**Purpose of Module for post-harvest handling and transfer:** This module provides an example template for use in post-harvest handling and transfer that your organization might use as part of your organization’s quality management practices relevant to APHIS regulations found at 7 CFR Part 340 for certain genetically engineered (GE) organisms.

**Biotechnology Quality Management Support:** APHIS Biotechnology Regulatory Services has developed this module as one of a series of modules. Biotechnology Quality Management Support is useful for any organization that wishes to develop or improve quality management practices related to the APHIS regulations cited above.

**Approach:** The module includes a template (below) that your organization can customize specific to your needs and operational practices for post-harvest handling and transfer of regulated GE organisms. Each section of the template has examples of what might be included in a standardized form for post-harvest handling and transfer. The template is not a standard, but should be considered as a tool to modify to meet your organization’s needs.

The example template is found on the APHIS BRS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/bqms>. Note that the template text in blue font serves as a prompt for describing your organization’s approach.

**Disclaimer:** This module provides a generalized guide for your organization’s quality practices relevant to your obligations under APHIS regulation found at 7 CFR Part 340.  Use of these modules and its content does not guarantee that the user’s activities are in compliance with 7 CFR part 340, and it does not eliminate the user’s obligations under any other statute or regulation.  If your organization wishes to use formal quality management systems, it is best to rely on qualified quality management professionals.

**1.0 PURPOSE:** *This procedure describes the controls your organization uses for post-harvest handling and transfer of regulated genetically engineered (GE) organisms; identification of those organisms; the way in which the process is monitored; and whether the monitoring and verification, as well as any changes in those activities, are effective. The procedure also explains the way in which planned activities are achieved and regulated activities are conducted. For example, species of regulated GE organism addressed in this procedure is [species name].*

**2.0 DEFINITIONS:** *Insert any terms, acronyms or reference to a glossary here that may apply to this procedure. For the sake of clarity, indicate any deviations in your terminology from the definitions and terms used in 7 CFR part 340.*

**3.0 RESPONSIBILITIES**

**3.1** *Identify and record the relevant personnel involved in the post-harvest handling and transfer of GE organisms regulated under 7 CFR part 340. For example, this could be accomplished with an organizational chart or defined directly in the procedure. The level of specificity might identify any quality management representatives, corporate staff, field supervisors, or someone else engaged in the procedures for post-harvest handling and transfer. In some cases, the procedure might require your organization to obtain information from multiple departments according to your organization’s structure (i.e.; legal, regulatory) — each of which could be described in this section.*

**4.0 POST-HARVEST HANDLING AND TRANSFER**

**4.1** *Describe how your organization transfers regulated GE organisms to storage and/or further conditioning after harvest. For example, your organization might describe if the harvest personnel and drivers (if applicable) are informed of what they are transporting, any paperwork they have to identify the regulated GE organisms, or instructions as to procedures to follow in the event of a loss of containment of the regulated GE organism during transfer.*

**4.2**  *Describe how your organization contains regulated GE organisms during transfer. For example, describe any specific containers or specifications for containers.*

**4.3** *Describe how your organization marks and/or labels regulated GE organisms during transfer. For example, describe the marking practices and any differences from other marking practices your organization uses, including practices described in the module for Storage or Movement and Import of Regulated GE Organisms.*

**4.4** *Describe how your organization maintains the identity and segregation of regulated GE organisms while under use and/or conditioning at your facilities or at subsequent facilities. For example, the description might explain how your operation identifies GE organisms and the method used to maintain the identity after it is harvested. Another example might be to describe practices your organization uses when the regulated GE organism is not under your control and what measures your organization uses to inform, instruct and monitor the practices of handlers who are outside your organization.*

**4.5** *Describe how your organization cleans equipment used for processing/conditioning and/or the evaluation of regulated GE organisms.*

**4.6** *Describe how your organization ensures identification and segregation of regulated GE organisms if harvested materials are dried or cleaned.*

**4.7** *Describe how your organization handles any misidentified regulated GE organisms. For example the description might reference other relevant procedures, such as Devitalization and Final Disposition or Regulatory Compliance Reporting, or other practices your organization might use.*

**4.8** *Describe how your organization monitors and verifies the effectiveness of the above planned activities and of any changes to those activities. For example, the description might include the relevance of the methods to compliance with APHIS regulations and the overall effectiveness of your organization’s quality practices.*

**4.9** *Describe how your organization trains relevant personnel to meet their defined roles and responsibilities.*

**4.9.9** *Describe how your organization keeps records on all the above activities.*

* 1. **REFERENCES**
	2. *List here any references that apply to this procedure.*

*Examples might include:*

 *Control of Documents*

 *Control of Records*

 *Competence, Awareness and Training*

 *Infrastructure*

* 1. *List here any records or forms that apply to this procedure.*

 *Examples might include:*

 *Master List of Documents*

 *Training record(s*