A NEW RISK ANALYSIS OF CLEAN-IN-PLACE (CIP) MILK PROCESSING

by

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Addendum

p 31&93 The international publication from this thesis is now in press and available as:

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STATEMENT OF DECLARATION

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[1] Davey, K. R., Chandrakash, S. & O'Neill, B. K. 2011. Friday 13th risk model of Clean-In-Place (CIP) in a milk plant. In *Proc. 41st Australasian Chemical Engineering Conference* (*Engineering a Better World*) September 18-21, Sydney, Australia, paper 150 (ISBN 9780858259225).

Davey, K. R., Chandrakash, S. & O'Neill, B. K. 2012. A novel risk analysis of Clean-In-Place milk processing, *Food Control* – status date 30 March 2012.

EXECUTIVE SUMMARY

The food and pharmaceutical industry are generally a nation's largest manufacturing sector – and importantly one of the most stable. *Clean-In-Place* (CIP)[2] is a ubiquitous process in milk processing as thorough cleaning of wet surfaces of equipment is an essential part of daily operations. Faulty cleaning can have serious consequences as milk acts as an excellent substrate in which unwanted micro-organisms can grow and multiply rapidly.

Davey & Cerf (2003) introduced the notion of *Friday 13th Syndrome*[3] i.e. the unexpected failure of a well-operated process plant by novel application of *Uncertainty Failure Modelling* (Davey, 2010; 2011). They showed that failure cannot always be put down to human error or faulty fittings but could be as a result of stochastic changes inside the system itself.

In this study a novel CIP failure model based on the methodology of Davey and co-workers is developed using the published models of Bird & Fryer (1991); Bird (1992) and Xin (2003); Xin, Chen & Ozkan (2004) for the first time. The aim was to gain insight into conditions that may lead to unexpected failure of an otherwise well-operated CIP plant. CIP failure is defined as failure to remove proteinaceous deposits on wet surfaces in the auto-set cleaning time.

The simplified two-stage model of Bird & Fryer (1991) and Bird (1992) was initially investigated. This model requires input of the thickness of the deposit (δ = 0.00015 m) and the temperature and Re of the cleaning solution (1.0-wt% NaOH). The deposit is considered as two layers: an upper layer of swelled deposit which can be removed ($x\delta$) by the shear from the circulating cleaning solution and a lower layer ($y\delta$) that is not yet removable. The output parameters of particular interest are the rate of deposit removal (R) and total cleaning time (t_T) needed to remove the deposit.

The more elaborate three-stage model of Xin (2003) and Xin, Chen & Ozkan (2004) is based on a polymer dissolution process. This model requires input values of temperature of

[2] *see* Appendix A for a definition of some important terms used in this research.

[3] Unexpected (unanticipated) failure in plant or product of a well-operated, well-regulated unit-operation.

the cleaning solution (T), critical mass of the deposit (m_c) and cleaning rate (R_m). The output parameters of particular interest are the rate of removal during swelling and uniform stage (R_{SU}), the rate of removal during decay stage (R_D) and the total cleaning time needed to remove the deposit (t_T). The two CIP models are appropriately formatted and simulations used to validate them as a unit-operation.

A risk factor (p) together with a practical process tolerance is defined in terms of the auto-set CIP time to remove a specified deposit and the actual cleaning time as affected by stochastic changes within the system (t_T'). This is computationally convenient as it can be articulated so that all values $p > 0$ highlight an unwanted outcome i.e. a CIP failure.

Simulations for the continuous CIP unit-operation are carried out using Microsoft Excel™ spreadsheet with an add-in @Risk™ (pronounced 'at risk') version 5.7 (Palisade Corporation) with some 100,000[4] iterations from Monte Carlo sampling of input parameters. A refined Latin Hypercube sampling is used because 'pure' Monte Carlo samplings can both over- and under-sample from various parts of a distribution. Values of the input parameters took one of the two forms. The first was the traditional *Single Value Assessment* (SVA) as defined by Davey (2011) in which a single, 'best guess' or mean value of the parameter is used. The output therefore is a single value. The alternate form was a *Monte Carlo Assessment* (MCA) (Davey, 2011) in which the 'best guess' values take the form of a probability distribution around the mean value. Many thousands of randomly sampled values for each input parameter are obtained using Monte Carlo sampling. Generally, in QRA the input parameters take the form of a distribution of values. The output therefore is a distribution of values with each assigned a probability of actually occurring.

The values of all inputs are carefully chosen for a realistic simulation of CIP.

Results reveal that a continuous CIP unit-operation is actually a mix of successful cleaning operations along with unsuccessful ones, and that these can tip unexpectedly. For example for the unit-operations model of Bird & Fryer (1991) and Bird (1992) failure to remove a

[4] Experience with the models highlighted that stable output values would be obtained with 100,000 iterations (or CIP 'scenarios').

proteinaceous milk deposit (δ = 0.00015 m) can occur unexpectedly in 1.0% of all operations when a tolerance of 6% is allowed on the specified auto-set cleaning time (t_T = 914 s) with a cleaning solution temperature of 60 ^{O}C. Using Xin, Chen & Ozkan (2004) model as the underlying unit-operation some 1.9% of operations at a nominal mid-range cleaning solution temperature of 75 ^{O}C could fail with a tolerance of 2% on the auto-set CIP time (t_T = 448 s).

Extensive analyses of comparisons of the effect of structure of the two CIP unit-operations models on predictions at similar operating conditions i.e. 2% tolerance on the auto-set clean time (~ 656 s) and 1%-sd in the nominal mean temperature of the NaOH cleaning solution at 65 ^{O}C, highlighted that the underlying vulnerability to failure of the simplified model of Bird & Fryer (1991) and Bird (1992) was 1.8 times that of the more elaborate model of Xin (2003) and Xin, Chen & Ozkan (2004).

The failure analysis presented in this thesis represents a significant advance over traditional analysis in that all possible practical scenarios that could exist operationally are computed and rigorous quantitative evidence is produced to show that a continuous CIP plant is actually a mix of failed cleaning operations together with successful ones. This insight is not available from traditional methods (with or without sensitivity analysis). Better design and operating decisions can therefore be made because the engineer has a picture of all possible outcomes.

The quantitative approach and insight presented here can be used to test re-designs to reduce cleaning failure through changes to the plant including improved temperature and auto-set time control methods.

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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.

TABLE OF CONTENTS	PAGE

LIST OF FIGURES PAGE

LIST OF TABLES **PAGE**