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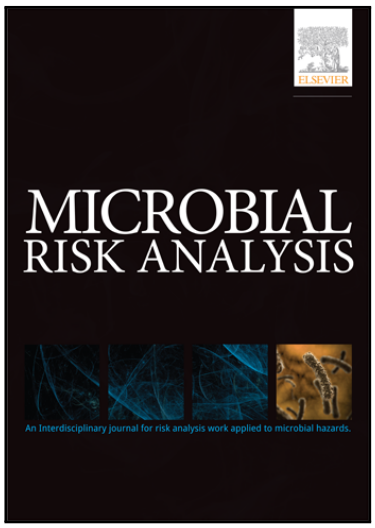

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ACCEPTED MANUSCRIPT

A Bayesian approach to estimating the uncertainty in the distribution of *Cronobacter* spp. in powdered infant formula arising from microbiological criteria test outcomes

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Abstract

The application of microbiological criteria related to foods has become well established for the protection of public health. Sampling plans will more likely detect a microorganism when the level of contamination is high. However, as the concentration of the microorganism drops, detection becomes more and more infrequent. *Cronobacter* spp. is an opportunistic pathogen that can occur infrequently and in low concentrations in powdered infant formula (PIF) with a distribution that is typically heterogeneous. This paper developed a Bayesian approach to quantify the uncertainty in the concentration of *Cronobacter* spp. clusters that may be present in a batch of PIF depending on the outcome of a sampling plan. Two approaches were developed. The first was a Bayesian methodology using a spreadsheet approach to develop the appropriate likelihood and posterior distributions based on an uninformed prior distribution. The second approach was similar but used an algebraic approach rather than a spreadsheet numerical approximation to characterise the uncertainty. Different sampling plans were considered based on the EC Microbiological Criteria for *Cronobacter* spp. When a zero positive test was the outcome of the sampling plans considered, the Bayesian analysis indicated that while the most likely outcome for all the sampling plans considered was zero clusters present, the analysis indicated that the true number of clusters present could be as high as several thousand clusters per tonne of powder depending on the sampling plan. The algebraic approach demonstrated that for zero or one positive tests, the uncertainty distribution could be approximated by a gamma distribution. Choice of the prior distribution influenced the level of uncertainty. The Bayesian approach demonstrates that even when zero positives are detected for a given sampling plan, there remains a considerable uncertainty in the true number of microorganisms that may be present undetected in a consignment of powder.

Key Words: Microbiological Criteria, *Cronobacter*, Bayesian, food safety, sampling plan, powdered infant formula,

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