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WATER QUALITY ASSESSMENTS THROUGH THE APPLICATION OF CAUSE AND EFFECT DIAGRAMS IN CONJUNCTION WITH HACCP AND RISK ASSESSMENT FOR "ROUA APUSENILOR" SPRING WATER BOTTLING PROCESS

Maria POPA[1], Ioana GLEVITZKY[2], Dorin POPA[1], Mirel GLEVITZKY[1]

[1]"1 Decembrie 1918" University of Alba Iulia, 11-13 Nicolae Iorga Street, Alba Iulia, Romania
[2]"Lucian Blaga" University of Sibiu, 4 Emil Cioran Street, Sibiu, Romania

Corresponding author email: ioana_glevitzky@yahoo.com

Abstract

In this paper, we approached the two dimensions of water quality assessments. The qualitative dimension which involves the analyses of the physicochemical and microbiological parameters of "Roua Apusenilor" spring water and the application of both HACCP principles and Ishikawa Diagrams as risk analysis steps. The paper highlights the high-quality groundwater parameters of "Roua Apusenilor" spring water according to the European legislation. The hazard analysis was used for risk assessment and for the identification of different types of hazards in a spring water bottling process. To identify the causes that may lead to a potential risk, the Cause and Effect Diagram was used, based on the analysis of the 5M. The paper presents this in detail for the bottling process stage. The main emphasis was put on the quantification of risk assessment by determining the Risk Class (RC) per identified processing hazard. Also, corrective actions were undertaken. For the bottling stage, critical control points have been identified in the Cause and Effect Diagram, based also on the analysis of the 5M. The two methods, HACCP in conjunction with Cause and Effect Diagrams, display enhanced effects on a larger scale when they are used in combination.

Key words*: HACCP, Ishikawa diagrams, risk assessment, spring water, water bottling process.*

INTRODUCTION

Clean drinking water can sustain every aspect of human life. Spring bottled water may contain lots of contaminants from the environment. The water bottling process also poses risk for spring water contamination. This determines the need to investigate the source, but also the spring water treatment process. Water quality assessments involve laboratory water analysis and a risk analyses methodology to avoid irregularity in the production system (Karnaningroem and Sunaya, 2020).

Water in nature is never pure; given the interactions with the environment, it contains gases, mineral and organic substances, dissolved in suspension (Bătrânescu et al., 1997). Water is a vital resource. Our health depends directly on the drinking water quality (WHO, 2004).

Underground waters are an important resource, considering that they are usually less polluted or even unpolluted compared to surface waters. Therefore, underground waters can be made potable without any treatment or just using minimal measures, sometimes only disinfection. (Negrea et al., 2009).

Water quality assessment is made by measuring certain parameters (physical, chemical and microbiological), whose limits are legally defined (Calisevici et al., 2011). In Romania, water quality drinking is set by Law no. 311/2004 complementary to Law no. 458/2002 which transpose Directive 98/83/EC. Drinking water must be healthy, clean, without microorganisms, parasites or substances which, by number or concentration, can be a potential hazard for human and animal health (Todoran et al., 2010).

Each organization uses various resources to achieve their short- and long-term goals increasing the prospect of their achievement. A general overview of references for some of the primary tools that might be used in quality risk management by industry and regulators include: Basic Risk Management Facilitation Methods (Flowcharts; Check Sheets; Process Mapping); Cause and Effect Diagrams (Ishikawa Diagram, Fishbone Diagram); Failure Mode Effects Analysis (FMEA),

Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP), Preliminary Hazard Analysis (PHA), Risk Ranking and Filtering, Supporting Statistical Tools (Control Charts, Design of Experiments (DOE); Histograms; Pareto Charts; Process Capability Analysis) (Chavda et al., 2015).

Fishbone (Cause and Effect or Ishikawa) diagram may be applied for identification of any phenomena in various life-spheres. It is the tool used to represent relationships between given results and their potential reasons. The graph is based on main reasons, from which detailed reasons stem, in such a way that the graph picture represents a fishbone. Ishikawa graph is most often used for analysis of production processes (Malinowska, 2010)

This method is based on the analysis of main reasons: 5Ms - method, machine, material, man, management. In the 5M+1E variant - environment-related reasons, in 7Ms – measurement, and in 8Ms - finances are additionally considered (Łuczak and Matuszak-Flejszman, 2007; Żuchowski and Łagowski, 2004).

The HACCP method is recognized as a quality risk management tool in different industries (Dahiya et al., 2009). According to article 5(1) of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, it is a legal obligation in European Union to implement and maintain an institutional food safety system, such as the HACCP.

In the food and pharmaceutical industry, the implementation and certification of the ISO 22000 standard (Food safety management systems), the Global Food Standard (BRC), FSSC 22000, the International Features Standard Food (IFS Food), the Safe Quality Food SQF 2000 and 1000 and the GLOBAL G.A.P. is currently optional (Zaharie Pop et al., 2018).

There are five primary principles in HACCP method: hazard analysis on the system, determination of critical control points and critical limits, establishment of monitoring procedures and organisation of corrective actions in the diversion of critical limits which have surpassed toleration limits. (Karnaningroem and Sunaya, 2020).

The HACCP methodology aims to prevent and reduce known risks that may occur at certain stages of the manufacturing process. It covers both good manufacturing practices (GMP) and safety of employees. HACCP is the systematic method (comprising seven principles) for the identification, assessment and control of safety hazards associated with physical, chemical, and biological hazards. The problems associated with the implementation of HACCP can be overcome by training and continuous education of all employees. The HACCP is proven to be economically efficient, its implementation and maintenance involving lower costs. In the cases involving non-conformities it leads to small scale losses, while ensuring the safety of goods (Tidjani, 2013).

The study aims to make a personal contribution to the possibilities of improving the methodology for identifying food safety hazards, assessing their occurrence and severity, establishing control measures for identified risks. To improve the quality of “Roua Apusenilor” spring water, the aim of the present paper is to follow the production steps of bottled water using the Ishikawa “5M” method in conjunction with the HACCP principles.

RESEARCH METHODOLOGY

The risk analysis method introduced in this study was tested on a water bottling company located in Transylvania, in the centre of Romania. The source is “Lucia Cave” in the village of Sohodol, Alba County. The registered trademark of the product is “Roua Apusenilor” still and carbonated spring water.

The factory has implemented the HACCP system (ISO 22000) for several years. The selection criteria of the enterprise for the study represented the production of a typical, most common and most important element for life – water.

Such a selection criteria allowed to compare the HACCP system and 5M-HACCP functioning in the same enterprises, and to determine risk areas for the production of the most important human product. The study was made in 2020.

The first stage of the research is a qualitative investigation of “Roua Apusenilor” spring water quality at source.

For the qualitative assessment of spring water, one sample (water source for the factory) was

collected and analysed in September 2020. The assessment was performed in the absence of atmospheric precipitation 7 days before, which could have influenced the results of laboratory analyses. The physicochemical and microbiological analyses were performed according to the working standards specific to each parameter.

The second stage presents the justification of the necessity to implement a management system for food safety according to the HACCP principles in conjunction with the Cause and Effect Diagrams. This can provide control over the technological process, in all stages, through the evaluation of the three possible risks: physical, chemical, and biological, based on the analysis of main reasons: 5Ms - man, method, machine, material, medium. For this, a generic HACCP model was developed.

The risk analysis involves several steps according to Figure 1:

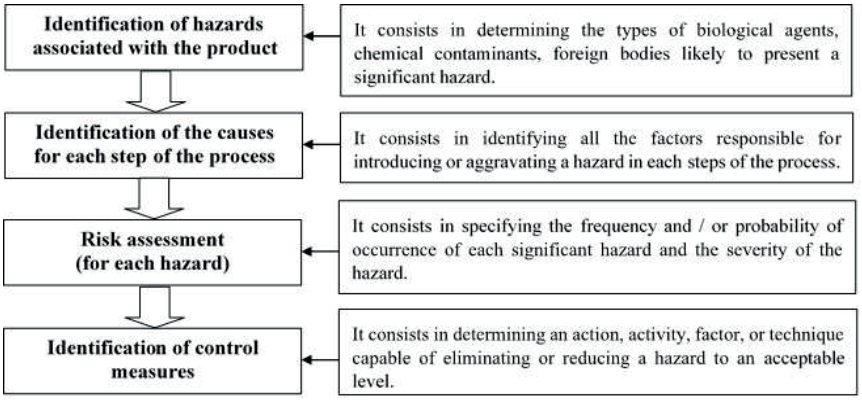

Figure 1. Steps of risk analysis

The proposed methodology identifies, assesses, and classifies all potential risks not only the chemical, physical, and biological (microbial and parasitological), ones as provided by the HACCP system.

Thus, the risk analysis considers the following potential risks that may affect food safety and the health of staff and consumers:

Biological risks represented by micro-organisms, parasites present in water or foodstuffs or that can accidentally contaminate them. These may exceed legal limits and cause diseases for the consumer during handling, processing, storage, and transport.

Chemical risks represented by chemical components or toxic substances specific to water or foodstuffs that are above the legal limit or by foreign chemicals that contaminate food.

Physical risks represented by foreign bodies that are found in water or in foodstuffs or may reach them during food handling.

When identifying the causes that can lead to the appearance of a potential risk, the cause-effect diagram is used, based on the analysis of the 5M; 5 Whys? methods. The diagram, also known as a Fishbone Diagram, is used to illustrate cause and effect relationships, which facilitates the separation of causes from the effects of a given problem and to discern its complexity (Luca, 2016).

The risk assessment is determined for each hazard by identifying the frequency and/or probability of occurrence and the impact of the identified hazard.

Frequency (F) is the probability that the identified risk will occur several times in the product or that the activity carried out will generate this risk several times. It is classified into 4 frequency levels:

- *low*, practically unlikely to occur ("theoretical risk");
- *medium*, it can appear, it happens to appear;
- *high,* occurs systematically, repeatedly;
- *critical*, it will certainly appear in the process, activity.

Severity/gravity (G) is the consequence of the identified risk to the product and food safety or

to the activity carried out in the context in which the department operates.
It is classified into 4 levels:
- *low*, causes low-level damage to products, consumers, and activity;
- *medium*, damage with an impact on the products and the activity carried out;
- *high*, substantial damage to the products and work carried out and/or causing disease for the final consumer;
- *critical,* fatal consequences for the products and activities carried out, serious disease, irremediable damage, manifesting immediately or after a longer period.
Impact (I) is the effect of the identified risk depending on the frequency of occurrence and its severity (as an arithmetic mean) depending on the 5M (man, method, machine, material, medium), on the product and food safety. It is classified into 4 levels:
- *low*, no measures required;
- *medium*, periodic measures are needed, often single actions;
- *high*, requires general control measures (e.g., procedures, working standards);
- *critical*, requires specific control and monitoring measures that are defined for a particular situation (e.g. Operational Prerequisite Programmes - oPRPs, Critical Control Point - CCP).
Risk class (RC) is the final effect of the identified risk on the product, process or activity:
- *low* (between 1 și 2): no special control and monitoring measures required;
- *medium* (between 2,1 și 2,5): single control measures are required;
- *high* (between 2,1 și 3): general control measures are required (e.g., generated by Prerequisite Programs - PRPs);
- *critical*, urgent and specific control and monitoring measures are required which are defined as Operational Prerequisite Programmes - oPRPs; Critical Control Point - CCP.
The "decision tree" model of the HACCP system was used to determine the CCP. The decision tree classifies data elements by asking a series of questions: Q1, Q2, Q3, Q4 (N.G.P. G.F.S., 2007): 1. Do control preventative measure(s) exist? 2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level? 3. Could contamination with identified hazard (s) occur in excess of acceptable level (s) or could this increase to unacceptable levels? 4. Will a subsequent step eliminate identified hazard (s) or reduce likely occurrence to an acceptable level?

RESULTS AND DISCUSSIONS

1. The analysis of "Roua Apusenilor" Spring Water

In Tables 1 and 2 the physicochemical and microbiological results of the sample of "Roua Apusenilor" spring water are presented.

Table 1. Results of the physicochemical analysis of "Roua Apusenilor" spring water

Parameter	Determined	Max. Admissible
pH	6.98	6.5 ÷ 9.5
Permanganate index, mgO_2/L	1.21	5.00
Ammonium, mg/L	<0.025	0.5
Nitrite, mg/L	<0.015	0.5
Nitrates, mg/L	3.95	50
Turbidity, JTU	0.92	5
Total hardness, °dH	11.05	Minimum 5.00
Iron, µg/L	<10	200
Aluminum, µg/L	<0.5	200
Chlorides, mg/L	2.83	250
Conductivity, µS/cm at 20 °C	390	2500
Dry residue at 180°C	192.5	-

Table 2. Results of the laboratory microbiological analysis of "Roua Apusenilor" spring water

Parameter	Determined, CFU	Max. Admissible, CFU
Coliform bacteria	0/250 ml	0/250 ml
Escherichia coli	0/250 ml	0/250 ml
Enterococcus faecalis	0/250 ml	0/250 ml
Total plate count 22 °C	1/ml	100/ml
Total plate count 37 °C	2/ml	20/ml
Pseudomonas aeruginosa	0/250 ml	0/250 ml
Clostridium perfringens	0/100 mL	0/100 mL

Tables 1 and 2 shows that the values of the parameters are within the established limits according to the national and European legislation in force. The quality of "Roua Apusenilor" spring water from "Lucia Cave" source, Sohodol village, is corresponding.

2. Analysis of potential risks through the concomitant use of the Ishikawa diagram and the HACCP principles

The method of verification of HACCP system was designed and tested according to the process map or the 5M-HACCP model presented in Figure 2.

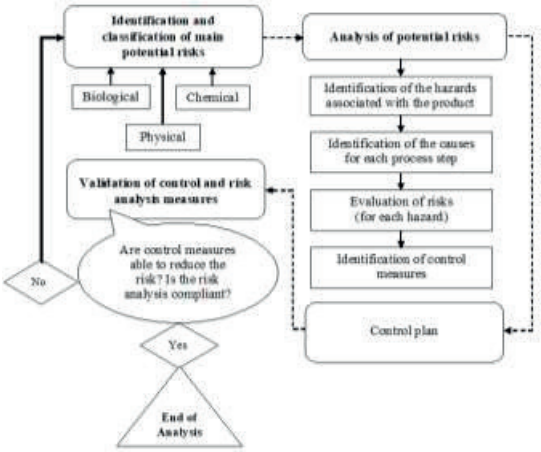

Figure 2. Logigram of the process

To identify the risks associated with food and the safety of staff and consumers the analysis is carried out for each class of hazards (physical, chemical, biological), on each class of products, and on each operation in the technological flow, according to the 5M.

Identification and analysis of the causes for each process operation

The cause is defined as all the practices, all the factors, all the situations responsible for introducing or aggravating a danger in each operation, or in each raw material, etc.

As examples Figures 3 and 4 show the determination of the causes that may generate the risks associated with bottled water, and those associated with the water bottling stage using the Ishikawa diagram based on the analysis of the 5M; 5 Whys? Method.

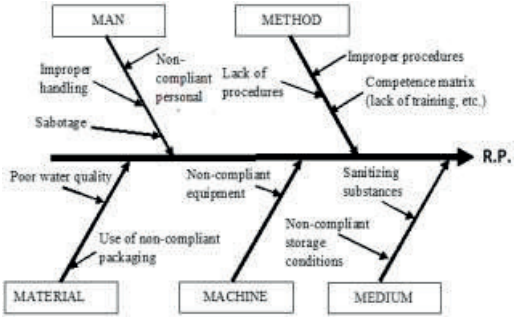

Figure 3. Determination of causes that can generate the risks associated with bottled water (R.P. - root problem)

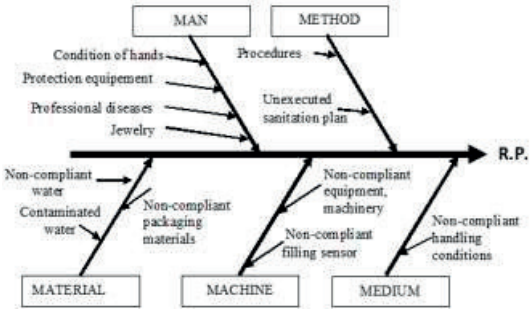

Figure 4. Determination of causes that can generate the risks associated with the water bottling stage

The analysis of the causes is performed for each potential hazard separately, on the 5M, on each operation, to identify all possible sources and then rule some to be negligible.

Table 3 presents the analysis of the causes, based on the 5 Whys? method for each hazard, related to the water bottling stage.

Table 4 shows the assessment of the hazards corresponding to the bottling stage for spring water based on the 5 Whys? method for each hazard, corresponding to the water bottling stage.

Table 3. Analysis of the causes, based on the 5M, for each hazard related to the water bottling stage

Process	Risk	M Type				
		Medium (M1)	Man (M2)	Method (M3)	Material (M4)	Machine (M5)
1. PET unpackaging 2. Placing the containers on the bottle conveyor belts 3. Filling 4. Capping	Physical	-Contamination with foreign bodies from the work environment; -Cross-contamination among handled products; - Air pollution.	-Foreign bodies from workers, work clothes; - Contamination from handling raw materials and packaging; - Contamination due to storage of open vials for filling.	-Lack of knowledge about working and sanitation standards; -Non-compliance with work and sanitation standards. -Unrevised working and sanitation standards.	-Cross-contamination among containers (PET bottles); -Contamination from water with impurities.	-Contamination from transport machinery, and equipment, paper, foils, labels; -Contamination from defective pallets
	Chemical	-Contamination from chemicals (including sanitizers) handled in the same space.	-Contamination from operators, work equipment. -CO_2 / O_3 overdose.	-Lack of knowledge about or non-compliance with work and sanitation standards; - Unrevised working and sanitation standards.	-Contamination with chemicals (including sanitizers) handled or stored in the area. -Use of impure CO_2 / O_3.	-Contamination from defective equipment.
	Biological	-Microbiological contamination from the work environment. -Development of microorganisms due to inadequate hygiene.	-Contamination from sick operators or those who have sick animals, dirty work equipment.	-Lack of knowledge about or non-compliance with work and sanitation standards; -Unrevised working and sanitation standards.	-Water contamination, microbiologically contaminated packaging.	-Contamination from machinery, pallets, unhygienic shelves.

Table 4. Hazards identification and risk class for the bottled stage for still water

Risk	M Type															RC
	Medium (M1)			Man (M2)			Method (M3)			Material (M4)			Machine (M5)			
	G	F	I	G	F	I	G	F	I	G	F	I	G	F	I	
Physical	3	1	2	3	1	2	2	1	1.5	2	1	1.5	3	2	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

Table 5. identification of control measures in case of chemical hazard for the spring water bottling stage

M Type	Risk	Measures	Responsible/Period
M1	- Contamination from chemicals (including sanitizers) handled in the same space. - CoVid 19 contamination from the infected environment	- Sanitation check using pH testing. - Removal of chemicals from space. - Sanitation of work environment and disinfection.	- CTC Flow / annually - Production coordinator / daily
M2	- Contamination from operators, work equipment. - CO2 / O3 overdose. - CoVid 19 contamination from infected operators.	- Checking operators and their equipment. - Monitoring dosage using rapid tests. - Monitoring the health of operators	-Production coordinator / daily. -Laboratory technician/ daily
M3	- Ignorance or non-compliance with work and sanitation standards, prevention measures. - Working and sanitation standards, unrevised prevention measures.	- Periodic training of production staff. - Periodic review of standards and procedures.	Operational staff/ at the time of employment quarterly, annually
M4	- Contamination with chemicals (including sanitizers) handled or stored in the area. - Use of impure CO_2 / O_3.	- Handling detergents only at the time of sanitation. - Periodic monitoring of CO_2 / O_3 purity.	Production coordinator / at the time of sanitation and after maintenance Chemical engineer / self-control program
M5	- Contamination from defective or improperly sanitized equipment. - Contamination from machinery, equipment infected with CoVid 19. - Non-calibration of measuring devices.	- Maintenance of equipment. - Compliance with sanitation and prevention standards. - Calibration of measuring devices according to the maintenance program.	Operational staff / according to schedule Production coordinator / at the time of sanitation. Technical manager / according to schedule

Tabel 6. Setting the CCP control plan for the spring water bottling stage

Type M	Risk	Procedures	CCP/PRPs					Corections / Corective Activities	Responsible	Record
			Q1	Q2	Q3	Q4	Type			
M1	- Contamination from chemicals (including sanitizers) handled in the same space. - CoVid 19 contamination from the infected environment	PRP	YES	NO	NO	-	none	Product separation, remediation / destruction	Technical and quality control	Sanitation sheets
M2	- Contamination from operators, work equipment. - CO2 / O3 overdose. - CoVid 19 contamination from infected operators.	PRP	YES	NO	NO	-	none	Product separation, remediation / destruction	Technical and quality control	Staff monitoring form.
M3	- Ignorance or non-compliance with work and sanitation standards, prevention measures. - Working and sanitation standards, unrevised prevention measures.	PRP Working standards and prevention	YES	NO	NO	-	none	Testing, retraining	Responsible for quality	Training report
M4	- Contamination with chemicals (including sanitizers) handled or stored in the area. - Use of impure CO_2 / O_3.	PRP Self-control program	YES	NO	NO	-	none	Product separation, destruction	Technical and quality control	Sanitation sheets, Maintenance sheet
M5	- Contamination from defective or improperly sanitized equipment. - Contamination from machinery, equipment infected with CoVid 19. - Non-calibration of measuring equipment	PRP Measuring equipment verification program	YES	NO	NO	-	none	Product separation, remediation / destruction	Technical and quality control	Sanitation sheets, Maintenance sheet

Identification and validation of control measures for each process operation

Control measures are established for the main causes that are determined to possibly lead to potential hazards. These consist of a series of techniques, activities or actions taken to reduce or eliminate a potential risk.

To establish the control measures, one starts from the stage of risk identification and hazard assessment.

Once the main causes generating potential hazards for each raw material/commodity/ process step have been established general control measures are set that can eliminate or reduce this potential risk.

For risk class 3, in addition to the determined control measures, the Preliminary Preparatory Programs will be used, which regulate working conditions, hygiene, production areas and food safety control.

If the analysis identifies potential risks in risk class 4, monitorisation, verification and validation of control measures will also be performed using Operational Prerequisite Program (oPRP) and Critical Control Points (CCPs).

Table 5 presents the identification of control measures in case of chemical hazard for the spring water bottling stage. To control the process of identifying potential hazards and their control measures, the establishment of a control plan is needed, which should define:

- stage of the process (place in the system),
- controlled hazard,
- control measures,
- the procedures controlling it,
- monitoring procedures,
- corrections and corrective actions,
- the person in charge of verifying the process,
- related records.

Table 6 sets out the CCP control plan established for the spring water bottling stage. The control plan is elaborated by the person in charge of the risk analysis from all the departments involved in the material flow.

The validation of control measures and risk analyses is performed by the food safety team measuring the effectiveness and efficiency of the process based on the following indicators:

- no. of risk analyses performed by each department listed in this standard/no. risk analysis required.
- no. of risk analyses validated by ESA/no. of risk analyses performed.

Among the records we can find a sheet for identifying and assessing the causes that may

generate potential risks, and a sheet for identifying risks, assessing, and establishing control measures.

CONCLUSIONS

The study follows the methods and means of risk investigation to ensure the quality and safety of bottled spring waters, also the introduction of new methodologies and techniques with a good intercalation capacity between them. The superior value of the finished products` quality also implies the rigorous knowledge of their physicochemical and microbiological composition. Thus, the physicochemical and microbiological parameters of the spring water were investigated, and it was determined that the quality characteristics of "Roua Apusenilor" Spring Water were met.

A new perspective was provided in the study of the dynamics of the risk-factor analysis in the bottling process of the spring water "Roua Apusenilor" by the simultaneous use of the Ishikawa diagram and the HACCP principles. The application of Tree diagram led to converging results thus corroborating the validity of conclusions derived from HACCP risk analysis. The synergistic effect of the two methods is observed: HACCP in conjunction with Cause-and-Effect Diagrams.

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