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Principles for Governance: Gene Editing Applications in Agriculture and the Environment

*Perspectives provided by the following
U.S.-Based Food-, Agriculture- and Conservation-Focused NGOs:*

Center for Science in the Public Interest, Consumer Federation of America, Environmental Defense Fund,
National Wildlife Federation, The Nature Conservancy, World Wildlife Fund - US



Executive Summary

Purpose:

This document provides a high-level set of considerations for addressing gene editing governance concerns that we share as U.S.-based food, agriculture and conservation NGOs. Principles are offered particularly in the context of the U.S. and as a starting point for collaboration with the diverse sectors that contribute to the responsible innovation and governance of biotechnology: scientists, product developers, regulators, civil society, and more. Our organizations look forward to proactively engaging in the societal processes of analysis and deliberation necessary to further refine and implement these principles.

Principles:

1. Gene editing technologies should be applied safely and ethically; care should be taken to avoid substantial risk and deliver tangible societal benefits.
2. Robust, inclusive societal engagement is essential.
3. Effective, science-based government regulation is required for realizing the full benefits of gene editing and managing for risks.
4. Voluntary stewardship and best practices should supplement regulatory oversight through engagement, transparency, and product assessments that consider a full range of risks and benefits (health and safety, social, economic, and ecological) prior to any release into the environment.
5. The public should have access to clear information identifying which gene editing applications are in use in food, agriculture, and the environment.
6. Inclusive access to gene editing technology and resources can help drive societal benefit.

Context

A myriad of potential applications has been proposed for the use of gene editing technologies in plants, animals and the environment, including for purposes of agriculture, conservation, and public health (e.g., vector control).¹ The rapid evolution of gene editing applications in agriculture and the environment carries potential positive and negative ecological, social and economic implications. Debates over the use of gene editing technologies encompass a wide and often polarized spectrum of perspectives on potential risks and benefits as well as both *whether* and *how* these technologies should be applied.

In the United States, applications of gene editing in agriculture and the environment are actively being researched, developed, and commercialized, and how U.S. biotechnology regulations apply to gene edited products is still being worked out. It is within this context that we, as U.S.-based food-, agriculture-, and/or conservation-focused NGOs, are concerned with the responsible governance of these technologies as they relate to our shared missions. We hold neither advocacy positions of strict opposition nor unconditional support for whether these and related genetic engineering technologies should be utilized. Yet to the extent that they are being and will continue to be developed and utilized in agriculture and the environment, it is critical that we consider *how* this occurs: for what purposes, under what conditions, where, when, with what societal input, and with what management, oversight, and stewardship. We offer governance principles specifically within the U.S. research, development, regulatory and social/cultural context, recognizing that, 1) these principles may or may not be directly relevant to other contexts and, 2) that governance of gene editing in the U.S. can affect social, economic, and environmental outcomes in other locations.²

The principles offered herein focus on genome (or gene) editing, which has various definitions. For purposes of this document we adopt the National Academies' definition of genome editing as "specific modification of the DNA of an organism to create mutations or introduce new alleles or new genes."³ Our principles are relevant to related technologies involving modification or creation of genetic material through methods other than traditional breeding (i.e., engineered gene drives, other forms of genetic engineering, and synthetic biology).

Gene editing technologies such as CRISPR/cas systems have created governance considerations due to the use of those techniques and the products they produce, including: greater diversity of potential applications; increased focus on cisgenic edits (edits involve genes of the particular species) rather than transgenic edits (edits involve incorporation of genes from other species); rapid evolution; decreased cost; and increased speed of use, ease of use, precision, efficiency and efficacy.

However, newer techniques are not divorced from the broader social, ecological, and economic histories, contexts, and debates related to earlier genetic engineering technologies and synthetic biology, including perceived prior harms and failures of biotechnologies to live up to promises of delivering broad societal benefit.

¹ For information on potential applications of gene editing in food, agriculture, and the environment, see, for example, National Academies of Sciences, Engineering, and Medicine (2017). **Preparing for Future Products of Biotechnology**. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24605> and Redford, K.H., Brooks, T.M., Macfarlane, N.B.W. and Adams, J.S. (eds.) (2019). **Genetic frontiers for conservation: An assessment of synthetic biology and biodiversity conservation**. Technical assessment. Gland, Switzerland: IUCN. xiv + 166pp, <https://doi.org/10.2305/IUCN.CH.2019.05.en>.

² The principles below address products designed for agricultural and environmental uses and include neither editing of the human genome nor of products developed for medical purposes.

³ The National Academies of Sciences Engineering and Medicine (2017)

Principles

Principle 1: Gene editing technologies should be applied safely and ethically; care should be taken to avoid substantial risk and deliver tangible societal benefits.

- a. **Avoid substantial risk.** Applications of gene editing technologies should be carefully and inclusively developed, applied and stewarded to manage for potential risks to agriculture, food systems, human health and priorities, non-human species, and the environment. Some potential uses may carry substantial potential risks; where regulatory bodies determine through science-based risk assessment that the potential risks associated with a particular use or application of gene editing are substantial and cannot be adequately managed, that product should not be approved for use and released in the environment.
- b. **A broad range of benefits should be considered.** Gene editing product developers are encouraged to consider, with the input of societal stakeholders, how gene editing could be applied to help to foster and support: ecological and social resilience, biological diversity, natural resources, human health, animal health and welfare, economic and rural development, equitable societal outcomes, food security and food sovereignty, climate resilience, energy security, and context-specific cultural values.

Principle 2: Robust, inclusive societal engagement is essential.

- a. **Prioritization of which applications to pursue and how to govern them should involve societal input.** Technology developers should take proactive, inclusive steps to identify, engage, and incorporate input of diverse communities, stakeholders, and/or publics at an early stage in the research and development cycle. This input should include priorities, concerns, objections and perspectives on risks and benefits of specific applications of gene editing. Developers should strive to create solutions acceptable and responsive to those engaged.
- b. **Stakeholder engagement is a precondition for social license.** Transparent, meaningful, respectful, two-way dialogue should incorporate diverse viewpoints and the preferences of different regions and cultures, including those that do not support the technology for proposed applications.
- c. **Stakeholder engagement should be a component of the regulatory process.** The regulatory process should engage proactively and meaningfully with stakeholders to help assess risks and benefits. Engagement should include and extend beyond traditional written comment processes.

Principle 3: Effective, science-based government regulation is required for realizing the full benefits of gene editing and managing for risks.

- a. **Regulators have the responsibility to assess the risks of gene-edited products for humans, animals, and the environment before release.** Applications that carry substantial risks that cannot be adequately managed should not be approved for use. Ongoing monitoring and oversight should identify and address any substantial impacts following product approval and use in agriculture or the environment; this should include the ability to withdraw approval, remove the product from the market, and – where possible – remove it from the environment. Applicable laws, including compliance with U.S. National Environmental Policy Act (NEPA), must be enforced during development, field testing, and, if relevant, implementation of approved applications of gene editing.
- b. **Regulation should be based on the best scientific evidence available and should be tailored and proportionate to the likelihood of risk.** Regulatory processes should incorporate the necessary scientific tests, analyses, and production procedures needed to assess the risks and safety of gene-edited products. These processes should incorporate expert and stakeholder input to identify relevant risks, data requirements, risk assessment methodologies, and risk management opportunities. Regulations should stipulate the conditions that trigger comprehensive risk assessments of individual products.

- c. **Use a tiered approach to align the assessment with the likely risk associated with a gene edited product.** Screening can determine which tier of risk assessment is appropriate based on the potential risk profile of the product. Assessment of low risk products should be expedited. At a minimum, risk assessment should assess whether the altered trait(s) have the potential to increase the probability of the following: 1) escape from cultured environments/invasion with harmful impacts (e.g., to native biodiversity, environmental quality, health, or other effects to the human environment); 2) unintended hybridization or successful out-crossing; and, 3) unintended impacts of the organism or management of that organism to health, resource availability, biodiversity, or ecosystem services.
- d. **Regulatory risk assessment should investigate the potential impacts of gene-edited products and should not assume that these products are fully analogous to those derived from conventional breeding.** The process of gene editing alone may not be predictive of the product's risk. Science- and risk-based oversight is needed to identify and manage any risks of gene edited products to humans and the environment.
- e. **Regulation of gene editing must balance societal safeguards with timely, efficient access to benefits.** Regulatory decisions should protect against substantial risks and should be made in a timely and efficient manner to allow for the broadest possible access and application of beneficial gene-edited products. The regulatory process should not be so onerous as to preclude the participation of smaller institutions in the development of beneficial gene-edited products.

Principle 4: Voluntary stewardship and best practices should supplement regulatory oversight through engagement, transparency, and product assessments that consider a full range of impacts (health and safety, social, economic, and ecological) prior to any release into the environment.

- a. **Regulation alone is not enough.** Technology producers and product developers should implement good stewardship, encompassing risk assessment and management, inclusive engagement, transparency, monitoring, and responsiveness to input and learnings. An industry-led and stakeholder-informed process could provide strong guidance for institutions regarding development, implementation and verification of best practices.
- b. **A product assessment should be conducted before product release.** Whereas traditional regulatory risk assessment usually focuses on safety, a product assessment should consider a gene edited product's potential for positive and negative impact on a variety of factors not addressed in the regulatory risk assessment, which could include health, environmental, cultural, economic, equity and management risks. . The assessment should address the potential to minimize any identified potential impacts through management. Stakeholder input should be incorporated into identification and framing of the product assessment.
- c. **Voluntary assessment of the benefits, impacts, and efficacy of gene edited products should continue throughout the lifecycle of the product, including post-market.** Following product release, data on benefits and impacts should be collected and shared, any adverse incidents should be reported to and investigated by regulatory authorities, and risk assessments should be updated. Contingency plans should be developed in case there is a need to withdraw a product from the marketplace and/or, as possible, from the environment.

Principle 5: The public should have access to clear information identifying which gene editing applications are in use in food, agriculture and the environment.

- a. **A national registry of gene editing applications in use in the U.S. should be established.** Such a registry would ensure basic public transparency and monitoring capabilities for the technology in open-field research and use of commercial and non-commercial applications in food, agriculture and the environment.

- b. **Accessible information should enable consumers and stakeholders to understand if consumer goods and other applications have been produced using gene editing.** These approaches can build public trust and understanding of this technology. When possible, consumers who wish to avoid goods made with gene editing technology should be enabled to do so.

Principle 6: Inclusive access to gene editing technology and resources can help drive societal benefit.

- a. **A diversity of investment sources can help to drive better societal outcomes for gene editing technologies.** Public sector investment can support societal benefit and enhanced evaluation of impacts.
- b. **Technology access enables opportunities for the broadest possible set of beneficial applications.** Technology access can be leveraged by a broader range of innovators for a wider range of crops, products, traits, and environmental and societal benefits. Technology developers should engage in efforts to share and license technology to enable cost-effective access across sectors and applications.
- c. **Technology access can enhance trust.** Past generations of biotechnology created significant concerns regarding control of and access to the tools, products, and benefits of innovation. Consumer acceptance and social license will be better achieved if developers ensure that gene editing technologies are accessible for use by a wide variety of public, private, and NGO institutions.

These principles are intended to provide a high-level framework for responsible innovation and governance of gene editing technologies. Implementation of these principles will require refinement of details on issues such as: defining and managing ‘substantial risk’ in various phases of research and development; developing processes for assessing, prioritizing and monitoring product benefits; describing effective societal engagement processes; coordinating across relevant regulatory agencies to comprehensively assess and manage for risks; developing stakeholder-informed and science-based tiered assessment approaches for relevant social, economic and ecological risks and benefits; developing guidance to define, implement and verify voluntary best practices; developing and implementing a registry of gene edited products; and pursuing pathways for diversifying technology investment, access, and societal benefits.