Virtual Breakout Session

Developers and Researchers

Americas, Africa, Europe

October 21, 2020

Participants

- Thirteen
  - 8 USA
  - 2 Latin America
  - 2 Africa
  - 1 Europe
- 8 public sector
- 5 private sector
- 3 active developers
  - All USA
  - 2 (primarily) large ruminants
  - 1 fish

Five Questions

- Challenges: What are the main challenges impacting development & application of genetic technology in animals?
- Regulatory Cooperation/Alignment: How do you envision regulatory cooperation in animal biotechnology being helpful?
- Scope of regulation: Does the country in which you work exempt any type of genome edited or genetically engineered animals or products?
- Preparing for Innovation: What is your country doing to encourage innovation and support developers?
- Next Steps: what follow-up activities would be beneficial?

Challenges

- USA and Europe
  - Regulation
    - Expensive
    - Unpredictable (US) or untested (EU) timelines
    - Process based and risk inappropriate
      - Contributes to cost and lengthy regulatory process
      - Inhibits broader use of technology
- Latin America & Africa
  - Lack of funding
  - Access to technology
- Public Perception & Communication
  - Public and some potential users don't understand difference between gene editing & transgenic technologies
    - Discussed using different terminology but not sure it would be effective and could be perceived as an attempt to "hide" the technology
  - European Court of Justice decision (gene edited = GMO) contributes to public confusion and increases distrust of gene editing technology
  - Continuing concern among some livestock producers that public won't accept gene edited products
    - Success of GM, plant-based meat substitutes (https://impossiblefoods.com/) in the U.S. indicates consumers buy a product that meets a need, regardless of technology

Regulatory Cooperation

- Mutual Recognition would be very helpful
  - Improve access to products
  - Reduce cost
- Trend towards mutual recognition noted as a positive step and noted specifically actions in several South American countries and Vietnam
- Single regulatory dossier accepted by multiple countries
- Noted the existence of the “Like-Minded Group” (USA, Canada, Brazil, Argentina, Paraguay, Uruguay, South Africa, New Zealand) engaged in discussions on regulatory harmonization and encourage the dialogues to continue

Scope of Regulation

- Any exemptions for gene edited animals?
  - USA: No
    - Recent changes by USDA give exemptions for some gene edited crops
  - Europe: No (see Slide 4)
  - Brazil: Yes, depending on nature of the edit
- Do regulatory processes affect choice of traits/technology?
  - Knock-outs easier to have approved
    - May prevent/delay use of gene editing for more knock-in or more complicated edits
  - Cost and time to obtain regulatory approval considered in business decisions on selection of traits and technical approaches
  - Presence of a functioning regulatory system also a decision factor

Preparing for Innovation

- USA
  - Department of Agriculture encourages innovation in genome engineering through grants
  - Reducing cost of regulation and increased certainty about regulatory timelines will stimulate additional innovation
- Developing Nations
  - Do not have luxury of ethical debates underway in developed nations
  - Funding is a challenge across the developing world
  - Does recent funding of gene editing project in cattle by Gates Foundation open the door for additional programs in the developing world?

Next Steps

- Among Developed Nations
  - Meaningful discussions targeting regulatory changes among regulators, policy makers, and developers (public & private) on risk-appropriate regulation, i.e., based on product not process
- Among Developing Nations
  - Funding, access to technology, and scientific capacities are limiting factors
  - Convene governments, international agencies, and donors and create a coherent approach towards stimulation of genome engineering innovations in developing countries and regions