A *FR 13* MICROBIOLOGICAL GLOBAL RISK MODEL – DEMONSTRATED FOR PASTEURIZATION OF RAW MILK WITH VIABLE *MYCOBACTERIUM AVIUM* SUBSP. *PARATUBERCULOSIS*

by

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A thesis submitted for the examination for the degree of
Doctor of Philosophy
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[1] Chandrakash, S., Davey, K.R., 2017 a. Advancing the *Fr 1*3 risk framework to an integrated three-step microbiological failure synthesis of pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*). Chemical Engineering Science 171, 1-18. http://dx.doi.org/10.1016/j.ces.2017.05.020

Chandrakash, S., Davey, K.R., 2017 b. A 4-step *Fr 13* microbiological pasteurizer model for raw milk involving a heat-up, holding for thermal inactivation, cool-down and storage of treated milk. AIChE J – *in preparation.*

Chandrakash, S., Davey, K.R., 2017 c. A review of the *Fr 13* risk assessment framework. Food Research International – *in preparation*.

Chandrakash, S., Davey, K.R., O'Neill, B.K., 2015. An *Fr 13* risk analysis of failure in a global food process – illustration with milk processing. Asia Pacific Journal of Chemical Engineering (Special Theme Research Article (**Invited paper**)) 10 (4), 526-541. http://dx.doi.org/10.1002/apj.1887

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. In: Proc. 44th Australasian Chemical Engineering Conference (Processing Excellence, Powering our Future), Perth, Australia, Sept. 27-Oct. 1, Paper 1475. ISBN: 9781922107381

Davey, K.R., Chandrakash, S., O'Neill, B.K., 2014. A novel Friday 13th risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26th European Modelling and Simulation Symposium - EMSS 2014, Bordeaux, France, Sept. 10-12. ISBN: 9788897999386

EXECUTIVE SUMMARY

Steady-state unit-operations are used globally in chemical engineering processing. Importantly however, there are naturally occurring (random) fluctuations in parameter values about a 'set' mean. These are not sufficient to be considered transient and a random change in one is often off-set by a change in another - with the result that the output remains seemingly steady. Significantly, traditional chemical engineering does not address these random fluctuations explicitly.

Davey and co-workers (e.g. Abdul Halim and Davey, 2015; Zou and Davey, 2016) have shown that these natural fluctuations can combine and accumulate in one direction and leverage unexpected and surprise behaviour across a 'failure - not failure' boundary. Their hypothesis they titled *Fr 13* (*Friday 13th*) to underscore the surprise element of the failure event. Their probabilistic *Fr 13* framework has been usefully applied to a number of 1-step unit-operations including failure in: UV irradiation for potable water (Abdul-Halim and Davey, 2015; 2016); thermal efficiency of a commercial coal-fired boiler (Davey, 2015), metals pitting (Davey et al., 2016), and; failure to remove whey protein deposits in Clean-In-Place milk processing (Davey et al., 2015). A significant advantage is that the framework can be used in quantitative 'second-tier' studies (Abdul-Halim and Davey, 2016) to improve design and safety of unit-operations. A limitation however is that the framework had been applied to only 1-step (single) unit-operations until very recently when Zou and Davey (2016) demonstrated its applicability to integrated 2-step membranes processing. Generally however, it is not known if there is any benefit in developing the framework as a useful tool for integrated, greater multi-step unit-operations and its possible combination (Davey et al., 2013) with existing software to enhance design capability. Davey (2011) had suggested these integrated multi-step analyses be termed 'global' models.

A research program is therefore undertaken with the aim to advance the *Fr 13* framework to gain unique insight into how naturally occurring fluctuations in apparent steady-state plant parameters can be transmitted and impact in progressively complex (in the context of 'integrated' not 'complicated') multi-step processes, and to assess the framework as a new design tool.

A logical and stepwise approach is implemented as a research strategy.

Because foods processing is globally the largest manufacturing sector, and within it, pasteurization is the most widely used unit-operation, a typical 3-step pasteurization unit-

operation, consisting of individual 1) heat-up, 2) holding and 3) cool-down, unit-operations is selected as a prudent and stringent test of the *Fr 13* risk thesis to multi-step unit-operations.

An initial assessment, based on typical commercial pasteurization equipment for raw milk (plate heat exchangers and an external-coil holding tube) is synthesized for the first time (Chandrakash et al., 2015; 2014; Davey et al., 2014) and a generalized method of notation for the *Fr 13* risk framework is developed to unambiguously identify particular unit-operations in integrated multi-step processes. Failure is defined in terms of not meeting a globally used Regulatory combination of temperature (*T*) - time (*t*) (72 ^{O}C, 15 s). Results revealed that pasteurization of raw milk is vulnerable to failure in 12.5 % of all cases over the long-term as a result of with-in system fluctuations in flows, and thermal conditions. If each simulation is (reasonably) considered a daily process this translated to some 46 failures each year with a 2 % design *tolerance* [2] to meet the required *T* - *t* pasteurization criteria.

Results highlighted that apparent steady-state pasteurization is actually a combination of successful and (potential) failed operations. This insight could not be obtained from existing traditional risk and hazard approaches, with or without sensitivity analyses.

A drawback soon acknowledged however, is that this equipment model did not explicitly address the reduction in unwanted levels of survival of potential contaminant micro-organisms in the treated milk. To overcome this, a microbiological global risk model is developed for the first time for the 3-step pasteurization. The logarithmic reduction of viable *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), a common bacterial contaminant and pathogen, is selected as an indicator of efficacy of process, and an inactivation model is then synthesized (Chandrakash and Davey, 2017 a).

Results showed that for a design Regulatory reduction of $\log_{10} = 5.5$ in viable *MAP* the 3-step pasteurization is vulnerable to failure in 5.75 % of cases with a 2 % design tolerance averaged over the long term. This equated to ~ 21 failures with viable *MAP* each year based on a daily operation.

To further test applicability of the risk framework to multi-step processing, a fourth integrated step, the storage of the pasteurized milk, is added for the first time (Chandrakash and Davey, 2017 b). A justification is that this simulated commercial practice more closely.

Results of simulation of this 4-step model showed that with a design tolerance of 2 % for a Regulatory design reduction of $\log_{10} = 5.5$ in viable *MAP* on heat-up to 72 ^{O}C with 15 s holding in commercial plate equipment, there would be no further failures i.e. the rate of

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[2] *see* Appendix A for a definition of important terms used in this research. The first use appears italicized

vulnerability to failure in a 4-step microbiological model for pasteurizing and storing milk remained 5.75 %, averaged over the long term.

Results from investigative second-tier studies with the new 4-step *Fr 13* model to improve design and safety, revealed vulnerability to microbiological failure can be readily mitigated by installing precise safety-integrity-level (SIL) mass flow control on the raw milk in existing plant to ensure a holding time of ≥ 15 s.

It is concluded the *Fr 13* framework appears generalizable to integrated multi-step steady-state processes without methodological problems and an advance over current existing risk/hazard methodologies. If properly developed, it is believed that this novel framework could be adopted as a new design tool for steady-state processing at both design and synthesis stages.

Research findings will aid a detailed understanding of factors that contribute to failures, and to increased confidence in steady-state unit-operations processing.

This research work is original and not incremental work. Findings will be of direct interest to risk analysts, milk processors and manufacturers of pasteurizer equipment.

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I am greatly indebted to my Father Mr Chandrakash Mariappan and my mother Mrs Muthuselvi Chandrakash who gave me an opportunity to come here and study in Australia.

I trust that the results of my research work justify the expectations and confidence of all the people concerned, and the interest and encouragement of my family, friends and colleagues.

DEDICATION

I would like to dedicate this thesis to my father Mr Chandrakash Mariappan. He passed away on September 6, 2013, the year I started my PhD candidature.

PUBLICATIONS MADE DURING RESEARCH CANDIDATURE

REFEREED SCIENTIFIC JOURNALS

Chandrakash, S., Davey, K.R., 2017 a. Advancing the *Fr* 13 risk framework to an integrated three-step microbiological failure synthesis of pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*). Chemical Engineering Science 171, 1-18. http://dx.doi.org/10.1016/j.ces.2017.05.020

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REFEREED CONFERENCE PROCEEDING(S)

Davey, K.R., Chandrakash, S., O'Neill, B.K., 2014. A novel Friday 13th risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26th European Modelling and Simulation Symposium - EMSS 2014, Bordeaux, France, Sept. 10-12. ISBN: 9788897999386

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OTHER RELATED

Davey, K.R., Chandrakash, S., O'Neill, B.K., 2015. A Friday 13th failure assessment of clean-in-place removal of whey protein deposits from metal surfaces with auto-set cleaning times. Chemical Engineering Science 126, 106-115. http://dx.doi.org/10.1016/j.ces.2014.12.013

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MANUSCRIPTS IN PREPARATION

Chandrakash, S., Davey, K.R., 2017 b. A 4-step *Fr 13* microbiological pasteurizer model for raw milk involving heat-up, holding for thermal inactivation of *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), cool-down and storage. AIChE J – *in preparation*.

Chandrakash, S., Davey, K.R., 2017 c. A review of the *Fr 13* risk assessment framework. Food Research International – *in preparation*.

TABLE OF CONTENTS **PAGE**

APPENDICES A – C

LIST OF FIGURES

LIST OF TABLES PAGE

CHAPTER 1

INTRODUCTION

Steady-state processing is globally used in the process industries. Advantages include ease of control and a uniform product quality (Ghasem and Henda, 2008; McCabe et al., 2001).

However, there will be naturally occurring, random fluctuations about 'set' parameter values. These are not sufficient on their own to be considered transient i.e. unsteady-state (Zou and Davey, 2016; Sinnott, 2005; Amundson et al., 1980), and have generally been overlooked in traditional chemical engineering as they can be off-set by fluctuations elsewhere, with the result the overall process output is seemingly unchanged.

Davey and co-workers, however, have hypothesized that these fluctuations about mean parameter values can accumulate in one direction in amounts sufficient to leverage significant change about a defined 'failure – non failure' boundary and in doing so make apparently well-operating processes vulnerable to (surprise) *failure*. They titled their probabilistic framework *Fr 13* (*Friday 13th*), to illustrate the surprise nature of the event. Published studies of application to 1-step unit-operations include: vulnerability to pitting of metals at sea (Davey et al., 2016); failure of thermal efficiency in a coal-fired-boiler (Davey, 2015); a sudden and surprise shift from 'safe to unsafe' in Clean-In-Place milk processing (Davey et al., 2011; 2013; 2015); a sudden shift from potable to non-potable water with ultraviolet irradiation (Abdul-Halim and Davey, 2016; 2015); a sudden shift from stable to unstable (washout) in fermenter operation (Patil et al., 2005; Patil, 2006); and, a sudden shift from sterile to non-sterile UHT milk (Davey and Cerf, 2003).

These acknowledged low-probability high-impact failures are the subject of the recent Blackett Review (Anon., 2012) in which they are seen as an emerging challenge for governments and operators of processes of all sizes; something compounded with increasing inter-connectedness globally of product and processes.

A current drawback however with development of this novel risk framework is that it is limited to largely 1-step unit-operations; although most recently Zou and Davey (2016) and Zou (2016) demonstrated the applicability of this novel risk framework to an integrated 2-step membrane processing operations. It is not known however if there is any benefit in applying the framework to progressively integrated multi-step 'global' processes and longer term coupling with commercial software (e.g. Aspen Plus™) to enhance design capability by providing significantly more powerful design and assessment techniques/tools than currently used.

A research program is therefore undertaken to advance the *Fr 13* risk framework to integrated multi-step processes. The overarching aim is to test the framework for multi-step, steady-state processing.

Multi-step processing is particularly used in the foods industries; these are important to Australia as a major exporter of ‘clean and green’ food product.

Within foods processing, pasteurization is the most widely used unit-operation, and it is therefore selected as a stringent test of the research thesis. Universally, pasteurization is based on a design (Regulatory) heat-and-hold temperature-time (72 ^{O}C, 15 s), in essentially standard, plate-heat exchanger equipment for 1) heat-up, 2) holding and 3) cool-down. A common contaminant pathogen in raw milk is viable *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), a vegetative cell (Madigan et al., 2003).

A justification for this work is that it will aid greater understanding of factors that contribute to unanticipated failures in pasteurized milk processing. A better understanding will lead to an increased confidence and safety and improved design and operation in pasteurization.

A stepwise and logical approach is adopted.

The relevant literature is reviewed in Chapter 2. The term ‘risk’ in steady-state processing is reviewed and a summary of results from *Fr 13* applications are presented. It is proposed here that the *Fr 13* novel risk framework be adopted and applied to multi-step processing. The foods industry, important to Australia as a major ‘green’ exporter, is selected to demonstrate this framework.

In Chapter 3 a 3-step pasteurization of raw milk is selected as a stringent test of application of *Fr 13* to multi-step processing. A model is synthesized for typical commercial pasteurization equipment to include integrated 1) heat-up, 2) holding and 3) cool-down, for the first time. A novel mathematical system of notation for the *Fr 13* framework is introduced to identify particular unit-operations in integrated multi-step processes. Although successful, a drawback soon acknowledged is that this equipment model did not explicitly address the reduction in unwanted levels of survival of potential contaminant pathogens in the treated milk.

To address limitations with this equipment model, in Chapter 4 a 3-step microbiological global risk model for pasteurizing the raw milk is synthesized for the first time. The logarithmic reduction of *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), a common bacterial pathogen, is selected as an indicator of efficacy of process, and an inactivation model is synthesized from independent published data for *MAP*. This is used in *second-tier* studies to assess re-designs. Most notably, failure in one unit-operation did not automatically lead to a failure in the inter-connected corresponding unit-operation. This information is new and is not available from alternate risk and hazard methods. The second-tier simulations highlighted that the overall microbiological pasteurizer vulnerability to failure can best be mitigated by 1) installing precise mass flow control on the input raw milk, and, 2) establishing stringent ways to maintain the design required holding time of the heated raw milk in the holding tube. This global microbiological model appears generalizable to a range of milk pathogens.

In Chapter 5 a 4-step microbiological global model is synthesized for the first time by integrating typical storage of the treated milk in the global model. This is undertaken because isothermal storage is used for the treated milk before packing and distribution or further processing to a range of dairy products. Despite the inclusion of this additional process step, the rate of vulnerability to *Fr 13* failure in the 4-step microbiological global risk model for pasteurizing and storing milk did not increase over the 3-step model, when viewed over the long term. It is concluded that there appear no methodological barriers to application of *Fr 13* to increasing multi-step (in the sense of ‘integrated’ not ‘complicated’) processing.

This thesis closes with Chapter 6 in which it is concluded that the probabilistic *Fr 13* framework is an advance over current existing risk/hazard methodologies. It is concluded the *Fr 13* framework appears generalizable and without methodological problems to integrated multi-step steady-state processes. Longer term, the probabilistic *Fr 13* framework has potential to be coupled with existing commercial design software e.g. Aspen Plus™ to enhance design capability by providing significantly more powerful design and assessment techniques/tools than that currently used.

Results from this original research will be of immediate interest to risk analysts, milk processors and equipment manufacturers, and; more widely, to researchers interested in improving knowledge and safety of processing.

A definition of some important terms used in this research is carefully defined in Appendix A and all symbols used are defined in the Nomenclature. Details of related mathematical developments are presented in Appendix B. A list of refereed publications arising from this research is given in Appendix C.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Steady-state unit-operations in chemical engineering processes are traditionally solved using the deterministic Single Value Assessment (SVA) methodology with or without sensitivity analysis. A drawback of this is that it does not account for naturally occurring random stochastic fluctuations in key process parameters that could potentially lead to process failures.

Unexpected, sudden and surprise failures also, called as *Friday 13th* events, are a notion that have long persisted in the industrial West (Suddath, 2009). These often manifest as failure events - and are widely acknowledged (often anecdotally) in the chemicals and food processing industries (Rosen, 2009; Ghasem and Henda, 2008; McCabe et al., 2001). These unexpected failures are often mistakenly blamed on 'human error' or 'faulty fittings' (Cerf and Davey, 2001; Davey, 2011).

However, Davey and co-workers have developed a quantitative probabilistic risk framework to illustrate that process failures can result from accumulation of random (stochastic) fluctuations within the process itself. This they titled the *Friday 13th* (*Fr 13*) risk framework. It has been successfully applied to a number of steady-state 1-step unit operations (e.g. Davey et al., 2016; Abdul-Halim and Davey, 2016; 2015; Davey, 2015; Davey et al., 2015), and, more recently for the first time to an integrated 2-step membrane processing of fruit juices (Zou and Davey, 2016). A major advantage claimed for the *Fr 13* risk framework is that because all possible practical plant outcome behaviours can be accounted for, including failures, it is advantageous over alternate risk/hazard approaches.

In this chapter, a detailed review of the *Fr 13* risk framework, recent developments, applications, benefits and limitations is presented and a comparison is made with traditional unit-operations solutions and alternative risk techniques.

To test and advance the risk framework a typical 3-step pasteurizer, consisting of integrated heat-up of raw milk, holding (for thermal inactivation) and cool-down of the treated milk is selected. Pasteurization of raw milk is globally important and is shown to be a stringent test of the *Fr 13* risk framework to multi-step processes.

To conclude this chapter, a steady-state batch-continuous pasteurization of raw milk process consisting of three (3) individual steps, 1) heating 2) holding and 3) cooling is selected for *Fr 13* investigation for the first time.

2.2 Traditional deterministic single value assessment (SVA) solution

The traditional method to computationally solve foods and chemical engineering unit-operations is a single point, deterministic approach, with or without a sensitivity analysis (Sinnott, 2005). Cerf and Davey (2001) and Davey and Cerf (2003) defined this methodology as Single Value Assessment (SVA).

In this traditional approach, model inputs are linked together with outputs via mathematical expressions such as addition, subtraction, multiplication and exponentiation. The equations can be conveniently solved in mathematical software like Microsoft Excel™ spread sheeting.

A single or 'best estimate' value of input parameters is used to solve for a single 'best estimate' outcome. A variation (± 1 to 5 %) is used around the mean value of inputs to test the robustness of the model results, for uncertainty in process parameters. Almost all chemical unit-operations used in foods and bio-processing can be addressed with this method (Foust et al., 1980; McCabe et al., 2001).

However, naturally occurring random fluctuations on inputs and its possible impact on plant outcome behaviour are not accounted for implicitly with this deterministic approach. In order to overcome this drawback, the probabilistic *Fr 13* framework is developed.

2.3 Risk, risk assessment and communication of risk findings

Steady-state unit-operations are widely used because of ease of control and uniform product quality (Ghasem and Henda, 2008; McCabe et al., 2001).

Risk in steady-state unit-operations are mainly characterized on the basis of its likelihood of occurrence and its impact. Risks can be separated into three (3) types, those which:

1) Most people could not necessarily identify and characterize, but about which many experts have a reasonable understanding
2) Are identified, but about which little is understood
3) Most, if not all, experts would struggle to identify.

High Impact Low Probability (HILP) risks are the type of risks that falls into the third category i.e. this type of risk is not easy to identify (Taleb, 2007). Identification of HILP is difficult because:

1) Quantitative data highlighting this type of risk is sparse and is not easily available
2) People are often unwilling to give credence to improbable notions specifically because most professional people consider them to be too improbable
3) If a problem is considered too complex the organisation or the government agency simply ignores it
4) There is often general ignorance and a lack of imagination (understanding) when considering these types of risks.

Risk assessment helps to identify how likely these unexpected improbable risk events occur and can be used to assess resulting potential losses and impact. There are three (3) main ways to undertake a risk assessment, they are:

1) Heuristic Method (Non numerical approach) – this method refers to a subjective score for a given risk where relevant stakeholders or experts provide their judgement
2) Deterministic Method – this method evaluates the likelihood of impact of losses made from single specific scenario that can be used to indicate the worst case scenario. In the case of natural occurring hazards practical deterministic boundaries are very hard to establish
3) Probabilistic Method – this method evaluates the likelihood of different levels of loss or damage, for a number of individual scenarios taken from a range of possible events. Decisions can then be taken whether to act based on a set level of risk tolerance.

Deterministic scenarios are often used to estimate the results of probabilistic models. Probabilistic methods should be used wherever and whenever it is applicable, this is because probabilistic methods support risk management process and can readily be used to evaluate defined process risk scenarios.

There are situations when one hazard event can affect the likelihood or impact of another event leading to joint risks. These types of joint risks have separate impacts that are connected to the same causal event (Anon., 2012; Taleb, 2007).

In most situations the likelihood of an event is uncertain, due to limited evidence, scientific disagreement or acknowledged ignorance about the underlying process. It should also be noted that for HILP events in complex systems there will always be incomplete knowledge i.e. uncertainty. Credibility is a key factor when communication of complex ideas such as HILP risks takes place. It is important to try and identify ways in which a lack of knowledge (uncertainty) can be communicated across decision makers without losing its significance. Lack of particular evidence will add to the overall uncertainty within risk assessment. Absence of this particular evidence can be straightforward to communicate, but, getting across the implications for the uncertainty in process risks may be more challenging.

In trying to identify effective communication methods, it is important to recognise that the public (people) do not actually think the same way as the users of risk assessment and expert risk assessors. This does not mean that public (people) are ignorant; it simply means that people use a different language to communicate or express risk results. In some cases, risk assessors may wish for the comfort of being able to suspend scientific decision on an issue, reducing their risk exposure by waiting to see the eventual outcome of the situation, but this strategy is untenable for many decisions in the real world scenario. With sufficient knowledge and informed judgement, uncertainty (lack of knowledge) in any process can be characterized statistically.

Renn (2008) has developed a new system of risk categorisation based on the evaluation of the 1999 annual report of the German Advisory Council on Global Change (WBGU, 2000); six genuine risk classes were identified and names from Greek mythology were given to them to signify how complex were the issues associated with them[3].

HILP risks cannot be overcome by expanding further knowledge about the system. The only way to avoid these risks is by obtaining expert opinion and knowledge. Risk analysts, researchers, processing industries and government agencies face the same difficult challenge in assessing and understanding HILP risks.

In order to study the effect of these HILP failures, the ‘Blackett Review’ (Anon., 2012) was commissioned by the Cabinet Office (CO) and the Ministry of Defence (MOD), United Kingdom. This review used a team of international experts from outside UK government to

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[3] 1) Damocles – Risk sources that have a very high potential for damage but a very low probability of occurrence i.e. HILP risks e.g. large scale chemical processing plant

2) Cyclops – Events where probability of occurrence is uncertain but maximum damage can be estimated e.g. floods and earthquakes

3) Pythia – Highly uncertain risks, where the probability of occurrence, the extent of damage and the way in which the damage manifests itself is unknown due to high complexity e.g. greenhouse effect

4) Pandora – Characterized by both uncertainty in probability of occurrence and the extent of damage, and high persistency e.g. organic pollutants

5) Cassandra – Paradoxical in the probability of occurrence and extent of damage are known, but there is no imminent societal concern because damage will occur in the future e.g. climate change

6) Medusa – Low probability low damage events, which due to specific characteristics nonetheless cause considerable concern for people. Often a large number of people are affected but this fact cannot be proven scientifically e.g. electromagnetic fields and mobile phone usage

present a leading cutting edge and up-to-date thinking on the best ways to assess and manage high impact low probability risks.

As a result of discussion at the review meeting that took place, eleven recommendations were made in the Blackett Review, they are:

1) Government should make greater use of external experts to inform risk assumptions, judgements and analyses
2) Government should continue to ensure the optimal and efficient balance of resources is used to address HILP risks versus any other risks
3) Departments should enhance their warning systems to better detect early signs of HILP risks as a mitigation measure to avoid strategic surprise
4) The assessment means by which the effectiveness of risk mitigation strategies should be reviewed often
5) Probabilistic analyses should be used wherever it is available and applicable. This supports risk management process to evaluate defined scenarios and inform decisions making about significant individual risks
6) The mechanisms to review risks and includes ‘near-misses’ (situation where a significant risk almost materialises) should be strengthened
7) Work should be done more closely with risk communication experts and behavioural scientists to develop internal and external communication strategies
8) Cabinet Office (CO) working with other departments should strengthen the scrutiny of the National Risk Analysis (NRA) by experts drawn from appropriate disciplines in the scientific, analytical and technical fields
9) CO should encourage government departments to develop and maintain a database of appropriate experts for NRA risk they own, and should ensure that it is kept under continual review
10) CO should encourage departmental process plant owners to consider using supplementary approaches to inform the likelihood and impact of assessments for scenarios within the NRA process
11) CO should work with government departments and experts to consider potentially linked risks[4] or compounding risks[5] to inform contingency planning appropriately.

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[4] Linked risks arise from separate effects due to a common causal event

[5] Compounding risks occurs where separate hazard events combine to increase the overall impact on a single area

Processing industries should enhance their warning systems to better detect early signs of HILP risk events so that surprise failures can be avoided.

The main recommendation made by the Blackett Review is that probabilistic analysis should be used wherever and whenever it can be applicable. This is because probabilistic methods take into account every plausible scenario (including process failures).

2.4 Probabilistic *Fr 13* framework

Recently Davey and co-workers have successfully illustrated that failures in processing plants can occur due to a combination of random, naturally occurring fluctuations in key input process parameters. The research hypothesis is that 'random, often surprisingly small changes in process parameters can add together in one direction in amounts sufficient to leverage significant change and thereby making processes vulnerable to sudden and unexpected failure, and sometimes catastrophic'. This approach is titled as *Fr 13* (*Friday 13th*) in order to express the unexpected nature of these failure events and is not explicitly addressed in commonly used traditional chemical engineering deterministic approach.

2.4.1 Development of the probabilistic *Fr 13* risk framework

The term *Fr 13* is coined by Davey and co-workers in order to explain naturally reoccurring 'unexpected' and 'surprise' failures in otherwise well-operated and well-regulated chemical and foods processing industries.

The central notion of *Fr 13* is that a combination and accumulation of naturally occurring, random fluctuations in key process parameter 'set' values can accumulate in one direction and can result in leverage highly significant, and often catastrophic, changes in process or product (Abdul-Halim and Davey, 2016; 2015; Davey, 2015; 2011). This can result in a process or product being unsafe, unstable or inefficient which in turn could have impact on public health, with or without fatalities (Cerf and Davey, 2001; Davey and Cerf, 2003; Davey et al., 2015; Davey, 2015; Abdul-Halim and Davey, 2016; 2015; Zou and Davey, 2016).

This new risk framework has been successfully applied to a number of steady-state 1-step unit-operations (e.g. Davey et al., 2016; Abdul-Halim and Davey, 2016; 2015; Davey, 2015; Davey et al., 2015), and, more recently successfully illustrated for the very first time to a 2-step membrane processing of fruit juices unit-operation model (Zou and Davey, 2016).

2.4.2 A *Fr 13* risk assessment

Importantly, the structure of the *Fr 13* framework is identical to the traditional deterministic SVA because additions, multiplication, exponentiations and other mathematical operations that connect the model parameters remain the same (Zou and Davey, 2016; Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2015; 2014; Davey, 2015; 2011; Davey et al., 2015; 2014; 2013; Patil et al., 2005).

However, in *Fr 13* simulation each process input parameter is defined as a probability distribution of values rather than a single 'best-guess' value, the mean of which will always agree with the deterministic SVA value, the output is therefore a distribution also.

There are five (5) identifiable components to a *Fr 13* risk assessment of steady-state unit-operations processes. These are:

i. Synthesize an underlying unit-operations model

An underlying unit-operations model must be established. This is normally achieved through synthesis and validation of key process parameters in a computational model and software for particular plant throughputs.

ii. Selection of suitable probability distributions

A probability distribution is used for all practically possible values that process input parameters can take. Generally, there are some 40 theoretical probability distributions that could be used, some examples include, Normal, Triangle, Beta-subjective, Pert (Vose, 2008). However, Davey and co-workers reported that the number of *Fr 13* failures is not sensitive to a range of distributions (Davey et al., 2015). However, this might not always be the case (Law, 2011). A possibility is that these distributions could also be based on expert opinion or experience (Davey, 2010; Law, 2011).

iii. Establishment of an unambiguous definition of process / product failure

A practical and unambiguous definition for process or product failure must always be established. In foods and chemical processing this is usually an unwanted reduction in process efficiency (e.g. Chandrakash et al., 2015; Davey, 2015; Zou and Davey, 2016), or the unwanted survival of contaminant pathogens (Cerf and Davey, 2001; Davey and Cerf, 2003), or spoilage microbes (Abdul-Halim and Davey, 2016; 2015; Chandrakash and Davey, 2017 a).

iv. Sampling using refined Monte Carlo (r-MC) with Latin Hypercube sampling

Monte Carlo (MC) is a statistical technique used to investigate the impact of risk by using randomly selected ‘what-if’ scenarios for simulation. It involves the random sampling of each probability distribution within a parameter to produce 1,000 or 100,000 of iterations. Each probability distribution is sampled in a manner that reproduces the shape of the distribution. *Uncertainty* (lack of knowledge) and *Variability* (effect of chance) are two major components of Monte Carlo Assessments (MCA) (Vose, 2008).

A r-MC with Latin Hypercube sampling is used because ‘pure’ MC can over-and-under estimate samples from a particular part of the distribution. This refinement ensures samples cover the entire range of the distribution. If the number of samples is sufficiently large, the output mean of a product of a large number of independent positive parameters with different distribution functions will be approximately normally distributed i.e. as per the Central Limit Theorem (CLT), the mean of a sufficiently large variable will be normally distributed (Devore, 2010; Snedecor and Cochran, 1989; Sullivan, 2004; Vose, 2008).

To ensure that the output distribution of the mean is sufficiently normal, a minimum number of samples is needed; this is usually some 1,000 to 50,000 (e.g. Davey et al., 2015; 2013; Abdul-Halim and Davey, 2016; 2015; Davey, 2015). This number can be established when a scatter plot of number of samples versus number of failures plateaus to a constant, highlighting sufficient samples. This can also be established reliably by visual inspection of the output risk distribution.

Since a large number of r-MC samples are used in the *Fr 13* simulation, it can reasonably be assumed that all process scenarios that can occur in practical process operation, including failures, are included.

v. Interpretation of process plant outcome behaviour with second-tier studies

The outcome from a *Fr 13* simulation is a distribution of all possible process behaviour configurations, this includes process failures.

A major advantage claimed for *Fr 13* risk assessment is that repeat simulations can be used to investigate process intervention strategies and re-design of the physical plant or make changes in operating practices i.e. second-tier studies (e.g. Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2016; Davey, 2015), to reduce the unexpected risk, and it can be applied at both analyses and synthesis stages.

This overall standardized *Fr 13* approach has been formulated on a 5-step algorithm that can readily be applied to any unit-operation. This 5-step algorithm is pioneered by The

University of Adelaide researchers (Cerf and Davey, 2001; Davey and Cerf, 2003), and consists of the following five (5) steps:

1) Structure pasteurized milk processing operations as identifiable separate unit-operations:
    a) Synthesize and validate mass and energy balance (including microbial kinetics) as key parameters in a suitable computational model for particular process duty
    b) Establish clear definition for process failure in each unit-operation
2) Identify key process parameters using traditional SVA (Single Value Assessment)
3) Derive, investigate and test plausible probability distributions for key parameters
4) Identify the risks involved in pasteurization, simulate process operation and its likely failures using uncertainty modelling approach together with r-MC (Monte Carlo) sampling:
5) Identify and rank the significance of the key process parameters on failures (risks)
    a) Investigate effects of 'what-if' scenarios and consequences of proposed intervention strategies. Evaluate risks and potential opportunities
    b) Distil insights from uncertainty modelling into advice for minimising risk of failure and improving pasteurized milk processing unit-operations.

2.5 Critical review of published case studies using probabilistic *Fr 13* failure method

Given the newness of *Fr 13* failure modelling there is little referred literature available (Chandrakash et al., 2013). The work is being pioneered by The University of Adelaide researchers.

Table 2-1 presents a chronological listing of established *Fr 13* case studies published to date in the refereed literature for the steady-state 1-step and 2-step unit-operations.

Table 2-1: Summary and chronological listing of published *Fr 13* risk assessments for steady-state 1-step and integrated 2-step unit-operations

Unit-operation	*Fr 13* model	Reference(s)
1. UHT milk sterilization	Failure of UHT sterilization defined as non-sterility of a 1 L pack of UHT milk. UHT parameters (D_r, z, T, t, C_0) were defined as probability distributions. 16 of 100,000 scenarios were found out to be failed operations. The risk was shown to be 16 times greater than industrially accepted criteria (~ 10^{-5}).	Cerf & Davey (2001); Davey & Cerf (2003)
2. Monod fermentation	Failure was defined as unexpected 'washout' of *Escherichia coli*. Investigated impact of variation of micro-organisms growth characteristics i.e. μ_{max}, $Y_{x/s}$, K_s, on the output dilution rate, D_{max}. Results underscored that small random changes in microbiological parameters significantly affected the productivity of fermentation.	Patil et al. (2005); Patil (2006)
3. Clean-In-Place (CIP) processing	A 2-stage (Bird and Fryer, 1991 a; b) and a 3-stage (Xin, Chen and Ozkan, 2004) CIP model were developed to further establish *Fr 13* framework. This was defined as failure to remove whey proteinaceous deposits on metal surfaces with an auto-set cleaning time, $t_T' < t_T$. Results revealed that 4.2 % of 2-stage (T = 50 ^{O}C) and 2 % of 3-stage (T = 75 ^{O}C) CIP operations failed despite a tolerance as a margin of safety. CIP was shown to be a mix of successful and unsuccessful events. Increased control of physical system e.g. T shown to reduce vulnerability to failures.	Chandrakash (2012); Davey et al. (2013; 2015)
4. UV irradiation for potable water	UV irradiation of *Escherichia coli* in potable water (turbulent flow) was assessed using *Fr 13* framework. Failure was defined in terms of design and actual reduction of *E.coli*. Simulations of parameters (I_o, k, Q) showed 16 % of UV operations failed to reduce *E.coli* to a Regulatory level ($10^{-4.35}$), with a 10 % tolerance. Increased control of physical system e.g. Q and I_0 shown to reduce vulnerability to failures.	Abdul-Halim & Davey (2016; 2015); Davey et al. (2012)
5. Coal-fired boiler (CFB)	*Fr 13* framework was further used to investigate fuel-to-steam efficiency of CFB. 20 parameters included coal feed and quality. 73 (per 10,000) failures as $\eta' < \eta$ = 77.82 % was found. This failure rate was equivalent to three (3) failures per year. Repeat simulations highlighted that pre-mixing of coal is a practical strategy to reduce vulnerability to CFB efficiency failures.	Davey (2015)
6. Pitting of metals at sea	*Fr 13* framework was applied to predict risk of metals (AISI 316L) pitting at sea. Demonstrated for Bass Strait. Pitting potential (E_{PIT}) with key parameters i.e. T and [CL^-] were simulated. 463 failures (9.26 %) as pitting initiation ($E_{\mathrm{PIT}} < E_{\mathrm{OCP}}$ + tolerance, %) were found (out of 5,000 iterations). Creation of original 'isorisques' i.e. contours of risk probability established a new atlas of World pitting risk.	Davey et al. (2016)
7. Membrane processing of fruit juices	*Fr 13* framework was applied to predict risk of fouled OD flux. Simulations showed the integrated 2-step UF-OD is expected to be vulnerable to surprise fouling failure in 10.5 % of all operations over an extended time. This equated to 39 surprise failures per year, distributed over the long term. Repeat simulations highlighted that reducing the variance about the mean transmembrane pressure and filtration time reduced fouling failures.	Zou & Davey (2016)

The *Fr 13* risk assessment was first applied to explain the vulnerability to failure in an otherwise well-operated and well-regulated 1-step UHT milk process plant (Cerf and Davey, 2001; Davey and Cerf, 2003). Failure in this UHT plant was defined as a non-sterile 1 L pack of UHT milk with viable micro-organisms (*Bacillus stearothermophilus* and *Bacillus thermodurans*) which might pose a serious risk to public health (with or without fatalities).

It can be seen from Table 2-1 that sterilization was the first 1-step unit-operation to be studied using *Fr 13* failure modelling (Cerf and Davey, 2001; Davey and Cerf, 2003).In Ultra High Temperature (UHT) milk sterilization the concentration of contaminant spores (C_0), decimal reduction time (D_r), thermal resistance (z), heating temperature (T) and residence time (t) were identified as key input parameters and were simulated with r-MC samplings. Results revealed that the risk value predicted using *Fr 13* framework was 1.6 x 10^5; this value was much greater than that of the traditional 'deterministic' value of 10^{-9}, additionally, this value was much greater than the industrially accepted value of 10^{-5} for the non-sterility of UHT milk packs. It was inferred from this study that a higher proportion of non-sterile milk packs practically existed due to random naturally occurring fluctuations within UHT process, thereby confirming this hypothesis.

Patil et al. (2005); Patil (2006) further adapted this novel *Fr 13* framework to a batch-continuous Monod fermenter (using *Escherichia coli*) process. The aim of this study is to investigate the impact of random variations in microbial growth parameters as model inputs on the output dilution rate, D_{max} of the process. Failure was defined as an unwanted low dilution rate compared to the value of $D_{max\ output}$ which was predicted by 'deterministic' SVA i.e. $D_{max} < D_{max\ output}$. *Fr 13* simulations revealed that even small variation in micro-organisms growth characteristics i.e. μ_{max}, $Y_{x/s}$, K_s, significantly affected the productivity of the fermentation process. This practical insight into an otherwise well-operated and well-regulated fermentation process contrasted sharply with the 'deterministic' SVA analysis and highlighted that these naturally occurring 'chance' fluctuations of fermentation process are not accounted for in 'deterministic' SVA process.

A *Fr 13* risk analysis was then applied to a steady-state 2-stage *Bird model* (Bird and Fryer, 1991 a; b; Bird, 1992) and 3-stage *Xin model* (Xin, 2003; Xin et al., 2004) Clean-In-Place (CIP) process by Davey et al. (2013; 2015). The aim of this study was to gain insight in random fluctuations in CIP input parameters that could potentially lead to failures in a well-operated and well-regulated CIP process plant. Failure in CIP process was defined in terms of auto-set cleaning time i.e. if the CIP process is not able to remove the present whey proteinaceous substances that are present on the equipment (metals) surface within an auto-set cleaning time the process is said to have failed. Results revealed that at a nominal cleaning solution temperature of 50 ^{O}C the 2-stage *Bird model* is susceptible to 42 failures out of 10,000 simulated scenarios i.e. 4.2 % of all operations with a process tolerance of 5 %. Also, the 3-stage *Xin* model, at a nominal cleaning solution temperature of 348 K (75 ^{O}C), this unit-operation has a within system, stochastic, tendency to fail; for realistic values of the key parameters, this is some 2 % of operations together with a process tolerance of 2 %, averaged over the long term; if each simulated scenario is thought of as a processing day then the failure rate is expected to be about one every 19 days of continuous CIP operation. These failures could occur despite all precautionary measures that could be taken and are not equally spaced in time. Second-tier studies were then carried out to find process intervention strategies to avoid these random failures (fluctuations) and to improve the process reliability and safety in CIP process. It was proposed that improving the reliability and precise control of the temperature of the cleaning fluid (*T*) would dramatically reduce these naturally occurring random failures (fluctuations).

Abdul-Halim and Davey (2015) successfully developed a *Fr 13* failure model to assess the unexpected risks in steady-state UV irradiation of *Escherichia coli* in potable water, failure of UV was defined in terms of design and actual reduction of *E. coli* together with a practical tolerance. The aim was to examine the impact of naturally occurring fluctuations in suspended solids concentration on failure to inactivate viable *E. coli*. Results revealed that 16 % of all successful UV operations can fail to achieve the design reduction in viable *E. coli* of $10^{-4.35}$ due to naturally occurring random fluctuations. Abdul-Halim and Davey (2016) demonstrated that although UV efficacy for potable water was initially reduced by the presence of suspended solids in the feed water which acts as both shielding and absorbing agents, fluctuations in the concentration of these solids however did not meaningfully impact overall vulnerability to failure to produce potable water. The efficiency of UV process was shown to be significantly highly impacted by fluctuations in feed water flow (*Q*). It was therefore proposed that this is strong quantitative evidence to emphasize that suspended solids should be removed prior to the UV reactor, and that an improved flow control has to be used to reduce the variance on the feed flow, rather than just increasing the UV dose.

Davey (2015) further developed this novel *Fr 13* framework by illustrating the vulnerability of a Coal-Fired-Boiler (CFB) to these naturally occurring random fluctuations in input parameters and its effect on the fuel-to-steam efficiency of the CFB. Simulations revealed that due to random fluctuations in 20 input CFB parameters 73 CFB operations could potentially fail per 10,000 simulated scenarios. This failure rate equated to three (3) failures per year, averaged over an extended period of time. This study concluded that pre-mixing and pre-sizing the consistent raw coal feed from batch to batch to a consistent and standardized fuel mixture reduced the unwanted random fluctuations in CFB efficiency thereby reducing the CFB failure rate.

Davey et al. (2016) further developed this methodology by successfully applying it to highlight failures due pitting of metals at sea in the Bass Strait. Pitting potential (E_{PIT}) with key input parameters such as temperature (T) and salinity (Cl^-) were defined as Normal and Truncated probability distributions. Simulation study revealed that 463 (9.26 %) failures as pitting initiation were found in 5,000 iterations. A significant outcome of this study was the development of 'isorisques'. These were defined by the authors of this study as contours of equal probability of the risk of pitting of metal as anticipated by naturally occurring random chance fluctuations in the sea surface temperature and sea salinity. These isorisques could be used to determine the change in pitting risk after a sudden shift in sea surface temperature or salinity following a major storm or ice melts.

More recently this novel *Fr 13* framework was applied to predict risk of integrated 2-step fouled OD flux (Zou and Davey, 2014 a; b; 2016). This is the very first time this novel *Fr 13* framework has been extended to study the effect on a global model (two or more interconnected unit-operations). Results revealed that the integrated 2-step UF-OD is expected to be vulnerable to surprise fouling failure in 10.5 % of all operations over an extended time. This equated to 39 surprise failures per year, distributed over the long term. Repeat simulations highlighted that reducing the variance about the mean value of transmembrane pressure and filtration time will reduce fouling failures. Additionally it was proposed in this study that adding a new enzymatic treatment step prior to UF operation reduces the overall UF-OD failures.

The second-tier studies and process intervention strategies that are obtained using this novel *Fr 13* framework to reduce failure cannot be obtained using existing risk analysis/hazard approaches. This is a significant advantage of this novel *Fr13* framework.

2.6 Advantages of *Fr 13* framework over current existing risk and hazard approaches

The *Fr 13* framework is predicated on well-established unit-operations model with r-MC samplings. It looks to quantify the impact of accumulation of random fluctuations in parameters on the behaviour of steady-state processes.

The term ‘risks’ in current existing risk assessment approaches represents ‘hazards’. However, in reality, Hazard = dormant, potential, threat; Risk = probability of event occurring; Hazard ≠ Risk; Risk = Hazard + Vulnerability.

Currently, there are three (3) main risk assessment techniques used in food and pharmaceutical industries (Davey, 2010). They are:

1) Hazard Analysis Critical Control Point (HACCP)
2) HAZard and OPerability studies (HAZOP)
3) Reliability Engineering (RE).

In food processing industries HACCP is the most widely used and recognized risk assessment method (Whiting and Buchanan, 1997). It focuses mainly on identifying and controlling the key process steps that most significantly affect the safety of the production. HACCP is a systematic approach to produce acceptable, safe product based on identification and management of critical control points[6] (Notermans and Mead, 1996; Notermans et al., 1995). HACCP was first developed and established by the National Aeronautics and Space Administration (NASA) in the 1960’s to help prevent food poisoning in astronauts.

Table 2-2 presents a comparison between traditional HACCP and novel *Fr 13* framework.

It can clearly be seen from Table 2-2 that the main drawback with HACCP is that the person carrying out HACCP studies can make his or her findings to fit existing controls, rather than changing them. This was however highlighted by Whiting and Buchanan (1997) that, as HACCP becomes more widely adopted, there are areas within this approach that need to be strengthened if the researchers were able to quantitatively link product attributes with public health concerns.

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[6] A critical control point is defined as any point or procedure in a specific food system where loss of control may result in an unacceptable health risk; it is a point where the loss of control might result in failure to meet (non-critical) quality specifications

Table 2-2: Comparison between HACCP and novel *Fr 13* framework

Criteria		**HACCP**	***Fr 13* framework**
1.	Methodology	Methodology based on 'template', requires constant updating and often neglected which eventually leads to failure	A standard fixed methodology. Simulations are performed using specialized software
2.	Sophistication	Identifies only 'hazard' Focuses only on 'single' or 'deterministic' events	Both 'hazard' and 'risk' can easily be identified i.e. focuses on combinations of all plausible events
3.	Assessment Requirements	Requires technical, human and material resources that are not always available to the company	Requires only technical resources that could be obtained from process industries or from literature
4.	Organizational needs	Requires sincere effort and involvement of all elements of the organization	No such effort is needed, can easily be performed by 'risk or safety engineer'
5.	Time	Time consuming process	Running simulations take time, but less time compared to performing HACCP study
6.	Identifying failures	Identification of a critical control point (CCP) requires logical approach, could mislead; could result in missing key CCP's	Based on standardized approach to identify failure, identification of such key CCP's not required
7.	Study Output	If not properly applied it may not result in an effective control system	If the model is set correctly the chance for making errors are negligible
8.	Cost	Studies result in higher cost	No such costs are involved
9.	Training needs	Cannot be applied without specific training	Cannot be applied without specific training
10.	Extendibility	Widely used tool for large-scale industries; small-scale industries do not benefit much from this study	Both large and small scale industries could be benefited
11.	Flexibility	Company carrying out HACCP can make its finding fit existing controls rather than changing them	Process intervention strategies obtained using *Fr 13* framework should definitely be made, there is no way to hide findings

HAZard and OPerability studies (HAZOP) are a ‘systematic, structured approach to questioning the sequential stages of a proposed operation in order to optimize the efficiency and the management of risk’ (Swann and Preston, 1995). However, Swann and Preston (1995) underscored the problem with HAZOP actions is that they are created at a stage when detailed design is underway, and to make a number of changes at this stage is inevitably expensive and causes potential delay, and these changes could be expensive, they have also stated that HAZOP’s are impracticable.

Table 2-3 presents a comparison between traditional HAZOP and novel *Fr 13* framework.

Table 2-3: Comparison between HAZOP and novel *Fr 13* framework

	Criteria	HAZOP	*Fr 13* methodology
1.	Design	Focuses only on ‘single’ or ‘deterministic’ events	Focuses on combinations of all plausible events
2.	Assessment Requirements	Requires commercial software	Also requires commercial software
3.	Identifying failures	Focuses on ‘guide-words’. Some hazards (failures) that are not related to a guide word can be overlooked	Standard fixed methodology is used to identify failures
4.	Training needs	Cannot be applied without specific training	Cannot be applied without specific training
5.	Time	Time consuming process	Running simulations take time, but less time compared to performing HAZOP study
6.	Cost	Studies result in higher cost	No such costs are involved
7.	Study Outputs	The success of identifying failures is greatly dependent on the knowledge, ability, experience and interaction of study performer	Based on quantitative methodologies, identifying process failures is an easy step
8.	Chance for errors	Performed only during the last stage of construction of the processing plant. There is no guarantee that all hazard and operability problems can be identified. Even if they are identified they can be overlooked during these stages. Therefore, complex systems cannot entirely be dependent on this study	If the model is set correctly the chance for making errors are low or negligible

Reliability Engineering (RE) is a widely used capability to predict something to 'fail-well' i.e. to fail expectedly without catastrophic consequences (O'Connor et al., 2002).

Table 2-4 presents a comparison between traditional RE and novel *Fr 13* framework.

Table 2-4: Comparison between Reliability Engineering (RE) and novel *Fr 13* framework

	Criteria	**Reliability Engineering**	***Fr 13* methodology**
1.	Design	Focuses only on 'single' or 'deterministic' events	Focuses on combinations of all plausible events
2.	Methodology	Can have significant startup costs associated with staff training and equipment needs	No significant costs are involved, only requires a commercial software
3.	Cost	Lowers operating cost by eliminating unnecessary equipment maintenance and system overhauls and increases equipment reliability	Lowers operating cost by proposing process intervention strategies that could be used to avoid 'surprise' failures and to perform second-tier studies
4.	Time	Time consuming process	Running simulations take time, but less time compared to performing Reliability studies
5.	Identifying failures	Reduces probability of sudden equipment failures	Reduces probability of sudden equipment failures
6.	Study Outputs	Focuses on maintenance activities on critical system components; savings potential cannot be seen readily by the management	Based on quantitative methodologies, identifying process failures is an easy step

These currently used risk assessment techniques have many drawbacks; they do not deal with all plausible events rather they deal with single 'deterministic' events and are essentially qualitative or subjective. Therefore, it can clearly be seen from Table 2-2, 2-3 and 2-4 that the novel probabilistic *Fr 13* framework is more advantageous than that of traditional HACCP; HAZOP and Reliability Engineering (RE) studies as this methodology is more quantitative and is based on existing underlying unit-operations.

2.6.1 Other current existing probabilistic risk approaches

The impact that fluctuations in physical plant parameters in an expected steady-value can have is also the subject of recent risk assessment approaches of Aven (2010), Flage and Aven (2009), Nilsen and Aven (2003), Milazzo and Aven (2012), Haimes (2009 a; b) and Haimes (2006; 2004; 1991). Milazzo and Aven (2012) used a quantitative risk approach for surprise failures of the rupture of pipes in the chemical industry. These authors suggested that while a probabilistic approach is useful, uncertainties still remain as to whether data used is applicable to a specific scenario. Two techniques to overcome this drawback were proposed. The first was to use chance (variability) distributions (e.g. Beta-distribution; Triangular distribution or Uniform distribution) for plant parameters together with an event tree model to propagate the uncertainties for risks. This is similar to that of the *Fr 13* risk framework. However, their preference was to use a quantitative risk approach, together with a qualitative risk technique, e.g. ‘score system’ of Low (L), Medium (M) and High (H) to further investigation of process uncertainties.

A drawback was that this approach remains largely qualitative or subjective relying on a ‘scored’ system and is therefore not rigorously quantitative. As acknowledged by Milazzo and Aven (2012) this approach restricts attention to the most credible scenarios.

2.6.2 Advantages of *Fr 13* framework over current existing probabilistic risk approaches

Because the *Fr 13* framework is embedded in established unit-operations processing (Foust et al., 1980; Ozilgen, 1998; McCabe et al., 2001) it is openly quantitative and, in principle generalizable (Davey, 2017) and provides a picture of all practically possible process scenarios including process failures. Both these approaches share the same goal, ‘to place stronger emphasis on the effect of uncertainties within process systems’.

A criticism of the term *Fr 13* is that it might be more widely considered to refer to a catastrophic event. Importantly, *Fr 13* as defined by Davey and Cerf (2003) and others does not imply actual breakage or ‘faulty fittings’ or even ‘human error’, but a sudden and surprise shift across a ‘failure – non failure’ boundary.

2.7 *Fr 13* as a terminology

Although *Fr 13* is carefully defined by Davey and co-workers as a particular plant outcome behaviour i.e. as that portion of a probability distribution of the numerical difference between the value of a key parameter outcome and the actual instantaneous value, plus an acceptable tolerance as a design margin of safety (mathematically this is $p > 0$), it is acknowledged that *Fr 13* might be thought of as referring to a catastrophic event.

Pointedly, the origin of the terminology was in UHT sterilization of raw milk (as 1 L cartons) (Davey and Cerf, 2003) where there could possibly be a catastrophic legacy, with or without fatalities. *Fr 13* was coined to quantitatively explain surprise failures that could arise from the naturally occurring random fluctuations in key parameter values about a process steady-state ‘controlled’ mean. The probabilistic element in *Fr 13* is to quantitatively mimic naturally occurring chance fluctuations. It was demonstrated that chance impact through unanticipated accumulation and combination of these fluctuations could lead to unsterile (failed) milk; ‘faulty fittings or human error’ need not be invoked as an explanation.

Suggestions for an alternative terminology include those based on Root Cause Analysis (RCA) (e.g. DNV’s Taproot™ methodology). Although, this does not involve probability assessment, and is typically undertaken only after an event has occurred. *Fr 13* could be renamed as ‘Iterative Random-Impacts Assessment (IRA)’ to predict and fix probable events before they occur (Zou and Davey, 2016). If the advancement of the framework is successful, and, adopted as a valuable design tool. IRA might be taken up.

2.8 Benefits and current limitations of *Fr 13*

The *Fr 13* framework has a number of advantages over alternative probabilistic methods e.g. Aven (2010), Milazzo and Aven (2012), Haimes (2009 a; b) and Haimes (2006; 2004; 1991).

In particular, is that it is based on sound underlying unit-operations, a principle well-established in chemical engineering. Further, the *Fr 13* probabilistic element provides a quantitative picture of all; mathematically practical possibilities process scenarios, including process failures. A result is the quantitative capacity of framework to distinguish the effect of targeted intervention strategies or design changes in second-tier simulations on plant behaviour.

Once established, a major benefit of the *Fr 13* framework is that it can be used in second-tier simulations to make physical changes to a process or operating practices to reduce vulnerability to process failure. This can be undertaken in both analyses and synthesis stages. For example, Davey (2015) concluded that coal could be pre-mixed and pre-sized to a consistent blend from batch-to-batch to provide standardized feed to a coal-fired-boiler to minimize the impact of fluctuations in process thermal efficiency about a required value.

A current drawback with development of the *Fr 13* framework is that the work is largely limited to single, i.e. 1-step unit-operations. However, this drawback was overcome recently by Zou and Davey (2016) when they successfully applied to a 2-step steady-state membrane processing of juices, and, more recently Chandrakash et al. (2017) successfully applied the *Fr 13* framework to a 3-step pasteurization of raw milk unit-operation. Therefore, it is very clear that this *Fr 13* framework can be used as a useful tool for multi-step foods and chemical unit-operations and processes with increasing complexity (in the sense of ‘integrated’ not ‘complicated’).

Since, milk acts as a perfect substrate for growth and multiplication of micro-organisms and that milk processing involves a series of interconnected unit-operations it is therefore selected as a timely and stringent test of development of the *Fr 13* framework to multi-step unit-operations processing.

2.9 Milk processing

Milk processing involves a series of interconnected unit-operations; some of them are heating, holding, cooling and storage. Temperature (*T*) plays a major role in processing of pasteurized milk, even a slight increase or decrease from the desired (required) value of the processing temperature (*T*) can have enduring impact on the processed milk which in turn can affect the consumer’s health (with or without fatalities).

Microbiological contamination in the food industry costs millions of dollars annually in terms of downgraded product (product that fails to meet manufacturing standards due to high levels of micro-organisms in it). In 2000, the total cost of potentially food borne infectious diseases in New Zealand, a country of barely 4 million people was estimated to be $ 88.8 million (Scott et al., 2000). In USA a report to the president in the year 1997 suggested that there were between 6.5 and 33 million cases per year, which results in 9000 death and costing $ 6.5 - $ 34.9 billion (FDA et al., 1997).

The global dairy industry is significantly large. In 2005, world milk production was estimated at 644 million tonnes, of which 541 million tonnes was cow’s milk. The leading producers of milk were the European Union (142 million tonnes), India (88 million tonnes), the United States of America (80 million tonnes), Russia (31 million tonnes), Brazil (25 million tonnes) and Australia (10 million tonnes). Australia accounts for nearly 7 % of the world milk production. In Australia, the dairy industry is one of the major and largest industries. The farm gate value is $ 3.9 billion in the year 2011, about 40, 000 people are employed in dairy farms and industry (Ledenbach and Marshall, 2009).

Milk processing contributes significantly to Australia's social and economic well-being. Australia produces about 10 million tonnes of milk annually. Major export markets are Japan, China, Indonesia and Malaysia.

A typical milk processing process in a dairy plant can be understood from Fig. 2-1.

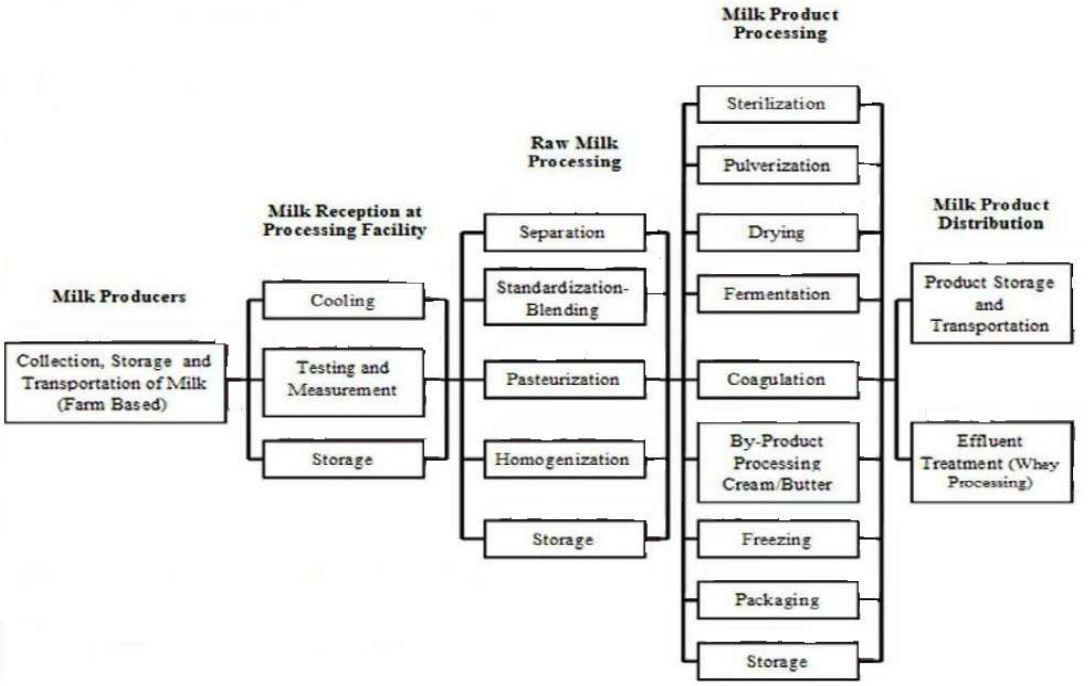

Fig. 2-1: Block diagram depicting a typical milk processing plant

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From Fig. 2-1, it can be seen that the methodology of processing milk consists of a series of unit-operations such as clarification, homogenisation, heat treatment (pasteurization), regeneration, cooling, storage, and effluent disposal. Heat treatment plays a major role i.e. heating milk to a particular temperature and holding milk at that temperature for a particular period of time to pasteurize (sterilise milk commercially). The reason for giving much importance to heat treatment unit-operation is that milk contains many micro-organisms and these micro-organisms are heat sensitive i.e. improper heat treatment can result in survival of these micro-organisms in milk. Therefore much care has to be taken to ensure that these micro-organisms are not viable (active) in milk during the time of heat treatment.

Viable pathogenic bacterial organisms play a vital role in food processing industries, this is particularly true in dairy industry as milk acts as a perfect substrate for microbial growth. Bacteria in milk have the ability to adhere and aggregate to stainless steel surfaces which results in biofilm formation in heat transfer equipment, storage tanks and milk processing lines (Chandrakash et al., 2014). The micro-organisms that are formed on equipment surfaces are based on various process parameters such as temperature, pH, flow conditions and presence of salts and other nutrients. Temperature plays a crucial role in the attachment of micro-organisms on process equipment surfaces. It has been shown that higher temperatures increases cell surface hydrophobicity and subsequently increases microbial attachment to equipment surfaces (Di Bonaventura et al., 2008).

Milk is a complex fluid and it contains both gram-positive and gram-negative microbial species (Madigan et al., 2003). Some of the common microbial species that are present in raw milk are: *Pseudomonas*, *Aeromonas*, *Acinetobacter*, *Serratia*, *Alcaligenes*, *Achromobacter*, *Enterobacter*, *Flavobacterium*, *Klebsiella*, *Arthrobacter*, *Bacillus*, *Clostridium*, *Lactobacillus*, *Listeria*, *Staphylococcus*, *Corynebacterium*, *Mycobacterium*, *Enterobacteriaceae* and *Micrococcus*. Gram-negative bacteria usually accounts for about 90 % of the bacterial content in raw milk (Cousin, 1982).

If bacterial load (content) in milk is left unchecked the micro-organisms has the tendency to form biofilms. A biofilm is defined as a ‘microbial community characterized by adhesion to a solid surface and by production of a matrix that surrounds the bacterial cells and includes extracellular polymeric substances (EPS), proteins and DNA’ (Marchand et al., 2012). Biofilm development is a result of successful attachment and subsequent growth of micro-organisms on process equipment surface (Blackman and Frank, 1996). The film is usually a few micrometres or a few millimetres thick and contains about 90 – 97 % water (Brooks and Flint, 2008).

2.10 Pasteurization

Pasteurization of milk is a very important process. Before pasteurization process the spread of infectious diseases like tuberculosis and typhus were common. With the advent of pasteurization method of processing milk the spread of these infectious diseases could be curbed. Pasteurization technique became a widely used heat treatment practice in milk processing. However, pasteurization method can remove micro-organisms only to a certain extent. There are several species of thermoduric bacteria (bacteria that can survive high heat treatment temperatures) that can survive during pasteurization process and pose a serious threat (with or without fatalities). If a consumer consumes this contaminated milk, his safety will be of a greater concern (Alfa-Laval, 1987; Oliver et al., 2005).

From the literature it can be inferred that temperature plays a very important role in milk processing. Bacterial attachment to equipment surfaces is mainly influenced by the physicochemical properties of environment such as temperature, pH and water activity (a_w) (Baranyi and Roberts, 1994).

To ensure the inactivation of all micro-organisms present in milk it is necessary to heat-up milk to a desired temperature and hold at that temperature for a particular (specific) period of time and then immediately cooled-down to a particular temperature. This combination of temperature and time is much important because of the fact that this combination decides the intensity of the heat treatment process. Based on this temperature and time combination pasteurization process is divided into three (3) types, they are:

i) Low Temperature Long Time (LTLT) pasteurization – this method of pasteurizing milk is the original first developed pasteurization process where milk is heated to a temperature of 63 ^{O}C in open vats and is held at that temperature of 63 ^{O}C for a period of 30 mins. This method of pasteurization is also called as ‘batch pasteurization’

ii) High Temperature Short Time (HTST) pasteurization – the HTST process of pasteurizing milk involves heating milk to a temperature of 72 – 75 ^{O}C with a 15 seconds holding time before it is immediately cooled again to a temperature of about 4 ^{O}C

iii) Ultra-High Temperature (UHT) pasteurization – The UHT process of pasteurizing milk involves two stages, first milk is heated to a temperature of 75 ^{O}C, and, then under pressure milk is heated to a temperature of 140 ^{O}C and is held at that

> temperature for about 4 seconds. After this the milk is quickly cooled and packed under aseptic conditions (Alfa-Laval, 1987).

HTST and UHT methods of pasteurizing milk are the two widely used methods for pasteurizing milk these days.

Pasteurization of milk is a global unit-operation process that consists of three (3) individual steps of 1) heating, 2) holding and 3) cooling. These three steps combined together form the 3-step global pasteurization process.

Computations to simulate the pasteurization of raw milk were carried out using standard Microsoft Excel™ spread-sheeting with a commercially available add-on, *@-Risk* version 5.5 (Palisade Corporation™). Because these are used almost universally it makes the communication of results simplified (Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2015; Davey, 2015; 2011; Davey et al., 2015; 2013). Additionally, the distributions defining the naturally occurring fluctuations in parameters can be entered, viewed, copied and pasted and manipulated as Microsoft Excel™ formulae.

2.11 Chapter summary and conclusions

Based on a critical review of the literature, the following important factors emerge:

1. Steady-state processing is very widely used in the foods and chemical industries

2. The emerging probabilistic *Fr 13* framework has been successfully developed and applied to a range of 1-step, steady-stated process unit-operations to provide new insights into how naturally occurring, random (stochastic) fluctuations in process parameters can lead to unexpected (surprise) failures in a well-operated plant. The impact of these fluctuations is usually considered problematic - and overlooked in traditional chemical engineering

3. A major advantage claimed for *Fr 13* is that, because it provides quantitative insight into underlying plant behaviour outcomes, including process failures, it can be used to devise process intervention strategies and re-design of physical process plant or to change operating practices to reduce risk i.e. second-tier studies. A benefit is that it can be applied at both the analysis and synthesis stages. It contrasts with traditional deterministic (SVA) solutions in chemical engineering as it takes account of both uncertainty (lack of knowledge) and variability (effect of chance). This is, strictly, a more mathematically correct approach

4. The framework has recently been developed and demonstrated for a 2-step, steady-state membranes processing of fruit juices. Importantly, findings suggest it might be applicable to more complex multi-step (in the sense of ‘integrated’ and not ‘complicated’) processes. Integrated, multi-step processes of two or more unit-operations are described as ‘global’ processes

5. Pasteurization of raw milk is universally important, and significantly, is a 3-step integrated, multi-step process. Pasteurization is important to Australia as a major foods exporter. The integrated 3-steps of 1) heating, 2) holding, and 3) cooling, play a vital role in determining the end quality of the treated milk.

6. Application of the *Fr 13* to 3-step pasteurization will provide a logical, step-wise and stringent test, of the applicability of the probabilistic framework to global processes.

In the next chapter, Chapter 3, an integrated 3-step *Fr 13* model for 1) heating, 2) holding, and 3) cooling is synthesized and tested with independent data for the first time. A comparison is made with traditional SVA solutions. The importance of the impact of naturally occurring, random fluctuations in pasteurizer parameters on plant outcome behavior is quantitatively demonstrated and discussed.

CHAPTER 3

A *FR 13* RISK ASSESSMENT OF AN INTEGRATED 3-STEP PASTEURIZER CONSISTING OF HEATING, HOLDING AND COOLING UNIT-OPERATIONS

Parts of this chapter have been published as:

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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. In: Proc. 44th Australasian Chemical Engineering Conference (Processing Excellence, Powering our Future), Perth, WA, Australia, Sept. 27-Oct. 1, paper 1475. ISBN: 9781922107381

3.1 Introduction

A review of the literature (Chapter 2) showed that the emerging *Fr 13* risk framework, although presently limited to demonstrated 1-step, and very recently to one 2-step process, appears to be amenable to multi-step integrated processing and that, globally important, 3-step pasteurization of raw milk provides the process linkages suitable for a stringent test of the risk research hypothesis for multi-step processing. In a typical 3-step pasteurization, raw milk at ~ 4 ^{O}C is heated to a bulk temperature of 72 ^{O}C using plate exchanger equipment, held at this temperature for 15 s, and then rapidly cooled to 4 ^{O}C for storage and further processing.

It is not known however whether naturally occurring random fluctuations in the pasteurizer parameters can significantly impact the treated milk. Evidence from the literature is strong nevertheless that random fluctuations in process parameters can lead to surprise failure, and these are very much a part of chemical engineering processing (Asao et al., 2003; Cerf and Davey, 2001; Patil et al., 2005; Davey 2011).

In this chapter an integrated 3-step equipment model consisting of 1) heating, 2) holding and 3) cooling is synthesized and investigated for the first time for the pasteurization of raw milk.

The aim is to investigate and quantify the impact of the accumulation of stochastic effects of the random fluctuations on the progressive interdependencies of a real process. A justification for selection of raw milk pasteurization is that it is universally used, and commercial data is available for realistic model development (Yapp and Davey, 2009). Importantly, the process linkages provide a suitable stringent test of the methodology to a simple global integrated 3-step process.

A *Fr 13* risk assessment is first carried out for each of the three individual unit-operations 1) heating, 2) holding and 3) cooling. These three (3) unit-operations are then synthesized into a global *Fr 13* pasteurization equipment model. *Fr 13* methodology is predicated on an underlying unit-operations model, together with a clear definition of process failure and a refined Monte Carlo (r-MC) with Latin Hypercube sampling of the key input process parameters.

It is hoped that insight gained from this chapter could be used to improve milk pasteurization process design, and overall findings be widely generalized.

3.2 Equipment unit-operations model

In the following, the milk pasteurization unit-operations are considered in order of their chronological appearance in the global equipment pasteurization model consisting of three (3) individual steps of 1) heating, 2) holding and 3) cooling. Each step is treated separately and then integrated into the new global equipment model. Regarding numeric subscripts on symbols, the first subscripts is the identity of that particular unit-operation item of equipment, and the second is the order in which it is connected in the global model. For example $PHE_{1\text{-}1}$ is the first plate heat exchanger used, which happens to be also the first unit-operation in the global model. Therefore, $L_{p,\ PHE\ 2\text{-}3}$ will be the length of the plates in a second plate heat exchanger used, which is the third unit-operation of the global model.

Fig. 3-1 shows a typical pasteurization process consisting of 3-steps heat-up, holding and cool-down processes.

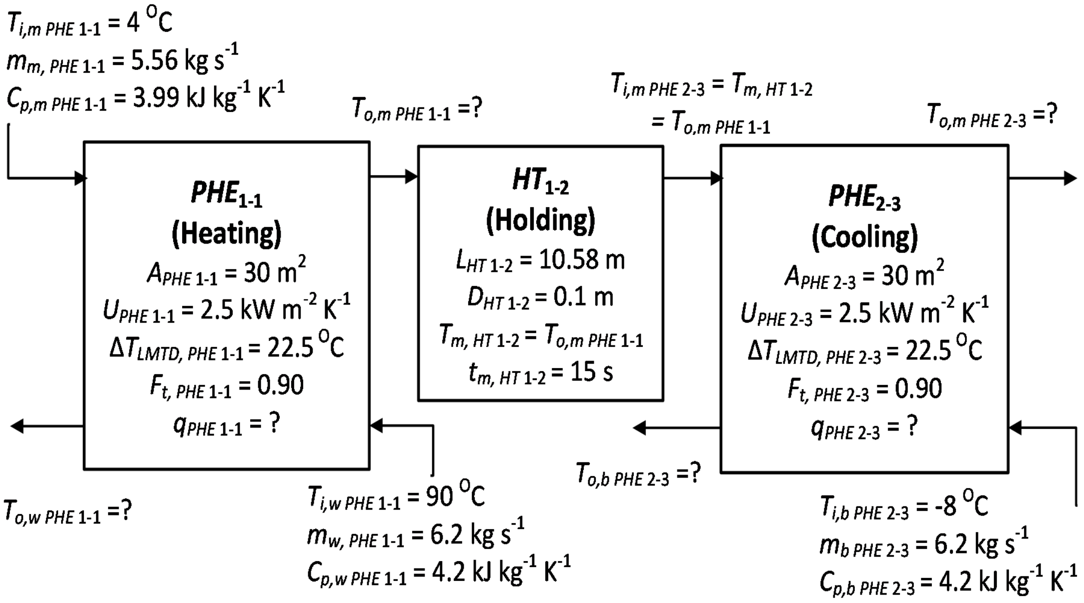

Fig. 3-1: A typical pasteurization process of raw milk consisting of integrated 3-steps 1) heating, 2) holding, and; 3) cooling processes

3.2.1 Heating ($PHE_{1\text{-}1}$)

An adequate unit-operations model for heating can be based on the commonly used Plate Heat Exchanger (PHE). A PHE consists of a stack of closely-spaced thin plates clamped together in a frame (Sinnott, 2005). Advantages include it is cheaper and compact, easy to maintain, more flexible and less likely to foul than shell-and-tube heat exchanger (Sinnott, 2005). All symbols used in this research work are defined in the Nomenclature section at the end of this thesis.

The heating unit $PHE_{1\text{-}1}$, Fig. 3-1, is assumed to have $A_{PHE\ 1\text{-}1}$ = 30 m^2 with an overall heat transfer co-efficient $U_{PHE\ 1\text{-}1}$ = 2.5 kW m^{-2} K^{-1} and temperature correction factor $F_{t,\ PHE\ 1\text{-}1}$ = 0.90 (Sinnott, 2005) to give $\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ = 22.5 ^{O}C (Kothandaraman and Subramanyan, 2007). The individual plates are length $L_{p,\ PHE\ 1\text{-}1}$ = 1.5 m and thickness $w_{p,\ PHE\ 1\text{-}1}$ = 0.15 m. The gap between plates is $b_{p,\ PHE\ 1\text{-}1}$ = 0.05 m (Anon, 2014).

As is seen from Fig. 3-1, the milk (typically) enters the $PHE_{1\text{-}1}$ at a temperature of $T_{i,m\ PHE\ 1\text{-}1}$ = 4 ^{O}C at a flow rate of $m_{m,\ PHE\ 1\text{-}1}$ = 5.56 kg s^{-1} with a specific heat $C_{p,m\ PHE\ 1\text{-}1}$ = 3.99 kJ kg^{-1} K^{-1} (Kessler, 2002). On the water side hot water enters at a temperature of $T_{i,w\ PHE\ 1\text{-}1}$ = 90 ^{O}C and at a flow rate of $m_{w,\ PHE\ 1\text{-}1}$ = 6.2 kg s^{-1} (Kessler, 2002). The physical properties of water do not vary significantly with temperature over a range of 5 ^{O}C - 120 ^{O}C so it is assumed $C_{p,w\ PHE\ 1\text{-}1}$ = 4.2 kJ kg^{-1} K^{-1}(Perry and Green, 1997).

The heat transfer equations for $PHE_{1\text{-}1}$ are (Sinnott, 2005):

$$q_{PHE\ 1-1} = U_{PHE\ 1-1} * A_{PHE\ 1-1} * \Delta T_{LMTD,PHE\ 1-1} * F_{t\ PHE\ 1-1} \qquad (3.1)$$

$$q_{PHE\ 1-1} = m_{m,PHE\ 1-1} * C_{p,m\ PHE\ 1-1} * (T_{o,m\ PHE\ 1-1} - T_{i,m\ PHE\ 1-1}) \qquad (3.2)$$

$$q_{PHE\ 1-1} = m_{w\ PHE\ 1-1} * C_{p,w\ PHE\ 1-1} * (T_{i,w\ PHE\ 1-1} - T_{o,w\ PHE\ 1-1}) \qquad (3.3)$$

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

$$D_{e,PHE\ 1-1} = \frac{2 * w_{p,\ PHE\ 1-1} * b_{p\ PHE 1-1}}{(w_{p,\ PHE\ 1-1} + b_{p\ PHE\ 1-1})} \qquad (3.4)$$

The number of plates ($n_{p,\ PHE\ 1\text{-}1}$) required is given by (Sinnott, 2005):

$$n_{p,\ PHE\ 1-1} = \frac{A_{PHE\ 1-1}}{\pi * D_{e,\ PHE\ 1-1} * L_{p,\ PHE\ 1-1}} \qquad (3.5)$$

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

$$T_{m,avg\ PHE\ 1-1} = \frac{T_{i,m\ PHE\ 1-1} + T_{o,m\ PHE\ 1-1}}{2} \qquad (3.6)$$

$$\mu_{m,\ PHE\ 1-1} = \left(\left(-0.00445\ T_{m,avg\ PHE\ 1-1}\right) + 0.947\right) * 10^{-3} \qquad (3.6\ a)$$

$$\rho_{m,\ PHE\ 1-1} = 1033.7 - (0.2308 * T_{m,avg\ PHE\ 1-1}) - (0.00246 * T^2_{m,avg\ PHE\ 1-1}) \qquad (3.6\ b)$$

Milk velocity ($v_{m,\ PHE\ 1\text{-}1}$) is calculated from the continuity equation of Kessler (2002):

$$v_{m,\ PHE\ 1-1} = \frac{4 * m_{m,PHE\ 1-1}}{\rho_{m,\ PHE\ 1-1} * \pi * D_{e,\ PHE\ 1-1}^{2}} \tag{3.7}$$

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

$$\mathrm{Re}_{\ PHE\ 1-1} = \frac{\rho_{m,1} * v_{m,1} * D_{e,PHE-1}}{\mu_{m,1}} \tag{3.8}$$

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

$$t_{r,\ PHE\ 1-1} = \frac{n_{p,\ PHE\ 1-1} * L_{p,PHE\ 1-1}}{v_{m\ PHE\ 1-,1}} \tag{3.9}$$

The pressure drop in $PHE_{1\text{-}1}$ can be calculated from (Kumbhare and Dawande, 2013; Sinnott, 2005):

$$\Delta P_{PHE\ 1-1} = 8 * j_{F,\ PHE\ 1-1} * \frac{L_{p,\ PHE\ 1-1}}{D_{e,\ PHE\ 1-1}} * \frac{\rho_{m,\ PHE\ 1-1} * v_{m,\ PHE\ 1-1}^{2}}{2} \tag{3.10}$$

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

$$j_{F,\ PHE\ 1-1} = 0.6 * (\mathrm{Re}_{PHE\ 1-1})^{-0.30} \tag{3.11}$$

Eq. (3.1) through Eq. (3.11) defines the individual heat-up unit-operation $PHE_{1\text{-}1}$ in raw milk pasteurization processing.

3.2.2 Holding ($HT_{1\text{-}2}$)

As is seen from Fig. 3-1 the milk leaving $PHE_{1\text{-}1}$ is held at a constant temperature for a fixed time. This is done in an external holding tube ($HT_{1\text{-}2}$) that consists of a pipe arranged in a spiral or zigzag pattern (Smith, 2011). The most widely used temperature-time combination is $T_{m,\ HT\ 1\text{-}2} = 72$ ^{O}C and $t_{m,\ HT\ 1\text{-}2} = 15$ s (Alfa Laval, 1987; Juffs and Deeth, 2007; Katoh and Yoshida, 2009). It is assumed that the diameter of the holding tube $D_{HT\ 1\text{-}2} = 0.1$ m (Berk, 2009) with length $L_{HT\ 1\text{-}2} = 10.58$ m. In a steady-state flow milk will enter the holding tube with a temperature equal to the outlet temperature of milk from $PHE_{1\text{-}1}$ i.e. $T_{m,\ HT\ 1\text{-}2} = T_{o,m\ PHE\ 1\text{-}1}$ and at a flow $m_{m,\ HT\ 1\text{-}2} = m_{m,\ PHE\ 1\text{-}1} = 5.56$ kg s^{-1}.

The general design equation for the holding tube is (Katoh and Yoshida, 2009):

$$t_{m,\ HT\ 1-2} = \frac{L_{HT\ 1-2}}{v_{m,\ HT\ 1-2}} \tag{3.12}$$

Because the temperature $T_{m,\ HT\ 1\text{-}2}$ is known milk density in the holding tube can be calculated using (Al Hilphy and Ali, 2013):

$$\rho_{m,\ HT\ 1-2} = 1033.7 - (0.2308 * T_{m,\ HT\ 1-2}) - (0.00246 * T^2_{m,\ HT\ 1-2}) \tag{3.13}$$

Milk velocity ($v_{m,\ HT\ 1\text{-}2}$) in the holding tube is obtained from the continuity equation (Kessler, 2002):

$$v_{m,\ HT\ 1-2} = \frac{4 * m_{m,\ HT\ 1-2}}{\rho_{m,\ HT\ 1-2} * \pi * D^2_{HT\ 1-2}} \tag{3.14}$$

Eq. (3.12) through Eq. (3.14) defines the individual holding unit-operation $HT_{1\text{-}2}$ in raw milk pasteurization processing.

3.2.3 Cooling ($PHE_{2\text{-}3}$)

Milk leaving $HT_{1\text{-}2}$ is cooled using another heat exchanger, the most commonly used is a Plate Heat Exchanger (PHE), $PHE_{2\text{-}3}$. This is assumed to have $A_{PHE\ 2\text{-}3} = 30$ m^2 with $U_{PHE\ 2\text{-}3} = 2.5$ kW m^{-2} K^{-1} and $F_{t,\ PHE\ 2\text{-}3} = 0.90$ (Sinnott, 2005) to give $\Delta T_{LMTD,\ PHE\ 2\text{-}3} = 22.5$ ^{O}C (Kothandaraman and Subramanyan, 2007). The individual plates and gap dimensions in $PHE_{2\text{-}3}$ are of the same dimensions as that of $PHE_{1\text{-}1}$ (Anon, 2014).

Milk enters $PHE_{2\text{-}3}$ at $T_{i,m\ PHE\ 2\text{-}3} = T_{m,\ HT\ 1\text{-}2}$ with $m_{m,\ PHE\ 2\text{-}3} = m_{m,\ HT\ 1\text{-}2} = 5.56$ kg s^{-1}. On the cooling side (typically) brine is supplied at a temperature of $T_{i,b\ PHE\ 2\text{-}3} = -8$ ^{O}C with a flow rate of $m_{b,\ PHE\ 2\text{-}3} = 6.2$ kg s^{-1} and with specific heat of brine, $C_{p,b\ PHE\ 2\text{-}3} = 4.2$ kJ kg^{-1} K^{-1} (Perry and Green, 1997).

The equations for $PHE_{2\text{-}3}$ are (Sinnott, 2005):

$$q_{PHE\ 2-3} = U_{PHE\ 2-3} * A_{PHE\ 2-3} * \Delta T_{LMTD,PHE\ 2-3} * F_{t,\ PHE\ 2-3} \tag{3.15}$$

$$q_{PHE\ 2-3} = m_{m,\ PHE\ 2-3} * C_{p,m\ PHE\ 2-3} * (T_{i,m\ PHE\ 2-3} - T_{o,m\ PHE\ 2-3}) \tag{3.16}$$

$$q_{PHE\ 2-3} = m_{b,\ PHE\ 2-3} * C_{p,b\ PHE\ 2-3} * (T_{o,b\ PHE\ 2-3} - T_{i,b\ PHE\ 2-3}) \tag{3.17}$$

The equivalent diameter of the plate $D_{e,\ PHE\ 2\text{-}3}$ is given by (Kessler, 2002):

$$D_{e,PHE\ 2-3} = \frac{2 * w_{p,\ PHE\ 2-3} * b_{p,\ PHE\ 2-3}}{(w_{p,\ PHE\ 2-3} + b_{p,\ PHE\ 2-3})} \tag{3.18}$$

The number of plates, $n_{p,\ PHE\ 2\text{-}3}$ is given by (Sinnott, 2005):

$$n_{p,\ PHE\ 2-3} = \frac{A_{PHE\ 2-3}}{\pi * D_{e,\ PHE\ 2-3}\, L_{p,\ PHE\ 2-3}} \tag{3.19}$$

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

$$T_{m,avg\ PHE\ 2-3} = \frac{T_{i,m\ PHE\ 2-3} + T_{o,m\ PHE\ 2-3}}{2} \tag{3.20}$$

$$\mu_{m,\ PHE\ 2-3} = \left(\left(-0.00445\ T_{m,avg\ PHE\ 2-3}\right) + 0.947\right) * 10^{-3} \tag{3.20 a}$$

$$\rho_{m,\ PHE\ 2-3} = 1033.7 - (0.2308\ T_{m,avg\ PHE\ 2-3}) - (0.00246\ T^{2}_{m,avg\ PHE\ 2-3}) \tag{3.20 b}$$

Milk velocity $v_{m,\ PHE\ 2\text{-}3}$ in $PHE_{2\text{-}3}$ is obtained from the continuity equation of Kessler (2002):

$$v_{m,\ PHE\ 2-3} = \frac{4 * m_{m\ PHE\ 2-3}}{\rho_{m,\ PHE\ 2-3} * \pi * D^{2}_{e,PHE-2-3}} \tag{3.21}$$

The recommended flow for milk is $0.5 < v_{m,\ PHE\ 2\text{-}3} < 1.5$ m s^{-1} (Kessler, 2002) in turbulent flow ($\mathrm{Re}_{PHE\ 2\text{-}3} > 4{,}000$) (Kessler, 2002; Hayhurst, 1997; Maroulis and Saravacos, 2003; Lewis and Heppell, 2000).

The Reynolds number ($\mathrm{Re}_{PHE\ 2\text{-}3}$) of the milk is obtained from (Sinnott, 2005):

$$\mathrm{Re}_{PHE\ 2-3} = \frac{\rho_{m,\ PHE\ 2-3} * v_{m,\ PHE\ 2-3} * D_{e,PHE\ 2-3}}{\mu_{m,\ PHE\ 2-3}} \tag{3.22}$$

The residence time of the milk ($t_{r,\ PHE\ 2\text{-}3}$) is computed from (Kessler, 2002):

$$t_{r,\ PHE\ 2-3} = \frac{n_{p,\ PHE\ 2-3} * L_{p,\ PHE\ 2-3}}{v_{m,3}} \tag{3.23}$$

The pressure drop in the $PHE_{2\text{-}3}$ is given by (Kumbhare and Dawande, 2013; Sinnott, 2005):

$$\Delta P_{PHE\ 2-3} = 8 * j_{F,\ PHE\ 2-3} * \frac{L_{p,\ PHE\ 2-3}}{D_{e,PHE\ 2-3}} * \frac{\rho_{m,\ PHE\ 2-3} * v^{2}_{m,\ PHE\ 2-3}}{2} \tag{3.24}$$

where the term $j_{F,\ PHE\ 2\text{-}3}$ is the friction factor of the liquid flowing through the plate which can be estimated using (Sinnott, 2005):

$$j_{F,\ \ PHE\ 2-3} = 0.6 * (\mathrm{Re}_{PHE\ 2-3})^{-0.30} \qquad (3.25)$$

Eq. (3.15) through Eq. (3.25) defines the individual cool-down unit-operation $PHE_{2\text{-}3}$ in raw milk pasteurization processing.

3.3 Traditional single value assessment (SVA) solution

The widely used methodology for solving a unit-operation model is a traditional single point or deterministic approach. This is called as Single Value Assessment (SVA) and is done with or without a sensitivity analysis (Cerf and Davey, 2001; Davey and Cerf, 2003).

For heating ($PHE_{1\text{-}1}$): from Eq. (3.1) $q_{PHE\ 1\text{-}1}$ = 1,518.75 kJ s^{-1}, using Eq. (3.2) $T_{o,m\ PHE\ 1\text{-}1}$ = 72.46 ^{O}C, and from Eq. (3.3) $T_{o,w\ PHE\ 1\text{-}1}$ = 31.68 ^{O}C , using Eq. (3.4) $D_{e,\ PHE\ 1\text{-}1}$ = 0.0750 m and from Eq. (3.5) $n_{p,\ PHE\ 1\text{-}1}$ = 85. Using Eq. (3.6) $T_{m,avg\ PHE\ 1\text{-}1}$ = 38.23 ^{O}C. With $T_{m,avg\ PHE\ 1\text{-}1}$ known using Eq. (3.6 a) $\mu_{m,\ PHE\ 1\text{-}1}$ = 0.00078 Pa s and from Eq. (3.6 b) $\rho_{m,\ PHE\ 1\text{-}1}$ = 1,021.28 kg m^{-3}. From Eq. (3.7) $v_{m,\ PHE\ 1\text{-}1}$ = 1.2329 m s^{-1} and using Eq. (3.8) $\mathrm{Re}_{PHE\ 1\text{-}1}$ = 121,560 (dimensionless). From Eq. (3.9) the residence time of the milk in heat-up $t_{r,\ PHE\ 1\text{-}1}$ = 103.32 s. Using Eq. (3.10) and Eq. (3.11) $\Delta P_{PHE\ 1\text{-}1}$ = 2,222.41 N m^{-2}.

For holding ($HT_{1\text{-}2}$): milk enters the holding tube at $T_{m,\ HT\ 1\text{-}2}$ = 72.46 ^{O}C (same as $T_{o,m\ PHE\ 1\text{-}1}$). Since the length of the holding tube ($L_{HT\ 1\text{-}2}$ = 10.58 m) is known, from Eq. (3.12) $t_{m,\ HT\ 1\text{-}2}$ = 14.9982 s. Using Eq. (3.13) $\rho_{m,\ HT\ 1\text{-}2}$ = 1,004.06 kg m^{-3}. From Eq. (3.14) $v_{m,\ HT\ 1\text{-}2}$ = 0.7054 m s^{-1}.

For cooling ($PHE_{2\text{-}3}$): using Eq. (3.15) $q_{PHE\ 2\text{-}3}$ = 1,518.75 kJ s^{-1}, using Eq. (3.16) $T_{o,m\ PHE\ 2\text{-}3}$ = 4.00 ^{O}C and from Eq. (3.17) $T_{o,b\ PHE\ 2\text{-}3}$ = 45.88 ^{O}C, using Eq. (3.18) $D_{e,\ PHE\ 2\text{-}3}$ = 0.0750 m and from Eq. (3.19) $n_{p,\ PHE\ 2\text{-}3}$ = 85. Using Eq. (3.20) $T_{m,avg\ PHE\ 2\text{-}3}$ = 38.23 ^{O}C. With $T_{m,avg\ PHE\ 2\text{-}3}$ known using Eq. (3.20 a) $\mu_{m,\ PHE\ 2\text{-}3}$ = 0.00078 Pa s and from Eq. (3.20 b) $\rho_{m,\ PHE\ 2\text{-}3}$ = 1,021.28 kg m^{-3}. Using Eq. (3.21) $v_{m,\ PHE\ 2\text{-}3}$ = 1.2329 m s^{-1} and from Eq. (3.22) $\mathrm{Re}_{PHE\ 2\text{-}3}$ = 121,560. From Eq. (3.23) the residence time of the milk in cool-down $t_{r,\ PHE\ 2\text{-}3}$ = 103.32 s. Using Eq. (3.24) and Eq. (3.25) $\Delta P_{PHE\ 2\text{-}3}$ = 2,222.41 N m^{-2}.

A summary comparison of the deterministic values obtained using the traditional single value assessment (SVA) for individual heating ($PHE_{1\text{-}1}$), holding ($HT_{1\text{-}2}$) and cooling ($PHE_{2\text{-}3}$) is presented in Table 3-1.

Table 3-1: Summary of the deterministic single value assessment (SVA) for each of 1) heating ($PHE_{1\text{-}1}$), 2) holding ($HT_{1\text{-}2}$), and; 3) cooling ($PHE_{2\text{-}3}$) unit-operations

$PHE_{1\text{-}1}$ (heating)			$HT_{1\text{-}2}$ (holding)			$PHE_{2\text{-}3}$ (cooling)		
Parameter	**SVA**		**Parameter**	**SVA**		**Parameter**	**SVA**	
Constants								
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	constant	$L_{HT\ 1\text{-}2}$ (m)	10.58	constant	$U_{PHE\ 2\text{-}3}$ (kW m^{-2} K^{-1})	2.5	constant
$A_{PHE\ 1\text{-}1}$ (m^{2})	30	constant	$D_{HT\ 1\text{-}2}$ (m)	0.1	constant	$A_{PHE\ 2\text{-}3}$ (m^{2})	30	constant
$\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ (^{O}C)	22.5	constant				$\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ (^{O}C)	22.5	constant
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	constant				$F_{t,\ PHE\ 2\text{-}3}$ (dimensionless)	0.90	constant
<u>Plate Properties</u>								
$w_{p,\ PHE\ 1\text{-}1}$ (m)	0.15	constant				$w_{p,\ PHE\ 2\text{-}3}$ (m)	0.15	constant
$b_{p,\ PHE\ 1\text{-}1}$ (m)	0.05	constant				$b_{p,\ PHE\ 2\text{-}3}$ (m)	0.05	constant
$L_{p,\ PHE\ 1\text{-}1}$ (m)	1.50	constant				$L_{p,\ PHE\ 2\text{-}3}$ (m)	1.50	constant
Inputs								
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	input	**$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)**	**72.46**	**input**	**$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**72.46**	**input**
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	input	$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.56	input	$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.56	input
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	input	$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	input	$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.99	input
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	input	$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	input	$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8	input
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	input	$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	input	$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.34	input
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	input				$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.38	input
Calculations								
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,518.75	Eq. (3.1)				$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,518.75	Eq. (3.15)
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	**72.46**	**Eq. (3.2)**				**$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**4.00**	**Eq. (3.16)**
$T_{o,w,\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	Eq. (3.3)				$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.88	Eq. (3.17)
$D_{e,\ PHE\ 1\text{-}1}$ (m)	0.0750	Eq. (3.4)				$D_{e,\ PHE\ 2\text{-}3}$ (m)	0.0750	Eq. (3.18)
$n_{p,PHE\ 1\text{-}1}$ (dimensionless)	85	Eq. (3.5)				$n_{p,PHE\ 2\text{-}3}$ (dimensionless)	85	Eq. (3.19)
$T_{m,avg\ PHE\ 1\text{-}1}$ (^{O}C)	38.23	Eq. (3.6)				$T_{m,avg\ PHE\ 2\text{-}3}$ (^{O}C)	38.23	Eq. (3.20)
$\mu_{m,\ PHE\ 1\text{-}1}$ (Pa s)	0.00078	Eq. (3.6 a)				$\mu_{m,\ PHE\ 2\text{-}3}$ (Pa s)	0.00078	Eq. (3.20 a)
$\rho_{m,\ PHE\ 1\text{-}1}$ (kg m^{-3})	1,021.28	Eq. (3.6 b)				$\rho_{m,\ PHE\ 2\text{-}3}$ (kg m^{-3})	1,021.28	Eq. (3.20 b)
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.2329	Eq. (3.7)				$v_{m,\ PHE\ 2\text{-}3}$ (m s^{-1})	1.2329	Eq. (3.21)
$\mathrm{Re}_{PHE1\text{-}1}$ (dimensionless)	121,560	Eq. (3.8)				$\mathrm{Re}_{PHE\ 2\text{-}3}$ (dimensionless)	121,560	Eq. (3.22)
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.32	Eq. (3.9)	$t_{m,\ HT\ 1\text{-}2}$ (s)	14.9982	Eq. (3.12)	$t_{r,\ PHE\ 2\text{-}3}$ (s)	103.32	Eq. (3.23)
$j_{F,\ PHE\ 1\text{-}1}$ (dimensionless)	0.0179	Eq. (3.11)	$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1004.06	Eq. (3.13)	$j_{F,\ PHE\ 2\text{-}3}$ (dimensionless)	0.0179	Eq. (3.25)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,222.41	Eq. (3.10)	$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.7054	Eq. (3.14)	$\Delta P_{PHE\ 2\text{-}3}$ (N m^{-2})	2,222.41	Eq. (3.24)

In Table 3-1 the SVA model is conveniently read down the column for each. The **bold text** highlights that the output from one unit-operation is the input to the chronologically, inter-connected one.

Notably, the results reported here in Table 3-1 agree well with values widely reported in the literature (Varzakas and Labropoulos, 2007; Tran et al., 2008).

3.4 Establishing a *Fr 13* failure model for global pasteurization process

In contrast to the traditional deterministic SVA simulation, in *Fr 13* simulation each process input parameter is defined as a probability distribution of values rather than a single ‘best-guess’ value, the mean of which will agree with the deterministic SVA value (Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2015; 2014; Davey, 2015; 2011; Davey et al., 2015; 2014; 2013; Patil et al., 2005). The output is therefore a distribution also.

Fig. 3-2 shows a schematic of the same pasteurization process consisting of 3-steps heating, holding and cooling processes established using *Fr 13* framework.

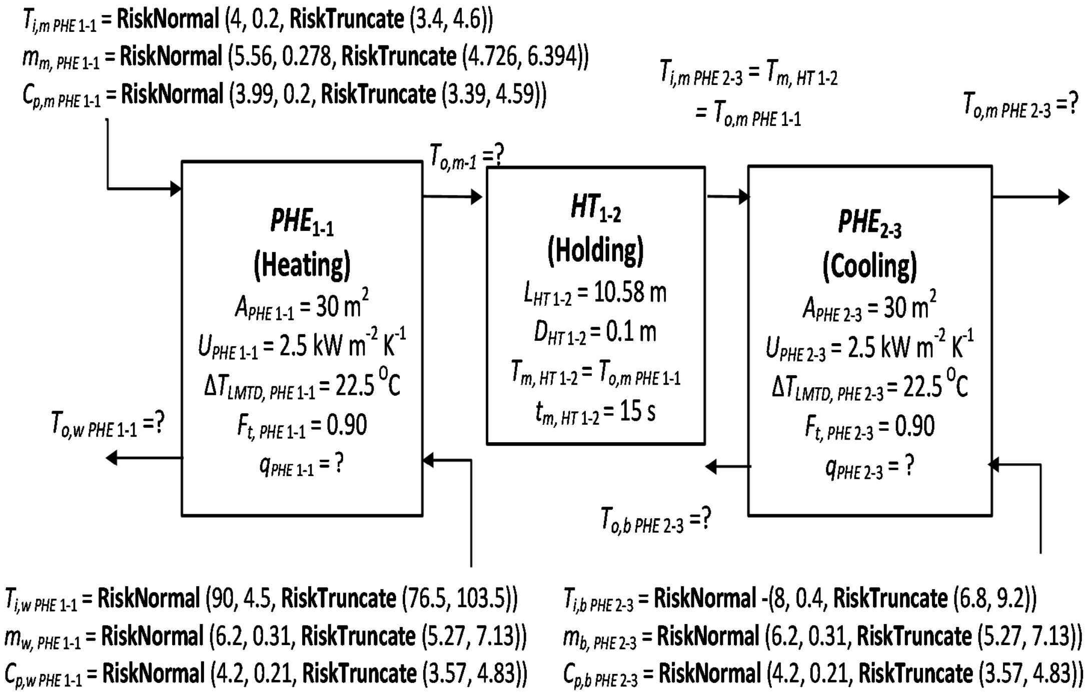

Fig. 3-2: A typical *Fr 13* pasteurization process of raw milk consisting of integrated 3-steps 1) heating, 2) holding, and; 3) cooling processes

The probability distributions for the input parameters for pasteurization of raw milk, in the absence of conditional information, are defined as **Normal** and **TruncatedNormal** so as to obviate nonsensical parameter values, namely, **RiskNormal** (mean, standard deviation, **RiskTruncate** (minimum, maximum)).

A standard deviation around the mean value in the distribution is assumed at stdev = 5 % with the minimum value = mean – 3 x stdev, and the maximum value = mean + 3 x stdev. An advantage of using ± 3 x stdev about the mean value to obtain the truncated minimum and maximum values is that nearly all values (99.73 %) the parameter can take will fall in this interval (Sullivan, 2004; Snedecor and Cochran, 1989; Vose, 2008).

For example, for the inlet raw milk temperature to $PHE_{1\text{-}1}$, $T_{i,m\ PHE\ 1\text{-}1}$, the distribution is **RiskNormal** (4, 0.2, **RiskTruncate** (3.4 ,4.6)). This is a normal distribution with a mean milk temperature = 4 ^{O}C, stdev = 0.2 ^{O}C (5 %) and temperature minimum = 3.4, and maximum = 4.6, ^{O}C.

Other input parameters in the global model for pasteurization of raw milk, $m_{m,\ PHE\ 1\text{-}1}$, $C_{p,m\ PHE\ 1\text{-}1}$, $T_{i,w\ PHE\ 1\text{-}1}$, $m_{w,\ PHE\ 1\text{-}1}$, $C_{p,w\ PHE\ 1\text{-}1}$, $T_{i,b\ PHE\ 2\text{-}3}$, $m_{b,\ PHE\ 2\text{-}3}$ and $C_{p,b\ PHE\ 2\text{-}3}$ are defined in similar manner, shown in Fig. 3-2.

A refined Monte Carlo (with Latin Hypercube) (r-MC) sampling of the probability distributions is used because ‘pure’ MC sampling can over- and under- estimate samples from particular parts of the distribution (Davey, 2015; 2011; Vose, 2008).

To ensure that the output distribution of the mean is sufficiently normal, a minimum number of samples is needed; this is usually some 1,000 to 50,000 (e.g. Davey et al., 2015; 2013; Abdul-Halim and Davey, 2016; 2015; Davey, 2015). This number can be established when a scatter plot of number of samples versus number of failures plateaus to a constant, highlighting sufficient samples. This can also be established reasonably reliably by visual inspection of the output distribution.

Computations to simulate the pasteurization of raw milk were carried out using standard Microsoft Excel™ spread-sheeting with a commercially available add-on, *@-Risk* version 5.5 (Palisade Corporation™). Because these are used almost universally it makes the communication of results simplified (Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2015; Davey, 2015; 2011; Davey et al., 2015; 2013).

Additionally, a major advantage of using standard spread sheeting tools is that the distributions defining the naturally occurring fluctuations in parameters can be entered, viewed, copied and pasted and manipulated as Excel formulae.

3.5 Defining pasteurization failure

3.5.1 *Fr 13* risk factor (*p*)

A suitable risk factor (P_1) for heating ($PHE_{1\text{-}1}$) can be defined in terms of the outlet temperature of milk from $PHE_{1\text{-}1}$ ($T_{o,m\ PHE\ 1\text{-}1}$) i.e.

$$P_1 = T_{o,m\ PHE\ 1-1}{}' - T_{o,m\ PHE\ 1-1} \tag{3.26}$$

where $T_{o,m\ PHE\ 1\text{-}1}{}'$ is the actual heating temperature (or more strictly, one possible practical scenario to reflect the impact of naturally occurring, within-system, fluctuations), and $T_{o,m\ PHE\ 1\text{-}1}$ is the required outlet heated temperature of milk from $PHE_{1\text{-}1}$ i.e. all $P_1 \leq 0$ infers failure due to insufficient heat-up milk temperature.

For $PHE_{1\text{-}1}$, a suitable and computationally more convenient failure risk factor (p_1) however can be defined in terms of the outlet temperature of milk from $PHE_{1\text{-}1}$ ($T_{o,m\ PHE\ 1\text{-}1}$) together with an acceptable $tolerance_1$ (Abdul-Halim and Davey, 2016; 2015; Chandrakash et al., 2015; Davey, 2015; 2011; Davey et al., 2015; 2013) such that:

$$p_1 = +tolerance_1 - 100\left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE1-1}} - 1\right) \tag{3.27}$$

With an assumed practical $tolerance_1 = 2$ % Eq. (3.27) becomes:

$$p_1 = +2 - 100\left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1\right) \tag{3.28}$$

Eq. (3.28) is computationally convenient because it defines failure in such a way that if the design heating temperature (72 ^{O}C) plus a $tolerance_1$ of 2 % is not reached then the milk heating unit-operation $PHE_{1\text{-}1}$ is said to have failed and is highlighted by $p_1 > 0$.

Eq. (3.1) through Eq. (3.11), together with Eq. (3.28), constitutes the *Fr 13* failure model for milk heat-up unit-operation ($PHE_{1\text{-}1}$).

Similarly, for $HT_{1\text{-}2}$ a suitable risk factor, p_2, can be defined in terms of milk holding time in $HT_{1\text{-}2}$ ($t_{m,\ HT\ 1\text{-}2}$) such that:

$$p_2 = +tolerance_2 - 100\left(\frac{t_{m,\ HT\ 1-2}{}'}{t_{m,\ HT\ 1-2}} - 1\right) \tag{3.29}$$

where $t_{m,\ HT\ 1\text{-}2}{}'$ is one possible practical scenario for the holding time and $t_{m,\ HT\ 1\text{-}2}$ is the required holding time to safely pasteurized milk. With a same $tolerance_2$ = 2 %, Eq. (3.29) becomes:

$$p_2 = +2 - 100\ (\frac{t_{m,\ \ HT\ 1-2}{}'}{\mathrm{t}_{m,\ \ HT\ 1-2}} - 1) \tag{3.30}$$

That is, if the required holding time plus 2 % is not reached then the holding unit-operation is said to have failed, as indicated by $p_2 > 0$.

Eq. (3.12) through Eq. (3.14), together with Eq. (3.30), constitutes the *Fr 13* failure model for holding ($HT_{1\text{-}2}$).

For $PHE_{2\text{-}3}$, p_3 can once again be defined in terms of the outlet temperature of milk from $PHE_{2\text{-}3}$ ($T_{o,m\ PHE\ 2\text{-}3}$) such that:

$$p_3 = -tolerance_3 + 100(\frac{T_{o,m\ PHE\ 2-3}{}'}{T_{o,m\ PHE\ 2-3}} - 1) \tag{3.31}$$

where $T_{o,m\ PHE\ 2\text{-}3}{}'$ is one possible practical scenario and $T_{o,m\ PHE\ 2\text{-}3}$ is the required outlet temperature of milk from $PHE_{2\text{-}3}$. With a same $tolerance_3$ = 2 %, Eq. (3.31) becomes:

$$p_3 = -2 + 100\ (\frac{T_{o,m\ PHE\ 2-3}{}'}{T_{o,m\ PHE\ 2-3}} - 1) \tag{3.32}$$

That is, if the design temperature plus 2 % is not reached then the milk cooling unit-operation is said to have failed and is revealed by $p_3 > 0$.

Eq. (3.15) through Eq. (3.25), together with Eq. (3.32), constitutes the *Fr 13* model for $PHE_{2\text{-}3}$ (cooling).

The synthesis of *Fr 13* risk factor equations for p_1, p_2 and p_3 Eq. (3.27); Eq. (3.29) and Eq. (3.31) respectively are shown in Appendix B.

3.6 Results

Some 10,000 random samples were found adequate for the *Fr 13* simulation.

A fixed 2 % tolerance in, respectively, each of Eq. (3.27), (3.29) and (3.31) is chosen for demonstration. For example, for $PHE_{1\text{-}1}$, this means that if the milk is not heated to a temperature of > ((1 + 0.02) x 72 =) ~ 73.4 $^{\mathrm{O}}$C then the unit-operation has failed.

For $PHE_{1\text{-}1}$, out of the 10,000 simulated scenarios there were 3,697 cases of $p_1 > 0$ i.e. failures to meet the specified outlet temperature of the milk due to random fluctuations within-system effects.

With these 3,697 values as inputs to $HT_{1\text{-}2}$, there were 2,325 failures to meet the holding time as is evidenced by $p_2 > 0$.

For $PHE_{2\text{-}3}$, there were 1,251 failures to meet the specified milk outlet temperature (i.e. $p_3 > 0$).

Therefore overall there is a failure rate of 12.51 % in the global pasteurization model.

Table 3-2 presents a comparative summary example of the 10,000 *Fr 13* simulations with a 2 % tolerance compared with that of the traditional SVA for $PHE_{1\text{-}1}$ (Table 3-1). An advantage of the presentation adopted for Table 3-2 is that the SVA can be read directly down column 2. The *Fr 13* model is given in columns 3 and 4, with the particular distributions defined in column 4. From the table it can be seen that the outlet temperature of the milk predicted by the SVA is 72.47 ^{O}C. However, the *Fr 13* result which has taken account of random fluctuations in parameters predicts a temperature of 70.93 ^{O}C; a process failure of heating. This failure is highlighted by $p_1 = 0.1134$, clearly $p_1 > 0$. Although this is a helpful comparison for the reader, a drawback is that one only *Fr 13* scenario can be compared directly.

Table 3-2: Comparative summary example of SVA and *Fr 13* results for $PHE_{1\text{-}1}$ (milk heating) with a 2 % tolerance on Eq. (3.27)

Parameter	SVA*	*Fr 13* model**	
Inputs			
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	**4.5176**	**RiskNormal** (4, 0.2,**RiskTruncate** (3.4, 4.6))
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	**6.1084**	**RiskNormal** (5.56, 0.278,**RiskTruncate** (4.726, 6.394))
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	**3.7439**	**RiskNormal** (3.99, 0.2,**RiskTruncate** (3.39, 4.59))
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	**85.6432**	**RiskNormal** (90, 4.5,**RiskTruncate** (76.5, 103.5))
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	**6.3081**	**RiskNormal** (6.2, 0.31,**RiskTruncate** (5.27, 7.13))
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	**4.0371**	**RiskNormal** (4.2, 0.21,**RiskTruncate** (3.57, 4.83))
Constants			
$A_{PHE\ 1\text{-}1}$ (m^2)	30	30	constant
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	2.5	constant
$\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ (^{O}C)	22.5	22.5	constant
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	0.90	Constant
Calculations			
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,518.75	1,518.75	Eq. (3.1)
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	72.47	**70.9289**	Eq. (3.2)
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	26.01	Eq. (3.3)
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.2329	1.3542	Eq. (3.7)
$\mathrm{Re}_{PHE1\text{-}1}$ (dimensionless)	122,643	133,163	Eq. (3.8)
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.42	94.07	Eq. (3.9)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,210.60	2,609.49	Eq. (3.10) & (3.11)
p_1 (dimensionless)		**3.4876**	Eq. (3.28)

* Single Value Assessment
** With Latin Hypercube Sampling

Fig. 3-3 presents a graphical summary of all 10,000 *Fr 13* scenarios for $PHE_{1\text{-}1}$. The 3,697 failures can be seen from the figure as a failure rate is 37 %, as highlighted by all values of $p_1 > 0$, and that the resulting output is **Normal**. An advantage of this presentation over tabulated data (Table 3-2) is that it all scenarios are conveniently summarized and those resulting in failure readily identified.

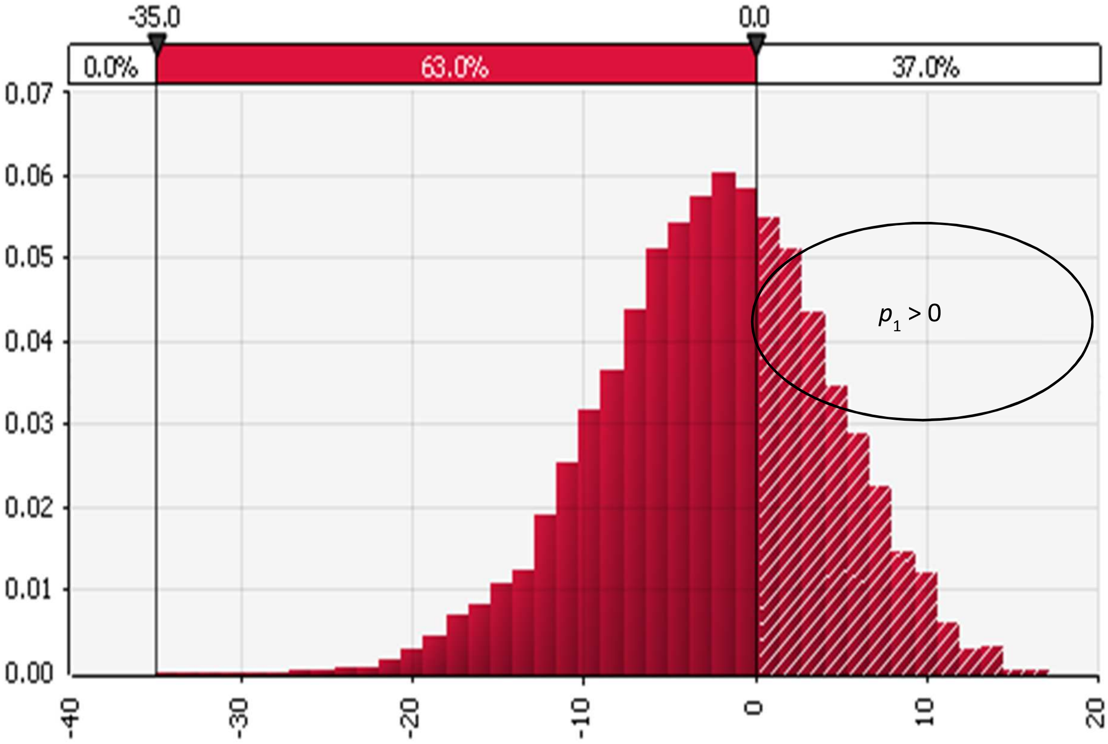

Fig. 3-3: *Fr 13* simulation output graph highlighting all failures for $PHE_{1\text{-}1}$ (milk heating), all $p_1 > 0$

Table 3-3 presents a selected 10 examples of the 3,697 failure scenarios in $PHE_{1\text{-}1}$ (milk heating). An advantage of this presentation is that the value of each of the contributing parameters that combined to produce each failure can be read down the column. For example, failure 2, column 3 (**bolded text**) an inlet milk temperature of $T_{i,m\ PHE\ 1\text{-}1}$ = 4.1847 ^{O}C in combination with a milk flow of $m_{m,\ PHE\ 1\text{-}1}$ = 6.1901 kg s^{-1} and $C_{p,m\ PHE\ 1\text{-}1}$ = 3.6761 kJ kg^{-1} K^{-1}, together with inlet heating water temperature of $T_{i,w\ PHE\ 1\text{-}1}$ = 92.6492 ^{O}C in combination with a water flow of $m_{w,\ PHE\ 1\text{-}1}$ = 6.3016 kg s^{-1} and $C_{p,w\ PHE\ 1\text{-}1}$ = 4.2609 kJ kg^{-1} K^{-1}. This gave rise to a heat duty of $q_{PHE\ 1\text{-}1}$ = 1,518.75 kJ s^{-1}, a water outlet temperature $T_{o,w\ PHE\ 1\text{-}1}$ = 36.09 ^{O}C, milk velocity $v_{m,\ PHE\ 1\text{-}1}$ = 1.3723 m s^{-1}, $Re_{PHE1\text{-}1}$ = 134,815 (dimensionless), residence time $t_{r,\,PHE\ 1\text{-}1}$ = 92.83 s, pressure drop $\Delta P_{PHE\ 1\text{-}1}$ = 2,669.67 N m^{-2}, milk outlet temperature $T_{o,m\ PHE\ 1\text{-}1}$ = 70.9278 ^{O}C and p_1 = 3.4892, clearly a process failure. It can be seen in the table that in all cases the outlet temperature of milk from $PHE_{1\text{-}1}$ ($T_{o,m\ PHE\ 1\text{-}1}$) is < 72 ^{O}C plus the practical tolerance (2 %), and resulted in $p_1 > 0$.

Table 3-3: Selected 10 of 3,697 *Fr 13* failure scenarios in $PHE_{1\text{-}1}$ with a 2 *% tolerance*

Input Parameter	***Fr 13* failures in $PHE_{1\text{-}1}$ (heating)**									
	1	**2**	3	4	5	6	7	8	9	10
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4.5176	**4.1847**	4.1534	4.1358	4.1746	4.5453	4.2752	4.1267	4.4087	4.1365
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.1084	**6.1901**	5.6884	5.8024	5.7011	5.8460	5.7283	5.7767	5.9062	5.7938
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.7439	**3.6761**	3.9986	3.9195	3.9921	3.9153	3.9807	3.9393	3.8695	3.9290
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	85.6432	**92.6492**	92.9425	96.7682	86.7940	87.9379	82.2283	95.0673	96.2238	99.7899
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.3081	**6.3016**	5.8057	6.3429	5.6633	6.2126	6.1086	6.8005	6.0493	6.2593
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.0371	**4.2609**	4.4058	4.0963	3.8073	4.3834	4.0311	4.2454	4.0521	4.0968
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,518.75	**1,518.75**	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	26.01	**36.09**	33.57	38.32	16.36	32.17	20.55	42.46	34.27	40.56
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.3542	**1.3723**	1.2610	1.2863	1.2639	1.2961	1.2699	1.2806	1.3094	1.2844
$\mathrm{Re}_{PHE\ 1\text{-}1}$	133,163	**134,815**	123,876	126,351	124,154	127,443	124,773	125,770	128,692	126,142
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,609.49	**2,669.67**	2,312.42	2,391.85	2,321.21	2,421.85	2,339.95	2,373.94	2,464.69	2,385.91
$t_{r,\ PHE\ 1\text{-}1}$ (s)	94.07	**92.83**	101.02	99.03	100.79	98.29	100.31	99.48	97.29	99.18
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	70.9289	**70.9278**	70.9242	70.9155	70.9063	70.8987	70.8792	70.8676	70.8625	70.8545
p_1	3.4876	**3.4892**	3.4942	3.5063	3.5190	3.5296	3.5567	3.5728	3.5799	3.5910

Table 3-4 presents the same selected 10 failures from Table 3-3 as corresponding inputs to $HT_{1\text{-}2}$ (milk holding). It can be seen from this table that all values of $p_2 > 0$ therefore indicating a process failure. This underscores that the milk would not have been held sufficiently long to meet the required holding time of $t_{m,HT\ 1\text{-}2}$ = 15 s plus the practical tolerance of 2 %. The particular combination of values of the process parameters that lead to failure can be conveniently read down the column.

Table 3-4: Corresponding 10 *Fr 13* failure scenarios from $PHE_{1\text{-}1}$ as inputs to $HT_{1\text{-}2}$ with 2 *% tolerance*

Input Parameter	***Fr 13* failures in $HT_{1\text{-}2}$ (holding)**									
	1	**2**	3	4	5	6	7	8	9	10
$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)	70.9289	**70.9278**	70.9242	70.9155	70.9063	70.8987	70.8792	70.8676	70.8625	70.8545
$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	6.1084	**6.1901**	5.6884	5.8024	5.7011	5.8460	5.7283	5.7767	5.9062	5.7938
$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1,004.96	**1,004.95**	1,004.96	1,004.96	1,004.97	1,004.97	1,004.98	1,004.99	1,004.99	1,005
$v_{m,\ HT\ 1\text{-}2}$ (m s^{-1})	0.7743	**0.7847**	0.7211	0.7355	0.7227	0.7410	0.7261	0.7322	0.7487	0.7344
$t_{m,\ HT\ 1\text{-}2}$ (s)	13.66	**13.48**	14.67	14.38	14.64	14.28	14.57	14.45	14.13	14.41
p_2	10.9333	**12.1333**	4.2	6.1333	4.4	6.8	4.8667	5.6667	7.8	5.9333

Table 3-5 summarizes these same 10 $T_{m,HT\ 1\text{-}2}$ outputs from ($HT_{1\text{-}2}$) as the corresponding inputs to $PHE_{2\text{-}3}$ (milk cooling). These tabulated data reveal that all 10 scenarios will fail to reach the design cooling temperature of $T_{o,m\ PHE\ 2\text{-}3} = 4\ ^{O}C$ plus the practical tolerance of 2 %, indicated by $p_3 > 0$.

Table 3-5: Corresponding 10 *Fr 13* failure scenarios from $HT_{1\text{-}2}$ as inputs to $PHE_{2\text{-}3}$ with 2 *% tolerance*

Input Parameter	***Fr 13* failures in $PHE_{2\text{-}3}$ (cooling)**									
	1	**2**	3	4	5	6	7	8	9	10
$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)	70.9289	**70.9278**	70.9242	70.9155	70.9063	70.8987	70.8792	70.8676	70.8625	70.8545
$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	6.1084	**6.1901**	5.6884	5.8024	5.7011	5.8460	5.7283	5.7767	5.9062	5.7938
$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.7439	**3.6761**	3.9986	3.9195	3.9921	3.9153	3.9807	3.9393	3.8695	3.9288
$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8.1675	**-8.1289**	-8.4756	-7.9873	-8.9875	-7.9935	-7.3256	-7.9879	-8.0235	-8.0397
$m_{b\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.3561	**7.3658**	7.9863	9.2369	8.7541	7.5647	8.7410	8.5778	8.0035	9.1047
$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.2547	**3.3214**	3.1257	3.5874	2.9987	3.4125	3.0258	3.7908	3.0025	2.9964
$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,518.75	**1,518.75**	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75
$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	47.8434	**53.9502**	52.3650	37.8459	47.8676	50.8396	50.0973	38.7188	55.1774	47.6303
$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)	4.5176	**4.1847**	4.1534	4.1358	4.1746	4.5453	4.2752	4.1267	4.4087	4.1365
p_3	10.94	**2.6175**	1.8350	1.3950	2.3650	11.6325	4.88	1.1675	8.2175	1.4125

3.7 Discussion

3.7.1 Pasteurization failures

Fr 13 simulation reveals that the global model for milk pasteurization is actually a mix of successful operations together with unsuccessful ones. The overall failure rate is 12.51 % of all operations as defined by failure to cool the milk leaving $PHE_{2\text{-}3}$ to the design temperature of 4 ^{O}C with a fixed tolerance of 2 %.

If each scenario can be considered as a batch-continuous day-operation then there would be on average over the long term (12.51/100 days x 365.25 days/year =) 46 failures each year to meet the required process criteria due to within-system random effects. However, it is not expected that these failures will be equally spaced in time.

3.7.2 Effect of *%tolerance*

A practical tolerance (*%tolerance*) is included in the risk factor (Eq. (3.27), (3.29) and (3.31)) to ensure the minimum design will actually be met. However, this value of tolerance has to be selected based on a good understanding of the process and cannot be too large because it will be wasteful not only in terms of energy (and possible capital equipment). If for example in $PHE_{1\text{-}1}$ the milk is too hot it might be irreversibly adversely affected and consequently may not be readily cooled, or, be problematic for the next interconnected unit-operation process. The milk pasteurization will have failed. The value of this practical tolerance will therefore need to be based on accumulated experience and good understanding of the process.

Repeat *Fr 13* simulations for the pasteurization model show that with decreasing values of *%tolerance* the number of pasteurization failures increase exponentially. This effect has been highlighted in the work of Davey and co-workers (Abdul Halim and Davey, 2015; 2016; Davey et al., 2015). This result underscores that as the limits on practical operation are reduced the effects of random change become pronounced.

3.7.3 Probability distributions used

A significant input to the *Fr 13* simulation is the choice of probability distribution to define pasteurization parameters. Some 40 different types of distributions exist (Vose, 2008). In the absence of expert knowledge **TruncatedNormal** distributions has been used to demonstrate *Fr 13* methodology, the mean value of which is typical of that used in commercial-scale milk pasteurization.

However, some experimentation with different forms of distributions (such as **Pert** (Davey et al., 2015; Vose, 2008) showed no meaningful change to the global pasteurization failure rate i.e. the failure rate more or less remained at 12.51 %.

In particular cases during simulations the distribution used might be refined by expert knowledge or by accumulated process experience.

3.7.4 Presentation of risk results

As highlighted in the Blackett Review (Anon, 2012) the presentation of risk data can present challenges.

The risk factor permits ready identification and sorting of all output (failure / non-failure) scenarios in standard spread-sheeting tools. These tools are accessible by a wide range of users of varying levels of sophistication. Summary presentation techniques such as illustrated in Fig. 3-3 gives a good, overall view of results.

A particular advantage of the tabulated presentations (Tables 3-3, 3-4 and 3-5) is that the value of each parameter in combination that led to failure can be clearly seen. This type of presentation of results can be used by engineers to gain insight into behavior of physical plant parameters control, and possible need for re-designs or changed controls.

3.7.5 *Fr 13* second-tier simulations

Because the effect of random fluctuations within a system is not dependent on the particular process system, it is therefore not reducible through further study (Davey, 2015; Davey et al., 2015; 2016). Vulnerability to *Fr 13* can only be reduced by physical changes to the system.

A particular advantage of a *Fr 13* risk model is that once adequately established it can be used in second-tier studies i.e. changes to physical plant system (Abdul Halim and Davey, 2015; 2016; Davey et al., 2013; 2015; 2016). Therefore, proposed physical changes to the system can be simulated using this novel *Fr 13* framework. A physical change such as a temperature/time controller is simulated through a judicial selection and testing of the probability distribution. Proposed interventions and design changes can be simulated in this way and when used iteratively a form of optimisation can be made.

This significant utility is not available with traditional SVA (with or without sensitivity analyses) (Sinnott, 2005) or current traditional risk and hazard approaches (CAC, 1998; O’Connor et al., 2002; Notermans et al., 1995; Notermans and Mead, 1996; Swan and Preston, 1995) because in these risk and hazard approaches the random (stochastic) element is not explicit.

3.7.6 Review of overall findings

The illustrated capability of this new *Fr 13* framework to simulate quantitatively the accumulation of random effects in a global model is an exciting development. Especially as there is potential for integration of this methodology with existing design software such as Aspen Plus ^{TM} to produce powerful design and risk assessment tools (Davey, 2010).

In its current form however application of the *Fr 13* pasteurization model could possibly be misleading. This is because a detailed analysis of overall results revealed that some failures in $PHE_{1\text{-}1}$ (milk heating) ($p_1 > 0$) did not lead automatically to a failure in $HT_{1\text{-}2}$ (milk holding) and subsequently in $PHE_{2\text{-}3}$ (milk cooling).

To highlight this randomness nature of failures, Table 3-6 presents 10 selected failure scenarios in $PHE_{1\text{-}1}$ that did not necessarily lead to a failure in either $HT_{1\text{-}2}$ and/or $PHE_{2\text{-}3}$.

For example, scenario 2, column 3 of the table (**bolded text**) for $PHE_{1\text{-}1}$: an inlet milk bulk temperature of $T_{i,m\ PHE\ 1\text{-}1}$ = 3.7046 ^{O}C in combination with milk flow of $m_{m,\ PHE\ 1\text{-}1}$ = 5.7857 kg s^{-1} and $C_{p,m\ PHE\ 1\text{-}1}$ = 3.9002 kJ kg^{-1} K^{-1}, together with inlet heating water temperature of $T_{i,w\ PHE\ 1\text{-}1}$ = 95.2403 ^{O}C in combination with a water flow of $m_{w,\ PHE\ 1\text{-}1}$ = 6.5181 kg s^{-1} and $C_{p,w\ PHE\ 1\text{-}1}$ = 4.4305 kJ kg^{-1} K^{-1} gave a heat duty of $q_{PHE\ 1\text{-}1}$ = 1,518.75 kJ s^{-1}, a water outlet temperature $T_{o,w\ PHE\ 1\text{-}1}$ = 42.65 ^{O}C, milk velocity $v_{m,\ PHE\ 1\text{-}1}$ = 1.2825 m s^{-1}, $Re_{PHE1\text{-}1}$ = 125,865 (dimensionless), residence time $t_{r,\ PHE\ 1\text{-}1}$ = 99.33 s, pressure drop $\Delta P_{PHE\ 1\text{-}1}$ = 2,380.66 N m^{-2}, but an milk outlet temperature $T_{o,m\ PHE\ 1\text{-}1}$ = 71.0086 ^{O}C , which is less than the design criteria of 72 ^{O}C plus the 2 % tolerance. The result is a $PHE_{1\text{-}1}$ failure indicated with p_1 = 4.0166 (which is > 0).

In turn, in $HT_{1\text{-}2}$ this led to: a milk holding temperature $T_{m,\ HT\ 1\text{-}2}$ = 71.0086 ^{O}C with a flow of $m_{m,\ HT\ 1\text{-}2}$ = 5.7857 kg s^{-1} which gave rise to $\rho_{m,\ HT\ 1\text{-}2}$ = 1004.91 kg m^{-3} and velocity of $v_{m,\ HT\ 1\text{-}2}$ = 0.7334 m s^{-1}, giving a holding time of $t_{m,\ HT\ 1\text{-}2}$ = 14.43 s which is (clearly) less than the design criteria of 15 s plus the 2 % tolerance. The result is p_2 = 5.8 (a failure in $HT_{1\text{-}2}$).

This accumulated effect of heat-up/holding in this scenario led in $PHE_{2\text{-}3}$ to: $T_{i,m\ PHE\ 2\text{-}3}$ = 71.0086 ^{O}C in combination with milk flow of $m_{m,\ PHE\ 2\text{-}3}$ = 5.7857 kg s^{-1} and $C_{p,m\ PHE\ 2\text{-}3}$ = 3.9002 kJ kg^{-1} K^{-1}, together with inlet cooling brine temperature of $T_{i,b\ PHE\ 2\text{-}3}$ = -8.1087 ^{O}C in combination with cooling water flow of $m_{b,\ PHE\ 2\text{-}3}$ = 8.0036 kg s^{-1} and $C_{p,b\ PHE\ 2\text{-}3}$ = 3.5633 kJ kg^{-1} K^{-1}. This gave rise to a heat duty of $q_{PHE\ 2\text{-}3}$ = 1,518.75 kJ s^{-1}, brine outlet temperature $T_{o,b\ PHE\ 2\text{-}3}$ = 45.1449 ^{O}C, and milk outlet temperature $T_{o,m\ PHE\ 2\text{-}3}$ = 3.7046 ^{O}C which is less than required minimum 4 ^{O}C plus the 2 % tolerance. This is not a failure of $PHE_{2\text{-}3}$ as indicated by p_3 = -9.3850 (< 0).

That is, overall, for scenario 2 of Table 3-6 the temperature of the heated-up milk leaving *PHE*$_{1-1}$ is less than the design criteria and is held in *HT*$_{1-2}$ for a period less than the design criteria but is subsequently cooled-down to better than the design criteria in *PHE*$_{2-3}$, at which stage the milk is might reasonably thought to have been pasteurized.

Table 3-6: Ten selected *Fr 13* scenarios in global integrated 3-step milk pasteurization model

Input Parameter	***Fr 13* scenario**									
	1	**2**	3	4	5	6	7	8	9	10
In *PHE*$_{1-1}$ (milk heat-up)										
$T_{i,m\ PHE\ 1-1}$ (^{O}C)	4.2330	**3.7046**	3.5509	3.7125	3.9628	4.2588	4.3578	4.1115	3.8772	4.0850
$m_{m,\ PHE\ 1-1}$ (kgs^{-1})	5.5053	**5.7857**	5.6285	5.6878	5.7296	5.6368	5.7996	5.6358	5.4347	5.4415
$C_{p,m\ PHE\ 1-1}$ (kJ kg^{-1} K^{-1})	4.1312	**3.9002**	4.0001	3.9682	3.9544	4.0377	3.9303	4.0296	4.1642	4.1728
$T_{i,w\ PHE\ 1-1}$ (^{O}C)	89.1914	**95.2403**	89.6724	86.6947	92.0102	90.5891	87.8550	89.3426	85.8083	81.4687
$m_{w,\ PHE\ 1-1}$ (kg s^{-1})	5.9872	**6.5181**	6.1243	6.1173	6.1607	6.0015	6.7875	5.9680	6.2541	6.0329
$C_{p,w\ PHE\ 1-1}$ (kJ kg^{-1} K^{-1})	4.1752	**4.4305**	4.2981	4.5594	4.5146	4.5886	4.5282	3.9118	4.3441	3.9734
$q_{PHE\ 1-1}$ (kJ s^{-1})	1,518.75	**1,518.75**	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75
$T_{o,w\ PHE\ 1-1}$ (^{O}C)	28.44	**42.65**	31.98	32.24	37.40	35.44	38.44	24.29	29.91	18.11
$v_{m,\ PHE\ 1-1}$ (m s^{-1})	1.2205	**1.2825**	1.2476	1.2608	1.2701	1.2496	1.2858	1.2494	1.2048	1.2063
Re$_{PHE\ 1-1}$	119,946	**125,865**	122,392	123,736	124,732	122,813	126,395	122,739	118,281	118,493
$\Delta P_{PHE\ 1-1}$ (N m^{-2})	2,187.10	**2,380.66**	2272	2,312.57	2,341.19	2,276.64	2,389.40	2,276.19	2,140.20	2,144.43
$t_{r,\ PHE\ 1-1}$ (s)	104.37	**99.33**	102.10	101.04	100.29	101.94	99.08	101.96	105.74	105.60
$T_{o,m\ PHE\ 1-1}$ (^{O}C)	71.0101	**71.0086**	71.0065	71.0030	70.9943	70.9891	70.9867	70.9865	70.9849	70.9723
p_1	4.0145	**4.0166**	4.0195	4.0243	4.0363	4.0435	4.0468	4.0471	4.0493	4.0666
In *HT*$_{1-2}$ (milk holding)										
$T_{m,\ HT\ 1-2}$ (^{O}C)	71.0101	**71.0086**	71.0065	71.0030	70.9943	70.9891	70.9867	70.9865	70.9849	70.9723
$m_{m,\ HT\ 1-2}$ (kg s^{-1})	5.5053	**5.7857**	5.6285	5.6878	5.7296	5.6368	5.7996	5.6358	5.4347	5.4415
$\rho_{m,\ HT\ 1-2}$ (kg m^{-3})	1,004.91	**1,004.91**	1,004.91	1,004.91	1,004.92	1,004.92	1,004.92	1,004.92	1,004.92	1,004.93
$v_{m,\ HT\ 1-2}$ (ms^{-1})	0.6979	**0.7334**	0.7135	0.7210	0.7263	0.7146	0.7352	0.7144	0.6889	0.6898
$t_{m,\ HT\ 1-2}$ (s)	15.46	**14.43**	15.83	14.67	14.57	15.81	14.39	15.95	15.36	15.84
p_2	-1.0667	**5.8**	-3.5333	4.2	4.8667	-3.4	6.0667	-4.3333	-0.4	-3.6
In *PHE*$_{2-3}$ (milk cool-down)										
$T_{i,m\ PHE\ 2-3}$ (^{O}C)	71.0101	**71.0086**	71.0065	71.0030	70.9943	70.9891	70.9867	70.9865	70.9849	70.9723
$m_{m,\ PHE\ 2-3}$ (kg s^{-1})	5.5053	**5.7857**	5.6285	5.6878	5.7296	5.6368	5.7996	5.6358	5.4347	5.4415
$C_{p,m\ PHE\ 2-3}$ (kJ kg^{-1} K^{-1})	4.1312	**3.9002**	4.0001	3.9682	3.9544	4.0377	3.9303	4.0296	4.1642	4.1728
$T_{i,b\ PHE\ 2-3}$ (^{O}C)	-8.1132	**-8.1087**	-8.5325	-7.9629	-8.0633	-8.4579	-7.9703	-7.8976	-7.9833	-8.0334
$m_{b\ PHE\ 2-3}$ (kg s^{-1})	8.0135	**8.0036**	8.9564	9.0896	9.2659	8.7411	8.5332	7.9853	7.7561	9.4523
$C_{p,b\ PHE\ 2-3}$ (kJ kg^{-1} K^{-1})	2.9874	**3.5633**	3.2544	3.1159	2.9987	3.0025	3.6984	3.7988	3.1120	2.9585
$q_{PHE\ 2-3}$ (kJ s^{-1})	1,518.75	**1,518.75**	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75	1,518.75
$T_{o,b\ PHE\ 2-3}$ (^{O}C)	55.3292	**45.1449**	43.5728	45.6620	46.5962	49.4099	40.1536	42.1691	54.9388	46.2763
$T_{o,m\ PHE\ 2-3}$ (^{O}C)	4.2330	**3.7046**	3.5509	3.7125	3.9628	4.2588	4.3578	4.1111	3.8772	4.0852
p_3	3.8250	**-9.3850**	-13.2275	-9.1875	-2.93	4.717	6.9450	0.7775	-5.07	0.13

A summary table, Table 3-7, illustrates these effects for the 10 selected scenarios of Table 3-6 in which **F** = failure and NF = not a failure, to meet the design criteria in each unit-operation of the global model. Table 3-7 serves to clearly visually underscore the effects of accumulation of random changes and is the first real evidence for the (developing) hypothesis of Davey and co-workers of the effects of chance on a global process.

Table 3-7: A visual summary of the ten selected *Fr 13* scenarios of Table 3-6 of the global integrated 3-step milk pasteurization model

Unit-operation	***Fr 13* scenario**									
	1	2	3	4	5	6	7	8	9	10
$PHE_{1\text{-}1}$	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**
$HT_{1\text{-}2}$	NF	**F**	NF	**F**	**F**	NF	**F**	NF	NF	NF
$PHE_{2\text{-}3}$	**F**	NF	NF	NF	NF	**F**	**F**	**F**	NF	**F**

F = Failure
NF = Not a Failure

The table shows (row 5) that of the 10 selected output failures from $PHE_{1\text{-}1}$ (row 3) only five gave rise to a global failure in the overall pasteurization criteria.

Were this table extended for all 10,000 scenarios, row 5 would show 1,251 failures (**F**) in the global pasteurization model. The random nature of *Fr 13* becomes quite apparent with this type of presentation. What such a table also highlights is the counter-intuitive accumulation of random fluctuations in key model parameters on overall process criteria.

Presentation of the simulated *Fr 13* results in this way has actually highlighted the need for a clearer definition of pasteurization failure. A process result such as that of scenario 2, column 3 of Tables 3-6 and 3-7 (also scenarios 3, 4, 5, and 9 all with p_3 = < 0) cannot automatically be interpreted as the milk is safely pasteurized. A caution is needed.

3.7.7 Defining failure in *Fr 13*

Whereas this illustration of a global model has defined failure in terms of equipment criteria, the real purpose of pasteurization of milk is to reduce the number of contaminant micro-organisms to an acceptable level (Juffs and Deeth, 2007; Lewis and Heppell, 2000).

It is clear an improved definition of pasteurization failure would that be based on a specified design criteria for reduction in number of viable contaminant micro-organisms in $HT_{1\text{-}2}$ and not equipment performance, or, at least a detailed check must be made that the number of viable contaminants has been reduced to the required level.

There are several micro-organisms that have the potential to survive milk pasteurization (Juffs and Deeth, 2007). Of particular concern is *Mycobacterium avium* subspecies *paratuberculosis* (*MAP*) a well-known and well-defined pathogen (Hammer et al., 2014; Koutchma et al., 2001; Madigan et al., 2003; Rademaker et al., 2007; Smith, 2011; van Asselt and Zwietering, 2005) and one for which there is significant data in literature.

Therefore, it is apparent that the definition of failure in $HT_{1\text{-}2}$ (milk holding) must not only include the physical plant system but also microbiological inactivation kinetics.

This development should be readily facilitated because of the generalized nature of *Fr 13* methodology and its predication on underlying unit-operations principles. An advantage of this generalised *Fr 13* framework is that the methods of synthesis and the presentation of data developed here can be used.

3.8 Chapter summary and conclusions

Based on a critical review of this chapter, the following important factors emerge:

1) A novel *Fr 13* risk analysis of a global food process for a 3-step integrated milk pasteurization process consisting of three interconnected unit-operations 1) heating, 2) holding and 3) cooling, has been successfully developed and quantitatively illustrated for the very first time, and; a generalized method of notation for the risk framework has been developed that permits unambiguous identification of particular unit-operations in integrated multi-step (global) processes

2) Simulations reveal that milk pasteurization is actually a mix of successful operations together with unsuccessful ones. The model shows an overall failure rate due to random effects, over the long term, of 12.51 % of all operations. This significant process insight cannot be obtained from traditional methods (with or without sensitivity analyses) or current risk and hazard methodologies. A major advantage of *Fr 13* methodology is that all possible process scenarios, including process failures that could practically exist can be quantitatively simulated

3) *Fr 13* analysis is a new process tool that can be used to quantitatively investigate the impact of process re-designs and proposed process interventions in second-tier studies

4) As the main aim of pasteurization process is to reduce the number of viable pathogenic micro-organisms in raw milk it is clear that an improved definition of pasteurization failure would that be based on a specified design criteria for reduction in number of viable contaminant micro-organisms in $HT_{1\text{-}2}$ and not equipment performance, or, at least a detailed check must be made that the number of viable contaminants has been reduced to the required level. Illustration with 3-step milk pasteurization process has underscored the fact that a caution is needed while defining process failure. The pasteurizer failures should better be based on a design reduction in the number of viable pathogens and not on the equipment (T-t) performance – after all milk is an excellent medium for micro-organism proliferation and it is a reduction in the number of viable contaminants that is the purpose of milk pasteurization

5) Because *Fr 13* methodology is based on underlying unit-operations principles, the methods illustrated for milk pasteurization are thought to be generalizable to a wide range of processes of increasing complexity and inter-connectedness in process linkages.

Despite its advance, the integrated 3-step equipment model developed in this chapter has some drawbacks, namely, it relies on equipment performance and does not explicitly address a design reduction in the number of viable pathogens. It is actually the reduction in the number of viable contaminants that is the true purpose of milk pasteurization. The definition of failure in $HT_{1\text{-}2}$ (milk holding step) should therefore include microbiological inactivation kinetics for a known milk pathogen.

In the next chapter, Chapter 4, a global microbiological risk model is developed for the first time for the integrated 3-step milk pasteurizer based around the acknowledged raw milk pathogen *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*).

CHAPTER 4

ADVANCING THE *FR 1*3 RISK FRAMEWORK TO AN INTEGRATED 3-STEP MICROBIOLOGICAL FAILURE SYNTHESIS OF PASTEURIZATION OF RAW MILK CONTAINING *MYCOBACTERIUM AVIUM* SUBSP. *PARATUBERCULOSIS* (*MAP*)

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Davey, K.R., Chandrakash, S. and O'Neill, B.K., 2014. A novel Friday 13th risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26th European Modelling and Simulation Symposium - EMSS 2014, Bordeaux, France, Sept. 10-12, paper 107. ISBN: 978-88-97999-38-6

4.1 Introduction

A review of the equipment model for the 3-step pasteurization of raw milk (Chapter 3) showed pasteurizer failure should better be based on a design reduction in the number of viable pathogens and not on the equipment (*T*-*t*) performance – after all milk is an excellent medium for micro-organism proliferation and it is a reduction in the number of viable contaminants that is the purpose of milk pasteurization.

In this chapter the *Fr 13* risk framework is applied for the first time to a microbiological failure synthesis of an integrated 3-step pasteurization of raw milk containing the viable pathogenic contaminant. The logarithmic reduction of viable *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), a common bacterial pathogen is selected as an indicator of efficacy of process and a thermal inactivation model synthesized from independent published data. This micro-organism when consumed in small dosages can be lethal to human health (Hammer et al., 2014).

This is integrated with the equations for the plate equipment behaviour to synthesize a global *Fr 13* microbiological risk model for the first time. The aim is to gain quantitative insight into plant operations that could lead to unwanted (surprise) survival of the bacterial pathogen. Results are used to quantitatively evaluate process intervention strategies that might be used to mitigate pasteurizer failure.

Second-tier simulation studies highlight that failure in the overall microbiological pasteurizer can best be mitigated by installing precise safety-integrity-level (SIL) mass flow control on the input milk to ensure a holding time of ≥ 15 s.

A comparison is made with traditional solution approaches and that of Chandrakash et al. (2015; 2014). The global microbiological model is shown to be generalizable in its current form to a range of milk pathogens.

It is hoped that insight gained from this chapter might demonstrate the general applicability of the *Fr 13* framework to multi-step, microbiological processing and could thereby be applied to improve batch-continuous pasteurization design and operation.

4.2 Microbiological unit-operations model

A 3-step integrated pasteurization of raw milk containing *MAP* is shown schematically in Fig. 4-1. The pasteurizer is seen from the L-to-R of the figure to consist of a plate heat exchanger (*PHE*) for 1) raw milk heat-up, which is connected to an insulated 2) holding tube

(*HT*) for *MAP* inactivation at the bulk heat-up temperature, and which is connected to a second plate heat exchanger for 3) cool-down of the heat-treated milk.

In addition to *MAP*, there are several micro-organisms that have the ability to survive raw milk pasteurization, including: *Bacillus cereus, Brucella melitensis, Enterobacter sakazakii, Staphylococcus aureus, Streptococcus agalactiae* and *Streptococcus zooepidemicus* (Juffs and Deeth, 2007; Hudson et al., 2003). Because of wide interest in *Mycobacterium avium* subsp. *paratuberculosis* in milk pasteurization (Cerf et al., 2007; Anon., 2002) and because reliable (independent) data were available for it, it is selected. *MAP* is a chronic enteric pathogen linked to Crohn's disease in humans (Stabel and Lambertz, 2004; Juffs and Deeth, 2007). Significantly, this micro-organism when consumed even in small dosages can have lethal effects on human health (Hammer et al., 2014). Viewed sequentially, raw milk enters the pasteurizer at around 4 ^{O}C and is heated to 72 ^{O}C and held for 15 s; it is then 'shock' cooled (Hudson et al., 2003) to 4 ^{O}C (Juffs and Deeth, 2007; Stabel and Lambertz, 2004; Yapp and Davey, 2009).

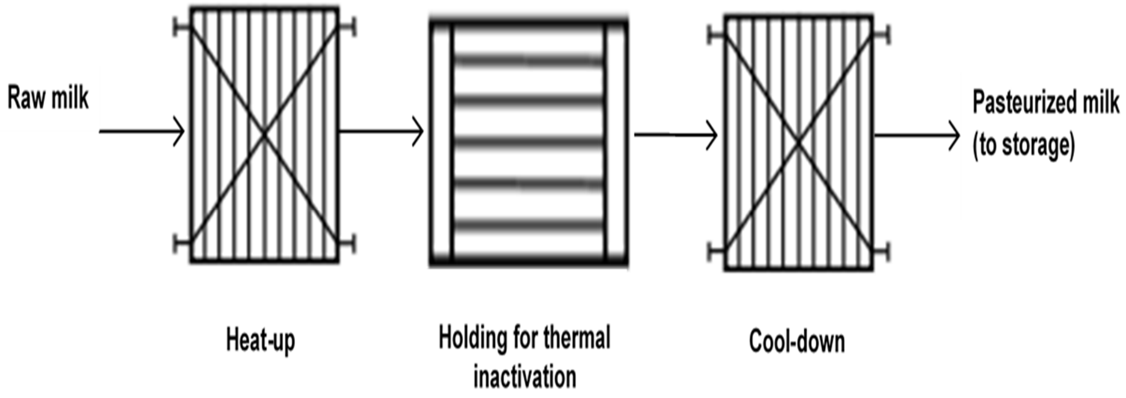

Fig. 4-1: Schematic of an integrated 3-step pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*) showing the three unit-operations 1) heat-up of raw milk, 2) holding for thermal inactivation, and; 3) cool-down of treated milk

Because milk heat-up and cool-down is, practically, rapid, a simplifying assumption is that no viable *MAP* is inactivated in these two steps. A justification is that this results in a conservatively 'safe' analysis.

All symbols used in this chapter are defined in the Nomenclature and follows the same pattern as the previous Chapter 3. This method has the advantage of ordered application to increasingly complex systems of interconnected unit-operations.

4.2.1 Heat-up ($PHE_{1\text{-}1}$)

The equipment model for raw milk heat-up is based on widely used plate heat exchangers that consist of a stack of closely-spaced (thin) plates clamped in a frame. These cost less and occupy less space, and are more flexible and require less maintenance, than shell-and-tube exchangers (Sinnott, 2005). Based on large-scale pasteurization practice, the area of $PHE_{1\text{-}1}$ is assumed at $A_{PHE\ 1\text{-}1}$ = 30 m^2 (with heat transfer co-efficient of $U_{PHE\ 1\text{-}1}$ = 2.5 kW m^{-2} K^{-1} and temperature correction factor of $F_{t,\ PHE\ 1\text{-}1}$ = 0.9 (Kothandaraman and Subramanyan, 2007; Sinnott, 2005). This gave $\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ = 22.5 ^{O}C. The individual plates were length $L_{p,\ PHE\ 1\text{-}1}$ = 1.5 m and thickness $w_{p,\ PHE\ 1\text{-}1}$ = 0.15 m. The gap between plates is $b_{p,\ PHE\ 1\text{-}1}$ = 0.05 m (Anon., 2014). Milk (typically) enters $PHE_{1\text{-}1}$ at $T_{i,m\text{-}1}$ = 4 ^{O}C at a flow of $m_{m,\ PHE\ 1\text{-}1}$ = 5.56 kg s^{-1} and a specific heat of $C_{p,m\ PHE\ 1\text{-}1}$ = 3.99 kJ kg^{-1} K^{-1} (Kessler, 2002). On the water-side $T_{i,w\ PHE\ 1\text{-}1}$ = 90 ^{O}C and $m_{w,\ PHE\ 1\text{-}1}$ = 6.2 kg s^{-1} (Kessler, 2002). Because the physical properties of water do not vary significantly with temperature over the range of 5 to 120, ^{O}C it is assumed that $C_{p,w\ PHE\ 1\text{-}1}$ = 4.2 kJ kg^{-1} K^{-1} (Perry and Green, 1997).

The generalized heat transfer equations used for milk heat up in $PHE_{1\text{-}1}$ were based on those of Sinnott (2005) such that

$$q_{PHE\ 1-1} = U_{PHE\ 1-1} * A_{PHE\ 1-1} * \Delta T_{LMTD,\ PHE\ 1-1} * F_{t,\ PHE\ 1-1} \tag{4.1}$$

$$q_{PHE\ 1-1} = m_{m,\ PHE\ 1-1} * C_{p,m\ PHE\ 1-1} * (T_{o,m\ PHE\ 1-1} - T_{i,m\ PHE\ 1-1}) \tag{4.2}$$

and

$$q_{PHE\ 1-1} = m_{w,\ PHE\ 1-1} * C_{p,w\ PHE\ 1-1} * (T_{i,w\ PHE\ 1-1} - T_{o,w\ PHE\ 1-1}) \tag{4.3}$$

The equivalent plate diameter in $PHE_{1\text{-}1}$ ($D_{e,\ PHE\ 1\text{-}1}$) used is given by Kessler (2002) as

$$D_{e,\ PHE\ 1-1} = \frac{2 * w_{p,\ PHE\ 1-1} * b_{p,\ PHE\ 1-1}}{(w_{p,\ PHE\ 1-1} + b_{p,\ PHE\ 1-1})} \tag{4.4}$$

The number of plates required for $PHE_{1\text{-}1}$ ($n_{p,\ PHE\ 1\text{-}1}$) is given by (Sinnott, 2005) as

$$n_{p,\ PHE\ 1-1} = \frac{A_{PHE\ 1-1}}{\pi * D_{e,\ PHE\ 1-1} * L_{p,PHE\ 1-1}} \tag{4.5}$$

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

$$T_{m,avg\ PHE\ 1-1} = \left(\frac{T_{i,m\ PHE\ 1-1} + T_{o,m\ PHE\ 1-1}}{2}\right) \tag{4.6}$$

$$\mu_{m,\ PHE\ 1-1} = \left(\left(-0.00445 * T_{m,avg\ PHE\ 1-1}\right) + 0.947\right) * 10^{-3} \tag{4.6 a}$$

and

$$\rho_{m,\ PHE\ 1-1} = 1033.7 - (0.2308 * T_{m,avg\ PHE\ 1-1}) - (0.00246 * T_{m,avg\ PHE\ 1-1}{}^{2}) \tag{4.6 b}$$

Milk velocity in *PHE*$_{1\text{-}1}$ ($v_{m,\ PHE\ 1\text{-}1}$) is calculated from the continuity equation (Kessler, 2002)

$$v_{m,\ PHE\ 1-1} = \frac{4 * m_{m,\ PHE\ 1-1}}{\rho_{m,\ PHE\ 1-1} * \pi * (D_{e,\ PHE\ 1-1})^{2}} \tag{4.7}$$

The recommended flow for whole milk in *PHE*$_{1\text{-}1}$ is, $0.5 < v_{m,\ PHE\ 1\text{-}1} < 1.5$ m s^{-1} (Kessler, 2002), with turbulent flow (Re > 4,000) (Hayhurst, 1997; Lewis and Heppell, 2000; Maroulis and Saravacos, 2003). The Reynolds number of the milk in *PHE*$_{1\text{-}1}$ (Re $_{PHE\ 1\text{-}1}$) is given by Sinnott (2005)

$$\mathrm{Re}_{\ PHE\ 1-1} = \frac{\rho_{m,\ PHE\ 1-1} * v_{m,\ PHE\ 1-1} * D_{e,\ PHE\ 1-1}}{\mu_{m,\ PHE\ 1-1}} \tag{4.8}$$

The bulk residence time of the milk in *PHE*$_{1\text{-}1}$ ($t_{r,\ PHE\ 1\text{-}1}$) is computed (Kessler, 2002) from

$$t_{r,\ PHE\ 1-1} = \frac{n_{p,\ PHE\ 1-1} * L_{p,\ PHE\ 1-1}}{v_{m,\ PHE\ 1-1}} \tag{4.9}$$

The pressure drop in *PHE*$_{1\text{-}1}$ ($\Delta P_{PHE\ 1\text{-}1}$) can be calculated from (Kumbhare and Dawande, 2013; Sinnott, 2005)

$$\Delta P_{PHE\ 1-1} = 8 * j_{F,\ PHE\ 1-1} * \frac{L_{p,\ PHE\ 1-1}}{D_{e,\ PHE\ 1-1}} * \frac{\rho_{m,\ PHE\ 1-1} * (v_{m,\ PHE\ 1-1})^{2}}{2} \tag{4.10}$$

where the term $j_{F,\ PHE\ 1\text{-}1}$ is the friction factor of the liquid flowing through the plates in *PHE*$_{1\text{-}1}$ and its value depends on the type of plate used. Generally for turbulent flow (Re > 4,000) the term $j_{F,\ PHE\ 1\text{-}1}$ can be described by (Sinnott, 2005)

$$j_{F,\ PHE\ 1-1} = 0.6 * (\mathrm{Re}_{\ PHE\ 1-1})^{-0.30} \tag{4.11}$$

Eqs. (4-1) through to Eq. (4-11) define heat-up of the raw milk containing viable *MAP*.

4.2.2 Holding for thermal inactivation ($HT_{1\text{-}2}$)

In contrast to the equipment model described in Chapter 3, this chapter is a microbiological model, the heated milk leaving $PHE_{1\text{-}1}$ (Fig. 4-1) is assumed to contain viable *MAP*. The stream is held at isothermal temperature in an holding tube ($HT_{1\text{-}2}$) (Smith, 2011) for a (typical) commercially used temperature-time combination of $T_{m,\ HT\ 1\text{-}2} = T_{o,m\ PHE\ 1\text{-}1} = 72\ ^{O}C$ and $t_{m,\ HT\ 1\text{-}2} = 15$ s (Alfa Laval, 1987; Juffs and Deeth, 2007; Katoh and Yoshida, 2009; Stabel and Lambertz, 2004; Hudson et al., 2003).

The decimal reduction time[7] for viable *MAP* at a reference temperature $T_{ref,\ HT\ 1\text{-}2} = 72\ ^{O}C$ is $D_{t,ref\ HT\ 1\text{-}2} = 1.2$ s with a *z*-value of $z_{HT\ 1\text{-}2} = 7.7\ ^{O}C$ (Rademaker et al., 2007). The decimal reduction time ($D_{t,\ HT\ 1\text{-}2}$) at any temperature value $T_{m,\ HT\ 1\text{-}2} = T_{o,m\ PHE\ 1\text{-}1}$ in $HT_{1\text{-}2}$ can be obtained from (van Asselt and Zwietering, 2005)

$$log_{10}\,D_{t,\ HT\ 1-2} = log_{10}\,D_{t,ref\ HT\ 1-2} - \frac{(T_{m,\ HT\ 1-2} - T_{ref,\ HT\ 1-2})}{z_{HT\ 1-2}} \qquad (4.12)$$

The thermal inactivation rate ($k_{d,\ HT\ 1\text{-}2}$) of viable *MAP* in $HT_{1\text{-}2}$ is obtained using (Koutchma et al., 2001; Smith, 2011)

$$k_{d,\ HT\ 1-2} = \frac{2.303}{D_{t,\ HT\ 1-2}} \qquad (4.13)$$

The logarithmic reduction in viable *MAP*, $(\log_{10}(N/N_0))_{HT\ 1\text{-}2}$ can be obtained from (Ibarz and Barbosa-Canovas, 2003)

$$\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2} = \frac{k_{d,\ HT\ 1-2} * t_{m,\ HT\ 1-2}}{2.303} \qquad (4.14)$$

Typically a 5.5 $\log_{10}$ reduction of *MAP* (> 99.99 %) is required in milk (Grant et al., 2001; Hammer et al., 2014; McDonald et al., 2005; Rademaker et al., 2007). Pasteurization is not intended to ‘sterilize’ the milk (Aiba et al., 1973).

It is assumed that the diameter of the holding tube is $D_{HT\ 1\text{-}2} = 0.1$ m (Berk, 2009) with length $L_{HT\ 1\text{-}2} = 10.58$ m. Milk is seen from the figure to enter the holding tube with a bulk temperature equal to that of $T_{o,m\ PHE\ 1\text{-}1}$ and at a typical commercial flow $m_{m,\ HT\ 1\text{-}2} = m_{m,\ PHE\ 1\text{-}1} = 5.56$ kg s^{-1} (Kessler, 2002).

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[7] This is the treatment time at given conditions for a 10-fold reduction in the viable population of exposed micro-organisms (Madigan et al., 2003; Shuler and Kargi, 1992). The Reader should note that this sometimes is incorrectly stated e.g. by Aiba et al. (1973)

The general design equation for an external holding tube is (Katoh and Yoshida, 2009)

$$t_{m,\ HT\ 1-2} = \frac{L_{HT\ 1-2}}{v_{m,\ HT\ 1-2}} \qquad (4.15)$$

Because the temperature of the milk in the holding tube ($T_{m,\ HT\ 1\text{-}2}$) is known, its density can be calculated (Al-Hilphy and Ali, 2013) from

$$\rho_{m,\ HT\ 1-2} = 1033.7 - (0.2308\ * T_{m,\ HT\ 1-2}) - (0.00246\ * T_{m,\ HT\ 1-2}{}^{2}) \quad (4.16)$$

Milk velocity in the holding tube $HT_{1\text{-}2}$ ($v_{m,\ HT\ 1\text{-}2}$) is obtained from the continuity equation (Kessler, 2002)

$$v_{m,\ HT\ 1-2} = \frac{4 * m_{m,\ HT\ 1-2}}{\rho_{m,\ HT\ 1-2} * \pi * (D_{HT\ 1-2})^{2}} \qquad (4.17)$$

Eqs. (4-12) through Eq. (4-17) define holding and thermal inactivation of contaminant *MAP* in the microbiological synthesis of the milk pasteurizer.

4.2.3 Cool-down (PHE$_{2\text{-}3}$)

Milk leaving the holding tube $HT_{1\text{-}2}$ is cooled to 4 ^{O}C using a second plate exchanger $PHE_{2\text{-}3}$ that is assumed to have plates and dimensions the same as for $PHE_{1\text{-}1}$ ($A_{PHE\ 2\text{-}3}$ = 30 m^{2} with $U_{PHE\ 2\text{-}3}$ = 2.5 kW m^{-2} K^{-1} and $F_{t,\ PHE\ 2\text{-}3}$ = 0.9 to give $\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ = 22.5 ^{O}C) (Anon., 2014). From Fig. 4-1 it can be seen that milk enters $PHE_{2\text{-}3}$ at $T_{i,m\ PHE\ 2\text{-}3} = T_{m,\ HT\ 1\text{-}2}$ with $m_{m,\ PHE\ 2\text{-}3} = m_{m,\ HT\ 1\text{-}2}$ = 5.56 kg s^{-1}. On the cooling side, brine (NaCl) is supplied at $T_{i,b\ PHE\ 2\text{-}3}$ = -8 ^{O}C with flow $m_{b,\ PHE\ 2\text{-}3}$ = 8.34 kg s^{-1}. The specific heat of the brine is assumed constant at $C_{p,b\ PHE\ 2\text{-}3}$ = 3.38 kJ kg^{-1} K^{-1} (Earle, 1983; Perry and Green, 1997).

In similar fashion to $PHE_{1\text{-}1}$ the generalized design equations used for $PHE_{2\text{-}3}$ are (Sinnott, 2005)

$$q_{PHE\ 2-3} = U_{PHE\ 2-3} * A_{PHE\ 2-3}\ * \Delta T_{LMTD,\ PHE\ 2-3} * F_{t,\ PHE\ 2-3} \qquad (4.18)$$

$$q_{PHE\ 2-3} = m_{m,\ PHE\ 2-3} * C_{p,m\ PHE\ 2-3} * (T_{i,m\ PHE\ 2-3} - T_{o,m\ PHE\ 2-3}) \quad (4.19)$$

and

$$q_{PHE\ 2-3} = m_{b,\ PHE\ 2-3} * C_{p,b\ PHE\ 2-3} * (T_{o,b\ PHE\ 2-3} - T_{i,b\ PHE\ 2-3}) \quad (4.20)$$

The equivalent diameter of the plate is given by

$$D_{e,\ PHE\ 2-3} = \frac{2 * w_{p,\ PHE\ 2-3} * b_{p,\ PHE\ 2-3}}{(w_{p,\ PHE\ 2-3} + b_{p,\ PHE\ 2-3})} \qquad (4.21)$$

The number of plates in $PHE_{2\text{-}3}$ is obtained from

$$n_{p,\ PHE\ 2-3} = \frac{A_{PHE\ 2-3}}{\pi * D_{e,\ PHE\ 2-3} * L_{p,\ PHE\ 2-3}} \tag{4.22}$$

The physical properties of milk as a function of temperature in the equipment model were obtained from (Al-Hilphy and Ali, 2013)

$$T_{m,avg\ PHE\ 2-3} = \frac{T_{i,m\ PHE\ 2-3} + T_{o,m\ PHE\ 2-3}}{2} \tag{4.23}$$

$$\mu_{m,\ PHE\ 2-3} = \left(\left(-0.00445 * T_{m,avg\ PHE\ 2-3}\right) + 0.947\right) * 10^{-3} \tag{4.23 a}$$

and

$$\rho_{m,\ PHE\ 2-3} = 1033.7 - (0.2308 * T_{m,avg\ PHE\ 2-3}) - (0.00246 * T_{m,avg\ PHE\ 2-3}{}^{2}) \tag{4.23 b}$$

Milk velocity in $PHE_{2\text{-}3}$ is calculated from the continuity equation (Kessler, 2002)

$$v_{m,\ PHE\ 2-3} = \frac{4 * m_{m,\ PHE\ 2-3}}{\rho_{m,\ PHE\ 2-3} * \pi * (D_{e,\ PHE\ 2-3})^{2}} \tag{4.24}$$

The recommended flow for whole milk in $PHE_{2\text{-}3}$ is the same as that for $PHE_{1\text{-}1}$ i.e. $0.5 < v_{m,\ PHE\ 2\text{-}3} < 1.5$ m s^{-1} (Kessler, 2002) with turbulent flow (i.e. Re > 4,000) (Hayhurst, 1997; Lewis and Heppell, 2000; Maroulis and Saravacos, 2003). The Reynolds number of the milk in $PHE_{2\text{-}3}$ ($\mathrm{Re}_{\ PHE\ 2\text{-}3}$) is

$$\mathrm{Re}_{\ PHE\ 2-3} = \frac{\rho_{m,\ PHE\ 2-3} * v_{m,\ PHE\ 2-3} * D_{e,\ PHE\ 2-3}}{\mu_{m,\ PHE\ 2-3}} \tag{4.25}$$

The residence time of the milk is computed from (Kessler, 2002)

$$t_{r,\ PHE\ 2-3} = \frac{n_{p,\ PHE\ 2-3} * L_{p,\ PHE\ 2-3}}{v_{m,\ PHE\ 2-3}} \tag{4.26}$$

The pressure drop is obtained from

$$\Delta P_{PHE\ 2-3} = 8\ * j_{F,\ PHE\ 2-3} * \frac{L_{p,\ PHE\ 2-3}}{D_{e,\ PHE\ 2-3}} * \frac{\rho_{m,\ PHE\ 2-3} * (v_{m,\ PHE\ 2-3})^{2}}{2} \tag{4.27}$$

where the term $j_{F,\ PHE\ 2\text{-}3}$ for turbulent flow (Re > 4,000) is given by

$$j_{F,\ PHE\ 2-3} = 0.6\ (\mathrm{Re}_{\ PHE\ 2-3})^{-0.30} \tag{4.28}$$

Eqs. (4-18) through Eq. (4-28) define cool-down of the heat-treated milk.

4.3 Traditional single value assessment (SVA) solution

The traditional method for solving a unit-operations model is the ‘deterministic’, single point, or Single Value Assessment (SVA) (Sinnott, 2005; Davey et al., 2015). Using this method the integrated 3-step microbiological pasteurization synthesis is solved as follows:

For milk heat-up, from Eq. (4.1) $q_{PHE\ 1\text{-}1}$ = 1,519 kJ s^{-1}, using Eq. (4.2) $T_{o,m\ PHE\ 1\text{-}1}$ = 72.46 ^{O}C, and from Eq. (4.3) $T_{o,w\ PHE\ 1\text{-}1}$ = 31.68 ^{O}C. Using Eq. (4.4) $D_{e,\ PHE\ 1\text{-}1}$ = 0.08 m and from Eq. (4.5) $n_{p,\ PHE\ 1\text{-}1}$ = 85. Using Eq. (4.6) $T_{m,avg\ PHE\ 1\text{-}1}$ = 38.23 ^{O}C. With $T_{m,avg\ PHE\ 1\text{-}1}$ known using Eq. (4.6 a) $\mu_{m,\ PHE\ 1\text{-}1}$ = 0.0008 Pa s and from Eq. (4.6 b) $\rho_{m,\ PHE\ 1\text{-}1}$ = 1,021.28 kg m^{-3}. From Eq. (4.7) $v_{m,\ PHE\ 1\text{-}1}$ = 1.23 m s^{-1} and using Eq. (4.8) $\mathrm{Re}_{PHE\ 1\text{-}1}$ = 121,560 (dimensionless). From Eq. (4.9) the residence time of the milk in heat-up $t_{r,\ PHE\ 1\text{-}1}$ = 103.32 s. Using Eq. (4.10) and Eq. (4.11) $\Delta P_{PHE\ 1\text{-}1}$ = 2,222 N m^{-2}.

For holding for thermal inactivation of *MAP*, the heated milk enters the holding tube at $T_{o,m\ PHE\ 1\text{-}1} = T_{m,\ HT\ 1\text{-}2}$ = 72.46 ^{O}C. Since the length of the holding tube ($L_{HT\ 1\text{-}2}$ = 10.58 m) is known, from Eq. (4.15) $t_{m,\ HT\ 1\text{-}2}$ = 15 s. Using Eq. (4.16) $\rho_{m,\ HT\ 1\text{-}2}$ = 1,004.06 kg m^{-3}. From Eq. (4.17) $v_{m,\ HT\ 1\text{-}2}$ = 0.71 m s^{-1}. From literature, for *MAP* the decimal reduction time at a reference temperature $T_{ref,\ HT\ 1\text{-}2}$ = 72 ^{O}C is $D_{t,ref\ HT\ 1\text{-}2}$ = 1.2 s with a *z*-value $z_{HT\ 1\text{-}2}$ = 7.7 ^{O}C (Rademaker et al., 2007). From Eq. (4.12) at $T_{m,\ HT\ 1\text{-}2}$ = 72.46 ^{O}C, $D_{t,\ HT\ 1\text{-}2}$ = 1.01 s. From Eq. (4.13) $k_{d,\ HT\ 1\text{-}2}$ = 2.29 s^{-1}. From Eq. (4.14) $(N/N_0)_{\ HT\ 1\text{-}2}$ =14.93 (dimensionless).

This logarithmic reduction of *MAP* is greater than the required 5.5 $\log_{10}$ reduction; therefore it can be concluded that the resulting pasteurized milk is ‘safe’.

For cool-down of the heated milk, using Eq. (4.18) $q_{PHE\ 2\text{-}3}$ = 1,519 kJ s^{-1} and from Eq. (4.19) $T_{o,m\ PHE\ 2\text{-}3}$ = 4 ^{O}C, from Eq. (4.20) $T_{o,b\ PHE\ 2\text{-}3}$ = 45.88 ^{O}C. Using Eq. (4.21) $D_{e,\ PHE\ 2\text{-}3}$ = 0.08 m and from Eq. (4.22) $n_{p,\ PHE\ 2\text{-}3}$ = 85. Using Eq. (4.23) $T_{m,avg\ PHE\ 2\text{-}3}$ = 38.23 ^{O}C. With $T_{m,avg\ PHE\ 2\text{-}3}$ known using Eq. (4.23 a) $\mu_{m,\ PHE\ 2\text{-}3}$ = 0.0008 Pa s and from Eq. (4.23 b) $\rho_{m,\ PHE\ 2\text{-}3}$ = 1,021.28 kg m^{-3}. Using Eq. (4.24) $v_{m,\ PHE\ 2\text{-}3}$ = 1.23 m s^{-1} and from Eq. (4.25) $\mathrm{Re}_{PHE\ 2\text{-}3}$ = 121,560. From Eq. (4.26) the residence time of the milk in cool-down $t_{r,\ PHE\ 2\text{-}3}$ = 103.32 s. Using Eq. (4.27) and Eq. (4.28) $\Delta P_{PHE\ 2\text{-}3}$ = 2,222 N m^{-2}.

A summary comparison of the deterministic values obtained using the traditional single value assessment (SVA) for individual heat-up ($PHE_{1\text{-}1}$), holding for thermal inactivation ($HT_{1\text{-}2}$) and cool-down ($PHE_{2\text{-}3}$) is presented in Table 4-1. The SVA model is conveniently read down the column for each. The bolded value highlights that the output from one unit-operation step is the input to the sequentially, inter-connected step.

Table 4-1: Summary of the deterministic single value assessment (SVA) for corresponding milk heat-up, holding for thermal inactivation of *MAP*, and; cool-down

Heat-up			Holding for thermal inactivation of *MAP*			Cool-down		
Constants								
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	constant	$L_{HT\ 1\text{-}2}$ (m)	10.58	constant	$U_{PHE\ 2\text{-}3}$ (kW m^{-2} K^{-1})	2.5	constant
$A_{PHE\ 1\text{-}1}$ (m^2)	30	constant	$D_{HT\ 1\text{-}2}$ (m)	0.1	constant	$A_{PHE\ 2\text{-}3}$ (m^2)	30	constant
$\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ (^{O}C)	22.5	constant				$\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ (^{O}C)	22.5	constant
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	constant				$F_{t,\ PHE\ 2\text{-}3}$ (dimensionless)	0.90	constant
Plate Properties								
$w_{p,\ PHE\ 1\text{-}1}$ (m)	0.15	constant				$w_{p,\ PHE\ 2\text{-}3}$ (m)	0.15	constant
$b_{p,\ PHE\ 1\text{-}1}$ (m)	0.05	constant				$b_{p,\ PHE\ 2\text{-}3}$ (m)	0.05	constant
$L_{p,\ PHE\ 1\text{-}1}$ (m)	1.50	constant				$L_{p,\ PHE\ 2\text{-}3}$ (m)	1.50	constant
Inputs								
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	input	**$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)**	**72.46**	**input**	**$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**72.46**	**input**
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	input	$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.56	input	$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.56	input
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	input	$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	input	$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.99	input
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	input	$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	input	$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8	input
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	input	$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	input	$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.34	input
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	input				$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.38	input
Calculations								
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	Eq. (4.1)				$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	Eq. (4.18)
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	**72.46**	**Eq. (4.2)**				**$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**4.00**	**Eq. (4.19)**
$T_{o,w,\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	Eq. (4.3)				$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.88	Eq. (4.20)
$D_{e,\ PHE\ 1\text{-}1}$ (m)	0.08	Eq. (4.4)				$D_{e,\ PHE\ 2\text{-}3}$ (m)	0.08	Eq. (4.21)
$n_{p,PHE\ 1\text{-}1}$ (dimensionless)	85	Eq. (4.5)				$n_{p,PHE\ 2\text{-}3}$ (dimensionless)	85	Eq. (4.22)
$T_{m,avg\ PHE\ 1\text{-}1}$ (^{O}C)	38.23	Eq. (4.6)				$T_{m,avg\ PHE\ 2\text{-}3}$ (^{O}C)	38.23	Eq. (4.23)
$\mu_{m,\ PHE\ 1\text{-}1}$ (Pa s)	0.0008	Eq. (4.6 a)				$\mu_{m,\ PHE\ 2\text{-}3}$ (Pa s)	0.0008	Eq. (4.23 a)
$\rho_{m,\ PHE\ 1\text{-}1}$ (kg m^{-3})	1,021	Eq. (4.6 b)	$t_{m,\ HT\ 1\text{-}2}$ (s)	15	Eq. (4.15)	$\rho_{m,\ PHE\ 2\text{-}3}$ (kg m^{-3})	1,021	Eq. (4.23 b)
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.23	Eq. (4.7)	$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1004	Eq. (4.16)	$v_{m,\ PHE\ 2\text{-}3}$ (m s^{-1})	1.23	Eq. (4.24)
$\mathrm{Re}_{PHE1\text{-}1}$ (dimensionless)	121,560	Eq. (4.8)	$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.71	Eq. (4.17)	$\mathrm{Re}_{PHE\ 2\text{-}3}$ (dimensionless)	121,560	Eq. (4.25)
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.32	Eq. (4.9)	$D_{t,\ HT\ 1\text{-}2}$ (s)	1.01	Eq. (4.12)	$t_{r,\ PHE\ 2\text{-}3}$ (s)	103.32	Eq. (4.26)
$j_{F,\ PHE\ 1\text{-}1}$ (dimensionless)	0.02	Eq. (4.11)	$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	2.29	Eq. (4.13)	$j_{F,\ PHE\ 2\text{-}3}$ (dimensionless)	0.02	Eq. (4.28)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,222	Eq. (4.10)	**$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$**	**14.93**	**Eq. (4.14)**	$\Delta P_{PHE\ 2\text{-}3}$ (N m^{-2})	2,222	Eq. (4.27)

Notably, these results agree well with those values widely reported in the literature (Varzakas and Labropoulos, 2007; Tran et al., 2008).

4.4 *Fr 13* model

4.4.1 Risk factors and defining failure

A failure risk factor for milk heat-up is defined such that

$$P_1 = T_{o,m\ PHE\ 1-1}{}' - T_{o,m\ PHE\ 1-1} \tag{4.29}$$

where $T_{o,m\ PHE\ 1\text{-}1}{}'$ is the actual temperature (or more strictly, one possible practical scenario to reflect the impact of naturally occurring, within-system, fluctuations), and

$T_{o,m\ PHE\ 1\text{-}1}$ is the required outlet temperature of milk from $PHE_{1\text{-}1}$ i.e. all $P_1 \leq 0$ will infer failure to attain design milk temperature. A computationally more convenient risk factor (p_1) however can be defined in terms of the outlet temperature of milk from $PHE_{1\text{-}1}$ ($T_{o,m\ PHE\ 1\text{-}1}$) together with an acceptable $tolerance_1$ (Abdul-Halim and Davey, 2016) such that

$$p_1 = +tolerance_1 - 100\left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE1-1}} - 1\right) \tag{4.30}$$

The development of the dimensionless form of Eq. (4.31), Eq. (4.33) and Eq. (4.35) below, is presented in detail in the Appendix B at end of this thesis.

With an assumed practical $tolerance_1$ = 2 % Eq. (4.30) becomes

$$p_1 = +2 - 100\left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1\right) \tag{4.31}$$

Eq. (4.31) is computationally convenient because it defines failure in such a way that if the design temperature (72 ^{O}C) plus a $tolerance_1$ of 2 % is not reached then milk heat-up is said to have failed and is highlighted by $p_1 > 0$.

Eqs. (4.1) through Eq. (4.11), together with Eq. (4.31), define the *Fr 13* failure synthesis for raw milk heat-up.

Similarly, for holding for thermal inactivation of *MAP*, a suitable risk factor for overall pasteurizer failure, defined as unwanted survival of *MAP*, can be characterized by a risk factor for heat treated milk (p_2) defined in terms of $\log_{10}$ reduction of viable *MAP* such that

$$p_2 = +tolerance_2 - 100\left(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}} - 1\right) \tag{4.32}$$

where $\log_{10}(N/N_0)_{HT\ 1\text{-}2}'$ is one possible practical scenario in reduction of viable pathogens and $\log_{10}(N/N_0)_{HT\ 1\text{-}2}$ is the required $\log_{10}$ reduction for safely pasteurized milk. With a $tolerance_2$ = 2 %, Eq. (4.32) becomes

$$p_2 = +2 - 100\left(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}} - 1\right) \tag{4.33}$$

That is, if the required 5.5 $\log_{10}$ reduction in *MAP* plus 2 % is not reached then holding for thermal inactivation is said to have failed, indicated by $p_2 > 0$.

Eqs. (4.12) through Eq. (4.17), together with Eq. (4.33), constitutes the *Fr 13* failure synthesis for holding for thermal inactivation of the milk contaminant *MAP*.

For heated milk cool-down, p_3 can be defined in terms of the outlet temperature of milk from $PHE_{2\text{-}3}$ ($T_{o,m\ PHE\ 2\text{-}3}$) such that

$$p_3 = -tolerance_3 + 100\left(\frac{T_{o,m\ PHE\ 2-3}{}'}{T_{o,m\ PHE\ 2-3}} - 1\right) \tag{4.34}$$

where $T_{o,m\ PHE\ 2\text{-}3}'$ is one possible practical scenario and $T_{o,m\ PHE\ 2\text{-}3}$ is the required outlet temperature of milk from $PHE_{2\text{-}3}$. With $tolerance_3$ = 2 %, Eq. (4.34) becomes

$$p_3 = -2 + 100\left(\frac{T_{o,m\ PHE\ 2-3}{}'}{T_{o,m\ PHE\ 2-3}} - 1\right) \tag{4.35}$$

That is, if the design temperature (4 ^{O}C) plus 2 % is not reached then the milk cool-down unit-operation is said to have failed and is revealed by $p_3 > 0$.

Eqs. (4.18) through Eq. (4.28), together with Eq. (4.35), constitute the *Fr 13* synthesis for heated milk cool-down.

4.4.2 *Fr 13* pasteurizer simulations

In contrast to the traditional deterministic SVA simulation, in the *Fr 13* framework each input parameter is defined by a probability distribution of values (the mean of which will agree with the deterministic SVA value). The output is therefore a distribution also.

The probability distributions for pasteurization of the milk, in the absence of conditional information, are defined as normal and truncated so as to obviate any nonsensical parameter values, namely, **RiskNormal** (mean, standard deviation, **RiskTruncate** (minimum, maximum)). A standard deviation around the mean value in the distribution is assumed at stdev = 5 % with the minimum value = mean – 3 x stdev, and the maximum value = mean + 3 x stdev. An advantage of using ± 3 x stdev about the mean value to obtain the truncated minimum and maximum values is that nearly all values (99.73 %) the parameter can possibly take will fall in this interval (Sullivan, 2004; Snedecor and Cochran, 1989; Vose, 2008). For example, for the inlet raw milk temperature to $PHE_{1\text{-}1}$, $T_{i,m\ PHE\ 1\text{-}1}$, the distribution is **RiskNormal** (4, 0.2, **RiskTruncate** (3.4 ,4.6)). This is a normal distribution with a mean milk temperature = 4 ^{O}C, stdev = 0.2 ^{O}C (5 %) and temperature minimum = 3.4, and maximum = 4.6, ^{O}C.

Other input parameters in the global *Fr 13* pasteurization model, $m_{m,\ PHE\ 1\text{-}1}$, $C_{p,m\ PHE\ 1\text{-}1}$, $T_{i,w\ PHE\ 1\text{-}1}$, $m_{w,\ PHE\ 1\text{-}1}$, $C_{p,w\ PHE\ 1\text{-}1}$, $T_{i,b\ PHE\ 2\text{-}3}$, $m_{b,\ PHE\ 2\text{-}3}$ and $C_{p,b\ PHE\ 2\text{-}3}$ are defined in similar manner, Fig. 4-2.

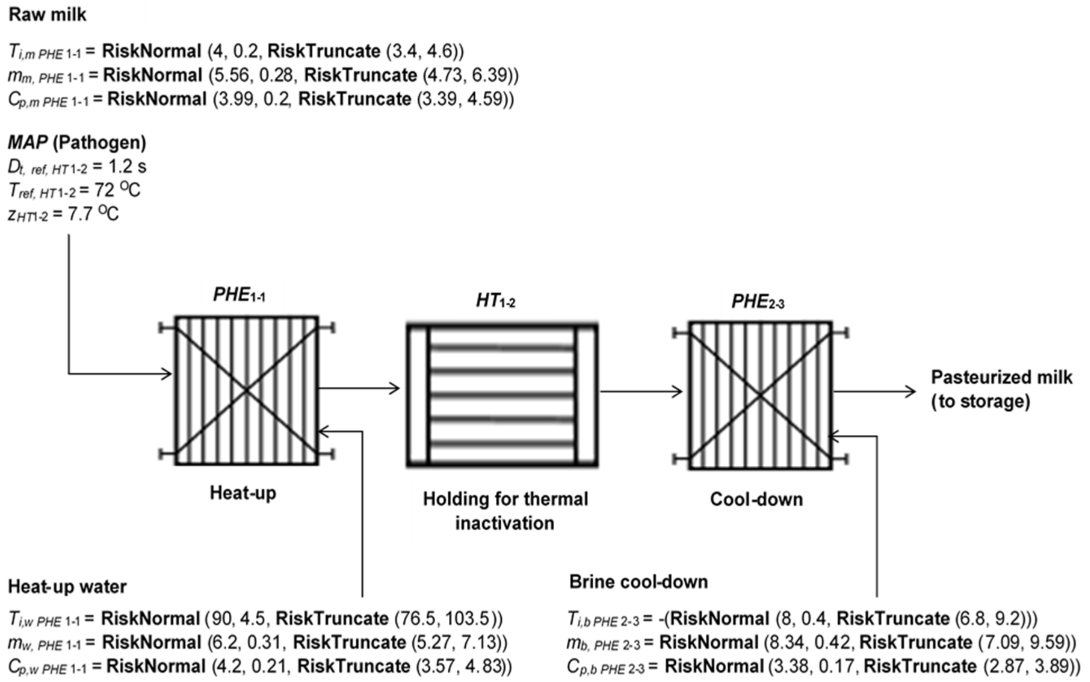


Fig. 4-2: *Fr 13* integrated 3-step global model for pasteurization of raw milk containing *MAP*

The schematic is similar as for Fig. 4-1 but importantly it highlights that all input parameters are distributions - which mimic naturally occurring fluctuations about the set steady-state value.

A refined Monte Carlo (with Latin Hypercube) (r-MC) sampling of these probability distributions is used; pure MC sampling can over- and under- estimate samples from particular parts of the distribution (Davey, 2015; 2011; Vose, 2008). To ensure that the output distribution of the mean is sufficiently normal, a minimum number of samples is needed

(Vose, 2008); this is usually some 1,000 to 50,000 (e.g. Davey et al., 2015; Abdul-Halim and Davey, 2015; 2016). This number can be established when a scatter plot of number of failures versus number of samples plateaus to a constant, highlighting sufficient samples. This can also be established reasonably reliably by visual inspection of the output distribution. Because a large number of r-MC samples is used it is reasonable to assume that all process scenarios that can actually occur, including failures, are included.

Computations to simulate pasteurization of raw milk containing the contaminant *MAP* were carried out with standard Microsoft Excel™ spread-sheeting using a commercially available add-on, *@-Risk* version 5.5 (Palisade Corporation™). Because spread sheeting is used almost universally it makes communication of results simplified (Zou and Davey, 2016; Abdul-Halim and Davey, 2016). Additionally, the distributions can be entered, viewed, copied and pasted and manipulated as Excel formulae.

4.5 Results

Table 4-2 a and 4-2 b present a comparative summary of the traditional SVA with *Fr 13* simulations of the pasteurizer for, respectively, heat-up and holding for thermal inactivation of *MAP*. For computational completeness, milk cool-down is shown in Table 4-2 c. 10,000 Latin Hypercube samples were found sufficient.

Comparative summary of the deterministic SVA with probabilistic *Fr 13* simulations for: (a) Heat-up of milk with a $tolerance_1 = 2$ %, failure of milk heat-up is defined by $p_1 > 0$, (b) Holding for thermal inactivation of *MAP* ($tolerance_2 = 2$ %), overall pasteurizer failure is defined by $p_2 > 0$, (c) Cool-down of heated milk ($tolerance_3 = 2$ %), failure to cool-down is defined by $p_3 > 0$. Column 3 is for one-only of 10,000 simulated scenarios.

Table 4-2 a, b and c: Summary of the *Fr 13* results for corresponding milk heat-up, holding for thermal inactivation of *MAP*, and; cool-down respectively

(a)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	**4.13**†	**RiskNormal**(4,0.2, **RiskTruncate** (3.4,4.6))
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	**6.18**†	**RiskNormal**(5.56,0.278, **RiskTruncate**(4.73,6.39))
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	**4.01**†	**RiskNormal**(3.99,0.2, **RiskTruncate** (3.39,4.59))
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	**91.59**†	**RiskNormal**(90,4.5, **RiskTruncate** (76.5,103.5))
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	**6.14**†	**RiskNormal**(6.2,0.31, **RiskTruncate** (5.27,7.13))
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	**4.18**†	**RiskNormal**(4.2,0.21, **RiskTruncate** (3.57,4.83))
Constants			
$A_{PHE\ 1\text{-}1}$ (m^2)	30	30	constant
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	2.5	constant
$\Delta T_{LMTD\ PHE\ 1\text{-}1}$ (^{O}C)	22.50	22.50	constant
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	0.90	constant
Calculations			
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	1,519	Eq. (4.1)
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	72.46	**65.46**	Eq. (4.2)
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	32.42	Eq. (4.3)
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.2329	1.37	Eq. (4.7)
Re $_{PHE\ 1\text{-}1}$ (dimensionless)	121,560	132,510	Eq. (4.8)
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.32	93.08	Eq. (4.9)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,222	2,672	Eqs. (4.10), (4.11)
p_1 (dimensionless)		**11.08**	Eq. (4.31)

(b)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)	72.46	**65.46**†	$= T_{o,m\ PHE\ 1\text{-}1}$
$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.56	**6.18**†	$= m_{m,\ PHE\ 1\text{-}1}$
Constants			
$L_{HT\ 1\text{-}2}$ (m)	10.58	10.58	constant
$D_{HT\ 1\text{-}2}$ (m)	0.1	0.1	constant
$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	72	constant
$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	1.2	constant
$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	7.7	constant
Calculations			
$t_{m,\ HT\ 1\text{--}2}$ (s)	15	13.55	Eq. (4.15)
$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1,004	1,008	Eq. (4.16)
$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.71	0.78	Eq. (4.17)
$D_{t,\ HT\ 1\text{-}2}$ (s)	1.01	2.53	Eq. (4.12)
$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	2.29	0.91	Eq. (4.13)
$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$	14.93	**5.36**	Eq. (4.14)
p_2 (dimensionless)		**4.63**	Eq. (4.33)

(c)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)	72.46	**65.46**†	= $T_{m,HT\ 1\text{-}2}$ (= $T_{o,m\ PHE\ 1\text{-}1}$)
$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.56	**6.18**†	= $m_{m,\ PHE\ 1\text{-}1}$
$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.99	**4.01**†	= $C_{p,m\ PHE\ 1\text{-}1}$
$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8	**-7.96**†	-(**RiskNormal**(8,0.4,**RiskTruncate**(6.8,9.2)))
$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.34	**8.22**†	**RiskNormal**(8.34,0.42,**RiskTruncate**(7.09,9.59))
$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.38	**3.46**†	**RiskNormal**(3.38,0.17,**RiskTruncate**(2.87,3.89))
Constants			
$A_{PHE\ 2\text{-}3}$ (m^{2})	30	30	constant
$U_{PHE\ 2\text{-}3}$ (kW m^{-2} K^{-1})	2.5	2.5	constant
$\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ (^{O}C)	22.50	22.50	constant
$F_{t,\ PHE\ 2\text{-}3}$ (dimensionless)	0.90	0.90	constant
Calculations			
$q_{\ PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	1,519	Eq. (4.18)
$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)	4.00	**4.13**	Eq. (4.19)
$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.88	45.41	Eq. (4.20)
p_3 (dimensionless)		**1.24**	Eq. (4.35)

*Traditional, deterministic Single Value Assessment

** *Fr 13* simulation with *Latin Hypercube* sampling

† Input values are reproduced from r-MC sampling; it is not implied they are measured to this significance

Both SVA and *Fr 13* simulation are each read down the appropriate columns. For example, for the *Fr 13* simulation of Table 4-2 a for heat-up, columns 3 and 4, a r-MC sample for the temperature for the raw milk = 4.13 ^{O}C is seen, in combination with mass flow of milk = 6.18 kg s^{-1}, specific heat of milk = 4.01 kJ kg^{-1} K^{-1}, inlet temperature of the heating water = 91.59 ^{O}C, mass flow of heating water = 6.14 kg s^{-1} and specific heat of the heating water = 4.18 kJ kg^{-1} K^{-1}, for which the resulting risk factor for heat-up, p_1 = 11.08. Because $p_1 > 0$, this highlights a process failure to heat the raw milk to the design (Regulatory) 72 ^{O}C plus a practical *tolerance* of 2 %. Importantly, the reader should note that all tabulated values are reproduced from the r-MC sampling and it is not implied they are measured to the significance shown.

Pointedly, the *Fr 13* model is seen from the tables to be identical to the SVA, with all mathematical operations that join parameters the same, but one in which parameters are defined by distributions of values and not by single values.

Importantly however, the results in Table 4-2 are for one-only process scenario.

The presentation of results for multiple scenarios can be conveniently presented as a summary output probability distribution (Law, 2011; Vose, 2008; Davey, 2015). For example, the outputs of the 10,000 scenarios for milk heat-up are summarised as Fig. 4-3. The *x*-axis is the computed value of p_1 from Eq. (4-31) and the *y*-axis is the probability of p_1 practically occurring. It is seen from the figure the output distribution is (sufficiently) normal, and; that the area under the curve is (52 x ~ 0.02) = one (1). The right-side of the figure shows, conveniently at a glance, the 5,637 failures i.e. scenarios with $p_1 > 0$ that occurred in the 10,000 simulations.

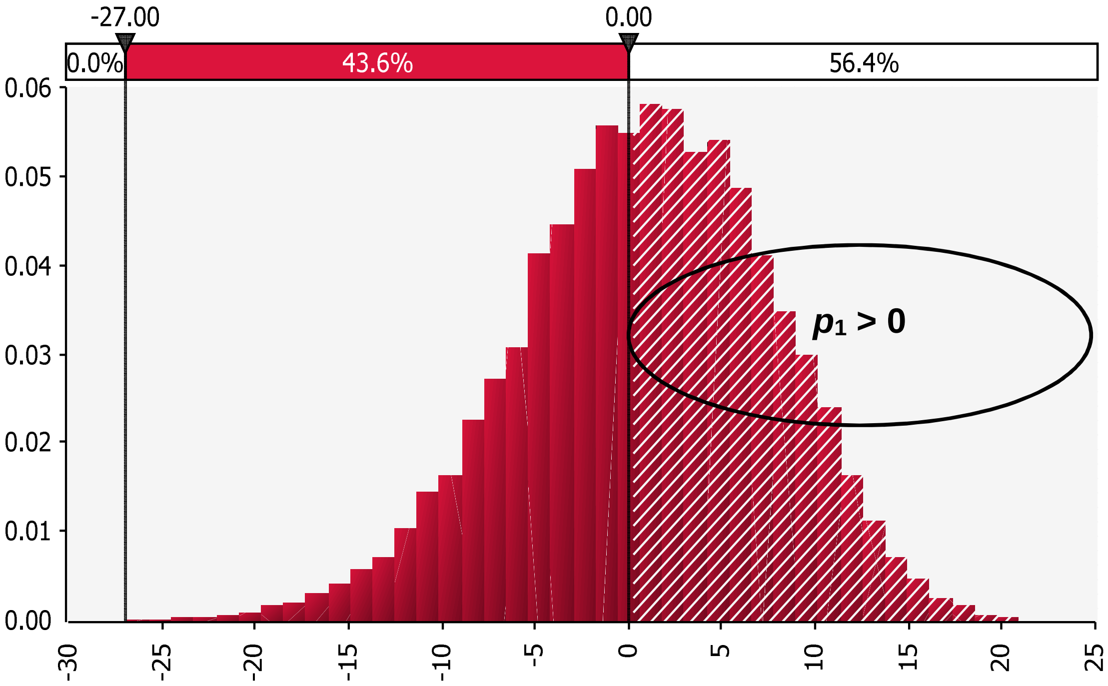


Fig. 4-3: *Fr 13* simulation of risk factor for heat-up of raw milk containing *MAP* with 10,000 simulated scenarios. To the R of the figure is shown the 5,637 failures in heat-up of raw milk ($p_1 > 0$)

Significantly however, a major advantage of the *Fr 13* framework is that each scenario can be readily identified separately, and the value of each parameter in combination individually ascertained. To illustrate this, 10 of the 5,637 failures in raw milk heat-up ($p_1 > 0$) together with the corresponding related impact these had on holding and overall pasteurizer outcome as survival of *MAP* are summarised as Table 4-3. (For completeness of the microbiological model corresponding milk cool-down is also shown in the table).

Table 4-3: Ten failures (of 5,637) in heat-up of raw milk ($p_1 > 0$) with corresponding outcomes in milk holding and thermal inactivation of *MAP* in the global *Fr 13* microbiological model for pasteurization of raw milk (p_2). For completeness corresponding milk cool-down (p_3) is also shown

Parameter	**Scenario in heat-up of raw milk**									
	1	2	3	4	5	6	7	**8**	9	10
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4.09†	4.21	3.9	4.25	4	4.04	4.09	**4.13**	4.2	4.02
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.85	5.96	6.26	6.02	6.14	6.09	6.05	**6.18**	6.02	6.11
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.21	4.15	3.93	4.12	4.02	4.05	4.09	**4.01**	4.12	4.05
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	87.11	81.08	90.39	85.44	79.31	80.36	93.00	**91.59**	84.39	85.75
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.84	6.09	5.98	5.55	6.06	6.21	6.46	**6.14**	5.73	5.99
$C_{p,w\ PHE\ 1\text{-}1}$ (kJkg^{-1}K^{-1})	4.26	4.23	4.15	4.22	3.77	3.94	4.02	**4.18**	4.17	4.18
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	65.67	65.65	65.65	65.61	65.61	65.57	65.53	**65.46**	65.46	65.36
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	34.95	22.16	29.12	20.50	12.84	18.36	34.51	**32.42**	20.92	25.04
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	1,519	1,519	1,519	1,519	1,519	1,519	**1,519**	1,519	1,519
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.3	1.32	1.39	1.33	1.36	1.35	1.34	**1.37**	1.33	1.35
$\mathrm{Re}_{PHE\ 1\text{-}1}$	125,575	127,925	134,179	129,071	131,660	130,665	129,640	**132,510**	129,191	131,013
$t_{r,\ PHE\ 1\text{-}1}$ (s)	98.27	96.49	91.92	95.63	93.69	94.40	95.15	**93.08**	95.49	94.10
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,436	2,513	2,730	2,551	2,643	2,609	2,574	**2,672**	2,558	2,624
p_1	10.79	10.81	10.82	10.87	10.88	10.93	10.99	**11.08**	11.09	11.22
Heat-up criteria	F††	F	F	F	F	F	F	**F**	F	F
Corresponding outcome in milk holding and thermal inactivation of *MAP*										
$T_{m,HT\ 1\text{-}2}$ (^{O}C)	65.67	65.65	65.65	65.61	65.61	65.57	65.53	**65.46**	65.46	65.36
$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.85	5.96	6.26	6.02	6.14	6.09	6.05	**6.18**	6.02	6.11
$L_{HT\ 1\text{-}2}$ (m)	10.58	10.58	10.58	10.58	10.58	10.58	10.58	**10.58**	10.58	10.58
$D_{HT\ 1\text{-}2}$ (m)	0.1	0.1	0.1	0.1	0.1	0.1	0.1	**0.1**	0.1	0.1
$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	72	72	72	72	72	72	**72**	72	72
$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	1.2	1.2	1.2	1.2	1.2	1.2	**1.2**	1.2	1.2
$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	7.7	7.7	7.7	7.7	7.7	7.7	**7.7**	7.7	7.7
$t_{m,\ HT\ 1\text{-}2}$ (s)	14.30	14.04	13.38	13.92	13.63	13.74	13.85	**13.55**	13.9	13.7
$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1,008	1,008	1,008	1,008	1,008	1,008	1,008	**1,008**	1,008	1,008
$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.74	0.75	0.79	0.76	0.78	0.77	0.76	**0.78**	0.76	0.77
$D_{t,\ HT\ 1\text{-}2}$ (s)	2.46	2.47	2.47	2.48	2.48	2.49	2.51	**2.53**	2.53	2.56
$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	0.94	0.93	0.93	0.93	0.93	0.92	0.92	**0.91**	0.91	0.9
$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$	5.81	5.69	5.42	5.61	5.49	5.51	5.52	**5.36**	5.49	5.34
p_2	-3.60	-1.45	3.52	0.01	2.18	1.84	1.61	**4.63**	2.2	4.88
Pasteurizer criteria	NF	NF	F	F	F	F	F	**F**	F	F
Corresponding outcome in milk cool-down										
$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)	65.67	65.65	65.65	65.61	65.61	65.57	65.53	**65.46**	65.46	65.36
$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.85	5.96	6.26	6.02	6.14	6.09	6.05	**6.18**	6.02	6.11
$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	4.21	4.15	3.93	4.12	4.02	4.05	4.09	**4.01**	4.12	4.05
$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-7.95	-7.86	-8.15	-8.35	-7.68	-8.19	-7.75	**-7.96**	-7.88	-8.03
$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	7.98	8.77	8.93	8.63	8.34	8.5	8.46	**8.22**	8.26	8.95
$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.67	3.23	3.16	3.53	3.3	3.23	3.28	**3.46**	3.13	3.68
$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)	4.09	4.21	3.9	4.25	4	4.04	4.09	**4.13**	4.2	4.02
$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	43.89	45.8	45.79	41.45	47.48	47.21	47.08	**45.41**	50.91	38.04
$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	1,519	1,519	1,519	1,519	1,519	1,519	**1,519**	1,519	1,519
p_3	0.3	3.31	-4.54	4.28	-1.93	-1.04	0.18	**1.24**	2.96	-1.41
Cool-down criteria	F	F	NF	F	NF	NF	F	**F**	F	NF

† All tabulated values are reproduced from r-MC sampling; it is not implied they are measured to this significance

†† F = Fail, NF = Not Fail, of particular unit-operation criteria

For example failure 8 (column 9, **bolded values**) of the table shows that an inlet raw milk temperature = 4.13 ^{O}C in combination with milk flow = 6.18 kg s^{-1}, $C_{p,m\ PHE\ 1\text{-}1}$ = 4.01 kJ kg^{-1} K^{-1}, $T_{i,w\ PHE\ 1\text{-}1}$ = 91.59 ^{O}C, $m_{w,\ PHE\ 1\text{-}1}$ = 6.14 kg s^{-1} and $C_{p,w\ PHE\ 1\text{-}1}$ = 4.18 kJ kg^{-1} K^{-1}, is heated to a milk outlet temperature = 65.46 ^{O}C, $T_{o,w\ PHE\ 1\text{-}1}$ = 32.42 ^{O}C, $q_{PHE\ 1\text{-}1}$ = 1,519 kJ s^{-1}, $v_{m,\ PHE\ 1\text{-}1}$ = 1.37 m s^{-1}, Re$_{PHE\ 1\text{-}1}$ = 132,510 (dimensionless), $t_{r,\ PHE\ 1\text{-}1}$ = 93.08 s and $\Delta P_{PHE\ 1\text{-}1}$ = 2,671.90 N m^{-2}, and resulted in p_1 = 11.08, a fail. This in turn is seen to correspondingly have led to a fail in holding to inactivate *MAP* highlighted by p_2 = 4.63. This means unwanted levels of survival of MAP in the treated milk. (It can also be seen in column 9 of the table that the milk is not cooled down to 4 ^{O}C plus the - 2 % *tolerance* as indicated by p_3 = 1.24).

Pointedly however, it can be seen from Table 4-3 that not all 10 selected fail scenarios in $PHE_{1\text{-}1}$ led to corresponding failure in $HT_{1\text{-}2}$ and failure to inactivate *MAP*. For example, failure scenario 3 (column 4) shows a failure in $PHE_{1\text{-}1}$ (p_1 = 10.82) led to a failure in $HT_{1\text{-}2}$ with survival of unwanted *MAP* (p_2 = 3.52) (and a corresponding not a failure in $PHE_{2\text{-}3}$ since p_3 = -4.54 i.e. $p_3 < 0$).

These corresponding risk factor data of Table 4-3 are conveniently summarized in Fig. 4-4. In the figure the value of the heat-up risk factor is immediately seen to be constant at $p_1 \sim 10.95$, demonstrating the 10 selected failures to raise the raw milk temperature to 72 ^{O}C (plus 2 % *tolerance*). The risk factor for holding and thermal inactivation of *MAP* however varies between $-3.60 \leq p_2 \leq 4.88$, demonstrating a swing away from success in scenarios 1 and 2 to a failure to meet the Regulatory log$_{10}$ reduction = 5.5 (plus 2 % *tolerance*) in viable numbers of *MAP* in all other cases (highlighted by $p_2 > 0$). (Whilst that for cool-down is $-4.54 \leq p_3 \leq 3.31$, demonstrating a swing away from success in scenarios 3, 5, 6 and 10 to fail to meet the Regulatory milk cool-down temperature of 4 ^{O}C (plus 2 % *tolerance*) in all other cases as highlighted by $p_3 > 0$).

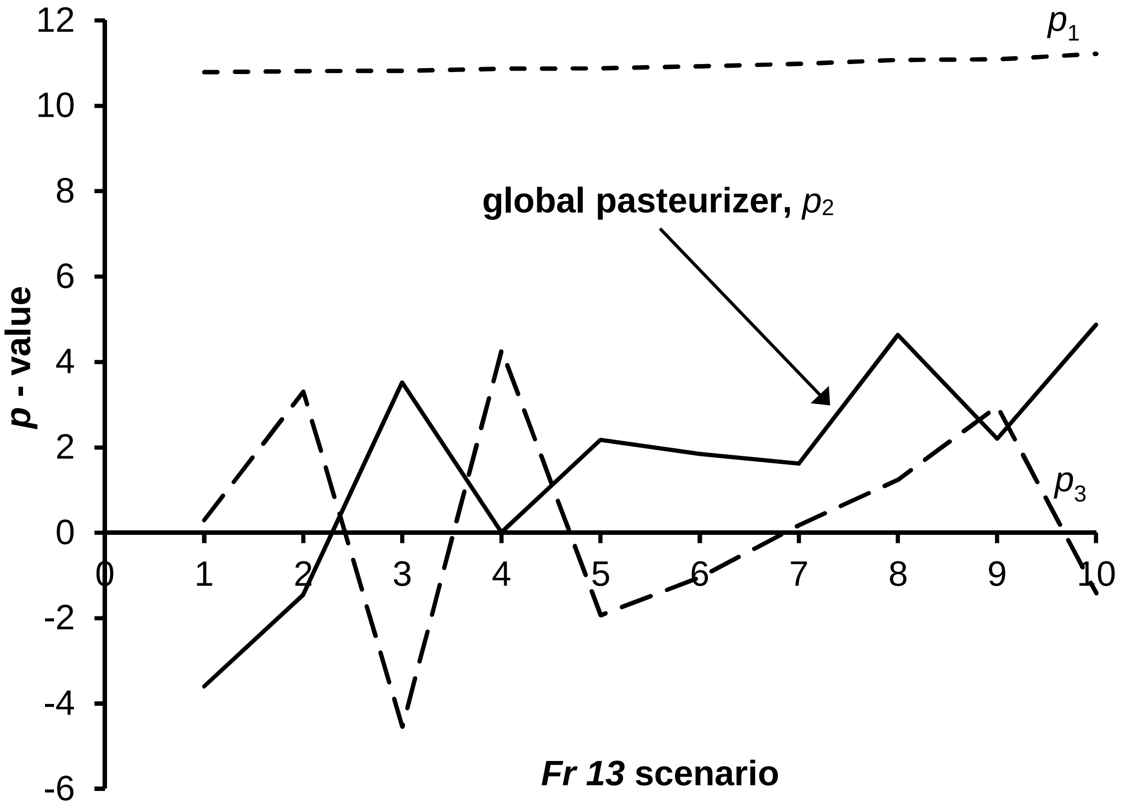


Fig. 4-4: Summary of corresponding risk factor data of Table 4-3 highlighting that of the initial 10 selected failures to heat-up the raw milk ($p_1 > 0$) eight failed in the overall global pasteurizer ($p_2 > 0$) to reduce viable *MAP* numbers. For completeness corresponding milk cool-down (p_3) is also shown

The global pasteurizer outputs are defined by the stream leaving $HT_{1\text{-}2}$ and clearly show that the pasteurizer fails to meet the reduction in viable *MAP* in eight (8) scenarios, namely: 3, 4, 5, 6, 7, 8, 9 and 10. That is, the result of an initial 10 failures in the first unit-operation translates to eight (8) fails in the global pasteurizer.

An alternative (visual) way to gain an immediate overall picture of the nature of the pasteurizer (adapted from Zou and Davey, 2016) is to display these 10 *Fr 13* corresponding failures as simply F = Fail, NF = Not Fail, Table 4-4. In the table, the F and corresponding NF of scenario 1 (row 3), and F and corresponding F of scenario 4 (row 6) of Table 4-3, respectively the probabilistic risk factor for heat-up and holding for thermal inactivation, p_1 and p_2 can clearly be seen.

Table 4-4: Visual summary of the 10 failures in heat-up of raw milk of Table 4-3 (p_1) and the corresponding eight global *Fr 13* microbiological failures (p_2) to pasteurize the raw milk containing *MAP*

Scenario	**p_1 (PHE$_{1\text{-}1}$)**	**p_2 (HT$_{1\text{-}2}$)**
1	F	NF†
2	F	NF
3	F	F
4	F	F
5	F	F
6	F	F
7	F	F
8	F	F
9	F	F
10	F	F

† NF = Not Fail; F = Fail with unwanted survival of *MAP* in the treated milk.

An extension of Table 4-4 would show all 5,637 x F in $PHE_{1\text{-}1}$, and all corresponding 575 x F in $HT_{1\text{-}2}$ (and 1,831 corresponding F in $PHE_{2\text{-}3}$). However, because failure of the pasteurization of the raw milk is characterized by the treated stream leaving $HT_{1\text{-}2}$ with unwanted survival of *MAP* ($p_2 > 0$), it is concluded there were 575 failures in the pasteurization simulations to reduce the number of viable *MAP* by the design reduction of $\log_{10} = 5.5$, plus 2 % *tolerance*.

Importantly, not all failures in $PHE_{1\text{-}1}$ predict failure in $HT_{1\text{-}2}$. The situation is actually highly mixed. To highlight this, Table 4-5 presents a further selected 10 mixed scenarios of $PHE_{1\text{-}1}$ together with the corresponding outcomes these had in $HT_{1\text{-}2}$ (and $PHE_{2\text{-}3}$).

Table 4-5: Ten (10) mixed scenarios in heat-up of raw milk with corresponding outcomes in milk holding and thermal inactivation of *MAP* and cool-down of the heated milk in the global *Fr 13* microbiological model for pasteurization. For completeness corresponding milk cool-down (p_3) is also shown

Parameter	**Scenario in heat up of raw milk**									
	1	2	**3**	**4**	5	6	7	8	9	**10**
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4.43[†]	3.98	**4.20**	**4.16**	4.13	4.28	4.12	4.19	4.07	**4.12**
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.78	5.81	**6.34**	**5.49**	6.19	5.95	5.43	5.63	5.72	**5.87**
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.16	4.14	**3.94**	**4.09**	4.13	4.17	3.88	3.83	3.8	**4**
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	91.12	85.66	**82.80**	**88.6**	91.76	86.93	87.35	94.6	89.43	**96.77**
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.99	5.9	**6.62**	**6.47**	6.23	6.43	6.61	6.59	6.54	**5.38**
$C_{p,w\ PHE\ 1\text{-}1}$ (kJkg^{-1}K^{-1})	4.43	3.91	**4.18**	**3.9**	4.25	4.19	4.18	4.19	3.96	**4.67**
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	67.56	67.17	**64.95**	**71.79**	63.53	65.45	76.32	74.59	73.99	**68.82**
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	33.93	19.84	**27.85**	**28.35**	34.32	30.64	32.32	39.58	30.88	**36.32**
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	1,519	**1,519**	**1,519**	1,519	1,519	1,519	1,519	1,519	**1,519**
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.28	1.29	**1.41**	**1.22**	1.37	1.32	1.2	1.25	1.27	**1.30**
$\mathrm{Re}_{PHE\ 1\text{-}1}$	124,759	125,025	**135,836**	**119,882**	132,093	127,673	119,993	123,910	125,648	**127,086**
$t_{r,\ PHE\ 1\text{-}1}$ (s)	99.49	99.06	**90.70**	**104.63**	92.91	96.65	105.79	101.99	100.39	**97.91**
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,380	2,400	**2,794**	**2,177**	2,686	2,506	2,126	2,267	2,330	**2,444**
p_1	8.16	8.71	**11.8**	**2.3**	13.76	11.09	-4	-1.6	-0.77	**6.42**
Heat-up criteria	F[††]	F	**F**	**F**	F	F	NF	NF	NF	**F**
	Corresponding outcome in milk holding and thermal inactivation of *MAP*									
$T_{m,HT\ 1\text{-}2}$ (^{O}C)	67.56	67.17	**64.95**	**71.79**	63.53	65.45	76.32	74.59	73.99	**68.82**
$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.78	5.81	**6.34**	**5.49**	6.19	5.95	5.43	5.63	5.72	**5.87**
$L_{HT\ 1\text{-}2}$ (m)	10.58	10.58	**10.58**	**10.58**	10.58	10.58	10.58	10.58	10.58	**10.58**
$D_{HT\ 1\text{-}2}$ (m)	0.1	0.1	**0.1**	**0.1**	0.1	0.1	0.1	0.1	0.1	**0.1**
$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	72	**72**	**72**	72	72	72	72	72	**72**
$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	1.2	**1.2**	**1.2**	1.2	1.2	1.2	1.2	1.2	**1.2**
$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	7.7	**7.7**	**7.7**	7.7	7.7	7.7	7.7	7.7	**7.7**
$t_{m,\ HT\ 1\text{-}2}$ (s)	14.47	14.41	**13.20**	**15.19**	13.53	14.07	15.33	14.79	14.56	**14.23**
$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1,007	1,007	**1,008**	**1,004**	1,009	1,008	1,002	1,003	1,003	**1,006**
$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.73	0.73	**0.80**	**0.7**	0.78	0.75	0.69	0.72	0.73	**0.74**
$D_{t,\ HT\ 1\text{-}2}$ (s)	1.93	2.03	**2.71**	**1.11**	3.25	2.53	0.62	0.77	0.84	**1.64**
$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	1.2	1.14	**0.85**	**2.07**	0.71	0.91	3.73	2.98	2.76	**1.41**
$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$	7.51	7.11	**4.88**	**13.65**	4.16	5.55	24.84	19.13	17.43	**8.70**
p_2	-34.59	-27.25	**13.26**	**-146.23**	26.33	1.02	-349.66	-245.86	-214.85	**-56.20**
Pasteurizer criteria	NF	NF	**F**	**NF**	F	F	NF	NF	NF	**NF**
	Corresponding outcome in milk cool-down									
$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)	67.56	67.17	**64.95**	**71.79**	63.53	65.45	76.32	74.59	73.99	**68.82**
$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.78	5.81	**6.34**	**5.49**	6.19	5.95	5.43	5.63	5.72	**5.87**
$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	4.16	4.14	**3.94**	**4.09**	4.13	4.17	3.88	3.83	3.8	**4**
$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-7.83	-7.51	**-8.23**	**-7.87**	-7.83	-7.83	-8.13	-8.68	-8.71	**-8.13**
$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8	7.89	**8**	**7.99**	8.34	8.45	8.67	8.13	8.34	**8.43**
$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.56	3.55	**3.35**	**3.08**	3.66	3.33	3.4	3.39	3.36	**3.45**
$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)	4.43	3.98	**4.2**	**4.16**	4.13	4.28	4.12	4.19	4.07	**4.12**
$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.51	46.68	**48.4**	**53.93**	41.96	46.08	43.49	46.46	45.58	**44.06**
$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	1,519	**1,519**	**1,519**	1,519	1,519	1,519	1,519	1,519	**1,519**
p_3	8.78	-2.52	**3.1**	**1.98**	1.29	5.11	1.04	2.78	-0.33	**1.09**
Cool-down criteria	F	NF	**F**	**F**	F	F	F	F	NF	**F**

[†] All tabulated values are reproduced from r-MC sampling; it is not implied they are measured to this significance.

[††] F = Fail, NF = Not Fail, of particular unit-operation criteria

It can be seen from Table 4-5 that not all 10 selected scenarios in PHE_{1-1} are failures (there are seven, namely scenarios 1, 2, 3, 4, 5, 6 and 10). These in turn led to three corresponding failures ($p_2 > 0$) in HT_{1-2} (scenarios 3, 5 and 6) and seven (7) non-failures. For corresponding failures, failure 3, column 4 (**bolded values** of the table shows F in PHE_{1-1} ($p_1 = 11.8$) which in turn resulted in F in global pasteurizer output (HT_{1-2}) ($p_2 = 13.26$) and a subsequent F in cool-down of the pasteurizer characterized by $p_3 = 3.1$). However, failures 4 and 10, columns 5 and 11 (**bolded value**) of the table shows F in PHE_{1-1} which in turn resulted in NF in HT_{1-2} (and subsequent F in cool-down of the pasteurizer PHE_{2-3}). For example for failure 4, the table (column 5) shows F in PHE_{1-1} ($p_1 = 2.3$) which in turn resulted in NF in global pasteurizer output HT_{1-2} ($p_2 = -146.23$) (and subsequent F in cool-down of the pasteurizer $p_3 = 1.98$).

In order to illustrate the random nature and pattern displayed in these 10 mixed scenarios of Table 4-5 a visual summary is presented in Table 4-6; the F and corresponding NF of scenarios 4 and 10 of Table 5, can be seen.

Table 4-6: Chromatic summary of the 10 mixed scenarios for heat-up (p_1) of Table 4-5 and corresponding three global *Fr 13* microbiological failures ($p_2 > 0$) to pasteurize the raw milk containing *MAP*

Scenario	p_1 (PHE_{1-1})	p_2 (HT_{1-2})
1	F	NF[†]
2	F	NF
3	F	F
4	F	NF
5	F	F
6	F	F
7	NF	NF
8	NF	NF
9	NF	NF
10	F	NF

[†] NF = Not Fail, F = Fail, with unwanted survival of *MAP* in the treated milk.

An advantage of Table 4-6 is that it permits an immediate overall picture of the pasteurizer outcome behaviour to be garnered.

4.6 Discussion

4.6.1 *Fr 13* simulations

The *Fr 13* simulations of the global model for pasteurization of raw milk proved to be stable, and because mean simulation outputs agreed with SVA values it is concluded that results were free of computational and programmable errors. Importantly (to reiterate), it is not to be inferred that the numerical values shown (as significant figures) in Tables 4-2 a, b and c through 4-3 and Table 4-5 are actually achieved; these values are those sampled randomly in the r-MC simulations.

It is clear from the data of Tables 4-4 and 4-6 that not all failed scenarios in heat-up will lead to failure in holding of the heated milk and inactivation of sufficient numbers of viable *MAP* as a consequence of the system naturally occurring stochastic fluctuations in operations. It is notable that this pasteurizer outcome behaviour might not have been expected, and might not have come to light with alternate risk and hazard assessments - there is no known reporting of this in any event.

The microbiological failure of the pasteurizer is characterized by the milk leaving $HT_{1\text{-}2}$, i.e. all $p_2 > 0$; the global process is nevertheless an integrated 3-step. Overall, if each simulation is, reasonably, considered a daily batch-continuous pasteurization, on average there would be (5.75/100 days x 365.25 days/year =) 21 failures each year to meet the required $\log_{10}$ reduction = 5.5 (plus 2 % *tolerance*) in viable numbers of *MAP* that could not be attributed to human error or faulty fittings (Abdul-Halim and Davey, 2016; 2015; Davey and Cerf, 2003). However, the distribution of these failures would not be expected to be equally spaced in time.

It can be concluded therefore that apparent steady-state pasteurization of raw milk is actually a mix of successful operations (94.3 %) together with unsuccessful ones (5.7 %).

4.6.2 Mitigating vulnerability to *Fr 13* microbiological failures

Those parameters controlling the pasteurizer failure synthesis of raw milk containing *MAP* can be identified using the Spearman Rank correlation coefficient - a measure of statistical dependence between two variables (Snedecor and Cochran, 1989), Table 4-7. This is readily available in *@Risk*. As is seen in the table there are two controlling parameters; these are the mass flow rate of raw milk entering the pasteurizer, $m_{m,\,PHE\ 1\text{-}1}$ and the specific heat of the milk, $C_{p,m\ PHE\ 1\text{-}1}$. These results show there is a strong correlation (0.69 and 0.68 respectively) between these and the risk factor for milk-heat-up, p_1; whereas the inlet milk temperature in shows a significantly lower correlation (0.04).

Table 4-7: Spearman Rank correlation coefficient (Snedecor and Cochran, 1989) for the controlling parameters in raw milk heat-up on the heating risk factor p_1

Parameter	Coefficient
$m_{m,\ PHE\ 1\text{-}1}$	+ 0.69
$C_{p,m\ PHE\ 1\text{-}1}$	+ 0.68
$T_{i,m\ PHE\ 1\text{-}1}$	- 0.04

The conclusion is that the raw milk flow entering the pasteurizer is overriding on pasteurizer outcome behaviour, with inlet temperature playing a less controlling role in overall microbiological failure of the pasteurizer with unwanted survival of viable *MAP*. Because the specific heat of the raw milk is a thermodynamic property and is governed by its temperature it cannot be readily controlled, it is apparent that vulnerability to *Fr 13* failure can best be mitigated by installing precise safety-integrity-level mass flow control on the raw milk input stream. In practical terms, an increased control means reducing the variance (stdev) on the pasteurizer parameters. To investigate the impact of any variance, repeat simulations were carried out for a range values $0 \leq \text{stdev} \leq 12$, % about the mean on each of the six (6) input raw milk probability functions (Table 2 a) with a constant *tolerance* = 2 %. The results are presented as Fig. 4-5.

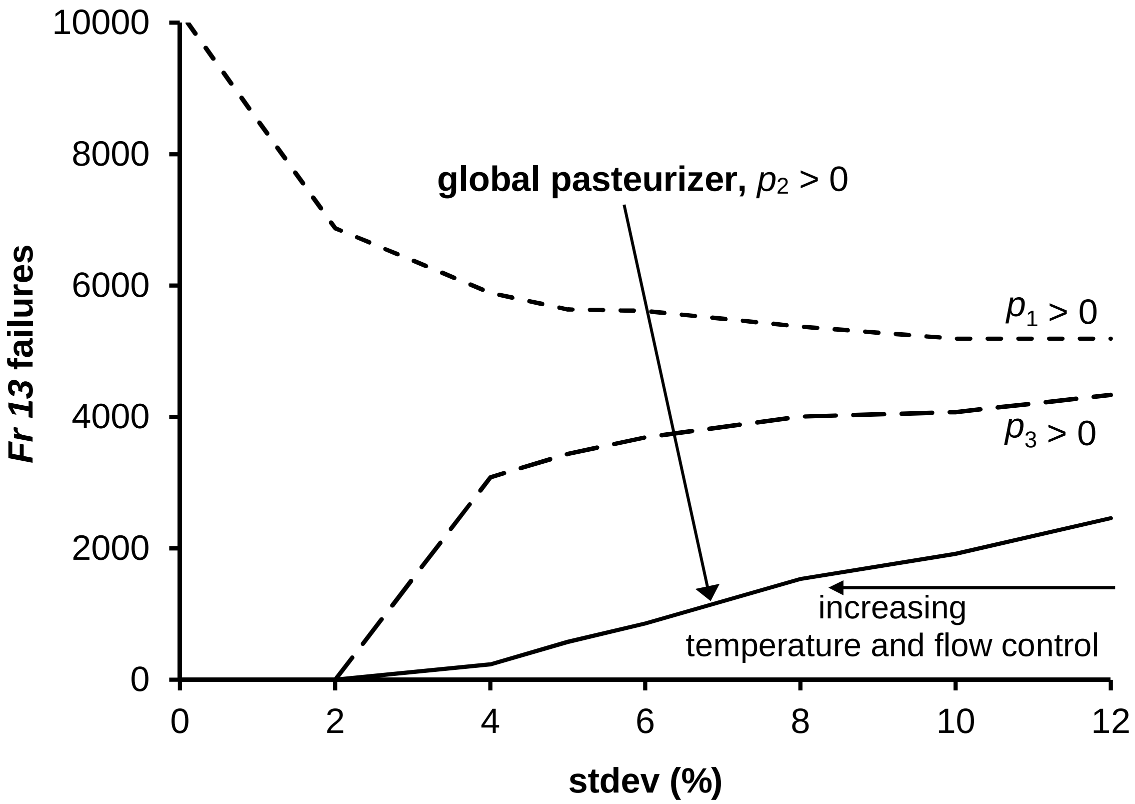


Fig.4-5: Impact of stdev on the number of failures in pasteurization of raw milk containing *MAP* per 10,000 scenarios for each of heat-up ($p_1 > 0$), holding and thermal inactivation of *MAP* ($p_2 > 0$), and; cool-down ($p_3 > 0$) with constant *tolerance* = 2 % on each unit-operation. Pasteurizer failure is characterized by the number of $p_2 > 0$

It can be seen in the figure that decreasing the stdev of fluctuations about the mean value with improved controls, increases failures in heat-up (p_1) and decreases meaningfully the number of *Fr 13* pasteurization failures overall (p_2). The number of failure to cool-down the milk is also seen to be reduced, p_3. Conversely, as control becomes less precise (increasing stdev) the number of failures increases. It appears that these overall global pasteurizer failures, p_2, will approach a constant long term failure rate of ~ 2.5 %.

This information could be readily used to guide pasteurizer control. Precise mass flow control in the pasteurizer could be achieved through application of a Safety Integrity Level (SIL) assessment – a formal classification method for performance of a global system (Capewell and Fernie, 2000; Foord et al., 2004).

A practical value of *tolerance* is included in the risk factors, respectively, Eqs. (4-31), (4-33) and (4-35), to ensure that the minimum reduction in viable *MAP* contaminants will be met. This is another way of stating a level of safety or reliability in the pasteurizer operation. Clearly, this value cannot be too large. If the value is too large it can result in over-treatment of the milk and be wasteful in terms of energy and potential irreversible loss of nutrition due to denaturation (e.g. Davey and Cerf, 1996; Burton, 1988).

To investigate the impact of *tolerance* repeat simulations were carried out for a range of values $0 \le tolerance \le 12$, % at constant stdev = 5 % on each of the pasteurizer input probability distributions (Table 2). Results are presented as Fig. 4-6.

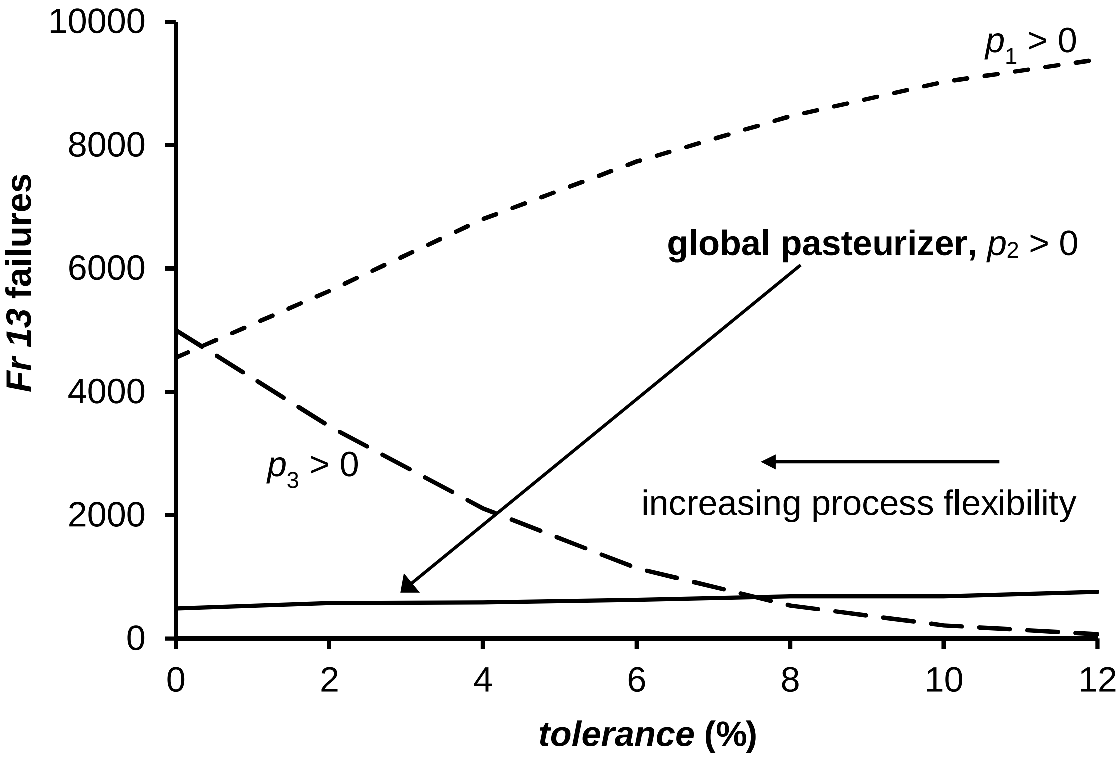


Fig. 4-6: Comparative summary of the impact of *tolerance* on the number of failures in pasteurization of raw milk containing *MAP* per 10,000 scenarios for each of heat-up ($p_1 > 0$), holding and thermal inactivation of *MAP* ($p_2 > 0$), and; cool-down ($p_3 > 0$) with stdev = 2 % in each unit-operations. Pasteurizer failure is characterized by the number of $p_2 > 0$

As expected, it is seen in Fig. 4-6 that increasing *tolerance* with a fixed stdev = 5 % increases the number of overall *Fr 13* failures in heat-up (p_1), but does not impact meaningfully the global pasteurizer output for thermal inactivation of *MAP* (p_2); and decreases the number of overall *Fr 13* pasteurization failures in cool-down (p_3). For example in $HT_{1\text{-}2}$ at a *tolerance* = 0 %, the number of failures in the global pasteurizer is predicted to be p_2 = 4.86 % and at a *tolerance* = 12 %, p_2 = 7.56 %. However, in $PHE_{2\text{-}3}$ at a *tolerance* = 0 % the number of failures is predicted to be p_3 = 50 % and this would be expected to fall to zero failure rate at a *tolerance* ~ 12 %.

Practically, increasing this *tolerance*, or safety, will permit an increased flexibility in process operations. However, the most suitable value will need to be decided based on accumulated process experience and expert knowledge (Davey, 2010; 2011). The impact however on mitigating failures can be readily tested in the *Fr 13* global microbiological synthesis.

4.6.3 Unexpected accumulations in the integrated 3-step synthesis

The simulation results of Table 4-5 (respectively, rows 17, 33 and 45) that are presented pictorially as Fig. 4-4 reveal an unanticipated pattern in the impact of accumulation of *Fr 13* failure in the global pasteurizer. In Fig. 4-4 this unanticipated pattern is evident as swings in the magnitude of p in either the positive or negative direction resulting in an array of, respectively, F and NF.

It is inferred therefore that in a daily operation of the pasteurizer it can actually fluctuate from an initial ‘fail’ to an overall pasteurization success i.e. ‘not-failure’ and actually result in a reduction of $\log_{10}$ = 5.5 (plus 2 % *tolerance*) in the number of viable pathogens as *Mycobacterium avium* subsp. *paratuberculosis* (e.g. scenarios 1 and 2 in Table 4-5 and scenarios 1, 2, 4, 7, 8, 9 and 10 in Table 4-7).

This appears, initially at least, to be counter-intuitive.

This outcome can be understood however for the reasons that where the raw milk is not heated to the (Regulatory) temperature of 72 ^{O}C (plus 2 % *tolerance*) in $PHE_{1\text{-}1}$ (fail), if it is held sufficiently long enough in $HT_{1\text{-}2}$ as a consequence of advantageous random fluctuation in combined milk flow and temperature in the fixed holding tube, the $\log_{10}$ reduction in *MAP* can result (e.g. scenarios 1 and 2 in Table 4-5 and scenarios 1, 2, 4, 7, 8, 9 and 10 in Table 4-7). These findings are new quantitative insights into microbiological processing, and are not available from alternate risk and hazard methods.

The pictorial presentation of Fig. 4-4 could be extended to illustrate all 5,637 failures in $PHE_{1\text{-}1}$, corresponding 575 failures in $HT_{1\text{-}2}$ and corresponding 3,442 failures in $PHE_{2\text{-}3}$ to aid insight.

An overriding step in a rigorous *Fr 13* study however is to prudently establish the distributions used to mimic the naturally occurring fluctuations in input parameters and to unambiguously define failure.

4.6.4 Establishing distributions for inputs and defining pasteurizer failure

The distributions that can be used to mimic fluctuations in the parameters in the pasteurization are constrained by practical considerations i.e. expected value and range possible (i.e. maximum, minimum), and variance about a mean. There are some 40 different distribution types that are available (*see* for example Vose, 2008). The choice of distribution is best based on expert knowledge or opinion or published (empirical) data. It is important only that the input (and consequent) output distribution covers all practically possible values, including chance accumulations of naturally occurring fluctuations that can lead to failure (Davey et al., 2015).

In the absence of specific literature or unconditional data, **TruncatedNormal** distribution is used for pasteurization. However, our experimentation with other distribution types including **BetaSubjective** (Cerf and Davey, 2001; Davey and Cerf, 2003), **Pert** (Davey et al., 2015) and **Triangle** resulted in similar failure rates i.e. the global failure rate in pasteurization of raw milk containing *MAP* remained more or less at ~ 5.75 %.

With these truncated distributions a 3 x stdev about the mean is chosen, because 99.73 % of the r-MC values the parameter can take will fall in this interval (Sullivan, 2004; Snedecor and Cochran, 1989; Vose, 2008). Practical considerations and constraints might apply elsewhere. For example a 2 x stdev will result in 95.45 % (Davey, 2015) of all values that parameter can take, and 1 x stdev, 68.2 % (Sullivan, 2004).

The definition of failure in the *Fr 13* pasteurization work of Chandrakash et al. (2015) is based on physical process equipment i.e. whether the raw milk is heated to the design temperature, or held in the holding tube for a minimum time, or, cooled to the output minimum temperature. Importantly however, because they could not directly demonstrate that all $p_3 \leq 0$ could be automatically interpreted as the milk is safely pasteurized, they concluded that it is not sufficient to define pasteurizer failure in terms of equipment performance. They argued rather that failure should be defined in terms of unwanted survival of viable microbial contaminants and - as reduction in numbers is the material purpose of the pasteurization. (This argument might also be made for much of foods processing regulations). Notably therefore, the overall failure rate found in the present work of (p_2 =) 5.75 % appears meaningfully lower than that reported by Chandrakash et al. (2015) of 12.51 %, especially given identical equipment ($PHE_{1\text{-}1}$, $HT_{1\text{-}2}$ and $PHE_{2\text{-}3}$) has been used in both studies to heat raw milk from 4 to 72, ^{O}C hold for 15 s and cool to 4 ^{O}C.

This is a finding that cannot be generalized presently in any manner. It is reassuring however that with the microbiological simulations with the same equipment the Regulatory (Juffs and Deeth, 2007; Hammer et al., 2014; McDonald et al., 2005) $\log_{10} = 5.5$ reduction in the widely recognised raw milk pathogen *MAP* is achieved.

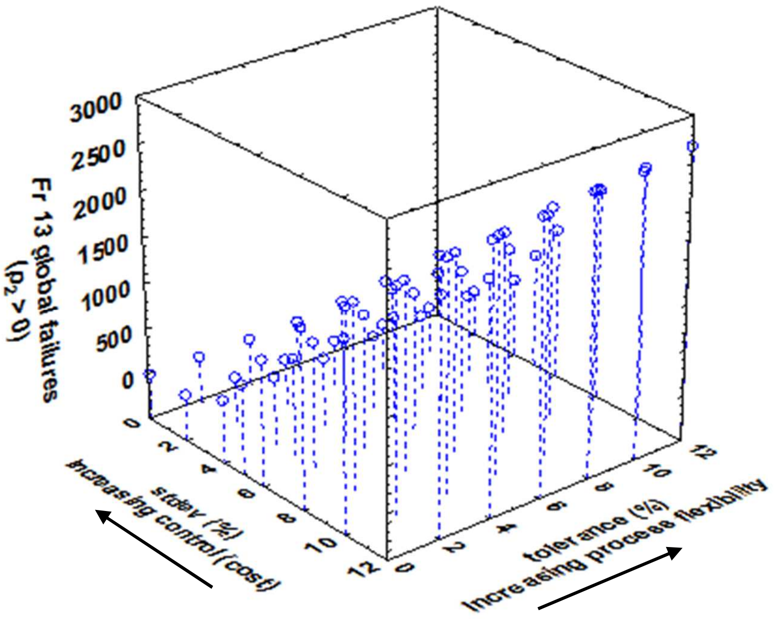
Significantly, this finding suggests that the Regulatory standard is in fact well-predicated.

4.6.5 Presentation of overall findings from *Fr 13* results

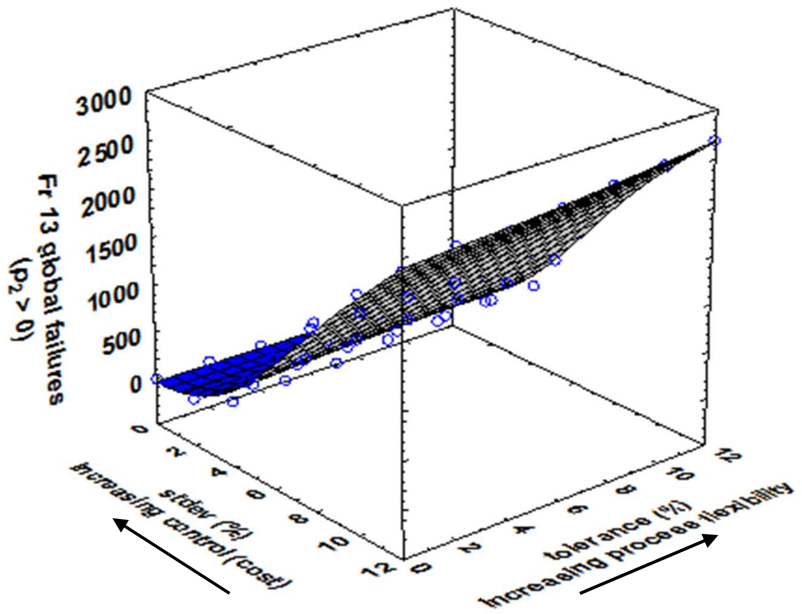
Although a major advantage in quantitatively identifying risk scenarios in *Fr 13* methodology is that these can be then used to make informed decisions about risks and ways to mitigate these, how 'best' to present risk data is a difficulty raised in general by the Blackett Review (Anon., 2012) but more specifically for *Fr 13* analyses by Zou and Davey (2016), Abdul-Halim and Davey (2016; 2015) and Davey (2015).

For the present pasteurization data, an overall visualization can be gained with a traditional 3-D presentation as both scatter and surface, plots, Fig. 4-7.

From the figure the combined impact of the value of *tolerance* (%) i.e. process flexibility and stdev (process control, cost) can be readily seen on global failure (value of $p_2 > 0$) for n = 64 selected scenarios. The figure is generated using commercial software (Statistica^{TM}, version 10, StatSoft Inc.). In the scatter plot (Fig. 4-7, Part a), it can be seen that with decreasing *tolerance* combined with decreasing stdev, the resulting number of failures decreases (lower L of the figure), indicating low likelihood of pasteurization failure. It can be seen also however that the most likely pasteurization failures will occur with greater *tolerance* combined with greater stdev (upper R of figure). These trends are clearly seen in the surface plot (Fig. 4-7, Part b). (The surface cannot be reliably extrapolated however).



a) Scatter Plot



b) Surface Plot

Fig. 4-7: Summary 3-D plot (n = 64) of the impact of *tolerance* (increasing process flexibility) and stdev (increasing process control and cost) on the number of *Fr 13* global microbiological failures to reduce viable *MAP* ($p_2 > 0$) per 10,000 scenarios

However this 3-D visualization does not actually demonstrate that there are nine distributions involved (*see* Fig. 4-2) and therefore might be of only limited value. A series of these 3-D plots animated in overlay could however be used to rapidly reflect the impact on the global pasteurizer of changes to input distributions, and thereby provide a focal point for study. Interestingly, the nature of the overall pasteurization risk factor values (p_2) does not appear recognisably random in Fig. 4-7; this is thought due, principally, to the large number (n = 64) of data plotted.

A major advantage of tabular presentations (e.g. Tables 4-5 and 4-7) is that the value of each combined contributing parameter that could lead to a microbiological failure can readily be identified, isolated and studied - although the table size increases significantly with increases in the number of input distributions. This detailed information can be used in second-tier studies (Chandrakash et al., 2015; Davey, 2015; 2011; Abdul-Halim and Davey, 2016; 2015; Zou and Davey, 2016) to look at the impact that changes to physical plant can have on vulnerability to process failure, and to propose process intervention strategies that might mitigate (unexpected) failures. This is important because vulnerability to impact of random fluctuations on failure cannot be mitigated by further study (or knowledge) of the system (Davey, 2011). An alternative presentation is a summary matrix, Table 4-8.

Table 4-8 presents a summary *Fr 13* risk assessment matrix of the impact of varying *tolerance* (%) and stdev (%) on global pasteurizer failures (p_2). It can be seen quantitatively (from R to L of the table) that with increased *tolerance* i.e. increased process flexibility, together with increased stdev i.e. less precision control of the heat-up temperature and milk flow rate, the percentage of global microbiological failures increases from a minimum of zero (0 %) to some 26.9 % averaged over the long term. At a table mid-range *tolerance* = 6 % and stdev = 6 % the failure rate is would be expected to be 10 % of all daily batch-continuous pasteurizations over the long term.

In summary, the matrix underscores that the better the control and the more minimum flexibility of operation, the less vulnerable the pasteurizer to inactivate viable *MAP*. This format is readily understood and could be useful in the design stage. An advantage however of the probability density function used to compute numbers of global failures as $p_2 > 0$ (Fig. 4-3) is that the portion of all operations due to random fluctuations can readily be seen - and be readily interrogated.

Table 4-8: Summary *Fr 13* risk matrix of the impact of varying *tolerance* (%) and stdev (%) on global microbiological pasteurizer failures (%)

Global microbiological pasteurizer failures (%)[*]

↓ (increasing control and $ cost)

stdev (%)	***tolerance* (%)** (increasing process flexibility) ←							
	12	**10**	**8**	**6**	**4**	**2**	**1**	**0.1**
12	26.9	25.9	25.5	24.9	24.6	24.3	24	23.9
10	22.4	21.9	21	20.7	20.3	20	19.6	19.5
8	18.1	17.8	17	16.7	15.7	15.3	14.9	14.8
6	11.4	11	10.6	10	9.6	8.9	8.6	8.3
4	3.6	3.6	3.2	2.9	2.4	2.3	2	1.9
2	0	0	0	0	0	0	0	0
1	0	0	0	0	0	0	0	0
0.1	0	0	0	0	0	0	0	0

[*] Arithmetic mean of two (2) simulations.

4.6.6 Results overview

Notably, some micro-organisms can grow in close association - this results in clumps of cells rather than individual cells in the liquid. Clumps it has been suggested provide protection from heat to the cells on the inside of the clump during heating and therefore aid the survival of particular cells post-treatment. This would impact model predictions as 'unsafe'. Significant clumping during heating leads also to 'tailing' of survivor curves, and the wrong interpretation that there is a more heat-resistant spore fraction (Klijn et al., 2001). (It is widely acknowledged there is a need for standardization of experimental protocols and validation procedures in the analyses of micro-organisms in milk (Condron et al., 2015)). Several studies however have demonstrated that the protective impact of clumps on reducing heat transfer and increasing survival of cells within clumps is negligible for heat processes (Davey, 1990; Cerf et al., 2007; Hasting et al., 2001).

It is concluded that the impact of clumping can therefore be ignored in the *Fr 13* microbiological pasteurizer failure synthesis.

In the simulations of the milk pasteurizer it is implicit that there is no reduction in number of viable *MAP* during the (rapid) passage of the milk in the plate heat exchangers used for milk heat-up ($PHE_{1\text{-}1}$) and milk cool-down ($PHE_{2\text{-}3}$). The residence time involved in these *PHE*s is ~ 103.32 s (Table 4-1, columns 2 and 8 row 30, and Table 4-2 a, column 2 row 20). In heat-up there will be some additional reduction in viable *MAP* as the milk reaches temperatures above say 50 ^{O}C, and again in the time in cooling from the design 72 ^{O}C in holding, to 50 ^{O}C in cool-down.

It is concluded the overall failure rate predicted of 5.75 % is therefore conservatively high; it would be expected practical failure rate would therefore be less.

Some additional modelling could be used to arrive at how much more reduction in viable numbers of the pathogen would occur (estimated at an overall ~ 1-$\log_{10}$).

The important thing is the *Fr 13* methodology has been demonstrated for the 3-step microbiological global model. Because, uniquely, the pasteurizer is defined by 3-only risk factors (p_1, p_2 and p_3) a 3-D representation of the impact of all naturally occurring micro-state fluctuations in the key parameters can be represented as a probability '*p*-cloud' of all possible real states of plant outcome behaviour of the pasteurizer, Fig. 4-8.

The figure, for all 10,000 scenarios, is generated using Statistica^{TM}, version 10 (StatSoft Inc.). From the 3-D figure, all p_1 that correspond with p_2 and subsequently p_3 can be identified. The steady macro-state of the pasteurizer is indicated at {0, 0, 0}.

The predicted pasteurizer failures are all seen in the volume shown in the top, R, quadrant (all $p_2 > 0$) of the figure. This method is limited however to processes of 3-only unit-operations. It does however give a good 'feel' for the apparent steady-state pasteurizer behaviour.

For more than three risk factors the format of Table 4-8 could be readily used to convey the vulnerability of a plant to gross failure behavior; a drawback however will be the individual risk factors are 'lost'.

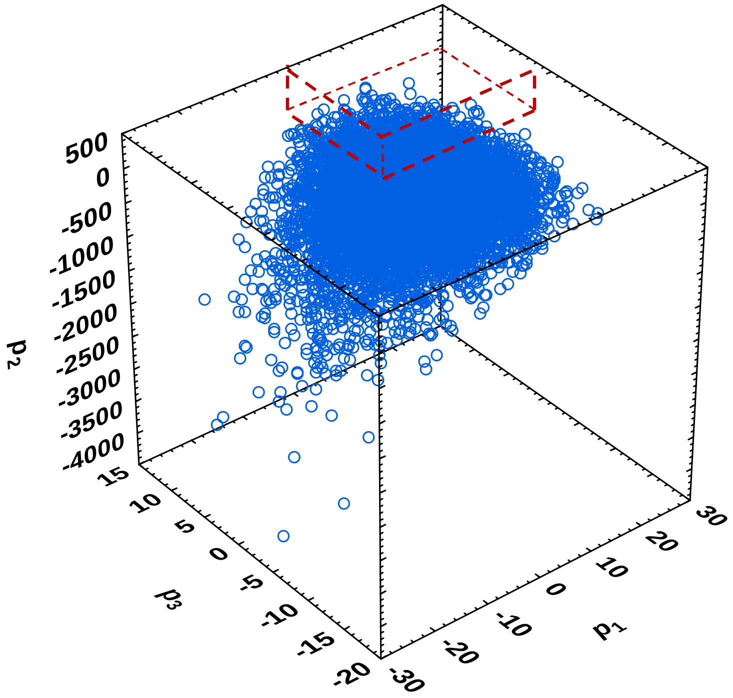


Fig. 4-8: 3-D plot showing the '*p*-cloud' of corresponding values of the risk factors (p_1, p_2, p_3) for all 10,000 scenarios of apparent steady-state pasteurization of the raw milk. Pasteurization failures are shown in the volume in the top, R, quadrant

A comparison of the global 3-step microbiological risk analysis with that of the 3-step equipment only model of Chapter 3 (Chandrakash et al. 2015) shows a failure rate (p_2) of, respectively, 5.75 and 12.51, % with a 2 % tolerance, averaged over the long term. That is there would be unwanted survival of viable *MAP* in 5.7 % of all cases of the milk leaving heat-up and holding, and 12 % of all heat-up and holding in the equipment model would fail to reach the design outlet milk bulk temperature.

These rates appear similar and in fact the difference is possibly not meaningful.

What is highlighted by both is that pasteurization will be a mix of successful and failed daily operations. Clearly, it is not expected these failures would be spaced equally in time. Overriding however is the extended microbiological risk model engages more directly the purpose of pasteurization i.e. the reduction in number of viable contaminant milk pathogens. The application of second-tier studies made possible with the *Fr 13* framework underscored the present highly practical value of the extended microbiological risk model in mitigating failure of milk pasteurization – although longer term it would be good to close-the-loop with experimental studies. Failures in pasteurization do occur but few data sufficient for model comparison are actually published in the refereed literature.

A failure of pasteurization with unwanted viable *MAP* will result in an increased health risk in further processing and ultimately the consumer. There will however not be any 'broken or faulty fittings', or, 'human error' or any disruption to operations.

To conclude, this work has involved demonstration of a 3- step unit-operation global model and, and together with findings from the 2-step unit-operation global model of Zou and Davey (2016) for a combined membrane ultrafiltration-osmotic distillation (UF-OD), it does establish a logical and step-wise approach that can be developed for careful testing of *Fr 13* framework to increasingly complex processes with larger numbers of unit-operations.

Although the global model for pasteurization involves a reduction in the number of viable *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*) it is clear that its generalized form could be used for a range of other contaminants in milk. Sound chemical engineering reasoning however would be to target the most heat resistant pathogen (control-step) and conclude that the less heat resistant contaminant would also be inactivated.

4.6.7 Closing-the-loop on the pasteurizer vulnerability and advancing the *Fr 13* framework

Conspicuously, in the present stage of development of the *Fr 13* framework it is not clear what impact might result from accumulated random fluctuations with an increased number of unit-operations on the behaviour of more complex global plants, or, whether generalizable findings could be made. To investigate this, a fourth step, storage of pasteurized milk is integrated to the global 3-step pasteurization model in the next chapter.

In order to further investigate multi-step processes a more generic chemical engineering process consisting of a feed stream, reactor, separator, product and recycle with purge (Davey, 2017) is needed in the hope of finding new knowledge and safety algorithms, work is currently underway to achieve this.

Evidence from the literature is strong that surprise failures are a part of chemical engineering processing (Asao et al., 2003), and persist in industrialized countries (Suddath, 2009). Because of increasing complexities and inter-connectedness of products and processing, the impact of these failures will have a significant high impact, and as acknowledged in the Blackett Review (Anon., 2012), there is a real need to develop practical and theoretical tools to anticipate these problems arising. This new knowledge and needed insights cannot come from existing alternate risk and hazard methodologies. For the present ‘closing the loop’ on *Fr 13* predictions is problematic. This is because availability and accessibility to unexplained failure data is generally classified and not disclosed (publicly at least). This is especially true in the case of dairy and general foods industries.

It can be inferred from this work, and together with that of Zou and Davey (2016) that there appears be no major methodological problems to advancing the framework.

A major advantaged claimed for a developed *Fr 13* framework is that the simulations could be used at both the synthesis and analysis stages to optimise safety of operation and maintenance of critical equipment and thereby counter-balance capital outlay and maintenance costs.

4.7 Chapter summary and conclusions

Based on a critical review of this chapter, the following important factors emerge:

1. A *Fr 13* risk analysis of an integrated 3-step global model for pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* has been developed and presented. Results reveal that (batch) continuous pasteurization is a mix of successful operations together with unsuccessful ones, with a fixed *tolerance* of 2 % on all three inter-connected unit-operations, 5.75 % of all operations result in failure due to cumulative impact of stochastic (random) effects

2. Most notably, failure in one unit-operation does not necessarily lead to a failure in the inter-connected corresponding unit-operation

3. Second-tier simulation studies highlighted that the overall microbiological pasteurizer failures can best be mitigated by 1) installing precise safety-integrity-level (SIL) mass flow control on the input raw milk, and, 2) establishing stringent ways to maintain the required holding time of raw milk in the holding tube

4. This global microbiological model is generalizable in its current form to a range of milk pathogens, and; there appears no methodological barriers to application of the *Fr 13* risk framework to increasing multi-step processes

5. Results will be of immediate interest to risk analysts, and of benefit to dairy processors and equipment manufacturers to improve knowledge and safety of processing.

It is evident from this chapter that the drawback the 3-step equipment model had can be overcome with this 3-step microbiological model for pasteurization.

In the next chapter, Chapter 5, in order to further test the applicability of the *Fr 13* framework to extended multi-step processing, a fourth integrated step, the storage of the pasteurized milk, is developed for the first time. A justification is that this simulates commercial practice more closely.

CHAPTER 5

A 4-STEP *FR 13* MICROBIOLOGICAL PASTEURIZER MODEL FOR RAW MILK INVOLVING HEAT-UP, HOLDING FOR THERMAL INACTIVATION, COOL-DOWN AND STORAGE OF TREATED MILK

Parts of this chapter have been published as:

Chandrakash, S., Davey, K.R., 2017 b. A 4-step *Fr 13* microbiological pasteurizer model for raw milk involving heat-up, holding for thermal inactivation of *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), cool-down and storage. AIChE J – *in preparation*.

Chandrakash, S., Davey, K.R., 2017 c. A review of the *Fr 13* risk assessment framework. Food Research International – *in preparation*.

5.1 Introduction

A review of the 3-step microbiological model for pasteurization in Chapter 4 showed that there appears no methodological barriers to application of *Fr 13* to increasing multi-step processing.

In this chapter, to further test applicability of the risk framework to multi-step processing, a fourth integrated step, the isothermal storage of the pasteurized milk, is included in the global process model for the first time (Chandrakash and Davey, 2017 a). The four steps are 1) heat-up, 2) holding for thermal inactivation, 3) cool-down, and; 4) isothermal storage of the pasteurized (treated) milk. A justification is that this simulates commercial practice more closely; isothermal storage is widely used for the treated milk before packing and distribution - or further processing to a range of dairy products.

The aim is to gain quantitative insight into pasteurization plant operations that could lead to 'unexpected' survival of the *MAP* following heat treatment and storage.

Results reveal that despite the inclusion of the additional process step, the underlying vulnerability to *Fr 13* failure did not increase i.e. when viewed over the long term the overall global failure rate remained at 5.75 %, the same as for the 3-step. Second-tier simulation studies reveal that the second-step (holding for thermal inactivation) plays a vital role in the end-quality of the stored treated milk before it goes to the next interconnected unit-operation, packing and distribution - or further processing to a range of dairy products. It should be ensured that a holding time of ≥ 15 s is always achieved for quality (safe) stored pasteurized (treated) milk.

5.2 4-step *Fr 13* microbiological pasteurizer model

The schematic of an integrated 4-step pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*) showing the four individual unit-operations, 1) heat-up of raw milk, 2) holding for thermal inactivation, 3) cool-down of processed (treated) milk and 4) isothermal storage of pasteurized milk is shown schematically in Fig. 5-1.

The pasteurizer is seen from the L-to-R of the figure to consist of a plate heat exchanger (*PHE*) for raw milk heat-up, which is connected to an insulated holding tube (*HT*) for *MAP* inactivation at the bulk heat-up temperature, which is in turn connected to a second plate heat exchanger for cool-down of the heat-treated milk and finally a well-insulated storage tank which is used to store the pasteurized milk. When viewed sequentially, raw milk enters the pasteurizer at ~ 4 ^{O}C and is heated to 72 ^{O}C and held for 15 s; it is then ‘shock’ cooled (Hudson et al., 2003) to 4 ^{O}C (Juffs and Deeth, 2007; Stabel and Lambertz, 2004; Yapp and Davey, 2009) and is then enters the well-insulated tank for storage at a temperature of 4 ^{O}C.

All symbols used in this chapter are defined in the Nomenclature and follow the same pattern as in Chapters 3 and 4. This method has the advantage of ordered application to increasingly complex systems of interconnected unit-operations.

The equations used to model heat-up of raw milk, holding for thermal inactivation and cool-down of treated milk remain as in Chapter 4; they are mentioned here for completeness.

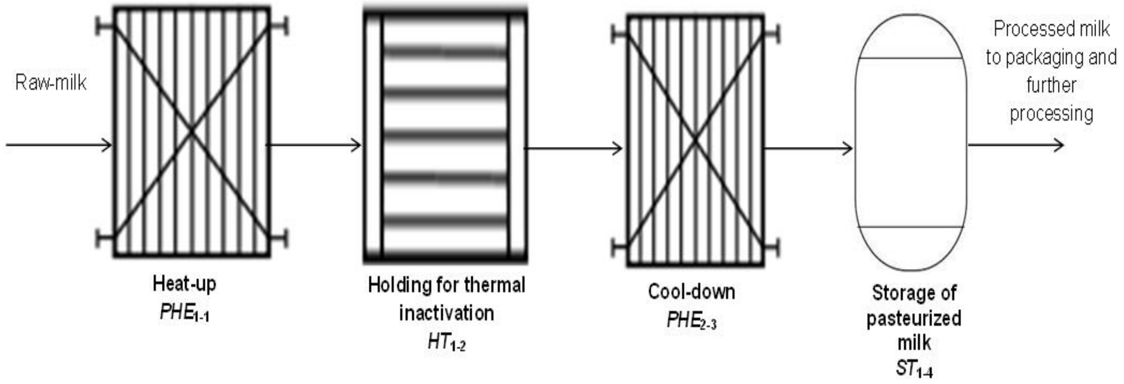


Fig. 5-1: Schematic of 4-step pasteurization of raw milk containing *MAP* showing individual 1) heat-up of raw milk, 2) holding for thermal inactivation, 3) cool-down of processed milk, and; 4) storage of treated milk unit-operations

5.2.1 Heat-up (PHE_{1-1})

The physical characteristics and the equations used to model PHE_{1-1} are (Chapter 4):

$$q_{PHE\,1-1} = U_{PHE\,1-1} * A_{PHE\,1-1} * \Delta T_{LMTD,\ PHE\,1-1} * F_{t,\ PHE\,1-1} \qquad (5.1)$$

$$q_{PHE\,1-1} = m_{m,\ PHE\,1-1} * C_{p,m\,PHE\,1-1} * (T_{o,m\,PHE\,1-1} - T_{i,m\,PHE\,1-1}) \qquad (5.2)$$

and

$$q_{PHE\,1-1} = m_{w,\ PHE\,1-1} * C_{p,w\,PHE\,1-1} * (T_{i,w\,PHE\,1-1} - T_{o,w\,PHE\,1-1}) \qquad (5.3)$$

$$D_{e,\ PHE\,1-1} = \frac{2 * w_{p,\ PHE\,1-1} * b_{p,\ PHE\,1-1}}{(w_{p,\ PHE\,1-1} + b_{p,\ PHE\,1-1})} \qquad (5.4)$$

$$n_{p,\ PHE\ 1-1} = \frac{A_{PHE\ 1-1}}{\pi * D_{e,\ PHE\ 1-1} * L_{p,PHE\ 1-1}} \tag{5.5}$$

$$T_{m,avg\ PHE\ 1-1} = \left(\frac{T_{i,m\ PHE\ 1-1} + T_{o,m\ PHE\ 1-1}}{2}\right) \tag{5.6}$$

$$\mu_{m,\ PHE\ 1-1} = \left(\left(-0.00445 * \ T_{m,avg\ PHE\ 1-1}\right) + 0.947\right) * 10^{-3} \tag{5.6 a}$$

and

$$\rho_{m,\ PHE\ 1-1} = 1033.7 - (0.2308 * T_{m,avg\ PHE\ 1-1}) - (0.00246\ * T_{m,avg\ PHE\ 1-1}{}^{2}) \tag{5.6 b}$$

$$v_{m,\ PHE\ 1-1} = \frac{4 * m_{m,\ PHE\ 1-1}}{\rho_{m,\ PHE\ 1-1} * \pi * (D_{e,\ PHE\ 1-1})^{2}} \tag{5.7}$$

$$\mathrm{Re}_{\ PHE\ 1-1} = \frac{\rho_{m,\ PHE\ 1-1} * v_{m,\ PHE\ 1-1} * D_{e,\ PHE\ 1-1}}{\mu_{m,\ PHE\ 1-1}} \tag{5.8}$$

$$t_{r,\ PHE\ 1-1} = \frac{n_{p,\ PHE\ 1-1} * L_{p,\ PHE\ 1-1}}{v_{m,\ PHE\ 1-1}} \tag{5.9}$$

$$\Delta P_{PHE\ 1-1} = 8 * \ j_{F,\ PHE\ 1-1} * \frac{L_{p,\ PHE\ 1-1}}{D_{e,\ PHE\ 1-1}} * \frac{\rho_{m,\ PHE\ 1-1} * (v_{m,\ PHE\ 1-1})^{2}}{2} \tag{5.10}$$

$$j_{F,\ PHE\ 1-1} = 0.6 * \ (\mathrm{Re}_{\ PHE\ 1-1})^{-0.30} \tag{5.11}$$

Eqs. (5-1) through to Eq. (5-11) define heat-up of the raw milk containing viable *MAP*.

5.2.2 Holding for thermal inactivation (*HT*$_{1\text{-}2}$)

$$log_{10}\ D_{t,\ HT\ 1-2} = log_{10}\ D_{t,ref\ HT\ 1-2} - \frac{(T_{m,\ HT\ 1-2} - T_{ref,\ HT\ 1-2})}{z_{HT\ 1-2}} \tag{5.12}$$

$$k_{d,\ HT\ 1-2} = \frac{2.303}{D_{t,\ HT\ 1-2}} \tag{5.13}$$

$$\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2} = \frac{k_{d,\ HT\ 1-2} * t_{m,\ HT\ 1-2}}{2.303} \tag{5.14}$$

$$t_{m,\ HT\ 1-2} = \frac{L_{HT\ 1-2}}{v_{m,\ HT\ 1-2}} \tag{5.15}$$

$$\rho_{m,\ HT\ 1-2} = 1033.7 - (0.2308\ * T_{m,\ HT\ 1-2}) - (0.00246\ * T_{m,\ HT\ 1-2}{}^{2}) \tag{5.16}$$

$$v_{m,\ HT\ 1-2} = \frac{4 * m_{m,\ HT\ 1-2}}{\rho_{m,\ HT\ 1-2} * \pi * (D_{HT\ 1-2})^{2}} \tag{5.17}$$

Eqs. (5-12) through Eq. (5-17) define holding and thermal inactivation of *MAP*.

5.2.3 Cool-down (*PHE*2-3)

$$q_{PHE\ 2-3} = U_{PHE\ 2-3} * A_{PHE\ 2-3}\ * \Delta T_{LMTD,\ PHE\ 2-3} * F_{t,\ PHE\ 2-3} \tag{5.18}$$

$$q_{PHE\ 2-3} = m_{m,\ PHE\ 2-3} * C_{p,m\ PHE\ 2-3}\ * (T_{i,m\ PHE\ 2-3} - T_{o,m\ PHE\ 2-3}) \tag{5.19}$$

and

$$q_{PHE\ 2-3} = m_{b,\ PHE\ 2-3} * C_{p,b\ PHE\ 2-3}\ * (T_{o,b\ PHE\ 2-3} - T_{i,b\ PHE\ 2-3}) \tag{5.20}$$

$$D_{e,\ PHE\ 2-3} = \frac{2 * w_{p,\ PHE\ 2-3} * b_{p,\ PHE\ 2-3}}{(w_{p,\ PHE\ 2-3} + b_{p,\ PHE\ 2-3})} \tag{5.21}$$

$$n_{p,\ PHE\ 2-3} = \frac{A_{PHE\ 2-3}}{\pi * D_{e,\ PHE\ 2-3} * L_{p,\ PHE\ 2-3}} \tag{5.22}$$

$$T_{m,avg\ PHE\ 2-3} = \frac{T_{i,m\ PHE\ 2-3} + T_{o,m\ PHE\ 2-3}}{2} \tag{5.23}$$

$$\mu_{m,\ PHE\ 2-3} = \Big(\big(-0.00445 * T_{m,avg\ PHE\ 2-3}\big) + 0.947\Big) * 10^{-3} \tag{5.23 a}$$

and

$$\rho_{m,\ PHE\ 2-3} = 1033.7 - (0.2308 *\ T_{m,avg\ PHE\ 2-3}) - (0.00246 * T_{m,avg\ PHE\ 2-3}{}^{2}) \tag{5.23 b}$$

$$v_{m,\ PHE\ 2-3} = \frac{4 * m_{m,\ PHE\ 2-3}}{\rho_{m,\ PHE\ 2-3} * \pi * (D_{e,\ PHE\ 2-3})^{2}} \tag{5.24}$$

$$\mathrm{Re}_{\ PHE\ 2-3} = \frac{\rho_{m,\ PHE\ 2-3} * v_{m,\ PHE\ 2-3} * D_{e,\ PHE\ 2-3}}{\mu_{m,\ PHE\ 2-3}} \tag{5.25}$$

$$t_{r,\ PHE\ 2-3} = \frac{n_{p,\ PHE\ 2-3} * L_{p,\ PHE\ 2-3}}{v_{m,\ PHE\ 2-3}} \tag{5.26}$$

$$\Delta P_{PHE\ 2-3} = 8\ * j_{F,\ PHE\ 2-3} * \frac{L_{p,\ PHE\ 2-3}}{D_{e,\ PHE\ 2-3}} * \frac{\rho_{m,\ PHE\ 2-3} * (v_{m,\ PHE\ 2-3})^2}{2} \tag{5.27}$$

$$j_{F,\ PHE\ 2-3} = 0.6\ (\mathrm{Re}_{\ PHE\ 2-3})^{-0.30} \tag{5.28}$$

Eqs. (5-18) through Eq. (5-28) define cool-down of the heat-treated milk.

5.2.4 Storage of pasteurized (treated) milk ($ST_{1\text{-}4}$) containing *MAP*

Storage of pasteurized milk is batch-continuous. Storage tanks vary in size from 20,000 to 125,000 L, are well-insulated and have a double shell with 70 mm mineral wool insulation in between them. The outer shell is made of either Stainless Steel (SS) or Mild Steel (MS) coated with an anti-corrosion paint (Alfa-Laval, 1987).

Surface of the storage tanks are made of Stainless Steel (SS) 304. Storage tanks have an agitator and some monitoring and control equipment fitted in order to monitor quality of stored pasteurized milk, to make drainage of the stored product easy the bottom of the tank slopes downwards at an inclination of 6 % towards the outlet (Alfa-Laval, 1987).

It is assumed that the storage tank used is 20,000 L capacity. The typical dimensions for a storage tank of 20,000 L capacity (up to 27,667 L) is length (height) $L_{ST\ 1\text{-}4}$ = 5.55 m and diameter $D_{ST\ 1\text{-}4}$ = 2.52 m and the number of agitators, $N_{A,\ ST\ 1\text{-}4}$ = 2 (Anon., 2015). Milk is stored for a period of 30 mins before it goes to the packaging and distribution or follow-up processing i.e. $t_{m,\ ST\ 1\text{-}4}$ = 30 min.

Thermal inertia is low i.e. walls of the storage tanks are quite thin.

In Chapter 4 it was shown that viable pathogenic *MAP* species has potential to survive 3-step pasteurization processing, and therefore storage. Unwanted viable *MAP* could pose a risk to interconnected unit-operations, where the stored milk goes to packaging or further dairy products processing. *MAP* species grow well at common refrigeration temperature of 0 to 15, ^{O}C (Juffs and Deeth, 2007).

The decimal reduction time ($D_{t,\ ST\ 1\text{-}4}$) for *MAP* $T_{m\ ST\ 1\text{-}4}$ = 4 ^{O}C is 3.8 mins (Augustin, 2011; Wijnands et al., 2009).

Since the decimal reduction time ($D_{t,\ ST\ 1\text{-}4}$) is known, the thermal inactivation rate ($k_{d,\ ST\ 1\text{-}4}$) for viable *MAP* can be calculated using (Koutchma et al., 2001; Smith, 2011)

$$k_{d,\ ST\ 1-4} = \frac{2.303}{D_{t,\ ST\ 1-4}} \tag{5.29}$$

The $\log_{10}$-reduction time for viable *MAP* can be calculated using (Ibarz and Barbosa-Canovas, 2003)

$$\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4} = \frac{k_{d,\ ST\ 1-4} * t_{m,\ ST\ 1-4}}{2.303} \tag{5.30}$$

Typically, a regulatory 5.5 $\log_{10}$ reduction of the viable psychrotrophic *MAP* (> 99.99 %) is required (Grant et al., 2001; Hammer et al., 2014; McDonald et al., 2005; Rademaker et al., 2007).

5.3 Traditional single value assessment (SVA) solution

Using the deterministic SVA the 4-step global microbiological pasteurizer synthesis is solved as follows:

For milk heat-up, from Eq. (5.1) $q_{PHE\ 1\text{-}1}$ = 1,519 kJ s^{-1}, using Eq. (5.2) $T_{o,m\ PHE\ 1\text{-}1}$ = 72.46 ^{O}C, and from Eq. (5.3) $T_{o,w\ PHE\ 1\text{-}1}$ = 31.68 ^{O}C. Using Eq. (5.4) $D_{e,\ PHE\ 1\text{-}1}$ = 0.08 m and from Eq. (5.5) $n_{p,\ PHE\ 1\text{-}1}$ = 85. Using Eq. (5.6) $T_{m,avg\ PHE\ 1\text{-}1}$ = 38.23 ^{O}C. With $T_{m,avg\ PHE\ 1\text{-}1}$ known using Eq. (5.6 a) $\mu_{m,\ PHE\ 1\text{-}1}$ = 0.0008 Pa s and from Eq. (5.6 b) $\rho_{m,\ PHE\ 1\text{-}1}$ = 1,022 kg m^{-3}. From Eq. (5.7) $v_{m,\ PHE\ 1\text{-}1}$ = 1.23 m s^{-1} and using Eq. (5.8) $\mathrm{Re}_{PHE\ 1\text{-}1}$ = 121,560 (dimensionless). From Eq. (5.9) the residence time of the milk in heat-up $t_{r,\ PHE\ 1\text{-}1}$ = 103.32 s. Using Eq. (5.10) and Eq. (5.11) $\Delta P_{PHE\ 1\text{-}1}$ = 2,222 N m^{-2}.

For holding for thermal inactivation of *MAP*, the heated milk enters the holding tube at $T_{o,m\ PHE\ 1\text{-}1} = T_{m,\ HT\ 1\text{-}2}$ = 72.46 ^{O}C. Since the length of the holding tube ($L_{HT\ 1\text{-}2}$ = 10.58 m) is known, from Eq. (5.15) $t_{m,\ HT\ 1\text{-}2}$ = 15 s. Using Eq. (5.16) $\rho_{m,\ HT\ 1\text{-}2}$ = 1,004 kg m^{-3}. From Eq. (5.17) $v_{m,\ HT\ 1\text{-}2}$ = 0.71 m s^{-1}. From literature, for *MAP*, the decimal reduction time at a reference temperature of ($T_{ref,\ HT\ 1\text{-}2}$) 72 ^{O}C is $D_{t,ref\ HT\ 1\text{-}2}$ = 1.2 s with a *z*-value $z_{HT\ 1\text{-}2}$ = 7.7 ^{O}C (Rademaker et al., 2007). From Eq. (5.12) at $T_{m,\ HT\ 1\text{-}2}$ = 72.46 ^{O}C, $D_{t,\ HT\ 1\text{-}2}$ = 1.01 s. From Eq. (5.13) $k_{d,\ HT\ 1\text{-}2}$ = 2.29 s^{-1}. From Eq. (5.14) $\log_{10}(N/N_0)_{HT\ 1\text{-}2}$ =14.93 (dimensionless).

This logarithmic reduction of *MAP* is greater than the required 5.5 $\log_{10}$ reduction; therefore it can be concluded that the resulting pasteurized milk is 'safe'.

For cool-down of the heated milk, using Eq. (5.18) $q_{PHE\ 2\text{-}3}$ = 1,519 kJ s^{-1} and from Eq. (5.19) $T_{o,m\ PHE\ 2\text{-}3}$ = 4 ^{O}C, from Eq. (5.20) $T_{o,b\ PHE\ 2\text{-}3}$ = 45.88 ^{O}C. Using Eq. (5.21) $D_{e,\ PHE\ 2\text{-}3}$ = 0.08 m and from Eq. (5.22) $n_{p,\ PHE\ 2\text{-}3}$ = 85. Using Eq. (5.23) $T_{m,avg\ PHE\ 2\text{-}3}$ = 38.23

^{O}C. With $T_{m,avg\ PHE\ 2\text{-}3}$ known using Eq. (5.23 a) $\mu_{m,\ PHE\ 2\text{-}3}$ = 0.0008 Pa s and from Eq. (5.23 b) $\rho_{m,\ PHE\ 2\text{-}3}$ = 1,021 kg m^{-3}. Using Eq. (5.24) $v_{m,\ PHE\ 2\text{-}3}$ = 1.23 m s^{-1} and from Eq. (5.25) Re$_{PHE\ 2\text{-}3}$ = 121,560. From Eq. (5.26) the residence time of the milk in cool-down $t_{r,\ PHE\ 2\text{-}3}$ = 103.32 s. Using Eq. (5.27) and Eq. (5.28) $\Delta P_{PHE\ 2\text{-}3}$ = 2,222 N m^{-2}.

For storage of the pasteurized milk, treated (pasteurized) milk enters the storage tank at $T_{m\ ST\ 1\text{-}4}$ = 4 ^{O}C and $m_{m\ ST\ 1\text{-}4}$ = 5.56 kg s^{-1}. For *MAP* the decimal reduction time at $T_{m\ ST\ 1\text{-}4}$ = 4 ^{O}C is 3.8 m (Augustin, 2011; Wijnands et al., 2009). Using Eq. (5.29) $k_{d,\ ST\ 1\text{-}4}$ = 0.61 min^{-1}, and from Eq. (5.30) $\log_{10}$ $(N/N_0)_{\ ST\ 1\text{-}4}$ = 7.95 (dimensionless).

This logarithmic reduction of *MAP* is greater than the required 5.5 $\log_{10}$ reduction of *MAP*; therefore it can be concluded that the resulting stored milk is ‘safe’ to go to the next interconnected unit-operation of packaging or other dairy products processing.

A summary comparison of the deterministic values obtained using the traditional single value assessment (SVA) for individual heat-up ($PHE_{1\text{-}1}$), holding for thermal inactivation ($HT_{1\text{-}2}$) cool-down ($PHE_{2\text{-}3}$) and isothermal storage ($ST_{1\text{-}4}$) is presented in Table 5-1. The SVA model is conveniently read down the column for each. The bolded value highlights that the output from one unit-operation step is the input to the sequentially, inter-connected step.

Table 5-1: Summary of the deterministic single value assessment (SVA) for corresponding milk heat-up, holding for thermal inactivation of *MAP*, cool-down, and; storage of treated milk

Heat-up			**Holding for thermal inactivation of *MAP***			**Cool-down**			**Storage of pasteurized milk containing *MAP***		
Constants									Tank		
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	constant	$L_{HT\ 1\text{-}2}$ (m)	10.58	constant	$U_{PHE\ 2\text{-}3}$ (kW m^{-2} K^{-1})	2.5	constant	Capacity (L)	20,000	constant
$A_{PHE\ 1\text{-}1}$ (m^{2})	30	constant	$D_{HT\ 1\text{-}2}$ (m)	0.1	constant	$A_{PHE\ 2\text{-}3}$ (m^{2})	30	constant	($L_{ST\ 1\text{-}4}$ = 5.55 m, $D_{ST\ 1\text{-}4}$ = 2.52 m)		
$\Delta T_{LMTD,\ PHE\ 1\text{-}1}$ (^{O}C)	22.5	constant				$\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ (^{O}C)	22.5	constant			
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	constant				$F_{t,\ PHE\ 2\text{-}3}$ (dimensionless)	0.90	constant			
Plate Properties											
$w_{p,\ PHE\ 1\text{-}1}$ (m)	0.15	constant				$w_{p,\ PHE\ 2\text{-}3}$ (m)	0.15	constant			
$b_{p,\ PHE\ 1\text{-}1}$ (m)	0.05	constant				$b_{p,\ PHE\ 2\text{-}3}$ (m)	0.05	constant			
$L_{p,\ PHE\ 1\text{-}1}$ (m)	1.50	constant				$L_{p,\ PHE\ 2\text{-}3}$ (m)	1.50	constant			
Inputs											
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	input	**$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)**	**72.46**	**input**	**$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**72.46**	**input**	**$T_{m,\ ST\ 1\text{-}4}$ (^{O}C)**	**4.00**	**input**
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	input	$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.56	input	$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.56	input	$m_{m,\ ST\ 1\text{-}4}$ (kg s^{-1})	5.56	input
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	input	$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	input	$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.99	input	$D_{t,\ ST\ 1\text{-}4}$ (mins)	3.8	input
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	input	$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	input	$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8	input			
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	input	$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	input	$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.34	input			
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	input				$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.38	input			
Calculations											
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	Eq. (5.1)				$q_{PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	Eq. (5.18)			
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	**72.46**	**Eq. (5.2)**				**$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)**	**4.00**	**Eq. (5.19)**			
$T_{o,w,\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	Eq. (5.3)				$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.88	Eq. (5.20)			
$D_{e,\ PHE\ 1\text{-}1}$ (m)	0.08	Eq. (5.4)				$D_{e,\ PHE\ 2\text{-}3}$ (m)	0.08	Eq. (5.21)			
$n_{p,PHE\ 1\text{-}1}$ (dimensionless)	85	Eq. (5.5)				$n_{p,PHE\ 2\text{-}3}$ (dimensionless)	85	Eq. (5.22)			
$T_{m,avg\ PHE\ 1\text{-}1}$ (^{O}C)	38.23	Eq. (5.6)				$T_{m,avg\ PHE\ 2\text{-}3}$ (^{O}C)	38.23	Eq. (5.23)			
$\mu_{m,\ PHE\ 1\text{-}1}$ (Pa s)	0.0008	Eq. (5.6 a)				$\mu_{m,\ PHE\ 2\text{-}3}$ (Pa s)	0.0008	Eq. (5.23 a)			
$\rho_{m,\ PHE\ 1\text{-}1}$ (kg m^{-3})	1,021	Eq. (5.6 b)	$t_{m,\ HT\ 1\text{-}2}$ (s)	15	Eq. (5.15)	$\rho_{m,\ PHE\ 2\text{-}3}$ (kg m^{-3})	1,021.28	Eq. (5.23 b)			
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.23	Eq. (5.7)	$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1004	Eq. (5.16)	$v_{m,\ PHE\ 2\text{-}3}$ (m s^{-1})	1.23	Eq. (5.24)			
$\mathrm{Re}_{PHE1\text{-}1}$ (dimensionless)	121,560	Eq. (5.8)	$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.71	Eq. (5.17)	$\mathrm{Re}_{PHE\ 2\text{-}3}$ (dimensionless)	121,560	Eq. (5.25)			
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.32	Eq. (5.9)	$D_{t,\ HT\ 1\text{-}2}$ (s)	1.01	Eq. (5.12)	$t_{r,\ PHE\ 2\text{-}3}$ (s)	103.32	Eq. (5.26)			
$j_{F,\ PHE\ 1\text{-}1}$ (dimensionless)	0.02	Eq. (5.11)	$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	2.29	Eq. (5.13)	$j_{F,\ PHE\ 2\text{-}3}$ (dimensionless)	0.02	Eq. (5.28)	$k_{d,\ ST\ 1\text{-}4}$ (min^{-1})	0.61	Eq. (5.29)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,222	Eq. (5.10)	**$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$**	**14.93**	**Eq. (5.14)**	$\Delta P_{PHE\ 2\text{-}3}$ (N m^{-2})	2,222	Eq. (5.27)	**$\log_{10}(N/N_0)_{ST\ 1\text{-}4}$**	**7.95**	**Eq. (5.30)**

The results reported in Table 5-1 agree well with those widely reported in the literature (Varzakas and Labropoulos, 2007; Tran et al., 2008).

5.4 *Fr 13* global model with storage of pasteurized milk

5.4.1 Risk factors and defining failure

From Chapter 4, a risk factor for failure of milk-heat up is

$$p_1 = +2 - 100\left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1\right) \tag{5.31}$$

Eqs. (5.1) through Eq. (5.11), together with Eq. (5.31), define the *Fr 13* failure synthesis for raw milk heat-up.

Similarly, a risk factor for holding for thermal inactivation of *MAP* is

$$p_2 = +2 - 100\left(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}} - 1\right) \tag{5.32}$$

Eqs. (5.12) through Eq. (5.17), together with Eq. (5.32), constitutes the *Fr 13* microbiological failure synthesis for holding for thermal inactivation of milk contaminant *MAP*.

Also, for cool-down, the risk factor is

$$p_3 = -2 + 100\left(\frac{T_{o,m\ PHE\ 2-3}{}'}{T_{o,m\ PHE\ 2-3}} - 1\right) \tag{5.33}$$

Eqs. (5.18) through Eq. (5.28), together with Eq. (5.33), constitutes the *Fr 13* synthesis for heated milk cool-down.

For storage of the pasteurized milk, a suitable risk, defined as unwanted survival of *MAP*, can be characterized by a risk factor for heat treated milk (p_4) in terms of a $\log_{10}$ reduction of viable *MAP* such that

$$p_4 = +tolerance_4 - 100\left(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}} - 1\right) \tag{5.34}$$

where $\log_{10}(N/N_0)_{ST\,1\text{-}4}'$ is one possible practical scenario in reduction of viable pathogens while the pasteurized (treated) milk is stored and $\log_{10}(N/N_0)_{ST\,1\text{-}4}$ is the required $\log_{10}$ reduction for safely stored treated milk. With a $tolerance_4 = 2$ %, Eq. (5.34) becomes

$$p_4 = +2 - 100(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}} - 1) \qquad (5.35)$$

That is, if the required 5.5 $\log_{10}$ reduction in *MAP* plus 2 % is not reached then storage of treated milk is said to have failed, indicated by $p_4 > 0$.

Eqs. (5.29) through Eq. (5.30), together with Eq. (5.35), constitutes the *Fr 13* failure synthesis for storage of treated (pasteurized) milk with contaminant *MAP*.

5.4.2 *Fr 13* pasteurizer simulations

Fig. 5-2 presents a schematic of the *Fr 13* global microbiological model for a 4-step pasteurizer model for raw milk involving 1) heat-up, 2) holding for thermal inactivation, 3) cool-down, and 4) isothermal storage of treated (pasteurized) milk. Each input parameter is seen to be defined by a probability distribution of values (the mean of which will agree with the deterministic SVA value).

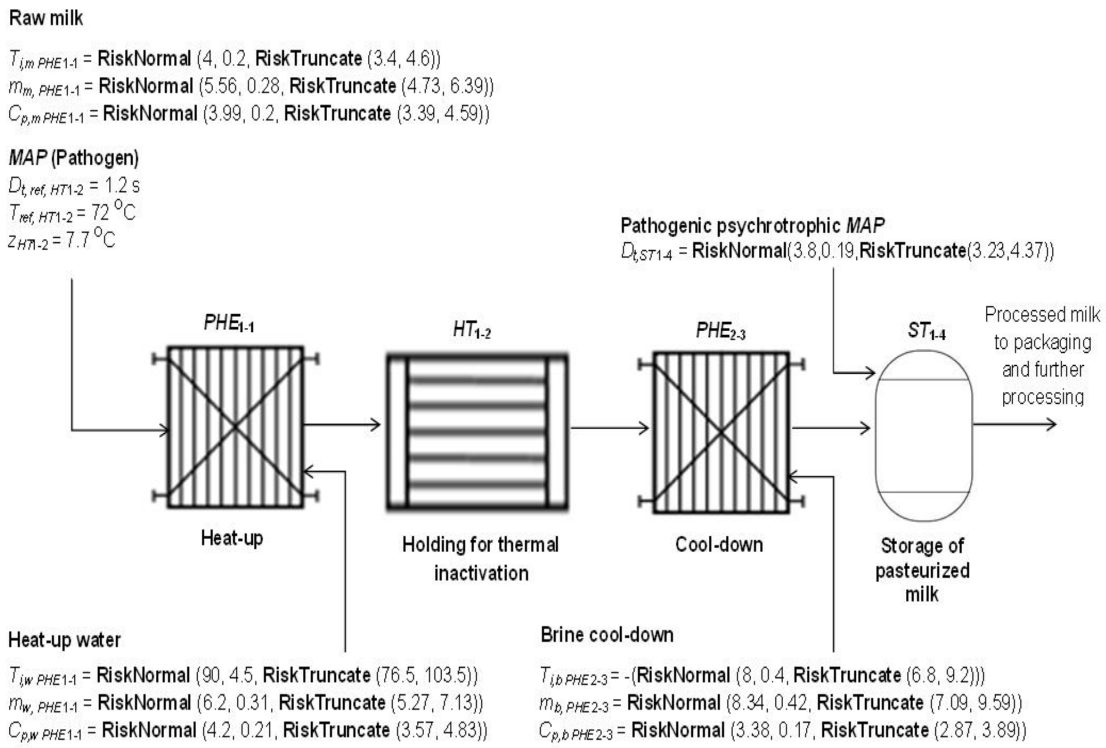


Fig. 5-2: *Fr 13* integrated 4-step global model for pasteurization of raw milk containing *MAP*

5.5 Results

Table 5-2 a, 5-2 b and Table 5-2 c present a comparative summary of the traditional SVA with *Fr 13* simulations of the overall pasteurizer for, respectively, 1) heat-up, 2) holding for thermal inactivation of *MAP* and 3) cool-down unit-operations. Table 5-2 d present a comparative summary of the traditional SVA with *Fr 13* simulations of step 4) of the overall pasteurizer for isothermal storage of the treated (pasteurized) milk.

10,000 Latin Hypercube samples were found sufficient. A comparative summary of the deterministic SVA with probabilistic *Fr 13* simulations for: (a) Heat-up of milk with a $tolerance_1$ = 2 %, failure of milk heat-up is defined by $p_1 > 0$, (b) Holding for thermal inactivation of *MAP* ($tolerance_2$ = 2 %), overall pasteurizer failure is defined by $p_2 > 0$, (c) Cool-down of heated milk ($tolerance_3$ = 2 %), failure to cool-down is defined by $p_3 > 0$ and (d) thermal inactivation of *MAP* during storage of treated (pasteurized) milk is defined by $p_4 < 0$. Column 3 is for one-only of 10,000 simulated scenarios.

Table 5-2 a, b, c and d: Summary of the *Fr 13* results for corresponding milk 1) heat-up, 2) holding for thermal inactivation of *MAP*, 3) cool-down, and; 4) storage of pasteurized (treated) milk

(a)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{i,m\ PHE\ 1\text{-}1}$ (^{O}C)	4	**4.13**†	**RiskNormal**(4,0.2, **RiskTruncate** (3.4,4.6))
$m_{m,\ PHE\ 1\text{-}1}$ (kg s^{-1})	5.56	**6.18**†	**RiskNormal**(5.56,0.278, **RiskTruncate**(4.73,6.39))
$C_{p,m\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	3.99	**4.01**†	**RiskNormal**(3.99,0.2, **RiskTruncate** (3.39,4.59))
$T_{i,w\ PHE\ 1\text{-}1}$ (^{O}C)	90	**91.59**†	**RiskNormal**(90,4.5, **RiskTruncate** (76.5,103.5))
$m_{w,\ PHE\ 1\text{-}1}$ (kg s^{-1})	6.2	**6.14**†	**RiskNormal**(6.2,0.31, **RiskTruncate** (5.27,7.13))
$C_{p,w\ PHE\ 1\text{-}1}$ (kJ kg^{-1} K^{-1})	4.2	**4.18**†	**RiskNormal**(4.2,0.21, **RiskTruncate** (3.57,4.83))
Constants			
$A_{PHE\ 1\text{-}1}$ (m^{2})	30	30	constant
$U_{PHE\ 1\text{-}1}$ (kW m^{-2} K^{-1})	2.5	2.5	constant
$\Delta T_{LMTD\ PHE\ 1\text{-}1}$ (^{O}C)	22.50	22.50	constant
$F_{t,\ PHE\ 1\text{-}1}$ (dimensionless)	0.90	0.90	constant
Calculations			
$q_{PHE\ 1\text{-}1}$ (kJ s^{-1})	1,519	1,519	Eq. (5.1)
$T_{o,m\ PHE\ 1\text{-}1}$ (^{O}C)	72.46	**65.46**	Eq. (5.2)
$T_{o,w\ PHE\ 1\text{-}1}$ (^{O}C)	31.68	32.42	Eq. (5.3)
$v_{m,\ PHE\ 1\text{-}1}$ (m s^{-1})	1.2329	1.37	Eq. (5.7)
Re $_{PHE\ 1\text{-}1}$ (dimensionless)	121,560	132,510	Eq. (5.8)
$t_{r,\ PHE\ 1\text{-}1}$ (s)	103.32	93.08	Eq. (5.9)
$\Delta P_{PHE\ 1\text{-}1}$ (N m^{-2})	2,222	2,672	Eqs. (5.10), (5.11)
p_1 (dimensionless)		**11.08**	Eq. (5.32)

(b)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{m,\ HT\ 1\text{-}2}$ (^{O}C)	72.46	**65.46**†	= $T_{o,m\ PHE\ 1\text{-}1}$
$m_{m,\ HT\ 1\text{-}2}$ (kg s^{-1})	5.56	**6.18**†	= $m_{m,\ PHE\ 1\text{-}1}$
Constants			
$L_{HT\ 1\text{-}2}$ (m)	10.58	10.58	constant
$D_{HT\ 1\text{-}2}$ (m)	0.1	0.1	constant
$T_{ref,\ HT\ 1\text{-}2}$ (^{O}C)	72	72	constant
$D_{t,ref\ HT\ 1\text{-}2}$ (s)	1.2	1.2	constant
$z_{HT\ 1\text{-}2}$ (^{O}C)	7.7	7.7	constant
Calculations			
$t_{m,\ HT\ 1\text{--}2}$ (s)	15	13.55	Eq. (5.15)
$\rho_{m,\ HT\ 1\text{-}2}$ (kg m^{-3})	1,004	1,008	Eq. (5.16)
$v_{m,HT\ 1\text{-}2}$ (m s^{-1})	0.71	0.78	Eq. (5.17)
$D_{t,\ HT\ 1\text{-}2}$ (s)	1.01	2.53	Eq. (5.12)
$k_{d,\ HT\ 1\text{-}2}$ (s^{-1})	2.29	0.91	Eq. (5.13)
$\log_{10}(N/N_0)_{HT\ 1\text{-}2}$	14.93	**5.36**	Eq. (5.14)
p_2 (dimensionless)		**4.63**	Eq. (5.34)

(c)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{i,m\ PHE\ 2\text{-}3}$ (^{O}C)	72.46	**65.46**†	= $T_{m,HT\ 1\text{-}2}$ (= $T_{o,m\ PHE\ 1\text{-}1}$)
$m_{m,\ PHE\ 2\text{-}3}$ (kg s^{-1})	5.56	**6.18**†	= $m_{m,\ PHE\ 1\text{-}1}$
$C_{p,m\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.99	**4.01**†	= $C_{p,m\ PHE\ 1\text{-}1}$
$T_{i,b\ PHE\ 2\text{-}3}$ (^{O}C)	-8	**-7.96**†	-(**RiskNormal**(8,0.4,**RiskTruncate**(6.8,9.2)))
$m_{b,\ PHE\ 2\text{-}3}$ (kg s^{-1})	8.34	**8.22**†	**RiskNormal**(8.34,0.42,**RiskTruncate**(7.09,9.59))
$C_{p,b\ PHE\ 2\text{-}3}$ (kJ kg^{-1} K^{-1})	3.38	**3.46**†	**RiskNormal**(3.38,0.17,**RiskTruncate**(2.87,3.89))
Constants			
$A_{PHE\ 2\text{-}3}$ (m^{2})	30	30	constant
$U_{PHE\ 2\text{-}3}$ (kW m^{-2} K^{-1})	2.5	2.5	constant
$\Delta T_{LMTD,\ PHE\ 2\text{-}3}$ (^{O}C)	22.50	22.50	constant
$F_{t,\ PHE\ 2\text{-}3}$ (dimensionless)	0.90	0.90	constant
Calculations			
$q_{\ PHE\ 2\text{-}3}$ (kJ s^{-1})	1,519	1,519	Eq. (5.18)
$T_{o,m\ PHE\ 2\text{-}3}$ (^{O}C)	4.00	**4.13**	Eq. (5.19)
$T_{o,b\ PHE\ 2\text{-}3}$ (^{O}C)	45.88	45.41	Eq. (5.20)
p_3 (dimensionless)		**1.24**	Eq. (5.36)

(d)

Parameter	**SVA***	***Fr 13* model****	
Inputs			
$T_{m,\ ST\ 1\text{-}4}$ (^{O}C)	4.00	**4.13**†	= $T_{o,m\ PHE\ 2\text{-}3}$
$m_{m,\ ST\ 1\text{-}4}$ (kg s^{-1})	5.56	**6.18**†	= $m_{m,\ PHE\ 1\text{-}1}$
Constants			
$L_{ST\ 1\text{-}4}$ (m)	5.55	5.55	constant
$D_{ST\ 1\text{-}4}$ (m)	2.52	2.52	constant
$H_{ST\ 1\text{-}4}$ (m)	3.12	3.12	constant
$N_{A,\ ST\ 1\text{-}4}$ (dimensionless)	2	2	constant
$t_{m,\ ST\ 1\text{--}4}$ (mins)	30	30	constant
Inputs			
$D_{t,\ ST\ 1\text{-}4}$ (min^{-1})	3.8	3.65	**RiskNormal**(3.8,0.19,**RiskTruncate**(3.23,4.37))
Calculations			
$k_{d,\ ST\ 1\text{-}4}$ (min^{-1})	0.61	0.63	Eq. (5.29)
$\log_{10} (N/N_0)_{ST\ 1\text{-}4}$	7.95	**8.22**	Eq. (5.30)
p_4 (dimensionless)		**-47.45**	Eq. (5.38)

*Traditional, deterministic Single Value Assessment

** *Fr 13* simulation with *Latin Hypercube* sampling

† Input values are reproduced from r-MC sampling; it is not implied they are measured to this significance

Both SVA and *Fr 13* simulation are each read down the (appropriate) columns of the table. For example, for the *Fr 13* simulation of Table 5-2 a for heat-up, columns 3 and 4, a r-MC sample for the temperature for the raw milk = 4.13 ^{O}C is seen, in combination with mass flow of milk = 6.18 kg s^{-1}, specific heat of milk = 4.01 kJ kg^{-1} K^{-1}, inlet temperature of the heating water = 91.59 ^{O}C, mass flow of heating water = 6.14 kg s^{-1} and specific heat of the heating water = 4.18 kJ kg^{-1} K^{-1}, for which the resulting risk factor for heat-up, p_1 = 11.08. Because $p_1 > 0$, this highlights a process failure to heat the raw milk to the design (Regulatory) 72 ^{O}C plus a practical *tolerance* of 2 %. Importantly, the reader should note that all tabulated values are reproduced from the r-MC sampling and it is not implied they are measured to the significance shown.

Significantly however, the results in Table 5-2 a, b, c and d are for one-only process scenario.

In this 4-step microbiological model there were overall 5,637 failure scenarios (with $p_1 > 0$) that occurred in the 10,000 simulations. (This resulted in an output graph which is all but identical to that presented in Chapter 4, Fig. 4-3, for the 3-step model). There were 575 failures in $HT_{1\text{-}2}$ and 1,831 corresponding failures in $PHE_{2\text{-}3}$.

There were no additional process failures with the fourth unit-operation integrated into the global model. This result is not unexpected however because the milk is shock-cooled (rapid) and with the resulting low temperature (4 ^{O}C) there is likelihood the pathogenic *MAP* will grow.

The overall underlying failure rate therefore remained at 5.75 % for all batch-continuous pasteurizations with storage of the treated milk.

5.6 Discussion

5.6.1 Integrated 4-step global *Fr 13* pasteurizer

The global 4-step microbiological failure of pasteurizer and storage of pasteurized milk is characterized by the stream leaving $HT_{1\text{-}2}$, i.e. all $p_2 > 0$.

When a fourth interconnected unit-operation is added to the 3-step pasteurizer of (Chapters 3 and 4) the overall global failure rate remained the same at 5.75 % i.e. no additional failures were generated in the fourth isothermal storage of pasteurized milk step ($p_4 = 0$). This implies that would be 21 failures (5.75/100 days x 365.25 days/year =) each year to meet the required logarithmic reduction of 5.5 (plus a 2 % *tolerance*) in the viable numbers of *MAP* that could not be attributed to human error or faulty fittings (Abdul-Halim and Davey, 2016; 2015; Davey and Cerf, 2003). However, this failure rate will not be equally spaced in time.

It can be concluded that despite the inclusion of this additional process step, when viewed over the long term, the rate of vulnerability to *Fr 13* failure in the 4-step microbiological global model did not increase over the 3-step model i.e. the overall global failure rate remained the same at 5.75 %.

5.6.2 Second-tier studies to mitigate failures in the integrated 4-step global microbiological model

The controlling process parameters in this global 4-step microbiological model are both the mass flow rate of raw milk entering the pasteurizer, $m_{m,\,PHE\ 1\text{-}1}$ and the specific heat of the milk $C_{p,m\ PHE\ 1\text{-}1}$.

The raw milk entering the pasteurizer is an overriding factor in the 4-step model and plays a very important role in the overall global 4-step microbiological model failure with unwanted survival of viable *MAP*.

Second-tier simulation studies highlight therefore that vulnerability to failure in the 4-step model can best be mitigated by maintaining precise SIL mass flow during the holding step ($HT_{1\text{-}2}$) and ensuring that a holding time of $\geq$ 15 s is achieved.

The important thing is that a global 4-step microbiological *Fr 13* model has successfully been established for the very first time

5.7 Chapter summary and conclusions

The following important factors emerge from this chapter:

1. A *Fr 13* risk analysis of an integrated 4-step microbiological global synthesis for pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*) and involving milk 1) heat-up, 2) holding 3) cool-down and 4) isothermal storage has been developed. Results reveal that a 4-step (batch) continuous pasteurization of raw milk is a mix of successful operations together with unsuccessful ones. With a fixed *tolerance* of 2 % on the integrated unit-operations some 5.75 % of all operations could result in failure to reduce viable *MAP* due to the cumulative impact of stochastic (random) effects. This rate is unchanged from the global 3-step microbiological model i.e. there were no additional failures generated when a fourth unit-operation of storage of treated pasteurized milk is included in a global microbiological synthesis. This result is not unexpected because *MAP* will not grow meaningfully at the storage temperature. The work however demonstrates the *Fr 13* framework to increasing multi-step processing

2. The overall failure to reduce viable *MAP* in an integrated 4-step pasteurization and storage of pasteurized (treated) milk is governed by the holding step ($HT_{1\text{-}2}$)

3. Failure in one unit-operation did not necessarily lead to a failure in the inter-connected unit-operation. Second-tier simulation studies highlighted that failures in the global microbiological pasteurizer can be mitigated by maintaining 1) precise SIL mass flow during the holding step ($HT_{1\text{-}2}$) and 2) by ensuring that a holding time of ≥ 15 s is always achieved

4. Significantly, there appears no methodological barriers to application of *Fr 13* framework to increasing multi-step (in the sense of ‘integrated’ not ‘complicated’) processing.

In the next chapter, Chapter 6, the conclusions that resulted from this research work and the future developments that can be made to advance this novel *Fr 13* framework are presented.

CHAPTER 6

CONCLUSIONS AND FUTURE DEVELOPMENT

6.1 Conclusions

1. Steady-state processes are used globally in chemical engineering. However, in steady state processing, there are naturally occurring random (stochastic) fluctuations in process parameter values about a ‘set’ mean. These are not sufficient to be considered transient and a random change in one is often off-set by a change in another, with the result that the output remains seemingly steady. In traditional chemical engineering these naturally occurring random fluctuations are not addressed explicitly. Davey and co-workers have shown however that these naturally occurring (random) fluctuations in process parameter values can combine and accumulate in one direction and leverage unexpected and surprise behaviour across a ‘failure - not failure’ boundary. This hypothesis they titled *Fr 13* to underscore the surprise element of the failure event

2. Because published *Fr 13* case studies were limited to 1-step (and recently to a 2-step) unit-operation a research program was undertaken with the aim to advance the *Fr 13* framework to investigate how naturally occurring random fluctuations in apparent steady-state processes can be transmitted and impact in progressively multi-step complex processes. Globally used 3-step pasteurization of raw milk was selected as a stringent test of the framework

3. *Fr 13* predictions from a 3-step equipment model synthesized for the first time for pasteurization of the raw milk consisting of 1) heating, 2) holding and 3) cooling, highlighted that apparent steady-state pasteurization is actually a mix of successful operations together with unsuccessful ones with a vulnerability to failure, over the long term, of 12.51 % of all operations. If each operation is considered a daily (batch-continuous) operation then 46 pasteurizer failures could arise every year due to failure to meet Regulatory equipment performance (*T*-*t*) standards (72 ^{O}C, 15 s). However, these failures would not be expected to be spaced equally in time. A generalized method of notation for the *Fr 13* risk framework was developed to clearly identify particular unit-operations in integrated multi-step processes that could be logically expanded for complex (in the sense of ‘integrated’ not ‘complicated’) processes. However, despite its advance, this 3-step equipment model highlighted that the definition of pasteurization failure should be predicated on a design reduction in the number of viable contaminant pathogens

4. A microbiological risk model was synthesized for the first time to address this drawback. A *Fr 13* risk analysis of an integrated 3-step global microbiological model, consisting of three unit-operations 1) heating, 2) holding and 3) cooling, for pasteurization of raw milk containing viable *Mycobacterium avium* subsp. *paratuberculosis* revealed that this (batch) continuous pasteurization is also a mix of successful operations together with unsuccessful ones, with a fixed *tolerance* of 2 % on all three inter-connected unit-operations, 5.75 % of all operations result in failure due to cumulative impact of stochastic (random) effects for a design Regulatory reduction of $\log_{10} = 5.5$ in viable *MAP*. If each operation is considered as a daily (batch-continuous) operation then 21 pasteurizer failures could arise every year due to potential survival of pathogenic *MAP*, however, this failure rate would not be expected to be spaced equally in time

5. To further test applicability of the *Fr 13* risk framework, a fourth step was integrated into the global microbiological model for pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* for the first time – this involved, heating, holding, cooling and storage of the milk. Results of simulations with this 4-step model showed that with a design *tolerance* of 2 % and a Regulatory reduction of $\log_{10} = 5.5$ in viable *MAP* on heat-up to 72 ^{O}C with 15 s holding and rapid cooling to 4 ^{O}C and storage, there were no additional failures over the 3-step microbiological model for pasteurizing of milk, remaining at 5.75 %, averaged over the long term. This finding was not unexpected however because *MAP* will not grow meaningfully at the storage temperature. The work however demonstrated the *Fr 13* framework to increasing multi-step processing

6. Importantly, this research has highlighted the fact that a failure in one unit-operation does not necessarily lead to a failure in inter-connected and integrated operations, that is to say, apparent steady-state process are a combination of successful and failed operations. This insight is new and cannot be obtained using traditional risk and hazard approaches, with or without sensitivity analyses

7. Second-tier simulation studies available with the *Fr 13* framework underscored that vulnerability to microbiological pasteurizer failures can best be mitigated by 1) installing precise safety-integrity-level (SIL) mass flow control on the input raw milk, and, 2) establishing stringent ways to maintain the required holding time of raw milk in the holding tube i.e. by ensuring that a holding time of ≥ 15 s is always achieved. To confirm these *Fr 13* predictions for the integrated 4-step pasteurization and storage of treated milk, process validation trials with experimental data are needed. However, this is beyond the scope of the current work

8. It is concluded that the *Fr 13* framework is generalizable to a range of generic global steady-state processes of increasing complexity and interconnectedness. That is there is no evidence of methodological barriers to advancement of the risk framework for integrated multi-step processes. If properly developed the framework could provide a new process design tool that could be adapted at both synthesis and analysis stages to provide new insight and knowledge about process plant behaviour

9. Findings from this research work will aid a detailed understanding of factors that could contribute to unexpected failures, and will result in increased confidence in steady-state processing of chemical engineering unit-operations.

This research work is original and not incremental work. Results obtained from this research work will be of direct interest to risk analysts, researchers, milk processors and manufacturers of pasteurizer equipment.

6.2 Recommendations for future research

Importantly, the success of this research shows that this novel *Fr 13* framework can, in principle, be applied to underlying minimize risk to failure in a range of global steady-state processes of increasing complexity and interconnectedness. The 4-step microbiological model for example could be further refined to incorporate degradation of milk proteins (Davey and Cerf, 1996) together with fouling of equipment during pasteurization. This would be useful for refined trade-off scenarios to develop physical changes (via second-tier studies) to plant, which in turn could be used to reduce vulnerability to surprise failures.

Given the success of this work, it is planned that *Fr 13* be tested for generic chemical engineering unit-operations processes. A generic unit-operations process consists of each of at least one feed(s) stream, reactor, separator, product, recycle and purge, stream. This work is currently in preparation (Davey, 2017) - where preliminary results indicate a counter-intuitive picture of apparent steady-state processing.

The proper and careful advancement of the *Fr 13* framework appears to offer real benefits that include an improved knowledge and understanding for practical re-design for a reduced risks processing. This work will continue to be of interest to a range of design engineers and operators of a range of unit-operations.

It is also recommended that framework has the potential to be coupled with current existing design software such as Aspen Plus™ and Batch Process Developer™ to produce a more powerful design and assessment tool for enhanced process design and for improved process outcomes in the foods and chemical industries.

APPENDIX A – A definition of some important terms used in this research

Failure	A scenario in which the a design value for success is not achieved
Fr 13 Syndrome	Event defined by an adverse outcome in which fluctuations in parameter values unexpectedly combined to result in (surprise) failure (defined by Davey and Cerf , 2003)
Fr 13 simulation	A novel probabilistic simulation (developed by Davey and Cerf, 2003) using refined (with Latin Hypercube) Monte Carlo (r-MC) sampling
HTST pasteurization	High-Temperature Short-Time pasteurization in which raw milk is heated to a temperature greater than 72 ^{O}C and held for a specific period (15 s)
LTLT pasteurization	Low Temperature Long Time (HTST) pasteurization, a method of pasteurizing milk, where the milk is heated to a temperature of 63 ^{O}C in open vats and is held at that temperature of 63 ^{O}C for a period of 30 mins. Also called ‘batch pasteurization’
Pasteurization	Pasteurization is the process of heat processing a liquid or a food to inactivate viable pathogenic bacteria to make the food safe to eat
Pasteurizer failure	The number of simulated pasteurization scenarios that does not necessarily achieve the required physical pasteurizer design or microbiological parameters in pasteurizer design
Probability	A numerical measure of the likelihood of a particular outcome of a stochastic process scenario
Risk modelling	A structured science based process, used to estimate the likelihood of risk
Second-tier studies	Process intervention strategies and re-design of physical plant based on *Fr 13* risk analyses results; carried out to reduce vulnerability to surprise (stochastic) failures (first defined by Davey, 2011)
Single Value Assessment	Traditional, deterministic model simulation for a desired model output with single value inputs (first defined by Davey and Cerf, 2003)
Tolerance	Overdesign, or, margin of safety

Uncertainty	A lack of knowledge, or level of ignorance, about the parameters that characterize the physical system which is being modelled. It is also referred to as a *Fact*. Uncertainty is sometimes reducible through further measurement r careful study, or by consulting more experts (Vose, 2008)
Unit-operation	An operation in which chemical as well as physical changes takes place e.g. mixing, heating, drying, evaporation, distillation and pasteurization
UHT pasteurization	Ultra-High Temperature (UHT) pasteurization, a method of pasteurizing milk and involves two stages, first milk is heated to a temperature of 75 ^{O}C, and, then under pressure milk is heated to a temperature of 140 ^{O}C and is held at that temperature for about 4 s. After this the milk is quickly cooled and packed under aseptic conditions
Variability	The effect of *Chance* on an outcome. It is a function of the system. Variability is not reducible through further study or careful measurement. It can be reduced through changing the physical system (Vose, 2008)

APPENDIX B - Synthesis of the risk factor for Chapters 3, 4 and 5

In this Appendix the dimensionless form of the risk factor for the pasteurized milk are developed for heat-up, holding for thermal inactivation and cool-down.

B.1 Raw milk heat-up, p_1

A risk factor (P_1) for heat-up ($PHE_{1\text{-}1}$) can be defined in terms of the outlet temperature of milk from $PHE_{1\text{-}1}$ ($T_{o,m\ PHE\ 1\text{-}1}$) i.e.

$$P_1 = T_{o,m\ PHE\ 1-1}{}' - T_{o,m\ PHE\ 1-1} \tag{3.26}$$

Dividing Eq. (3.26) by $T_{o,m\ PHE\ 1\text{-}1}$ gives

$$P_1 = \frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - \frac{T_{o,m\ PHE\ 1-1}}{T_{o,m\ PHE\ 1-1}} = \frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1 \tag{B.1}$$

More conveniently however, a dimensionless risk factor p_1 can be defined as

$$p_1 = \left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1\right) * 100 \tag{B.2}$$

Adding a practical *tolerance* over design heat-up temperature of raw milk $T_{o,m\ PHE\ 1\text{-}1}$, the risk factor for raw milk heat up Eq. (B.2) becomes

$$p_1 = +tolerance_1 - 100 * \left(\frac{T_{o,m\ PHE\ 1-1}{}'}{T_{o,m\ PHE\ 1-1}} - 1\right) \tag{B.3}$$

B.2 Milk holding, p_2

In the equipment model a risk factor (P_2) for holding ($HT_{1\text{-}2}$) can be defined in terms of holding time of milk $t_{m,\ HT\ 1\text{-}2}$ i.e.

$$P_2 = t_{m,\ \ HT\ 1-2}{}' - t_{m,\ \ HT\ 1-2} \tag{B.4}$$

Dividing Eq. (B.4) by $t_{m,\ \ HT\ 1-2}$ gives

$$P_2 = \frac{t_{m,\ \ HT\ 1-2}{}'}{t_{m,\ \ HT\ 1-2}} - \frac{\mathrm{t}_{m,\ \ HT\ 1-2}}{\mathrm{t}_{m,\ \ HT\ 1-2}} = \frac{t_{m,\ \ HT\ 1-2}{}'}{t_{m,\ \ HT\ 1-2}} - 1 \tag{B.5}$$

p_2 can conveniently be defined as

$$p_2 = \left(\frac{t_{m,\ HT\ 1-2'}}{t_{m,\ HT\ 1-2}} - 1\right) * 100 \tag{B.6}$$

Adding a practical *tolerance* over design holding time of milk, Eq. (B.6) becomes

$$p_2 = +tolerance_2 - 100 * \left(\frac{t_{m,\ HT\ 1-2'}}{t_{m,\ HT\ 1-2}} - 1\right) \tag{B.7}$$

Similarly, in the integrated microbiological model of holding for thermal inactivation of *MAP*, a suitable risk factor for overall pasteurizer failure, defined as unwanted survival of *MAP*, can be characterized by a risk factor for heat treated milk (p_2) defined in terms of $\log_{10}$ reduction of viable *MAP* such that

$$p_2 = +tolerance_2 - 100\left(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}} - 1\right) \tag{B.8}$$

where $\log_{10}(N/N_0)_{HT\ 1\text{-}2}{}'$ is one possible practical scenario in reduction of viable pathogens and $\log_{10}(N/N_0)_{HT\ 1\text{-}2}$ is the required $\log_{10}$ reduction for safely pasteurized milk.

B.3 Treated milk cool-down, p_3

Similarly, risk factor (P_3) for cool-down ($PHE_{2\text{-}3}$) can be defined in terms of milk outlet temperature from $PHE_{2\text{-}3}$ ($T_{o,m\ PHE\ 2\text{-}3}$) i.e.

$$P_3 = T_{o,m\ PHE\ 2-3}{}' - T_{o,m\ PHE\ 2-3} \tag{B.10}$$

Dividing Eq. (B.10) by $T_{o,m\ PHE\ 2\text{-}3}$ gives:

$$P_3 = \frac{T_{o,m\ PHE\ 2-3'}}{T_{o,m\ PHE\ 2-3}} - \frac{T_{o,m\ PHE\ 2-3}}{T_{o,m\ PHE\ 2-3}} = \frac{T_{o,m\ PHE\ 2-3'}}{T_{o,m\ PHE\ 2-3}} - 1 \tag{B.11}$$

p_3 can be defined as

$$p_3 = \left(\frac{T_{o,m\ PHE\ 2-3'}}{T_{o,m\ PHE\ 2-3}} - 1\right) * 100 \tag{B.12}$$

Adding a practical *tolerance* over design treated milk cool-down temperature $T_{o,m\ PHE\ 2\text{-}3}$, Eq. (B.12) becomes

$$p_3 = +tolerance_3 - 100 * \left(\frac{T_{o,m\ PHE\ 2-3'}}{T_{o,m\ PHE\ 2-3}} - 1\right) \tag{B.13}$$

Since milk is being cooled-down from a higher treated temperature to a lower treated temperature, and, in order to make all values of $p_3 > 0$ as failures, Eq. (B.13) has to rewritten as

$$p_3 = -tolerance_3 + 100 * \left(\frac{T_{o,m\,PHE\,2-3'}}{T_{o,m\,PHE\,2-3}} - 1\right) \tag{B.14}$$

B.4 Storage of pasteurized (treated) milk, p_4

A risk factor (p_4) for storage of pasteurized milk ($ST_{1\text{-}4}$) can be defined similarly to that of holding ($HT_{1\text{-}2}$) can be defined in terms of holding time of milk $t_{m,\,HT\,1\text{-}2}$ i.e.

$$p_4 = +tolerance_4 - 100(\frac{\log_{10}\left(\frac{N}{N_0}\right)_{ST\,1-4}{}'}{\log_{10}\left(\frac{N}{N_0}\right)_{ST\,1-4}} - 1) \tag{B.15}$$

where $\log_{10}(N/N_0)_{ST\,1\text{-}4}{}'$ is one possible practical scenario in reduction of viable pathogens while the pasteurized (treated) milk is stored and $\log_{10}(N/N_0)_{ST\,1\text{-}4}$ is the required $\log_{10}$ reduction for safely stored treated milk.

APPENDIX C – Refereed publications from this research

Refereed Scientific Journals

Chandrakash, S., Davey, K.R., 2017 a. Advancing the *Fr 1*3 risk framework to an integrated three-step microbiological failure synthesis of pasteurization of raw milk containing *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*). Chemical Engineering Science 171, 1-18. http://dx.doi.org/10.1016/j.ces.2017.05.020

Chandrakash, S., Davey, K.R., O'Neill, B.K., 2015. An *Fr 13* risk analysis of failure in a global food process – illustration with milk processing. Asia Pacific Journal of Chemical Engineering (Special Theme Research Article (**Invited paper**)) 10 (4), 526-541. http://dx.doi.org/10.1002/apj.1887

Refereed Conference Proceeding(S)

Davey, K.R., Chandrakash, S., O'Neill, B.K., 2014. A novel Friday 13th risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26th European Modelling and Simulation Symposium - EMSS 2014, Bordeaux, France, Sept. 10-12. ISBN: 9788897999386

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. In: Proc. 44th Australasian Chemical Engineering Conference (Processing Excellence, Powering our Future), Perth, Australia, Sept. 27-Oct. 1, paper 1475. ISBN: 9781922107381

Other Related

Davey, K.R., Chandrakash, S., O'Neill, B.K., 2015. A Friday 13th failure assessment of clean-in-place removal of whey protein deposits from metal surfaces with auto-set cleaning times. Chemical Engineering Science 126, 106-115. http://dx.doi.org/10.1016/j.ces.2014.12.013

Davey, K.R., Chandrakash, S., 2015. Modelling the effect of pH, sodium chloride and sodium pyrophosphate on the thermal resistance of *Escherichia coli* 0157:H7 in ground beef. Food Research International 75, 11-12. http://dx.doi.org/10.1016/j.foodres.2015.05.030

Manuscripts in Preparation

Chandrakash, S., Davey, K.R., 2017 b. A 4-step *Fr 13* microbiological pasteurizer model for raw milk involving heat-up, holding for thermal inactivation of *Mycobacterium avium* subsp. *paratuberculosis* (*MAP*), cool-down and storage. AIChE J – *in preparation*.

Chandrakash, S., Davey, K.R., 2017 c. A review of the *Fr 13* risk assessment framework. Food Research International – *in preparation*.

NOMENCLATURE

The equation number given after description refers to that in which the symbol is first used or defined.

$A_{PHE\ 1\text{-}1}$	Heat transfer area $PHE_{1\text{-}1}$ (m^2), (3.1); (4.1); (5.1)
$A_{PHE\ 2\text{-}3}$	Heat transfer area $PHE_{2\text{-}3}$ (m^2), (3.15); (4.18); (5.18)
$b_{p,\ PHE\ 1\text{-}1}$	Gap between plates $PHE_{1\text{-}1}$ (m), (3.4); (4.4); (5.4)
$b_{p,\ PHE\ 2\text{-}3}$	Gap between plates $PHE_{2\text{-}3}$ (m), (3.18); (4.21); (5.21)
$C_{p,m\ PHE\ 1\text{-}1}$	Specific heat of milk $PHE_{1\text{-}1}$ (kJ kg^{-1} K^{-1}), (3.2); (4.2); (5.2)
$C_{p,m\ PHE\ 2\text{-}3}$	Specific heat of milk $PHE_{2\text{-}3}$ (kJ kg^{-1} K^{-1}), (3.16); (4.19); (5.19)
$C_{p,w\ PHE\ 1\text{-}1}$	Specific heat of water $PHE_{1\text{-}1}$ (kJ kg^{-1} K^{-1}), (3.3); (4.3); (5.3)
$C_{p,b\ PHE\ 2\text{-}3}$	Specific heat of water $PHE_{2\text{-}3}$ (kJ kg^{-1} K^{-1}), (3.17); (4.20); (5.20)
$D_{e,PHE\ 1\text{-}1}$	Equivalent diameter of plate $PHE_{1\text{-}1}$ (m), (3.4); (4.4); (5.4)
$D_{e,PHE\ 2\text{-}3}$	Equivalent diameter of plate $PHE_{2\text{-}3}$ (m), (3.18); (4.21); (5.21)
$D_{HT\ 1\text{-}2}$	Diameter of holding tube $HT_{1\text{-}2}$ (m), (3.14); (4.17); (5.17)
$D_{t,\ HT\ 1\text{-}2}$	Decimal reduction of pathogen *MAP* at $T_{m,HT\ 1\text{-}2}$ $HT_{1\text{-}2}$ (s) (4.12); (5.12)
$D_{t,\ ST\ 1\text{-}4}$	Decimal reduction of pathogen *MAP* in $ST_{1\text{-}4}$ (min) (5.29)
$D_{t,ref\ HT\ 1\text{-}2}$	Decimal reduction of pathogen *MAP* at $T_{ref,\ HT\ 1\text{-}2}$ $HT_{1\text{-}2}$ (s) (4.12); (5.12)
$F_{t,\ PHE\ 1\text{-}1}$	Temperature correction factor $PHE_{1\text{-}1}$ (dimensionless), (3.1); (4.1); (5.1)
$F_{t,\ PHE\ 2\text{-}3}$	Temperature correction factor $PHE_{2\text{-}3}$ (dimensionless), (3.15); (4.18); (5.18)
HT	Holding tube (Fig. 3-1; 4-1; 5-1)
$j_{F,\ PHE\ 1\text{-}1}$	Friction factor for liquid through $PHE_{1\text{-}1}$(dimensionless),(3.11);(4.11); (5.12)
$j_{F,\ PHE\ 2\text{-}3}$	Friction factor for liquid through $PHE_{2\text{-}3}$ (dimensionless), (3.25); (4.28); (5.28)
$k_{d,\ HT\ 1\text{-}2}$	Thermal inactivation rate of viable *MAP* $HT_{1\text{-}2}$ (s^{-1}) (4.13); (5.13)
$k_{d,\ ST\ 1\text{-}4}$	Thermal inactivation rate of viable *MAP* $ST_{1\text{-}4}$ (min^{-1}) (5.29)
$L_{HT\ 1\text{-}2}$	Length of holding tube $HT_{1\text{-}2}$ (m), (3.12); (4.15); (5.15)
$L_{p,\ PHE\ 1\text{-}1}$	Length of the plate $PHE_{1\text{-}1}$ (m), (3.5); (4.5); (5.5)
$L_{p,\ PHE\ 2\text{-}3}$	Length of the plate $PHE_{2\text{-}3}$ (m), (3.19); (4.22); (5.22)
$\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}$	Log reduction of viable *MAP* $HT_{1\text{-}2}$ (dimensionless) (4.14); (5.14)
$\log_{10}\left(\frac{N}{N_0}\right)_{HT\ 1-2}{}'$	Log reduction of viable *MAP* $HT_{1\text{-}2}$ *Fr 13* simulation (dimensionless) (4.32)
$\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}$	Log reduction of viable *MAP* $HT_{1\text{-}2}$ (dimensionless) (5.30)
$\log_{10}\left(\frac{N}{N_0}\right)_{ST\ 1-4}{}'$	Log reduction of viable *MAP* $HT_{1\text{-}2}$ *Fr 13* simulation (dimensionless) (5.34)

$m_{m,\,PHE\;1\text{-}1}$	Mass flow rate of milk $PHE_{1\text{-}1}$ (kg s^{-1}), (3.2); (4.2); (5.2)
$m_{m,\,HT\;1\text{-}2}$	Mass flow rate of milk $HT_{1\text{-}2}$ (kg s^{-1}), (3.14); (4.17); (5.17)
$m_{m,\,PHE\;2\text{-}3}$	Mass flow rate of milk $PHE_{2\text{-}3}$ (kg s^{-1}), (3.16); (4.19); (5.19)
$m_{m,\,ST\;1\text{-}4}$	Mass flow rate of milk $ST_{1\text{-}4}$ (kg s^{-1}), (Table 5-1)
$m_{w,\,PHE\;1\text{-}1}$	Mass flow rate of water $PHE_{1\text{-}1}$ (kg s^{-1}), (3.3); (4.3); (5.3)
$m_{b,\,PHE\;2\text{-}3}$	Mass flow rate of water $PHE_{2\text{-}3}$ (kg s^{-1}), (3.17); (4.20); (5.20)
$n_{p,\,PHE\;1\text{-}1}$	Number of plates required $PHE_{1\text{-}1}$ (dimensionless), (3.5); (4.5); (5.5)
$n_{p,\,PHE\;2\text{-}3}$	Number of plates required $PHE_{2\text{-}3}$ (dimensionless), (3.19); (4.22); (5.22)
P_1	Failure risk factor for milk heating and heat-up (^{O}C), (3.26); (4.29)
p_1	Risk factor for heating unit-operation (dimensionless), (3.27); (4.30); (5.31)
p_2	Risk factor for holding unit-operation (dimensionless), (3.29); (4.32); (5.32)
p_3	Risk factor for cooling unit-operation (dimensionless), (3.31); (4.34); (5.33)
p_4	Risk factor for storage of treated milk unit-operation (dimensionless), (5.34)
PHE	Plate heat exchanger (Fig. 3-1; 4-1; 5-1)
$q_{PHE\;1\text{-}1}$	Heat duty $PHE_{1\text{-}1}$ (kJ s^{-1}), (3.1); (4.1); (5.1)
$q_{PHE\;2\text{-}3}$	Heat duty of $PHE_{2\text{-}3}$ (kJ s^{-1}), (3.15); (4.18); (5.18)
$\mathrm{Re}_{PHE\;1\text{-}1}$	Reynolds number $PHE_{1\text{-}1}$ (dimensionless quantity), (3.8); (4.8); (5.8)
$\mathrm{Re}_{PHE\;2\text{-}3}$	Reynolds number $PHE_{2\text{-}3}$ (dimensionless quantity), (3.22); (4.25); (5.25)
ST	Storage tank (Fig. 5-1; 5-2)
$T_{m,avg\;PHE\;1\text{-}1}$	Average milk temperature $PHE_{1\text{-}1}$ (^{O}C), (3.6); (4.6); (5.6)
$T_{m,avg\;PHE\;2\text{-}3}$	Average milk temperature $PHE_{2\text{-}3}$ (^{O}C), (3.20); (4.23); (5.23)
$T_{m,HT\;1\text{-}2}$	Holding temperature of milk $HT_{1\text{-}2}$ (^{O}C), (3.13); (4.12); (5.12)
$T_{m,ST\;1\text{-}4}$	Storage temperature of milk $ST_{1\text{-}4}$ (^{O}C), (Table 5-1)
$T_{ref,\,HT\;1\text{-}2}$	Reference temperature for pathogen MAP $HT_{1\text{-}2}$ (^{O}C) (4.12); (5.12)
$T_{i,m\;PHE\;1\text{-}1}$	Inlet temperature of milk $PHE_{1\text{-}1}$ (^{O}C), (3.2); (4.2); (5.2)
$T_{i,m\;PHE\;2\text{-}3}$	Inlet temperature of milk $PHE_{2\text{-}3}$ (^{O}C), (3.16); (4.19); (5.19)
$T_{o,m\;PHE\;1\text{-}1}$	Outlet temperature of milk $PHE_{1\text{-}1}$ (^{O}C), (3.2); (4.2); (5.2)
$T_{o,m\;PHE\;1\text{-}1}'$	Outlet temperature of milk $PHE_{1\text{-}1}$ using *Fr 13* simulation (^{O}C), (3.26); (4.29); (5.31)
$T_{o,m\;PHE\;2\text{-}3}$	Outlet temperature of milk $PHE_{2\text{-}3}$ (^{O}C), (3.16); (4.19); (5.19)
$T_{o,m\;PHE\;2\text{-}3}'$	Outlet temperature of milk $PHE_{2\text{-}3}$ using *Fr 13* simulation (^{O}C), (3.31); (4.34); (5.33)
$T_{i,w\;PHE\;1\text{-}1}$	Inlet temperature of water $PHE_{1\text{-}1}$ (^{O}C), (3.3); (4.3); (5.3)
$T_{i,b\;PHE\;2\text{-}3}$	Inlet temperature of water $PHE_{2\text{-}3}$ (^{O}C), (3.17); (4.20); (5.20)
$T_{o,w\;PHE\;1\text{-}1}$	Outlet temperature of water $PHE_{1\text{-}1}$ (^{O}C), (3.3); (4.3); (5.3)
$T_{o,b\;PHE\;2\text{-}3}$	Outlet temperature of water $PHE_{2\text{-}3}$ (^{O}C), (3.17); (4.20); (5.20)

$t_{m,HT\ 1-2}$	Holding time HT_{1-2} (s), (3.12); (4.14); (5.14)
$t_{m,HT\ 1-2}'$	Holding time HT_{1-2} using *Fr 13* simulation (s), (3.29)
$t_{m,ST\ 1-4}$	Storage time of treated (pasteurized) milk ST_{1-4} (mins), (5.30)
$t_{r,\ PHE\ 1-1}$	Residence time of milk PHE_{1-1} (s), (3.9); (4.9); (5.9)
$t_{r,\ PHE\ 2-3}$	Residence time of milk PHE_{2-3} (s), (3.23); (4.26); (5.26)
$U_{PHE\ 1-1}$	Overall heat transfer coefficient PHE_{1-1} (kW m^{-2} K^{-1}), (3.1); (4.1); (5.1)
$U_{PHE\ 2-3}$	Overall heat transfer coefficient PHE_{2-3} (kW m^{-2} K^{-1}), (3.15); (4.18); (5.18)
$v_{m,\ PHE\ 1-1}$	Milk velocity PHE_{1-1} (m s^{-1}), (3.7); (4.7); (5.7)
$v_{m,\ PHE\ 2-3}$	Milk velocity PHE_{2-3} (m $s^{-1,}$), (3.21); (4.24); (5.24)
$v_{m,HT\ 1-2}$	Milk velocity holding tube HT_{1-2} (m s^{-1}), (3.14); (4.15); (5.15)
$w_{p,\ PHE\ 1-1}$	Thickness of the plate PHE_{1-1} (m), (3.4); (4.4); (5.4)
$w_{p,\ PHE\ 2-3}$	Thickness of the plate PHE_{2-3} (m), (3.18); (4.21); (5.21)
$z_{HT\ 1-2}$	*z*-value for pathogen *MAP* HT_{1-2} (^{O}C) (4.12); (5.12)
$\Delta P_{PHE\ 1-1}$	Pressure drop PHE_{1-1} (N m^{-2}), (3.10); (4.10); (5.10)
$\Delta P_{PHE\ 2\ -3}$	Pressure drop PHE_{2-3} (N m^{-2}), (3.24); (4.27); (5.27)
$\Delta T_{LMTD,\ PHE\ 1-1}$	Log mean temperature difference between liquids PHE_{1-1} (^{O}C), (3.1); (4.1); (5.1)
$\Delta T_{LMTD,\ PHE\ 2-3}$	Log mean temperature difference between liquids PHE_{2-3} (^{O}C), (3.15); (4.18); (5.18)

Greek Symbols

$\rho_{m,\ PHE\ 1-1}$	Density of milk PHE_{1-1} (kg m^{-3}), (3.6 b); (4.6 b); (5.6 b)
$\rho_{m,\ HT\ 1-2}$	Density of milk HT_{1-2}(kg m^{-3}), (3.13); (4.16); (5.16)
$\rho_{m,\ PHE\ 2-3}$	Density of milk PHE_{2-3}(kg m^{-3}), (3.20 b); (4.23 b); (5.23 b)
$\mu_{m,\ PHE\ 1-1}$	Viscosity of milk PHE_{1-1} (Pa s), (3.6 a); (4.6 a); (5.6 a)
$\mu_{m,\ PHE\ 2-3}$	Viscosity of milk PHE_{2-3} (Pa s), (3.20 a); (4.23 a); (5.23 a)

Other

MAP	*Mycobacterium avium* subsp. *paratuberculosis*
stdev	Standard deviation
$tolerance_1$	(3.27); (4.30); (5.31)
$tolerance_2$	(3.29); (4.32); (5.32)
$tolerance_3$	(3.31); (4.34); (5.33)
$tolerance_4$	(5.34)

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