

**MEASUREMENT OF FOOD SAFETY
THROUGH A RISK ASSESSMENT FOR THEIR USERS**

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Abstract

There are many national and international standards that mandate certain parameters in order to guarantee food safety. Many different risk assessment methods are available and recommended. However, they all have different parameters, advantages and disadvantages. The authors developed a simplified risk assessment method that could be applied in the food industry.

Key words: *safety, food, risk, assessment method*

I. INTRODUCTION

Food safety has become a priority issue during the last decade due to the globalization of food markets and several serious food crises, such as the Bovine Spongiform Encephalopathy and the classical swine fever in 1997, the Belgian dioxin affair in 1999, the foot and mouth disease in 2001, the outbreaks of Avian Influenza in Asia since 2005, various large Salmonella outbreaks in USA in 2008, the large melamine contamination scandal in China in 2008, etc. [1]

WHO claims that “food safety is an increasing important public health issue”. Food borne diseases are widespread, which not only threatens public health, but also significantly reduces the economic productivity. (<http://www.who.int/mediacentre/factsheets/fs237/en/>)

According to WHO's estimation, foodborne and water borne diarrheal diseases kill approximately 2.2 million people annually. (food safety who: <http://www.who.int/foodsafety/en/>) ”About 13 million children under the age of 5 die each year from infections and malnutrition, most often attributable to contaminated food”.(<http://www.who.int/mediacentre/factsheets/fs237/en/>) According to CDC's research and analysis based on the information from multiple surveillance systems and other sources, foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States every year. (Food-related illness and death in the United States, <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>)

The costs of the food contamination are a social and economic burden to the community. “In the United States, the estimated annual medical costs/productivity losses due to the 7 major foodborne pathogens range from \$6.6 billion to \$37.1 billion”, according to USDA and CDC figure. (Introduction to Food Safety Risk Analysis: <http://depts.washington.edu/foodrisk/overview.html>) \$500 million was lost in fish and fishery product in Pure in 1991 due to cholera.

(<http://www.who.int/mediacentre/factsheets/fs237/en/>)

More than 200 known diseases are transmitted through food (Bryan FL. Diseases transmitted by foods. Atlanta: Centers for Disease Control; 1982.). Take one for an example, E. coli, which is one of the most common foodborne pathogen. A random search on internet on Auexample, 2011 brought out a food poisoning breakout at Lynnwood day care one day before that an infant and a toddler have tested positive E. coli. (<http://www.heraldnet.com/article/20110812/NEWS01/708129837>) E. coli related disease causes diarrhea and stomach cramping, sometimes even kidney failure or death, especially for young children and elderly. By August 13th, 310,248 pounds of ground beef products has been recalled in 2011 due to E. coli contamination. (<http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/>) It is a direct threat to public health and survival challenge to the companies affected by the negative publicity.

Food Safety related Hazards

Different from other industries, the food industry needs an excellent understanding of the characteristics of products being handled to efficiently prevent the development of potential hazards and to control the ones that exist.

Three categories of hazards are related to food safety: biological hazards, chemical hazards and physical hazards.

Biological food hazards include bacterial pathogens, viruses and parasites. Typical hazardous microorganisms frequently cause foodborne illnesses including *Listeria monocytogenes*, *Escherichia coli* O157:H7, *Salmonella typhi*, and so on. *Listeria monocytogene* is one of the most virulent foodborne pathogens. It caused the highest fatality rate among foodborne bacterial pathogens. *Listeria monocytogenes* always result in septicemia, meningitis, encephalitis and so on. The main sources of *Listeria monocytogens* are raw milk, ice cream, raw meats and sea food. It can survive at temperatures as low as 0°C. The infection of E. Coli O157:H7 leads to hemorrhagic diarrhea, abdominal cramps, and even kidney failure, especially in young children and elderly. It is transmitted via the fecal-oral route, and the main source of infection is undercooked food, such as, ground beef, unpasteurized milk, vegetables and water. *Salmonella typhi* normally causes diarrhea, and the infection can be very serious to small children and the elderly. The main food sources are meats, poultry, eggs and milk. Hepatitis A and Norwalk viruses are representations of enteric viruses associated with food. Undercooked meat or contaminated ready-to-eat foods may be infected by parasites.

Chemical food hazards are the chemical substances or compounds that exist in food, which will cause health problems to sensitive population or even the general public by consumption. Different from biological hazards that always have a quick response, chemical hazards can either cause acute foodborne illnesses by a high dose, or result in chronic illness at a lower level. Hazardous chemicals in food may be the product ingredients, intentionally added or unintentionally added into food. Naturally occurring chemicals include shellfish toxins, mycotoxins, scombrototoxin (histamine), ciguatera toxin, and toxic mushroom species and so on. Paralytic Shellfish Poison (PSP) and Diarrhetic Shellfish Poison (DSP) are two types of shellfish toxins. PSP toxins are neurotoxic alkaloids that can block the entrance of sodium ions into nerve cells, and people may be died because the muscles of respiration loss control. DSP causes slight sickness in the GI system. Mycotoxin is the metabolic product of fungus. The common kinds of mycotoxins include aflatoxins, trichothecene mycotoxin, ochratoxins, saxitoxins, and grayanotoxins. They exist in different kinds of foods and have various symptoms, but they all threaten human and animals safety and health. Furthermore, there are added chemicals in the process. Agricultural chemicals, such as, pesticides, fungicides, fertilizers, and growth hormones are added to facilitate the good growth of raw material. Food additives are added as preservatives, flavor enhancers, nutritional additives or color additives. The application of additives should follow the allowable limits under GMPs. Chemicals added into food products unintentionally are also a threat to customers, such as cleaners and sanitizers (HACCP guidelines, P366).

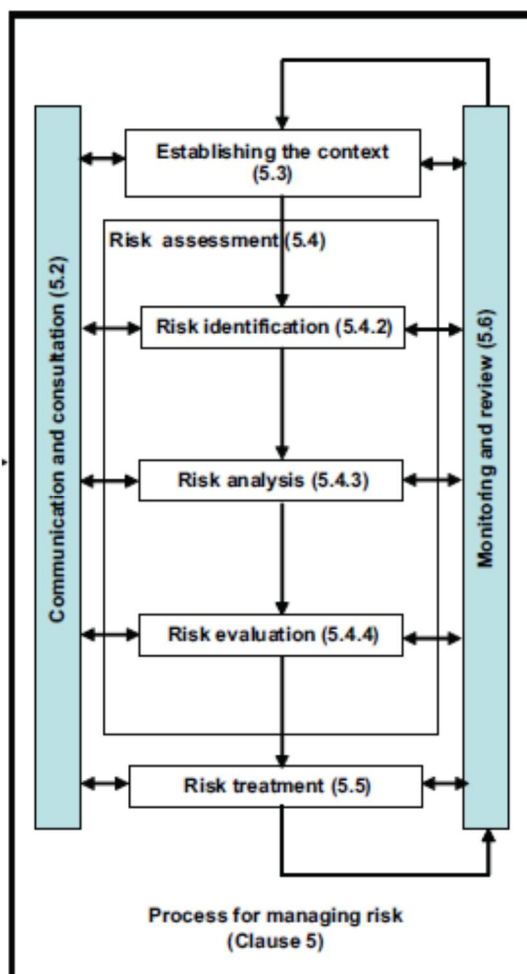
Physical food hazards mean the objects in food that may cause injuries or illnesses. The main materials considered as physical hazards include glass fixtures, wood, stone, metal fragments, insulation, bone, plastic, and others. Physical food hazards are usually not as harmful as others; however, it can cause life threatening events for young children and elders.

II. RISK ASSESSMENT TECHNIQUES ISO 31010:2010 APPLICABLE TO THE FOOD INDUSTRY

ISO 31000 is a family of standards relating to risk management codified by the International Organization for Standardization. The main goal of ISO 31000:2009 is to provide principles and generic guidelines on risk management. ISO 31000 provide a universally recognized paradigm for practitioners and companies employing risk management processes. The purpose of ISO 31000:2009 is to be applicable and adaptable for "any public, private or community enterprise, association, group or individual" (http://www.iso.org/iso/catalogue_detail.htm?csnumber=43170)

The authors believe that ISO 31000 risk assessment techniques could be applied in the food industry. The following process for managing risk (Clause 5) was selected for detailed evaluation of the applicable risk assessment tools.

Fig. 2 ISO 31000 process for managing risk (Clause 5)



HACCP plan and risk assessment techniques alignment. Section *B.7 Hazard analysis and critical control points (HACCP)* is discussed in ISO 31010. Practical applications and risk assessment techniques utilized in food safety are presented below. Additional techniques applicable to food safety are discussed in ISO 31000. The following qualitative methods are sometimes used by food manufacturers.

B.14 Fault tree analysis (FTA)

B.15 Event tree analysis (ETA)

B.16 Cause-consequence analysis

B.19 Decision tree analysis

B.21 Bow tie analysis

B.26 Bayesian statistics and Bayes Nets

B.28 Risk indices

B.29 Consequence/probability matrix

B.30 Cost/benefit analysis (CBA)

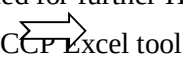
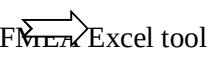
B.31 Multi-criteria decision analysis (MCDA)

The application of the HACCP plan in food manufacturing is recommended by FDA because it is considered the most effective and efficient management system to prevent and control food hazards, and to produce safe products. HACCP provides more scientific safety assurance theory that prevents the safety hazards before they occur instead of evaluating the products by end-testing (HACCP).

HACCP has seven principles:

1. Conduct a hazard analysis
2. Identify critical control points
3. Establish critical limits for each critical control point
4. Establish critical control point monitoring requirements
5. Establish corrective actions,
6. Establish record keeping procedures
7. Establish procedures for ensuring the HACCP system is working as intended. (USFDA, <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm>).

The following techniques were selected for further HACCP and ISO 31000 alignment analysis:

1. Risk Identification (5.4.2.) 
2. Risk Analysis (5.4.3.) 
3. Risk Evaluation (5.4.4.) 

Detailed description of the tools is presented below.

1. Risk Identification

In a HACCP plan, CCP identification is the foundation of the whole plan. CCP is a point or a step in the food processing where controls can be applied to prevent, eliminate or reduce the occurrence or the severity of food hazards. The identification process is based on the knowledge of the production process, characteristics of the food products and the potential food hazards. The authors developed a CCP decision tree as an Excel form with step directions to facilitate the identification process. For each procedure may cause or already have food hazards, the first thing that needs to be considered is that (Q1.) if there is any control measure for the identified hazard. If yes, the efficiency of the measurement should be evaluated by that (Q2.) if the occurrence of the hazard will be eliminated or reduced to an acceptable level. If the answer is positive, then, it is a CCP. If the answer is negative, then the severity of the hazards will be evaluated. If no health threat exists from this food hazards, it is not a CCP and the process stops. If the contamination is serious enough to risk people's health, then consider the subsequent step. If there is no efficient subsequent step, it is a CCP; otherwise, it is not. For this process, if the (Q1.) preventive measure doesn't exist for the identified hazard, then, the necessity of the control will be questioned. If there is no necessity, it is not a CCP. If the control is necessary, this step needs to be modified with a preventive measure, and get back into the evaluation cycle we discussed before. The Excel based tool is presented below.

Fig. 1 CCP identification tool

CCP DECISION TREE FORM							
Product or Process Name:							
Developed by:							
Date:							
Process/Step	Hazard	Q1a. Q1a. Do preventive measures exist for the identified hazard(s)?	Q1b. Q1b. Is control at this step necessary for safety?	Q2. Q2. Does this step eliminate or reduce the likely occurrence of a hazard(s) to an acceptable level?	Q3. Q3. Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?	Q4. Q4. Will a subsequent step eliminate hazard(s) or reduce the likely occurrence to an acceptable level?	CCP #
		If No--go to Q1b.	If No--not a CCP.	If No--go to Q3.	If No--not a CCP.	If No--CCP.	
		If Yes--go to Q2.	If Yes--modify step, process or product and return to Q1a.	If Yes--CCP	If Yes--go to Q4.	If Yes--not a CCP.	

2. Risk Analysis (5.4.3.)

According to ISO 31000, risk analysis involves developing an understanding of the risk. Risk analysis provides an input to risk evaluation and to decisions on whether risks need to be treated, and on the most appropriate risk treatment strategies and methods. The authors suggest utilizing Failure Mode and Effect Analysis (FMEA) at this stage of the risk evaluation.

FMEA is a methodology to analyze the potential failure modes that may occur in a product or process, and the risk assessment, such as, the severity, the occurrence and the detected level of each failure mode, then, to prioritize all the failure modes based on their urgency, and provide with prevention actions, especially to the most urgent failure to eliminate or minimize the hazard. (siliconfareast.com)

The system safety tools, such as FMEA, could be applied to assist hazard analysis in food processing. FMEA form provides a detailed analysis of each operation based on the occurrence, the severity and the detection of hazards, which in theory could be a continuation of the CCP hazard analysis. Therefore, this evaluation can be used to facilitate the risk assessment and prioritization of the Critical Control

Points. The evaluation system leads to a RPN (risk priority number) to describe the risk of hazard by the complete information in the form. The analysis of the recommended actions includes an evaluation of the effectiveness of each action. This can also be a guideline of the critical control actions. Compare the RPNs of different operations, the priority of operations that requires controls will be listed from the highest number to the lowest. The organization can allocate their finances wisely with the PRNs. According to the information FMEA can bring to the hazard analysis, it is an effective tool to be used in the food processing.

An example of FMEA & RPN worksheet is presented below.

Fig. 3 Example of FMEA & RPN worksheet

FMEA & RPN WORKSHEET									
Part or Process Name		Suppliers & Departments				Prepared By			
Design/ Mfg Responsibility		Model Date				FMEA Date			
Other Areas Involved		Engineering Change Level							
Process Operation, Function or Purpose	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Controls Evaluation Method	PE	S x O	RPN

After the determination of the most hazardous processes, a detailed analysis of the process or operation could be done.

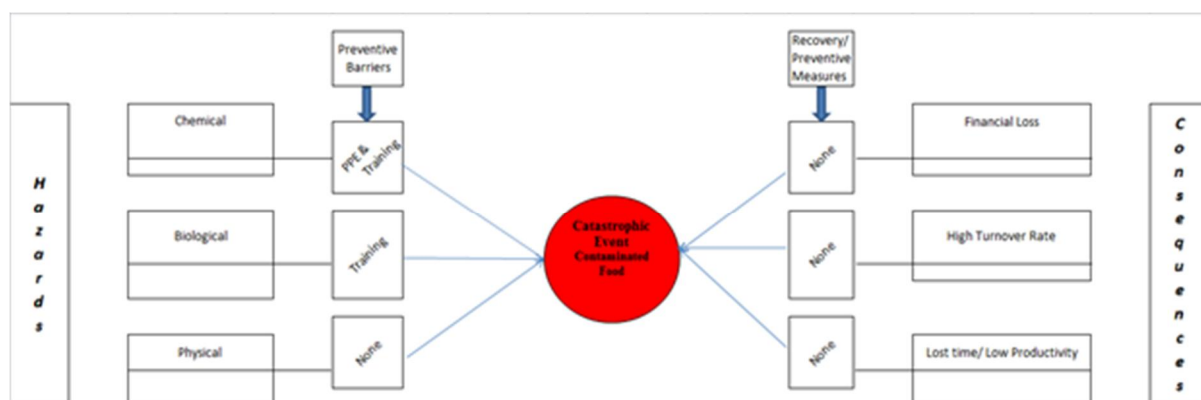
3. Risk Evaluation (5.4.4.)

The purpose of risk evaluation is to support the decision making process. It is usually based on the outcomes of risk analysis, and the priority for environmental, health, and safety interventions. Risk evaluation involves relating the level of risk found during the risk assessment process with risk criteria established when the CCPs were considered. Decisions should be made in accordance with legal, regulatory and other requirements. In some cases, the risk evaluation can lead to further analysis. For instance, FMEA could be performed for a process and detailed FMEA may be necessary for each step of the process. Performing detailed FMEA for specific steps of the process may be time consuming. However, such decision will be influenced by the organization's risk acceptance and the risk criteria that have been established.

We can utilize conventional Bow-Tie risk assessment methodology. ISO 31000 defines Bow tie analysis as a simple diagrammatic way of describing and analyzing the pathways of a risk from causes to consequences. The focus of the bow-tie is on the barriers between the causes and the risk, and the risk and consequences. However, the “conventional” Bow Tie analysis is not a quantitative tool.

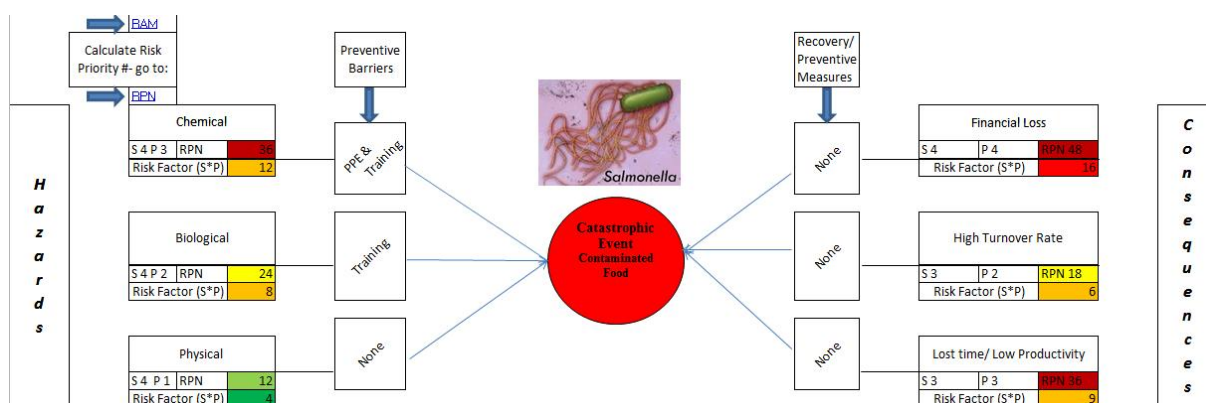
Conventional” Bow Tie analysis is presented below.

Fig. 4 Example of Conventional” Bow Tie analysis



Dr. Popov developed a modified Bow-Tie analysis where, the hazards and consequences are quantitatively defined based on the risks and probabilities of occurrence. We can use a conventional risk assessment matrix from the Prevention through Design standard to produce a risk factor (which is Severity x Occurrence) or a Risk Priority Number (RPN) from FMEA. A combination of both is presented below.

Fig. 5 Example of modified Bow-Tie analysis



III. ISO 31000 AND FOOD SAFETY MANAGEMENT SYSTEMS INTEGRATION EXAMPLE

Food Safety Related Hazards

Food industry is different from other industries. It needs an excellent understanding of the characteristics of products being handled to efficiently prevent the development of potential hazards and to control the ones that exist. Three categories of hazards are related to food safety: Biological hazards; Chemical hazards and Physical hazards. In order to avoid or minimize food safety hazards, development

and implementation of an effective HACCP plan is recommended. HACCP plan is widely accepted methodology for effective Food Safety Management System.

Safety Analysis Data

The frozen salmon processing was evaluated according to the HACCP management system, and six CCPs were identified. They are the key points that may cause defects with product quality or food safety. An example of partially complete CCP Decision Tree Form is presented below.

Figure 6. CCP Decision Tree Form

CCP DECISION TREE FORM							
Product or Process Name: <u>Salmon Processing</u>		FMEA					
Developed by: <u>Ying Zhen</u>							
Date:							
Process Step	Hazard	Q1a. Do preventive measures exist for the identified hazard(s)?	Q1b. Is control at this step necessary for safety?	Q2. Does this step eliminate or reduce the likely occurrence of a hazard(s) to an acceptable level?	Q3. Could contamination with identified hazard(s) occur in excess of acceptable levels or	Q4. subsequence step eliminate hazard(s) or reduce the likely occurrence to an acceptable	CCP #
		If No-go to Q1b.	If No-not a CCP.	If No-go to Q3.	If No-not a CCP.	If No-not a CCP.	
		If Yes-go to Q2.	If Yes-modify step, process or product	If Yes-CCP	If Yes-go to Q4.	If Yes-not a CCP.	
Salmon receiving	chemical and biological contamination	Yes. BBT control, potable water		Yes			CCP1
Loining, skinning and trimming	physical hazards	Yes. x-ray bone detection		Yes			CCP2
Inject CO	Chemical contamination	Yes. needle inspection		Yes			CCP3
Chilling	Biological contamination	Yes. temps 3°C, curing time 24hrs		Yes			CCP4
Metal Detection on individual package	Physical contamination	Yes. metal detection on individual package		Yes			CCP5
Metal Detection on individual box	Physical contamination	Yes. metal detection on individual box		Yes			CCP6

CCPs and hazards were transferred to FMEA tool. FMEA form provides a detailed analysis of each operation based on the occurrence, the severity and the detection of hazards, which is the same theory with the hazard analysis of CCP. Therefore, this evaluation can be used to facilitate the identification of the CCP and further risk assessment based on the hazards. The evaluation system leads to a RPN (risk priority number) to describe the risk of hazard by the complete information in the form.

Severity, Probability/Occurrence, and Detection were evaluated on a 1-5 scale. Where:

•Severity:

1-Insignificant

2-Negligible

3-Marginal

4-Critical

5-Catastrophic

•Probability/Occurrence

1-Unlikely

2-Seldom

3-Occasional

4-Likely

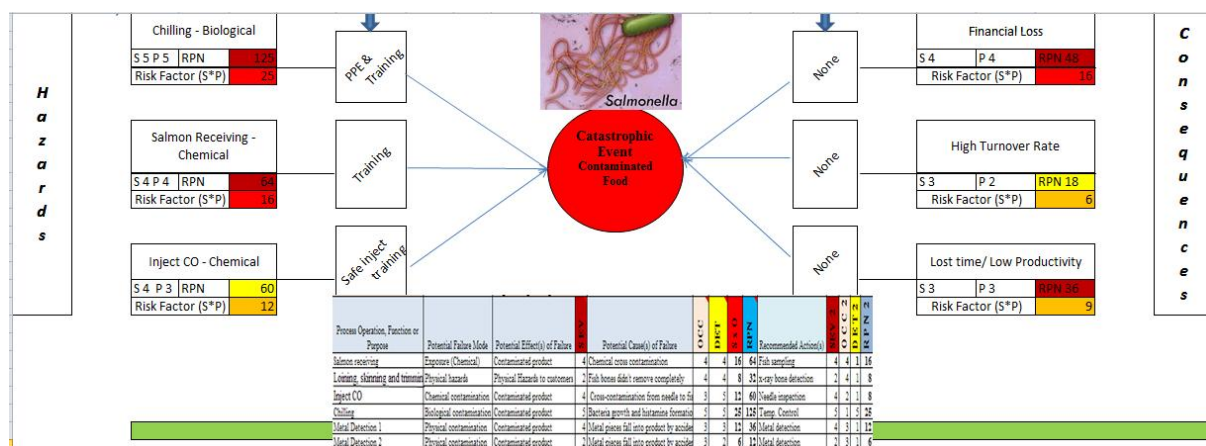
- 5-Frequent
- Detection
- 1.Unlikely
- 2.Rarely
- 3.Occasional
- 4.Likely
- 5.Detectable

Figure 7. FMEA detailed analysis based on CCPs

Process Operation, Function or Purpose	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	DET	S x O	RPN
Salmon receiving	Exposure (Chemical)	Contaminated product	4	Chemical cross contamination	4	4	16	64
Loining, skinning and trimming	Physical hazards	Physical Hazards to customers	2	Fish bones didn't remove completely	4	4	8	32
Inject CO	Chemical contamination	Contaminated product	4	Cross-contamination from needle to fish	3	5	12	60
Chilling	Biological contamination	Contaminated product	5	Bacteria growth and histamine formation	5	5	25	125
Metal Detection 1	Physical contamination	Contaminated product	4	Metal pieces fall into product by accident	3	3	12	36
Metal Detection 2	Physical contamination	Contaminated product	2	Metal pieces fall into product by accident	3	2	6	12

The analysis of the recommended actions includes an evaluation of the effectiveness of each action. This can also be a guideline of the critical control actions. Compare the RPNs of different operations, the priority of operations need to be controlled will be listed from the highest number to the lowest. The organization can distribute their budget wisely with the PRNs. According to the information FMEA can bring to the hazard analysis, it is an effective tool to be used in the food processing. After the detailed analysis, the top three ranked hazards can be transferred to the Bow-Tie analysis form. See Current State (before controls) Bow-Tie analysis Fig. 8 below.

Figure 8. Bow-Tie diagram based on FMEA detailed analysis



Next step is to identify preventive measures/CCPs controls. According to the FMEA form data, the identified process operations were improved significantly after implementing the recommended actions/CCP controls (see recommended actions column). Although the severity of the potential failure did not decline, the control reduced the probability of occurrence and the chances that the failure cannot be identified, which finally reduced the priority score of RPN. The FMEA tool not only showed the necessity of controls, but also prioritized the control actions. According to Figure 9, bacteria growth during chilling was the most urgent possible failure.

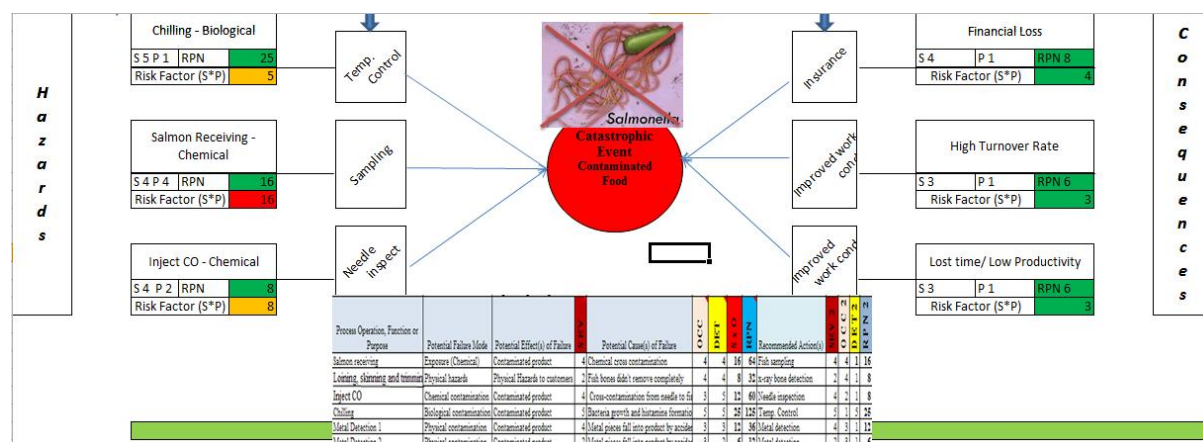
Figure 9. FMEA assessments of CCPs

Process Operation, Function or Purpose	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	DET	S x O	RPN	Recommended Action(s)	SEV 2	OCC 2	DET 2	RPN 2
Salmon receiving	Exposure (Chemical)	Contaminated product	4	Chemical cross contamination	4	4	16	64	Fish sampling	4	4	1	16
Loining, skinning and trimming	Physical hazards	Physical Hazards to customers	2	Fish bones didn't remove completely	4	4	8	32	x-ray bone detection	2	4	1	8
Inject CO	Chemical contamination	Contaminated product	4	Cross-contamination from needle to fish	3	5	12	60	Needle inspection	4	2	1	8
Chilling	Biological contamination	Contaminated product	5	Bacteria growth and histamine formation	5	5	25	125	Temp. Control	5	1	5	25
Metal Detection 1	Physical contamination	Contaminated product	4	Metal pieces fall into product by accident	3	3	12	36	Metal detection	4	3	1	12
Metal Detection 2	Physical contamination	Contaminated product	2	Metal pieces fall into product by accident	3	2	6	12	Metal detection	2	3	1	6

Proper temperature control can reduce the risk of bacteria growth by 4/5. The chemical contamination of the salmon material was the second highest concern of the food poisoning. Fish sampling cannot reduce the severity and the occurrence, but the ability of detection was obviously improved, which made the threat drop to 1/4.

All the CCPs should be supervised strictly by the measures of the control limits if it is available. The same top three ranked hazards and recommended actions are transferred to the Future State (after controls) Bow-Tie analysis form.

Figure 10. Bow-Tie diagram based on FMEA recommended actions



The reader will notice that the risks associated with the hazards changed colors from red/yellow to green due to implementation of proper controls. In order to keep the benefits of the safety and the efficiency improvements, engineering control and administration control should be applied at the same time. The engineering control should make sure all the CCP controls are strictly enforced, such as the temperature control for certain operations and the necessary equipment updated for accurate results. The administration control work with management closely to make sure the operation is effective, which includes proper documentation, training and supervision.

IV. CONCLUSIONS

Nowadays the food safety has become a priority issue. The Codex Alimentarius Commission at FAO/WHO, European Authorities and Food and Drugs Administration in the USA developed meanwhile a wide range of standards, codes and guidelines that mandate certain procedures and tools in order to maintain a high level of food safety, public health and consumer protection. HACCP is the internationally and nationally recognized systematic approach to control those points in food manufacturing, which are critical to product safety. In practice, the hazard analysis provides more a qualitative evaluation method and appears to be one of the most difficult steps in the HACCP procedure, because appropriate identification of potential hazards and assessment of their risk is rather complex and requires much technological knowledge and information.

To perform the assessment in a uniform way several guidelines have been proposed by the European Scientific Committee for Foods and Codex Alimentarius Commission, which contain some essential elements of a semi quantitative risk assessment: No-Observed-Adverse-Effect-Level, Acceptable Daily Intake, Benchmark Dose, Minimal Effective Dose, etc. Exposure assessment and hazard characterization thus provide an estimate of severity of negative health effect and the probability that these adverse effects occur after exposure to the specific hazard.

The authors developed a simplified quantitative risk assessment method that could be applied by the companies and the authorities in the food industry. The estimation of the risk is based on the Failure Mode Effect Analysis (FMEA) principles and a modified Bow-Tie analysis. Specific risk priority numbers, which are a product of severity, occurrence and ability to detect, have to be calculated and subsequently the effect of each control measure to be quantitatively estimated.

Risk assessment and calculation of RPN for food safety hazards is of theoretical and practical interest. Risk classification of food safety hazards as “low”, “medium”, and “high” is a normal practice and convenient one for HACCP plans development. However, such classification is not exactly precise and leads to some ethical questions. For instance, what are the acceptable levels of the lethal effect or the frequency of hazards? Are they the same for the customers and the suppliers? What are the risk tolerance levels acceptable to food inspection authorities? At the same time, the suggested method for quantitative evaluation could be used to develop a database for different types of food and determination of measurable risk levels. Practical applications of such methods would unify and simplify the control activities in food safety management and reduce the hazards.

The combination of the ISO 31000 suggested risk assessment methodologies and implementation of CCPs controls, designed to minimize food related illnesses, will improve food quality and reduce financial losses. Risk factors and Risk Priority Numbers could be reduced significantly by implementation of preventive measures. The risk of food contamination in the presented example was reduced significantly and the food product was made safer for customers.

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