Framework for Responsible
Use of Gene Editing in Agriculture

A GUIDE TO ACHIEVING VERIFICATION

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COALITION FOR
RESPONSIBLE
GENE EDITING
IN AGRICULTURE

CONTENTS

A GUIDE TO ACHIEVING VERIFICATION

The Verification Guide provides an overview of the verification processes which should be used in conjunction with the Verification Checklist. The processes outlined in this document should be adapted to the specific needs of the organization, its structure, the activities verified, the product(s) involved and the relevant product markets. Individual situations will vary according to the needs of each organization. The example scenarios are illustrative of verification questions for the verifier to use when documenting an organization's commitment to the principles outlined in the framework based on the breadth of the organization's activities.

I. Verification Objectives and Scope

The intent is to identify and share organizational policies, procedures and practices that demonstrate a commitment to responsible gene editing. The intent is to verify conformance with the framework at the organizational level, however, these policies and practices may also be applied at the product or application level as requested.

Participation in the Framework for Responsible Use of Gene Editing in Agriculture (Framework) is encouraged for all organizations developing applications or products using gene editing in food and agriculture.

For the purposes of the framework, gene editing is defined as a suite of technologies designed to intentionally alter predetermined DNA sequences in the genome and result in precise, targeted insertions, deletions or other changes for genetic improvement. The Responsible Use of Gene Editing framework was developed with non-transgenic applications in mind.

The framework is intended to apply to any corporation, business, academic or governmental organization that utilizes gene editing and/or its outputs in the commercial research, development or manufacture of food and agricultural products. The Framework is intended to cover plants, animals, microbes and other organisms used in agriculture and food. Program participants have committed to independent third-party verification consistent with the principles, commitments and management practices outlined in the Framework. This is in addition to the routine practice of self-assessment of the effectiveness of the participant's own internal quality management systems and/or any mandatory or voluntary regulatory oversight activities.

The Verification Guide was developed to provide guidance to program participants and verifiers that the commitments in the Framework have been met. Verifications are intended, unless otherwise noted in the Framework, to be at a systems level. The verifier is expected to verify and document, by examination of objective evidence, if the program participant has established and implemented programs, policies and/or procedures consistent with the Framework principles.

The Framework Principles included in this Guide are:

A. Transparency

B. Stakeholder Engagement

C. Safety and Quality

D. Trade and Market Considerations

E. Social Considerations

F. Continuous Improvement

G. Verification

A program participant may be involved in various stages of development and/or commercialization of a gene-edited plant, animal, microbe or other organisms used in agriculture and food. For example, an organization may limit its business to commercial research and development whereas another organization may have multiple integrated functions bridging from laboratory to commercial production and distribution. The program defines four Development Stages.

The Development Stages included in the Guide are:

Commercial Research – Pursuit of advancing scientific knowledge with the intent of commercialization. Includes research to determine possible uses for the findings or to determine new ways of achieving some specific and predetermined objectives. Research includes proof of concept experimentation that is required as part of product development. Commercial research can occur in a company or academic setting.

Commercial Development – Work using existing knowledge gained from research or practical experience for the purpose of creating new or improved products/processes. For the Coalition's purposes Commercial Research becomes Commercial Development when gene editing is applied to an organism in order to directly achieve a pre-defined commercial product goal. This includes, but is not limited to, licensing, field trials, scale-up production and other pre-commercial activity.

Commercial Sales – Market introduction and/or sale of products.

Product Lifecycle – Includes post-introduction monitoring, manufacturing, distribution, issues response and product discontinuation.

The Guide is organized first by Framework Principle and then within each principle by Development Stage. This is intended to give the user a clear understanding of the commitments agreed to by each program participant.

This Guide provides an introduction to the verification processes, including how to prepare for the verification. The Guide also provides example verification questions and objective evidence for each verification component that a qualified verifier may observe during the course of the verification. For each of the verification questions provided in the checklists, the verifier will confirm that related systems, policies, procedures, and/or work instructions are in place, and can be objectively verified, for each relevant Framework Principle and Development Stage commitments.

Because each organization is different, there are example scenarios that may be applicable for an organization, illustrating examples of appropriate questions that may be asked beyond the checklist, as well as questions that may be out-of-scope.

The provided examples of objective evidence should not be considered a prescriptive nor exhaustive list of possible objective evidence. The program participant may substitute or modify indicators of objective evidence to address local conditions based on a thorough analysis and adequate justification to the verifier, who is responsible for ensuring that revised indicators are consistent with the spirit and intent of the Framework Principles.

II. Verification Process

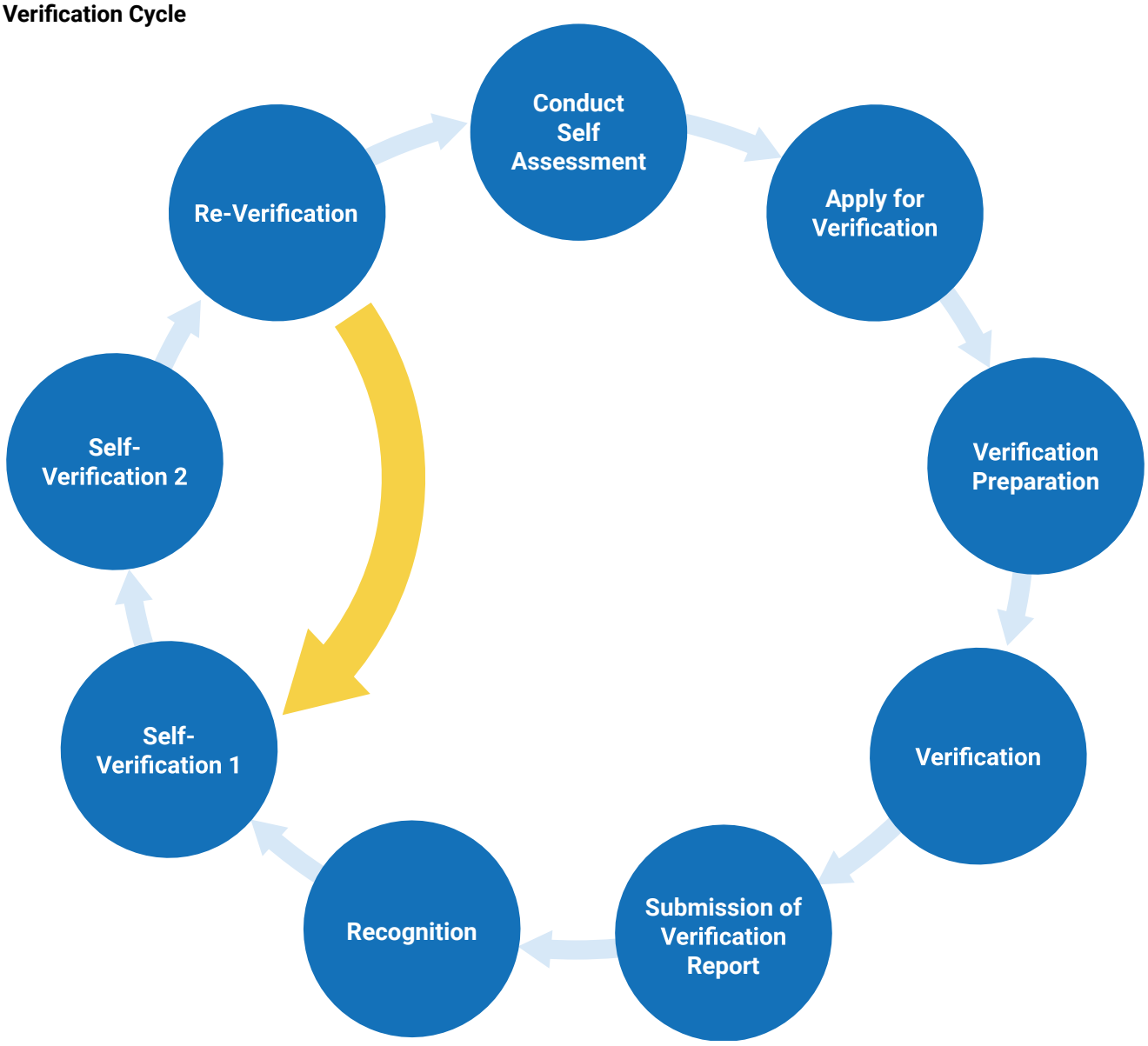
A. SELF ASSESSMENT

A self-assessment is an internal, objective activity designed to add value and improve an organization's operations and assist it in preparing for an external verification by a third-party. The self-assessment is intended to identify the systems strengths, weaknesses, and potential areas for improvement. This activity will compare an organization's documented policies and procedures relevant to its participation in the Framework with evidence of activities performed and records maintained.

The goals of a self-assessment include:

- Examining the effectiveness of the implementation of systems in meeting the Framework Commitments
- Prove that there is conformance to the Framework Principles
- Evaluate the need for improvements or corrective actions
- Prepare the team for a third-party verification.

Verification Cycle



The self-assessment process may include the following steps:

The Framework will provide a Self-Assessment Tool to assist program participants through the process.

B. PREPARATION

The Verification Body will assign a qualified verifier to a program participant after the participant has applied for verification and indicated that they are ready for verification. The Verification Body will initiate a pre-verification consultation between the parties to ensure there is a common understanding of the verification process and to jointly determine the specific Framework Commitments and Development Stages which apply. The purpose of the initial contact is to:

- Establish communication channels between the program participant and the assigned verifier;
- Verify the relevant Framework Commitments and Development Stages and accompanying Verification Checklist based on the organization's activities;
- Provide information on the proposed timing and verification team composition (if applicable);
- Request access to relevant documents; and
- Make arrangements for the timing of the verification.

The verifier will prepare a verification plan that provides the basis of the agreement between the parties. This plan will be reviewed and accepted by the verifier, the program participant and Verification Body before verification activities begin. The plan will confirm the following:

- The verification objectives;
- The verification criteria and any reference documents;
- The verification scope, including identification of the organizational and functional units and processes to be verified (Framework Commitments and Development Stages);
- The dates, places and how verification activities are to be conducted;
- The expected time and duration of verification activities, including meetings with the program participants' management;
- The roles and responsibilities of the verifier, the verification team members from the organization being verified and accompanying persons (if applicable);
- The allocation of appropriate resources to critical areas of the verification;
- The verification report topics;
- Logistical arrangements (i.e. type of virtual meeting, document transfer, etc.);
- Matters related to confidentiality; and
- Any verification follow-up actions.

The program participant will need to specify document confidentiality, retention and destruction requirements as part of formal agreement to have a verification conducted. The verifier will review, handle and retain

documents exclusively and in strict accordance with any confidentiality agreements. A Framework Verification Report (Appendix I) which outlines the findings of the verification will be made available to the Framework Oversight Committee for review. The confidentiality agreement is intended to cover those supporting documents that may be used as objective evidence and may include proprietary information which will not be included in the Framework Verification Report.

The program participant may provide documentation to be reviewed by the assigned verifier prior to additional verification activities. The documentation may include relevant management system documents and records, and previous verification or audit reports. The review will consider the size, nature, and complexity of the organization, and the objectives and scope of the verification. If the documentation is found to be inadequate, the verifier should inform the program participant and initiate a discussion on additional documentation that may be required. The Verification Body may also be contacted to assist in resolving any differences. At this step a decision should be made as to whether the program participant is prepared for the verification and if it should be continued or delayed to allow for the participant to provide additional documentation.

C. PERFORMING THE VERIFICATION

1. Opening Meeting

The verification should commence with an opening meeting to:

- Confirm the verification plan, scope and timelines;
- Provide a short summary of how the verification activities will be undertaken;
- Provide an opportunity for the program participant to provide relevant organizational overviews;
- Confirm closing meeting times (e.g., daily and overall);
- Confirm communication channels; and
- Provide an opportunity for the program participant to ask questions.

2. Collecting Information and Sampling for Objective Evidence

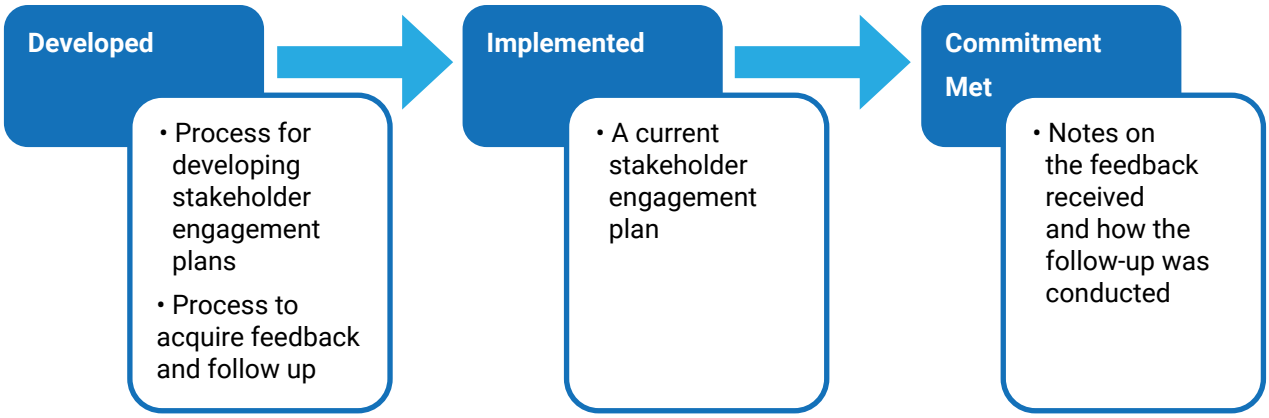
There is not a set amount of time a verifier should spend performing the document review or other verification activities as the type, size and complexity of the program participants will vary considerably. During the verification, information relevant to the verification objectives, scope and criteria should be collected by appropriate sampling and should be verified. Only information that is verifiable may be used as verification evidence and this should be recorded. The sources of information chosen may vary according to the scope and complexity of the verification and the organization.

Assigned verifiers will use their outlined procedures for collecting objective evidence. Records, procedures and processes that are used to document, establish and/or verify systems relevant to the subject of the verification will be sampled.

Verification evidence should be evaluated to determine whether the program participant's systems, policies, procedures, and/or work instructions meet the Framework Principles' commitments. The determination should be summarized by the verifier to indicate locations, functions or processes that were verified. Verification determinations for each applicable Framework program commitment along with the supporting evidence should be recorded.

There must be sufficient objective evidence to confirm the establishment and implementation of the program participant systems based on the relevant Framework Principles and Development Stages. Importantly, a program participant must show through evidence: 1) existence of a process, procedure, or plan for each relevant Framework Commitment; 2) that they have implemented the process, procedure, or plan into their operations and that it is in active use; and 3) that the process, procedure, or plan meets the identified commitment.

For example, looking at Commitment 3 under the Stakeholder Engagement Principle: Stakeholder engagement plans should include mechanisms for giving feedback or following up on input after engagement.

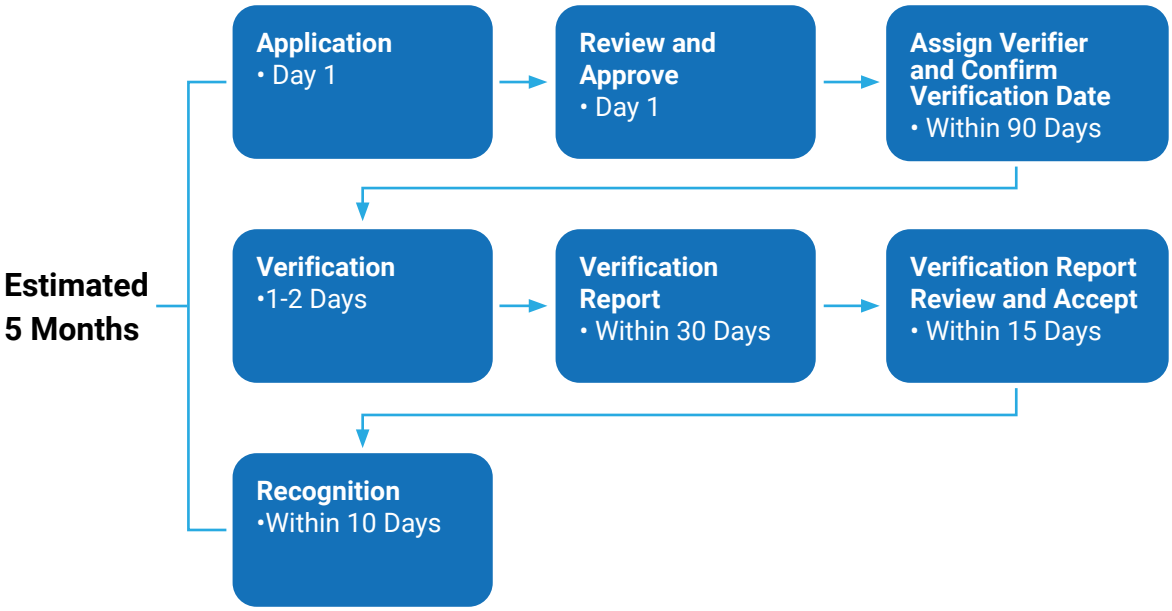


Determinations and their supporting verification evidence should be recorded and then reviewed with the program participant to obtain acknowledgement that the verification evidence is accurate and that the determinations are understood. Every effort should be made to resolve any differences of opinions concerning the verification evidence and/or determinations, and unresolved points should be recorded.

3. Closing Meeting

A closing meeting, chaired by the verifier, should be held to present the verification findings and conclusions so that they are understood and acknowledged by the program participant. Minutes of the meeting, including records of attendance, should be kept. Any differences of opinion regarding the verification findings and/or conclusions between the parties should be discussed and, if possible, resolved during the closing meeting. The program participant will have the opportunity in the closing meeting to ask for clarification around any findings and to respond with additional objective evidence as appropriate. If differences of opinion are unresolved, the divergent opinions should be recorded. If these unresolved differences result in a negative determination, the program participant may challenge that determination and initiate the Dispute Resolution Procedure (Appendix II). The verifier should indicate that a detailed verification report will be prepared and sent to the participant within 30 days of the closing meeting.

Expected Timeline for Verification Process



D. FRAMEWORK VERIFICATION REPORT

The Framework Verification Report will be submitted by the verifier to the program participant within 30 days of the closing meeting. The program participant will have 15 days to acknowledge receipt of the report and either accept the report as written or challenge any of the determinations within the report.

If the program participant accepts the report they will notify the verifier who will submit the report to the Verification Body for final approval. The report should be dated, reviewed, and approved in accordance with verification program procedures.

If the program participant challenges any determination within the report the Dispute Resolution Procedure will be initiated.

The Framework Verification Report is the property of the Center for Food Integrity. The verifier and all report recipients should respect and maintain the confidentiality of the report as determined by the Framework Oversight Committee.

As part of the program value for participants, it is expected that verifiers may provide additional information to the organization being verified of potential opportunities for improvement. This would include observations made by the verifier that do not impact their determinations for each commitment but rather gives the participant some additional information of potential improvements to their systems from a third-party reviewer.

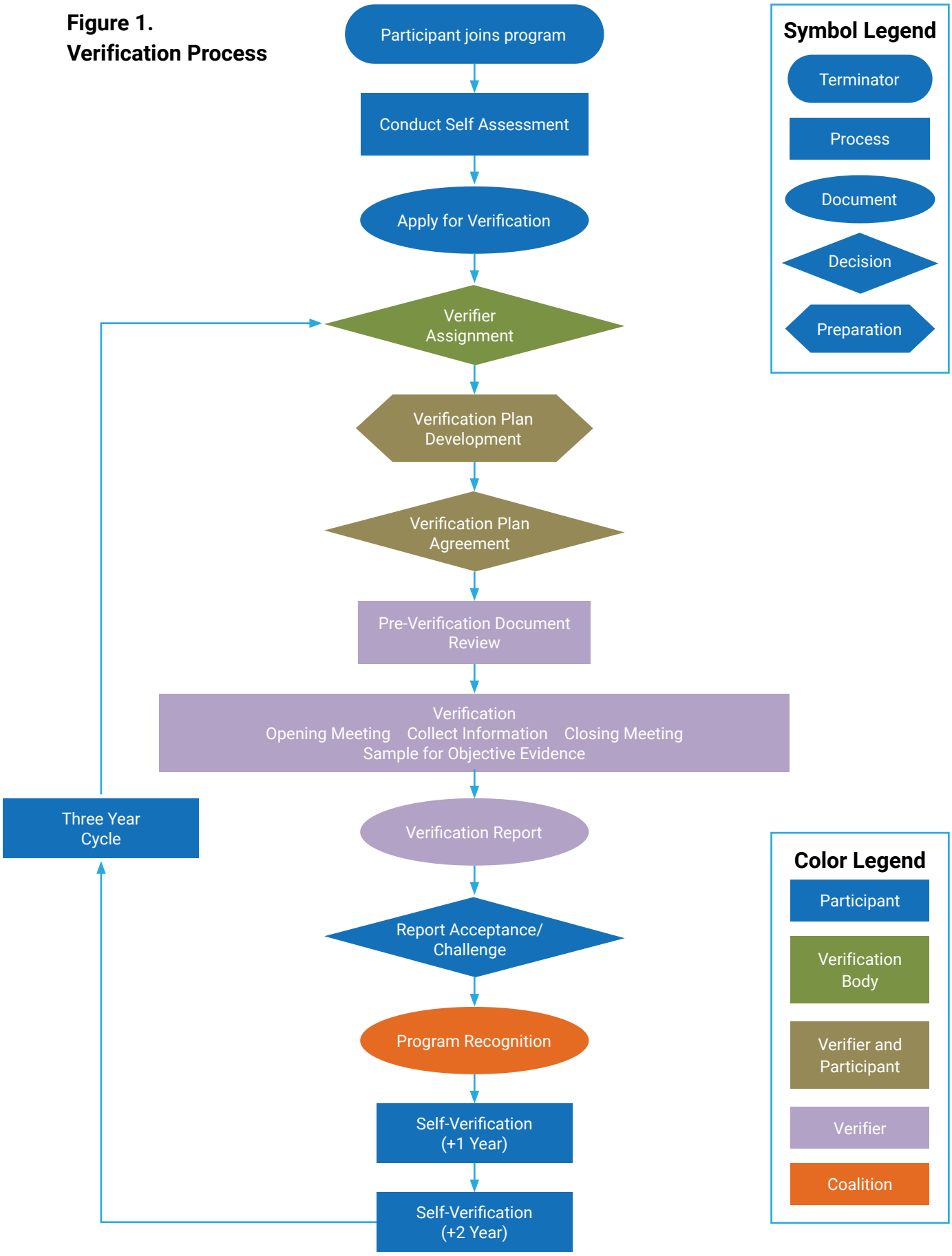
E. PROGRAM RECOGNITION

Successful completion of requirements will be communicated from the Verification Body to the Administrative Body. As determined by the Framework Oversight Committee the recognition of successful completion will be conferred to the participant (Appendix III: Recognition Policy). The policy includes examples of appropriate and inappropriate ways in which recognition may be publicized. Any use must NOT infer a guarantee of anything related to specific products developed by the participant, including guarantees related to safety of the product, efficacy of the product, impact on trade, or compliance with applicable regulations.

F. ONGOING VERIFICATION

Organizations must verify that they are still in conformance via a self-verification on an annual basis, and complete a full re-verification every three years, or following any change in ownership or major restructuring which could impact conformance with the framework. Re-verification will include documentation or evidence of actual implementation of the organization's processes and policies that support the commitments.

Figure 1.
Verification Process



III. Verification Questions and Objective Evidence

1. Objective Evidence

Verification questions are designed to obtain objective evidence regarding the program participant's systems conformance to the commitments outlined within the Framework principles. Objective evidence allows the program participant to prove, or demonstrate, that they have appropriate systems and programs in place, that those systems and programs have been implemented, and the commitment has been met. Examples of objective evidence may include but are not limited to policy statements, operating procedures, study and research results, stakeholder meeting follow up actions, regulatory submissions, database records, quality metrics, self-assessments, and training program competency records.

2. Open-ended Questions

The majority of questions verifiers ask should be open-ended questions, which typically require more than a one-to-two word answer and cannot be answered with a simple "yes" or "no". Examples of open-ended questions often include words such as "describe", "how", "what", or "explain process for". Such questions allow the program participant to explain their organization's approach, systems, and tools in depth.

3. Example Verification Questions and Examples of Objective Evidence

The Verification Checklist has been designed to align with the Framework document. Each question has examples of objective evidence that may be provided to demonstrate the practice has been developed, has been implemented, and is adequate to meet the relevant commitment. It is important to recognize that not all questions will be applicable to an organization, and the examples of objective evidence provided will differ, depending upon the size and complexity of the organization.

For example, a smaller organization may conduct only one-on-one training, which is required prior to being able to execute certain activities, whereas a larger organization may have complex training systems, including web-based with training coordinators. Labeling and tracking systems and procedures in larger organizations often use complex databases or management systems, whereas a smaller organization may rely upon notebooks for traceability. This guide and other resources will provide examples of processes and information that may be a part of the program participant systems applicable to the scope of the activities.

The following questions are examples of those found in the Verification Checklist. Each organization should consider the types of objective evidence applicable to their organization.

EXAMPLE QUESTIONS AND TYPES OF OBJECTIVE EVIDENCE		
Questions/Instructions	**Objective Evidence**	**Out of Scope Questions**
Where has your organization publicly posted its statement of support for the Coalition values and principles? Please include the statement and the associated web link or other way in which it is made public.	• Website link • Policy Statement	Why is the statement of support not on your website homepage?

Describe your process for identifying, prioritizing, and engaging relevant stakeholders and developing the appropriate information to share as part of the engagement plan.	• Standard Operating Procedures • Stakeholder Mapping • Stakeholder Matrix • External Communications • Meeting Agenda and Minutes • Presentations	Did you ask stakeholders to sign a non-disclosure agreement before meeting with them?

It is recognized that no two organizations are alike, and many different situations will be identified during the verification. In the example scenarios above, example clarifying questions are provided of how the verifier may evaluate if appropriate systems, programs, policies or procedures have been developed, implemented, and sufficient to meet the relevant commitment. Out-of-scope questions include those which focus on activities or information that go beyond the Framework Commitment such as specification-type information rather than process or systems-related information.

IV. Framework Principles and Development Stages

The following sections introduce each principle, the commitments included within each principle, general guidance on meeting the commitment, potential scenarios that may be encountered during the verification, and example questions a verifier may ask to evaluate if appropriate systems or programs have been developed, implemented, and are sufficient to meet each relevant commitment.

The guidance is included to assist the program participant in meeting the commitments. However, this is provided solely as a guide, and program participants may provide whatever objective evidence is necessary for the verifier to make a positive determination that they have undertaken the appropriate activity to meet the commitment.

Reminder: For each sample question, the program participate must show sufficient objective evidence: 1) that they have developed a process, procedure, or plan for each relevant Framework Commitment; 2) that they have implemented the process, procedure, or plan into their operations and that it is in active use; and 3) that the process, procedure, or plan meets the identified commitment.

A. Transparency

Introduction

Organizations seeking to demonstrate responsible use must, within the limits required to protect intellectual property and confidential business information, implement processes for:

- Meaningful documentation and disclosure of processes used to develop gene-edited products.
- Comprehensive and forthright disclosure of the technology used in production to include:
  - Disclosing the scientific concepts at work in the gene-edited product in a relatable manner for effective communication with interested stakeholders.
  - Communicating in a way that promotes comprehension among a non-specialist audience and avoids confusing terminology.
- Commitment to transparent and effective communication of conformance with this framework.

Organizations using the framework will, within the limits required to protect intellectual property and confidential business information, transparently share information and engage with stakeholders and consumers about the application of gene editing technologies. Information to be shared will include:

- the nature of gene editing methods employed,
- intended use and benefits of proposed products,
- plausible safety concerns, if any, and how they are being managed,
- mechanisms for stakeholder input and feedback during the life of the product, and
- information that allows the public to know that a gene-edited agricultural product may be part of the food chain, where applicable.

The need to protect intellectual property and confidential business information may limit transparency at certain stages of the development and commercialization process, but those involved in gene editing should always strive for more transparency rather than less. When there are legitimate reasons for not sharing, those reasons should be disclosed.

Confidential Business Information (CBI): Information that is maintained as confidential by the developer and may relate to trade secrets, processes, operations, style of works or other information of commercial value, the disclosure of which could cause substantial harm to the competitive position of the business or organization.

CBI guidance: The Framework encourages companies to define CBI appropriately and maximize transparency.

Examples of what is likely included: trade secrets (i.e. formulas, recipes, manufacturing processes and marketing strategies), business processes, business operations, inventory details, customers or clients, revenue sources, and cost of goods.

Transparency Commitments Applying to All Stages of Development

The following commitments are relevant to program participants engaged in any stage of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 1: Publicly pledge support for/commitment to the framework.

Guidance: Framework participants will be publicly listed on the Coalition for Responsible Gene Editing website as supporters of the Responsible Gene Editing Framework and in the process of being verified. Once a participant completes the Verification Process, the organization will be listed on Responsible Gene Editing website as in full conformance with the framework.

Applicants will create and post a statement of support for Coalition values and principles as they apply to their organization. The statement of support may be developed through a collaborative effort among relevant departments and should be widely distributed and understood internally and be available to the public. This may be done through an organization website or other publicly available source.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Where has your organization publicly posted its statement of support for the Coalition values and principles? Please include the statement and the associated web link or other way in which it is made public.	• Website link • Policy Statement
2	Describe the activities undertaken which highlight the organizations commitment to the Coalition values and principles.	• Policy Statements • Training Program and Records • Management Reviews

Commitment 2: Make summary of policies and practices relevant to conformance with framework principles available to interested stakeholders on a publicly available website.

Guidance: More detailed information about each policy or practice will be available upon request, subject to confidential business information constraints. For universities, information may be published on a college, school or department website (vs. a laboratory-specific site) and may include university policies as well as requirements to qualify for government research funding.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process developed to make these summaries available to stakeholders.	• Standard Operating Procedures • Policy Statements
2	Where are the summaries publicly available? Show examples as available.	• Website • Other Resource
3	Describe the process to request more detail and how more detailed information is made available through the request.	• Standard Operating Procedures • General Email • Website • Specific Phone Number

- *If you are involved only in the Commercial Research stage, continue to the Safety and Quality section.*

Transparency Commitments Applying to Commercial Development, Commercial Sales, and Product Lifecycle Stages

The following commitments are relevant to program participants engaged in the stages of Commercial Development, Commercial Sales, and Products Lifecycle, in addition to the previous commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 3: Communicate the advantages and disadvantages of gene editing and the benefits of resulting products or applications.

Guidance: When sharing application or product information, the expectation is that it will be at a species/crop/organism and trait combination level. Organizations are not required to share information at the individual hybrid or variety level. An organization may develop general information sheets, frequently asked questions or other materials which outline the benefits of its gene editing technology and the resulting products or applications. An organization may also refer to similar information created in collaboration with others as part of their participation in a trade association.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to develop communications materials related to the advantages and disadvantages of gene editing technologies and the benefits in the resulting products or applications. Please include the materials developed.	• Standard Operating Procedures • Communications Plan • Meeting Agenda and Notes • Materials Developed • Communications or marketing studies Conducted • Trade Association Participation
2	How is this information communicated with or made available to relevant stakeholders?	• Communications Plan • Stakeholder Engagement Plan • Meeting Minutes • Website • Trade Association Website and Information

Commitment 4: Proactively seek input from interested stakeholder groups (both supportive and critical) as appropriate based on the stage of the product development process, novelty of application and potential for stakeholder concern or other issues.

Guidance: See Stakeholder Engagement section for more specific guidance on Commitments to seek input at each of the development stages.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to identify and solicit input from interested stakeholders. Show outcomes of this process.	• Standard Operating Procedures • Communications Plan • Stakeholder Engagement Plan • Meeting Agenda and Notes
2	Describe input or an information exchange that has occurred with stakeholders both supportive and critical.	• Meeting notes • Correspondence with stakeholders • Meeting Records • Feedback and Action Items Registers

Commitment 5: If a regulatory submission needed to enable a commercial release is made to a U.S. regulatory agency for a gene-edited agricultural product, there should be public acknowledgement of the regulatory submission identifying the organism, trait, and the agency to which the submission has been made. This should be done within 45 days of the application being complete.

Guidance: Complete is defined as when the regulatory agency determines that it has the information required to complete its assessment.

For animals "complete" is when the Administrative New Animal Drug Application has been filed, as that is when all the technical sections are deemed completed, or adequate, under an Investigational New Animal Drug process.

For the two above provisions, confidential business information need not be made available. In addition, if a regulatory agency requires that the applicant keep its submissions confidential, then it should not be disclosed. However, if a regulatory agency is prevented from making the submission public but the applicant is not prevented by law, then the applicant should abide by the two obligations above.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to publicly acknowledge a regulatory submission within the outlined timeframe and show records of its completion (if applicable).	• Standard Operating Procedure • Work Instructions • Timeline Records
2	Describe the process to provide a summary of the regulatory submission within the outlined timeframe. Show summaries if available.	• Standard Operating Procedure • Work Instructions • Company or third-party website that includes access to the regulatory submission • Regulatory Submission and Summary

Commitment 6: At a time no later than the announcement that a product is being commercially released, a summary of the regulatory submission and the non-confidential business information from the underlying regulatory submission shall be made publicly available.

Commitment 7: For a product of gene editing that is exempt from pre-market regulatory review in the U.S., and a regulatory submission is not made, and is on a commercial track (i.e. commercial candidate lines identified), there should be public acknowledgement of the organism, trait type, and exemption, no later than one year prior to planned commercial introduction.

Guidance: For plants, information should be made public not more than 120 days after the developer makes an exemption determination and such an acknowledgement should include the basis of the exemption. Confidential business information is not expected to be made publicly available.

Prior stakeholder engagement might indicate earlier public disclosure would be beneficial. Information should be posted on a company, trade association or other organization website or online resource.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process for publicly acknowledging the organism, trait type, and exemption for a product deemed to be on a commercial track. Provide current examples as appropriate.	• Standard Operating Procedure • Work Instructions • Commercial Pipeline • Press Release • Website Content
2	Describe the process used to make an exemption determination and timing for public disclosure and supporting records.	• Standard Operating Procedure • Commercial Pipeline

<u>Transparency Commitments Applying to Commercial Sales and Product Lifecycle Stages</u>

The following commitments are relevant to program participants engaged in the stages of Commercial Development and Product Lifecycle, in addition to previous commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 8: If conducted, provide access on a public website to summaries of research on potential safety and environmental impact, positive or negative. Provide background data and analysis of summarized studies upon request, subject to confidential business information.

Guidance: While gene editing technologies do not introduce additional levels of risk in relation to other breeding technologies, sharing research information related to safety, environmental or other impacts builds trust among stakeholder groups and consumers. When sharing application or product information, the expectation is that it will be at a species/crop/organism and trait combination level, not at the individual hybrid or variety level. Previously developed primary research may be referenced to assist in meeting the commitment.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process for developing and making publicly available summaries of relevant research. Please include web links to summaries if conducted.	• Standard Operating Procedure • Website • Study/Research • Study/Research Summaries

2	Describe the process to make additional information available upon request and show records of contacts and follow up if available.	• Standard Operating Procedures • General Email • Website • Specific Phone Number • Correspondence

Commitment 9: Commit to publicly share unanticipated adverse effects revealed after commercialization, if any, (within 60 days of confirmation by agency with jurisdiction) to human or animal health or the environment and resulting resolution activities.

Guidance: Gene editing technologies are not known to cause higher rates of adverse effects than other breeding technologies, however sharing information regarding those effects which have been confirmed by a government agency with jurisdiction builds trust among stakeholders and consumers. Adverse impact and resolution activities should be posted on a company website within 60 days of confirmation by the agency with jurisdiction.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to publicly share adverse effects to human or animal health or the environment should they occur and identified resolution activities.	• Standard Operating Procedure • Gap Analysis • Corrective/Preventative Action Procedures

Commitment 10: Once a microorganism, crop or animal/trait is commercially available, make information available that allows the public to know that it may now be part of the food chain, where applicable.

Guidance: Information should be made publicly available through the commercial life of the product vs. a one-time announcement such as a press release. This may be accomplished through a company, trade association or other organization website or online resource.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process utilized to inform the public that a product may now be available as part of the food chain. Show examples of the information and where it can be located by the public.	• Standard Operating Procedure • Release Statements and Information • Website
2	Describe the process to review and update the information available throughout the products' commercial lifecycles.	• Standard Operating Procedure • Management Reviews • Review Records

B. Stakeholder Engagement

Introduction

Framework participants will engage a balanced and representative group of stakeholders to anticipate the economic, environmental, and social implications, positive or negative, of product development projects, and engage with end users and other relevant stakeholders at an early stage in order to understand their needs and concerns. Organizations will engage in public dialogue and clearly explain what they are doing, why they are doing it, what the potential public benefits are, what the plausible safety concerns, if any, are, and how these are being addressed. Framework participants should avoid overstatements as to the benefits and safety of their work.

An organization's product development process should provide meaningful and accessible opportunities to offer input and feedback. Stakeholder trust will be based, in part, on the frequency and success of activities in these areas.

While feedback from stakeholders may be kept in a program participant's records and used to provide objective evidence during verification that a stakeholder engagement commitment is being met, this information, as appropriate, will be kept confidential.

Stakeholder Engagement Commitments Applying to Commercial Development, Commercial Sales and Product Lifecycle Stages

The following commitments are relevant to program participants engaged in the Commercial Development, Commercial Sales, and Product Lifecycle stages of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 1: Have a stakeholder engagement plan to proactively and reactively engage with stakeholders who express an interest or may potentially be interested in their work.

Guidance: Staeholder engagement plans should be scalable based on stage of development, interest, and potential impact of the product/technology.

Stakeholder engagement plans should include actions that promote effective engagements by:

1. giving voice to stakeholders,
2. acknowledging they have been heard, and
3. explaining how and why decisions have been made.

In addition to the above, the engagement plan should outline the specific goals of the engagement which may be tailored to differing audiences as appropriate. These may include updates and getting feedback on certain focused activities. These focused activities are included in Commitment 2.

Differing stakeholder audiences may require different types and levels of information and engagement plans should prioritize those most likely impacted by the product.

Stakeholder engagement plans will vary by stage of product development and may include:

Stakeholder mapping to identify appropriate audiences, including/with special attention to marginalized groups or those most likely to be affected positively or negatively by the product/technology

- Contact mechanisms such as mail, email, website contact pages and/or toll-free telephone numbers
- Stakeholder surveys
- Stakeholder advisory councils
- Collaboration through third parties such as participation in scientific or industry outreach programs or activities.

In addition, internal considerations should be given to training staff on how to effectively communicate and enhance relationships with identified stakeholder groups, how to track and measure progress on the engagement plan, and a process for regular review and update of the plan.

Relevant groups for engagement may include, but are not limited to:

- Relevant members of the product value chain, including farmers, growers, ranchers, those involved in the trade or import/export of relevant products, fresh produce, food and feed sectors, and retailers
- Government legislatures and related agencies
- International organizations as appropriate
- Researchers in government and academia
- Non-profit and advocacy organizations

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your process to develop and implement a stakeholder engagement plan. Include process to review and update the plans as necessary. Show examples of the engagement and follow up action and tracking.	• Standard Operating Procedures for plan development, plan implementation, plan review and update • Engagement Plans • External Communications • Work Instructions for Implementing the engagement plan • Engagement and Communications Records • Meeting Agenda and Minutes • Follow Up Action Log
2	Describe your process for identifying, prioritizing, and engaging relevant stakeholders and developing the appropriate information to share as part of the engagement plan.	• Standard Operating Procedures • Stakeholder Mapping • Stakeholder Matrix • External Communications • Meeting Agenda and Minutes • Presentations
3	What is your process for identifying employees responsible for stakeholder engagement and training those employees?	• Training Program and Records, Competency Exams • Job Descriptions • Organizational Charts

Commitment 2: Stakeholder engagement plans should include mechanisms for giving feedback or following up on input after engagement.

Guidance: Key to successful stakeholder engagement is effective two-way communications which provides stakeholders with relevant information and provides opportunity for stakeholders to provide feedback. Communication back to those providing input or feedback is important to build trust and enhance relationships

While it is anticipated that all feedback may not be actionable there should be a mechanism in place to determine actionable feedback, implementing any activities related to that feedback, and communicating back to relevant stakeholders. For feedback that is not actionable there should be a process established to inform stakeholders and explain, to the degree possible, why certain feedback may not be actionable by the organization. A summary of stakeholder engagement and resulting actions should be posted on the organization's website or otherwise made publicly available.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the processes to attain relevant stakeholder feedback, evaluate the feedback, implement any activities based on the feedback, and follow up with stakeholders. If available, include examples of feedback and any action or follow up taken based on the feedback.	• Standard Operating Procedure for each element described • Engagement plans • Meeting Agenda and Minutes • A Summary of Stakeholder Input or Feedback • Feedback mechanism (i.e. meetings, participation in events, websites, toll free phone numbers) • Follow up actions plans
2	Describe the process to notify/explain decisions related to actionable and non-actionable feedback and resulting records. Demonstrate the process is being followed.	• Standard Operating Procedure • Follow up action plans • Examples of Stakeholder communications (emails, meeting notes, etc.)

Commitment 3: Make publicly available a summary of the feedback and actions being taken, if any, as a result of stakeholder engagement. A public summary of stakeholder feedback must respect a stakeholder's desire for their feedback or identity to remain confidential.

Guidance: Post of summary of input received and resulting actions on the organization's website. If feasible, distribute a summary of input received and resulting action to stakeholders that provided input and feedback. In the event no stakeholder input or feedback is received, that should be noted in the posting.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to post relevant feedback. Describe mechanisms for making feedback summaries public and noting relevant actions taken. Show where/how relevant information is publicly available.	• Standard Operating Procedure • Release Statements and Information • Website • A Summary of Stakeholder Input or Feedback • Engagement plans

Commitment 4: Provide opportunities for both collaborative stakeholder engagement as well as engagement with individual organizations.

Guidance: Engagement may include general opportunities to collaborate with large segments of relevant stakeholder groups. This collaborative engagement may include participation in trade, professional or consumer meetings, workshops, conferences or other opportunities for broad engagement with relevant stakeholders. These opportunities may include participation in trade association stakeholder engagement activities.

Individual organization engagement includes an opportunity for feedback and engagement on products, applications, or programs specific to a company or organization. This engagement will be more tailored to the specific stakeholder groups identified, provides opportunities for two-way communications on key issues, and allows opportunities for direct follow-up based on the specific information needs of the stakeholder.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the engagement plan activities for collaborative stakeholder engagement and describe activities implemented.	• Engagement plans • Events attended • Presentations
2	Describe the engagement plan activities for individual stakeholder engagement and describe activities implemented	• Engagement plans • Meeting Agenda and Minutes • Emails • Follow up actions

Stakeholder Engagement Commitments Applying to Commercial Sales and Product Lifecycle Stages

The following commitments are relevant to program participants engaged in the Commercial Sales and Product Lifecycle stages of product development, in addition to previous commitments. During the verification, each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 5: Provide a mechanism and process for questions or concerns.

Guidance: Mechanisms should be established once a product is being commercialized to get early and post-market feedback from stakeholders. These may include a website, mailing address, email or toll-free number mechanisms for reporting questions and concerns. An organization should also have a process in place to ensure questions are answered and identified concerns are addressed. Organizations should have an identified employee(s) responsible for this activity and establish appropriate documentation policies for recording and responding to questions and concerns.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to receive and respond to questions and concerns following commercialization of a product. If applicable, provide examples of feedback received through the described mechanisms and how concerns were/would be addressed.	• Standard Operating Procedure • Website • Email or Toll-free phone numbers for questions and concerns reporting • Feedback Records • Action Item Logs

Stakeholder Engagement Commitments Applying to the Product Lifecycle Stage

The following commitments are relevant to program participants engaged in the Product Lifecycle stage of product development, in addition to previous commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 6: Solicit post-market introduction input from stakeholders on impacts/benefits of gene-edited products and make publicly available a summary of the feedback and actions being taken, if any, as a result. A public summary of customer feedback must respect a stakeholder's desire for their feedback or identity to remain confidential.

Guidance: This commitment focuses on proactive engagement with relevant stakeholders at various points following post-market introduction of products. This should provide stakeholders with an opportunity to share relevant information on any impacts and benefits from the products that they may have experienced. While specific timelines should be developed based on the product, product impacts, and level of stakeholder interest, the framework recommends that a program participant solicits and reviews input for two years after a new product introduction.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to solicit post-market impacts from relevant stakeholders. Demonstrate the process is being followed.	• Standard Operating Procedure • Post-market Stakeholder Surveys • A Summary of Stakeholder Input or Feedback (if there is no feedback, indicate as such) • Release Statements and Information • Website • Consumer Affairs contact process • Quality Assurance contact process
2	Describe the process to make summaries of the feedback and resulting actions being taken based on the feedback available. Demonstrate the process is being followed.	• Standard Operating Procedure • A Summary of Stakeholder Input or Feedback • Website • Contact options to request summary

C. Safety and Quality

Introduction

Framework participants recognize safety and quality are important to all stakeholders. Organizations following the framework are committed to the ethical, legal, and safe use of biological materials. Organisms or products developed using gene editing carry no unique safety concerns or risks vs. organisms developed using other selective breeding techniques. We recognize that to maintain trust, framework participants should disclose steps taken to assure safety and quality and to meet applicable regulatory requirements.

Creating a culture of quality and safety must be a priority for organizations following the framework. Quality management systems assure that applications or products meet the intended performance or quality attributes. Identifying policies, processes, and procedures being utilized provides transparency for product stewardship and quality management.

Framework participants recognize public concerns about potential off-target edits* and unintended consequences as a result. Because of gene editing's precision, the likelihood of unintended changes to the DNA with negative impact is much lower with gene editing as compared to natural genetic variation or products produced using other breeding techniques. Consistent with our commitment to transparency, the Framework includes commitments specific to off-target edits to acknowledge the concern and convey appropriate scientific rigor to minimize and mitigate any such occurrences.

* *Off-target definition: An off-target edit is defined as an unintended change to a DNA sequence that can occur during genome editing due to the sequence similarity between the off-target site and the intended target.*

Safety and Quality Commitments Applying to All Stages

The following commitments are relevant to program participants engaged in any stage of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 1: Create a culture of safety so that everyone, at all levels of the organization, understands the critical importance of safety and quality.

Guidance: Program participants commit to sharing information relevant to safety assessments or other research related to product safety that they may have conducted or that may have been conducted by a third-party or government agency. Program participants are expected to meet all legal and regulatory requirements applicable to their operations. Organizations may implement appropriate business policies and practices which outline a code of ethical behavior. This code may include a list of organizational standards, principles, and/or sets of values that govern its operations and the actions of its employees.

Examples of verifiable evidence may include: establishing safety training courses and documenting completion by employees, developing Standard Operating Procedures specific to the development of gene-edited products, and/or engaging a third-party safety consultant or regulatory agency

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes to meet applicable legal requirements. Demonstrate the process is being followed.	• Standard Operating Procedure • Policy Statements • Notifications from Relevant Regulatory Agencies
2	Describe your process to assure safety of product development and commercialization. Demonstrate the process is being followed.	• Standard Operating Procedure • Relevant compliance/safety records • Safety Assessments • Policy Statements
3	Does your organization have a specific code, policy or statement outlining its commitment to ethical behavior?	• Code of Ethics • Policy Statements • Organizational Standards

Commitment 2: Compliance with the federal, state and local animal welfare laws as well as adoption of best practice guidelines to ensure appropriate health and well-being of animals involved directly in research (e.g. for feeding or nutritional studies) and as potential end-products.

Guidance: Program participants are committed to complying with all applicable animal welfare laws. Helpful processes and procedures could be intended to:

- Assist in ensuring compliance
- Identify and correct issues with compliance
- Identify changes to regulations and implement updates to processes as needed
- Train and inform employees regarding legal and regulatory requirements
- Document retention policies as appropriate.

Best practice guidelines have been developed by several organizations and include but are not limited to "The Guide for the Care and Use of Agricultural Animals in Research and Teaching" (FASS – Federation of Animal Science Societies) and "Guide for the Care and Use of Laboratory Animals" (National Research Council). Organizations may adopt, as appropriate, species specific best practices through other accredited organizations. Procedures should be developed, and employees trained on relevant best practices. Procedures may include:

- Regular review and updates of relevant best practice processes
- Identify and record nonconformities
- Documentation and recordkeeping.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes in place to comply with applicable federal, state, and local animal welfare laws. Demonstrate the process is being followed.	• Standard Operating Procedures for compliance, change management, document retention • Training programs and records • Notifications or other relevant communications from Regulatory Agencies
2	Describe any best practice programs your organization adheres to and your processes to consistently follow best practices. Demonstrate the practices are being followed.	• Standard Operating Procedures • Training programs and records • Animal welfare audit results

- *If you are involved only in the Commercial Research stage, continue to the Continuous Improvement section.*

Safety and Quality Commitments Applying to Commercial Development, Commercial Sales and Product Lifecycle Stages

The following commitments are relevant to program participants engaged in Commercial Development, Commercial Sales and the Product Lifecycle stages of product development, in addition to previous commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 3: Processes or products derived from gene editing should meet or exceed local, state and national laws and standards for environmental protection.

Guidance: Program participants are committed to complying with all applicable local, state and federal environmental regulations, such as those promulgated by the U.S. Environmental Protection Agency. Helpful processes and procedures could be intended to:

- Assist in ensuring compliance
- Identify and correct issues with compliance
- Identify changes to regulations and implement updates to processes as needed
- Train and inform employees regarding legal and regulatory requirements
- Document retention policies as appropriate.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes in place to comply with applicable federal, state, and local environmental laws. Demonstrate the process is being followed.	• Standard Operating Procedures for compliance, change management, document retention • Training programs and records • Notifications or other relevant communications from Regulatory Agencies

Commitment 4: Processes or products derived from gene editing should meet or exceed local, state and national laws and standards for food safety.

Guidance: Compliance with applicable local, state and federal regulations. Program participants are committed to complying with all applicable local, state and federal food safety regulations, such as those promulgated by the U.S. Food and Drug Administration and U.S. Department of Agriculture. Helpful processes and procedures could be intended to:

- Assist in ensuring compliance
- Identify and correct issues with compliance
- Identify changes to regulations and implement updates to processes as needed
- Train and inform employees regarding legal and regulatory requirements
- Document retention policies as appropriate.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes in place to comply with applicable federal, state, and local food safety laws and regulations. Demonstrate the process is being followed.	• Standard Operating Procedures for compliance, change management, document retention • Training programs and records • Notifications or other relevant communications from Regulatory Agencies

Commitment 5: Products are deemed fit for purpose through performance evaluation and testing.

Guidance: "Fit for purpose" refers to quality management activities that ensure products as well as the means used to produce them are consistent and help to achieve and maintain a desired level of quality or function. Determining fit for purpose may include standard evaluations such as:

- Geographic and production system adaptation
- Performance characteristics, relative to existing commercial hybrids/varieties/breeds/strains
- Processing characteristics appropriate for that crop or species, such as milling for wheat, sugar yield for sugar beets, oil quality for canola and sunflower or storage characteristics for fruits and vegetables
- End-user characteristics (as appropriate for that crop or species), such as protein content for soybeans, bread-making characteristics for wheat, cooking quality for rice, flavor characteristics for fruits, and compositional characteristics of meat and milk
- Other helpful guidelines and best practices may be found in the *ASTA Guide to Seed Quality Management*

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes implemented to assure products are fit for purpose as described in the guidance. Demonstrate the process is being followed.	• Standard Operating Procedures for evaluating product performance • Product testing procedures • Testing Results and Records • Evidence of field trials • Product Performance Evaluations
2	Describe performance, processing or end user characteristics applicable to your products and systems used to evaluate their performance. Demonstrate the process is being followed.	• Product testing protocols • Quality specifications • Testing Results and Records • Field trial results • Product Performance Evaluations

Safety and Quality Commitments Applying to Commercial Research and Commercial Development Stages

The following commitments are relevant to program participants engaged in Commercial Research and Development stages of product development, in addition to previous applicable commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 6: Ensure human health and safety of those engaged in gene editing processes through conformance with standard laboratory practices as defined by the research organization and appropriate oversight agencies.

Guidance: Program participants are committed to complying with the Occupational Safety and Health Administration Laboratory Standard regulations as well as any additional institutional or local safety policies, regardless of the work being done in the laboratory. Helpful processes and procedures could be intended to:

- Assist in ensuring compliance
- Identify and correct issues with compliance
- Identify changes to regulations and implement updates to processes as needed
- Train and inform employees regarding requirements
- Document retention policies as appropriate.

Verification Questions and Objective Evidence:

	Example Verification Questions	Example Objective Evidence
1	Describe your processes in place to comply with the OSHA Laboratory Standard and/or any additional institutional or local safety policies. Demonstrate the process is being followed.	• Standard Operating Procedures for compliance, change management, document retention • Safety Records • Training programs and records

Commitment 7: Effectively implement biosafety protocols for laboratory, contained facilities and field research involving experimental gene-edited organisms to minimize the potential for inadvertent release of the organisms from containment.

Guidance: Organizations should have a commitment to adopt best practices tailored to organism and application, recognizing those practices may change as technology evolves. Research organizations should have an institutional biosafety lead whose responsibilities need not be restricted to gene editing research. For academic institutions this may be an Institutional Biosafety Committee. Other organizations should have an individual, team or functional area that provides biosafety oversight of gene editing research. Best practices include protocols for general biosafety; laboratory, greenhouse, or facility access; recordkeeping; control of undesired species; decontamination and inactivation of research materials; and avoiding unintended transmission or releases.

Additional resources:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules for suggested protocols at Biosafety Level 1. Specifically, Appendix G of the NIH Guidelines covers physical containment for standard laboratory experiments; Appendix L lists physical and biological containment conditions and practices suitable for greenhouse experiments with plants; and Appendix M specifies containment and confinement practices for research involving whole animals and experiments involving gene-edited microorganisms tested on whole animals.
- ASTA Guide to Seed Quality Management Practices Module 2: Breeding or evaluation in greenhouse or other contained facility and Module 3: Working in seed laboratories or storage facilities. The modules provide guidance for identifying product integrity and control concerns; determining control points to manage plausible safety concerns, if any; establishing preventative measures, monitoring procedures, corrective measures and verification procedures; and establishing record keeping and documentation procedures.
- A Practical Guide to Containment - Plant Biosafety in Research Greenhouses is a reference on appropriate biosafety and containment guidelines for research conducted in greenhouses.
- For plant field trials, best practices include protocols in the ASTA Guide to Seed Quality Management, specifically Module 4: Breeding in the field, for identifying product integrity and control concerns; determining control points to manage plausible safety concerns, if any; establishing preventative measures, monitoring procedures, corrective measures and verification procedures; and establishing record keeping and documentation procedures.
- For animal field trials, see FDA Draft Guidance #187 for Industry "Regulation of Intentionally Altered Genomic DNA in Animals" which covers shipments in interstate commerce of new animal drugs for tests in vitro and in laboratory research animals and for clinical investigation in animals. In general, the Investigational New Animal Drug regulations specify labeling and record-keeping requirements, animal disposition, and conditions under which food from animals used for clinical investigations can be introduced into the food supply.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the processes used, and the implementation of, biosafety protocols. Demonstrate the processes are being followed	• Standard Operating Procedures • Work Instructions • Training Program and Records • Safety Records • Records pertaining to implementing/ following programs outlined in the "Additional Resources" section

Commitment 8: While the likelihood of off-target changes to the DNA is low, protocols used for gene editing should be developed to limit the potential for off-target edits.

Guidance: As gene editing technology evolves, so does the ability to further limit off-target edits. Those involved in gene editing should stay current with the latest research applicable to their specific gene editing technology to limit off-target edits. A developer should identify and implement appropriate design criteria for the genome editing reagents, such as guide RNA, to achieve the desired outcome. A developer should apply appropriate screening, breeding and selection process(es) to confirm the intended phenotype.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the principles and process for selecting the protocols used and the results of those protocols to limit the potential for off-target edits.	• Work Instructions • Principles and process for selecting protocols • Records • Training Program and program review to iterate on results to continue to improve internal processes

Safety and Quality Commitments Applying to Commercial Development Stage

The following commitments are relevant to program participants engaged in the Commercial Development stage of product development, in addition to previous applicable commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 9: Implement appropriate processes to characterize the intended edit(s) and remove undesirable phenotypes from the gene-edited plant, animal or microorganism.

Guidance: Developers leverage genetic variation that exists for a given species from numerous sources of genetic material to generate improved characteristics. During the development and selection process, any off-types, unstable lines, or lines showing undesirable characteristics due to their genetic make-up are discarded. Well-designed, experience-based development and selection protocols deliver products with desired characteristics and limit the possibility of off-types or other undesirable characteristics. Practices to implement include:

- Confirm the intended edit was made.
- Use current bioinformatic tools to predict potential off-target edits.
- Characterize potential off-target edits with likely phenotypic consequences based on best available information. Commercially desirable or neutral phenotypic traits can be preserved, others will be discarded or eliminated.
- Confirm that the gene editing reagents were removed.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to characterize the intended edits and to remove unintended phenotypes. Demonstrate that the process is being followed.	• Standard Operating Procedures • Work Instructions • Confirmation records

Safety and Quality Commitments Applying to Commercial Sales and Product Lifecycle Stages

The following commitments are relevant to program participants engaged in Commercial Development and Product Lifecycle stages of product development, in addition to previous applicable commitments. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 10: If required, products are tested, labeled, and commercialized in accordance with existing regulatory requirements.

Guidance: Program participants should establish appropriate processes and procedures to meet regulatory requirements related to product testing, labeling and commercialization. Processes and procedures should be implemented to:

- Assist in ensuring compliance
- Identify and correct issues with compliance
- Identify changes to regulations and implement updates to processes as needed
- Train and inform employees regarding requirements
- Document retention policies as appropriate.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your processes in place to comply with applicable regulations regarding product testing, labeling and commercialization. If applicable, show product test results and labels. Demonstrate that the processes have been implemented.	• Standard Operating Procedures for compliance, change management, document retention • Corrective/Preventative Action Procedures Training programs and records • Notifications or other communications from relevant Regulatory Agencies

D. Trade and Market Considerations

Introduction

An overarching commitment in the framework is compliance with relevant laws, regulations and standards in the country in which the developer/company operates, as well as in key markets* as identified in a trade and market risk assessment. Due to the global nature of agriculture and food, organizations should have in place policies and practices that support products being developed using gene editing technologies and are managed in a responsible manner that:

- supports international trade,
- facilitates the flow of goods in commerce,
- enables choice and coexistence with diverse production systems, and
- meets applicable regulatory requirements in key countries of production and import with functioning** regulatory systems.

Referencing the 2009 BIO launch guide:

* *Meet applicable regulatory requirements in key markets (which at a minimum shall include the United States, Canada, and Japan) prior to commercialization of a new biotechnology product in commodity corn, soybeans, and canola in the United States or Canada, unless determined otherwise in consultation with the value chain for the crop.*

** *A "functioning" regulatory system is science-based, with clearly defined timelines and processes for regulatory review and decision-making, and appropriate protection for proprietary information and data. The regulatory decision-making processes must be predictable, completed in a timely manner, and not subject to undue political influence.*

Market and Trade Consideration Commitments Applying to the Commercial Development Stage

The following commitments are relevant to program participants engaged in the Commercial Development stage of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier

Commitment 1: Prior to commercialization, conduct a market and trade assessment appropriate to the gene-edited product that anticipates and considers the potential domestic and international impacts on relevant stakeholders up and down the value chain.

Guidance: Best practices include identifying key production countries and potential import markets, prior to the commercialization of any new gene-edited product. As part of the market and trade assessment, consult at an early stage with the value chain for the specific crop, species, microorganism, or product. The market and trade assessment can assist in identifying value-chain stakeholders and in guiding the organization in the development of regulatory, stewardship and commercialization plans by considering such factors as:

- Potential domestic and international markets;
- Potential impacts on relevant stakeholders up and down the value chain;
- The countries expected to import the product(s) of gene editing;
- The types of products (direct product, by-product, processed product) and approximate volume to these markets;
- The pre-market regulatory system, if any, and how it functions; and
- The need for, and status of, regulatory approval.

The assessment should be reviewed at key points during product development and commercialization planning.

Useful references include:

- BIO Product Launch Stewardship Policy and Annexes
- CropLife International Product Launch Stewardship

Trade and export associations can provide information and resources to assist in conducting the market and trade assessment, in particular for potential import market requirements.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe the process to conduct a market and trade assessment. Demonstrate that the process was implemented.	• Standard Operating Procedure • Market and Trade Assessment

Market and Trade Consideration Commitments Applying to the Commercial Development and Commercial Sales Stages

The following commitments are relevant to program participants engaged in Commercial Development and Commercial Sales stages of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 2: Develop and implement management plans that enable the flow of goods and support issues identified in the market and trade assessment. Follow best practices to restrict inadvertent or accidental presence of gene-edited products in the agricultural supply chain.

Guidance: Management plan should be developed based on information attained during the market and trade assessment. Organizations should consider appropriate processes and plans that manage the introduction of a product into the market. Management plans will help an organization initiate actions that promote the coordinated introduction of new products, minimize trade disruptions and facilitate the availability of products.

Types of activities that may be included in a management plan:

- Identifying and communicating with relevant stakeholders
- A commercialization plan based on the intended use and market scope of the product (international commodity stream versus local specific directed use)
- Details of a closed-loop or identity preserved system as appropriate
- Management and training of employees

Useful references include:

- BIO Product Launch Stewardship Policy and Annexes
- CropLife International Product Launch Stewardship
- ASTA Guide to Seed Quality Management
- ASTA Guide to the Evaluation of Gene-edited Plants, or the equivalent, relevant industry

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your process to develop and show implementation of a Product Management Plan.	• Standard Operating Procedure • Management Plans • Management Reviews • Regulatory Plans
2	Identify best practices to limit inadvertent or accidental presence of gene-edited products in the agricultural supply chain. Show records of the practices being followed.	• Standard Operating Procedure • Management Plans • Closed-loop or IP system plans

Commitment 3: Undertake early and regular consultations with relevant stakeholders while conducting the trade and market assessment and while developing and implementing the management plan.

Guidance: Relevant stakeholders should include representatives across the value chain. For example, foodservice and retail organizations, industry associations and trade and export groups. The development and implementation of a communication plan for market and trade considerations is recommended for guiding an organizations' personnel and informing stakeholders. Communication to identified stakeholder groups often begins during the commercial development of the product and can continue throughout the marketing phase.

The nature of information-sharing and communication may be different depending on crop, animal or microorganism/product-type and commercial reach of the company, supply chain, markets, and potential end-users.

Additional resources include:

- BIO Product Launch Stewardship Policy and Annexes
- ASTA Best Practices: Seed Industry Information-Sharing for Products of Gene Editing

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your process to consult with relevant stakeholders while conducting the trade and market assessment and developing and implementing the management plan. Show examples of consultation.	• Management Plan • Communications Plan • Stakeholder Mapping/Stakeholder Matrix • External Communications • Meeting Agenda and Minutes

Commitment 4: Manage product introductions so they allow for the choice of different forms of agriculture that support coexistence. Coexistence is the practice of managing different quality characteristics in a way that enables different value chains to operate and restrict accidental or inadvertent comingling and thereby possibly compromising economic value.

Useful references include:

- BIO Product Launch Stewardship Policy and Annexes

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe how your organization manages product introductions to allow for the choice of different forms of agriculture that support coexistence.	• Standard Operating Procedures • Policy Statements and/or Public Commitments • Management Plans • Closed-loop or IP systems • Communications Plans

Commitment 5: Meet applicable regulatory requirements in key countries with functioning regulatory systems identified in the trade and market assessment prior to commercialization of a new gene-edited product in the United States.

Guidance: There is an additional layer of complexity with exports because regulatory requirements may be applied asynchronously across different countries for the same commercial product which can lead to trade disruptions. Consequently, coordination with the value chain downstream of the organization at an early stage is important. A regulatory plan may be developed based on information from the market and trade assessment. The plan may include any submissions or notifications, and monitoring evolving regulatory requirements and communications on status of these submissions or notifications to impacted stakeholders.

Useful references include:

- CropLife International Product Launch Stewardship

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Show that regulatory requirements were met in countries identified prior to commercialization in the United States.	• Management Plans • Management Reviews • Regulatory Plans • Notifications or communications from or to regulatory agencies

E. Social Considerations

Introduction

Consumers expect food to be safe and are increasingly interested in how food production systems impact social responsibility, environmental sustainability, food animal welfare and other factors. Acknowledging and addressing potential social considerations is an important step in meeting expectations for transparency and building trust in gene editing.

The aim of the social consideration process is to help individuals and groups engaging with gene editing consider a variety of perspectives on different topics. It is designed to stimulate dialogue and support better-informed decisions that address potential challenges and embrace the opportunities associated with gene editing.

As part of framework participants' commitment to transparency and stakeholder engagement, this is an opportunity to proactively address social considerations and potential impacts, positive and negative, we know are important to stakeholders. This calls for open discussion and sharing of ideas, and a readiness to engage others who bring diverse perspectives to the conversation.

Social Considerations Commitments Applying to All Stages of Product Development

The following commitments are relevant to program participants engaged in any stage of product research or development. During the verification each of the commitments identified below that are within the scope of operations of the program participant, will be verified by an independent third-party verifier.

Commitment 1: Consider relevant potential social considerations of using gene editing by completing the Social Considerations Questionnaire at an organization level.

Guidance: Appendix IV is the Social Considerations Questionnaire with Hypothetical Responses which includes questions and examples of potential responses. These potential responses are designed to be illustrative only; each program participant's responses will vary widely depending on its organization and level of involvement in gene editing. Not all categories may be relevant to all organizations.

The Social Considerations Questionnaire is intended to be completed on behalf of an organization. However, an organization may complete the questionnaire for an individual application or product being developed with gene editing and voluntarily disclose their deliberations for that specific product or application. This is optional but recommended for any new trait or application which may raise concerns among stakeholders due to its unique nature or potential impacts. This is an opportunity to communicate unique benefits and address potential concerns.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Please show the completed *Social Considerations Questionnaire.*	• Completed *Questionnaire*

F. Continuous Improvement

Introduction

The Coalition is committed to improving organizational performance and the framework model. The Administrative and Verification Bodies will provide support and training to assist gene editing organizations in effectively utilizing the framework to improve organizational performance. The framework will be reviewed and revised as needed to integrate learning about new technologies, best practices and results of monitoring and evaluation activities. The Framework will be reviewed periodically to ensure that its requirements contribute to the Coalition's defined objectives.

Continuous Improvement Commitments Applying to All Stages of Product Development

The following commitments are relevant to program participants engaged in any stage of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 1: Provide input and feedback on the framework, suggesting revisions as needed over time to maintain relevance with evolving technologies, best practices and stakeholder expectations.

Guidance: Feedback on the framework should be provided to the Center for Food Integrity, via the website, to be considered and incorporated as appropriate as determined by the framework oversight body and leadership.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	Describe your process to gather feedback on the Framework and to provide that feedback to the relevant governing bodies of the Framework. If applicable, provide examples of feedback provided to the Coalition.	• Standard Operating Procedure • Management Reviews • Examples of feedback provided if they exist • Participation in Coalition committees • Participation in Coalition meetings, webinars or other activities • Employee Suggestion / Feedback Opportunities and Mechanisms

G. Verification

Introduction

Framework participants recognize that consumers and other stakeholders may require assurance that they are, in fact, living up to their commitments and following the Responsible Use Framework. Independent verification provides demonstrable evidence that framework participants are meeting the spirit, intent and specifications of the framework. The verification mechanism is designed to be credible, evidence-based, and feasible for a range of organizations in terms of complexity and cost to comply.

Verification Commitments Applying to All Stages of Product Development

The following commitments are relevant to program participants engaged in any stage of product development. During the verification each of the commitments identified below that are within the scope of operations of the program participant will be verified by an independent third-party verifier.

Commitment 1: Conduct self-assessment of conformance with Principles and Commitments and submit assessment on an annual basis.

Guidance: Guidance and a Self-Verification tool will be provided.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	What is your process/plan to conduct the initial self-assessment?	• Standard Operating Procedure • Self-Assessment Plan • Completed Self-Verification Checklist
2	What is your process/plan for annual self-assessment? Was the assessment conducted and submitted annually?	• Standard Operating Procedure • Self-Assessment Plan • Completed Self-Assessment form • Communications showing Self-Assessment was submitted

Commitment 2: Submit organization's processes to comply with the framework for review by a Verifying Body.

Guidance: The participant should develop and implement a process to complete the program verification. This process should include:

- A timeline of activities associated with preparing for and carrying out the verification.
- Identifying those within the organization responsible for each activity.
- Any relevant training associated with the process.
- Management oversight of the process.

Activities may include a review and self-assessment of internal policies, procedures, systems, and programs relevant to each Framework Principle prior to the program verification. Employees responsible for conducting each activity should be identified through job descriptions, standard operating procedures, organizational charts or by some other means which clearly outlines roles and responsibilities. As appropriate, training should be conducted to ensure these roles and responsibilities are understood. Specific training associated with these activities should be conducted, but the organization should consider including an overview of its commitments related to the Framework Principles as part of general employee onboarding activities and any general refresher training.

Verification Questions and Objective Evidence:

	Example Verification Questions	**Example Objective Evidence**
1	What is your process/plan to undergo the Framework verification?	• Standard Operating Procedure • Verification Plan

Appendix I: Verification Summary Report

Verifier Information

Name:	
Company:	
Address:	
City:	State:
Telephone:	Email Address:

Program Participant Information

Company:	
Contact Name:	
Address:	
City:	State:
Telephone:	Email Address:
Stages to Be Verified: ❑ Commercial Research ❑ Commercial Development ❑ Commercial Sales ❑ Product Lifecycle	

E. Instructions and Requirements

1. Each Principle must be successfully completed. 75% of the applicable commitments within a Principle must be passed for it to be considered successfully completed. There will be an opportunity within an agreed-to timeframe (not to exceed 90 days) to correct any commitment failures and be re-verified.

2. Each commitment within the Principles is expected to be met as applicable to the program participant's operations and stages of development as indicated. The box prior to each commitment should be checked if that commitment is applicable to the program participant.

3. The commitments highlighted in red must be successfully completed for a program participant to be recognized as having successfully met the program requirements. Successfully completed means the verifier has made a determination that the program participant has developed appropriate processes, procedures or activities for the commitment and they have been properly implemented (unless noted as Pass – In progress) which has resulted in a Pass rating.

4. A designation of Pass - In Progress signifies that the program participant has developed the appropriate process, procedure, or activity but has not yet had the opportunity to utilize it and therefore will not have any associated records at this time to confirm implementation.

5. A designation of Pass - Opportunity for Improvement (OFI) signifies that while the program participant has developed and implemented the appropriate process, procedure, or activity there was an identified OFI that they should consider implementing. An OFI is part of the continuous improvement process and is for internal program participant use only. The program participant may choose to implement or discard OFIs as appropriate for their operations.

6. A designation of Fail signifies that the verifier has determined that there is a major non-conformity (or a pattern of minor non-conformities) within a commitment that must be addressed before a Pass determination can be made. A Fail may be addressed within an agreed to timeframe (not to exceed 90 days) and re-verified. If the verifier and the program participant do not agree on the determination of a Fail it can be referred to the Dispute Resolution Procedure.

7. If a re-verification is needed to successfully complete the verification the verifier will only focus on what needs to be corrected. A re-verification of all other commitments will not be necessary. There will be an expectation that progress is shown relative to each commitment that is not passed in successive self-verifications or during the next full verification cycle.

Principle A: Transparency Pass ___ Fail ___

Transparency Commitments Applying to All Stages of Development

- ❑ *Commitment 1: Publicly pledge support for/commitment to the framework.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

- ❑ *Commitment 2: Make summary of policies and practices relevant to conformance with framework principles available to interested stakeholders on a publicly available website.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Transparency Commitments Applying to Commercial Development, Commercial Sales, and Product Lifecycle Stages

- ❑ *Commitment 3: Communicate the advantages and disadvantages of gene editing and the benefits of resulting products or applications.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

- ❑ *Commitment 4: Proactively seek input from interested stakeholder groups (both supportive and critical) as appropriate based on the stage of the product development process, novelty of application and potential for stakeholder concern or other issues.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

- ❑ *Commitment 5: If a regulatory submission needed to enable a commercial release is made to a U.S. regulatory agency for a gene-edited agricultural product, there should be public acknowledgement of the regulatory submission identifying the organism, trait, and the agency to which the submission has been made. This should be done within 45 days of the application being complete.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 6: At a time no later than the announcement that a product is being commercially released, a summary of the regulatory submission and the non-confidential business information from the underlying regulatory submission shall be made publicly available.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 7: For a product of gene editing that is exempt from pre-market regulatory review in the U.S., and is on a commercial track (i.e. commercial candidate lines identified), there should be public acknowledgement of the organism, trait type, and exemption, no later than one year prior to planned commercial introduction.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Transparency Commitments Applying to Commercial Sales and Product Lifecycle Stages

- ❑ *Commitment 8: If conducted, provide access on a public website to summaries of research on safety and environmental outcomes, positive or negative. Provide background data and analysis of summarized studies upon request, subject to confidential business information.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 9: Commit to publicly share unanticipated adverse effects revealed after commercialization, if any, within 60 days of confirmation by agency with jurisdiction, to human or animal health or the environment and resulting resolution activities.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 10: Once a microorganism, crop or animal/trait is commercially available, make information available that allows the public to know that it may now be part of the food chain, where applicable.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle B. Stakeholder Engagement Pass___ Fail___

Stakeholder Engagement Commitments Applying to Commercial Development, Commercial Sales and Product Lifecycle Stages

- ❑ *Commitment 1: Have a stakeholder engagement plan to proactively and reactively engage with stakeholders who express an interest or may potentially be interested in their work.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 2: Stakeholder engagement plans should include mechanisms for giving feedback or following up on input after engagement.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 3: Make publicly available a summary of the feedback and actions being taken, if any, as a result of stakeholder engagement. A public summary of customer feedback must respect a stakeholder's desire for their feedback or identity to remain confidential.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 4: Provide opportunities for both collaborative stakeholder engagement as well as engagement with individual organizations.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Stakeholder Engagement Commitments Applying to Commercial Sales and Product Lifecycle Stages

- ❑ *Commitment 5: Provide mechanism and process for questions or concerns.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Stakeholder Engagement Commitments Applying to the Product Lifecycle Stage

- ❑ *Commitment 6: Solicit post-market introduction input from stakeholders on impacts/benefits of gene-edited products and make publicly available a summary of the feedback and actions being taken, if any, as a result. A public summary of customer feedback must respect a stakeholder's desire for their feedback or identity to remain confidential.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle C. Safety and Quality Pass___ Fail___

Safety and Quality Commitments Applying to All Stages

- ❑ *Commitment 1: Commitment 1: Create a culture of safety so that everyone, at all levels of the organization, understands the critical importance of safety and quality.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 2: Compliance with the federal, state and local animal welfare laws as well as adoption of best practice guidelines to ensure appropriate health and well-being of animals involved directly in research (e.g. for feeding or nutritional studies) and as potential end-products.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Safety and Quality Commitments Applying to Commercial Development, Commercial Sales and Product Lifecycle Stages

- ❑ *Commitment 3: Processes or products derived from gene editing should meet or exceed local, state and national laws and standards for environmental protection.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 4: Processes or products derived from gene editing should meet or exceed local, state and national laws and standards for food safety.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

- ❑ *Commitment 5: Products are deemed fit for purpose through performance evaluation and testing.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Safety and Quality Commitments Applying to Commercial Research and Commercial Development Stages

- ❑ *Commitment 6: Ensure human health and safety of those engaged in gene editing processes through conformance with standard laboratory practices as defined by the research organization and appropriate oversight agencies.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 7: Effectively implement biosafety protocols for laboratory, contained facilities and field research involving experimental gene-edited organisms to minimize the potential for inadvertent release of the organisms from containment.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 8: While the likelihood of unintended, off-target changes to the DNA is low, protocols used for gene editing should be developed to limit the potential for off-target edits.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Safety and Quality Commitments Applying to Commercial Development Stage

- ❑ *Commitment 9: Implement appropriate processes to characterize the intended edit(s) and remove undesirable phenotypes from the gene-edited plant, animal or microorganism.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Safety and Quality Commitments Applying to Commercial Development and Product Lifecycle Stages

- ❑ *Commitment 10: If required, products are tested, labeled, and commercialized in accordance with existing regulatory requirements.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle D. Market and Trade Considerations Pass__Fail__

Market and Trade Consideration Commitments Applying to the Commercial Development Stage

- ❑ *Commitment 1: Prior to commercialization, conduct a market and trade assessment appropriate to the gene-edited product that anticipates and considers the potential domestic and international impacts on relevant stakeholders up and down the value chain.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Market and Trade Consideration Commitments Applying to the Commercial Development and Commercial Sales Stages

- ❑ *Commitment 2: Develop and implement management plans that enable the flow of goods and support issues identified in the market and trade assessment. Follow best practices to restrict inadvertent or accidental presence of gene-edited products in the agricultural supply chain.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 3: Undertake early and regular consultations with relevant stakeholders while conducting the trade and market assessment and while developing and implementing the management plan.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 4: Manage product introductions so they allow for the choice of different forms of agriculture that support coexistence. Coexistence is the practice of managing different quality characteristics in a way that enables different value chains to operate and restrict accidental or inadvertent comingling and thereby possibly compromising economic value.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 5: Meet applicable regulatory requirements in key countries with functioning regulatory systems identified in the trade and market assessment prior to commercialization of a new gene-edited product in the United States.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle E. Social Considerations Pass___ Fail___

Social Considerations Commitments Applying to All Stages of Product Development

- ❑ *Commitment 1: Consider relevant potential social considerations of using gene editing by completing the Social Considerations Questionnaire at an organization level.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle F. Continuous Improvement Pass___ Fail___

Continuous Improvement Commitments Applying to All Stages of Product Development

- ❑ *Commitment 1: Provide input and feedback on the framework, suggesting revisions as needed over time to maintain relevance with evolving technologies, best practices and stakeholder expectations.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Principle G. Verification Pass___ Fail___

Verification Commitments Applying to All Stages of Product Development

- ❑ *Commitment 1: Conduct self-assessment of conformance with Principles and Commitments and submit assessment on an annual basis.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail
- ❑ *Commitment 2: Submit organization's processes to comply with the framework for review by a Verifying Body.*
  - ❑ Pass
    - ❑ In Progress
    - ❑ Opportunity for Improvement
  - ❑ Fail

Summary of Findings

Objective evidence that demonstrates conformance with the commitments are in place for the following Principles:

- ❑ Transparency
- ❑ Safety and Quality
- ❑ Social Considerations
- ❑ Verification
- ❑ Stakeholder Engagement
- ❑ Market and Trade Considerations
- ❑ Continuous Improvement

Objective evidence that demonstrates conformance with the commitments are in place for All of the mandatory commitments:

❑ Yes ❑ No

Signature: _____ Date: _____

For Verification Body Office Use Only	
Date Report Received:	Received By:
Reviewed By:	Forwarded to Administrative Body:

Appendix II: Dispute Resolution Procedure

Purpose

The following procedures shall be pursued in order to arbitrate the identified dispute that has occurred between a Program Participant and/or the Qualified Third-Party Verifier within the Framework for Responsible Use of Gene Editing in Agriculture. This procedure will be enacted upon the formal notification of either a Program Participant or Qualified Verifier that a dispute with significant differences exists and that the ultimate resolution of this dispute requires additional resources and arbitration of a third-party.

Procedure

The following actions shall be initiated by either or both parties involved in the identified dispute.

1. **Advise the Verification Body of Dispute**

   Prior to requesting intervention in the defined dispute, the respective parties involved are expected to make a good faith effort to resolve the dispute among themselves. When a mutually satisfactory agreement cannot be reached by either of the parties, the designated representative of the Verification Body will be notified in writing (by one or more of the involved parties) to request that the Dispute Resolution Process be employed. The formal notification process shall include a one-page statement with the following information.

   a. Names, addresses, and contact details of the individual parties involved in the dispute.
   b. Date and/or timeframe in which the dispute has occurred.
   c. A summary statement of the core issues involved in the dispute.
   d. A desired conclusion or mitigation of the dispute.

2. **Initial Attempt at Resolution**

   The designated representative of the Verification Body shall review the information provided, contact and discuss the dispute with each of the respective parties, and provide a recommended resolution to address the dispute. The designated representative establishes the timeframe in which the actions are handled, (a) depending upon the circumstances involved in the dispute, and (b) after consultation with the aggrieved parties.

   a. If the dispute can be resolved then the outcome and decision shall be documented and record placed and maintained by the Verification Body with a copy forwarded to Administrative Body (step 9).
   b. If initial recommendations to resolve the dispute cannot be obtained, then the designated representative shall follow the remaining procedures (step 3).

3. **Formal Documentation**

   The designated representative shall formally request individual detailed documentation from the Program Participant and Qualified Verifier. The respective individual detailed document submittal shall be required to follow the identified format and include the information.

   a. Names and contact information of other individuals either relating to or involved in the dispute.
   b. Details about the additional individuals' relationship to or within the dispute.
   c. Additional description of the extenuating circumstances involved in the dispute.
   d. Appending of any documentation supporting the position of the Program Participant involved in the dispute.
   e. Identification of additional mitigating conditions, financial and/or economic impacts.

4. **Convene Dispute Resolution Panel**

   The Framework Oversight Committee Dispute Resolution Panel will be constituted as needed with the following considerations: 1) the Panel is representative of the groups participating in the FOC; 2) the Panel will include subject matter experts as appropriate (i.e. animal, plant, microorganisms); 3) no representative of a party to the dispute, nor a direct competitor with a conflict of interest, shall be appointed to the Panel; and 4) anyone appointed to the panel must agree to confidentiality and non-disclosure of confidential business information.

5. **Documentation Review**

   The Dispute Resolution Panel shall review the submissions from both parties and determine the additional steps required in the investigation of the dispute. These steps shall take into consideration involving a third party or additional interviews. The Dispute Resolution Panel can also direct the designated representative to proceed with additional investigative actions.

6. **Dispute Resolution Panel Ruling**

   The Dispute Resolution Panel, acting as the ultimate resolution authority, shall have the right to rule on the dispute, based on the evidence presented.

7. **Communicate Decision**

   The designated representative shall formally communicate the decision of the Framework Oversight Committee Dispute Resolution Panel to both parties.

8. **Request Additional Documentation**

   In the event that either of the parties appeals against the decision then a formal submission shall be requested by the Framework Oversight Committee who will make a determination on the appeal.

9. **Document Outcome**

   The final outcome and decision shall be documented and a record maintained.

Appendix III: Recognition and Usage Policy

Successful completion of verification requirements will be communicated from the Verification Body to the Administrative Body. The Administrative Body will notify the Framework Oversight Committee of successful verifications and proceed with recognition. Recognition will include listing on the Coalition website and public announcement via press release and/or other communication channels.

Once verified, applicants will receive a letter and certificate of conformance with the Framework for Responsible Use of Gene Editing and may use such designation in marketing, business correspondence or other communications. Any use of conformance claims on product packaging or labels is not currently allowed. Any use must NOT infer a guarantee of anything related to specific products developed by the participant, including guarantees related to safety of the product, efficacy of the product, impact on trade, or compliance with applicable regulations.

Examples of acceptable usage statements include but are not limited to the following:

- (Company/Organization) is a Participant in the Coalition for Responsible Gene Editing in Agriculture.
- (Company/Organization) is a Participant in good standing in the Coalition for Responsible Gene Editing in Agriculture.
- (Company/Organization) supports the Framework for Responsible Use of Gene Editing in Agriculture and is committing to following its Principles in our utilization of gene editing in food and agriculture.
- (Company/Organization) is a Participant in the Coalition for Responsible Gene Editing in Agriculture and we are working toward verification of our policies and practices relating to gene editing in food and agriculture.
- Our policies and practices have been verified to be in conformance with the Principles and Commitments of the Framework for Responsible Use of Gene Editing in Agriculture.
- We support the Coalition for Responsible Use of Gene Editing in Agriculture and its mission of building trust in the use of gene editing in food and agriculture.
- We are committed to following the Framework for Responsible Use of Gene Editing in Agriculture and to its principles of transparency, stakeholder engagement, safety and quality, social considerations, trade and market considerations, continuous improvement and verification.

Statements making the following types of claims are not acceptable:

- Statements claiming specific products have been verified by the Coalition, unless an individual product or application has undergone a separate verification.
- Claims or statements implying products have been “approved”, “guaranteed”, are “safe” or are “regulated” by the Coalition or Framework.
- Claims or statements implying that products or applications from Participant organizations are better, safer or more responsible than from non-participants.

Please consult the Administrative Body for guidance or review of proposed language.

Appendix IV: Social Considerations Questionnaire

Using the Questionnaire

In this section you will find questions designed to help you consider potential social considerations related to the use of gene editing. Carefully considering the questions and exploring different perspectives assures a broader view of the technology and its potential implications, both perceived and actual. This process will help organizations better engage in dialogue about the technology and consider stakeholder perspectives when making decisions. The process may also help communicate more clearly about the decision to use the technology. The social considerations questionnaire is an opportunity to communicate social benefits (positive impact on natural resources, enhanced animal well-being, etc.) as well as address potential concerns (limited access to benefits, negative impact on bio-diversity, etc.).

Consideration of these topics is likely already occurring as part of strategic planning, product development, corporate or social responsibility or other functions, and as part of stakeholder engagement activities. This section of the framework provides the opportunity to acknowledge that these discussions are happening internally and/or with external stakeholders, within your organization and/or through an industry association. All activities which contribute to understanding stakeholder perspectives may be included here.

The depth and scope of social considerations will vary by organization depending on the anticipated use and applications of gene editing and may change over time. Social consideration conversations are an opportunity to communicate unique benefits as well as address potential concerns, especially when considering novel or unique applications.

Responses on the Social Considerations Questionnaire are intended to be at the organizational, not the application, level. You may elect to provide application-specific information if you choose, but it is not required. The responses should be consistent with how the organization analyzes impacts of their product portfolio – if your organization only assesses impacts at the organization level, then complete the questionnaire at that level. If it is done for a particular product (e.g. gene-edited wheat), or for a unique or novel application, then you may include responses at that level.

We suggest you consider each question and the prompts supplied from the perspective of different stakeholders. The questions and prompts in the questionnaire and guidance document are not intended to be an exhaustive list of all potential topics. Please consider topics specific to your organization that may not be captured in the examples. You may opt to gather input directly from stakeholders to help you prepare to complete the questionnaire. When completing the questionnaire, consider a broad a range of perspectives, taking into account different experience and understanding, levels of awareness of gene editing and value systems.

For each question, take time to consider the different opportunities and potential topics that stakeholders may raise. Is this an opportunity to highlight benefits that may not have been considered before, or address areas of concern? Remember, there are no right or wrong answers, and there will never be consensus. The goal is to demonstrate you are engaging stakeholders in discussion about social considerations of gene editing.

SOCIAL CONSIDERATIONS QUESTIONNAIRE TEMPLATE

Please use this template to complete the Social Considerations Questionnaire.

1. Use the Explanation of Factors and Potential Questions to Consider columns to stimulate discussion and/or stakeholder engagement, and as a guide to the type of information to address in the summary column.

2. To assist in the Social Considerations, several potential topics for each factor are provided below. These are examples designed to demonstrate the range of topics or questions that may be considered. Your responses will vary depending on your organization's anticipated use and applications of gene editing. Not all factors or topics will be relevant to your organization. Your responses should be at the organizational, not the application, level. You may elect to provide application specific information if you choose, but it is not required.

3. Summarize the outcomes of your considerations and/or stakeholder engagement in the far right column. This is intended to be a high level summary; supplemental documents or resources may be referenced or included as attachments at your discretion.

SOCIAL CONSIDERATIONS QUESTIONNAIRE			
FACTOR	**EXPLANATION OF FACTORS**	**POTENTIAL QUESTIONS TO CONSIDER**	**SUMMARIZE THE OUTCOMES OF YOUR CONSIDERATIONS AND/ OR STAKEHOLDER ENGAGEMENT**
Purpose of utilizing the technology (Social responsibility)	What's the purpose of using gene editing? What is the benefit of using gene editing vs. other breeding methods or other approaches?	• What is the organization's mission and how does gene editing support that mission? • How does gene editing fit into the organization's business objectives and values? • Why was gene editing selected as the breeding method? Why is gene editing being used instead of conventional methods? What is the benefit of using gene editing? Could this be accomplished with conventional methods? • Who benefits from the use of the technology – farmers, food manufacturers, consumers? • Have you considered the socio-economic costs associated with gene editing versus other methods? • How will your company address social considerations?	
Potential impacts, positive or negative, of the various applications of gene editing and gene-edited products developed by your organization for **environmental sustainability** (incl. natural resources)	Describe the potential consequences that you have considered (positive, negative or neutral) of gene editing, or gene-edited products developed by your company or organization, on agricultural resources, ecosystem functions and biodiversity. Are the broad consequences likely to be different from other options available to address the same challenge?	• What are the impacts to biodiversity in target species and other species dependent upon the target (ex: pests), if any? • What are the environmental impacts, positive or negative, on other inputs in the system? Will it result in a shift of resource use or need for land, water and inputs? • How long are the sustainability gains likely to last? What systems would need to be implemented to make the sustainability gains last longer?	

Potential impacts, positive or negative, of the various applications of gene editing and gene-edited products developed by your organization for **economic sustainability** (incl. economic resources)	Describe the potential consequences that you have considered (positive, negative or neutral) of gene editing, or gene-edited products developed by your organization, on rural and food production economies. Are the consequences likely to be different from other options available to address the same challenge? How would users or others access the technology? Have you considered the impact on the downstream supply chain and consumer choice?	• Are economic resources used in the value chain affected positively or negatively by the use of gene editing? • Does use of the technology increase or decrease reliance on a specific resource? • Does it maximize the value of inputs? • Does the use of gene editing or gene-edited products impact efficient use of resources, and if so in what way? • Will downstream producers and supply chains need to adjust to accommodate the use of the technology and could there be costs associated with that? • Will the use of the technology impact conventional products and their marketing? How might this impact choice for farmers or consumers?	
Potential impacts, positive or negative, of the various applications of gene editing and gene-edited products developed by your organization **for food production systems**	Describe the potential consequences that you have considered (positive, negative or neutral) of gene editing, or gene-edited products developed by your organization, on ag/food production practices and economics. Are the consequences likely to be different from other options available to address the same challenge?	• How does using the technology enhance the productivity and well-being of the food value chain? • What processes are in place, if needed, to monitor and act on potential impacts? • What special stewardship or IP may be needed to avoid impacts on trade or food production systems? • How might different consumers react to the products produced by your company and what information might be relevant to those questions?	

Potential impacts, positive or negative, of the various applications of gene editing and gene-edited products developed by your organization for **food animal welfare**	Describe the potential consequences that you have considered (positive, negative or neutral) of gene editing, or gene-edited products developed by your organization, on the welfare of gene-edited animals or on food animals that consume them. Are the consequences likely to be different from other options available to address the same challenge?	• Does using the technology impact the welfare of food animals? • What processes are in place to monitor and act on potential impacts, if needed? How are they being managed? • Does the use of the technology change the need for or type of inputs for animal production? • Have you considered how the use of gene editing interacts with other strategies to improve animal welfare?	

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The Guide to Achieving Verification is an educational tool and is guidance to assist verifiers and program participants in the implementation of verification of the Framework for Responsible Use of Gene Editing in Agriculture. The Verification Guide is flexible and its application will differ according to the size, nature and complexity of the organization and products involved.

This Guide is not, and should not be used as, a substitute for (1) a user's own individual understanding of its legal requirements, (2) consultation by a user with its legal counsel and other advisors, or (3) direct contact with appropriate regulatory agencies.

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