



Alternate Curriculum

9/1/18 to 8/31/21 USDA Center

Background

- FDA plans to issue guidance on what is expected for alternate curricula in order to be considered equivalent to standardized curriculum
- The Produce Safety Alliance Grower training is the FSMA Standardized Curriculum
- Produce Safety Rule has no language that requires entities to follow a specific review process to determine equivalency

Language

- Standardized Curriculum
- Add-On Content
- Alternate Curricula
- Modified Curriculum: Modality and Minor Accommodations
- Equivalent Curricula

Scope of Project

- Part of technical assistance the FSOP Center USDA grant, we propose a review process for Alt Curriculum with support of FDA
- Any organization or entity can submit a request to the Regional Center for an alternate curricula review (not just Cooperative Agreement grantees)

Review Process

- Best Practice Guide for those considering the development of Alternate Curriculum
- Review process in 3 steps to get ready for FDA
Review with outcome of Ready for FDA or Not
- All step materials are shared with FDA
- Through ncrfsma.org website

Review Criteria

- Cooperative Agreement with National Sustainable Agriculture Coalition (NSAC)
- FDA Guidance Document
- Critical Objectives based on Produce Safety Rule and Good Agricultural Practices

Review Process: Step 1

- Responsibility: North Central Region FSMA Center
- Objective: To determine if the proposed learning objectives and learning activities are adequately covered and at least equivalent to the standardized curricula as described in FDA's guidance.
- Details: No material needs to be developed at this step
- Output to Submitter: Filled out "Review Form #1" with feedback will be supplied by the North Central Region FSMA Center with a designation of "Ready for Stage 2" or "Not Ready for Stage 2".

Review Process: Step 2

- Responsibility: North Central Region FSMA Center
- Objective: Initial evaluation to determine if the course content and learning activities support the learning objectives as described in Stage 1.
- Details: Course materials for each proposed learning objectives must be developed at this stage
- Output to Submitter: Filled out “Review Form #2” with feedback will be supplied by the North Central Region FSMA Center with a designation of “Ready for Stage 3” or “Not Ready for Stage 3”

Review Process: Step 3

- Responsibility: Three External Reviewers
- Objective: Evaluation to determine if the proposed learning objectives are adequately met, whether the Produce Safety Rule is appropriately cited within the course content, and that content is technically/scientifically accurate and complete (topics are adequately covered).
- Details: Materials must be submitted.
- Output to Submitter: Filled out “Review Form #3 Summary Sheet” with a designation of “Ready for FDA Review” or “Not Ready for FDA Review”.

Questions?

