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Aseptic Processing of Multiphase Foods: Fundamentals, Product, Process, Equipment, and Validation Considerations K.P. Sandeep

Dept. of Food, Bioprocessing and Nutrition Sciences North Carolina State University Presented at IFTPS Annual Meeting Mar. 9, 2012 San Antonio, TX

Outline

- Fundamentals
 - UHT/Aseptic processing system and components
- Product Considerations
 - pH, water activity, ingredients, properties
- Process Considerations
 - Microorganisms, flow, heat transfer, t-T for safety/quality
- Equipment Considerations
 - Pump, HX, hold tube, back pressure valve
- Validation Considerations
 - Microbial, TTIs, modeling, thermomagnetic switches

Fundamentals

Ultra High Temperature (UHT)

- UHT = Aseptic
- All pathogenic and spoilage organisms (including spores of *C. botulinum*) are killed
- Thermophilic organisms may survive
- Commercially sterile product
- 284 °F (140 °C) for 4 s
- Shelf life: 1-2 years
- UHT/Aseptic processing covered under – 21CFR108, 21CFR113, 21CFR114







Aseptic Processing

- A continuous thermal process in which the product and container are sterilized separately and brought together in a sterile environment
- Components: Pump, deaerator, heat exchanger, hold tube, cooling unit, back pressure device, filler, surge tank

• Temperature: 125 - 140 °C (257 - 284 °F)

Aseptic Processing System



Back Pressure and Steam Tables

Table A.4.2 Properties of Saturated Steam										
			Specific volume (m ³ /kg)		Enthalpy (kJ/kg)		Entropy (kJ/[kg K])			
Temperature (°C) psi		Vapor pressure (kPa)	Liquid	Saturated vapor	Liquid (<i>H</i> c)	Saturated vapor (<i>H</i> _v)	Liquid	Saturated vapor		
100	14.696	101.35	0.0010435	1.6729	419.04	2676.1	1.3069	7.3549		
105	17.523	120.82	0.0010475	1.4194	440.15	2683.8	1.3630	7.2958		
110	20.779	143.27	0.0010516	1.2102	461.30	2691.5	1.4185	7.2387		
115	24.519	169.06	0.0010559	1.0366	482.48	2699.0	1.4734	7.1833		
120	28.793	198.53	0.0010603	0.8919	503.71	2706.3	1.5276	7.1296		
125	33.662	232.1	0.0010649	0.7706	524.99	2713.5	1.5813	7.0775		
130	39.173	270.1	0.0010697	0.6685	546.31	2720.5	1.6344	7.0269		
135	45.395	313.0	0.0010746	0.5822	567.69	2727.3	1.6870	6.9777		
140	52.400	361.3	0.0010797	0.5089	589.13	2733.9	1.7391	6.9299		
145	60.247	415.4	0.0010850	0.4463	610.63	2740.3	1.7907	6.8833		
150	69.007	475.8	0.0010905	0.3928	632.20	2746.5	1.8418	6.8379		

What is the minimum gauge pressure required at the back pressure valve if your process temperature is 130 °C?

Min. gauge pressure = (39.173 – 14.696) + 10 (for safety) = ~35 psi

Product Considerations (pH, a_w, target organism, ingredients, properties)

Classification of Foods based on pH

- Low acid: pH ≥ 4.6; Acid: pH < 4.6 (*C. botulinum*)
- More specific classification
 - Low acid: pH > 5.3
 - Red meat, poultry, seafood, milk, corn, peas, lima beans, potatoes, cauliflower
 - Medium acid: 4.5 < pH < 5.3
 - Spaghetti, soups, sauces, asparagus, beets, pumpkin, spinach, green beans, turnip, cabbage
 - Acid: 3.7 < pH < 4.5
 - Tomato, pear, fig, pineapple, apricot, yogurt, white cheese, beer
 - High acid: pH < 3.7
 - Sauerkraut, pickles, berries, citrus, rhubarb, wine, vinegar, plums, currants, apples, strawberries, peaches

Classification of Foods Based on mc or a_w

- High moisture foods (50+% → 70-99%)
 Fruits, vegetables, juices, raw meat, fish
- Intermediate moisture foods (15-50%)
 - Bread, hard cheeses, sausages
- Low moisture foods (0-15%)
 - Dehydrated vegetables, grains, milk powder, dry soup mixes

Importance of a_{w} **: Honey at 20% mc is shelf stable, while potato at 20% is not**

Effect of a_w on Reactions





Critical a_w for Microbial Growth

- *C. jejuni*: 0.98
- *C. botulinum* (types A, B, E): 0.95, 0.94, 0.97 resp.
- Pseudomonas fluorescens, Campylobacter coli: 0.97
- Yersinia enterocolitica: 0.96
- Clostridium perfringens, E. coli, Salmonella, Vibrio cholerae: 0.95
- Vibrio parahaemolyticus: 0.94
- Bacillus cereus: 0.93
- Listeria monocytogenes: 0.92
- Bacillus subtilis: 0.91
- Staphylococcus aureus: 0.86
- Most molds: 0.80
- No microbial growth: 0.50

Effect of a_w on Microbial Growth



Role of Ingredients in Product Quality

• Pre-treatment

- Pasteurize dairy ingredients to minimize fouling in UHT
- Pre-cook meat pieces for appropriate texture
- Add Ca salts to increase firmness
- Use modified high-temperature starch or a blend
- Harvest vegetables before peak ripeness and process immediately (calcify if needed)
- Use IQF where possible when using frozen veggies
 Caution: Initial temperature of product will be lower
- Use volumetric tempering/thawing when possible

Categories of Properties

- <u>Physical</u>
 - Density (ρ) material/particle, apparent, bulk
- <u>Rheological</u>
 - Viscosity (μ), consistency coefficient (K), flow behavior index (n)
- <u>Thermal</u>
 - Specific heat (c_p), latent heat (λ), thermal conductivity (k)
 - Thermal diffusivity ($\alpha = k/\rho c_p$)
- Mass Transfer
 - Diffusivity
- <u>Electrical/Electromagnetic</u>
 - Conductivity (σ), dielectric constant (ϵ '), loss factor (ϵ ")

Water activity & heat transfer coefficient are NOT properties

Density (p)

• Solids

- Dimension method (for regular shaped solids)
- Buoyant force method (based on mass in air and water)
- Volume displacement method
 - Liquid displacement method
 - Solid (sand or glass beads) displacement method
 - Pycnometer (gas or liquid) method several ISO & ASTM standards are based on this method

Density = Mass / Volume

Units: kg/m³

Where is density used?

Mass flow rate = (Density) * (Volumetric Flow Rate)

Density: Pycnometer Method



Density (p) by Pycnometer Method



V_a, V_b: Volume of air in cells A & B resp.

Close valve 2, fill air in A, close valve 1: $P_a V_a = m RT_a$ Open valve 2: $m = m_a + m_b$ Thus, $P_a V_a / RT = P_{new} V_a / RT + P_{new} V_b / RT$ Solve for V_b and hence for volume of sample and then ρ

Flow Behavior Curve (Shear stress versus shear rate)



Source: Singh & Heldman, 2001

Viscosity (µ) -- Newtonian Fluids

- A measure of resistance to flow
- Units: Pa·s or centipoise (cP)
 - $-1 cp = 0.001 Pa \cdot s$
- Viscosity (μ) of water at 20 °C = 1 cP
 - Viscosity of water decreases by ~3% for every 1 °C
- Measurement of viscosity
 - Tube viscometer (Cannon-Fenske)
 - Rotational viscometer (Brookfield, Haake)

Empirical technique (Bostwick consistometer)
 Where is viscosity used?

N_{Re} = (Density) (Avg. vel.) (Diameter) / (Viscosity) Reynolds number determines flow type: Laminar/Turbulent

Tube Viscometer

• Principle

- Measure pressure drop (ΔP) versus volumetric flow rate (\dot{V}) across a straight section of tube (Length = L, radius = r)

$$\mu = \frac{\pi \Delta P r^4}{8 L \dot{V}}$$

Plot ΔP vs. \mathbf{V} Slope = 8 L $\mu / \pi r^4$

Obtain µ from slope

<u>Units</u> r, L: m ΔP: Pa V: m³/s μ: Pa·s

Rotational Viscometer (Newtonian Fluid)

• Principle

- Measure torque [a measure of shear stress (σ) in Pa] versus rpm [a measure of shear rate ($\dot{\gamma}$) in s⁻¹]



nist.gov

$$\mu = \frac{T}{8\pi^2 NL} \left(\frac{1}{R_i^2} - \frac{1}{R_o^2} \right)$$

T: Torque (N·m) N: Revolutions per second (s⁻¹) L: Spindle length (m)

R_i, R_o: Radius of spindle, cup resp. (m)

Plot "T" on y-axis versus "N" on x-axis. The slope of this graph is $8\pi^2 L\mu/[1/R_i^2 - 1/R_o^2]$ ". Obtain μ from this.

Rotational Viscometer (Non-Newtonian Fluid)

Torque (T) versus rotational speed (N) relation for power-law fluids is given by: Ln(T) = n Ln(N) + I

Where,
$$I = -n Ln \left[\left(\frac{n}{2} \right) \left(\frac{1}{2\pi K L} \right)^{1/n} \left(\frac{1}{R_i^{2/n}} - \frac{1}{R_o^{2/n}} \right) \right]$$

Thus,
$$K = \begin{bmatrix} \left(\frac{n}{2}\right) \left(\frac{1}{R_i^{2/n}} - \frac{1}{R_o^{2/n}}\right) \\ \frac{1}{(2\pi L)^{1/n}} e^{-I/n} \end{bmatrix}$$

Hence, 'n' is determined as the slope of the graph with Ln (T) on the y-axis and Ln (N) on the x-axis and K is determined from the above equation with "I" being the intercept of the graph.

Bostwick Consistometer



In Line Viscometer



Effect of Temperature on Viscosity

An increase in temperature results in a decrease in the viscosity of a fluid and is described by the Arrhenius equation:

*'***iscosity**

$$\mu_2 = \mu_1 \, e^{\frac{\mathbf{E}_a}{\mathbf{R}} \left(\frac{1}{T_2} - \frac{1}{T_1}\right)}$$

 μ , μ_1 , μ_2 : Viscosity at temp. T, T₁, T₂ resp. (Pa s) A: Frequency factor (Pa s) E_a: Activation energy for viscous flow (J/mol) R: Universal gas constant (= 8.314 J/mol K) T, T₁, T₂: Temperature (K; °C NOT okay)

 $\mu = A e^{\frac{E_a}{RT}}$

Temperature

For power-law fluids, the following expression is valid for the consistency coefficient, K_T at temperature, T:

$$\mathbf{K}_{\mathrm{T}} = \mathbf{K}_{\mathrm{0}} \, \mathbf{e}^{\frac{\mathbf{E}_{\mathrm{a}}}{\mathbf{R}\mathbf{T}}}$$

K₀: Constant (Pa sⁿ)

Activation Energy

Fluid	Concentration	n	E _a (kcal/g mole)	μ _{app} at 50 °C, 100 s ⁻¹
Depectinized apple juice	75° Brix	1	14.2	150.0
Depectinized apple juice	50° Brix	1	8.4	4.0
Depectinized apple juice	30° Brix	1	6.3	1.6
Depectinized apple juice	15° Brix	1	5.3	0.7
Cloudy apple juice	40° Brix	1	5.8	4.9
Cloudy apple juice	30° Brix	1	5.1	2.0
Cloudy apple juice	65.5° Brix	0.65	9.1	258.5
Cloudy apple juice	50.0° Brix	0.85	6.1	25.0
Apple sauce	11.0° Brix	0.30	1.2	730.0
Concord grape juice	50° Brix	1	6.9	15.0
Concord grape juice	30° Brix	1	6.2	1.8
Peach puree	11.7° Brix	0.3	1.7	190.0
Pear puree	16.0° Brix	0.3	1.9	375.0
Filtered orange juice	18.0° Brix	1	5.8	1.5
Filtered orange juice	10.0° Brix	1	5.3	0.8

Apparent Viscosity (Non-Newtonian Fluids)

- For Newtonian fluids, the ratio of shear stress to shear rate is independent of the magnitude of shear rate
 This ratio of shear stress to shear rate is called viscosity (µ)
- For non-Newtonian fluids (pseudoplastic, dilatant, Bingham), the ratio of shear stress to shear rate is dependent on the magnitude of shear rate
 - This ratio of shear stress to shear rate is called the apparent viscosity (μ_{app}); $\mu_{app} = \sigma/\gamma = K \dot{\gamma}^n/\dot{\gamma} = K \dot{\gamma}^{n-1}$
 - The magnitude of apparent viscosity MUST be accompanied with the magnitude of shear rate
 - Eg., The apparent viscosity of fluid 'A' is 20 Pa \cdot s at a shear rate of 25 s⁻¹

Apparent Viscosity (contd.)

For pseudoplastic and dilatant fluids, $\mu_{app} = K \dot{\gamma}^{n-1}$

For pseudoplastic fluids, μ_{app} decreases with an increase in shear rate For dilatant fluids, μ_{app} increases with an increase in shear rate



Effect of Temperature on Apparent Viscosity

Arrhenius equation for Newtonian fluids:

$$\mu = A e^{\frac{E_a}{RT}}$$

Arrhenius equation for non-Newtonian fluids:

$$\mu_{app} = K_{T} \left(e^{\frac{E_{a}}{RT}} \right) \dot{\gamma}^{n_{avg}-1}$$

For conc. OJ (From -18.8)
$$n_{avg} = 0.774$$
$$K_{T} = 4.65 \text{ x } 10^{-9} \text{ Pa s}^{0.774}$$
$$E_{a}/R = 5668.25 \text{ K}$$

For conc. OJ (From -18.8 °C to 29.2 °C):

Time Dependent Fluids

- Thixotropic fluids
 - Exhibit a decrease in shear stress (and μ_{app}) over time at constant shear rate
 - Eg., starch-thickened baby foods, yogurt, condensed milk, mayonnaise, egg white
- Rheopectic fluids
 - Exhibit an increase in shear stress (and μ_{app}) over time at constant shear rate
 - Eg., Lubricants, printer's inks
- Thixotropy and rheopecty may be reversible or irreversible





Various Solution Viscosities

- Various terms (listed below) are used to describe the effect of dissolving a polymer (say, protein or gum) in a solvent (say, water)
 - Relative viscosity (η_{rel}) : $\eta_{rel} = \eta_{solution} / \eta_{solvent}$
 - Specific viscosity (η_{sp}): $\eta_{sp} = \eta_{rel} 1$
 - Reduced viscosity (η_{red}): $\eta_{red =} \eta_{sp} / C$
 - Inherent viscosity (η_{inh}): $\eta_{inh} = [Ln (\eta_{rel})] / C$
 - Intrinsic viscosity (η_{int}): $\eta_{int} = [\eta_{sp} / C]_{C_{ab}}$

C: Concentration of solution in g/dl or g/100 ml

Suspension Viscosity

- What is the effective viscosity (μ_e) of a suspension of solids in a Newtonian fluid?
 - Einstein's law of viscosity of dilute suspensions
 - $\mu_e / \mu_{fluid} = 1 + 2.5$ (C)
 - Higher order approximations for dilute suspensions
 - $\mu_e / \mu_{fluid} = 1 + 2.5 (C) + 5.2 (C^2)$
 - $\mu_e / \mu_{fluid} = 1 + 2.5 (C) + (35/8) C^2 + (105/16) C^3 + (1155/128) C^4 + ...$

Specific Heat (c_p)

- Energy required to raise temperature of unit mass of substance by 1 °C (units: J/kg K)
- Method of mixture
 - Mix sample with water in a calorimeter
- Comparison method
 - Compare cooling rate of sample with that of water
- Adiabatic method
 - Known amount of heat is added to a closed test chamber
- Differential scanning calorimetry (DSC)

<u>Where is specific heat used?</u>

Q = (mass flow rate) (specific heat) (temperature change)

Specific Heat (DSC Method)

- Temperature or heat flux held constant
- Energy required or temperature diff. measured


DSC Method (Contd.)



Source: Rahman, 1995

Thermal Conductivity (k)

- Energy transmitted per unit time across unit thickness of a material of unit area when a temperature gradient of 1 °C exists across it (units: W/m·K)
- Line heat source thermal conductivity probe

 Solid and liquid foods
- Fitch apparatus
 - Solid foods

Where is thermal conductivity used?

 $Q = kA (\Delta T)/(\Delta x)$ Conduction in a solid

Thermal Conductivity Probe

Line heat source method



Source: Rao & Rizvi (1995)

Thermal Conductivity (k) & Diffusivity (α)

KD2 Pro (Manufacturer: Decagon Devices) 30 mm dual needle probe Units of α: m²/s $\alpha = k / (\rho c_p)$



Fitch Method



 $k = \frac{m c_p L}{At} \ln \left| \frac{T_0 - T_{\infty}}{T - T_{\infty}} \right|$ m, c_p, A, T: For heat sink

(mass, sp. ht., area, temp.)

 T_0 : Initial temp. of heat sink T_∞ : Temp. of heat sourceL: Thickness of sample

Source: Rahman, 1995

Empirical Correlations

 $k = 0.61 (X_w) + 0.20 (X_p) + 0.205 (X_c) + 0.175 (X_f) + 0.135 (X_a)$ Choi & Okos, 1984

 $c_{p} = 4.187 (X_{w}) + 1.549 (X_{p}) + 1.424 (X_{c}) + 1.675 (X_{f}) + 0.837 (X_{a})$ <u>Heldman & Singh, 1981</u>

w: water, p: protein, c: carbohydrates, f: fat, a: ash

Effect of Temperature on k, α , ρ , c_p)

Property	Component	Temperature function	Standard error	Standard % error
k (W/[m °C])	Protein	$k = 1.7881 \times 10^{-1} + 1.1958 \times 10^{-3}T - 2.7178 \times 10^{-6}T^{2}$	0.012	5.91
	Fat	$k = 1.8071 \times 10^{-1} - 2.7604 \times 10^{-3}T - 1.7749 \times 10^{-7}T^{2}$	0.0032	1.95
	Carbohydrate	$k = 2.0141 \times 10^{-1} + 1.3874 \times 10^{-3}T - 4.3312 \times 10^{-6}T^{2}$	0.0134	5.42
	Fiber	$k = 1.8331 \times 10^{-1} + 1.2497 \times 10^{-3}T - 3.1683 \times 10^{-6}T^{2}$	0.0127	5.55
	Ash	$k = 3.2962 \times 10^{-1} + 1.4011 \times 10^{-3}T - 2.9069 \times 10^{-6}T^{2}$	0.0083	2.15
	Water	$k = 5.7109 \times 10^{-1} + 1.7625 \times 10^{-3}T - 6.7036 \times 10^{-6}T^{2}$	0.0028	0.45
	Ice	$k = 2.2196 - 6.2489 \times 10^{-3}T + 1.0154 \times 10^{-4}T^{2}$	0.0079	0.79
α (m ² /s)	Protein	α = 6.8714 × 10 ⁻² + 4.7578 × 10 ⁻⁴ T - 1.4646 × 10 ⁻⁶ T ²	0.0038	4.50
	Fat	$\alpha = 9.8777 \times 10^{-2} - 1.2569 \times 10^{-4} T - 3.8286 \times 10^{-8} T^2$	0.0020	2.15
	Carbohydrate	$\alpha = 8.0842 \times 10^{-2} + 5.3052 \times 10^{-4} T - 2.3218 \times 10^{-6} T^2$	0.0058	5.84
	Fiber	$\alpha = 7.3976 \times 10^{-2} + 5.1902 \times 10^{-4} T - 2.2202 \times 10^{-6} T^2$	0.0026	3.14
	Ash	$\alpha = 1.2461 \times 10^{-1} + 3.7321 \times 10^{-4}T - 1.2244 \times 10^{-6}T^{2}$	0.0022	1.61
	Water	$\alpha = 1.3168 \times 10^{-1} + 6.2477 \times 10^{-4}T - 2.4022 \times 10^{-6}T^{2}$	0.0022×10^{-6}	1.44
	Ice	$\alpha = 1.1756 - 6.0833 \times 10^{-3}T + 9.5037 \times 10^{-5}T^{2}$	0.0044×10^{-6}	0.33
ρ (kg/m ³)	Protein	$\rho = 1.3299 \times 10^{3} - 5.1840 \times 10^{-1}T$	39.9501	3.07
	Fat	$\rho = 9.2559 \times 10^2 - 4.1757 \times 10^{-1}T$	4.2554	0.47
	Carbohydrate	$\rho = 1.5991 \times 10^3 - 3.1046 \times 10^{-1}T$	93.1249	5.98
	Fiber	$\rho = 1.3115 \times 10^3 - 3.6589 \times 10^{-1}T$	8.2687	0.64
	Ash	$\rho = 2.4238 \times 10^3 - 2.8063 \times 10^{-1}T$	2.2315	0.09
	Water	$\rho = 9.9718 \times 10^2 + 3.1439 \times 10^{-3}T - 3.7574 \times 10^{-3}T^2$	2.1044	0.22
	Ice	$\rho = 9.1689 \times 10^2 - 1.3071 \times 10^{-1} \text{T}$	0.5382	0.06
c _p (kj/[kg °C])	Protein	$c_{\rm p} = 2.0082 + 1.2089 \times 10^{-3} T - 1.3129 \times 10^{-6} T^2$	0.1147	5.57
	Fat	$c_{\rm p} = 1.9842 + 1.4733 \times 10^{-3}T - 4.8008 \times 10^{-6}T^2$	0.0236	1.16
	Carbohydrate	$c_{\rm p} = 1.5488 + 1.9625 \times 10^{-3}T - 5.9399 \times 10^{-6}T^2$	0.0986	5.96
	Fiber	$c_{\rm p} = 1.8459 + 1.8306 \times 10^{-3}T - 4.6509 \times 10^{-6}T^2$	0.0293	1.66
	Ash	$c_{\rm p} = 1.0926 + 1.8896 \times 10^{-3}T - 3.6817 \times 10^{-6}T^2$	0.0296	2.47
	Water	$c_p = 4.0817 - 5.3062 \times 10^{-3}T + 9.9516 \times 10^{-4}T^2$	0.0988	2.15
	Water ^b Ice	$c_{\rm p} = 4.1762 - 9.0864 \times 10^{-5}T + 5.4731 \times 10^{-6}T^2$ $c_{\rm p} = 2.0623 + 6.0769 \times 10^{-3}T$	0.0159	0.38

Source: Choi and Okos (1986).

^{*a*}For the temperature range of -40 to 0° C.

^bFor the temperature range of 0 to 150°C.

Electrical Conductivity (σ)

- Prepare sample in a cylindrical tube
 - Length (L) and c.s. area (A) are known
- Apply electric field by means of electrodes at either end of tube
 - Measure current (I) for a given voltage (V)
- $\sigma = (L I) / (A V)$
- Units: Siemens/m

Where are electrical properties used?

Ohmic heating: Rate of heating depends on electrical cond.

Dielectric Properties

- Dielectric constant (ε')
 - Ability of a material to absorb electromagnetic energy
 - Capacitive component
- Dielectric loss factor (ε'')
 - Ability of material to convert absorbed electromagnetic energy into heat
 - Conductive component

Where are dielectric properties used?

In radio frequency and microwave heating Loss tangent, Tan $\delta = \varepsilon''/\varepsilon'$ (measure of rate of heating) Power dissipated as heat (in W/m³) = 55.61 x 10⁻¹² E² f ε'' <u>Note: E is in V/m and f is in Hz</u>

Dielectric Properties (Static Measurement)

Open ended coaxial probe with Network Analyzer



Dielectric Properties (Dynamic Measurement)



Process Considerations

(Target organism, D, z, F, C, flow, heat, hold, cool, homogenization, hydration, deaeration)

Classification of Bacteria

- Based on Oxygen
 - Aerobes (Need oxygen for growth)
 - Microaerophile: Need only small amount of oxygen for growth
 - Anaerobes
 - Obligate: Oxygen prevents growth
 - Facultative: Can tolerate some degree of oxygen
- Based on temperature
 - Psychrotrophs (Grow best from 58 68 °F; grow slowly at refrigerator temp)
 - Mesophiles (Grow best from 86 98 °F -- warehouse temps)
 - Thermophiles (Optimum: 122 150 °F; spores can survive 250 °F for 1+ hr)
- Based on salt, acid, water activity (a_w) , osmotic pressure
 - Halophiles (Can not grow in absence of salt)
 - Acidophiles (Can grow in high acid conditions even at pH of 2.0)
 - Xerophiles (Can grow in low a_w conditions)

Osmophiles (Can grow in high osmotic pr. conditions – high sugar foods)
 Resistance of viruses > spores of bacteria > vegetative cells of bacteria > molds and yeasts
 Target organism & surrogate need to be identified for each product-process combination

Examples of Microorganisms in Different Categories

- Aerobe: B. subtilis, M. tuberculosis, Pseudomonas aeruginosa
- Microaerophile: Campylobacter jejuni, Heliobacter pylori
- Anaerobe: C. botulinum, C. butyricum, C. perfringens
- Facultative anaerobe: L. monocytogenes, S. enteritidis, Shigella sonnei
- Psychrophile: Yersinia enterocolitica, Aeromonas hydrophila
- Mesohphile: E. coli, B. licheniformis, Thiobacillus novellus
- Thermophile: B. stearothermophilus, B. coagulans
- Hyperthermophile: Thermococcus celer, pyrodictium brockii
- Halotolerant (1-6% salt): *Staphylococcus aureus, Halomonas elongata*
- Halophile (6-15% salt): Vibrio fischeri, Tetragenococcus halophilus
- Extreme halophile (15-30% salt): *Halobacterium salanarium*
- Acidophile: Alicyclobacillus acidiphilus/acidoterrestris
- Xerophile: Trichosporonoides nigrescens, Xeromyces bisporus
- Osmophile: Chromohalobacter beijerinckii, Saccharomyces cerevisiae

Factors Affecting Growth of Microorganisms

Intrinsic

- <u>pH</u>: *C. botulinum* does not grow below a pH of 4.6
- <u>Moisture</u>: Spoilage bacteria require a_w of 0.90+; *C. bot*: 0.94+; *S. aureus*: 0.84; xerophilic molds & osmophilic yeasts: 0.61
- <u>Nutrients</u>: Carbs, fats, proteins, minerals
- <u>Redox potential</u>: Aerobes prefer +ve redox potential
- <u>Antimicrobial resistance</u>: Allicin in garlic, eugenol in cloves, thymol in sage, lysozyme in eggs
- Biological structure: Skin and shell offer protection

• Extrinsic

- <u>Relative humidity</u>: Low a_w foods pick up moisture at high RH
- <u>Oxygen/gas content</u>: CO₂ can inhibit growth
- <u>Temperature</u>: Growth range of -34 °C (psychrophiles) to 100 °C (hyperthermophiles)

Target Microorganism

- The most <u>heat</u> resistant microorganism likely to be of public health concern in a particular food product subjected to a particular <u>thermal</u> process
 - What if pressure is used to destroy microorganisms?
- What is the maximum initial load?
- What is an acceptable final probability of survival?

Surrogate Microorganism

Characteristics

- Similar kinetics (z value) as target organism
- Need to have survivors at end of process
- Should be able to translate data of surrogate to that of target (eg.: 5 log destruction of surrogate equates to a 12 log kill of target organism)
- Non-pathogenic

Organisms of Concern for Aseptic Processing

- Target: Clostridium botulinum
 - Type A and non-proteolytic type B
- Geobacillus stearothermophilus

 Flat sour spoilage; store below 43 °C to prevent growth
- Spores of C. thermosaccarolyticum
 - $D_{121.1 \circ C} \sim 195 min$
- *Desulfotomaculum nigrificans*: Anaerobic thermophile
 - Sulphide-stinker spoilage (H₂S is generated and dissolves in container/food: Flat container no bulge)

Surrogates for Aseptic Processing

- B. stearothermophillus
- B. subtilis
- C. sporogenes
- B. sporothermodurans

D & z values



D & z values of Microorganisms

Microorganism	D _{T (in °F)} (min)	z Value (°F)
Low acid foods: Thermophiles (spores)		
Flat sour group (B. stearothermophilus)	$D_{250} = 4.0$ to 5.0	14 to 22
Gaseous spoilage group (C. thermosaccharolyticum)	$D_{250} = 3.0$ to 4.0	16 to 22
Sulfide stinkers (C. nigrificans)	$D_{250} = 2.0$ to 3.0	16 to 22
Low acid foods: Mesophiles (spores) Putrefactive anaerobes		
C. botulinum, Type A & B	$D_{250} = 0.1$ to 0.2	14 to 18
C. sporogenes group (incl. PA 3679)	$D_{250} = 0.1$ to 1.5	14 to 18
Acid Foods: Thermophiles (spores)		
B. coagulans	$D_{250} = 0.01$ to 0.07	14 to 18
Acid Foods: Mesophiles (spores)		
B. Polymyxa & B. macerans	$D_{212} = 0.1$ to 0.5	12 to 16
Butyric anaerobes (C. pasteuranium)	$D_{212} = 0.1$ to 0.5	12 to 16
High Acid Foods: Mesophiles (non-spore formers)		
Lactobacillus sp., Leuconostoc sp., yeasts, molds	$D_{150} = 0.5 \text{ to } 1.0$	8 to 10

D & z values of Organisms of Concern in Low Acid Foods

Organism	Medium	D _{121.1 °C} (mins)	z value (°C)
C. botulinum	Phosphate buffer	0.26	9.0
	Pureed peas	0.09	8.3
	Meat/vegetables	0.11	9.8
	Seafood	0.05	7.4
	Poultry	0.05	7.4
	Rock lobster	0.30	10.8
B. subtilis	Phosphate buffer	0.48	14.3
B. stearothermophilus	Phosphate buffer	2.48	9.4
C. sporogenes	Strained pea	1.00	9.1

D & z values of Enzymes & Quality Attributes

Enzyme or Quality Attribute	D _{T (in °C)} (min)	z Value (°C)	
Peroxidase from black radish	$D_{80} = 232$	28	
Peroxidase from green beans	$D_{80} = 15$	27	
Polygalacturonase from papaya	$D_{80} = 20$	6.8	
Lipoxygenase from peas	$D_{80} = 0.09$	8.5	
Catalase from spinach	$D_{80} = 0.02$	8.3	
Lipase from <i>Pseudomonas</i> spp.	$D_{120} = 25$	26	
Protease from Pseudomonas spp.	$D_{120} = 300$	28	
Thiamin in carrot puree (pH = 5.9)	$D_{121} = 158$	25	
Thiamin in pea puree (natural pH)	$D_{121} = 247$	27	
Lysine in soybean meal	$D_{121} = 786$	21	
Chlorophyll A in spinach (natural pH)	$D_{121} = 34.1$	45	
Anthocyanin in grape juice (natural pH)	$D_{121} = 17.8$	23.2	
Betanin in beet root juice (pH = 5.0)	$D_{100} = 46.6$	58.9	
Carotenoids in paprika (natural pH)	$D_{60} = 0.04$	18.9	

F Value (Based on Time-Temperature Data)

$$F = \int_{0}^{t} 10^{\frac{T - T_{ref}}{z}} dt = \sum_{i=1}^{n} 10^{\frac{T_{i} - T_{ref}}{z}} \Delta t_{i}$$

 $10^{\frac{T-T_{ref}}{z}}$: Lethal rate

• For a constant temperature process,

$$F = 10^{\frac{T - T_{ref}}{z}} \Delta t$$

∆t: Process/holding time

- Conservative F value is based on
 - Center temperature of can (for retorting)
 - Center temperature at holding tube exit (for aseptic processing of a liquid product)
 - Center of particle that receives the least heat treatment (for aseptic processing of a particulate product)

 $F_0 = F$ value when $T_{ref} = 250 \text{ °F}$ & z = 18 °F (or $T_{ref} = 121.1 \text{ °C}$ & z = 10 °C)

Interpretation of F Value

F value is the time of processing/holding at the reference temperature that yields the same amount of microbial as in the process (constant or variable temperature) under consideration.

It facilitates the comparison of the lethal effect of different processes.

F Value (Based on Microbial Data)

•
$$F = D_{ref} log \frac{N_0}{N}$$

- D_{ref}: D value at reference temperature (NOT process temperature)
- N₀: Initial microbial count
- N: Final microbial count
- <u>Example</u>: A 5 log reduction in microbial population yields -- $F = 5 D_{ref}$

Cook Value (C Value)

$$F = \int_{0}^{t} 10^{\frac{T - T_{ref}}{z}} dt$$

$$C = \int_{0}^{t} 10^{\frac{T - T_{ref}}{z_c}} dt$$

<u>Component</u>	<u>z value (°C)</u>
Bacterial spores	7-12
Vegetative cells	4-8
Enzymes	10-50
Vitamins	25-30
Proteins	15-37
Sensory attribute (Overall)	25-47
Sensory attribute (Texture softening)	25-47
Sensory attribute (Color)	24-50

Source: Improving the thermal processing of foods (Richardson, 2004)

<u>Note</u>: Generally, for canning & aseptic processing, $T_{ref} = 121.1 \text{ °C}$ (or 250 °F) Also, $z_c >> z$ in most cases

Time-Temperature Optimization



<u>Note</u>: Generally, $z_c \gg z$

Type of Flow and its Effects

- Laminar
 - (Fastest velocity) / (Average velocity) = 2.0
 - Wider distribution in residence time and quality
- Turbulent
 - (Fastest velocity) / (Average velocity) = 1.2
 - Narrower distribution in residence time and quality

Mixing can also narrow residence time distribution and quality differences

Reynolds Number (for Power-Law Fluids)

$$N_{GRe} = \frac{\rho \overline{u}^{2-n} d_h^n}{K \left(\frac{3n+1}{4n}\right)^n 8^{n-1}}$$

$$\sigma = \mathbf{K}(\gamma)^n$$

- N_{GRe}: Generalized Reynolds number
- K: Consistency coefficient (Pa·sⁿ)
- n: Flow behavior index
- ρ: Density of fluid (kg/m³)
- \overline{u} : Average velocity of fluid (m/s)
- d_h: Hydraulic diameter (m)

The critical Reynolds number $[N_{Re(critical)}]$, beyond which flow is no longer laminar, is given by:

$$N_{\text{Re(critical)}} = 2100 \frac{(4n+2)(5n+3)}{3(3n+1)^2}$$



Damage by Shear

- Maximum effect towards end of heating, in holding, and beginning of cooling
 - Minimize tube length
 - Maximize tube diameter
 - Avoid cross-sectional area changes
 - Minimize use of valves
- Positive displacement pump minimizes shearing
- Back pressure device
 - Diaphragm-type minimizes damage to some particles
 - Use of pressurized tank eliminates additional damage

Effect of Heating, Holding, and Cooling

- Heating
 - Rapid/volumetric heating method is generally better
 - Exception: Very high ' h_{fp} ' in conventional heating can result in higher mass average cook value
 - Eg: Outer ring/shell (high mass) of sphere heats much faster than heat penetrates inside (due to low ' α ')
- Holding
 - Helical holding tubes result in better mixing
- Cooling
 - Rapid cooling desirable (co-current and nonregenerative initial cooling; vacuum)

'h_{fp}' data from Literature

Source	Method	N _{Re}	$h_{fp} (W/m^2 \cdot K)$	Fluid	T (°C)	Geometry
Heppell (1985)	Microbiol.	5250 - 50000	2180 - 7870	Water	139	Sphere
Chand. et al. (1988)	Stationary	6 - 142	56 - 90	Starch Sol	129	Cube
	Particle	761 - 2144	65 - 107	Water	129	Cube
Chang &(1989)	Stationary	500-1000	239 - 303	Water	75	Cube
Sastry et al. (1990)	Rel. Vel.	7300 - 43600	180 - 1327	Water	45	Sphere
	Mov. Therm.	7300 - 43600	688 - 3005	Water	45	Sphere
Mwangi et al. (1993)	Thermochrom	73 - 369	58 - 1301	Glycerin	85	Sphere
Zitoun & Sastry (1994)	Rel. Vel.	21 - 270	286 -1034	Starch Sol	45	Cube
	Liq. Crystal	21 - 270	268 - 928	Starch Sol	45	Cube
Bala & Sastry (1994a)	Rel. Vel.	15 - 798	401 - 1684	Starch Sol	45	Sphere
	Liq. Crystal	15 – 798	857 - 2010	Starch Sol	45	Sphere
	Mov. Therm.	15 - 798	363 - 1522	Starch Sol	45	Sphere
Zareifard &	Calorimetric	4050-5937	500-2000	Sugar Sol	75-100	Sphere
Ramaswamy (1999)						

'h_{fp}' for Forced Convection over a Sphere $N_{Nu} = hd_c/k_f = f(N_{Re}, N_{Pr}) - similar$ to flow in a pipe $N_{Nu} = 2 + 0.6 (N_{Re})^{0.5} (N_{Pr})^{0.33}$ For $1 < N_{Re} < 70,000$ $0.6 < N_{p_r} < 400$ and OR $N_{Nu} = 2 + [0.4(N_{Re})^{0.5} + 0.06 (N_{Re})^{0.667}] \{N_{Pr}\}^{0.4} (\mu_b/\mu_w)^{0.25}$ For $3.5 \le N_{Re} \le 7.6 \ge 10^4$, $0.71 \le N_{Pr} \le 380$, $1 \le \mu_b/\mu_w \le 3.2$

<u>Note</u>: For all forced convection situations, use bulk temperature of fluid to determine properties (unless otherwise specified)

'h_{fp}' from Experiments

- Lumped capacitance method
 - Create metal object of similar size and shape as object of interest
 - Entire metal object will be at same temperature
 - Rise in temp. of object is related to ' h_{fp} '
- Ablation
 - Melting of object (change in mass) is related to ' h_{fp} '
- Inverse method
 - Use experimental time-temperature data in governing heat transfer equations to back calculate ' h_{fp} '
Other Process Factors

Homogenization

- Raw side versus processed side
 - Homogenization at high temperature is generally better

Hydration

- Allow sufficient time to ensure homogeneity

Deaeration

- Minimizes oxidative quality loss

Equipment Considerations (Pumps, HX, Mixers, BPV)

Choice of Pumps

- Dynamic (momentum change)
 - Centrifugal

Several impellers in series

For more viscous or particulate products

-- Self-priming, non-priming)

- Axial flow (Single stage, multistage -- Closed impeller, open impeller)
- Radial flow, mixed flow (Single suction, double suction -- Self-priming, non-priming)
- Peripheral flow (Single stage, multistage
- Special

Product enters from 2 sides

• Jet (eductor, injector), gas (or air) lift, hydraulic ram, electromagnetic, vortex, laminated rotor, inclined rotor, regenerative turbine, rotating casing, reversible centrifugal

Displacement

Pumping is done on both sides of piston

- Reciprocating
 - Piston (Direct acting steam double acting, power: crank & flywheel single/double)
 - Plunger (Simplex, duplex, triplex, multiplex)
 - Diaphragm (Simplex, multiplex -- fluid operated, mechanically operated)
- Rotary

Many cylinders

• Single rotor

- Vane (internal, external), piston (axial, radial), flexible member (tube, liner, vane), screw & wheel

• Multiple rotor

- Gear (external, internal), lobe (single, multiple), circumferential piston (internal, external), screw

Direct Heating

- Culinary steam is utilized
 - Non-condensable gases are removed using a de-aeration tank
- Pre-heating is usually done
- ~120 °F temperature rise by steam
 - Addition of steam increases volume by $\sim 12\%$
 - Rule of thumb: ~1% volume change for a ΔT of 10 °F
 - Need to factor this in calculating holding length and time
- Categories
 - Steam injection (OR Direct Steam Injection OR DSI)
 - Steam is forced through a properly designed sanitary nozzle
 - Complete condensation of steam is essential ($\Delta P_{nozzle} \ge 10 \text{ psi}$)
 - » Incomplete condensation can result in non-uniform temperatures
 - Steam infusion
 - Milk is introduced into a vessel flooded with steam

Note: Both of the above systems require vacuum chambers to remove steam that condensed

Steam Injection



www.process-heating.com

Steam Infusion





Double and Triple Tube HX



Variations: Corrugated, dimple-tube, twisted tube, mixer insert



Multitube HX



<u>Caution</u>: Fouling/clogging of one tube could result in underprocessing a portion of the product

Shell & Tube: (One & Two Pass)









Shell & Tube: Cross-Flow



Helical Heat Exchanger



Axial & Secondary Flow Profiles (Dean Effect)

- $N_{De} = N_{Re} (r/R)^{1/2}$
- Curvature, pitch, flow rate, and viscosity affect strength of secondary flow
- Critical N_{Re} for turbulence is much higher
- 'h' increases and so does pressure drop





Scraped Surface Heat Exchanger (SSHE)



Advantage: Mixing of viscous foods

Disadvantage: Particle damage, uncertain residence time, cleaning issues



Type of Heat Exchanger

- Plate, multi-tube
 - Wider residence time distribution
- Tubular
 - Narrower residence time distribution
- Scraped Surface Heat Exchanger
 - High mixing; possibly wider residence time distribution
- APV double-cone Jupiter
 - Solids and liquid are processed separately
- Stork Rota-Hold
 - Longer process time for particulates



Ohmic Heating

- 7 electrode housing machined from PTFE, encased in SS; Electrodes connected by SS spacer tubes
- Electrical conductivity, voltage, C.S. area, interelectrode spacing, specific heat, particle conc.
- Field distorted around mtls. of low conductivity
 Causes localized hot and cold spots
- ~ linear relation btwn. temp. and conductivity
- Simultaneous heating of liquid & solids (1-2°/s)
- Problems: Product reformulation, runaway heating
- Liquid whole eggs, tomato sauces, soups

Continuous Flow Microwave (Institutional Level Package)



<u>Pipes in heating section</u>: Ceramic-Plastic combo (to withstand heat and pressure) <u>Optional</u>: Add static mixers between heaters to equalize temperatures

Academic and Commercial Success with Continuous Flow Microwave



February 13, 2008. <u>1st FDA Letter of No Objection for</u> a MW sterilized food product: Low Acid, Shelf Stable, MW -Sterilized, Aseptically Packaged Sweet Potato Puree

2007 & 2009: <u>NSF</u> Compendium -- Industry-Nominated Technology Breakthroughs 2008: <u>ASABE</u> Food Engineering Award 2009: <u>IFT</u> Food Technology Industrial Achievement Award 2010: <u>USDA-ARS</u> Technology Transfer Award 2012: <u>IFTPS</u> Marvin Tung Award

This technology was extended to dairy products including milk and salsa con queso Salsa con queso received one of the highest sensory scores from <u>U.S. Army Natick</u> The technology is in the process of being used for other low-acid & acid foods

Mixing (Bends, Coils, Static Mixer)





Types of Back Pressure Valves



Validation Considerations (t-T data, modeling, micro, TTI, thermomagnets)

What does Validation Involve?

- Assurance of a certain degree of microbial kill of the target microorganism for every portion of product
 - -5 log reduction of target organism for acidified foods
 - $-12 \log reduction of C. botulinum for low-acid foods$
 - 12D process

Premise: Initial microbial load is controlled below a pre-set value

Validation Techniques

- Time-temperature data
 - Verify with microbiological plating
- Mathematical modeling
 - Verify with microbiological plating
- Microbiological plating
 - Cannot detect below a certain value
 - Not useful for a 12D process
- Time-temperature integrators
 - Certain level of destruction of a chemical/enzyme

Validation Based on t-T Data

- Batch systems
 - Conduct temperature distribution tests
 - To identify cold spot
 - Conduct heat penetration tests
 - To determine temperature at cold spot
- Continuous systems
 - Cold spot identification is system & process specific and based on certain assumptions
 - Heat penetration tests done at cold spot(s) in fluid

OR

 Determine t-T data for a "conservatively" heating location in a multiphase product

Sensors to Determine Residence Time

- Conventional: Stop watch, salt injection
- Digital video imaging
- MRI
- Laser-Doppler-Velocimetry
- Magnetic implants
- <u>Other</u>: Pulsed Laser Velocimetry (PLV), Positron Emission Particle Tracking (PEPT), Computer Automated Radioactive Particle Tracking (CARPT), Gamma Ray Emission Particle Tracking (γEPT)

Sensors to Determine Temperature

- Conventional methods
 - Filled systems, bimetallic, thermocouple, RTD, thermistor, pyrometer
- Melting point indicators
- Thermochromic dyes
- Chemiluminescent dyes
- Magnetic thermometry
- MEMS-based system (RF telemetry optional)

Off-the-Shelf MEMS-Based System



A smaller chip, with RF telemetry capability, is being developed

Validation Based on Mathematical Modeling

- Commercial software
 - Model flow and time-temperature data
 - CFD-ACE, Fluent, Flow3D, ANSYS, Comsol
 - Determine F₀ value
 - NumeriCAL, AseptiCAL, HydroCAL (JBT FoodTech)
 - Finite difference based mathematical modeling
- Develop your own model

Temperature Distribution in Fluid During Microwave Heating (ANSYS)



Temperature Distribution in Particles during Microwave Heating (In-House Modeling)



Couple flow (3-D), heat transfer, electromagnetics; track particles

Microbiological Plating (Surrogate Microorganisms)

- B. stearothermophillus
- B. subtilis
- B. coagulans
- C. sporogenes

Surrogate representative of target? How to translate data of surrogate to target?

Time Temperature Integrators

Chemical TTI

- Thiamine inactivation
- Color change by sugar and amino acid groups reduction
- Methylmethionine sulfonate (MMS) degradation
- Physical TTI (based on diffusion)
 - Distance traveled by chemical that melts and diffuses on a wick paper

Biological TTI

- Protein-based
 - Enzymatic (α amylase from *B. amyloliquifaciens*, *B. licheniformis*)
 - Non-enzymatic (Immunochemical: heat affects binding site of proteins)
- Microbiological

BIUs and TTIs





SGM Biotech: *B. stearothermophilus*

Beta Glucosidase from *Pyrococcus furiosus*

Implant Thermomagnetic Switch



Magnet: As light as 0.08 g

Carrier Particle

- What is a conservative carrier particle?
- A hollow plastic particle of a given wall thickness
- It should be the fastest flowing particle
 - Adjust density based on RTD studies
- It should also be the slowest heating particle
 - Adjust thermal diffusivity to the lowest value based on the real food particles in the system



External Magnetic Sensors


Magnetic Signals

injection 150	n.co 10 • 1/4 Hold 15 • • • • • • • • • • • • • • • • • • •	Not Used	Not Used
1/3 HTR 15.00	1000 1/2 Hold 15	10.45 Not Used	10 Nof Used
2/5 HTR 15.07	7/22 10 3/4 Hold 15:	6	
Exit HTR Enter Hold 1509	847 10 Exit Hold 151	6	6

Low-Acid Foods: Scheduled Process

- Based on
 - Nature of product and how it heats
 - pH, properties (viscosity, thermal diffusivity, etc.)
 - Container in which product is packed
 - Characteristics of target organism
 - Growth & death curves, heat resistance
 - Thermal processing procedures and controls
 - Conventional, ohmic, microwave, etc

Low-Acid Foods: 12D Process

- Assumption: Heaviest load of *C. botulinum* spores in raw canned food is 10¹²
 - Very conservative value
 - -C. botulinum in meats is at ~0.1 to 7.0 spores per kg meat
- Thus, a 12D process ensures safety
- $D_{250 \circ_F}$ for C. bot in many foods is 0.2 min
- Thus, a 12D process equates to $F_0 = 2.4 \text{ min}$
- With a factor of safety, $F_0 = 3.0 \text{ min}$

Practically Used F₀ Values for Low Acid Foods

- F₀ value required for a safe process decreases from
 3.0 min as pH decreases
- Generally, a 5D process for *C. sporogenes* is used to prevent spoilage (more severe than 12D for *C. bot*)
- Presence of salt and nitrites decreases required F₀ value
- Example: If reqd $F_0 = 6$ min at pH of 6.0, it may be 4.0 min at a pH of 5.3. In cured meat products containing 150 ppm nitrite and 3-4% brine, it may be 0.3-1.5 min.

Process Filing (FDA Form 2541c)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration								NOTE: No commercial processor shall engage in the processing of low-acid			FORM APPROVED: OMB No. 0910-0037 EXPIRATION DATE: 8/31/2011				
FOOD PROCESS FILING FOR LOW-ACID ASEPTIC SYSTEM						EMS		İ	foods unless o	completed Form	s FDA 2541	FDA USE ONLY		ONLY	
(USE FDA BOOKLET TITLED "ASEPTIC PACKAGING SYSTEM SUPPLEMENT")									Food and Drug	g Administration	n, 21 CFR	DATE RECEIVED BY FDA		DA	
(TYPE OR PRINT ALL INFORMATION REQUESTED, IF AN ITEM DOES NOT APPLY ENTER 'NA'. FILE ACIDIFIED ASEPTIC (pH 4.6 or BELO							FORM	(2641a)	108.35 (c)(1) and (2).						
1. FCE						7.	7. PRODUCT NAME, FORM OR STYLE, AND PACKING MEDIUM								
2. ESTABLISHMENT NAME						-									
ADDRESS (No. and Street)						8.	8. NAMES OF STERILIZING SYSTEMS								
							a. Product ¹								
CITY STATE							b. Packaging								
					9.	PRC	CESS OR	ORIGIN							
3. SID 2.0					NO.	Source fo	or 8.a. and 8	.D.				Date (mm/yyyy)			
						a.									
							b								
	_ REPEACE	<u><u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u></u></u>	Y M M	DDS	s s s										
						10	10. CONTAINER TYPE (Check one)								
							a. Tinplate or b. Aluminum c. Glass								
2 0 -	6. SUP SID 2 0 /						Steel Can Can Can								
YYYY MM DD SSS							d. Uther (specify below and in item 22 if necessary)								
11. MAXIMUM 12. pH WATER	Makes at	13. MAXIMUM C	CONSISTENCY	OR VISCOSIT	Y IN CENTIP	DISES OR	OR APPROPRIATE UNITS 14. SPECIFIC 15. INSIDE DIAME- 16.					- 16. HOLDING TUBE LENGTH			
ACTIVITY ² Normal Max. ³	77±2°F C	Value at her Temp T	other emp (°F)		Units			N	lethod Name		AT 77 ±	2°F T	UBE (Inches)	(Inches)	
0		-											-		
17. OTHER CRITICAL CONTROL	18. CC	NTAINER DIMEN	ISIONS	19.	SCH	IEDULED F	ROCE	ESS		20. MAXIMU	M 21.1	THRUPUT	FO	OTNOTES	
FACTORS (Check all that apply)	Diameter o	Inches and Sixtee	nths)	- Minimum	Time (sec)	Temp (*F		Least Sterilizing	Flow	FOOD FI RATE (gi	_OW (al/ r	(containers / ninute)	1 For steam increase a	injection, enter volume nd thermal expansion	
Percent Solids	No. Length	Width	Height	Temp (°F)			'	Value (F _o) ⁵	Factor	min) ~		-	factors in 2	2.	
	1												2 If reduced an adjunct	water activity is used as to the process, spec-	
89 Mothed of Proceeding	2												ity the max	imum water activity.	
70 Eormulation	3												normally io tables or v	w-acid fruits, vege- egetable products for	
							-						the purpos sing, speci	e of thermal proces- ty the maximum	
in 22)	4				-			•	-				finished pr	oduct equilibrium pH.	
72 Particulates (specify maxi- mum size in 22)	5							•	•				4 If a critical	factor is in the process.	
73 Other (specify in 22)	6								-				process ad	ent scientific basis of lequacy.	
22. COMMENTS							AUTHORIZED COMPANY REPRESENTATIVE								
NAM				NAME (7	ype o	r Print)			TITLE						
SIGN				SIGNATU	VATURE DATE PHONE N				ENO.						
EORM EDA 2541c (4/10) PREV	/IOUS EDITION IS	OBSOLETE											PSC	Oraphics: (301) 443-1090 EF	

Concluding Remarks

- Characterize your product
 - pH, water activity, ingredient specs, properties
- Develop appropriate process based on
 - Target microorganism, flow type, heat transfer
 - Optimize t-T based on safety and quality parameters
- Select appropriate equipment
 - Pump, HX, hold tube, back pressure device
- Develop validation protocol
 - Microbial, TTIs, modeling, thermomagnetic switches
- File process and plan for process deviations

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K.P. Sandeep Professor & Department Research Leader Department of Food, Bioprocessing and Nutrition Sciences North Carolina State University kp_sandeep@ncsu.edu 919-515-2957 http://www.ncsu.edu/project/foodengineer

Site Director Center for Advanced Processing and Packaging Studies http://fst.osu.edu/capps