Virtual Breakout Group Session in Animal Biotechnology - Europe

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Overarching Questions:

1. *Challenges* – What are the biggest regulatory challenges for agricultural and food applications of animal biotechnology?
   - What are your recommendations to help overcome these challenges?

   The welfare of farmed animals is a sensitive issue in Europe, especially in the context of any effects of genetic modifications. Fishes and insects being quite mobile, any environmental impacts are an issue particularly with regard to effects on biodiversity, effects in unintended areas (i.e., outside the area of intended use, including natural ecosystems and protected areas) and possible transboundary movement. One hypothesis is that Europeans may need to see a compelling reason to utilize gene technology, or else they may tend to prefer traditional breeding methods. For instance, Europeans may only adopt GM/GE animals when "classical" systems can't solve a problem they face or when there is a clear benefit for the society, the environment, or animal welfare. International harmonization is an issue.

   There are useful EU guidance documents, for example on food safety of genetically engineered foodstuffs as well as guidance for ERA of GM animal applications. Other guidance documents, e.g., on genome-edited organisms and gene drive applications, are in development; this will take some time as the science is developed case-by-case. A concerted effort to educate decisionmakers and the public is needed.

2. *Regulatory Cooperation, Alignment and Compatibility* – How do you envision regulatory cooperation in animal biotechnology oversight in your region?
   - To what extent is it possible (just neighboring countries? globally?)?
   - What are the main challenges to cooperation and potential regional approaches?
     - Is mutual recognition an option for your country?
     - Can we do joint reviews?
   - What mechanisms can help improve regulatory cooperation and alignment/compatibility?

   Most countries in Europe are, of course, part of the European Union. The EU promulgates directives which inform development of national policies. Field trials and contained use are conducted under national oversight.

Regarding joint review of applications by multiple countries, scientific data and advice are shared effectively among member states at the EU level. There is good transparency of discussion, while confidential data are protected. Risk assessment is considered separately from risk management, and member states may adopt different conditions for use.

Individual counties may adopt stricter conditions for use or even ban cultivation of specific GM organisms. Such measures are in place in a number of EU member States for particular GM plants. These national differences are allowed in EU regulations because, at least for GM plants, the respective countries present different environments and, hence, countries may set different conditions for use.

The regulatory process in the EU works reasonably well, but decision making and the development of policy is lengthy and contentious. There is some sense that innovative agricultural solutions are not given a full chance for adoption; if a qualified majority between countries cannot be achieved, authorization usually takes very long if it is achieved at all. Under Brexit, agricultural biotechnology policies may change in the UK.

3. *Scope of regulation* – [If regulations are *not* in place] Does your country need to have regulations in place for Genetically Modified (GM)/Engineered animals in order to make a determination that an animal is not GM (i.e., conventional)?
   - Could your country put in place policies for genome editing that would allow for use/import of "non-GM" genome-edited or cisgenic animals without having regulations in place for GM?
     - Are you working on that?

   - What are the knowledge gaps/sources of uncertainty in relation to genome editing?

   - How does your country plan to deal with different determinations in different jurisdictions relative to what is or is not regulated under your biotech/GMO laws? (i.e., trade issues associated with regulatory misalignment)

   - When writing your regulations/guidances, did [will] you consider what regulatory processes are already in place in your country for *conventional* products to protect the public, animals, and the environment? For example, requirements for slaughter, food safety, animal health, or the control of diseases . . .
     - Have you identified any potential hazards (or types of traits) of concern that would plausibly escape the safety measures in place for conventional animals?

   The EU does not yet have an agreed-upon policy specifically for regulating gene-edited animals, although there are ongoing discussions. While the trigger for the regulatory approach is the process by which the product is made, what is critical for safety is the phenotype of the animal produced and its envisaged use/release in its receiving environment. Confidence in the regulatory policy, however, will emerge only from meta-analysis of the experience of many case-by-case

evaluations of individual applications. Again, while the EU policy may be unified, a country may decide on stricter conditions of use of gene-edited animals. The key question is whether a product is as safe as its conventionally bred counterpart.

Earlier discussion of offspring of cloned animals suggests that there would be challenges as to the identification and traceability of some categories of genome-edited animals and for certain traits it may not be enforceable. In practice, such products could enter the EU as semen from edited individuals. It was noted that the challenges faced may be very similar to those for cloned animals and their offspring, where other non-EU countries deemed them conventional as there was no way to distinguish them.

There was also discussion of different risk profiles for farm animals and pest species, with the control of pest species (or disease vectors) being the more challenging.

It was noted that the EU may need to change its regulations in light of the Court of Justice case, as the process triggers whether a product falls under the GMO regulations or not.

4. *Preparing for Innovation* - What is your country doing to encourage innovation and support developers in the application process?
   - What steps can be taken to [draft/adapt] regulations able to adapt to the future technologies?
   - How might one achieve effective regulation while reducing regulatory burden so that public-sector developers can participate (i.e., to avoid only/mainly big companies controlling products)?
   - Are the costs of meeting regulatory requirements a consideration in your process?

   It was noted that globally, developers are urged to consult early with regulators. While not standard before in some institutions like EFSA, pre-consultations will become more regular under the new transparency rules in effect from March 2021.

   Some member states have more active (animal) biotech sectors, and some states are better at communicating to their publics about biotechnology and its potential benefits. This should allow small- and medium-scale enterprises to succeed. Greater harmonization among countries would be quite helpful. As the UK exits the EU, there will be a consultation later this year regarding what regulatory processes may be changed. The prime minister recognizes the UK's advanced animal biotech sector. The Swiss have an interesting mechanism for supporting innovation in the crop biotech sector vis-a-vis strict precautionary legislation, in which the government set up a protected test site and companies may use these facilities.

   Innovation in the animal biotechnology sector being politically sensitive, effective communication is required. The animal biotech sector has case studies of both bad and good handling of public outreach, for example with GM mosquitos (mainly outside of EU), to inform future efforts.

5. *Next steps* - Identify potential follow-up activities that would be beneficial within your region.
   - What types of activities?

- For what target audiences?
- What can be done virtually?
- What are the next steps?

The issues facing adoption of animal biotechnology are not just about science, but also about public acceptance. We need proactive information sharing, including voters and leaders. Engagement needs to be within each different member state, as they are not all the same. Different countries have had different experiences of information sharing and adoption outcomes for GM crops, with more transparent approaches for communication and participation generally leading to higher public acceptance.

It would be good to discuss with other countries what they are doing, including countries that are developing new products, those that are applying/using these products, and those countries that have developed regulatory approaches to allow for use of these products.

In the EU different directorates general (DGs) –health, environment, and agriculture – are involved; to achieve a holistic policy for animal biotech, it may be useful to convene representatives from each DG to discuss overarching goals and needs for agricultural production. Also needed is discussions with all decision makers and their respective stakeholders to decide on the protection goals. This may involve trade-offs as the values and priorities of different stakeholders are not the same.