

Operator: Validation Manager
Process: Validation
Session Start: 22-11-2013 09:33:20
Session Stop: 22-11-2013 09:33:30
Session Name: Smoke House Validation
Session Text:

Vessel: Smoke House
Product: Food
Time Zone: UTC offset 01:00:00



Smokehouse #2

Thermal Process Validation for Smokehouse VIRGINIA FOOD, INC.

Procedures: The Thermal Process Validation includes the use of a GAMP4-Approved Ellab Tracksense Mini PRO Loggers and a Valsuite PRO Software compliant to FDA 21 CFR Part 11.10 Loggers were positioned strategically in critical areas of Smokehouse #2 and another to measure %RH using the psychrometric method of Dry and Wet Bulbs automatically calculated to produce Temp.Dew Point and %RH.

The process schedules are as follows:

Process Cycles: VF Bacon\Reddening: 30mins at 45minsDrying: 60mins at 60degC Smoking: 30mins at 60degC Bake: 15mins at 65degC

Product IT during bake (Bacon): 54degC Smoking 2: 15mins at 65degC

Summary and Evaluation of Results

The succeeding pages are the list data, statistic reports generated from Valsuite PRO and graphical presentations from the HDT/Validation performed in Smokehouse #2. Results show that the smokehouse #2 is able to provide the products (Bacon) the predetermined process schedules and parameters.Smokehouse #2 is therefore validated.

Recommendations:Note that there are installed sensors to measure %RH in the smokehouse. To be able to utiize these and complete in-process monitoring, we strongly recommend that a water reservoir is installed for one of the sensors provided in the front corner of the smokehouse.

