

Third International Workshop for Regulation of Animal Biotechnology

June 26-30, 2017 – Charlottesville, Virginia, USA

DRAFT Program

Day 1

Introduction to Animal breeding and biotechnologies

Animal breeding systems: Structure of different animal breeding sectors and regions:

Sectors: Cattle and Buffalo, Small mammals (goats and sheep), Poultry, Aquaculture

Science and technological advances in animal biotechnologies

Technologies covered: Livestock cloning, Genetically engineered animals (emphasizing food and agriculture applications), Gene editing in animals (emphasizing food and agriculture applications), Gene drives

Potential for Animal Biotechnologies in Different Animal Industry and Production Sectors.

Some key questions addressed:

- How can animal biotechnology be applied to practical animal breeding and dissemination?
- What are industry sector perspectives on animal biotechnology
 - Opportunities/needs for biotechnology
 - Barriers to adoption of new technologies (in developed and developing countries)
 - Impact of regulations on industry adoption/utilization of new technologies
- Potential impact of animal biotechnology on food and economic security?

Day 2

Introduction to GM Animal Risk Assessment

- Overview of risk assessment-management framework
- General principles and methodologies for environmental risk assessment (Cartagena)
- Objective, general principles and methodologies for food safety assessment (Codex)
- International organizations and guidances
- Practical risk assessment advice
- Hypothetical case studies
- Panel discussion

Communication: Communicating risk

Biotechnology and Developing Countries

- Biotechnology in developing countries: challenges and opportunities; strategies for the future.
- International biotechnology programs in developing countries – the role of non-profit biotech research institutions
- Developing biosafety regulations in developing countries; experiences from various countries; what works and what does not?

Science, Regulation and Policy - Working Together to Encourage Innovation, Public Health and Safety

Regulation in a rapidly evolving environment: Evaluating risk without stifling innovation

Breakout sessions: Dialog on guidance gaps, capacity-building needs and strategies

Topics: Food safety assessment, Environmental biosafety assessment, Handling of socioeconomic issues, Opportunities for harmonization

- Report back to whole group

Day 3

Regulatory approaches in different countries. to include presentations and panel discussions addressing both genome editing and gene drives. [Selected regulatory frameworks may include: Argentina, Australia, Brazil, Canada, China, India, Japan, US, and others]

Communication short talk

Case Studies: Regulatory experiences with GE animals

Panel: GE insects, including mosquitos, crop and animal pests, silkworms: Regulatory process, communication with public, lessons learned, prospects.

Panel: GE fishes, including Atlantic salmon and perhaps Glofish: Challenges in the process, environmental issues, food safety issues, lessons learned, prospects.

Panel: Disease resistant traits: pigs and cattle, aquaculture, and chickens: Challenges in the process, lessons learned, prospects.

Panel: Production and welfare traits: poultry, cattle and pigs. Challenges in the process, lessons learned, prospects. Focus on traits that could be created with conventional breeding, but would take much longer.

Day 4

Harmonization of Regulatory Approaches. Again, here we should focus on genome-edited animal regulation.

- Need for international communication - Lessons learned from plant biotechnology regulation
- Challenges and opportunities for regulatory harmonization in animal biotechnology
- Regulatory Coordination: Domestic and International Challenges
- Data Transportability

Technology and Science-directed Regulation

Panel: Challenges to making regulations that are science-based while still addressing public concerns. Among the challenges: Ethical issues, Socio-economic Considerations, Process-based versus product-based regulation, Hypothesis-driven regulations, Food animal versus public health applications, Environmental release of animals developed via biotechnology, Dealing with public concerns in a science-based (and risk-based) regulatory system, encouraging innovation while protecting safety

Regional Breakout groups

Focus on address regional animal biotechnology oversight issues

Potential topics of discussion and debate:

- Special features of animal biotechnology, which could benefit region
- Capacity and capability of countries in your region to develop GMOs and their products
- Challenges and prospects for developing genetically engineered animals in region
- Training opportunities available for animal scientists/regulators
- Identifying capacity and challenges of developing new regulatory framework
- Creating regional public awareness and best communicate about biotechnology
- Relevant international trade agreements, and effects on uptake of biotechnology in region

Report back and general dialog – next steps

Wrap-up talk with tie in to next day: Science and risk communication strategies and practice

Day 5

This portion of the workshop will be limited to a smaller number of participants to allow for “hands-on” activities. It will be designed for communication needs of regulators by Dr. William Hallman, Rutgers University, New Jersey, USA; previous Chair of Risk Communication Advisory Committee of U.S. Food and Drug Administration

Principles and methodologies of science and risk communication.

Topics to include: Principles of risk communication, Knowing your audience, Message development, Dealing with the media, “hands-on” communication activities

Hosted by: U.S. Department of Agriculture (USDA) and Virginia Polytechnic Institute and State University (VPI&SU)



Organizing committee: Eric Hallerman (VPI&SU -USA), Diane Wray-Cahen (USDA), Yanina Petracca (Argentine Ministry of Agroindustry), Hellen Mbaya Kajuju (Kenyan National Biosafety Authority), Bruce Whitelaw (Roslin Institute – UK), Mark Walton (GloFish, USA), Bill Hallman (Rutgers University – USA), S.R. Rao (Indian Ministry of Science & Technology)