Integration of FMEA and Human Factor in the Food Chain Risk Assessment

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Abstract**—**During the last decades, a number of food crises such as Bovine Spongiform Encephalopathy (BSE), Mad-Cow disease, Dioxin in chicken food, Food-and-Mouth Disease (FMD), have certainly inflected the reliability of the food industry. Consequently, the trend in applying different scientific methods of risk assessment in food safety has obtained more attentions in the academic and practice. However, lack of practical approach considering entire food supply chain is tangible in the academic literature. In this regard, this paper aims to apply risk assessment tool (FMEA) with integration of Human Factor along the entire supply chain of food production and test the method in a case study of Diary production, and analyze its results.

Keywords**—**Food Risk Assessment, FMEA, Human Factor.

I. Introduction

VARIOUS food born outbreaks raised the consciousness of agri-food organizations and supply chains to enhance products safety. A food outbreak over the milk poisoned by Melamine in China in 2008 made it obvious that, due to worldwide market, hazards can be effectively spread to other natural ways of life inside the same nation, and even to other countries [1], [2]. Despite the general belief that food in developed countries considered as safe, there are many reasons that show food hazards are still a raising issue even in more developed nations [3], [4]. The foodborne outbreak of Enterohaemorrhagic *Escherichia coli* (EHEC) in Germany in 2011, bringing about 53 dead and 3842 unhealthy individuals [5], showed the depth of the outcomes for the health of buyers, as well as for the economy of the firms and nations.

Food hazards are grouped into three main sources that are in microbiological, chemical or physical nature and are the results of contamination in different forms [6], i.e. primary contamination, secondary contamination, and crosses contamination, depends where the contamination occur along the food production chain (farm to table). Some of these hazards (e.g. antibiotic resistance, drug residues) or primary contamination that happen in primary production phase could be solved on primary stage or farm level [7], while other hazards like *Listeria monocytogenes*, could not be controlled solely at farm level [8].

Therefore, the focus of food safety management in recent years has shifted from single organization to the entire supply chain. International food organization (e.g. FAO, WHO, CAC) and legislation bodies (e.g. European Commission, EFSA), and private food producers and retailors have shared the idea of "Food safety and quality are best assured by an integrated, multidisciplinary approach, considering the entire food chain" [9].

Food safety is connected to food quality and it is perceived as the fundamental basis and the principle driving force of food quality management [10]. Food safety in line with quality management should not be linked to the product itself but should be associated to the process along the food chain [11]. Author [12] emphases the necessary for supply chain coordination in food safety objectives and introduced a model for coordination of quality management systems in food supply chains.

In respect to the food safety approaches, various concepts for safety control exist; the most general and adopted concepts are Good Manufacturing Practice (GMP), ISO 22000, and Hazard Analysis Critical Control Points (HACCP) [12]. Additionally techniques like Failure Mode and Effects Analysis (FMEA) were successfully applied in food safety management [13], [14]. All of these concepts are proposed to control food safety and have in common that they are built on fundamental hygiene practice and preventive safety measurement approach.

The most recent food safety regulation from the European Union put more emphasis on the safety of the consumers. The entire food supply chain in all nodes of suppliers, production, distribution and retailer have the safety responsibility according to (EC) 178/2002 (Article 17, paragraph 1) to meet the requirements stated in food legislation. Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and sanitation standard operational procedures, have been also considered among these prerequisites [15], [16], they can be seen as foundations of HACCP and further towards approaches using food safety risk analysis [9]. However, there are criticism by some authors on the issues in HACCP at farm level, due to unclear definition of hazards [17], usually most of hazards are controlled at the down stream food chain [18] farmers lacks expertise and resources to develop and operate a HACCP program and because of a lack of GMP/GHP preconditions [19].

As mentioned above, food hazards that are the main concern of food safety management expose risk on consumers, society, and economy in general. Thus, the main aim of the food safety control and management is to eliminate or reduce the risk of food hazards. This risk mainly consists of the possible extent of consequence (i.e. food born disease severity) and the probability of the food born disease

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occurrence. Risk assessment is necessary to support the decision makers regarding regulation, governance, and control of the processes [20]. Risk assessment has become an integrated part of the EU food safety legislation and according to World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures all preventive measures need to be risk based [9]. The result of the risk assessment would be input of the risk management, i.e. the recommendation and development of the scentific preventive measures and control. Therefore, the output of the risk assessment needs to be transferred into regulations, or operation procedures like GHP, or HACCP.

II. Human Factor in the Food Safety

More and more often safety managers in worldwide companies are considering Human and Organization Factors (HOF) in safety analyses. This is due to the fact that in the most cases human error has been realized as the cause of unwanted events. However, foreseen human behavior especially during everyday work is a nontrivial task.

Systematic measures must provide reliable outcomes. To guarantee the reliability of systematic measures and procedures, e.g. safety control of food, it is essential to validate these measurement processes. This procedure validation often covers technical and machinery aspects, while the important role of human factor in this procedure is often neglected. The author [21] disputes that: "Frequently the steps in the process which involve human intervention are the weak links in the process (. . .) Quite often in validation work the human element is ignored while mechanical and technological aspects are studied in great detail". Similar to other industries, within the food safety procedure, this issue is tangible as well, and it might originate from the fact that technical and instrumental aspects are covered by the HACCP in more details comparing to the Human Factor. Risk analysis can bridge that gap, but up to now few results have been presented in which the human factor is fully taken into account in the food risk management. For this reason, many researchers started to work on human and organization issues. To determine the human factor influence on safety, within European Community, Innovation thought Human Factors in Risk Analysis and Management (InnHF) project has been established. In this regard, the current study has been performed as a part of main research in Food Supply Chain Risk Management. Within the food safety field of research, there are very few studies considering the role of HOF and its effects on the final product and consumers' health, while most of the food process operations and controls perform by human. There are limited studies on human behavior in food safety control [22], HACCP implementation [23] or food hygiene practice [24] and human errors in water incidents [25]. However, analyzing the human or organization failure in a general perspective and more scientific approach (risk assessment) is lacking within the food safety literature and food industry as well. Therefore, this study aims to investigate the role of human factor within food safety domain, and its influence on the final product safety and ultimately on the consumer's health. The risk assessment method used in this research is FMEA with integration of HOF and a case study in an Italian dairy production has been applied to validate and test the method.

III. Research Method

Several tools are available for the risk analysis. Failure Mode Effect Analysis (FMEA); Fault Tree Analysis (FTA); Hazard Analysis and Critical Control Points (HACCP); Hazard Operability Analysis (HAZOP); Preliminary Hazard Analysis (PHA) and Risk Ranking and Filtering. We choose FMEA, a tool which is commonly used and well documented within the process industry, it is a very-user friendly, effective to identify and assess how potential failures can affect the performance of a process or a product. The FMEA tool is used, taking into account human factor as a potential cause of failures, as well as machines, equipment, and process.

As a case study, the production process of a dairy producer in Italy has been analyzed: and a team of expertise in food safety management, supply chain management, risk management, and food biologist have participated to perform the analysis. In the first step, we delimited the study on the sub production of the Milk procedure because it is the base product for the most of other dairy products as well. In the next step we map the entire supply chain of the milk product (Fig. 1), and to simplify the risk assessment procedure, entire supply chain is divided into seven sub sections (i.e. feeding, milking, heating, milk process, final storage, transport, retailer). Each of these sub-sections covers some component of the FMEA table, following by the failure that may happen in each process and the possible cause of that failure. The consequence of each failure mode has been identified, using experts' opinion and food outbreak statistics.

The severity of each failure has been estimated (Table I) using food expert judgment in the case company. Then the risk management team analyzed the probability (Table II) of each consequence using the following qualitative method.

TABLE I
SEVERITY SCALE

0	Zero effect	No health issue
1	Minor	Minor health issue without medication
2	Moderate	Less serious health issue, medication
3	Major	Serious health issue, hospitalization
4	Catastrophic	Critical health issue, risk of death

TABLE II
PROBABILITY SCALE

1	Rare	Not known contamination
2	Infrequent	Source of contamination but likely to be eliminated along the process
3	Common	Potential contributory factor
4	Probable	Contributory factor
5	Highly probable	Principle contributory factor

The risk assessment is performed using formula:

Risk index = Severity * Consequence
Threshold >=Risk index 15

Therefore the Risk index >= 15, will be critical risk that need to be eliminated or reduce to the acceptable level (<15).

As it is presented in the FMEA (Table IV), the most hazards situations are related to cooling and packaging, heating, and milking processes (Table III).

TABLE III
RISK ASSESSMENT RESULTS

High Risk failure	Possible Cause
Cooling and Packaging (index 20)	Human failure in control, failure in GMP
Heating (index 16)	Human failure in control, failure in Equipment
Milking (index 15)	Human failure, failure in GMP

The common cause of all these events is Human Failure, following by Hygiene environment in GMP and failure in equipment. Other important Human effect in this study is the controlling role, as almost all control of temperature and time is performed by human, and failure in each control can cause major hazards in the following steps or final product.

The recommendation for reducing the risks is firstly, improving the food safety knowledge of the staff by providing training and education. Secondly, applying more automated control systems such as IT system and central control in these critical control points (e.g. the conceptual model of [26]) to reduce human failure in controlling system.

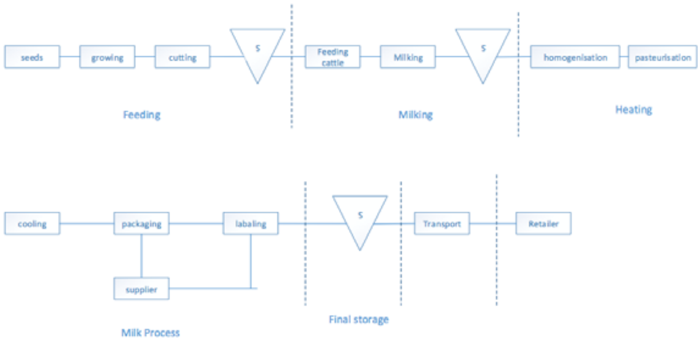

Fig. 1 Milk production supply chain

TABLE IV
FMEA OF THE MILK SUPPLY CHAIN

Component of the Milk Supply Chain	Description of action	Failure Mode	Possible Causes	Possible Consequences	Estimated Severity	Estimated Probability	Risk Index
Supplier	Providing cattle feedings	Contaminated animal feeds	Nonstandard pesticides or fertilizers Storage condition Human error	Contaminated Milk Chemical hazards	3	1	3
	Providing Packages and labels	Contaminated Packages, or non-proper labels	Package/label material Non hygiene production of package/label Machinery failure	Cross contamination milk Biological Or Chemical hazards	3	3	9
Milking Process	Feeding cattle	Contaminated feeding	Human disease or failure	Biological or Chemical hazards in raw milk	2	5	10
	Milking cattle	Biological Contamination of milk	Human disease or failure Non hygiene equipment	Biological hazards in raw milk	3	5	15
	Storage of milk in tank	Chemical or Biological contamination	Not hygiene tank (Machine)	Biological or Chemical hazards in raw milk	3	2	6
		Growing the pathogens	Failure in time and temperature control (Machine, human)	Biological hazards in raw milk			
Heating process	Homogenization and Pasteurization	Not eliminating the pathogens	Failure in time and temperature control (Machine, human)	Biological hazards in the final products	4	4	16
Cooling and Packaging	Cooling (0<C<5°) Packaging the milk Labeling the product Sending to the final storage	Cross contamination of chemical or biological hazards	Non hygiene package Non hygiene environment Human failure in control	Biological or Chemical hazards in the final product	4	5	20
Storage	Storage of product	Growing the pathogens	Time and temperature failure (Machine, human)	Biological or Chemical hazards in the final product	1	2	2
Transport	Transport final product to the retailers	Growing the pathogens	Improper conditions of the vehicle Improper temperature of vehicle	Increasing the hazards of disease	1	4	4
		Decreasing the quality of product	Not delivering on time schedule	Bad Quality products No hazards in safety	0	2	0
Retailer	Storage in store And selling to final consumers	Decreasing the quality of product	Not controlling the shelf time Improper temperature of refrigerators (machine, human)	Bad Quality products No hazards in safety	1	1	1

IV. Conclusion

The aim of this paper is to perform structured analyses by identifying the weaknesses in the food supply chain through the application of the 'Failure Modes Effects Analysis' (FMEA) technique. In our hands, FMEA appeared to be a valuable tool in reaching our objective to identify risks, including those related to human factors. Process steps that were initially neglected or thought uncritical turned out to be of major importance. For example, the role of human failure in controlling the cooling and packaging process was not considered as a major risk before performing the FMEA; however, FMEA showed that is actually a major risk. Overall, the human factor turned out to be the most important possible cause of the risk and these human risks are not directly covered by classical analytical validation. In the further studies, we are aiming to develop more general approach to identify the weakest point of the food supply chain using quantitative risk assessment integration with human factor analysis.

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Mohsen Shirani works as a Marie Curie research fellow at Politecnico di Torino, Italy. This study is a part of InnHF – (Innovation through human factors in risk analysis and management) Marie Curie Actions Initial Training Networks. The INNHF main objective is to formalize an approach and make it possible to integrate the current and developing assessment methods recommended or required by recognized industrial standards and methodologies, with an easy to use but complete human factors and system health management approach.

The author PhD research focus is on the Food Safety Supply Chain; the main objective is introducing new model and approach in Risk Assessment of the entire food supply chain (farm to table) with integration of HOF (Human Organization Factor). The result would be in interest of Food Regulation and Standards authorities as well as Food Business Industries and Stakeholders.

http://www.innhf.eu/index.php/recruitment/fellows/12-fellows/22-mohsen-shirani

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- Marie Curie ITN: INNHF—Innovation through Human Factors in Risk Analysis and Management (2011-2015) – Coordinator
- FP7 SME: TOSCA - Total Operation Management for Safety Critical Activities (2013-2016)
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