Good morning. My name is Chuck Meek. I have been asked to provide some technical detail about the two processing systems mentioned by Mr. Herbein in his discussion of product losses in ESL high temperature systems and HTST pasteurization systems. I have an engineering degree from Penn State University, and I retired in 2014 after spending 36 years in the food process equipment industry. During those 36 years I worked for two companies, Cherry-Burrell (now called SPX) and Tetra Pak, doing design and application engineering of processing systems for fluid food products. This included some design of HTST pasteurization systems, but was mostly concentrated in the design of high temperature ESL and aseptic processing systems. Over the last 17 years, I have taught numerous programs for FDA Advanced Milk Processing courses on the regulatory aspects of ESL processing systems and I have been on the NCIMS Aseptic Program Committee for 8 years.

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The information I would like to present to this hearing is related to the two different types of processing systems utilized for HTST and ESL dairy products, and how those differences relate to the variations in product and fat loss as described by Mr. Herbein. We will see that these variations are related to several different aspects of these process systems, and we will try to answer some questions about how these differences in the processing systems contribute to the product loss variations.

- What is the major source of product loss in HTST and ESL systems?
- How do differences in system design contribute to additional product losses in ESL systems?
- How do the products being processed in these systems contribute to additional product losses in ESL systems?
- How do factors of practicality and public health contribute to additional product losses in ESL systems?

Both HTST pasteurizers and ESL processing systems experience product loss in similar fashions. There are several different areas of the processing plant where product losses could occur, such as receiving stations, blending operations and packaging, however those losses would be similar for both HTST and ESL dairy product production. What I want to focus on are the differences in product loss in the thermal processing systems themselves.

Product could be lost because of spillage or leakage from a processing system, but the primary source of product loss is when there is a changeover from water to product or product to water. Whenever these dissimilar fluids (product and water) are used to push one another through the process system, there is invariably mixing that occurs at the boundary between them. This area of mixing is often called the "interface" or "interface layer". These changeovers occur during initial start-up of the system when product is first brought into the system after it has been sanitized, any time there is a radical change of products being produced through the system, whenever the system must be cleaned, and when the system is finally shut down.

Whenever a changeover is taking place, the processor must assure that none of the intermixed fluids in the interface reaches the final point of use, be it a pasteurized storage tank or filling machine, and that only good product that meets the appropriate quality standards passes on to that final point of use. This means that, when pushing water from the system with product, the processor must wait until the interface layer has passed the point of use and he is certain that only good product is in the line at that point. To achieve that certainty, the processor must necessarily allow some volume of good product to pass the point of use before allowing the flow forward to the tank or filler. All of the product mixed in the interface layer as well as whatever good product passes the point of use before forward flow is initiated becomes lost product. In the case of a changeover where water is pushing product from the system, for example prior to a CIP cleaning, the access of the product flow to the point of use must be terminated before the interface layer has reached that point. Again, any good product ahead of the interface when the point of use is closed off as well as product mixed in the interface layer is lost product. The volume of product lost to the interface layer will depend on the design of the processing system and the nature of the product. The amount of good product lost before or after the interface during a changeover may vary considerably depending on the technology used in determining when the "good" product has reached or passed the point of use. Certain electronic sensors can make this determination fairly accurately, while manual timing will be much less accurate.

Therefore, our first consideration in the comparison of losses between an HTST pasteurization system and an ESL processing system is the relative amount of product that is lost during each of these changeovers in each type of system. The type of equipment in the process system and the total length of piping, as well as the nature of the product will all have an effect on the amount of mixing that takes place during each changeover through the system. Exhibit A is a schematic depiction of a typical HTST processing system for fluid milk. What I would like to point out on this drawing and the following one is the type of equipment that is involved with the milk flow (the lines shown in red). The major pieces of equipment involved in this HTST system that might contribute to mixing the product and water are a product balance tank, plate heat exchanger, centrifugal separator, homogenizer, and two centrifugal pumps. Because of the small number of components, they can generally be placed in a fairly compact arrangement, minimizing the interconnecting piping.

Exhibit B shows a typical processing system for ESL products. This figure illustrates a direct steam injection type of system. ESL dairy products can be and are produced on other types of systems which are less complex, but the dairy product from a direct type of system are considered to have the product quality necessary to compete with HTST pasteurized milk for color and flavor. Notice that in this system, the major components are somewhat similar to what was shown in the HTST pasteurization system, with the replacement of the centrifugal separator from the HTST system with the steam injector and vacuum flash cooling chamber in the ESL system. This substitution is an important factor in the relative amount of product loss experienced in these two types of systems. The centrifugal separator, by its nature, does not, in itself, create significant mixing of product and water. However, the vacuum vessel creates a pool of product or water, depending on the original fluid in the line before the changeover. Significant mixing will take place before all the liquid in this pool is displaced by the following fluid coming through the line. In addition, you can see that there are significantly more valves, pipelines, pumps and heat exchangers required for the complete functioning of the high temperature ESL system. This means that the ESL processing system cannot be assembled in nearly as compact a fashion as the typical HTST pasteurizer, resulting in significantly longer interconnecting piping between the components. This additional piping length adds even more opportunity for mixing of the two fluids in the ESL system.

Besides the differences in the components and layout of the HTST and ESL systems contributing to additional mixing of product and water, the actual products being processed will affect the amount of product loss that occurs. ESL processing systems are often required to handle a far wider range of products than the typical HTST pasteurizer. ESL systems are often used to process specialty products containing higher solids and higher fat contents. Determining where the cut-off point is around the interface layer is more difficult with these specialty products, so the processors must allow for a wider margin of safety when determining the arrival or passage of the interface layer at the point of use during a changeover to assure that the product going forward for sale meets the proper specifications. While most dairy processors install recovery systems to recover as much of the high value product as possible, these issues of determining the transition point between interface and good product and when to open or close access to the final point of use mean that there is always some good product that is lost.

Now that we have established that individual changeovers in an ESL processing system generally produce a higher rate of product loss than changeovers in an HTST pasteurizer, we also need to consider the relative frequency of these changeovers between the two types of systems. To do this, we need to consider what situations would lead to changeovers occurring in the two different types of systems. In both systems there will be changeovers on the initial start-up of production and shut-down of the systems. The differences in frequency, however, arise from the operational reasons that each type of system might be required to perform changeovers during a production day.

The public health controls of both types of systems look at temperature, flow and pressure parameters to determine that they are operating within the guidelines of public safety as set forth by the Pasteurized Milk Ordinance (PMO). Failure to maintain the set standards of public safety require corrective actions be taken to return the systems to a condition in which they are again producing safe products. A significant corrective action taken by both these systems is the shifting of the Flow Diversion Valve (FDV) to a divert position to prevent compromised product from going forward to the point of use. Whenever a system fault occurs that caused the

FDV to divert, the PMO requires that all product contact surfaces between the Holding Tube and the FDV be brought up to pasteurization temperature for pasteurization time to "re-sanitize" the pasteurized portion of the system[1]. The automation action to achieve this "re-sanitizing" condition is called "sequence logic".

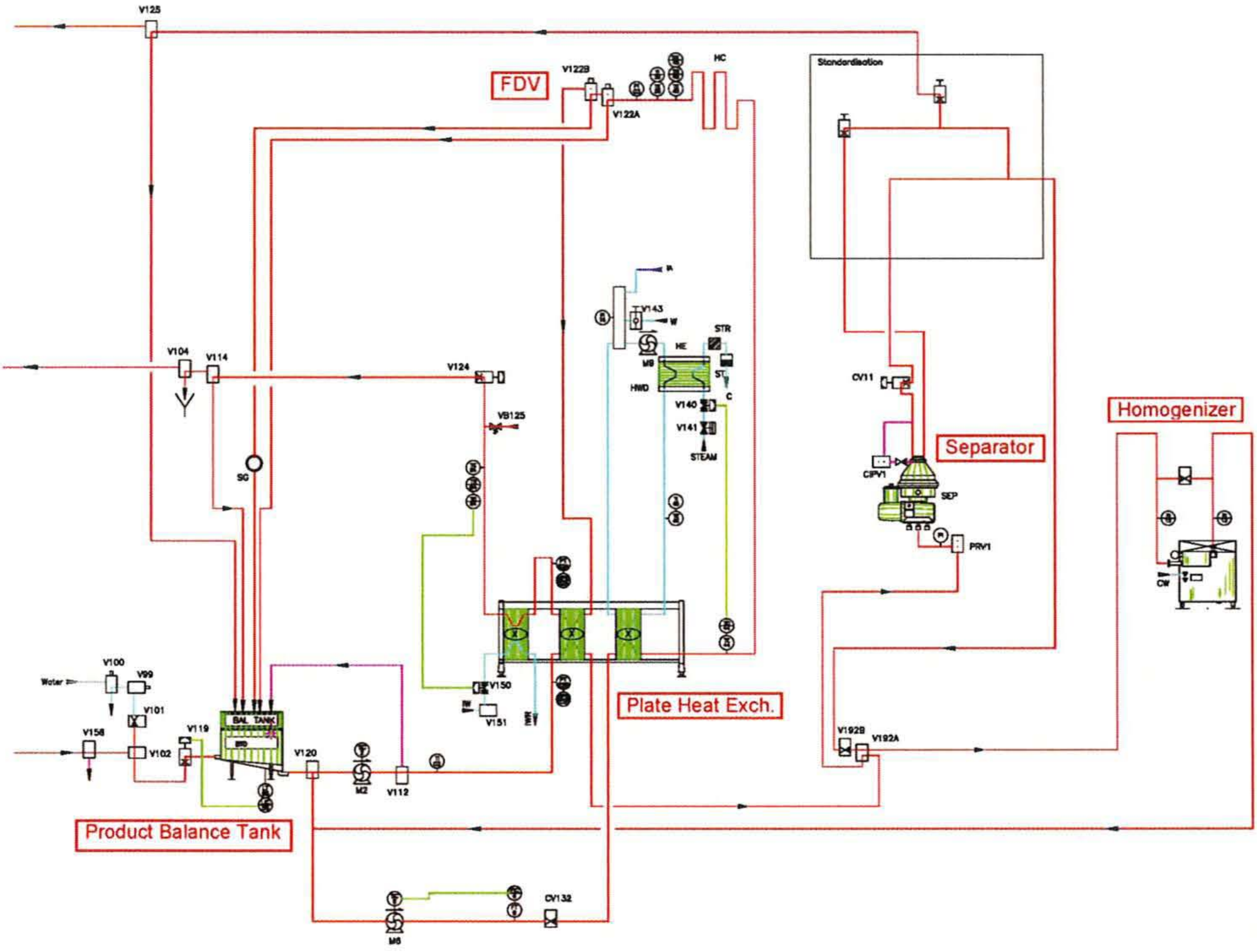
In the case of an HTST pasteurizer, a pressure fault simply requires stopping a booster pump[2]. Only a temperature fault or a flow rate fault will cause the FDV to divert[3]. When this happens in the HTST system, the system will go into a recycle mode with product circulating back from the FDV to the Product Balance Tank. Since the processing temperature in the heater section of an HTST pasteurizer is only in the range of 170°F, recirculation of the product for some period of time would not be detrimental to the product quality. In most cases however, the temperature or flow problem will correct itself quickly and the system will try to perform the sequence logic steps to reinitiate forward flow of the FDV. If the HTST system experienced a low temperature fault at the Holding Tube, the location of the FDV on an HTST pasteurizer immediately following the Holding Tube (refer to Exhibit A), means that the short amount of piping between the Holding Tube and the FDV is returned to pasteurization temperature almost immediately and the HTST system goes right back into forward flow production. If there is a flow fault, there is a time delay of only 15 or 25 seconds once legal flow has been reestablished. In either case, there is no need for any changeover between product and water.

In an ESL system, on the other hand, the PMO imposes considerably more instrumentation requirements on the control system. While only the Holding Tube temperature or Flow Meter faults were cause for a diversion action in an HTST pasteurizer, there are five or possibly six different parameters on an ESL processing system whose fault will trigger a flow diversion[4]. While all manufacturers do their best to design their ESL systems to minimize these faults, the wide range of products being processed, and the increased complexity of ESL processing systems does lead to more frequent process faults than might be seen on HTST pasteurizers. Once a FDV fault occurs, the ESL system, like the HTST pasteurizer, could go into recycle until the problem is resolved and then re-sanitize through sequence logic. However, this recirculation is simply not practical. As shown in Exhibit B, the FDV in an ESL system is located at the end of the system, after the final cooler. This is done for safety purposes so that if there is a diversion event, product is not being diverted to the open Product Balance Tank at 284°F. With the FDV located at the end of the system, that means that all the additional piping and equipment between the Holding Tube and the FDV must be returned to pasteurization temperature before resuming forward flow. This includes the final portions of the system that were at refrigerated temperatures. Re-heating all this equipment and piping takes a considerable length of time and would require many re-circulations of the product in the system. Since the product in the ESL system is being heated to approximately 284°F, repeated heating to this temperature would cause totally unacceptable changes to the color and flavor of the product.

The point of an ESL processing system is, as the name implies, to produce a product with extended shelf life. The processing goal that has been the target of the U.S. dairy processors is to thermally process the product to a condition approaching commercial sterility. This level of microbiological purity is what is required to achieve the shelf life needed to make the distribution of ESL products successful. To approach this condition of commercial sterility, extreme care must be taken to assure the cleanliness of the equipment and piping within the ESL system. Therefore, it has been the practice of ESL processors to consider any FDV fault a breach of the "sterility" of their system, requiring the system to be cleaned and re-sterilized before production can be resumed. Therefore, any time there is a flow diversion event, the ESL system must perform a product to water changeover to prepare the system for CIP and re-sterilization. Obviously, the frequency of these system faults is related to many factors such as products, system maintenance, operator training and system design, but the essential fact is that there is much more opportunity for such faults to occur in an ESL system compared to an HTST pasteurizer, and the severity of each fault in terms of potential product loss is significantly greater in the ESL processing system.

Another factor in the frequency of product/water changeovers, is, as was mentioned, the fact that ESL processing systems are asked to process a wider range of high solids and high fat products more frequently than are HTST pasteurizers. These specialty products have the natural tendency to create fouling in piping and heat exchangers of the process system more readily than standard fluid milk products. This increased fouling means that the ESL processing system must stop product production more frequently than an HTST pasteurizer in order to perform a CIP cleaning. Also, these specialty products are often run in smaller batches than basic fluid milk products. When there is an incompatibility between successive products, a water flush (or even a cleaning in the case of allergens) must be performed to prepare the system for the next product. Every time the production is interrupted for cleaning or a product change, there are additional product to water and water to product changeovers generating additional product losses.

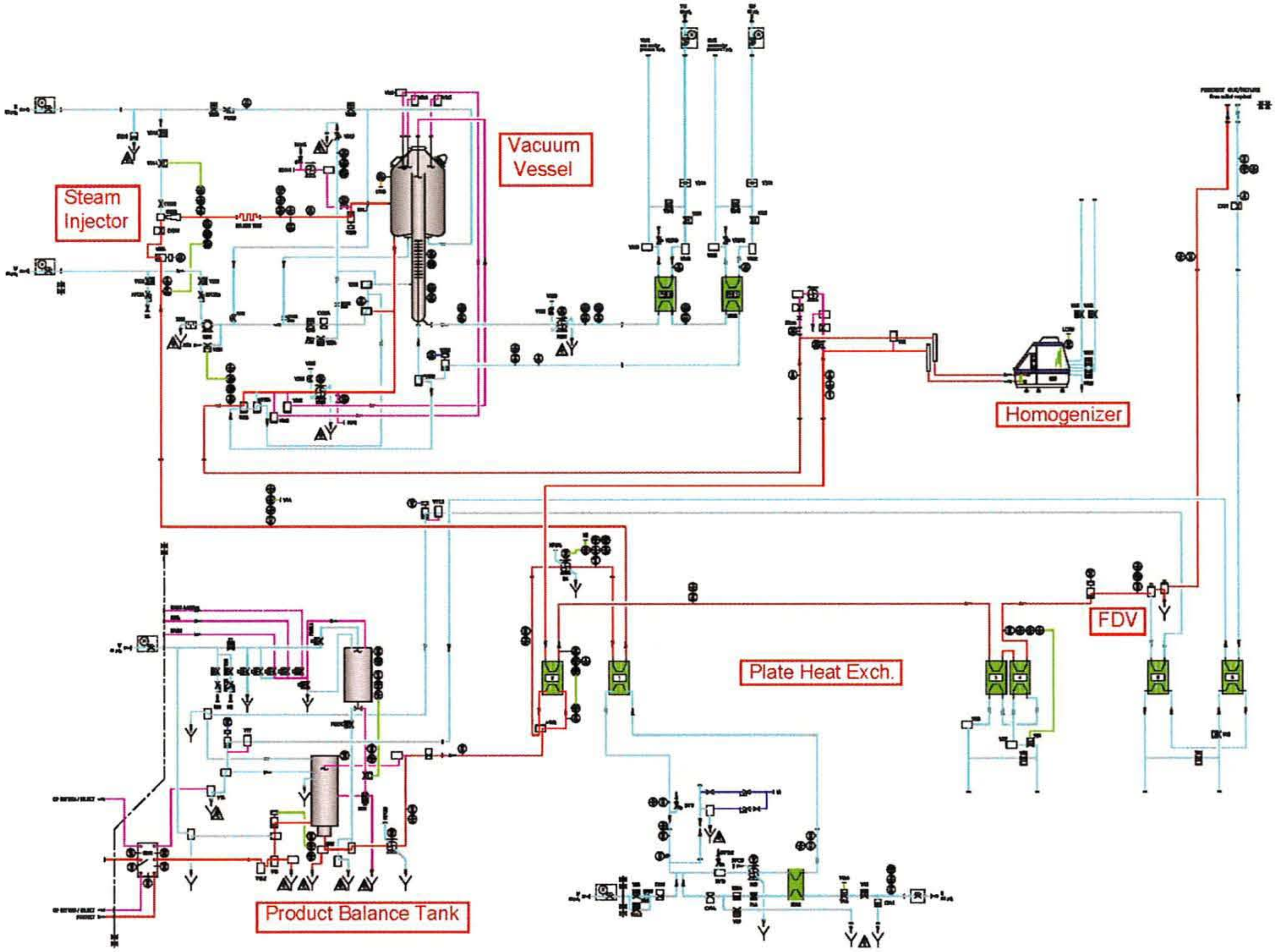
So, we have said that the majority of product losses occur during changeovers between water and product, that these changeovers occur due to a variety of factors in each type of processing system, and that the relative amount of product lost in a changeover in an ESL processing system is larger than that lost in an HTST pasteurizer. We have also indicated that the frequency of these product and water changeovers is higher in ESL systems than HTST pasteurizers due to several factors including increased regulatory requirements for public safety monitoring, operational differences due to the location of the FDV to meet safety standards, more frequent CIP cleaning required due to processing of specialty products, and the need for more separations between incompatible specialty products. It seems clear that even a normally operated, well maintained ESL processing system is going to experience a higher volume of product loss than an HTST pasteurizer.



<u>EXHIBIT A</u>

Typical HTST Pasteurizer System Schematic

Used by permission of Tetra Pak



<u>EXHIBIT B</u>

Typical ESL Processing System Schematic

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[1] Grade "A" Pasteurized Milk Ordinance (2013 Revision), SECT. 7, Item 16p(B); APPENDIX H; APPENDIX I.

[2] Grade "A" Pasteurized Milk Ordinance (2013 Revision), SECT. 7, Item 16p(C).

[3] Grade "A" Pasteurized Milk Ordinance (2013 Revision), SECT. 7, Item 16p(B), 2, a.; APPENDIX H

[4] High flow, Regenerator differential pressure (1 or 2), Injector differential pressure, Hold Tube pressure, Hold Tube temperature