Green Light for Continuous Flow Microwave Sterilization of Aseptic Multiphase Products

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North Carolina State University
Aseptia Inc.
SinnovaTek Inc.

Center for Advanced Processing and Packaging Studies (CAPPS) :

NSF Sponsored Industry/University Collaborative Research Center

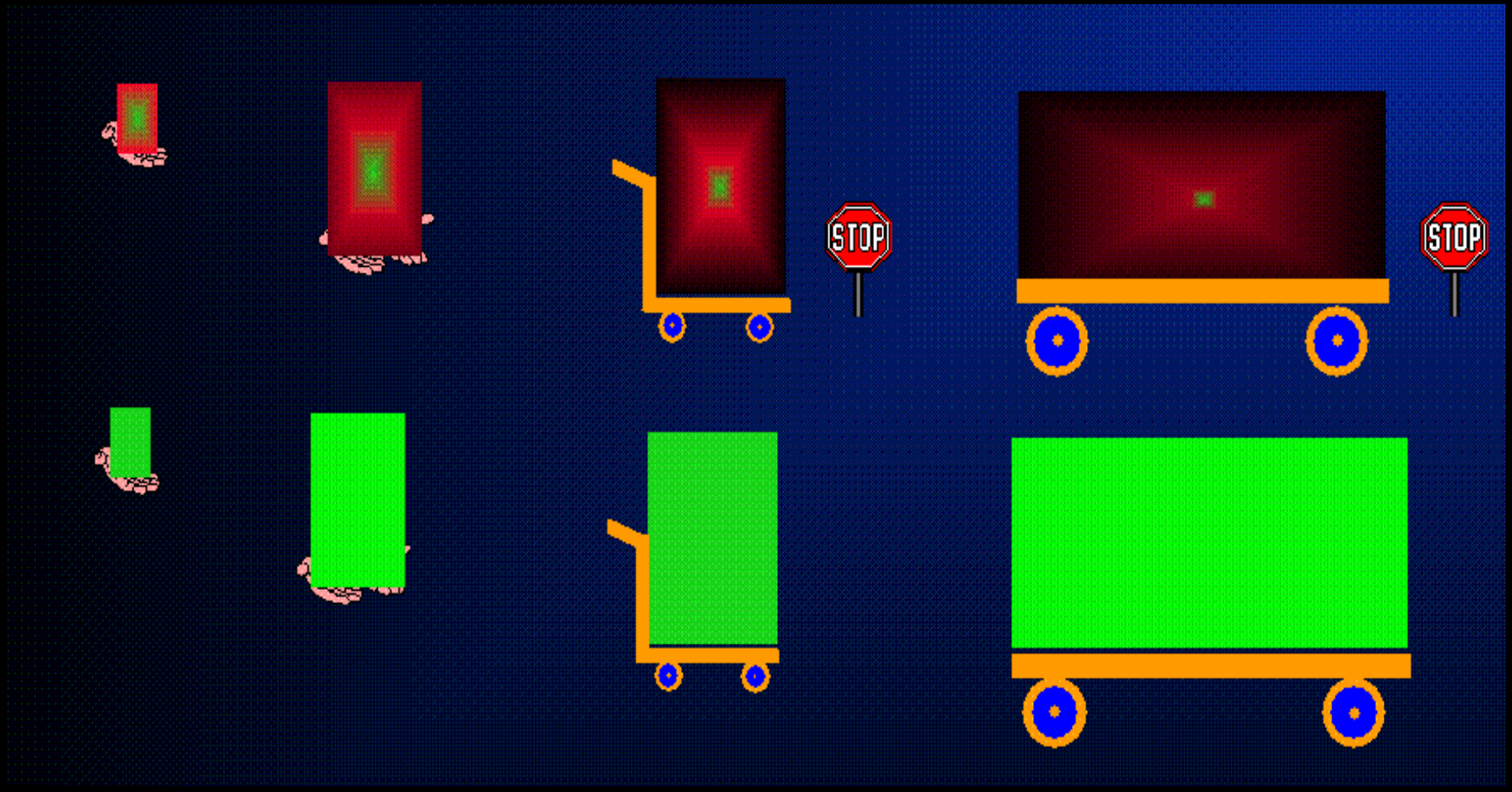
CAPPS Mission

To conduct industrially relevant research directed at developing methods and technologies for the safe production of marketable, high quality aseptic and refrigerated, extended shelf-life products.

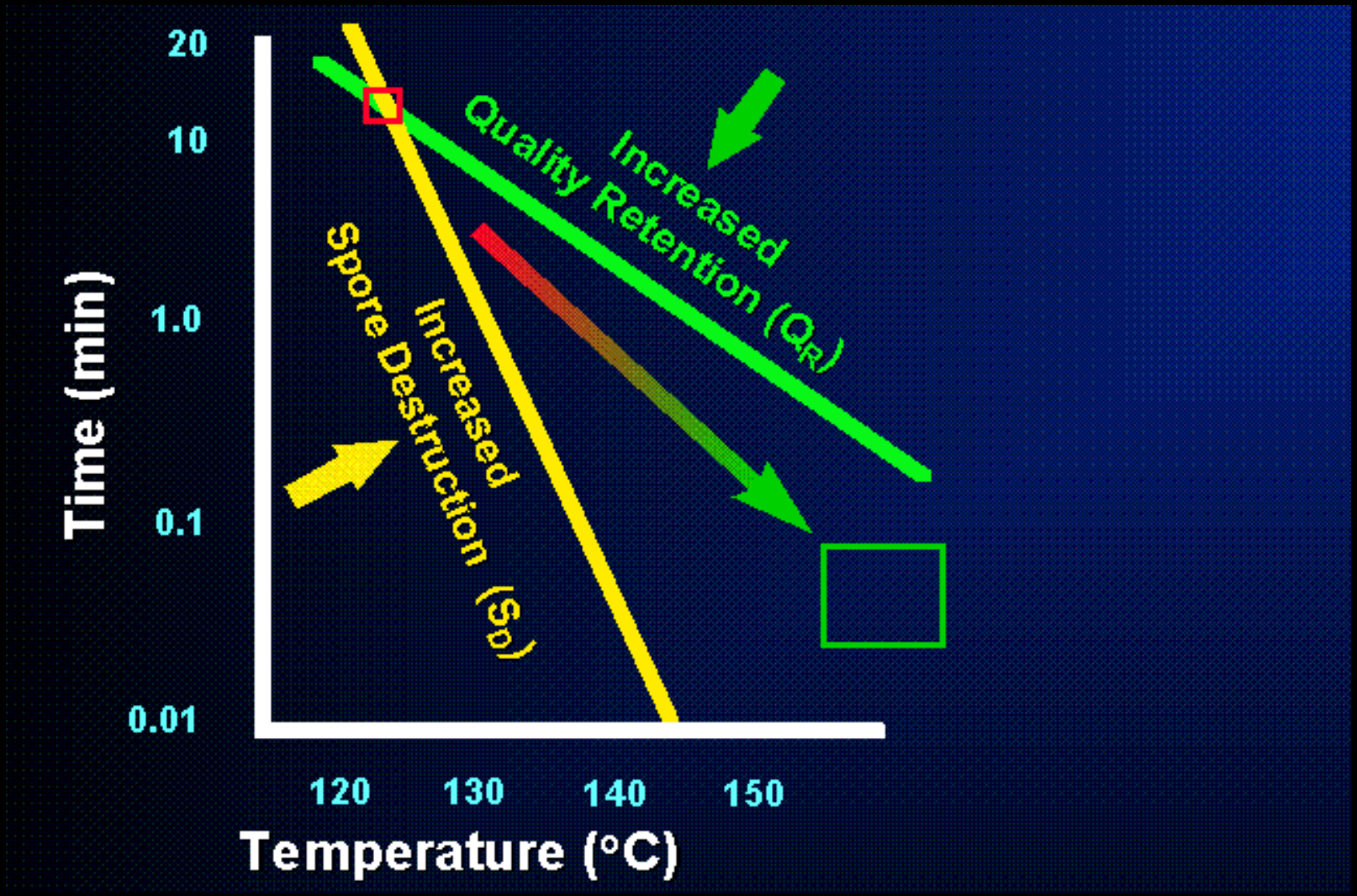
Key Questions:

- Why aseptics ?
- Why high temperatures ?
- Why advanced heating ?

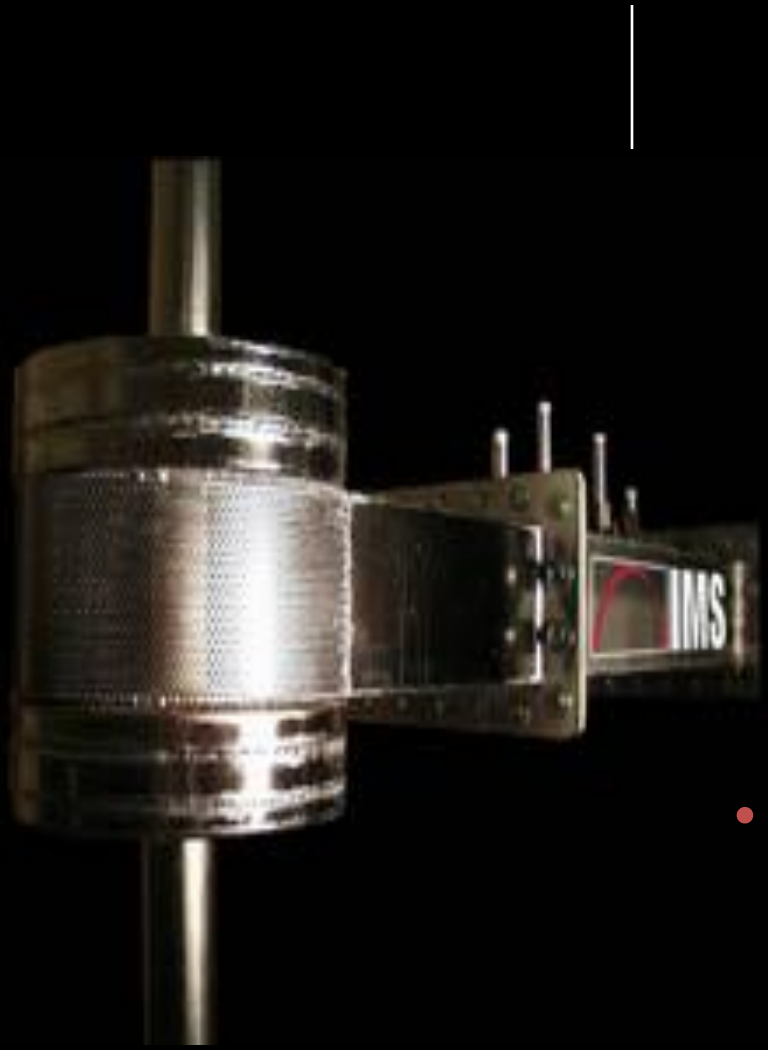
Why aseptics ?

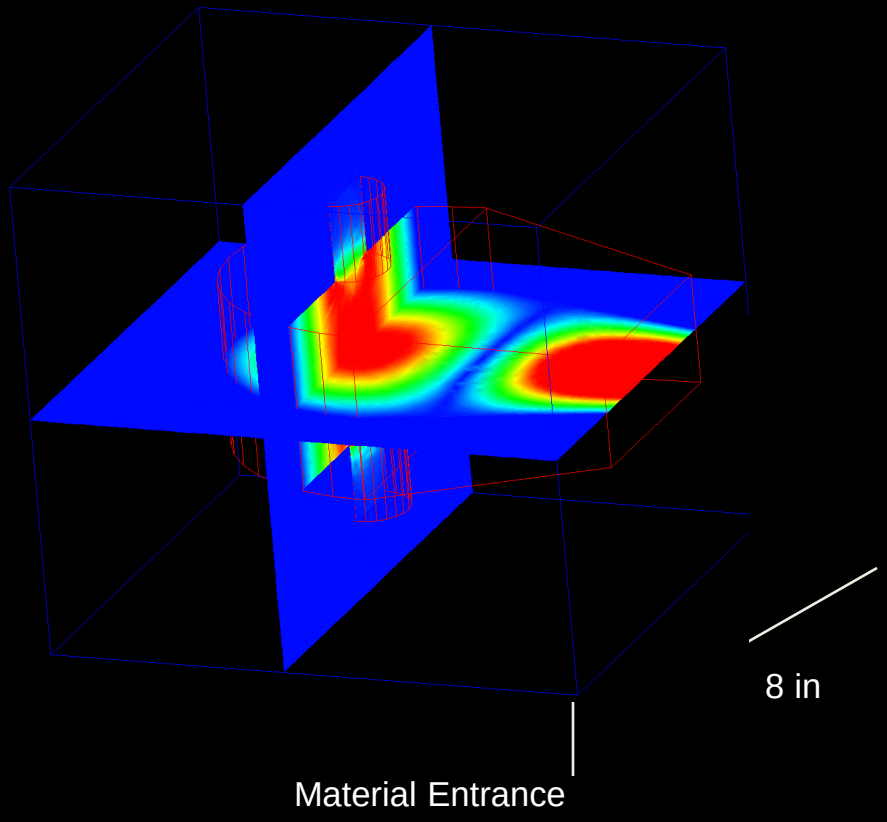


Why high temperatures ?



1997 – IMS Cylindrical Heating Technology



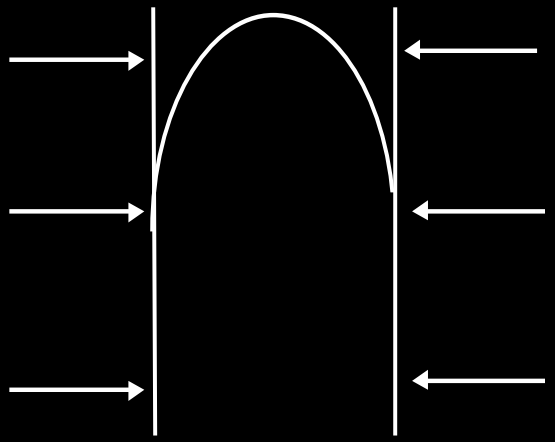


- Computer model of focused microwave energy creating uniform heat distribution (red area) throughout the cylindrical exposure region

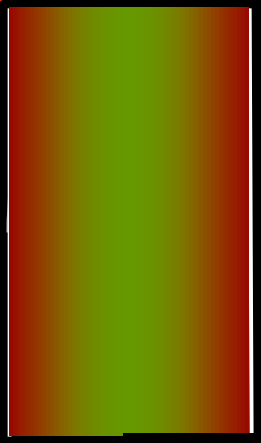
Significance

Thermal treatment of viscous fluids, emulsions and suspensions under laminar flow conditions - Conventional

Flow distribution

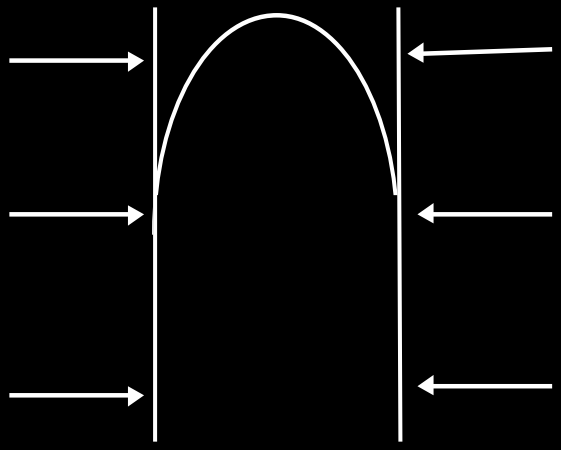


Temperature distribution

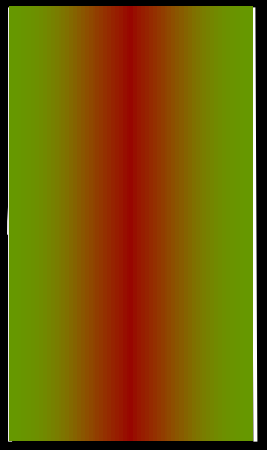


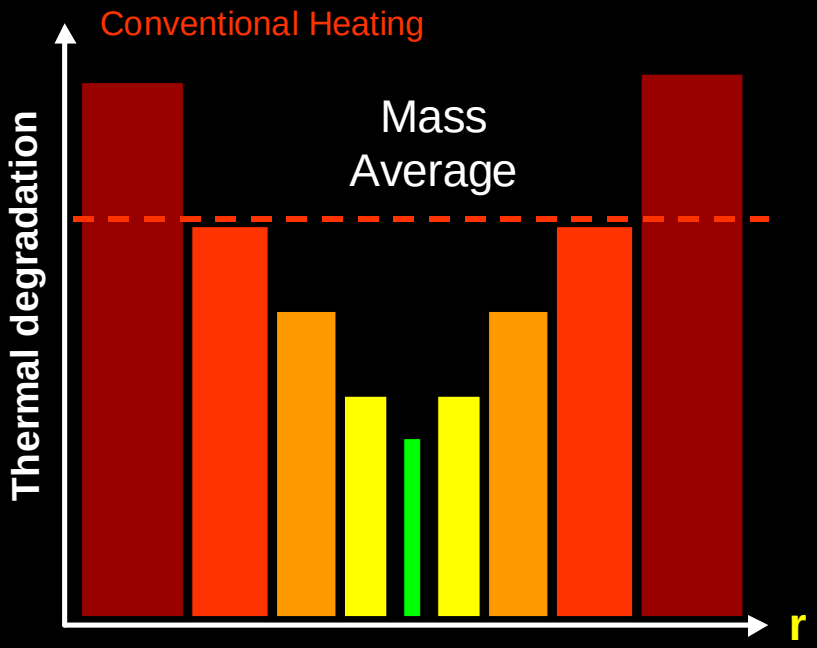
IMS Microwave Cylindrical Reactor
- Focused Energy Delivery

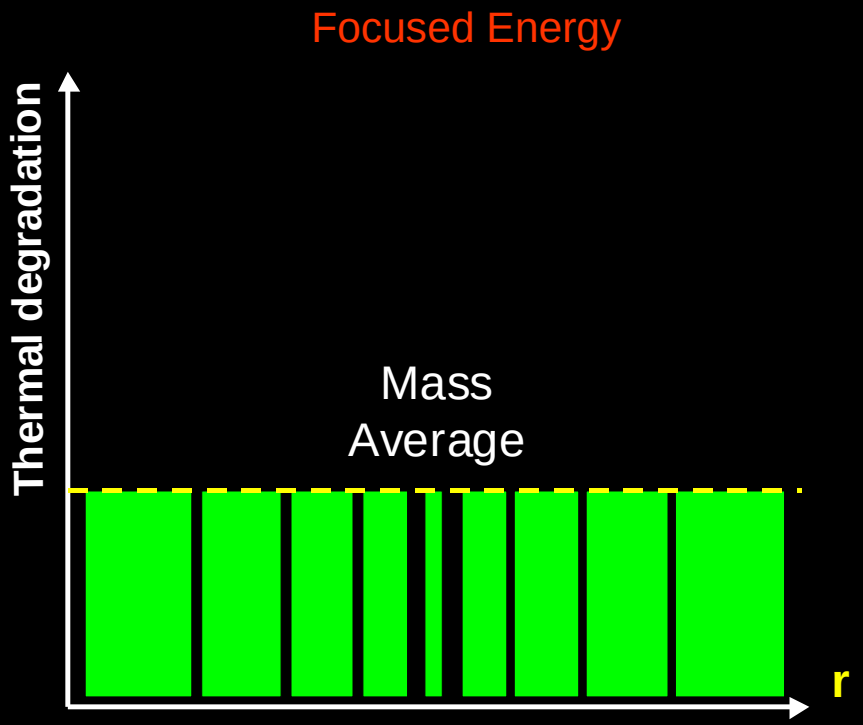
Flow distribution

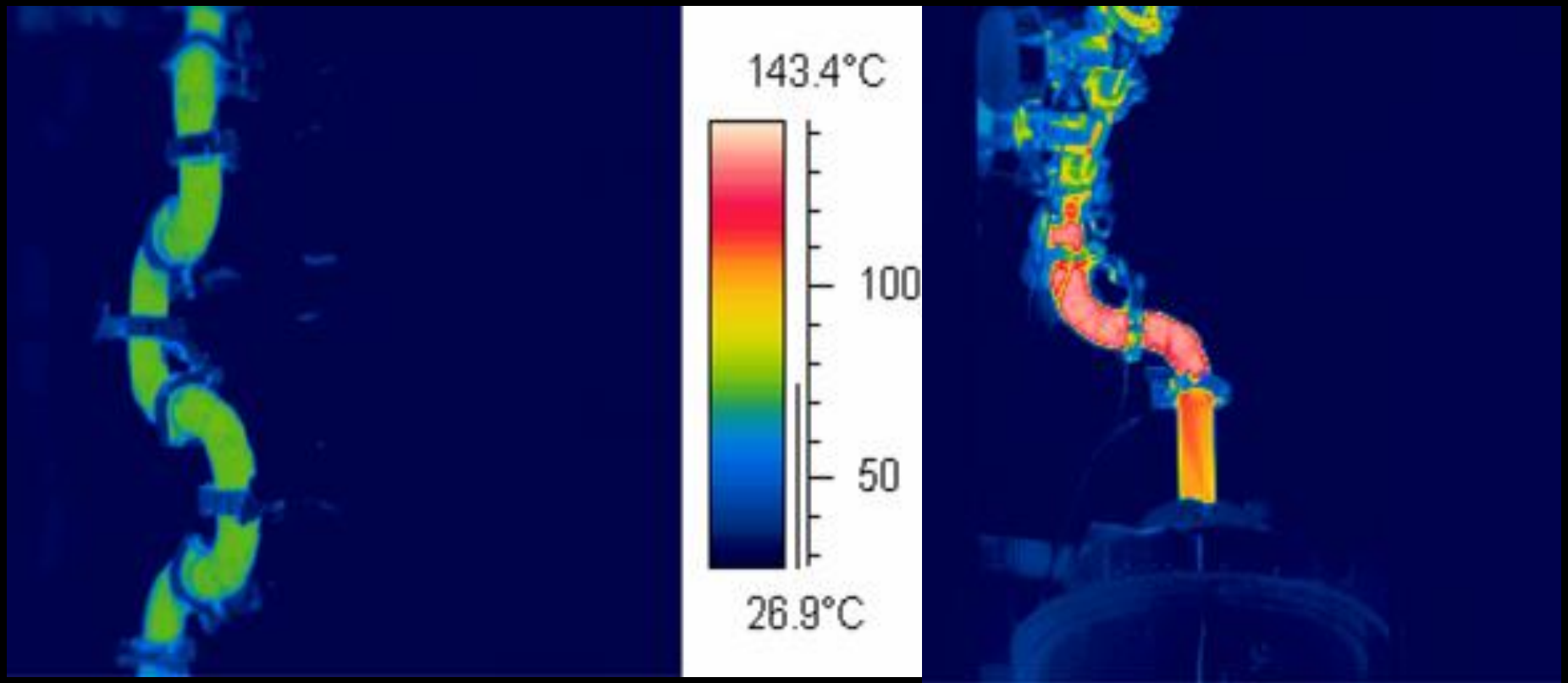


Temperature distribution

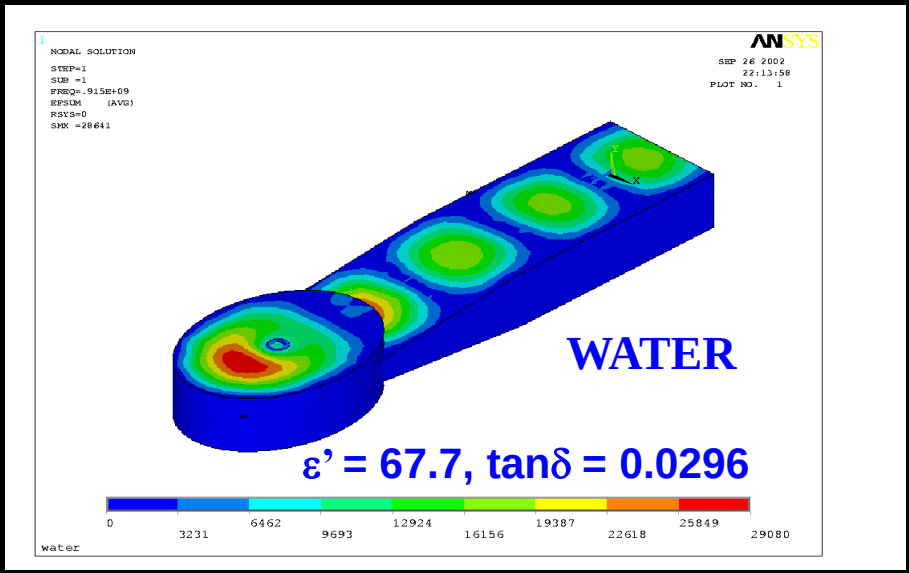


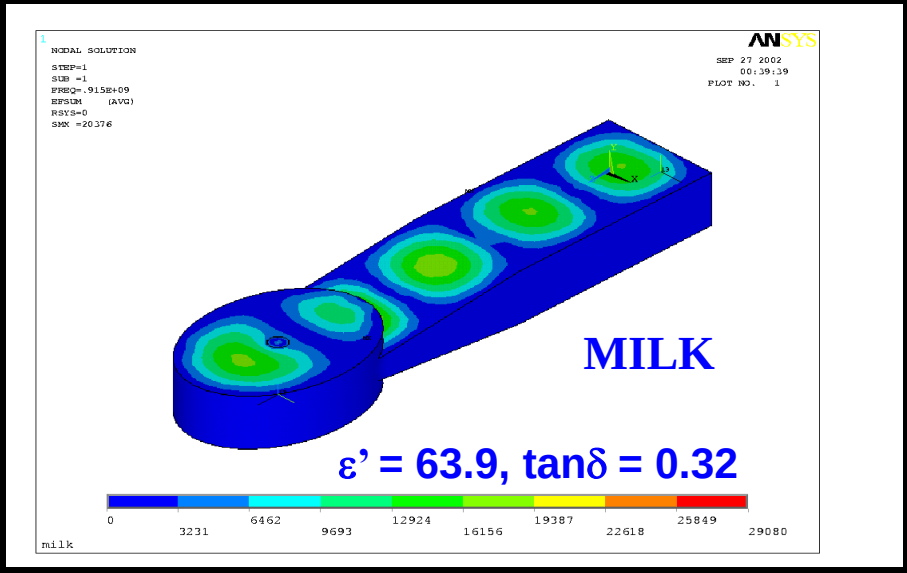

Conventional Heating
Thermal degradation
Mass
Average
r


Focused Energy
Thermal degradation
Mass
Average
r


143.4°C
100
50
26.9°C

Electric Field Distribution
(Effect of Material Properties)





1st Industrial Batch

February 13, 2008.

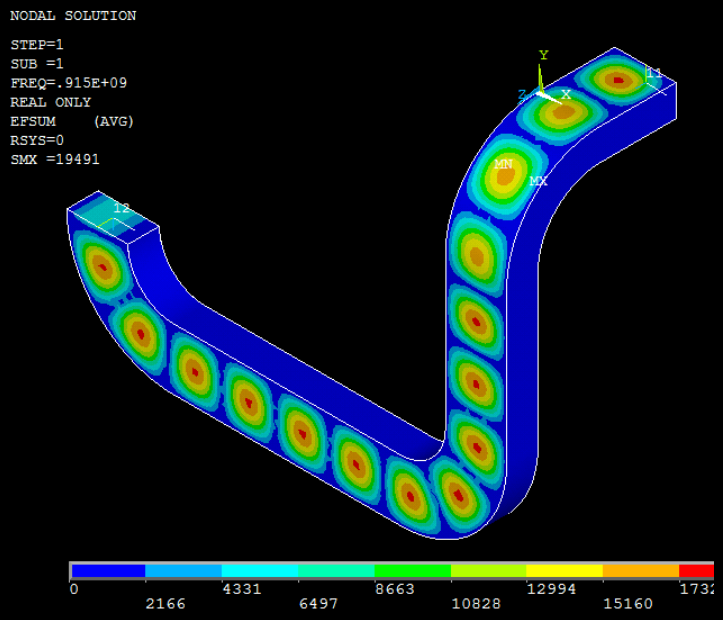
FDA Letter of No Objection:

Low Acid, Shelf Stable, MW - Sterilized, Aseptically Packaged Sweet Potato Puree

2007, 2009, 2011, 2013, 2015:
NSF Compendium of Industry-Nominated Technology Breakthroughs
2008. FPSA/FPEI Food Engineering Award
2009. IFT Food Technology Industrial Achievement Award
2010. USDA / ARS Technology Transfer Award
2012. IFTPS Marvin Tung Award
2012. NCSU Innovator of the Year Award
2014. NCSU Chancellor's Innovation Fund

— Ipomoea Batatas —
COVINGTON
THE BEST YAM VODKA ON EARTH
COVINGTON
COVINGTON
SAN FRANCISCO WORLD SPIRITS COMPETITION
2013
GOLD MEDAL
GOURMET VODKA
THE BEST YAM VODKA ON EARTH

Yamco LLC, Snow Hill, N.C.
The first commercial installation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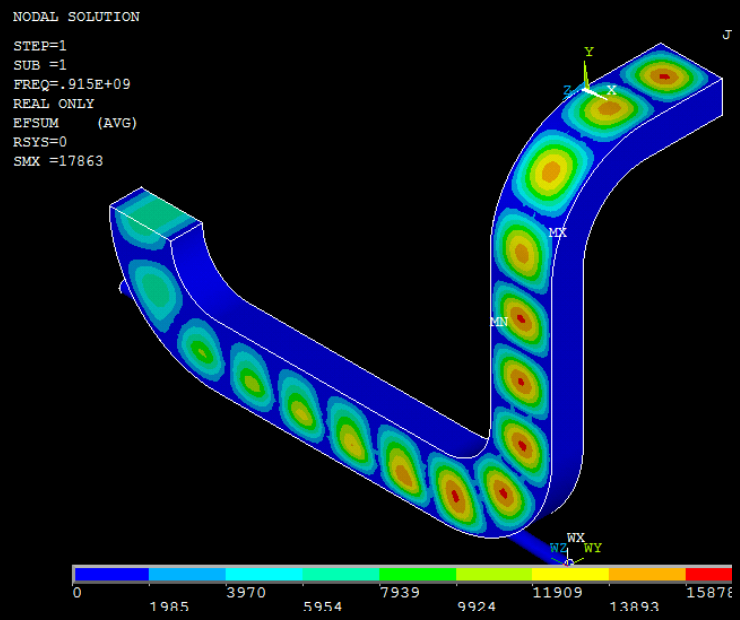
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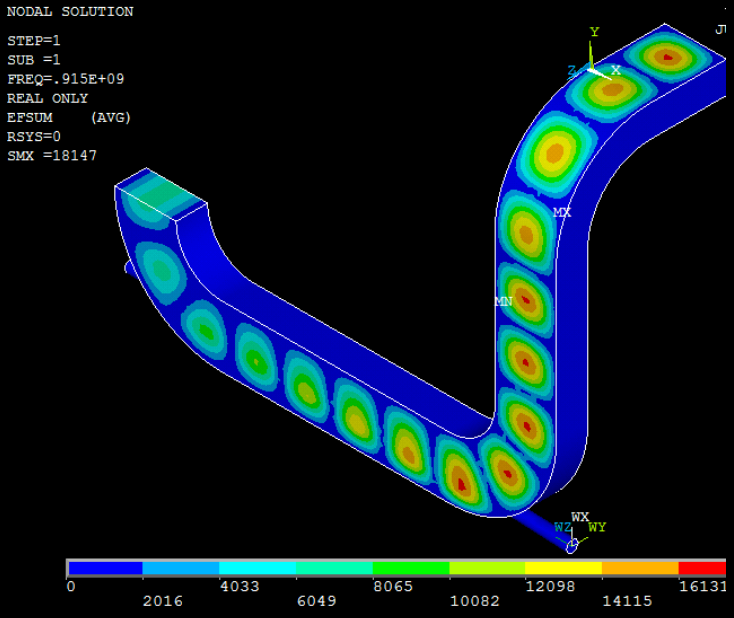
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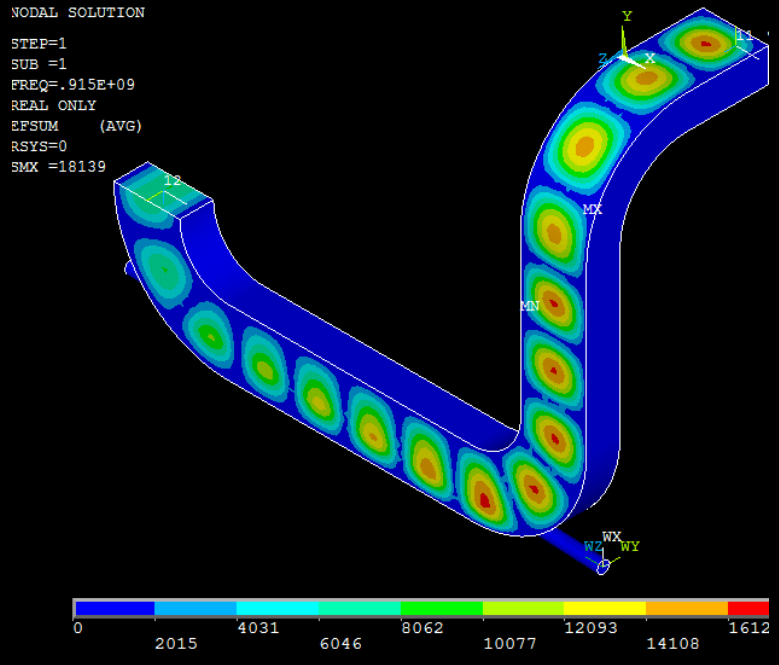
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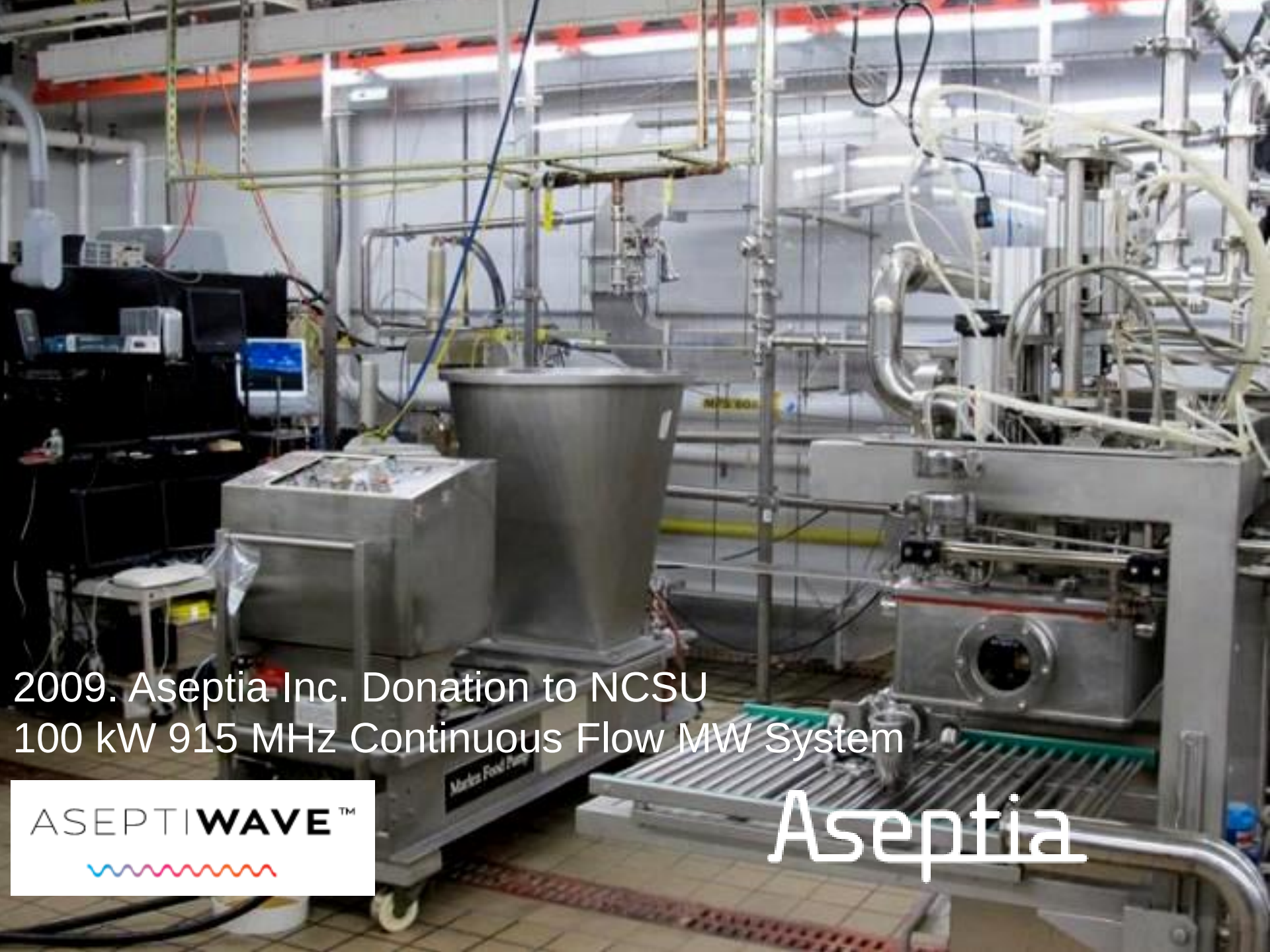
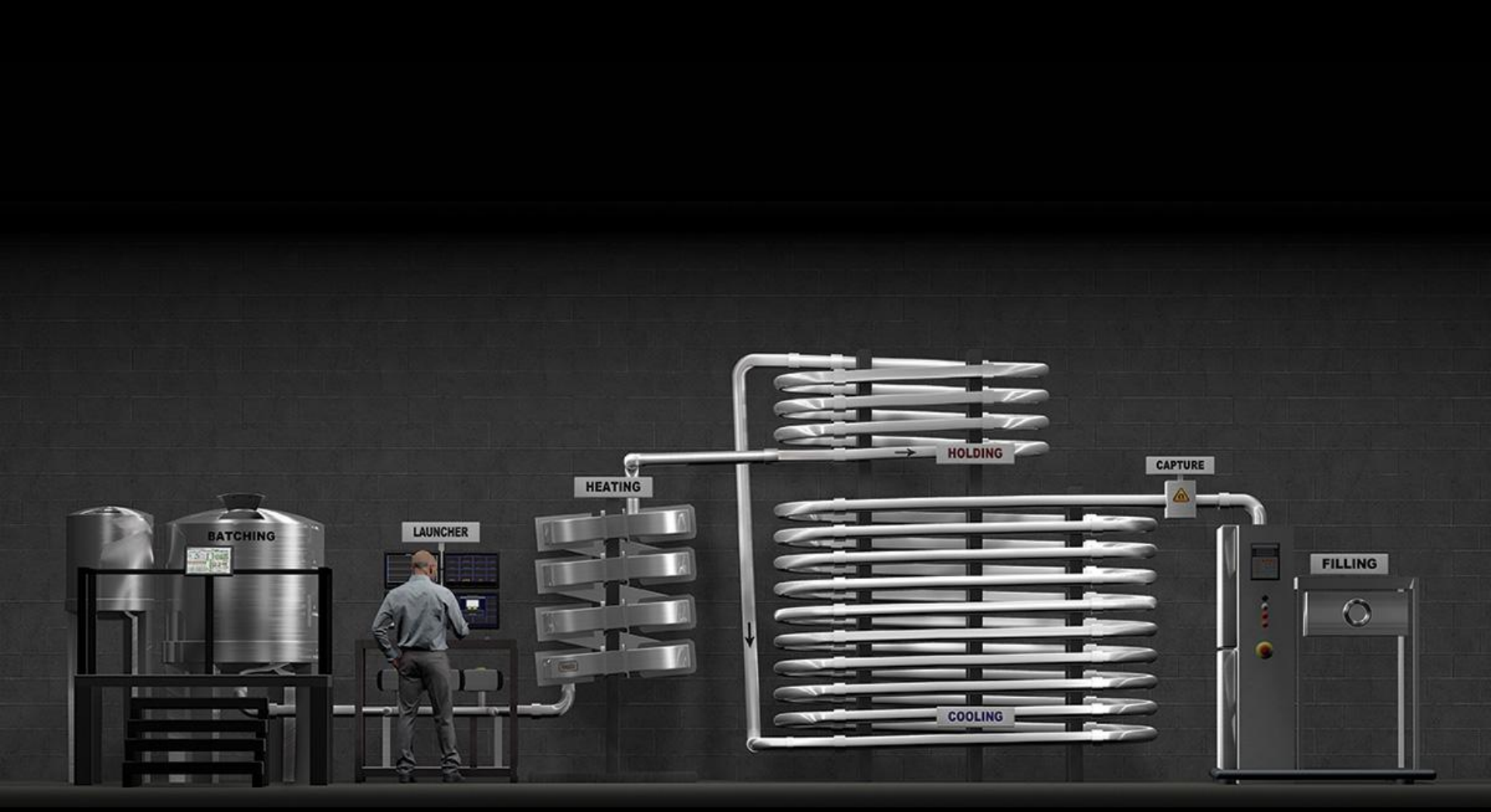

2009. Aseptia Inc. Donation to NCSU
100 kW 915 MHz Continuous Flow MW System
ASEPTIWAVE™
Aseptia

ASEPTIWAVE™

Heat the **product,** not the pipes.

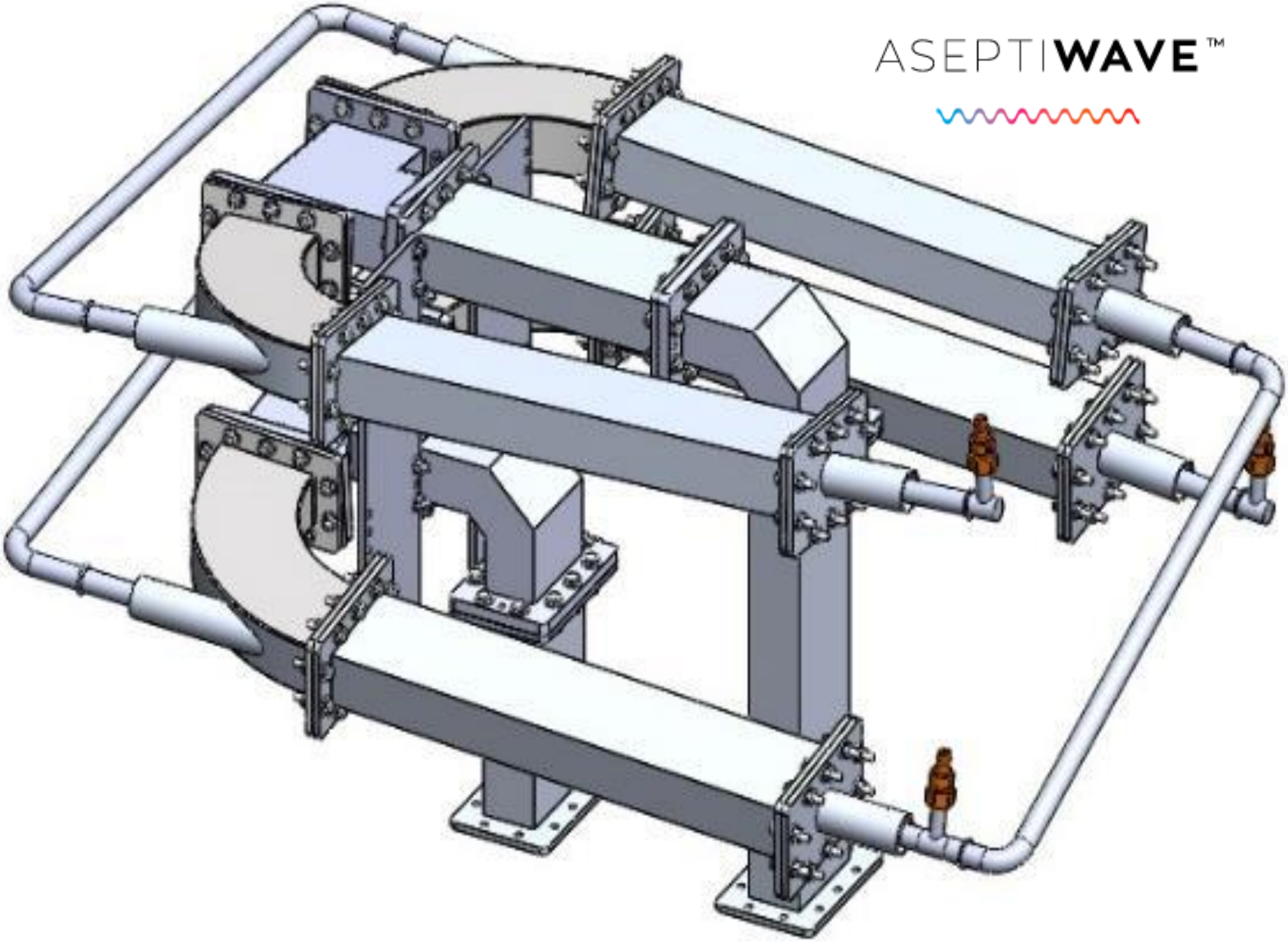
AseptiWave™ introduces a totally new paradigm to the industry. Remove the inefficiencies of traditional heating technology and start heating the product itself. The benefits are huge.

Aseptia

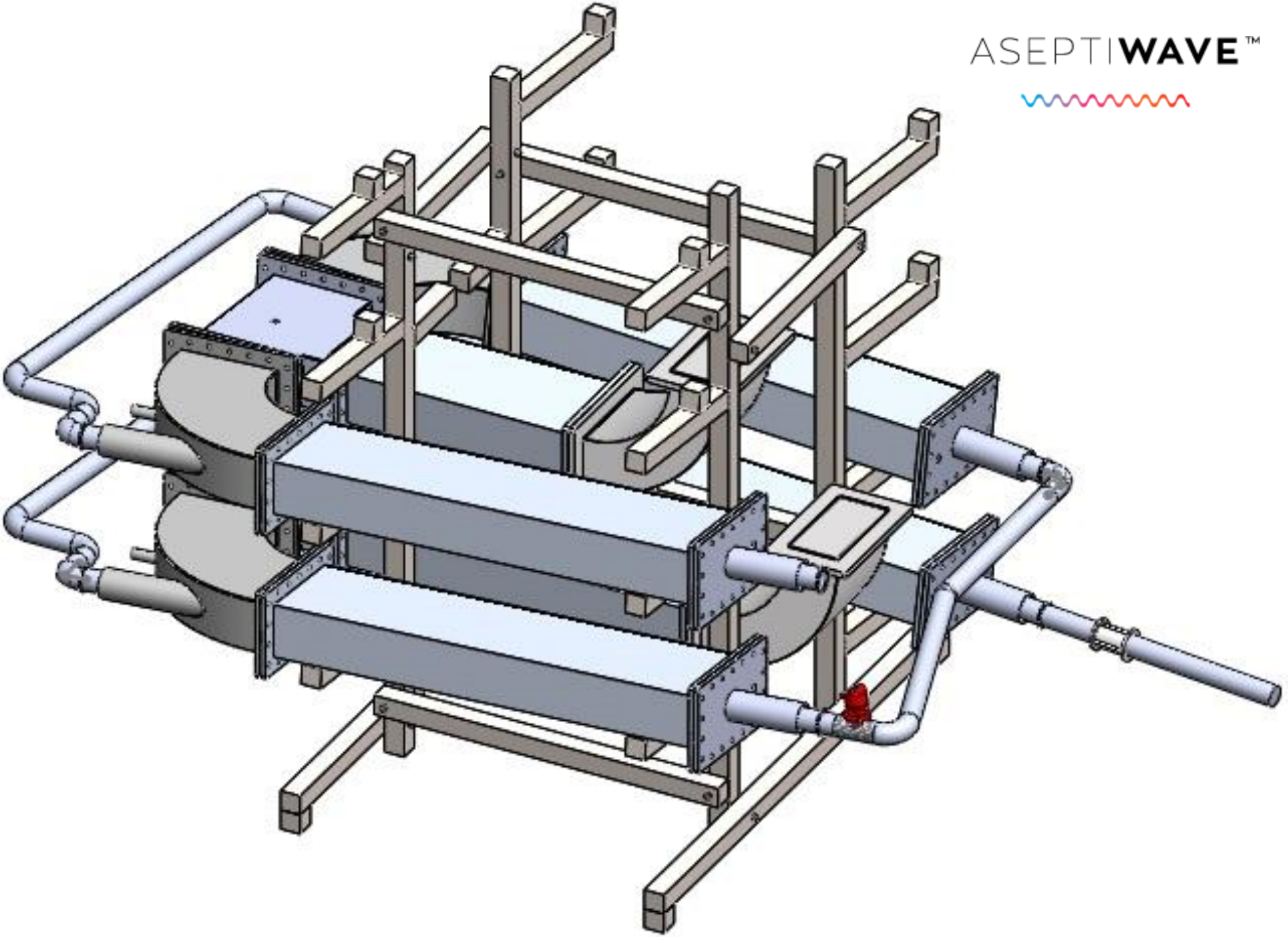

BATCHING
LAUNCHER
HEATING
HOLDING
CAPTURE
FILLING
COOLING

Aseptia

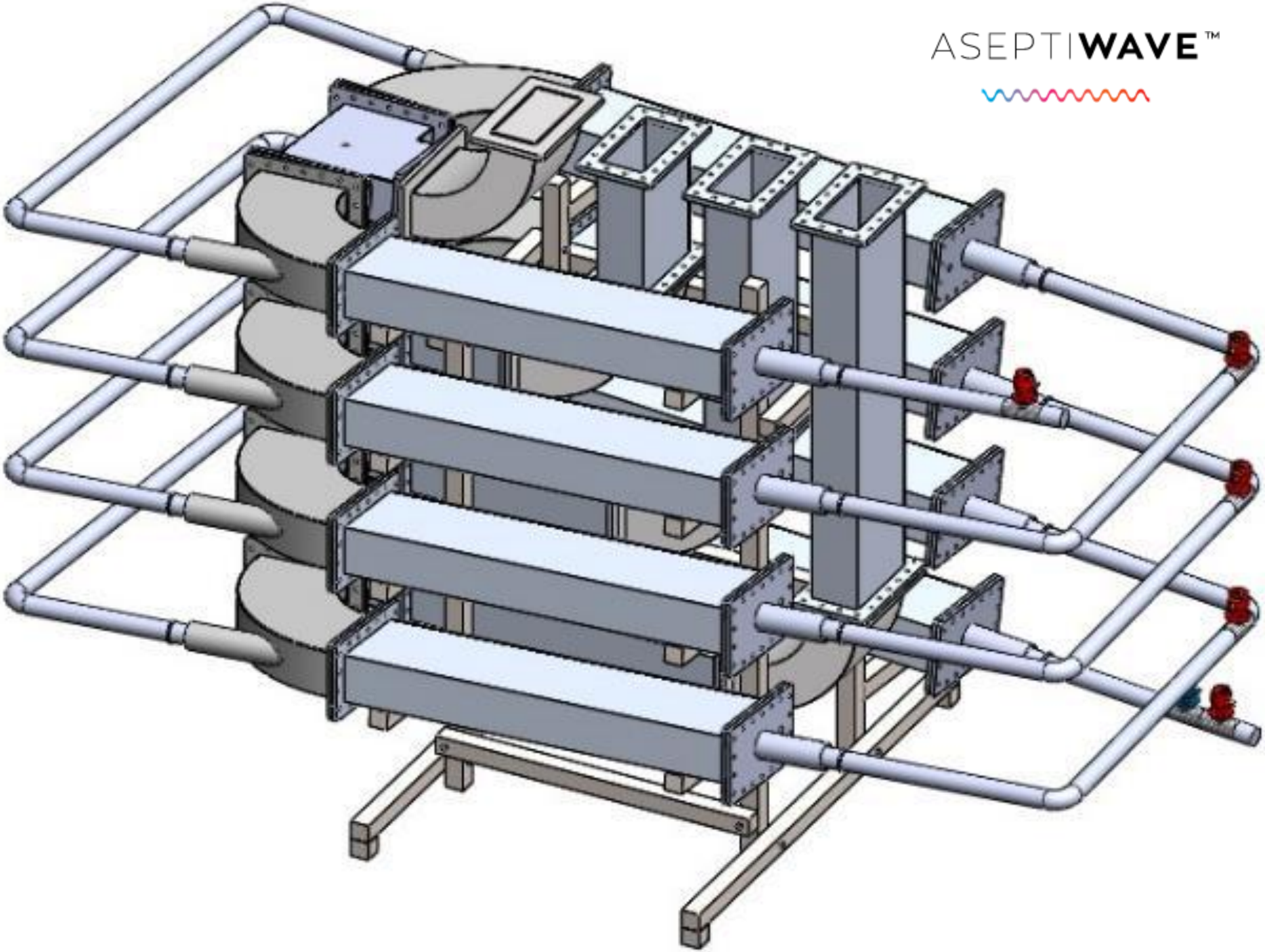
ASEPTIWAVE™



ASEPTIWAVE™



ASEPTIWAVE™



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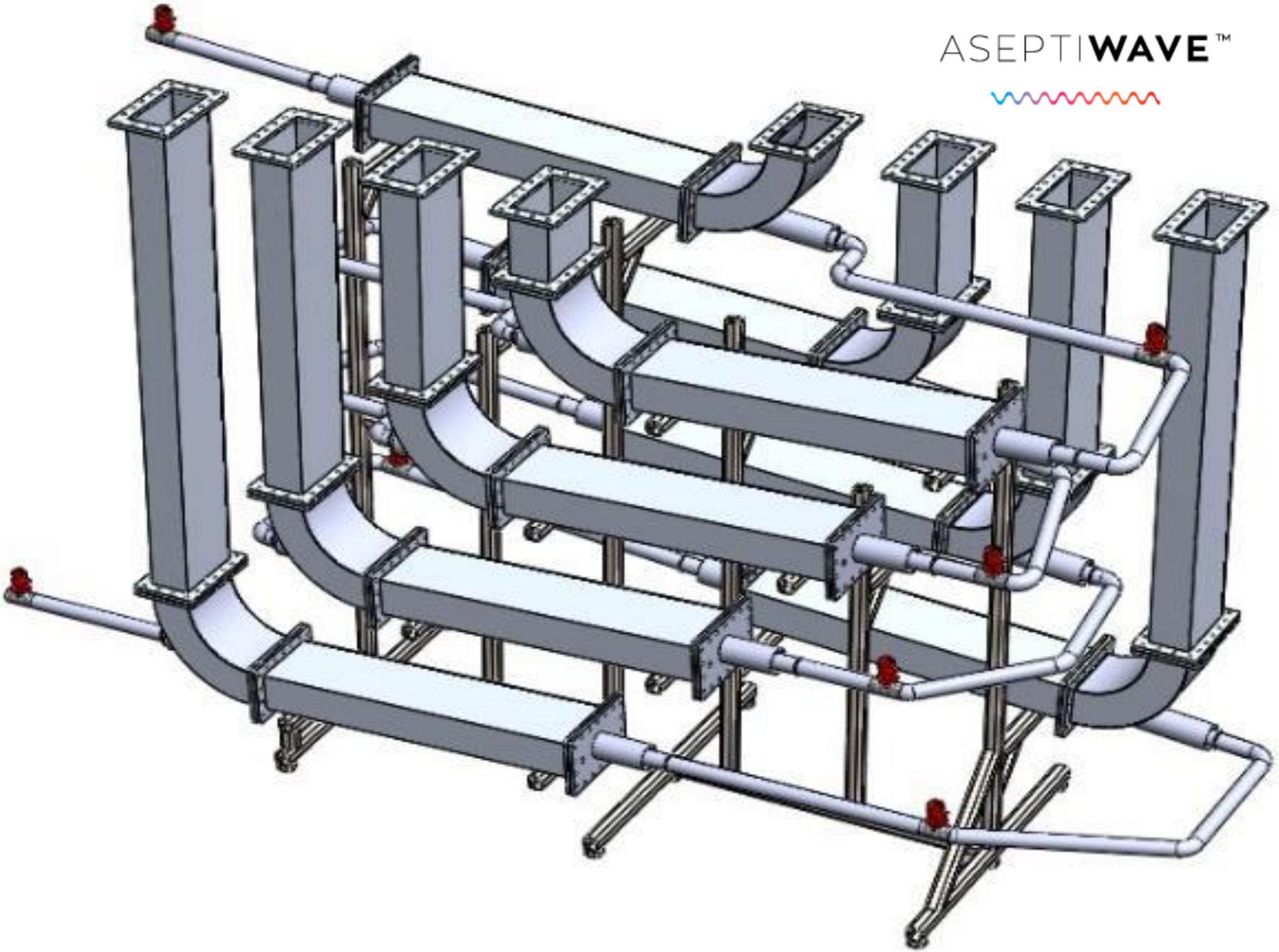


ASEPTIWAVE™

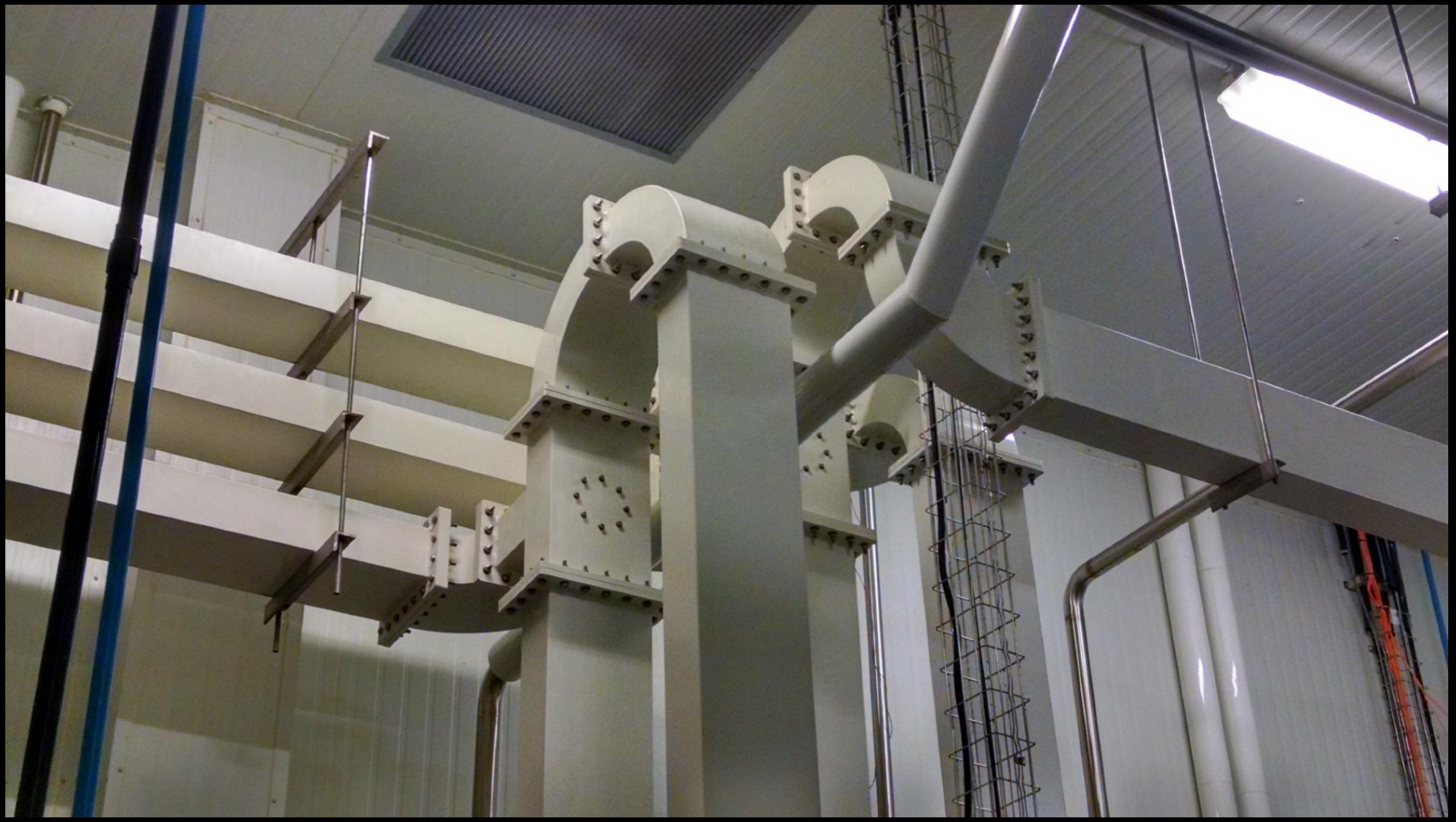
Aseptia

ASEPTIWAVE™

Aseptia

ASEPTIWAVE™

Aseptia



ASEPTIWAVE™

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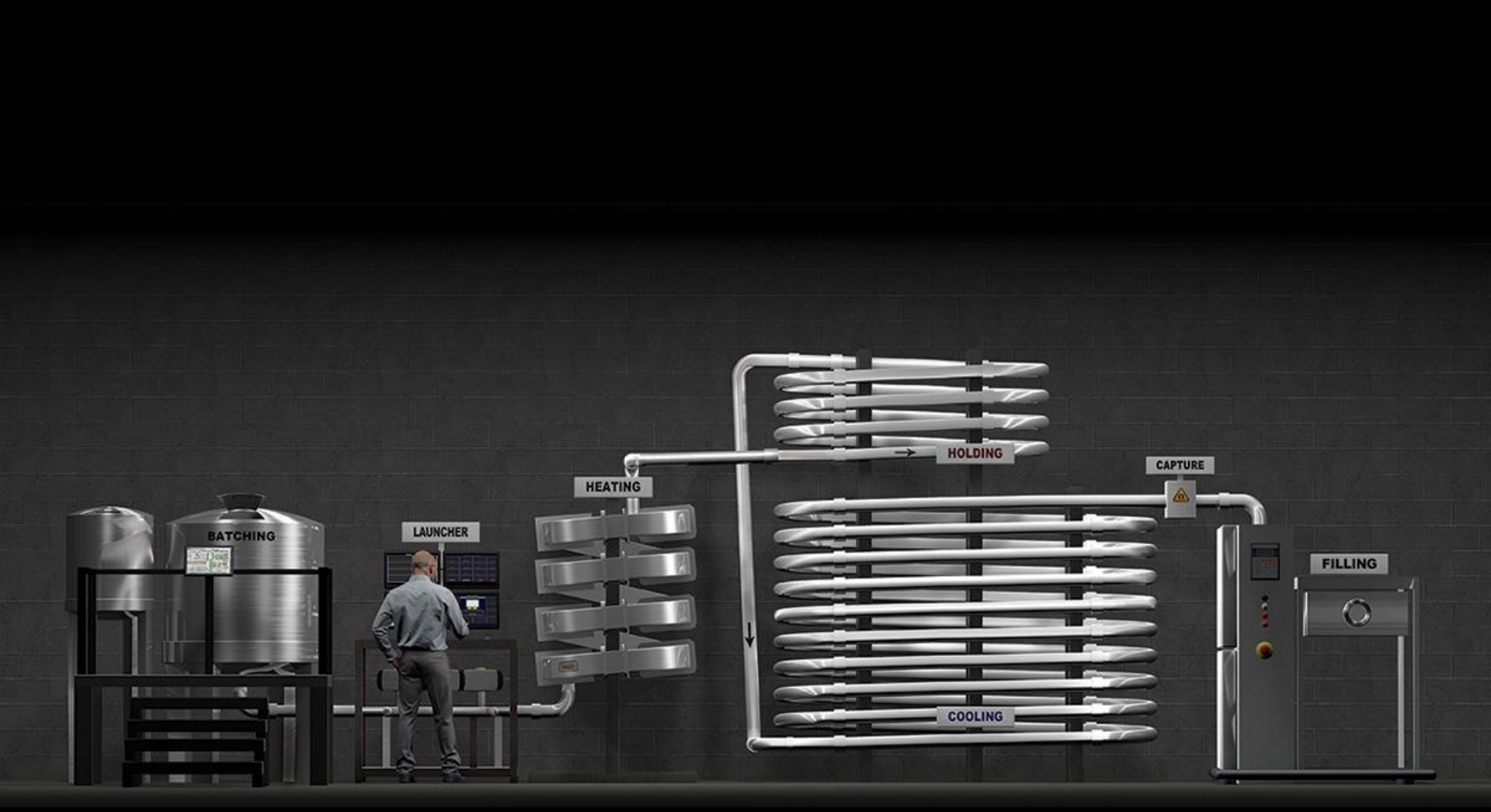
ASEPTIWAVE™

Aseptia



ASEPTIWAVE™

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ASEPTISENSE™

Get **inside** your validation.

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ASEPTISENSE™

BioPods™

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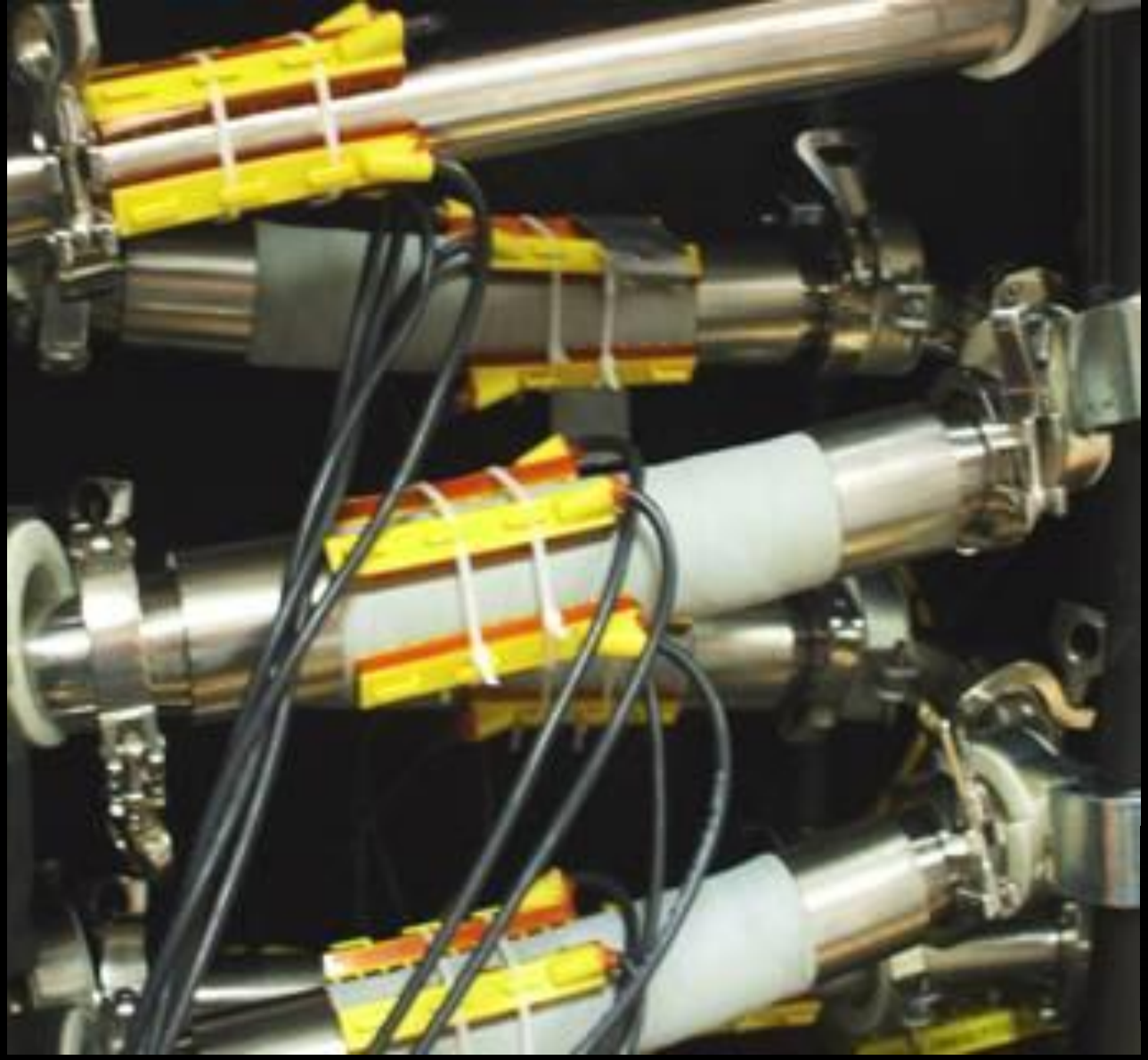
ASEPTI**SENSE**™

ASEPTI**SENSE**™

ASEPTISENSE™

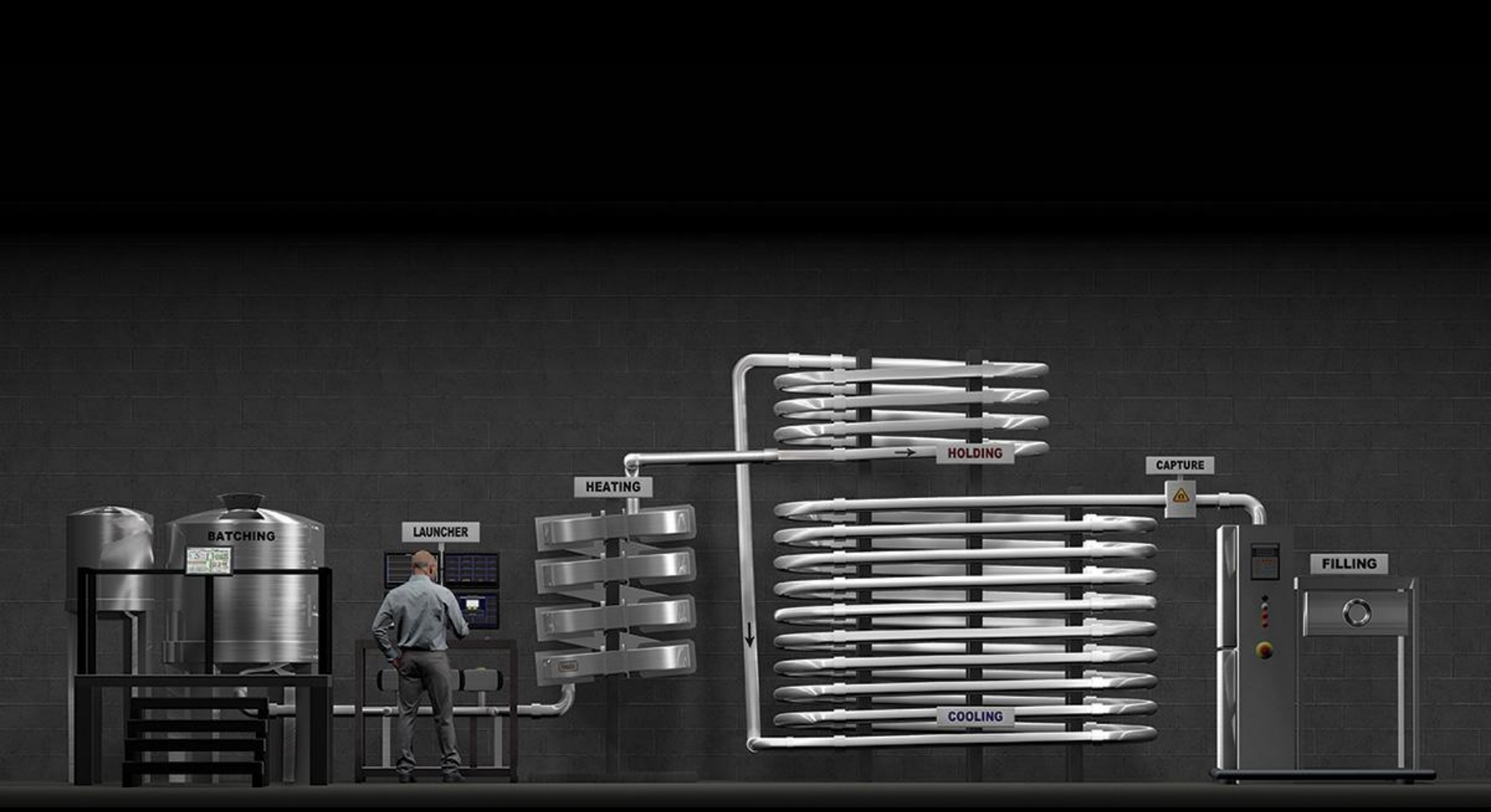


ASEPTISENSE™

Aseptia

ASEPTISENSE™

Aseptia


BATCHING
LAUNCHER
HEATING
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CAPTURE
FILLING
COOLING

Aseptia

A BioPod's Journey through AseptiSense

ASEPTISENSE™

1. Launch

BioPods with the embedded bio-cache are launched just prior to heating.

2. Heat

BioPods are tracked through the heating process. Information on temperature, velocity, and split-times between sensors are recorded. The captured data is critical in identifying validation failures that are due to uneven heating or a lack of sufficient initial heating.

3. Hold

The holding area is critical in ensuring successful product sterilization. If effective sterilization temperatures were achieved during heating then effective *times* for sterilization will be achieved here in the holding area. AseptiSense sensors are largely concentrated in this area to account for the importance of overseeing the product's time-at-temperature.

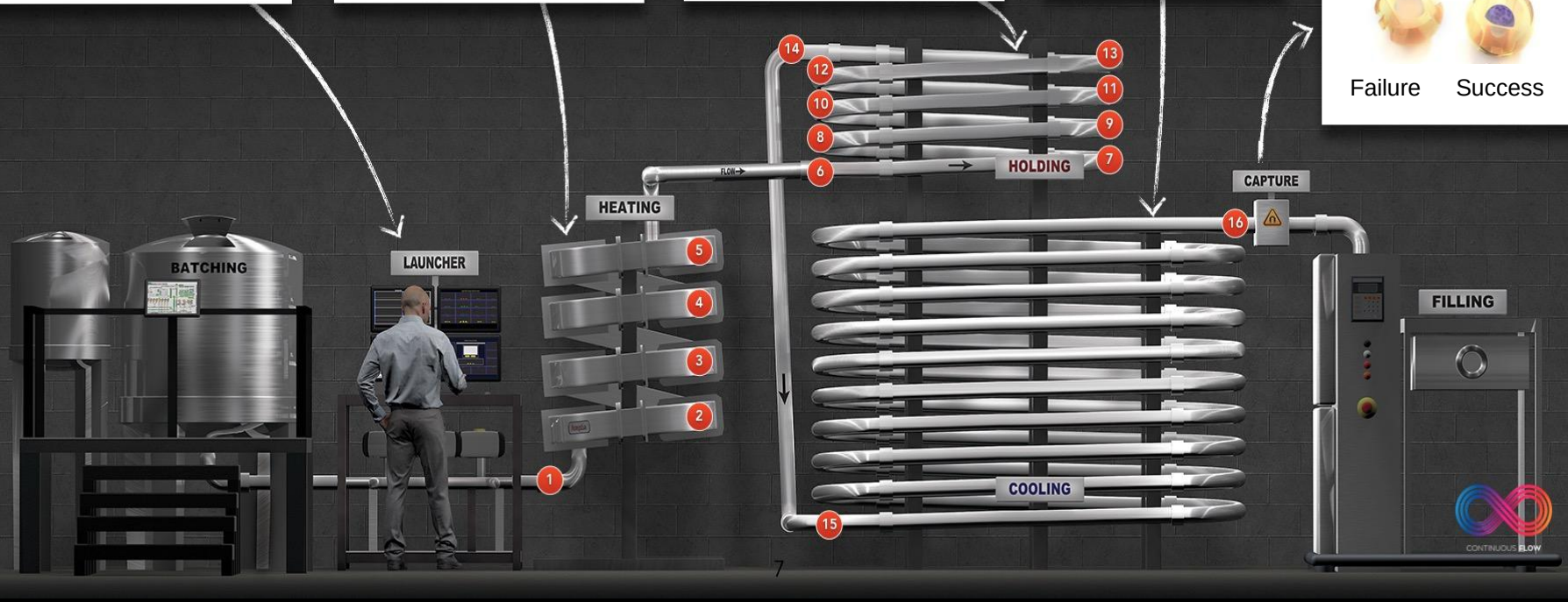
4. Cool

A reduced number of sensors are used in the cooling section because the success of sterilization has already been determined in the Heat and Hold sections. Sensors in the cooling area may give more insight.

5. Capture

BioPods are captured using a proprietary device and inoculated in-situ for 72 hours. After inoculation inspection immediately delivers the results on the success or failure of the process.

Failure Success



Combibloc Aseptic Carton Line

SIG Combibloc CB505 filler

Line capable of filling beverages, purees, and particulate (chunky) products

Five sizes – 500mL, 750mL, 32ounce, 1L

Tear off and screw top available

Aseptia

Aseptic Form Fill and Seal – Sealed Air Flavour Mark FMAS5005

Aseptia

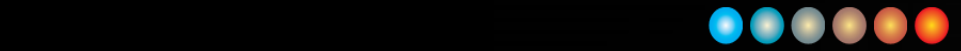
Aseptia

ASEPTIWAVE™

ASEPTISENSE™

Aseptia

ASEPTISENSE™



Aseptia

EDISON AWARDS
EDISON UNIVERSE
GOLD
ASEPTIWAVE™
Aseptia

BLACK & VEATCH
EDISON AWARDS
cisco
EDISON AWARDS
ERPILLAR
EDISON AWARDS
WINNER
2016
ASEPTISENSE™
Aseptia

Dr. Josip Simunovic
Aseptia Co-Founder &
Chief Science Officer
Research and Development
Award 2016

IFT 2015 Food Expo
Innovation Award

IFT 2015 Industrial
Achievement Award

Dr. Pablo Coronel
Aseptia Process Authority
Industrial Scientist Award 2015

Edison Award
Gold, 2015

Edison Award
Silver, 2016

Ranked #20
Fastest Growing
Private Companies
in America 2015

Top 100 Most
Innovative Companies 2014

Aseptia

In 2015, Aseptia received two FDA letters of no questions, allowing commercial production of aseptically packaged, low acid particulate products preserved using AseptiWave, Aseptia's continuous flow microwave sterilization technology:

1. For single solid / particulate ingredient products
2. For multiple solid / particulate ingredient products

Validation and data generation for the filings have been performed using AseptiSense, Aseptia's particle flow monitoring and safety valiation system.

Aseptia

Dr. Pablo Coronel

Aseptia Process Authority

2015 IFT Industrial Scientist Award

> 50 FDA Filings

- FDA LONQ for MW sterilized single particulate type soup
- FDA LONQ for MW sterilized multiple particulate type soup

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Objective of validation

- To provide **scientific proof** that the process will be safe
  - Comply with regulations (21 CFR 113, 21 CFR 110)
  - Literature data
  - Temperature data
  - Microbial inoculation / challenges

- Worst case [particle] must be defined
  - Thermal treatment should be **conservative**

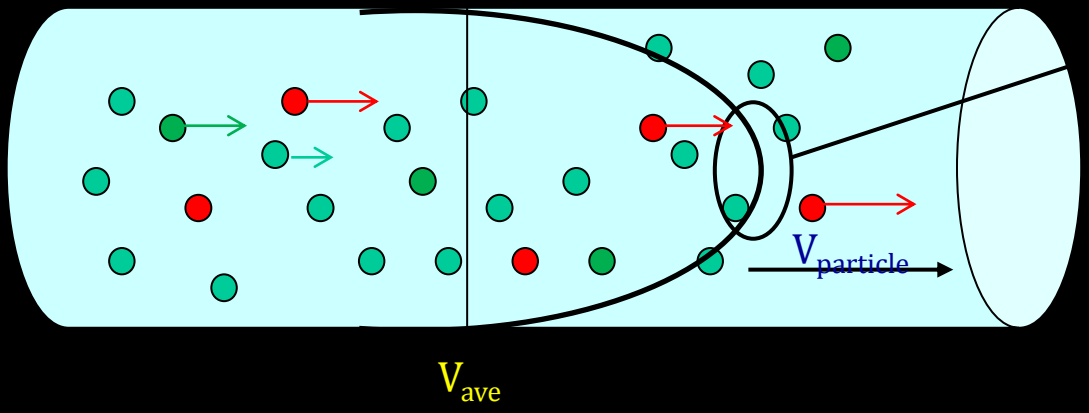
What about particles?

- Temperature history **inside** the particles determines the thermal process given to them
  - Monitoring temperatures inside particles is not practically achievable
  - Temperature of liquid can be monitored
- Particulate foods need to be characterized based on their properties

What about particles?

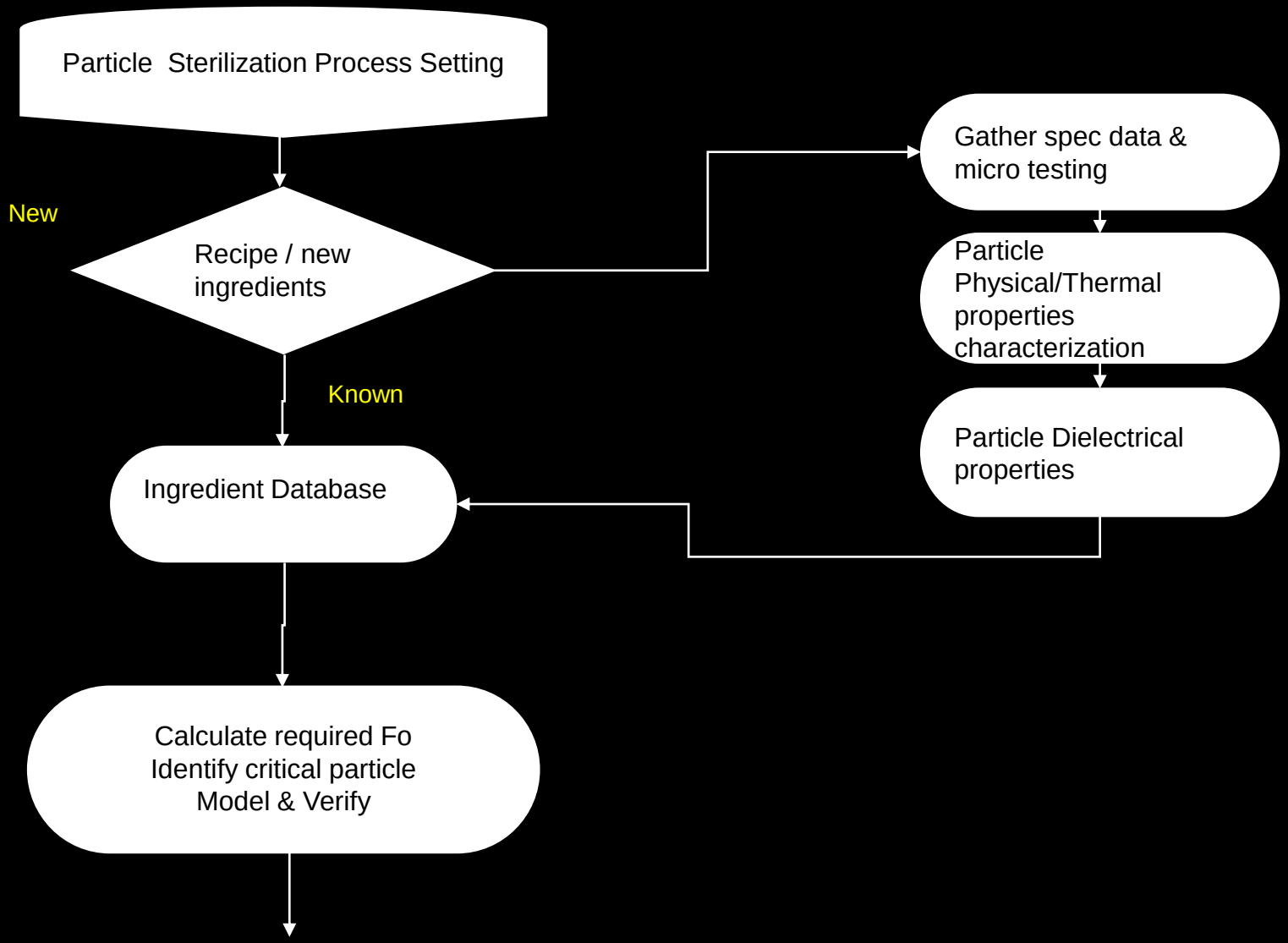
Particle processing needs to be characterized both theoretically and experimentally

- Particles shape /size / distribution
- Which is the fastest ?
- Which is the slowest heating ?
- What is the effect of natural variation
- How fast does it heat in advanced heating technologies?

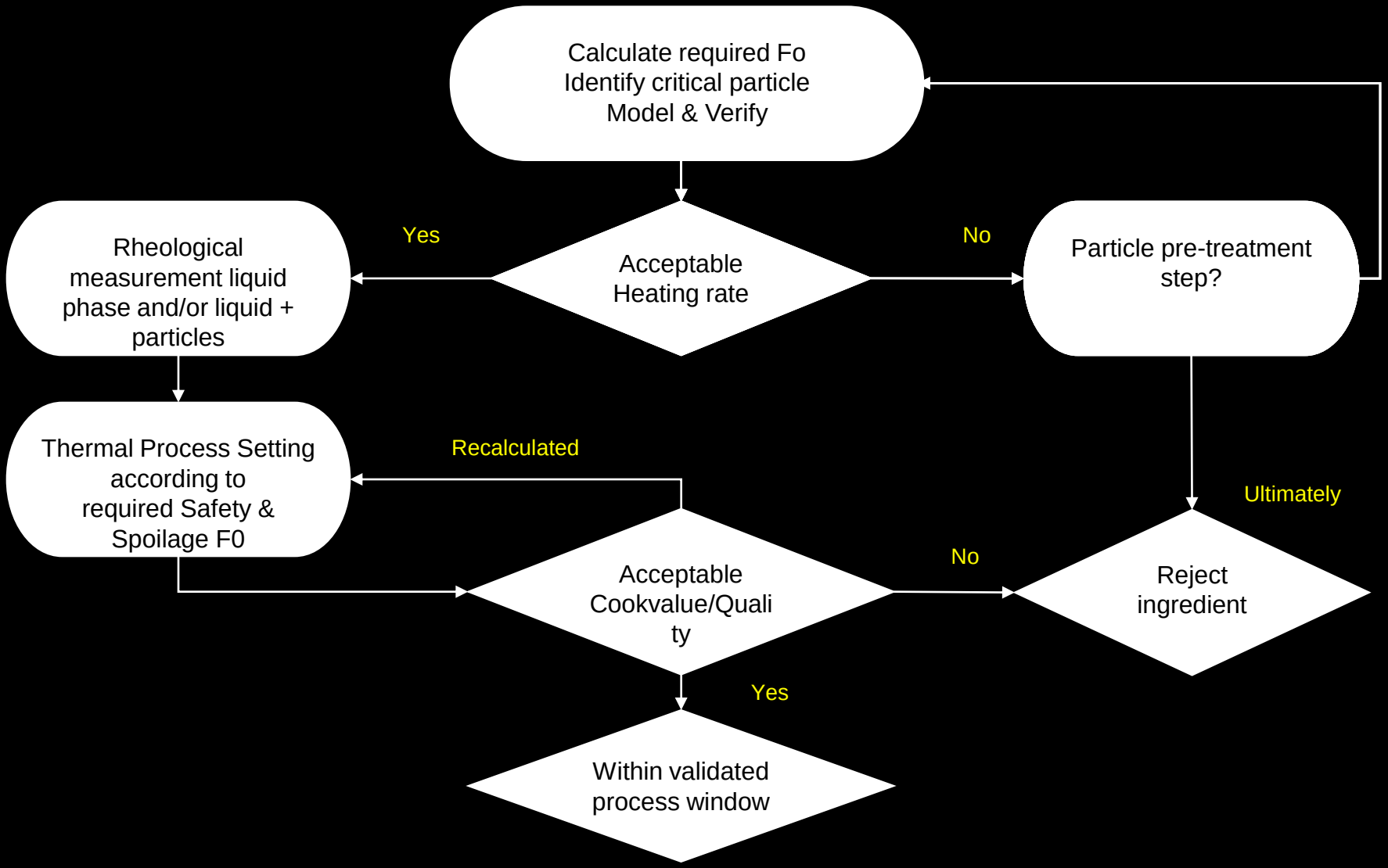


$V_{max} = 2\ V_{ave}$??

Particle Validation Pathway



Particle Validation Pathway



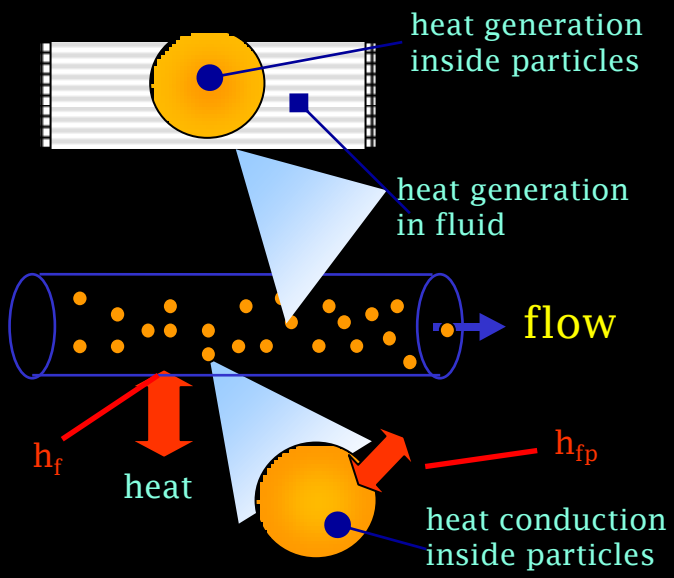
Particle Validation Pathway

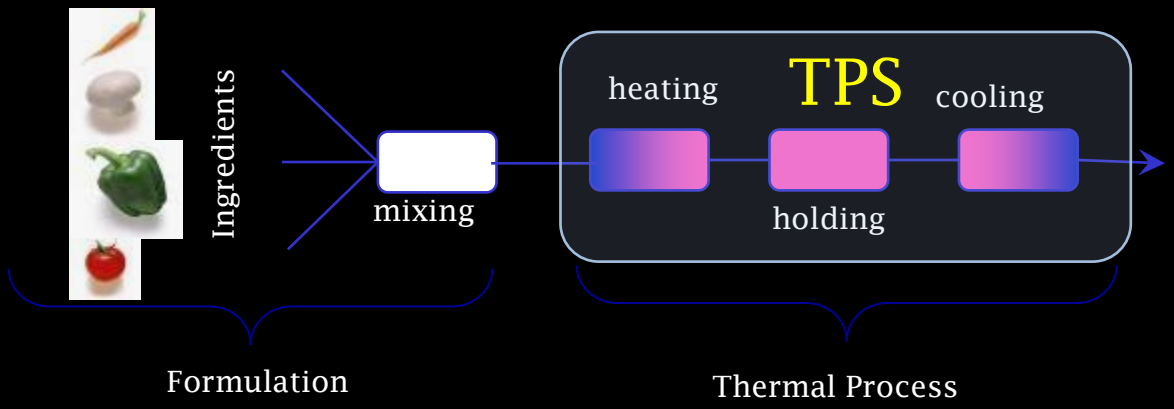
1. Develop mathematical model for process
2. Create a database of ingredients
   - Thermal Properties
   - Dielectric Properties
   - Flow properties
3. Simulated particles
   - Design based on conservative characteristics
4. Test temperature penetration of surrogate particles and real food
5. Instrumentation
   - Back pressure for particles
   - Instrumentation (RTD – Temperatures)
6. Microbial Challenges

Mathematical Model

Thermal Process Simulator (TPS)

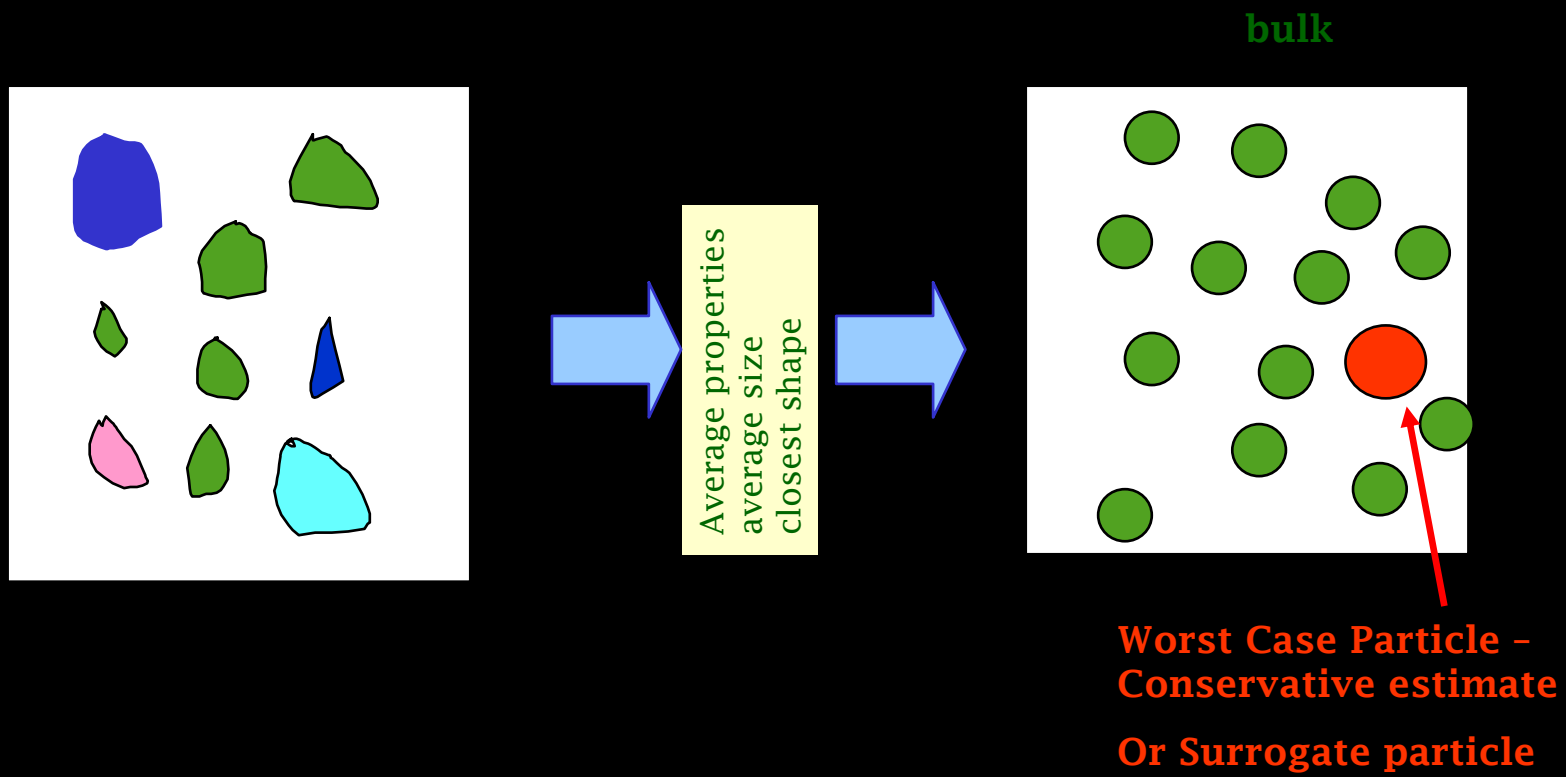
- Model built to simulate temperature in continuous processing
- Product Properties, and Process Line configuration are the input of the model
- Temperature profile is the output
- Safety and Quality parameters are calculated

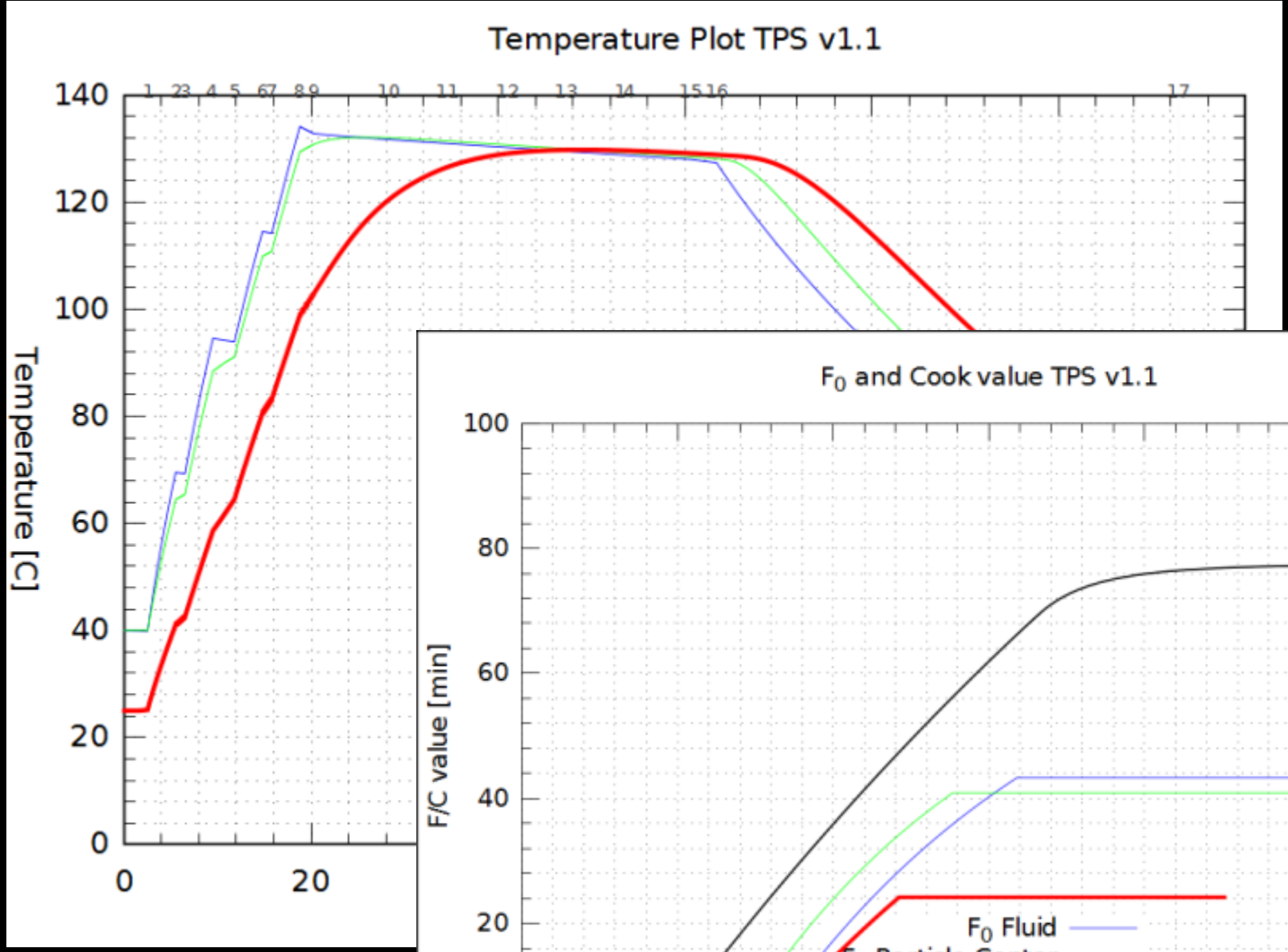




Mathematical Model

Particle population is approximated to one uniform bulk population in a carrier fluid and a worst case




Temperature Plot TPS v1.1
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80
100
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2
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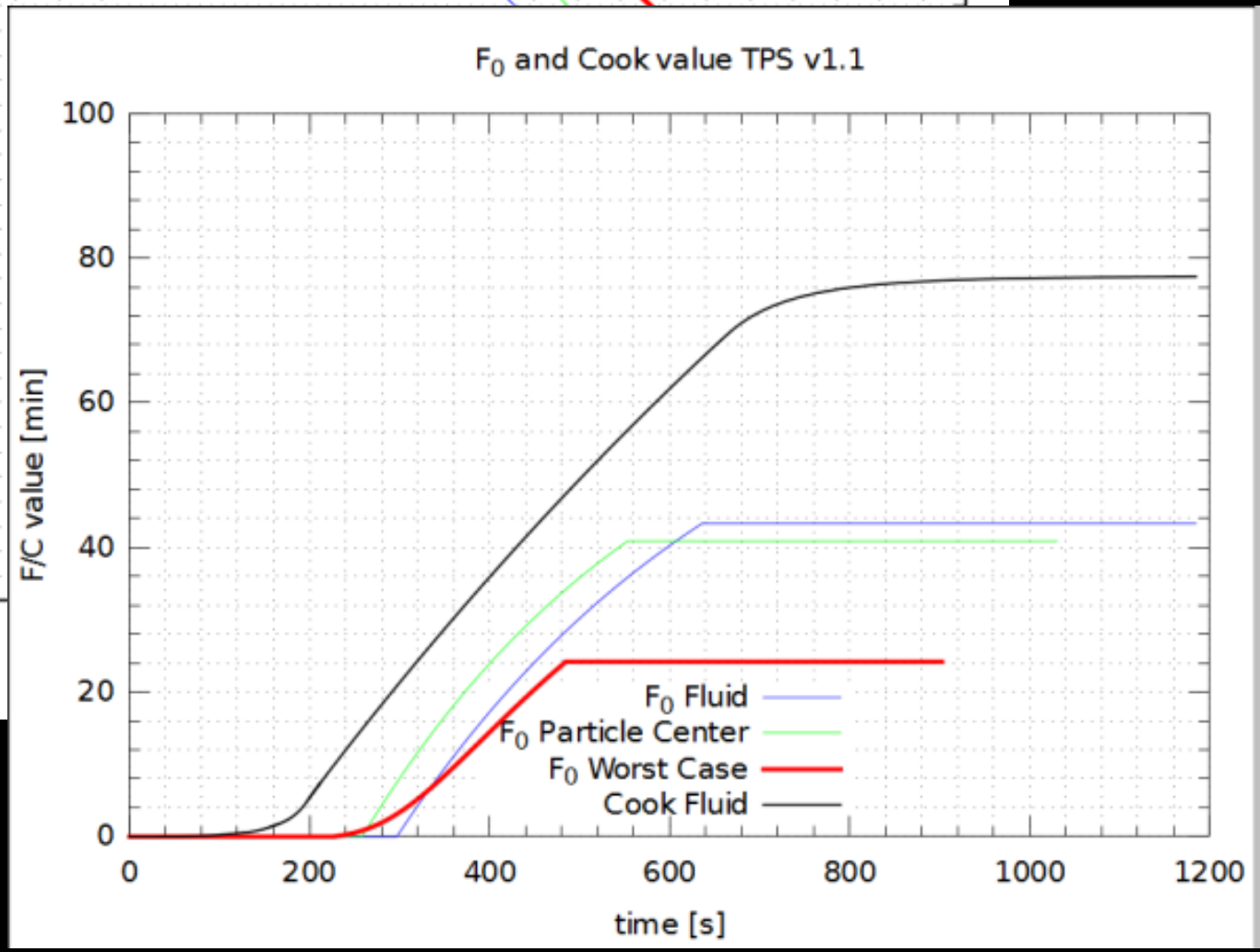
F_0 and Cook value TPS v1.1
F/C value [min]
0
20
40
60
80
100
0
200
400
600
800
1000
1200
time [s]
F_0 Fluid
F_0 Particle Center
F_0 Worst Case
Cook Fluid

MODEL NEEDS TO BE VALIDATED!!!

Particle Validation Pathway

1. ☑ Develop mathematical model for process
2. Create a database of ingredients
   - Thermal Properties
   - Dielectric Properties
   - Flow properties
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Ingredient Database

- Thermal properties
  - Thermal Conductivity
  - Cp
  - Thermal Diffusivity
- Flow properties
  - Density
  - Rheology
- Electrical / Dielectric Properties
  - Dielectric Properties
  - Electrical Conductivity

Particle Validation Pathway

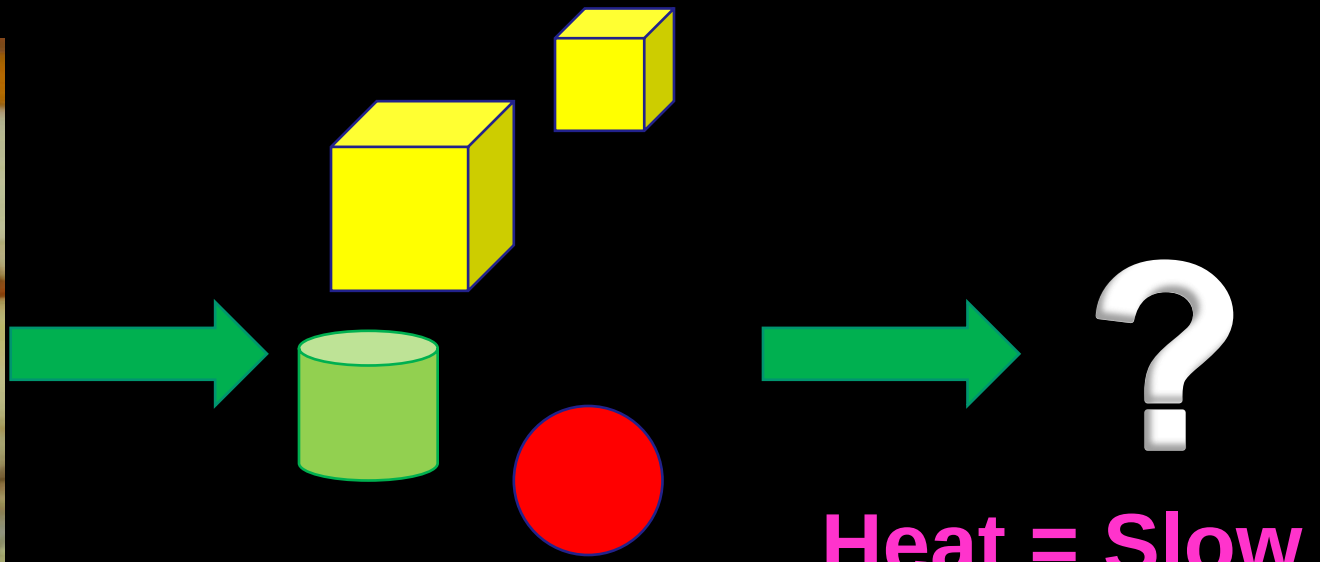
- [x] Develop mathematical model for process
- [x] Create a database of ingredients
  - Thermal Properties
  - Dielectric Properties
  - Flow properties

3. Simulated particles
   - Design based on conservative characteristics
4. Test temperature penetration of surrogate particles and real food
5. Instrumentation
   - Back pressure for particles
   - Instrumentation (RTD – Temperatures)
6. Microbial Challenges

Determination of Critical Particle

Which is the most conservative particle?

- Thermal and physical properties
- Account for variations of properties due to natural variability /process
- Simulate



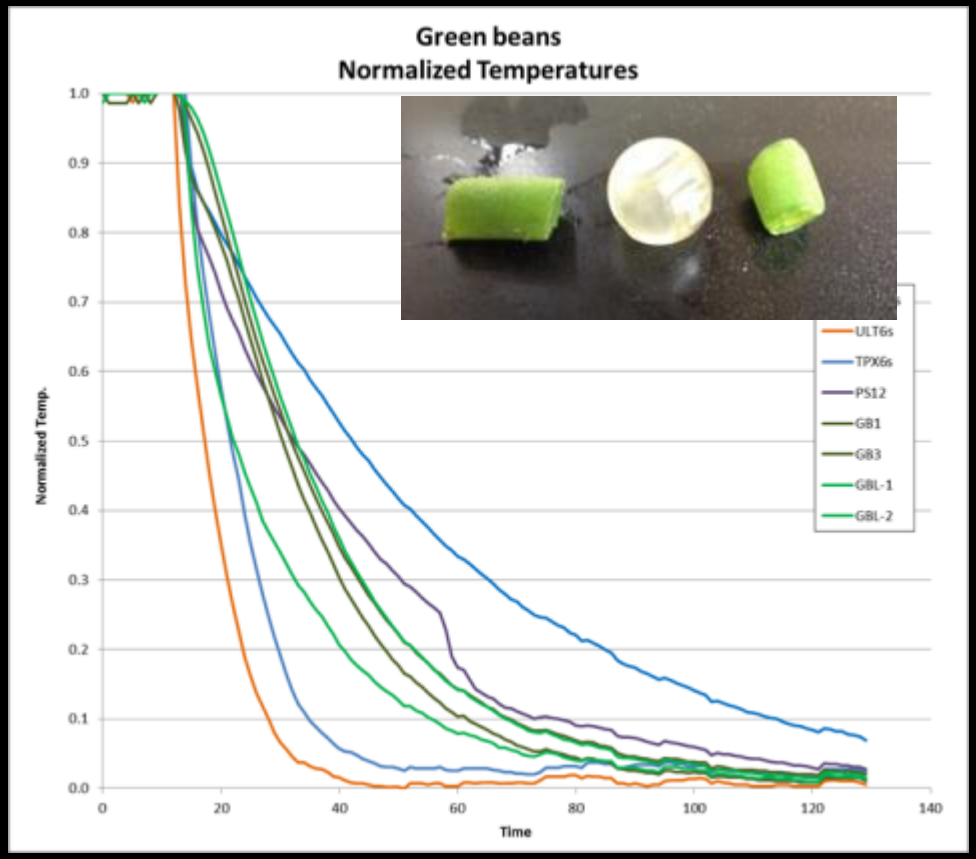
Heat = Slow
Flow = Fast

ASEPTISENSE™

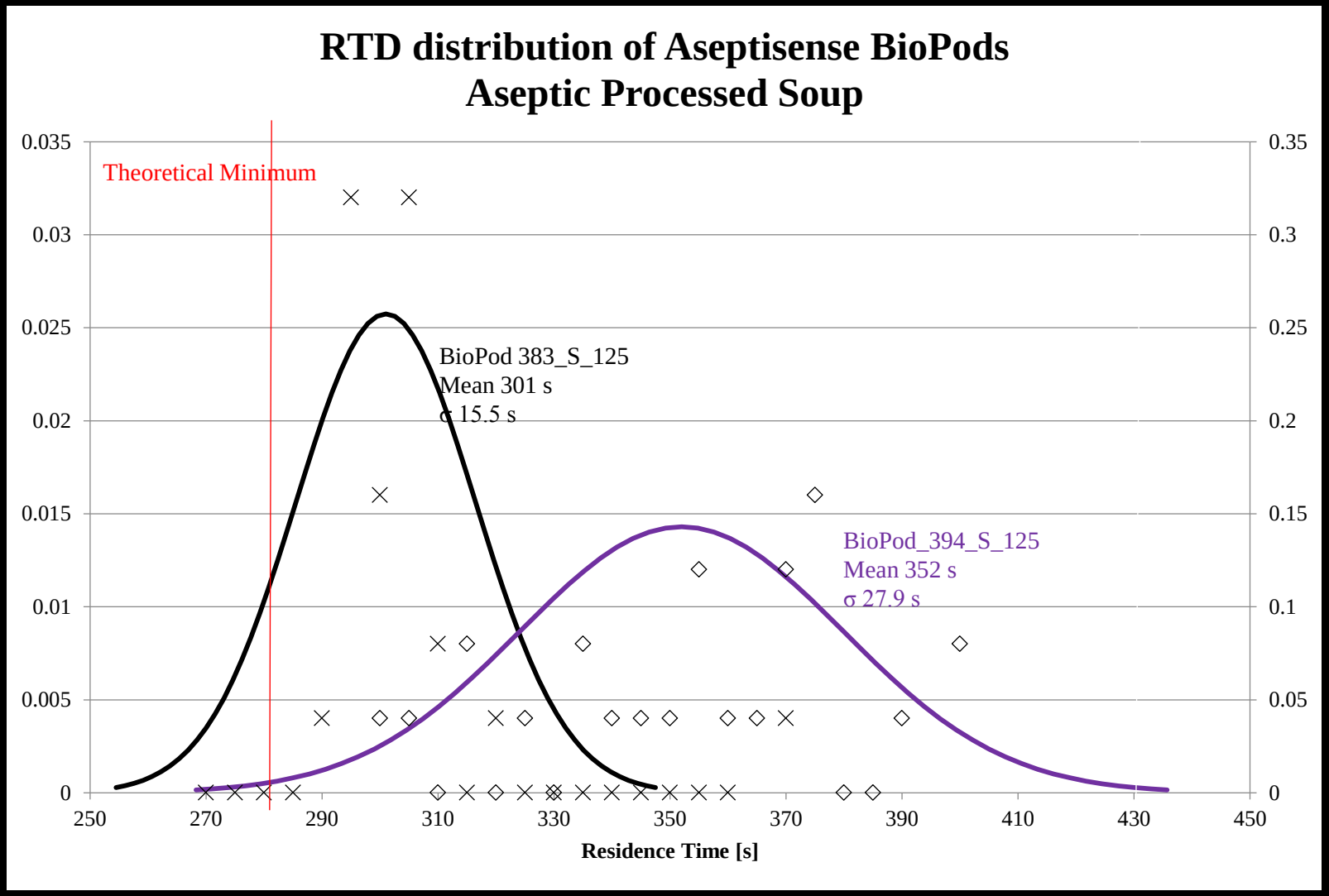
Aseptisense BioPods are used as simulated particle to determine the worst case for validation

Simulated particles can be **engineered** to be representative of the critical particle

Thermally conservative



Flow conservative



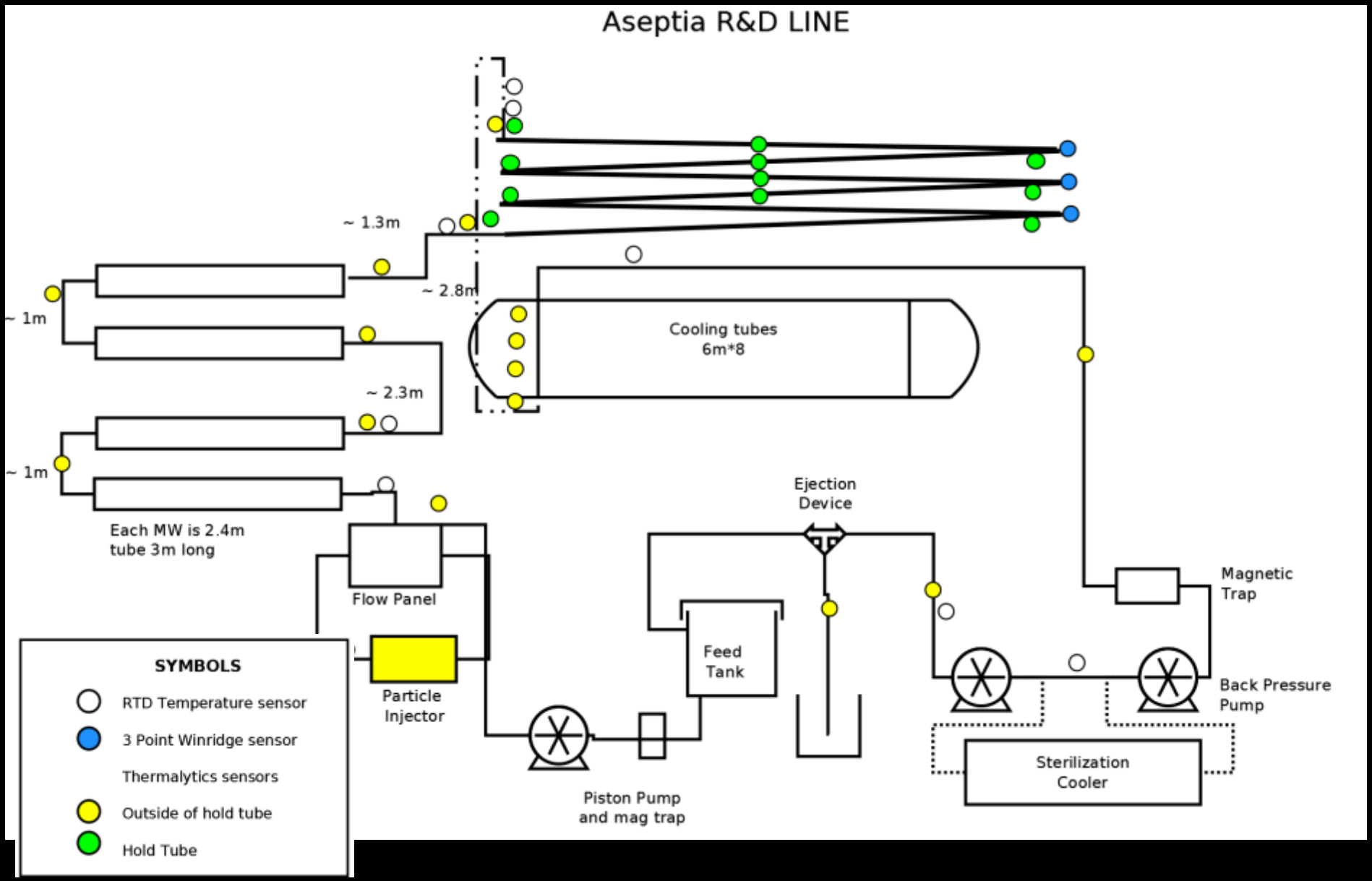
Due to conservative nature of particles, both thermally and flow-wise it is expected that if surrogate particles are properly treated all other particles will be properly processed

Particle Validation Pathway

- ☑ Develop mathematical model for process
- ☑ Create a database of ingredients
  - Thermal Properties
  - Dielectric Properties
  - Flow properties
- ☑ Simulated particles
  - Design based on conservative characteristics
- ☑ Test temperature penetration of surrogate particles and real food

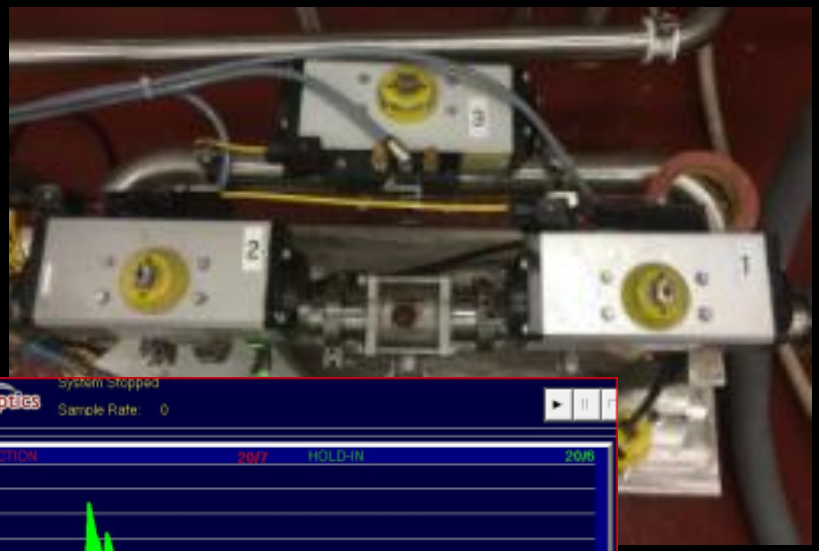
5. Instrumentation
   - Back pressure for particles
   - Instrumentation (RTD – Temperatures)
6. Microbial Challenges

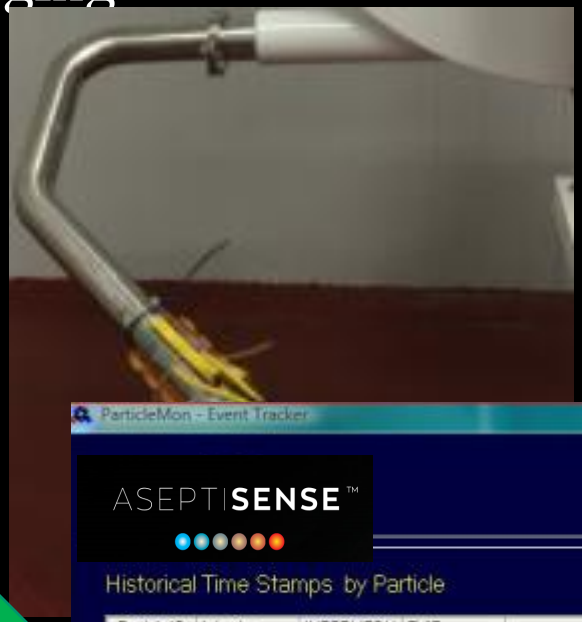
Instrumentation

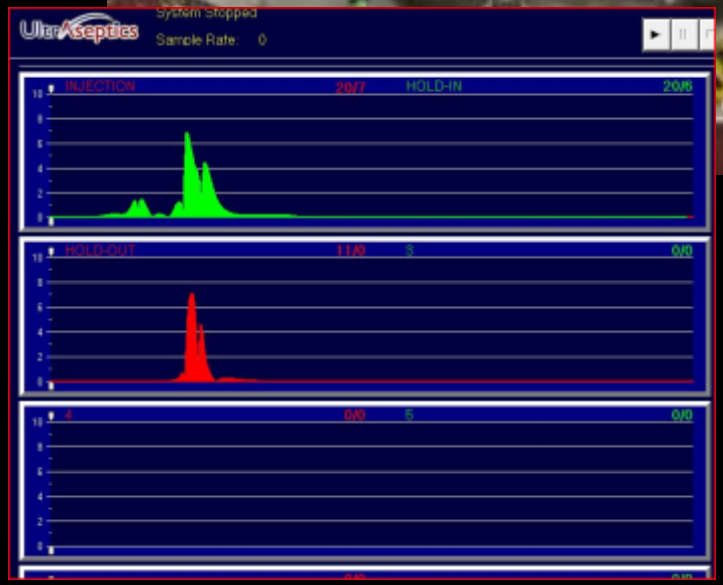


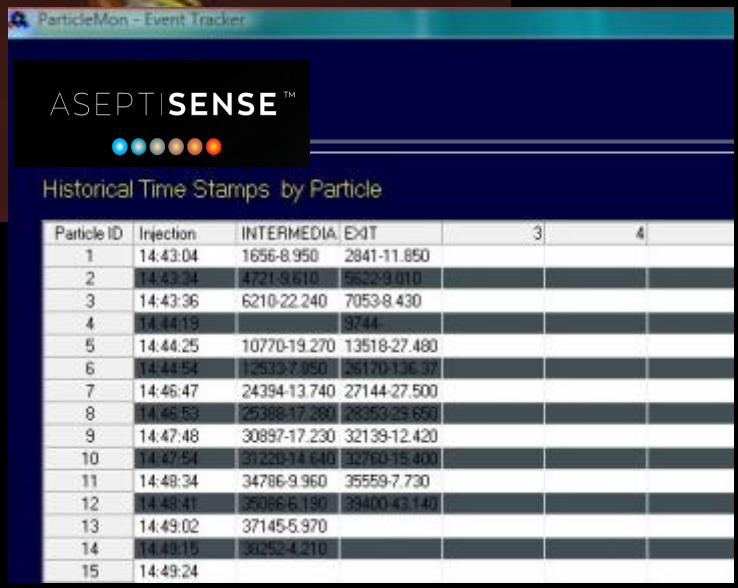
Instrumentation

- RTD sensors used are Aseptisense sensors
- Particle Injector, sensors and dataloging









Particle ID	Injection	INTERMEDIA	EXIT	3	4
1	14:43:04	1656-8.950	2841-11.850		
2	14:43:24	4721-8.610	5622-9.010		
3	14:43:36	6210-22.240	7053-8.430		
4	14:44:19		9744		
5	14:44:25	10770-19.270	13518-27.480		
6	14:44:54	12533-7.050	26120-136.37		
7	14:46:47	24394-13.740	27144-27.500		
8	14:46:53	25388-17.280	28353-23.650		
9	14:47:48	30897-17.230	32139-12.420		
10	14:47:54	31220-14.640	32760-15.400		
11	14:48:34	34786-9.960	35559-7.730		
12	14:48:41	35086-6.190	39400-43.140		
13	14:49:02	37145-5.970			
14	14:49:15	39252-4.210			
15	14:49:24				

Particle Validation Pathway

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Microbial Challenge

Thermal process is designed based on the worst case particle defined before

- RTD experimental (at temperature)
- Temperature profile estimated by Model

Modeled Lethality for the particles will be credited only in the holding tube

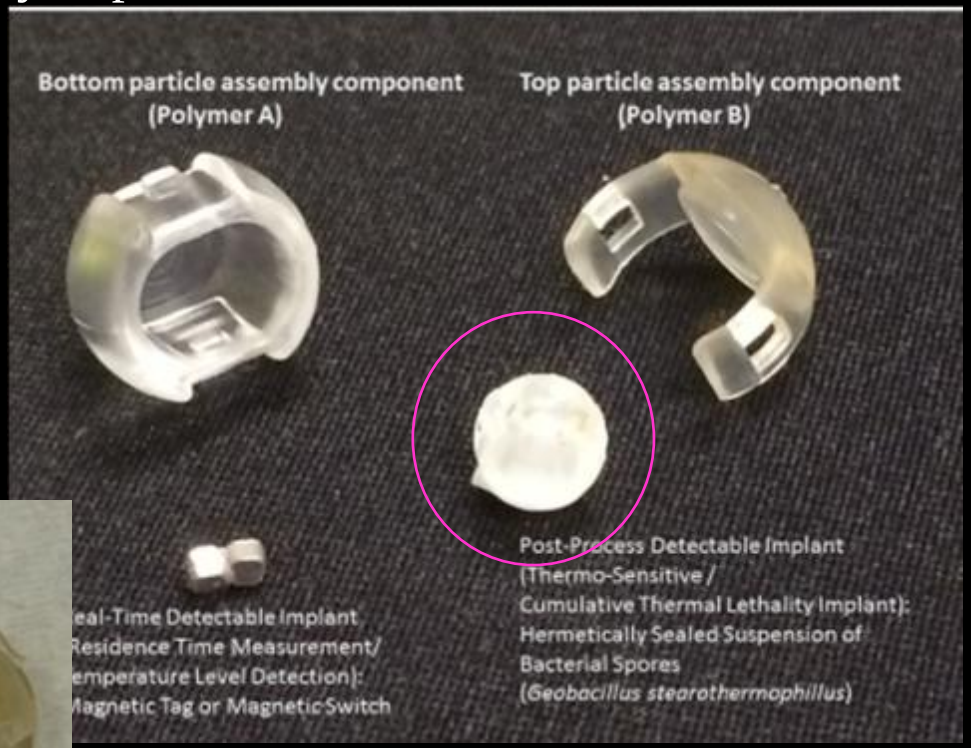
Theoretical setting and experimental confirmation

VALIDATE MODEL

Microbial Challenge

- Microbial loads are added to the surrogate particles either as load of the main particle or inside a secondary implant

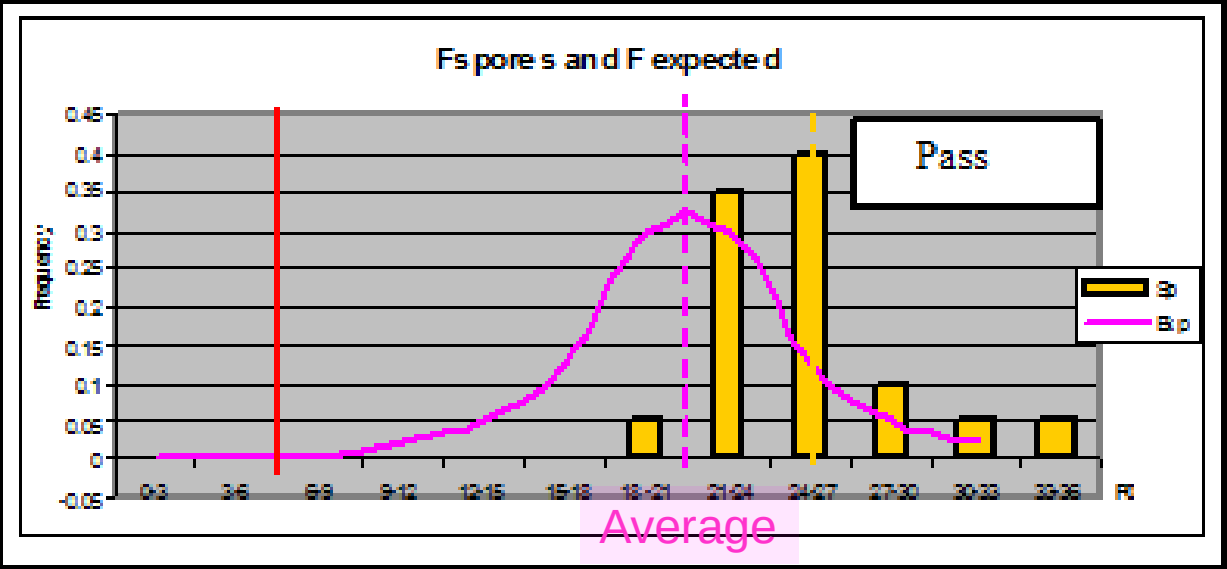
G.stearothermophillus from MesaLabs are used
These suspensions have a colored indicator for growth.
The indicator gives a simple positive/negative read after 48h of incubation
D_{121} = 1.5 min
Z = 7.8 C



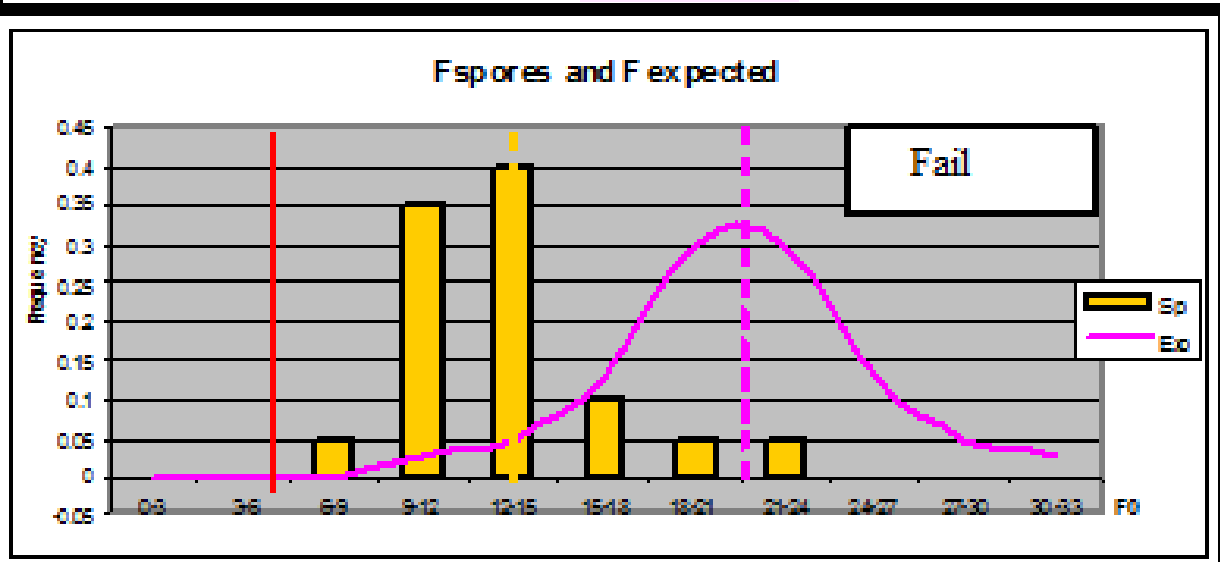
Microbial Challenge

MODEL VALIDATION

Predicted



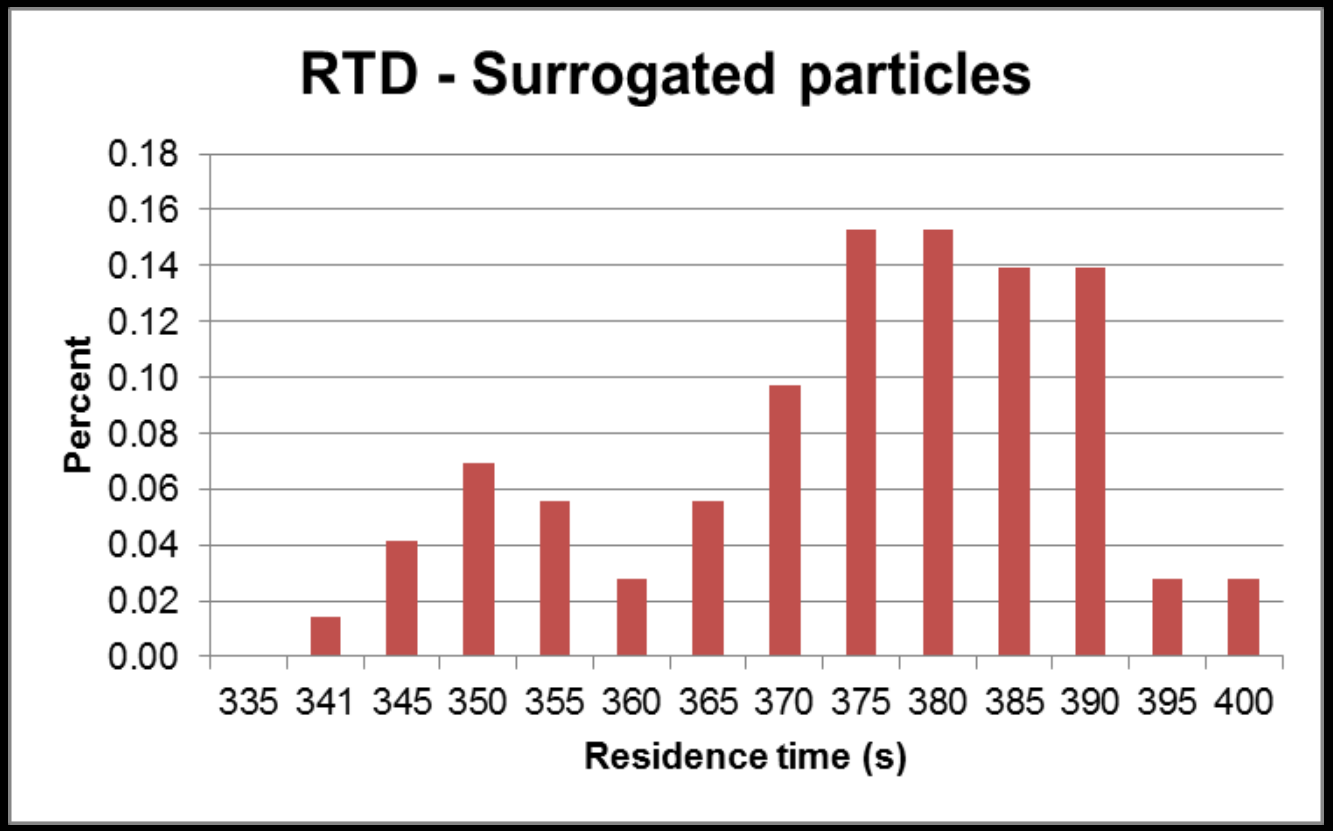
Observed



ASEPTISENSE

MODEL VALIDATION

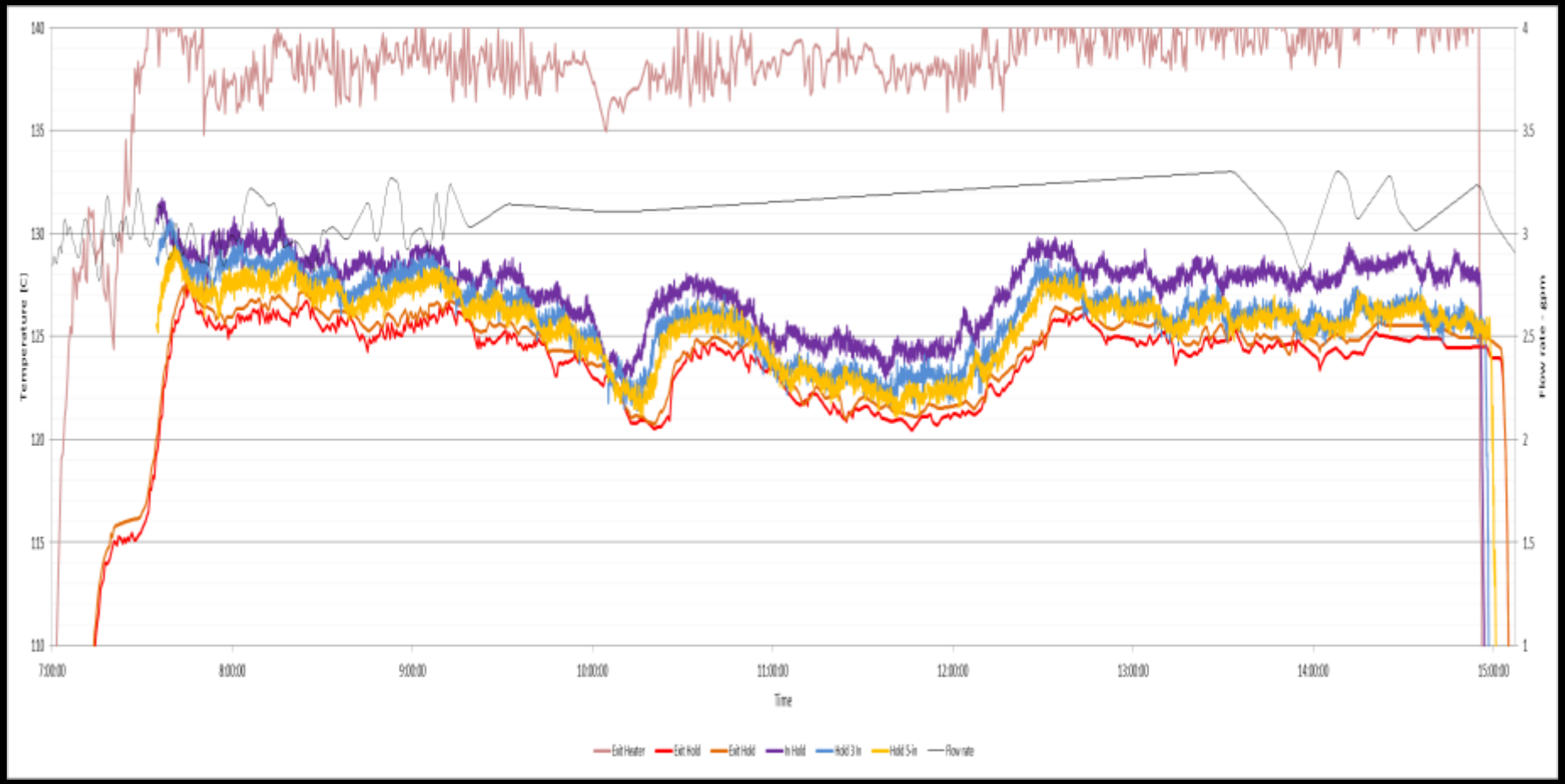
EXPERIMENTAL



Min [s]	337.0
Max [s]	483.6
Average [s]	374.0
σ [s]	21.593

MODEL VALIDATION

EXPERIMENTAL



MICROBIAL CHALLENGE RESULT

- Microbial challenges showed that the process designed and implemented by Aseptia was sufficient to provide the required thermal treatment
- The model based process was conservative, and can be applied to other products

Particle Validation Pathway

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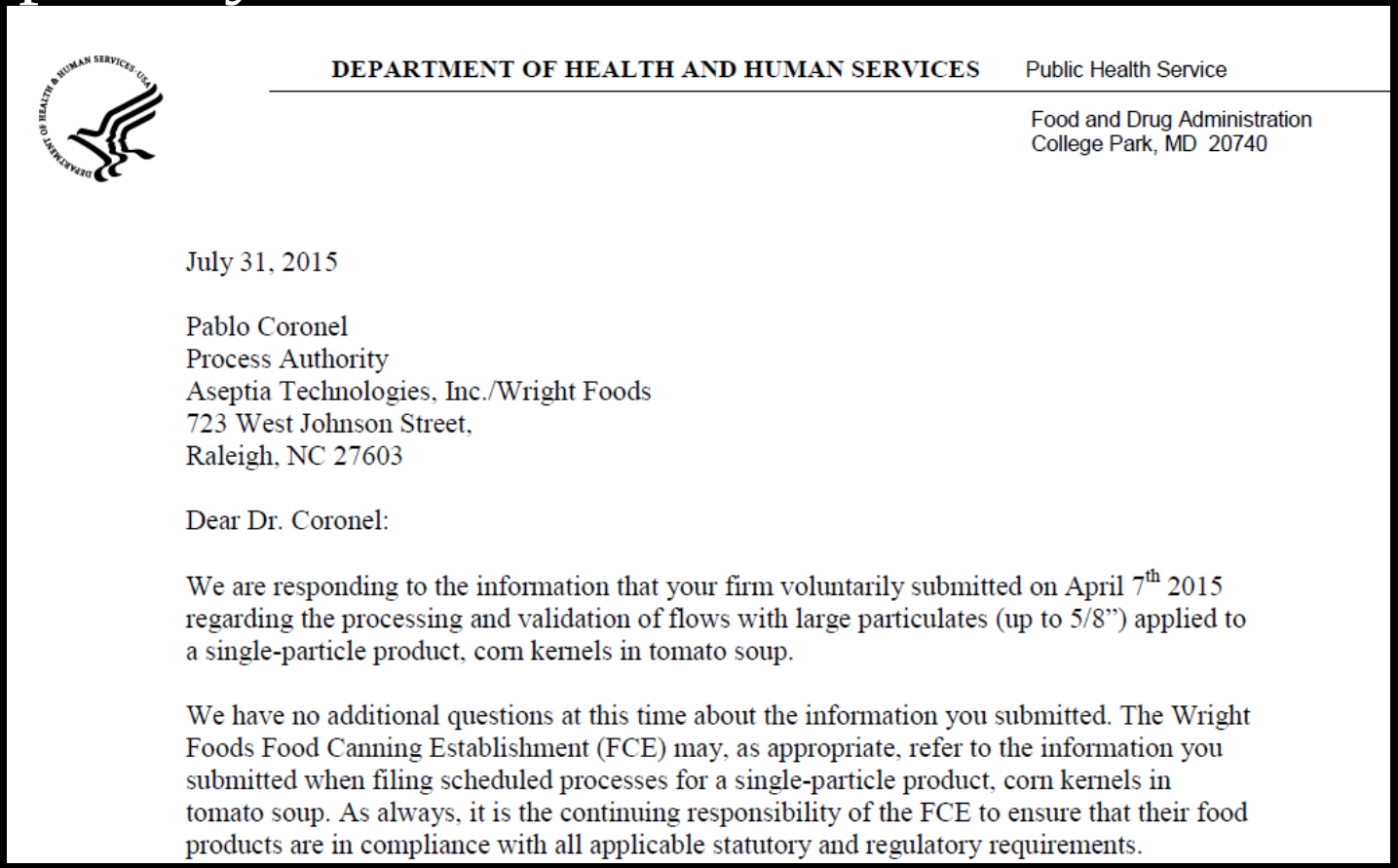
- ✓ Microbial Challenges

WAS IT WORTH IT?

Accepted by FDA on 07/31/2015



DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

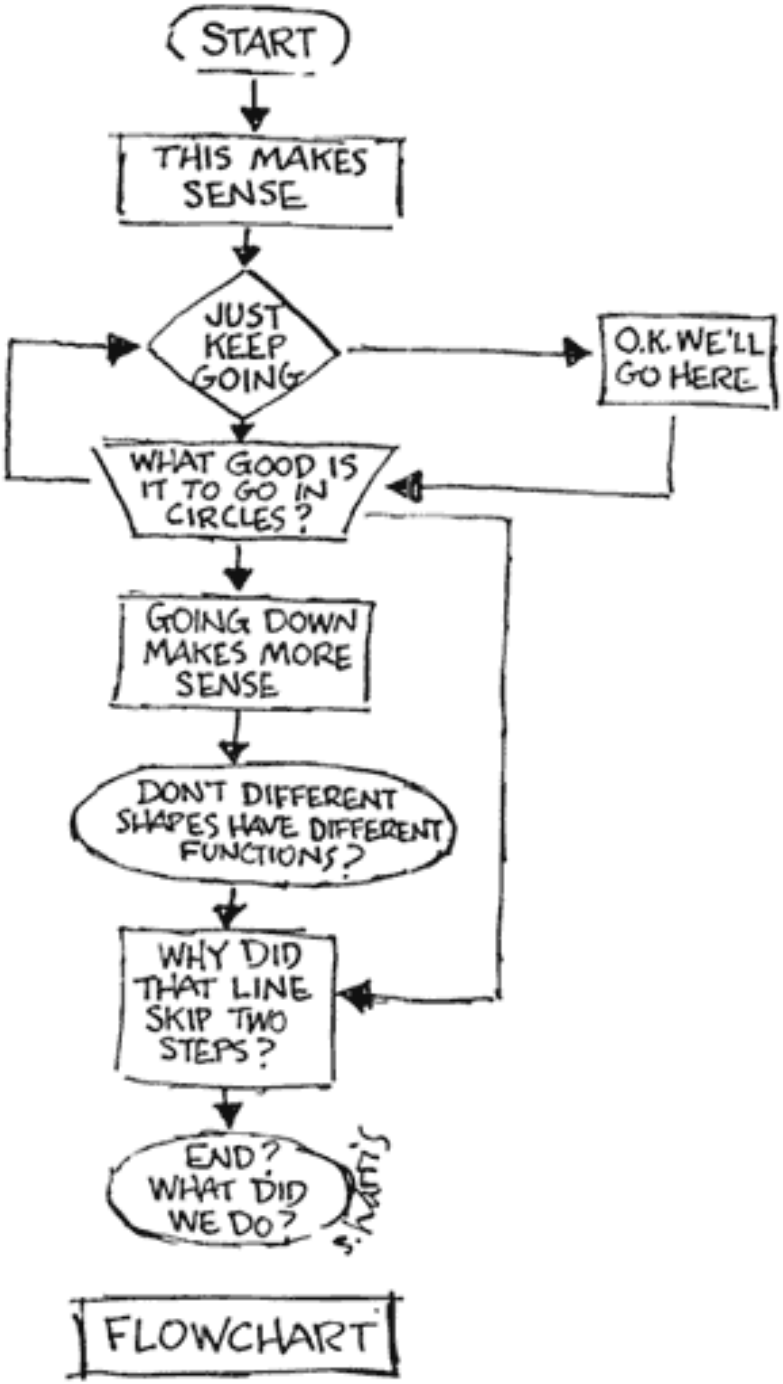
July 31, 2015

Pablo Coronel
Process Authority
Aseptia Technologies, Inc./Wright Foods
723 West Johnson Street,
Raleigh, NC 27603

Dear Dr. Coronel:

We are responding to the information that your firm voluntarily submitted on April 7th 2015 regarding the processing and validation of flows with large particulates (up to 5/8") applied to a single-particle product, corn kernels in tomato soup.

We have no additional questions at this time about the information you submitted. The Wright Foods Food Canning Establishment (FCE) may, as appropriate, refer to the information you submitted when filing scheduled processes for a single-particle product, corn kernels in tomato soup. As always, it is the continuing responsibility of the FCE to ensure that their food products are in compliance with all applicable statutory and regulatory requirements.


START
THIS MAKES SENSE
JUST KEEP GOING
O.K. WE'LL GO HERE
WHAT GOOD IS IT TO GO IN CIRCLES?
GOING DOWN MAKES MORE SENSE
DON'T DIFFERENT SHAPES HAVE DIFFERENT FUNCTIONS?
WHY DID THAT LINE SKIP TWO STEPS?
END? WHAT DID WE DO?
FLOWCHART

THANK YOU