

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

COMMITTEE NAME: Product Assessment Committee

DATE OF FINAL REPORT: October 29, 2019

COMMITTEE ASSIGNMENT: Council I Council II Council III Executive Board

REPORT SUBMITTED BY: Veronica Bryant, Product Assessment Committee Chair and Jon Freed, Vice Chair

COMMITTEE CHARGE(S):

Issue # III-024

The Product Assessment Committee was created to leverage the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) challenge study guidelines document to create tools that are easier for the end users to understand and implement. Charges for this committee include creating:

1. A standardized template and checklist of appropriate criteria to consider when reviewing a challenge study, including directions for use.
2. A tool to assist in selecting appropriate organisms.
3. Standardized guidance on how to interpret results.
4. Direction on when it is appropriate to use computer modeling to either support or replace an inoculation study.
5. Report the committee's findings and recommendations back to the Conference at the 2020 Biennial Meeting.

COMMITTEE WORK PLAN AND TIMELINE:

During initial committee meeting September 21, 2018, it was determined that committee work would be accomplished as follows:

1. Committee work will be split into two subcommittees. Subcommittee #1 will handle charges, 2 (create a tool to assist in selecting appropriate organisms) and 4 (direction on when it is appropriate to use computer modeling to either support or replace an inoculation study). Subcommittee #2 will handle the charges 1 (create a standardized template and checklist of appropriate criteria to consider when reviewing a challenge study) and 3 (direction on how to interpret results).
2. Subcommittees will be allowed to do work concurrently and will work on charges subsequently.
3. Subcommittee #1 will be led by chair Veronica Bryant and will consist of Bryant, Burgess, Burns-Savage, Bush, Krzyzanowski, Willis, Bongo-Box, Derr, Karlicek, Mers, and Schaffner. Phone conferences will be held monthly on the first Friday of each month at 2:00 PM EST to discuss progress on charges.
4. Subcommittee #2 will be led by co-chair Jon Freed and will consist of Freed, Boyer, Curtis, Gordon, Pelech, Romo, Touhey, Wijesekera, Craig, Crownover, Shelton, and Thesmar. Phone conferences will be held monthly on the first Wednesday of each month at 2:00 PM EST to discuss progress on charges.
5. The chair and co-chair will monitor attendance of voting and non-voting members and voting members of the full committee will vote to excuse members if unexcused absence of the voting member becomes a pattern.
6. It is anticipated that work will be completed as follows:
 - a. March 1: Overall guidance document outline completed
 - b. May 1: Guidance document sections for charges 2 and 3 to be completed
 - c. July 1: Product Assessment evaluation checklist completed
 - d. Example challenge study using checklist will be completed by October 1
7. Periodic reports were submitted by March 1, 2019 and July 1, 2019 to the Council III Chair.
8. Final guidance document to be submitted to Council III Chair by November 1, 2019.

COMMITTEE ACTIVITIES:

1. Dates of committee meetings or conference calls: The entire committee met on 9/21/18, 2/15/19, 4/26/19, 8/27/19, and 9/26/19. A smaller workgroup met on 9/11/19.

Sub-Committee #1 met on 11/2/18, 12/7/18, 1/4/19, 2/1/19, 3/1/19, 4/5/19, 5/3/19, 6/7/19.

Sub-Committee #2 met on 12/5/18, 1/2/19 and 2/6/19. There were additional smaller group meetings with section owners on 1/9/19, 1/23/19, 4/17/19 and 5/8/19.

2. Overview of committee activities:

a. Overview of committee activities:

At the 9/21/18 meeting we decided to break out into two distinct sub-committees with each sub-committee working on two charges. Each of the sub-committees is also splitting work into smaller groups to accomplish charges. Documents are being shared via email, and software programs with shared editing capabilities. At the entire committee meeting on 2/15/19 we aligned to add additional sections to our guidance document (Introduction, definitions and laboratory qualifications). The committee aligned to our timelines with a target date for document completion of 10/1/19.

At the Sub-Committee #1 meeting on 11/2/18 we agreed to start with Charge #2 and move to work on Charge #4 when finished. During the meetings on 11/2/18, 12/7/18, and 1/4/19, it was determined that organism selection needs to highlight Table 2 and Appendix C already in the document, and this information could not be distilled into a flow chart. During the meeting on 2/1/19, final terminology for the outline was discussed and drafted and the committee moved to discuss Charge #4 during the next meeting.

At the Subcommittee #1 meetings on 3/1/19, 4/5/19, and 6/7/19, resolution of the two charges for the subcommittees were completed. Information regarding these charges will be included in the guidance document. The determination was made that computer modeling alone is not a suitable replacement for a challenge study.

At the Sub-Committee #2 meeting on 12/5/18 we agreed on a work strategy to address our charges. By the 1/2/19 meeting we aligned on creating content based on the NACMCF sections 1, 3 and 8 - 11. Our sub-committee assigned out section owners and began to create content. At the 2/6/19 meeting we reviewed first drafts of each section and aligned on a checklist format.

Draft versions of the guidance document were reviewed by all members and discussed during 4/17 and 5/8 committee meetings. A subgroup consisting of Todd Mers, Robert Curtis, Jon Freed and Veronica Bryant met to make final edits to the guidance document and incorporate all changes from the group.

At the 9/11/19 meeting, a group of committee members, FDA representatives, and FSIS representatives met to discuss final document edits. In attendance was Susan Shelton, Jon Freed, Veronica Bryant, Robert Curtis, Charles Idjagboro, and Meryl Silverman. FSIS and FDA concerns with the document were discussed, and edits were made in advance of the final vote.

At the meeting on 9/26/19, the full committee met to discuss the final versions of the documents. There were not enough voting members present at the time of the meeting to have quorum. An email vote was called to vote on the worksheet and the final document. The vote was 9-0 in favor to approve the document. We had 5 voting members who did not vote.

3. **Charges COMPLETED and the rationale for each specific recommendation:**

- A.a. Charge #1 Create a standardized template and checklist of appropriate criteria to consider when reviewing a challenge study, including directions for use. *Template is included in Guidance Document and attached as a "content document."*
- A.b. Charge #2 Create a tool to assist in selecting appropriate organisms. *Tool is included in Section 4.0 of the Guidance Document and attached as a "content document."*
- A.c. Charge #3 Create standardized guidance on how to interpret results. *Guidance is included as Checklist for Retail Challenge Study and Challenge Testing Worksheet to Determine Microbiological Stability of Formulation and attached as a "content document."*
- A.d. Charge #4 Provide direction on when it is appropriate to use computer modeling to either support or replace an inoculation study. *Guidance is included in the Section 11.0 of the Guidance Document and attached as a "content document."*

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. **Issue #1: Report - Product Assessment Committee** Acknowledgement of 2018-2020 Product Assessment Committee Report, thank the committee members for their work, and disband the committee.

a. List of content documents submitted with this Issue:

- (a.1) Committee Member Roster
- (a.2) Guidance Document entitled, "Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators" (see attached PDF).
- (a.3) Checklist for Retail Establishment Challenge Study
- (a.4) Challenge Testing Worksheet to Determine Microbiological Stability of Formulation

b. List of supporting attachments: **No supporting attachments submitted**

Product Assessment Committee Meeting Minutes

FSIS Report, Establishment Guidance For the Selection of a Commercial or Private Microbiological Testing Laboratory - <https://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>

Evaluation and Definition of Potentially Hazardous Food - <https://www.fda.gov/downloads/food/foodborneillnesscontaminants/ucm545171.pdf>

Parameters for Determining Inoculation Pack/Challenge Study Protocols - https://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2-b4fc89a9668c/NACMCF_Inoculated_Pack_2009F.pdf?MOD=AJPERES

2. **Committee Issue #2:** Recommend acceptance of the committee generated guidance document entitled, "Using NACMCF Parameters for Challenge Study Protocols for Retail Food

Operators and Regulators” included in Issue #1: Report- Product Assessment Committee and; inclusion of the guidance document on the CFP website in PDF form

3. Committee Issue #3: Recommend acceptance of the *“Checklist for Retail Establishment Challenge Study”* included in Issue #1: Report-Product Assessment Committee and; inclusion of the checklist on the CFP website in editable Word and in PDF form.

4. Committee Issue #4: Recommend acceptance of the *“Challenge Testing Worksheet to Determine Microbiological Stability of Formulation”* included in Issue #1: Report-Product Assessment Committee and; inclusion of the worksheet in editable Word and in PDF form.

5. Committee Issue #5: The Committee recommends a letter be sent to FDA requesting the Food Code, Annex 3 be amended to include the *“Using NACMCF Parameters for Challenge Study Protocol for Retail Food Operators and Regulators”* guidance document reference.