CRA Seeks Additional Feedback on Proposed New Rules

The CRA is soliciting additional feedback on proposed new rules that would grant testing allowances for licensees who voluntarily participate in certification-based incentive programs.

If you would like to provide feedback on the proposed rules below, please send an email to CRA-AdminRules@michigan.gov with the subject line "GACP GMP Proposed Rules". While there is no hard deadline for providing feedback, comments are more likely to be considered if they are received sooner rather than later.

Good Agricultural Collection Practices (GACP) Incentive Program

Licensees enrolled in the Good Agricultural Collection Practices (GACP) Incentive Program will be granted the following testing allowances:

- Removal of testing requirements for E.coli, Salmonella, and Total Coliforms from full compliance panel testing.

Requirements for participating in the GACP Incentive Program:

1. Licensees who choose to take part in a certification-based incentive-based program must first become GACP certified by an accreditation body or certification program authorized by the agency. The agency will publish a list of accredited bodies capable of issuing GACP certification.

2. In order to receive approval by the agency for enrollment in to the GACP waiver program, a licensee must be licensed as a cultivator or microbusiness. Prior to enrollment, licensee must submit proof of GACP certification to the CRA and must receive written approval from the agency prior to enrollment in the incentive-based program.

3. Upon enrollment, licensee agrees to terms and conditions of the incentive-based program.

    a. Licensee agrees to participate in random audits as prescribed by the agency. As part of these audits, licensee agrees to incur all costs associated with the audit-testing.

i. A licensee agrees to have testing conducted on as many batches of harvested flower as selected by the agency.

ii. The licensee agrees to schedule a laboratory sampling within 24 hours of receiving a request for audit by the agency and submit confirmation of scheduling to the agency.

iii. Once audit results have been received from the contracted laboratory, the licensee will send notification to the agency that testing has been completed. This notification must include Metrc tag number and all Certificates of Analysis associated with the audit.

b. If the batch passes for the additional tests – upload results to record(s) as demonstration of ongoing compliance. If the batch fails for additional tests – upload results to record(s) as demonstration of non-compliance. In instance of non-compliant, failing batch, the licensee will be required to immediately resume full panel testing.

i. A letter will be sent to the licensee that indicates their failure to maintain compliance with the program, and subsequent removal from some or all portions of the program.

ii. The licensee is temporarily barred from the program until they can demonstrate six months of compliance.

4. In addition to the above requirements, licensees will need to submit monthly, on-going environmental audits of their facility throughout their enrollment in this program. These must be accompanied by the following documents from the licensee including but not limited to: the results of environmental audits, results of recent full compliance test results, standard operating procedures, and any supporting documentation related to the results of the environmental audits. These documents will need to be tracked to ensure monthly submission. Incomplete submissions must be returned to the licensee for follow-up. Licensee must provide complete submissions upon follow-up, or they will be temporarily barred from the program until they come into compliance.

5. Any public health and safety violations issued against the licensee will result in temporary removal from the program. If these violations are upheld, the licensee must comply with all stipulations outlined in the consent order to become re-enrolled in the program. If a licensee must be re-enrolled, they must begin the enrollment process, beginning at submission and receipt of an approved request.

Good Manufacturing Practices (GMP) Incentive Program

Licensees enrolled in the Good Manufacturing Practices (GMP) Incentive Program will be granted the following testing allowances:

- Reduced testing frequency on specific batches of products which have been assessed by GMP certification body and received approval by the agency and MDARD. Any deviations must be documented and audited by the licensee and those deviations must be reported to CRA.

- After a six-month demonstration of capability, the licensee may be permitted to drop testing frequency to 1x/batch/month for any products which meet the criteria specified below.

- Reduced testing will also result in a decrease of homogeneity testing to 1x/batch/year instead of 1x/batch/6 months.

Requirements for participating in the GMP Incentive Program:

1. Licensees who choose to take part in a certification-based incentive-based program must first become GMP certified by an accreditation body or certification program authorized by the agency. The agency will publish a list of accredited bodies capable of issuing GMP certification.

2. In order to receive approval by the agency for enrollment in to the GMP waiver program, a licensee must meet all of the following requirements:

    a. Must be licensed as a microbusiness or processor.

    b. Prior to enrollment, licensee must submit proof of GMP certification to the CRA and must receive written approval from the agency prior to enrollment in the incentive-based program.

        i. On the submitted form the licensee must clearly note which program(s) they wish to enroll in:

            1. Beverage Production.

            2. Product specific allowances for reduced batch.

            3. Reduced homogeneity testing requirement (1x/year).

3. Upon enrollment, licensee agrees to terms and conditions of the incentive-based program.

a. Licensee agrees to submit all products that they wish to have enrolled in the program, including all of the following:

    i. Product name and product formulation.

    ii. Any previously performed stability studies.

    iii. A completed plan and data related to stability testing, submitted as a written proposal.

    iv. Expiration dates related to each product, which are supported by data gained from the product stability study.

b. Licensee agrees to participate in random audits as prescribed by the agency. As part of these audits, licensee agrees to incur all costs associated with the audit-testing.

    i. A licensee agrees to have testing conducted on as many production batches as selected by the agency.

    ii. The licensee agrees to schedule a laboratory sampling within 24 hours of receiving a request for audit by the agency and submit confirmation of scheduling to the agency.

    iii. Once audit results have been received from the contracted laboratory, the licensee will send notification to the agency that testing has been completed. This notification must include Metrc tag number and all Certificates of Analysis associated with the audit.

c. If the batch passes for the additional tests – upload results to record(s) as demonstration of ongoing compliance. If the batch fails for additional tests – upload results to record(s) as demonstration of non-compliance. In instance of non-compliant, failing batch, the licensee will be required to immediately resume full panel testing.

    i. A letter from the Agency will be sent to the licensee that indicates licensee’s failure to maintain compliance with the program, and subsequent removal from some or all portions of the program.

    ii. The licensee is barred from specific portions or the entire program until they can demonstrate 6 months of compliance.

4. In addition to the above requirements, licensees will need to submit to the Agency monthly, on-going environmental audits of their facility throughout their enrollment in this program. These must be accompanied by the following documents from the licensee including but not limited to: the results of environmental audits, records of formulation, batch records, certificates of analysis for ingredients, standard operating procedures, as well as any supporting documentation related to the results of the environmental audits. These documents will need to be tracked to ensure monthly submission. Incomplete submissions must be returned to the licensee for follow-up. Licensee must provide complete submissions upon follow-up, or they will be temporarily barred from the program until they come into compliance.

5. Any public health and safety violations issued against the licensee will result in temporary removal from the program. If these violations are upheld, the licensee must comply with all stipulations outlined in the consent order to become re-enrolled in the program. If a licensee must be re-enrolled, they must begin the enrollment process, beginning at submission and receipt of an approved request.