14.50	Science diplomacy interface of regulation of gene editing and agricultural biotechnology	Mr Muhammad Adeel (MU)/Embassy of Pakistan, Brussels

14.50 – 15.00

15.00 – 15.15

Session 6.

15.15 – 16.00	The future of trade in GEd produce	
16.00 – 16.15	Key Outcomes	Dr Craig McLure, Head of Grain Technology, CBH Group Helen Macpherson, Partner, Baker & McKenzie, Sydney Professor Michael Jones/ Mr M. Adeel
16.15	Meeting close	

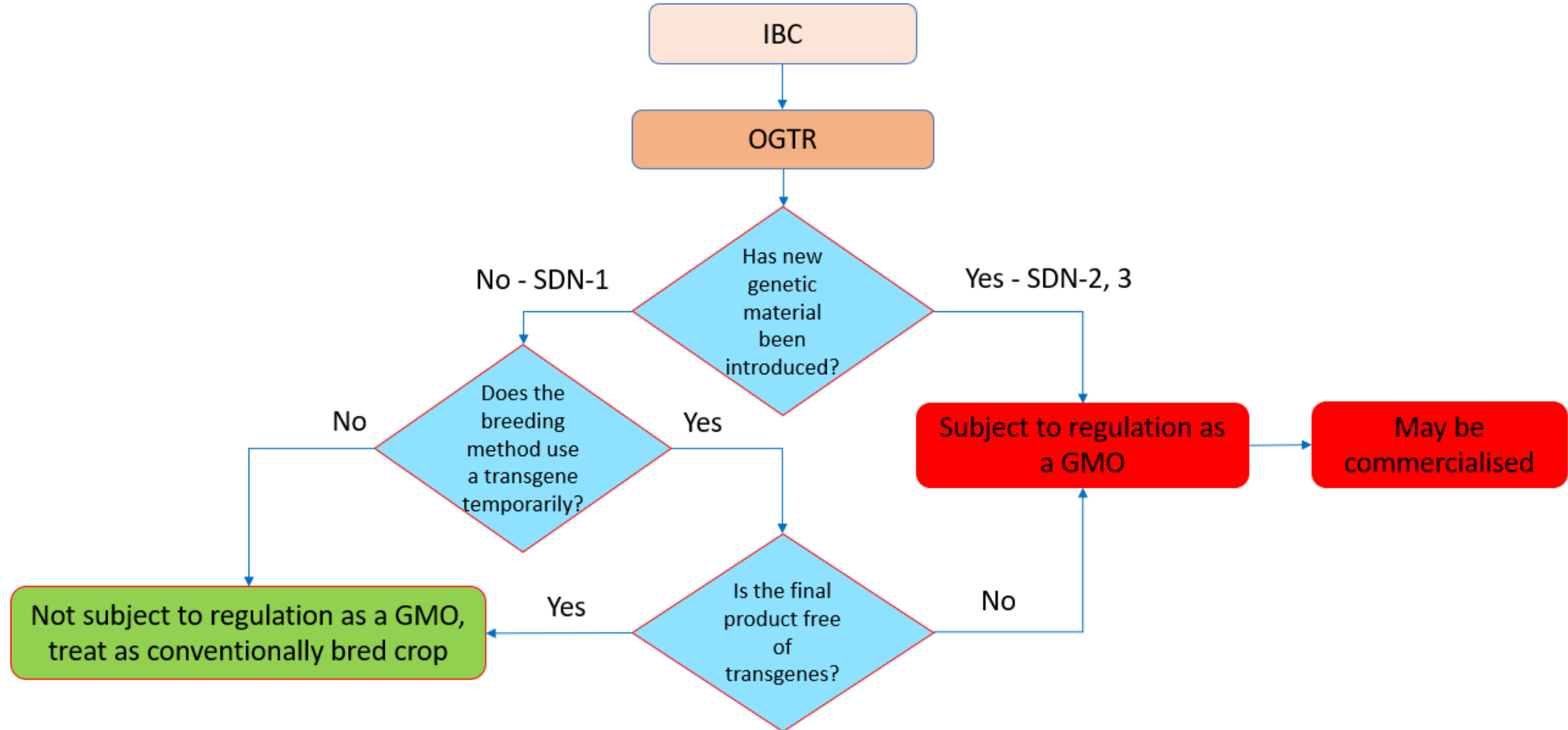
Enabling trade in gene-edited produce in Asia and Australasia: the developing regulatory landscape and future perspectives.

Michael G. K. Jones ^{1,*}, John Fosu-Nyarko ¹, Sadia Iqbal ¹, Muhammad Adeel ¹, Rhodora Romero-Aldemita ², Mahaleetchumy Arujanan ³, Mieko Kasai ⁴, Wei Xun ⁵, Bambang Prasetya ⁶, Satya Nugroho ⁷, Osman Mewett ⁸, Shahid Mansoor ⁹, Muhammad Jawad Akbar Awan ⁹, Reynante L Ordonio ¹⁰, S.R. Rao, ¹¹ Abhijit Poddar ¹², Penny Hundleby ¹³, Nipon Iamsupasit ¹⁴ and Kay Khoo ¹⁵

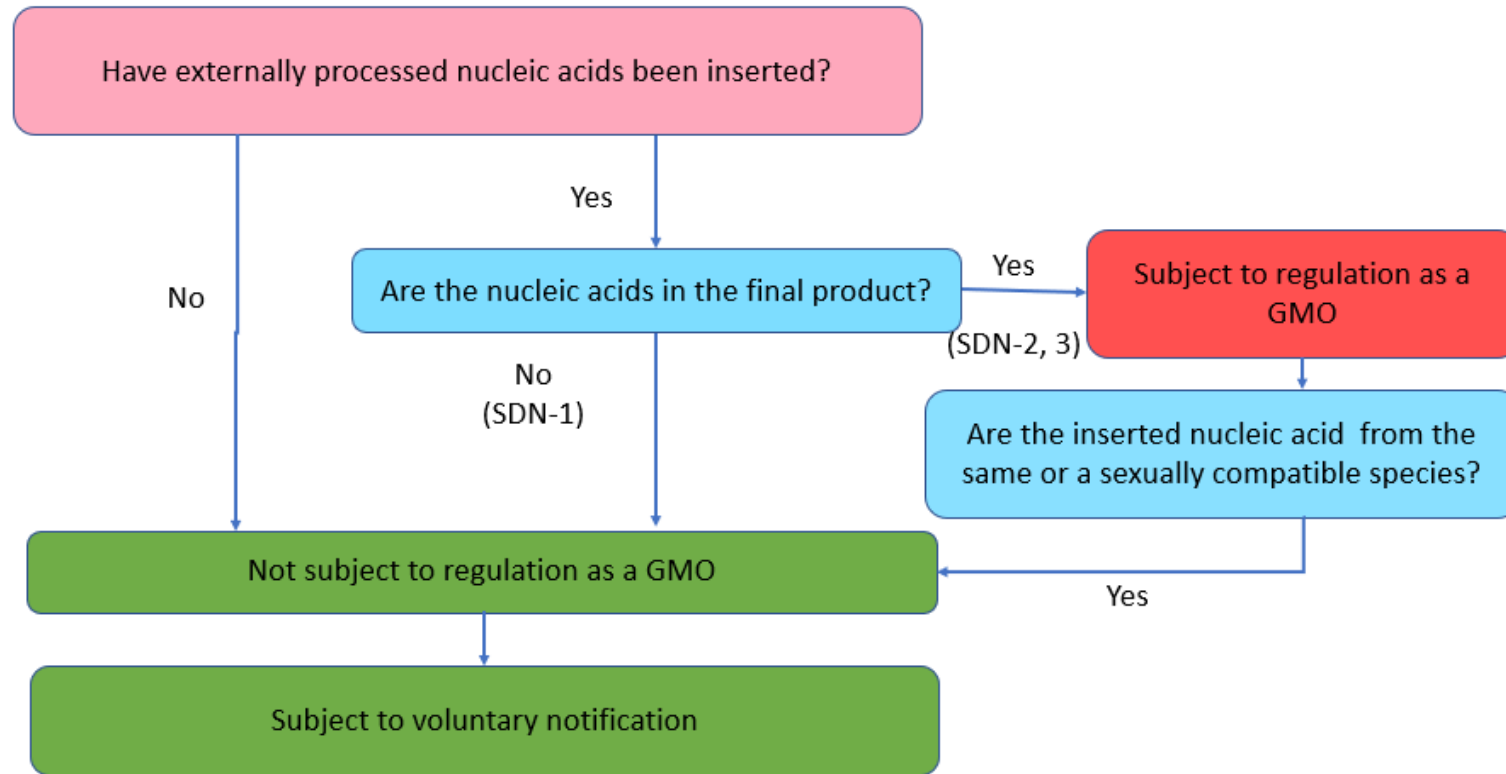
Plants 2022, 11(19), 2538,
36pp; <https://doi.org/10.3390/plants11192538>

- ¹ Crop Biotechnology Research Group, Murdoch University, Perth WA 6150, Australia; m.jones@murdoch.edu.au; j.fosu-nyarko@murdoch.edu.au; s.iqbal@murdoch.edu.au; adeel.muhammad@hotmail.com
- ² ISAAA-BioTrust Global Knowledge Center on Biotechnology, International Service for the Acquisition of Agri-biotech Applications (ISAAA), Khush Hall, IRRI, Los Banos, Laguna 4031, Philippines; raldemita@isaaa.org
- ³ 4-8-27 Monash University Sunway Campus, Jalan Lagoon Selatan, Bandar Sunway, 41,650 Petaling Jaya, Selangor, Malaysia; maha@bic.org.my
- ⁴ Japan Plant Factory Association; mkasai@npoplantfactory.org
- ⁵ Research Center of Biology and Agriculture, University of Science and Technology Beijing, Beijing 100024, China ; weixun@ustb.edu.cn
- ⁶ National Biosafety Committee of Genetically Engineered Products (KKH-PRG); Research Center for Testing Technology and Standards, National Research and Innovation Agency (BRIN); bambang.prasetya@gmail.com
- ⁷ Research Center for Genetic Engineering, Research Organization for Life Sciences and Environment, National Research and Innovation Agency (BRIN); saty002@brin.go.id
- ⁸ Australian Seed Federation, 20 Napier Cl, Deakin, Canberra, ACT 2600, Australia; omewett@asf.asn.au
- ⁹ National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad, Pakistan; shahidmansoor7@gmail.com; jawad_awan@outlook.com
- ¹⁰ Crop Biotech Center, Philippine Rice Research Institute, the Philippines; rlordonio@gmail.com
- ¹¹ Sri Balaji Vidyapeeth University, Pondicherry, 607402, India; raghudbt@gmail.com
- ¹² MGM Advanced Research Institute Pondicherry; 607402, India; abhijit2talk@gmail.com
- ¹³ John Innes Centre, Norwich, Research Park, Norwich, UK; penny.hundleby@jic.ac.uk
- ¹⁴ Biotechnology Alliance Association, Thailand; niponiamsupasit@yahoo.com
- ¹⁵ Regulatory Affairs Manager, Seeds Asia-Pacific, BASF Australia Ltd.; kay.khoo@basf.com
- * Correspondence: m.jones@murdoch.edu.au; Tel. +61 (0)414239428

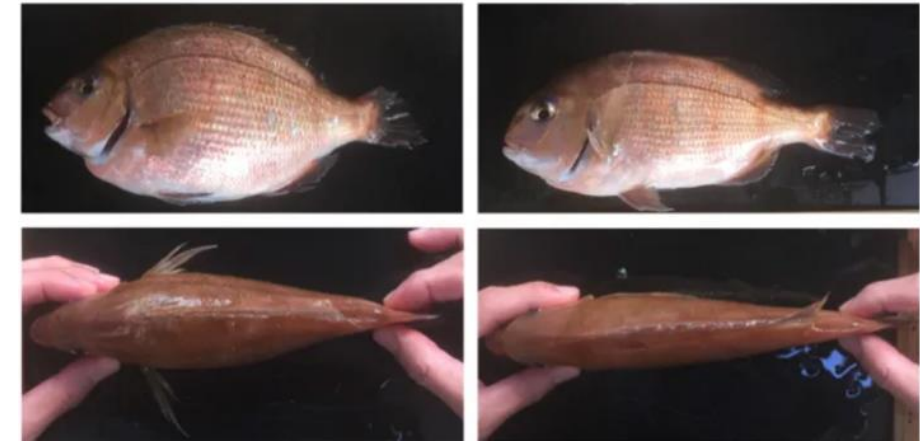
Pathways to de-regulation of GEd products in Australia (SDN-1 only)



Pathways to de-regulation of GEd products in Japan (SDN-1 and 2)



Red sea bream

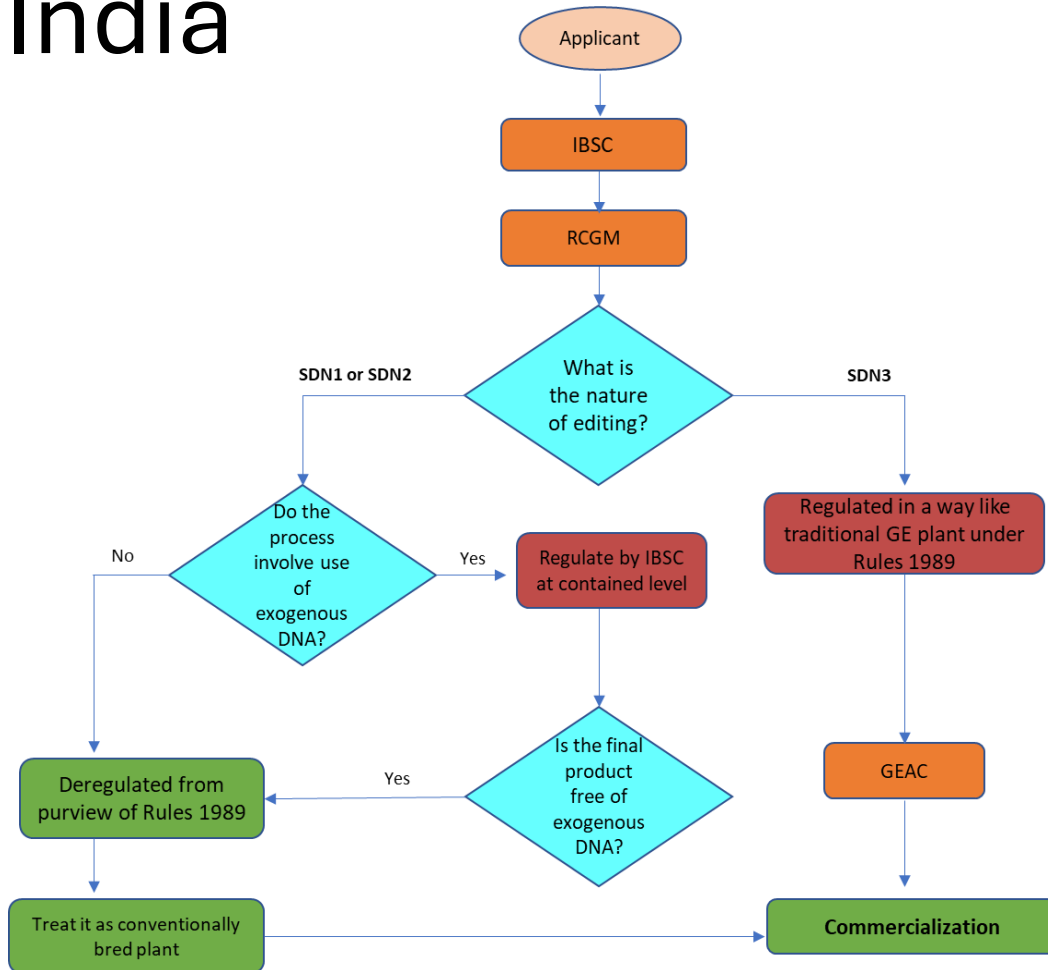


Sicilian Rouge high GABA tomatoes

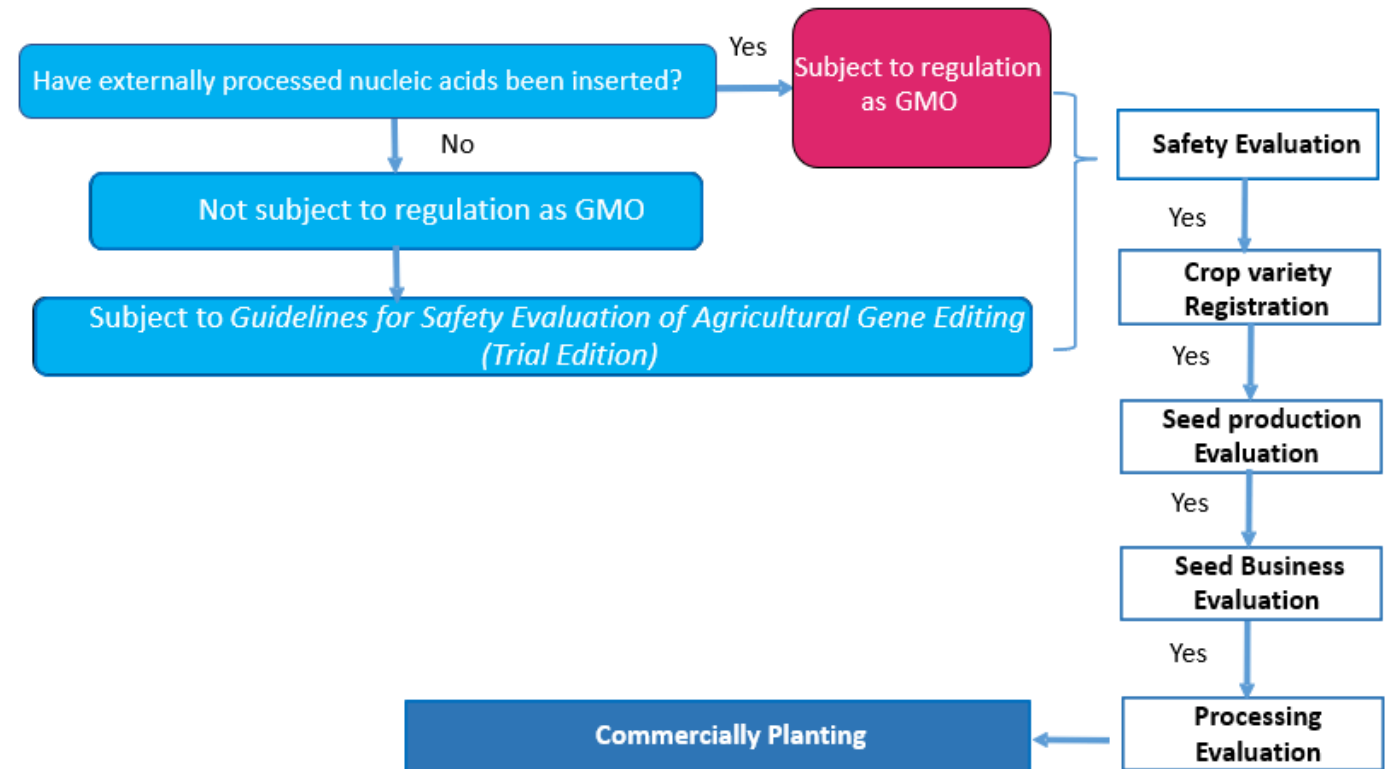


Pathways to de-regulation of GE products in India (SDN-1 and 2) and China (evolving)

India



China



Genetic Technology (Precision Breeding) Act 2023 for plants in England - 3rd March 2025

- ‘This legislation is crucial for unlocking the potential of precision breeding to develop more nutritious, sustainable and environmentally friendly crops’
- ‘With little progress now expected on the stalled gene editing file at the EU until 2026 at the earliest... Britain has a golden opportunity to steal a march on our European counterparts, and to deliver on the Government’s vision to make the UK a science and technology superpower’
- ‘...hopes of a three-way agreement between the EU Commission, Council and Parliament are now fading after the Council of Ministers repeatedly failed to reach a common position on the Commission’s proposals, while MEPs voted in February to ban the use of patenting in gene edited plants – effectively torpedoing the incentive for innovators to invest’

North and South America, Africa

Regulations in place to approve growth of GEd plants in the Americas:

North America

- United States
- Canada

South America

- Argentina
- Brazil
- Chile
- Paraguay
- Uruguay
- Colombia
- Honduras
- Guatemala

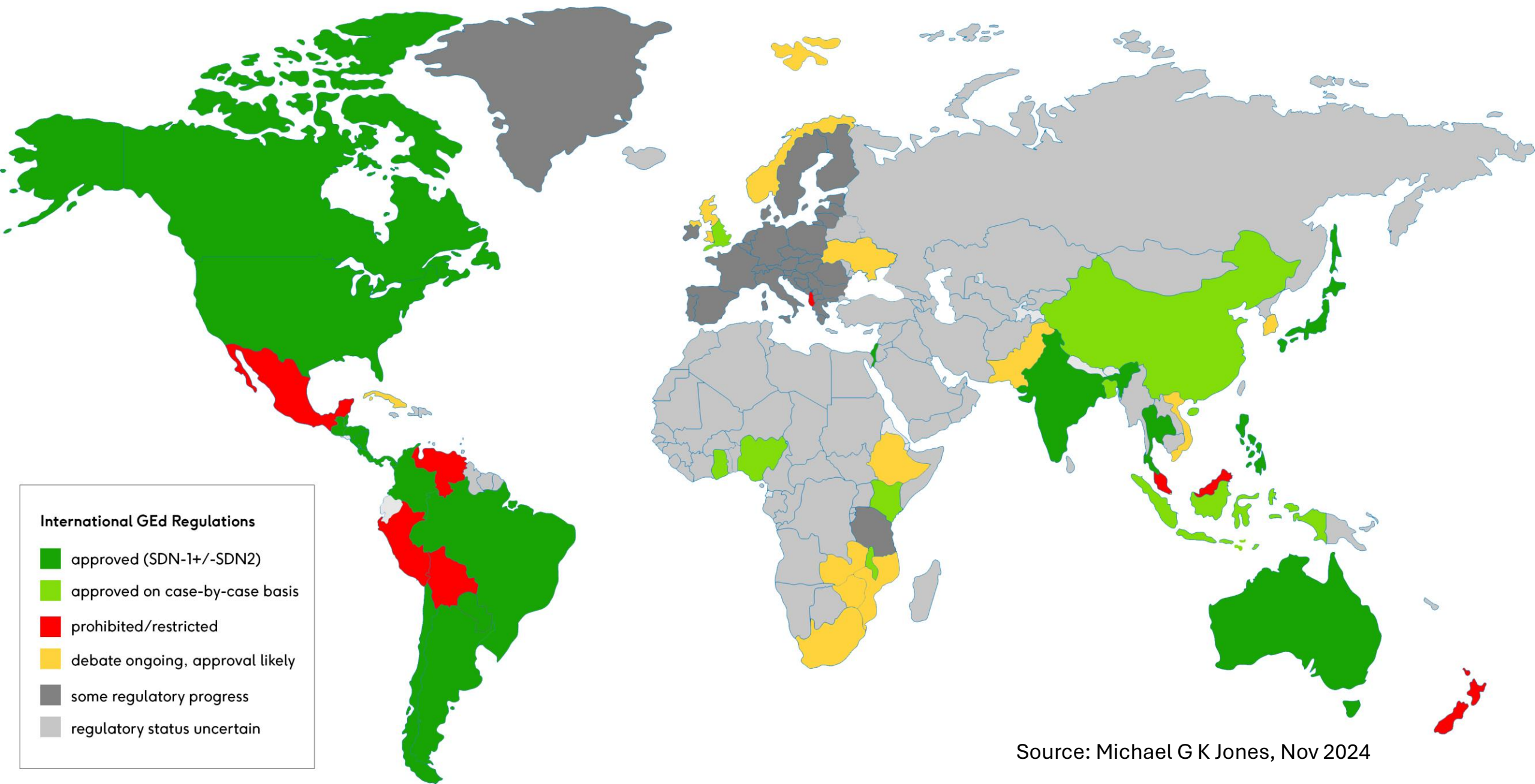
Regulations in place/developing for growth of GEd plants in Africa

- Nigeria
- Ghana
- Kenya
- Malawi
- Uganda
- Zimbabwe
- Ethiopia

- Mozambique
- Botswana

- South Africa (as GMOs at present)

The current global status of Gene-Editing Regulations – November 2024



Source: Michael G K Jones, Nov 2024

So, when will it be possible to trade gene-edited produce?

- **North America** – USA and Canada - now
- **South America** – LATAM countries - Argentina, Brazil, Chile, Paraguay, Uruguay, have own GEd trade agreement
- **EU** – well...currently GEd produce regulated as GMOs, however, the European Commission passed SDN-1, elections, new parliament, now some revised proposals, maybe passed in **2026**
- **UK** – **England** has liberal GEd regulations, but not Wales, Scotland and Northern Ireland
- **Asia-Pacific** – trade in GEd produce now starting between **Japan, Philippines, Thailand**
- **African countries** – potentially Nigeria, Ghana, Kenya, Malawi, with Botswana, Ethiopia, Sudan and Eswatini (Swaziland), Mozambique, S Africa?, establishing GEd policies



Golden rice – Philippines

m.jones@murdoch.edu.au

+61 (0)414239428



Support/collaborations: Australian Commonwealth Government (DAFF), COGGO, Bioceres, GB, ISAAA, MABOC, CropLife; APAARI, AgrifuturesAustralia, ARC