THE APPLICATION OF THE FAILURE MODES AND EFFECTS ANALYSIS (FMEA) METHODOLOGY TO IMPROVE MEAT PRODUCTS QUALITY

Gabriela FRUNZĂ[1]

e-mail: frunza.gabriela@uaiasi.ro

Abstract

Failure Modes and Effects Analysis (FMEA) it is a predictive and preventive methodology specific to non-compliance and risk management. The FMEA is a modern tool used in the purpose of identifying potential failure modes, the causes and effects of each nonconformity (on a system, subsystem, or component part), for keeping under control the technological processes and to improve the quality of finished products. The aim of this study was the application of the FMEA to improve meat products quality (pasteurized and smoked salami). The FMEA methodology application is distinguished as specificity the Action Priority (AP) establishment 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 (P), chemical (C) and biological (B), for all ingredients and for all stages of the technological flow for meat products. 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 actions and the lowering of potential nonconformities. Based on AP, the identified potential nonconformities can be classified in the Low priority category even if the old considered Risk Priority Number (RPN) value is higher than 100 (125, for the row material storage, at the level of P hazards). On the other hand, at values lower than 100 of the RPN, the AP can be in the Medium priority category (96, for the stage of cutting, deboning, choosing meat, at the level of C hazards), the value of S being the decisive element. After corrective action (CA) application, AP was lowered, the quality of the meat products being improved.

Key words: failure modes and effects analysis, quality, hazards, meat.

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 AIAG-VAD FMEA 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:

1. Highest priority (H) -the FMEA team "Needs" to identify an appropriate action or improve the prevention or detection controls;
2. Medium priority (M) -the FMEA team "should" identify an appropriate action or improve the prevention or detection controls;
3. Low priority (L) - 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 food safety team to address the associated design or process risk.

The FMEA is very similar to Hazard Analysis and Critical Control Points (HACCP) 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. That hazards if are left uncontrolled could result in illness or even death of consumers. In applying

[1] "Ion Ionescu de la Brad" University of Life Sciences, Iasi, Romania

process of HACCP System, the hazards specific to each stage of the technological flow, are assessed according to the probability/ frequency of occurrence and the severity of the effects of the manifestation on the consumer, establishing risk classes (four risk classes, establish by: Severity *x* frequency of occurrence by Risk class method), 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 (D) of hazards (Pop C., *et al.*, 2019).

These three elements (S, O and D) are used for evaluation 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.

The aim of this study was the application of the FMEA to improve meat products quality.

MATERIAL AND METHOD

The working methodology consisted in collecting and processing information based on practical experience 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 meat product (pasteurized and smoked salami) have been phased, realizing the setting of the technological flow stage, identification, for each step in the flow, of potential nonconformities/hazards (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 RPN, evaluating AP, setting critical control points (CCPs) and establishing the HACCP plan.

RPN=A x S x O (*value from 1 to 10*)

AP= S to A to O (*fom standard table with value from 1 to 10)*

At the same time, after establishing the AP, CA were identified for each category of hazards specific to the different stages of the flowchart.

RESULTS AND DISCUSSIONS

Technological steps specific to meat product are schematically presented (*figure 1),* through a flowchart diagram, which uses standardized international symbols according with *Codex alimentarius* guidance.

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").

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) based on AP *(table 1)*, the identified potential nonconformities can be classified in L category even if the RPN value is higher than 100, on the step two of technological flow, for the Raw material storage and preparation (125, at the level of F hazards). On the other hand, the AP can be in M category (at 120 values of the RPN, smaller value than previously, for Quantitative and qualitative reception, at the level of F and C hazards and respectively 160 on the stage of Raw material storage and preparation, for C hazard).

The value of S is 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. This provide solution to ambiguous recommendation from previous AIAG method. This method has make no sense in determining the AP, for example for the severity if the score is 10, while occurrence is 2 and detection is 2, RPN it will be 40. 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.

In this study, after applying the FMEA methodology was observed at the level of B hazard the majority of AP was from H category, the FMEA team "Needs" to identify an appropriate action or improve the prevention or detection controls. The CA application led, in all cases, to considerable diminution of AP. 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.

After the analysis conducted the biological hazard was in majority of cases for AP framed in H category (with exception of Final labelling, packaging, storage and delivery).

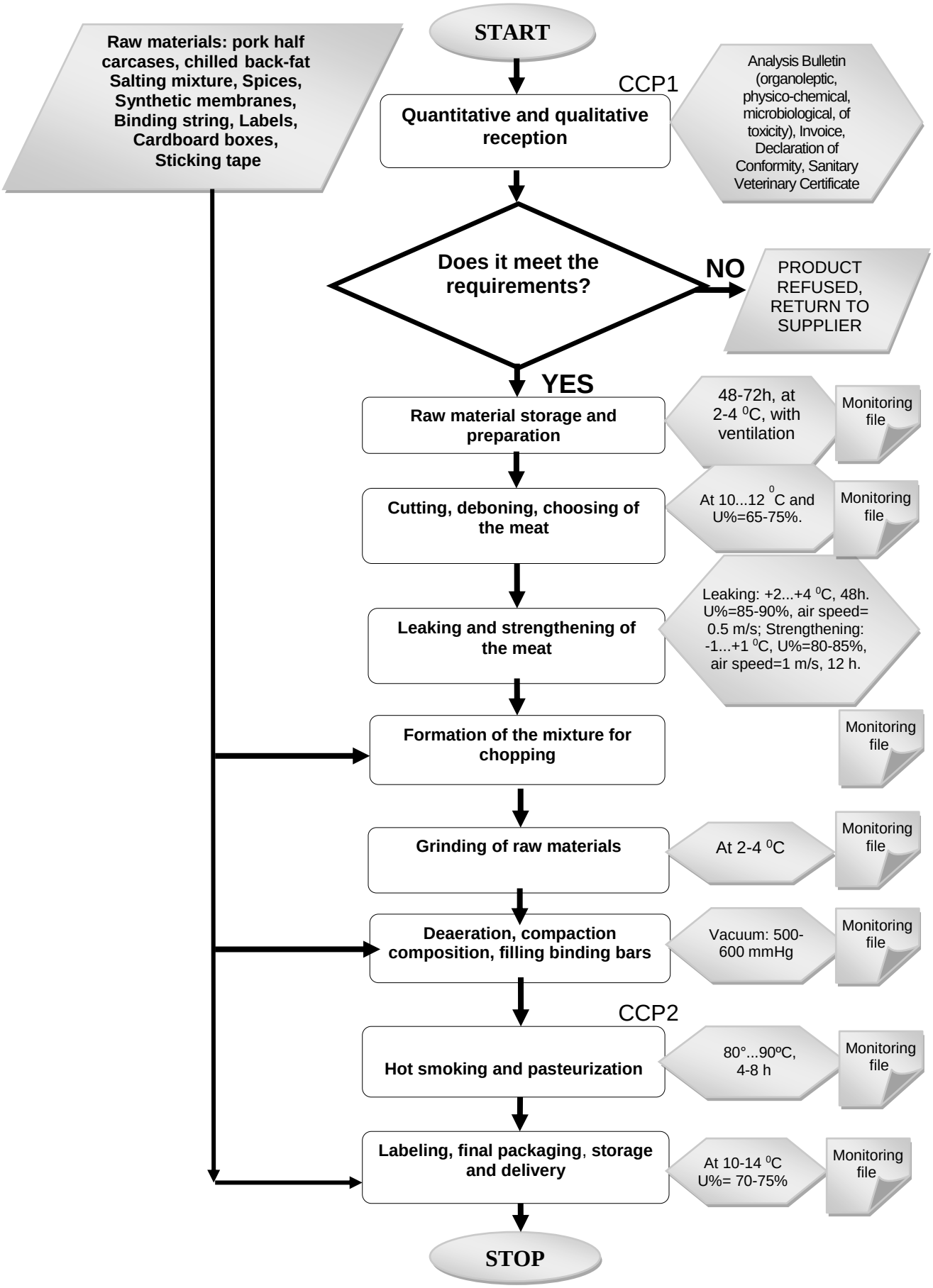

Figure 1. **The flowchart of meat products (pasteurized and smoked salami)**

Table 1.

Failure modes and effects analysis (FMEA) specific for flowchart stages for processing of meat products (pasteurized and smoked salami)

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	Untrained personal, bad handling. Unselected supplier	4	6	5	120	M	Provider evaluation Batch rejection. Personal training	4	2	1	8	L
		C	Antibiotics, mycotoxins, pesticide residues, heavy metals (Pb, Cu, Hg, Zn), detergents.	Unselected supplier. Personal negligence	8	5	3	120	M	Provider evaluation. Documents control from supplier. Batch rejection.	8	2	1	16	L
		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	9	7	4	252	H	Provider evaluation. Batch rejection Personal training. Checking analysis bulletins, sanitary veterinary certificates. Trichinoscopic results examination. Checking transport conditions and thermograms. The temperature of raw materials control and recording.	9	2	1	18	L
2	Raw material storage and preparation	P	Foreign bodies, hair, insects, personal objects, etc.	Improper handling. Unselected supplier	5	5	5	125	L	Personal training. Respecting hygiene procedures / preliminary programs (PRP)	5	2	1	10	L
		C	Traces of detergents, disinfectants	Improper rinsing of machinery /equipment.	8	5	4	160	M	Personal training. Respecting hygiene procedures.	8	2	1	16	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 control, monitoring, recording Pest Control, Disinsection, Disinfection (DDD)	9	3	2	54	L
3.	Cutting, deboning, choosing meat	P	Bone fragments, hair, insects, personal objects, etc.	Improper handling. Personal negligence	5	5	5	125	L	Personal training. Compliance with procedures, PRP, metrological verification plan	5	2	1	10	L
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	8	4	3	96	M	Personal training. Respecting hygiene procedures	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unhygienic handling Inappropriate temperature and conditions of processing	9	6	3	162	H	Checking staff hygiene, machinery, utensils, equipment, work environment by performing sanitation tests	9	2	2	36	L
4.	Leaking and strengthening of the meat	P	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	5	5	2	50	L	Personal training -	5	2	1	10	L
		C	Traces of detergents, disinfectants	Unselected supplier. Personal negligence - faulty rinsing (machines, utensils, equipment)	8	4	3	96	M	Personal training. Hygiene procedures implementation	8	2	2	32	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	6	3	162	H	Checking the staff, machinery, utensils, equipment, work environment hygiene performing sanitation tests. Ventilation control in deposits. Keeping maintenance plan.	9	2	1	18	L
5.	Formation of the mixture for chopping	P	Hair , insects, personal objects, etc.	Improper handling. Untrained staff	5	4	2	40	L	Personal training	5	2	1	10	L
		C	Inadequate dosage of additives. Traces of detergents, disinfectants	Non-compliance of the equipment used. Faulty rinsing (machines, utensils, equipment)	8	3	2	48	L	Personal training. Respecting hygiene procedures and maintenance plan.	8	2	1	16	L

Flow stages		Noncompliance/Hazard		Causes	S	O	D	RPN	AP	Corrective Actions (CA)	S	O	D	*RPN	AP
		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 performing sanitation tests.	9	2	1	18	L
6.	Raw materials shredding	P	Foreign bodies, hair, insects, personal objects, etc.	Noncompliance manipulation. Untrained personal. Personal negligence	5	3	2	30	L	Personal training. Respecting hygiene procedures. PRP.	5	2	1	10	L
		C	Inadequate dosage of additives. Traces of detergents, disinfectants	Untrained personal. Improper rinsing of machinery and equipment	8	3	2	48	L	Personal training. PRP. Use of product standard and recipes.	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	7	3	189	H	Performing periodic sanitation tests. Personal training	9	2	1	18	L
7.	Composition compaction, filling and binding	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 Checking and application of maintenance plan	5	2	1	10	L
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	8	2	1	16	L	Personal training. PRP	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	4	3	108	H	Checking the staff, machinery, utensils, equipment, work environment state of hygiene by performing sanitation tests. Personal training	9	2	1	18	L
8.	Hot smoking and pasteurization	P	Foreign bodies, hair, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training. PRP.	5	2	1	10	L
		C	Traces of detergents, disinfectants. Possible residues of aromatic polycyclic hydrocarbons	Personal negligence. Outdated of smoking cells	8	4	3	96	M	Personal training. PRP.	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Salmonella, Staphylococcus aureus*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	8	4	288	H	Monitoring of smoking specific parameters. Sanitation of smoking cells. Performing sanitation tests. Personal training	9	2	1	18	L
9.	Final labelling, packaging, storage and delivery	P	Foreign bodies, pests.	Improper handling. Uninstructed staff. Personal negligence. Noncompliance of DDD plan	5	2	1	10	L	Personal training. Maintaining and compliance of the DDD plan	5	1	1	5	L
		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	8	3	1	24	L	Personal training. PRP.	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. Performing sanitation tests.	9	1	1	9	L

* RPN after corrective action; L – low priority action; M –medium priority action; H – highest priority action.

The highest RPN value from B hazards was observed at the level of the CCPs established (252/ CCP1 for qualitative raw material reception-failure of trichinoscopic examination, and respectively 288/ CCP2 for Hot smoking and pasteurization-unsanitary conditions manipulation and, inadequate temperature).

After CA, AP was visible lowered for all stages of flowchart, thus improving the quality of the manufactured meat products (pasteurized and smoked salami).

The possibility of diminishing the risks signalled by the FMEA methodology, through preventive and corrective interventions, was reported in other similar studies conducted for food safety specific to the different categories of food products (Arvanitoyannis S.I. and Savelides S.C., 2007 for chocolate production, Arvanitoyannis S.I. and Varzakas T.H., 2007a/b for manufacturing of strudel and potato chips, Arvanitoyannis S.I. and Varzakas T.H., 2008a/b for industrial processing of salmon and octopus and Varzakas T.H. and Arvanitoyannis S.I., 2008 for ready to eat vegetables, Ozilgen S. *et al*., 2013 for red pepper and Ozilgen S., 2012 for Turkish delight, Shirani M. and Demichela M., 2015 for diary production, Wang X. and Lu Q., 2015 for meat chain), further demonstrates the utility application of FMEA.

CONCLUSIONS

The new FMEA methodology, based on AP, the identified potential nonconformities can be classified in the L priority category even if the old considered RPN value is higher than 100 (125, for the row material storage, at the level of P hazards). At values lower than 100 of the RPN, the AP can be in the M priority category (96, for the stage of cutting, deboning, choosing meat, at the level of C hazards), the value of S being the decisive element. The biological hazard was framed in H category in majority of cases for AP analyzed (with exception of final stages of flowchart). After CA, AP was visible lowered for all stages of flowchart. The personal training, the most frequent CA (the human resources being the active factor that influence the quality of food products), health status control, strict personal hygiene, strict hygiene of personal equipment's, machine, work equipment's, work surfaces, periodically sanitation tests are the principal CA that can lower the potential hazards occurrence, and AP value. This instruments are effective and very closed for the top management of any organization, being in accordance with international law and standards; if they are applied the quality of the products will be improved.

REFERINCES

AIAG & VDA Handbook, 2019 - *Failure Mode and Effects Analysis (FMEA). Design FMEA, Process FMEA, and FMEA for Monitoring and System Response*, 79-122.

Arvanitoyannis S.I., Savelides S.C., 2007 - *Application of failure mode and effect analysis and cause and effect analysis and Pareto diagram in conjunction with HACCP to a chocolate-producing industry: a case study of tentative GMO detection at pilot plant scale.* International Journal of Food Science & Technology, 42 (11), 1265-1289.

Arvanitoyannis S.I., Varzakas T.H., 2007a - *A conjoint study of quantitative and semi-quantitative assessment of failure in a strudel manufacturing plant by means of FMEA and HACCP, Cause and Effect and Pareto diagram*. International Journal of Food Scie. and Techn., 42, 1156-1176.

Arvanitoyannis S.I., Varzakas T.H., 2007b- *Application of failure mode and effect analysis (FMEA), cause and effect analysis and Pareto diagram in conjunction with HACCP to a potato chips manufacturing plant.* International Journal of Food Science&Technology, 4212, 1424-1442.

Arvanitoyannis S.I., Varzakas T.H., 2008a - *Application of ISO 22000 and Failure Mode and Effect Analysis (FMEA) for industrial processing of salmon: a case study.* Critical reviews in Food Science and Nutrition, 48, 411-429.

Arvanitoyannis S.I., Varzakas T.H., 2008b- *Application of failure mode and effect analysis (FMEA) and cause and effect analysis for industrial processing of common octopus (Octopus vulgaris) – Part II,* International Journal of Food Science and Technology, 44, 79–92.

Pop C., Frunză G., Ciobanu M.M., 2019 - *Study regarding application of the FMEA method within a food safety management system.* Scie. Papers-Animal Scie. Series, Iași, 71(24), 189-196.

Ozilgen S., 2012 - *Failure Mode and Effect Analysis (FMEA) for confectionery manufacturing in developing countries: Turkish delight production as a case study*, Ciênc. Tecnol. Aliment., Campinas, 32(3), 505-514.

Ozilgen S., Bucak S., Ozilgen M., 2013 - *Improvement of the safety of the red pepper spice with FMEA and post processing EWMA quality control charts,* Journal Food SciTechnol, 50(3), 466–476.

Shirani M., Demichela M., 2015- *Integration of FMEA and Human Factor in the Food Chain Risk Assessment.* International Journal of Social, Behavioral, Educational, Economic, Business and Industrial Engineering, 9(12), 4050-4053.

Varzakas T.H., Arvanitoyannis I.S., 2008- *Application of failure mode and effect analysis and cause and effect analysis on processing of ready to eat vegetables – part II,* International Journal of Food Science and Technology, 44, 932–939.

Wang X., Lu Q., 2015 - *Formulation and Implementation of Meat Product HACCP Plan Based on FMEA*, Advance Journal of Food Science and Technology, 7(8), 579-583.