**Purpose of Module for Preventative Action**: This module provides an example template that your organization might use as a form for corrective and/or preventative actions 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 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 form (below) that your organization can customize specific to your needs and operational practices for the design and implementation of corrective and/or 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.

**Corrective Action  Preventive Action  #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(QMR Assigns)

**SECTION 1 – Description**

Request as a result of:  Nonconformance  Internal Audit  Non-compliance   
 Management Concern  External Audit  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Problem Description or attach report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Initial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 2 – Review and acceptance**  Initial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Owner: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Assigned: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigation Due Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 3 – Filled out by owner**

Determine Root Cause: (Not required for Preventive Action.) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(May attach supporting data.)

Evaluating the need for action(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(May attach supporting data.)

Determination and implementation of action(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(May attach supporting data.)

**SECTION 4 – Review of action taken to determine effectiveness**

|  |  |  |
| --- | --- | --- |
| Action Effective:  Yes  No | Initial: \_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Explain (may attach supporting data):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

Action closed QMR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_