



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- Are the current regulations / standards fit for purpose / out of date ?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

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;

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.

Diversity... commonality and harmony

- Definitions are the key

Martin

LMO definition from Cartagena Protocol

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 - 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;**

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

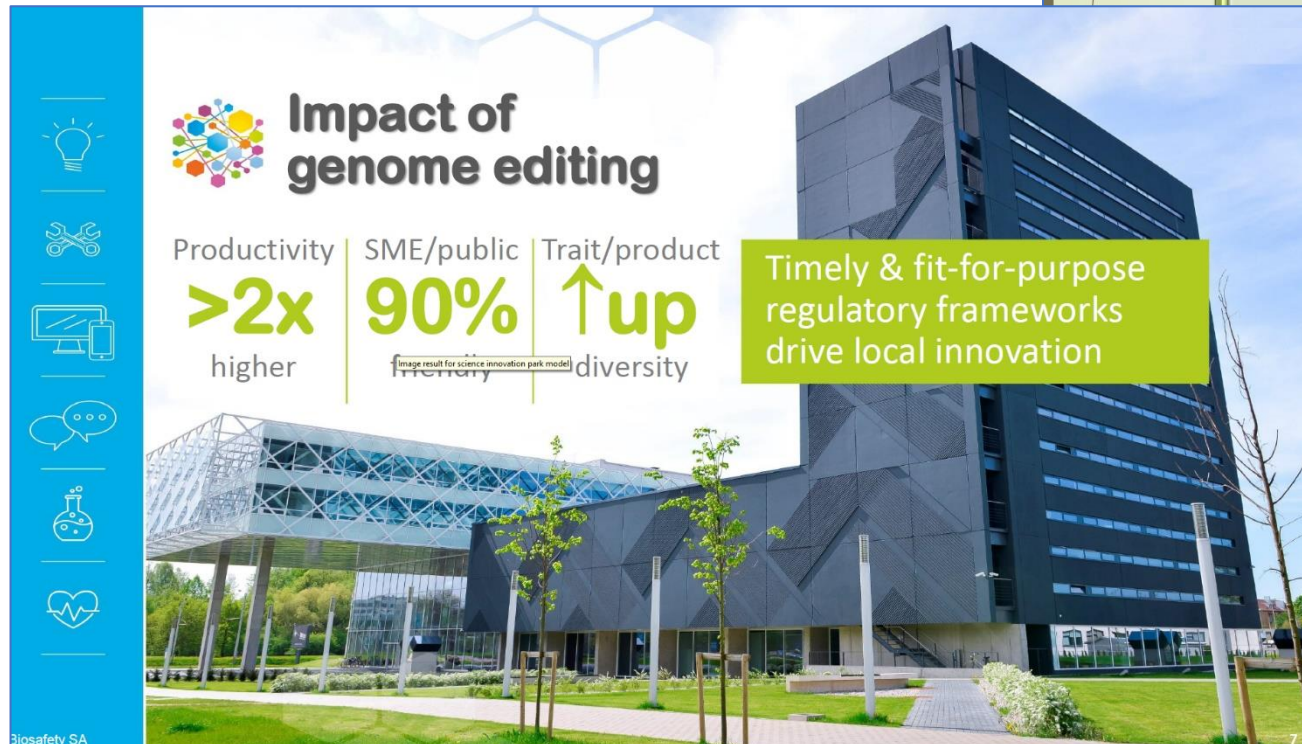
- Article 3. Under this Law, it shall be considered:
- I – an organism: each and every biological entity that is capable of reproducing or transferring genetic material, including virus and other classes that may be made known;
- II – deoxyribonucleic acid - DNA, ribonucleic acid - RNA: genetic material 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



Need To harness Emerging Technologies

First focus was on gene drives for control and elimination of malaria

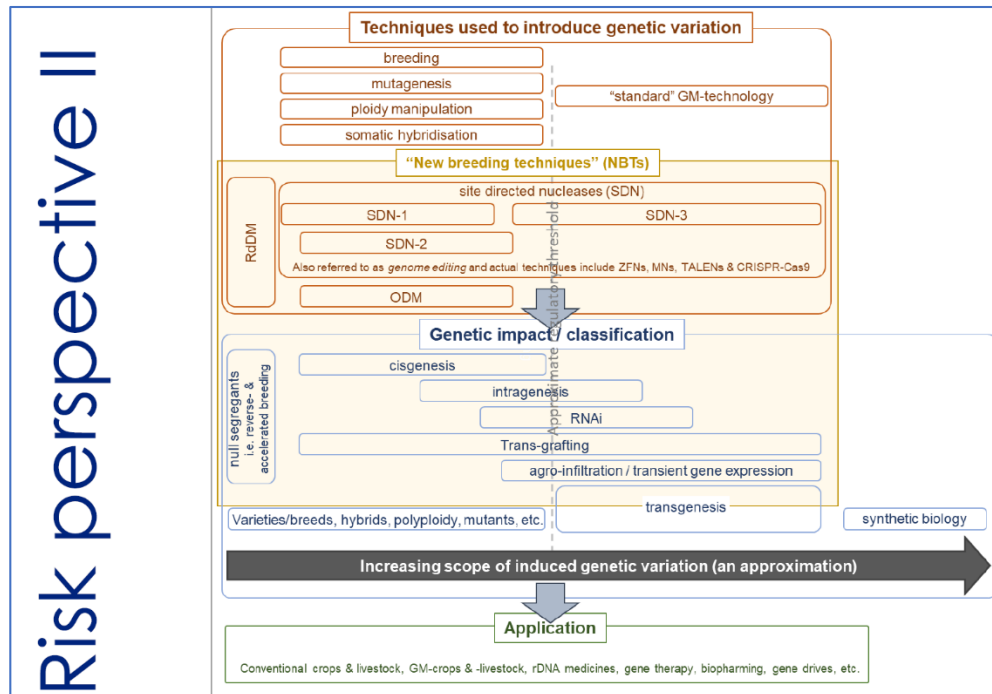
Genome Editing Technologies

Member states requested capacity strengthening in Genome Editing

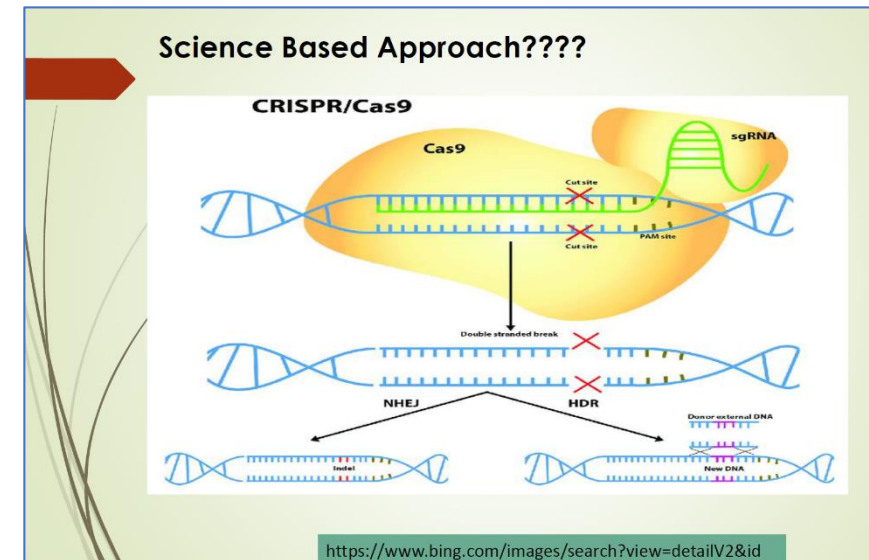
Diversity... commonality and harmony

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

Hennie



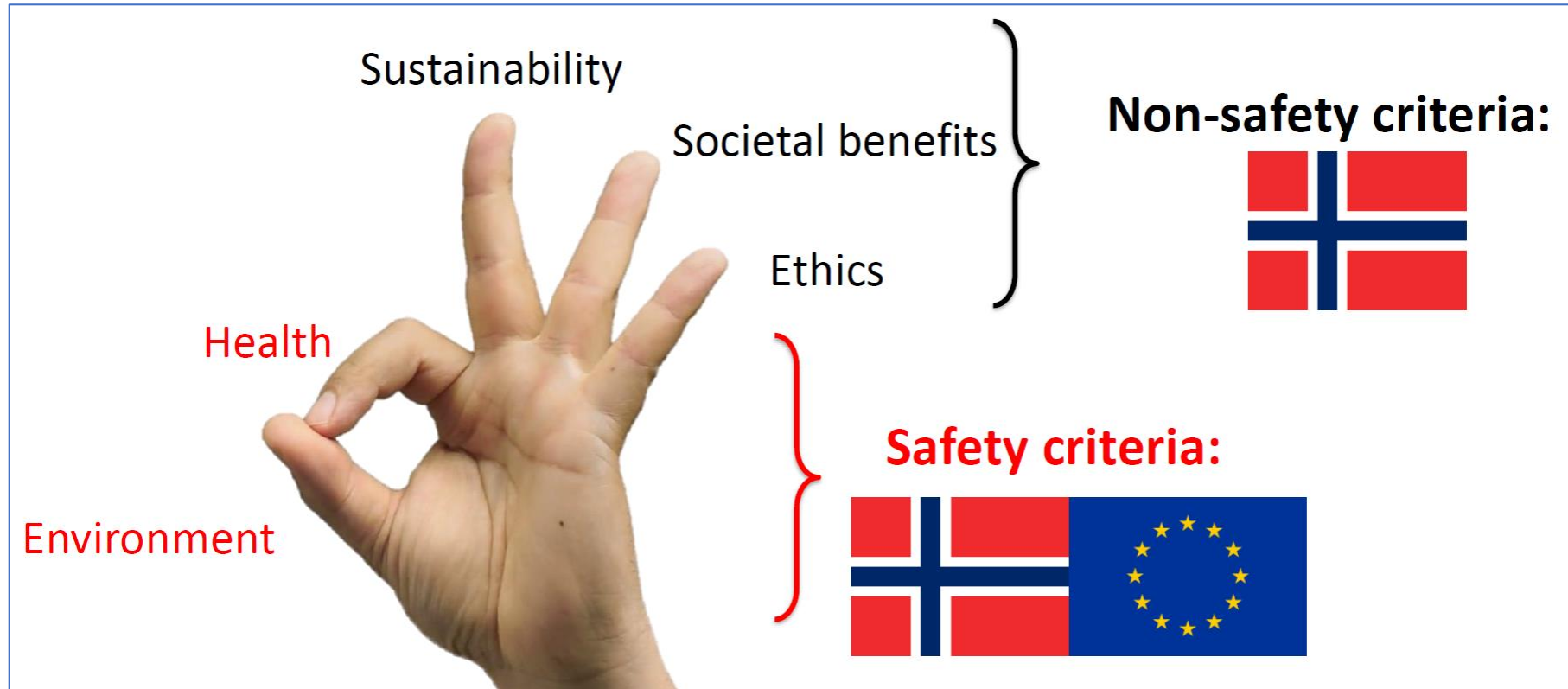
Silas



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

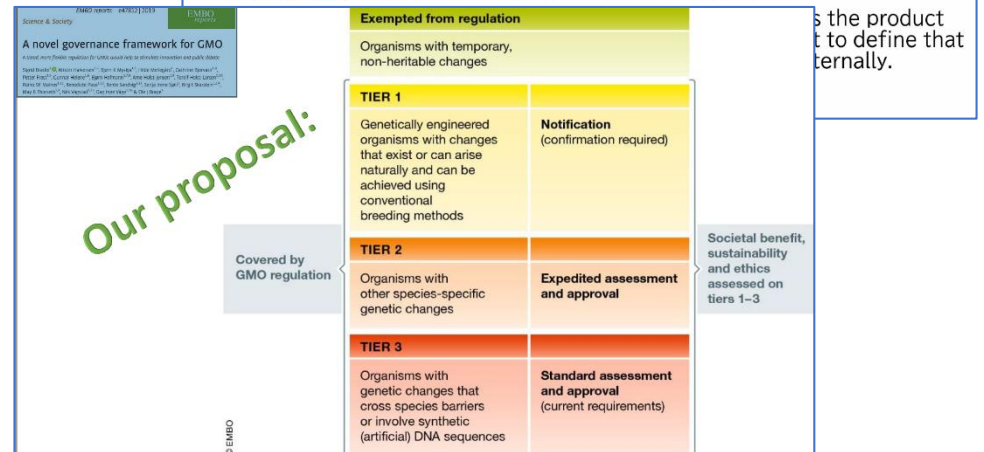
✓As a product-based evaluation, same regulation of genetically modified foods under the Food Sanitation Act will not be applied to genome editing foods that modified DNA sequences *indistinguishable from natural mutation or conventional artificial mutagenesis*.

MOE,

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

Definition: Process-based

Arne

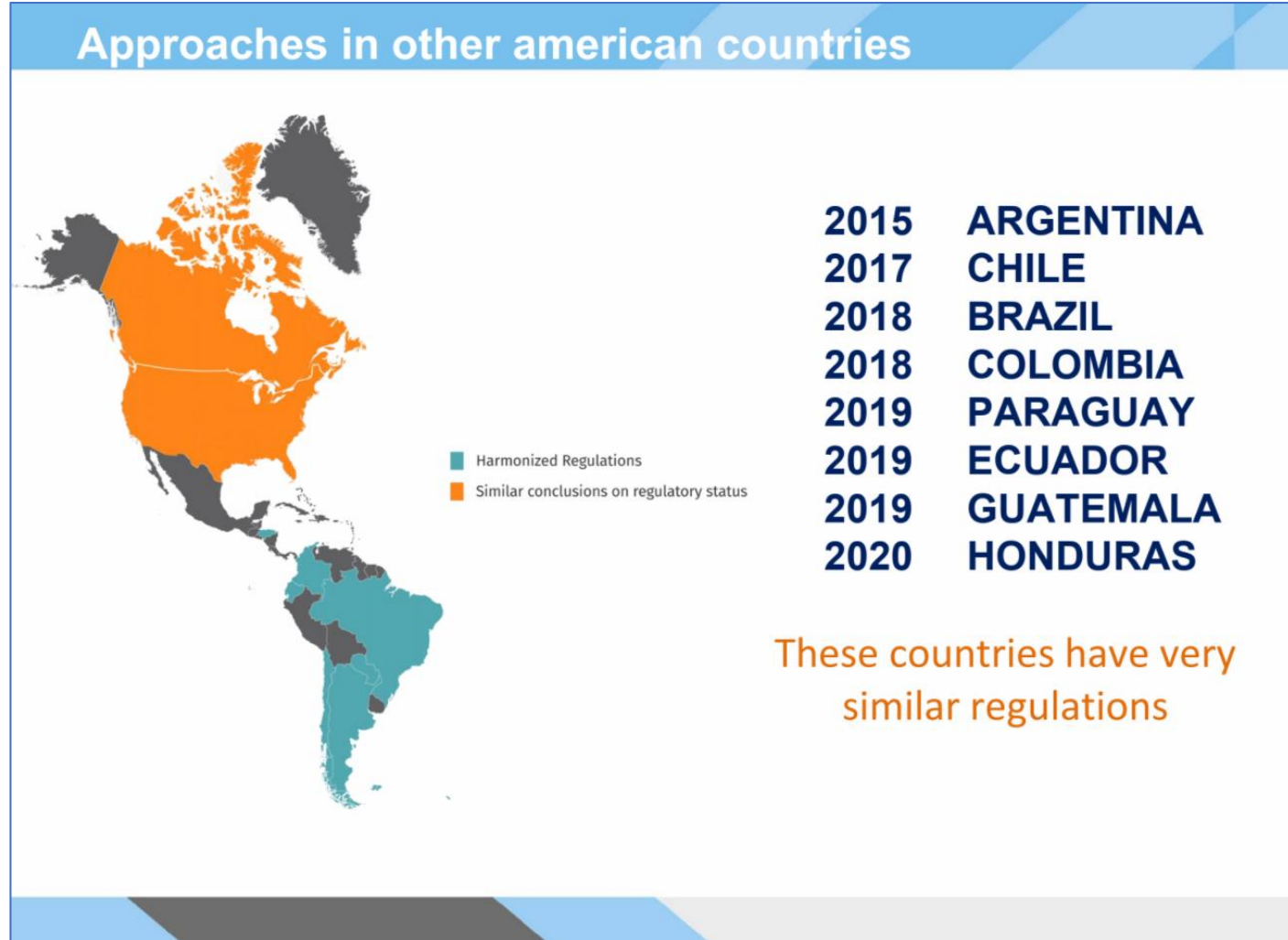


How to communicate effectively

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

Diversity... commonality and harmony

Agustina



Arne

