Emerging Gene Editing Technologies in Agriculture

Meeting Summary

Friday, October 14, 2016

Overview of Discussion

Gene editing technologies and their potential applications to human health, food, and agriculture are accelerating. Robust conversations about the technologies' use in medicine and human subjects are underway, but constructive and in-depth societal dialogue must also take place about how gene editing technologies can be deployed within food and agriculture.

On October 14, AGree brought together experts and leaders from diverse sectors, including non-government organizations (NGOs), the public sector, academia, and private companies to:

- Provide an overview of emerging gene editing technologies to explain differences and similarities between CRISPR, zinc fingers, and TALENs and how they differ from other advanced agricultural technologies (e.g., transgenics);
- Explore applications of gene editing techniques for food and agriculture;
- Identify and discuss the positive opportunities gene editing presents for global challenges, consumers, researchers, companies, and others; and
- Identify and discuss questions being raised about gene editing that may impact the trajectory of these technologies.

Key Insights

Several themes emerged from the discussions, which are detailed below.

The Nature of Gene Editing Technologies

The use of gene editing technologies can result in a spectrum of outcomes, spanning those that could have been achieved through conventional breeding techniques to those that could not have been. Additional background information is available from the October 10, 2016, AGree *Gene Editing Technologies 101* webinar that features overview presentations by Neal Gutterson,

Vice President of Research and Development at DuPont, and Jennifer Kuzma, Goodnight-NCGSK Foundation Distinguished Professor in the Social Sciences and Co-Director of the Genetic Engineering and Society Center at North Caroline State University.

Opportunities

Several applications of gene editing technologies for crops and livestock are already under development, presenting traits to improve disease resistance, attractiveness to consumers, and animal welfare. Examples include:

- Hornless cattle;
- Waxy corn;
- Mushrooms that resist browning;
- Pigs resistant to porcine reproductive and respiratory syndrome virus (PRRSV);
- Wheat resistant to powdery mildew; and
- Chickens that produce only female offspring.

Participants noted several potential benefits that gene editing applications in agriculture could provide, which include but are not necessarily limited to the following.

- **Public health benefits:** Applications of these technologies in food and agriculture have the potential to contribute to public health by providing consumers in the U.S. and internationally with foods (including produce and meats) that are more nutrient-dense and protein-rich.
- **Benefits to communities in developing countries:** Due to its relatively low cost, gene editing technologies present promising opportunities to impact crops beyond just commodities and deliver economic, social, and environmental benefits to smallholder farmers and communities in developing countries.
- **Supply chain benefits:** One potential application includes inserting a genetic barcode into products to facilitate supply chain monitoring and traceability.

Social License Challenges

The eventual success of gene editing technologies' applications to food and agriculture will depend upon public confidence, acceptance and trust. Several participants noted that building consumer trust should be a top focus. Participants shared the following reflections on lessons learned from past experiences with genetically modified organisms (GMOs).

- Initial discussions about the introduction of genetic engineering in the 1980's and 1990's did not adequately consider issues regarding public confidence, understanding, and acceptance, and ways to address those issues through transparency.
- Mixed messages engender public distrust: it is confusing to say that gene editing technologies are both revolutionary *and* really no different from what has been done in the past.
- The term "GMO" has in many cases become synonymous with aspects of the food system that are unpopular among consumers, including non-technical issues such as corporate consolidation and control.

To foster public understanding, appreciation, and acceptance, some participants suggested it will be important to help consumers understand the broad social, nutritional, environmental, and animal welfare benefits possible through gene editing technologies' applications, as well as the potential downsides of the technologies.

Appropriate Regulatory Frameworks

Plant and animal applications of gene editing technologies do not fit neatly within existing U.S. regulatory frameworks (i.e., the Coordinated Framework). For example, gene edited animals may be regulated as animal drugs under existing law. Participants emphasized that the revision to the Coordinated Framework for biotechnology provides an opportunity to shape future regulatory laws and regulations related to gene editing.

New regulatory paradigms developed in the U.S. and internationally will be critically important to the development of gene editing's applications to food and agriculture. Participants recognized an over-arching need for consensus-building among diverse stakeholders on this topic. The technologies have the potential to be democratically utilized and applied to achieve broad societal benefit, as long as regulatory frameworks are developed appropriately.

Participants expressed a range of perspectives and ideas about the appropriate regulation of gene editing technologies' applications, including the following.

- **Risk-based regulation:** The risks posed by various applications of gene editing technologies fit along a continuum; for example, products that could have been developed through conventional breeding techniques often carry a lower risk profile than those that could not have been. Some participants expressed that the level of regulatory oversight should correspond to the degree of risk posed by a product, including the future consequences and indirect outcomes associated with a product's implementation – this could be characterized as a risk-based framework. They noted

that simply regulating products according to whether or not they could be classified as GMOs would be inadequate. Others emphasized that even risk-based regulations inevitably involve value judgements, as decisions must be made about the levels of risk that are permissible.

- **Regulation dependent upon end use:** Participants also suggested that the degree of federal regulation could depend upon a product's intended use. For example, foods might benefit from more robust oversight than fibers meant for clothing.
- **Premarket approval:** It was noted by some participants that the process used for transgenic GMOs (i.e., a voluntary notification system) has not successfully built public trust in the technology. This lesson should inform the development of a regulatory framework for applications of gene editing technologies.
- **Federal resources:** Participants indicated that resources to implement regulations remain a concern; the Food and Drug Administration has 2.5 FTEs (full time equivalents) to review biotechnology-derived foods.
- **Labeling**: Some participants noted that labeling foods for ingredients that are accepted as safe creates a negative stigma against those products among consumers. Others noted that labels help to increase transparency and thereby build consumer trust and confidence.
- **Building public trust:** It was repeatedly stressed that federal regulation plays an important role in building public trust. Efforts to develop a regulatory framework should seek to balance this goal with appropriate risk-based regulation. Some consumer-facing companies would like to see the development of a federal regulatory framework for applications of gene editing technologies in order to provide a credible assurance of safety for their customers. In the absence of federal regulations, companies might need to set their own policies for products containing gene edited ingredients.

Global Context

Participants discussed global dimensions of gene editing technologies' applications and regulatory frameworks, including implications for international trade, intellectual property (IP) considerations, and the current state of internationally-focused agricultural research.

Perspectives shared by participants included the following.

- **Trade implications of regulation:** As respective country regulations impact U.S. global trade, harmonization of regulatory programs across the globe is crucial. A U.S. regulatory framework can be developed in ways that increase the likelihood of harmonization, by establishing a precedent that other countries can follow.

  - Brazil is currently in the early stages of dialogue regarding regulation of gene editing technologies' applications to food and agriculture.
  - Efforts are also underway to support socially compatible regulatory frameworks in developing countries for biotechnology applications to food and agriculture, including gene editing technologies. The greatest success thus far has occurred in countries that are able to involve local scientific expertise in regulatory efforts.
- **Intellectual property (IP) considerations:** It is widely recognized that IP protections incentivize innovation. However, consumers are interested in *who* will benefit from IP rights and related licensing of gene editing technologies. Will consumers perceive "big agriculture" to be the primary beneficiary, or will they perceive benefits as more broadly shared? Equity, fairness, and affordability must be factored into the public discourse around gene editing technologies' use.
- **Public funding for agricultural research:** Funding for international agricultural research has been extremely volatile, due in part to recent fluctuations in commodity prices and waning donor interest. In addition, funding for domestic agricultural research, particularly in the land-grant system, is in decline, while many national research programs in developing countries face similar challenges. Sufficient public funding must be available to enable public-private partnerships to develop and deploy applications of gene editing technologies.

Continuing the Dialogue

Participants expressed strong interest in continuing discussions. Issues of particular interest included regulatory frameworks for applications of gene editing technologies, their connection to consumer trust and acceptance, and global trade and commerce issues. Further dialogue among diverse experts will help ensure that applications of gene editing technologies can contribute to broad societal benefits.

Participants

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