Adopted by the MFRPA Board June 22, 2019

MANUFACTURED FOOD REGULTORY PROGRAM ALLIANCE

PROCESS FOR RECOMMENDING CHANGES TO THE MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS

BACKGROUND

The US Food and Drug Administration (FDA), Manufactured Food Regulatory Program Standards (MFRPS) are a set of ten standards that form a framework for state manufactured food safety program operations and procedures and provide a uniform basis for measuring and continuously improving the performance of state manufactured food regulatory programs. The implementation of the standards will assist state programs with prioritizing their surveillance, prevention, intervention, and response activities to ensure the safest possible food supply and ultimately reduce the incidence of food-borne illness.

The MFRPS areas of focus include:

- Standard 1 – Regulatory Foundation
- Standard 2 – Training Program
- Standard 3 – Inspection Program
- Standard 4 – Inspection Audit Program
- Standard 5 – Food-related Illness, Outbreaks and Response
- Standard 6 – Compliance and Enforcement Program
- Standard 7 – Industry and Community Relations
- Standard 8 – Program Resources
- Standard 9 – Program Assessment
- Standard 10 – Laboratory Services

The Manufactured Food Regulatory Program Alliance (MFRPA) was formed with the intent to provide a forum for state manufactured food regulatory agencies to interact with each other and FDA, in the development and improvement of their respective state manufactured food safety programs. These activities and the resulting program improvements provide the groundwork for the state agencies to increasingly operate in a nationally integrated food safety system with FDA and each other.

The MFRPA serves as the forum to periodically evaluate and make recommendations on MFRPS to FDA. With representation from all of the states enrolled in the standards, the MFRPA can make recommendations for enhancements or modification to the standards, evaluate the language of the standards and corresponding forms or tools used to document conformance with the standards, and provide a mechanism to

receive, evaluate, and ultimately vote on recommended modifications to the standards. Those recommendations will be provided to FDA for consideration in updating the next version of the standards.

PROPOSING MODIFICATIONS TO THE STANDARDS

Any Alliance Member may submit a proposal to modify or enhance a MFRPS standard to the MFRPA Board for consideration. Each proposal shall be submitted on the form provided by the Board and shall include any additional documentation that is necessary to support the request. Each proposal must be fully completed and clearly identify the standard element to be modified, the proposed language to modify in the standard, and the basis for the modification.

The MFRPA will initiate the MFRPS change proposal process every three years, or more often at the MFRPA Board's discretion. The deadline for receipt of proposals during a change proposal year is five months prior to the annual MFRPA meeting. Sufficient time must be provided for the workgroups to review the proposal(s) and make recommendations to the Board, so that the proposal(s) can be discussed during the next MFRPA annual meeting. Late proposals received within 45 days after the deadline must receive special Board approval to be evaluated and discussed during the next annual meeting. Those proposals not receiving Board approval and those proposals received more than 45 days after the deadline will be scheduled for consideration during the following cycle. The MFRPA Board will publish the dates that proposals are due, at least 3 months prior to the submission deadline.

ACCEPTANCE OF PROPOSAL AND ASSIGNMENT TO WORKGROUP

Proposals for modification of the standards received by the MFRPA Board will be reviewed for completeness and relevancy to the MFRPS Standards. The Board may delegate this function to an individual or workgroup who reports their activities directly to the Board. Any proposal determined to be incomplete or not relevant to the MFRPS standards will be returned to the submitter with an explanation. The submitter may revise and resubmit the proposal at their discretion.

Once the proposal has been accepted, it will be assigned to one of four workgroups for evaluation and consideration. The workgroups are charged with reviewing the content of the proposal, evaluating and/or amending the proposed language to be modified in the standard, and making a recommendation with regard to the proposal. The workgroup recommendation may take the form of:

- Acceptance of the proposal as submitted, with a recommendation to present to the voting delegates at the MFRPA meeting;
- Acceptance of the proposal with workgroup amended language to be modified in the standard; and a recommendation to present to the voting delegates at the MFRPA meeting;

- Rejection of the proposal as submitted, with a recommendation to leave the standard in its present form.

Each workgroup shall consist of a Chair, Co-Chair, volunteers from state food safety personnel from MFRPS enrolled states, AFDO technical staff, and FDA. The Chair of the workgroup shall be a State Food Safety Program Manager, State Laboratory Director or equivalent position within a state program. The four workgroups will be assigned proposals for the standards as follows:

- Workgroup I: Standard 1 – Regulatory Foundations; Standard 2 – Training; Standard 8 – Program Resources; and Standard 9 – Program Assessment.

- Workgroup II: Standard 3 – Inspection Program; Standard 4 – Auditing Program; and Standard 6 – Compliance & Enforcement.

- Workgroup III: Standard 5 – Food Outbreak & Response; and Standard 7 – Community Relations.

- Work Group IV: Standard 10 – Laboratory.

Workgroup recommendations will be submitted to the Board for concurrence on the workgroup's recommendation. The Board, at their discretion, may add their recommendation to the proposal submitted by the workgroup, but may not modify any of the proposed standards language submitted by the workgroup. If the Board determines that the workgroup did not address the issue raised in the original proposal, or that the proposed standards language or recommendation is not consistent with good food safety or program management practices, they may return the proposal to the workgroup for further evaluation. All workgroup recommendations must be submitted to Board no later than 2 months prior to the MFRPA meeting, to ensure they can be prepared and disseminated prior to the MFRPA annual meeting.

BOARD INITIATIED PROPOSALS

The MFRPA Board may initiate its own proposal(s) to modify the standards and submit them directly to the membership and voting members without submitting the proposal(s) for review by one of the workgroups. This flexibility allows for late and short turn-around submissions on critical issues that need to be addressed within the standards. The Board will prepare the proposed language modification to the standards and the justification for the change using the approved form. Upon 2/3^{rds} vote of the MFRPA Board, the proposal(s) will be submitted for presentation to the membership during the first day of the annual meeting. During the presentation of these proposals to the membership, the Board or their designee shall notify the members that the proposal did not go through the normal workgroup evaluation process. The Board will take input from participants during the first day of the meeting, and at the Board's discretion, may modify any proposed standards language based on the input received.

PRESENTATION AT THE MFRPA ANNUAL MEETING

All proposals will be presented on the first day of the MFRPA annual meeting. The workgroup will provide an overview of the proposal, the workgroup's and the Board's recommendation(s), and any proposed modification to standards language. The workgroup will take input from participants during the first day of the meeting, and at the workgroup's discretion, may modify any proposed standards language or their recommendation based on the input received. The workgroup must submit all proposals and recommendations to the Board by the close of business on the first day of the annual meeting.

VOTING ON PROPOSALS

Prior to the conclusion of the annual meeting, voting delegates from each enrolled state, will be assembled for voting on the proposals recommending changes to the standards. Each delegate will be provided with a copy of each proposal, any proposed standards language revisions, and the recommendations from the workgroup and the Board. Each proposal will be presented, and an opportunity for discussion amongst the voting delegates will be provided prior to voting. Modifications to the recommendations or the proposed standards language revisions will not be allowed at this time. Each proposal as presented shall be voted on by the delegates. Each State Food Program Manager, or their designee shall have one vote to either accept or reject the proposed language as submitted. Those proposals receiving a majority vote in favor of the proposal will be compiled and forwarded to the FDA for consideration, within 60 days of the close of the MFRPA annual meeting.

Proposal recommendations submitted to FDA are not automatically accepted for modification of the standards. FDA will evaluate the merits of each proposal and must make changes through their administrative processes, which includes posting any proposed changes in the Federal Register for comments. Because of this lengthy process, formal modifications to the language of the standards will not occur every year, but more likely once every three years.

MANUFACTURED FOOD REGULATORY PROGRAM ALLIANCE

PROPOSAL TO MODIFY MANUFACTURED FOOD REGULATORY PROGRAM STANDARD

SUBMITTER NAME:	DATE:
AGENCY:	
EMAIL:	PHONE:

STANDARD YOUR PROPOSAL SEEKS TO MODIFY:

DESCRIBE THE CURRENT STANDARD REQUIREMENT:

DESCRIBE YOUR PROPOSED CHANGE & PROVIDE YOUR PROPOSED LANGUAGE:

WHAT PROBLEM OR DEFFICIENCY DOES YOUR PROPOSAL ADDRESS:

FOR BOARD USE ONLY: ☐ **ACCEPTED** ☐ **REJECTED**

DATE PROPOSAL RECEIVED:

PROPOSAL #

ASSIGNED TO WORKGROUP:

Submit your completed form and additional supporting documents via email to pkennelly@afdo.org. Submission deadline is Month, ##, Year.