How to maintain a low moisture thermal process between validations

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Topics to cover:

– Maintaining a properly calibrated unit
  • Temperature
  • Dwell time
  • Product flowthrough
– Performing thermal mapping
  • Interpreting results
– Understanding equipment changes that can affect microbial kill
  • Hot oil/water as a heating medium
  • Hot air as a heating medium
– Knowing when it’s time to validate again
Maintaining a properly calibrated unit

Three primary elements of a validated low moisture food kill step:

• 1. Temperature
  • The amount of heat/thermal energy in the system
  • Monitored with thermal probes

• 2. Dwell Time
  • The length of time product spends in heat
    • Continuous system
      • Product is carried through the system by a conveyor belt
      • Calibrate belt speed
    • Batch system
      • Product is removed from heat by operators when indicated by timer
      • Calibrate timers
Maintaining a properly calibrated unit

- 3. Product flowthrough
  - The amount of product present in the system during thermal processing
  - This is most important in continuous and batch systems where product completely fills the belt or basket
  - Continuous system – this is controlled via bed depth
    - Can be verified with a ruler
    - Many systems have bars or gates that physically limit bed depth
  - Batch system – uses batch size
    - Weight of product in basket
    - Calibrate scales
Maintaining a properly calibrated unit

• All devices and equipment components responsible for monitoring or controlling temperature, dwell time, and product flowthrough (where applicable) should be calibrated **at least yearly**
Performing Thermal Mapping

- Thermal mapping allows the processor to obtain temperature readings from multiple points throughout the product bed during processing
- Like other verification activities, this should be performed at least yearly
- Should be performed while process is running at full capacity
Probes we like:

• Due to their size and ruggedness, we like the MadgeTech HiTemp 140
Performing Thermal Mapping

• Continuous process – place probes on belt, in the vertical center of the product bed (if full)
  • Position probes horizontally across belt so they map out the bed as the belt moves
  • Some dataloggers already come as a horizontal array
  • For individual probes, place evenly across bed
Performing Thermal Mapping

• Batch process – Use individual probes to cover the area
• In large baskets, capturing data from multiple depths is very important
Interpreting Thermal Mapping Data

• Many datalogger software platforms can export data as an Excel file.

• This can be very convenient for evaluation and storage, BUT

• Raw graphed data is often not as useful as it could be…
Raw Thermal Mapping Data in Excel

Date & Time

Value

Q28872 - Temperature (°F)
R23252 - Temperature (°F)
R22647 - Temperature (°F)
R22645 - Temperature (°F)
Polished Thermal Mapping Data in Excel
How to clean up thermal mapping data

• Tighten up time and temperature axes
  • Data from before and after the probes are in the heat treatment are not useful
  • In this case, since the temperatures shoot up and drop down very rapidly, we don’t need temperature data below 150 °F
• Set temp. axis scaling to 5 °F
  (really Excel…50 °F increments?!?!?)
• Label probe positions
• Remove data markers
  (they just get in the way)
• Thicken lines
• These data can be used to place probes at known cold spots during the next major maintenance event
Understanding equipment changes that can affect microbial kill

• In addition to the 3 primary factors that influence thermal lethality
  • Temperature
  • Time
  • Product Flowthrough

• There are multiple other factors that can affect a unit’s ability to enact a good kill
  • Product Infeed Temperature – temperature of the raw product going into the unit
    • Colder incoming product is more challenging to bring up to the target temperature
    • This is especially important for northern facilities that store raw product outside
    • Incoming product temp. in summer much higher than in winter
Watch-outs for oil and hot water systems

- Temperature drop when product enters hot oil
- Heat distribution – batch units can have significant variation in temperature (up to 50 °F)
- Probes are often placed in the oil return, not the product bed
Watch-outs for hot air systems

- Hot air is a very difficult medium for achieving consistent thermal kill
  - Baffles – direct hot air movement, can be improperly aimed
  - Fan Speeds – we have seen a systems fail their validations because the cooling zone fans were too strong and were pulling hot air out of the heating zones
  - Belt changes – since the hot air must pass through the belt, changing the type of perforations can affect air flow and lethality
    - Dirty belts = worst case
Watch-outs for hot air systems

- Leading Edge – in full-bed conveyor systems, the hot air can go around the front of the product bed instead of through it.
  - We include samples in this zone during surrogate validations
Knowing when it’s time to validate again

• FSMA says to revalidate (21cfr117.160):
  • (ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards [presenter note – a “significant change”]; and
  • (iii) Whenever a reanalysis of the food safety plan reveals the need to do so

• What is a significant change?

• Can multiple insignificant changes add up to something significant?
Knowing when it’s time to validate again

- It’s best to re-validate on a routine basis
- How often should we re-validate?
  - The “significant change” rule leaves a lot open to interpretation and judgement
  - Do we really believe that a thermal process can operate for 5, 10, or more years with no change in function from day 1?
- Some of our clients re-validate every year due to SQF or customer requirements
- FSMA requires a reassessment of the Food Safety Plan every 3 years
  - While a re-validation isn’t required at this time, we recommend re-validating every 3 years to stay ahead of unforeseen changes or system drift
QUESTIONS?