



Guidelines for the submission of a Corrective Action and Preventative Action (CAPA) Plan for Growers

The MCA, Office of Laboratory Services (MCA-OLS) will track the following conditions and a licensee will be required to submit a CAPA if any of the four conditions are met:

- An overall product testing passing rate of 85% or less for two consecutive months;
- An overall average total of 80,000 CFU/g or greater for the month for Total Aerobic Microbial Counts (TAMC) and/or Total Yeast and Mold Counts (TYMC), excluding retest values and R&D testing;
- A total of 10 or more batches (lots) failed for TAMC and/or TYMC for the month, excluding retest values and R&D testing; or
- Two or more test failures for pesticides, mycotoxins, and heavy metals within a 60 day period.

The MCA-OLS will notify a licensee if any of the four conditions are met. Then the licensee must submit to MCA-OLS a CAPA plan within 15 business days after the notification which includes the following details:

- An investigation determining the root cause of the contamination;
- A detailed plan outlining steps to effectively reduce the high failure rate and/or CFU/g counts;
- If applicable, updated and implemented standard operating procedures to ensure passing samples in the future; and
- In addition, the MCA may require a processor to:
 - Conduct further investigation; and
 - Implement additional procedures to prevent future contamination.

From the date the CAPA plan is approved, the MCA-OLS will monitor the licensee's adherence and the effectiveness of the implemented CAPA plan for a period of six months. MCA-OLS will provide a report and letter regarding the effectiveness of the CAPA plan at the end of the six month period.

Please direct any questions regarding this guidance to the MCA-OLS at mca.labs@maryland.gov.