Jacques Bichier (ME, Agricultural Engineering, University of Florida) Sr. Project & Research Engineer - Processing Authority 28 years experience Jacques Bichier has supported JBT FoodTech projects and customers since 1991. As a member of the Process Technologies Lab group, Jacques blends his expert knowledge of thermal processing design, equipment, and numerical modeling with an aptitude for programming and validating automated computer control systems. In a truly unique position, Jacques can merge his practical experience with all aspects of thermal process development and optimization, mathematical modeling, regulatory requirements, and control design into a single project. Jacques greatly contributes to the design and technical support of thermal processes and control systems for sterilization equipment such as continuous rotary, hydrostatic, full-immersion, steam/air and water spray technologies; for tuna pre-cooking equipment such atmospheric and vacuum precookers; and for aseptic equipment. He frequently assists our customer base in meeting the regulatory requirements for these processes and in preparing a complete validation plan for their computer control systems. Taking advantage of his diverse skills, Jacques has presented at conferences and has conducted many workshops and training sessions in the US and overseas on the development and optimization of thermal processes, the use of NumeriCAL, TunaCAL, and AseptiCAL software, and the operation and validation of computer control systems.

Paul Gerhardt (PhD, MS Food Science, University of California, Davis; BS Bacteriology, UC Davis) Research Fellow, Preservation Technologies 30+ years' experience Paul brings over 30 years of applied research, process authority, food safety, and production experience to the JBT Process Technologies group. He joined JBT in 2017 after an 18-year career at The National Food Laboratory, having led both the Aseptic and Food Safety/Research Microbiology business units. In addition to continuous thermal process sterilization of foods, he has a wide range of expertise in diverse packaging sterilization technologies to include bath, spray, condensing- and non-condensing vapor hydrogen peroxide technologies; hybrid peroxide+UV; peracetic acid (several chemistries); electron beam; wet heat, superheated steam, and dry heat; high-pressure processing. During his extensive experience in working with Clostridium botulinum, he developed surrogate organisms for several of these technologies and is an expert in assessing processing technology efficacy, microbiological risk, and developing optimized processes/formulations. He is a California Almond Board approved process authority and regularly interfaces with FDA. Paul provides microbiological, regulatory, and in-plant expertise for the development of new sterilization and pasteurization technologies at JBT as well as providing technical support to existing customers of JBT equipment.

Development and Validation of Processes for Low-Acid Particulate Foods: A JBT Turn-Key Solution

Jacques Bichier
Paul N. M. Gerhardt, Ph.D.
JBT Process Technologies Laboratory
February 28, 2023

Presentation Outline

- Discussion of Particulate Product Process Solutions
- Assessment of Particulate Product/Process:
- Nata de Coco in Papaya Nectar
- Process Development/Validation Meeting Requirements of FDA
  - F-Value Criteria
  - Residence Time Measurements
  - Process Development with AseptiCal®
  - Scheduled Process
  - Microbiological Validation

ASEPTIC PROCESSES FOR PARTICULATE PRODUCTS

The Obvious Question:

At what point (particle size) can a product not be filed as a homogeneous product?

Homogeneous vs. Particulate Low-Acid Process Development

Homogeneous Low-Acid Process Development

Very simple for vast majority of products:

1. Laminar or turbulent flow?
   - Reynold's Number calculation--Is turbulent an option?
   - Assume: V_{avg}/V_{max} = 0.5 (laminar) or 0.833 (turbulent)
2. Decide F_o: Conventional 5.0 minutes, or if cocoa-containing, 8.5 minutes
   - Lethality uniform throughout product and credited in hold-tube only
3. Calculate Hold Tube Exit Temperature based on maximum (corrected) flow rate

Process Factors are simple:

Laminar: Maximum (corrected) Flow Rate, Minimum HT Exit Temperature

Turbulent: Maximum (corrected) Flow Rate, Minimum HT Exit Temperature, Specific Gravity, Viscosity

Homogeneous vs. Particulate Low-Acid Process Development

Particulate Low-Acid Process Development

Not simple:

1. **Particles heated by surrounding fluid, so**
   - **Must know interplay carrier liquid/bulk particle heating**
2. **Requires the ability to model/predict cold-spot heating of worst-case particle**
   - **Advanced computations require specific process development software**
3. **Inputs into model require:**
   - **In-system residence time measurement of fastest particle**
     - **Determine Flow fluid dynamics (Laminar/Turbulent) and flow behavior**
   - **Physical parameter measurements for both particles and liquid**
   - **Establishment of parameters for heat exchangers**
4. **Lethality credited in heating system and in hold tube**

Scheduled Process established via calculations based on results of 1-4, above

Homogeneous vs. Particulate Low-Acid Process Development

Particulate Low-Acid Process Development

Critical Factors are not simple:

1. **"Particulate Species"--Process based on worst-case "particulate species"**
   - **Particulate composition (determines heat capacity, thermal conductivity)**
   - **Geometry—Both shape and size**
2. **Particulate mass fraction (maximum % particulates in system)**
3. **Carrier fluid composition:**
   - **Viscosity, specific gravity, heat capacity**
4. **Product initial temperature**
5. **Product temperature profiles in all heaters, hold-tube exit**
6. **Maximum flow rate**

Therefore:
Product, once filed and validated, cannot easily be reformulated without completely new process development/validation

Marketing/product rollout/product development decision makers *must understand this*!

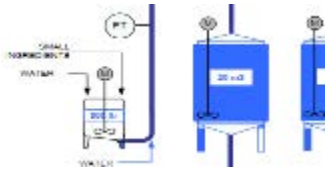
Requirements for Establishment of Particulate Thermal Process

Prerequisites:

1. UHT equipment must be able to deliver a controlled scheduled process to the product
2. *Likely requires dedicated* particulate-processing stream
   - Particulate processing system likely will limit product range
   - Hold tubes having switchable lengths may be used to overcome particulate size differences, etc.
3. Products must be of a type and formulated in a manner ensuring that all critical factors will be delivered (e.g.: carrier fluid viscosity not too high)
4. Specifications for particulate ingredient especially critical
   - e.g.: How is incoming worst-case particle size controlled?
   - May require restrictive specifications for suppliers (e.g.: geometry of particulate must be well defined)

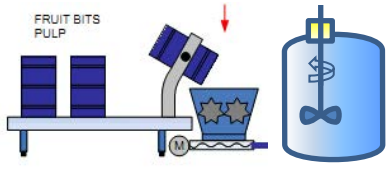
JBT Processing Solution

Dual-Stream Processing:
Separate treatment for liquid and particles

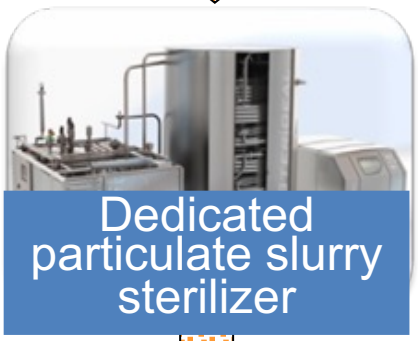


base product

Standard Basic Sterideal® UHT



particulate slurry



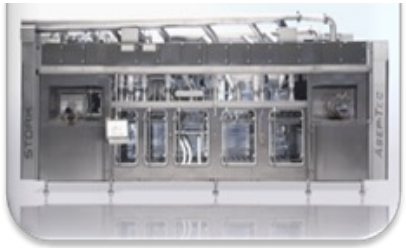
Dedicated particulate slurry sterilizer

Steritank® aseptic tanks

Aseptic in-line blending

Aseptic Tank

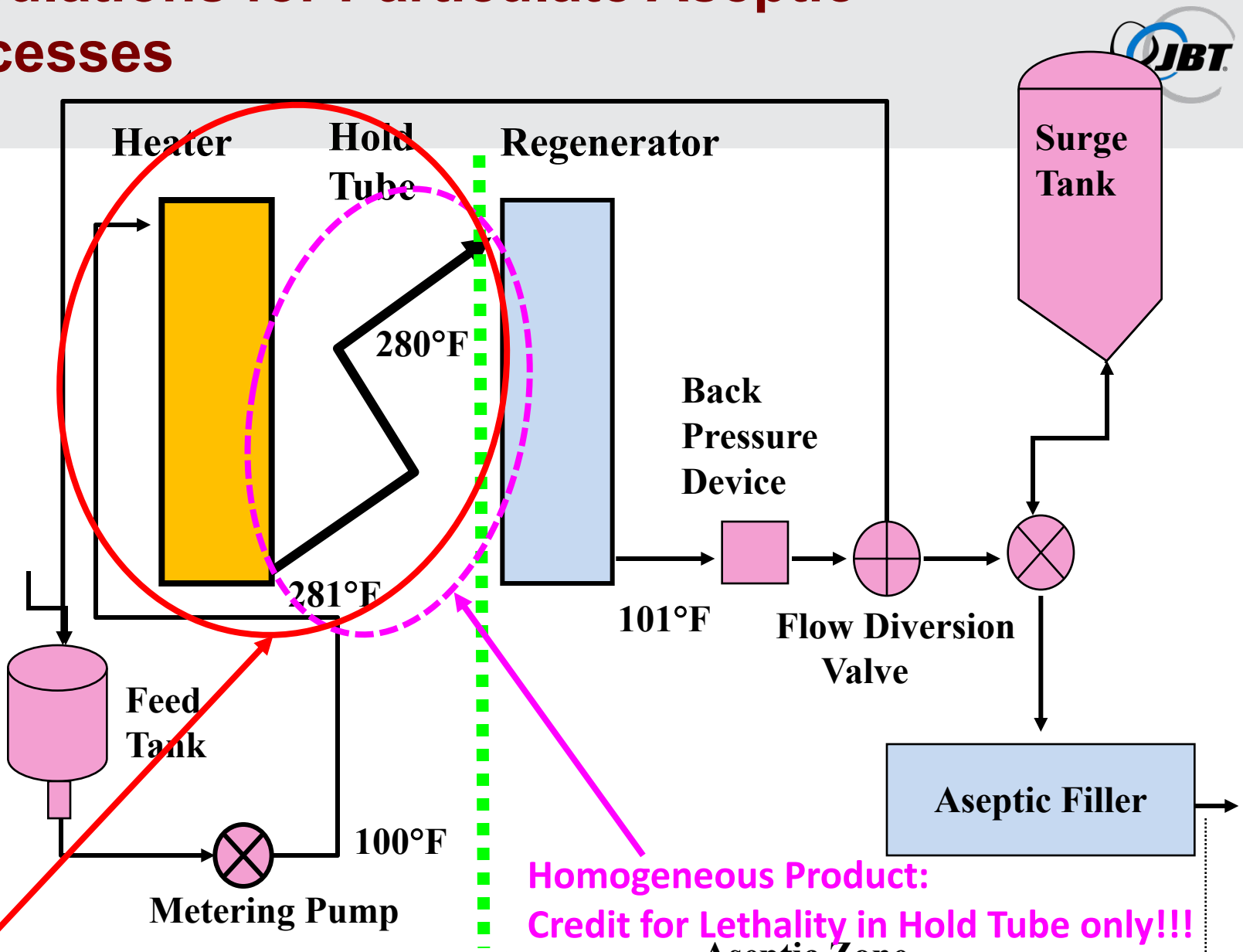
Aseptic Filler



Advantages:

- Large-particle capability on existing line for a minimal investment
- Optimized separate thermal treatment of particulates
- Specialized particulate handling pump

Calculations for Particulate Aseptic Processes



Particulates:

Take credit for Lethality in Heaters + Hold Tube!!!

Example of Hypothetical Particulate Product: Nata de Coco in Papaya Nectar

All data presented in example hypothetical and may not represent actual measurements or literature reference values.

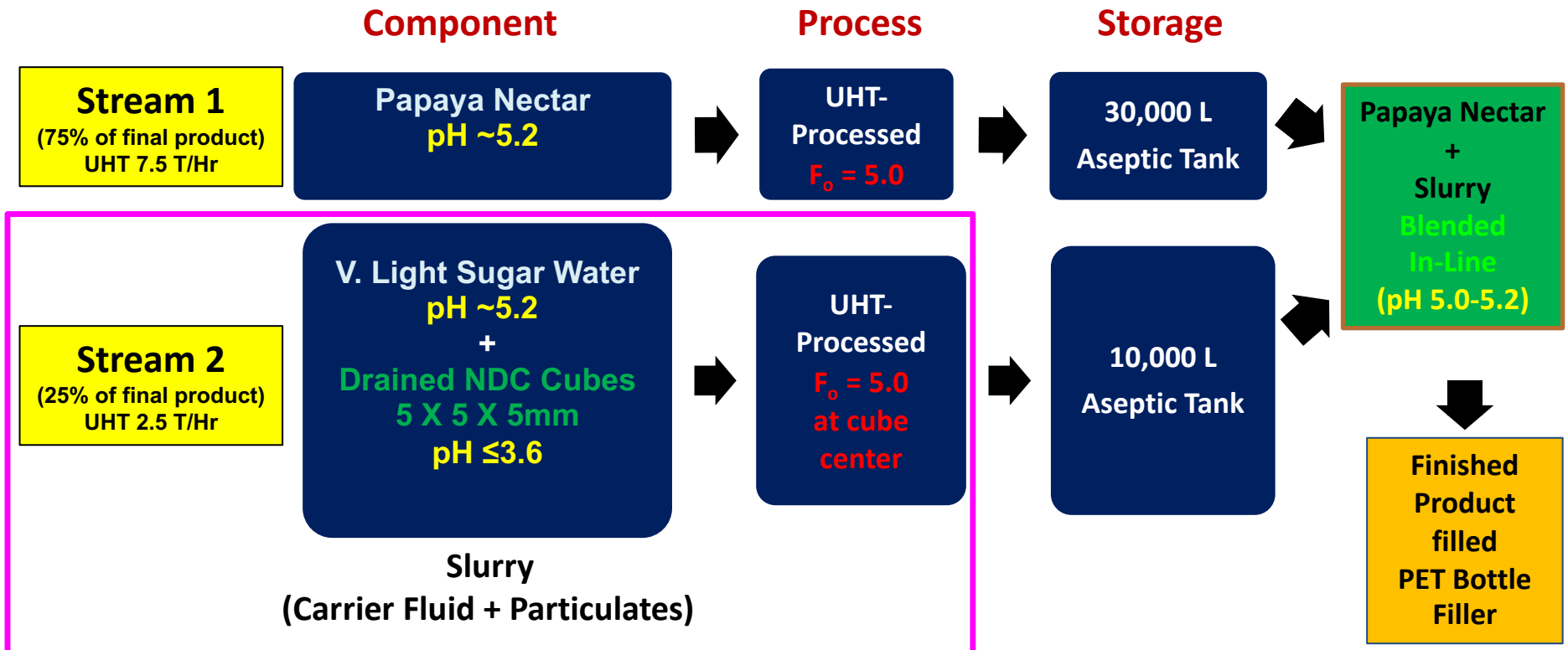
DO NOT USE MEASUREMENTS SHOWN TO ESTABLISH YOUR OWN ASEPTIC PROCESS

Product Description:
Nata de Coco in Papaya Nectar

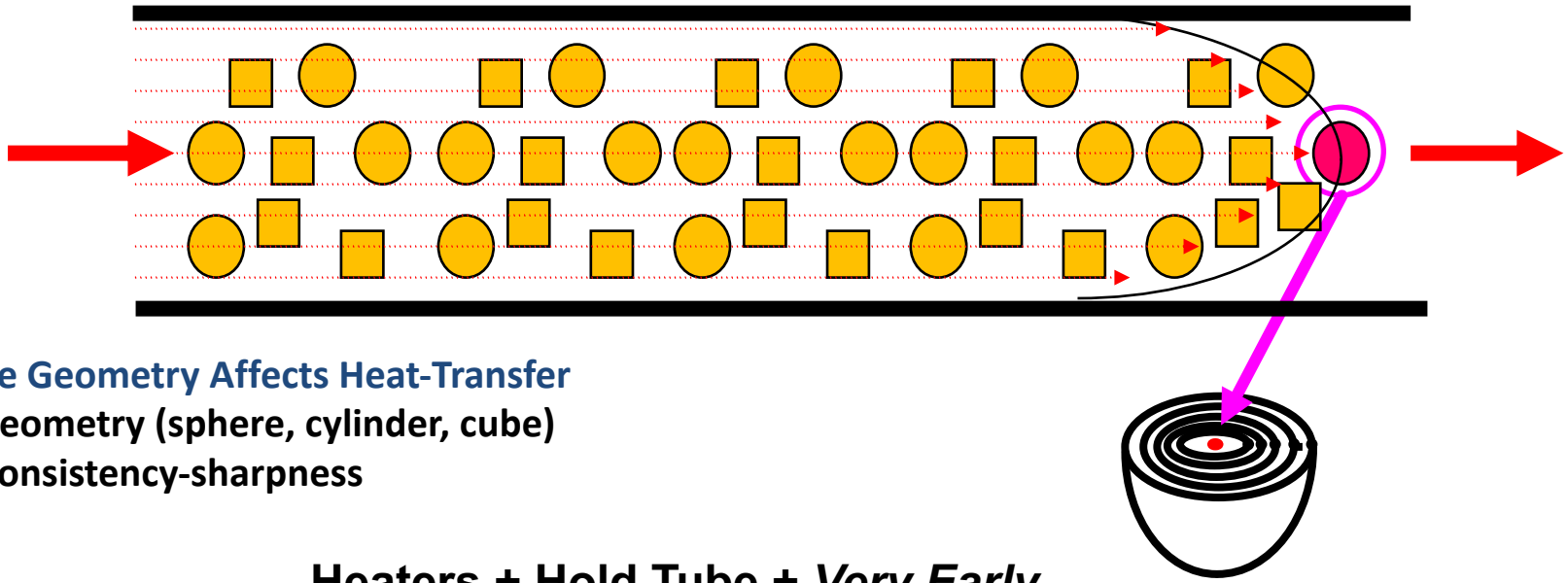
~10% Nata de Coco (NDC) particles
~90% formulated Papaya Nectar.

Final pH: 5.0-5.2.

The product therefore must be classified as a LACF product, even though its NDC component is fermented/acidified.



Overview of Thermal Process of Slurry (Carrier Fluid + Particulates)



Particle Geometry Affects Heat-Transfer

Edge geometry (sphere, cylinder, cube)

Edge consistency-sharpness

Heaters + Hold Tube + *Very Early* Cooling Heat Carrier Fluid

Particle is Heated by Carrier Fluid

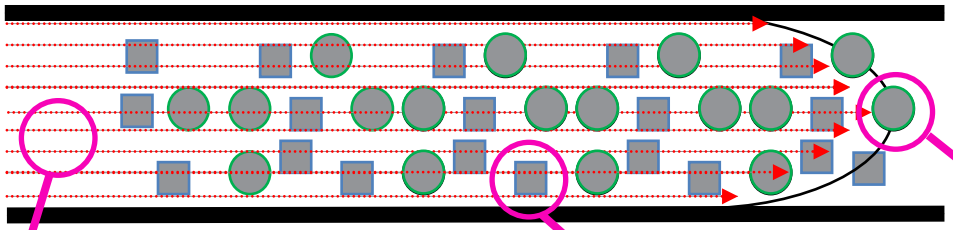
- **The Core of the fastest moving particulate is the LSZ.**

Requirements for Establishment of LACF Aseptic Particulate Thermal Process

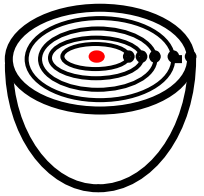
1. **Determine criteria for an appropriate F-value for the slowest-heating particle.**
   - F_o-value, as delivered in the LSZ of the slowest heating particle is appropriate.
   - This lethality must be delivered upon particles exiting the hold tube
2. **Establish the residence time distribution of particles within the system.**
   - The heating of a particle is dependent on the residence time of particle within the heating matrix.
   - Thermal process based on the residence time of the fastest-moving particle in the system.
3. **Develop a conservative mathematical model to predict LSZ lethality using:**
   - Product component physical parameter measurements
   - Establish mass/energy balances for defined product/process conditions
   - JBT AseptiCal® Particulate Process Development/Validation modeling program used to design scheduled process.
4. **Establish a List of Critical Factors and procedures for their control.**
5. **Microbiological validation to validate the mathematical model/document the lethality delivered.**

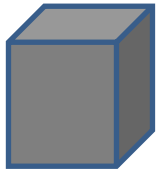
Requirement 1: Criteria for F-value for the Slowest-Heating Particle. Product/Process Assessment

An appropriate F-value criterion is dependent on product composition (matrix) for the slowest-heating particle.



The center of the fastest-moving particle is the LSZ



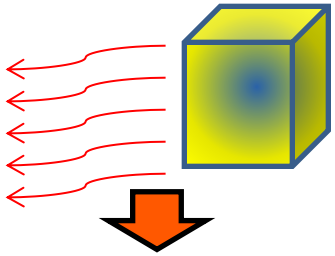


Bulk Carrier Fluid—Flavored Sugar Water

- pH ~ 5.2

Particulate—Nata De Coco (as received)

- Fermented product (*Acetobacter xylinum*)
- Contains acetic acid, other antimicrobials
- Received commercially sterile
- pH ≤3.6
- Acidified with citric acid and possibly acetic acid



Particulate—Nata De Coco (as batched/processed/final product)

- Acids/antimicrobials diffuse out (gradient—concentration changes)
- pH equilibrates (gradient—concentration changes)
- Batching residence time controlled only to ensure adequate mixing
- Therefore matrix poorly defined—"worst case" cannot be reliably defined

Factors potentially allowing relaxed process conditions cannot be considered, hence the "conventional" F_o = 5.0 minutes is appropriate sterilization criterion

Requirement 2: Establish Residence Time Distribution of Particles Within the System

Particle Residence Time Measurement

Statistical Distribution

- Distribution - Free Method (Run at Least 299 Particles)

Only the Statistically Fastest Moving Particle Represents the Least Thermal Treatment of the System

$C = 1-(1-P)^N$

$N= [\ln(1-C)]/[\ln(1-P)]$

$N = \ln(1-0.95)/\ln(1-0.01) = 299$

C: Confidence of collecting the "fastest" particle fraction, 95%

P: The Fastest particle fraction, 1% (equivalent to 3*stdv)

N: Population size, collected number of particle, 299 minimum

- **Residence Time Measurement**
- **Microbial Process Validation**

Requirement 2: Establish Residence Time Distribution of Particles Within the System

a. <u>Overall System Must Be Defined</u>:

The physical layout of the system and final product composition are established

- Product particle (average particle)
  - Nata de Coco, 5X5X5mm cube. Filler valve-limiting particle size: 5.3 mm
  - Specific gravity
- Carrier Fluid
  - Specific Gravity
  - Viscosity
  - Particle Concentration. Volume particles/volume carrier fluid practical limit: 30% (>30% starts clogging system). 40% was used for simulation as conservative approach in heat/mass balance.
- Physical Constraints
  - Metering Pump Speed
  - Piping Diameter

Results of Carrier Fluid and NDC/Alginate Particle Measurements

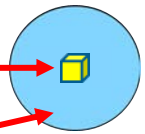
Method	Component		
	Carrier Fluid (g/cm^3)	NDC (g/cm^3)	Na-Alginate (g/cm^3)
Gas Pycnometer	1.024	1.010	1.012

Requirement 2: Establish the Residence Time Distribution of Particles Within the System, Cont'd

Hall-Effect Sensor Method

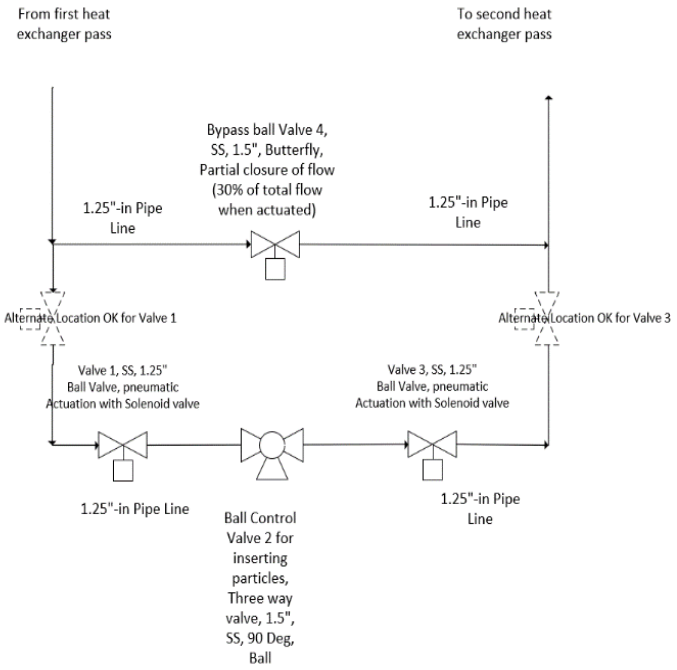
b. Residence Time Tracer Particle Developed (Magnetic Particle)

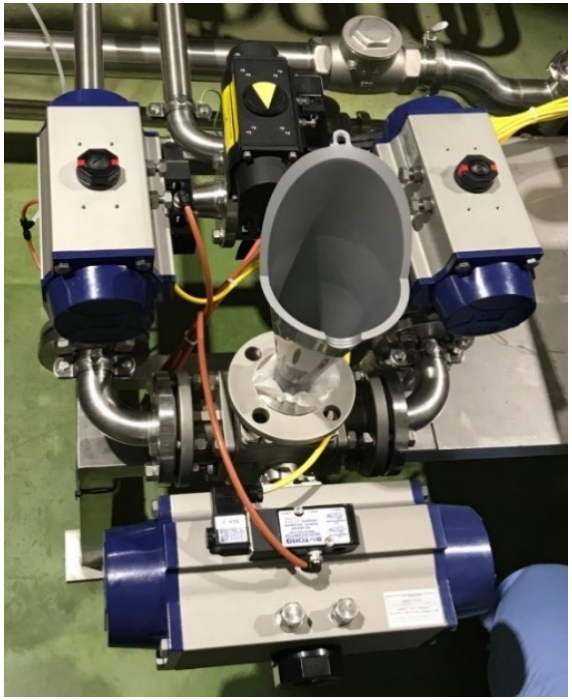
- Product particle:
  - Nata de Coco, 5X5X5mm cube (heat / mass balance).
  - Specific gravity of product 1.010g/cc
  - Filler valve-limiting particle size: 5.3 mm
- Worst-case Particle Geometry to carry magnets: Sphere (moves fastest through the system)
- Sphere must have s.g. equal to or slightly less than product particle
- Spherical particle, 8mm diameter appropriate
- Sphere will not fit through filling valve channel (must be recoverable)
- High s.g. of magnet limits minimum size of magnetic particle
- Materials:
- 2mm Neodymium rare-earth magnet, nickle-plated
  - Specific gravity: 7.44g/cc, Volume: 0.00800cc
- Low-Density Epoxy-Syntactic Foam (fills entire void volume)
  - Custom-formulated
  - Volume: 0.26000cc, Required specific gravity: 0.811g/cc



Requirement 2: Establish the Residence Time Distribution of Particles Within the System, Cont'd

c. Residence Time Measurements: Equipment Setup





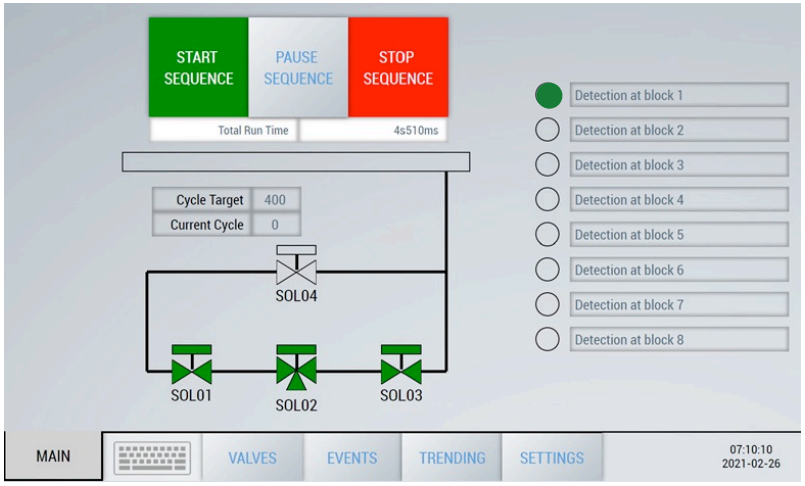
Label	Location	Length (cm)	Comments
Block 8	dosing	600	At dosing station 600 cm after entrance to preheater E1
Block 1	E1 end	8,000	End of preheater E1 and beginning of preheater E2
Block 2	E2 end	6,000	End of preheater E2 and beginning of preheater E3
Block 3	E3 end	13,000	End of preheater E3 and beginning of holding tube
Block 4	HT end	3,000	End of holding tube and beginning of cooler E4
Block 5	E4 end	7,000	End of cooler E4 and beginning of cooler E5
Block 6	E5 end	7,000	End of cooler E5 and beginning of cooler E6
Block 7	E6 end	3,000	End of cooler E6

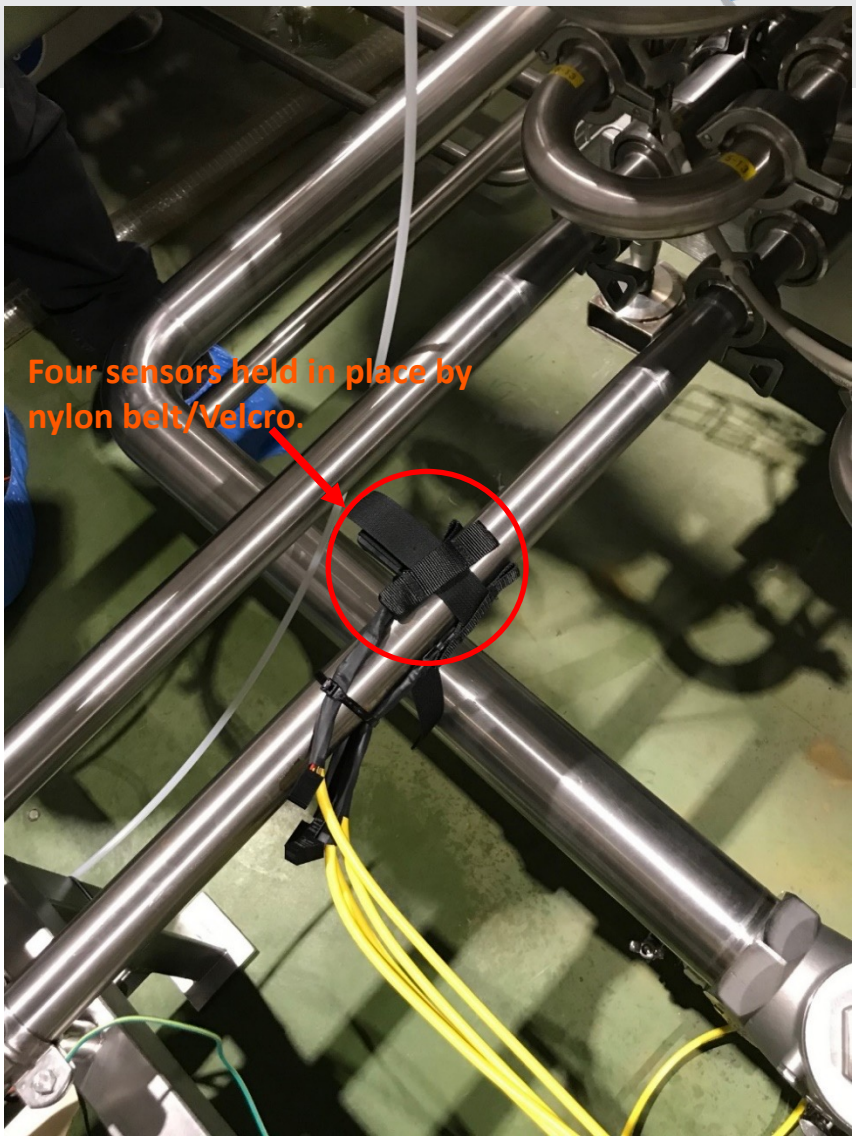
Requirement 2: Establish the Residence Time Distribution of Particles Within the System, Cont'd

c. Equipment Setup, Cont'd

Four Sensors Around Pipe Detect Passing Magnets

- Controller configured to flush a magnetic particle once every ~10.7 seconds.
- Voltage spikes >0.25 volts detected by any of the four sensors at a station were recorded as a positive ID at that station.





Requirement 2: Establish the Residence Time Distribution of Particles Within the System, Cont'd

d. Results of Residence Time Experiments:

Parameter	Detection Interval (Block X to Block Y)											
	8 ⇨ 1			1 ⇨ 2			2 ⇨ 3			3 ⇨ 4		
Total Number of Samples	900			900			900			900		
Test Number	Test 1	Test 2	Test 3	Test 1	Test 2	Test 3	Test 1	Test 2	Test 3	Test 1	Test 2	Test 3
Number of Particles Identified by Sensors	250	350	300	250	350	300	250	350	300	250	350	300
Average Particle Travel Time (sec)	71.0	73.3	73.4	54.0	55.4	55.7	129.1	119.4	119.7	29.3	29.5	29.6
Travel Time Fastest Particle (sec)	66.5	68.5	69.5	50.7	51.0	52.4	120.0	114.8	113.7	27.5	27.0	28.1
Travel Time Slowest Particulate (sec)	92.6	79.4	77.4	70.2	58.8	59.7	158.8	136.3	130.1	37.6	30.4	32.6
Median Particle Travel Time (sec)	68.8	73.4	73.4	52.5	55.4	55.6	124.6	119.5	119.7	28.7	29.6	29.6
V_{avg}/V_{max} Fastest Particle	0.897	0.924	0.938	**0.890**	0.898	0.922	0.961	0.918	0.910	0.962	0.944	0.979

- **Experiments need to be based on residence time measurements of at least 299 particles through the UHT system for 95% confidence of measuring the residence time of the fastest 1% of particles.**
- **Measurements of particle residence time demonstrated a minimum V_{avg}/V_{max} = 0.890**
- **Result indicative of Turbulent Flow dynamics**
- **An assumption of V_{avg}/V_{max} = 0.833 is conservative relative to this measurement and can be assumed in all calculations for Scheduled Process**

Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within the Slowest-Heating Particle

a. **Considerations**:

Physical Parameter Measurements of Average Particle and of Largest Particle

- Average particle is smaller than 5x5x5 mm
- Largest particle observed was 5x5x10 mm
- Shape: cube or rectangular

b. **Requirements/Required Measurements**:

i. Density of carrier fluid, NDC

ii. Viscosity of carrier fluid.

iii. Determine h_{fp} for the carrier fluid—heat transfer from fluid to particle

iv. Thermal conductivity k and specific heat c_p for the NDC and alginate

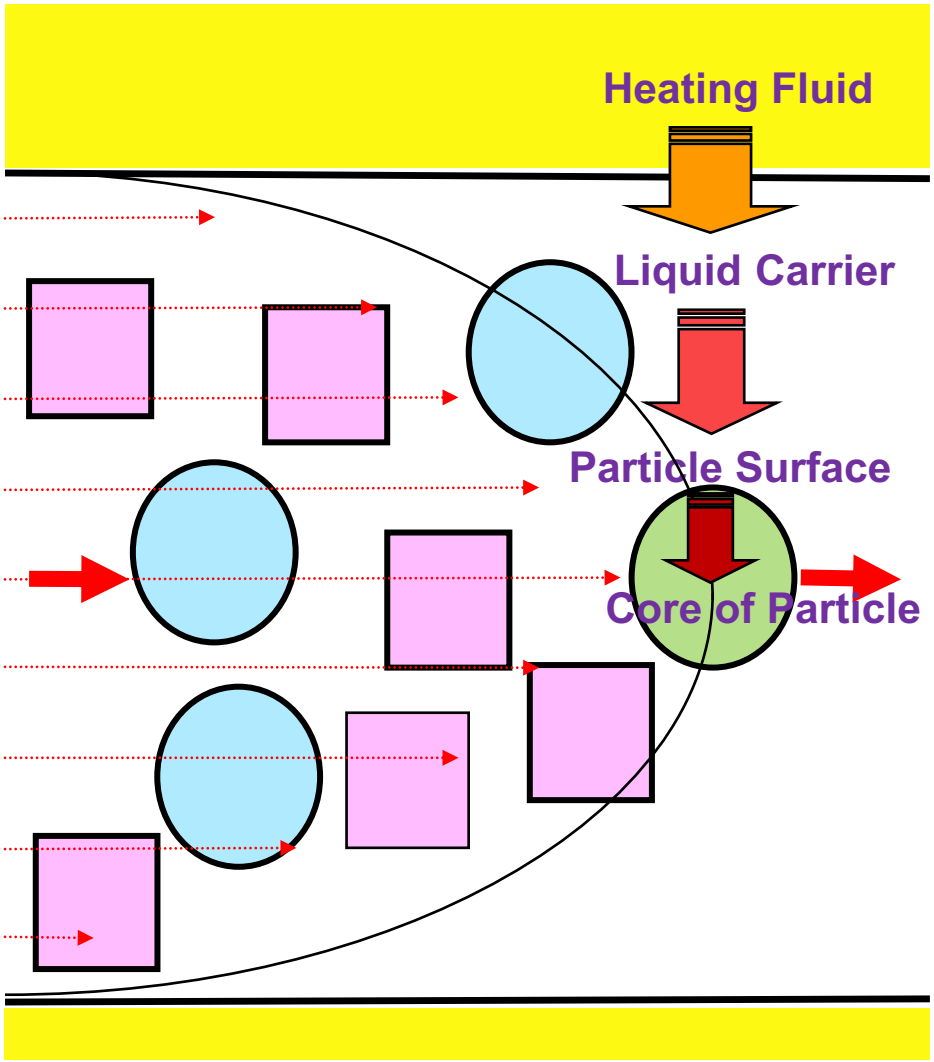
v. Overall heat transfer coefficient U from heating media to carrier fluid (AseptiCAL™ Model and real time data).

- Objective is to get the time/temperature of the carrier fluid to match the reading from the RTDs installed in the system.

vi. Establishing mass/energy balances for defined product/process conditions (AseptiCAL™).

Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within Slowest-Heating Particle:

Heat Transfer from Heater to Particle Center



Inputs Required for AseptiCal™

	Description	Purpose
U	Overall Heat Transfer Coefficient (Each Heater)	Energy balance Heaters/Product Average Particle/Fluid Properties In System must agree with model
h_{fp}	Fluid:Particle Convective Heat Transfer Coefficient (Each Heater)	Modeled benchtop for Particle Geometry (Al block) Product Fluid C_p, μ, ρ; Particle k
k	Thermal Conductivity Through Particle	Determined benchtop with thermal Conductivity meter or and confirmed with product block in retort

Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within the Slowest-Heating Particle, Cont'd

Determination of U:

- **Requires process runs**
- **AseptiCal inputs use "average particle" heating characteristics**
- **U: Depends on many variables including**
  - Fluid properties (viscosity, Cp)
  - Flow velocity
  - Product & heating medium temperatures
  - Particle mass fraction

Determination of h_{fp} :

•Cube aluminum blocks dimensions 5X5X5mm and Type K thermocouple at center (University of Parma)

•Aluminum blocks were submerged into hot carrier fluid at 80˚C. Temperature of the thermocouple recorded every second.

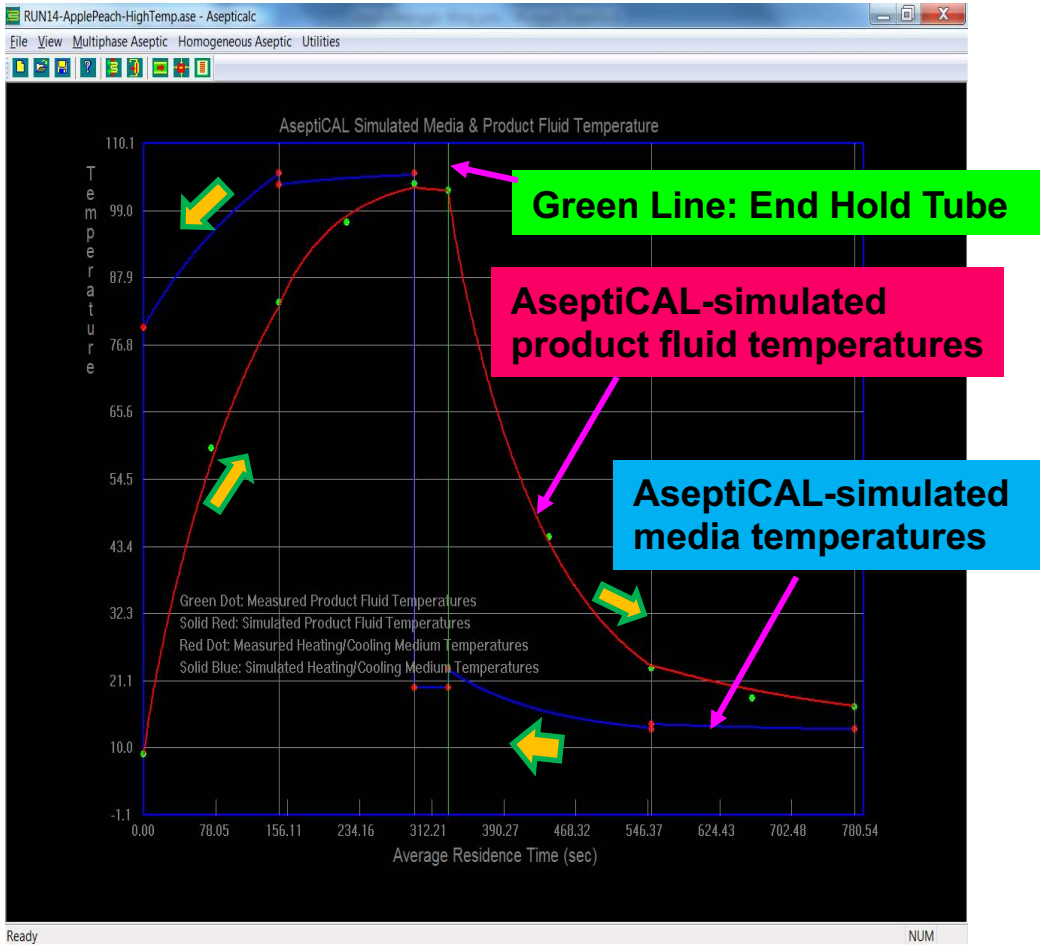
•By plotting $-\ln(\frac{T_\infty - T(t)}{T_\infty - T_i})$ VS time t, determine h_{cp} from the slope of the semi-log plot since the properties of the aluminum are well known.

Result: h_{fp} for 5x5x5 mm cube was used for all AseptiCAL™ calculations with NDC

Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within the Slowest-Heating Particle, Cont'd

Determining Overall U with AseptiCAL™:

1. Run energy/mass balance for each heating and cooling segment;
2. Modify U for each segment until RTD actual values from test runs are met.



$$-\ln\left(\frac{T_f - T_p(t)}{T_f - T_{pi}}\right) = h_{fp} * \frac{A_{surface}}{\rho * c_p * V} * t$$

Modeling Fluid Temperatures

Identify an "Average" Heat Effect Particle Flowing in Average Velocity

↓

Modify Heat Transfer Parameters, i.e. h, U

↓

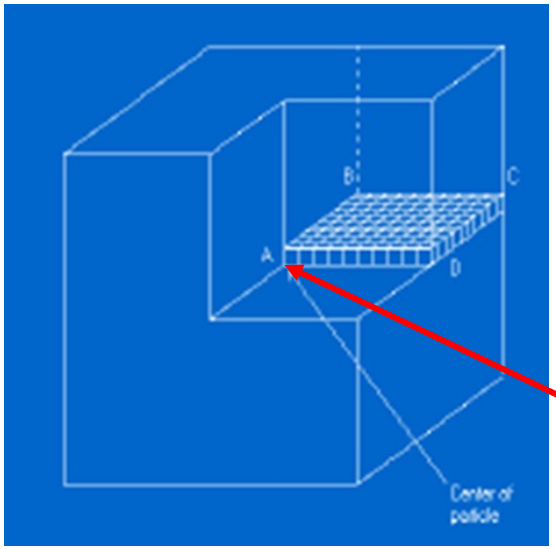
Match Fluid Temperatures at least **Three Points** for each Heat Exchanger

↓

Finish Modeling all Heat Exchangers & Hold Tube

Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within the Slowest-Heating Particle, Cont'd

1. Run simulation for worst-case particulate:
   - Fastest particulate (V_{avg}/V_{max} = 0.833)
   - Largest particulate (5.3 x 5.3 x 10 mm).
2. Adjust temperatures in final heater to get target F_o-value = 5.0 for NDC at Hold Tube Exit



Heat Penetration into Cube

Slab intersected by Slab intersected by Slab

$$\frac{\partial T}{\partial t} = \alpha\left[\frac{\partial^2 T}{\partial x^2} + \frac{\partial^2 T}{\partial y^2} + \frac{\partial^2 T}{\partial z^2}\right]$$

$$-k\partial T/\partial \vec{n} = h(Te - Ts)$$

$$T = T(x,y,z,t)$$

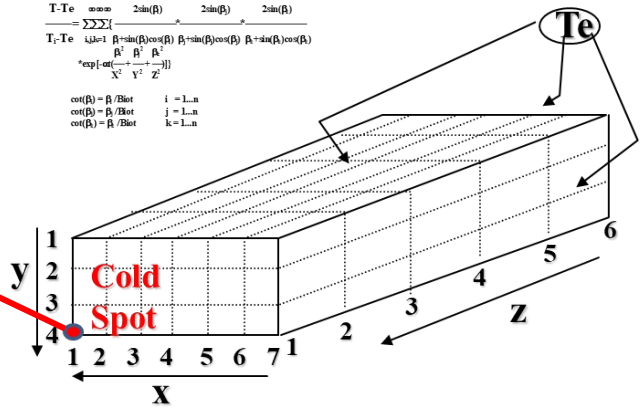
$$T(x,y,z,0) = T_i$$

$$\frac{T-Te}{T_i-Te} = \sum_{i,j,k=1}^{\infty}\sum\sum\left\{\frac{2\sin(\beta)}{\beta_i+\sin(\beta_i)\cos(\beta_i)}\cdot\frac{2\sin(\beta)}{\beta_j+\sin(\beta_j)\cos(\beta_j)}\cdot\frac{2\sin(\beta)}{\beta_k+\sin(\beta_k)\cos(\beta_k)}\cdot\exp\left[-\alpha t\left(\frac{\beta_i^2}{X^2}+\frac{\beta_j^2}{Y^2}+\frac{\beta_k^2}{Z^2}\right)\right]\right\}$$

$$\cot(\beta_i) = \beta_i/Biot \quad i = 1..n$$

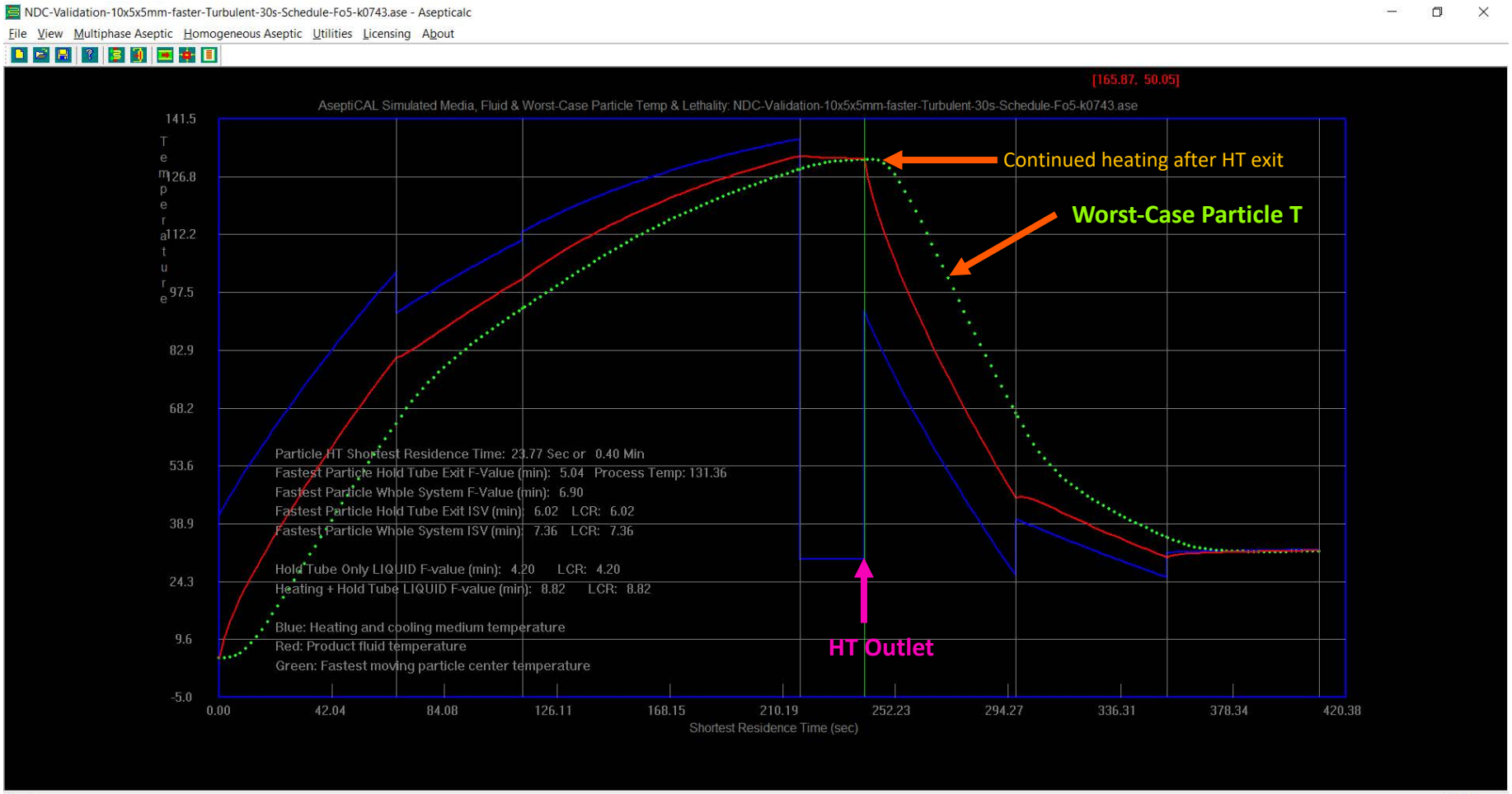
$$\cot(\beta_j) = \beta_j/Biot \quad j = 1..n$$

$$\cot(\beta_k) = \beta_k/Biot \quad k = 1..n$$



Requirement 3: Develop a Conservative Mathematical Model to Predict Lethality Within the Slowest-Heating Particle, Cont'd

Process Predicting F_o-Value of 5.0 Minutes in LSZ at Hold-Tube Outlet Established using JBT AseptiCal®



Requirement 4: Establish a List of Critical Factors and Procedures for Their Control

Scheduled Process for Nata de Coco

Requirement 4: Establish a List of Critical Factors and Procedures for Their Control

Scheduled Process for Nata de Coco

John Bean Technologies Corporation
2300 Industrial Avenue
Madera, California 93637

Phone: 559/661-3193
Fax: 559/661-3161

September 2, 2021

JBT Reference Letter #XXXX

[redacted]

The processes defined in this letter relates only to these UHT sterilizers and the identified product. The particulate process has been demonstrated to obey turbulent flow dynamics as formulated, [redacted] water without added sugars or thickeners. **Reformulation of product from that validated for parameters below is not permitted under this recommendation and may require revalidation.** Our recommended process is as follows:

CRITICAL FACTORS: **Simulated Data**

Nata de Coco Slurry Component. Critical factors for UHT-processing of the particulate component (Nata de Coco slurry only) of the beverage are as follows:

Critical Factor	Description	TAG Number	Units	Critical Limit	
				Minimum	Maximum
Formulation of Slurry					
1	Particle size[a]	manual	mm	---	5.3 X 5.3 X 5.3
2	Particle concentration	record	% w/w	---	30
3	Slurry mix time after batching[b]	PLC	min.	5	---
Processor Physical Dimensions					
4	Inside Diameters[c]	---	cm/in	5.00/2.00	---
5	1st Heater length	---	cm/in	8000/3,000	---
6	2nd Heater length	---	cm/in	6,000/2,000	---
7	3rd Heater length	---	cm/in	13,000/5,000	---
8	Hold Tube Length	---	cm/in	3,000/1,200	---
Processing Parameters[d]					
9	Flow Rate	FMXXX	L/Hr; gpm	---	3,000/12.00
10	Initial Temperature	TXXXXX	°C/°F	10/50	---
11	Exit T 1st Heater	TXXXXX	°C/°F	80.0/175	---
12	Exit T 2nd Heater	TXXXXX	°C/°F	100.0/212.0	---
13	Exit T 3nd Heater	TXXXXX	°C/°F	131.0/268.0	---
14	Exit T Hold Tube[e]	TXXXXX	°C/°F	137.0/277.0	---

[redacted]

[redacted]

September 2, 2021

[redacted]ved assuming the conservative,

Nonparticulate Beverage Component. [redacted] factors are as described in the JBT Corp[redacted] UHT (direct heating) and used as the [redacted] containing). Critical factors are as follow[redacted]

Critical Factor	Description	TAG Number	Units	Critical Limit	
				Minimum	Maximum
Physical Dimensions					
15	Hold-Tube Inside Diameter	---	cm/in	6.00/2.50	---
16	Hold Tube Length	---	cm/in	2,000/800.0	---
Processing Parameters					
17	Flow Rate[e]	FMXXXX	L/Hr; gpm	---	6,000/25.00
18	Exit Temperature	TXXXX	°C	135.0/275.0	---

[e] Residence time calculation uses laminar flow characteristics ($V_{avg}/V_{max} = 0.5$). Residence time assumes a thermal expansion factor of 1.00, resulting in a hold tube residence time of 16.13 seconds. Least lethality delivered under these conditions is $F_o = 5.0$.

We hope that we have provided the information that you require. If you have any questions or comments, please do not hesitate to contact me via email at paul.gerhardt@JBTC.com or by telephone at +1(559)661-3193.

Best Regards,

Paul N. M. Gerhardt, Ph.D.
Research Fellow, Preservation Technologies
JBT Corporation

Requirement 5: Microbiological Validation of Model and Documentation of Lethality Delivered

Assessment and Approach per Test:

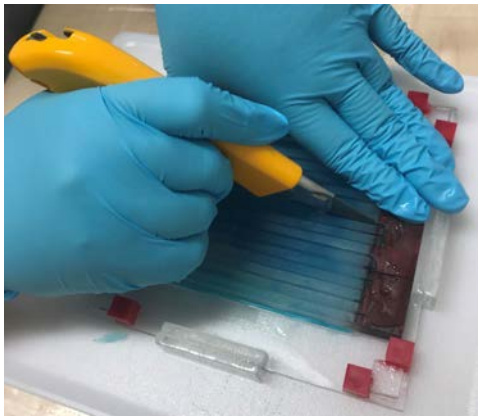
- **Need ≥299 intact processed particles for 95% confidence of sampling the fastest 1%.**
- **Na-alginate particles inoculated with *C. sporogenes* PA3679 used to validate particulate LACF UHT processes.**
- **Calibrated heat resistance is $D_{250°F}$ = 1.0 min.; z = 17.8F°.**
- **Organisms evenly distributed throughout the particle--not just at the particle center.**
- **Validation quantifies an integrated sterilization value (ISV) delivered by the entire process (heating + hold tube + cooling).**
- **JBT AseptiCal® calculates ISV for processes delivered at hold tube exit and processes delivered by entire system.**
- **Organism was subcultured under very conservative conditions.**

Requirement 5: Microbiological Validation of Model and Documentation of Lethality Delivered

Preparation of Inoculated Alginate Cube Particle, 5.3mm

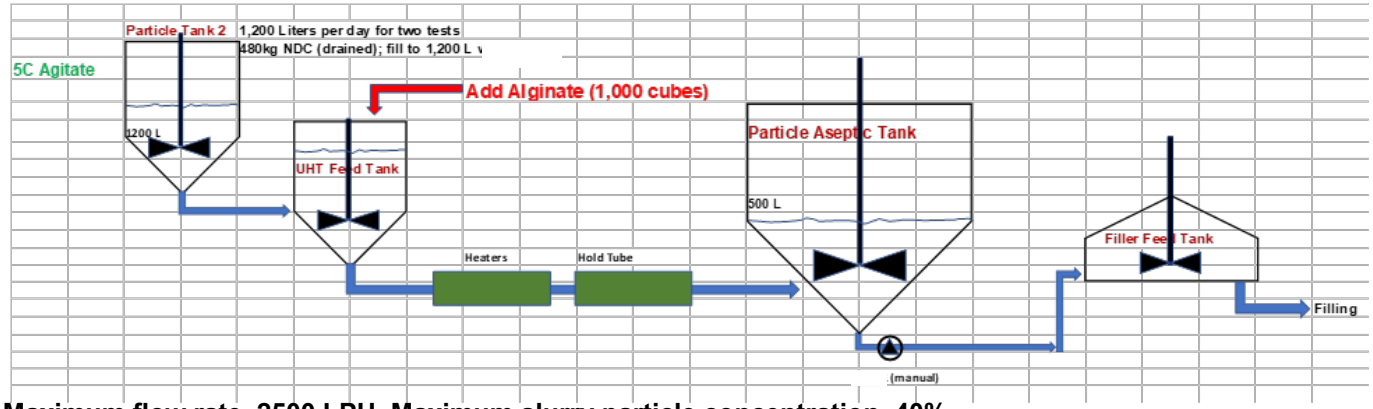
Alginate suspension inoculated with *C. sporogenes* poured into mold

Cured alginate gel cubes cut and sorted for defects



Requirement 5: Microbiological Validation of Model and Documentation of Lethality Delivered

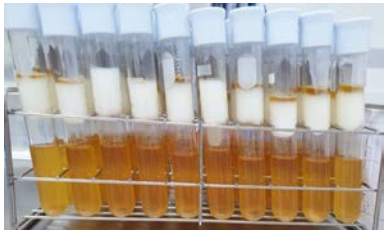
Execution of Microbiological Validation



Maximum flow rate, 2500 LPH, Maximum slurry particle concentration, 40%

Addition, Processing, Filling, and Recovery of Inoculated Cubes

Individual cubes aseptically transferred to separate TPGYE Broth tubes



(Incubated tubes positive for target organism shown)

Requirement 5: Microbiological Validation of Model and Documentation of Lethality Delivered

Microbiological Validation Results:

Test	HT Exit Temperature (°C)	Velocity Profile AseptiCal® Calculation (V_{avg}/V_{max})	Center of Fastest Particle (LSZ) (as modeled with AseptiCal®)		Integrated Fastest Single Particle (compares to microbiological results)	
			F_o HT Exit (minutes)	F_o Total (minutes)	ISV HT Exit (minutes)	ISV Total (minutes)
(Scheduled)	**133.0**	**0.833**	**5.0**	**7.0**	**6.0**	**8.0**
1	131.4	0.892	4.8	6.0	5.2	6.9
2	131.8	0.892	5.0	6.8	5.5	6.8
3	132.5	0.892	5.3	6.5	6.0	7.1
4	128.0	0.892	3.5	4.2	4.5	4.9
5	124.0	0.892	1.0	1.5	1.3	1.8

Test	Log Reduction, Based on ISV		Initial Count/ Alginate Cube N_o / Log N_o	Microbiological Result (nonsterile/total)
	LCR HT Exit minimum	LCR Total minimum		
(Scheduled)	6.2	8.3	N.A.	N/A
1	5.4	7.3	6.0×10^5 / 5.60	0/299
2	5.7	7.1	6.0×10^5 / 5.60	0/299
3	6.6	7.2	2.0×10^5 / 5.30	0/299
4	4.8	5.1	2.0×10^5 / 5.30	131/299
5	1.5	2.1	2.4×10^5 / 5.38	299/299

Simulated Data

- **Halvorson-Ziegler Calculation cannot be applied since particles have different residence times.**

CONCLUSIONS

- JBT has installed processing solutions for LACF Aseptic Particulate products.
- Optimized processing of particulates requires a dedicated particulate processing system.
- The JBT can develop conservative, optimized-quality thermal particulate processes
- Processes are developed by:
  - Obtaining physical measurements of component ingredients
  - Measuring particulate flow through UHT heating and hold tube systems
  - Developing a safe, optimized scheduled process via JBT AseptiCal™
- For US FDA-products JBT microbiologically validates the thermal process
- JBT thus provides a turnkey particulate processing solution by providing sterilizers optimized for production of such products and also the technical support to develop and validate the particulate scheduled thermal process

Questions?

Jacques Bichier

Senior Research Engineer

Email: Jacques.bichier@jbtc.com

Paul N. M. Gerhardt, Ph.D.

Research Fellow, Preservation Technologies

Email: Paul.gerhardt@jbtc.com

For AseptiCal™ Leasing

Jeff Dahl

Email: Jeff.dahl@jbtc.com