Committee Report

Committee Name : Post Harvest Processing Committee
Chairperson: Angela Ruple
Date of Meeting: October 25, 2015 **Approved By:**_____
Recorder: None **Printed Name:** Angela Ruple

Committee Members Present:

X Angela Ruple
(Chairperson)(NOAA Delegate)
☐ Jose Barreiro
☐ Peter Brown
X Erin Butler
X Austin Doctor
☐ John Lin
☐ Chris Nelson
X Tim Parsons

X Laura Johnson
X Debra Scoville
X Keith Skiles
X Wec Terry
☐ John Tesvich
X Kirk Wiles
☐ David Wallace
X Brian Yarmosh
☐ Bill Kramer

(EPA Delegate)
X John Veazey
(FDA Delegate)
☐ Jessica Jones
(FDA Advisor)
☐ Lizzie Evans
(FDA Advisor)
☐ John Bowers
(FDA Advisor)

Charges

Charge 1: Proposal 09-231 Post-Harvest Handling Definition and New Model Ordinance Chapter (Recommendations 2-5 from the 2013 Committee Report)

1. Change the title of Model Ordinance Chapter XVI, Post-Harvest Processing to "Processes and Procedures for Pathogen Reduction" in order to include pathogen reduction processes that are not associated with labeling claims, which was the intent of Proposal 09-231.

2. Add a new section to the newly titled Chapter XVI (Recommendation 2) to be titled "Pathogen Reduction Processes that are not associated with Labeling Claims."

3. The committee recommended that a work group be established to develop language for the new section of Chapter XVI and report the findings to the appropriate committee as determined by the Conference Chairman. It is further recommended that the work goup meet quarterly until the new section is complete so that it can be submitted as a proposal at the next ISSC meeting.

4. Requested the Conference Chairman to appoint an appropriate work group or committee to work with FDA to establish target levels for pathogen reduction processes that do not require labeling that will achieve the required risk reduction goals. (The intent of the committee is to use the information developed by this work group to determine if additional validation protocols are needed.)

Findings & Conclusions:

In order to address recommendations 2-5 listed above, a subcommittee was formed and met via conference call on May 27, 2015 (Subcommittee members: Angela Ruple, Chris Nelson, John Schwartz, John Tesvich, Kirk Wiles, John Veazey, Lizzie Evans, John Bowers, and Jessica Jones). The subcommittee made recommendations to the full committee. The full committee was not able to meet but agreed upon the recommendations of the subcommittee via email. The findings and conclusions of the committee included recommendations to rename Chapter XVI and separate the requirements for pathogen reduction involving labeling claims and those that do not involve labeling claims. The Committee has submitted two new proposals for the 2015 Conference to address this charge.

Recommendations:

1. The title of Chapter XVI should be changed to Processes and Procedures for Pathogen Reduction. A new section @.01 Processes and Procedures Involving Labeling Claims should be added to the existing chapter between the Title and A (see proposal 15-223). A new section @.02 Processes and Procedures Not Involving Labeling Claims should be added to Chapter XVI

2. The contents of the new section @.02 should be as indicated in proposal 15-223.

3. The subcommittee concluded that the development of blanket target levels and validation protocols for all possible processes for pathogen reduction would be complex without knowing what the processes are. The committee recommends an alternate approach as follows:

   a) a new committee be established to serve as a resource to the ISSC to assist with evaluation of specific processes designed to reduce pathogens to determine target levels and recommend specific validation and verification protocols.

   b) The Committee should be a standing committee and would develop target levels and validation and verification protocols as needed to support the NSSP.

These recommendations are addressed in Proposal 15-302

Charge 2: Proposal 13-220 Post-Harvest Processing Validation and Verification Costs

Findings & Conclusions: The Committee considered the following discussions of a subcommittee formed to evaluate the possibility of reducing the costs associated with PHP Validation and Verification protocols:

After discussions by the subcommittee of the existing validation and verification procedures for validation and verification of processes and procedures to reduce pathogens that involve labeling claims, Dr. John Bowers (FDA) was asked to determine the statistical assurance that the existing procedures provide. The following is a summary of his findings:

> With respect to an overall objective of having a high level of statistical confidence that <30/g is being achieved, the validation in and of itself isn't aiming to achieve a really high level of confidence. Instead, it is more like you have about a 50% chance of passing (or failing) validation when you are right at the limit of 30/g in the end product (i.e., consistently getting right at 30/g with little variation). If the levels are a little bit lower, say 20/g not 30/g, the probability of passing increases drastically to almost 95% (i.e., if pass validation test would be about 95% confidence that true level is <40/g). At the 30/g limit, the confidence actually increases through the Verification testing, which is why, to achieve a high level of statistical confidence for 30/g, there is a need to do the verification tests, so after time the level of confidence for <30/g would build as one accumulated many tests that are all passing.

The subcommittee also discussed reducing cost by using other methods for vibrio analysis. It was determined that while the vibrio detection methods are costly, there is only one approved method for *Vibrio vulnificus*. There is a less expensive method for *Vibrio parahaemolyticus*, but use of that method for VV would need to be validated, which would involve some time and additional expense. Additionally, to use this method, the validation and verification protocol would need to be revised to be based upon plate counts.

Another suggested way to reduce cost is in the area of equipment validation. The FDA members of the subcommittee are exploring the possibilities of equipment validation as an avenue for reducing cost.

Based upon these findings and discussions of where the real area of need is for cost reduction, Ken Moore, as submitter of the proposal, has agreed to survey industry members currently involved in pathogen reduction (with labeling claims) as well as laboratories currently involved in validation and verification analyses to determine which costs are most burdensome. He will report his findings back to the Committee at its meeting in Salt Lake City.

Response From Ken Moore:

As indicated in the recent PHP Committee conference call, I have followed up with those included in PHP validation and verification. I have heard that the cost of sample analysis is much lower than previously suggested. One laboratory is conducting most of the analysis and the cost is as follows:

Validation approximately 6300.00
Verification (monthly or quarterly) 750.00

The firms involved in PHP do not consider these costs as an obstacle to the voluntary expansion of PHP.

I submitted proposal 13-220 for the purpose of reviewing current cost. The information listed above suggested that the cost is reasonable. I recommend no action on Proposal 13-220.

Recommendations: No Action Rationale: It has been determined that the current costs of PHP validation and verification is not an obstacle to the voluntary expansion of PHP.