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STUDY REGARDING THE APPLICATION OF THE FMEA (FAILURE MODES AND EFFECTS ANALYSIS) METHOD TO IMPROVE FOOD SAFETY IN FOOD SERVICES

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Abstract

The aim of this study was the application of the latest FMEA (Failure Modes and Effects Analysis) method to improve food safety (for soup production) in food services. One of the major changes with the new FMEA method is that the Risk Priority Number (RPN) has been replaced by the Action Priority (AP) process. The working methodology consisted in the collection and processing of information based on practical experience provided by food industry and food services specialists, as well as those from the literature related to similar studies. Among the steps and activities required to apply the FMEA method is distinguished, as specificity, the calculation of AP depending on the severity (S) of consequences of manifestation of nonconformities to the consumer, on the probability of occurrence (O) of a potential hazard for food safety and on the probability of its detection (D). The AP was determined for each category of identified potential hazards (physical, chemical and biological) for all ingredients and for all stages of the technological flow. Through AP, a quantitative assessment can be made of the potential food safety problems in a system, and respectively a prioritization of implementation of preventive, corrective actions and the improve of prevention or detection controls. Based on AP, the identified potential nonconformities can be classified now in the Low priority category even if the old considered RPN value is higher than 100 (125, for the row material storage, at the level of physical hazards). On the other hand, at values lower than 100 of the RPN, the AP can be in the Medium priority category (96, for preparation of ingredients, at the level of chemical hazards), the value of S being the decisive element for classification of potential hazards and nonconformities.

Key words: *failure modes and effects analysis, food safety, soups.*

INTRODUCTION

Quality is defined as the group of those product characteristics that satisfy explicit and implicit customer requirements. Thanks to the adoption of predefined standards, Quality Assurance means to give to the customer the warranty that the company works on the basis of these requirements. In Food Industry two different aspects of product quality can be identified: on one hand, food safety and sanitary integrity, compulsory requirements for selling a food; on the other hand all those components, such as exterior aspect, functionality, nutritional characteristics, etc., that attract the customer (Scipioni et al., 2002) FMEA (Failure Modes and Effects Analysis) it is a predictive and preventive method specific to non-compliance and risk management. The FMEA is a modern tool used in the purpose of identifying potential failure modes (of appearance of nonconformmities), the causes and effects of each failure (nonconformities) on a system, subsystem, or component part.

FMEA has been applied in areas such as the automotive industry, the plastics industry, food service, software, healthcare (Chen, et al., 2020), etc. Traditionally, FMEA has been conducted according to manufacturer perspective until recently the customer perspective has been incorporated in FMEA (Shahin, 2004; Koomsap and Charoenchokdilok 2016). The concept of customer-oriented FMEA arises from the observation that customers are the ones who are directly affected by the occurrence of failure and how they perceive the effects of failure may differ from the manufacturer or provider, leading to different prioritization with and without customer involvement; therefore, their viewpoint must be considered in the FMEA process (Labajan and Koomsap, 2019). The standard BS EN IEC 60812:2018, Failure modes and effects analysis (FMEA and FMECA-failure modes effects and

criticality analysis) includes significant technical changes with respect to the previous edition, transposed in automotive industry in special. One of the major changes with the new AIAG-VAD (*Automotive Industry Action Group-Verband der Automobilindustrie*) FMEA manual, is that the Risk Priority Number (RPN) has been replaced by the AP process. Where RPN considers occurrence, severity and detection rankings equally (OxSxD) now which correlates to the new AP system considers first the severity then the occurrence values and so on.

The AP tables included in the new manual take all 1000 variations of S, O and D into consideration. The tables assign one of three suggested rankings for each action based upon the S, O and D values. The AP rankings are as follows:

H - Highest priority. The FMEA team "Needs" to identify an appropriate action or improve the prevention or detection controls.

M – Medium priority. The FMEA team "should" identify an appropriate action or improve the prevention or detection controls.

L–Low priority. The FMEA team "could" improve upon the prevention and detection rankings. Although the team is not prevented from taking action at any level.

The "Could, Should and Needs" descriptive terms communicate the urgency for the team to address the associated design or process risk.

The FMEA is very similar to HACCP (Hazard Analysis and Critical Control Points) booth being concerned with customer safety and requirements set by legislation. The FMEA goes further in examining in detail every aspect of customer requirements /satisfaction. HACCP drives excellence in every aspect of food safety and is used to guarantee the safety of the food produced by identify and eliminate biological (B), chemical (C) and physical (P) hazards in a food production process. Hazards that if left uncontrolled could result in illness or even death of consumers. The hazards specific to each stage of the technological flow, are assessesd according to the probability (frequency) of occurrence and the severity of the effects of the manifestation on the consumer, establishing risk classes and later stages of the process which constitute critical control points (CCPs). The FMEA method extends this hazard assessment by introducing a new parameter, namely, probability of detection of hazards (Pop C., et al., 2019). These three elements (severity of the effect, hazard occurring probability, and probability of detection) are used to calculate action priority (AP).

Using AP in the decisional process of establishing a CCP, bring a plus of precision and trust in the functioning, control and evaluation of food quality and safety management systems specific to the food products. There has been a steady increase in the number of ethnic restaurants all over the world. International soups are linked to different nations or cultures. For example, Borscht is a beet soup originally from Russia. It is not uncommon to find authentic Indian and Thai soups offered as specialties. Soup is almost always offered on both lunch and dinner menus in restaurants. The soups use ingredients that are associated with a culture's cuisine, and in North-East of Romania the Rădăuțean soup is one of the most consumed/requested by customers, being present in the majority of restaurants. The aim of this study was the application of FMEA (Failure Modes and Effects Analysis) method to improve food safety (for Rădăuțean soup) in food services.

MATERIALS AND METHODS

The working methodology consisted in collecting and processing information based on practical experience and provided by specialists from food industry domain, as well of those related to similar studies provided by the literature.

The activities required to apply the FMEA method in a food safety management for manufacturing of an assortment of soup have been phased, realizing the setting of the technological flow stages (flow diagram, identification, for each step in the flow, of potential hazards (nonconformities, physical, chemical and biological), identifying the causes that led to the emergence of dangers, determining the probability of occurrence of each hazard category (O), determining the severity (seriousness) of the occurrence of the hazard to the consumer (S), establishing the probability of detection of hazards (D),

calculating the AP, setting critical control points (CCP), establishing the HACCP plan.
At the same time, after calculating AP, corrective actions were identified for each category of hazards specific to the different stages of the flow chart.
The corrective actions application led, in all cases, to considerable diminution of AP value.
The results obtained have led to the formulation of some conclusions and recommendations for improving and expanding the FMEA application within food safety management systems.

RESULTS AND DISCUSSIONS

Technological steps specific to the preparation of Rădăuțean soup are schematically presented in Figure 1, through a flow chart diagram, which uses standardized international symbols.
For the technological flow was identified the three categories of potential hazards, P, C and B, as well as the generators causes of their occurrence. The new process FMEA uses specific colors for warning the team depending on the AP ranking: red „must", yellow „should", green „could" (Table 1 and Table 2).

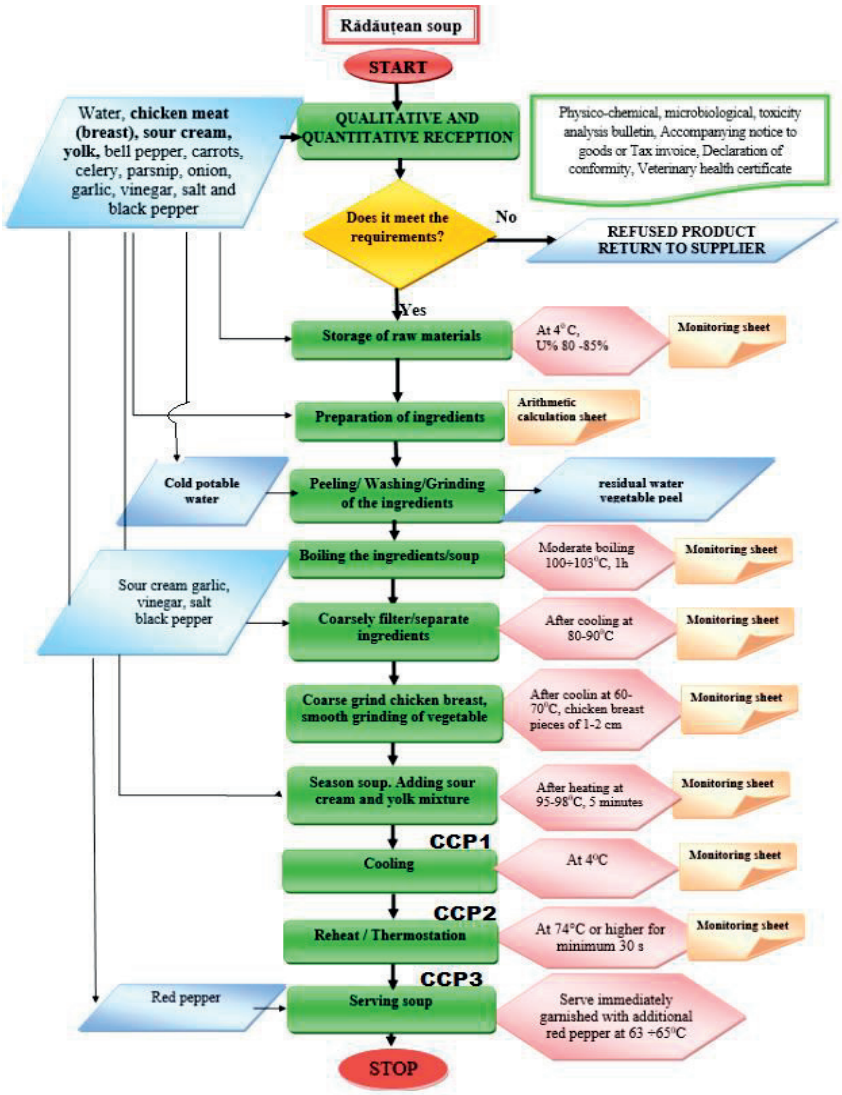

Figure 1. The technological steps of Rădăuțean soup

Table 1. Application of the FMEA methodology for Rădăuțean soup

Risk analysis → Risk evaluation → Risk mitigation

Risk / Ingredients		Nonconformity	CAUSE	Nonconformity effects	S	O	D	RPN	AP	CORECTIVE ACTIONS (CA)	S	O	D	RPN	*AP after CA
Water	P	Impurities, foreign bodies, sediments	Unauthorized supplier, negligence of cooks	Consumer dissatisfaction, loss of customers.	5	5	3	75	L	Supplier selection; checking the analysis bulletins periodically Personal training	5	2	3	42	L
	C	Pesticide residues, heavy metals (Pb, Cu, Hg, etc)	Unauthorized supplier	Affecting the health of consumers	7	3	7	147	M	Supplier selection; checking the analysis bulletins periodically Personal training	7	1	1	7	L
	B	Contamination with microorganisms.	Unauthorized supplier; missing analysis bulletins	Customer /consumer illness.	9	5	5	225	H	Supplier selection; checking the analysis bulletins periodically Personal training	9	1	3	27	L
Chicken meat	P	Impurities from evisceration, handling etc.	Unauthorized supplier, negligence of cooks	Consumer dissatisfaction, loss of customers.	5	5	3	75	L	Supplier selection; checking the analysis bulletins periodically Personal training	5	2	3	30	L
	C	Antibiotics, pesticide residues, heavy metals (Pb, Cu, Hg, Zn), detergents.	Unselected/ Unauthorized supplier. Personal negligence	Affecting the health of consumers	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	1	8	L
	B	Contamination with pathogenic microorganisms (*Salmonella, E. coli*)	Unauthorized supplier, negligence of chefs, lack of analysis bulletins and veterinary certificates.	Serious illness of consumers. Dangerous product. Expenses for hospitalization of clients.	9	5	5	225	H	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	9	2	2	36	L
Vegetables	P	Impurities: sand, earth, straw, leaves etc	Unauthorized supplier, negligence of cooks (non-compliance with the stages/parameters of the technological flow)	Consumer dissatisfaction, loss of customers.	5	5	3	75	L	Supplier selection; checking the analysis bulletins periodically Personal training	5	2	3	30	L
	C	Pesticide residues, heavy metals	Unselected supplier. Personal negligence	Affecting the health of consumers	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	1	8	L
	B	Diseases, microbial contamination, insects, larvae etc.	Unauthorized supplier, negligence of chefs, lack of analysis bulletins	Notable consumer dissatisfaction, possible digestive disorders, additional costs .	9	5	3	135	H	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	9	1	1	9	L

Ingredients \ Risk		Nonconformity	CAUSE	Nonconformity effects	S	O	D	RPN	AP	CORECTIVE ACTIONS (CA)	S	O	D	RPN	*AP after CA
Sour cream	P	Impurities: hair, sand, straw etc.	Unauthorized supplier, negligence of cooks	Consumer dissatisfaction, loss of customers.	5	3	3	45	L	Supplier selection; checking the analysis bulletins periodically Personal training	5	2	3	30	L
	C	Antibiotics, pesticide residues, heavy metals (Pb, Cu, Hg, Zn), detergents.	Unselected supplier. Personal negligence	Affecting the health of consumers	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	1	8	L
	B	Contamination with pathogenic microorganisms: *E. coli, Enterobacteriaceae, Shigella dysenteriae*.	Unauthorized supplier; negligence cooks (), lack of analysis bulletins.	Serious illness of consumers. Dangerous product. Expenses for hospitalization of clients.	9	5	4	180	H	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	9	2	3	54	L
Eggs	P	Impurities: manure etc.	Unauthorized supplier, negligence/untrained staff.	Inconvenients for kitchen staff. Supplementary costs	5	3	3	45	L	Supplier selection; quality control from reception. Personal training	5	1	1	5	L
	C	Antibiotics, pesticide residues, heavy metals	Unauthorized supplier. Personal negligence	Affecting the health of consumers	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	4	32	L
	B	Contamination with pathogenic microorganisms: (*Salmonella, E. coli*)	Unauthorized supplier; negligence cooks, lack of analysis bulletins.	Serious illness of consumers. Dangerous product. Expenses for hospitalization of clients.	9	5	4	180	H	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	9	1	2	18	L
Vinegar	P	Foreign bodies, sediments.	Unauthorized supplier; the chef's negligence.	Consumer dissatisfaction, loss of customers.	5	2	2	20	L	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	5	1	1	5	L
	C	Pesticide residues, heavy metals (Pb, Cu, Hg, etc)	Unauthorized supplier. Personal negligence	Affecting the health of consumers	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	1	8	L
Salt and pepper	P	Impurities, sand, foreign bodies.	Unauthorized supplier; the chef's negligence.	Consumer dissatisfaction, loss of customers.	4	3	2	24	L	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	4	1	1	4	L
	C	Impurity salts ($CaSO_4$, $CaCl_2$, $MgSO_4$, $MgCl_2$), heavy metals (Pb, Cu, Hg, etc)	Unauthorized supplier	Possible damage of the health of consumers	8	5	3	120	M	Supplier selection; checking the analysis bulletins periodically (for each batch). Personal training	8	1	1	8	L

*AP =AP after CA

Table 2. Application of the FMEA methodology for technological steps of Rădăuțean soup

No	Flow stages	Noncompliance/Hazard		Causes	S	O	D	RPN	AP	Corrective Actions (CA)	S	O	D	RPN	*AP
1.	Quantitative and qualitative raw material reception	P	Foreign bodies, hair, insects	Non-compliant handling. Untrained personal. Unselected supplier	4	6	5	120	H	Provider evaluation Batch rejection. Personal training	4	1	1	4	L
		C	Antibiotics, mycotoxins, pesticide residues, heavy metals (Pb, Cu, Hg, Zn), detergents.	Unselected supplier. Personal negligence	8	5	3	120	H	Provider evaluation. Documents control from supplier. Batch rejection.	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella sp, Staphylococcus aureus, Listeria monocitogenes*	Unsanitary manipulation. Unselected supplier. Inadequate temperature and transport conditions.	9	7	3	**189**	**H**	Provider evaluation. Batch rejection. Personal training. Checking analysis bulletins, sanitary veterinary certificates. Checking transport conditions and thermograms. The temperature of raw materials control and recording.	9	1	1	9	L
2	Raw material storage	P	Foreign bodies, hair, insects, personal objects, etc.	Improper handling. Unselected supplier	5	5	5	125	L	Personal training. Respecting hygiene procedures. PRP	5	1	1	5	L
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	8	5	4	160	H	Personal training. Respecting hygiene procedures.	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unhygienic handling. Inappropriate temperature and conditions of storage	9	5	4	180	H	Personal training. Enhance raw material temperature monitoring, control and recording.	9	1	1	9	L
3.	Preparation of ingredients	P	Bone fragments, hair, insects, personal objects, etc.	Improper handling. Personal negligence	5	5	5	125	M	Personal training. Compliance with procedures, metrological verification plan	5	1	1	5	L
		C	Traces of detergents, disinfectants	Improper rinsing of equipment. Personal negligence	8	4	3	96	M	Personal training. Respecting hygiene procedures	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unhygienic handling. Inappropriate temperature and conditions of preparation	9	6	3	162	H	Checking staff hygiene, machinery, utensils, equipment, work environment by performing sanitation tests.	9	1	1	9	L
4.	Peeling/ Washing/ Grinding of the ingredients	P	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	5	5	2	50	L	Personal training	5	1	1	5	L
		C	Traces of detergents, disinfectants	Unselected supplier. Personal negligence - faulty rinsing (machines, utensils, equipment)	8	4	3	96	M	Personal training. Respecting hygiene procedures	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella etc.*	Unsanitary manipulation. Contaminated water. Inadequate environmental conditions	9	6	3	162	H	Checking the staff, utensils, equipment, work environment hygiene by performing sanitation tests. Keeping maintenance plan. Checking analysis bulletins	9	1	1	9	L
5.	Boiling the ingredients/soup	P	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	5	4	2	40	L	Personal training	5	1	1	5	L
		C	Traces of detergents, disinfectants	Faulty rinsing (utensils, equipment)	8	3	2	48	L	Personal training.	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	5	3	135	H	Personal training. Checking the staff, machinery, utensils, equipment, work environment state of hygiene by sanitation tests.	9	3	1	27	L
6.	Coarsely filter/ separate	P	Foreign bodies, hair, insects, personal objects, etc.	Noncompliance manipulation. Untrained personal. Personal negligence	5	3	2	30	L	Personal training	5	1	1	5	L

No	Flow stages	Noncompliance/Hazard		Causes	S	O	D	RPN	AP	Corrective Actions (CA)	S	O	D	RPN	*AP
	ingredients	C	Traces of detergents, disinfectants	Untrained personal. Improper rinsing of equipment	8	3	2	48	L	Personal training	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature conditions	9	7	3	189	H	Performing periodic sanitation tests. Personal training. Ventilation control	9	2	1	18	L
7.	Coarse grind chicken breast, smooth grinding of vegetable	P	Foreign bodies, hair, insects, personal objects, metallic fragments etc.	Noncompliance manipulation. Untrained personal. Personal negligence. Lack of maintenance plan	5	2	2	20	L	Personal training	5	1	1	5	L
		C	Traces of detergents, disinfectants	Improper rinsing of equipment.	8	2	1	16	L	Personal training	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	4	3	108	H	Checking the staff, utensils, equipment, work environment state of hygiene by performing sanitation tests. Personal training	9	1	1	9	L
8.	Season soup. Adding sour cream and yolk mixture	P	Foreign bodies, hair, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training	5	1	1	5	L
		C	Traces of detergents, disinfectants.	Personal negligence. Outdated of smoking cells	8	4	3	96	M	Personal training	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	5	2	90	H	Monitoring of smoking specific parameters. Sanitation of smoking cells. Performing sanitation tests. Personal training	9	1	1	9	L
9.	Cooling soup	P	Foreign bodies, hair.	Improper handling. Uninstructed staff. Personal negligence	5	3	2	30	L	Personal training	5	1	1	5	L
		C	Development of other types of molds with mycotoxin production	Failure to comply technological parameters. Inappropriate hygiene	9	3	2	54	L	Personal training	9	1	1	9	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Inappropriate hygiene of storage areas. Personal negligence	9	3	1	27	L	Performing periodic sanitation tests. Personal training	9	1	1	8	L
10.	Reheat / Thermostation	P	Foreign bodies.	Improper handling. Uninstructed staff. Personal negligence.	5	2	1	10	L	Personal training. Maintaining and compliance with the DDD plan	5	1	1	5	L
		C	Traces of detergents, disinfectants	Faulty rinsing equipment.	8	3	1	24	L	Personal training	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Inappropriate hygiene of storage areas. Personal negligence	9	2	2	36	L	Personal training	9	1	1	9	L
11	Serving soup	P	Foreign bodies, hair, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training	5	1	1	5	L
		C	Traces of detergents, disinfectants.	Personal negligence. Outdated of smoking cells	8	2	2	32	L	Personal training	8	1	1	8	L
		B	Non-compliance with the stages / parameters of the technological flow. Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate environmental conditions	9	3	5	135	M	Personal training	5	1	1	9	L

*AP =AP after CA

There are high differences compared to the old FMEA methodology which based on the RPN value automatically applies corrective actions (at values higher than 100 resulting in serious quality problems).

At present, after the application of the new methodology (AIAG/VDA, 2019) different values of RPN are observed, but based on AP, the identified potential nonconformities can be classified in category L even if the RPN value is higher than 100 (125, for the row material storage, step two of technological flow, Table 2). On the other hand, at values lower than 100 of the RPN, the AP can be in M category (96, for preparation of ingredients, at the level of C hazards, table 2), the value of S being the decisive element for classification of potential hazards and nonconformities.

The 2019 AIAG/VDA FMEA handbook replace the improvement prioritization through RPN threshold to AP risk matrix that determine the level of risk based on combination of S, O and D ranking (Edly and Hood, 2020). This provide solution to ambiguous recommendation from previous AIAG method that required to prioritized based on highest S first, the O second and the D third. This method has make no sense in determining the action, for example the severity score is 10, while occurrence is 2 and detection is 2. It is because the O and D are already considered as low as practicable. The S being so high, it does not matter if the possibility of O and D is low, even if the danger seriously affects the health of a single consumer (and not of a group), the consequences of non-compliance are just as serious.

The possibility of diminishing the risks signalled by the FMEA methodology, through preventive and corrective interventions, was also reported in other similar studies conducted for food safety specific to the different categories of food products in Greece (Arvanitoyannis and Savelides, 2007 for chocolate production, Arvanitoyannis and Varzakas, 2007a/b for manufacturing of strudel and potato chips, Arvanitoyannis and Varzakas, 2008a/b for industrial processing of salmon and common octopus and Varzakas and Arvanitoyannis, 2008 for processing of ready to eat vegetables) and in Turkey (Ozilgen, 2012 for Turkish delight and Ozilgen, et all., 2013 for red pepper spice). Other approaches in Italy (Shirani, 2015 for milk), Poland (Trafialek, 2014 for the audit process) and China (Wang, 2015 for the meat supply chain) further demonstrates the utility application of FMEA.

In order to obtain a quality product, the raw materials and the technological process are very important, along with the training of the human resource involved, in the field of quality management and food safety.

Following the analysis performed for the most potential biological hazards, the AP from category H was identified (for the stages before boiling the soup, but also for the water and basic ingredients used, especially those of animal origin).

For the potential chemical hazards, the ranking of the AP in category M was observed, and for the physical ones, the classification was made mainly in category L (Table 1 and Table 2).

The compliance and monitoring of critical limits (the parameters related to each technological stage) ensure the conformity of the obtained product.

After the application of heat treatments (the boiling of soup) the biological hazards are reduced, if the necessary time are respected. Also the stages after boiling must be carried out in strict hygienic conditions, the staff being healthy, responsible and previously trained, to satisfy the requirements of consumers and to ensure the quality and safety of the food produced.

In the same time the storage of ingredients are very important Rațu et al., 2014, Rațu et al., 2015, Murariu et al., 2019, especial of hen eggs, chicken meat (breast) and sour cream.

Another key element is the reception stage, which is usually a very important control point, preceded by the conclusion that is taken after the decision-making process based on the fulfilment of the standard requirements. If the raw or auxiliary materials do not meet the requirements are rejected, so the system is not loaded with possible non-conformities.

CONCLUSIONS

In the new FMEA method, based on AP, the identified potential nonconformities can be classified now in the L category even if the old considered RPN value is higher than 100 (125,

for the row material storage, at the level of physical hazards). On the other hand, at values lower than 100 of the RPN, the AP can be in the M category (96, for preparation of ingredients, at the level of chemical hazards), the value of S being the decisive element for classification of potential hazards and nonconformities.

FMEA method combined with HACCP principles provides a solid basis for identifying food hazard and CCPs specific to the manufacturing process of soups, offering the possibility of applying control measures, monitoring and corrective intervention.

The greatest efficiency in FMEA application in a food safety management system is achieved at the design stage because it emphasizes the preventive nature of the method, essential aspect in order to achieve food products safe for consumption.

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