***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*** ***X 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 <u>COMPLETED</u> 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.

**Committee Name: Product Assessment Committee 14 Voting Members**

| Last Name | First Name | Position (Chair/Member) | Constituency |
|---|---|---|---|
| Bryant | Veronica | CHAIR | Regulator - State |
| Freed | Jonathan | VICE CHAIR | Industry - Retail |
| Boyer | Renee | Voting Member | Academic |
| Burgess | Victoria | Voting Member | Industry - Retail |
| Burns Savage | Nikki | Voting Member | Regulator - Local |
| Bush | Lauren | Voting Member | Consumer |
| Curtis | Robert | Voting Member | Industry - Retail |
| Gordon | Tammy | Voting Member | Regulator - State |
| Krzyzanowski | Rebecca | Voting Member | Regulator - State |
| Pelech | Todd | Voting Member | Regulator - State |
| Romo | Nela | Voting Member | Industry - Service |
| Touhey | Michael | Voting Member | Regulator - Local |
| Willis | Richard | Voting Member | Industry - Service |
| Bongo-Box | Christina | At-Large Non-Voting | Industry - Service |
| Craig | Betsy | At-Large Non-Voting | Industry - Support |
| Crownover | David | Voting Member | Industry - Support |
| Karlicek | Dianna | At-Large Non-Voting | Regulator - Local |
| Mers | Donald Todd | At-Large Non-Voting | Regulator - State |
| Schaffner | Don | At-Large Non-Voting | Academia |
| Shelton | Susan | At-Large Non-Voting | Regulator - State |
| Thesmar | Hilary | At-Large Non-Voting | Industry - Retail |
| Wijesekera | Dilshika | At-Large Non-Voting | Industry - Retail |

**22 Total Members (5Industry:5Regulatory:0Academia:1Consumer)**

| Employer | City | State | Telephone | Email |
|---|---|---|---|---|
| NC DHHS | Gastonia | NC | | veronica.bryant@dhhs.nc.gov |
| Amazon | Seattle | WA | | jonfreed@amazon.com; |
| Virginia Tech University | | VA | | rraiden@vt.edu; |
| Publix Super Market | Boynton Beach | FL | | Victoria.Burgess@Publix.com; |
| Southern Nevada Health District | Las Vegas | NV | 702-759-1634 | ntburns@cox.net; |
| Stop Foodborne Illness | New York | NY | | laurenb31@gmail.com; |
| Starbucks Coffee Corp | Seattle | WA | 415-542-6064 | rcurtis@starbucks.com |
| SCDHEC | Columbia | SC | 803-896-0640 | gordontl@dhec.sc.gov; |
| Michigan Department of Ag & RD | Roscommon | MI | 517-719-7919 | krzyzanowskir@michigan.gov; |
| Arizona Department of Health Services | Phoenix | AZ | 602-364-3122 | todd.peelch@azdhs.gov; |
| El Pollo Loco | West Covina | CA | 949-689-3101 | nromo@elpolloloco.com; |
| Washoe County Health District | Reno | NV | 775-328-2698 | mtouhey@washoecounty.us; |
| Mandalay | Las Vegas | NV | | rwillis@mandalaybay.com; |
| Little Caesars Enterprises, Inc | Detroit | MN | | christina.bongo-box@lcecorp.com; |
| MenuTrinfo | Fort Collins | CO | 970-295-4370 | menu@menutrinfo.com; |
| Microbac Laboratories Inc | Pittsburgh | PA | 412-699-0919 | david.crownover@microbac.com; |
| Washoe County Health District | Reno | NV | 775-328-2614 | dkarlicek@washoecounty.us; |
| Ohio Department of Agriculture | Reynoldsburg | OH | | tmers@agri.ohio.gov; |
| Rutgers University | New Brunswick | NJ | | don.schaffner@rutgers.edu; |
| Washington State Department of Health | Olympia | WA | 509-212-1206 | susan.shelton@doh.wa.gov; |
| FMI | Arlington | VA | 202-220-0658 | hthesmar@fmi.org; |
| Instacart | Seattle | WA | | Dilshika.wijesekera@instacart.com |

## Introduction

This document summarizes important points from the NACMCF document to assist retail food operators and regulators to use the document more easily. This document provides practical guidance to retail food facility operators looking to submit a food product for a challenge study, as well as to retail food regulators looking for assistance in reviewing a challenge study for approval. This CFP guidance document will primarily focus on extended holding of food products at room temperature, and extended date marking beyond 7 days, as these are the challenge studies primarily seen at retail. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Parameters for Determining Inoculated Pack/Challenge Study Protocols is the accepted reference for conducting and reviewing challenge studies. The NACMCF document is detailed and comprehensive but may be difficult for some end users to apply without more training. Laboratories conducting challenge studies should have a complete and working understanding of the NACMCF document.

Different parts of this CFP guidance document are applicable to different stakeholders. Much of the NACMCF document is intended for use by the laboratory conducting the challenge study, specifically sections 3.0 through 12.0. Retail food operators should familiarize themselves with sections 1.0 through 3.0, but they should also understand sections 8.0 and 10.0 as their input is required. Retail food safety regulators working for agencies who approve variances within a jurisdiction should be familiar with sections 10.0 and 11.0 as they, along with their respective expert food microbiological laboratory personnel, are the ones reviewing challenge studies for approval.

The section numbers referenced in the NACMCF document were maintained in this guidance document to provide ease of reference between this document and the original NACMCF document.

## Definitions

(Note: These definitions were adapted from standard dictionary definitions, using the context of the NACMCF document, and were written by the CFP committee.)

**Anaerobic environment:** An environment where little or no free oxygen exists. Certain microorganisms, such as *Clostridium botulinum* (the organism that causes botulism), can grow in anaerobic environments.

**Challenge test/study:** Microbiological testing performed to determine if a particular food requires time and/or temperature control to prevent pathogenic bacterial growth.

**Competitive microflora:** Yeasts, molds, and/or bacteria naturally or normally present in a food that can alter the behavior of the pathogen of concern. Competitive microorganisms can come from starter cultures, excessive inoculation, or typical or atypical spoilage organisms present in the food or introduced during the study. A challenge study food sample should be collected from fresh product (i.e. within the first 10% of its normal shelf-life).

**Control limit:** A maximum and/or minimum value needed to control a biological, chemical or physical factor to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

**Gas permeability:** The state or quality of a material that allows gases to pass through it.

**Headspace volume:** Headspace is the internal volume of a package that is not occupied by the product.

**Inactivation:** To make or render something not active; to disable or cause not to function.

**Indigenous microflora:** The naturally occurring microorganisms in food in its natural state.

**Inoculate:** Intentionally introducing microorganisms into food or other substrate to see the extent to which they will grow, decline or survive.

**ISO/IEC:** The International Organization for Standardization/ International Electrotechnical Commission; a joint technical committee that sets standards for lab testing and calibration.

**Multi-component product:** A product, such as a chocolate chip cookie or a pizza, composed of distinct ingredients with varying fat, water, salt, or other constituents. A component can shield other ingredients from lethality during processing or alter the environment, such as by adjusting water activity ($A_w$) or pH, to allow microbial growth not generally expected with the ingredient.

**Pathogen:** A microorganism, such as *Salmonella*, that can cause illness or disease.

**Product variability:** The difference between batches (lots) of food in terms of specific properties such as color, texture, pH, water activity, etc.

**Sampling interval:** The timeframe that determines how often measurements will be taken during a challenge study.

**Spoilage organisms:** Bacteria, yeasts, and molds, that when present in a food in high concentrations, causes food to spoil or become otherwise unfit for eating.

**Starter culture:** Bacteria yeasts or mold, deliberately used during food production to cause specific changes in a food (carbon dioxide production, acid production, etc.).

**Surrogate organisms:** A nonpathogenic microorganism with similar growth or inactivation characteristics to a pathogenic microorganism

**Worst-case formulation:** A worst-case food formulation should have acidity, moisture, salt, $A_w$, etc. at extreme values identified for the product variability that are closest to those optimal for pathogen growth.

## NACMCF section commentary

As noted above, the section numbers referenced below refer to the original numbering in the NACMCF document and have been retained in this to provide easy cross-referencing between this CFP guidance document and the original NACMCF document. In some case numbers appear to be missing if a section of the NACMCF document is not referenced in this CFP guidance document.

### 1.0 Obtaining expert advice and identifying a laboratory

The study should[1] be designed, conducted and evaluated by expert food microbiologists with knowledge of food products, food pathogens, and statistics. Personnel performing the study should have a combination of education, such as a B.S. in Microbiology, evidence of knowledge of basic microbiological techniques, and at least 2 years of challenge study experience or supervision by a microbiologist with that expertise.

A laboratory selected for challenge testing should be able to demonstrate prior experience in conducting or validating challenge studies and should meet laboratory standards for capacity and capability. Certifications (such as *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*) help identify laboratories capable of testing, but don't necessarily qualify a laboratory to design and conduct challenge studies. To conduct challenge studies, labs should also have approval and capacity to handle the organism(s) of concern as well as ensure appropriate microbial strains are used.

---

Note: The committee uses the word should instead of must throughout the document as there may be instances where a scientifically valid study does not have all required components in order to be valid.

### 3.0 Factors related to test product

*3.1* Product preparation.

The test product should be prepared under conditions most conducive to growth or survival based on the intended conditions of use and expected product variability (i.e. worst-case formulation). This includes ensuring the product is at equilibrium for physical properties (water activity, moisture, temperature, and pH) and that it is inoculated in areas most likely to become contaminated and/or where organisms would grow. The critical physical properties should be at worst-case limits for the finished product.

Multi-component products may take longer to equilibrate and should be inoculated prior to equilibration. Studies to determine growth, inactivation or survival of a pathogen present due to recontamination should be inoculated after equilibration.

*3.2 Product variability.*

Knowledge of the product variability over several product lots is needed to determine the appropriate testing parameters for a challenge study. The greater the variability, the more samples of product should be evaluated to identify the worst-case limits. Wherever possible, food should be processed to mimic conditions used during commercial operations and be representative of normal production. Adjustments to acidity, moisture, salt, water activity, etc. should be made to test a "worst case scenario".

*3.3 Competitive microflora.*

Inoculated product should contain typical levels of competitive microflora, including starter cultures, but take care not to introduce atypical spoilage microorganisms. The study should ensure that the product evaluated was obtained and inoculated within the first 10% of its shelf life; for example, a product with a 30-day shelf-life should have the sample obtained and inoculated within 3 days of production.

## 4.0 Target Organisms

*4.1 Identifying Pathogens of Concern*

Organism selection is an important part of study design. A qualified study designer will determine what organism(s) to select. The organism(s) chosen will depend on a variety of factors, including the food storage temperature, pH, and aw. For example, consider *Clostridium botulinum* as a selected organism when evaluating foods held in anaerobic environments.

There are tables included in the NACMCF document that discuss organism selection that should be used to determine the proper organism for the challenge study. These tables are labeled as Table 2, and Appendix C [4] [5] of the original NACMCF document. Both tables should be used together to select the proper organism for test. Preliminary testing on product for pH and water activity may be needed to help select organism(s) of concern.

*4.2 Surrogate Organisms*

There are certain circumstances in challenge testing that allow for the use of non-pathogenic surrogate organisms. If surrogates are to be used, their choice should be justified and valid for the food and the process being tested. The use of surrogate organisms may be most helpful to reduce cost and risk in product formulation design prior to conducting the challenge study.

**8.0 Storage Conditions**

*8.1 Packaging*

Products should be testing using the same conditions used for commercial packaging, including packaging materials and the process used for actual packing of the product. Attributes to consider include gas permeability, headspace volume, vacuum levels, and headspace gas composition. The conditions of the environment for packaging should also match the environment for commercial packaging.

*8.2 Storage and Shipping temperatures*

Storage and shipping temperatures should take into consideration product temperature variation. Humidity should also be taken into consideration for these tests.

NACMCF recommends that refrigerated foods be tested at 44.6°F (7 °C) to account for expected consumer storage temperature in the United States but may also be tested at other temperatures for a better understanding of microbial growth patterns. If a product may be subject to variation of temperatures during its shelf life, the product should be tested using these temperature variations.

Products being tested to determine their safety at ambient temperature should be tested using the expected storage room temperatures (typically 24 to 35°C or 75.2 to 95°F).

**Reference 9.0 Sample Considerations**

*9.1 Sampling*

The number of samples analyzed at each time interval should be at least two and any studies should be replicated at least twice with different batches of product and inocula. The number of replications depends on the product and the inoculum.

**10.0. Duration of study and sampling intervals**

For study duration parameters based on product shelf life, see chart 10.1.

*Chart 10.1*

| Product type | Proposed Shelf Life | Additional Safety Margin |
|---|---|---|
| Sold for Immediate Service | 7 to 10 days | 50% |
| Sold for Immediate Service | 10 days to 3 months | 25% to 50%* |
| Sold for Immediate Service | 3 to 6 months | 25% |
| Packaged for Retail Sale at the food establishment | Any | 50% |

* at the discretion of the study designer

Food packaged at the retail establishment should use the most conservative additional safety margin provided in the NACMCF document, which is an additional 50%. Since the NACMCF document does not provide information on safety margin beyond 6 months, it is recommended that the proposed shelf life for a packaged product be determined by the microbiologist conducting the study, and should be between 7 days and 6 months.

Samples, including controls, should be analyzed initially after inoculation (*or after a short equilibration period at the direction of the study designer*) and then at least five to seven times over the duration of the study. For longer-shelf-life products, it may be necessary to have more than seven sampling points.

A study may be terminated when growth of the target pathogen exceeds 1 log for two or more consecutive sampling intervals, except in the case of *S. aureus*, *B. cereus* or *C. perfringens* where NACMCF recommends 3-log. Studies may also be terminated when gross spoilage occurs.

## 11.0. Interpreting test results

The results of a microbiological growth study must be interpreted and evaluated by an expert microbiologist who will consider all relevant factors and the thresholds in the chart below. Smaller increases may be significant depending upon the enumeration methods, number of samples and replicates used, and the variability among data points. The regulatory authority can use more restrictive pass/fail criteria for a specific challenge study based on the intended use of the product and the target consumer population (i.e. highly susceptible population).

**The Pass/Fail criteria for test pathogens are listed below.**

***Chart 11.1***

| Pathogen | Pass | Fail |
|---|---|---|

| | | |
|---|---|---|
| *C. botulinum* | No toxin detected for the duration of the study. | Any toxin detected during the study. |
| *S. aureus, B. cereus* or *C. perfringens* (if applicable) | In lieu of toxin testing, less than 3-log CFU/g growth above the initial inoculum level across all replicates. | Equal to or greater than 3-log CFU/g growth above the initial inoculum level in any replicates. |
| All other pathogens | Less than 1-log CFU/g growth above the initial inoculum level across all replicates. | Equal to or greater than 1-log CFU/g growth above the initial inoculum level in any replicates. |

***A product does not support pathogen growth if growth has not exceeded the initial inoculum level by the limits listed above throughout the intended shelf life of the product and across replicate trials.**

When publishing the final report, ensure that the lab specifically states that the challenge study was conducted following the NACMCF Protocols.

## Computer Modeling

The use of computer modeling for product assessment and pathogen growth in the absence of any laboratory data is limited. Only experimentally validated models for the specific pathogen(s) of concern should be used. Modeling can usually be used in excluding specific organisms of concern from consideration in challenge studies, (e.g., modeling shows than one pathogen grows faster, so the slow grower is excluded from subsequent laboratory studies).

## Reference Documents:

1. *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

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

3. *Parameters for Determining Inoculation Pack/Challenge Study Protocols* - https://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2-

CFP Guidance Document on Using the NACMCF Parameters for Challenge Study Protocols For Retail Food Operators And Regulators

*b4fc89a9668c/NACMCF_Inoculated_Pack_2009F.pdf?MOD=AJPERES*

Sample Checklist for Retail Establishment Challenge Study for Extended Shelf Life or Holding Outside Temperature Control – Product not to be packaged

## Section 1.0 – Laboratory Selection

| | | |
|---|---|---|
| YES | NO | Does laboratory selection meet appropriate criteria from Section 1.0 of NACMCF document? (See Table 1 in the NACMCF document) |

## Section 3.0 – Factors related to tested product

| **Critical Physical Property** | **Range for Product** (indicate NA if not applicable) |
|---|---|
| Water activity ($a_w$) | |
| pH | |
| Salt content | |
| Moisture | |
| Other (including nitrites or inhibitors): | |
| **Intended Conditions for Storage** | **Range for Product** (indicate NA if not applicable) |
| Storage temperature | |
| Storage shelf life | |
| Shelf life duration during challenge study | |

| | | |
|---|---|---|
| YES | NO | Was product prepared and tested at intended conditions of use? |

## Section 4.0 – Organism Selection

### Use Table 2 and Appendix C from NACMCF document to determine answers

| **Pathogen (Expand rows as needed)** | **Growth in the $a_w$ of food being tested?** | **Growth in the pH of food being tested?** | **Concern in the food product category?** |
|---|---|---|---|
| | YES \| NO | YES \| NO | YES \| NO |
| | YES \| NO | YES \| NO | YES \| NO |

## Section 9.0 – Sample Considerations

| | | |
|---|---|---|
| How many samples were analyzed initially and at required time intervals? _____ | | |
| YES | NO | Was sample replicated as required (2+ for most pathogens, 5+ for *C. botulinum*) |
| YES | NO | Does lab provide sample preparation information that is appropriate for food being tested? |
| YES | NO | Does lab provide information on enumeration of pathogens/measurement of toxins conducted using validated methods in a qualified lab? (NACMCF Appendix A)? |

## Section 10.0 – Duration of Study and Sampling Intervals

| | | |
|---|---|---|
| YES | NO | Does growth inhibition study provide adequate safety margin for shelf life? |
| YES | NO | Were at least 5 to 7 sampling intervals done during challenge study? |
| Maximum shelf life allowed based on study and safety margin: _____ | | |

**Section 11.0 – Interpreting Test Results** (note that a product does not support pathogen growth if growth does not exceed the initial inoculum level by the limits listed below throughout the intended shelf life of the product and across replicate trial)

- **Most foodborne pathogens: 1-log increase above the initial inoculum level**
- ***S. aureus*: 3-log increase above the initial inoculum level**
- ***C. botulinum*: No toxin should be detected in the product**

| Pathogen (Expand rows as needed) | Initial Inoculum level (CFU/g) | Highest Growth Level (CFU/g) | Total Growth (CFU/g) |
|---|---|---|---|
| | | | |
| | | | |

| | | |
|---|---|---|
| YES | NO | Do results of study meet PASS/FAIL criteria in Section 11 of NACMCF document? |

| COMMENTS ON AREAS OF STUDY THAT DO NOT MEET NACMCF CRITERIA (expand rows as needed) |
|---|
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

DRAFT CFP Challenge Testing Worksheet to Determine Microbiological Stability of a Formulation

| Protocol | Actual |
|---|---|
| Appropriate Study Design, Data Collection, and Data Interpretation Conducted by a Qualified Individual?<br>(See Table 1 of the NACMCF Executive Secretariat. 2010 Parameters for Determining Inoculated Pack/Challenge Study Protocols. J. Food Prot. 73(1):140-202) as well as Institute of Food Technologists. 2001. Evaluation and Definition of Potentially Hazardous Foods. (IFT/FDA Contract No. 223-98-2333. Task Order No. 4 December 31.) | |
| Appropriate Challenge Microorganisms Selected?<br>See Tables 4-1/6-1 of the (IFT Report and Table 2 and Appendix C of the NACMCF Report | |
| Proper Inoculum Level Used to Meet Objective?<br>Typically, Between 2 and 3 log CFU/g | |
| Does Study Describe Preparation of Inoculum Using Appropriate Media and Under Conditions to Optimize Growth? | |
| Was Inoculation Method Used That Does Not Change the Critical Parameters of the Product Formulation Undergoing Challenge? | |
| Was Study Conducted for a Duration That Being at Least the Desired Shelf Life of the Product, plus an Additional Time of the Intended Shelf Life to Provide for Expected Consumer Consumption? See Section 10.0 Duration of Study and Sampling Intervals NACMCF Report (25-50%) as Well as NIST Handbook 130 E. Uniform Open Dating Regulation 3.3.1. Reasonable Period for Consumption. (30%). | |
| Was Each Key Factor Variable Tested that Controls a Product's Microbiological Stability Under Worst-Case Conditions? | |
| Did the Analysis Include the Supporting Data (Information Regarding the Product's Formulation, Types of Ingredients, Processing, and Final Packaging)? | |
| Did the Product Study Represent and Support the Conditions (Temperature, Packaging, Humidity, etc. ) the Product Will Go Through at the Retail Level? | |
| Sample Analysis<br>Were Duplicate and, Preferably, Triplicate Samples of Each Lot (at least two) Used? Were the Levels of Live Challenge Microorganisms Enumerated at Each Sampling Point? | |
| Was Appropriate Toxin Testing Performed at Each Time Point using the Most Current Validated Method?<br>Were Uninoculated Control Samples Analyzed for Background Microflora at Each or Selected Sampling Points? | |
| Data Interpretation<br>Once the Study is Completed, Was the Data Analyzed to See How the Pathogens Behaved Over Time (Died, Remained Stable, or Increased)? In the case of Toxin-Producing Pathogens, was any Toxin Detected Over the Designated Challenge Period? | |
| Pass/Fail Criteria<br>Note: The Significance of a Population Increase Varies with the Hazard Characterization of Each Microorganism. See IFT Report, Part 9 of Chapter 9 Microbiological Challenge Testing.<br>The Exclusive Use of Computer Models are Not Recommended as they Address and Model only Certain Pathogens, and Do Not Mimic the Environmental Conditions at Retail or the Growth of Bacteria in Real Food Systems. | |

Note: This worksheet does not address the implementation of the product's handling once approved, as the local regulatory authority will likely require that procedures from the establishment also be submitted and implemented regarding the handling of the product as part of a variance or other approval.

First Meeting 9/21
Friday, September 21, 2018

Call Recap:

1. We have a very small committee with only a few At-large members who can become voting members (ie not voting members on other committee's). PLEASE let Veronica or I know if you change roles so we can make arrangements.
2. Everyone volunteered to be on this committee and we commit to treating everyone with respect, dignity and assume positive intent.
3. Our committee will break up into four sub-committees and begin working on each of the charges concurrently. Rank each subcommittee in order of preference. Respond back by 9/28. Subcommittee work will begin in October on a monthly cadence.
4. Committee meetings will be every 3-4 months.
5. Share with the Committee any relevant guides, templates or work that you currently use. Thank you Todd for sharing your work.

Readings and Courses:

1. Sign up for Don Schaftner's course on microbial challenge studies in 2019. Put yourself on the waitlist below: https://www.foodprotection.org/events-meetings/workshops-conferences/microbial-challenge-testing-for-foods-workshop/
2. Read and review the attached three documents:
    a. NACMCF Challenge Study Document
    b. IFT PHF Document
    c. Todd's Challenge Study Process Flow

Subcommittee signup based on Charging Document:

| Subcommittee | Preference |
|---|---|
| **Template / checklist for reviewing challenge study** | |
| **Organism selection tool** | |
| **Interpreting Results Guidance tool** | |
| **Computer modeling appropriateness** | |

Nov 2. 2018 Notes
Introductions
Review of Charges

1. **A tool to assist in selecting appropriate organisms.**
2. **Direction on when it is appropriate to use computer modeling to either support or replace an inoculation study.**

Strategy to Complete Charges
Page 20, Appendix C, Table 2
Start with Appendix C, Next Step: pH and water activity, narrow down organisms
If food isn't on the list, go to table 2
Don provided historical information about the NACMCF document and said that it started as an idea of a decision tree, but it was too complicated.
Who is the end user of these tools? What kind of tool and for who?
**Common pitfalls, what are the things that are show mistakes, failures, etc of studies that have been looked at**
**Difference between HACCP validation and challenge study: Two projects that confuse people, good for industry to see comparison. Examples: processing facility, validate piece of equipment, no challenge study on final product.**
**Criteria for lab selection: Component of the NACMCF document needs to be highlighted for both industry and regulatory**
Resource Review

Next Steps
For next call, everyone should think about

December 2018 Subcommittee #1 12/7/18
Discussion Items

- Opened meeting with review of action items from last meeting and action items. Main action item was discussion of what causes challenge studies to be turned down from experience.
- Discussion began with Nikki; challenge studies submitted for processes, i.e. Peking duck that does did not include actual scientific data. Wanted to use anecdotal information of lack of outbreaks to get challenge study passes. **All agreed that this is important information and would cause a challenge study to be denied.**
- **Second discussion item from Dr. Schaffner; challenge studies that use the incorrect pathogens for the study. Not necessarily choosing the wrong organism completely but using stand ins or surrogates incorrectly**. For example, people choosing *Clostridium sporogenes* instead of *C. botulinum*. Tests with *C. sporogenes* are significantly cheaper than C. botulium, but it will not properly predict growth of *C. botulinum*. Another example is doing a challenge study using generic *E. coli* instead of pathogenic *E. coli*. Pathogenic *E. coli* is more acid tolerant and so does not react the same way as generic *E. coli.*
- Third discussion item was from Veronica; discussion of choosing incorrect parameters for the challenge study. For example, if the study was extending holding at room temperature and the

study is conducted at 50°F. **All agreed choosing wrong parameters would lead to challenge study denial.**

- Discussion was had about laboratory selection. Victoria asked if local regulatory jurisdictions deny challenge studies based on "wrong lab" used. Regulators on the call agreed that they cannot require or suggest one lab over another. Accreditation of the lab is not required, but specific parameters must be met. Study must be designed by a PhD and must use validated methods. **All agreed information from Appendix B needs to be highlighted in report.**
- There is a list of university laboratories that are process authorities that was put together by Purdue University in 2011. Discussed if list could be updated by a university. Also discussed university labs may be used for challenge studies even though they are not good for routine testing. Also, same laboratory that does routine L. monocytogenes testing probably not able to do challenge studies. Any lab that does the challenge study needs to understand challenge studies and how they work.
- Committee members discussed that definitions are necessary early on to determine the scope and make sure information and recommendations are clear. Some terms that require definitions are process authority, challenge study, product assessment, HACCP validation, etc. Dr. Schaffner stated that some terms won't be able to be clearly defined. Example is a product assessment for a process deviation. Universities are contacted to validate a process deviation, which could require a challenge study, sometimes Dr. Schaffner stated that deviation can be validated via computer modeling in some cases. This item will be important for Charge 2 of subcommittee.
- **Committee agreed that for Charge 1, A tool to assist in selecting appropriate organisms, information is already available in chart format in Table 2 and Appendix C. Committee's job is to market and organize information so that people know where to find it.** Report will be written to help point people to the information in the document. Dr. Schaffner stated that as a writer of the original document, he is willing to help explain some of the technical language if there are items that are difficult to understand.

Action item for January Meeting:

- Review NACMCF document and determine questions about technical language and items that need to be further explained. Decision was made to split the document into sections for review. **All committee members must review document and record questions or items that need clarification. These items must be submitted to Veronica Bryant by January 3, 2019.** The assignment is split by the bold headings within the JFP version of the document. Assignments for document review are as follows:

  Victoria Burgess and Nikki Burns-Savage
  - Types of challenge studies
  - Determining when a challenge study is needed
  - Obtaining expert device and identifying a laboratory
  - Type of study

  Lauren Bush and Rebecca Krzyzanowski
  - Factors related to the test product

- Target organisms
- Inoculum levels

Richard Willis and Dianna Kerlicek
- Inoculum preparation
- Method of inoculation
- Storage conditions
- Sample considerations

Todd Mers and Samuel Derr
- Duration of study and sample intervals
- Interpreting test results
- Elements to include in the report

Veronica Bryant and Christina Bongo-Box
- Appropriate uses of mathematic modeling
- Limitations of applying results to similar foods
- Existing protocols for applying to wide varieties of foods

SubCommittee #2 December 5 Notes:

1. Defining the scope of when this should be used (ie when the pH and water activity call for a product assessment OR anytime a product assessment is done)
    a. We will define this as only when the pH and water activity call for a product assessment

2. Process and timeline: We should define the directions for assessing the challenge study first and then come up with template and checklist.

Next Steps:
1. Use the NACMAS document and formatting
2. Robert/Susan/Todd to come up with sections/steps for directions when assessing a PA.
3. We will assign out the sections from there.

Important Dates:
1. I am going to push our 1/2 call to 1/9 and reserve the 1/2 call for Robert Susan Todd and I to come up with the Sections that we will discuss and assign out on the 1/9 call.

Share with the Group ANY Product assessments:
1. Veronica - NACMAS does have an example in the appendix.
2. Tammy Gordon can pull a few PA's

January 2019 Meeting

Discuss follow-up from previous meeting. Continued to work on the charges related to developing a tool for computer modeling.

Most of the discussion was around the idea that the two charts already exist in the NACMCF document. Trying to rewrite these items and charts that already exist in Table 2 and Appendix C are going to be challenging. Most of the discussion surrounded around how to repackage the information already in the NACMCF document to be more accessible.

Discussed whether tables should be put into the guidance document or just referenced. No consensus reached.

Notes:

We used the NACMCF doc outline listed below to determine what sections would be applicable to our charging documents and our sub-committee. These include:

1.0 Obtaining expert advice and identify a lab.

3.0 Factors related to the test product

8.0 Storage condition

9.0 Sample considerations

10.0 Duration of study and sampling intervals

11.0 Interpreting results

On our 1/9 call we will be aligning these with the broader sub-committee and then forming groups to write instructions regarding their sections for use.

Section 1 & 3 - Susan Shelton
Sections 8 & 9 - Todd Pelech
Sections 10 & 11 - Robert Curtis

Currently we are tracking but do not intend to include in our write up the following:

1. Ongoing product verification

2. Humidity control during tests (not mentioned in NACMCF)

3. Non-pathogen surrogates selection

4. Self-Testing/Certification of results (pH & water activity)

***Notes for the call:***
The below Google Doc will be used to collaborate on our outlines.
https://docs.google.com/document/d/1HKyuoVvFNNJiAja6Ztr4lajZ4buPF4KqNYXbAmdlG6g/edit?usp=sharing

We reviewed the Committee Spring Report and agreed that:

- Looks good
- Timelines are reasonable
- Checklist might be hard

I have made the following updates to the report:

1. Moved the Report submittal deadline to 3/1 vs. 2/1. This gives us time to get everyones outline into the google doc in our agreed upon formatting. Goal is to have this done by 2/18.

2. Included our caveat in the Spring Report that we are only looking at challenge studies that determine if a product is TCS or ones that extend the shelf life of TCS products.

We aligned that we will follow the outline created by Robbie (Attached) that is in line with the NACMFS doc and we will go relevant chapter by chapter and include information in our instructional assessment doc.

Veronica is working to get approval to use a Pizza Sauce Example which we can use as a sample assessment to evaluate.

Our next All-Committee Meeting will be week of 2/11.

February 2019 minutes
Notes from PAC February 1, 2019

Chili Challenge Study discussion – Michigan only saw listeria, not bacillus or salmonella
Some cyclotrophic bacillus
Should consider abuse situations – in NACMCF

Guidance document may need to address regulator concerns with conditions

Can we give guidance on categories of products?
Parameters that would be necessary for complex processes

Cannot be reduced to a flow chart

Job Aid – designing a study from start to finish
Where can we add value
Can we copy the table into our document? Needs to point to a table
Point to the document with a few examples

**Action Items for Committee:**
**Come up with talking points on organism selection that needs to be included**

**Come up with rea world examples that have been submitted**

Situations where you can use surrogates, but they must be validated for the food and for the process that you are developing.
Rule out formulations versus rule in

2/6/19

1. All work product is attached.
2. We will upload/combine all work into the Google Doc
3. Send out the Committee report prior to 2/15 call

Writing Style:
- When writing the section remember that the audience is the regulator
- Pull out relevant information from the NACMCF doc

Full Committee Meeting:
***Overall:***
General Comments on the Committee Report - None
Don will check the entire doc for any plagiarism via his plagiarism software.
No issues with using the NACMCF titles.

***Timeline:***
Doc to be completed 10/1 which will leave use one month for committee review

***Action Items for Document:***
1. Add a definitions section - Any volunteers?
2. Add an introduction / who is the audience / how to use this doc section - Any volunteers?
3. Add a section around how to select a lab, what questions to ask, vetting a labs capability. Reference the FSIS doc here. - Any Volunteers?
4. Along with our doc submit a recommendation that CFP create a national group to review challenge studies - We need to understand what this looks like (ie add it to the doc, a separate doc?

***Overall Meeting:***
1. Susan Shelton presented sections 1 & 3
2. Nikki presented section 4
3. Todd presented sections 8 & 9
4. Nela presented sections 10 & 11

Aligned to using the Pizza Sauce example (need to attach it) throughout the document.

Volunteers please contact Veronica or Jon.

March 1, 2019
The following items were discussed in relation to Charge #4 – when to use computer modeling. Becky K discussed that Michigan used a group to discuss how computer modeling can be used and the following were some of the factors related to their decision.

- Some of the language used by FSIS is Non refrigerated shelf stable
- Data from salt, pH and water activity to show shelf life
- Refrigerated perishable, more than seven days
- More extensive than just modeling, must show they meet modeling requirements
- Technical advisory committee, what organisms, MSU, OSU, USDA, meat association
- Specific program for cured meat
- Deviation from code, use modeling
- Part of full haccp and variance, but modeling is just shelf life extending

April 5, 2019

Discussion continued around use of computer modeling. Need to add this information into the already in process guidance document. Difficult to use modeling alone.

Discussion continued on the best way to complete this charge. Consensus beginning around writing statement to be included in guidance document. Computer modeling might be available for use like being used in Michigan. Michigan documents were not able to be reviewed prior to this meeting.

Action items are for committee members to review documents and determine best steps to move forward.

FDA Rep Introductions – And thank you for your participation in our sub-committee group. We look forward to your contributions.

Reminders: Please review the google doc and put all comments feedback by 4/19 (tomorrow)

Volunteers:
Final Doc Editor - Robbie
"Sample Review" - Hilary Thesmar

Comments/Ideas to make the doc purpose more clear/easier to use are to:

Break it up into sections:
1. Food service relevant items
2. Labs - Remove the Lab components as this is not the intended audience (See Robbies comment below)
3. Regulator relevant items

Robbie - remove the lab components as it is not part of our introduction.

Call out the exclusion of manufacturing processes.

I will compile the above into the google doc.

June 2019 Notes

1. Jon to "clean" doc and repaste edited version in Google doc. Veronica will include this link to the committee. The FSIS folks will get the word docs separately. Google doc here. The current version is at the top of the doc and the old version at the bottom. Format is not 100% but I am not going to fix it.
2. Veronica send out the edited version of the whole report to the whole committee. Don will run through plagiarism software and everyone can comment. Pull off all the checklist stuff and only send the doc. Accept all changes and send a "clean" copy.
3. Veronica we are seeking 1-2 more volunteers on the developing the checklist/example. We already have Hilary Thesmar but want at least one more regulator to support this
4. Checklist and Sample group to meet in July.

August 2019 Notes

- Draft document has been completed. All members have had ability to review document and make changes.
- Document was submitted to FDA reps in word format since Google Doc is not allowed for them.
- All discussion has been completed on the document, final vote will be taken at final meeting.
- Discussion around how to proceed with checklist. Current format is long.
- Workgroup will continue to work towards a better format for this checklist and will present at the final meeting.
- Unsure if example document will be able to be created due to limited time and no finalized checklist format.

September 2019 Notes

- Number of voting members present does not constitute quorum of voting members.
- Asked Becky K who is familiar with Board procedure if email vote could be called, it was decided that it was allowable to conduct votes via email.
- Email vote will be sent out on guidance document, document in final format that all are comfortable with.
- Checklist format still not finalized. Worksheet to compare protocol with actual submitted was created. Discussion on this format with mixed feelings.
- Some feel that it does not give enough guidance on how to move forward with a challenge study.
- Checklist in current format too long with too much information on lab selection.
- Determination was for Veronica to work on checklist to condense and send out to members for review.
- After meeting – email vote was sent out on guidance document and worksheet. Vote was 9-0 with several members not completing vote.
- Veronica sent out revised checklist for vote, vote was 11-0 with 2 members not voting.
- Discussion via email about keeping all documents separate for ease of council deliberation.