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## A knowledge based reliability engineering approach to manage product safety and recalls



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### ABSTRACT

*Purpose:* Managing processed food products' safety and recall is a challenge for industry and governments. Contaminated food items can create a significant public health hazard with potential for acute and chronic food borne illnesses. This industry study examines the challenges companies face while managing a processed food recall situation and devise a responsive and reliable knowledge management framework for product safety and recall supply chain for the focal global manufacturing and distribution enterprise.

*Method:* Drawing upon the knowledge management and product safety and recall literature and reliability engineering theory, this study uses a holistic single case based approach to develop a knowledge management framework with Failure Mode Effects and Criticality Analysis (FMECA) decision model. This knowledge management decision framework facilitates analysis of the root causes for each potential major recall issue and assesses the reliability of the product safety and recall supply chain system and its critical components.

*Results:* The main reasons highlighted for a recall and associated failure modes in a knowledge management framework are to devise appropriate deployment of resources, technology and procedures to recall supply chain. This study underscores specific information described by managers of a global processed food manufacturer and their perspectives about the product safety and recall process, and its complexities. Full scale implementation of product safety and recall supply chain in the proposed knowledge management framework after the current pilot study will be carried out eventually through expert systems. This operational system when fully implemented will capture the essence of decision making environments comprising goals and objectives, courses of action, resources, constraints, technology and procedures.

*Implications:* The study recognizes the significance of communication, integration, failsafe knowledge management process design framework, leveraging technology such as Radio Frequency Identification (RFID) within all levels of supply chain for product traceability and the proactive steps to help companies successfully manage a recall process and also reestablish trust among the consumers. The proposed knowledge management framework can also preempt product recall by acting as an early warning system. A formal knowledge management framework will enable a company's knowledge be cumulative for product safety and recall and serve as an important integrating and coordinating role for the organization.

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## 1. Introduction

As the world becomes more connected, there is increased concern regarding global food safety. The 2008 recall of Irish pork from 21 countries caused a country-wide destruction of pork products and resulted in a scare of food borne illnesses throughout the northern global hemisphere (Potter 2009). In the US alone, the

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http://dx.doi.org/10.1016/j.eswa.2014.03.007 0957-4174/© 2014 Elsevier Ltd. All rights reserved. Centers for Disease Control and Prevention (CDC) estimates, roughly 76 million people suffer food borne illness each year, in which approximately 300,000 are hospitalized, and about 5000 die (New York Times, 2009). The United States Department of Agriculture (USDA) predicts a continued increase in food related illnesses and recalls in the future. In fact, with additional improvements in outbreak surveillance and the technical ability to identify outbreak strains of pathogens, it is likely that there will be more warnings, advisories, and recalls in the future (Hallman & Cuite, 2009). Therefore, it is crucial that the focal company (i.e., processed foods manufacturer and distributor) in a supply chain take immediate steps to implement an effective strategy to recall food products and communicate the recalls to customers in a timely manner or more illnesses and deaths will result.

A product recall is a request to return to the manufacturer a batch or an entire production run of a product, usually due to the discovery of safety issues primarily to protect the public from consuming the questionable product. Recall is also an effort to limit liability for corporate negligence and to improve or avoid damage caused by negative publicity (Chen, Ganesan, & Liu, 2009; Hendrick and Singhal, 2003, 2005; Hill & Westbrook, 1997; Jarrell & Peltzman, 1985). Food recall is specific to the recall of processed foods, for example, the peanut butter recall in early 2009 by the Peanut Corporation of America (Peanut Products Recall, 2009). In the US, there have been numerous incidents of food recalls in the recent past. The recall incidents recorded by the Food and Drug Administration (FDA) vary from mere labeling and packaging errors to serious health hazards. The FDA website provides statistics of recall numbers between 2004 and 2013. The number of recalls recorded has risen from around 4700 incidents in 2004 to nearly 8044 incidents in 2013 (see Fig. 1). Food product recalls decreased in 2013 compared to 9460 in 2012 and are at the same levels as in 2009.

We begin with what roles the US government and international agencies play in the recall process. If company's management fails to voluntarily take action, the government agencies responsible for the product have the legal authority to request or force the recall process on the company (Kolman, 2008). The agencies governing the food recall process in the United States are the FDA and the United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS). At a national level, the CDC acts as an online resource for credible health information by maintaining health related data from individual states. Both the FDA and USDA are responsible for evaluating the seriousness of a recall. The level of publicity and the magnitude of the recall depend on the assessment of the severity.

There have been numerous recall incidents throughout the world. Some recent incidents include the pork dioxin recall in Ireland in 2008 (Food Safety Authority of Ireland, 2008) and the melamine tainted milk recall in China (Reuters, 2010). Different countries have different governing bodies to provide guidelines and support for a safe recall process, as well as, maintain quality and standards. For example, the Food Safety Authority of Ireland governs recalls in Ireland.

Knowing that food safety is a high priority, the purpose of this industry study is to examine the challenges global manufacturers face while managing a processed food recall situation in their supply chains. To be more specific, the purpose of this study is to devise a responsive and reliable knowledge management framework with a Failure Mode Effects and Criticality Analysis decision model for processed food safety and recall supply chain system. Such a framework is needed to achieve timely communication not only within the focal manufacturing and distribution enterprise which is part of the supply chain but also with government personnel involved and customers throughout the globe. It is increasingly becoming evident to manufacturers that through integration, standardization and proceduralization there are tremendous opportunities for improvements in product quality, logistics, reduction in product design time, manufacturing setups and factory and office overheads. By organizing cumulative knowledge and expertise of the manufacturing enterprise to aid decision making, knowledge bases can be catalysts for achieving these improvements.

In closely reviewing pertinent literature, the author was unable to find any such research which proposes building a knowledge management framework for an organization using FMECA model for risk assessment and its management in a global supply chain. The impetus for this study was due to a lack of such expert and intelligent knowledge management framework for product safety and recall supply chain in the literature. Such a system is not available in real life for the processed foods industry. The major components of the proposed product safety and recall supply chain system are knowledge management framework and FMECA model for assessment of risk which facilitates failure analysis through a fault tree and criticality index analyses. Specifically, this study leads to identifying the main reasons for food recalls and also understanding the root causes for major issues in terms of their likelihood of occurrence and significance. The proposed framework can be effective in responding to product safety and recall event and also as an early warning system to preempt such crisis event

The final outcome from this pilot study is the implementation of an expert and intelligent knowledge management systems framework which will be used to support decision making and problem solving applications pertaining to processed food products safety and recall. The expected benefits of such a system include: enhanced problem solving, improved decision quality, ability to solve complex problems and consistent decisions by management to preempt or respond to crisis product safety and recall events. However, the challenge in implementing these systems is extracting the expertise needed to develop the knowledge base. It is difficult to extract an expert's knowledge and codify it into a format that can be used in an automated application. These systems differ from traditional decision support systems in that the knowledge base is

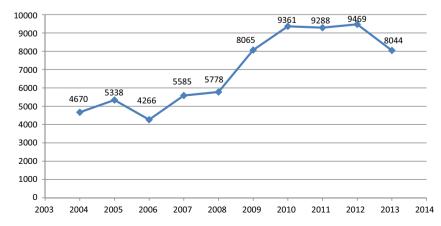


Fig. 1. Recalled products – all classes (Class I, II and III) fiscal year 2004–2013 (source: enforcement activity, FDA 2014).

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