Food Control 21 (2010) 1338–1348

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Exposure Assessment based on a combination of event and fault tree analyses and predictive modelling

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ARTICLE INFO

Article history:
Received 9 December 2009
Received in revised form 19 April 2010
Accepted 27 April 2010

Keywords:
Predictive modelling
Fault tree analysis
Pasteurized milk
Failures
Food chain
Safety
Process deviation
Industry
Event tree analysis

ABSTRACT

Predictive modelling is a scientific discipline that permits assessment of the impact of process stage deviations when integrated in a stage of the food chain. Predictive modelling is traditionally used to assess the exposure of consumers to the presence of hazards, e.g. *Listeria monocytogenes* due to the occurrence of deviations in the food chain. However, failures related to food safety can occur through the food chain and are not captured by predictive models, e.g. failure of process conditions, incorrect inspections or analyses, etc. Therefore, to address both deviations and failures, predictive modelling must be combined with other techniques. This paper presents a new approach based on a combination of traditional predictive modelling, and event/fault tree analysis techniques, which allow the representation of normal and abnormal (i.e. failures) variations of parameters throughout the food chain for a better estimation of the real impact of such deviations and failures on consumer safety. A combination of event tree and fault tree analysis techniques is adopted to represent a failure anywhere in the food chain, also including failures in the processing parameters in the food industry. For the sake of clarity in the introduction of this approach, an application example is presented considering pasteurized milk, in which human exposure to *L. monocytogenes* is assessed.

1. Introduction

In the last two decades, predictive modelling (PM) has established itself as a scientific discipline in its own right, with regular, scientific articles, books and internet websites. Current applications of PM in an industrial context are varied but can be summarised into three groups of activities: (a) product innovation (microbial growth or inactivation rate, development of new products and processes, determination of storage conditions and shelf-life, etc.); (b) operational support, such as supporting food safety decisions, assessing the impact of process deviations on microbiological safety and the quality of food products; and (c) incident support (estimating the impact on consumer safety or product quality in the case of problems with products in the market).

A predictive model formulates a stochastic process representing the presence of a microbiological, chemical or physical load in food, which depends on a set of intrinsic parameters (e.g. pH, water-activity, acids, salt and preservatives), extrinsic parameters (e.g. chilling, modified atmosphere) or processing parameters (e.g. heat treatment, pressurisation and irradiation). It is clear that these parameters are susceptible to the variability inherent to the characteristics of the products and the operational equipment; predictive modelling is able to represent such variability.

Furthermore, failures related to food safety can occur throughout the whole food chain, such as failures of process equipment, at retail and in the home, which significantly influence food safety attributes as they suppose large and abnormal variations of operational parameters. Predictive modelling alone is not appropriate to represent such failures. Doménech, Escriche, and Martorell (2009), proposed a new approach to integrate Critical Control Point (CCP) effectiveness assessment into predictive modelling to represent the effect of failures linked to process parameters in the food industry. A new predictive model incorporating control of process parameters was developed based on the concept of a control cell.

This paper presents an extension of the approach proposed in Doménech et al. (2009) to address other failures than those introduced in the food industry. The control cell is replaced by a combination of event tree and fault tree analysis techniques to represent a failure anywhere in the food chain, also including failures in the processing parameters in the food industry. Thus, a new approach based on a combination of traditional predictive modelling and event/fault tree analysis techniques is proposed, which permits representation of normal and abnormal (i.e. failures) variations of parameters throughout the food chain for a better estimation of the real impact of such deviations/failures on consumer safety. Domenech, Escriche, and Martorell (2008) introduced a similar

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0956-7135/$ - see front matter
doi:10.1016/j.foodcont.2010.04.007

new approach focusing on food quality attributes. The challenge now is the extension of the new approach focusing on food safety attributes. For the sake of clarity in the introduction of this model an application example is presented considering the food chain for pasteurized milk, in which the human exposure to *Listeria monocytogenes* is assessed.

2. Food chain

In this paper, the following stages of the food chain of pasteurized milk are considered: raw milk, industrial processing, distribution, retail, transport to home and home.

2.1. Raw milk

A complete Exposure Assessment starts at the earliest stages in the production of milk, so that it can include the effect of the environment and health problems of cows. In this step, good production practices are essential to assure hygienic conditions that guarantee a minimum total bacterial count. Also, poor storage and milk transportation practice may offer opportunities for contamination and growth of pathogenic micro-organisms such as *L. monocytogenes* in raw milk.

2.2. Industrial processing

The production process of pasteurized milk normally includes several stages such as holding, mixing, pasteurization, packaging and cold storage. However, in order to simplify the application example, this paper considers only two stages: pasteurization and cold storage.

Pasteurization has the aim of destroying thermolabile pathogens such as *L. monocytogenes* and it is considered a Critical Control Point (CCP) essential to assure milk safety. In order to check that the pasteurizer works well, i.e. free of deviations and failures, a continuous temperature monitoring system is added. In this case, only temperature pasteurization is monitored based on the study of Whiting and Buchanan (1997), which demonstrates that pasteurization time is also important but not nearly as critical as temperature. After pasteurization, milk is packaged. Herein recontamination due to packaging is not considered.

Packaged milk is stored in batches in a cold room until it is delivered. Each batch is sampled while in cold storage to ensure the absence of *L. monocytogenes*, as a means to verify that the process was operated under appropriate conditions.

2.3. Distribution

Milk is transported under strictly controlled time and temperature conditions until it reaches the retailers. Changes in the level *L. monocytogenes* can occur if distribution conditions are not correct.

2.4. Retail

High temperatures in refrigerated milk at retail can permit the growth of *L. monocytogenes* to a level that can endanger consumer health. During this stage, pasteurized milk can be sampled for inspection in order to check the quality and safety level. Thus, the application example carried out in this paper considers inspections performed on a regular basis as an Administrative control.

2.5. Transport to home

Transport to home is carried out under normal ambient temperatures. So, long time and ambient temperature may significantly affect the growth of *L. monocytogenes* at this stage.

2.6. Home refrigerator

Long times and unsuitable temperatures in domestic refrigerators may jeopardize milk safety since *L. monocytogenes* can even grow at refrigerator temperatures (FAO/WHO, 2004). In this stage, the consumers' attitude is essential in order to reduce the risk to health due to consumption of pasteurized milk contaminated by *Listeria*. The consumer has to manage the milk correctly and comply with the Use-by-Date of the package. In this application example it is considered that milk is not ingested after this date.

3. Methodology

3.1. Stage-based model of hazard evolution through the food chain

Fig. 1 provides a schematic view of the stage-based model developed to represent the evolution of a hazard through the stages of the food chain, which is based on the principles introduced in Domenech et al. (2008). In particular, the evolution of *L. monocytogenes* (LM) CFU/ml through the stages of pasteurized milk chain introduced in Section 2 is considered. The model is a result of combining three major techniques: event tree analysis (ETA), fault tree analysis (FTA) and predictive modelling.

Event tree analysis is an inductive logic method for identifying the various sequences which can be generated from a single initiating event. There are several types of event trees. The one used herein is a type of phenomenological event tree (Aven, 1992; Zio, 2007).

The starting point of the event tree is an "initiating event", represented by a "logic variable" *I*, which may lead to a hazard to consumers' health. In this paper, the initiating event represents presence of *L. monocytogenes* in raw milk, which is associated with a level of *L. monocytogenes* CFU/ml represented by LM_0.

The event tree provides systematic coverage of the time sequence of hazard propagation through a series of stages of the food chain starting from the initiating event, i.e. from farm to fork. Several stages of the food chain give rise to a branching of the tree depending on the fulfilment of a given "condition", represented by a "branching event" within the tree. In typical event tree logic it is customary to associate the "top branch" with the fulfilment of the condition, and the "bottom branch" with the non-fulfilment of the condition. The event tree structure is the same as that used in decision tree analysis. Each branching event following the initiating event is conditional on the occurrence of its precursor event. Outcomes of each precursor event are most often binary (success or failure, true or false, yes or no, reject or accept, etc.). In this paper, the rule adopted is to associate the "top branch" with the fulfilment of the "stage rejection" condition and the "bottom branch" the complementary condition, i.e. "no stage rejection" or "stage acceptance".

The event tree is a graphical representation of a "logic model" which identifies possible outcomes, i.e. consequences, following an initiating event. The "consequence tracing" part of the event tree analysis involves taking the initiating event and following the branching events that can result in undesirable consequences. The following types of consequences can be considered on the basis of those proposed for the agro-food sector in (Domenech, Escriche, & Martorell, 2007; Doménech, Escriche, & Martorell, 2006):