

Fourth International Workshop on Regulatory Approaches for Animal Biotechnology

Location: Brazil (*venue to be confirmed*)

September 14-18, 2020

[DRAFT program: February 12, 2020]

Day 1 -- September 14th

Welcome, Introduction and goals of workshop

Session 1: Animal breeding and biotechnologies

Goal: To increase understanding of breeding techniques used in agriculture, the importance of variation/diversity in a breeding context, and how new technologies could be utilized in animal breeding programs.

- Animal breeding and the role of genetic variation and diversity
- Genomic selection, trait discovery and practical applications
- Role of new technologies in animal breeding and future potential
- Practical breeding approaches panel

Session 2: Animal biotechnologies in the pipeline.

Goal: Survey of products being created, their potential benefits/challenges they may be addressing, express range of complexities of characteristics relative to potential risk profiles

- Overview of biology of animal biotechnologies

Potential presentation themes:

- Livestock and aquaculture: Disease tolerance, welfare, climate change resilience, and production
- Food composition and “novel” food traits
- Non-confined animals (e.g., grazing animals, wildlife conservation, Insects)
- Gene Drives

Evening reception

Day 2 -- September 15th

Session 3: Conventionally-bred animals and biosafety

Goal: Increase awareness of processes and frameworks in place to protect food safety and animal health for conventionally-bred animals

Potential presentation themes:

- Biosafety and the farm
- Protecting human and animal health
- Protecting the genetics in the breeding population
- How do agencies/ministries with shared responsibility work together

Session 4: Regulatory approaches (and triggers) in different countries

Goal: Lay groundwork for regional discussions and share information on regulatory approaches, potentially identifying commonalities for regulatory cooperation

- Regulatory approaches of different countries – focus on approaches for genome edited animals

Session 5: Regional and Developer breakout groups

Goal: Identify regional commonalities, etc. including challenges and opportunities. Discuss opportunities for regional engagement and regulatory cooperation between countries.

Day 3 -- September 16th

Session 6: Risk/Safety Assessment

Goal: How to effectively minimize risk while enhancing opportunities and access to potential benefits.

- Problem Formulation: Identification, evaluation, mitigation and control of risks.
- Considerations for: food safety and nutrition, animal and herd health, environment
- Special considerations for gene drives

Session 7: Panel for developer – regulator dialog

Goal: Discussion of scientific rationale and legal basis framing regulatory approaches and assessment criteria

Session 8: Case Studies: Regulatory experiences with genetically engineered and genome-edited animals

Goal: Sharing what worked, what didn't, and what could have been improved

- Panels with regulators and developers
- Communicating with the public about GMOs and genome edited organisms

Session 9: Concepts in regulatory approaches

Goal: Sharing information about standard setting bodies, their roles, and drawing from experience

- Codex Alimentarius, OECD
- Familiarity – drawing from previous knowledge and experience

Session 10: Problem formulation exercise for regulators

Goal: hands on table top exercises

Day 4 -- September 17th

Session 11: Panel discussion – Exploring opportunities for regulatory cooperation?

Goal: Identify potential approaches for regulatory cooperation or alignment or mutual recognition

- Examples of regulatory cooperation, including for conventional food products
- Small group regional discussions on regulatory cooperation

Session 12: Socio-economic impact of animals created using biotechnology and dialog on ethical issues

Goal: Identify and discuss socioeconomic issues posed by animal biotechnology.

Potential presentation themes:

- Ethical issues for genome editing of agricultural animals
- Socio-economic issues in international fora, impacts on small holders
- Socio-economic impact of regulatory approaches
- Seeking input/comment from public, Government outreach efforts

Session 13: Follow-ups and future interests

Goal: Framework for continuing engagement and regional activities, plans for deliverables

Day 5 -- September 18th

Session 14: Farm or lab visit (optional)

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