FMEA USED AS RISK ASSESSMENT METHOD IN FOOD LABELING

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Abstract: *Failure Mode and Effects Analysis (FMEA), is widely used within multiple industries to improve and manage overall quality. The purposes of this method are: the early recognition of failure risks and the reduction of occurrence to a minimum; the avoidance of the possibility of liability claims; the reduction of costs for: for a change caused due to the failures; for additional work (non value added) due to rejects / scrap or rework; for warranty claims in external areas. [1], [2] In this paper we shall use this method for evaluation of the consumer risk information, based on the data acquired during FP7-PEOPLE-2012-IRSES ID: 318946 – NUTRILAB Project. The results shows that the mention regarding "Substances or products causing allergies or intolerances", "The quantity of certain ingredients or categories of ingredients" and "Special storage conditions and/or conditions of use" are the most important issue for consumer risk. The same method can be extended to other group of products and other risk issues.*

Keywords: *risk assessment, food labeling, FMEA.*

1. Introduction

Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. "Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual.

"Effects analysis" refers to studying the consequences of those failures. Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected [13, 14].

The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones. Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is used during design to prevent failures. Later it's used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

Begun in the 1940s by the U.S. military, FMEA was further developed by the aerospace and automotive industries. Several industries maintain formal FMEA standards. In this paper we shall use this method for evaluation of the consumer risk information, based on the data acquired during FP7-PEOPLE-2012-IRSES ID: 318946 – NUTRILAB Project.

2. FMEA as method for risk analysis in food labelling

FMEA will be applied for risk analysis in the area of health and safety and for important projects. In the product development process the design FMEA will be applied before the process FMEA [5]. The most important items are the following:

Design FMEA recognizes functional failure modes of the product very early in the design phase, recognize potential safety and environment problems to eliminate doubts and set priorities for design improvement.

Also it helps with the development of a detailed test to check the design and the identification of potential critical inputs and outputs.

Process FMEA it is initiated in early in the process improvement investigation after a process map is available; when a new process are being designed; when existing processes are being changed; after process function are defined, but before specific hardware is selected or released to manufacturing.

Update/review of process FMEA it will be made:

RPN (Risk Priority Number)

The result of a FMEA is the product of three quantitative ratings, in relation to failure effect, cause frequency and detection capability. It is calculated as:

RPN = Importance (severity) x Occurrence x Detection.

Severity (of Effect) is the importance of possible effect on customer requirements - could also concern safety and other risks if a failure occurs (1=Not Severe, 10=Very Severe).

Occurrence (of Cause) is the frequency with which a given cause occurs and creates Failure Mode. Can sometimes refer to the frequency of a Failure Mode (1=Not Likely, 10=Very Likely).

Detection (capability of Current Controls) is the ability of current control scheme to detect: the causes before creating failure mode and or the failure modes before causing effect (1=Likely to Detect, 10=Not Likely to Detect).

The rating for severity of effect, occurrence and detection will be within the range of 1…10 [15, 9, 6];

The method was applied on the results of the project FP7-PEOPLE-2012-IRSES 318946 – NUTRILAB. This is a multidisciplinary and comparative Joint Exchange Programmed with the mission to identify and examine how nutritional labeling in European countries and out of Europe fulfills the actual legislation requirement.

Fulfilling the nutritional labelling criterions related to European regulation no 432/2012, 1169/2011, 1333/2008, 1924/2006, it is a difficult task, studied by numerous researchers from different locations in the European Union, and the NUTRILAB project was looking forward to the accomplishment of the mentioned criterions in the countries around the Black Sea. In this direction, these regulations were fully studied and identified: Regulation 1924/2006; Regulation 1333/2008; Directive 89/398/EEC of 3 May 1989; Regulation 1169/2011.

After analyzing regulations, a number of information categories were identified that have a very clear specification and can be statistically analyzed [7, 8, 9]. These types of information are:

- the name of the food product, the list of ingredients,
- substances or products causing allergies or intolerances,
- the quantity of certain ingredients or categories of ingredients,
- the net quantity of the food, (g, ml, kg),
- the date of minimum durability or the ‘use by’ date,
- any special storage conditions and/or conditions of use,
- the name or business name and address of the food business operator, the country of origin or place of provenance,
- instructions for use where it would be difficult to make appropriate use of the food in the absence

of such instruction,

- language, font size, the energy value, per portion or %, kcal and kJ,
- fat, protein, carbohydrates, saturates, sugars, salt, polios, starch, fibers,
- MUFA, PUFA, vitamins, minerals, conclusions, recommendations, notes.

3. Results

Data obtained during NUTRILAB project were evaluated from consumer risk point of view. From all information categories, the following were considered having a big risk impact:

- substances or products causing allergies or intolerances
- the quantity of certain ingredients or categories of ingredients
- the date of minimum durability or the ‘use by’ date
- any special storage conditions and/or conditions of use
- language
- font size

A numerical value is then assigned to the severity of the failure (S), the frequency of occurrence (O) and the detectability of the failure (D). These numbers are multiplied to give the RPN. The RPN is an index that gives the relative quality risk associated with each failure mode [2, 4].

With the FMEA table completed (see table 1, case of sausages), steps in risk issues can be identified by comparing their relative RPNs. The steps with the highest numbers are the biggest risk. A cross-functional team can then decide at what level they will consider an RPN acceptable. A good way to visualize these

relative risks is with a Pareto diagram, the chart created by economist Vilfredo Pareto. This diagram is a simple, easy-to-use method of visually representing which problems are the most vital to quality [1, 10, 15].

A similar analyze was performed for the case of salami and the results are presented in table 2 and figure 2.

Tabel 1 . *FMEA Tabel (study case: sausages)*

Risk Issue	Severity of the failure (S)	Frequency of occurrence (O)	Detectability of the failure (D)	RPN
Substances or products causing allergies or intolerances	10	9,00	10,00	900,00
The quantity of certain ingredients or categories of ingredients	8	3	10	240,00
Date of minimum durability or the ‘use by’ date	8	1,00	5,00	40,00
Special storage conditions and/or conditions of use	7	3,00	8,00	168,00
Language	7	3,00	1,00	21,00
Font size	8	3,00	1,00	24,00

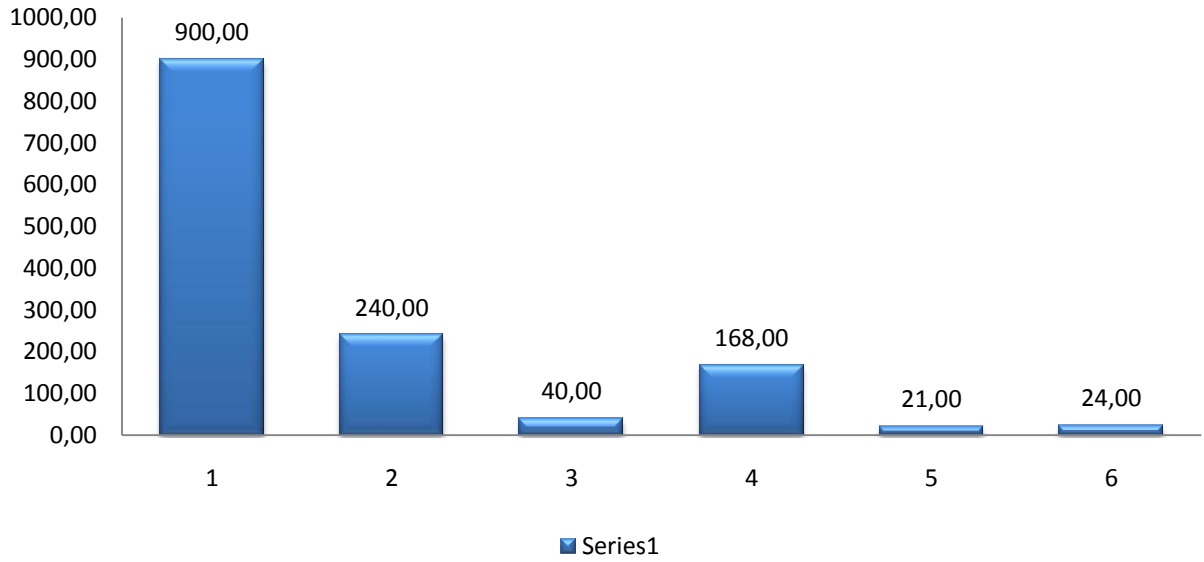

Fig. 1. *Paretto Diagramm (study case: sausages)*

In figure 3 it is presented a comparison between Paretto diagramms for the 2 case products. The values over 100 need special actions for reducing the risks (S, O or D). In figure 4, there is presented a comparative study of % all criterion fulfilling between different kind of meat product.

Tabel 2. *FMEA Tabel (study case: salami)*

Risk Issue	Severity of the failure (S)	Frequency of occurence (O)	Detectability of the failure (D)	RPN
Substances or products causing allergies or intolerances	10	6,00	10,00	600,00
The quantity of certain ingredients or categories of ingredients	8	2	10	160,00

Date of minimum durability or the 'use by' date	8	2,00	5,00	80,00
Special storage conditions and/or conditions of use	7	3,00	8,00	168,00
Language	7	3,00	1,00	21,00
Font size	8	4,00	1,00	32,00

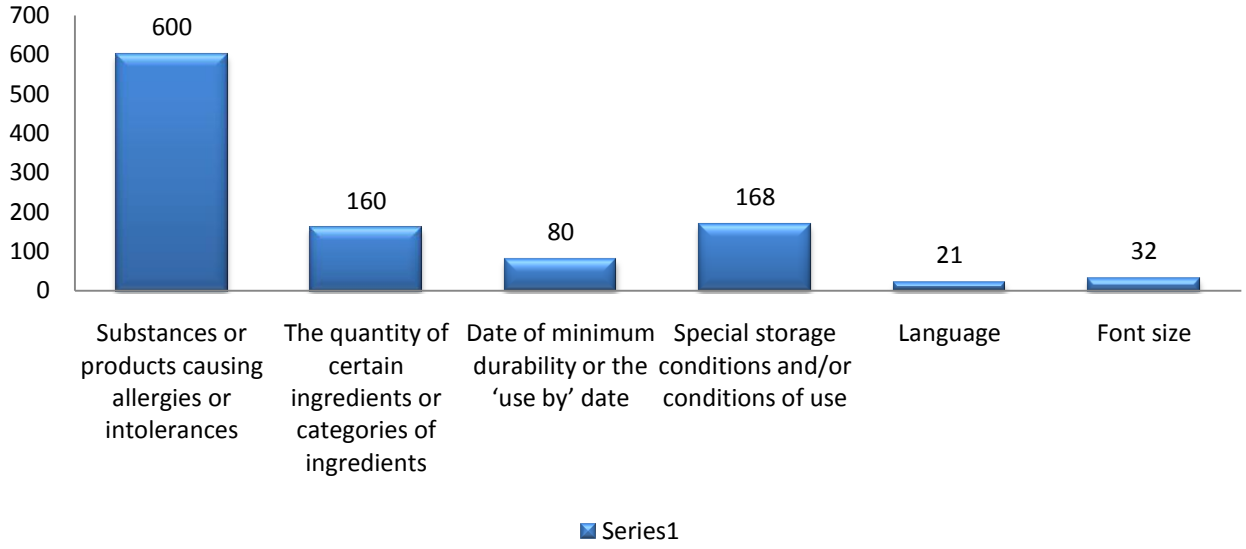

Fig. 2. *Paretto Diagramm (study case: salami)*

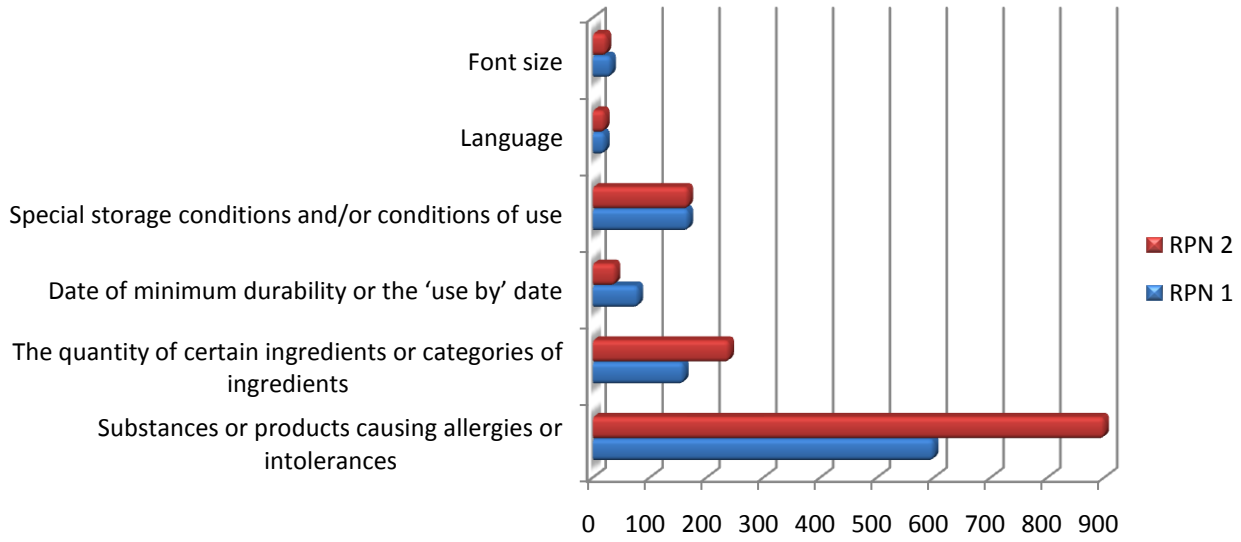

Fig. 3. *Comparative study between Paretto Diagramms (study case: salami vs sausages)*

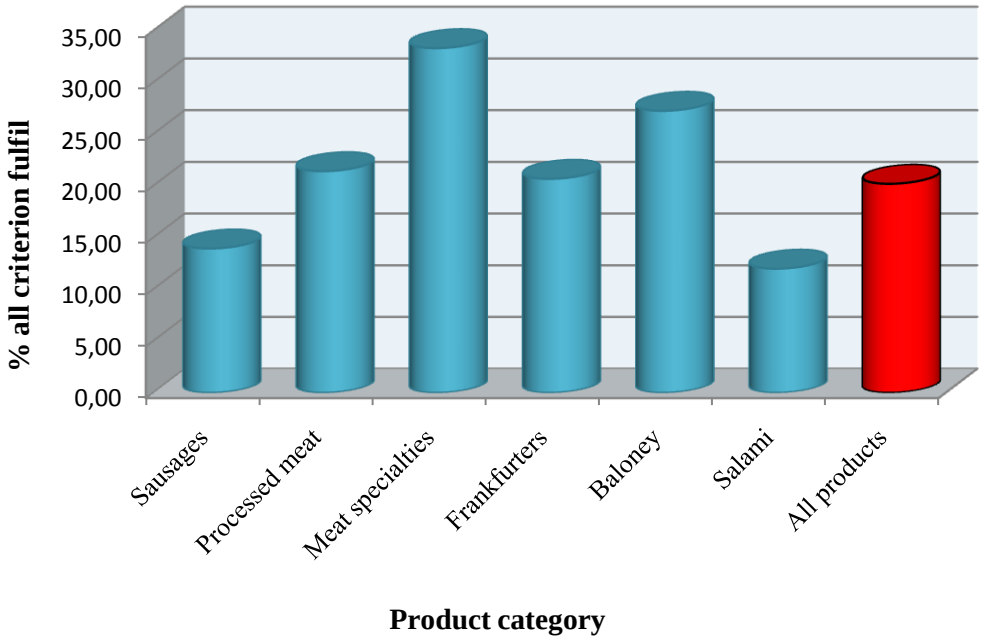

Fig. 4. *Comparative study of % all criterion fulfilling between different kind of meat product*

Conclusions

The knowledge gained through the FMEA process can then be applied to other products and processes to reduce the risk of consumer. This will build understanding of the CCP methodology, which can be applied to quality risks in the process, allowing the principle of using CCPs to ensure that the safety of the product is continuously under control [3].

The combination of the analysis techniques of FMEA and the control point methodology of HACCP helps create a system where the quality, and safety, of the product is being monitored and ensured by CCPs.

The method can be extended to other group of products and other risk issues.

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