Large Processors – Processed Meat

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Validation of the HACCP Plan is required by 9CFR417.4. In addition Draft Guidance: HACCP System Validation was issued by FSIS in March 2010.

Validation needs to be done on both Critical Control Points and Prerequisite programs, as they are both parts of a HACCP system. Examples of a prerequisite program is the addition of an antimicrobial like sodium lactate / sodium diacetate or room temperature control.

Validation has two parts:

1. Scientific support
2. In plant validation

Scientific Support

Most often, scientific support is from peer reviewed journal articles or the regulatory requirements or Guidance Material from the Agency. The patty cooking regulation (9CFR318.23) is an example of the regulatory requirement. Even when using the regulations, the intervention will need in plant validation.

When a journal article is not available, then a challenge study may be necessary. Other options include processing authorities, or pathogen modeling programs.

Challenge Studies

Most challenge studies are done at an off site laboratory, away from the production facility, due to the use of pathogens. When designing the test, the critical parameters for both the intervention and the product being tested, need to be determined. If validating an existing product, the laboratory will need to replicate these critical parameters. If validating a heat process, the heating curve need to match the processor's process, or if validating an antimicrobial application, ensure that spray coverage and dwell times match the actual process. When making product for use in the challenge study, purposely make a product that is at the extremes of what is seen during actual production. For most microbiological challenge studies, use the low end of product specification range for salt and the high end for moisture. Once validated, these critical parameters will be limits for the process and product that can not be exceeded.

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In Plant validation

In plant validation, the second part of validation itself has two parts:

1. Validation of individual interventions
2. Validation of the HACCP System

Validation of Individual Interventions

The type of intervention will dictate the type of validation that can be done. The validation can be testing that shows a reduction of indicator organisms, or other measurements showing the critical parameters of the scientific support are being met.

Examples of Validation of Individual Interventions

1. A post package pasteurization system. The scientific support is a challenge study showing a multiple log reduction in Listeria monocytogenes. This intervention could be validated by showing a multiple log reduction in Aerobic Plate Count in samples pulled before and after the process.
2. An antimicrobial being applied to the surface of a product. The scientific support is a challenge study where the product was totally submerged for a certain length of time in a solution of a certain concentration. In this case the validation would be measuring the time the product is submerged and the concentration of the antimicrobial during production.

Determining which of the parameters are the critical parameters is the key to this type of validation. If a parameter could effect the success of an intervention, than it is a critical parameter. In Appendix A – Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products, time and temperature are obviously critical parameters, but so is humidity.

Validation of the HACCP System

This is a validation of the entire process from start to finish to show that all the processing steps are operating as designed. The March 2010 Draft Validation Guidance document recommended at a minimum, the use of indi-

cator organisms tested on the raw materials and finished product, as well as pathogen testing on the finished product.

To gain a better understanding of the interventions, all of the pathogens of concern in your HACCP plan can be tested at multiple steps through the process.

Typical pathogens of concern for a RTE meat product:

Listeria monocytogenes

Salmonella

E coli O157:H7 in items containing beef.

Campylobacter in items containing poultry.

Staphylococcus aureus

Clostridium perfringens

Bacillus cereus at the processing steps after spice addition.

In addition test for the appropriate indicator organisms like Aerobic Plate Count and Lactic Acid Bacteria.

Sampling points for a RTE meat product with CCPs of cooking and chilling:

1. Raw meat at receiving – the purpose of sampling the raw material is to see what the initial microbiological load is on the raw materials, entering the process.
2. Raw in-process product just prior to cooking – sampling after all the non-meat ingredients are added, and all the raw further processing is completed. This sampling point will show if the process or added ingredients have changed the microbiological load.
3. Cooked product after cook and chill - This is the validation of the CCPs. Sample from different scenarios like full smokehouse vs. partially loaded smokehouse, or full impingement cooker belt vs. half full belt.
4. Finished goods in the package. Test for the pathogens of concern in your packaging process – typically only Listeria monocytogenes. This shows the post lethality processing is working as designed.

Sample quantity needs to be sufficient enough to show that the process is working as designed. In the above example, the sampling occurred over three days, with 20 samples pulled at each sample location each day, for a total of 60 samples at each location. 240 total.

Validation of maximum holding times for raw materials and work in process product can be done at the same time, by holding a portion of the raw samples prior to testing. The hold time and temperature would be the highest allowed by your prerequisite programs.

Enumerating the pathogens at the raw material and raw in process steps, provides useful information on the microbiological loads prior to the interventions. Most Probable Number testing could be done but adds significantly to the to the cost of validation.

In plant validations need to be completed with in the first 90 days of a new HACCP plan. They should be repeated when process or products change.

References

1. Draft Guidance: HACCP Systems Validation. March 19, 2010. United State Department of Agriculture, Food Safety and Inspection Service. **[AU1: The reference 1 "Guidance, 2010" is not cited in the text. Please add an in-text citation or delete the reference.]**