Validating the challenging processes

Andrew Green & Philip Richardson
Campden BRI, Chipping Campden,
Glos GL55 6LD. UK

Thermal processing objectives

- Application of thermal energy to destroy pathogenic and spoilage microorganisms

- Achieve commercial sterility in thermally processed products

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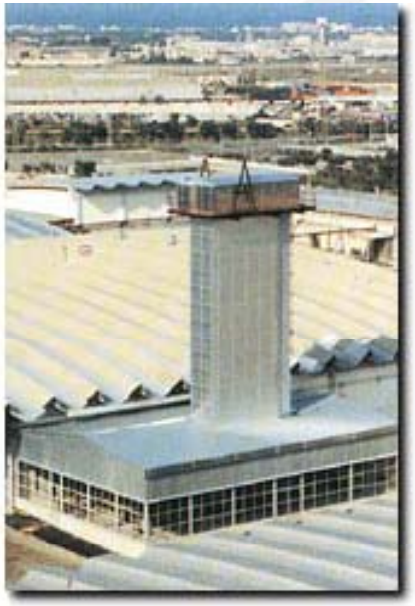

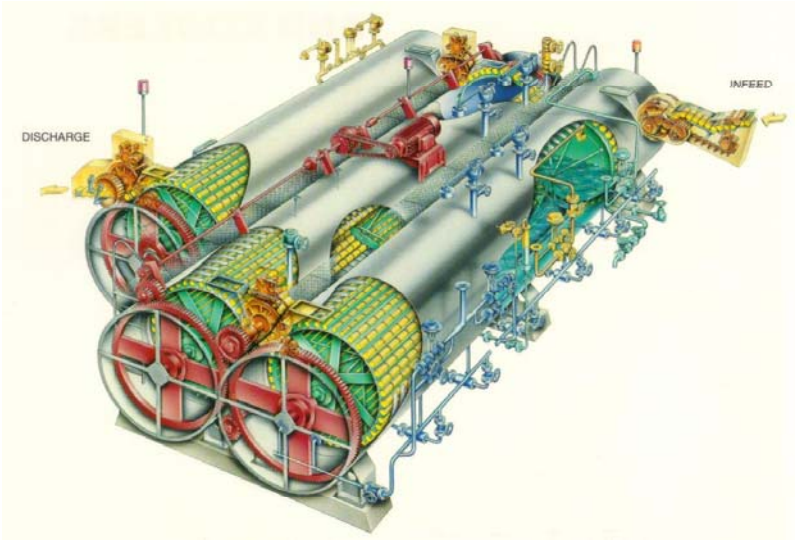

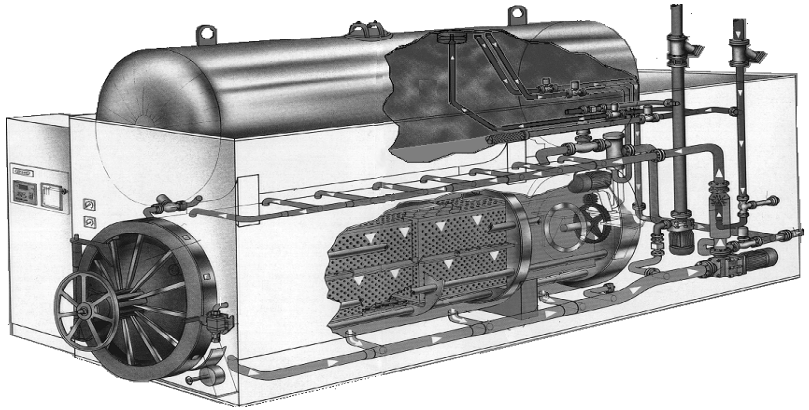

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Achieving commercial sterility

Depends on product characteristics and the intended distribution and storage conditions

Sterilisation

12-log reduction in *C. botulinum* spores ($F_0$3 process)

low-acid, ambient stable products

Pasteurisation

e.g. 6-log reduction in *Listeria monocytogenes* (< $F_0$3 process)

control of product pH, water activity, storage temperature, shelf life

JE Gaze (2006), Pasteurisation: a food industry practical guide, CCFRA

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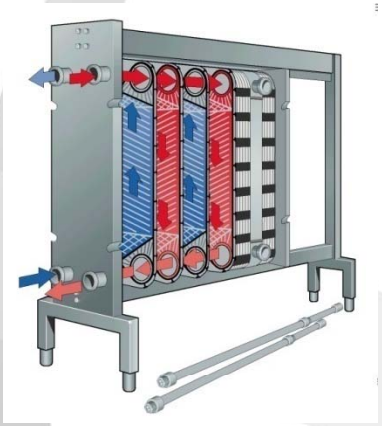
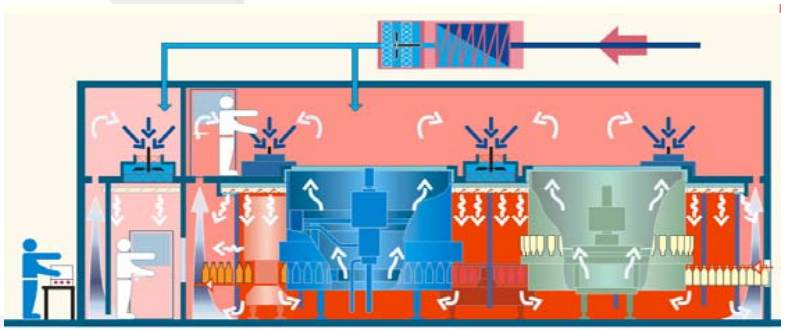
Commercial sterility: of equipment and containers used for aseptic processing and packaging of food…..



…….the conditions achieved and maintained by application of heat or other methods, sufficient alone or in combination with other appropriate treatments, which renders such *equipment and containers* free from microorganisms capable of growing in the food at temperatures at which the food is likely to be held during manufacture, distribution and storage.



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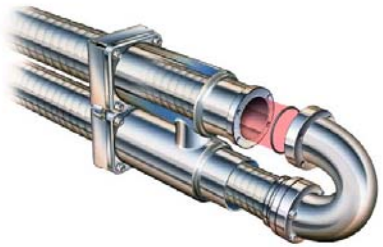
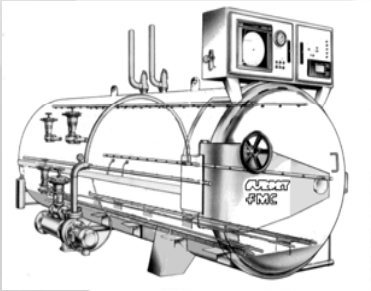
When to validate a Process

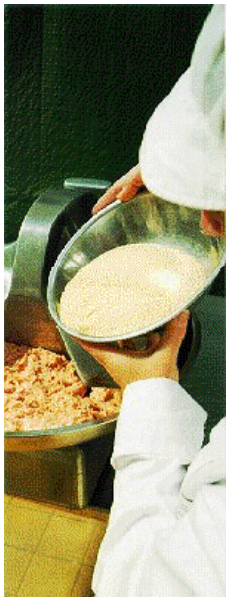


Modified processing equipment



New processing equipment

New products



Reformulation

New packaging formats

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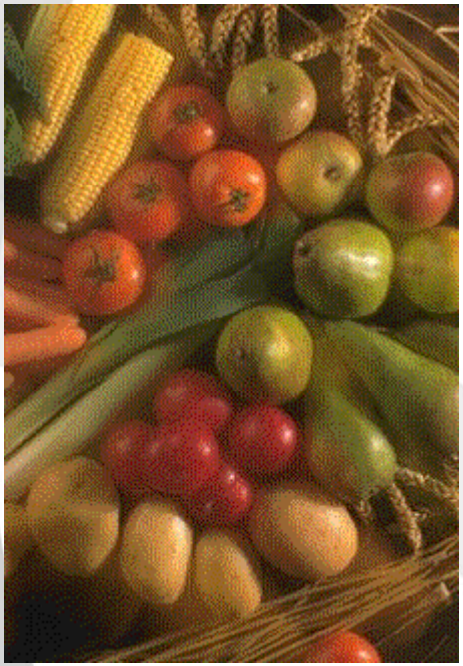
Acidified or Chilled products



- **Consider the ingredients**
- **Consider the typical micro flora**
- **Consider the impact of the process steps**
- **Review degree of final thermal process needed**

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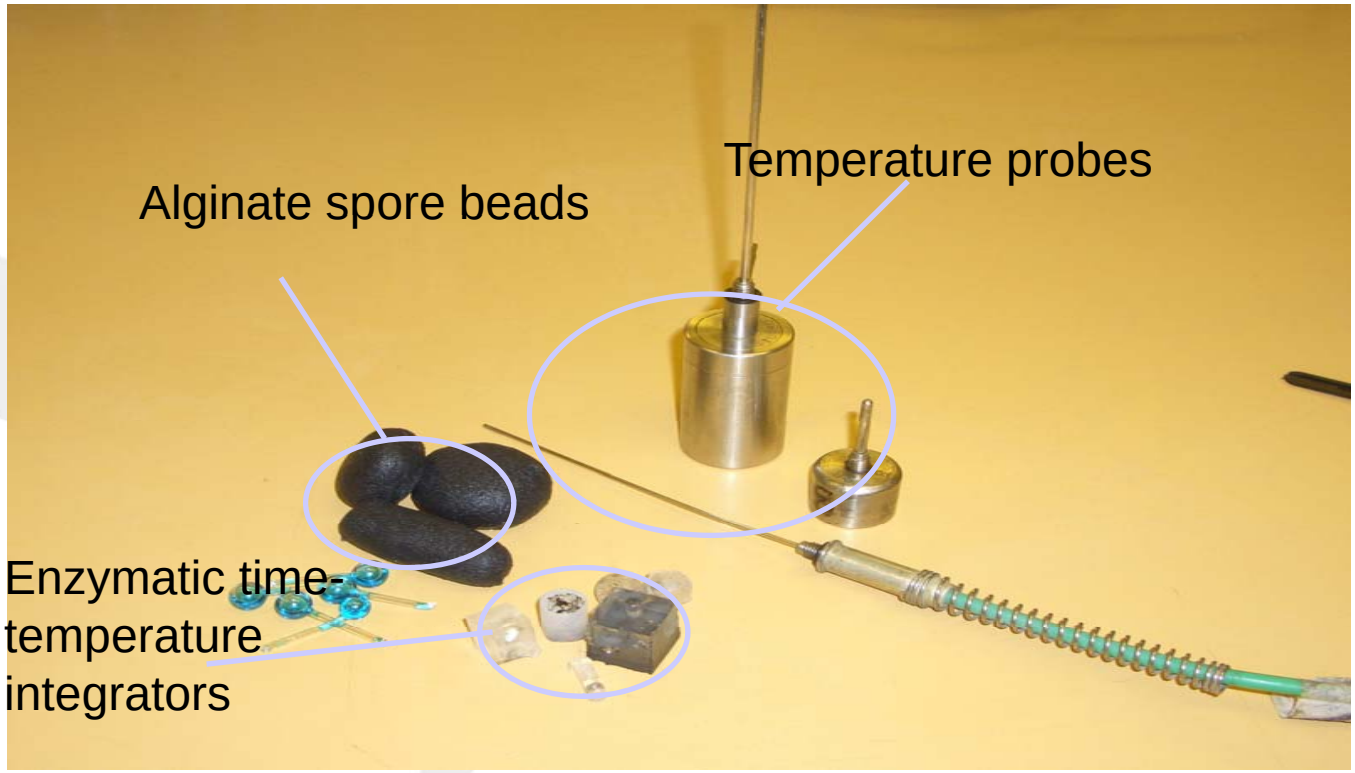
Validation methods and tools



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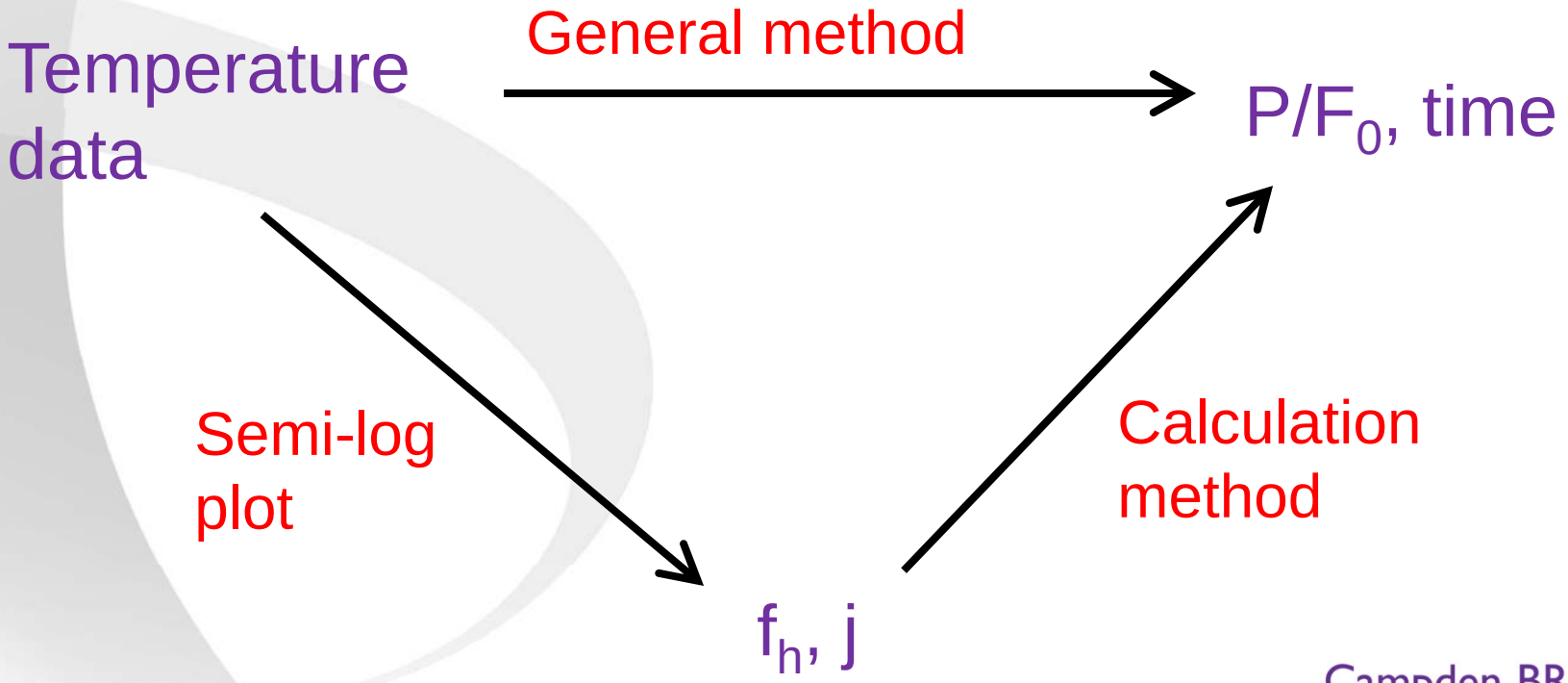
Temperature measurement

- Point temperature measurement using thermocouple or PRT-based sensors



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Microbiological validation

- Use of marker organisms with matching death kinetics to the target
  - Similar z-value
  - Larger D-value (survivors essential for accurate calculation)

$$\mathrm{F} = \int_0^t 10^{(T - T_{ref})/z} dt = D_{Tref}.\log(N_0 / N)$$

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Microbiological validation

- Inoculation
  - Returns average process achieved throughout container
  - Dilution effects on initial numbers
  - Simple for liquid products, difficult for solids
- Encapsulation
  - Returns a point measurement
  - Higher loading achievable
  - Distribution analysis
  - Applicable to continuous processes

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Time-temperature integrators

- Chemicals with similar ‘death’ kinetics to microorganisms
- α-amylase from thermophilic *Bacillus* sources
- Microlitre quantities encapsulated in silicone tubes
- Used in similar way to alginate beads
- Measuring log-reduction of enzyme activity

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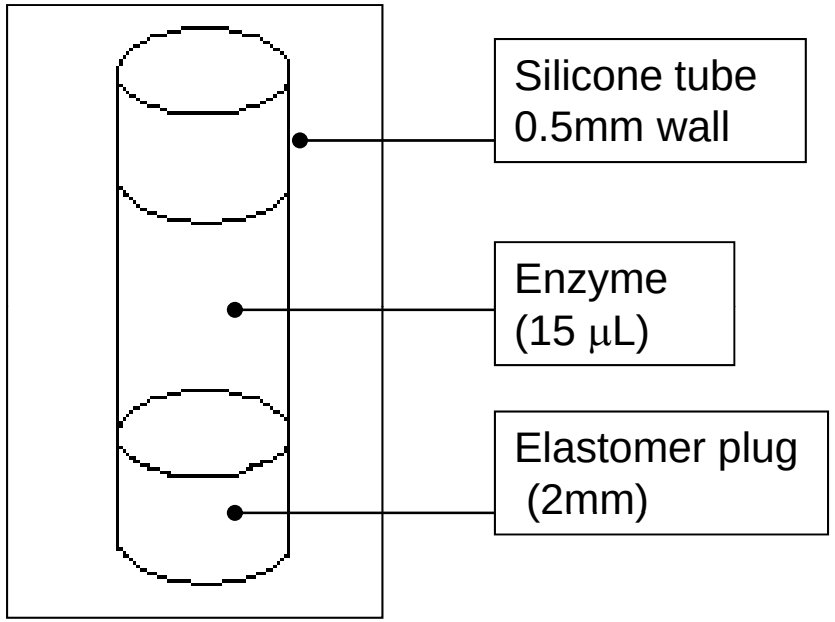
Particle construction

- Quick and easy construction
- Can be made in large numbers
- Incorporated into food simulants



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Applications

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TTIs – recent developments

- Time-temperature integrators for the measurement of sterilisation processes
- Rapid assay development
- Surface pasteurisation applications

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Sterilisation TTI

- Amylase sources investigated
  - *Pyrococcus furiosus*
  - Recombinant yeast
- Assay development
  - Discontinuous methods
  - Phadebas method

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Surface pasteurisation

- current objectives

- Determine the loading and type of microbial species present
- Determine the vectors of the contamination to the packaging
- Assess the efficacy of pre filling decontamination processes
- Develop an accurate and reliable method to measure the level of surface pasteurisation

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Why?

- To produce guidelines providing advice on package pasteurisation issues.
- To assess the potential for energy savings brought about by reduced thermal processes.

How to measure & quantify is a key question

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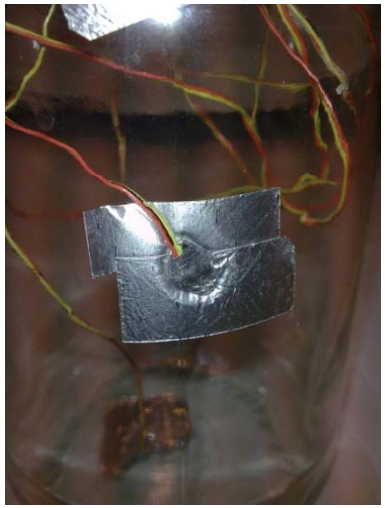
Flat tipped thermocouples

- Type K thermocouples with a flattened tip plugged into a squirrel data logger.
- Record time temperature data in real time
- Potentially very difficult to pass through a pasteurisation tunnel



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Thermocouple production

- Type K thermocouple wire connected to a plug and the ends twisted and soldered
- Tip dipped into a blob of solder to form a metallic ball shape on the tip
- Ball of solder flattened in a vice to form a flat tipped thermocouple.

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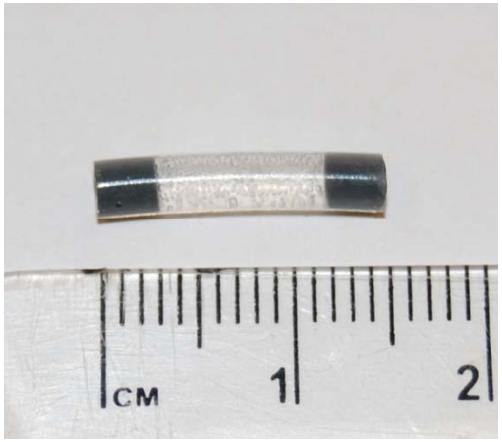
Standard TTIs

- Based upon the use of an amylase with similar death kinetics to that of the target organism.
- Lethalities determined by measuring the enzyme activity before and after processing.



- A well established method for measuring the extent of a process.
- Simple to produce, but no real time data.
- Current design not practical for surface measurment.

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Standard TTIs

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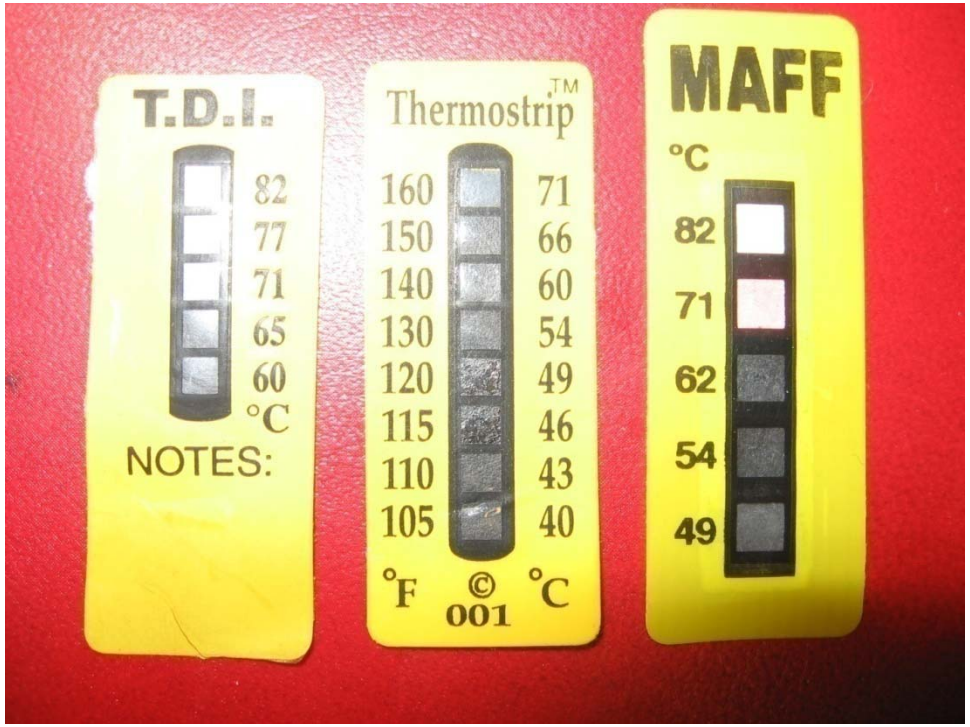
Thermochromic inks

Produce a colour change at a specific temperature

No quantitative data



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Reversible thermochromic inks

This one gives a reversible colour change at 70°C

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Thermochromic inks

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Bubble TTI

- Approaches can include:
- Using an existing mould to form a bubble TTI in layers
- Spray on surgical dressing over the enzyme
- Half a TTI tube
- Layers of elastomer plus O rings

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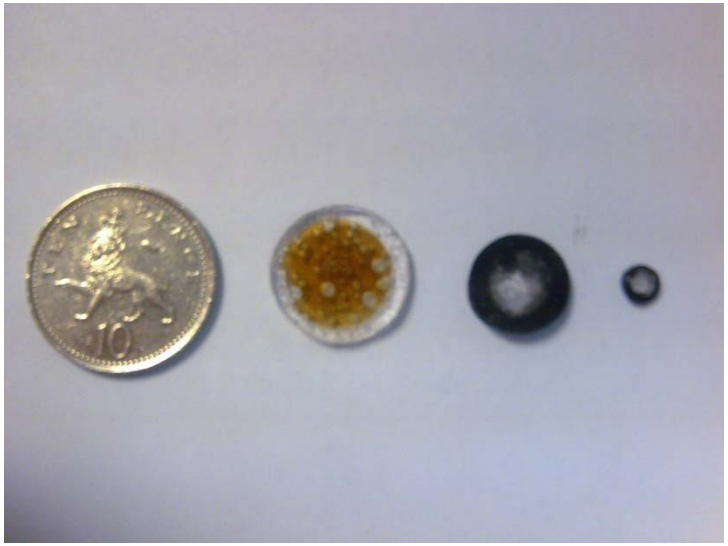
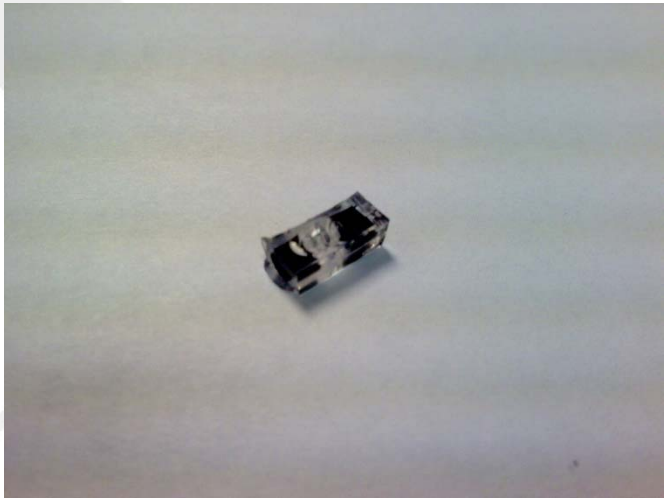
Bubble TTI





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TTI production

- Heat sealed tray film cut into strips and folded over.

- A soldering iron is used to form a narrow seam on all but a fraction of the remaining three sides.

- The enzyme is then injected and the hole sealed behind it.

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Results so far

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TTI v Thermocouples

- Thermocouples and surfaces TTIs fixed in various locations on the inside of a glass jar
- Jar filled with hot water at a specific temperature (depending upon TTI type) for a specific process time to achieve a target P value.
- Jar emptied, TTIs removed and sent for analysis.

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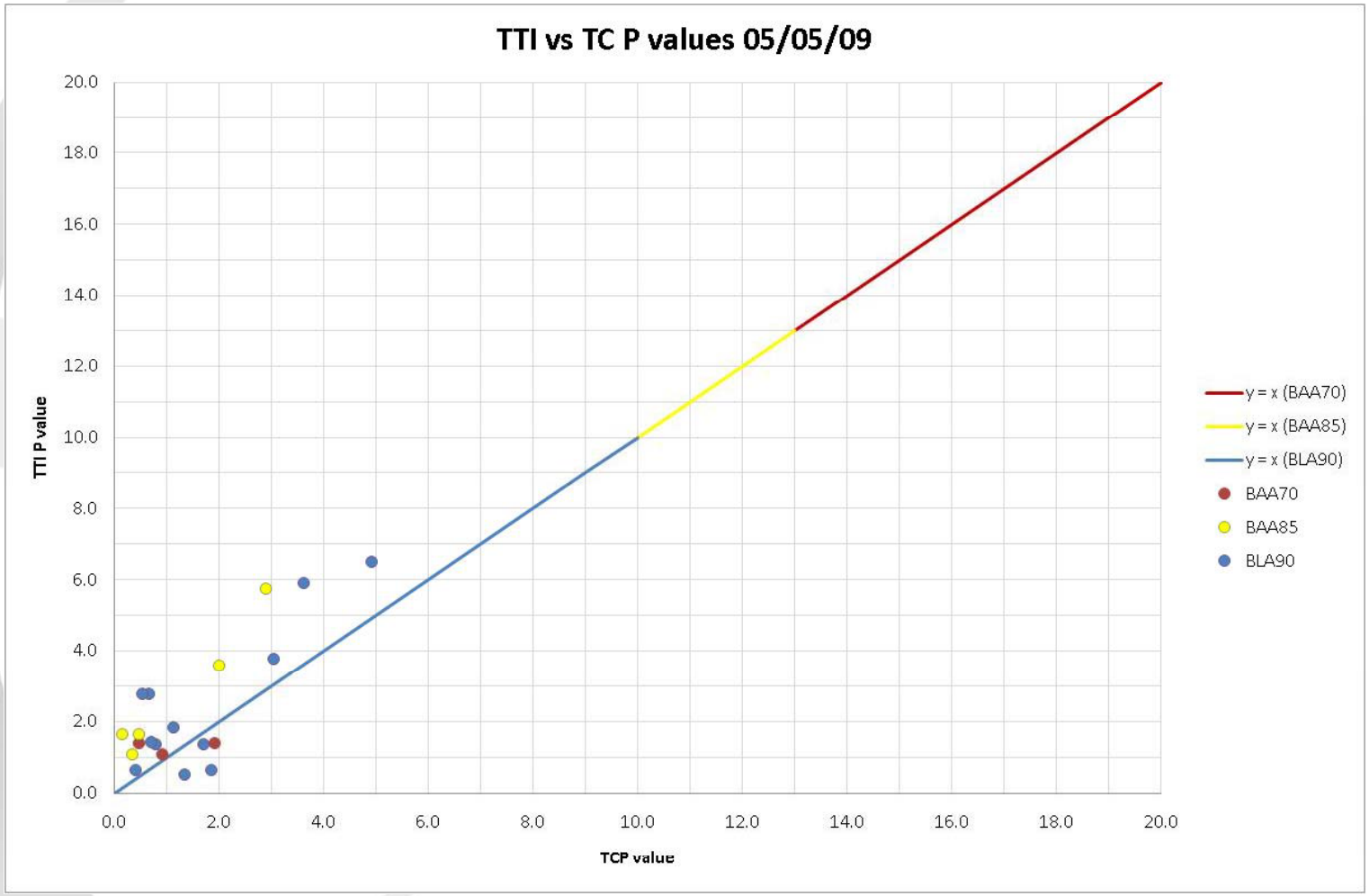
TTI and Thermocouple P values



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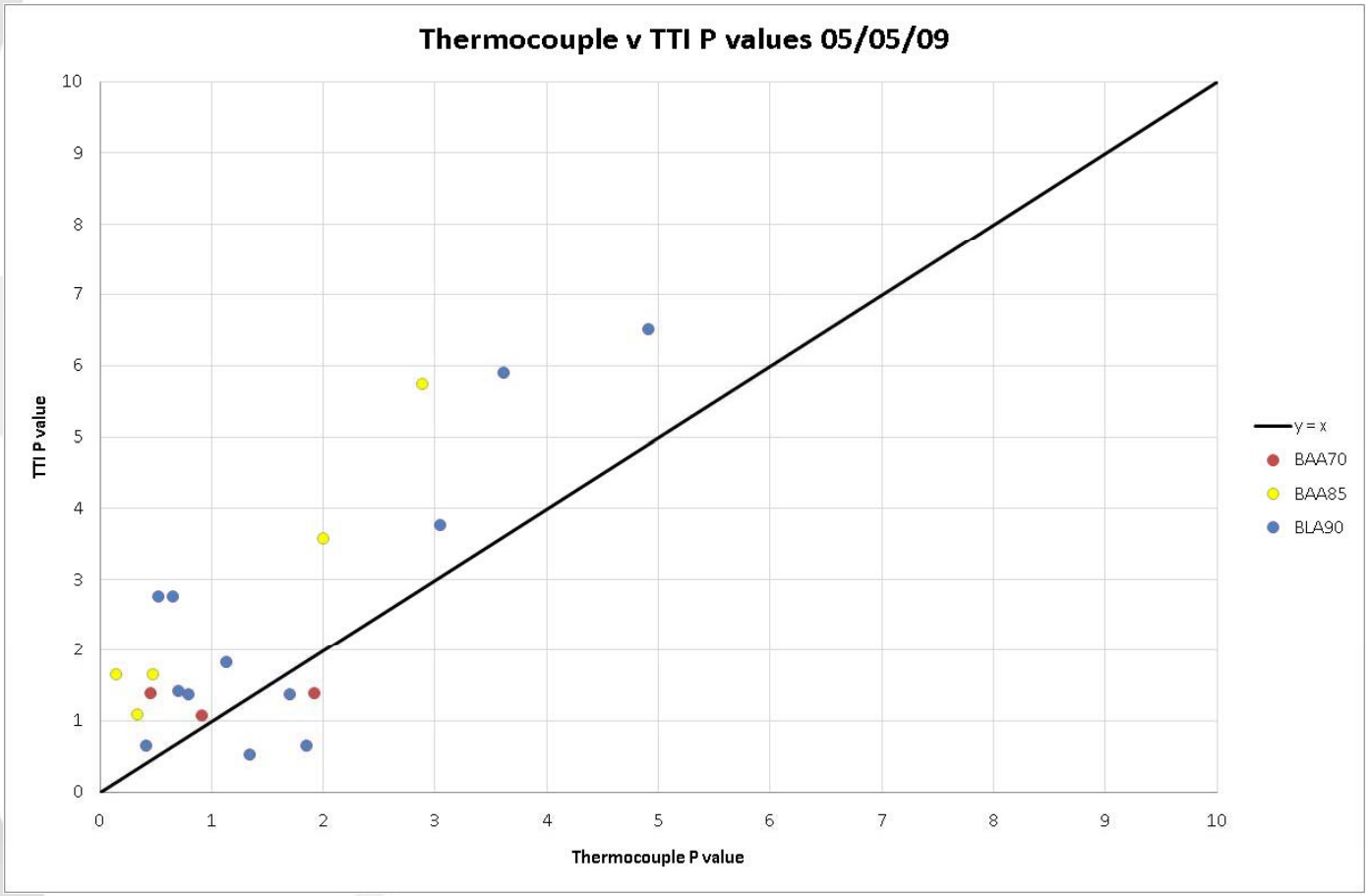
TTI and Thermocouple P values



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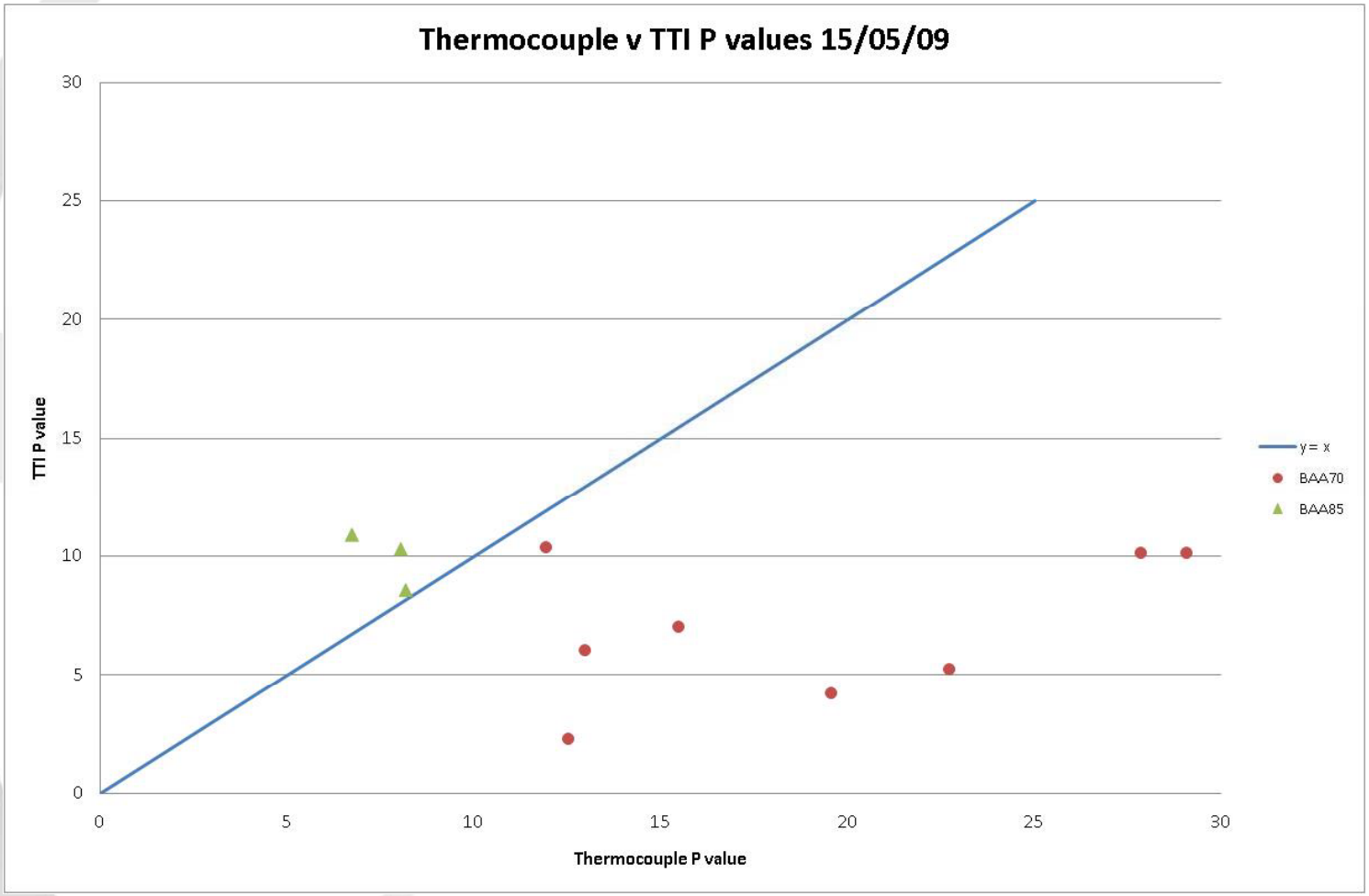
TTI and Thermocouple P values



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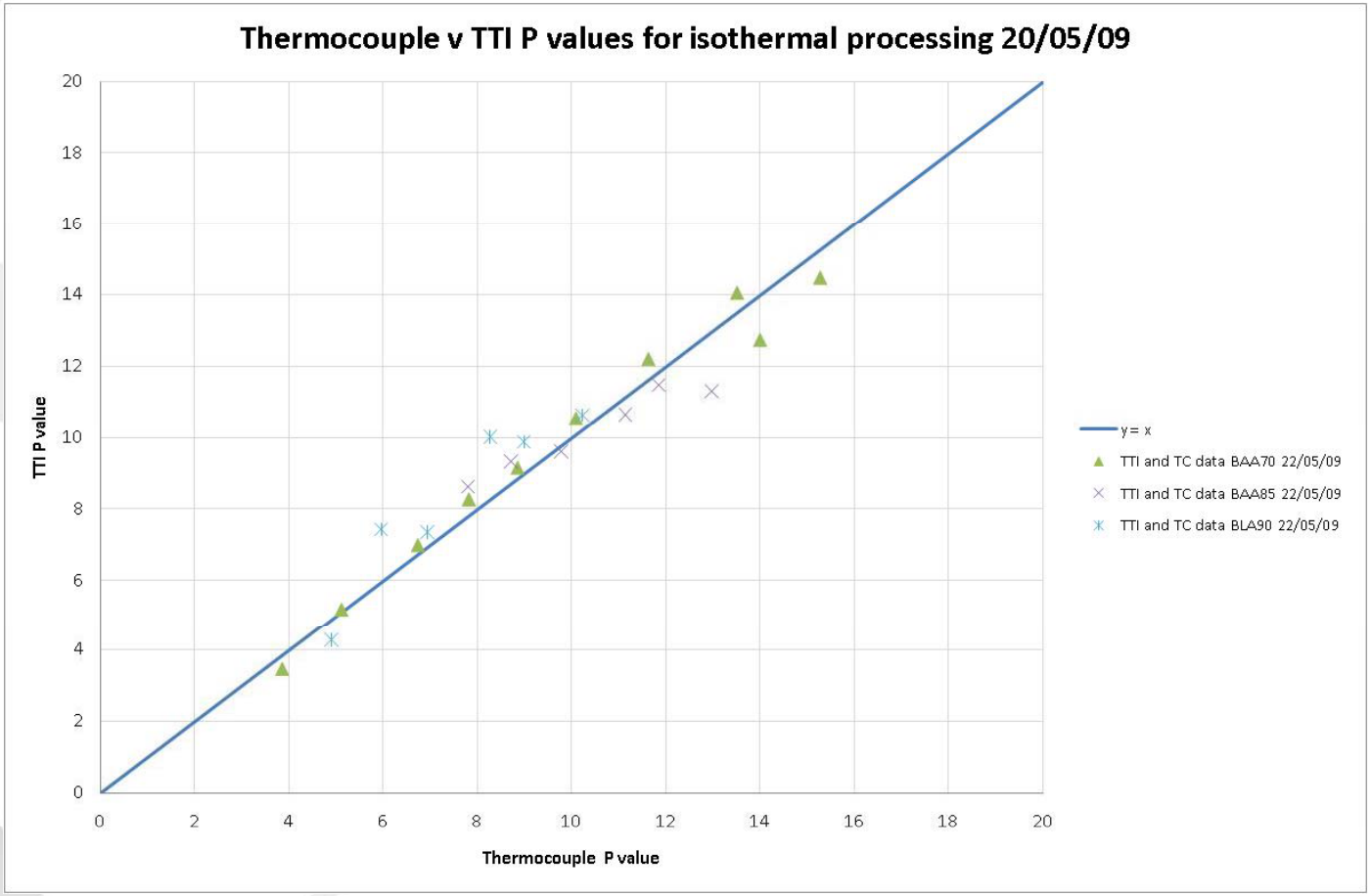
Isothermal TTI processing

TTIs processed in a water bath running at the reference temperature for the TTI



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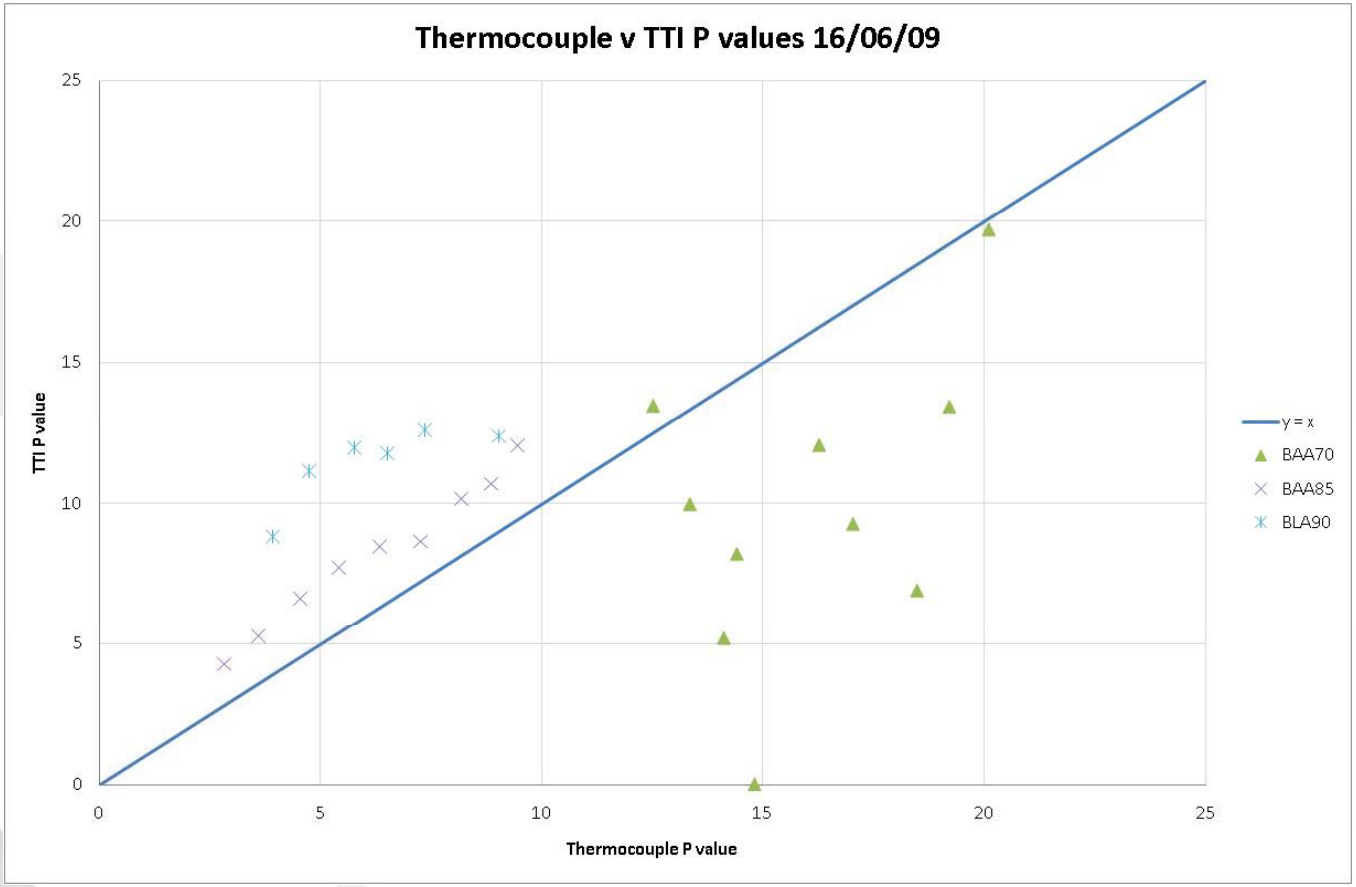
Non isothermal TTI processing

Water heated to reference temperature and then held to achieve target P value



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TTI calibration

BAA70

Temp (°C)	Gradient	D value	log D
65	-0.0212	47.2	1.674
70	-0.1045	9.6	0.981
75	-0.2955	3.4	0.529

BAA85

Temp (°C)	Gradient	D value	log D
80	-0.0677	14.8	1.169
85	-0.1278	7.8	0.893
90	-0.2715	3.7	0.566

BLA90

Temp (°C)	Gradient	D value	log D
85	-0.0399	25.1	1.399
90	-0.2603	3.8	0.585
95	-0.5860	1.7	0.232

TTI	Gradient	z value
BAA70	-0.1144	**8.7**
BAA85	-0.0603	**16.6**
BLA90	-0.1167	**8.6**

Target processes

70°C for 2 minutes (z = 7.5C°)
85°C for 5 minutes (z = 8.3C°)
90°C for 10 minutes (z = 9.0C°)

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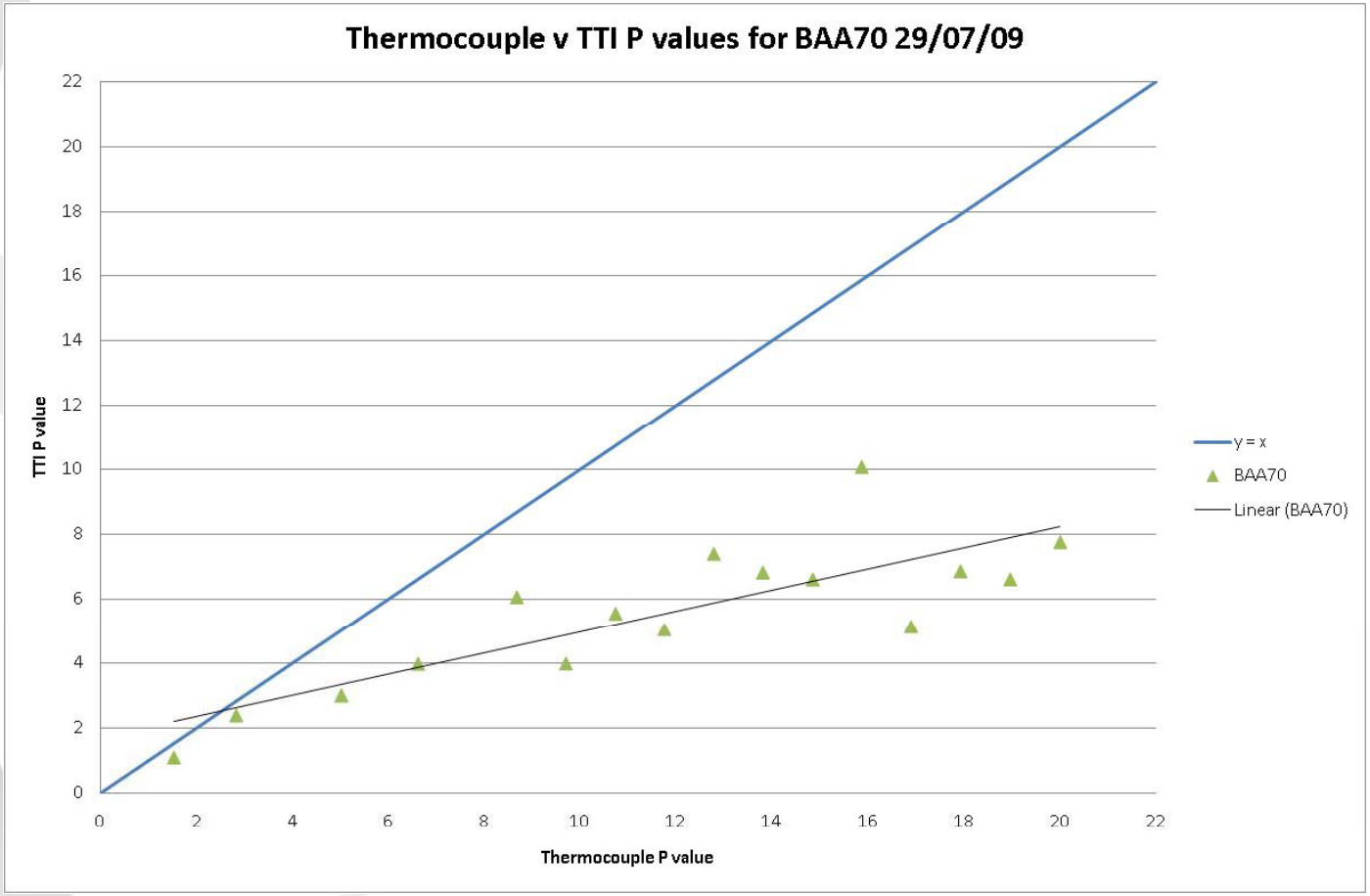
Processing above T_{ref}

BAA70 processed in a water bath at 75°C from 60°C



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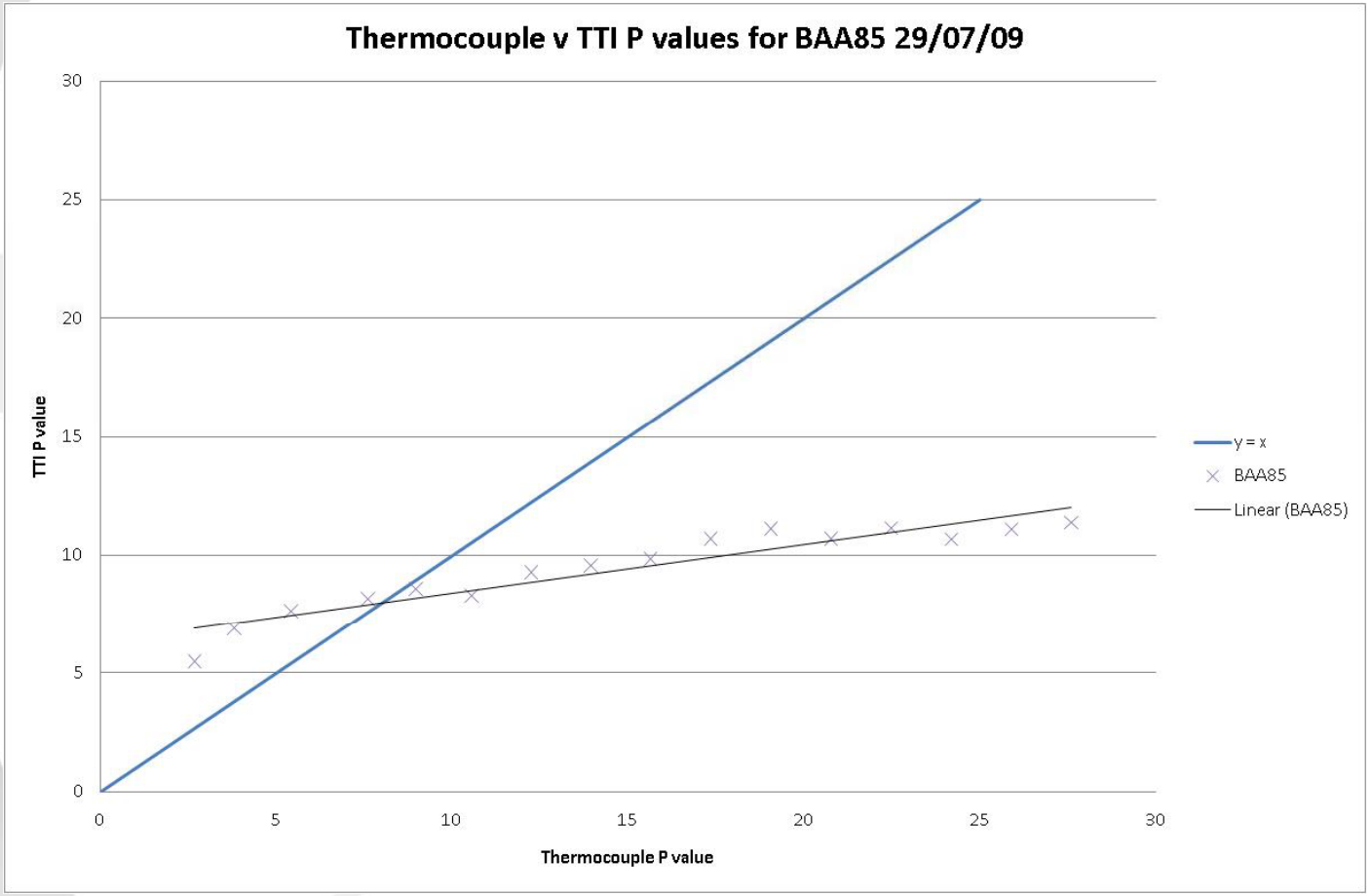
Processing above T_{ref}

BAA85 processed in a water bath at 90°C from 60°C



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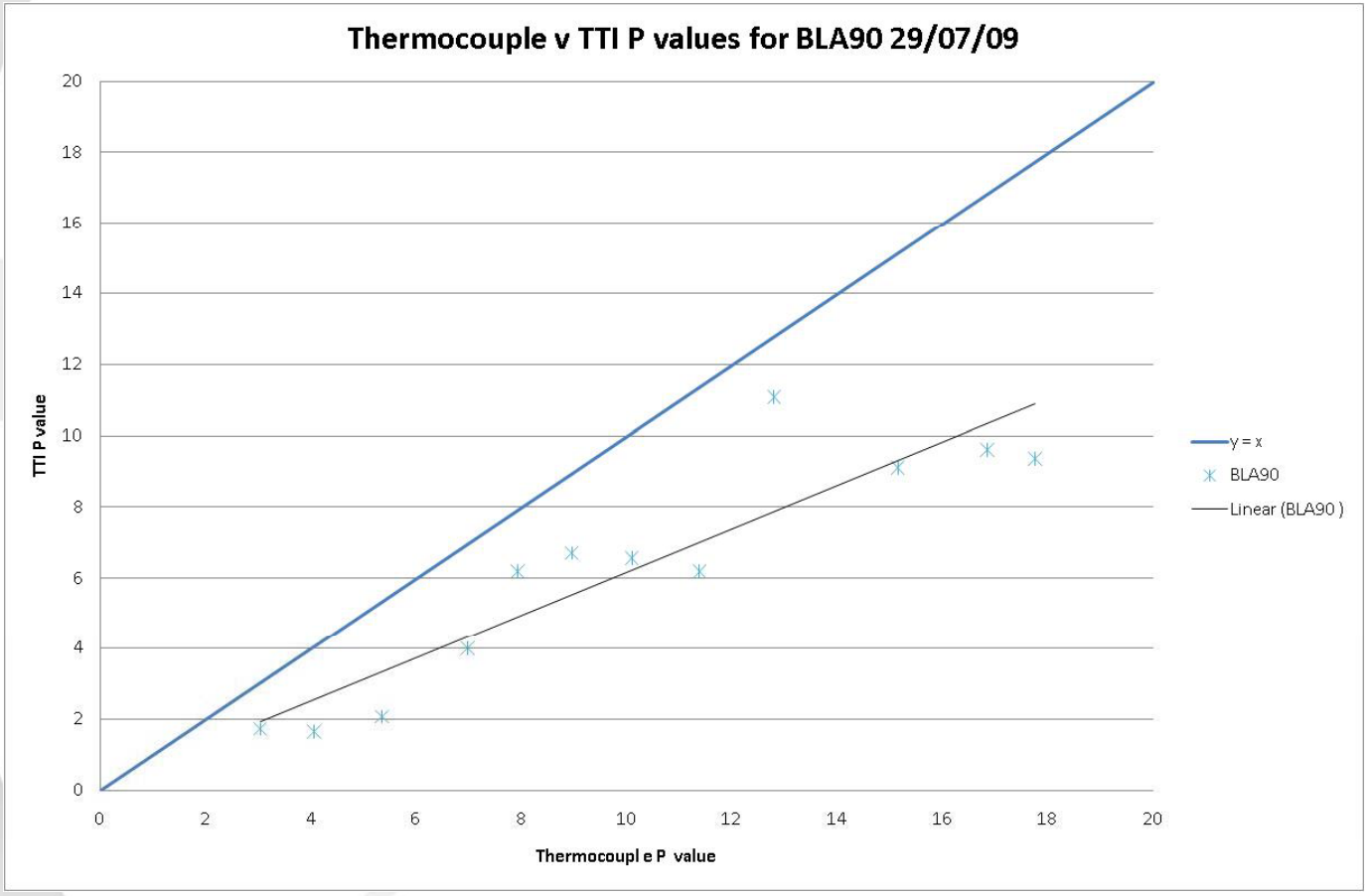
Processing above T_{ref}

BLA90 processed in a water bath at 95°C from 60°C



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Estimating P values

- z-value greater than target z-value for BAA70 and BAA85
- z-value for BLA90 very close to target z-value

	$T > T_{ref}$	$T < T_{ref}$
$z_a > z_{target\ process}$	P_a underestimated	P_a overestimated
$z_a < z_{target\ process}$	P_a overestimated	P_a underestimated

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TTI calibration

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Target processes

70°C for 2 minutes (z = 7.5C°)
85°C for 5 minutes (z = 8.3C°)
90°C for 10 minutes (z = 9.0C°)

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What do these results tell us?

- The z-values for BAA70 and BAA85 are higher than those of the target processes.
- Unless the surface temperature is equal to or greater than the reference temperature then the TTIs will overestimate the P-value.
- This may be difficult or impossible to achieve for processes based upon 85°C or 90°C without using an external heat source.

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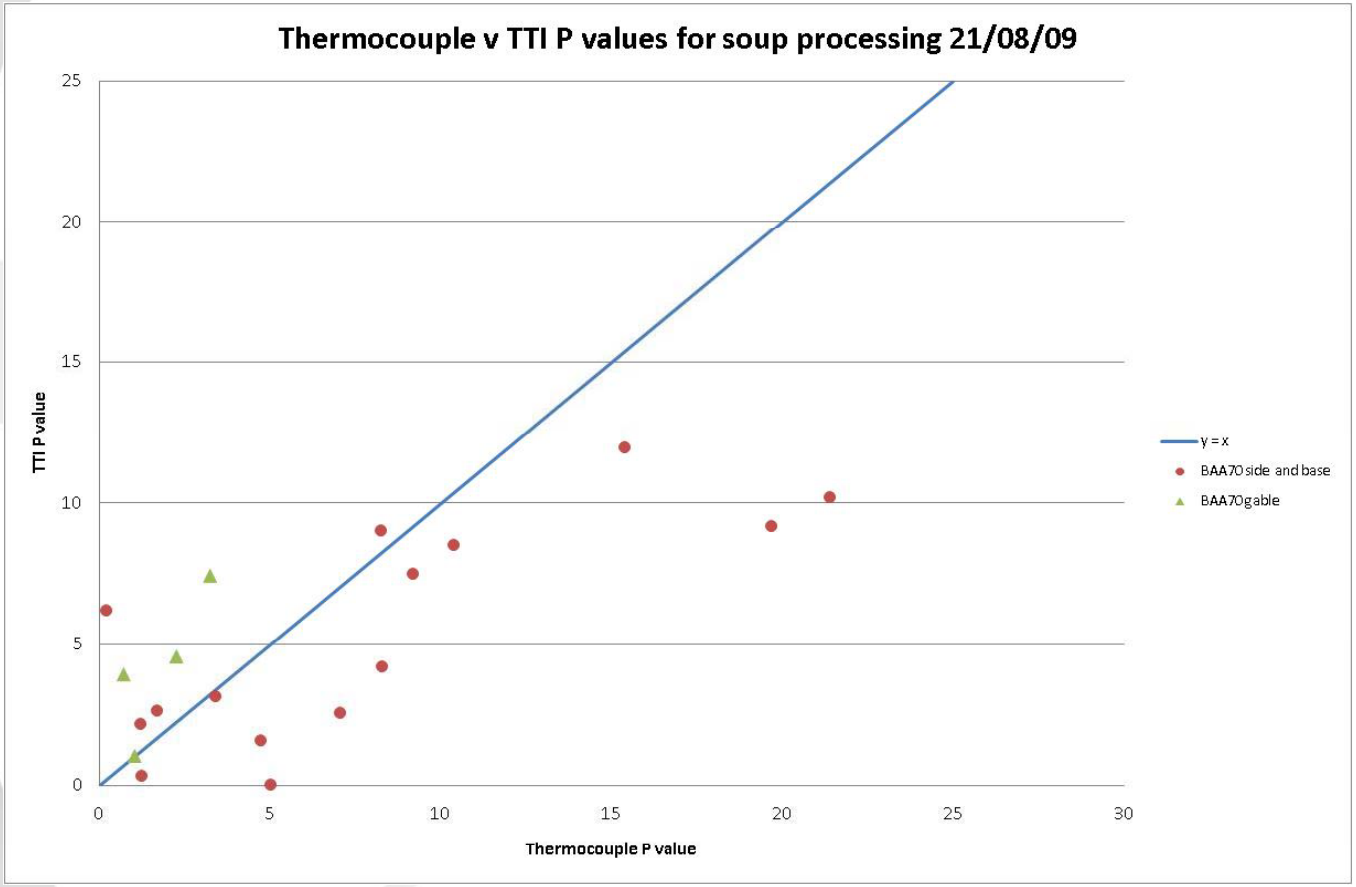
Processing soup in cartons

BAA70 processed using a fill temperature of approx 85°C



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The next steps

- Investigate the barrier properties of the tray film in more detail.
- Investigate the use of thermal imaging to find the position of the cold points within a pack before using TTIs.
- Carry out further hot fill tests using BAA70 in using a range of other products and packaging formats e.g. jars and plastic trays.
- As part of another research project – investigate improve manipulation and control of enzyme D and z-values

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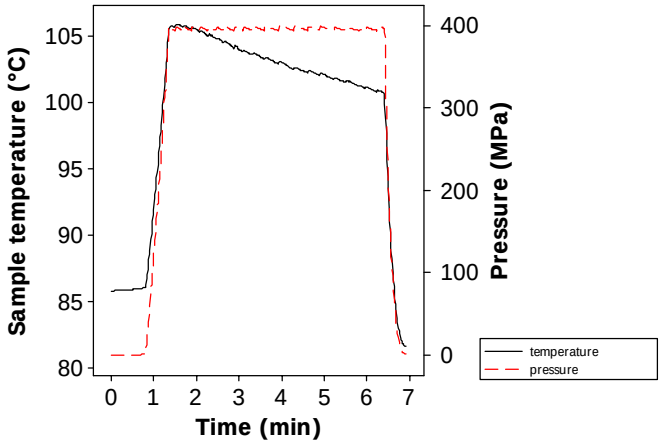
High pressure sterilisation

- HPP for pasteurisation well established and effective
- Bacterial spores are resistant to HPP alone
- Various approaches for sterilisation suggested (e.g. Wilson & Baker, 1997; Meyer, 2000)
- Growing body of evidence for microbiological efficacy
- Very limited data on quality effects

Image courtesy of Nigel Rogers, Avure



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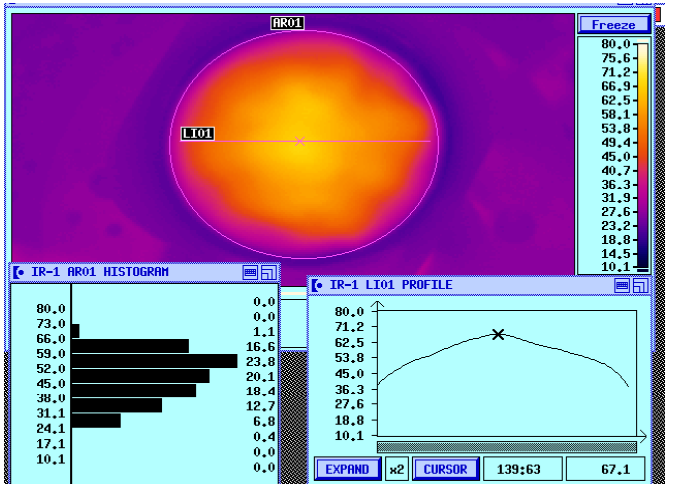
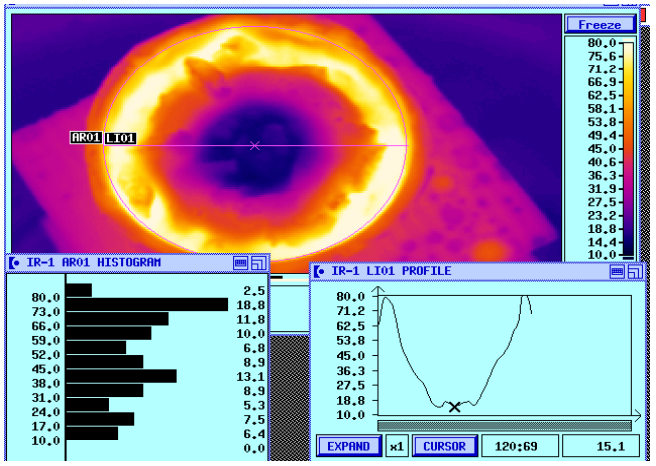
Microwave Processing





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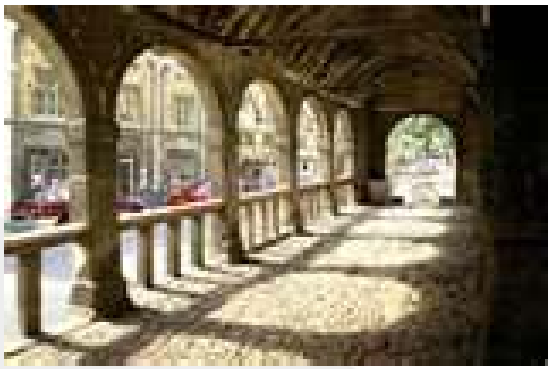
Our Thermal Processing Event – June 23 & 24 2010, Chipping Campden, UK.



- 2 day event:
- Day 1 – Sustainability.
- Day 2 - Process Safety & Development.

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