To: Senator Patty Murray, Chair of the U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)
From: Science and Technology Policy Analyst
Date: April 25, 2022
Subject: Consensus Conference - USA Genome Editing of Pigs

Executive Summary

Gene-editing technology has been broadly used in medical treatment and therapy development and entertainment since early 2000s. CRISPR, a more precise and more effective method to transform valuable traits or remove undesirable traits in DNAs, is promised to solve contemporary social problems by improving quality, variety, and productivity of foods, increasing disease resistance, alleviating global hunger and medical resource shortage, etc. However, ethical concerns about animal welfare and the disadvantaged follow the excitement of the new techniques, and opinion gaps between the experts and the public gradually expand.[i] To keep the scientific techniques moving forward, meanwhile protecting diversity and equity of organisms, especially human beings and animals, consensus conference allows citizens with various backgrounds to attend, brings diverse opinion lenses to the discussion, and impacts policy making accordingly and ultimately.

Choice of Method and Design

The traditional ways of gathering opinions about regulations of gene-edited pigs are through public comment on published draft guidance, testimonies proposed by biological scientists or medical researchers, and public hearing held by the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP).[ii] [iii] [iv] [v] Under these processes, the minority are usually excluded from joining the discussion and expressing their statements. Although germline human genome editing is still prohibited across the states, it is possible that biological scientists use pigs as tools to transplant organs in humanity bodies to "change" the abnormal ones. The disability studies scholars and women with genetic differences are in tremendous worries about "being disappeared" with the genetic scissors without anyone noticing because of them being "imperfect."[vi] In addition, food safety and impacts to the environment are also under debates, where people with innate immune system disorders barely have a chance to speak for themselves.[vii] Diversity and inclusion are little considered in the dialogues regarding genome editing technology.

With a properly designed consensus conference, stakeholders with various power of impacts, scientists with expertise in gene-editing techniques, ethicists emphasizing moral rules in actions and decisions, government agencies considering the feasibility and the fundings of the proposals, and lay people such as consumers can all be involved in the discussion. While the outcome is not

obligately a single and concrete consensus, which can also be an agreement about the navigating direction, it assures different stakeholders to state their ideas and commitments.[viii] A successful consensus conference should make sure to reach the consensus by agreement instead of majority voting, have all necessary interests represented, maintain a productive and flexible climate for communication and problem solving, and that the participants follow the ground rules and commit to carrying out their agreements.[ix]

Counterarguments

Opponents may argue that a consensus committee makes people feel like they've done their jobs because they've reached an acceptable conclusion among the participants, but it is not necessarily the best option to implement. In addition, the feasibility of the agreement is not always guaranteed in a consensus conference, even with the participation of government agency officials. Thus, it is only a valid process when reaching the agreement is more important than getting accurate plan to solve social problems under the discussion topic.[x] However, the result consensus does not ensure that no one is sacrificed. Moreover, if persuasion and compromise did not work well during the process, the meeting could last forever.[xi]

To respond to the criticisms, consensus conference is as far the best way to include diverse stakeholders to discussion that has no right or wrong answers and power up the minority. A careful participant recruitment process with motivation and experience assessment can help reduce the possibility of lack of enthusiasm in keeping moving forward even after the conference as well as the flaws of underrepresentation. Furthermore, at least a degree of evidence should be provided showing that the proposed option will not sacrifice others' rights or quality of live severely during their parlance. Public officials are invited to the conference to examine the feasibility and provide visions about fundings of the recommended agreements. Last but not least, time will be allotted by experienced facilitators, who are the officials from the U.S. FDA and Senate and assist with guiding the discussion to a convergence when the topics start to diverge.

Consensus Committee

Focal Issue

The consensus conference will focus on the regulation recommendations of gene-edited pigs as food and as organisms.

Location

In order to avoid further burdens on moving, especially for attendees who are disadvantaged, this consensus meeting is planned to be virtual, but the facilitators, public officials from the U.S. FDA and Senate, will reach out to the selected participants in advance to the meeting start to know

about their needs in assistance with equipment or technical skills to operate the software to successfully participate in the conference.

Facilitation/Ground Rules[xii]

To ensure the quality of the deliberation and that the exercise is legitimate both in the eyes of the participants and of policymakers, participants will have to agree to the following ground rules with their signatures, and the facilitators will pause or suspend the conference not based on how the discussion aligns with their opinions but if emergency or necessary.

1. We agree that all participants in the process are equal and will show our respect using gentle candor in comments and not interrupting speakers.
2. We agree to attend and fully participate in all meetings, and all of our meetings are open to the media and to the public unless we close all or a portion of them by consensus.
3. We agree that no relevant topics are excluded from consideration unless we agree they are.
4. Agreements reached at prior meetings, unless implemented, are always open for further consideration.
5. We agree that silence on decisions is agreement. The facilitators and other participants cannot read our minds. If it appears that the group is reaching a consensus on an issue, if no one voices disagreement, it is assumed that all are in agreement.
6. We agree that we will not attribute ideas or comments made by participants to others outside of this process.

Participant and Recruitment

Generally, the recruitment will be processed both through the Internet and personal visits. A questionnaire investigating motivation of registration, degree of acknowledgement and personal statements/opinions about the focal issue, and plans about preparation for attending the meeting will be released to multiple social media and government websites. Nevertheless, in order to reach the underrepresented groups, the facilitators will select representatives from their connections or by recommendations after they conduct in-depth interviews with them. Approximately 31 participants will be selected to join in the consensus conference.

- Government officials from NIHRAC[xiii], FDA, IBCs[xiv], SCROs[xv], the U.S. Senate, etc.: 5 people
- Bio-scientists in relative fields such as bioengineers, biochemists, biomedical scientists: 5 people
- Animal science researchers in fields such as genetics and breeding, animal products, reproductive physiology, nutrition: 5 people

- Ethicists with focus in biological professional: 3 people
- Animal welfare advocacy groups: 3 people
- Animal genetics companies: 3 people
- Lay people/mere citizens: 7 people, at least two-thirds of the composition should be the disadvantaged or the underrepresented

Agenda[xvi]

There are two sessions in this consensus conference and they are arranged within one day to reduce the inconveniency of occupying participants' schedules.

Session One

The first half of the first session will help the attendees get basic insights of the others' backgrounds and build relationships. The facilitators first invite everyone to introduce themselves including their backgrounds and their standpoints. After the brief introductions, there will be 8 discussion rooms set in the virtual meeting. Attendees are allowed to jump in and out of different discussion rooms, talk to whoever they would like to, and the topics are unlimited. While it is more preferrable to have about 4 people in a room at the same time, there is no strict rules about the number of people in the same group at one time. In the second half of the first session, the facilitators will have participants prepare for their speeches based on their statements and hand in the drafts before the session wraps up. A 15-minute break sits in the transition of the first half and the second half.

Session Two

Session two allows stakeholders to ask experts questions, discuss and state their own ideas, and reach the consensus. This session will be held in the main room in the virtual meeting and will last for 5 hours, 1.5 hour for questions and 3.5 hours for discussion. Several short breaks will be inserted according to the facilitators' observation of attendees' needs.

Outcome

The outcome of this consensus conference is expected to be a consensus/agreement report with an attendee list in the document, which will later be published on government website. The report should include the method and information of this consensus conference being held, the summaries of draft statements collected in the first session, disagreements and compromises happened during the discussion, and the final regulation recommendations.

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