ULBS
Universitatea "Lucian Blaga" din Sibiu

Interdisciplinary Doctoral School
Doctoral field: Engineering and Management

DOCTORAL THESIS
SUMMARY

CONTRIBUTIONS TO THE IMPROVEMENT OF QUALITY-RISK- FOOD SAFETY INTEGRATED MANAGEMENT SYSTEM FOR BOTTLED SPRING WATER PRODUCTION PROCESS

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SUMMARY

INTRODUCTION

The research topic addressed in the doctoral thesis cover a more specific subject., reflected in the proposal to improve the quality-risk- food safety integrated management system, specific to a bottled spring water production process.

The aim of the scientific approach is to comprehensively address in a dimensional analysis the components: quality, risk, food safety and security, in an interdisciplinary perspective in the field of integrated quality management, with applicability in all units operations in food processing, but the thesis particularizing the implementation for the production and bottling of spring water.

In each company the management is subject to different disturbances with factors with direct or indirect action, respectively internal and external influences (the effect of uncertainty). The influence of disruptive factors (harmful elements) can destabilize the activity, leading to the impossibility of achieving the proposed objectives. The specific activities of an organization inevitably involve uncertainties and risks, which must be managed through identification, evaluation and treatment / elimination, along with the establishment of control / monitoring measures to limit the consequences and actions in the short or long term.

On the other hand, in accordance with the objectives of the study, the global issue of the quality of surface water used to obtain drinking water, but also groundwater, as a clearly superior quality resource, is taken into account, in accordance with the requirements of sustainable development. Integrated water resources management is a defining, global, complex approach, both in terms of quality indicators and from a technical point of view, when water becomes a raw material in the food industry.

In Romania, the condition of natural water sources is not a good one, they are relatively poor and unevenly distributed, compared to other countries. The water supply source are represented by rivers and groundwater[1]. The statistical data of the Romanian Water Association show that the entire urban population, but also a large percentage of the rural population has centralized water supply systems. In the context of sustainable urban development, as the optimal solution to facilitate access, respectively to ensure and meet the growing needs of the drinking water population, the use of surface water as an easily accessible source of drinking water has been imposed in the last century. All this because

[1] Oprean Letiția, *Apa – resursă fundamentală a dezvoltării durabile. Metode și tehnici neconvenționale de*

the spring water or drilling water in the soil is insufficient compared to the existing needs. The disadvantage is that surface waters (rivers, lakes, reservoirs, sea) cannot be used as such, but must be treated to correct organoleptic, physico-chemical and biological properties, so that they meet the legal quality requirements of in terms of potability. Groundwater is an essential source because, unlike the surface, it is less polluted and can be made to drink with minimal resources, sometimes only through a disinfection treatment.[2]

Starting from these theoretical premises and from the problems identified within the bottled spring water production company - Monopolis SA from Câmpeni, the establishment in which the case study was carried out, this thesis proposes new methods to improve the quality-risk-food safety integrated management system. This company is the only production unit in Alba County that bottles spring water. It started its activity in 2005, being located in the Apuseni Mountains, Romania.

KEYWORDS

This PhD thesis includes the following keywords: *management, quality, food safety, security, kaizen, spring water, risk, integrated management system, noncompliance.*

GENERAL FRAMEWORK OF THE THESIS

The doctoral thesis was inspired by a long experience in the field of organizational management in the food industry and also as a continuation of scientific research carried out in previous and current jobs as: quality assurance engineer in the Research and Development Departament, engineering technologists, analytical laboratory engineer (chemicals in food) or quality manager. As technology and quality criteria are constantly changing, further research is needed on the development of all forms of innovation and how these improvements meet the needs of society. All positions were aimed at quality assurance, implementation of technologies and standards for improving product quality, respectively risk assessment and food safety and security in both government-agency and business industries workplace sectors.

From the accumulated experience I have found that in industrial management, and especially in the processing and manufacturing stage of the food supply chain, the need to improve the integrated quality-risk-food safety management system is continuous, an observation supported by theoretical studies and research in this thesis.

[2] Vică M.L., Popa M., Matei H.V., Glevitzky Ioana, *Siserman C.V. Study of groundwater quality in urban area*

THE AIM AND THE OBJECTIVES OF THE RESEARCH

The aim *of the doctoral thesis is to improve the quality-risk-food safety integrated management system for bottled spring water production process, by developing and implementing a set of specific tools for risk assessment, report and analysis, as well as by development of a new risk assessment methodology at the level of the production unit.*

The current state of research examines trends and shifts in this research field, methodologies, theoretical frameworks and their impact on previous research. Personal contributions, respectively the research itself, all support this approach.

The research carried out within the thesis, the experimental results obtained and their processing and interpretation followed mainly four aspects:

1) Conceptual approach and implementation of an integrated quality - risk - food safety system in a bottled spring water production plant;
2) Obtaining personal contributions in the process of evaluation and prediction over time of quality indicators for spring waters in Alba County, these being used as a source of water in bottled spring water production process;
3) Systemic approaches that emphasize the importance of quality issues, by conceptually addressing the risk in the integrated food quality, safety and security management system, as well as occupational health and safety applicable to any organization, but customizing it to a spring water production plan (Monopolis SA);
4) Development and implementation of tools for detection, analysis and solving of risks in a unit of spring water bottling.

The objectives *of the thesis, correlated with the proposed purpose and the theoretical premises, are:*

1. *Conceptual risk analysis in the quality, security and food safety management system together with improving workplace health and safety for a water bottling plant.*
2. *To review the current state of knowledge regarding integrated water resources management.*
3. *Approaching the quality management system in the form of a process, by implementing an integrated quality-risk-food safety analysis.*
4. *Development and implementation of new tools for reporting, analyzing and solving non-compliances.*

5. *Proposing a new risk assessment methodology for the process of bottling spring water within the Monopolis Company.*
6. *The reasoning that led to the general research conclusions, personal contributions as well as directions for future research.*

THESIS CHAPTERS AND SECTIONS

The thesis is structured in 6 chapters, the first 3 describe the theoretical aspects related to: *Risk management in the integrated quality management system*, *The importance of water for mankind and the management of sustainable development of water resources*, *Spring water - raw material in bottled water manufacturing in Alba County.*

Based on theoretical principles, experimental studies, applied techniques and research tools, all led to the *Conceptual Design of the integrated quality management system within Monopolis Company*, *Development of a new risk assessment methodology by applying Isikawa diagrams corroborated with the HACCP system*, respectively *Elaboration of tools for signaling, analysis and resolution of noncompliance (Auto-quality Matrix, 5M worksheet)* contained in chapters 4 and 5. In Chapter 6 are formulated *The research conclusions, personal contributions and new open research directions.*

The approach of this thesis starts with the ***Introduction***, which aims to be a synthesis of the whole thesis. Here are presented the professional and personal motivations of choosing the research topic, the importance of the research, the research objectives, respectively the anticipated results.

Further, an algorithm of theoretical and applied study for improving the management and quality of bottled water was developed and applied. This has been achieved through a systemic and interdisciplinary approach, with means and procedures currently used worldwide and by applying their own concepts for their investigation.

Chapter 1 of the thesis presents a summary of the current state of the literature on *the conceptual approach to risk in the integrated quality management system*. This first chapter was outlined by studying the current standards and bibliographic references or with an impact on the studied field. A review of risk-related issues in the integrated quality management system was conducted in this regard.

A brief description of the conceptual approach to risk in the Integrated Quality Management System (IQMS) is given in terms of quality, food safety - security and occupational health and safety standards using ISO 9001, ISO 22000, ISO 45001, IFS,

respectively the Kaizen management system, as an indicator of measuring food safety and security for a certain product - water.

The chapter aims at the theoretical analysis related to the identification, implementation and validation of food quality, safety and security systems, using specific standards and concepts. The study is a theoretical investigation into the risk assessment of the quality management system, the application of the Hazard Analysis and Critical Control Point (HACCP) system, the implementation of the food security system according to the IFS Food standard, the analysis and risks of injury and/or professional disease for all jobs within the organization in accordance with the ISO 45001 standard, respectively particular aspects regarding the Kaizen management system.

The study justifies the importance of developing a plan for the prevention and protection of all risk factors that include effective technical, organizational, hygienic and sanitary measures in food companies.

Chapter 2, entitled: *The current state of knowledge on integrated water quality management* involved the preparation of a bibliographic documentation on the importance of water in the world and the access to quality water sources, as well as its characterization by physico-chemical and microbiological analysis.

Starting from water scarcity around the world and the need to guarantee free, safe access to quality water, in adequate quantities for drinking, cooking, personal hygiene and sanitation facilities. The situation is presented at the global level, respectively in Romania, where not all the rural population benefits from the possibility of access to centralised (drinking) water supply, being used alternative sources (springs water or wells). The decrease or lack of water resources, due to environmental pollution, climate change, is a real danger for agriculture, respectively from the perspective of quality and food security.

At the same time, the types of microorganisms that can cause contamination of water sources and water during the bottling process have been described, and a documentation of the legislation and international standards relating to water quality parameters and the methods of determination and maximum levels for certain contaminants of drinking water. All of these studies were performed to identify major hazards in the contamination of spring waters in accordance with the hygiene requirements of food quality, safety and security systems.

The general objective of sustainable development in the field of water is aimed at ensuring the growing water needs of the population, in relation to the fact that the planet's resources are limited and taking into account the continuous degradation of the environment. In this context, the water quality norms, the main organoleptic, physical, chemical and

biological indicators of water, as well as the national and Community acquis on sustainable water management are presented.

The policies that support the sustainable and integrated management of water resources worldwide and in the European Union were presented. Strategies and policies for reducing consumption, reuse and recirculation of water are presented, including through a unitary approach closely linked to regional development and integration.

In ***Chapter 3***, entitled *Spring waters, source for a water bottling plant in Alba County*, provided a new perspective in the study of the dynamics of drinking water behavior in the world and Romania, later customizing the research for Alba County, Romania. The chapter begins by presenting the water resources of Alba County in subchapter 3.1.

Within section 3.2., the county area was divided into 5 zones of major interest (I: Alba Iulia - Teiuș; II: Sebeș - Cugir; III: Cîmpeni - Zlatna; IV: Blaj and V: Aiud - Ocna Mureș).The water sources were monitored monthly.

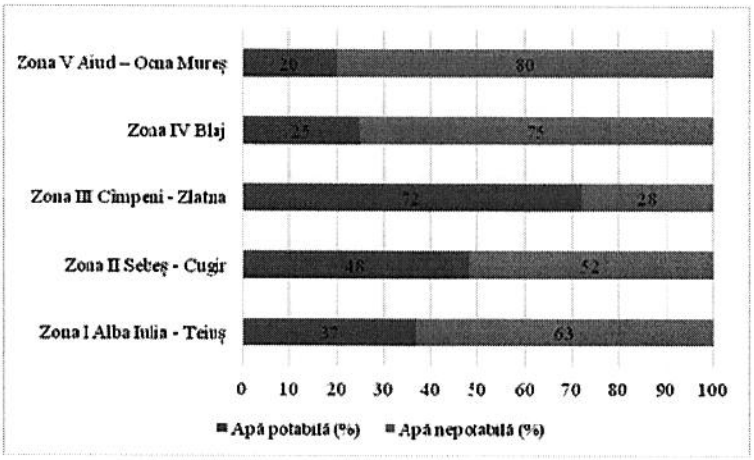


Figure 1. The quality of public water sources in Alba county for the 5 areas

Of the 132 sources investigated in the period 2017-2019 from a physico-chemical and microbiological point of view, only 38 are drinkable. Due to the fact that the time testing of water quality parameters is laborious and expensive, starting from the nitrogen cycle in water, in subchapter 3.3, were presented theoretical aspects about statistical analysis and data modeling. The elaboration of statistical mathematical models allows the estimation of the searched parameters without the need for additional experimental determinations. In order to achieve and solve this objective, the evolution of the main parameters used to characterize the water quality was followed in time. All these were used to establish the predictions of the parameters studied in subchapter 3.4.

In order to correlate the values of the extrapolation function of the total aerobic mesophilic bacterial (TVC) with the storage time and the content of nitrates, nitrites, respectively ammonium ions, first degree and second degree polynomial equations were

tested with one or two independent variables, respectively. To study the accuracy of the model were calculated: the adequacy dispersion (mean square deviation) - σ^2, the standard deviation - σ, the model accuracy indicator - R^2, respectively the correlation coefficient - R.

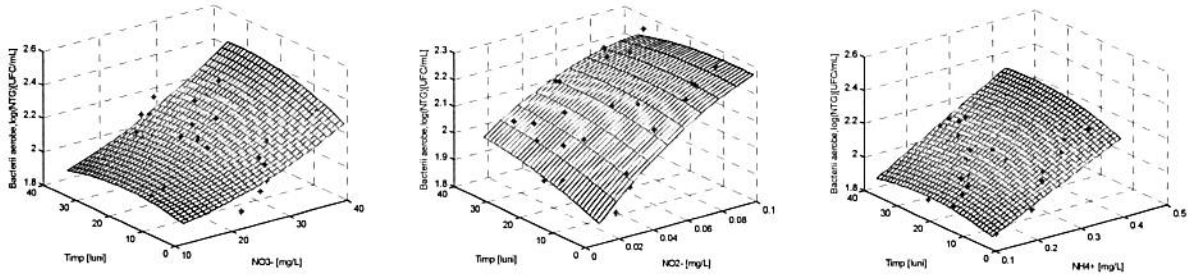


Figure 2. The variation of the microbial growth due to the content of nitrates, nitrites, ammonium ions and time for the spring in Area I - Alba Iulia-Teiuş

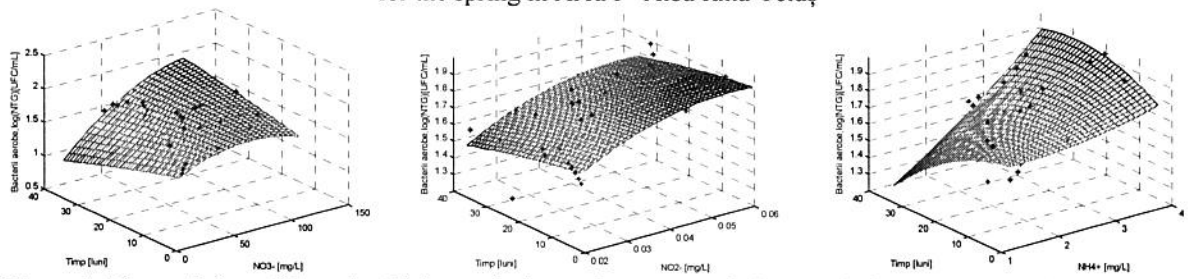


Figure 3. The variation of the microbial growth due to the content of nitrates, nitrites, ammonium ions and time for the spring in Area II – Sebeş-Cugir

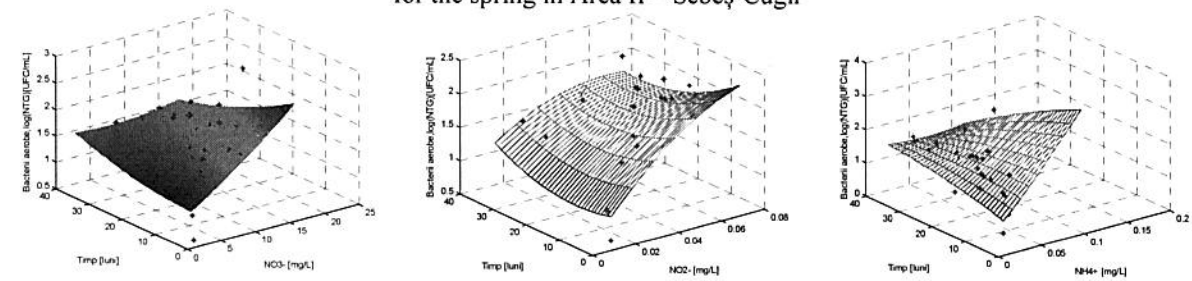


Figure 4. The variation of the microbial growth due to the content of nitrates, nitrites, ammonium ions and time for the spring in Area III – Câmpeni - Zlatna

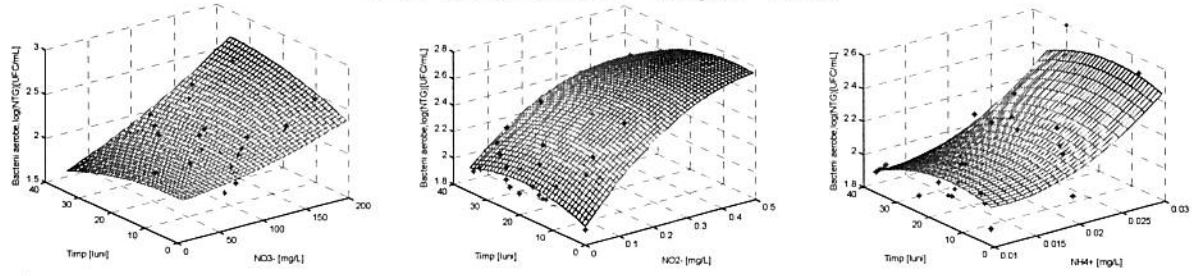


Figure 5. The variation of the microbial growth due to the content of nitrates, nitrites, ammonium ions and time for the spring in Area IV – Blaj

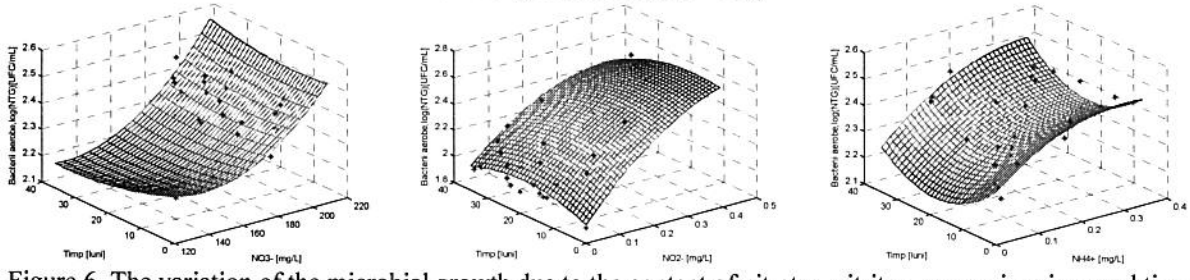


Figure 6. The variation of the microbial growth due to the content of nitrates, nitrites, ammonium ions and time for the spring in Area V – Aiud-Ocna Mureş

For the processing of the resulting experimental data, the regression and correlation analysis was used, obtaining:

- the series of experimental data show good correlations;
- there was an satisfactory correlation between the variation of the microbial growth and the other physico-chemical parameters of the water, over time;
- association of different parameters that characterize the processes or phenomena (nitrogen cycle in water) to highlight the connections between them - the results obtained being important for defining statistical mathematical models;
- it was found that it is necessary to take into account as many parameters of the process or phenomenon as possible, considered as influencing factors, in the case of water quality investigation, especially for bottled spring waters.

The proposal of the form of mathematical models based on the existing experimental data was made by regressions, these being the fundamental tool of predictive analytics, and ensured:

- The elaboration, representation and interpretation of mathematical models that establish the connections, respectively the functional dependencies between the characteristic quantities of the analyzed parameters;
- The identification of appropriate connections and dependencies between the parameters of the studied waters, where complex laws are applied, but which are expensive to study and involve a long time for solution.

The conclusions resulting from the study regarding the modeling of the analyzed parameters are:

- for each sample analyzed, regardless of the sampled area, a comparison was made between the prediction of the model and the experimental results of the actual process/phenomenon. It is found that the mathematical equations obtained from statistical modeling have different correlation coefficients, but close in value. This confirms a functional dependence of the correlated parameters and is an argument for a unique spring water quality monitoring mechanism;

- the resulting correlation coefficients range between 0.670 and 0.928, the correlative analysis indicating that there are appreciable correlations between the parameters taken into account and the modeling accuracy is good;

- the accuracy of the model increases with the increase of the number of parameters taken in the analysis.

The study then focused in section 3.5. on the mountain area - III Câmpeni-Zlatna, for the qualitative investigation of the spring water source bottled by the Monopolis Company

from Câmpeni, Romania. The monitoring of the water quality from the mentioned source was carried out during the research for a period of 10 years, finding a continuous pollution, which leads to the confirmation of the hypothesis according to which the water resources of mankind become insufficient and contaminated over time. The finished bottled product was also analyzed - still and carbonated spring water, finding that the determined organoleptic, physico-chemical and microbiological parameters falls within the limits allowed by legislation.

A documentation was made regarding the testing and monitoring of quality indicators using mathematical modeling, by developing statistical and predictive models, with direct influences on the estimation of spring water quality in Alba County over time. This aspect is related to the systemic approach to the issue of the thesis, aiming to present the general notions related to mathematical modeling, the presentation of the characteristic elements of statistical models as well as the stages of statistical modeling.

Based on it, the interpretation, comparison, mathematical processing of the experimental results and the elaboration of statistical and predictive models for the assessment of water quality were taken into account. Subsequently, the performance of the statistical mathematical models resulting from the experimental studies was validated and tested.

In this way, a modern perspective was ensured in the study of the dynamics of drinking water behavior in the world, customizing the research on Câmpeni area, Alba County, by using the measurement of physico-chemical parameters and microbiological control. Results obtained from laboratory analyzes and the use of the computer as a tool to control and predict the potability of spring waters were the basis of the investigation. The qualitative physico-chemical and microbiological parameters of the spring water over a 14-year time horizon were investigated, as well as a complete current analysis. It was presented what is the level of accessibility (including the evolution over time) of water resources in the region identified for study and by applying their own concepts for their investigation as well as statistical inference.

Chapter 4, *the conceptual design of the integrated quality management system within Monopolis Company, from Romania*, presents in section 4.2 the organization and micrologistic system of the organisation, together with the description of the production stages for bottling still and carbonated spring water with their particularities in subchapter 4.3, all this as a starting point in the procedural approach of the quality management system, by implementing an integrated quality-risk-food safety analysis presented in section 4.4.

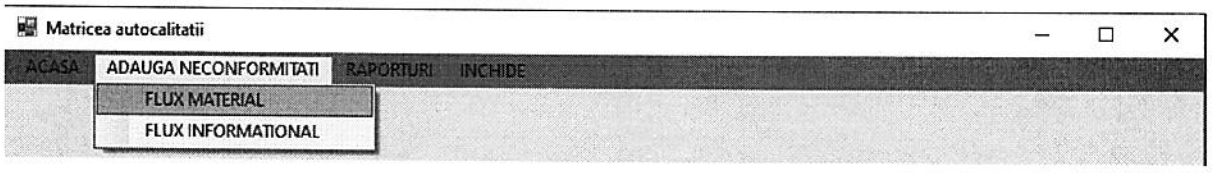
The study started with the presentation of the technology of treatment and bottling of spring water. Based on the technological flow chart, the procedural approach of the system as

a whole was followed, which is an investigation regarding the risk assessment within the quality management system, the application of the HACCP system, the implementation of the food security system - IFS Food Standard, analysis and assessment of the risks of injury and occupational diseases for all jobs within the organization in accordance with the ISO 45001 standard, respectively specific aspects of the implementation of the Kaizen concept. The chapter aims at identifying, implementing and validating food quality, safety and security systems, using specific standards and concepts applicable to Monopolis Company. The instrumentation of the integrated quality, safety and security system was investigated from the perspective of the standards ISO 9001, ISO 22000, ISO 45001, respectively IFS.

The study shows the importance of implementing risk-controlling standards that include effective measures in the company. Chapter 4 concludes with a summary of the conclusions reached on the topic.

Chapter 5, entitled *The development of a new methodology for integrated signaling and risk analysis*, started from the need to analyze the existing problems within the organization in a centralized form and with a certain frequency.

The research carried out within the company confirms in section 5.1. the need to analyze the existing problems within the organization in a centralized form and with a certain frequency. The purpose of the research is to identify the reported nonconformities, which led to the design of a tool for reporting and analyzing nonconformities within the Monopolis Company, transposed into an application called AQM (Auto-quality Matrix). This materialized through the design of a graphical interface using the Visual Basic (VB) programming language, as a strategic tool for studying non-conformities in material and information flow, which can influence the company's activity. The autocality matrix is a powerful "tool" that helps to identify non-conformities as close as possible to the section / area / department that generates them, GEMBA (Japanese term meaning "at source"). For the continuous improvement of quality, the Auto-quality Matrix can be built on two flows: on the material flow (AQM Gemba Productive), respectively on the information flow (AQM Gemba Services).



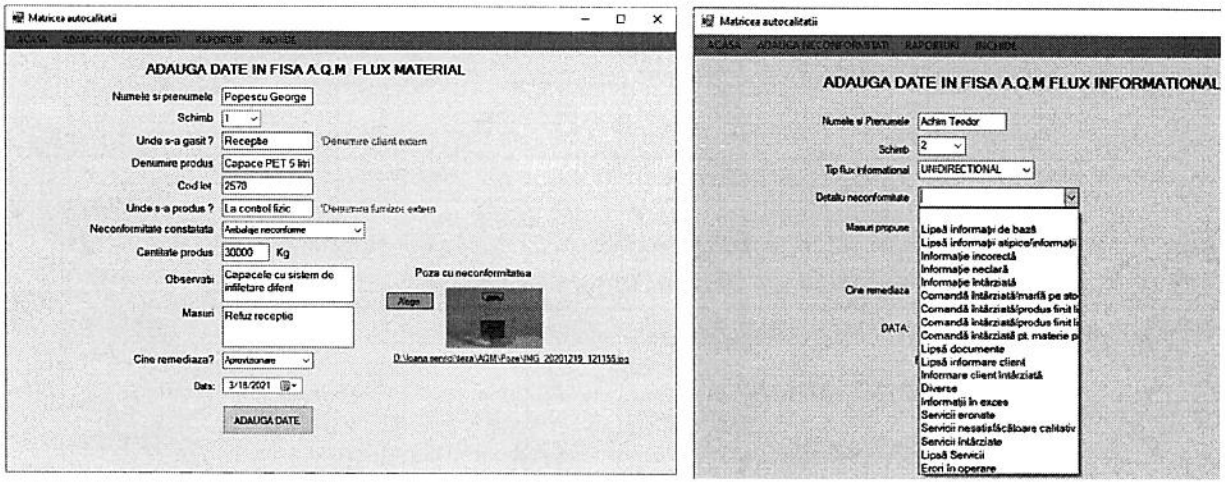


Figure 7. Windows for non-compliance on material and information flow

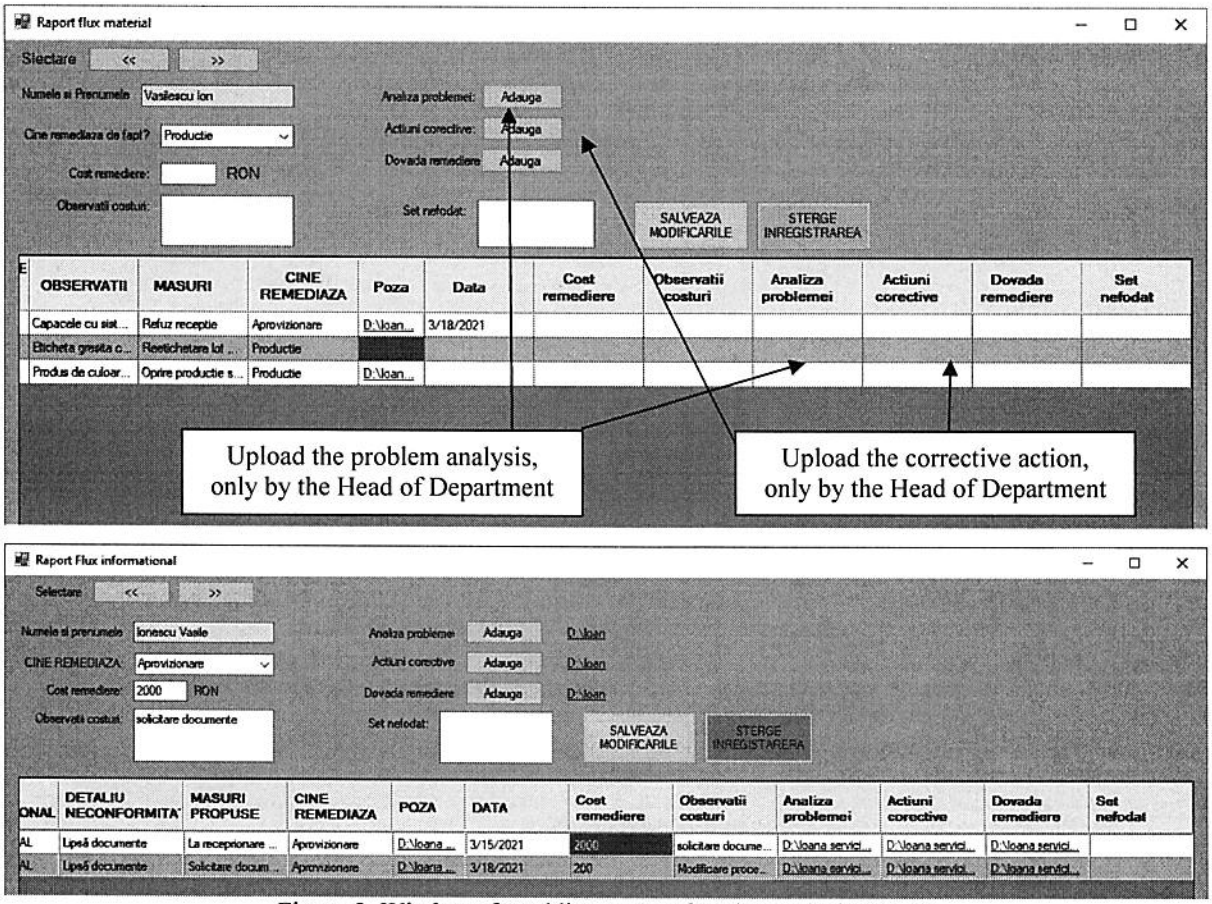


Figure 8. Windows for adding nonconformity analysis actions

Once the non-compliance has been identified, it is necessary to establish the main causes that generate the reported problem, all of which lead to finding remedial solutions, as well as the actions to be taken to prevent the recurrence of non-compliance in the future. In this regard, a complex tool in the form of a non-compliance settlement sheet was designed in Subchapter 5.2, starting with the concept of "the 5M".

The aim of the research is to identify the main causes that generate the reported nonconformities, to identify solutions to remedy them, as well as to find actions, respectively

solutions to be taken to prevent future recurrence of nonconformities, using the concept "5M". All this is concentrated in a proposed complete non-compliance form (figure 9).

Thus, a theoretical and applied research algorithm was designed and used to improve the management of bottled water quality and safety, through an integrated and multidisciplinary approach, using various methods and techniques in the scientific field and by implementing their own approaches to their investigation.

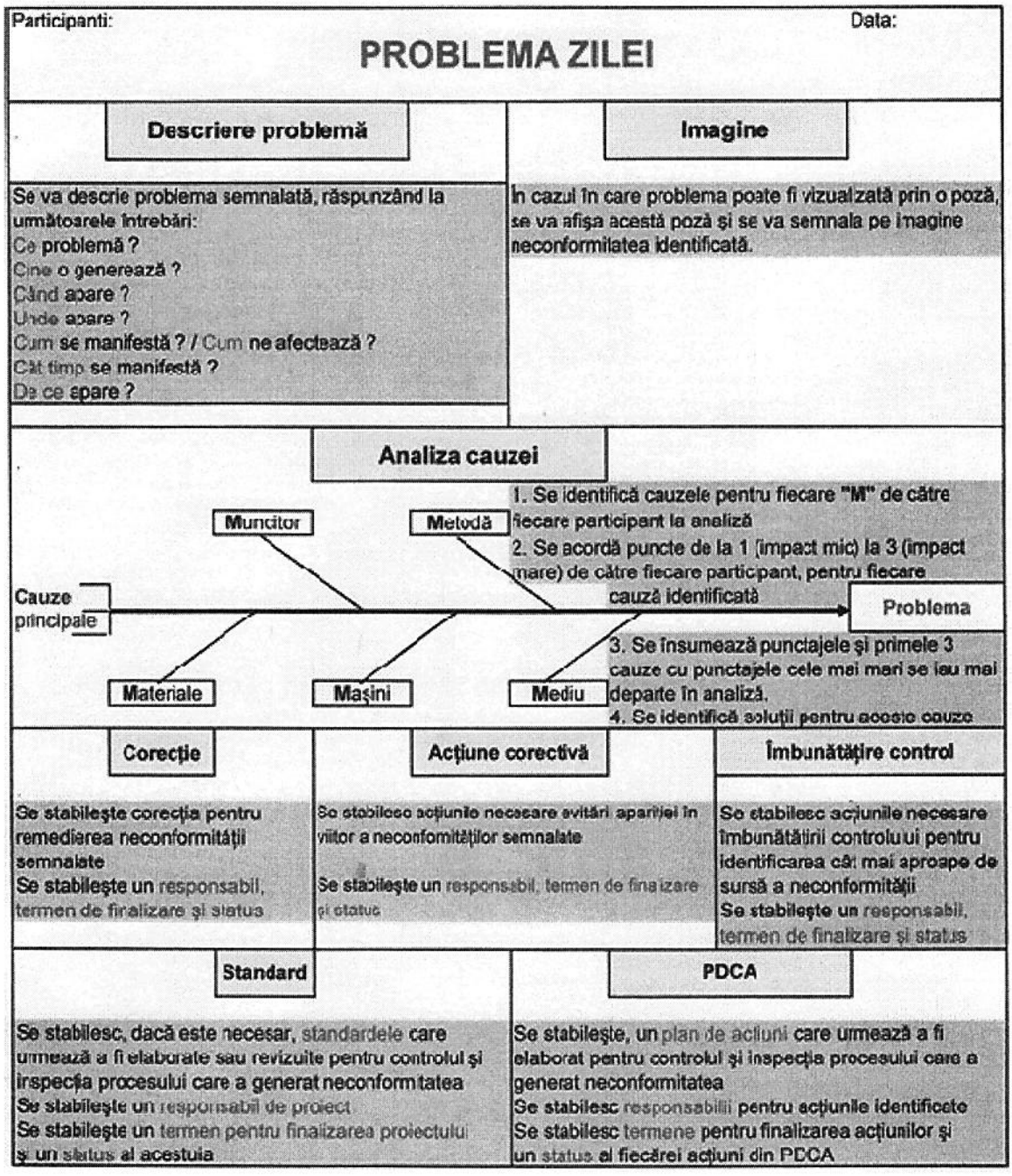


Figure 9. Identified non-compliance worksheet

Section 5.3. presents a new risk assessment methodology for the spring water bottling process within Monopolis Company by applying Ishikawa diagrams in conjunction with the improved HACCP system.

This new risk investigation technique aims to ensure a much higher level of quality and safety of bottled spring water, using the improved classical methods, but with a good ability to intercalate between them. A new perspective was provided in the study of the dynamics of the analysis of risk factors in the bottling process of the "Roua Apusenilor" spring water from Câmpeni by the simultaneous use on the technological flow of the product of Ishikawa diagrams and HACCP principles.

The methodology proposed to extend the typology of physical, chemical and biological risks provided by the ISO 22000 standard, with some additional ones: allergens, fraud / sabotage, Kosher / Halal, RASFF (The Rapid Alert System for Food and Feed), CoVid19 or others (GMO, Irradiation, HPA, PPA, etc.) depending on the specific technological process. At the same time, the causes were identified for each operation in the technological flow based on the analysis of the "5M" (man-people, method, materials, machines, environment). For each identified risk and cause, its impact (I) was established according to the severity (G) and probability (F) of occurrence. The final effect is defined as risk class (CL), being the arithmetic mean of the impact resulting from each stage of the process based on the risks and causes.

Table 1. Identification of hazards and determination of the risk class for the bottled stage for plain water

Stage	Risk	People/1			Method/2			Materials/3			Machines/4			Environmental/5			CL
		G	F	I	G	F	I	G	F	I	G	F	I	G	F	I	
BOTTLING	**Physical**	3	1	*2*	3	1	*2*	2	1	*1.5*	2	1	*1.5*	3	1	*2.5*	**1.9**
	Chemical	3	1	*2*	3	1	*2*	2	1	*1.5*	3	1	*2*	4	1	*2.5*	**2**
	Biological	3	1	*2*	3	1	*2*	3	2	*2.5*	3	1	*2*	3	2	*2.5*	**2.2**
	Allergens	1	0	*0.5*	2	1	*1.5*	1	0	*0.5*	2	1	*1.5*	1	1	*1*	**1**
	Fraud	0	0	*0*	4	1	*2.5*	1	1	*1*	2	1	*1.5*	1	1	*1*	**1.2**
	Kosher/Halal	0	0	*0*	2	1	*1.5*	2	1	*1.5*	0	0	*0*	0	0	*0*	**0.6**
	RASFF	0	0	*0*	2	1	*1.5*	0	0	*0*	2	1	*1.5*	1	1	*1*	**0.8**
	CoVid 19	3	1	*2*	3	1	*2*	1	1	*1*	1	0	*0.5*	2	1	*1.5*	**1.4**
	Other	0	0	*0*	2	1	*1*	0	0	*0*	0	0	*0*	2	1	*1.5*	**0.5**

Thus, an innovative approach to risk analysis issues was developed using the advantages offered by the ISO 22000 standard (improved HACCP principles) in conjunction with the cause-effect diagram, based on the "5M" analysis. In the risk assessment, using the two tools, the possibility of cumulative or synergetic effects is considered, the result being a better control of all factors that may affect the technological process.

This new, modern perspective in the study of the dynamics of risk factor analysis through the concomitant use of the Ishikawa diagram and the HACCP system can be extrapolated and applied to any manufacturing process in the food industry and beyond.

Chapter 5 concludes with a brief description of the conclusions based on the arguments and information presented.

Based on the research carried out and based on professional experience in the field, in ***Chapter 6***, entitled *Elaboration of general conclusions, personal contributions and future research directions*.

The objectives of the studies and research undertaken take into account the global issue of water security in the context of sustainable development. Integrated water resources management is a complex approach, both in terms of quality indicators and from a technical point of view, when water becomes a raw material in the food industry.

The conclusions are represented by:

- the analysis of the investigated water sources from Alba county, respectively of the water used for bottling by the Monopolis Company from Câmpeni, in order to evaluate its quality and to establish the degree of potability in time.

- the perspective of addressing the risk in the integrated food quality, safety and security management system, as well as occupational health and safety within Monopolis Company, respectively improving the activities and standardized processes - Kaizen.

- implementation of tools for signaling and analyzing non-conformities within Monopolis Company. By designing the AQM application (Auto-quality Matrix), respectively of a file for the treatment and management of non-conformities, using the concept "the 5M".

- development of a new risk assessment methodology for the spring water bottling process within Monopolis Company, by applying Ishikawa diagrams in conjunction with the improved HACCP system.

The main *contributions* of this paper through theoretical and practical research are:

- Systematization and synthesis of information from 214 bibliographic sources for an interdisciplinary systemic approach and analysis, using different means and procedures of global relevance and by implementing their own concepts for their investigation.
- Approaching a modern perspective in the study of time dynamics of spring water quality, by using microbiological control and physico-chemical parameters obtained from laboratory determinations, as well as using the computer as a control and prediction tool.
- Elaboration of mathematical models that allow the estimation of the microbiological quality of spring waters according to physico-chemical parameters, based on experimental data. In this context, polynomial correlations of first order with 2 independent variables, respectively of second order with 3 independent variables were

made and three-dimensional surfaces were generated.

- Establishing a methodology based on mathematical models, through which the experimental data taken over can be further processed with the help of specialized software.
- Carrying out a risk study in the integrated food quality, safety and security management system, as well as occupational health and safety, customized on the technological process of bottling spring water.
- Development of a management system improvement model based on the Kaizen strategy.
- Establishing a methodology for implementing the tools for reporting and analyzing existing non-conformities within the organization.
- The design of a software application, entitled Auto-Quality Matrix (AQM), which aims to manage identified non-conformities.
- Achieving a complex risk assessment methodology by applying Ishikawa diagrams in conjunction with the improved Hazard Analysis and Critical Control Point (HACCP) system. Both physical, chemical and biological risks (recommended by the standards) were used, but the assessment was extended to other risks identified in the industry as: allergens, fraud / sabotage, Kosher / Halal, RASFF, CoVid 19 etc. This leads to better risk assessment results for the entire food safety management system.

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