USDA ISAAA IICA VIRGINIA TECH

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- Are the current regulations / standards fit for purpose / out of date ?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

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Hennie


## Scope & purpose

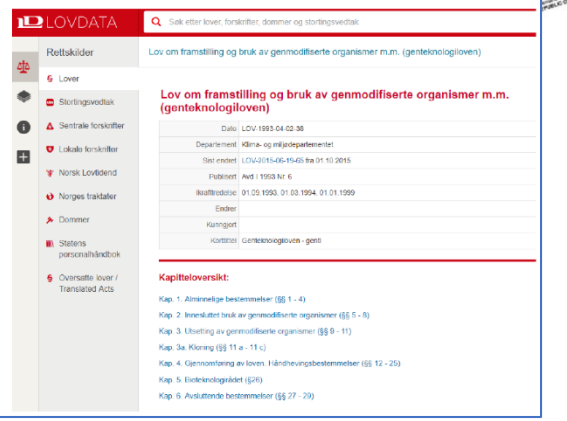
ASSAf

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

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?



# Diversity… commonality and harmony

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

Hennie

**Findings** ASSAf

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

Martin

## LMO definition from Cartagena Protocol

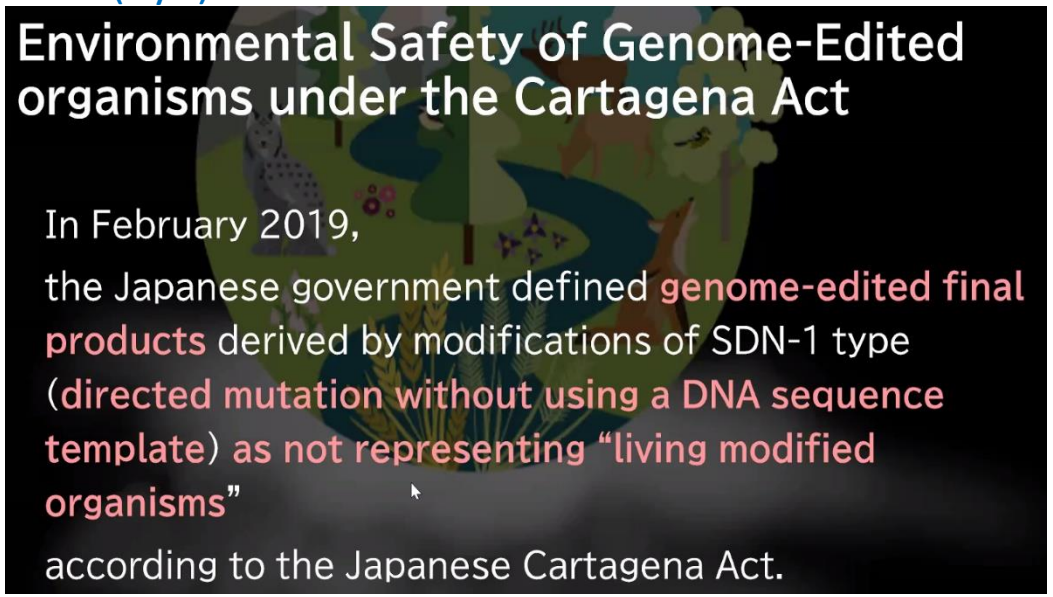
- "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- "Modern biotechnology" means the application of:

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;

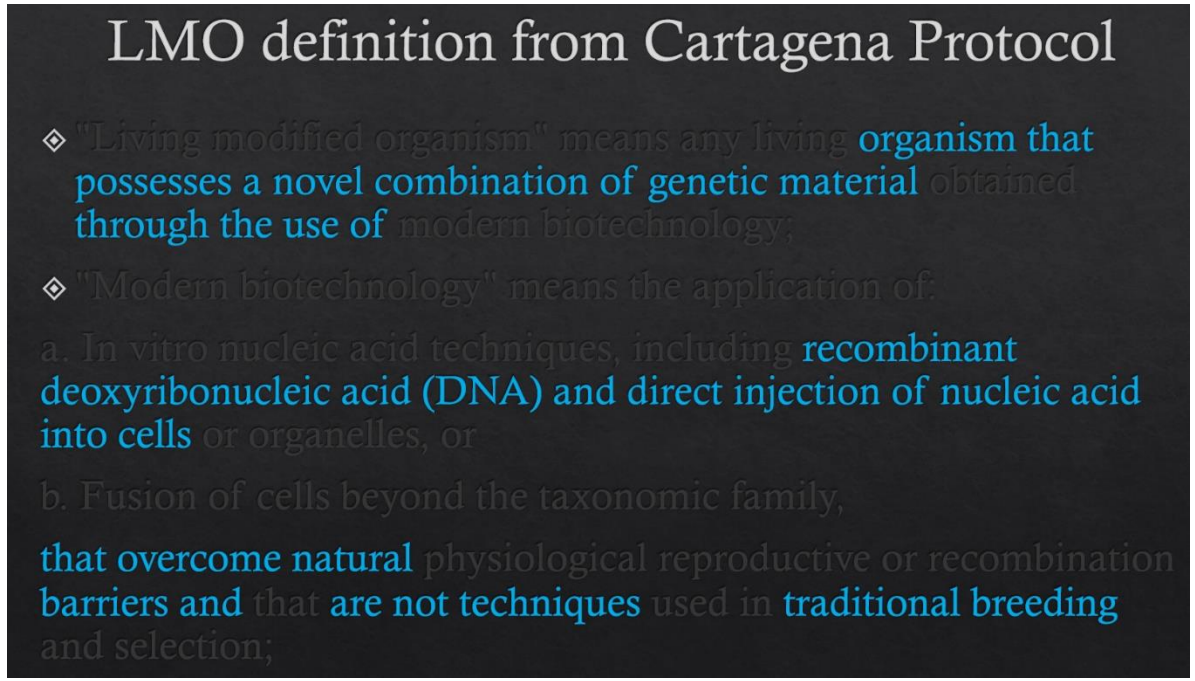
Mai (Ryo)



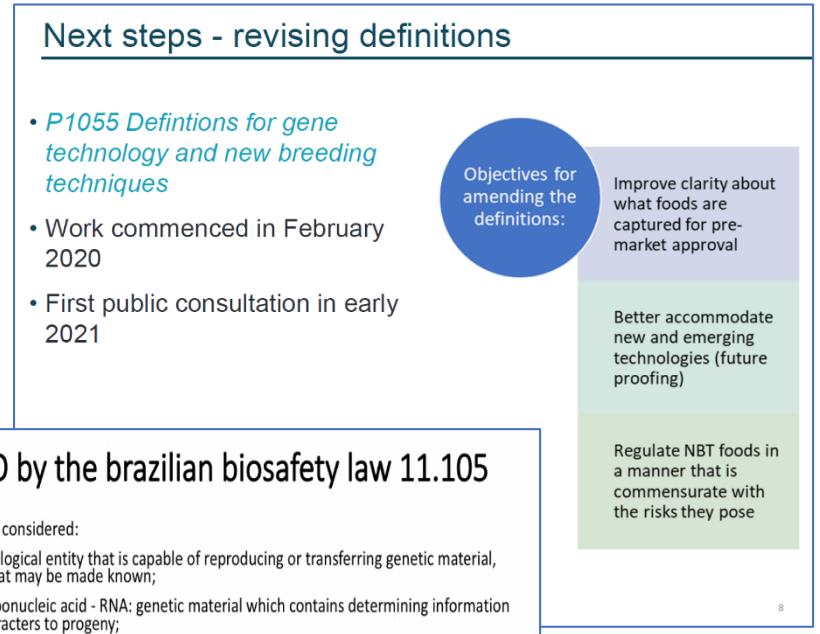
# Diversity… commonality and harmony

- Definitions are the key

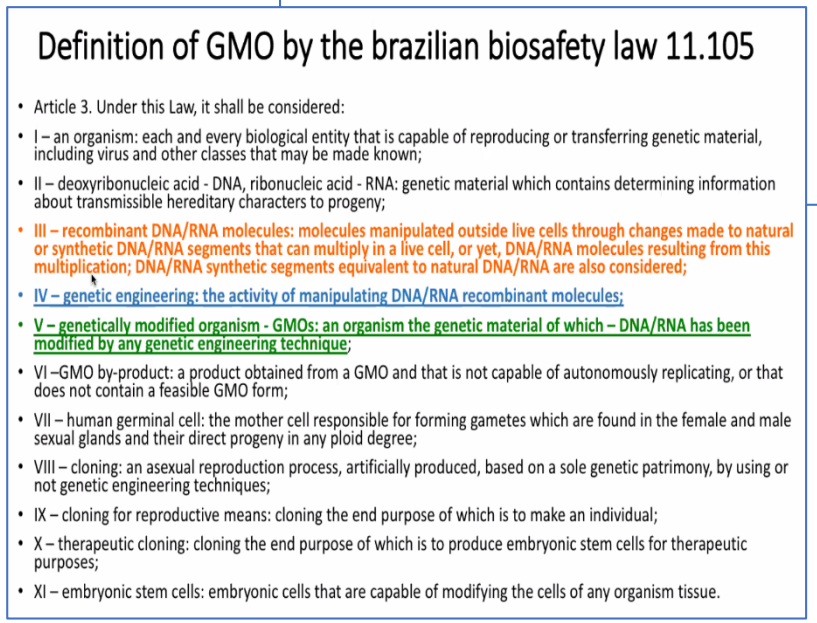
Martin




Lisa




Maria

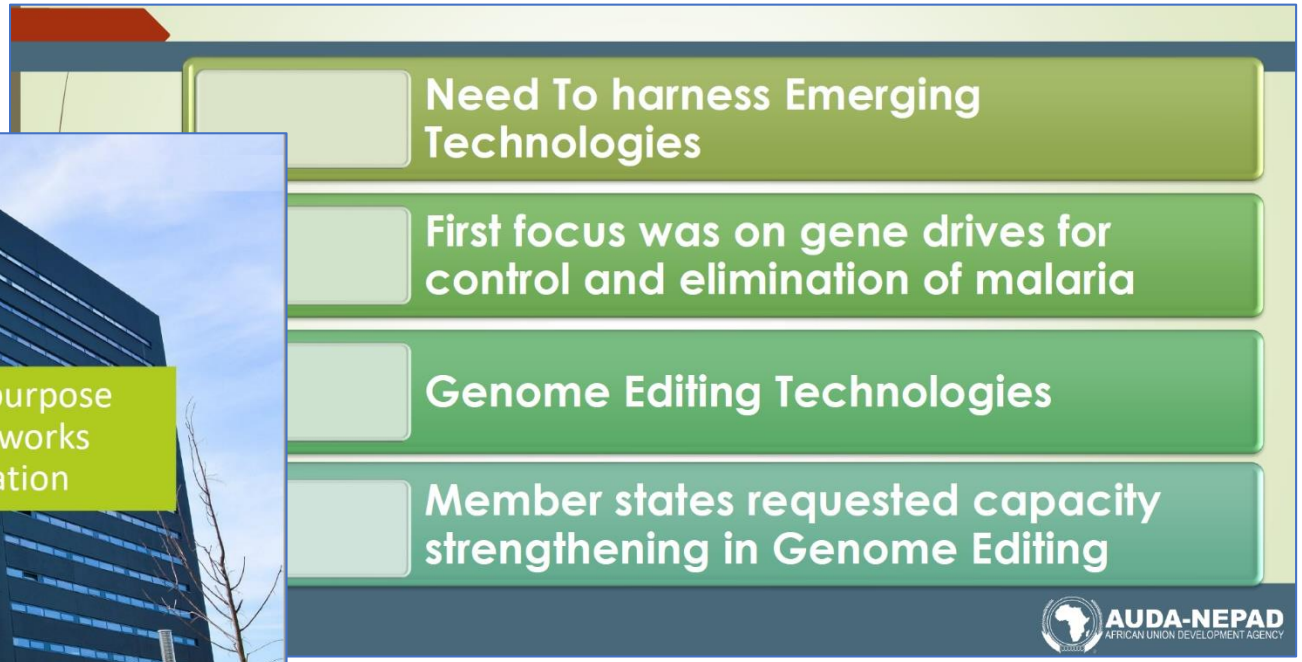


# Diversity… commonality and harmony

- Barriers to innovation = loss of potential benefit

Hennie

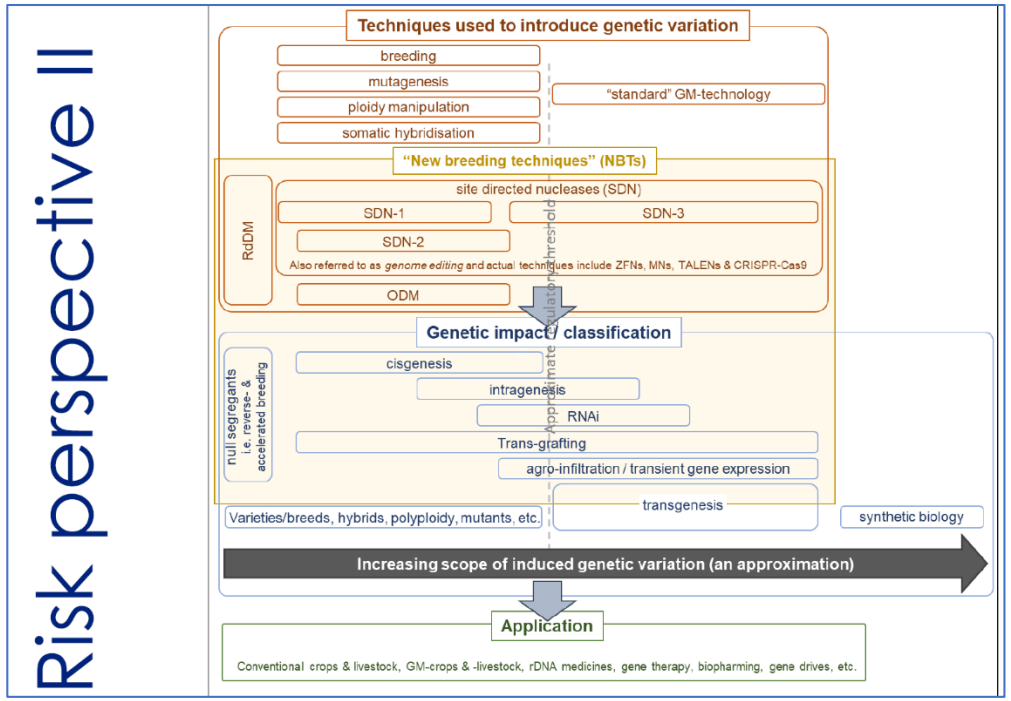

Silas



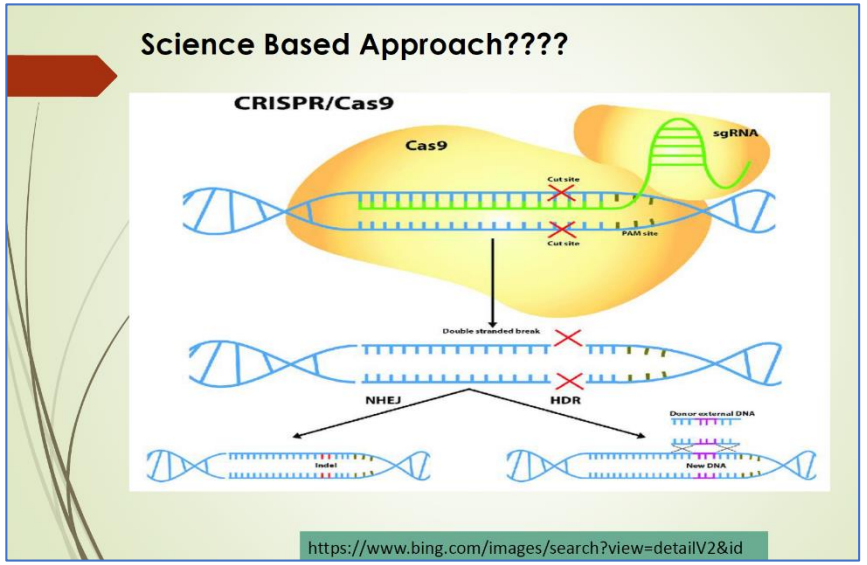
# Diversity… commonality and harmony

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

Hennie



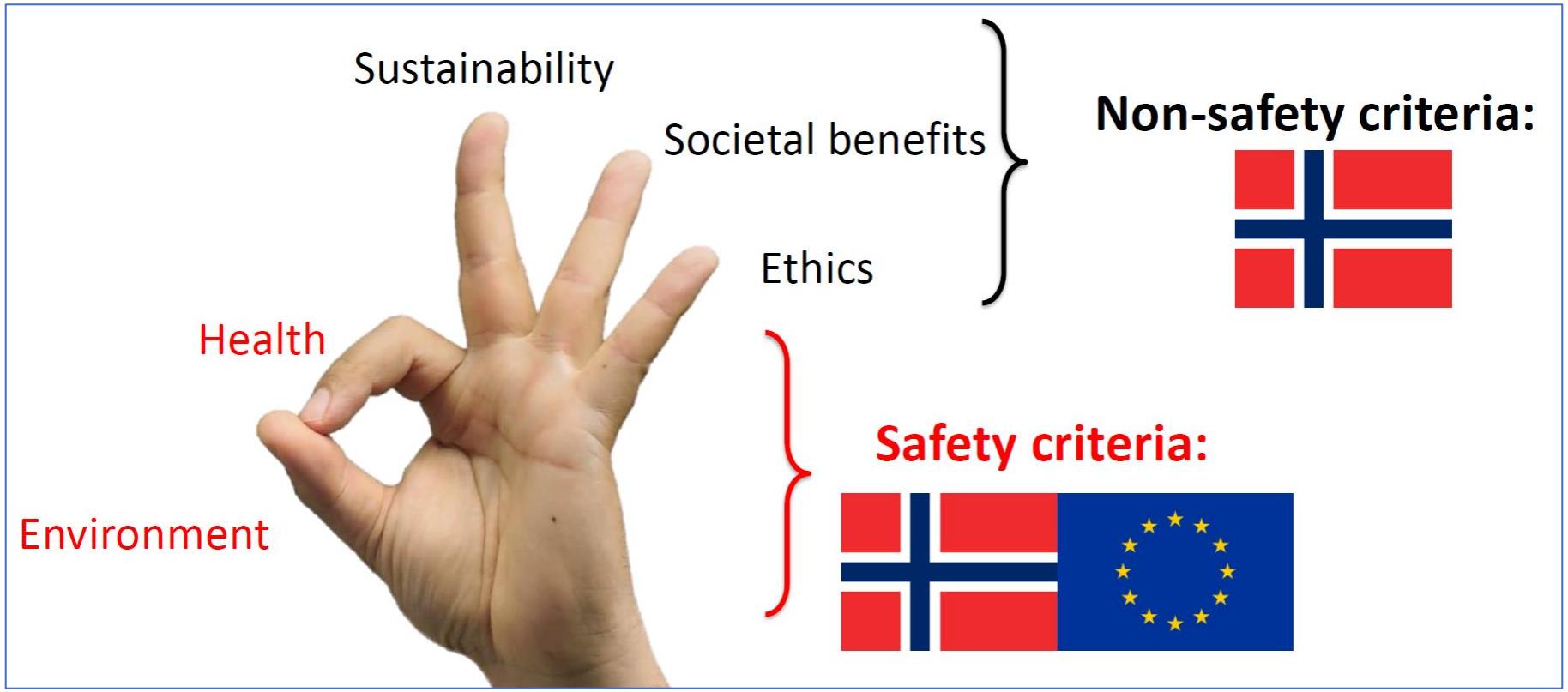

Silas



# 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

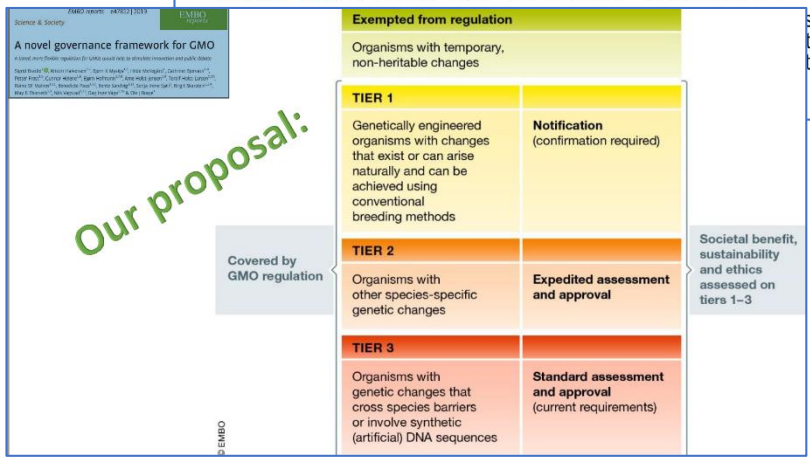
✓As a product-based evaluation, same regulation of genetically modified foods under the Food Sanitation Act will not be applied to genome editing foods that modified DNA sequences indistinguishable from natural mutation or conventional artificial mutagenesis.

MOE, Definition: Process-based

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

s the product
t to define that
ternally.

Arne



Hennie


How to communicate effectively
TRUST > knowledge
Start with WHY
Get diverse ALLIES to vouch for sound information
SEEING is believing!
://www.melaniekross.com/wp-content/uploads/2014/09
cessful-people-communicate-.jpg

# Diversity… commonality and harmony

Agustina

## Approaches in other american countries


| | |
|---|---|
| 2015 | ARGENTINA |
| 2017 | CHILE |
| 2018 | BRAZIL |
| 2018 | COLOMBIA |
| 2019 | PARAGUAY |
| 2019 | ECUADOR |
| 2019 | GUATEMALA |
| 2020 | HONDURAS |

These countries have very similar regulations

Arne