SUMMARY
2021 Gene Drive Research Forum
Bridging Gaps in Stakeholder Engagement
Virtual meeting, December 13-15, 2021

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Introduction and participant information

The 2021 Gene Drive Research Forum, focused on bridging gaps in stakeholder engagement, was held December 13-15, 2021 to discuss connecting theoretical and applied stakeholder engagement, integrating social science into risk assessments, and increasing regulatory capacity through stakeholder collaborations.

Stakeholder engagement, a "practical process to involve stakeholders in an activity", started to evolve as a field of study and practice in the 1960s when businesses started thinking about a broader set of actors of relevance (e.g., consumers, suppliers, shareholders, employees, and nearby communities) and shifted away from a shareholders/stock holder mind set. This shift led to the development of guidelines and best practices, many of which are now standard practice across sectors.

Stakeholder engagement in the gene drive space might encompass information sharing, consultation, participation, negotiation and partnerships, decision making, identifying and managing grievances, monitoring, reporting, etc. In 2016, the US National Academies of Sciences, Engineering, and Medicine published a report titled Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values[1], which defined groups of individuals that might be engaged with regard to gene drive technologies.

- Community: A group of people who live near enough to a potential field trial or release site that they have tangible and immediate interest in the gene drive project.
- Stakeholder: A person with a professional or personal interests sufficient to justify engagement, but may not have geographic proximity to a potential release site for a gene drive technology.
- Publics: Groups who lack the direct connection to a project that stakeholders and communities have but nonetheless have interests, concerns, hopes, fears, and values that can contribute to democratic decision making.

[1] National Academies of Sciences, Engineering, and Medicine. 2016. Washington, DC: The National Academies Press. doi: 10.17226/23405.

Stakeholder engagement is not necessarily easy. Tensions can occur between those engaging and those engaged due to confusion about expectations and requirements, only one perspective being offered leading to a narrow view of reality, and/or biases and lack of self-awareness. And there can be issues around imagined neutrality of the 'external' actors in engagement activities with real possibilities for power imbalances, for conflicts of interest, and/or for conflating of neutrality, objectivity, and honesty.

During each session, Forum participants broke into small groups to discuss, under Chatham House Rule, their own views, opinions, and ideas. Moderators for the small groups were provided with questions to facilitate discussion; however, the meeting organizers encouraged moderators and participants to follow any interesting path of conversation within the context of the session's topic. This allowed room for innovation of thought and resulted in some fascinating conversations and insights.

Major themes emerged across the individual small group discussions. And rather than summarizing each discussion individually, the following is an interpretation of the ideas generated, issues identified, and questions posed that were relevant to bridging gaps in stakeholder engagement, as well as action items that with follow-up might lead to short- and long-term solutions to bridge those gaps. While the organizers worked diligently to assemble a diverse group of individuals representing a broad range of experiences and expertise, geographical locations, familiarity with gene drive technologies, profession, race, and sex, it is important to note that these meeting outcomes are not consensus-driven or the result of a formal recommendations development process and may require additional vetting among other stakeholders. Operating across applications in conservation, food security/agriculture, and public health, participants were working in the following spheres: advocacy, anthropology, bioethics, biological sciences (entomology, genetics, molecular biology, parasitology, etc.), engagement, funding, mathematical modeling, policy, regulatory, regulatory sciences, risk assessment, and social sciences.

Participant and observer organizations (country)

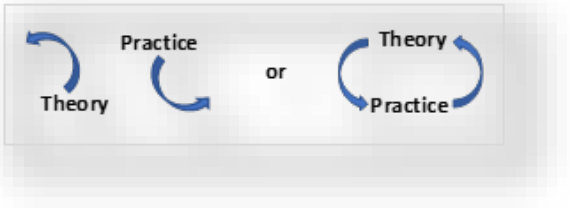
- Agroscope (Switzerland)
- Bill & Melinda Gates Foundation (United States of America)
- Biosafety South Africa (South Africa)
- Biotechnology and Biological Sciences Research Council (United Kingdom)
- Cambea Consulting Ltd. (United Kingdom)
- Commonwealth Scientific and Industrial Research Organisation (Commonwealth of Australia)
- Delphine Thizy Consulting (Kingdom of Belgium)
- Environmental Health Safety Consultancy, Ltd. (Republic of Kenya)
- European Food Safety Authority (Republic of Italy)
- Foundation for the National Institutes of Health (United States of America)
- Harvard University (United States of America)
- Ifakara Health Institute (Tanzania)
- Imperial College London (United Kingdom)
- Institut de Recherche en Science de la Santé (Burkina Faso)
- Island Conservation (United States of America)
- Japan Agency for Medical Research and Development (Japan)
- Liverpool School of Tropical Medicine (United Kingdom)
- McMaster University (Canada)
- National Institute of Public Health of Cabo Verde (Republic of Cabo Verde)
- National Institutes of Health (United States of America)
- National Invasive Species Council (United States of America)
- North Carolina State University (United States of America)
- Office of the Gene Technology Regulator (Commonwealth of Australia)
- Open Philanthropy (United States of America)
- Outreach Network for Gene Drive Research
- Peking University (People's Republic of China)
- Policy Consultants (United States of America)
- Predator Free 2050 Limited (New Zealand)
- Regulatory Consultants (Democratic Republic of São Tomé and Príncipe; The Netherlands)
- Retired regulators (United States of America)
- Revive & Restore (United States of America)
- Texas A&M University (United States of America)
- The Hebrew University of Jerusalem (Israel)
- Uganda Virus Research Institute (Uganda)
- U.S. Department of Agriculture (United States of America)
- U.S. Department of State (United States of America)
- University of Adelaide (Commonwealth of Australia)
- University of British Columbia (Canada)
- University of California San Diego (United States of America)
- University of California, Davis (United States of America)
- University of Dar es Salaam (Tanzania)
- University of Exeter (United Kingdom)
- University of Ghana (Republic of Ghana)
- University of Otago (New Zealand)
- University of Sciences, Techniques and Technologies of Bamako (Republic of Mali)
- Western Michigan University (United States of America)

December 13, 2022: Connecting theoretical/conceptual and applied stakeholder engagement
Chair: Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé

Forum participants acknowledged that individuals developing theory about or practicing stakeholder engagement both provide important contributions to address issues of local, national, regional, and global concern. In addition, participants recognized that these contributions often can be either intertwined or at odds. Social scientists and engagement practitioners tend to work in different ecosystems with different requirements and different measures of success. During this session, Forum participants explored similarities, complementarities, and differences for those working in applied/practical spaces of engagement and those working in the theoretical/conceptual spaces, explored challenges and barriers for developing closer working relationships, and explored mechanisms for bridging 'gaps' between theory and practice.

<u>Partnership of practice and theory.</u>

Theory is "a way to design and perceive facts and organize their representation … to define, describe, understand, explain, represent and predict". Social scientists have tools to monitor and evaluate engagement activities, to understand theoretical approaches, and to develop theories that might underpin and bring rigor to practice. Practitioners, who "put to practical use" theory by "applying general principles to solve definite problems" in actionable, functional, practical manners, have the tools and experience to understand the specific stakeholders to be engaged in a manner that is necessary to create value for communication efforts. Practitioners bring an understanding of the stakeholder's access to technology, cultural beliefs and values, domestic and social expertise, education levels, historical events, linguistic diversity, political landscape, priorities, religion, sources of trust, transportation, vocations, etc. However, efforts to convert stakeholder engagement theory into practically applied approaches may fail if assumptions for engagement activities are inaccurate or inappropriate for a specific given situation.



Mechanisms for iterative processes of input and feedback – theory to practice to theory to practice, etc. – to improve theories and to improve practice in a given situation may not be established or functioning. Discipline-related cultural divides combined with other barriers to communication such as lexicons and languages used to communicate might lead to misunderstandings, misinterpretations, and/or duplication of efforts negatively impacting alignment, coordination, and collaboration among social scientists and engagement practitioners.

Who is a theoretician and who is an engagement practitioner? Forum participants thought it might be interesting to explore why a dichotomy of theorist versus practitioner exists. Who works in which ecosystem and when? Is this dichotomous characterization of individuals as 'theoreticians' or 'practitioners' useful or detrimental? The answer may be that it depends on the circumstances.

Theoreticians may not always know the utility of their theories, so feedback from application of theories is needed. And, often, practitioners do not have time and other resources to contemplate new theories, apply them specifically, or to provide feedback to contribute to the iterative process of theory refinement. Building fair and equitable bridges between these professional communities is important.

Action items:

- Provide resources to allow for formal intradisciplinary engagement (e.g., field site visits).

- Define and create safe, inclusive opportunities for social scientists and engagement practitioners to engage in conversations to exchange ideas, to discuss similarities and differences between theory and practice with an eye to identifying solutions, and to create collaborations.
- Provide resources (e.g., funding) and time for practitioners to participate at meetings, conferences, and workshops.
- Define the incentives for each group to recognized that connecting these professional communities is beneficial.
- Explore the benefits and disadvantages of dichotomous characterizing of individuals.

Currency of success and knowledge sharing

Measures of success for engagement practitioners and for academic theorists differ widely, but that difference should not imply that success for one is bought at the cost of success for the other. In academia, the currency of success largely lies in the dissemination of theories, data, and analyses through publications and citations; for practitioners, the currency for success largely lies in problem solving through mediating, engaging stakeholders in conversation, etc. Academics are recognized as experts through their publications, but how are practitioners recognized as experts when the currency for success may not have a public face? The current 'gold standard' for disseminating information and for measuring success is publishing; however, publishing can be a daunting task for practitioners who may lack the time and resources to write, who may encounter language barriers with English as the primary language for scientific publication (as compared to the compendium of languages used by practitioners), or who may work with confidential or sensitive information not for public consumption. This creates a tension between transparency and inclusiveness, as implied by publication, and creating a safe space and a sense of trust, as is needed for confidential or sensitive discussions.

Action items:

- Explore fit-for-purpose methods to demonstrate value and achievement, and to attribute and reward contribution.
- Identify new or modify existing methods of knowledge sharing to make theoretical information accessible to practitioners while also normalizing this as a method of public dissemination that obviates the need for publication in traditionally accepted academic channels.

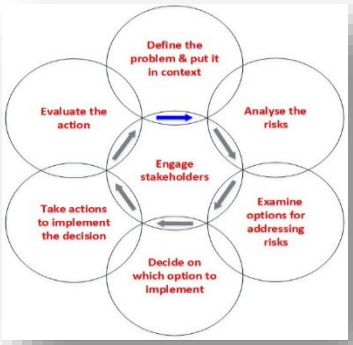
Communication

The language of academic publication is generally English, but practitioners work in many other languages. Publications, meetings (including this one), conferences, and other means of communications are principally conducted in English, often making them inaccessible to colleagues who do not speak it or may be uncomfortable communicating (in written and/or oral form) in English. And not only might there be a language barrier, but the social science and practitioner lexicons differ, potentially contributing to broad disconnects between these two professional groups. Academic speak can come across as exclusive and excluding anyone outside the academic sphere. Lastly, it is important to note that written and oral communication abilities require potentially distinct skill sets.

Action items:

- Improve accessibility by including interpretation services for events and other resources.
- Build a common lexicon for communicating about engagement theory and practice.

December 14, 2022: Exploring why and how to integrate stakeholder engagement into risk assessment
Chair: Keith Hayes, Ph.D., Commonwealth Science and Industrial Research Organisation



Geoff Hosack, Ph.D., CSIRO, as informed by the [US] Presidential/Congressional Commission on Risk Assessment and Risk Management (1997)[2]

Scientific risk assessment is based on a scientific process to "build, test, evaluate, and update measurable hypotheses". Risk assessment is an iterative process, that is both time and resource intensive. In some arenas, the risk assessment report has been burdened as the fundamental evaluative decision-making tool for new technologies, including gene drive; however, risk assessments are one of the tools in the toolbox that should be used to advise decision-making processes. Guidelines demonstrate that stakeholders are central to a risk-based decision making process. However, there is a difference between risk assessment and risk perception at the individual or community level, where opinions and values may be incorporated into a specific product's risk assessments and/or may play a role separately in the decision making. Risks identified for gene drive-modified products may be based on scientific data and may be based on concerns, opinions, perceptions, or values that align with socio-cultural beliefs, religious convictions, and/or other cultural mores. Are potential risks identified by different stakeholder groups different? Do potential risks identified carry the same influence in the risk assessment or decision-making processes? Do different stakeholders carry the same influence? Who should engage stakeholders and when, and what elements of engagement might be considered? The scientific risk assessment process may be driven by data, but stakeholder input also may be included – this is the link with risk communication. During this session, meeting participants explored the process of incorporating stakeholder perspectives into the process of assessing risk for gene drive-modified products.

<u>Challenges for incorporating stakeholder and community input into scientific risk assessment processes</u>

Robust engagement activities for risk assessment processes can be resource intensive. Resources available – funding and time – directly affect stakeholder engagement activities. Are there enough funds to conduct useful engagement activities? For example, in conducting public consultation there is a tension between wanting broad engagement and the availability of resources. Conduct far-reaching, in-person activities and resources may quickly dwindle; conduct online consultations and representation may be limited. Below are challenges and barriers to stakeholder engagement that were discussed.

- Interests and priorities: Individuals or stakeholder groups may not engage because gene drive is a low priority, or they lack interest in the subject.
- Uncertain products: Stakeholder interest may wane with the lack of a specific product narrative. Discussing future-oriented products in a very dynamic research situation may signal that some risks identified today may not be relevant for the final gene drive product.
- Polar bears versus penguins: Often, those with highly biased views speak loudest but these may not represent the majority viewpoints. "How [do we] focus on the penguins in the middle rather than the polar bears on either end?"
- Scientific/technical literacy: The level of scientific/technical literacy of stakeholders might impact their participation in engagement for risk assessment.
- Process literacy: Some individuals claiming to want to be involved in the risk assessment process actually want to be involved in the decision making process.

[2] https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=55006

- Communication of concerns: For scientific risk assessment, stakeholder concerns, opinions, perceptions, or values may need to be translated into measurable, testable hypotheses that are driven by data, which can present a challenge when stakeholders lack the means (language, lexicon, knowledge, etc.) to concretely articulate concerns, opinions, perceptions, or values in a way that they can be mapped to the endpoints of the risk assessment.
- Stakeholder compensation: There is a tension between providing compensation to demonstrate appreciation for a stakeholder's opinions and time that might facilitate participation, and the appearance of compensation-induced conflict of input or coercion to participate.
- Cultural/political divergences: The framework of current recommendations for stakeholder engagement in risk assessment processes are oriented to western cultural/political settings. In non-western societies, acceptable frameworks may look very different.
- Transparency: Stakeholders may require information about the purpose of engagement processes for risk assessment, how the information collected will be used and incorporated into the risk assessment, and about limitations of risk assessment processes.

Action items:

- Build scientific/technical literacy; Invest in education, translation, and interpretation
- Identify appropriate, locale-specific compensation/gift structures to facilitate engagement.
- Develop stakeholder engagement recommendations for risk assessment processes using frameworks that are culturally and politically appropriate for given geographies.
- Explore ways to mitigate issues associated with a lack of independence in funding sources.
- Create mechanisms/platforms to support transparency requirements.

<u>Conducting stakeholder engagement for risk assessment</u>

Recommendations and requirements for who – project team, regulators, independent third party – conducts risk assessment and its associated stakeholder engagement, when, and how vary among countries. There may be stakeholders that product developers engage for risk assessment processes, stakeholders that regulators (bound by statute) engage, and stakeholders that third parties engage; stakeholder groups that very likely overlap.

Action item: Create stakeholder engagement recommendations for risk assessment processes conducted by project teams or independent third parties.

<u>Stakeholder labels and citizen science</u>

A broad variety of stakeholder groups may be engaged for risk assessment – government officials, indigenous peoples and local communities, scientists, and others with interest and opinions and who also have knowledge of gene drive technologies. How are individuals or stakeholder groups 'labeled' when engaged to provide input to risk assessment processes, and are these 'labels' different from engagement labels used for communities, used around technology development, or used for consent? In addition, to seeking input from, meeting participants discussed employing the power of "citizen science", where the general populace is involved with collecting information that can feed into a scientific process through a defined mechanism.

Action items:

- Revisit 'labels' applied to stakeholders for engagement in the risk assessment processes.
- Explore how citizen science might be used as an effective engagement tool.

December 15, 2021: Exploring stakeholder collaborations for regulatory capacity strengthening/building
Chair: Brinda Dass, Ph.D., Foundation for the National Institutes of Health

Forum participants explored areas of regulatory capacity that need to be strengthened or built and why the capacity is needed. They discussed the potential beneficiaries, explored various mechanisms for building or strengthening capacity, and considered who might conduct these activities for building regulatory capacity. The outcomes of these conversations are summarized below

What

- Mathematical modeling: In the gene drive technologies development sphere, it is generally recognized that mathematical modeling, "a representation in mathematical terms of the behavior of real devices and objects"[3], will play an important role in the development of gene drive-modified products as well as an important decision-support tool. Understanding modeling (at a stakeholder-appropriate level) – the value, how to use, and how to critique the data, assumptions, and results – will be important for many decision-making opportunities, including those around gene drive technologies.
- Regulatory sciences: Regulatory science, "the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of investigational products and that inform regulatory decision-making" bridges research and regulation, and "encompasses basic and applied sciences and contributes to the development of regulatory standards and tools."[4]
- Regulatory processes: Many gene drive stakeholders might benefit from better knowledge about regulatory processes, as these processes are often an enigma to those outside the field.
- The Convention on Biological Diversity (CBD): The CBD, "a practical tool for translating the principles of Agenda 21 into reality"[5] is a multilateral treaty and understanding its impact on regulatory processes may influence research activities.
- Risk assessment: Building capacity in risk assessment will aid decision-making processes.
- Broad courses (biosafety, genetics, risk assessment, etc.): Courses that especially incorporate teachings about gene drive technologies and regulatory systems in a broader context.
- Research and regulatory activities and processes
- Stakeholder engagement activities and processes
- Any other critical gaps in scientific/gene drive technology knowledge that regulators identify as necessary and relevant to regulatory processes and decision-making
- Any other critical gaps in regulatory knowledge that researchers/developers identify as necessary and relevant to product development processes and decision-making

Beneficiaries

- Early-, mid-, mature-career level professionals

[3] https://www.sfu.ca/~vdabbagh/Chap1-modeling.pdf
[4] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf
[5] Agenda 21 (https://sustainabledevelopment.un.org/outcomedocuments/agenda21); CBD (https://www.cbd.int/convention)

- Ethics oversight and/or advisory committees (institutional, local, national)
- Indigenous peoples
- Institutional biosafety committees
- Journalists
- Local communities
- Policy makers
- Regulators
- Scientists (local to field testing sites and elsewhere)
- Students (undergraduate and graduate)
- Other stakeholders interested in regulatory processes for gene drive technologies

<u>How and by whom</u>

- Create Communities of Practice
- Attend conferences
- Develop courses, trainings, workshops to create long-term capacity
    - Master classes
    - On-demand/continuous access training courses
    - University-level courses (undergraduate/graduate)
    - Workshops centered on case-studies (mock scenarios)
- Establish database(s) to publicly share data, risk assessments, etc. to help build public capacity.
- Operate forums – to achieve the formal and informal exchange of information, knowledge sharing, and communication of lessons learned for:
    - Regulators only, intra-agency or interagency (national, international)
    - Regulators plus researchers
    - Regulators plus communities and other stakeholders
    - Researchers (biological, social science, etc.) plus regulatory scientists
    - Combined stakeholder groups across broad disciplines and sectors
- Offer seminars/webinars
- Conduct site visits and more extended immersion, learning by doing, opportunities
- Expand team representation to include regulatory science member
- Offer regulator to regulator mentorships, intra-agency or interagency (national, international)

The activities listed above might best be conducted by respected organizations with convening power and that will not benefit from the technology itself, such as academic institutions, professional societies, and scientific academies.

Action items for all regulatory capacity sections above in addition to the specific ideas listed:

- Explore barriers inhibiting regulators from speaking with scientists and the public and identify solutions to open these lines of communication.
- Identify options for funders supporting both product development and regulator capacity building/strengthening that will decrease conflicts of interest (real or perceived)
- Generate high-level political commitment to building/strengthening regulatory capacity