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Office of the Gene Technology Regulator

# Regulation of GM and gene edited animals – Australian situation and other reflections

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**Asia Oceania Animal Biotechnology Regional  
Virtual Workshop**

*31 August 2021*



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## Overview

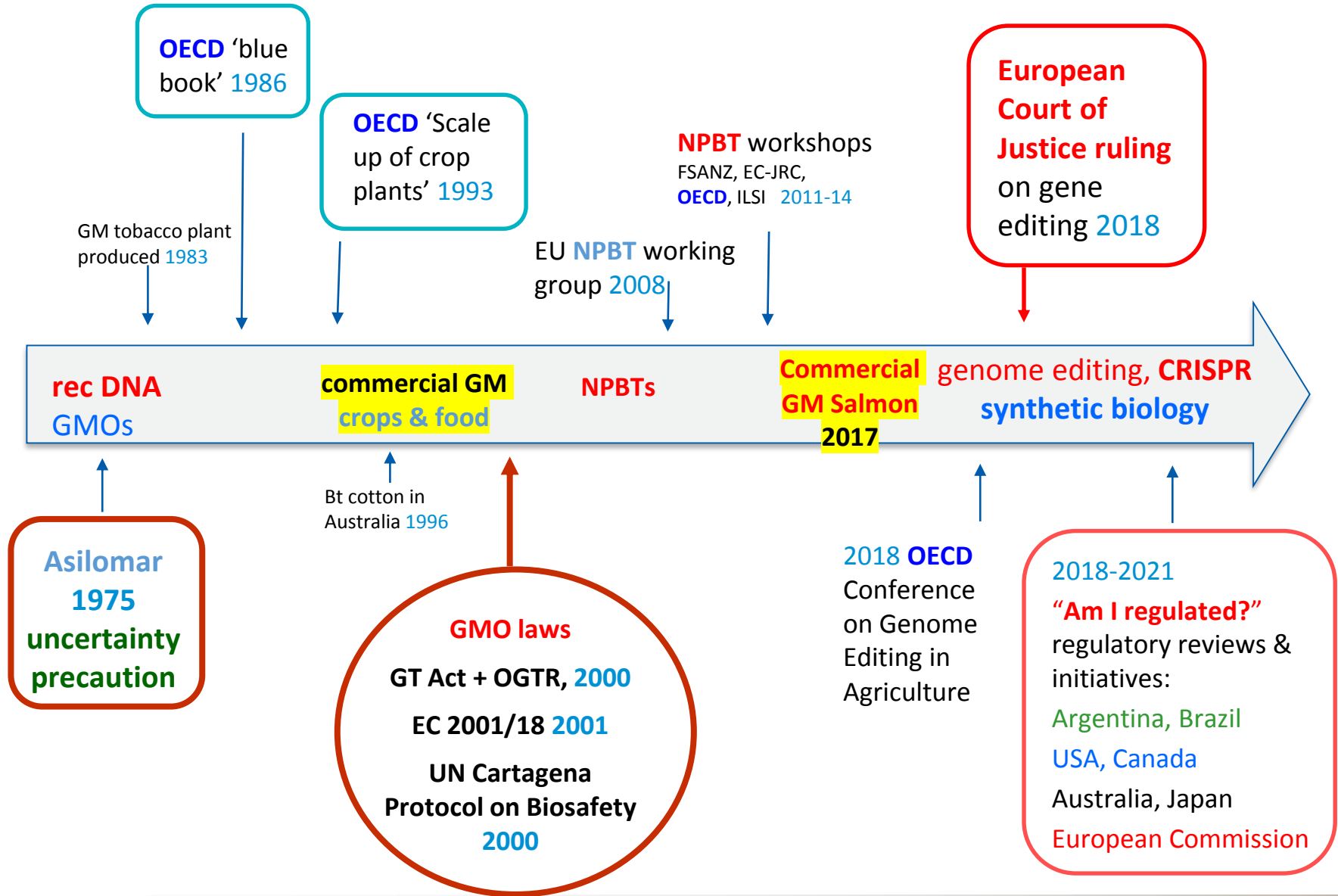
- **Key message – legal vs scientific definitions**
- **Background to genome editing & regulation**
- **Definitions & Principles**
- **Global state of play & implications**
- **Australia & genome editing – GMOs**

**No GM animals approved in Australia  
for field trial or commercial production**

*Disclaimer – my analysis, not legal advice*



# History – rDNA to genome editing





## Context – rDNA, GMO (& GM food) laws

### Concepts for rDNA laws c. 2000

- new technology – precautionary, ‘pre-market assessment’
- exclude ‘traditional’ breeding, mutagenesis techniques

### Regulatory approaches

GMO-specific laws – **process ‘trigger’**  
technology, ~rDNA

*e.g.*

EU, Australia,  
Argentina, Korea, *et al.*

Novelty – **product ‘trigger’**

*\*process may be considered*

Canada\*,  
New Zealand\*

Adapt existing laws

*\*process &/or product*

USA

(*e.g.* pest sequences)

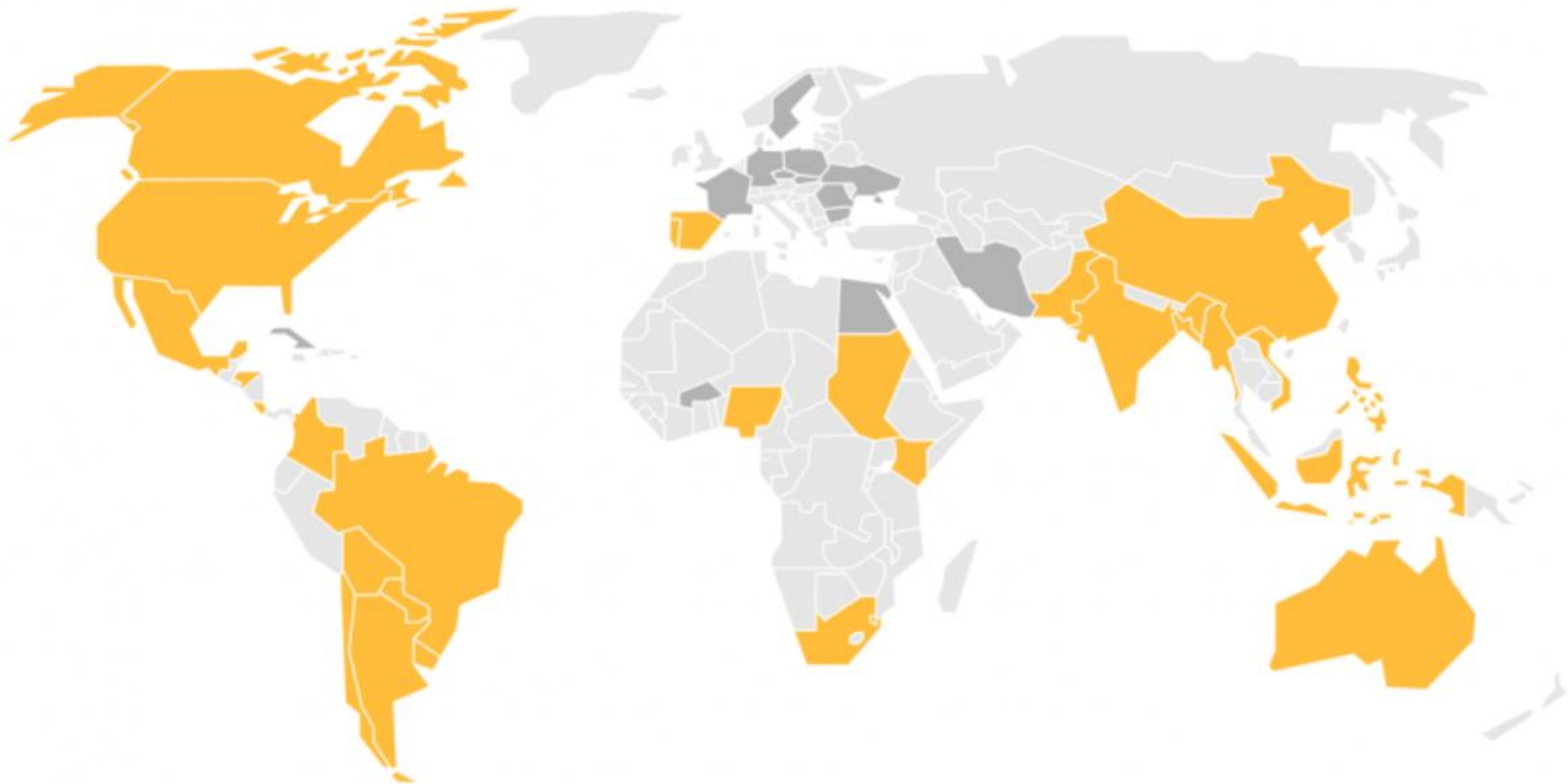


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# Context – GMO production internationally & rapid application of new genome editing techniques

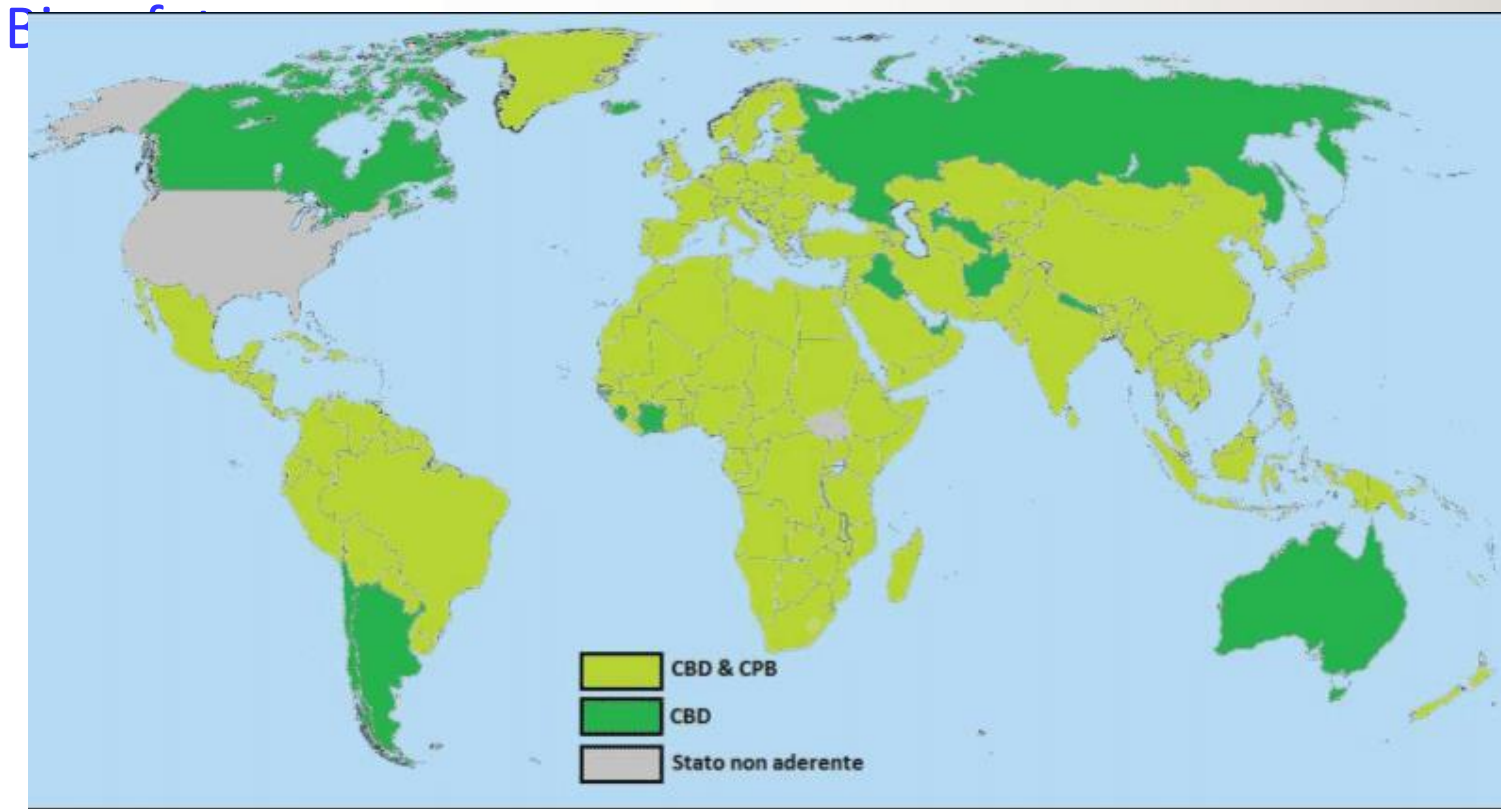


Genetic Literacy Project, April 2020



## Context – international agreements & GMOs

Parties to Cartagena Protocol on



Mariotti (2016)

[www.researchgate.net/publication/311965379\\_La\\_biodiversita\\_e\\_i\\_suoi\\_hotspot\\_in\\_Italia\\_e\\_altrove](http://www.researchgate.net/publication/311965379_La_biodiversita_e_i_suoi_hotspot_in_Italia_e_altrove)



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## Context – international regulatory landscape

- Different countries
  - Different laws & legal systems
  - Different definitions
  - Different approaches, policies, publics
- ... can lead to different regulatory outcomes:*
- what is regulated and how?



# The 'problem' - transgenics to genome editing

2000

'recombinant DNA,  
genetic modification'



2021

'genome editing'



transgenics

cisgenesis,  
intragensis

oligo-directed  
mutagenesis (ODM),  
NPBTs  
CRISPR, ZFN (SDNs)

= 'GMO'



= 'GMO'







# The 'problem' - transgenics to genome editing

2000

- 35S-transgene-nos

**Different** definitions

resulted in

**same** regulatory outcomes

= GMO 'everywhere'

= harmonised (practically)

2021

- NPBT, genome edited

**Different** definitions

may result in

**different** regulatory outcomes

= **asymetry** – GMO in country A

**but** not GMO in country B

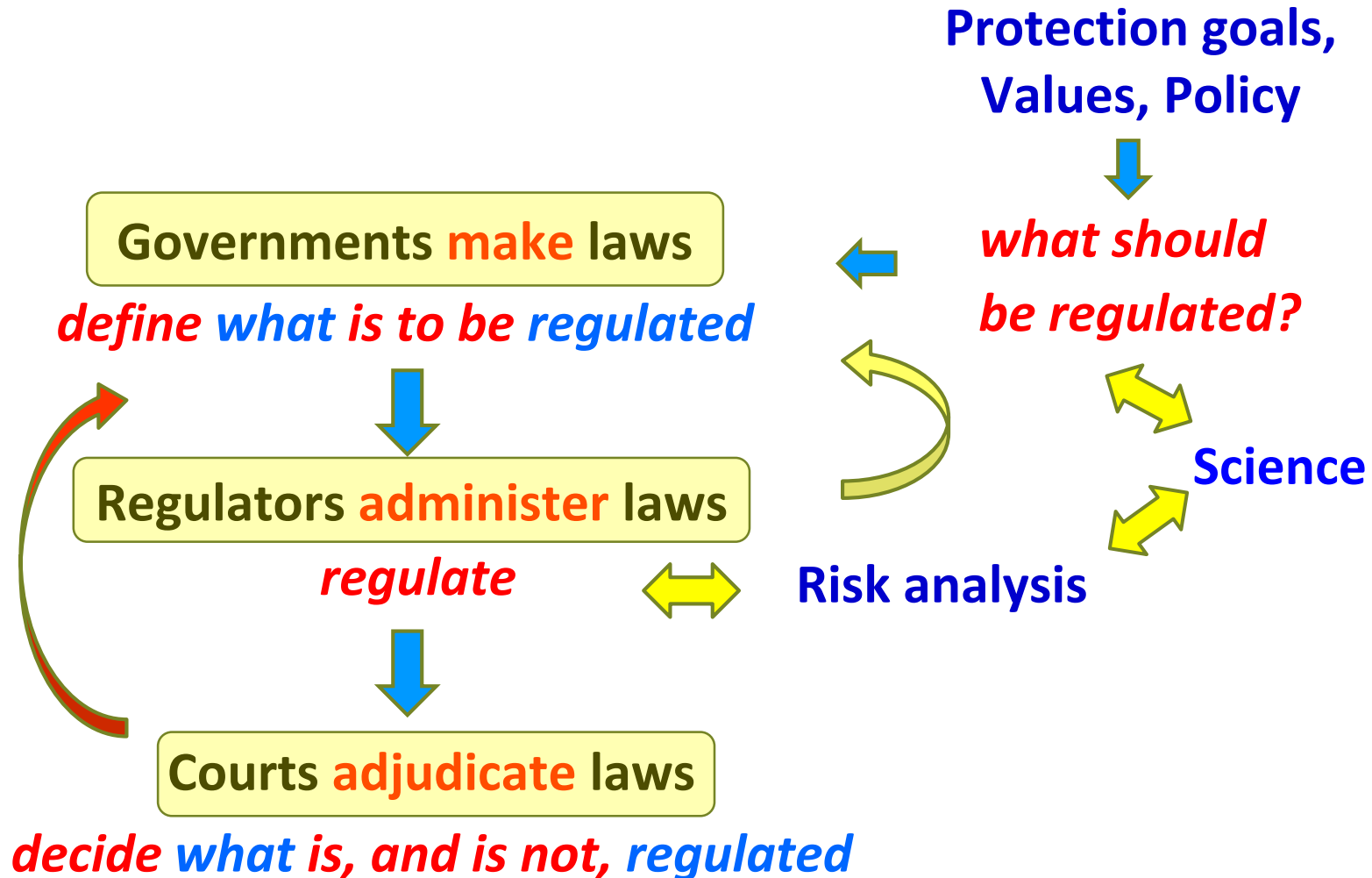
**uncertainty** in definitions = **GMO ??**

potential **identity** with naturally occurring mutants

**risk** proportionate regulation ?



# Regulation – roles & responsibilities





# Designing/amending regulation - principles

Broad consultation and discussion



Risk,  
Science



Legislatio  
n

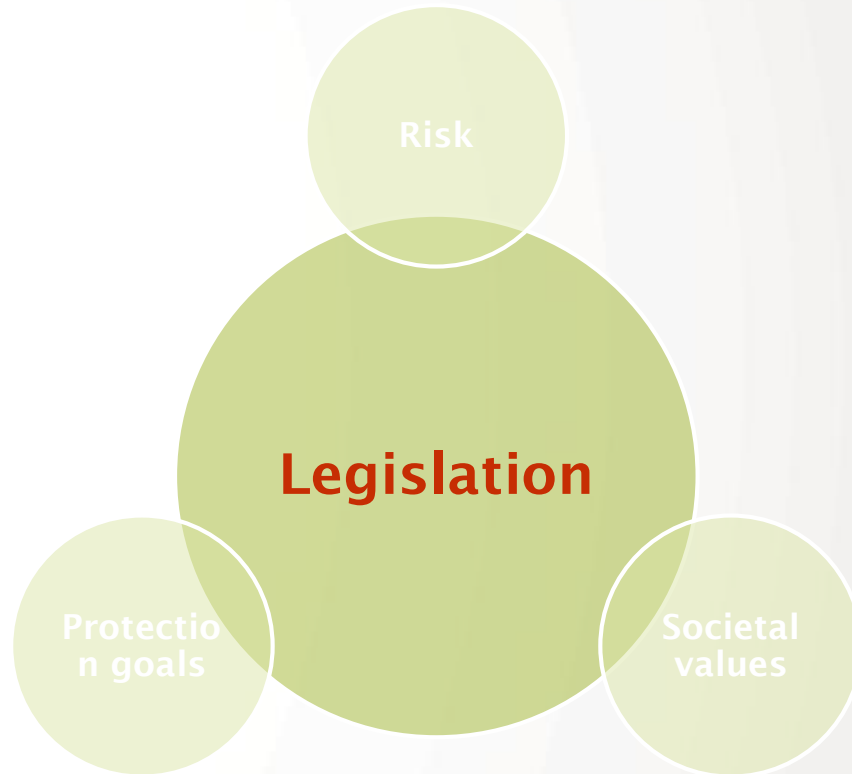
Protectio  
n goals

Societal  
values





# Administering regulation - principles



**Fair and equitable application of laws**

**Compliance**

**cannot interpret laws:**

“this is what it *meant to say*”

“this is what it *should have said*”



## ***Definitions – e.g. Australia's Gene Technology Act***

**GMO = organism modified by gene technology** (broad capture)

= organism declared a GMO\*

≠ organism declared **not** a GMO\*

**gene technology = any technique for modification of genes**  
or other genetic material (broad capture)

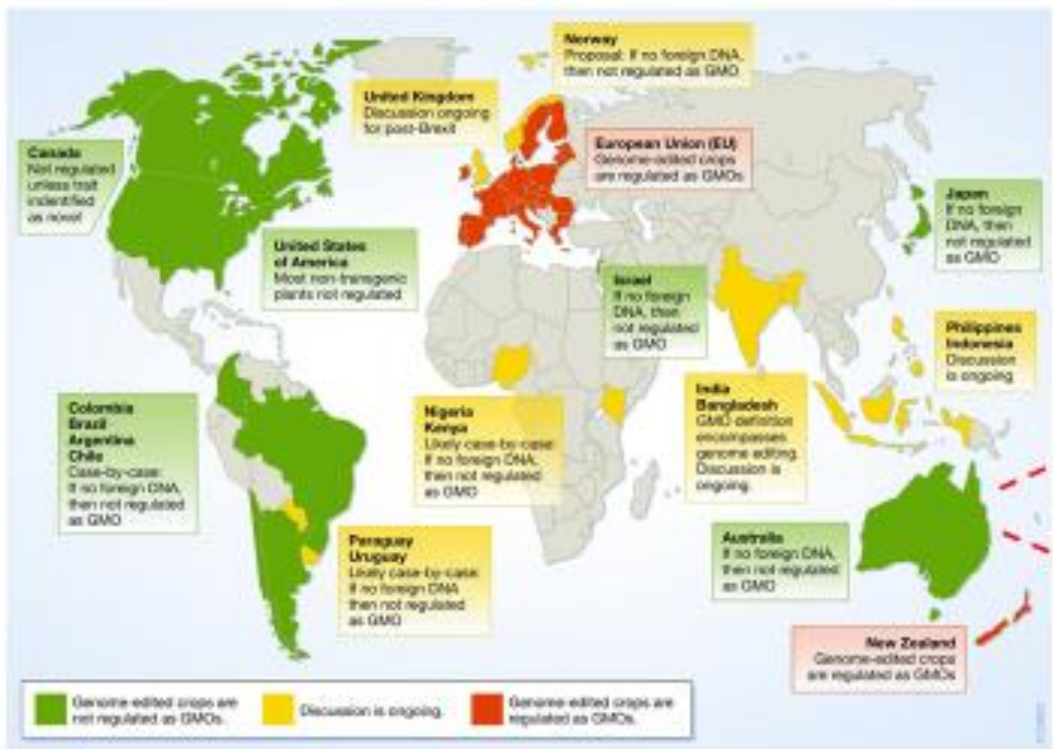
≠ sexual reproduction, homologous recombination

≠ any **technique** declared **not** gene technology\*

\* GT Regulations – inclusions & exclusions



# Regulatory status – pitfalls of overviews



“Words matter ...”

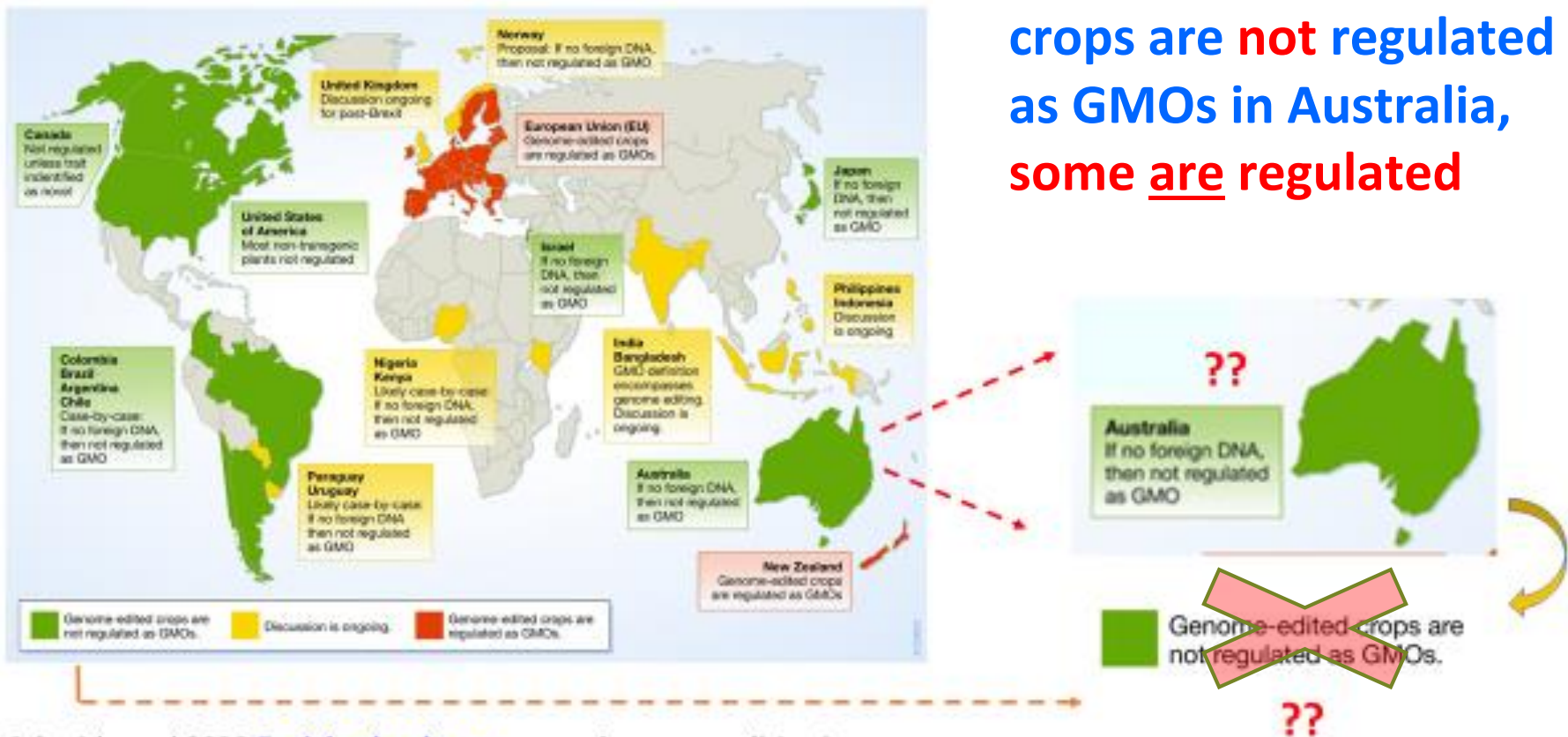


Schmidt et al 2020 [Evolving landscape](#) around genome editing in agriculture. EMBO Rep, DOI: (10.15252/embr.202050680)



# Regulatory status – pitfalls of overviews

*Some* genome edited crops are **not** regulated as GMOs in Australia, **some** are regulated



Schmidt et al 2020 [Evolving landscape](#) around genome editing in agriculture. EMBO Rep, DOI: (10.15252/embr.202050680)



## Definitions

### *International definitions - Cartagena Protocol & CODEX*

(g) “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) “Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) “Modern biotechnology” means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;





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# Regulatory reactions to genome editing

## Legal Decisions / clarifications

- European Court of Justice, 2018
- New Zealand High Court, 2014

genome editing = GMO

## Regulatory reviews, changes, approaches

- Argentina & Brazil – pre-assessment viz. GMO or not GMO
- Australia, Japan – reviews, regulatory changes / clarifications
- Canada – May 2021 – consultation on guidance
- USA – “am I regulated”, new exclusions

## International – Convention on Biological Diversity

- ‘synthetic biology’ (ongoing debates)



# Australia & genome editing – **GMOs** – definitions & exclusions

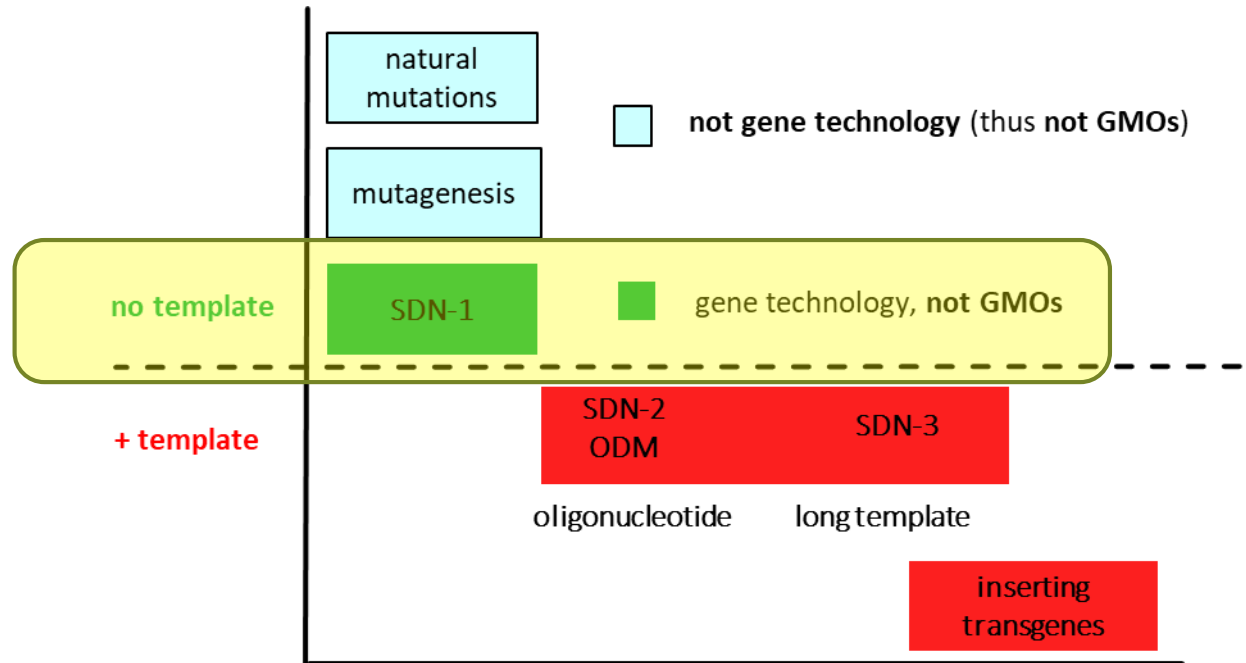
## Process features

targeted changes:  
 unguided repair

template guided  
 repair

2019 changes to  
 GT Regulations:

***SDN-1 exclusions***



Extent of sequence changes →

point mutations,  
 deletions

long sequences inserted

## Product features



# Australia and genome editing regulation

## GMOs

**2019** – **GT Regulations** amended to clarify regulation of **SDN-1**, **SDN-2** (following a *technical review 2017-18*)

## **2018** – **Policy review GT Act**

“... recommends updating, where required, the **existing definitions** in GT Act to **clarify the scope of regulation** *in light of ongoing technical advances*. ... take into account ... ongoing work internationally.”

***work ongoing ...***

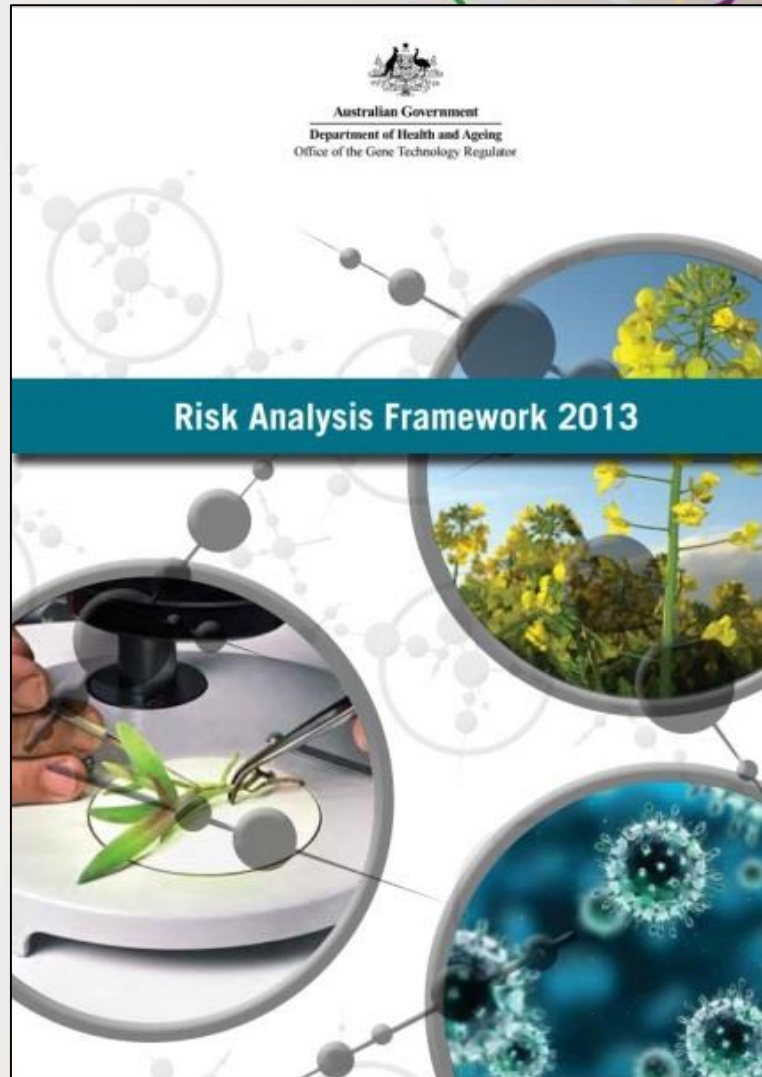
*More info* – **2020 Consultation Regulatory Impact Statement & Explanatory Paper**  
(definitions)

<https://consultations.health.gov.au/best-practice-regulation/gene-technology-scheme-cris/>



## Australian GMO risk assessment

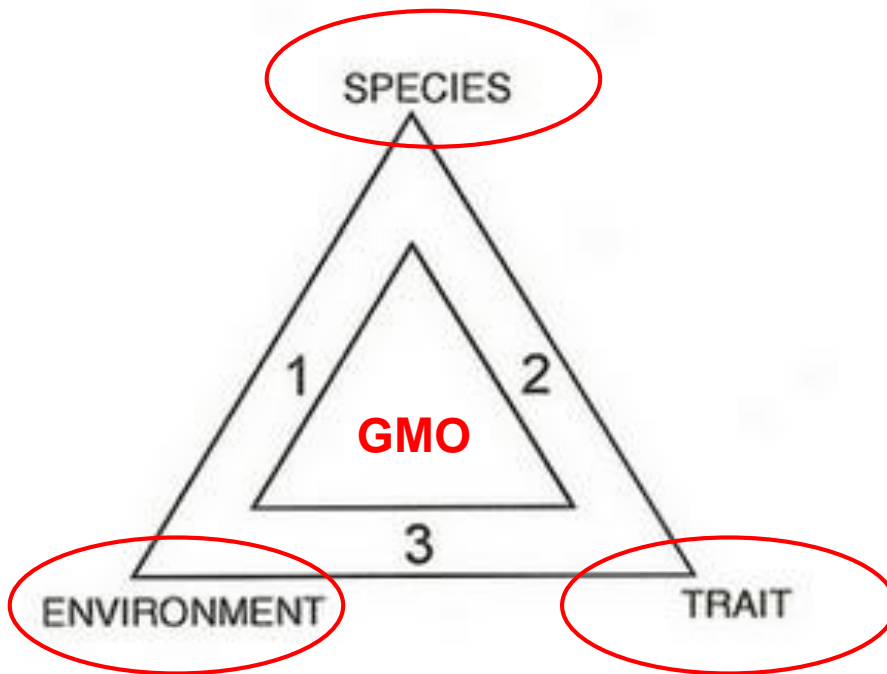
- Adapt / adopt existing guidance  
*eg* Australian Standards, OECD
- Define terms and concepts
- Qualitative, comparative assessments
- Focus on **harm** and **plausible pathways to harm**
- Distinguish **events vs harm**
- **Regulatory science to support decision making on risk – need to know vs nice to know**





# OECD Guidance & Principles

[www.oecd.org/science/biotrack/](http://www.oecd.org/science/biotrack/)



Environmental risk assessment  
of GMOs:

*interaction* of

- **biology** of parent organism
- GM **trait**
- receiving **environment**
- intended **use**

- **familiarity**
- **case by case**
- **step by step**



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## OECD & genome editing – risk assessment

Working Party for the Harmonisation of Regulatory Oversight in Biotechnology

2014 – Workshop Environmental Risk Assessment (ERA) of products derived from New Plant Breeding Techniques

“**Current guidance** and tools for ERA of transgenic plants are **applicable** to plants developed by NPBTs, *where such ERA is required.*”

2014 – present – ongoing information sharing on experiences with risk assessment / regulation of NPBT / genome editing

<https://www.oecd.org/chemicalsafety/biotrack/> -

*Recent Developments in Delegations on Biosafety (2021)*



# GMO environmental risk assessment considerations

- is the parent organism a **weed / pest / pathogen** ?
- **phenotype of the GMO, receiving environment**
- will the modification **increase weed/pest potential / pathogenicity** ?
- will the GMO be **toxic / harmful** – **species specificity** ?
- will the modification **confer a selective advantage** ?
- **spread in space and time** ? (GMO vs parent)
- **gene transfer** (**occurrence vs harm**) ?
- can the parent / GMO **be controlled** ?

GT Regs +  
application  
forms

GRAFO



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## Recap – regulatory landscape genome editing

- Genome editing & regulation – **rapid scientific advances**
- Definitions, policy approaches
- Principles – precautionary legislation,
- Global state of play & implications
- Ongoing scientific & regulatory policy debate:  
risks gene edited vs conventional, rDNA

### Key messages:

- **legal vs scientific definitions**
- **regulatory landscape is still evolving**





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