Primus FSMA Addendums Revision Updates (Rev 0 to Rev 1)

Document: Ranch v17.12 Checklist

- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).

Document: Ranch v17.12 Questions and Expectations

- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).

Document: Greenhouse v17.12 Checklist

- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).

Document: Greenhouse v17.12 Questions and Expectations

- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).

Document: Harvest Crew v17.12 Checklist

- Header on page 1 changed to Q#1.01 – 1.05
- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).
- Question 6.04: FSMA Produce Rule Reference updated to 122.44(a4)

Document: Harvest Crew v17.12 Questions and Expectations

- Question 1.04: FSMA Produce Rule Reference updated to 112.21(d).
- Question 6.04: FSMA Produce Rule Reference updated to 122.44(a4)

Document: GMP v17.12 Checklist

- Header on page 1 changed to Q#1.01-1.04
- Question 2.07: Revised question content
- Question 2.10: Revised question content
- Question 2.12: Question added
- Question 2.13: Question added
- Question 3.05: FSMA Preventive Control Reference updated to 117.165(4i)

Document: GMP v17.12 Questions and Expectations

- Question 2.01: Revised expectation content
- Question 2.07: Revised question and expectation content
- Question 2.08: Revised expectation content
- Question 2.10: Revised question and expectation content

- Question 2.12: Question added
- Question 2.13: Question added
- Question 3.05: FSMA Preventive Control Reference updated to 117.165(4i)

Revised Content to Current Version:

Please refer below for changes to be included in the next revision update. The content below in red has been updated and should be used in conjunction with the most current FSMA addendum checklists and questions and expectations when conducting these addendums.

Document: GMP v17.12 Questions and Expectations Rev. 1

- Question 2.08: Expectation
    - Rev. 1 expectation - "Defined record templates are required for recording preventive control monitoring. The parameters on the records should reflect those in the preventive control program. These templates should be managed under the document control program. Monitoring recording requirements vary depending on preventive control type."
    - Updated expectation - "Clear and simple standard operating procedures (SOPs) should be written for each monitoring process(es) of the preventive controls, even those that are documented in plan or chart formats (e.g., process preventive controls). These SOPs should expand the monitoring activities in detail in the form of work instructions, and match what is written in the preventive controls program."