STUDY REGARDING APPLICATION OF THE FMEA METHOD WITHIN A FOOD SAFETY MANAGEMENT SYSTEM

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Abstract

The paper aims the study of application of FMEA (Failure modes and effects analysis) method in a food safety management system for the manufacturing of an assortment of raw-dried salami. The working methodology consisted in the collection and processing of information based on practical experience and provided by food industry 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 Risk Priority Number (RPN) depending on the probability of occurrence of a potential hazard for food safety, the severity (seriousness) of consequences of its manifestation to the consumer and the probability of its detection. RPN was determined for each category of identified potential hazards (physical, chemical and biological) at all stages of the technological flow. The highest RPN values (over 100 points) were determined for the cold smoking (288), drying-ripening (252), reception (252), shredding (189), storage of raw materials (180) and for leakage, strengthening of the meat (162). Through RPN, a quantitative assessment can be made of the potential food safety problems in a system, and respectively a prioritization of implementation of preventive and corrective actions. The results obtained led to the formulation of some conclusions and recommendations for improvement and enlargement FMEA applying within food safety management systems.

Key words: failure modes and effects analysis, food safety, salami

INTRODUCTION

FMEA (Failure modes and effects analysis) is a modern tool used in the purpose of identifying potential failure modes (of appearance of nonconformities), the causes and effects of each failure (nonconformities) on a system, subsystem, or component part. This method was elaborated in the '50s-60s by expert technicians in reliability, to study both deficiencies in operation as well as ways of ensuring maximum availability of a strategic military equipment for NASA activity [9].

Subsequent, the method has been retrieved and applied and in other areas such as the automotive industry, the plastics industry, food service, software, healtcare, etc. In 1973, U.S. The Environmental Protection Agency report describes the application of FMEA to wastewater treatment plants. [7]. Also, NASA's use of FMEA as an application for HACCP (for the Apollo Space Program) allowed it to be transferred to civil food industry (food industry in general)[13].

Between the two methods (systems) there are many similarities in terms of purpose and the principle of operation as well as the implementation methodology (s). The HACCP system is a scientific food safety management system, based on prevention, which allows permanent identification, evaluation and control of the associated risks of food products. This system identifies the potential dangers (physical, chemical and biological) specific to each stage of the technological flow, assesses these hazards 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).

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The FMEA method extends this hazard assessment by introducing a new parameter, namely, probability of detection of hazards. These three elements (hazard probability, severity of the effect and probability of detection) are used to calculate a risk priority number (RPN), also defined as a critical index. Using RPN 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 meat products (and of other categories of food). Applying the FMEA method to a food safety management system for the manufacture of a dry-salami, performs a comprehensive analysis of the potential hazards (nonconformities, defects) specific to raw-dried and smoked meat products; at the same time, allows a precise assessment of them by calculating the risk priority numbers, specific to each category of potential non-conformities (biological, chemical and physical hazards).

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 system for manufacturing of an assortment of raw-dried salami have been phased, realizing the setting of the technological flow stages (flow diagram, identification, for each step in the flow, of hazards potential (defects, nonconformities - physical, chemical and biological), identifying the causes that led to the emergence of dangers, determining the probability of occurrence of each hazard category (A), determining the severity (the seriousness) of the occurrence of the hazard to the consumer (S), establishing the probability of detection of hazards (D), calculating the Critical Index (RPN), setting critical control points (CCP), establishing the HACCP plan.

At the same time, after calculating RPN corrective actions were identified for each category of hazards specific to the different stages of the flow for which this index had a value greater than 100 points. The corrective actions application led, in all cases, to considerable diminution of RPN.

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 DISCUSSION

Technological steps specific to the manufacture of an assortment of raw-dried salami (Quantitative and qualitative raw material reception, Storage of raw material, Cutting, boning, choosing meat, Leaking and strengthening of the meat, Formation of the mixture for chopping, Grinding of raw materials, Deaeration, compaction composition, filling and binding of bars, Cold smoking, Drying and curing, Labelling, final packaging, storage and delivery) are schematically presented in fig. 1. through a flow chart diagram, which uses standardized international symbols.

For each stage of the technological flow was identified the three categories of potential hazards, physical, chemical and biological as well as the generators causes of their occurrence (Table 1).

According to the FMEA methodology, each category of potential hazards (corresponding to the different stages in the flow) was assessed from the perspective of three key criteria: the probability of occurrence of danger (associated within the FMEA method with the defect, failure mode or non-compliance), the severity (seriousness) of manifestation of potential hazard in final consumption (to the consumer) and the probability of detection of identified potential hazards.

Probability of occurrence of potential hazards (occurrence, O) is evaluated on a scale of 1 to 10 based on the determination tables [17] and a previous experience with similar processes; the score 1 indicates a minimum probability or even theoretical emergence of the danger, while the one of 10 points suggests that the potential danger will almost certainly appear in the process if control procedures are not applied and, as the case, preventive or corrective action.

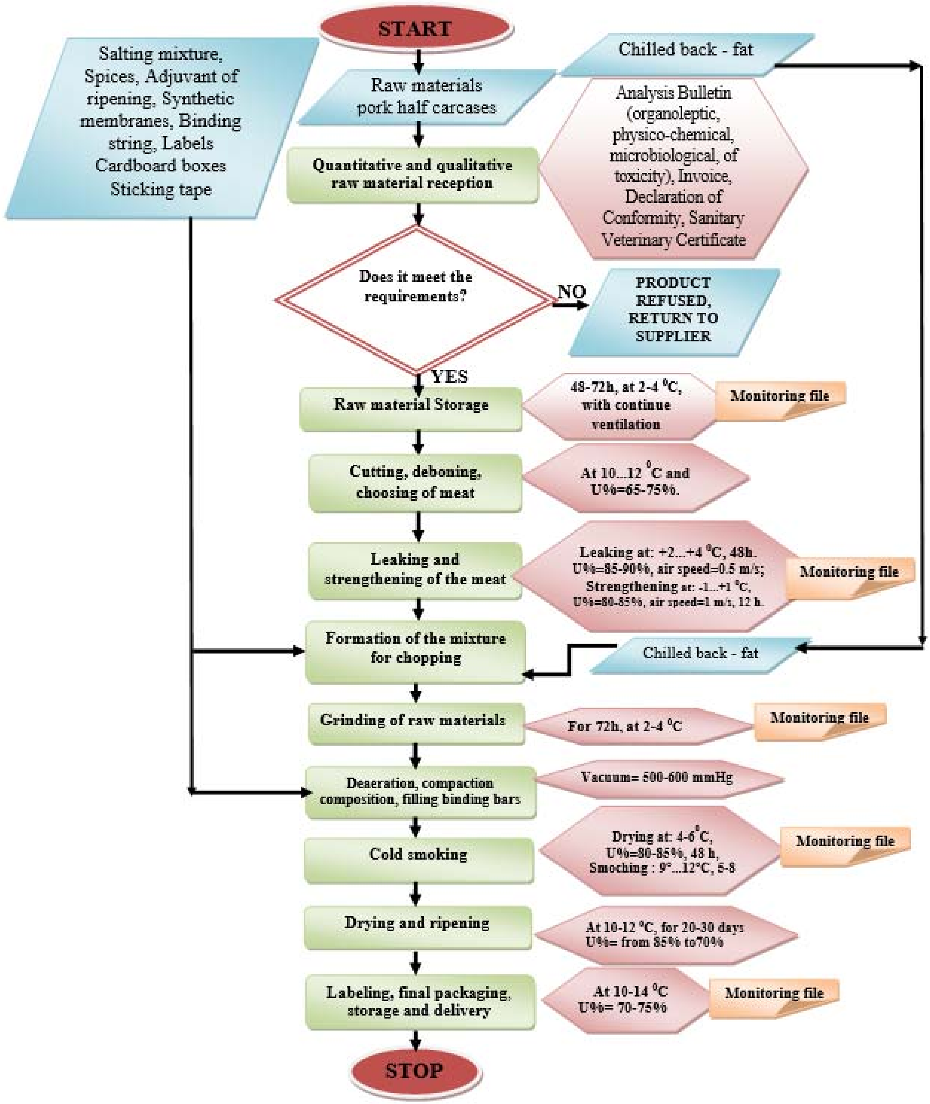

Fig. 1 The technological steps of raw-dried salami -adaptation after Banu et all, 2003 [6]

Table 1 Failure modes and effects analysis (FMEA) specific for stages of processing of raw-dried salami

No	Flow stages		Noncompliance/Hazard	Causes	A	S	D	RPN	Corrective Actions (CA)	A	S	D	*RPN
1.	Quantitative and qualitative raw material reception	F	Foreign bodies, hair, insects	Non-compliant handling. Untrained personal. Unselected supplier	6	4	5	120	Provider evaluation Batch rejection. Personal training	2	4	1	8
		C	Antibiotics, mycotoxins, pesticide residues, heavy metals (Pb, Cu, Hg, Zn), detergents.	Unselected supplier. Personal negligence	5	8	3	120	Provider evaluation. Documents control from supplier. Batch rejection.	2	8	1	16
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella sp, Staphylococcus aureus, Trichinella spiralis, Listeria monocitogenes*	Unsanitary manipulation. Unselected supplier. Inadequate temperature and transport conditions. Failure of trichinoscopic examination	7	9	4	252	Provider evaluation Batch rejection Personal training. Checking analysis bulletins, sanitary veterinary certificates. Trichineloscopic examination results. Checking transport conditions and thermograms. The temperature of raw materials control and recording.	2	9	1	18
2	Raw material storage	F	Foreign bodies, hair, insects, personal objects, etc.	Improper handling. Unselected supplier	5	5	5	125	Personal training. Respecting hygiene procedures. PRP	2	5	1	10
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	5	8	4	160	Personal training. Respecting hygiene procedures.	2	8	1	16
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unhygienic handling. Inappropriate temperature and conditions of storage	5	9	4	180	Personal training. Enhance raw material temperature monitoring, control and recording.	3	9	2	54
3.	Cutting, deboning, choosing meat	F	Bone fragments, hair, insects, personal objects, etc.	Improper handling. Personal negligence	5	5	5	125	Personal training. Compliance with procedures, PRP, metrological verification plan	2	5	1	10
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	4	8	3	96	Personal training. Respecting hygiene procedures	2	8	1	16
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unhygienic handling. Inappropriate temperature and conditions of processing	6	9	3	162	Checking staff hygiene, machinery, utensils, equipment, work environment by performing sanitation tests	5	9	2	90
4.	Leaking and strengthening of the meat	F	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	5	5	2	50	Personal training -	-	-	-	-
		C	Traces of detergents, disinfectants	Unselected supplier. Personal negligence - faulty rinsing (machines, utensils, equipment)	4	8	3	96	Personal training. Respecting hygiene procedures	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	6	9	3	162	Checking the staff, machinery, utensils, equipment, work environment hygiene by performing sanitation tests. Ventilation control in deposits. Keeping maintenance plan.	2	9	1	18
5.	Formation of the mixture for chopping	F	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	4	5	2	40	Personal training	-	-	-	-
		C	Inadequate dosage of additives. Traces of detergents, disinfectants	Non-compliance of the equipment used. Faulty rinsing (machines, utensils, equipment)	3	8	2	48	Personal training. Respecting hygiene procedures and maintenance plan.	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	5	9	3	135	Personal training. Checking the staff, machinery, utensils, equipment, work environment state of hygiene by performing sanitation tests.	3	9	1	27

No	Flow stages		Noncompliance/Hazard	Causes	A	S	D	RPN	Corrective Actions (CA)	A	S	D	*RPN
6.	Raw materials shredding	F	Foreign bodies, hair, insects, personal objects, etc.	Noncompliance manipulation. Untrained personal. Personal negligence	3	5	2	30	Personal training	-	-	-	-
		C	Inadequate dosage of additives. Traces of detergents, disinfectants	Untrained personal. Improper rinsing of machinery and equipment	3	8	2	48	Personal training	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	7	9	3	189	Performing periodic sanitation tests. Personal training	2	9	1	18
7.	Deaeration, compaction composition, filling and binding of bars	F	Foreign bodies, hair, insects, personal objects, metallic fragments etc.	Noncompliance manipulation Untrained personal. Personal negligence. Lack of maintenance plan	2	5	2	20	Personal training	-	-	-	-
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	2	8	1	16	Personal training	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	4	9	3	108	Checking the staff, machinery, utensils, equipment, work environment state of hygiene by performing sanitation tests. Personal training	2	9	1	18
8.	Cold smoking	F	Foreign bodies, hair, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	Personal training	3	5	2	30
		C	Traces of detergents, disinfectants. Possible residues of aromatic polycyclic hydrocarbons	Personal negligence. Outdated of smoking cells	4	8	3	96	Personal training	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	8	9	4	288	Monitoring of smoking specific parameters. Sanitation of smoking cells. Performing sanitation tests. Personal training	5	9	2	90
9.	Drying ripening	F	Foreign bodies, hair, pests.	Improper handling. Uninstructed staff. Personal negligence	3	5	2	30	Personal training	-	-	-	-
		C	Development of other types of molds with mycotoxin production	Failure to comply technological parameters. Inappropriate hygiene of storage areas.	3	9	2	54	Personal training	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Inappropriate hygiene of storage areas. Personal negligence	7	9	4	252	Performing periodic sanitation tests. Personal training	4	8	3	96
10.	Final labelling, packaging, storage and delivery	F	Foreign bodies, pests.	Improper handling. Uninstructed staff. Personal negligence. DDD plan noncompliance	2	5	1	10	Personal training. Maintaining and compliance with the DDD plan	-	-	-	-
		C	Traces of detergents, disinfectants Contamination with chemicals substances from inks and adhesives.	Faulty rinsing machines, equipment. Use of unauthorized inks and adhesives for the food industry. Migration of chemicals from the packaging in products	3	8	1	24	Personal training	-	-	-	-
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Inappropriate hygiene of storage areas. Personal negligence	2	9	2	36	Personal training	-	-	-	-

* RPN after corrective action

The Gravity (Severity, S) is evaluated on a scale of 1 to 10 depending on the level of harm to the health of the consumer as a result of exposure to a potential hazard identified in the final product at the time of consumption; Score 1 suggests that the effects on the health of the consumer are minor or absent while the 10 points indicate the possibility of some fatal consequences, serious illnesses or incurable injury occurring immediately or after a certain period of time.

The probability of detection (Detection, D) in the process of the potential hazard (failure mode) is estimated based on a determination table as well as previous experience with similar processes, being measured on a scale of 1 to 10 points; the minimum score suggests a very low probability that the potential danger identified to reach the customer (eg 0-2%) while the maximum score indicates a very high probability that the danger (defect) not to be identified in the process and reach the consumer (E.g. in over 80% of cases).

Based on the three determined parameters (O, S, D) for each stage of the technological flow, respectively the category of hazards, Risk Priority Number (RPN) was calculated as a result of multiplication O *x* S *x* D. Considering that the maximum value of the three parameters is 10 points, the highest RPN can be 1000 points, respectively 10 x 10 x 10, which would mean that the potential hazard (failure mode) will have a secure occurrence, is not detectable by inspection and had a very high severity (seriousness).

In the conducted study the highest RPN values were recorded for the category of biological hazards in: the cold smoking stages (288), drying-curing (252), reception (252), Grinding (189), raw material storage (180), leakage and strengthening of meat (162), cutting, deboning, choosing (162), forming of mixture (135), deaeration, compaction composition, filling and binding bars (108).

These results are used to establish risk minimization measures (preventive or, where appropriate, corrective actions) for each situation where the RPN has a greater value than 100 points as well as of hierarchy interventions according to the level of this value. Simulating the corrective actions and subsequently recalculating RPN highlights the possibility of a significant reduction of risk (Table 1).

For a better representation of RPN utility, in setting and prioritizing preventive and corrective interventions in a food safety management system its percentage contribution has been calculated before and after corrective action; the information is presented tabular in a decreasing order the RPN value (Table 2 and Table 3).

As can be seen, after applying the corrective actions, RPN may decrease considerably **(**Table 3), and for some stages (eg Reception, Leakage and hardening of the meat, Raw materials shredding) even a risk cancellation can be made for potential hazards identified. For a better view of the RPN percentage contribution in the quantitative assessment of the risks, specific to each stage of the process, graphical representation was chosen through the Pareto Diagrams (Figure 2 and Figure 3)

The possibility of diminishing the risks signalled by the RPN through preventive and corrective interventions was also reported in other similar studies conducted for food safety management systems specific to the different categories of food products in Greece (Arvanitoyannis and Savelides, 2007 for chocolate production [1], Arvanitoyannis and Varzakas, 2007a/b for manufacturing of strudel and potato chips [2, 3], Arvanitoyannis and Varzakas, 2008a/b for industrial processing of salmon and common octopus [4, 5] and Varzakas and Arvanitoyannis, 2008 for processing of ready to eat vegetables [15]) and in Turkey (Ozilgen, 2012 for Turkish delight [10] and Ozilgen, et all., 2013 [11] for red pepper spice). Other approaches in Italy (Shirani, 2015 for milk [12]), Poland (Trafialek, 2014 for the audit process [14]) and China (Wang, 2015 for the meat supply chain [16]) further demonstrates the utility application of FMEA.

Table 2 shows the RPN estimated before applying corrective actions and then it was calculated again (Table 3) to understand their influence in the process of improving food safety.

Table 2 Estimated RPN prior to the corrective actions

No	Technological flow stages	RPN	% RPN	Cumulative RPN%
1	Cold smoking	288	0.167	0.167
2	Reception of raw material	252	0.146	0.313
3	Drying and ripening	252	0.146	0.459
4	Raw materials Shredding	189	0.109	0.568
5	Raw material Storage	180	0.104	0.672
6	Cutting, deboning, choosing	162	0.094	0.766
7	Leaking- strengthening	162	0.094	0.860
8	Formation of the mixture	135	0.078	0.938
9	Deaeration, compaction filling and binding of bars	108	0.063	1.00
TOTAL		**1728**	1	1.00

Table 3 Estimated RPN after corrective actions implementation

No	Technological flow stages	RPN	%RPN	Cumulative RPN%
1	Drying and ripening	96	0.256	0.256
2	Cutting, deboning, choosing	90	0.240	0.496
3	Cold smoking	90	0.240	0.736
4	Raw material Storage	54	0.144	0.880
5	Formation of the mixture	27	0.072	0.952
6	Deaeration, compaction filling and binding of bars	18	0.048	1.00
7	Reception of raw material	0	-	-
8	Leaking- strengthening	0	-	-
9	Raw materials Shredding	0	-	-
Total		**375**	1.00	1.00

The Pareto diagrams (Figures 2 and Figure 3) have been built to view percentage contribution of specific RPN for each stage of processing related to total RPN of the process, before and after implementation of corrective actions.

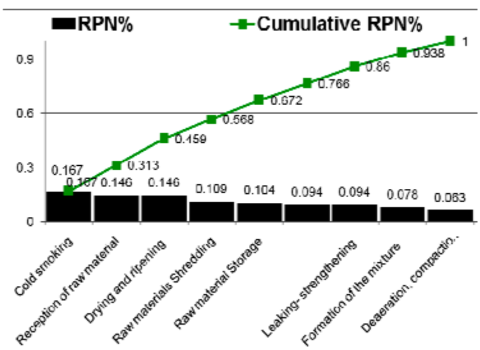

Fig. 2 Pareto Diagram for raw- dried salami before applying corrective action

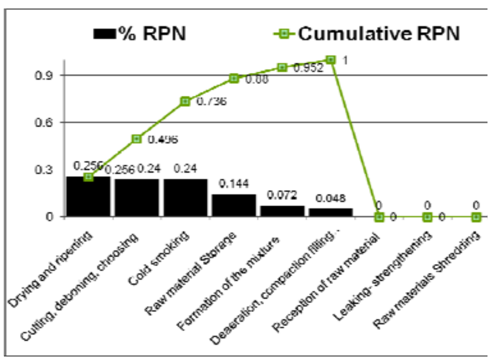

Fig. 3 Pareto Diagram for raw- dried salami after applying the corrective actions

CONCLUSIONS

Between the two methods (HACCP and FMEA) implemented in practice through specific systems of each, there are many similarities because both are preventive and use risk analysis techniques. FMEA method combined with HACCP principles provides a solid basis for identifying critical control points (CCPs) specific to the manufacturing of raw-dried meat products offering the possibility of applying control measures, monitoring and corrective intervention by drawing up the HACCP plan.

Given the FMEA method has a high degree of specificity and complexity, its application should be carried out by a multidisciplinary team and the hazard assessment should be individualized, for each hazard in part. 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.

Applying the FMEA method in a food safety management system based on Hazard Analysis Critical Control Points (HACCP) contributes to improving the quality and safety of products by the fact that performs a quantitative assessment more accurate of the risks. This evaluation allows faster targeting and prioritization of control measures as well as preventive and corrective interventions.

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