



WEBINAR SERIES:

Regulatory Approaches for Agricultural Applications of Animal Biotechnology

Session 2 • September 2020



Summary of Day 1 of Session 2:

Regulatory approaches to Genome Edited Livestock

- Australia Lisa Kelly
- Argentina Agustina Whelan
- Brazil Rubens Nascimento
- Japan Mai Tsuda (Ryo Ohsawa)
- Norway Arne Holst-Jensen
- African Union Silas Obukosia
- Kenya Dornington Ogoyi
- South Africa Hennie Groenewald
- Argentina/Brazil Agustina & Maria Dagli - some real examples

Diversity... commonality and harmony

- Are the current regulations / standards fit for purpose / out of date ?

Lisa

Why the review?



- Unclear if foods derived using NBTs are captured by current definitions
- FSANZ constrained from providing interpretive advice in relation to the scope of definitions

Key review questions:

- are the definitions in the *Australia New Zealand Food Standards Code* for 'food produced using gene technology' and 'gene technology' fit for purpose given the emergence of NBTs
- is pre-market safety assessment of NBT foods justified based on risk

17/09/2020



Arne

The Gene Technology Act (Genteknologiloven) regulates contained use and release of GMOs

- Law entered into force in 1993
 - almost unchanged since
- Is it adequate for present technological and political realities?
 - especially in light of genome editing?

Hennie

THE REGULATORY IMPLICATIONS OF NEW BREEDING TECHNIQUES

Scope & purpose



- evaluate risk / benefit implications
- ascertain applicability of existing legislation

Diversity... commonality and harmony

- The regulations are sufficient (esp. in relation to Cartagena Protocol)

Hennie

Findings



4. GMO Act sufficient > regulation threshold = genetic variation beyond that which may occur naturally.

Mai (Ryo)

Environmental Safety of Genome-Edited organisms under the Cartagena Act

In February 2019, the Japanese government defined **genome-edited final products** derived by modifications of SDN-1 type (**directed mutation without using a DNA sequence template**) as not representing “**living modified organisms**”

according to the Japanese Cartagena Act.

Martin

LMO definition from Cartagena Protocol

- ◇ "**Living modified organism**" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- ◇ "**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;

Diversity... commonality and harmony

- Definitions are the key

Martin

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Lisa

Next steps - revising definitions

- *P1055 Defintions for gene technology and new breeding techniques*
- Work commenced in February 2020
- First public consultation in early 2021

Objectives for amending the definitions:

Improve clarity about what foods are captured for pre-market approval

Better accommodate new and emerging technologies (future proofing)

Regulate NBT foods in a manner that is commensurate with the risks they pose

Maria

Definition of GMO by the brazilian biosafety law 11.105

- Article 3. Under this Law, it shall be considered:
 - I – an organism: each and every biological entity that is capable of reproducing or transferring genetic material, including virus and other classes that may be made known;
 - II – deoxyribonucleic acid - DNA, ribonucleic acid - RNA: genetic material which contains determining information about transmissible hereditary characters to progeny;
 - III – **recombinant DNA/RNA molecules: molecules manipulated outside live cells through changes made to natural or synthetic DNA/RNA segments that can multiply in a live cell, or yet, DNA/RNA molecules resulting from this multiplication; DNA/RNA synthetic segments equivalent to natural DNA/RNA are also considered;**
 - **IV – genetic engineering: the activity of manipulating DNA/RNA recombinant molecules;**
 - **V – genetically modified organism - GMOs: an organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique;**
 - VI – GMO by-product: a product obtained from a GMO and that is not capable of autonomously replicating, or that does not contain a feasible GMO form;
 - VII – human germinal cell: the mother cell responsible for forming gametes which are found in the female and male sexual glands and their direct progeny in any ploid degree;
 - VIII – cloning: an asexual reproduction process, artificially produced, based on a sole genetic patrimony, by using or not genetic engineering techniques;
 - IX – cloning for reproductive means: cloning the end purpose of which is to make an individual;
 - X – therapeutic cloning: cloning the end purpose of which is to produce embryonic stem cells for therapeutic purposes;
 - XI – embryonic stem cells: embryonic cells that are capable of modifying the cells of any organism tissue.

Diversity... commonality and harmony

- Barriers to innovation = loss of potential benefit

Silas

Hennie

Impact of genome editing

Productivity	SME/public	Trait/product
>2x higher	90% frequency	↑up diversity

Timely & fit-for-purpose regulatory frameworks drive local innovation

Image result for science innovation park model

Biosafety SA

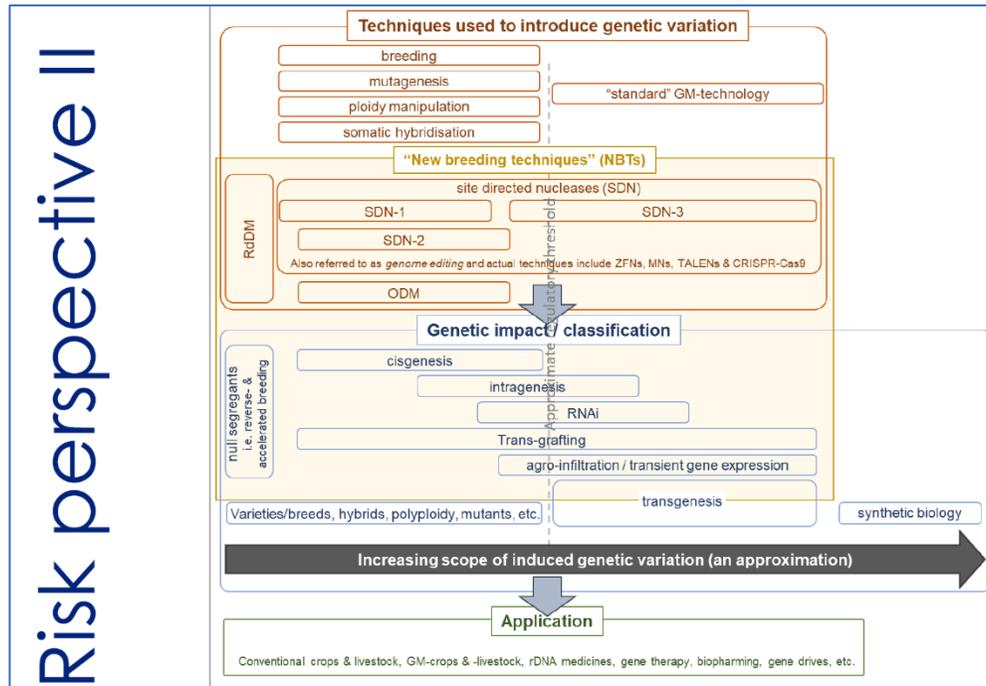
- Need To harness Emerging Technologies
- First focus was on gene drives for control and elimination of malaria
- Genome Editing Technologies
- Member states requested capacity strengthening in Genome Editing

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

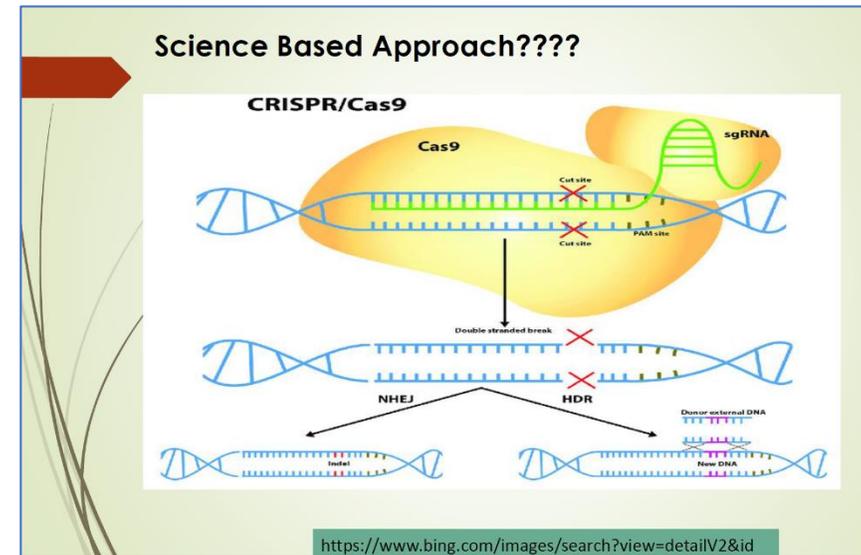
Diversity... commonality and harmony

- Risk is the key – real / measurable / perceived
- How to use science to correctly evaluate risk?

Hennie



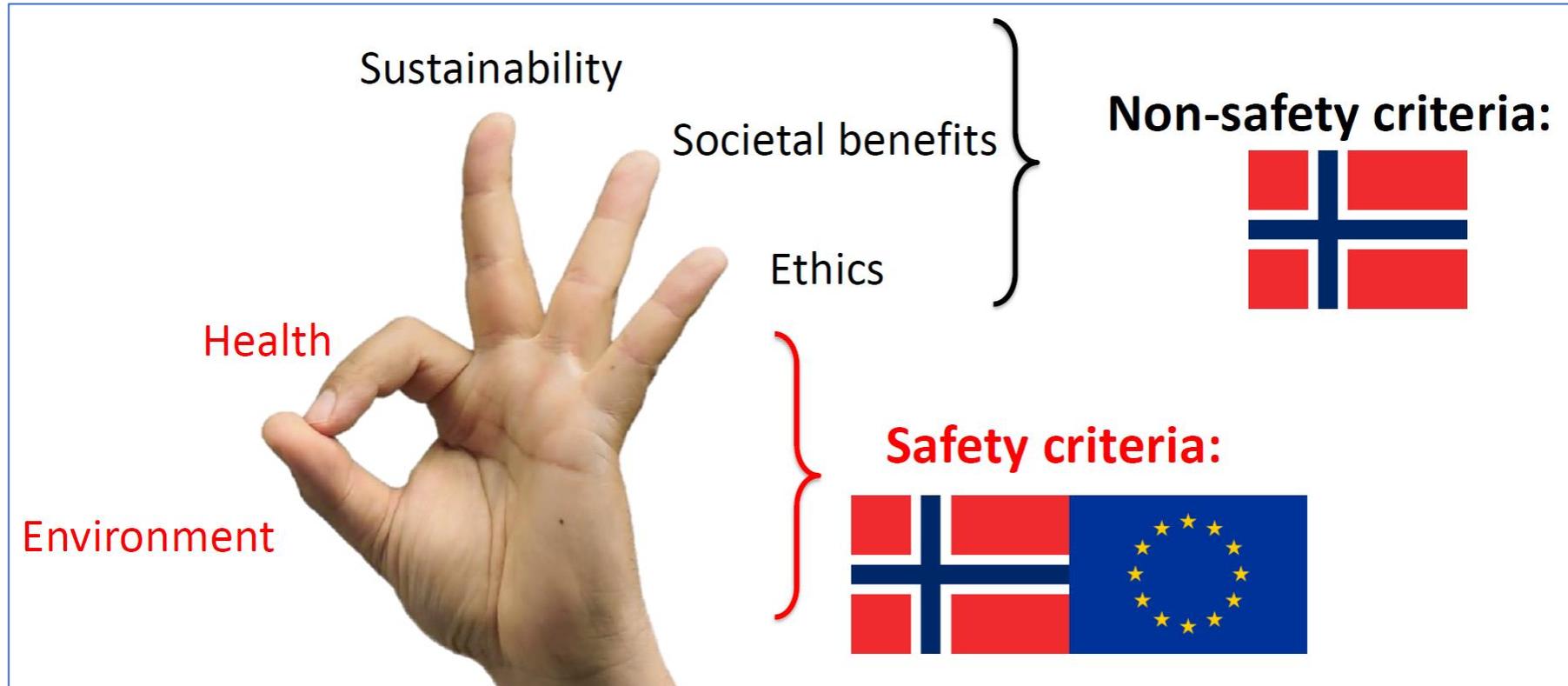
Silas



Diversity... commonality and harmony

- Is benefit a consideration?

Arne



Diversity... commonality and harmony

- What is the trigger for regulation?
 - Process
 - Product
- What level of regulation is appropriate?
 - Risk tiering
- Public confidence is essential
- NEW Breeding Technologies – implication: breeding is a technology?

Mai (Ryo)

Handling of SDN-2 by MHLW and MOE

MHLW,

✓ **Product-based judgment**

✓ As a product-based evaluation, same regulation of genetically modified foods under the Food Sanitation Act will not be applied to genome editing foods that modified DNA sequences **indistinguishable from natural mutation or conventional artificial mutagenesis**.

MOE,

✓ LMO is defined as “**the organism containing extracellularly processed nucleic acid or its replicate**” according to Cartagena Act.

Definition: Process-based

Arne

is the product to define that internally.

A novel governance framework for GMO		Exempted from regulation	Societal benefit, sustainability and ethics assessed on tiers 1–3
Covered by GMO regulation		Organisms with temporary, non-heritable changes	
TIER 1	Genetically engineered organisms with changes that exist or can arise naturally and can be achieved using conventional breeding methods	Notification (confirmation required)	
TIER 2	Organisms with other species-specific genetic changes	Expedited assessment and approval	
TIER 3	Organisms with genetic changes that cross species barriers or involve synthetic (artificial) DNA sequences	Standard assessment and approval (current requirements)	

Our proposal:

How to communicate effectively

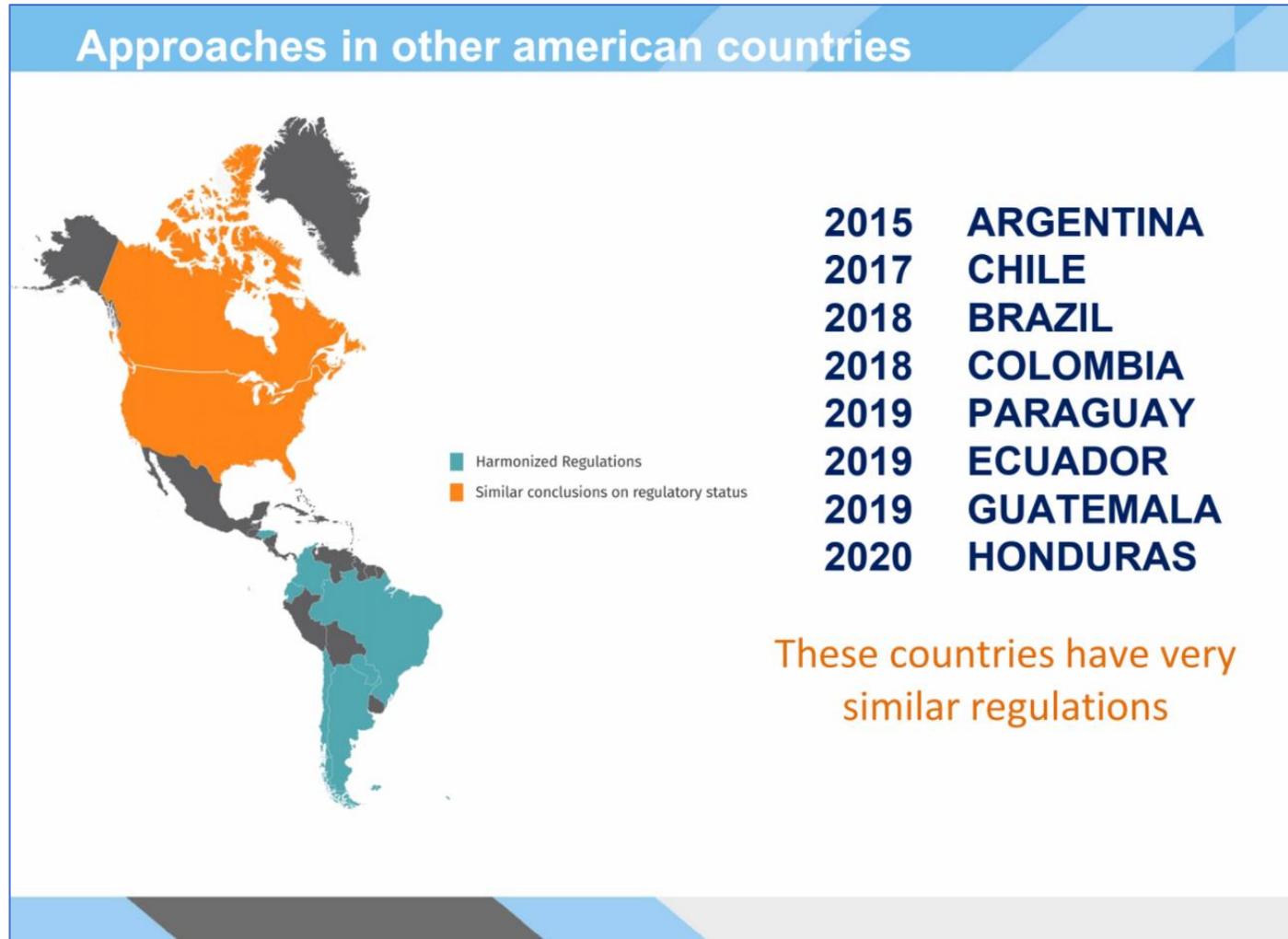


- TRUST > knowledge
- Start with WHY
- Get diverse ALLIES to vouch for sound information
- SEEING is believing!



Diversity... commonality and harmony

Agustina



Arne

