Boundary Spanning Thermo-Bacteriology Learnings to Variable Water Activity (Aw) Thermal Processes and Allied Domains

presented by:

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Process Tek

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Boundary Spanning Thermo-Bacteriology Learnings to Variable Water Activity (Aw) Thermal Processes and Allied Domains

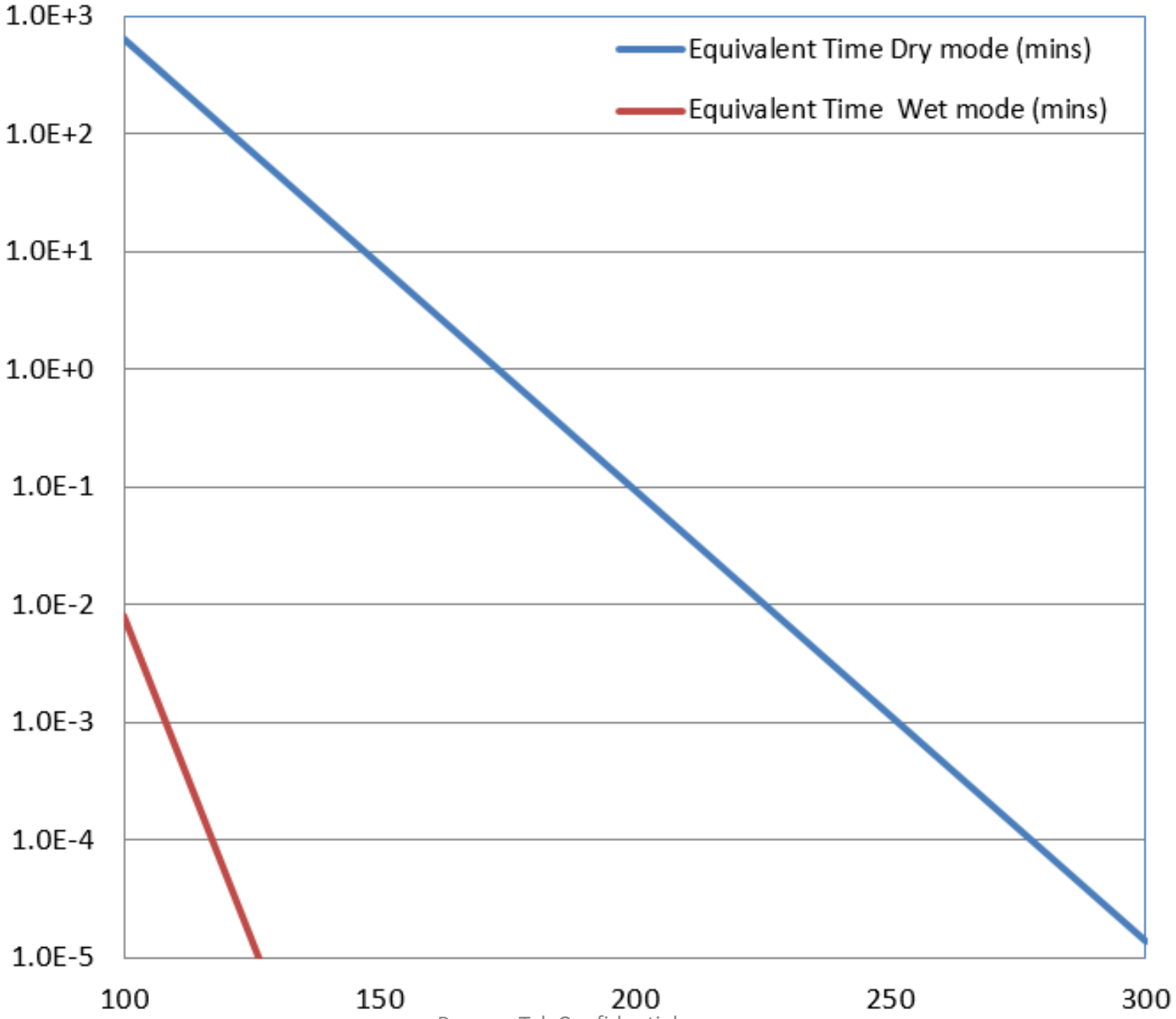
- Varying Water Activity
- Points to Consider
- Lessons Learned

Varying Water Activity Thermal Processes

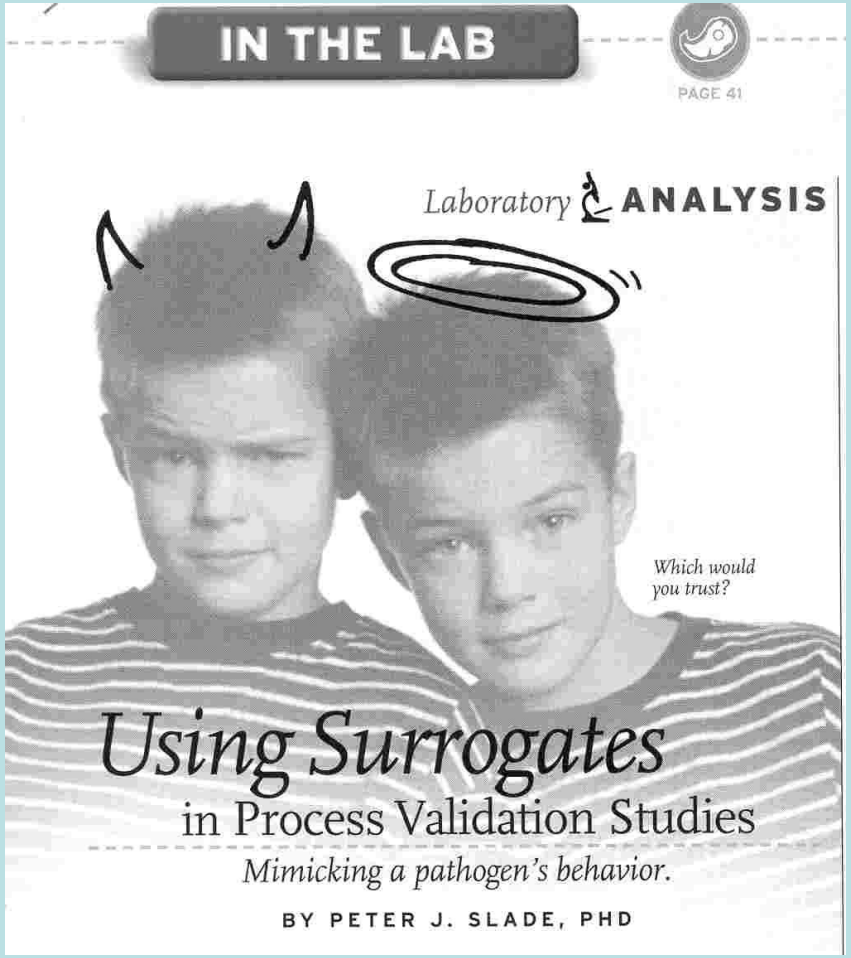
- During Thermal Processes in Toaster Ovens & Fluid Bed Dryers, the Water Activity changes with Time & Temperature
- Thermal Process Calculations apply only to the extent of integrating Lethal effects, but D & z values change with Aw
- Microbiological Approaches should be utilized for Validations

Varying Water Activity Thermal Processes

- Conventional Physical Thermal Processing Approaches
  - Time-Temperature Mapping and Minimum Residence Time Distribution
  - Calculation issues due to Varying Aw with *both* the Time & the Temp
- Microbiological Thermal Processing Approaches
  - Pathogen of Concern in Process Intervention for ***"Log Reduction"***
  - Logistics and Risks of Microbial Process Challenge Studies
    - Direct use of Pathogen of Concern in the Plant Process
    - Use of accepted Pathogen "***surrogates***" in the Plant Process


1.0E+3
1.0E+2
1.0E+1
1.0E+0
1.0E-1
1.0E-2
1.0E-3
1.0E-4
1.0E-5
100
150
200
250
300
Equivalent Time Dry mode (mins)
Equivalent Time Wet mode (mins)

Resistant Indicator Organisms



Surrogate Considerations

- Nonpathogenic
- Inactivation characteristics & kinetics used to predict target
- Behavior similar to target (pH, Temperature, Oxygen)
- Stable & consistent growth
- Easily yield high-densities
- Constant until deployed
- Easily enumerated
- Easily differentiated

Biological Monitoring Systems and Bioburden

Product Microbial Control Process **Biological Validation Process**

$$D_T^P (\log N_O^P - \log N_F^P) = F_O^P = D_T^{BI} (\log N_O^{BI} - \log N_F^{BI})$$

$$0.5 \text{ min. } (\log 10^2 - \log 10^{-6}) = 4.0 \text{ min.} = 1.0 \text{ min. } (\log 10^6 - \log 10^2)$$

Pflug, 1998

Varying Water Activity Thermal Processes

A “hybrid” approach to validating processes with varying Aw:

- Establish “fastest” particles (flake, shred, nut, seed, leaf, etc.)
- Assess Time, Temp and Water Activity ***profiles*** for process
- “Worst case” pathogen inactivation resistance parameters
- Most resistant pathogen of public health concern
- Reference Temperature, D and z values at “worst case” Aw
- Required minimum $F_{Tp}(D_p, z_p)$ value for “log reduction”, LR_p

Varying Water Activity Thermal Processes

- Develop challenge “carriers” and “process entry” approaches
- Select characterized non-pathogenic spores for studies
- Identify Spores with resistance (D & z)
- Bacterial Spores with max Heat Resistances at Aw limits
  - Moist Heat (Aw=1) Resistant G stearothermophilus spores
  - Dry Heat (Aw=0) Resistant B atropheaus spores
- Concurrent ***identical*** validations using *both* challenge spores

Validation Design Basis

Almond Board of Californina Validation & 4 Log Red [SE PT 30] Dry Roasting G'line:

Calculated D_{121C} = 25 mins & z = 26.1 C^o

van Asselt & Zwietering - Int'l J Fd Micro 107 (2006) 73-82 Regression - [1,141] reported Salmonella Resistance values

Upper 95% Prediction Interval for D_{70C} = 4 mins & z = 9.1 C^o

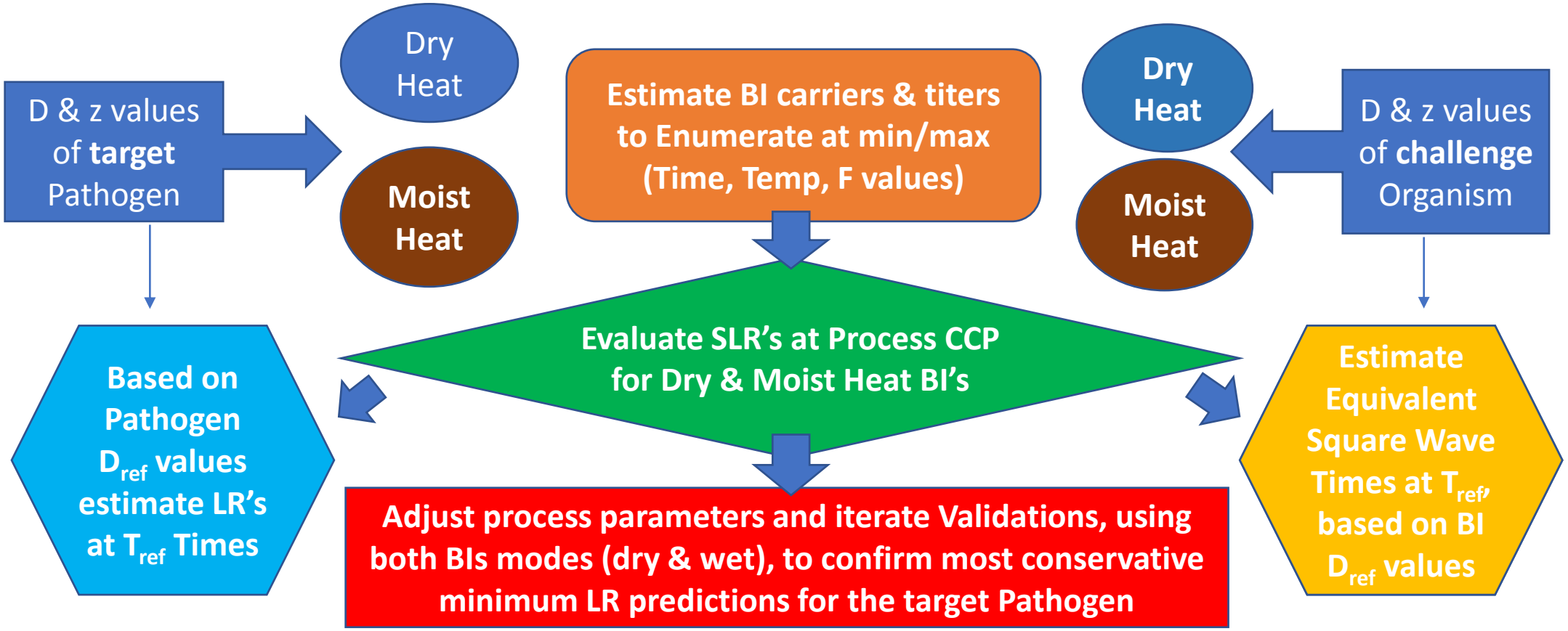
Moist Heat Mode

BIU Heat Resistance Reference Temperature	^{o}C	121.0
Decimal Reduction Time of D-value of Challenge	min.	2.4
z-value (Temp Coeff of the Challenge D-value)	C^{o}	8.6
[As measured/provided per Certificate of Analysis]		
Pathogen Heat Resistance Reference Temperature	^{o}C	70.0
Decimal Reduction Time or D-value of Pathogen	min.	4.0
z-value (Temp Coeff of the Pathogen D-value)	C^{o}	9.1
[Highest Reported Heat Resistance from Literature]		

Dry Heat Mode

BIU Heat Resistance Reference Temperature	°C	160.00
Decimal Reduction Time of D-value of Challenge	min.	1.80
z-value (Temp Coeff of the Challenge D-value)	C°	54.50
[As measured/provided per Certificate of Analysis]		
Pathogen Heat Resistance Reference Temperature	°C	121.00
Decimal Reduction Time or D-value of Pathogen	min.	25.00
z-value (Temp Coeff of the Pathogen D-value)	C°	26.10
[Highest Reported Heat Resistance from Literature]		

Thermobacteriology and Dryer Lethality



Pathogen ↔ Validation Cross-Correlations

$$D2 = 10^{\{[(T1 - T2) / z] + (\log D1)\}}$$

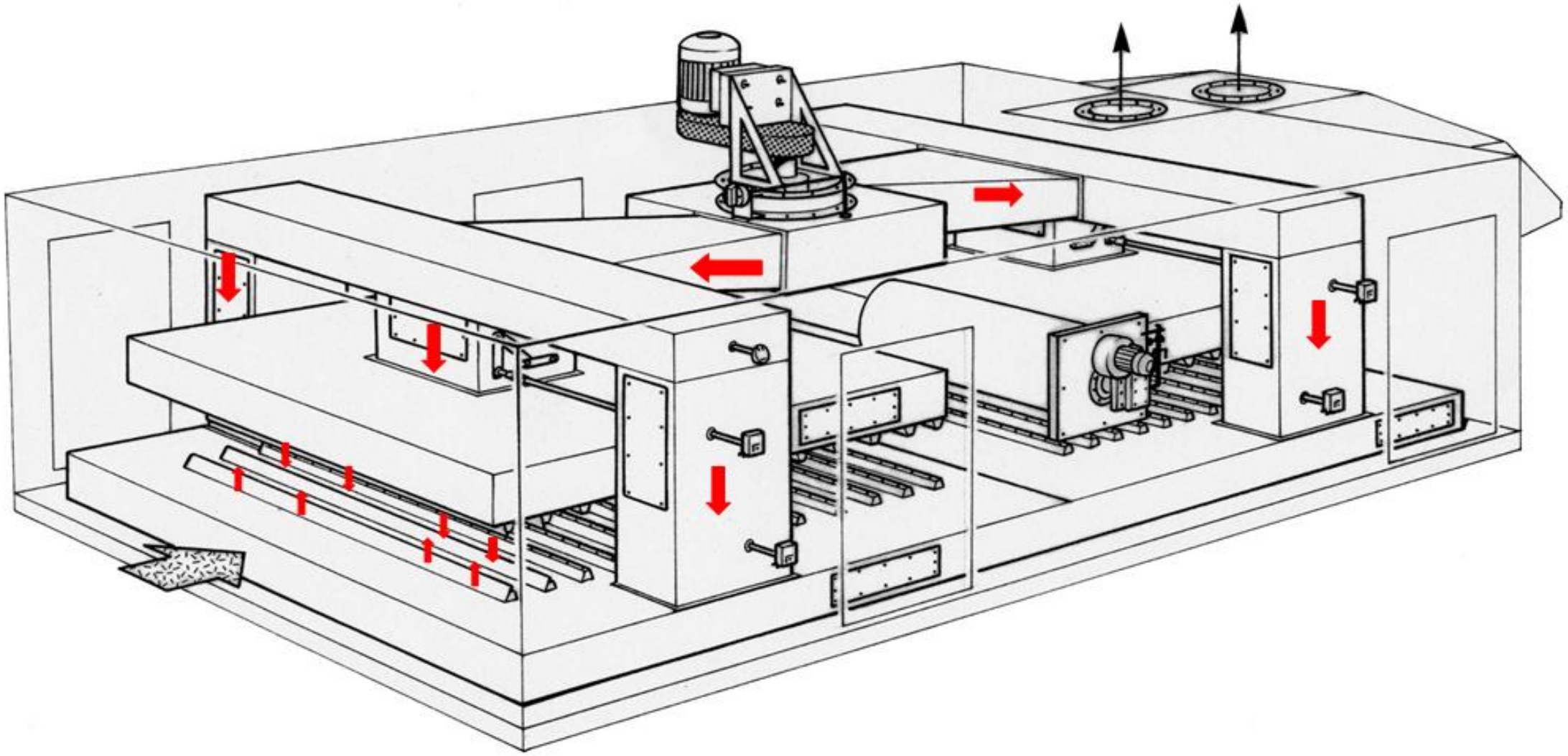
Pathogen ↔ Validation Cross-Correlations

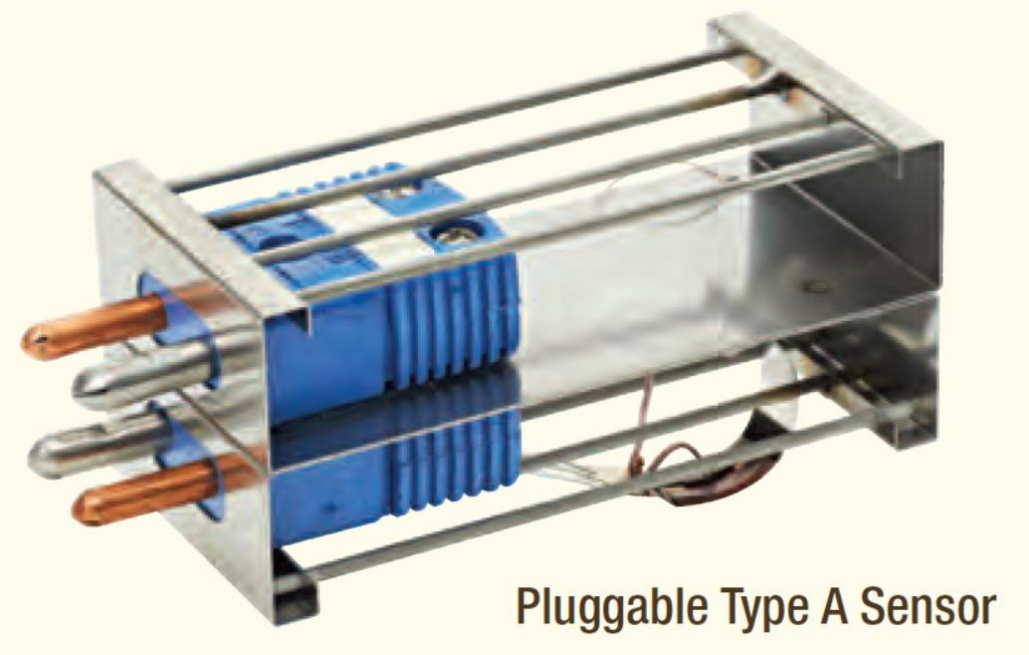
- $F_{Tp} = D_{Tp} * [\text{ log reduction }]_p$

- $F_{Tv} = D_{Tv} * [\text{ log reduction }]_v$

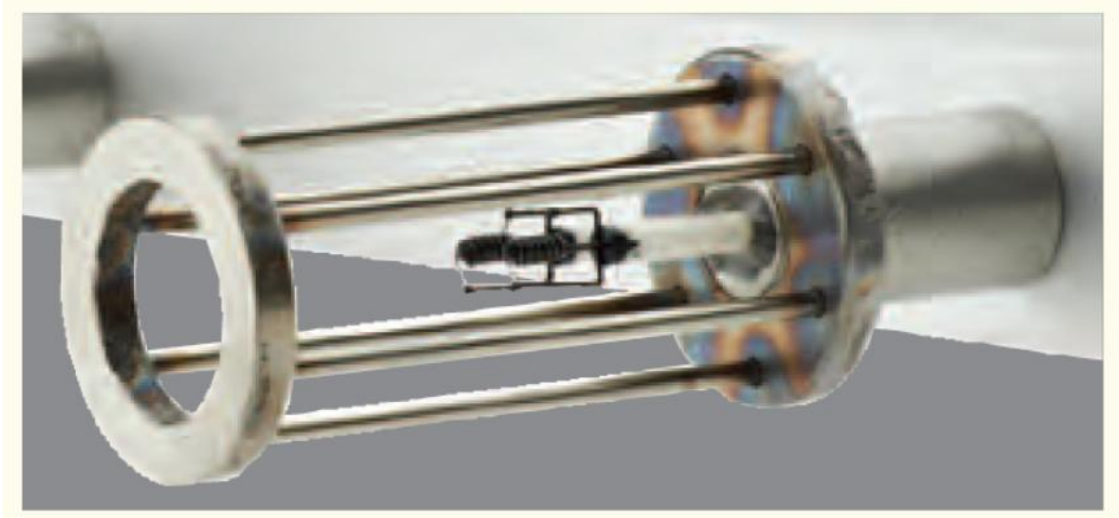
Validation Test Methodology

- B. atrophaeus & G. stearothermophilus BIUs vacuum dropped to ***embed*** (10 across) into center of product
- B. atrophaeus & G. stearothermophilus BIUs ***tethered*** (10 across) on ***wires with weighted guides***
- Controls handled identically to BIU Coupons or Discs
- Enumerated unexposed BIUs to verify CoA Titers
- Survivors in *Embedded* & *Tethered* BIUs Enumerated
- Pathogen Log Reductions computed from measured BI Log Reductions & Equivalent T_{ref} Process Times

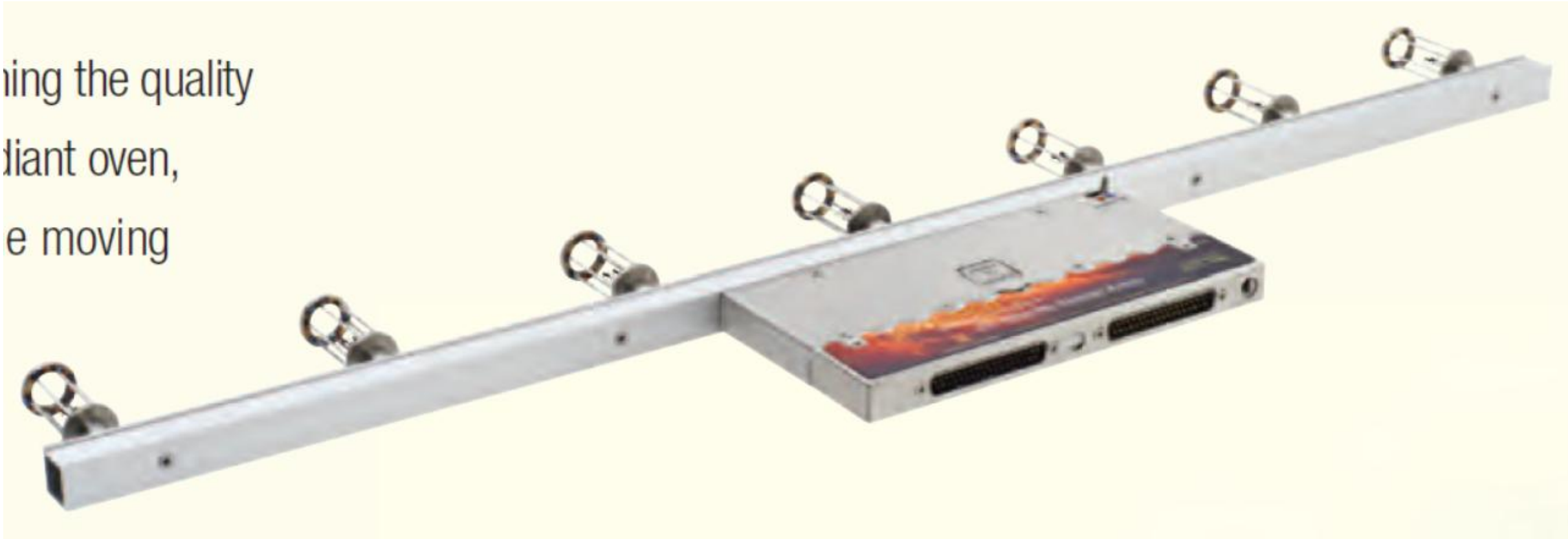




Pluggable Type A Sensor



Air Velocity Sensor


ing the quality
diant oven,
e moving

Moist Heat Mode

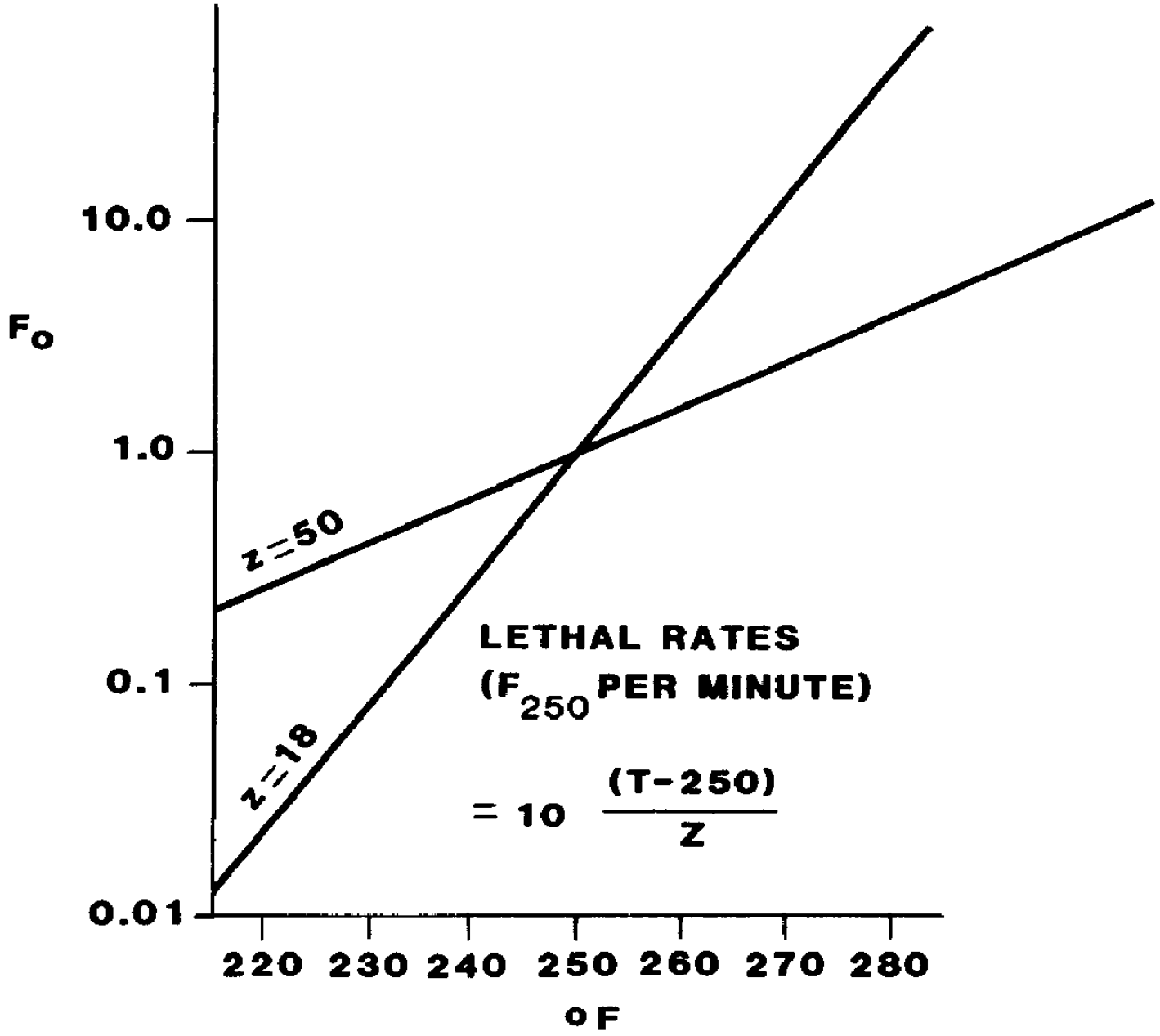
Process Reference Temperature for computations	°C	260.0
[Recommend using Process CCP lower limit value]		
Actual "Log Red" in Process for BIU Challenge used	[na]	1.2788E+00
[From Pre-& Post Treatement Counts of Challenge]		
Equivalent Time at Process Reference Temperature	sec.	1.2658E-14
[Calculated Square Wave Process at Ref. Temp.]		
Predicted "Log Red" in Process for Target Pathogen	[na]	3.9927E+04
[In Calculated Equivalent Process Time at Ref Temp]		

Dry Heat Mode

Process Reference Temperature for computations	°C	260.00
[Recommend using Process CCP lower limit value]		
Actual "Log Red" in Process for BIU Challenge used	[na]	1.30
[From Pre-& Post Treatement Counts of Challenge]		
Equivalent Time at Process Reference Temperature	sec.	2.06
[Calculated Square Wave Process at Ref. Temp.]		
Predicted "Log Red" in Process for Target Pathogen	[na]	290.02
[In Calculated Equivalent Process Time at Ref Temp]		

Thermal Modalities (Jeong et al '09)

- Traditional D & z value Model modified to account for dynamic water status at surface of product (not humidity of bulk processing air) under humid heating conditions
- Modified Model needs dew point of processing air and dynamic surface temperature history of product during moist-air heating
- Despite higher surface temperatures at low-humidity conditions, a high-humidity process achieves greater LR in shorter durations
- Efficacy of moist-air greater than dry processes, due to effects of process humidity on the dynamic D-value
- D-values proportional to humidity gradients in cooling


10.0
1.0
0.1
0.01
F_o
z=50
z=18
LETHAL RATES
(F_{250} PER MINUTE)
$= 10^{\frac{(T-250)}{Z}}$
220 230 240 250 260 270 280
°F

Points to Consider
&
Lessons Learned

- Polite Suggestions for IFTPS
- Pragmatic Advise for a younger me

Points to Consider

- Safety not a Competitive Advantage
- Lessons Learned Forums
- Work Around Books
- Process Labeling
- Chemistry of Canning

CAST® Issue Paper

Number 56
October 2015

Process Labeling of Food: Consumer Behavior, the Agricultural Sector, and Policy Recommendations

Certified Organic
rbST Free
Shade Grown
100% Natural
Free Range
Non-GMO

The 12D Stratagem

- Origins of 12D concept are obscure
- D-Value has been in use only since 1950
- Esty and Meyer (1922) determined time for reduction in spore populations of about 11 or 12 log cycles
- Hicks (1961) indicated this degree of Cl. botulinum reduction was required in LACFs
- 12D is only meaningful when applied to Cl. botulinum for Public Health Safety
- A 12D process, killing 10^{12} microorganisms and 10^{-12} probability of a non-sterile unit, are **not** synonymous
- At most, 12D is a time for a 12 SLR

Pflug 1995

Probability of a Nonsterile Unit - PNSU

- A definitive term or phrase for application to products that should be free of microbial contamination
- PNSU concept is direct and meaningful. It merges statistics with microbiology
- It also relates directly to the Microbial Safety Index (MSI) proposed by Dr. Campbell
- The MSI is the negative common logarithm of the probability that a unit is contaminated with a viable organism
- An PNSU of 10^{-6} would equal an MSI of 6
- PNSU should be used for sterilization process design, validation and monitoring discussions
- MSI can be applied to the consumer safety area

Pflug, 1981

THE CHEMISTRY OF CANNING

To preserve fruits and vegetables, you must first sterilize them and then seal them in airtight containers. In this graphic, we take a look at some of the key parts of the process.

ACIDITY

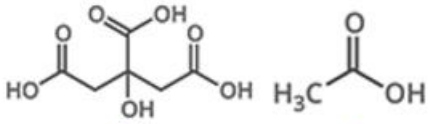
Two types of foods are destined for canning. High-acid foods have a high enough acidity to block the growth of bacteria. Low-acid foods need to have acid added (often from lemon juice or vinegar), or they must be sterilized at a higher temperature (see right).

HIGH-ACID FOODS pH<4.6

Fruits and foods with added acid (e.g., pickles)

LOW-ACID FOODS pH>4.6

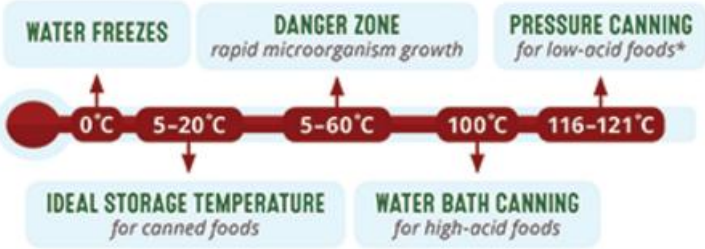
Red meat, poultry, seafood, and fresh vegetables (tomatoes can have pH > 4.6 in some cases)



CITRIC ACID & ACETIC ACID

Both can be used to lower the pH of low-acid foods to ensure it is below pH 4.6

THE IMPORTANCE OF TEMPERATURE



** Pressure cooker at 10 psi (116°C) and 15 psi (121°C) needed to reach these temperatures*

Heating foods to the correct temperature is important because it kills microbes that might otherwise grow under some storage conditions. In the case of low-acid foods, you must use a pressure cooker to reach the required temperature. The temperature at which jars are stored can also affect the quality of canned produce.

BOTULINUM SPORES AND CANNING

Botulinum spores reside on most fresh foods. Though they're usually harmless, under the right conditions, they can germinate into bacteria that make deadly botulinum toxin. Acidity and temperature are key to preventing toxin production in canned goods.

C. BOTULINUM SPORES

C. BOTULINUM BACTERIA

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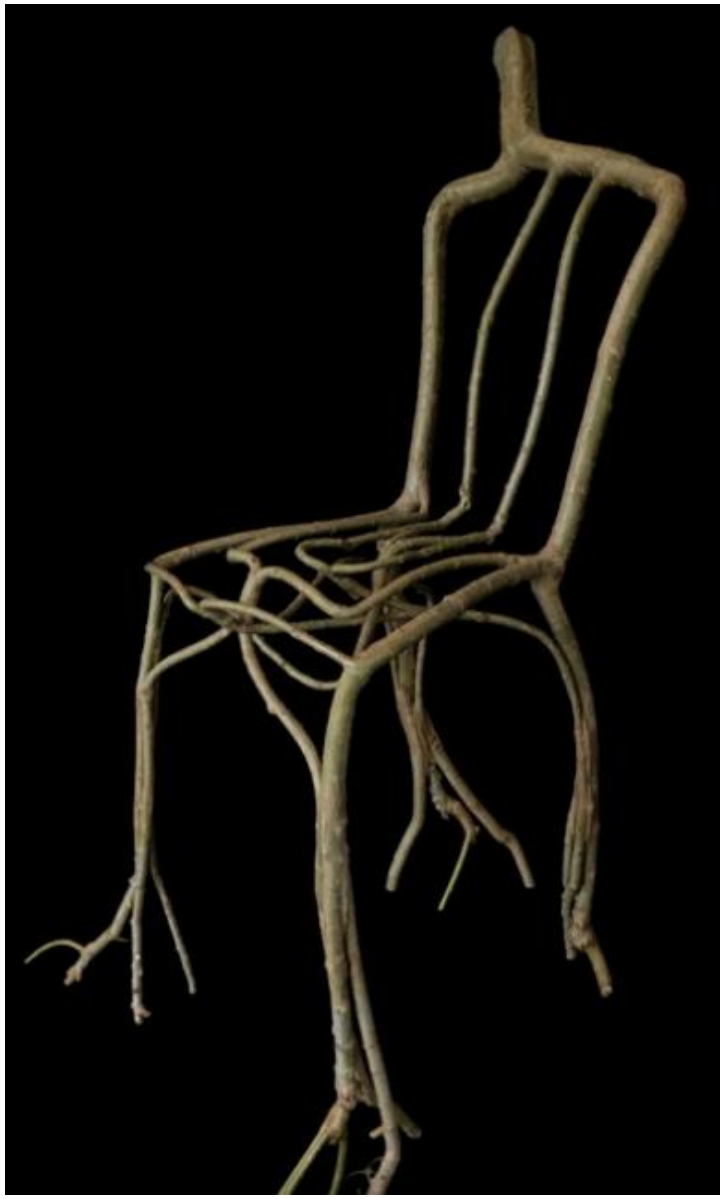
Process Tek Confidential

Alternate Points to Consider

- Furniture Farming
- Diesel Gate Software
- Stock Market Funds
- Military Inspections
- Control of Microorganisms

YouTube

YouTube



Heavy air pollution enshrouded Tiananmen Square in Beijing last month.

Credit: Imagine China/Newscom

VISUAL CHINA GROUP, VIA GETTY IMAGES

Smog in the northern Chinese city of Xi'an in 2013. Air-quality officials there were accused of falsifying test results.

(Re)-Validations!

Wads of Cotton Used to Cheat
Testing of Air Quality in China

Sterility Maintenance - Retort & Aseptic

- In-Container (Retorts) in contrast with In-Flow (Aseptics) Sterilization
- Container Closure Integrity
  - Hermetic Seals made before Retorting (non-sterile), but are an integral part of the Aseptic (sterile) operations
  - Retorts are “de-facto” Seal Integrity Testers, whilst Sealing is integral to Aseptic Manufacture, and is assured and monitored by sealing parameters
- Re-Contamination in Retorting is primarily “post-process”, whilst it is, more often than not, “in-process” in Aseptics
  - Cooling Rates or Water Microbiology cause post-process re-contamination
  - Vectors for in-process re-contamination are varied and much more complex

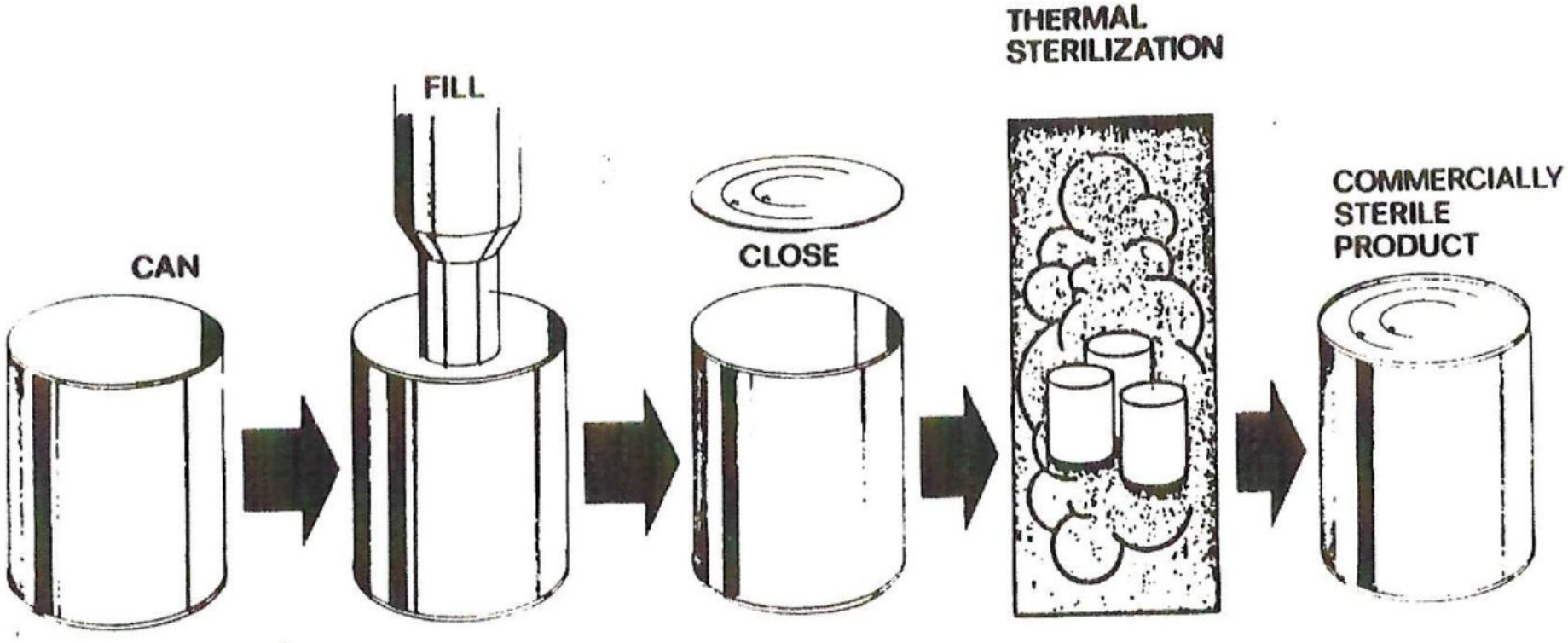
Sterility Maintenance in Aseptics

- Holder or Cooler Sterility compromised in (Water ↔ Product) switch, or In-Process Sterile Rinses, if flow rates and pressure drops are not controlled to account for viscosities, etc., for the designed F_o
- Processor can also sometimes re-contaminate sterilized product in Coolers, Re-Generators, Vacuum Chambers, Valve Clusters, etc.
- Aseptic Tank can re-contaminate its sterile content, if over-pressure air is not sterile, due to missing, miss-seated or breached Absolute Air Filters, Faulty Sterile Sample Port Valves, Poor Barrier Seals, etc.
- Interventions, HEPA Leaks, ΔP Errors, Container Sterilization Faults, and other vectors may also re-contaminate the “aseptic work zone”

Aseptic Work Zone – Sterility Maintenance

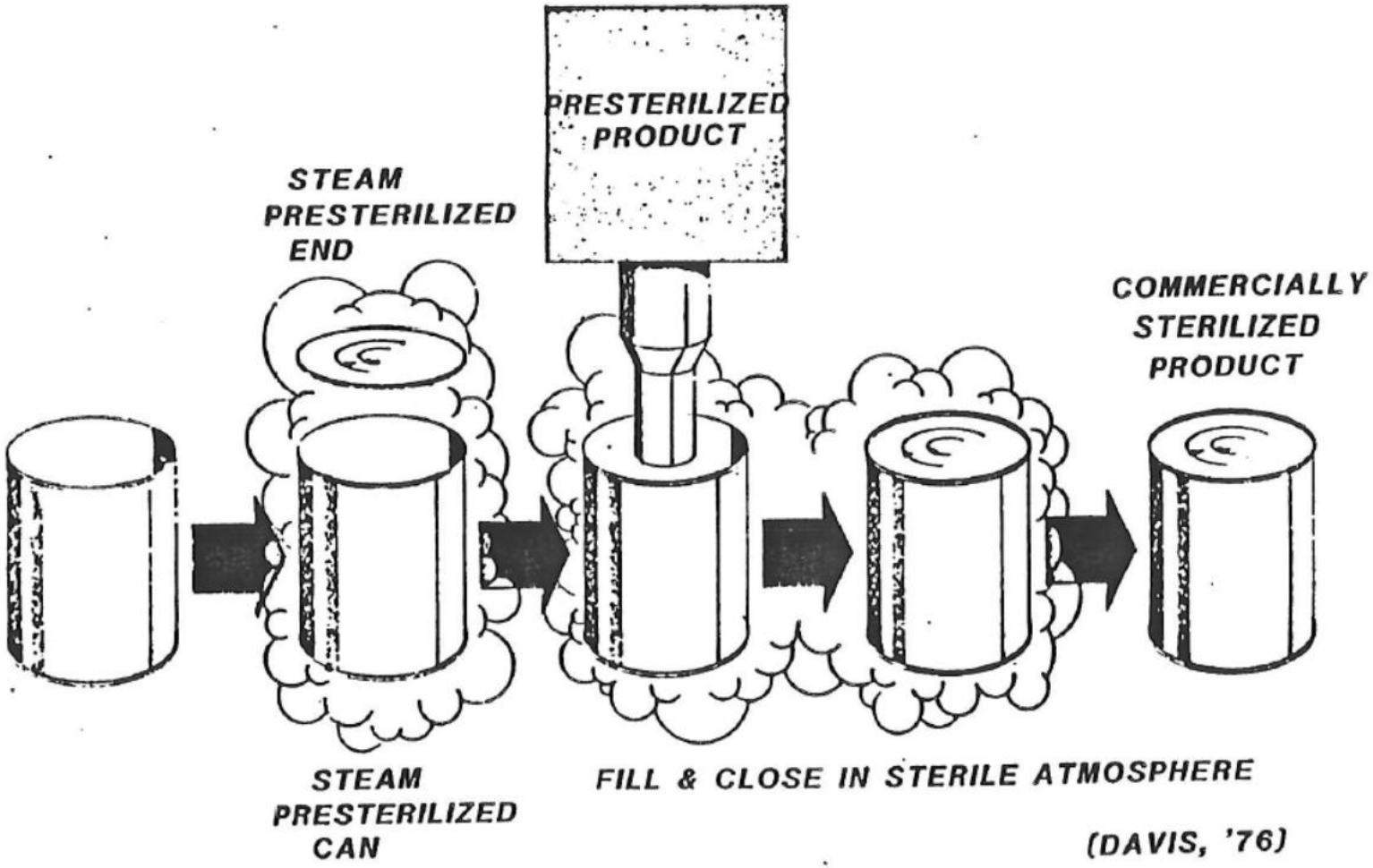
- ***Analogy*** – Actively "*managed*" vs. passively "*indexed*" Stock or 401K Funds
- Original Aseptic Canning System - Active mode of SM of the AWZ
- Current Aseptic Packaging Systems – Passive mode of SM of the AWZ
- Active SM – inactivation kinetics understood, monitored and controlled, with added ability to kill stray contaminants which may enter the critical AWZ
- Passive SM – prevention of re-contamination of the AWZ is, at best, a "probabilistic" modality, not controlled or monitored.
- "Downward Flow HEPA Air Laminarity" is not readily assured in AWZ's with multitudes of moving, entering and exiting parts, all at very speeds.
- CFD Models & Smoke Tests of the efficacy of Passive SM of AWZ's are only "snap shots" in time, nothing more and nothing less!

THERMAL STERILIZATION



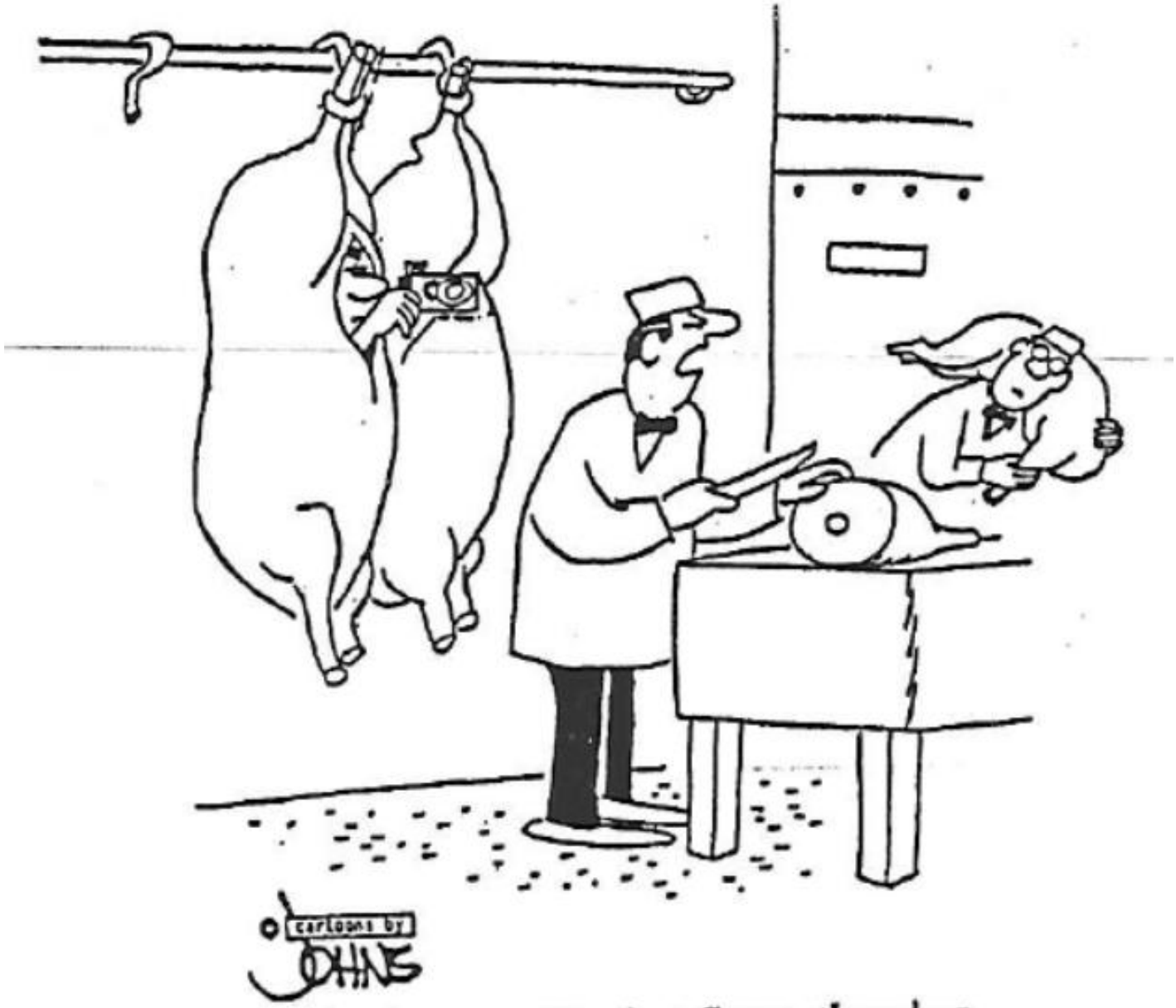
(DAVIS, '76)

ASEPTIC CANNING



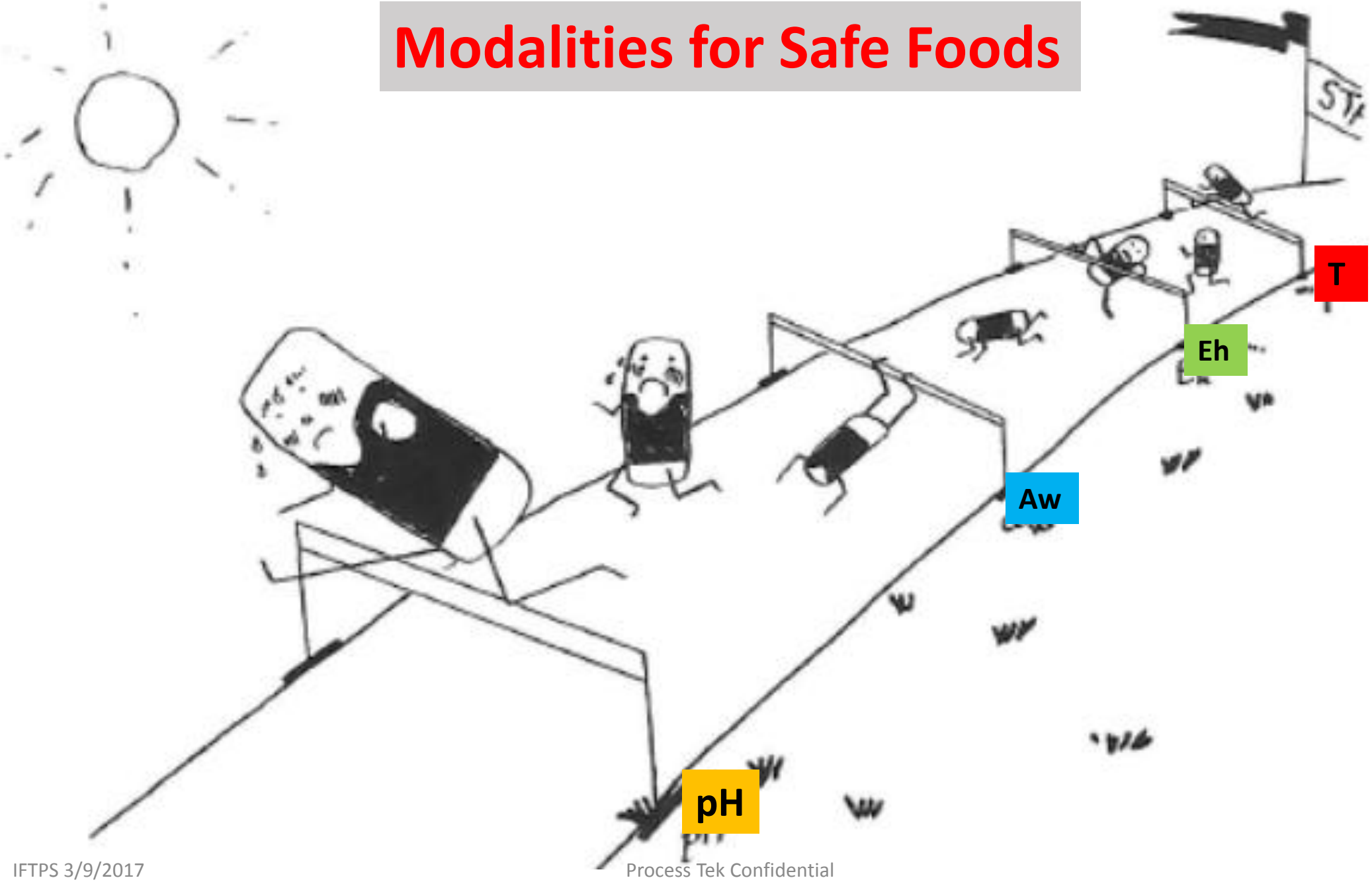
Aseptic Work Zone – Sterility Maintenance

- Steam Barriers or Anti-Microbial Locks (Liquid H_2O_2, PAA, UV, Plasma, etc.) can potentially be used as Active modes of Sterility Maintenance of AWZ
- Cold Sterile Condensate or Absolute Filtered (<0.2µ) Sterile Air, while used as barriers, are strictly speaking Passive modes of Sterility Maintenance
- HEPA & ULPA filtered Air, is neither Sterile nor an Active mode for SM of AWZ's. Used exclusively for SM of AWZ's
- Downward Flow Laminar HEPA Air has roots in NASA Clean Room Design, is cost effective and accepted.
- But like all Passive SM modalities, not as reliable, robust or reproducible as an Active SM modality, for "bank end of the aseptic business" – its AWZ!



"Watch yourself today, Steve, there's a government inspector about!"

Modalities for Safe Foods



Microbial Control Process Engineering

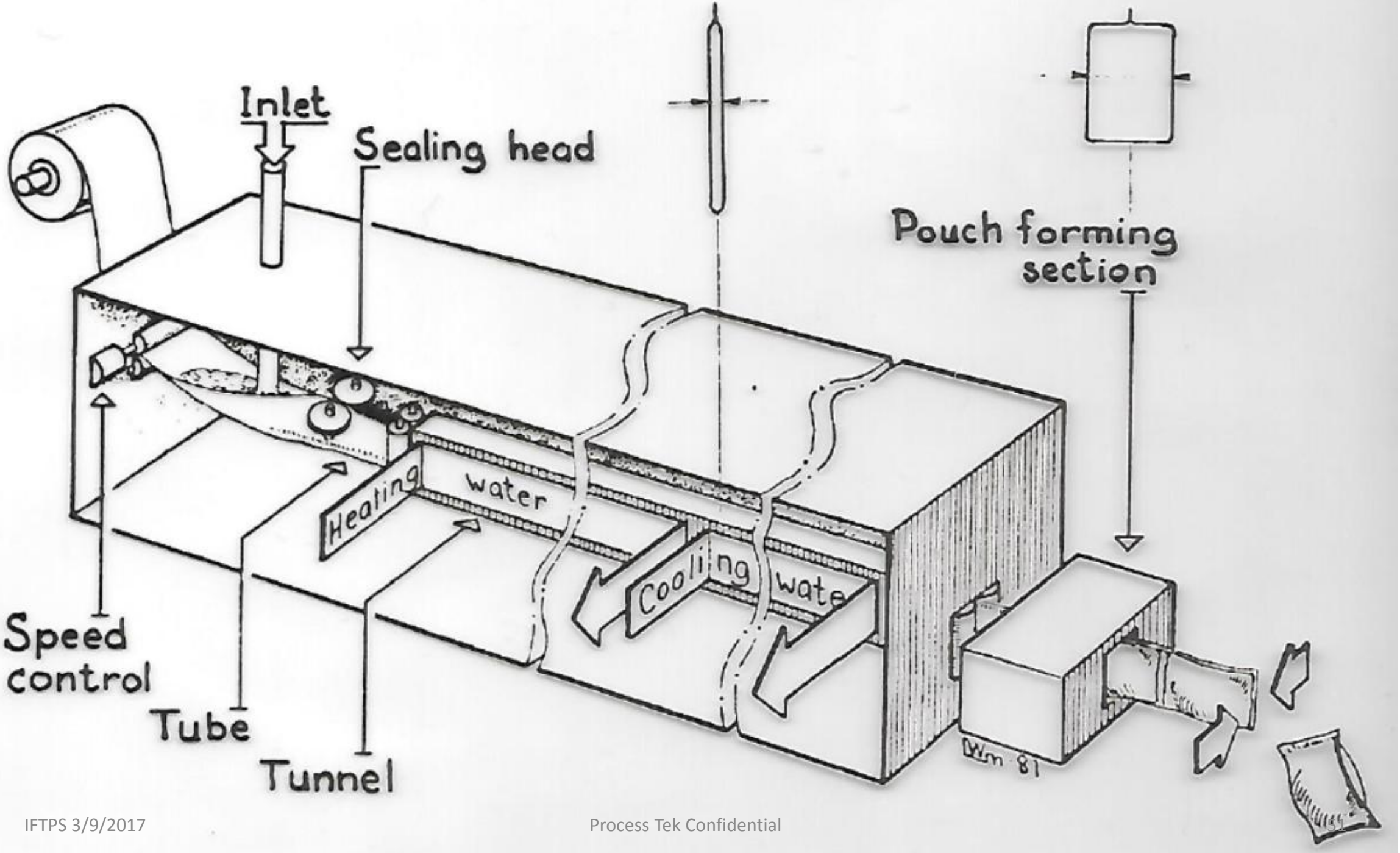
Inactivation
Inhibition
Prevention

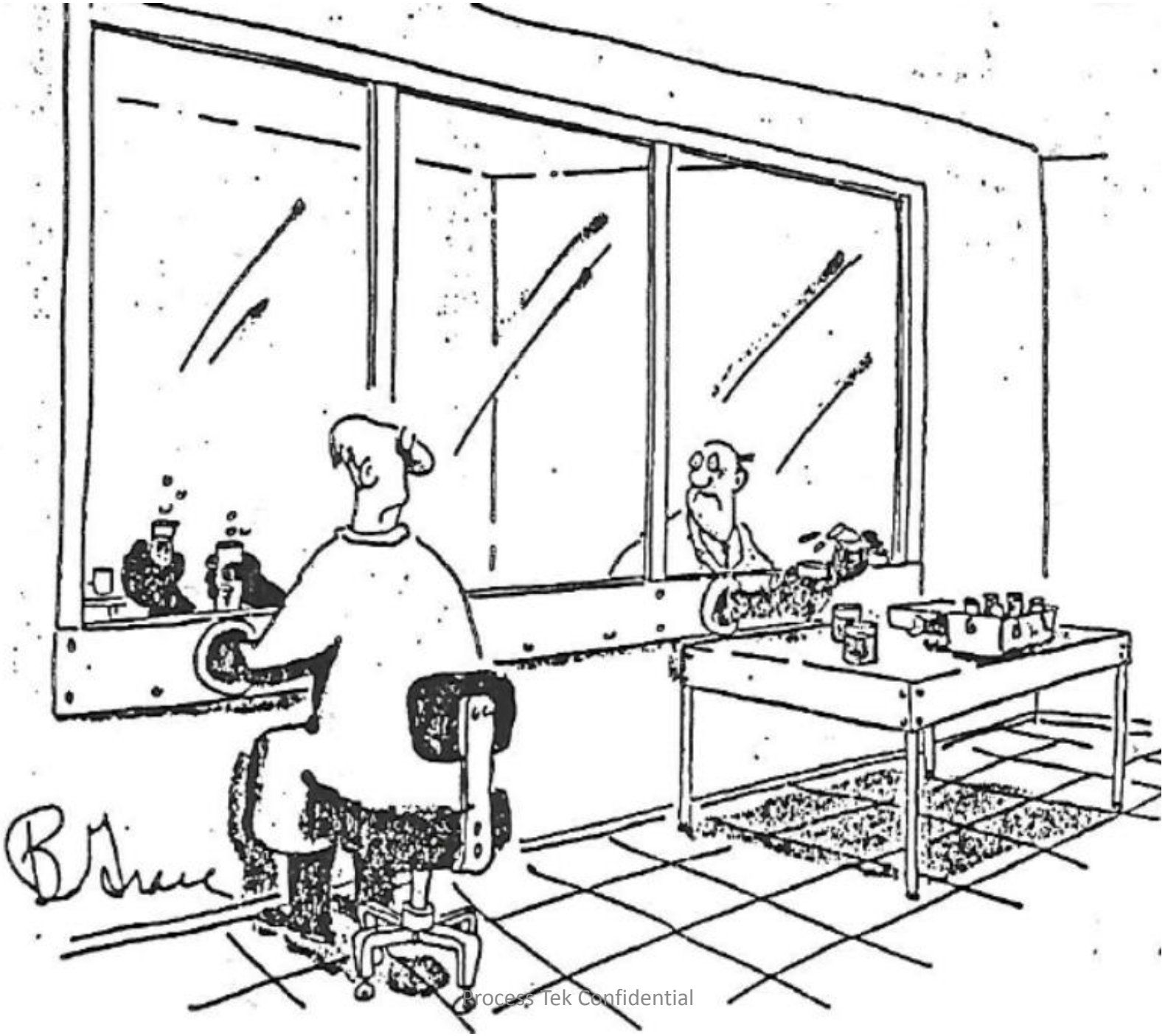
In-Container Past. & Steril.
Aseptic Filling & Packaging
Hot-Fill, Seal, Hold & Cool
Cold Fill & Blow, Fill & Seal
Clean or Aseptic Manufacture

Cleaning & Sanitation
Saturated Steam
Superheated Steam
Dry or Incinerated Air
Extrusion & Molding
EtO, PAA, H_20_2 (Gas, Liq, Vap)
Gamma & E Beam Rad.
UV, μλ & Pulsed Light
Hyberbaric Processes
Filtration & Wash-Offs
pH & Aw Controls
New & Novel Processes

They Got Away!

- Highways & Harvesting Pancreas
- Symphony Orchestra Infection Control
- Stork’s Bokfard & RotaHold
- AlfaStar’s Achilles & MultiTherm
- Spoilage of Meat Analogs

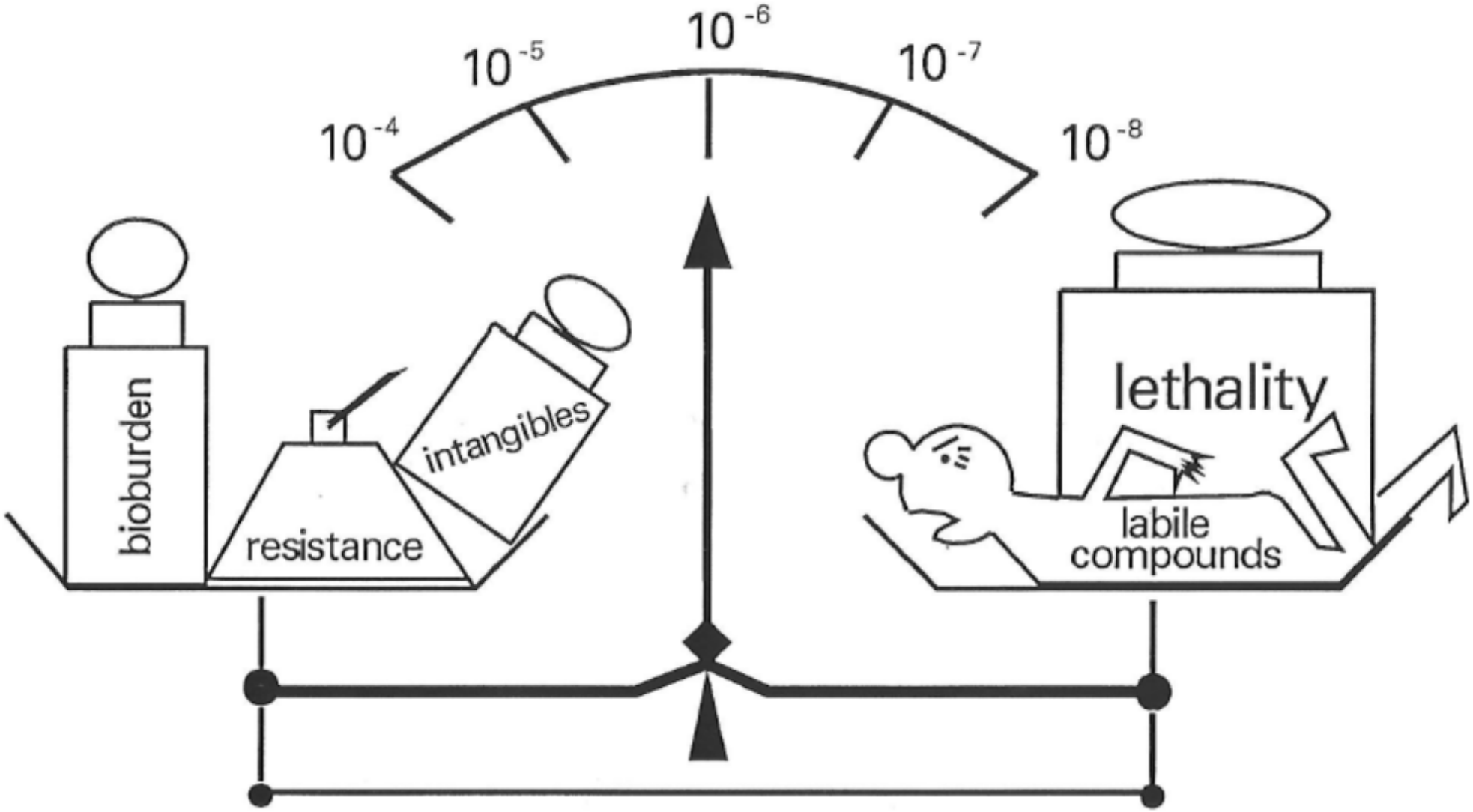

Inlet
Sealing head
Pouch forming section
Heating water
Cooling wate
Speed control
Tube
Tunnel
Wm 81



Lessons Learned

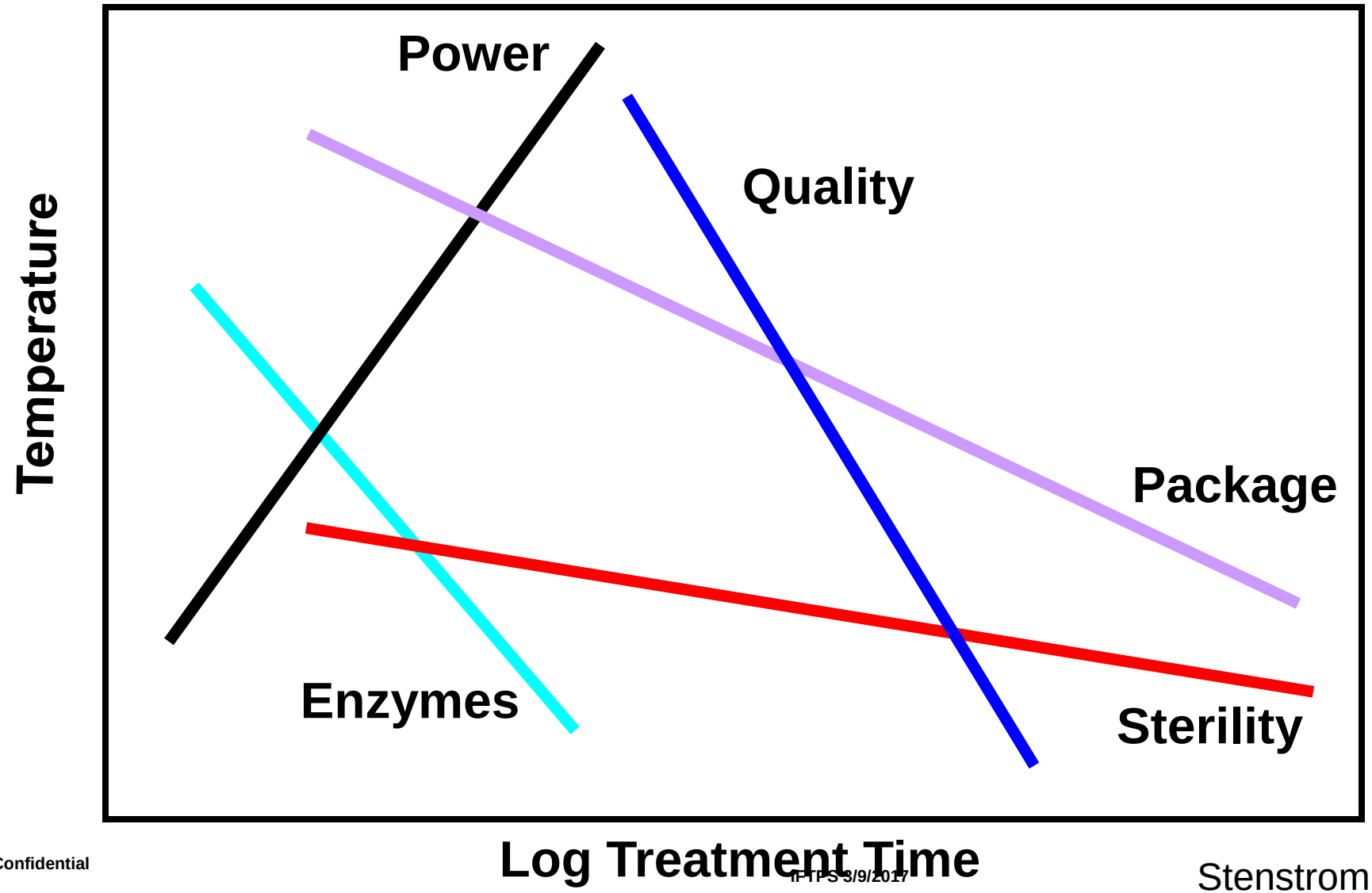
- Co-Optimizing Processing Priorities
- Selective & Differential Sterilization
- Aseptic & Retort Sterile Formulations
- Sterility by Virtue of Manufacturing
- Microbial Control Process Engineering

Assurance of Sterility



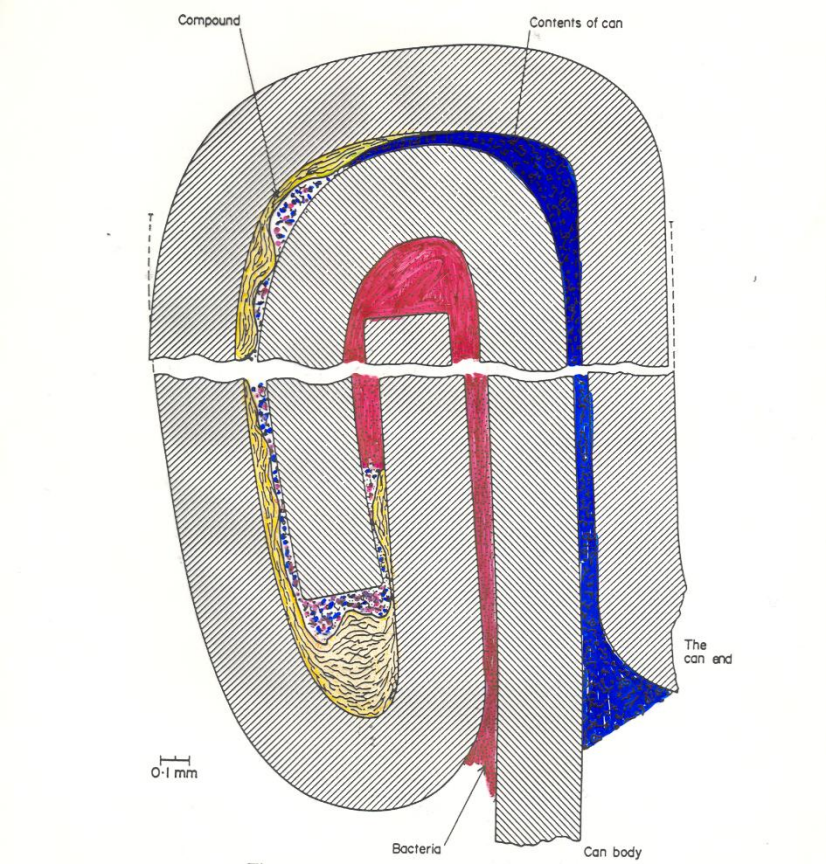
Sterilization Is a Compromise Without Concessions

A Concept Diagram for Sterilization



Stenstrom, 1982

Transient Seal Leaks



Hardware, Software, Nowhere

- Even the most powerful and sophisticated computer programs never can compensate for lack of engineering expertise and experience
- The use of software tools without adequate skills and proper experience is not only useless but can be quite dangerous.

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Horwitz, ‘98

Software Considerations

- Software does not degrade over time
- Software problems are design failures
- All software has “bugs”
- The failure of software verification via mathematical - like proofs has been one of the great disappointments in computer science over the last decade

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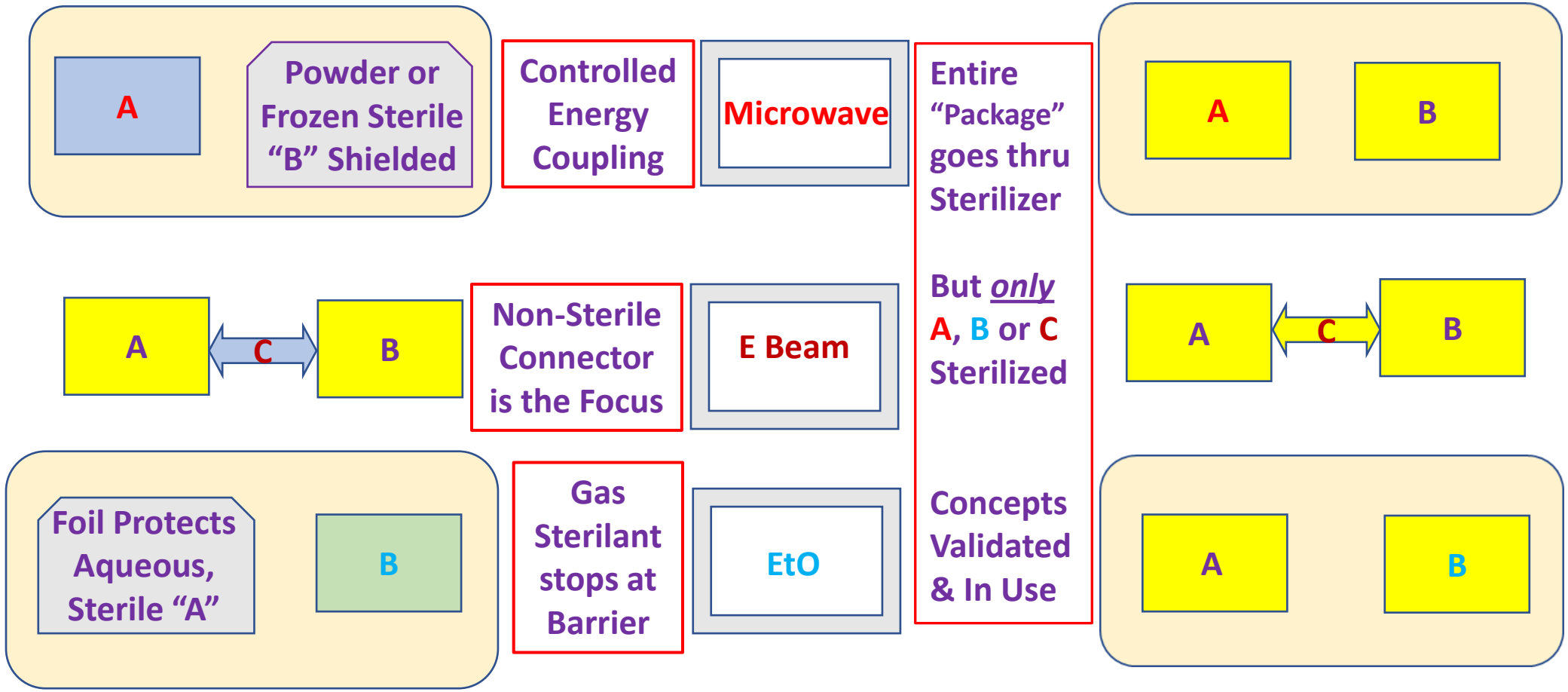
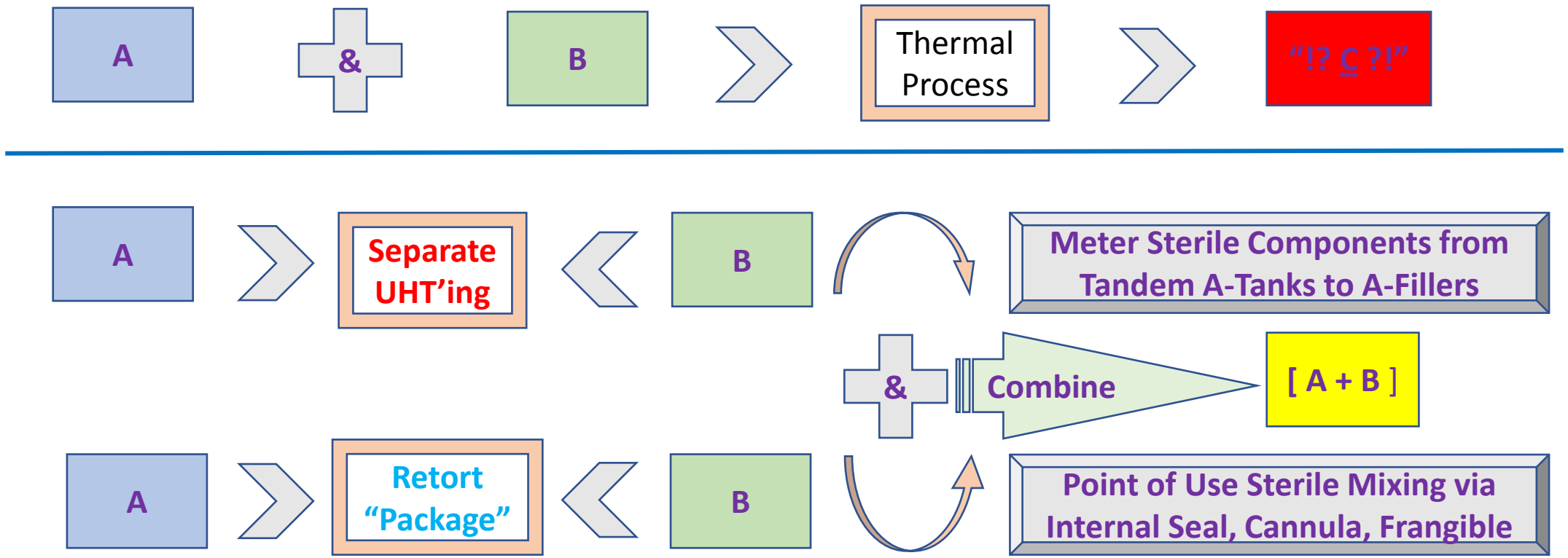
Herrick & Berthrong, ‘89

Selective or Differential Sterilization

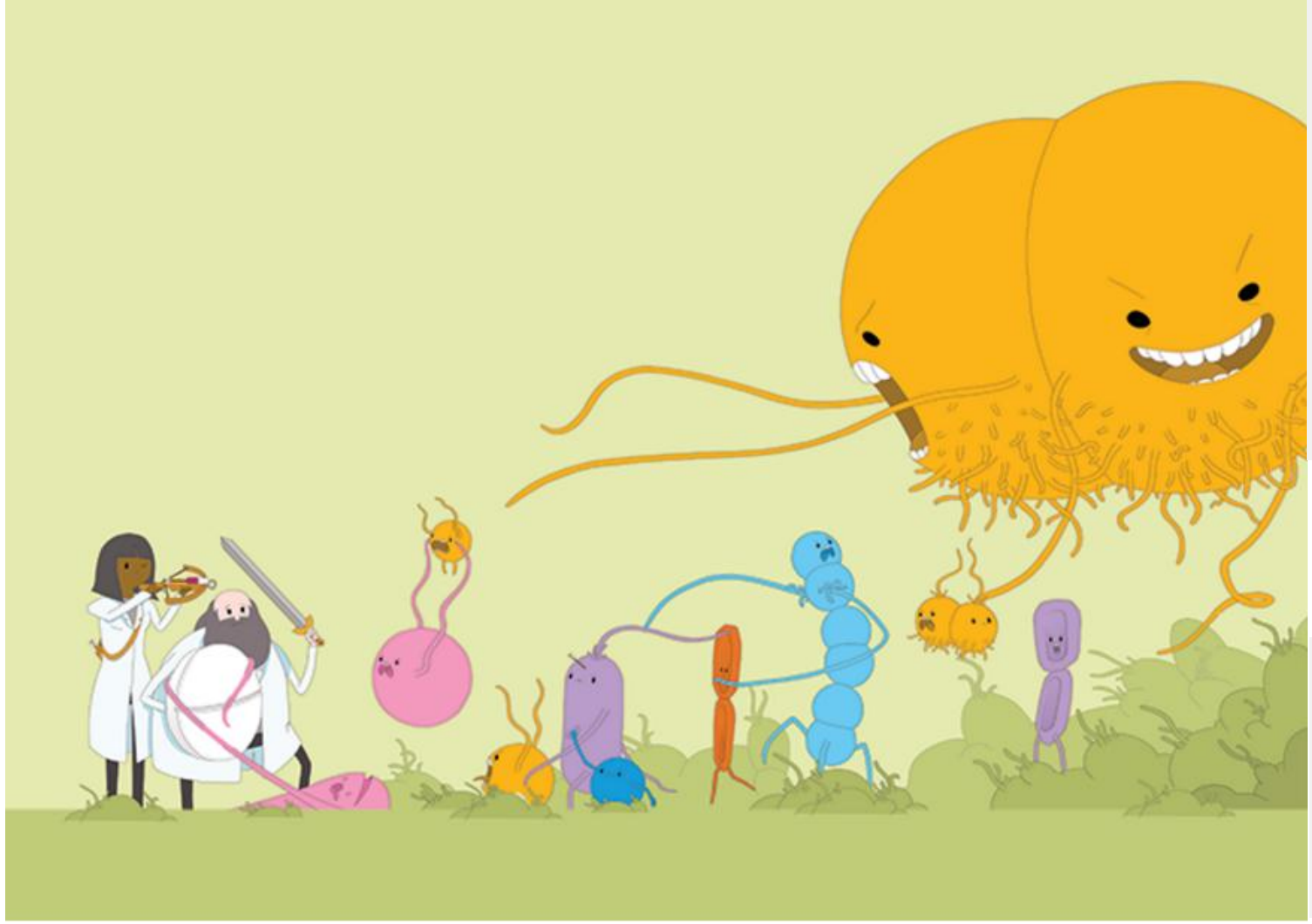


Retort & Aseptic Sterile Formulations



More Lessons Learned

- Perils & Rewards of Botulism
- Reference Standards
- Boots & Suits
- Veracity & Tenacity of Bugs
- Microbial Control 101



Credit: Rick C. Smith

"Today we face pathogens that are essentially resistant to all of the major classes of antibiotics."

—**Kenneth Hillan,** CEO, Achaogen

"Bugs will always win."

—**Evan Loh,** president and chief medical officer, Paratek Pharmaceuticals

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What's really Clean?

If a surface is not or cannot be adequately and effectively ***Cleaned***, it can not and is not reliably and reproducibly ***Sterilized***, especially in ***Aseptics***

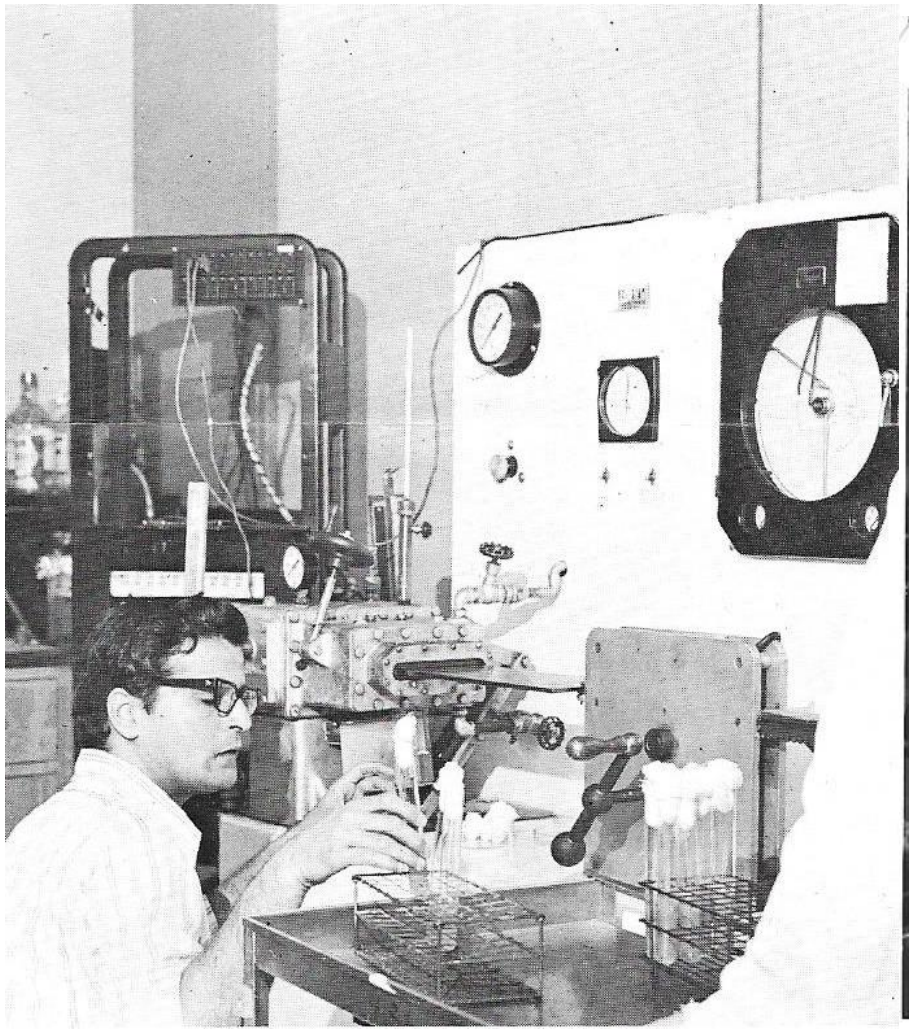
Mud bath: The idea of 'cleanliness' has never been straightforward in Western societies. DARRYL DYCK/CP

THE DIRT ON CLEAN
An Unsanitized History
By Katherine Ashenburg
Knopf, 358 pages, $35

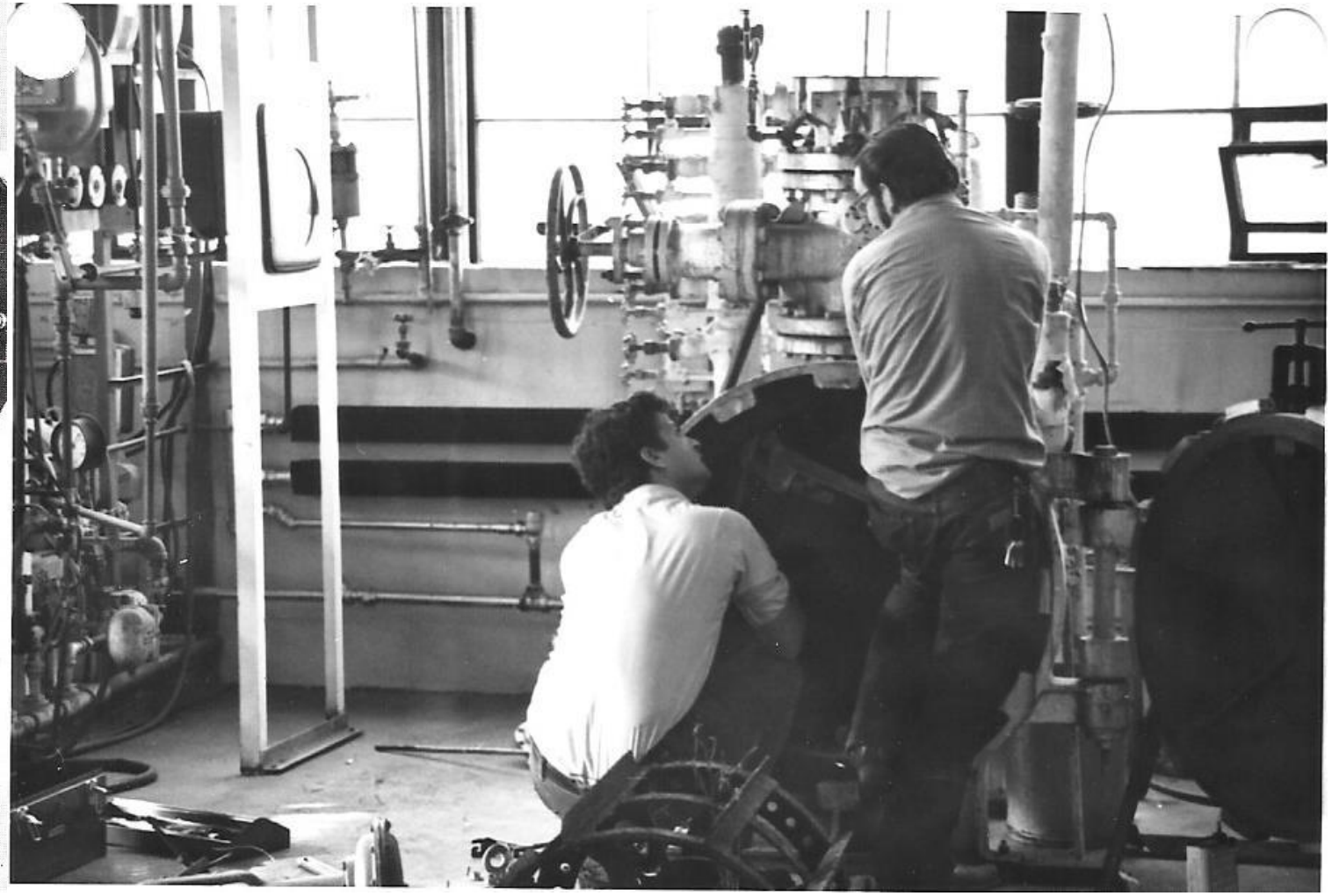
Life Lessons

- Prof Stumbo’s Resistometer
- Prof Ball’s HTST Retort Filler
- Prof Pflug’s Miniature Retort
- Prof Tung’s Admonishment

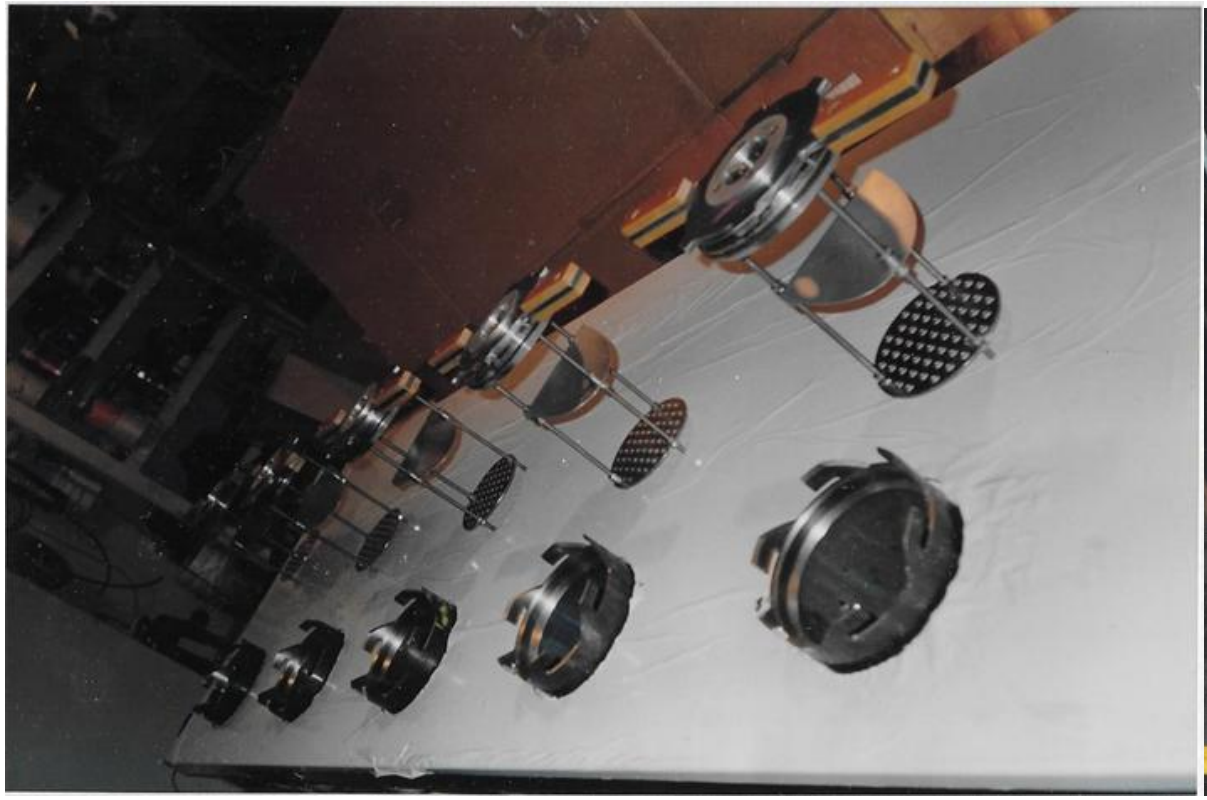
Thermo-Resistometer

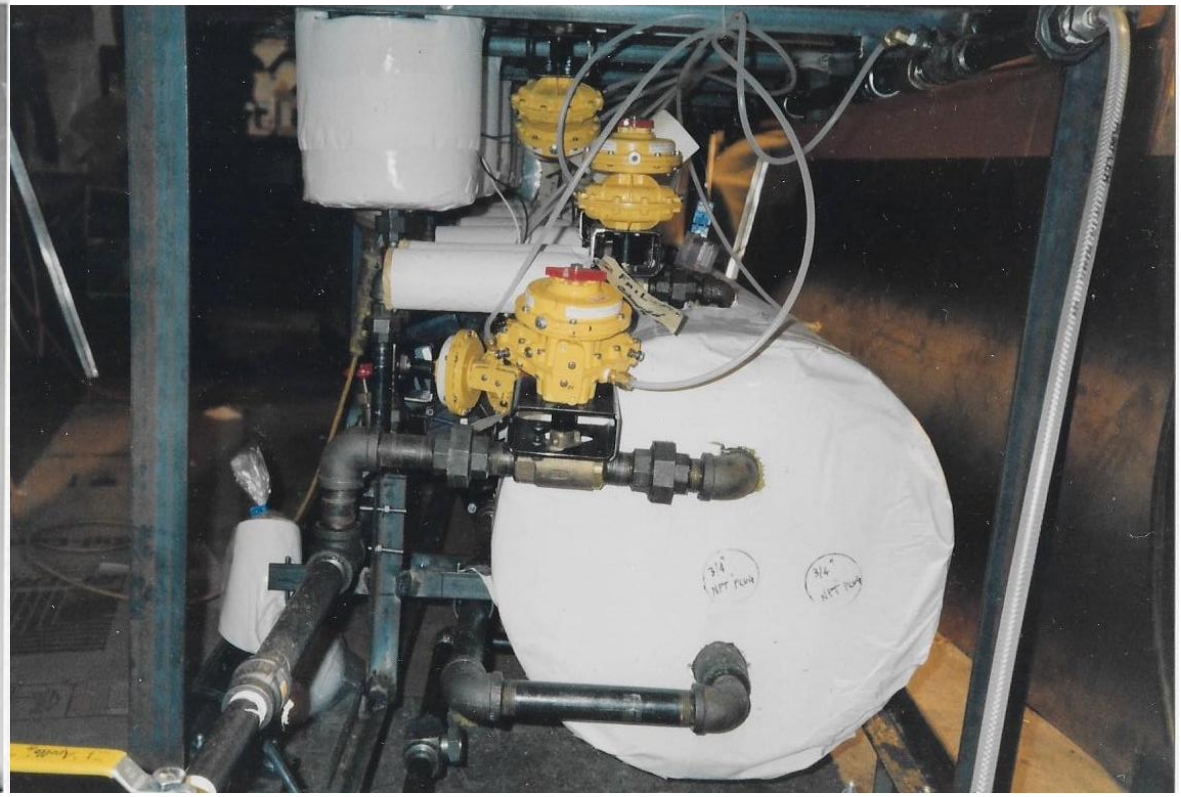


Retort HTST Solids Filler



Miniature TDT Retort





Continuing Life Lessons

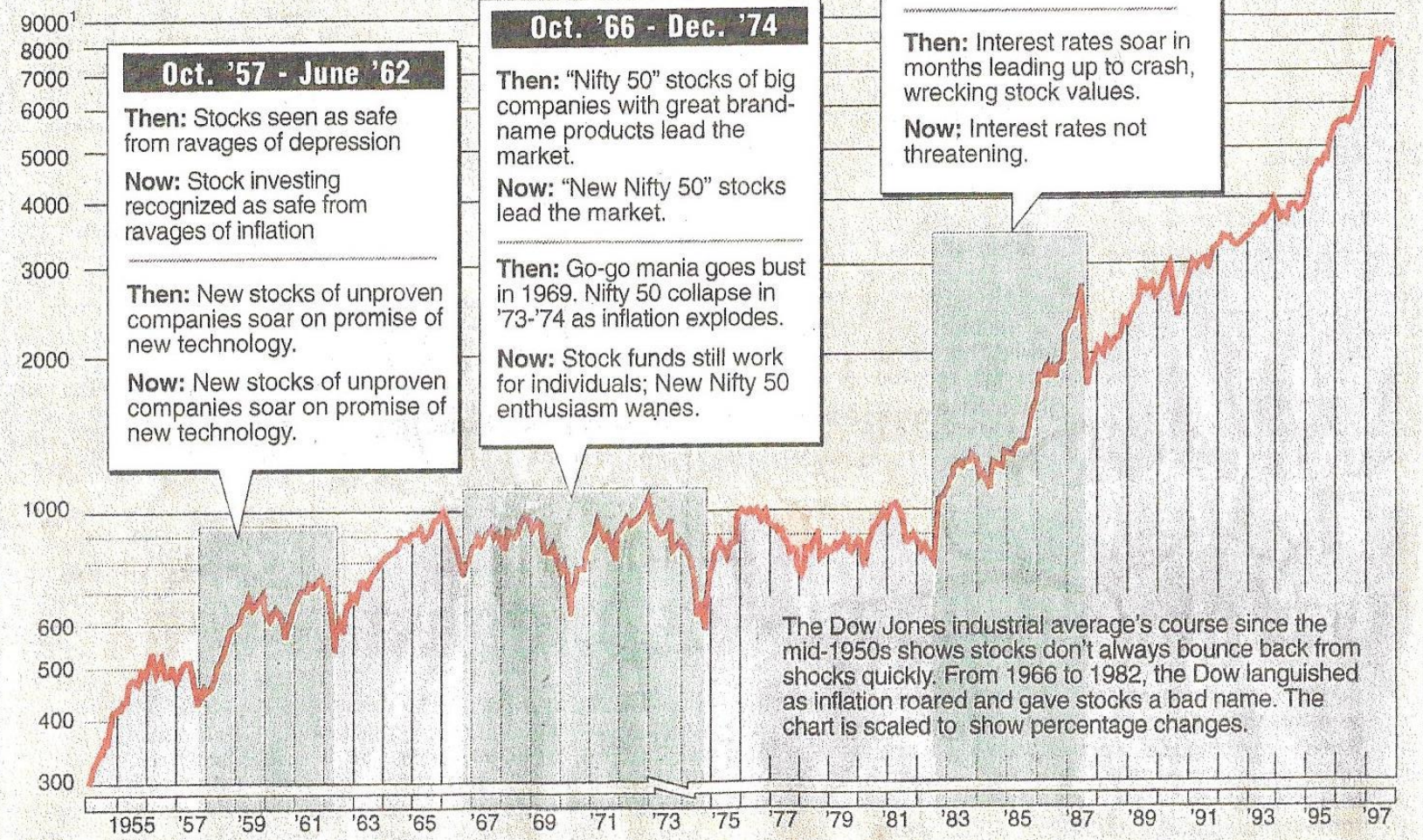
- Carnegie Hall
- Secrets of Success
- Swimming with Sharks
- Stock Market Analog
- Greek & Roman Technology

Stock Market Crash 10th Anniversary

Looking back to see the market's future

Sunday marks the 10-year anniversary of the 1987 stock market crash that stopped a five-year run of the bulls. But other bull-to-bear-market periods of the last four decades hold more similiarities to the market today and perhaps better clues to what comes next.

Dow Jones industrial average



Oct. '57 - June '62

Then: Stocks seen as safe from ravages of depression

Now: Stock investing recognized as safe from ravages of inflation

Then: New stocks of unproven companies soar on promise of new technology.

Now: New stocks of unproven companies soar on promise of new technology.

Oct. '66 - Dec. '74

Then: "Nifty 50" stocks of big companies with great brand-name products lead the market.

Now: "New Nifty 50" stocks lead the market.

Then: Go-go mania goes bust in 1969. Nifty 50 collapse in '73-'74 as inflation explodes.

Now: Stock funds still work for individuals; New Nifty 50 enthusiasm wanes.

Aug. '82 - Oct. '87

Then and Now: Stock prices climb quickly to amazing new highs.

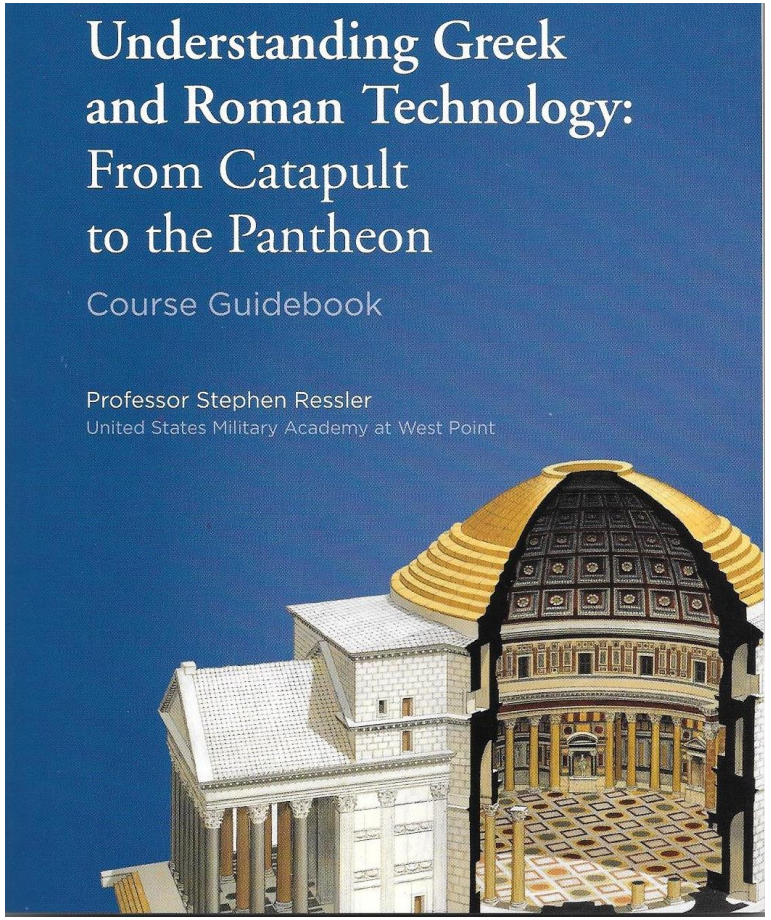
Then: Interest rates soar in months leading up to crash, wrecking stock values.

Now: Interest rates not threatening.

The Dow Jones industrial average's course since the mid-1950s shows stocks don't always bounce back from shocks quickly. From 1966 to 1982, the Dow languished as inflation roared and gave stocks a bad name. The chart is scaled to show percentage changes.

1– Logarithmic scale used to show percentage changes.

De Architectura
Marcus Vitruvius Pollio (c. 70 - c. 150 BC)



- Sole surviving treatise on Ancient Engineering
- Job Description of an Architect suggests a learned and broadly educated person
- May enable us become more learned and more broadly educated professionals

Qualifications of the Architectus (Vitruvius, c. 150 BC)

- Skillful with the Pencil, to prepare Sketches and Plans
- Geometry, to rightly apply the Square and the Level in Construction
- History, as architectural features draw from historical antecedents
- Philosophy, so he may be courteous, just and honest
- Medicine, so he may judge Water Quality
- Law, so he may draw up Construction Contracts
- Astronomy, so he can design Sun Dials
- Musical Ear, to properly adjust the tension of Catapult Springs, by plucking them and discerning the correct musical notes

Thank you,

for your courtesy, your consideration and your attention!

All the best, to all of you, always!