

# Primus Addendum

General Regulations

## Primus Produce Rule and Preventive Controls Addendum v17.12

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### 1. INTRODUCTION

- a. Food Safety legislation differs from one country to another. These addendums have been developed to ensure that for the current versions of the PrimusGFS and Primus Standard audits, portions of the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) Produce Safety Rule and Preventive Controls Rule are being met. The addendums will not guarantee legal compliance with the FSMA rules, as only the FDA can provide approval for regulatory compliance but these practices and parameters are used as a reference for the applicant's conformance and establishing minimum acceptable criteria as of December 2017. If there are no documented laws or good practice guidelines, users should permit a certain degree of risk assessment to meet minimum criteria.
- b. This addendum has been created by Azzule and establishes voluntary requirements to be an aid in meeting the FSMA Produce Rule and Preventive Controls Rule, and/or buyer/importer requirements of Agricultural sector products, (including horticultural, grains, and pulses) at a world-wide level.

### 2. AUDITING COMPANIES & AUDITOR REQUIREMENTS

- a. Approved or provisionally approved Auditing Companies are responsible for ensuring that auditors conducting the addendums are approved to conduct PrimusGFS or Primus Standard audits for the current version and specific scope.
- b. Auditors must have successfully completed additional training courses applicable to the addendums they are auditing (eg. PCQI or Produce Rule trainings). Trainings should have been administered by a recognized institution or Training Center.
- c. Auditing Companies and the personnel they employ must be free of any conflict of interest in the audit process and maintain the confidentiality of all client specific information, except as required by this addendum or by law.
- d. The Auditing Company has the responsibility to ensure that their auditors are current on good practices and to be able to apply relevant laws and regulations. The Auditing Companies shall maintain records of all relevant training taken by the auditors.

### 3. AUDITING COMPANIES & AUDITOR REQUIREMENTS

#### 1. APPLICATION

- a. Applicants must provide the Auditing Company the following information. For more details, please refer to the Primus-GFS or Primus Standard General Regulations as applicable for the client's certification audit.
  - i. Organization details
  - ii. Contact information
  - iii. Details about the operation(s) to be included in the scope of the addendum
  - iv. Field or facility operation products covered in the scope of the addendum

2. ADDENDUM EXECUTION

- b. The addendum should be used in conjunction with the most current version of PrimusGFS or Primus Standard audits.
- c. The addendum should be completed at the same time as the food safety audit. If completed on a different day, the decision to accept the addendum is based on specific buyer/importer requirements.

**4. EVALUATION**

4.1 CONFORMANCE BY INDIVIDUAL QUESTIONS

- a. To verify conformance to the addendum requirements, the addendum checklists and questions and expectations shall be used.

Conformance for questions	
Answer	Criteria
Total conformance <i>(Can be Yes or No, depending on the question)</i>	To meet the question and/or conformance criteria in full.
Non-conformance <i>(Can be Yes or No, depending on the question)</i>	The question or conformance criteria have not been fully met. Justifications should be included in the auditor’s comments.
Non-applicable	The question or conformance criteria have not been fully met. Justifications should be included in the auditor’s comments.

Table 1. Addendums – Statements of conformance for questions.

In case of finding deficiencies for the question and/or the expectations for that question, assign the answer to each question as described above in the general statement of the table (Table 1). When the requirement is not applicable for the operation being audited, Non- applicable answer is given.

**5. REQUIREMENTS FOR ADDENDUM REPORTS**

- a. The report will be always issued from the Azzule Online Audit System.
- b. The auditor must enter the information into the Azzule Online Audit System to generate a preliminary report within 15 calendar days.
- c. The audit report will be written in the language that the applicant requests (English and Spanish are currently the only languages available in the Azzule Online Audit System), but the information inputted to the Azzule Online Audit System shall also be provided in English.

- d. Every report shall include as a minimum the following information:
- i. Name of the Auditing Company
  - ii. Name of the applicant organization
  - iii. Details about the operation
  - iv. Date and time of the audit
  - v. Name and version of the PrimusGFS or Primus Standard audit to which the addendum will be linked
  - vi. Audit scope – details of the process
  - vii. Product(s) observed during audit, similar product(s) not observed and product(s) applied for but not observed
  - viii. Names of personnel involved in the audit from the applicant organization
  - ix. Auditor name
  - x. Answers and comments for each of the questions in the addendum

## 6. DISTRIBUTION OF ADDENDUM REPORTS

- a. Auditing Companies must provide and make available the information for each audit process, including but not limited to, addendum details, and outcome to Azzule by using the Azzule Online Audit System or by any other means established by Azzule.
- b. The documented addendum reports generated by the Auditing Company in the auditing process for each operation, including those submitted through the Azzule Online Audit System, should be provided to the applicant, the Auditing Company, and Azzule.
- c. Ownership of the addendum report, determination of details made available and authorization for access shall remain with the applicant. Except where required by law, the Auditing Company shall not release any addendum information of the applicant to any outside party without applicant's authorization. The Auditing Company shall document any and all communications between Auditing Company and applicant whereby applicant authorizes the release of information to an outside party.

## 7. DISTRIBUTION OF ADDENDUM REPORTS

- a. The applicant organization will have access to submit corrective actions to address any non-conformances raised. The applicant organization must submit evidence of the actions taken in order to have the corrective actions evaluated by the Auditing Company.
- b. The CAs will be evaluated by the CB per the applicant's request. A CA review will not be mandatory based on the current addendum regulations.
- c. The applicant should check their importer/buyer requirements regarding non-conformances due to some importers/buyers