**Purpose of Module for Preventative Action**: This module provides an example template for use in preventative action that your organization might use as part of your organization’s quality management practices relevant to APHIS regulations 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 the design and implementation of preventative actions. Each section of the template has examples of what might be included in a standardized form for preventative actions. 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. **PURPOSE:** *This procedure describes the controls your organization uses for taking preventative action to eliminate the causes of non-conformance with your organization’s quality management practices, especially those which might lead to actions by your organization that are not in compliance with APHIS regulations found at 7 CFR part 340. In general, preventive actions are designed to be appropriate to the effects of potential problems. This procedure also considers the ways in which a preventative action is monitored, as well as the effectiveness of the monitoring and verification for identifying any changes in those activities.*

**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. For example, the following might be some of the definitions used:*

* ***Preventative action*** *- Action to eliminate the cause of a potential non-conformity or other potential undesirable situation.*
	+ *NOTE 1: There can be more than one cause for a potential nonconformity.*
	+ *NOTE 2: Preventative action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.*

**3.0 RESPONSIBILITY**

**3.1** *Identify and record the relevant personnel involved in taking preventative actions for your organization. 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 taking preventative actions. In some cases this 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 PREVENTIVE ACTION PROCEDURE**

**4.1** *Describe how your organization reviews your quality management non-conformities. For example, such non-conformities might be identified as a result of internal or external audits, customer comments, internal personnel, field coordinators, field auditors or inspectors, outside consultants or a management concern.*

 *Describe how your organization addresses issues related to non-compliance with regulatory requirements under APHIS regulations found at 7 CFR part 340. Examples might include the following:*

* *Assigning an owner for following up on non-conformity or non-compliance, as well as any associated preventative actions*
* *Using forms or documents within your organization for preventative actions.*

**4.2** *Describe how your organization determines the root cause(s) of the quality management system non-conformance or regulatory non-compliance. (See form [name])*

**4.3** *Describe how your organization evaluates the need for preventative action to ensure that the quality management system non-conformance or regulatory non-compliance do not occur. (See form [name])*

**4.4** *Describe how your organization determines and implements actions to be taken to prevent the quality management system non-conformance or regulatory non-compliance.*

**4.5** *Describe how your organization creates records of the results of preventative actions taken and determines how long to keep and where to keep the records. [Note: Any forms generated here would be a record once completed.]*

**4.6** *Describe how your organization reviews a preventative action taken to determine its effectiveness.* *For example, a review for effectiveness might take place shortly after the preventative action or might be done at a later date.*

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

**5.0 REFERENCES**

**5.1** *List here any references that your organization uses in its procedures for preventative action.*

*Examples might include:*

 *Control of Documents*

 *Control of Records*

 *Management Review*

* 1. *List here any records or forms that apply to your organization uses in its procedures for preventative action.*

 *Examples might include:*

 *Document Status Form*

 *CPAR Form*