Session VII: Northern America and Europe Breakout Discussion

Context: The group included 26 individuals representing the government, academic, and private sectors. Discussion was held by Zoom on November 30, 2020 and led by Mark Walton (AquaBounty). Notes were taken and this report drafted by Eric Hallerman (Virginia Tech) and Justin Bredlau (U.S. Department of Agriculture).

Participants:

Justin Bredlau – U.S. Department of Agriculture
Steve Brody – Genus
Nathalie Dore – Agriculture Canada
Stephen Dugan – Health Canada
Michael Eckerstorfer – Environment Agency Austria
Ana Granados – EFFAB - European Forum of Farm Animal Breeders
Eric Hallerman – Virginia Tech University
Teele Jairus – Ministry of Environment, Estonia
Sabreena Larson – Acceligen
Michael Lohuis – Semex
Heather Lombardi – U.S. Food and Drug Administration
Joan Lunney – U.S. Department of Agriculture – Agricultural Research Service
Javier Martinez – Medicines and Medical Devices Spanish Agency (AEMPS)
Alan Mileham – Genetic Visions, ST Genetics
Adam Moyer – U.S. Food and Drug Administration
Laura Moussa – U.S. Food and Drug Administration
Heiner Niemann – Hannover Medical University
Londa Nwadike – Kansas State University
Sri Reddy – Genus
Pablo Ross – ST Genetics
Frank Siewerdt – U.S. Department of Agriculture – National Institute for Food and Agriculture
Xiuchun (Cindy) Tian – University of Connecticut
Scott Tyack – Aviagen
Alison Van Eenennaam – University of California – Davis
Mark Walton – AquaBounty (Moderator)
Diane Wray-Cahen – U.S. Department of Agriculture

Summary of key points

1. What are the main either challenges or limitations you find relevant to the animal biotech sector in your country, and how to overcome such limitations?

A number of differing views were expressed.

Cindy Tian said that, in addition to the need for more funding for research, the key and ultimate problem is public acceptance. There is resistance in the United States in general to both science and genetic engineering. The public is concerned about GMO safety. It does not matter how great a

technology is, if the public doesn't want it, there is no place for it in the society. Therefore, the government should fund projects for public education and outreach on this topic. The University of Connecticut is developing a working group for public education, but there is not enough funding.

Frank Siewerdt noted that USDA-NIFA does not have a specific program on communication of science, but those could be encompassed under programs that cover social aspects. Under these Requests for Applications, there could be funding available for outreach of topics of interest to this group.

Information and links provided by Frank following the discussion:

> There is not an RFA from a specific program aimed at the education/communication purposes that were raised in today's discussion. However, other RFA have some possibilities for exploring.
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> Those that are interested should start by looking at the RFA below. The last one is, in principle, limited to educating the undergraduate student population, which could provide medium to long-term results. I encourage those that are interested in exploring funding opportunities to contact directly the National Program Leaders listed in each RFA for guidance. It is worth keeping in mind that funding may only be used following direct guidance from the 2018 Farm Bill, as interpreted by NIFA. I think it is worth exploring the possibilities.
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> https://nifa.usda.gov/sites/default/files/rfa/FY-2020-and-2021-BRAG-RFA.pdf
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> https://nifa.usda.gov/sites/default/files/rfa/FY-2020-AFRI-Education-Workforce-Development-Modification-%2007162020.pdf
>
> https://nifa.usda.gov/sites/default/files/rfa/19_National%20F_46-Modification-2nd.pdf
>
> NIFA regularly hosts stakeholder meetings to gather input from a broad public to use in future RFA. If this type of activity is not currently contemplated, I encourage the participants of this forum to become involved in these hearing meetings so NIFA can stay relevant in the communication and education arena as well.
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> One additional resource for the group is NIFA's Institute of Youth, Family, and Community, which may have programs that fit these needs. The institute's acting deputy director is Dr. Siva Sureshwaran: https://nifa.usda.gov/staff-contact/siva-sureshwaran

Frank Siewerdt thought that Science will find answers to problems, but whom will the public trust? Who has the authority to work on communication?

Ana Granados said that public acceptance in Europe is also related to the regulatory framework, where there are concerns on plant breeding and GMOs, and the regulatory framework is very diverse among countries. Political acceptance is key. We can inform a lot of people, but objectivity must come from authority. She had no ideas on how to solve this difficult issue.

Alison Van Eenennaam noted that there are popular GMOs (e.g., impossible burger and GloFish), so not everyone is opposed. The regulatory side is more of a challenge and very expensive to get through, even for gene edits that could happen through conventional breeding. This cost of regulation is especially challenging for academics and small companies.

Nathalie Dore said that Canada has a good regulatory framework. Canada conducts a public opinion survey every five years, and results have shown that consumers have no idea how GM products are regulated. Consumers are primarily concerned about food safety and environmental impact. The issue of benefits is critical to public acceptance. (e.g., those linked to climate change issues are better received)

Michael Eckerstorfer noted that Europe is in the middle of the discussion regarding implementation of new regulations aimed to increase the transparency of authorization procedures and to facilitate pre-submission consultations between developers and regulators at the EU-level and in all EU countries. The current regulatory framework for biosafety has shortcomings for new biotechnology methods and gene editing—based on a study of the European Commission due in April 2021 there will be further discussions addressing pending issues. He wondered whether the shift towards plant-based diets would influence the future market volume of all animal-derived foods, including GM animal foods.

Michael Lohuis said that many companies are likely waiting for examples of the "perfect" application to pave the way for public acceptance of animal biotechnology. The experience of AquaBounty—with its long regulatory and public acceptance pathway—scares animal ag companies and makes them reluctant to get involved in biotech.

Joan Lunney asked whether the distinction between GMO vs CRISPR technologies may affect consumer acceptance, as well as how the product is regulated (e.g., FDA as a drug vs. USDA as a food animal) and whether this distinction change public perception.

While there was disagreement over whether public acceptance or regulation are the main concern. There was agreement on the need to address communication towards consumer values.

2. What steps can be taken to increase positive interaction among developers, regulators, farmers, consumers and other stakeholders?

Heather Lombardi suggested that a lot of this is seeking common ground and a path forward. She suggested having conversations in non-confrontational settings, such as conferences, to gain better understanding. She recommended that regulators should attend meetings wherever they can and set up meetings (governments need to allow equal opportunity with different groups), to encourage working together and finding a path forward.

Michael Eckerstorfer noted that of late, there have been a lot more interactions among regulators and developers in Europe. Pre-submission consultations are beginning in Europe to improve this interaction. He indicated that there was a need for frank conversations to avoid misunderstandings, which may lead to roadblocks during the authorization procedures.

Cindy Tian emphasized the importance of interactive dialog. Scientists need to learn and teach communication skills to include interactive dialog training for communicating with the public—which is totally different than teaching students in classroom where our authority is readily accepted. Where and how to create a venue to propagate science information? We need to focus on young generations (starting in grade school) who will be the most frequent user of the technology products. Scientists need to engage with university students and university institutions (such as dining halls) to ensure a consistent message about the safety and benefits of GM foods is communicated broadly. She used the example of dining halls and dietetic programs that promote organic and non-GM as examples of mixed

messages coming from academic institutions. Even scientists working on biotechnology are not completely clear on the benefits, broader impacts, and controversies of GMOs, despite of their deep expertise in the technology itself.

Eric Hallerman noted the importance of including relevant information in undergraduate coursework in genetics to demystify genetic modification methods. Importantly, once students understand the need for application of such tools, then they are onboard for the applications. The new thing is applying the methods to animals. The key point is to teach not just how, but why.

Ana Granados felt that in Europe, transparency in regulations is not enough, and wondered whether it was too late for a dialog as disapproval is already established. In the EU there is a lot of focus on organic production. She noted that it is important not only to engage with the public, but also with organizations and societies.

What about communicating with farmers?

Alison Van Eenennaam responded that producers are tentatively interested in genome editing but are concerned about uncertainties around cost of bringing products to market and of markets reacting badly to the technology, as they did for rbST and GMOs generally. She expressed concern around the natural foods industry monetizing fear. She also indicated that farmers are proactively engaging with her and that unlike with genetic engineering, breed associations are asking if certain traits could be introduced for them. However, if gene-editing would be regulated as a drug—as opposed to a food—it is a non-starter for the livestock industry.

Heather Lombardi noted that that there are costs of regulatory oversight, but we get public acceptance with regulatory approval. This is valuable. We need to optimize the regulatory process and need work on the communication side.

Cindy Tian expressed puzzlement by differences in regulatory oversight between plants and animals, which creates confusion even among scientists. For example, point mutation knockout in plants is not regarded as GMO yet animals with the same type of mutation are regulated as drugs. The costly process allows mainly big corporations to gain approval of their products, which because of public mistrust of, for example, Monsanto, increases mistrust of the products at issue. Regulations should be streamlined so small firms and academic institutions can also afford the approval process and therefore, shifting away from the association of GMOs with large corporations.

Diane Wray-Cahen asked whether there is an example of how regulatory approval decreases concern and promotes acceptance of a biotech product? It did not seem like regulatory approval really helped promote public acceptance of biotechnology in the past (example of rbST was cited).

Sabreena Larson noted that issues associated with regulatory fees are not a big problem. At least for FDA, fees are dependent on the working capital of the developer, and exemptions to fees exist.

Diane Wray-Cahen noted, that it was not the fees that were the issue, but rather the costs are associated with the studies needed to support the applications to get through the regulatory process.

Alison van Eenennaam also noted that the cost is not the fees—but rather the cost of maintaining herds or flocks for a multigenerational safety study, which can take years in the case of a some large animals, and the inability to market milk, meat or eggs during that period. She also noted the high cost of having

to destroy those animals at the end of the study. [Note this is a dual cost – cost of incineration and cost of lost revenue from sale of the animal products.]

Steven Dugan noted that for organisms that are regulated under the Canadian Environmental Protection Act, there are no fees associated with submitting a notification other than any costs in developing the regulatory package. There is the possibility of requesting waivers for certain information requirements and pre-notification consultations are available to answer questions and assist in putting together a complete package. As well, there is also a research and development exemption.

Cindy Tian noted that the public only thinks about big corporations. Smaller companies can navigate the regulatory process, but the public doesn't know that due to promotion by certain groups of people. Streamlining the regulatory process would, however, allow smaller companies to develop their products.

The moderator asked whether and how cost is considered by the regulatory agencies.

Heather Lombardi replied that FDA does not consider financial costs. She said that regulators must be mindful of some of the challenges of smaller developers; noting also that time is also expensive. She thought that there are ways to streamline, in order to make regulatory pathways more efficient. The end goal is to get the product on the market.

Javier Martinez replied that the EU system does not take costs into account. However, there are reductions in taxes for smaller companies that do help.

Michael Eckerstorfer added that there are no regulatory fees in Austria or at the EU-level. However, he noted that the overall system is too costly for small companies and that the time it takes for EU regulatory decision making is a challenge for developers.

Overall, we had no solution as to how to promote development of animal biotechnology products by small companies. Developers and academics think that regulatory costs are a major barrier to entry, but it is not the regulatory fees that are the problem because exemptions or lower fees exist for smaller companies.

3. How can we help scientists and regulators to be better narrative communicators and to interact effectively with civil society on such issues?

Alison Van Eenennaam suggested that we must teach our students appropriate communication skills and that scientists should try to do a lot of public outreach. She gave a public debate she took part in as an example of how engaging can change minds (https://www.intelligencesquaredus.org/debates/genetically-modify-food). She noted that the vocal opponents are a relatively small percentage of the public and that the center tends to be interested in the dialog. The public is not necessarily opposed, but vocal small groups have monetized their opposition. We need to frame the discussion around potential benefits and choices that we face (e.g. would they prefer the conventional countermeasure, e.g. dehorning, or the genome editing solution?).

Cindy Tian said that we need to teach students to engage in active dialogue, not only to teach. Her group developed videos for YouTube and video games for how to navigate grocery aisles. A consistent message to the public is needed. Scientists are not always great at talking about intended uses of biotech products, for example, we may explain how we can develop Bt corn, but do not necessarily

understand the benefits outside of the scientific merits. To help reach more people with a consistent and informative message, UConn has developed an online workshop course for extension agents.

Nathalie Dore reported that FAO has developed a public communication package with key messages with topics of interest, history, and benefits of food biotech for farmers.

Michael Eckerstorfer noted an interesting approach from the Netherlands to promote "safe by design"—i.e., biosafety considerations are integrated into every step of the design and development process of product, starting at the earliest stages of development. This approach has been proposed for nanotech and biotech and with student projects, e.g. as those submitted to the iGEM (a respective OECD project to describe and encourage the approach is under development and may start 2021).

Eric Hallerman noted that fisheries provides an interesting context because unless science is applied in the management process, then it does not matter. In fisheries, fishers might feel like science gets in the way, that it limits catches. Hence, fisheries students are trained in how to communicate science to non-technical audiences. This might provide a case study of how to approach curricula in applied genetics. We need more incorporation of coursework in communications and science in society.

Ana Granados noted that the problem is not always training to communicate, but lack of time for scientists to do so. Communication part is given to others because the scientists do not have support for public communication and must use their personal time. Scientists do not have the means to communicate their science.

Mark Walton suggested that funding agencies need to support time for communication as part of the funding process.

The discussion showed that there are many scientists working on communication through outreach and engagement. Scientists need training on how to present science and its benefits to the general public. There is concern that scientists do not have the time, resources, or incentives to do so.

Among communication resources that have been developed to date are:

Cornell Alliance for Science made this video about genome editing for polled trait in cattle (https://allianceforscience.cornell.edu/blog/2016/03/video-precision-breeding-offers-new-alternative-to-dehorning-cattle/).

There is a 30-minute video for the USDA-BRAG funded grant called "Making a CRISPR Cow" at https://www.youtube.com/watch?v=fYBWDNt8rTo&feature=youtu.be.

FDA has posted a webinar, https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/cvm-public-webinar-genome-editing-animals-04252019-04252019.

Genome Canada has recently awarded funding to explore "Barriers and opportunities for commercialization of gene-edited beef and dairy products" https://www.ontariogenomics.ca/funding-opportunities/awarded-projects/genomics-in-society-interdisciplinary-research-teams-gisirt/#Commercialization-of-Gene-Edited-Beef-and-Dairy-Products.

Jill McCluskey at Washington State received a grant "Social interaction and consumer acceptance of genome editing in domestic livestock" available at CRIS https://cris.nifa.usda.gov/cgi-bin/starfinder/122683/crisassist.txt.

To increase transparency and public participation in the regulatory process, the New Substances Program in Canada has commenced a "Voluntary Public Engagement Initiative". Notifiers voluntarily provide a brief summary which is published on the Program's website to enable the public to submit science-related comments. https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/voluntary-public-engagement-initiative.html.

4. What can we do to address marketing and trade issues?

Michael Eckerstorfer said that labels as a means of providing information is established and not much debated in Europe. The struggle with food labeling is that there is so much that might be labelled and limited attention by consumers. There are some unnecessary/confusing labels, e.g., that salt is cholesterol-free.

Diane Wray-Cahen noted that the challenge with genome editing is that different countries make different decisions relative to what is regulated (as biotech). There is no way to trace a product through international trade if definitions of biotech/GMO differ, i.e., an exporting country does not consider a product to be GMO and the importing one does. The cost of tracing animal products is quite expensive.

Javier Martinez noted that while labeling is standard in Europe, the ability to trace a product that is identical to a natural outcome makes it very challenging to enforce regulations.

Steve Brody observed that gene editing is new, or non-existent in some key production and trade markets, and will have to be accepted or not on a market-by-market basis. He observed that Regulators are beginning to note the importance of international trade and marketing. While not part of the formal risk assessment, developers are being asked by regulators about how we are preparing for export markets. Developers hope that harmonization of regulation is realized among countries, that approval by some progressive countries might inform decisions by others. Even if a company is not going to market in Europe, they still need to engage with European policy because the EU is considered to be a thought leader.

Pablo Ross asked, when you cannot distinguish two products, but the label is different, what is the point of the label? At the same time, there is a lot of information that could be provided (e.g., cattle breed) that is not included. Does this affect the product? We need to think critically about the objective of the label.

Nathalie Dore noted that in Canada on the grain side, developers often delay the commercialization of new products until export is possible in major markets. Regulatory procedures and timelines may vary considerably between countries, leading to asynchronous product approvals. How do we overcome regulatory issues so farmers can access new products, address agronomic issues, and export? Asynchronous biotech approvals are not a safety concern, as the product has been found to be safe and authorized in multiple markets. The question is how to pursue international discussions to overcome these regulatory differences and get farmers access to the traits they need.

Cindy Tian, referring to the point of labelling two things that are the same, noted that consumers are concerned about how things are made, e.g., organic food. Even some conventional produce are equivalent to organic produce in terms of pesticide residues, the public still wants labels (despite that

many organic-food users don't know organics are not about nutrition or safety). Diane Wray-Cahen noted that consumers are most concerned about pesticides, but that does not go on labels. She noted that people do not understand what "organic" means, and now some producers need to pay for the "non-GMO" label too in order to compete, although "organic" already means "non-GMO". Pablo Ross suggested that people buy organic because they think its healthier and that people are misled.

Alison Van Eenennaam noted that voluntary labelling is allowed, sometimes even when misleading (e.g., non-GMO salt). She noted the issues pertaining to clones. All of the semen from clones that have gone to Europe are not traced. And wondered whether that will also happen for gene-edited products. Ana Granados noted that there is no regulation on cloned offspring or food from them. It was too complicated to trace through 5-6 generations, so regulations and labels were never developed. The problem is the supply chain, labeling the origin of meat, and food processers did not want to do it. Diane Wray-Cahen observed that labelling costs money. The cost of labelling cloned products was an estimated 800 million Euros per year, so the European Parliament stopped pursuing the issue.

5. What potential follow-up activities would be beneficial?

Cindy Tian noted that China has invested heavily in the development of animal biotechnology. A large proportion of all genetically engineered organisms are reported by Chinese scientists and she suggested that Chinese stakeholders should be more involved. The Chinese government is looking at the USDA/FDA for leads.

Eric Hallerman noted the Chinese participated in past programs and technical exchanges in both directions. Eric and Diane Wray-Cahen noted that future engagements with China are likely. Diane Wray-Cahen noted that we would be working to make the information on the website available to China (Google cannot be used there).

Michael Eckerstorfer suggested the utility of information and data sharing so European institutions (as well as institutions from all countries which require using detection as an enforcement tool) can develop analytical detection methods for GEd products. He suggested that sneaking undetectable products into trade may backfire. OECD or other established international fora might provide an established forum for information exchange to enhance transparency as products are approved and/or placed on the global market.

Steve Brody suggested that the types of dialogues embodied in these workshops need to continue. Talking internationally to open markets provides a way to force decisions by regulatory agencies to make sure that products are reviewed and assessed for risk. Often, regulators will say bring forward a real product and timeline to force the issue. Diane Wray-Cahen asked how we can share information from those exchanges more broadly. Steve suggested discussion at regional economic forums by organizations such as APEC, Mercosur, the CPTPP, and USMCA. Sabreena Larson suggested stakeholder meetings to discuss what is in the product pipeline, though COVID has stalled that. The regulatory process becomes a reality as products are developed. Other possible forums might be organized by the Food and Agriculture Organization or OIE (World Organization for Animal Health).