The Science Behind The Differences Between Batch and Continuous Thermal Processes

The basis for virtually all continuous thermal processing, (for sterilization) is the fundamental science behind retort/autoclave sterilization. These batch processes were originally aimed at eliminating *Clostridium botulinum* as the target organism. Holding the product at the equivalent of 250˚F (121˚ C) for 5 minutes became the standard for the elimination of bacteria, sterilization. This "equivalent" is often confusing because it represents the cumulative impact of a process that ranges from 20 to 120 minutes depending on the package. Today, variations of this process, using different target organisms, are used in different industries. These, however are batch processes, and while they are effective means of delivering a specific level of bacterial reduction (i.e. log reduction), they also have a number of shortcomings including:

- Excessive damage to the products due to thermal exposure
- Variation of product quality within a single batch
- Variation of quality between batches
- Inefficient use of time and potential highly labor intensive
- Limited ability for scaling up for larger throughput or demand
- Inefficient use of energy

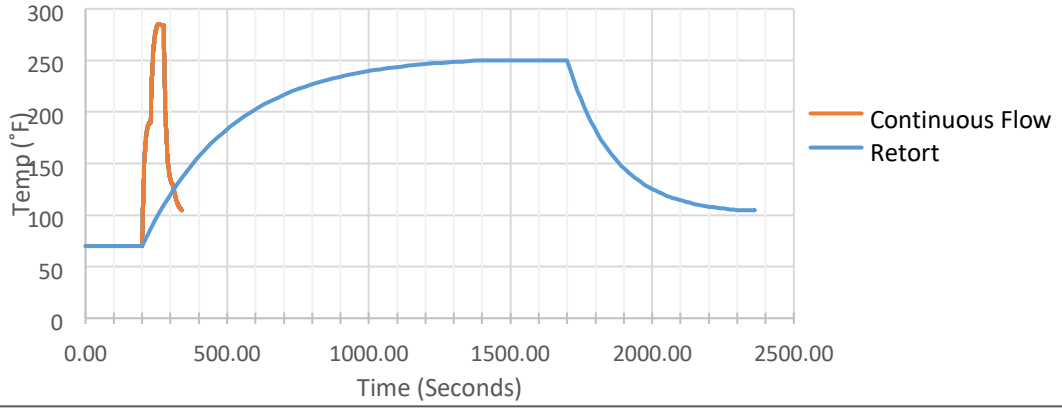
Changing the style of process from batch to continuous thermal sterilization processes such as Hot-Fill, High Acid Aseptic Processes, and Low Acid Aseptic Processes (UHT) eliminates the overwhelming majority of these problems. Let's see why this is true.

Minimizing Damage To The Product Due To Thermal Exposure

In thermal processing, the goal is to sterilize the product, while minimizing thermal damage to the product. Due to the long heat-up time, hold time, and cool-down time, batch processes such as retort/autoclaving expose products to an excessive amount of heat to sterilize the product. Thus, while the product is sterile, the thermal exposure damages the product resulting in issues such as the denaturing of proteins, dramatic loss of nutrients such as vitamins and minerals, and development of undesirable characteristics like changes of viscosity or discoloration. The result of these negative changes is a loss of functionality in the product. This results in often having to use more and/or more expensive ingredients to get the desired functionality.

In continuous thermal processing, heating times tend to be less than 2 minutes, hold times are often as little as 2-30 seconds, and the cooling time is often 2 minutes or less. The overall heat exposure is less than 5 minutes, a fraction of that of a batch process. Figure 1.0 below represents the Time-Temperature Histories (TTH) of a batch and a continuous thermal process. This TTH is the temperature of the product as it is processed over time. This figure compares a batch/retort process to a continuous thermal process that have roughly the same level of bacterial reduction (called the log reduction of bacteria) for sterilization.

Figure 1.0: Time-Temperature Histories-Batch and Continuous



Without getting too far into the mathematical details, the area under the curves significantly represents the totality of reactions affecting the product quality. As you can see, the area under the batch process curve is much, much larger than that of the continuous process. This shows the damage to products in the batch process is dramatically higher than the continuous process. Loss of some nutrients or their functionality, such as many vitamins and proteins, in batch processes can be as high, or higher, than 90% whereas continuous flow processes actually retain 90% or more of those same nutrients. Thus, the continuous process yields the same level of sterility, but with much less damage to the product or media. Said differently, the product has the same level sterility in both processes, but the continuous thermal process yields product that is much higher quality or functionality. Interestingly, when many products are converted from batch to continuous sterilization the use level of some ingredients can be reduced because of higher retention. This can lead to significant cost savings.

Variation In The Quality Of Product Within A Single Batch

Figure 2.0 shows an example of heat exposure of a batch of product containers in an autoclave. Red represents a higher level of overall heat exposure, whereas blue represents a lower amount of heat exposure. While all of the product has been sterilized, there is tremendous variation in the amount of heat exposure of product within the batch. The product near the outside and corners of the batch are considerably over-processed, while the product in the center is minimally processed. This results in a wide range of product quality where the product from the center of the batch will have a higher level of functionality compared to the product near the outside and corners.

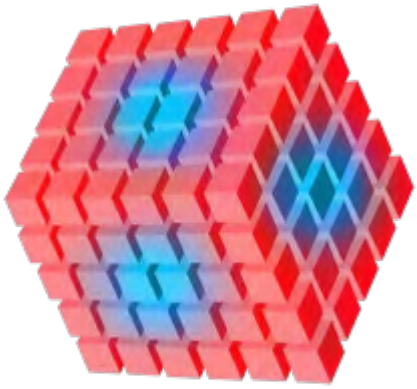


Figure 2.0

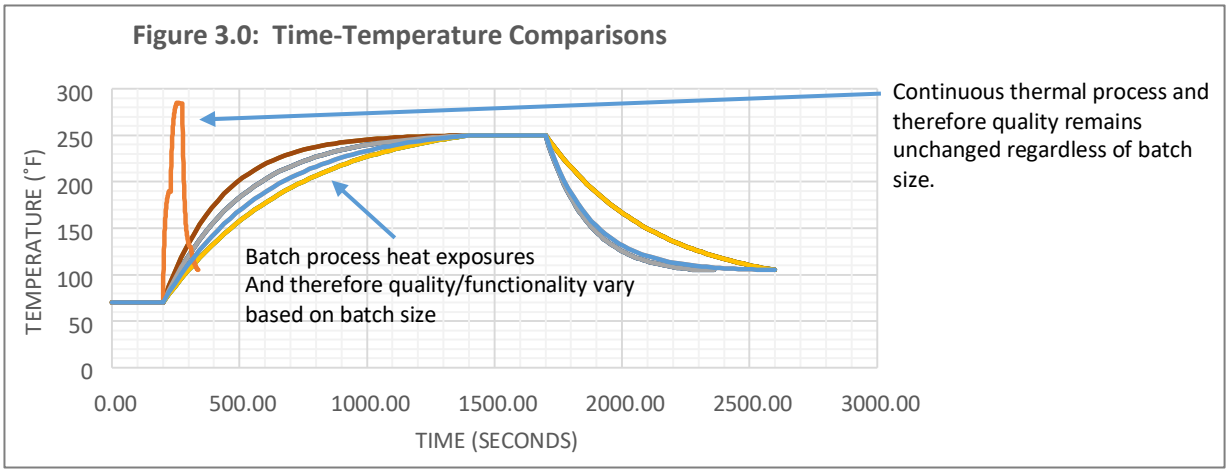
In continuous flow thermal sterilization, the product is pumped through a series of heat exchangers to rapidly reach temperature, through a hold tube to ensure the proper exposure time for sterilization, and then through heat exchangers to cool the product to the fill temperature. This process ensures that ALL

of the product, regardless of the batch size, has the same overall heat exposure, eliminating the variation of quality within a batch.

Variation Of Quality Between Batches

As previously shown for batch/autoclave processes, there is a wide range of product quality within a batch. This same heating phenomenon also causes quality variation between different size batches. As seen in Figure 3.0 below, smaller batches or packages in red heat more rapidly than larger batches and can be hot longer than larger batches. This difference in exposure causes significant differences, or variation, in quality. Thus, not only is there wide variability of quality within a batch, there is also wide quality variability between batches. In many products like microbial or biotech media, this translates into a large variation in functionality and sometimes in sterility. In extreme cases, it leads to insufficient sterilization and contaminated media or products.

As can also be seen in Figure 3.0, continuous thermal sterilization processes do not have these issues. They have the same, minimal heat exposure each time, regardless of batch size. Quality and functionality of the product are very consistent.



Handling In Batch Vs Continuous Thermal Processes

Due to the nature of autoclaving/retorts, products are handled multiple times. They must be prepared, filled into packages, arranged on the retort rack, and then the batch must then be loaded into the retort. Once sterilized and cooled, the product packages must be removed from the retort, cooled further to dry and label, then put into cases for shipment or future use. This must be done for each batch.

Using continuous thermal sterilization, once the product is mixed, it is fed into the processor. Packaging of the product is done at the processor outlet in a sterile hood and the packages are placed into cases for shipment or future use. It is a very efficient use of manpower enabling more product to be processed in less time with fewer people.

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Scale-Up Of Batch and Continuous Thermal Processes

As demand increases for batch processed products, increasingly larger batches can be put into an autoclave or retort, but this increased load can lead to longer processing times and corresponding losses of product quality. Similarly, using larger containers lead to longer heating and process times and increased losses of product quality.

Additionally, batch processes, using retorts or autoclaves occupy a finite amount of space and can handle only a limited size batch for each run. Thus, multiple, labor intensive runs must be conducted each day to keep up with demand. However, due to the length of the cycle of batch processes, it is only possible to conduct a limited number of batches per day. Thus, to keep up with increased demand, more retorts/autoclaves are needed, which in turn require more space and labor.

Continuous thermal sterilization processes scale-up much more easily. As demand increases, it is simply a matter of processing for a longer period during the day. Since batch size does not affect the process, as demand increases, they continue to yield consistent and higher quality product than batch processes. Additionally, continuous processes require less labor, and are not subject to the same type of repeated cycle times as batch processes, so they enable you to keep up with demand more easily than retorts or autoclaves. With good growth, ultimately more or larger continuous sterilizers may be needed and these too are easily scaled-up. New systems simply need to have the same Time-Temperature History to produce the same thermal impact and quality of the original system.

Energy Efficiency In Batch and Continuous Sterilization

Batch processing, like autoclave and retorts, heat the volumes of products from the outside in, through multiple layers of packaging. This is an inefficient method of heating both in terms of time, and the energy required to heat the product. There is also no opportunity to reclaim or reuse that energy. Continuous flow thermal sterilizers utilize heat exchangers that transfer heat much more efficiently to sterilize products. As such, they can process more product with lower energy costs. In some cases, these systems are designed to recycle their energy and become even more efficient.

Summary

Overall, compared to batch processes like retorts or autoclaves, continuous thermal sterilizers

- Are dramatically less damaging and produce higher quality products, often enabling less ingredients to be used to obtain the same functionality from a sterile product.
- Yield consistent quality products regardless of batch size, or package.
- Are easily scaled up as demand increases.
- Use less labor and energy making it less expensive to produce sterile product
- Will use less room and scale more easily to accommodate changes (i.e. increases) in demand

The end result is that continuous thermal sterilizers produce higher quality, more consistent product with lower operational costs, and thus make you more money. Contact us at MTI BioScience for more information and to see how we can help you.