**Purpose of Module for Environmental Release Planning and Monitoring:** This module provides an example template for use in environmental release planning and monitoring 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 environmental release planning and monitoring of regulated GE organisms. Each section of the template has examples of what might be included in a standardized form for environmental release planning and monitoring. 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 environmental release planning and monitoring 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 environmental release planning and monitoring 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 procedure for environmental release planning and monitoring. In some cases, the procedure might require your organization to obtain information from multiple departments according to your organization’s structure (e.g., legal, regulatory) — each of which could be described in this section.*

**4.0 ENVIRONMENTAL RELEASE PLANNING AND MONITORING PROCEDURE**

**4.1**  *Describe how your organization addresses pre-planting handling and transfer of regulated GE organisms. For example, describe how you prevent the unintended release of the regulated GE organisms.*

**4.2** *Describe how your organization prepares/cleans planting equipment and how the quality of the work is verified. For example, you might describe your organization’s practices for carefully inspecting equipment to ensure against unintended release of regulated GE organisms. Another examples might be to describe how your organization uses cleaning checklists to provide some verification.*

**4.3** *Describe how your organization uses physical markers and/or global positioning system (GPS) coordinates to identify the field release sites, including boundaries, where applicable. For example, describe how you identify locations of environmental release sites through the use of maps or other means.*

**4.4** *Describe how your organization documents environmental field release site(s). For example, the documented procedure might address the development of environmental field release site maps indicating surrounding land uses,

separation distances employed, and alleys/fallow zones/border rows, where applicable.*

**4.5** *Describe how your organization verifies reproductive controls and/or isolation. For example, describe your organization’s relevant methods (e.g., physical separation, isolation, temporal separation, sterility, etc.), frequency, efficacy, and the ability of the person or persons performing the monitoring and verification activities. See also 4.7 below.*

**4.6** *Describe how your organization prepares for harvest and the equipment cleaning. For example, your organization might describe how it decides the decision process used for which environmental release sites are harvested and the procedures that will be used for each harvest activity, including responsibilities for cleaning equipment, and relevant checklists used by personnel.*

**4.7** *Describe how your organization monitors environmental release sites for volunteer regulated GE plants following harvest.*

 ***4.7.1*** *For examples of in-season activities:*

* + - *Describe how your organization verifies the effectiveness of reproductive controls.*
		- *Describe how your organization monitors for possible deleterious effects on plants.*
		- *Describe how your organization ensures that the environmental field release site, is monitored for volunteer regulated GE plants and/or viable plant parts. The description might include monitoring frequency, which personnel conduct the monitoring, and who is responsible to ensure that the relevant personnel are monitoring as planned. In cases where there are multiple sites, the description might also include site-specific considerations.*

 ***4.7.2*** *For examples of post-harvest activities:*

* + - *Describe how your organization communicates any post-harvest land use restrictions to the person or persons who might use the land in the future. The description might include who in your organization is responsible for the communication, as well as any provisions for follow up communications in subsequent years.*
		- *Describe how your organization ensures that the environmental field release site, is monitored for volunteer regulated GE plants and/or viable plant parts. The description might include the methods your organization uses to control, devitalize and/or dispose of volunteer

		plants (e.g., disking, chemical treatment, etc.), monitoring frequency, which personnel conduct the monitoring, and who is responsible to ensure that the relevant personnel are monitoring as planned. In cases where there are multiple sites, the description might also include site-specific considerations.*

**4.8** *Describe how your organization trains relevant personnel to fulfill their defined roles and responsibilities related to environmental release planning and monitoring.*

**4.9** *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*

 *Responsibility and authority*

 *Communication*

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

 *Examples might include:*

 *Master List of Documents*

 *Training record(s)*