A NOVEL FRIDAY 13TH RISK ANALYSIS OF A GLOBAL FOOD PROCESS - APPLICATION TO PASTEURIZATION OF RAW MILK CONTAINING *MYCOBACTERIUM AVIUM PARATUBERCULOSIS*

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ABSTRACT

A novel *Fr 13* global model for pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* that consists of three unit-operations, heating, holding and cooling, is presented for the first time and compared with traditional methods. A global model is defined by us as two or more inter-connected unit-operations. The aim was to gain quantitative insight into stochastic effects that can lead to surprise failure of an otherwise well-operated pasteurization plant. Failure is defined in terms of criteria for safe operation and a risk factor is developed for each unit-operation in terms of actual and design performance, together with a practical tolerance. Simulations are based on a refined Monte Carlo sampling of key parameters. Results reveal that, with a tolerance overall of 3 %, pasteurization is vulnerable to failure in 8.4 % of all (batch) continuous operations over a prolonged time. This insight cannot be obtained from traditional methods.

Keywords: pasteurization failure, global milk model, process failure, *Fr 13th* risk modelling

1. INTRODUCTION

The food industries are very important to Australia as a major exporter. In particular, Australia is a major exporter of milk and milk products. Raw milk is an excellent substrate for pathogen growth (Madigan and Martinko 2006). Unexpected (surprise) failure of pasteurization can therefore have a serious impact on consumer health (with or without fatalities). According to the recent *Blackett Review* (Anon 2011) low probability-high impact failures are a growing theoretical and practical challenge for processors in a wide range of industries. In milk pasteurization, unexpected failures are acknowledged and real events.

In recent years Davey and co-workers have illustrated a novel risk assessment titled *Friday 13th syndrome* (*Fr 13*) to address acknowledged, unexpected (surprise) failure in otherwise well-operated plant (Davey and Cerf 2003; Davey, Chandrakash and O'Neill 2013; Abdul Halim and Davey 2014; Chandrakash, Davey and O'Neill 2014). Unit-operation case studies include surprise fermenter washout (Patil, Davey and Daughtry 2005), an unexpected and sudden shift from potable to non-potable water (Davey, Abdul Halim and Lewis 2012) and sudden shift from safe to unsafe Clean-In-Place processing in milk processing (Davey, Chandrakash and O'Neill 2013). Their underlying research hypothesis is that: *random changes in process parameters can accumulate in one direction in amounts sufficient to leverage significant change and thereby make processes vulnerable to sudden and unexpected (surprise) failure.*

A major advantage of a *Fr 13* study is that it provides quantitative insight into plant behaviour that can be used to devise process intervention and re-design strategies to reduce risk of unexpected failure; it can be applied at both the analysis and synthesis stages (Davey 2011). It is timely that this new methodology be applied to several inter-connected unit-operations that define a process. A global model was defined by Davey and co-workers as two or more inter-connected unit-operations.

Chandrakash, Davey and O'Neill (2014) recently presented a simplified global *Fr 13* analysis for the first time to heating, holding and cooling of (batch) continuous pasteurization of milk. The justification was that raw milk is processed universally (and substantial commercial data are available for model validation). Importantly, the multiplicity of manufacturing steps and linkages provided a stringent test for the research hypothesis. Results from this study revealed that pasteurization is actually a continuous mix of successful and failed operations, with about 11.5 % likely to fail over the long term, despite good design and maintenance. However, because their definition for failure was based on plant physical parameters they argued this result could be misleading. It became apparent that failure must take account of microbiological kinetics of any contaminant pathogen.

Here the work of Chandrakash, Davey and O'Neill (2014) is developed further for real-time processing. Failure in the holding unit-operation is defined as a reduction in viable pathogen numbers and not residence time of the milk in the holding tube. It is hoped that insight gained from this study can be applied to improve pasteurization design, and; findings be more widely generalized for foods processing.

The *Fr 13* global model for raw milk pasteurization is predicated on inter-connection of the underlying unit-operations, heating, holding and cooling, together with an unambiguous definition of failure and a refined Monte Carlo (r-MC) (*Latin Hypercube*) sampling of parameters. A comparison is made with traditional solution methods.

2. MATERIALS AND METHODS

2.1 Raw milk pasteurization as inter-connected unit-operations of Heating (PHE-1), Holding (H-2) and Cooling (PHE-3)

Figure 1 is a schematic of raw milk pasteurization with heating (PHE-1), holding (H-2) and cooling (PHE-3) unit-operations. Each unit-operation is analyzed separately and then overall. All symbols used are carefully defined in the Nomenclature.

2.1.1. Heating (PHE-1)

An adequate unit-operations model for raw milk heating can be based on a Plate Heat Exchanger (PHE) (Chandrakash, Davey and O'Neill 2014). A PHE consists of a stack of closely-spaced (thin) plates clamped in a frame (Sinnott 2005). Advantages over shell-and-tube exchangers include cost, maintenance and flexibility (Sinnott 2005).

Based on commercial practice A_{PHE-1} = 33 m^2 with heat transfer co-efficient U_{PHE-1} = 2.5 kW m^{-2} K^{-1} and temperature correction factor F_{t-1} = 0.92 (Kothandaraman and Subramanyan 2007; Sinnott 2005) to give ΔT_{LMTD-1} = 20 ^{O}C. The individual plates are length $L_{p,1}$ = 1.5 m and thickness $w_{p,1}$ = 0.15 m. The gap between plates is $b_{p,1}$ = 0.05 m (Anon 2014).

Milk (typically) enters PHE-1 at $T_{i,m-1}$ = 4 ^{O}C at a flow m_{m-1} = 5.56 kg s^{-1} and a specific heat $C_{p,m-1}$ = 3.99 kJ kg^{-1} K^{-1} (Kessler 2002). On the water-side $t_{i,w-1}$ = 90 ^{O}C and m_{w-1} = 6.2 kg s^{-1} (Kessler 2002). Because the physical properties of water do not vary significantly with temperature over a range of 5 ^{O}C - 120 ^{O}C, it is assumed that $C_{p,w-1}$ = 4.2 kJ kg^{-1} K^{-1} (Perry and Green 1997).

The generalized heat transfer equations for PHE-1 are (Sinnott 2005):

$$_{1} = m_{m-1}C_{p,m-1}(T_{o,m-1} - T_{i,m-1}) \qquad (1\text{-}1)$$

$$_{1} = m_{w-1}C_{p,w-1}(t_{i,w-1} - t_{o,w-1}) \qquad (1\text{-}2)$$

$$_{1} = U_{PHE-1}A_{PHE-1}\Delta T_{LMTD-1}F_{t-1} \qquad (1\text{-}3)$$

The required equivalent plate diameter ($D_{e,PHE-1}$) is given by (Kessler 2002):

$$D_{e,PHE-1} = \frac{2w_{p,1}b_{p,1}}{(w_{p,1}+b_{p,1})} \qquad (1\text{-}4)$$

The required number of plates (n_{PHE-1}) for this PHE-1 can be determined using (Sinnott 2005):

$$n_{PHE-1} = \frac{A_{PHE-1}}{\pi D_{e,PHE-1}L_{p,1}} \qquad (1\text{-}5)$$

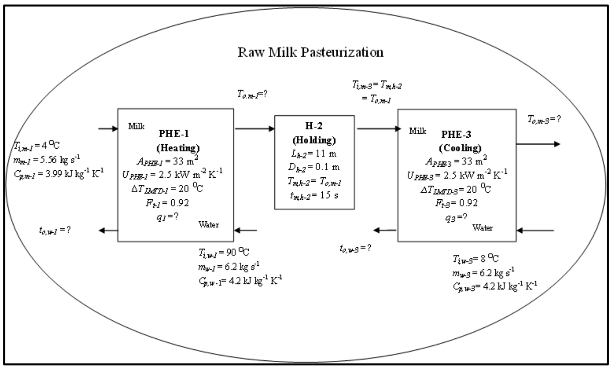

Figure 1: A Global Model for Pasteurization of Raw Milk Containing *Mycobacterium avium paratuberculosis*

The physical properties of milk can be determined as a function of temperature and are obtained using (Al-Hilphy and Ali 2013):

$$T_{m,avg-1} = \frac{T_{i,m-1}+T_{o,m-1}}{2} \qquad (1\text{-}6)$$

$$\mu_{m,1} = \left(\left(-0.00445\, T_{m,avg-1}\right) + 0.947\right) * 10^{-3} \qquad (1\text{-}6\text{ a})$$

$$\rho_{m,1} = 1033.7 - 0.2308\, T_{m,avg-1} - 0.00246\, T_{m,avg-1}^2 \qquad (1\text{-}6\text{ b})$$

Milk velocity ($v_{m,1}$) is estimated from the continuity equation of Kessler (2002):

$$v_{m,1} = \frac{4m_{m-1}}{\rho_{m,1}\pi D_{e,PHE-1}^2} \qquad (1\text{-}7)$$

The recommended flow rate for raw milk in a PHE is 0.5 < $v_{m,1}$ < 1.5 m s^{-1} (Kessler 2002) in turbulent flow (Re > 4,000) (Hayhurst 1997; Maroulis and Saravacos 2003). The Reynolds number (Re$_1$) of the milk is given by (Sinnott 2005):

$$\text{Re}_1 = \frac{\rho_{m,1}v_{m,1}D_{e,PHE-1}}{\mu_{m,1}} \qquad (1\text{-}8)$$

The residence time of the milk ($t_{r,1}$) in PHE-1 is computed from (Kessler 2002):

$$t_{r,1} = \frac{n_{PHE-1}L_{p,1}}{v_{m,1}} \qquad (1\text{-}9)$$

The pressure drop in PHE-1 can be calculated from (Kumbhare and Dawande 2013; Sinnott 2005):

$$\Delta P_{PHE-1} = 8j_{F,1}\frac{L_{p,1}}{D_{e,PHE-1}}\frac{\rho_{m,1}v_{m,1}^2}{2} \qquad (1\text{-}10)$$

where the term $j_{F,1}$ is the friction factor of the liquid flowing through the plate; its value depends on the type of plate used. Generally for turbulent flow (Re > 4,000) the term $j_{F,1}$ can be described by (Sinnott 2005):

$$j_{F,1} = 0.6\text{Re}_1^{-0.30} \qquad (1\text{-}11)$$

Eqs. (1-1) through Eq. (1-11) define the heating unit-operation PHE-1 of the global model for milk pasteurization.

2.1.2. Holding (H-2)

As is seen from Figure 1, milk leaving PHE-1 is held at a constant temperature for a fixed time. The general design equation for the holding tube (H-2) (Katoh and Yoshida 2009) is:

$$t_{m,h-2} = \frac{L_{h-2}}{v_{m,h-2}} \quad (2\text{-}1)$$

The external holding tube (H-2) generally consists of a tube in a spiral pattern (Sinnott 2005; Smith 2011). The most widely used temperature-time combination is $T_{m,h-2}$ = 72 ^{O}C and $t_{m,h-2}$ = 15 s (Alfa Laval 1987; Juffs and Deeth 2007; Katoh and Yoshida 2009). It is assumed that the diameter of the holding tube D_{h-2} = 0.1 m (Berk 2009) with length L_{h-2} = 11 m. In steady-state flow, milk will enter the holding tube with a temperature equivalent to $T_{o,m-1}$ and a flow of m_{m-2} = 5.56 kg s^{-1}.

Because the temperature $T_{m,h-2}$ is known, milk density in the holding tube can be calculated using the correlation of Al Hilphy and Ali (2013):

$$\rho_{m,2} = 1033.7 - 0.2308\, T_{m,h-2} - 0.00246\, T_{m,h-2}^2 \quad (2\text{-}2)$$

Milk velocity ($v_{m,h-2}$) in the holding tube is obtained from the continuity equation (Kessler 2002):

$$v_{m,h-2} = \frac{4m_{m-2}}{\rho_{m,2}\pi D_{h-2}^2} \quad (2\text{-}3)$$

There are several microbial species of concern that have the ability to survive pasteurization: *Mycobacterium avium* subsp. *paratuberculosis*, *Bacillus cereus*, *Brucella melitensis*, *Enterobacter sakazakii*, *Staphylococcus aureus*, *Streptococcus agalactiae*, and; *Streptococcus zooepidemicus* (Juffs and Deeth 2007). Reliable data are available in the literature that can be used to model *Mycobacterium avium paratuberculosis*. This micro-organism consumed in small dosages can have lethal effects (Hammer, Kiesner and Walte 2014).

The decimal reduction time for this micro-organism at a reference temperature $T_{ref,h-2}$ = 72 ^{O}C is $D_{t,ref,h-2}$ = 1.2 s with a *z*-value z_{h-2} = 7.7 ^{O}C (Rademaker, Vissers and Giffel 2007). The decimal reduction time ($D_{t,h-2}$) at any temperature value $T_{m,h-2}$ = $T_{o,m-1}$ in H-2 can be obtained from (van Asselt and Zwietering 2005):

$$log_{10} D_{t,h-2} = log_{10} D_{t,ref,h-2} - \frac{T_{m,h-2} - T_{ref,h-2}}{z_{h-2}} \quad (2\text{-}4)$$

The microbial death rate ($k_{d,h-2}$) for *Mycobacterium avium paratuberculosis* in H-2 can be obtained using (Koutchma, Bail and Ramaswamy 2001; Smith 2011):

$$k_{d,h-2} = \frac{2.303}{D_{t,h-2}} \quad (2\text{-}5)$$

The logarithmic reduction in *Mycobacterium avium paratuberculosis* ($\log_{10}$ $(N/N_0))_{h-2}$ in H-2 can be obtained from (Ibarz and Barbosa-Canovas 2003):

$$\log_{10}\left(\frac{N}{N_0}\right)_{h-2} = \frac{k_{d,h-2}t_{m,h-2}}{2.303} \quad (2\text{-}6)$$

The steps involved in computation of $D_{t,h-2}$ are detailed in Appendix C. Typically a 5.5 $\log_{10}$ reduction is required (Hammer, Kiesner and Walte 2014; McDonald et al. 2005; Rademaker, Vissers and te Giffel 2007).

Eqs. (2-1) through Eq. (2-6) define the holding unit-operation H-2 for raw milk pasteurization.

2.1.3. Cooling (PHE-3)

Milk leaving H-2 is cooled in a second plate heat exchanger PHE-3. This is defined by A_{PHE-3} = 33 m^2 with U_{PHE-3} = 2.5 kW m^{-2} K^{-1} and F_{t-3} = 0.92 (Kothandaraman and Subramanyan 2007; Sinnott 2005) to give ΔT_{LMTD-3} = 20 ^{O}C. The individual plates are the same dimensions as PHE-1 (Anon 2014).

From Figure 1 it can be seen that milk enters PHE-3 at $T_{i,m-3}$ = $T_{m,h-2}$ with m_{m-3} = m_{m-2} = 5.56 kg s^{-1}. On the cooling-side (typically) water is supplied at $t_{i,w-3}$ = 8 ^{O}C with a flow m_{w-3} = 6.2 kg s^{-1}. The specific heat of water is a constant $C_{p,w-3}$ = 4.2 kJ kg^{-1} K^{-1} (Perry and Green 1997).

The generalized heat transfer design equations for PHE-3 are (Sinnott 2005):

$${}_3 = m_{m-3}C_{p,m-3}(T_{i,m-3} - T_{o,m-3}) \quad (3\text{-}1)$$

$${}_3 = m_{w-3}C_{p,w-3}(t_{o,w-3} - t_{i,w-3}) \quad (3\text{-}2)$$

$${}_3 = U_{PHE-3}A_{PHE-3}\Delta T_{LMTD-3}F_{t-3} \quad (3\text{-}3)$$

The equivalent plate diameter $D_{e,PHE-3}$ is given by (Kessler 2002):

$$D_{e,PHE-3} = \frac{2w_{p,3}b_{p,3}}{(w_{p,3} + b_{p,3})} \quad (3\text{-}4)$$

The required number of plates (n_{PHE-3}) for PHE-3 can be determined by using (Sinnott 2005):

$$n_{PHE-3} = \frac{A_{PHE-3}}{\pi D_{e,PHE-3}L_{p,3}} \quad (3\text{-}5)$$

The physical properties of milk can be determined as a function of temperature and can be obtained using (Al-Hilphy and Ali 2013):

$$T_{m,avg-3} = \frac{T_{i,m-3} + T_{o,m-3}}{2} \quad (3\text{-}6)$$

$$\mu_{m,3} = \left(\left(-0.00445\, T_{m,avg-3}\right) + 0.947\right) * 10^{-3} \quad (3\text{-}6\text{ a})$$

$$\rho_{m,3} = 1033.7 - 0.2308\, T_{m,avg-3} - 0.00246\, T_{m,avg-3}^2 \quad (3\text{-}6\text{ b})$$

Milk velocity $v_{m,3}$ in PHE-3 is obtained from the continuity equation of Kessler (2002):

$$v_{m,3} = \frac{4m_{m-3}}{\rho_{m,3}\pi D_{e,PHE-3}^2} \quad (3\text{-}7)$$

Typical values are 0.5 < $v_{m,3}$ < 1.5 m s^{-1} (Kessler 2002) in turbulent flow (Re > 4,000) (Hayhurst 1997; Kessler 2002; Lewis and Heppell 2000; Maroulis and Saravacos 2003). The Reynolds number (Re_3) of the milk is obtained from (Sinnott 2005):

$$Re_3 = \frac{\rho_{m,3}v_{m,3}D_{e,PHE-3}}{\mu_{m,3}} \quad (3\text{-}8)$$

The residence time of the milk ($t_{r,3}$) is computed from (Kessler 2002):

$$t_{r,3} = \frac{n_{PHE-3}L_{p,3}}{v_{m,3}} \quad (3\text{-}9)$$

The pressure drop in the PHE-3 is given by (Kumbhare and Dawande 2013; Sinnott 2005):

$$\Delta P_{PHE-3} = 8j_{F,3}\frac{L_{p,3}}{D_{e,PHE-3}}\frac{\rho_{m,3}v_{m,3}^2}{2} \quad (3\text{-}10)$$

where the term $j_{F,3}$ is the friction factor of the liquid flowing through the plate and can be estimated using (Sinnott 2005):

$$j_{F,3} = 0.6\mathrm{Re}_3^{-0.30} \quad (3\text{-}11)$$

Eqs. (3-1) through Eq. (3-11) define the cooling unit-operation PHE-3 for milk pasteurization.

2.2. Traditional Solution Method (SVA)

The traditional method for solving a unit-operations model is the traditional single point approach or Single Value Assessment (SVA) method (Sinnott 2005).

For PHE-1: From Eq. (1-3) q_1 = 1,518 kJ s^{-1}, using Eq. (1-1), $T_{o,m-1}$ = 72.43 ^{O}C and from Eq. (1-2) $t_{o,w-1}$ = 31.71 ^{O}C. From Eq. (1-4) $D_{e,PHE-1}$ = 0.075 m and from Eq. (1-5) n_{PHE-1} = 93. Using Eq. (1-6) $T_{m,avg-1}$ = 38.18 ^{O}C. With $T_{m,avg-1}$ known using Eq. (1-6 a) $\mu_{m,1}$ = 0.00078 Pa s and from Eq. (1-6 b) $\rho_{m,1}$ = 1,021.29 kg m^{-3}. From Eq. (1-7) $v_{m,1}$ = 1.2329 m s^{-1} and from Eq. (1-8) Re_1 = 121,073. From Eq. (1-9) $t_{r,1}$ = 113.15 s. Using Eq. (1-10) and (1-11) ΔP_{PHE-1} = 2,226.14 N m^{-2}.

For H-2: Milk enters the holding tube at $T_{m,h-2}$ = 72.43 ^{O}C (same as $T_{o,m-1}$). Using Eq. (2-2) $\rho_{m,2}$ = 1,004.13 kg m^{-3}. From Eq. (2-3) $v_{m,h-2}$ = 0.7054 m s^{-1}. Since the length of the holding tube (L_{h-2}) is known, using Eq. (2-1) t_{h-2} = 15.59 s. Since $D_{t,ref,h-2}$ = 1.2 s, $T_{ref,h-2}$ = 72 ^{O}C and z_{h-2} = 7.7 ^{O}C, using Eq. (2-4) at $T_{m,h-2}$ = 72.43 ^{O}C, $D_{t,h-2}$ = 1.0236 s. From Eq. (2-5) $k_{d,h-2}$ = 2.2499 s^{-1}. Using Eq. (2-6) $\log_{10}(N/N_0)_{h-2}$ = 14.6483 > 5.5. The pasteurized milk is therefore "safe".

For PHE-3: From Eq. (3-3) q_3 = 1,518 kJ s^{-1}, using Eq. (3-1) $T_{o,m-3}$ = 3.91 ^{O}C and from Eq. (3-2) $t_{o,w-3}$ = 66.3 ^{O}C. Using Eq. (3-4) $D_{e,PHE-3}$ = 0.075 m and from Eq. (3-5) n_{PHE-3} = 93. Using Eq. (3-6) $T_{m,avg-3}$ = 38.13 ^{O}C. With $T_{m,avg-3}$ known, from Eq. (3-6 a) $\mu_{m,3}$ = 0.00078 Pa s and from Eq. (3-6 b) $\rho_{m,3}$ = 1,021.29 kg m^{-3}. Using Eq. (3-7) $v_{m,3}$ = 1.2329 m s^{-1} and from Eq. (3-8) Re_3 = 121,073. From Eq. (3-9) $t_{r,3}$ = 113.15 s. Using Eq. (3-10) and (3-11), ΔP_{PHE-3} = 2,226.14 N m^{-2}.

The SVA solution is summarized as Table A-1, Appendix A. The bold-text values in the table underscore that the output from one unit-operation is the input to the next.

3. *FR 13* RISK MODEL

3.1. Defining failure

For PHE-1 a suitable risk factor (p_1) can be defined in terms of the outlet milk temperature ($T_{o,m-1}$) together with an acceptable tolerance (Davey 2011; Chandrakash, Davey and O'Neill 2014; Davey, Chandrakash and O'Neill 2013). such that:

$$p_1 = -\%tolerance_1 + 100\left(1 - \frac{T_{o,m-1}'}{T_{o,m-1}}\right) \quad (1\text{-}12)$$

where $T_{o,m-1}'$ is the actual temperature that is obtained due to the impact of stochastic effects (or more strictly, the particular r-MC scenario value). With a practical *%tolerance* = 3 % (Brigitte Carpentier, Laboratoire de securite sanitaire de Maisons-Alfort, France, *pers. comm.*), Equation (1-12) becomes:

$$p_1 = -3 + 100\left(1 - \frac{T_{o,m-1}'}{T_{o,m-1}}\right) \quad (1\text{-}13)$$

That is, if the design temperature plus 3 % is not reached then the heating unit-operation is said to have failed. Eq. (1-13) is computationally convenient (Davey 2011) because all $p_1 > 0$ are failures.

Eqs. (1-1) through (1-11), together with Eq. (1-13), define the *Fr 13* model for PHE-1.

Similarly, for H-2, p_2 can be defined such that:

$$p_2 = -\%tolerance_2 + 100\left(1 - \frac{\log_{10}(\frac{N}{N_0})_{h-2}'}{\log_{10}(\frac{N}{N_0})_{h-2}}\right) \quad (2\text{-}7)$$

where $\log_{10}(N/N_0)_{h-2}'$ is the $\log_{10}$ reduction due random effects. With $\%tolerance_2$ = 3 % on Eq. (2-7) becomes:

$$p_2 = -3 + 100\left(1 - \frac{\log_{10}(\frac{N}{N_0})_{h-2}'}{\log_{10}(\frac{N}{N_0})_{h-2}}\right) \quad (2\text{-}8)$$

That is, if the required 5.5 $\log_{10}$ reduction plus 3 % is not reached then the holding unit-operation is said to have failed since all $p_2 > 0$.

Eqs. (2-1) through (2-6), together with Eq. (2-8), is seen to constitute the *Fr 13* model for H-2.

For PHE-3, p_3 can be defined in terms of outlet temperature of milk from PHE-3 ($T_{o,m-3}$) such that:

$$p_3 = -\%tolerance_3 + 100\left(\frac{T_{o,m-3}'}{T_{o,m-3}} - 1\right) \quad (3\text{-}12)$$

With $\%tolerance_3$ = 3 %, Eq. (3-12) becomes:

$$p_3 = -3 + 100\left(\frac{T_{o,m-3}'}{T_{o,m-3}} - 1\right) \quad (3\text{-}13)$$

That is, if the design temperature plus 3 % is not reached then the cooling unit-operation is said to have failed revealed by all $p_3 > 0$.

Eqs. (3-1) through (3-11), together with Eq. (3-13), are seen to constitute the *Fr 13* model for PHE-3.

3.2. *Fr 13* simulations

In contrast to the traditional SVA simulation, in *Fr 13* simulation each process parameter is defined as a probability distribution of values, the mean of which will agree with the SVA (Patil, Davey and Daughtry 2005; Patil 2006; Davey 2011; Chandrakash, Davey and O'Neill 2014; Davey, Chandrakash and O'Neill 2013; 2011).

In the absence of specific information, the probability distributions for the input parameters for pasteurization of the milk are defined as: **RiskNormal** (mean, standard deviation, **RiskTruncate** (minimum, maximum)). (Some 40 distribution types are available *see* for example Vose 2008; Davey and Cerf 2003). A standard deviation around the mean was assumed at stdev = 5 % and the minimum and maximum practical values defined by ± 3 *x* stdev on this mean value. An advantage of using 3 *x* stdev about the mean to obtain the minimum and maximum values is that nearly all values (99.73 %) the parameter can take will fall in this interval (Vose 2008).

For example for the inlet milk temperature to PHE-1 ($T_{i,m-1}$) the risk function becomes: **RiskNormal** (4, 0.2, **RiskTruncate** (3.4 ,4.6)).

The other parameters are similarly defined and are shown in the *Fr 13* global model schematic for pasteurization of raw milk containing *Mycobacterium avium paratuberculosis* as Figure 2.

A r-MC sampling (*Latin Hypercube*) of the probability distributions is used because 'pure' MC sampling can over- and under- sample from parts of the distribution (Vose 2008; Davey 2011). To ensure that the output distribution is sufficiently *Normal*, a minimum number of random samples is needed; this is usually 1,000 to 50,000 samples (K R Davey – *unpublished data*). This is simple to establish visually.

For each of heating, holding and cooling, simulations were carried in Microsoft Excel™ with a commercially available add-on *@-Risk* (pronounced *at risk*) version 5.5 (Palisade Corporation™). An advantage is that because spread-sheeting tools are used universally this makes ready communication of results (Davey 2011).

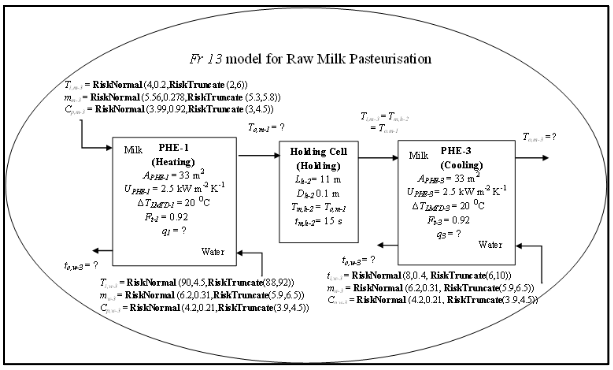

Figure 2: The *Fr 13* Global Model for Pasteurization of Raw Milk Containing *Mycobacterium avium paratuberculosis*

4. RESULTS

Detailed *Fr 13* simulations for each of heating, holding and cooling, and a comparison with traditional SVA, are presented as Tables B-1, B-2 and B-3 in Appendix-B. 1,000 Latin Hypercube samples were needed to ensure that the outputs were sufficiently *Normal* for all three. From Appendix B it can be readily appreciated that one only scenario can be reported using tabular methods for comparison.

However, process scenarios can be conveniently presented as easily digested output distributions (Davey 2011; 2010). For example, Figure 3 presents all 1,000 *Fr 13* output scenarios for heating, PHE-1. The figure is seen to be convenient because all process failures ($p_1 > 0$) can be visually identified. The right-side of the figure shows all 308 failures, $p_1 > 0$, identified to meet the required outlet temperature of raw milk $T_{o,m-1} = 72\ ^{O}C$ due to stochastic effects.

With these 308 temperature values as inputs to the holding tube (H-2) and *%tolerance* = 3 % there were 44 failures to meet the required logarithmic reduction of *Mycobacterium avium paratuberculosis* $\log_{10}(N/N_0)_{h-2} = 5.5$ as was evidenced by all $p_2 > 0$. However, with the same 308 output values as inputs to PHE-3, there were 84 failures ($p_3 > 0$) to meet the specified milk outlet temperature ($T_{o,m-3} = 4\ ^{O}C$) due to random effects in PHE-3.

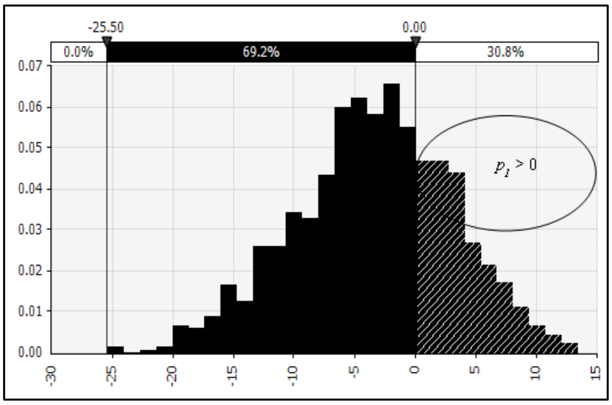

Figure 3: *Fr 13* Simulation of Risk Factor (p_1) for Heating Raw Milk Containing *Mycobacterium avium paratuberculosis* with 1,000 Simulated Scenarios

Table 1 represents four (4) out of 308 failures in PHE-1. It can be seen from Table 1 that the outlet temperature of milk ($T_{o,m-1}$) from PHE-1 is < 72 ^{O}C and this resulted in $p_1 > 0$. A major advantage of this presentation is that the value of each of the contributing parameters to each particular process failure can be identified. For example, failure 2, column 3 (**bold-text**) of the table shows an inlet raw milk temperature of $T_{i,m-1} = 4.3971\ ^{O}C$ in combination with a milk flow of $m_{m-1} = 5.8656$ kg s^{-1} and $C_{p,m-1} = 3.96$ kJ kg^{-1} K^{-1}, together with an inlet heating water temperature of $t_{i,w-1} = 95.23\ ^{O}C$ in combination with a water flow of $m_{w-1} = 6.7962$ kg s^{-1} and $C_{p,w-1} = 4.3609$ kJ kg^{-1} K^{-1}, which gave rise to a heat duty of $q_1 = 1{,}518$ kJ s^{-1}, a water outlet temperature $t_{o,w-1} = 44.01\ ^{O}C$, milk velocity $v_{m,1} = 1.3001$ m s^{-1}, $Re_1 = 127{,}398$, residence time $t_{r,1} = 107.78$ s, pressure drop $\Delta P_{PHE-1} = 2{,}437.70$ N m^{-2}, milk outlet temperature $T_{o,m-1} = 69.75\ ^{O}C$ and $p_1 = 0.6951$ (failure).

Table 1: Four of 308 Failures ($p_1 > 0$) in PHE-1

Parameter	*Fr 13* in PHE-1 (Heating)			
	1	2	3	4
$T_{i,m-1}$ (^{O}C)	4.0303	**4.3971**	4.2765	3.7058
m_{m-1} (kg s^{-1})	5.6788	**5.8656**	5.9014	6.2506
$C_{p,m-1}$ (kJ kg^{-1} K^{-1})	4.0422	**3.96**	4.2557	4.0798
$t_{i,w-1}$ (^{O}C)	91.93	**95.23**	90.09	90.66
m_{w-1} (kg s^{-1})	5.6231	**6.7962**	5.6392	6.8461
$C_{p,w-1}$ (kJkg^{-1}K^{-1})	3.8557	**4.3609**	4.2418	4.3988
q_1 (kJ s^{-1})	1,518	**1,518**	1,518	1,518
$t_{o,w-1}$ (^{O}C)	21.91	**44.01**	26.63	40.26
v_{m-1} (m s^{-1})	1.2587	**1.3001**	1.3067	1.3834
Re_1	123,352	**127,398**	126,324	133,030
ΔP_{PHE-1} (N m^{-2})	2,307.15	**2,437.70**	2,471.30	2,728.60
t_{r-1} (s)	111.33	**107.78**	107.24	101.29
$T_{o,m-1}$ (^{O}C)	70.15	**69.75**	64.72	63.23
p_1	0.1417	**0.6951**	7.6411	9.6942

Table 2 reports the above same reported four (4) failed scenarios as inputs to H-2 (holding). It can be seen from

Table 2 that not all $p_2 > 0$. This underscores that not all scenarios from PHE-1 resulted in failure in H-2 i.e. the viable load ($\log_{10}(N/N_0)_{h-2}$) can be achieved if milk is held for a sufficiently long period in the holding tube. Table 2 presents four (4) of the total 44 failures in H-2.

Table 2: Four Fail Scenarios from PHE-1 Input to H-2

Parameter	*Fr 13* in H-2 (Holding)			
	1	2	3	4
$T_{m,h-2}$ (^OC)	70.15	69.75	64.72	63.23
m_{m-2} (kg s^{-1})	5.6788	5.8656	5.9014	6.2506
ρ_{m-2} (kg m^{-3})	1,005.40	1,005.63	1,008.46	1,009.27
$v_{m,h-2}$ (m s^{-1})	0.7195	0.7430	0.7455	0.7889
L_{h-2} (m)	11	11	11	11
D_{h-2} (m)	0.1	0.1	0.1	0.1
$T_{ref,h-2}$ (^OC)	72	72	72	72
$D_{t,ref,h-2}$ (s)	1.2	1.2	1.2	1.2
z_{h-2} (^OC)	7.7	7.7	7.7	7.7
$D_{t,h-2}$ (s)	1.3762	1.4497	2.7863	3.3798
$k_{d,h-2}$ (s^{-1})	1.6735	1.5886	0.8266	0.6814
$\log_{10}(N/N_0)_{h-2}$	11.1091	10.2120	5.2960	4.1254
$t_{m,h-2}$ (s)	15.29	14.81	14.76	13.94
p_2	-104.98	-85.67	0.7096	21.9935

Table 3 summarizes the four (4) $T_{m,h-2}$ outputs from (H-2) as inputs to PHE-3 (cooling). The tabulated data reveal that not all four (4) scenarios will fail to reach the design cooling temperature of 4 ^OC ($T_{o,m-3}$) i.e. not all $p_3 > 0$. Table 3 presents four (4) of 84 *Fr 13* failures in PHE-3 i.e. an overall failure of 8.4 % in the global model for pasteurization of raw milk.

Table 3: Four Scenarios from H-2 Input to PHE-3

Parameter	*Fr 13* in PHE-3 (Cooling)			
	1	2	3	4
$T_{i,m-3}$ (^OC)	70.15	69.75	64.72	63.23
m_{m-3} (kg s^{-1})	5.6788	5.8656	5.9014	6.2506
$C_{p,m-3}$ (kJ kg^{-1} K^{-1})	4.0428	3.9600	4.2557	4.0798
$t_{i,w-3}$ (^OC)	8.0981	8.1245	8.4345	7.9953
m_{w-3} (kg s^{-1})	6.48	6.44	6.28	6.12
$C_{p,w-3}$ (kJ kg^{-1} K^{-1})	4.08	4.43	4.41	4.08
q_3 (kJ s^{-1})	1,518	1,518	1,518	1,518
$t_{o,w-3}$ (^OC)	65.52	61.33	63.25	68.79
$T_{o,m-3}$ (^OC)	4.0303	4.3971	4.2765	3.7058
p_3	-2.2432	6.9264	3.9124	-10.3554

5. DISCUSSION

The global model for pasteurization of raw milk containing *Mycobacterium avium paratuberculosis* reveals a failure rate, over the long term, of 8.4 % of all (batch continuous) operations. That is pasteurization is actually a mix of successful operations together with unsuccessful ones.

The distribution of these failures would not be expected to be equally spaced in time. If each batch continuous (daily) process is considered one scenario on average there would be (8.4/100 days x 365.25 days/year =) 31 failures each year to meet the $\log_{10}$ reduction in contaminants that could not be attributed to human error or faulty fittings (Davey and Cerf 2003, Davey, Chandrakash and O'Neill 2013).

This significant new insight is not available from traditional methods (with or without sensitivity analysis). A significant advantage of *Fr 13* simulation is that all possible scenarios are simulated.

The distributions used in the global model parameters are constrained by practical considerations. However, in the absence of specific data the choice of distribution is at present, to some degree, arbitrary. There are some 40 different probability distributions that can be used (Vose 2008). In particular cases, however these might be defined by detailed expert knowledge or process experience (Davey 2010; 2011; Davey, Chandrakash and O'Neill 2013). However, some experimentation with different forms (e.g. with Beta-subjective *see* Davey and Cerf 2003) in the present model resulted in no meaningful change in failure rate i.e. the failure rate more or less remained the same at ~ 8.4 %. In part it is thought this result is because data used in the model reflects large-scale commercial pasteurization of raw milk (Yapp and Davey 2009).

We believe the ability demonstrated here to quantitatively study the cumulative effect of stochastic changes in a global model is an exciting new development; in particular because this new ability has the potential to be integrated with existing commercial design software such as Aspen Plus™ to produce significantly more powerful design and risk assessment tools (Davey 2010; Davey, Chandrakash and O'Neill 2013; Chandrakash, Davey and O'Neill 2014).

Although the global model for pasteurization involves a reduction in the viable numbers of *Mycobacterium avium paratuberculosis* it is clear the generalized form of the *Fr 13* methodology means it could be used for a range of contaminants and/or changes to process equipment. The methodology is flexible because it is predicated on the underlying principles in unit-operations modelling (Sinnott 2005). The particular micro-organism is of concern because of its association with Crohn's disease in humans; it is often inactivated during pasteurization of raw milk but has the ability to survive, if it survives a small dosage can have lethal effect on consumers (Hammer, Kiesner and Walte 2014).

The *Fr 13* global model established and demonstrated here can now be used in second-tier studies (Davey 2010; 2011) to quantitatively simulate intervention strategies and design changes that might be made to minimize unexpected failure due to stochastic effects and to improve process safety in the pasteurization of raw milk. This research is currently being undertaken.

6. CONCLUSIONS

A novel *Fr 13* risk analysis of a global model for pasteurization of raw milk containing *Mycobacterium avium paratuberculosis* has been developed and presented for the first time.

Results reveal that batch continuous pasteurization is a mix of successful operations together with unsuccessful ones, with some 8.4 % of all operations resulting in failure due to cumulative impact of stochastic effects. This insight cannot be obtained using existing risk methodologies (with or without sensitivity analysis).

A significant advantage of *Fr 13* risk modelling over traditional risk approaches is that all possible scenarios that could exist can be quantitatively simulated.

The global model is generalized in form and can be readily used to simulate a range of contaminants and process equipment in pasteurization of raw milk.

NOMENCLATURE

A_{PHE-1}	Heat transfer area PHE-1 (m^2), Eq. (1-3)
A_{PHE-3}	Heat transfer area PHE-3 (m^2), Eq. (3-3)
$C_{p,m-1}$	Specific heat milk PHE-1 (kJ kg^{-1} K^{-1}), Eq. (1-1)
$C_{p,m-3}$	Specific heat of milk PHE-3 (kJ kg^{-1} K^{-1}), Eq. (3-1)
$C_{p,w-1}$	Specific heat water PHE-1 (kJ kg^{-1} K^{-1}), Eq. (1-2)
$C_{p,w-3}$	Specific heat of water PHE-3 (kJ kg^{-1} K^{-1}), Eq. (3-2)
$D_{e,PHE-1}$	Equivalent diameter plate PHE-1 (m), Eq. (1-4)
$D_{e,PHE-3}$	Equivalent diameter plate PHE-3 (m), Eq. (3-4)
D_{h-2}	Diameter holding tube H-2 (m), Eq. (2-3)
$D_{t,ref,h-2}$	Decimal reduction time at $T_{ref,H-2}$ (s), Eq. (2-4)
$D_{t,h-2}$	Decimal reduction time in H-2 (s), Eq. (2-4)
F_{t-1}	Temperature correction factor PHE-1 (dimensionless), Eq. (1-3)
F_{t-3}	Temperature correction factor PHE-3 (dimensionless), Eq. (3-3)
L_{h-2}	Length holding tube H-2 (m), Eq. (2-1)
$L_{p,1}$	Length plate PHE-1 (m), Eq. (1-5)
$L_{p,3}$	Length plate PHE-3 (m), Eq. (3-5)
Re_1	Reynolds number PHE-1 (dimensionless), Eq. (1-8)
Re_3	Reynolds number PHE-3 (dimensionless), Eq. (3-8)
$T_{m,avg-1}$	Average (bulk) milk temperature PHE-1 (^OC), Eq. (1-6)
$T_{m,avg-3}$	Average (bulk) milk temperature PHE-3 (^OC), Eq. (3-6)
$T_{m,h-2}$	Holding temperature milk H-2 (^OC), Eq. (2-2)
$T_{i,m-1}$	Inlet temperature raw milk PHE-1 (^OC), Eq. (1-1)
$T_{i,m-3}$	Inlet temperature milk PHE-3 (^OC), Eq. (3-1)
$T_{o,m-1}$	Outlet temperature milk PHE-1 (^OC), Eq. (1-1)
$T_{o,m-1}'$	*Fr 13* scenario value $T_{o,m-1}$ (^OC), Eq. (1-12)
$T_{o,m-3}$	Outlet temperature pasteurized milk PHE-3 (^OC), Eq. (3-1)
$T_{o,m-3}'$	*Fr 13* scenario value $T_{o,m-3}$ (^OC), Eq. (3-12)
$T_{ref,h-2}$	Reference temperature for microbial growth in H-2 (^OC), Eq. (2-4)
U_{PHE-1}	Overall heat transfer coefficient PHE-1 (kW m^{-2} K^{-1}), Eq. (1-3)
U_{PHE-3}	Overall heat transfer coefficient PHE-3 (kW m^{-2} K^{-1}), Eq. (3-3)
$b_{p,1}$	Gap between plates PHE-1 (m), Eq. (1-4)
$b_{p,3}$	Gap between plates PHE-3 (m), Eq. (3-4)
$j_{F,1}$	Friction factor liquid through plate PHE-1 (dimensionless), Eq. (1-11)
$j_{F,3}$	Friction factor liquid through plate PHE-3 (dimensionless), Eq. (3-11)
$k_{d,h-2}$	Microbial death rate H-2 (s^{-1}), Eq. (2-5)
$\log_{10}(N/N_0)_{h-2}$	$\log_{10}$ reduction of *Mycobacterium avium paratuberculosis* in H-2 (dimensionless), Eq. (2-6)
$\log_{10}(N/N_0)'_{h-2}$	*Fr 13* scenario value $\log_{10}(N/N_0)_{h-2}$, Eq. (2-7)
m_{m-1}	Mass flow rate raw milk PHE-1 (kg s^{-1}), Eq. (1-1)
m_{m-2}	Mass flow rate milk H-2 (kg s^{-1}), Eq. (2-3)
m_{m-3}	Mass flow rate milk PHE-3 (kg s^{-1}), Eq. (3-1)
m_{w-1}	Mass flow rate water PHE-1 (kg s^{-1}), Eq. (1-2)
m_{w-3}	Mass flow rate water PHE-3 (kg s^{-1}), Eq. (3-2)
n_{PHE-1}	Number plates required PHE-1 (dimensionless), Eq. (1-5)
n_{PHE-3}	Number plates required PHE-3 (dimensionless), Eq. (3-5)
p_1	Risk factor heating PHE-1(dimensionless), Eq. (1-12)
p_2	Risk factor holding H-2 (dimensionless), Eq. (2-7)
p_3	Risk factor cooling PHE-3(dimensionless), Eq. (3-12)
q_1	Heat duty PHE-1 (kJ s^{-1}), Eq. (1-1)
q_3	Heat duty PHE-3 (kJ s^{-1}), Eq. (3-1)
$t_{m,h-2}$	Holding time H-2 (s), Eq. (2-1)
$t_{r,1}$	Residence time milk PHE-1 (s), Eq. (1-9)
$t_{r,3}$	Residence time milk PHE-3 (s), Eq. (3-9)
$t_{i,w-1}$	Inlet temperature water PHE-1 (^OC), Eq. (1-2)
$t_{i,w-3}$	Inlet temperature water PHE-3 (^OC), Eq. (3-2)
$t_{o,w-1}$	Outlet temperature water PHE-1 (^OC), Eq. (1-2)
$t_{o,w-3}$	Outlet temperature water PHE-3 (^OC), Eq. (3-2)
$v_{m,1}$	Milk velocity PHE-1 (m s^{-1}), Eq. (1-7)
$v_{m,3}$	Milk velocity PHE-3 (m s^{-1}), Eq. (3-7)
$v_{m,h-2}$	Milk velocity holding tube H-2 (m s^{-1}), Eq. (2-1)
$w_{p,1}$	Thickness plate PHE-1 (m), Eq. (1-4)
$w_{p,3}$	Thickness plate PHE-3 (m), Eq. (3-4)
z_{h-2}	Temperature change ten-fold reduction in $D_{t,h-2}$ for *Mycobacterium avium paratuberculosis* H-2 (^OC), Eq. (2-4)
ΔP_{PHE-1}	Pressure drop PHE-1 (N m^{-2}), Eq. (1-10)
ΔP_{PHE-3}	Pressure drop PHE-3 (N m^{-2}), Eq. (3-10)
ΔT_{LMTD-1}	Log-mean temperature difference PHE-1, Eq. (1-3)
ΔT_{LMTD-3}	Log-mean temperature difference PHE-3, Eq. (3-3)

Greek symbols

$\rho_{m,1}$	Density milk PHE-1 (kg m^{-3}), Eq. (1-6 b)
$\rho_{m,2}$	Density milk H-2(kg m^{-3}), Eq. (2-2)
$\rho_{m,3}$	Density milk PHE-3(kg m^{-3}), Eq. (3-6 b)
$\mu_{m,1}$	Viscosity milk PHE-1 (Pa s), Eq. (1-6 a)
$\mu_{m,3}$	Viscosity milk PHE-3 (Pa s), Eq. (3-6 a)

Other

$\%tolerance_1$	Tolerance p_1 PHE-1, Eq. (1-12)
$\%tolerance_2$	Tolerance p_2 H-2, Eq. (2-7)
$\%tolerance_3$	Tolerance p_3 PHE-3, Eq. (3-12)

APPENDIX A – TRADITIONAL SVA COMPUTATIONS FOR RAW MILK PASTEURIZATIION

Table A-1 presents a summary of the traditional Single Value Assessment (SVA) computations for heating (PHE-1), holding (H-2) and cooling (PHE-3) unit-operations for raw milk pasteurization. The **bold-text** values in Table A-1 underscores that the output from one unit-operation is the input to the next interconnected unit-operation.

Table A-1: Summary of Traditional Single Value Assessment (SVA) Computations for Raw Milk Pasteurization with Heating (PHE-1), Holding (H-2) and Cooling (PHE-3) Unit-operations

PHE-1 (Heating)			**H-2 (Holding)**			**PHE-3 (Cooling)**		
Process Parameter	**SVA**	**Equation**	**Process Parameter**	**SVA**	**Equation**	**Process Parameter**	**SVA**	**Equation**
Constants								
U_{PHE-1} (kW m^{-2} K^{-1})	2.5	constant	L_{h-2} (m)	11	constant	U_{PHE-3} (kW m^{-2} K^{-1})	2.5	constant
A_{PHE-1} (m^2)	33	constant	D_{h-2} (m)	0.1	constant	A_{PHE-3} (m^2)	33	constant
ΔT_{LMTD-1} (^{O}C)	20	constant				ΔT_{LMTD-3} (^{O}C)	20	constant
F_{t-1} (dimensionless)	0.92	constant				F_{t-3} (dimensionless)	0.92	constant
Plate Properties								
$w_{p,1}$ (m)	0.15	constant				$w_{p,3}$ (m)	0.15	constant
$b_{p,1}$ (m)	0.05	constant				$b_{p,3}$ (m)	0.05	constant
$L_{p,1}$ (m)	1.50	constant				$L_{p,3}$ (m)	1.50	constant
Inputs								
$T_{i,m-1}$ (^{O}C)	4	input				**$T_{i,m-3}$ (^{O}C)**	**72.43**	**input**
m_{m-1} (kg s^{-1})	5.56	input	m_{m-2} (kg s^{-1})	5.56	input	m_{m-3} (kg s^{-1})	5.56	input
$C_{p,m-1}$ (kJ kg^{-1} K^{-1})	3.99	input	$D_{t,ref,h-2}$ (s)	1.2	input	$C_{p,m-3}$ (kJ kg^{-1} K^{-1})	3.99	input
$t_{i,w-1}$ (^{O}C)	90	input	$T_{ref,h-2}$ (^{O}C)	72	input	$t_{i,w-3}$ (^{O}C)	8	input
m_{w-1} (kg s^{-1})	6.2	input	z_{h-2} (^{O}C)	7.7	input	m_{w-3} (kg s^{-1})	6.2	input
$C_{p,w-1}$ (kJ kg^{-1} K^{-1})	4.2	input				$C_{p,w-3}$ (kJ kg^{-1} K^{-1})	4.2	input
Calculations								
q_1 (kJ s^{-1})	1,518	Eq.(1-3)				q_3 (kJ s^{-1})	1,518	Eq.(3-3)
$t_{o,w-1}$ (^{O}C)	31.71	Eq.(1-2)				$t_{o,w-3}$ (^{O}C)	66.29	Eq.(3-2)
$D_{e,PHE-1}$ (m)	0.0750	Eq.(1-4)				$D_{e,PHE-3}$ (m)	0.0750	Eq.(3-4)
$n_{p,PHE-1}$ (dimensionless)	93	Eq.(1-5)				$n_{p,PHE-3}$ (dimensionless)	93	Eq.(3-5)
$T_{m,avg-1}$ (^{O}C)	38.21	Eq.(1-6)				$T_{m,avg-3}$ (^{O}C)	38.22	Eq.(3-6)
$\mu_{m,1}$ (Pa s)	0.00078	Eq.(1-6 a)				$\mu_{m,3}$ (Pa s)	0.00078	Eq.(3-6 a)
$\rho_{m,1}$ (kg m^{-3})	1,021.29	Eq.(1-6 b)	$\rho_{m,2}$ (kg m^{-3})	1,004.13	Eq.(2-2)	$\rho_{m,3}$ (kg m^{-3})	1,021.29	Eq.(3-6 b)
$v_{m,1}$ (m s^{-1})	1.2329	Eq.(1-7)	$v_{m,h-2}$ (m s^{-1})	0.7054	Eq.(2-3)	$v_{m,3}$ (m s^{-1})	1.2329	Eq.(3-7)
Re_1 (dimensionless)	121,549	Eq.(1-8)	$D_{t,h-2}$ (s)	1.0236	Eq.(2-4)	Re_3 (dimensionless)	121,551	Eq.(3-8)
$t_{r,1}$ (s)	113.66	Eq.(1-9)	$k_{d,h-2}$ (s^{-1})	2.2499	Eq.(2-5)	$t_{r,3}$ (s)	113.65	Eq.(3-9)
$j_{F,1}$ (dimensionless)	0.0179	Eq.(1-11)				$j_{F,3}$ (dimensionless)	0.0179	Eq.(3-11)
ΔP_{PHE-1} (N m^{-2})	2,222.46	Eq.(1-10)	**$T_{m,h-2}$ (^{O}C)**	**72.43**	**input**	ΔP_{PHE-3} (N m^{-2})	2,222.45	Eq.(3-10)
$T_{o,m-1}$ (^{O}C)	**72.43**	**Eq.(1-1)**	**t_{h-2} (s)**	**15.59**	**Eq. (2-1)**	**$T_{o,m-3}$ (^{O}C)**	**4.00**	**Eq.(3-1)**
			$\log_{10}(N/N_0)_{h-2}$	**14.6483**	**Eq.(2-6)**			

APPENDIX B – COMPARISON SVA WITH *FR 13*

Tables B-1, B-2 and B-3 present a summary comparison of detailed *Fr 13* results with those of traditional Single Value Assessment (SVA) for heating (PHE-1), holding (H-2) and cooling (PHE-3) unit-operations for pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. The table layout follows the presentation methodology of Davey and co-workers (Chandrakash 2012; Chandrakash, Davey and O'Neill 2014; Davey, Chandrakash and O'Neill 2013; Davey 2011).

Table B-1: Comparative Summary of SVA and *Fr 13* Results for Heating (PHE-1) with *%tolerance* = 3 %

Process Parameter	SVA*	*Fr 13* model**	
Inputs			
$T_{i,m-1}$ (^{O}C)	4	**4.2765**	**RiskNormal**(4,0.2, **RiskTruncate** (3.4,4.6))
m_{m-1} (kg s^{-1})	5.56	**5.9014**	**RiskNormal**(5.56,0.278, **RiskTruncate**(4.726,6.394))
$C_{p,m-1}$ (kJ kg^{-1} K^{-1})	3.99	**4.2557**	**RiskNormal**(3.99,0.2, **RiskTruncate** (3.39,4.59))
$t_{i,w-1}$ (^{O}C)	90	**90.0902**	**RiskNormal**(90,4.5, **RiskTruncate** (76.5,103.5))
m_{w-1} (kg s^{-1})	6.2	**5.6392**	**RiskNormal**(6.2,0.31, **RiskTruncate** (5.27,7.13))
$C_{p,w-1}$ (kJ kg^{-1} K^{-1})	4.2	**4.2418**	**RiskNormal**(4.2,0.21, **RiskTruncate** (3.57,4.83))
Constants			
A_{PHE-1} (m^{2})	33	33	constant
U_{PHE-1} (kW m^{-2} K^{-1})	2.5	2.5	constant
ΔT_{LMTD-1} (^{O}C)	20	20	constant
F_{t-1} (dimensionless)	0.92	0.92	constant
Calculations			
$t_{o,w-1}$ (^{O}C)	31.71	26.63	Eq. (1-2)
q_1 (kJ s^{-1})	1,518	1,518	Eq. (1-3)
v_{m-1} (m s^{-1})	1.2329	1.3067	Eq. (1-7)
Re_1 (dimensionless)	121,549	126,324	Eq. (1-8)
$t_{r,1}$ (s)	113.66	107.24	Eq. (1-9)
ΔP_{PHE-1} (N m^{-2})	2,222.46	2,471.3	Eq. (1-10), (1-11)
$T_{o,m-1}$ (^{O}C)	72.43	**64.72**	Eq. (1-1)
p_1 (dimensionless)		**7.6411**	Eq. (1-13)

Table B-2: Comparative Summary of SVA and *Fr 13* Results for Holding (H-2) with *%tolerance* = 3 %

Process Parameter	SVA*	*Fr 13* model**	
Inputs			
$T_{m,h-2}$ (^{O}C)	72.43	**64.72**	$= T_{o,m-1}$
m_{m-2} (kg s^{-1})	5.56	**5.9014**	$= m_{m-1}$
Constants			
L_{h-2} (m)	11	11	constant
D_{h-2} (m)	0.1	0.1	constant
$T_{ref,h-2}$ (^{O}C)	72	72	constant
$D_{t,ref,h-2}$ (s)	1.2	1.2	constant
z_{h-2} (^{O}C)	7.7	7.7	constant
Calculations			
$\rho_{m,2}$ (kg m^{-3})	1,004.08	1,008.46	Eq. (2-2)
$v_{m,h-2}$ (m s^{-1})	0.7054	0.7455	Eq. (2-3)
$t_{m,h-2}$ (s)	15	14.7559	Eq. (2-1)
$D_{t,h-2}$ (s)	1.0236	2.7863	Eq. (2-4)
$k_{d,h-2}$ (s^{-1})	2.2499	0.8266	Eq. (2-5)
$\log_{10}(N/N_0)_{h-2}$	14.6483	5.2960	Eq.(2-6)
p_2 (dimensionless)		**0.7096**	Eq. (2-8)

Table B-3: Comparative Summary of SVA and *Fr 13* Results for Cooling (PHE-3) with *%tolerance* = 3 %

Process Parameter	SVA*	*Fr 13* model**	
Inputs			
$T_{i,m-3}$ (^{O}C)	72.43	**64.72**	$= T_{m,h-2}$ ($= T_{o,m-1}$)
m_{m-3} (kg s^{-1})	5.56	**5.9014**	$= m_{m-2}$
$C_{p,m-3}$ (kJ kg^{-1} K^{-1})	3.99	4.2557	$= C_{p,m-1}$
$t_{i,w-3}$ (^{O}C)	8	**7.5845**	**RiskNormal** (8,0.4, **RiskTruncate** (6.8,9.2))
m_{w-3} (kg s^{-1})	6.2	**6.6789**	**RiskNormal** (6.2,0.31, **RiskTruncate** (5.27,7.13))
$C_{p,w-3}$ (kJ kg^{-1} K^{-1})	4.2	**4.3987**	**RiskNormal** (4.2,0.21, **RiskTruncate** (3.57,4.83))
Constants			
A_{PHE-3} (m^{2})	33	33	constant
U_{PHE-3} (kW m^{-2} K^{-1})	2.5	2.5	constant
ΔT_{LMTD-3} (^{O}C)	20	20	constant
F_{t-3} (dimensionless)	0.92	0.92	constant
Calculations			
$t_{o,w-3}$ (^{O}C)	66.29	63.25	Eq. (3-2)
q_3 (kJ s^{-1})	1,518	1,518	Eq. (3-3)
$T_{o,m-3}$ (^{O}C)	4	**4.2765**	Eq. (3-1)
p_3 (dimensionless)		**3.9124**	Eq. (3-13)

APPENDIX C – SAMPLE CALCULATION $D_{t,\,h-2}$

Steps for estimating Decimal Reduction time (D_t) in H-2 at $T_{m,h-2} = T_{om-1} = 72.43$ ^{O}C for *Mycobacterium avium paratuberculosis*

<u>From literature</u>

$T_{ref} = 72$ ^{O}C; $D_{t,ref,\,h-2} = 1.2$ s; $z_{h-2} = 7.7$ ^{O}C; $T_{m,h-2} = T_{o,m-1} = 72.43$ ^{O}C; $t_{m,h-2} = 15$ s

Using Eq. (2-4),

$$log_{10}D_{t,h-2} = log_{10}D_{t,ref,h-2} - \frac{T_{m,h-2}-T_{ref}}{z} \quad (2\text{-}4)$$

$$log_{10}D_{t,h-2} = log_{10}1.2 - \frac{72.43-72}{7.7}$$

Solving we get,

$$log_{10}D_{t,h-2} = 0.02333$$

$$\boldsymbol{D_{t,h-2} = 1.0236\ s}$$

Using Eq. (2-5),

$$k_{d,h-2} = \frac{2.303}{D_{t,h-2}} \quad (2\text{-}5)$$

$$= \frac{2.303}{1.0236}$$

Solving we get,

$$\boldsymbol{k_{d,h-2} = 2.2499\ s^{-1}}$$

Using Eq. (2-6),

$$\log_{10}\left(\frac{N}{N_0}\right)_{h-2} = \frac{k_{d,h-2}t_{m,h-2}}{2.303} \quad (2\text{-}6)$$

$$\log_{10}\left(\frac{N}{N_0}\right)_{h-2} = \frac{2.2499 * 15}{2.303}$$

Solving we get,

$$\boldsymbol{\log_{10}(N/N_0)_{h-2} = 14.6483}$$

REFERENCES

Abdul Halim, N., Davey, K. R., 2014. A new Friday 13th risk assessment of UV irradiation for potable water in turbulent flow in a series annular-reactor. *Food Control*. (*submitted-May* 2014).

Anon., 2014. Individual plate characteristics in a Plate Heat Exchanger (PHE): http://www.armstrongpumps.com/Data/pdfbrochures/Links/02_09_003_/113.12L_phe_brochure.pdf [accessed 24th March 2014]

Anon., 2011. Blackett Review of High Impact Low Probability Risks, Government Office for Science (UK): http://www.bis.gov.uk/assets/goscience/docs/b/12-519-blackett-review-high-impact-low-probability-risks.pdf [accessed 17th May 2014].

Al-Hilphy, A.R.S., Ali, H.I., 2013. Milk flash pasteurization by the microwave and study its (*sic*) chemical, microbiological and thermo physical characteristics. *Food Processing and Technology*, 4 (7), 1–5.

Alfa-Laval, 1987. *Dairy Handbook-Food Engineering*. Sweden: Alfa Laval Firm.

Berk, Z., 2009. *Food Process Engineering and Technology*. 1st ed. USA: Academic Press.

Cerf, O., Davey, K.R., 2001. An explanation of non-sterile (leaky) milk packs in well operated UHT plant. *Transactions of Institution of Chemical Engineers, Food and Bioproducts Processing (Part C)*, 79 (4), 219-222.

Chandrakash, S., Davey, K.R., O'Neill, B.K., 2014. A novel risk analysis of failure in a global food process – preliminary application to milk processing. *Australasian Chemical Engineering Conference*, Perth (Australia) (*submitted*-June 2014).

Chandrakash, S., 2012. *A New Risk Analysis of Clean-In-Place (CIP) Milk Processing*. Thesis (MEngSc). The University of Adelaide.

Davey, K.R., 2011. Introduction to fundamentals and benefits of Friday 13th risk modelling technology for food manufactures. *Food Australia*, 63 (5), 192-197.

Davey, K.R., 2010. A novel proposal to advance the discipline and to quantitatively safeguard important hygienic bio-processes. *Proceedings of 40th Australasian Chemical Engineering Conference (Engineering at The Edge)*, paper 0495. Sept. 26-29, Adelaide (Australia).

Davey, K.R., Cerf, O., 2003. Risk modelling–An explanation of Friday 13th syndrome in well-operated continuous sterilisation plant. *Proceedings of 31st Australasian Chemical Engineering Conference*, paper 61. Sept 28-Oct 1, Adelaide (Australia).

Davey, K.R., Abdul Halim, N., Lewis, D., 2012. Friday 13th failure modelling: A new quantitative risk assessment of UV irradiation of potable water. *Proceedings of 42nd Australasian Chemical Engineering Conference (Quality of Life Through Chemical Engineering)*, Sept. 23-26, Wellington (New Zealand).

Davey, K.R., Chandrakash, S., O'Neill, B.K., A new risk analysis of Clean-In-Place milk processing. *Food Control*, 29 (1), 248-253.

Davey, K.R., Chandrakash. S, O'Neill, B.K., 2011. Friday 13th failure of Clean-In-Place operations in a milk process plant, *Proceedings of 41st Australasian Chemical Engineering Conference (Engineering a Better World)*, paper 150. Sept. 18-21, Sydney (Australia).

Hammer, P., Kiesner, C., Walte, H.G.C., 2014. *Short communication*: Effect of homogenization on heat inactivation of *Mycobacterium avium* subspecies *paratuberculosis* in milk. *Journal of Dairy Science*, 97 (4), 2045-2048.

Hayhurst, A.N., 1997. Introduction to heat transfer. In: P. J. Fryer, D. L. Pyle, C. D. Rielly, ed. *Chemical Engineering for the Food Industry*. 1st ed. London: Blackie Academic and Professional. 105-152.

Ibarz, A., Barbosa-Canovas, G.V., 2003. *Unit Operations in Food Engineering*. USA: CRC Press.

Juffs, H., Deeth, H., 2007. *Scientific Evaluation of Pasteurisation for Pathogen Reduction in Milk and Milk Products*. Food Standards Australia and New Zealand (FSANZ).

Katoh, S., Yoshida, F., 2009. *Biochemical Engineering: A Textbook for Engineers, Chemists and Biologists*. Germany: Wiley-VCH Verlag GmbH and Co.

Kessler, H.G., 2002. *Food and Bio Process Engineering-Dairy Technology*. 5th ed. Germany: Kessler Publishing House.

Kothandaraman, C.P., Subramanyan, S., 2007. *Heat and Mass Transfer Data Book*. 6th ed. India: New Age International.

Koutchma, T., Le Bail, A., Ramaswamy, H.S., 2001. Comparative experimental evaluation of microbial destruction in continuous-flow microwave and conventional heating systems. *Canadian Biosystems Engineering*, 43, 3.1-3.8.

Kumbhare, M.B., Dawande, S.D., 2013. Performance evaluation of Plate Heat Exchanger (*sic*) in laminar and turbulent flow conditions. *International Journal of Chemical Sciences and Applications*, 4 (1), 77-83.

Lewis, M., Heppell, N., 2000. *Continuous Thermal Processing of Foods-Pasteurization and UHT Sterilization*. USA: Aspen Publishers Inc.

Madigan, M.T., Martinko, J.M., 2006. *Biology of Microorganisms*. USA: Pearson Prentice Hall.

Maroulis, Z.B., Saravacos, G.D., 2003. *Food Process Design*. USA: Marcel Dekker Inc.

McDonald, W.L., O'Riley, K.J., Schroen, C.J., Condron, R.J., 2005. Heat inactivation of *Mycobacterium avium* subsp. *paratuberculosis* in milk. *Applied and Environmental Microbiology*, 71 (4), 1785-1789.

Patil, R.A., 2006. *Novel Application of Quantitative Risk Assessment Modelling to a Continuous Fermenter*. Thesis (MEngSc). The University of Adelaide.

Patil, R.A., Davey, K.R., Daughtry, B.J., 2005. A new quantitative risk model of a fermenter for *Friday 13th Syndrome*. *Proceedings of 33rd Australasian Chemical Engineering Conference (Smart Solutions-Doing More with Less)*, paper 407. Sept. 25-28, Brisbane (Australia).

Perry, R.H., Green, D.W., 1997. *Chemical Engineers' Handbook*. 7th ed. USA: McGraw Hill.

Rademaker, J.L.W., Vissers, M.M.M., te Giffel, M.C., 2007. Effective heat inactivation of *Mycobacterium avium* subsp. *paratuberculosis* in raw milk contaminated with naturally infected feces. *Applied and Environmental Microbiology*, 73 (13), 4185-4190.

Sinnott, R.K., 2005. *Chemical Engineering Design*. 4th ed. USA: Elsevier Butterworth-Heinemann.

Smith, P.G., 2011. *Introduction to Food Process Engineering*. 2nd Edition. UK: Springer Science.

Vose, D., 2008. *Risk Analysis - A Quantitative Guide*. 3rd ed. UK: Wiley and Sons.

van Asselt, E.D., Zwietering, M.H., 2005. A systematic approach to determine global thermal inactivation parameters for various food pathogens. *International Journal of Food Microbiology*, 107 (1), 73-82.

Yapp, E., Davey, K.R., 2009. *A Detailed Mass and Energy Audit of a Milk Processing Plant*. Thesis (Hons). The University of Adelaide.

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