**Purpose of Module for Devitalization and Final Disposition:** This module provides an example template for use in devitalization and final disposition 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 devitalization and final disposition of regulated GE organisms. Each section of the template has examples of what might be included in a standardized form for devitalization and final disposition. 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 devitalization and final disposition 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 devitalization and final disposition 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 DEVITALIZATION AND FINAL DISPOSITION PROCEDURE**

**4.1** *Describe how your organization renders regulated GE organisms nonviable when they are in the field. For example, describe any relevant rules, regulations, and guidance your organization follows, how your organization conveys that information to those performing tasks, and how your organization documents tasks to demonstrate the devitalization and final disposition of regulated GE organisms in the field.*

**4.2**  *Describe how your organization renders regulated GE organisms nonviable when they are in storage and/or other means of containment. For example, describe any relevant rules, regulations, and guidance your organization follows, how your organization conveys that information to those performing tasks, and how your organization documents tasks to demonstrate the devitalization and final disposition. Examples of final disposition might include the fate of regulated GE organisms harvested, removed, destroyed and/or otherwise terminated from an environmental release and/or movement. Such fates include various in-field methods of termination (e.g., grinding, disking, deep burial, etc.) and off-field termination (e.g., containment, landfill disposal, etc.).*

**4.3** *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 for compliance with APHIS regulations and the overall effectiveness of your organization’s quality practices.*

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

**4.5** *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)*