



**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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## STATEMENT OF DECLARATION

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<sup>1</sup> 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>

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*.

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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. 44<sup>th</sup> 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 13<sup>th</sup> risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26<sup>th</sup> 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 13<sup>th</sup>)* 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 °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*<sup>2</sup> 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 °C with 15 s holding in commercial plate equipment, there would be no further failures i.e. the rate of

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<sup>2</sup> 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  $\geq 15$  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>

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 13<sup>th</sup> risk analysis of a global food process – application to pasteurization of raw milk containing *Mycobacterium avium paratuberculosis*. In: Proc. 26<sup>th</sup> 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. 44<sup>th</sup> 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 13<sup>th</sup> 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*.

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