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.