THE APPLICATION OF THE FAILURE MODES AND EFFECTS ANALYSIS (FMEA) METHODOLOGY WITHIN A FOOD SAFETY MANAGEMENT SYSTEM

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Abstract

Failure Modes and Effects Analysis (FMEA) methodology is used for identifying potential failure modes, the causes and effects of each nonconformity 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 bread quality. Among the steps and activities required to apply the FMEA methodology is distinguished as specificity the evaluation of Action Priority (AP) and Risk Priority Number (RPN), 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/RPN was determined for all stages of the technological flow specific to the manufacture of bread, for all ingredients and for each category of potential hazards identified: physical (P), chemical (C) and biological (B). Through AP, a quantitative assessment can be made of the potential food safety problems in a system, and respectively a prioritization of implementation of corrective actions (CA) a substantial decrease of nonconformities. The highest values of AP/RPN were observed for biological hazards in the technological stages of bread cooling (AP High/ RPN 270) and packaging (AP High/ RPN 192). After the application of AC, there is a clear decrease in the value of O and D, however the value of S is maintained as a distinct element.

Key words: bread, Failure Modes and Effects Analysis

INTRODUCTION

Failure Modes and Effects Analysis (FMEA) methodology is used for identifying potential failure modes, the causes and effects of each nonconformity for keeping under control the technological processes and to improve the quality of finished products.

FMEA is based on BS EN IEC 60812:2018 standard, Failure modes and effects analysis (FMEA and FMECA-failure modes effects and criticality analysis) from automotive industry [1].

The FMEA is an analysis led by a team to identify the possible failure modes in a system and the causes and effects associated with them [8]. When unacceptable failure effects are verified, design changes must be made to either eliminate or reduce the failure causes. The first uses of FMEA as a structured methodology can be found in the United States' Department of Defense and applied by the National Air Force and Space Administration (NASA) for the Apollo plan to improve the system's reliability in the 1960s. FMEA methodology it is applied in the design phase of the realization of the products, in order to avoid potential non-conformities, or at least to reduce their frequency of occurrence, to control technological processes and to improve the overall quality of the products made [7].

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

MATERIAL AND METHOD

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.

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The activities required to apply the FMEA method in a food safety management for manufacturing of breed 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 Risk Priority Number (RPN) and evaluating the Action Priority (AP), setting critical limits for all stages and critical control points (CCP), 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, corrective actions were identified for each category of hazards specific to the different stages of the flow chart. 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

The main technological steps of bread production are taken in study (Quantitative and qualitative raw material reception, Raw material preparation, Flour sifting, Dosage of raw and auxiliary materials, leaven Kneading and fermentation for the dough, Dough kneading, Dough pre-fermentation, Dough division and pre-shaping (rounding), Dough pre-fermentation and shaping, Dough fermentation and notching, Dough baking, Bread Cooling, Bread packaging and Storage-Delivery) with critical limits previously established (Figure 1). The technological steps are schematically presented through a flowchart diagram, which uses standardized international symbols according with *Codex alimentarius* guidance. For the technological flow (Table 1), 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".

The highest values of RPN/AP and the most serious potential failure in terms of food safety were observed especially at the level of the technological stage of bread cooling (270/ AP High) of the Quantitative and qualitative raw material reception (252/ AP High) and for the step of packaging (189/AP High) for B hazards.

After the application of CA, there is a clear decrease in the frequency of O and D of nonconformities, however as a distinct element of FMEA/HACCP methodology, the value of S is maintained.

Through AP, a quantitative assessment can be made of the potential food safety problems in a system, and respectively a prioritization of implementation of corrective actions (CA) and the lowering of potential nonconformities. The CA application for the food safety management systems specific for breed production led, in all cases, to considerable diminution of AP.

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 and Savelides, 2007 for chocolate, Arvanitoyannis and Varzakas, 2007a/b for strudel and potato chips, Arvanitoyannis and Varzakas, 2008a/b for industrial processing of salmon and octopus and Varzakas and Arvanitoyannis, 2008 for processing of ready to eat vegetables, Ozilgen, et al., 2013 for red pepper spice and Ozilgen, 2012 for Turkish delight, Shirani, 2015 for milk), Trafialek, 2014 for the audit process) (Wang, 2015 for the meat supply chain) further demonstrates the utility application of FMEA [3-6, 9-11, 14, 15].

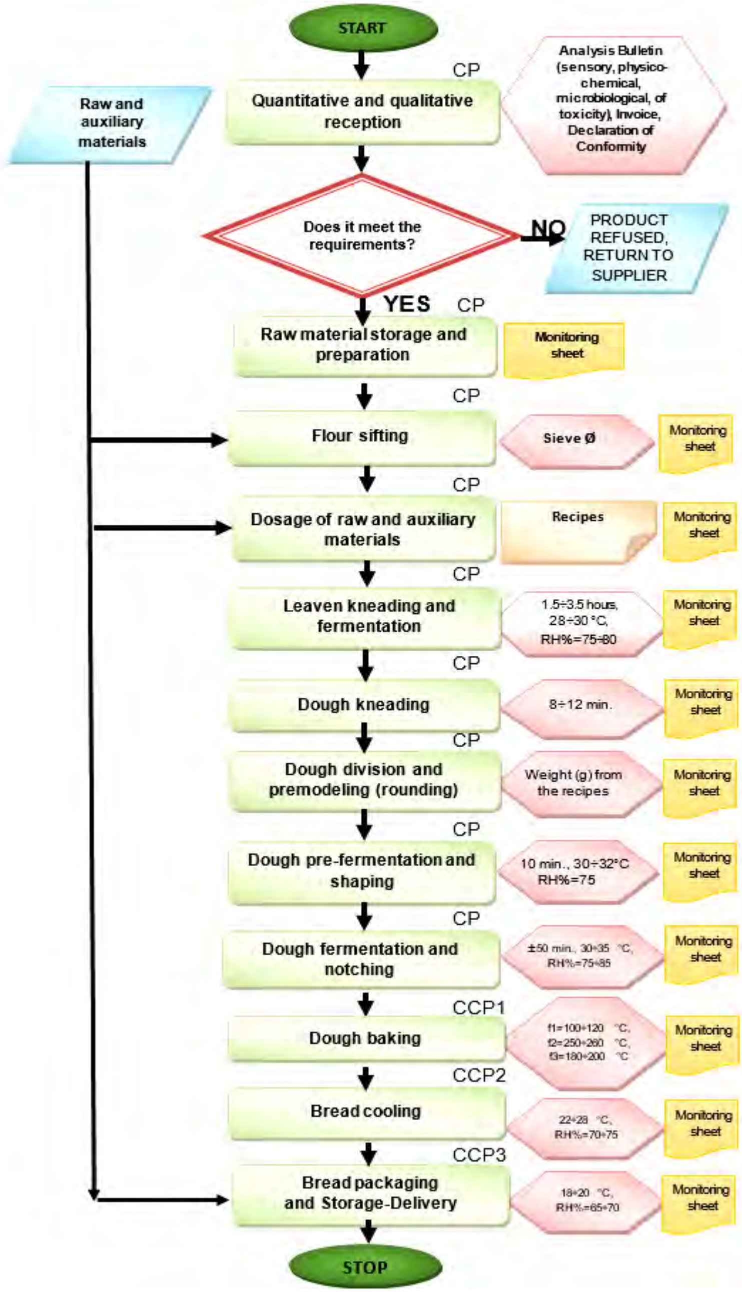

Figure 1. The flowchart of bread in compliance with *Codex Alimentarius* guidance

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 S is established the standardized AP (Table 1).

Table 1 Failure modes and effects analysis (FMEA) specific for stages of processing of bread

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, insect's, metallic impurities, dust, pebbles, seeds, vegetable waste etc.	Untrained personal, bad handling. Unselected supplier	4	6	5	120	M	Provider evaluation. Compliance with Prerequisite Programs. Batch rejection. Personal training	4	2	1	8	L
		C	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, Staphylococcus aureus, Bacillus mesentericus, Listeria monocitogenes*	Unsanitary manipulation. Unselected supplier. Inadequate temperature and transport conditions	9	7	4	252	H	Provider evaluation. Batch rejection Personal training. Checking analysis bulletins. Checking transport conditions. The humidity and temperature of raw materials control and recording	9	3	2	54	L
2.	Raw material preparation	P	Foreign bodies: hair, insects, personal objects etc.	Improper handling. Unselected supplier	5	5	5	125	L	Personal training. Respecting hygiene procedures and Prerequisite Programs	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: *Bacillus mesentericus, Escherichia coli, Staphylococcus aureus.*	Unhygienic handling. Inappropriate temperature and conditions of storage	9	5	4	180	H	Pre -operational inspection. Personal training. Enhance raw material temperature monitoring, control and recording	9	3	1	27	L
3.	Flour sifting	P	Hair, insects, personal objects etc.	Improper handling. Personal negligence	5	5	5	125	L	Personal training. Compliance with procedures, Prerequisite Programs, 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, 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	1	18	L
4.	Dosage of raw and auxiliary materials	P	Hair, insects, personal objects etc.	Improper handling. Untrained staff	5	5	2	50	L	Compliance with Prerequisite Programs. Personal training	5	2	1	10	L
		C	Traces of detergents, disinfectants Inadequate dosage of additives.	Unselected supplier. Personal negligence. Faulty rinsing (utensils, equipment)	8	4	3	96	M	Personal training. Compliance with Prerequisite Programs. Hygiene procedures implementation	8	2	2	32	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus.*	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

Flow stages		Noncompliance/Hazard		Causes	S	O	D	RPN	AP	Corrective Actions (CA)	S	O	D	RPN	AP
5.	Kneading and fermentation of the leaven for the dough	P	Hair, insects, personal objects, etc.	Improper handling. Untrained staff	5	4	2	40	L	Personal training	5	2	1	10	L
		C	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
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	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	3	1	27	L
6.	Dough kneading	P	Foreign bodies, hair, insects, personal objects etc.	Noncompliance manipulation. Untrained personal. Personal negligence	5	3	2	30	L	Personal training. Performing inspections	5	2	1	10	L
		C	Traces of detergents, disinfectants	Untrained personal. Improper rinsing of machinery and equipment	8	3	2	48	L	Personal training. Performing inspections	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	7	3	189	H	Performing periodic sanitation tests. Personal training	9	4	1	36	L
7.	Dough division and shaping (rounding)	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. Performing inspections	5	2	1	10	L
		C	Traces of detergents, disinfectants	Improper rinsing of machinery and equipment.	8	2	1	16	L	Personal training. Performing inspections	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	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	3	1	27	L
8.	Dough pre-fermentation and shaping	P	Foreign bodies, hair, insects	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training. Performing inspections	5	2	1	10	L
		C	Traces of detergents, disinfectants	Personal negligence	8	4	3	96	M	Personal training. Performing inspections	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	5	1	45	M	Monitoring of specific parameters. Sanitation of fermentation cells. Performing sanitation tests. Personal training	9	2	1	18	L
9.	Dough fermentation and noching	P	Foreign bodies: hair, insects, 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	Faulty rinsing machines, equipment	8	3	1	24	L	Personal training. Performing inspections	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Inappropriate hygiene of fermentation areas. Personal negligence	9	5	2	90	H	Personal training. Checking the staff, machinery, utensils, equipment, work environment	9	1	1	9	L

Flow stages			Noncompliance/Hazard	Causes	S	O	D	RPN	AP	Corrective Actions (CA)	S	O	D	*RPN	AP
10.	Dough baking	P	Foreign bodies: personal objects, metallic fragments etc.	Noncompliance manipulation Untrained personal. Personal negligence. Lack of maintenance plan	5	2	2	20	L	Personal training. Checking the staff, machinery, utensils, equipment, work environment	5	2	1	10	L
		C	Traces of detergents, disinfectants.	Improper rinsing of machinery and equipment.	8	2	1	16	L	Personal training. Checking the staff, machinery, utensils, equipment, work environment,	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus, Bacillus mesentericus etc.*	Unsanitary manipulation. Inadequate temperature and time of baking	9	4	3	108	H	Monitoring baking parameters Checking the staff, machinery, utensils, equipment, work environment, hygiene by performing sanitation tests. Personal training	9	2	1	18	L
11.	Bread Cooling	P	Foreign bodies: hair, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training. Performing inspections	5	2	1	10	L
		C	Traces of detergents, disinfectants.	Personal negligence.	8	4	3	96	M	Personal training. Performing inspections	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	3	7	270	H	Monitoring of cooling parameters. Sanitation of cooling cells. Performing sanitation tests. Personal training	9	3	2	54	L
12	Bread packaging	P	Foreign bodies: pests, insects.	Improper handling. Uninstructed staff. Personal negligence	5	5	4	100	L	Personal training. Performing inspections	5	2	1	10	L
		C	Traces of detergents, disinfectants.	Personal negligence.	8	4	3	96	M	Personal training. Performing inspections	8	2	1	16	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Unsanitary manipulation. Inadequate temperature and environmental conditions	9	3	7	189	H	Monitoring of cooling parameters. Sanitation of cooling cells. Performing sanitation tests. Personal training	9	2	1	18	L
13.	Storage-Delivery	P	Foreign bodies, pests. Flattened, cracked, deformed bread.	Improper handling. Uninstructed staff. Personal negligence. Noncompliance of DDD plan	5	2	1	10	L	Personal training. Maintaining and compliance of the DDD plan. Placing and transporting the bread in crates only after cooling. Respecting hygiene procedures / Prerequisite Programs.	5	1	1	5	L
		C	Traces of detergents, disinfectants.	Faulty rinsing machines, equipment. Migration of chemicals substances from the packaging in products	8	3	1	24	L	Personal training. Respecting hygiene procedures and Prerequisite Programs.	8	1	1	8	L
		B	Pathogenic microorganisms: *Escherichia coli, Staphylococcus aureus etc.*	Inappropriate hygiene of storage areas. Personal negligence	9	2	2	36	L	Personal training. Respecting hygiene procedures and Prerequisite Programs. Sanitation tests.	9	1	1	9	L

* RPN after corrective action; (green) L – low priority action; (yellow) M –medium priority action; (red) H – highest priority action.

*DDD plan=Pest control, Disinsection and Disinfection

Through AP, a quantitative assessment can be made of the potential food safety problems in a system, and respectively a prioritization of implementation of CA and the lowering of potential nonconformities. After the application of CA, there is a clear decrease in the frequency of O and D of nonconformities. Thus we have a quantifiable dimension of reducing hazards and improving the quality of manufactured products by the values of *RPN (Figure 2) and of the AP from H to L (Table 1).

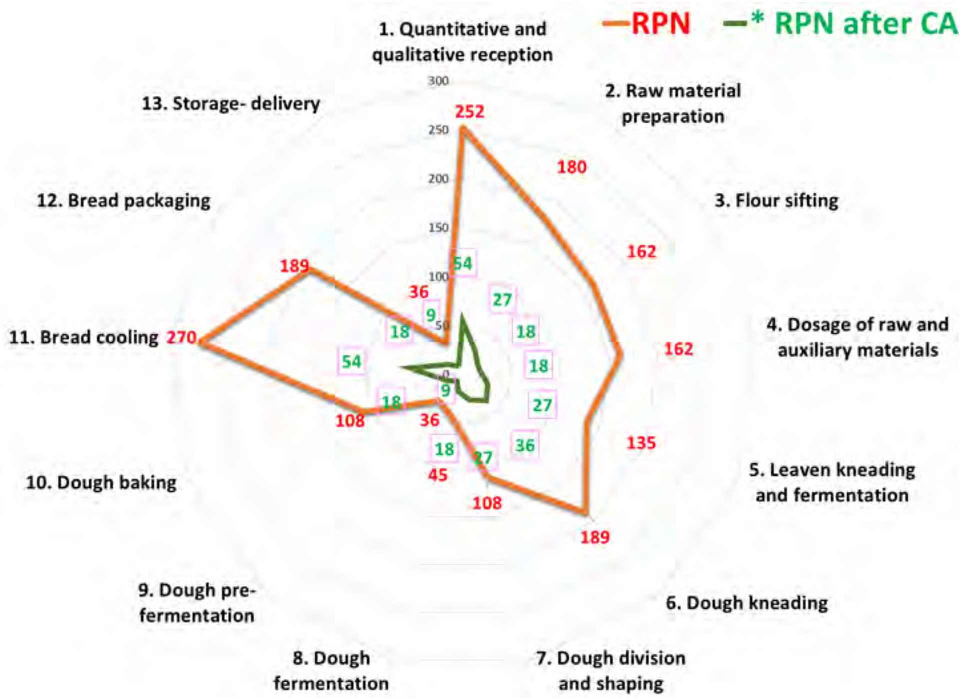

Fig. 2 RPN values before and after Corrective Action

The FMEA technique is widely used in numerous industries to assess and mitigate the risk of unexpected failures.

Companies' risk management is increasingly fundamental in manufacturing companies with an almost saturated production cycle. It is fundamental to prevent the occurrence of a failure as much as possible because it leads, in most cases, to a loss of production and, therefore, to severe economic losses [8].

Much more recent studies apply the FMEA methodology as proactive diagnosis techniques, or for human resource risk control on the health sector [2, 7, 12] together with fault diagnosis and prognosis methods [13], being the most useful tools for risk and reliability analysis in food processing systems.

CONCLUSIONS

The highest values of RPN/AP and the most serious potential failure in terms of food safety were observed especially at the level of the technological stage of bread cooling (270/ AP High), of the Quantitative and qualitative raw material reception (252/ AP High) and packaging (189/AP High) for biological hazards. The B hazard was framed in H category in majority of cases for AP analyzed (with exception of final stages of flowchart). The principal CA that can lower the potential hazards occurrence, and AP value are: the personal training (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 and environment, compliance with pest control, disinsection and disinfection plan and dally sanitation tests. This instruments are effective and very closed for the top management of any organization, being in accordance with international law and standards; if this CA are right applied the quality of the products will definitely be improved. Applying the FMEA methodology in the design phase of the realization of the products, the financial advantages will be significant also by avoiding the costs of treating non-conformities (non-compliant products, rewarding dissatisfied consumers, or worse, consumers who have suffered illnesses, etc.).

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