MEDICAL UNIVERSITY - PLEVEN

FACULTY “PUBLIC HEALTH”

DEPARTMENT "Hygiene, medical ecology, occupational diseases and emergency medicine"

Dr Tsvetelina Vitkova

CRITICAL ANALYSIS AND HEALTH- HYGIENE EVALUATION OF THE APPLICATION OF “HACCP” SYSTEMS IN THE PRODUCTION OF BULGARIAN FOODS

ABSTRACT

of the Dissertation
for the award of the scientific degree “doctor”

Scientific specialty: Hygiene

Supervisor:

Assoc. Prof. Dr Rositsa Enikova, d.m.

Pleven, 2022

The dissertation in written in 176 pages and is illustrated with 28 tables and 26 figures. The bibliography contains 252 titles, of which 67 in Cyrillic and 185 in Latin.

The dissertation was discussed and proposed for defense at a Board meeting of the Department of psychiatry and medical psychology, Medical university – Pleven, that took place on 09.12.21.

The official defence will take place on 24 February 2022 at 11:00 AM at – Medical University, according to Decision of the Rector of MU Pleven № 3380/21.12.2021 before a scientific committee:

Internal for Medical University – Pleven:

1. Assoc. Professor dr. Vanya Birdanova, MD, PhD
2. Assoc. Professor Mariyana Stoynovska, MD, PhD

Reserve member:

3. Prof. Mishel Salvator Israel, PhD

External for Medical University – Pleven:

1. Prof. Dr. Veselka Duleva, MD, PhD
2. Assoc. Professor Desislava Gyurova, PhD
3. Assoc. Professor dr. Darina Naydenova, MD, PhD

Reserve member:

4. Assoc. Professor dr. Stanislava Harizanova, MD, PhD

Materials, related to the defense are published on the internet site of MU – Pleven.

Acknowledgements

1. To my research supervisor Assoc. Prof. Dr. Rositsa Enikova-Kosovska, MD for the unreserved, continuous support and mentoring.

2. To the whole team of the Department of Hygiene, Medical Ecology, Occupational Diseases and MBS for the support and assistance.

3. To the owners and the teams from the food production sites for the assistance.

4. To my daughter Ralitsa Dimitrova for the unreserved help and assistance and my husband Dr. Georgi Dimitrov.

Table of contents:

Used abbreviations:

BFSA	Bulgarian Food Safety Agency
BDS	Bulgarian State Standard
ULFDRKFI	Upper limit for daily risk-free food intake
GMO	Genetically modified organism
SG	State Gazette
PDD	Permissible daily dose
GMP	Good Manufacturing Practices
GHP	Good Hygiene Practices
EC	European Community
LRA	Large Ruminant Animals
EC	European Union
CCP	Critical Control Point
CP	Critical Point
MRL	Maximum residue limits
MH	Ministry of Health
MAF	Ministry of Agriculture and Forestry
MAF	Ministry of Agriculture and Food
MAFI	Ministry of Agriculture and Food Industry
MSM	Mechanically separated meat
OPRP	Operational prerequisite programs
PAH	Polycyclic aromatic hydrocarbons
PRP	Prerequisite programs
AWD	Acceptable weekly dose
PCB	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzodioxins
PCDFs	Polychlorinated dibenzofurans
WHO	World Health Organization
UFVP	Union of Fruit and Vegetable Producers
FBO	Food business operators
FSMS	Food safety management system
TD	Technological Documents
POP	Persistent organic pollutants
FAO	Food and Agriculture Organization
CNS	Central Nervous System
CAC	Codex Alimentarius Commission
CDC	Centers for Disease Control
EFSA	European Food Safety Authority

EPEC	Enteropathogenic E.coli
ETEC	Enterotoxigenic E.coli
FDA	Food and Drug Administration
FSSC	Food Safety System Certification
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRSA	Methicillin-resistant Staphylococcus aureus
NASA	National Aeronautics and Space Administration
PCDFs	Polychlorinated Dibenzofuran
PDCA	Plan-Do-Check-Act
QMRA	Quantitative Microbial Risk Assessment
STEC	Shiga-verotoxigenic E.coli
U.S.EPA	United States Environmental Protection Agency
U.S.FDA	U.S. Food and Drugs Administration
VTEC	Verotoxigenic E.coli
WHO	World Health Organization

INTRODUCTION

The introduction of HACCP systems into the practice of all manufacturing establishments, catering establishments and even in larger food outlets, through the European Union legislation (EU Regulations №№ 852/2004, 853/2004, 178/2002) pursues basic medical goals set by public health authorities. The first and most important is to limit and minimize the incidence of food toxicoinfections, intoxication and infections that occur explosively among large contingents of the population with all the health, social and economic consequences for civilized countries. The second objective is to minimize the possible mainly chronic exposures of the population to contaminants and additives, mycotoxins and other chemical hazards with less direct and more often remote effects. The third goal is to construct an internal control system that creates security and the absence of physical, chemical and biological hazards in the final product. The goal is not control by performing expensive and time-consuming hazard analyzes in the finished product, but operatively, hourly measurement of these parameters of the technological process, which effectively eliminate them or minimize their quantity and impact.

With the implementation of the European legislation in the practice of production and supply of food and health control over them, the development and operation of HACCP systems has become a common practice, which undoubtedly plays a significant preventive role for food safety in Bulgaria. At the same time, the development, implementation and maintenance of this systematic preventive medical activity and the respective responsibilities are placed entirely in the hands of food business operators. Specialists with different qualifications work in the field of production and in public catering. The main place is occupied by the engineer-technologists, but the jobs are also occupied by people with diverse educational qualifications, often extremely far from competencies in the field of food and biology, infectology, epidemiology, chemical and other food safety. Adequate determination of the levels of danger and, ultimately, the effectiveness of the preventive approach depends on their qualifications. At the same time, the lack of sufficient experience, the sometimes incompetent consulting assistance in the development of the systems, the entry of unprepared and commercially oriented specialists, the borrowing of inappropriate elements of the systems from other industries, naturally lead to inadequacy and incompleteness of these systems, to underestimating significant hazards with a high degree of risk or vice versa – exasperating the importance of other, insignificant factors in food production, which meaninglessly aggravate the practice of internal control. Therefore, a visible reduction in the incidence of food poisoning, toxicoinfections and infections in the countries of the European region is not observed compared to previous years, when the legislative measures for widespread implementation of HACCP and the principles of risk analysis did not work. This trend is typical for our country as well, so it must be subjected to critical analysis in order to strengthen the preventive role of internal food control.

The most important fundamental element in the creation of HACCP systems is the identification of hazards to human health with an assessment of the respective risk.

This requires in-depth knowledge of the physical, chemical and biological factors in food in the modern conditions of production and supply and in the conditions of free movement of goods in our increasingly globalized reality. Risk assessment requires a high medical culture, based on knowledge of the immediate possible effects of hazards, as well as their long-term consequences.

When developing HACCP systems, it is not possible to create unified algorithms. Each production and supply of food has its own specific features. These are national and traditional recipes, technologies, culinary practices, originality of raw materials and quality requirements for them and ready meals, etc., but also human factors, culture of activities, regulations, presumed social impacts relevant to the degrees of risk.

At the same time, the intensive penetration of the implementation of HACCP systems in our country coincided with the establishment of the Bulgarian Food Safety Agency. This predetermines a qualitatively new approach to the notification, registration, epidemiological investigation, diagnosis and prevention of foodborne diseases. This activity is no longer carried out entirely by the health authorities, but by the BFSA, where the qualification of the specialists is insufficient for adequate medical actions. The results are obvious - in a number of districts of the country such morbidity is not registered, and where there is registration, the diagnosis is incomplete and inaccurate. The restructuring of the state health control continues, it is necessary to develop and improve the practice in the field of monitoring the morbidity of both infectious and chronic non-infectious diseases related to food and nutrition of the population. The hygienic condition of food production, catering, trade and transport is the basis for the prevention of acute and chronic pathologies related to food and nutrition.

The nutrition of the population in Bulgaria, as in all other countries, has its national nuances, types and assortments of food products and dishes, production and culinary technologies. In this aspect, achieving a full risk assessment and harmonization of HACCP systems with it is a key preventive measure to ensure adequate and effective control of food safety.

This determined the main topic, goal and tasks of the present dissertation.

The MAIN OBJECTIVE of the dissertation is to perform a critical analysis of the hygienic condition of food production in the country and the design and operation of HACCP systems to eliminate the risk to public health.

In developing the main goal, we set the following

MAIN TASKS:

1. Analysis of the hygienic condition of the production of food of animal and non-animal origin;
2. Analysis of the prerequisite programs and actions in the development and implementation of HACCP systems;
3. Health and hygiene expertise and medical assessment of the real dangers in food production and their minimization through the methodology of HACCP systems;

4. Analysis of the design and operation of actually operating HACCP systems in the production of food of animal and non-animal origin.

METHODS AND MATERIALS

In developing the dissertation, we used the methodology of Codex Alimentarius, presented in the document "Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System". The critical analysis of the productions covered by the study included the main elements of the structure of the sites, the specifics of the food production, as well as the systems for internal control and monitoring of the preventive procedures.

1. Analysis and evaluation of the structure and organization of work in the enterprise

The analysis and assessment of the structure of food establishments as an element of the prerequisite hygiene conditions for their productions was performed on the basis of the following criteria, according to EU Regulations №№ 852/2004 and 853/2004 [194, 196]:

1.1. Assessment of prerequisite conditions and activities (building stock, premises, water supply, sewerage, lighting and ventilation, solid waste, pest control);

1.2. Assessment of the environmental conditions for production and safety of the specific type of food production;

1.3. Assessing the potential risk of contamination of food from the environment "with microbial pathogens, chemicals, foreign bodies, food spoilage agents, unacceptable colors and unwanted or pathogenic substances, such as sawdust or decomposing materials";

1.4. Review of the Good Manufacturing Practices (GMP) and the Good Hygiene Practices (GHP) available to the business operator - company, branch, and assessment of the possibilities for their application and compliance with the General Principles of Food Hygiene;

1.5. Evaluation of the systems for cleaning, washing and disinfection of the working premises, equipment, inventory (GHP);

1.6. Evaluation of the premises and facilities for maintaining the personal hygiene of the staff;

1.7. Assessment of the structure of the storage premises for raw materials, materials, packaging and finished products;

1.8. Evaluation of the personnel employed in the production;

1.9. Detailed description with evaluation of the produced products (main raw materials, suppliers, specifications and analytical certificates, recipes, characteristics of nutritional, biological value and safety of the final product, additives and potential contaminants, principles of technology, internal control system);

1.10. Analysis and evaluation of the Technological documentation - according to the criteria established in the current national legislation (definition, classification, technical requirements, quality and safety standards, sampling methods and test methods, packaging and marking, content of the label, storage, durability, technological instruction, production control, documentation);

1.11. Analysis of the intended use, assessment of the expected ways of use of the product by the end consumer, the instructions for use. In specific cases, vulnerable groups of the population assess whether or not the wording of the considerations and guidelines is correct;
1.12. Evaluation of production technology (machines and equipment, technological processing, process diagram, criteria and responsibilities in internal production control);
1.13. Evaluation of the storage base and refrigeration facilities in the production and storage of raw materials, semi-finished products and finished products;
1.14. Evaluation of vehicles and equipment for internal and external transport;
1.15. Assessment of work with staff (health status, rules of personal hygiene, protective clothing, behavior, training - initial, continuing, access to work sectors);
1.16. Requirements for the records in the documentation - legibility, signatures of the responsible persons, storage, deadlines;
1.17. Rules and procedures for withdrawing products from the market.

2. Analysis and evaluation of the development and functioning of the HACCP system

The actual critical analysis of the HACCP systems developed and applied in the productions was performed in accordance with the Guidelines for the implementation of procedures based on the principles of risk analysis and critical control points in certain areas of the food industry (Brussels, European Commission, Directorate General for consumer health ') and covered the following key stages in the development and operation of HACCP systems:
2.1. Assignment of HACCP tasks by the management of the food enterprise (scope of the system, processes, type of production);
2.2. Evaluation of the composed multidisciplinary teams under HACCP (competence, functions, management, qualification, team work, external consultants);
2.3. Assessment of the terms and definitions used in the HACCP documentation and of their compliance with the terms and definitions given in the above document.
2.4. Evaluation of the product description compiled by the HACCP team, including relevant safety data (composition, principles of handling, packaging, storage, shelf life, method of use, evaluation criteria);
2.5. Evaluation of the description of the use of the product - standard, expected; target consumer groups, including vulnerable groups;
2.6. Evaluation of the description of the technological process. Compilation of a technological diagram with technical data, preparation, processing, packaging, storage, distribution; on-site inspection of the technological diagram);
2.7. Assessment of the expected physical, chemical or biological hazards in the individual steps of the technological process. Risk analysis of each identified potential hazard on the principle of severity / probability - according to the presented model scheme /Figure 1/:
2.8. Assessment of the identified critical control points - according to the "decision tree" (see Figure 2):
2.9. Assessment of the parameters of the technological process, which are crucial for elimination or reduction of the level of risk in the critical control points;

2.10. Evaluation of the defined critical limits of the parameters for each critical control point;
2.11. Evaluation of the system for monitoring the parameters in the critical control points;
2.12. Assessment of the proposed corrective actions taken when the monitoring shows that the specific critical control point is out of control;
2.13. Assessment of the established verification procedures, confirming that the HACCP system works effectively;
2.14. Evaluation of HACCP documentation - assessment of the procedures and records appropriate to the application of HACCP principles in a given food business.

MODEL FOR QUANTITATIVE HAZARD ASSESSMENT

RISK LEVEL (R = P x E): scale from 1 to 7

Probability						
Likely	4	4	5	6	7
Possible	3	3	4	5	6
Unlikely	2	2	3	4	5
Rare	1	1	2	3	4
		1	2	3	4
		Low	Moderate	High	Very High
			Severity		

Figure 1 - Model hazard assessment scheme

According to the above algorithms for critical analysis and assessment of the condition and hygiene of production and the composition and operation of HACCP systems, the following food productions on the territory of the Republic of Bulgaria were inspected:
1. HACCP in the production of pasteurized egg products (Chapter 1);
2. HACCP in the production of sterilized canned vegetables (Chapter 2);
3. HACCP in the production of catering culinary desserts and confectionery (Chapter 3);
4. HACCP in the production of catering culinary products - soups, cooked hot dishes with meat, roasted and grilled meat products (Chapter 4);
5. HACCP plan for the production of pasteurized canned vegetables (Chapter 5);
6. HACCP system in the production of sauces (Chapter 6);
7. HACCP plan in the production of jams, marmalades and toppings (Chapter 7);
8. HACCP in the production of germinated seeds and their products (Chapter 8);
9. HACCP in an enterprise for the production of minced meat, meat preparations and cuts of red and white meat (Chapter 9);
10. Some characteristics, solutions and omissions in the design and operation of HACCP systems in the food industry (Chapter 10).

RESULTS AND DISCUSSIONS:

The results of the analysis of the hygienic condition of different types of food production on the territory of the country, most of them in Pleven district, gave grounds for important findings on the prerequisite documentation, on the established

HACCP systems and on their functioning. The analyzes also provided grounds for critical remarks and recommendations, mainly related to the elimination of the risk of foodborne disease to the health of the population.

CHAPTER 1

HACCP IN THE PRODUCTION OF PASTEURIZED LIQUID EGG PRODUCTS

Pasteurized egg products, which are semi-finished products in the confectionery, bakery, catering, ready-to-eat, soup, dessert, and other food industries, have serious potential as potential carriers of food hazards and any breakthrough in their safety would be important for the health of the population. Salmonella-contaminated egg products are particularly relevant. The risk of this and its assessment are also of special interest to the World Health Organization. It is no coincidence that the EU Microbiological Regulations define Salmonella spp. as the main criterion for the safety of egg products. In our country there is a rich research experience on the microflora of raw and pasteurized egg mass as semi-finished products for the production of dry egg products - egg white, yolk and melange. It was acquired during 5 years of systematic monitoring and hygienic-technological control in a large enterprise (town of Debelets), equipped with equipment of the company "Sanovo" (Denmark). The results show very high levels of contamination of the raw egg mass with indicator microorganisms. The total number of mesophilic aerobic microorganisms there reaches 10^8 cfu/g, the predominant number of samples is in the range of 10^5 - 10^6, but pasteurization and heat drying sharply reduce the microflora by 3 to 4 lg, reducing the number of mainly non-spore-forming species and allow achieving of decontamination by pathogenic microorganisms. As a result, salmonella bacteria were isolated in Bulgarian powdered eggs in only 0.89% of the finished batches. Experimental prognostic-microbiological studies show that in dried egg powder Salmonella enteritidis strains and indicator microorganisms survive no more than 2 to 3 months, due to the low water content of the product.

The enterprise for production of pasteurized egg products has an independent building stock, located and designed according to the legislation in force in the country. The equipment is complex, manufactured by the famous company "Sanovo" (Denmark), and the technological processes are specific to this type of high-protein animal products.

The company currently produces the following assortments of egg products:

1. Pasteurized egg products (according to TD 01-2008);
2. Liquid pasteurized egg whites (according to TD 02-2011);
3. Fresh pasteurized egg melange HORECA (according to TD 03-2012);
4. Quick-frozen pasteurized egg melange (according to TD 04-2012);
5. Dried eggshells (TD 05-2011).

The analysis of the internal control system of the enterprise and specifically of HACCP gave grounds for the following findings, critical remarks and recommendations:

The main part of the company's prerequisite programs are the manuals for good production and hygiene practice (GMP & GHP) in accordance with the requirements of the EU Regulations №852/2004 and №853/2004 and with the specifics of the production.

The leading place in the HACCP team is occupied by the technologist of the enterprise - a person with appropriate university education and experience in technological processes.

The specialists in the company are well acquainted with the modern legislation and handle the current regulations. The team knows well the theory, philosophy and technology of HACCP, which allowed them to orientate themselves in a methodological way to the development and application of the system of action in the company. In addition, the technologists follow the current special literature, know the publications of the WHO/FAO, Codex Alimentarius and the European Organization of Egg Product Producers (European EGG Processors Association).

The most important prerequisite documents are the Technological documentation for the manufactured products. Their analysis gives rise to the following findings:

TD have been developed in full accordance with the form approved in our national legislation (Ordinance № 1 of the Ministry of Health/2016), but there are grounds for critical remarks on their content. Not all Regulations cited in the document are relevant today. Many of them have been repealed and replaced by EU Regulations or updated national documents and this requires updating the texts of the TD. An example is EU Regulation №1169/2014 on food labeling, which should include all modern regulations, including company specifications.

The production technology is consistent with the thermal stability of the high-protein egg mass and the corresponding resistance of the unwanted microflora. Table 1 shows the main technological parameters that determine the safety of the products, and Figure 2 shows the scheme of the production process with the later applied critical control points.

The gentlest is the temperature regime in egg white production, where temperatures do not exceed 57ºC. This preserves not only the basic egg proteins from thermal denaturation, but also the specific proteins with immunogenic properties, as well as lysozyme in fresh, stored no more than 2 months in the refrigerator hen eggs.

The risk of residual microflora here, as well as in the yolks and melange, is not to be underestimated and requires very strict ongoing control with informal application of more indicator microbiological tests. We will look at this issue further, in the sections on production control and in the discussion of the HACCP system.

Table 1 - Main technological parameters related to the safety of pasteurized egg products

Type of Product	Flow rate l / h	Pasteurization, ºC	Holding time, ºC	UHT ºC	Cooling, ºC	Downtime, min
Melange	3 000	65	65	67	4	7-8
Egg whites	3 000	55	55	57	4	7-8
Egg yolks	1 500	65	65	66	4	13-14

With regard to section 4 (Qualitative indicators and norms), the authors have shown maximum restraint, typical of today's trends in the practice of business operators. The quality and safety criteria are minimized in order to facilitate control and reduce its cost.

– In the document for pasteurized egg white, yolk and melange only pH and dry matter are normalized, but the content of the main component - protein is not standardized;

– The document for pasteurized yolk and pasteurized melange does not regulate the content of proteins, lipids, added sugars and salt;

– The dry matter is presented in a very wide range, and this betrays the "hidden" assortments with more or less added sugar which are obviously intended for use in confectionery. An alternative solution is to create a separate company TD for this category of pasteurized egg products.

– Of the safety indicators in TD, only the microbiological ones are normalized - for the pathogenic Salmonella spp. and for the indicator Enterobacteriaceae, in strict accordance with EU Regulations №2073/2005 and №1441/2007.

– The TD lacks criteria and norms for chemical contaminants due to the fact that EU Regulation №1881/2006 for egg products regulates only POPs.

The section of the TD with the description of the technological process is developed seriously and objectively, without unnecessary details, but with a clear indication of the most important technological stages, crucial for the safety of the finished product.

The sections for packaging, labeling and marking, storage and transport are designed correctly, it could affect the compliance of the refrigeration chain for this risky product.

The determined shelf life under refrigeration conditions up to 30 days is a reasonable solution provided that all preventive measures against contamination with psychrotrophs, especially with microscopic fungi, are implemented in the production. However, there is no information on how this decision was made, on what basis the durability was determined - own experience, experiment or borrowing from someone else's legal framework. The use of preservatives is obviously crucial.

Formally correct, but very concise and without details, the section for production control has been developed.

The analysis of the HACCP system itself and of the presented HACCP plan gives grounds for the following discussions:

For the purposes of our study, the analysis of health hazards is of the utmost importance. According to the presented materials we can make the following findings:

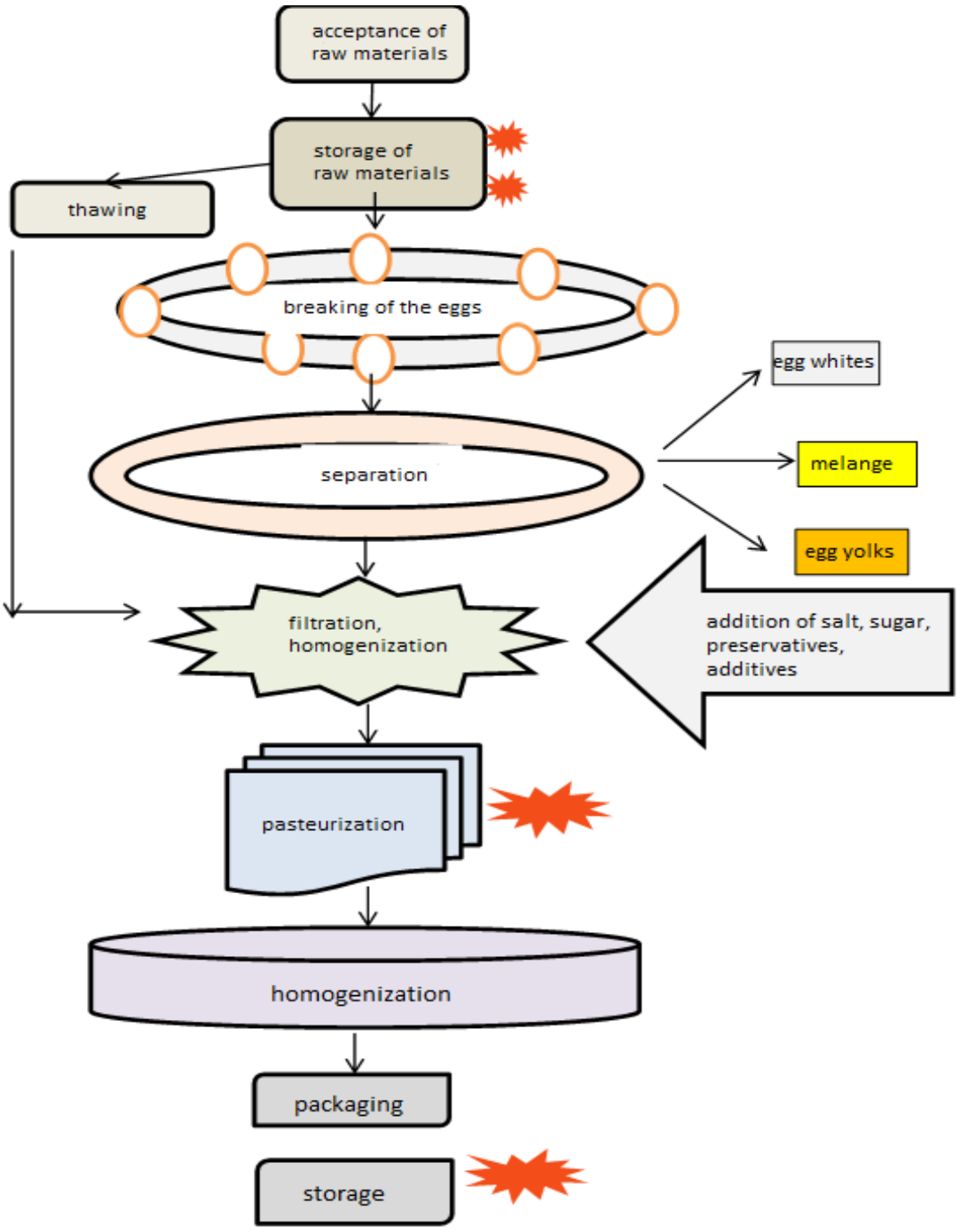

Figure 2 - Scheme of technological processes in the production of pasteurized egg products

Of the physical hazards, the remains of eggshells are rightly mentioned - real mechanical contaminants of the egg mass, which are removed by filtration and this solves the problem. Detergent residues and disinfectants are listed as chemical hazards.

Along with them, many mycotoxins have been pointed out as dangers, which, in accordance with their nature and mechanisms of biosynthesis from microscopic fungi, have no place either in eggs or in their products. HACCP has not been developed in the direction of taking preventive measures against mycotoxins, but the very presence of these harmful biotoxins in the documentation is pointless and only burdens both the information and the system itself.

The leading main role in pasteurized egg products is rightly assigned to biological contaminants - bacteria and microscopic fungi.
The contents of healthy, normally laid hens' eggs are generally sterile. The sterilely is preserved even in cracked eggs, as long as the sub-shell is undamaged. The real contaminants are the eggshells themselves, from which many microorganisms can enter the egg mass, regardless of whether or not there are visible mechanical contaminants on their surface. The eggs are laid from the cloacas of the birds. So therefor, their shells are contaminated with all fecal microorganisms - *Enterobacteriaceae* (including *Escherichia, Salmonella, Citrobacter, Klebsiella, Enterobacter, Proteus, Providencia, Morganella, Yersinia*, etc.), with *Staphylococcus, Micrococcus, Campy Clostridia*. Pasteurization is fatal to many of the raw egg mass microorganisms. However, the authors of the plan identify only "pathogenic psychrophiles" and molds as a risky residual microflora, but it is not clear what "pathogenic psychrophiles" are. Authentic microorganisms - indicators of the effect of technology are absent in the hazard analysis. Even more illogical, enterococci (along with molds) are listed as hazards in the refrigeration and storage sections.
Our analysis shows that the HACCP system for pasteurized egg products is correctly built on the main danger - microbiological contamination, but it is described incompletely and without knowledge of the real microflora of the raw material and the finished product. The team that developed the system obviously does not have the necessary knowledge on the problem. There is no verification microbiological test anywhere in the HACCP plan.
It is understandable that a current detailed and daily microbiological control on precise indicators, covering all the above pathogenic and non-pathogenic, but dangerous for the production microorganisms, is not feasible mainly for resource reasons. However, it is important that the manufacturer of pasteurized egg products includes in the verification procedures periodic inspections of the actual microbiological condition of the production according to the criteria important for both safety and quality.
The latest editions of the TD also include preservatives - derivatives of benzoic and sorbic acid. Obviously, this is the result of production experience with breakthroughs and hygiene problems.
We can also give critical remarks on the overall condition of the HACCP documentation. The electronic library is presented through an extraordinary number of illogical documents, mixed with administrative, financial and other forms and records.

IN CONCLUSION:
The internal control system developed by the team in the enterprise for production of pasteurized liquid egg products, including pre-requisite activities and HACCP-system is methodologically correct. The critical control points and the corresponding observed criteria and critical limits are adequate to the specifics of the production process. Through monitoring, systematic internal control and the corresponding prevention of hazards in the production of pasteurized egg products can be realized.

The highlighted critical assessments give rise to the following specific recommendations:

1. The prerequisite programs for GMP and GHP should be periodically updated and in their new versions to achieve full harmonization with the order specified in EU Regulations №№ 852/2004 and 853/2004, but with full reflection of the specifics of production;

2. A complete revision of the Technological documentation is required with the following additions:

– Updating the normative documents specified in the TD;

– Development of separate TD for natural pasteurized egg products and for those intended for confectionery production;

– Complementing the physico-chemical criteria in the TD with indicators such as "sugar content", "table salt", "total protein". If necessary - marking in the TD the different produced assortments depending on the quantities of added sugars;

– In the section for internal technological control supplementation with microbiological criteria, indicators for the effect of technologies on the microflora of the pasteurized egg mass. Harmonization of these criteria with the criteria for verification in the HACCP system;

3. Updates and corrections of the established HACCP system are needed:

– In the section "hazard analysis" to clear all unnecessary and non-production hazards - e.g. "Mycotoxins", "enterococci", "pathogenic psychrophiles" and others. Indicate in the same section the authentic microbiological hazards carrying the risk (if necessary to use competent external consultancy);

– The total number of mesophilic and psychrotrophic microorganisms, microscopic fungi, Enterobacteriaceae and individual genera of them, e.g. E. coli, Proteus, of the genera Bacillus, Pseudomonas, Entrococcus, Staphylococcus, Listeria, etc., selected according to the specifics and the effect of the technological and hygienic actions in the production.

– In the section "verification" to specify the checks of the effect of the technological and hygienic measures through periodic examination of the microbiological condition of the production according to integrated microbiological criteria. We consider it appropriate to specify at least the following criteria:

- ✓ Total number of mesophilic aerobic and facultative anaerobic microorganisms
- ✓ Total number of psychrotrophic microorganisms;
- ✓ Total number of molds and yeasts;
- ✓ Total number of Enterobacteriaceae.

4. It is necessary to introduce a strict order in the documentation of the internal control system, with an orderly register, with the elimination of redundant forms, with complete separation of the administrative documents from those under GMP, GHP and HACCP.

This will eliminate the dangers of purely formal implementation of HACCP plans and of overloading the team with daily completion of non-essential forms.

CHAPTER 2

HACCP IN THE PRODUCTION OF STERILIZED CANNED VEGETABLE PRODUCTS

The company has its own building stock and modern infrastructure. The traditions of the company have deep roots, and the recipes include traditional for our country and sought-after assortments. Modern methods of canning fruits and vegetables are used. The team consists of experienced and well-trained staff, familiar not only with technological processes, but also with modern European legislation concerning food quality and safety. The food quality and safety management system in accordance with FSSC 22 000 standards has been built, maintained and periodically updated in the enterprise.

According to the prerequisite data:

The company's products are sterilized canned vegetable products - one-component and multi-component ("ready meals"), as there are no fundamental differences in the technology in terms of potential health hazards to the consumer.

The team’s strong suit is the specificity - for each range a separate, individual TD has been developed, thus it is possible to present the most detailed data for each product. However, not in all cases, the texts of the TD have been revised and updated in accordance with the changes in the legislative and by-laws.

Product definitions are presented concisely and accurately. The main section - "Health and quality indicators and standards" is developed comprehensively, in the spirit of Bulgarian traditions for clear and specific standardization and high demands on quality and safety.

Organoleptic criteria have the most direct relation to the general consumer perception, tolerance, satisfaction not only of the taste, but also of the aesthetic needs of the consumer. In the one-component assortments the ratios main product:filling are standardized. In the multicomponent ones, the ratios of individual important components of the recipe are standardized.

The physico-chemical criteria depend on the main composition of the cans, the added table salt, starch, citric acid, sugar, vegetable fats and other non-vegetable components. So far, the TD does not reflect the content of dietary fiber. The concentration of table salt is normalized in all assortments, which varies from 0.7% to 2.0%. But the most important criterion is the active acidity (pH), the value of which is crucial for the effectiveness of sterilization regimes. It is standardized in all assortments and its value in most of the production exceeds 4.2, which considered a risk limit for the development of pathogenic clostridia. The company's products contain cans of low acidity, with a pH of 6.0 and higher (peas, green and ripe beans, chickpeas), in which the risk of residual post-sterilization microflora is high, including that of clostridia and in particular C. botulinum. However, in these circumstances, the risk is not only from them, but also from the aerobic bacilli such as B. srearothermophilus, B. coagulans, B. megatherium, B. subtilis, B. brevis, B. cereus, which cause spoilage, expressed by bulging or flat acid fermentation, and anaerobic clostridia such as C. thermosacharolyticum, C. histolyticum, C. sporogenes, C. bifermentans, C. butiricum, C. nigrificans, C. pasteruranum and

others. Some of these microorganisms are thermophilic and are the main causes of squamous fermentation.

The technological documentation also includes toxicological indicators - toxic elements, standardized according to the tradition of the Bulgarian standards - honey, arsenic, inorganic tin, in all assortments of canned vegetables. This, with the exception of tin, is not harmonized with EU Regulation № 1881/2006, which requires the standardization of lead (up to 0,10 mg / kg for vegetables and up to 0,20 mg / kg for legumes), of cadmium up to 0, 05 mg / kg and of inorganic tin - up to 200 mg / kg. Undoubtedly, it is most correct to place the requirements for toxic elements at the entrance (during the incoming control) - when accepting the raw materials with the appropriate certificate from the suppliers for the absence of lead and cadmium. This would solve the problem of toxicological criteria.

The technological documentation also formulates the requirements for industrial sterility - the most important condition for the safety of foods preserved by sterilization. The criterion "thermophilic micro-organisms" - aerobic, facultative anaerobic and anaerobic, can be included in the specifications with the stipulation that their control should be carried out only if there are special indications for this - deterioration of the properties of individual batches.

Preparation of raw materials by separation, cleaning, washing, flotation, etc. before sterilization it removes most of the soil and microbial contaminants and is the most important preventive stage of the technological processing of canned food. To achieve microbiological safety, ie industrial sterility, the type and volume of packaging are of particular importance.

The main raw materials - tomatoes, peppers, etc., are an excellent environment for the development of microscopic fungi and can be carriers of mycotoxins (patulin), but the problem is still in the research phase, not clarified at European level and not set in the relevant Regulations.

Probably due to the not very strict sterilization regime and due to the dangers of the development of fungal flora after the opening of the airtight packages by the consumer in one of the assortments - lyutenitsa "Smart" is planned to use potassium sorbate. The authors should know that the use of preservatives in sterilized cans is unacceptable and this should be corrected in the production, respectively, in the relevant documentation.

The most important section laying the foundations of HACCP is the one with the description of the technological process. In the considered technological documentation of the company for the separate assortments it is described in principle, with marking of the main stages. Details such as specific technological parameters, such as temperatures, exposures to thermal effects, atmospheric pressure in autoclaves and rotomats, are apparently recorded in the GMP Work Instructions and are not provided to us for the critical analysis of the System. The considerations for this are probably related to the confidential nature of the technological parameters, which is understandable. In Figure 3 we present a typical diagram of the processes in which the critical and critical control points are indicated.

It should be noted that the preparation of raw materials, which are both fresh and frozen, even dried, is a very complex, stepwise process, different for different

vegetables, their freshness and degree of processing at the time of entering the technological cycle. Unfortunately, complete information on all regimes has not been provided, probably for the above reasons of confidentiality. This does not allow for a more in-depth comment on the effectiveness of pre-sterilization and sterilization heat effects on the main hazards - microbiological.

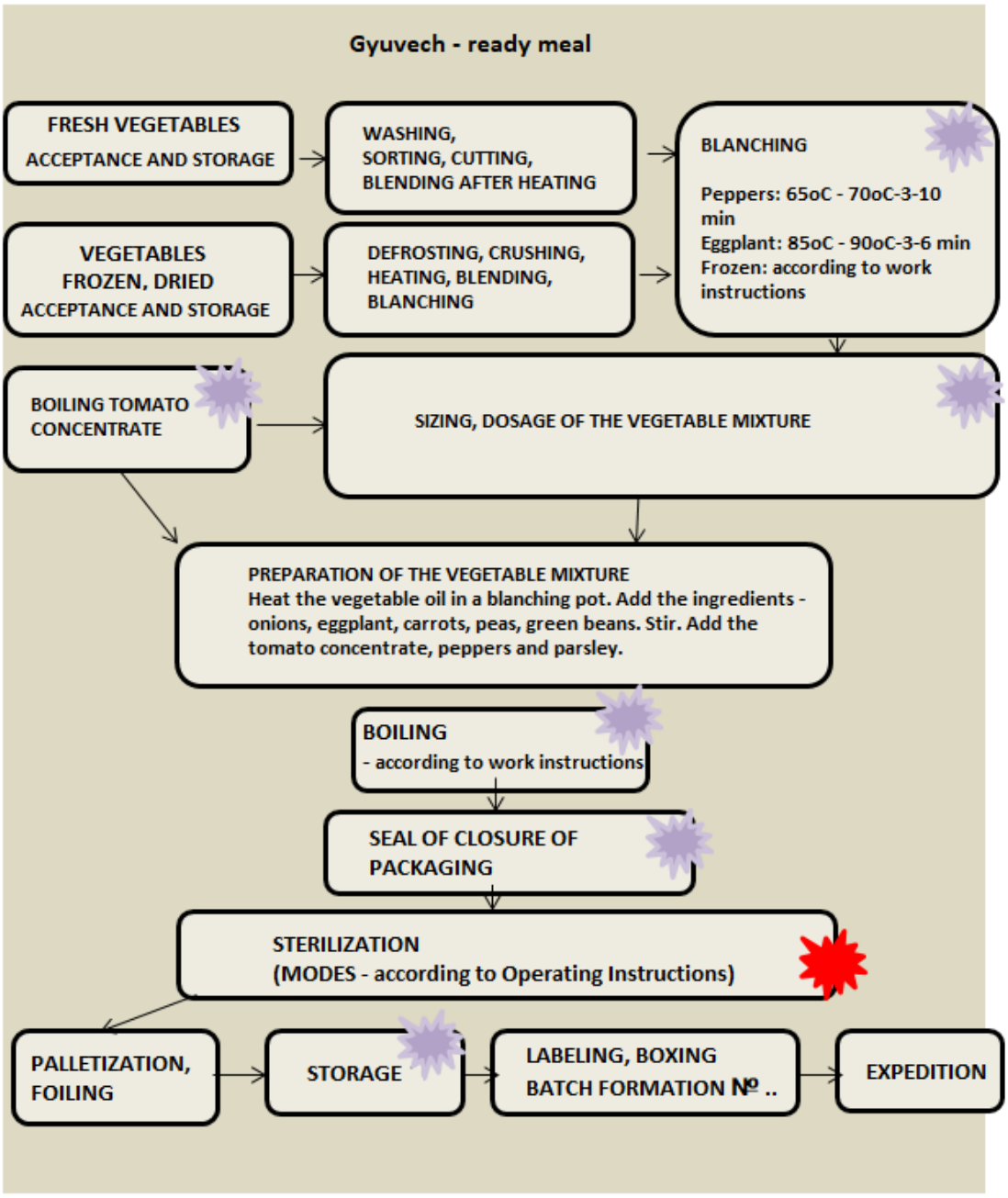

Figure 3- Multicomponent canned vegetables (Casserole - ready meal)

Legend to the figure:

Control Pont (CP)

Critical Control Point (CCP)

There is one very important point in the Technological documentation - the so-called "Storage" of the finished product, ie. storage of cans under certain temperature conditions for a certain period of time - during which defects in sterilization could possibly occur, expressed mainly by bulging.

According to the HACCP plan:

The hazard analysis is presented separately for sterilized canned vegetables and sterilized ready meals. It is detailed and individual for each assortment.

In the hygiene of the canning production and specifically in that of the company, the biological dangers are at the forefront. The main one being known and current is the danger of pathogenic anaerobes and in particular, of C. botulinum.

The approach adopted by the team in the analysis is correct, the hazards are considered in detail for each step in the technological processes, they are assessed according to the probability and seriousness, their complex significance; the physical, chemical, biological hazards are formulated separately, the allergens are targeted. The general approach is literate, objective, implemented systematically and consistently. As a final result, the analysis provides a basis for determining critical and critical control points.

However, there are also inaccuracies in the interpretation of the significance of biological hazards. For example, the wording "staff contamination with pathogenic micro-organisms (E. coli)" is inappropriate. Also no less inaccurate is the wording "Survival of spores of pathogenic bacteria - E. coli, S. aureus, enterococci, coliforms during storage." The cited microorganisms are neither pathogenic nor form spores. Spores can indeed survive, but these are the spores of microbes of the genera Bacillus and Clostridium, which are a danger that comes with the raw materials. The cited E. coli, L. monocytogenes, Salmonella, S. aureus, hepatitis A viruses are non-spore-forming and for them the operations are fatal even during blanching. The team is obviously not aware of the indicators of the hygiene process and pathogenic bacteria.

The biological danger in the blanching stage is very professionally noted - blanchers can become a nest of permanent reinfection with heat-resistant microorganisms.

In the analysis of the dangers of other types of damage to the products that pose a risk to human health, the second place of interest to the team is occupied by physical hazards - mainly mechanical damage and foreign bodies associated with dosing and filling operations in packaging, especially glass. Chemical hazards are given due attention, but their severity and likelihood of occurrence are limited.

The undisputed critical control point in this production - the sterilization regime, has been correctly determined by the team.

Thus, the analysis of the hazards in the production of sterilized canned vegetables in the company, gives grounds for the identification of 4 critical points (CP) and 1 critical control point (CCP), as follows:

- CP 1: in the stage of pre-processing / blanching - biological;
- CP 2: in the stage of vegetable dosing - physical;
- CP 3: in the stage of closing the packages - physical;
- CP 4: in the stage of post-sterilization storage - biological.
- CCP 1: in the sterilization stage - biological.

With this essentially correct approach in the development of HACCP principles, the team has adequately identified the hazards and the relevant control and critical control point, using the standard course of questions from the "decision tree". Here comes the place of the verification of the HACCP procedures, in which the answers

to the questions about their effectiveness in CP or CCP are given by the periodic microbiological analyzes. The documentation provided to us for critical analysis does not contain information on the implementation of this principle (№ 6) of HACCP.

The documentation of HACCP activities for canned vegetables and ready-made vegetable dishes is well constructed and ensures traceability of batches and processes.

We systematize the critical remarks and the proposals for corrections and optimization to the prerequisite programs and to the HACCP system for production of canned vegetables, as follows:

a) to the Technological documentation:

– To quote the updated legislative and normative acts in the TD;

– In the incoming control to set requirements for the content of toxic elements in the raw materials (lead, cadmium, copper, arsenic);

– In the assortment "Lutenitsa Smart" to eliminate the use of potassium sorbate;

– In the labels in the section with nutritional information to specify the numerical values for the individual criteria;

– In the table with the indicators for industrial sterility to exclude the incorrect entries (eg "vegetative forms of non-spore-forming and spore-forming, d"). Include additional microbiological criteria such as "yeast" and "thermophilic micro-organisms". In Table 2 we offer an entirely new record of microbiological criteria and requirements:

– To include in the technological schemes a section "storage" with the corresponding standardized temperature and other mode.

Table 2. Recommended microbiological criteria and requirements

Microbiological indicators	Requirements
1. Mesophilic aerobic and facultative anaerobic micro-organisms:	
1.1. Vegetative forms of spore-forming and non-spore-forming	*Not allowed*
1.2. Spores of aerobic spore-forming agents, CFU / g, not more than:	*10*
2. Mesophilic anaerobic microorganisms	*Not allowed*
*3. Thermophilic microorganisms **	*Not allowed*
4. Molds and yeasts	*Not allowed*

* The indicator is examined only in case of deterioration of the quality, spoilage and other special indications

b) To the HACCP System:

– Incorrect descriptions of biological hazards should be deleted and the texts should be re-edited. For example, "contamination with pathogenic microorganisms (E. coli) by staff" (in this case cited as an indicator criterion), "survival of spores of pathogenic bacteria - E. coli, St.aureus, enterococci, coliforms during storage" (cited microorganisms in general do not form spores);

– In the verification procedures it is obligatory to include microbiological tests - once on the efficiency of the preparatory blanching and secondly - the

efficiency of the actual sterilization. In Tables 3 and 4 we offer the following two verification procedures:

Table 3 - HACCP verification for sterilized canned vegetables in CP 1 (preparation of raw materials / blanching)

Criteria	Frequency
Total number of mesophilic aerobic and facultative anaerobic microorganisms, CFU / g	Every 6 months
Spores of mesophilic aerobic and facultative anaerobic microorganisms, CFU / g	Every 6 months
Thermophilic microorganisms - vegetative and spore forms	Every 6 months
Enterobacteriaceae, CFU/g	Every 6 months
Mold and yeast, CFU / g	Every 6 months

Table 4 - HACCP verification for sterilized canned vegetables in CCP 1 (sterilization)

Criteria	Frequency
Mesophilic aerobic and facultatively anaerobic microorganisms - vegetative forms of spore-forming and non-spore-forming; spores	Monthly
Mesophilic anaerobic microorganisms	Monthly
Thermophilic microorganisms – vegetative and spore forms	Every 3 months
Molds and yeast, CFU/g	Monthly

CHAPTER 3

HACCP IN THE PRODUCTION OF CATERING CULINARY DESSERTS AND CONFECTIONERY

The company is a combined site for the production of a wide range of culinary products, among which desserts and pastries occupy a large share. According to the nature of the activities and the manufactured products, the site is classified in the group of those with a high degree of risk. The culinary desserts are based on milk or pasta, and the confectionery products are of the pasta type, mainly sponge cakes. The different assortments hide various degrees of danger and probability. It is known that traditionally the predominant number of outbreaks of food diseases in our country are after consumption of culinary products and through the fault of catering establishments.

The prerequisite programs are detailed and concretized to the authentic goals and conditions of production of catering and confectionery products and represent a

type of GMP and GHP. We consider the content of the Technological documentation separately.

In the Technological documentation for "Culinary desserts" the formal order defined in Ordinance № 1/2016 of the Ministry of Health and the Ministry of Agriculture is observed. Desserts are classified into two radically different heterogeneous groups: milk-based desserts (milk with rice, milk with semolina, semolina halva, creme brulee, caramel creams, caramel with croissant and caramel with Easter cake); and dough-based desserts (biscuit cake, baked pasta, milk pie, stuffed pancakes).

The nutritional and biological value of desserts can be judged by the integrated physico-chemical indicators (Table 5):

Table 5 - Physico-chemical criteria for evaluation of culinary desserts with milk and dough base:

INDICATORS	REQUIREMENTS	
	Of desserts with a milk base	Of desserts with a dough base
Dry matter, % of total mass	-	40 - 60
Carbohydrates, % of total mass	30 - 40	40 - 60
Total sugar, %	18 - 25	-
Fat, %,	no more than 1,0	2,0 – 5,0
Saturated fatty acids, %, no more than	0,5	-
Total protein, %	0,5	2,0 – 5,0
Table salt, % of total mass, no more than	5,0	-

These are low-fat products with a high carbohydrate content and a small amount of protein. An unnaturally and unjustifiably high concentration of table salt has been declared, which we consider to be a gross technical error that must undergo a correction. Of the safety indicators, only the microbiological ones are regulated, which are minimized - only staphylococci and molds.

The technological processes for desserts are classic culinary technologies with the application of heat treatment in suitable appliances - a tilting bratt pan for cooking and a combination oven for baking - Figure 4:

Essentially, this scheme includes two completely different technological schemes, the differences being in the nature of the thermal regime, the packaging, the method of serving and the shelf life. Cooked "bulk" products are perishable with a shelf life of up to 30 hours, while baked desserts are packaged and stored in refrigerated conditions for up to 5 days. They are at risk of secondary contamination.

The definition that "cooking" is performed at a temperature of 100°C - 130°C, which is actually sterilization, leads to confusion. It is necessary to clarify the technological parameters in the relevant texts of the TD.

The real possibility of secondary contamination in many manual operations after heat treatment brings a risk. In view of this, in order to ensure the safety of the culinary desserts, it is appropriate to include Escherichia coli (n = 5; c = 2; m <1; M <10) as a criterion for the hygiene process, and for milk desserts with semolina and

rice. - and Bacillus cereus (n = 5; c = 2; m <1; M <10). The absence of Salmonella spp. (N = 5; c = 2; m - absence in 25 g) also needs to be standardized.

In the HACCP documentation provided to us, we did not find research to explain the shelf life of the products.

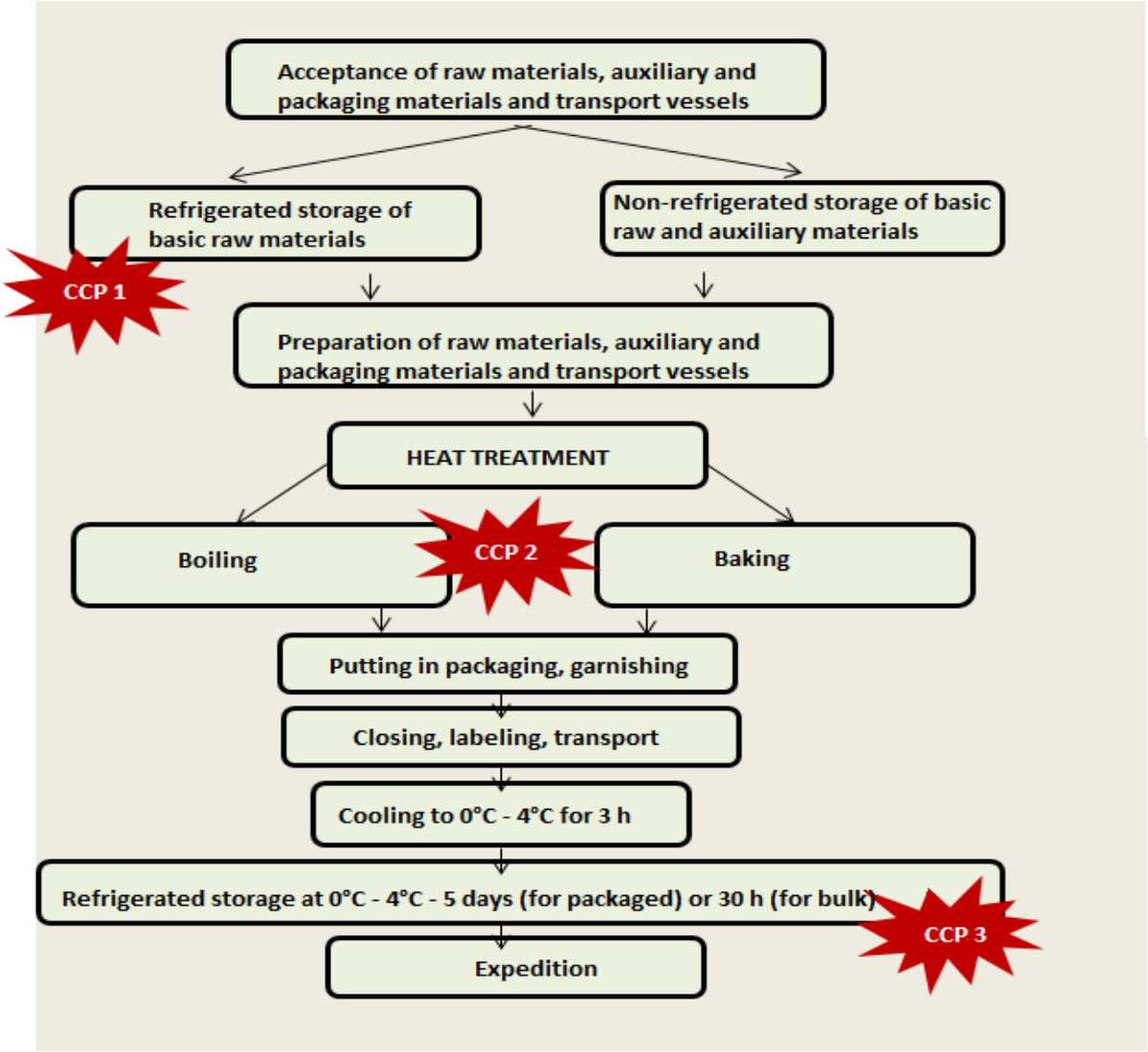

Figure 4 - Technological processes in the production of desserts

Spongecake pastries are small petit fours, cakes, cake rolls, sweets, biscuits and more. The following creams are used: Bavarian, dairy cream, butter, mixed and various glazes, couverture, chocolate. A part of the assortment refers to the moist confectionery products, which have a limited shelf life and must be stored in refrigerated conditions. The other part is dry confectionery that does not require low temperature storage.

The standardization of the physico-chemical indicators is wrong and unrealistic and does not provide a basis for control and self-control. The microbiological criteria for the production emphasize safety - salmonella, staphylococci, coliforms.

The production technology is traditional for confectionery. The sponge cake dough is baked at temperatures from 170°C to 300°C, depending on what products the confectionery bases are used in. The products are brought to readiness by manual operations with the use of filling masses, cold creams, syrups, glazes, couvertures and

the corresponding decoration. This is the actual critical control point where secondary contamination is possible - see Figure 5.

Moist confectionery products are stored in refrigerated conditions at 0 - 4°C for up to 5 days, for some assortments (mini cakes and mini rolls) - up to 1 month. The logic of these differences in shelf life is not clear. Dry durable confectionery products (eg biscuits) are stored for up to 8 days in a dry and well ventilated place.

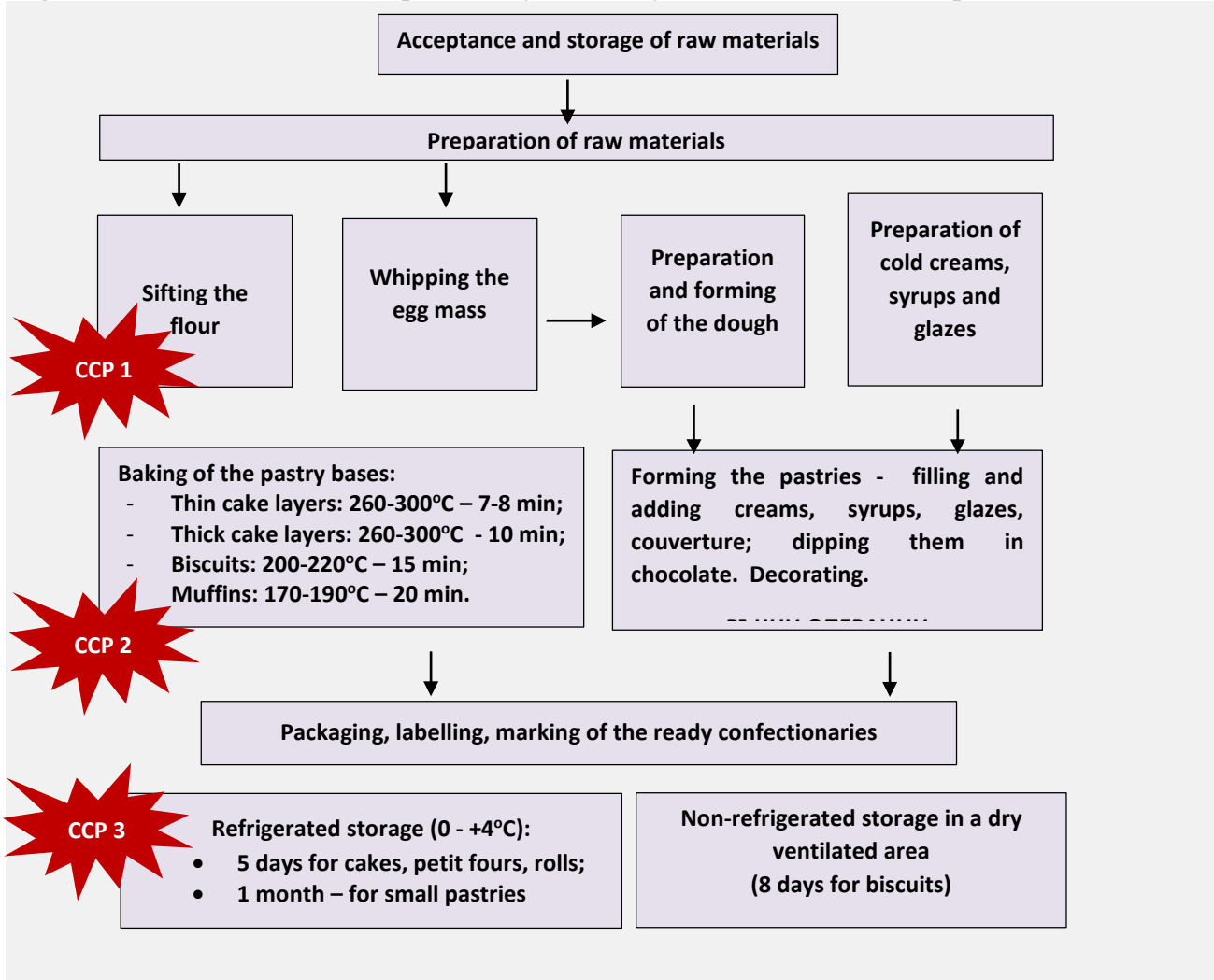

Figure 5 - Technological scheme of the production of confectionery of sponge cake dough

Confectionery products from puff pastry and choux pastry dough are a very heterogeneous group not only in terms of assortment, but also as a degree of risk. These are oriental pastries (baklava, triguni) and choux pastry dough products such as eclairs, walnut sweets, petit fours, cheese pastries and more. The recipes for both types contain creams, glazes, couverture, jam, fondant. In addition to conventional raw materials, the products contain coconut and hydrogenated palm oil and technological additives: tartrazine dye, sunset yellow, gelling agent pectin, E 407, E 401, lecithin, preservatives, acid regulators, etc., which require special control.

The physico-chemical parameters are indicated very briefly, and their limits are unreasonably wide (eg sugar, % of dry matter - 1.0 - 20.0) and do not reflect the specifics of the different assortments of this group of confectionery.

The technology is typical for confectionery production: dough preparation; baking at set temperature parameters depending on the purpose of the confectionery

bases; preparation of creams (at this stage cold creams from dry semi-finished products), syrups, fondant, couvertures; inserting the fillings, decorating, shaping; packaging. Manual operations are predominant, which creates a risk of secondary contamination with unwanted microorganisms - the main dangers for both the consumer and the product.

The analysis of the HACCP plans for culinary desserts and confectionery gives grounds for the following conclusions and suggestions for corrections:

The approach of the team in developing the HACCP plan for the production of culinary desserts and confectionery is systematic and logical and follows the basic principles of HACCP set by Codex Alimentarius. The hazard analysis highlights microbial agents as leading biological hazards in the refrigerated storage of raw materials, in the heat treatment of products and in the storage of finished dessert products.

Additional manual operations after heat treatment lead to secondary contamination of some of the desserts with microorganisms. This applies to both culinary desserts and moist sponge cake-based confectionery. There is a risk of getting pathogenic staphylococci, salmonella, listeria, intestinal viruses, Escherichia coli, Bacillus cereus and others. Then there is no process that could decontaminate the products. CCP 2 is not adequate for these assortments. It is very important to move CCP 2 after the manual operations.

There are no categories and boundaries marked with exact numbers. There is compliance with the rules of high level of personal hygiene and hygiene of the working environment:

– operators with signs of diseases are not allowed - inflammatory processes in the upper respiratory tract, skin; gastrointestinal discomfort or disorders;

– high level of hygiene of work clothes;

– regular microbiological control of hands, work clothes, work environment and tools;

– periodic monitoring of carriers of pathogenic staphylococci in the upper respiratory tract and skin of staff and of carriers of intestinal infections;

– high and controlled level of washing and disinfection of the room, work surfaces and tools;

– and others.

The other two critical control points, CCP 1 and CCP 3, have been identified correctly and adequately to the hazard levels.

Microbiological regulation is incomplete and insufficiently reflects the specifics of the hazards. For verification of the system according to Principle 6, it is appropriate for the internal monitoring program to include microbiological criteria as follows:

Table 6 - HACCP verification monitoring program for culinary desserts and moist confectionery

Criteira	Norms				Frequency
		c	***m***	***M***	
E.coli, CFU/g		2	1	10	Every month
****Bacillus cereus, CFU/g***		2	10	100	Every 3 months

Salmonella spp.		0	Absence in 25 g		Every 6 months
Coagulase-positive staphylococci, CFU/g		2	10	100	Every 6 months

***** The criterion applies only to the assortments with semolina and rice

The internal monitoring program should also cover samples of the work environment, tools and operators. Samples from the working environment and tools are taken after washing and disinfection and immediately before the start of the working process (Table 7).

Table 7 - Required microbiological criteria for samples from the work environment, the tools and the operators involved in the design of the products and coming into direct contact with the production:

Types of samples	Microbiological criteria	Norms	Frequency
Work surfaces - swabs	*Coliforms*	Should not be found	Every month
Confectionery tools- swabs	*Coliforms*	Should not be found	Every month
Staff hands- swabs	*Coliforms*	Should not be found	Every 2 months
	Coagulase-positive staphylococci,	Should not be found	
Workwear - swabs	*Coliforms*	Should not be found	Every 2 months
Upper respiratory tract - taken with a sterile swab from the nose and throat	Coagulase-positive staphylococci,	Should not be found	Every 6 months

Some additional summaries and recommendations to the TD and HACCP plans:

– Primary contamination of raw materials with microorganisms has no essential meaning for desserts and confectionery products due to the high temperatures applied in production;

– The physico-chemical criteria set out in the TD are too broad, this limits effective quality monitoring and should be competently revised;

– The shelf life of the products should be motivated by appropriate analytical procedures;

– Adequate staff training, constant monitoring, registration of hygiene procedures, periodic laboratory tests of the working environment for the presence or carrier of pathogenic staphylococci, intestinal bacteria and other unwanted microorganisms are required;

– Serious revision of the verification procedures is required with external control of the desired criteria for composition, physico-chemical and microbiological characteristics of the finished products.

Only after such additions and clarifications will the HACCP system acquire an adequate format and will be able to fulfill its preventive role in preventing foodborne diseases due to this type of production.

CHAPTER 4

HACCP IN THE MANUFACTURING OF CATERING CULINARY PRODUCTS - SOUPS, COOKED HOT MEAT DISHES, ROASTED AND GRILLED MEAT PRODUCTS.

The manufacturer produces various catering foods, offered on site or feeding other establishments and commercial sites and carrying hazards with a high degree of seriousness and probability, resp. high degree of risk. The company has a suitable building stock and well-developed infrastructure. The internal control system was developed by the HACCP team in the form of company programs for GMP and GHP.

An essential part of the prerequisites is the Technological documentation, which in structure meets the requirements of Ordinance № 1/2016 of the Ministry of Health and the Ministry of Agriculture and Food. In is the catering production of the company is divided into three large groups - soups, cooked meat dishes and roasted meat products.

The soups are produced by the company according to traditional multi-component Bulgarian recipes and are classified into three groups - meat, meatless, cold soups. The raw materials used are also contained in the names of the assortments of meat, fish, offal, fresh vegetables, eggs, yogurt, sunflower oil, legumes, spices. The TD for "Cooked meat dishes" contains a detailed description of ready-made multi-component dishes for direct consumption, prepared with chicken, pork and beef, minced meat and offal according to traditional Bulgarian recipes such as kebab, kavarma, moussaka, meatloaf, meatballs, drobsarma and others. The dishes also contain eggs; milk; legumes; cheese; fresh, frozen and canned vegetables; butter and sunflower oil; flour; spices.

The organoleptic characteristics give a good description of the soups, emphasizing their appearance. The organoleptics of the cooked meals are presented in separate tables, dividing them into four groups - one-component with meat with sauce, multi-component with meat, with poultry and minced meat.

In the normalization of the physicochemical parameters, logically, negligible difficulties arose with very wide limits of the dry matter and fat content (Table 8).

Table 8 - Physico-chemical parameters for soups and ready meals

INDICATORS	REQUIREMENTS	
	Soups	**Cooked meals**
Dry mass, % of the total mass	**10 - 15**	**10 - 50**
Fat content, % of the total mass	**5,0 – 20,0**	**2,0 – 30,0**
Acidity (for example acetic acidity), %	**0,10 – 0,20**	**0,15 – 0,40**
Table salt, %, no more than:	**1,0**	**1,0**

This is due to the complex multi-component composition of soups and cooked meals and the peculiarities of culinary processing. In order to avoid this wide range of

requirements, it would be appropriate to differentiate and present the rationing of physicochemical parameters separately. There is no criterion for protein content. This is not compensated by organoleptic characteristics in which quantitative ratios of the meat component to the sauce, for example, or other non-meat ingredients of soups and dishes are not marked. The announced relatively low salt content is positive for consumer health.

The technological process for soups is similar to that for ready meals. The importance of heat treatment is crucial. The meat is cooked in a combination oven/tilting bratt pan until the temperature inside reaches 75°C, and in practice - even higher. The vegetable ingredients are separately cooked or stewed. Afterwards follows mixing and the following culinary procedures and, of course, cooking. The addition of plant spices carries the risk of large amounts of soil microflora containing heat-resistant spores. This has a strong effect on the residual microflora of the products.

In some of the hot soups there is a special risky moment - the addition of egg-based thickener. The composition and method of preparation of the egg-based thickenerc are not reflected in the TD at all, but it is known that they most often cause secondary contamination and introduction of pathogenic microorganisms into the soups and during further storage their reproduction creates large infectious doses. In Bulgaria, severe food outbreaks of salmonellosis have been described, caused by soups thickened with egg mixtures. This circumstance has been taken into account in the past and in the hygiene rules for public catering establishments mandatory procedures have been created for the application exclusively of cooked egg-based thickeners. This procedure must be included in the text of the TD technology section.

The microbiological criteria for assessing the hygiene of the processes in soups are presented by only one indicator - Coliforms (n = 5; c = 2; m = 100; M = 1000 CFU / g). It actually reflects the risk of secondary contamination. The technology of hot soups, as we will see later, excludes residual microflora represented by non-spore-forming bacteria.

The criteria for microbiological safety of cooked dishes are selected in a very special way. The sulfite-reducing clostridia (n = 5; c = 2; m = 10; M = 100 cfu / g), Pseudomonas spp. (n = 5; c = 2; m = 10; M = 100 cfu / g), and yeast (n = 5; c = 2; m = 10; M = 100 cfu / g).

The residual microflora is scarce and is represented by spore forms of mesophilic and thermophilic bacteria. Another issue is that the subsequent operations of poring, dividing, placing in different types of packaging, storage until the time of consumption lead to inevitable secondary contamination and very rapid dispersal of residual spores and re-imported microorganisms if the refrigeration chain is broken. Indeed, in culinary processing very important criteria for the hygiene of the processes are the spore-forming microorganisms - representatives of the residual primary microflora. However, aerobic microorganisms of the genus Bacillus (Bacillus cereus) are not regulated, which are a more common and reliable criterion for process hygiene. There are no more integrated criteria for secondary contamination - Coliforms or at least E. coli. Instead, Pseudomonas spp. Is mentioned, which is a very good indicator of secondary contamination, but is relatively rare, and its presence

would be an expression of extremely poor hygiene. The logical solution is to replace it with Coliforms or at least E. coli. Yeast is really a good hygienic indicator – they are also a secondary contaminant and are related to the shelf life of ready meals.

The EU Regulation № 2073/2005 for 'ready-to-eat foods', such as hot soups and cooked meals, explicitly regulates the absence of Listeria monocytogenes. However, we should take into account the footnote stating that this safety criterion does not apply to proven Listeria-fatal technology. Pathogenic microorganisms - salmonella, listeria, staphylococci, die during cooking and can get into soups and dishes only by the mechanism of secondary contamination by operators and the working environment. This gives grounds to list pathogenic microorganisms in the list of microbiological indicators and norms only in cases of epidemic and other special indications.

In the final sections of the TD there are oversights in soups and, similarly, in ready meals with meat. There is no procedure for heating chilled soups and dishes. The temperature for storage in a warm state before consumption is not clarified. This temperature should not be lower than 65^{o}C. Lower temperatures would play the role of a thermostat for thermophilic microorganisms, and below 45^{o}C - for mesophilic bacteria. The expiration date after the expedition is not specified. Warm ready-to-eat meals are transported immediately to the enterprises in which they are sold. These important details should be reflected in the TD and to be added to the "Storage, Transport and Disposal" section. In their absence, the manufacturer disclaims any responsibility for safety in the period after shipment to the final consumer.

The cooked culinary products of the company (on a grill, plate or in a combination oven) are mainly meat-based, from minced and whole meat, there are also potato assortments. The epidemic risk of them should not be underestimated. There is a risk that the temperature wont penetrate deep inside the meat, especially when grilling or on a plate. This is due to the low thermal conductivity of the meat mass, especially if it also contains animal fats. The likelihood of cells remaining viable inside meat products, especially after grilling, has been proven. A violation of the refrigeration chain during storage can lead to the proliferation of these cells and cause infectious processes. Such cases are described by the practice in our country and the risk of them is not negligible.

The technological documentation is developed for cooked culinary products, intended for expedition to the market, mainly culinary stands in the supermarkets or in public catering establishments. For this purpose, immediately after the heat treatment and hot packing, the products are cooled for 3 hours at 0 - + 4^{o}C and placed in special refrigerating chambers at a temperature from 0 to + 4^{o}C for 30 hours. No storage requirements have been developed after this period - both for temperature and for its duration. Thus, the producer does not take responsibility for the safety of meat products after the shipment. This circumstance obliges him to offer products free of pathogenic and indicator microorganisms, and this should be reflected in the main prerequisite documents - TD.

The qualitative characteristics in organoleptics are described for each of the products. The physico-chemical parameters conscientiously reflect not only the water content and the fat content, but also the protein content (20 - 40%), although this is

not necessary for the products of whole meat. The upper limit of table salt is high (2.5%), especially for whole meat products, as well as for the potato assortments. It is not recommended that this product of the company enter the unwanted ranking of unhealthy foods.

A special approach has been taken as far as the microbiological criteria is concerned. Only Listeria monocytogenes is normalized. However, Salmonella spp., Which is more likely to be in Bulgarian foods, must also be included in the norms for roasted meat products. There are also no criteria for process hygiene. For this purpose, it is recommended to include E. coli (n = 5; c = 2; m = 10; M = 100); Bacillus cereus (n = 5; c = 2; m = 10; M = 100); sulfite-reducing clostridia (n = 5; c = 2; m = 10; M = 100).

The HACCP plan is compiled in a logical order following the development steps and is particularly detailed in the main, crucial stages. The three groups of culinary products - cooked meat dishes, soups and baked culinary products, have separate hazard analyzes. Biological hazards are leading. The critical limits are clarified in the pre-requisite data, they are confirmed in the TD and this gives grounds for an exact monitoring and clear corrective actions.

A significant omission in the HACCP documentation is the absence of CCP and appropriate monitoring for the sector that offers hot culinary products. The storage of hot culinary soups and dishes in the sector must be a separate control point with clearly marked permissible parameters - temperature above 65ºC and realization - until the end of the working day.

The most complicated for business operators is the designation and conduct of verification procedures. In essence, the section records procedures that are performed at the monitoring stage (eg cooking or boiling temperatures or those in refrigeration facilities). There is no real verification of the effect on the organoleptic and microbiological qualities of the production. The monitoring program should record all additions with pathogenic and indicator microbiological indicators, which should be used in the verification of procedures throughout the process, not only of production, but also of storage of finished products. We offer in Tables 9, 10 and 11 appropriate verification programs for the three types of products:

Table 9 – Verification program for ready-to-eat soups

Criteria	Norms				Frequency of testing
	n	c	m	M	
Coliforms, cfu/g	5	2	10	100	Every month
Salmonella spp.	5	0	Absence in 25 g		Every 6 months
Listeria monocytogenes, cfu/g	5	0	<100	-	Every 6 months

Table 10 – Verification program for ready-to-eat meals with meat

Criteria	Norms				Frequency of testing
	n	c	m	M	
Coliforms, cfu/g	5	2	10	100	Every month

Сулфитредуциращи клостридии, *cfu/g*	5	2	10	100	Every 3 months
Bacillus cereus	5	2	10	100	Every 3 months
Yeast, *cfu/g*	5	2	10	100	Every 3 months
Salmonella spp.	5	0	Absence in 25 g		Every 6 months
Listeria monocytogenes, cfu/g	5	0	<100	-	Every 6 months

Table 11 – Verification program for ready-to-eat cooked meals with meat

Criteria	Norms				Frequency of testing
	n	c	m	M	
Coliforms, cfu/g	5	2	10	100	Every month
Salmonella spp.	5	0	Absence in 25 g		Every 6 months
Listeria monocytogenes, cfu/g	5	0	<100	-	Every 6 months

In conclusion, we believe that after adjustments the prerequisite programs, technological documentation and HACCP-plans of the company can be built correctly and successfully applied with in-depth verification of processes, for more reliable conditions for the production of safe and quality catering products, which is generally a carrier of high levels of risk.

CHAPTER 5

HACCP PLAN FOR THE PRODUCTION OF PASTEURIZED CANNED VEGETABLE PRODUCTS

The products produced are typical pasteurized canned vegetable products according to traditional Bulgarian recipes - lutenitsa, tomato products. Lutenitsas are both classic and spicy assortments and ones with mushrooms. Canned tomatoes are tomato paste, tomato sauce, peeled diced tomatoes. No preservatives are used in hermetically sealed glass packages, benzoate and sorbate are used in those undergoing one-stage pasteurization. Technological additives are traditional - modified starch, citric acid. Sucralose is used as a sweetener.

The manufacturer has a separate building stock. The teams obviously have sufficient professional experience and knowledge in the field of modern European requirements for food safety control systems and the respective responsibilities of the manufacturer. The documentation is developed smoothly and logically, consistently and clearly.

The complex of prerequisite activities is indicated in GMP and GHP Programs and in Technological documentation for all produced assortments, in plans and procedures, in orders, registers and other documents. These activities precede the development of HACCP, but set the main specific problems of production in a clear and consistent order.

The main technological processes are high pasteurization, there is also the localization of the critical control points, determined during the development of the HACCP plans.

In the Technological documentation we find serious gaps in many sections, especially in the health and hygiene indicators and norms and other details related to the safety of the finished products.

Schematically, the technological processes of production of the two groups of products - lutenitsa and tomato products, are very similar and are presented in Figure 6.

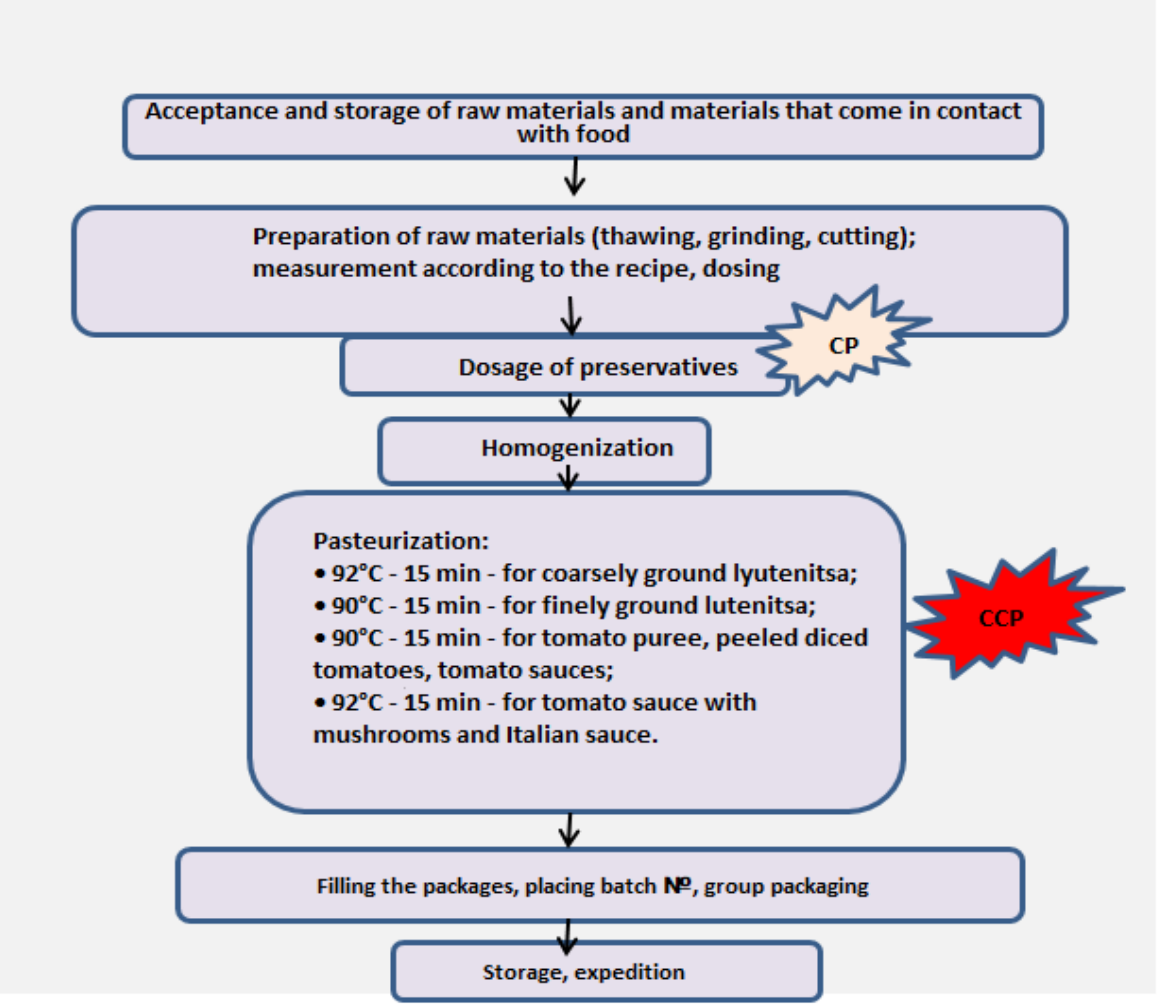

Figure 6 - Technological scheme of the processes of production of pasteurized canned food with preservatives: lyutenitsa (traditional, Danube, Pleven, homemade rural, homemade, spicy), lyutivka, appetitka - coarsely ground and finely ground; tomato paste, tomato sauces and diced peeled tomatoes in tomato sauce

The critical analysis of the Technological documentation gives grounds for the following more important conclusions:

A dry matter content of no less than 15 - 16% was found in TD for lyutenitsa. The active acidity varies widely - 3.5 to 5.0. First of all, the standardized very high content of table salt is impressive. An integral norm for all assortments has been established - 3.5%, which definitely puts lyutenitsa in the group of unhealthy foods. At the same time, the nutritional information announces completely different values,

much lower - from 1.42 to 2.49. We consider it necessary to indicate the amount of salt in real terms, different for different assortments and not more than 1.5 to 2.0%.

Another serious defect in TD for lyutenitsa is the normalization of microbiological indicators - Table 12:

Table 12 - Microbiological requirements for lyutenitsa and tomato products

Indicators	Characteristics and norms
Sulfite-reducing clostridia, cfu/g	< 10
Mesophilic aerobic and facultative anaerobic microorganisms, cfu/g	< 10
Molds, cfu/g	< 100
Yeast, cfu/g	< 100

The first discrepancy is that there are no differences in requirements between the assortments with single pasteurization, added preservatives and non-sterile packaging (plastic buckets) and those with double pasteurization, one of which is quite high, without preservatives and packed in glass jars. And these differences should be significant.

It is very important that microbiological standards ensure the absence of anaerobic microorganisms in the hermetically sealed packages of lyutenitsa. The indicator "sulfite-reducing clostridia" refers to anaerobes, but has a much lower diagnostic sensitivity than the indicator "anaerobic microorganisms", determined by the method of BDS 6916/87.

Pasteurization does not provide complete industrial sterility, so the requirement for the permissible number of mesophilic aerobic and facultative anaerobic microorganisms as recorded - below 10 cfu / g, is unrealistically demanding. Pasteurized products contain residual microflora, most often represented by aerobic spore-forming species and micrococci. The practice in our country for this type of products - pasteurized canned foods, is normalization of aerobic and facultative anaerobic microorganisms to 8,000 cfu / g. In assortments subjected to double high pasteurization, it is more appropriate to limit this number to 100 cfu / g.

The norm for molds and yeasts is too undemanding. Their presence in quantities up to 100 cfu / g dooms the spoilage products during storage. Such a presence also means the inefficiency of pasteurization regimes. Such a rule is particularly incompatible for assortments with double pasteurization, packed in hermetically sealed packages.

This incompatibility of the criteria for microbiological purity with the nature, technology and durability of lyutenitsa leads to insufficiently adequate actions in the implementation of the HACCP system and specifically in the monitoring and verification of the processes. Without microbiological criteria, no real internal control of product safety could be achieved. The fact that there are no accidents does not mean that potential microbiological hazards are excluded. These could be, in the first place, unwanted changes and spoilage of production, and more seriously, though less likely, is the risk of foodborne illness.

The second technological documentation, which is being worked on in the workshop "Canned Vegetable Products", is a combined document describing the various tomato products produced - tomato paste, tomato sauces, peeled diced tomatoes and peeled diced tomatoes in tomato sauce. Tomato puree and peeled diced tomatoes are produced in two versions - with preservatives and without preservatives.

In the TD for tomato products at dry matter = 9 and pH, varying from 3.5 to 5.0, similar to lyutenitsa, a very high content of table salt is standardized. The established integral norm for all assortments - 3.5%, is inadmissible and definitely puts tomato products in the group of unhealthy foods. In the announced nutritional information, the values are much lower and practically do not exceed 2.0%, which is a real upper limit for all assortments in the group.

The normalization of microbiological parameters in tomato concentrates is also defective - similar to lyutenitsa (Table 12).

The correct presentation of the health-hygiene and quality indicators and the set norms is of exceptional importance for the functioning of the HACCP plans with a goal to establish adequate monitoring and verification of the System in the course of its implementation.

The section related to product labeling has been unconvincingly developed. The requirements of Regulation № 1169/2011 have not been taken into account.

According to the HACCP system: The hazards identified by the HACCP team in the raw materials for the production of canned vegetables are physical (foreign bodies), chemical (pesticide residues, heavy metals, mycotoxins), biological contaminants (pathogenic microorganisms). Eliminating them is a task at the stage of incoming control. One serious danger - the content of mycotoxins - has not been sufficiently assessed here. It is known that mostly patulin is a characteristic contaminant not only of fruits, but can also be found in tomato and pepper concentrates. To eliminate this danger, mycotoxins must become part of the certificates used to accept these two main raw materials. The dangers associated with the storage of raw materials are mainly the potential opportunities for reproduction of microorganisms, including pathogenic, in the absence of temperature regimes, oxidative changes in vegetable oils, the likelihood of contamination by foreign bodies.

The dangers associated with the technological processes are the contamination with foreign bodies (physical), the incorrect dosing of food additives and especially preservatives (chemical), and the survival of microorganisms in pasteurization procedures (biological). The risk of preservative overdose is associated with a control point (CP) for all assortments containing sorbate and / or benzoate.

The real critical control points (CCP) are in the pasteurization stages. The set parameters of the heat treatment are fixed in the TD, and the monitoring in the CCP logically covers the temperatures and exposure of impact. The necessary corrective actions in case of deviations from the parameters in CP and CCP are adequately described.

In the verification, in addition to the standard audit activity with current routine inspections, internal and external audits, calibration of measuring equipment, other steps, an important element is the taking and analysis of samples of finished products

in external accredited laboratories, which is carried out on an annual basis. The aim in this plan is to cover as many indicators and assortments as possible. There are also microbiological indicators, which, when properly formulated in TD, are reliable indicators of the hygiene of the processes, guaranteeing the absence of pathogenic microorganisms.

The analysis of the Internal Control System in the production of pasteurized canned vegetable products gives grounds for the following generalized findings and recommendations:

• In a very well-developed pre-requisite production program, significant discrepancies are found mainly in the Technical Documentations, which are otherwise a well-laid basis for the development of the HACCP system:

– It is necessary to reduce the norm for the content of table salt in lyutenitsas and canned tomatoes to no more than 1.5 - 2.0%;

– It is necessary in the assortments in hermetically sealed packages instead of “sulfite-reducing clostrides” to standardize the indicator “mesophilic anaerobic microorganisms - not allowed” in the sense of BDS 6916-87;

– It is expedient the assortments with a single heat treatment to normalize the total number of mesophilic aerobic and facultative anaerobic microorganisms up to 8,000 cfu / g, and in those with double - up to 100 cfu / g;

– In both lyutenitsa and tomato products the norm for mold and yeast should be "no more than 10 cfu / g";

– In the section for incoming control of raw materials in pepper and tomato concentrates to require certificates for the absence of mycotoxin patulin.

• The HACCP plan for the production of pasteurized canned vegetable products (lyutenitsa and tomato products) has been developed methodologically correctly, in accordance with the requirements of the Codex Alimentarius and the relevant EU Regulations and ISO standards. The section related to Principle 6 "Verification" should be supplemented by periodic inspections by microbiological analysis of the production in accordance with the adjusted microbiological safety criteria.

CHAPTER 6

HACCP SYSTMES IN THE PRODUCTION OF SAUCES

The sauces are intended for direct consumption and can essentially be referred to as "Emulsion products", with a high water content and a lot of technological additives. The company produces a variety of assortments - mustard, mayonnaise sauces, tomato sauces ("Samurai", "Chile", "Mexican", "Barbecue", "Ketchup"), culinary sauces - "Garlic" and "Tartar". The composition of the sauces includes a variety of raw materials, including allergens: tomato concentrate, egg powder - yolk, milk powder, vegetable oil, modified starch, dried peppers and chili powder, garlic, parsley and dill, pickles, mustard flour, sugar, cooking salt. The technological additives that are used are the stabilizers: xanthan gum and guar gum, acetic and citric acids, the sweetener sucralose, the preservatives potassium sorbate and sodium benzoate, the colorants beta-carotene and paprika.

The company has an independent building stock, the sauces are produced in a separate and organized for the production workshop. The team responsible for quality, safety and the internal control system is well acquainted with modern European legislation in the field of food hygiene. The documentation is developed professionally and consistently. The complex of prerequisite activities is indicated in 10 separate Programs under GMP and GHP and in Technological documentation for all produced sauces, with plans and procedures, orders, instructions, lists, registers and other documents closely related to the specifics of production.

In the Technological documentation we find some gaps in many sections, mostly in the health and hygiene indicators and norms. The main health and hygiene and quality indicators for the whole group of sauces are presented in Tables 13 and 14.

Table 13 Health and hygiene and quality indicators for culinary sauces

Type of sauce	Physico-chemical and microbiological indicators and standards							
	Dry matter, %	Salt, %	pH	Fat %	*Salmonella*, в 25 g	Coagulase positive staphylococci cfu/g	*E.coli*, cfu/g	Mold, Fungi, cfu/g
>5	6 - 9	2.5-3.5	3,5-4,5		Absent	< 100	< 10	< 100
>5	>7	< 2.5	3,5-4.5		Absent	< 100	< 10	< 100
>25	>30	< 2,5	4.0-5.0		Absent	< 100	< 10	< 100
<12	>7	< 2.5	3.5-4.6		Absent	< 100	< 10	< 100

Table 14 Health and hygiene and quality indicators for culinary tomato based sauces

Type of sauce	Physico-chemical and microbiological indicators and standards						
	Dry matter,	Salt, %	pH	*Sulfite reducing clostridia, CFU/g*	Mold, CFU/g	*Fungi*, CFU/g	Mesophilic aerobic and facultatively anaerobic microorganisms
Ketchup	> 8	< 2.5	3.5-4.5	< 1	<10	<10	Are not allowed
Sauce Chili, Mexican and Barbeque*	>8 >20*	< 2.0	3.5-5.0	< 1	<10	<10	Are not allowed

The technological processes in the different sauces are presented schematically in figures 7-8.

The main technological processes for some of the assortments are high pasteurization, there is also the localization of the critical control points, determined during the development of the HACCP plans.

The technology of other parts of the sauce production does not include heat treatment. This carries a risk of microbial contamination of the finished product with the microbes of the raw materials, as well as secondary contamination in case of non-observance of the hygiene of the personnel and the working environment. Only the composition - low pH, the presence of preservatives and insufficiently favorable for the development of bacteria and microscopic fungi nutrients, is a limiting factor of microbial processes. It has been experimentally proven that large doses of viable cells of Salmonella spp. die in mayonnaise products in less than 48 hours, and the microflora does not develop for weeks. In this sense, for sauces without pasteurization, the microbiological criteria for safety and hygiene of the processes are drawn up correctly enough.

In the production of mustard (Figure 7), the sauces Garlic and Tartar and mayonnaise sauce "Samurai" there is no heat treatment, respectively the isn't an operation that performs microbial decontamination. The composition, high acidity, preservatives are not a favorable environment for microorganism. The situation is similar with mayonnaise, which the company produces with very low fat content.

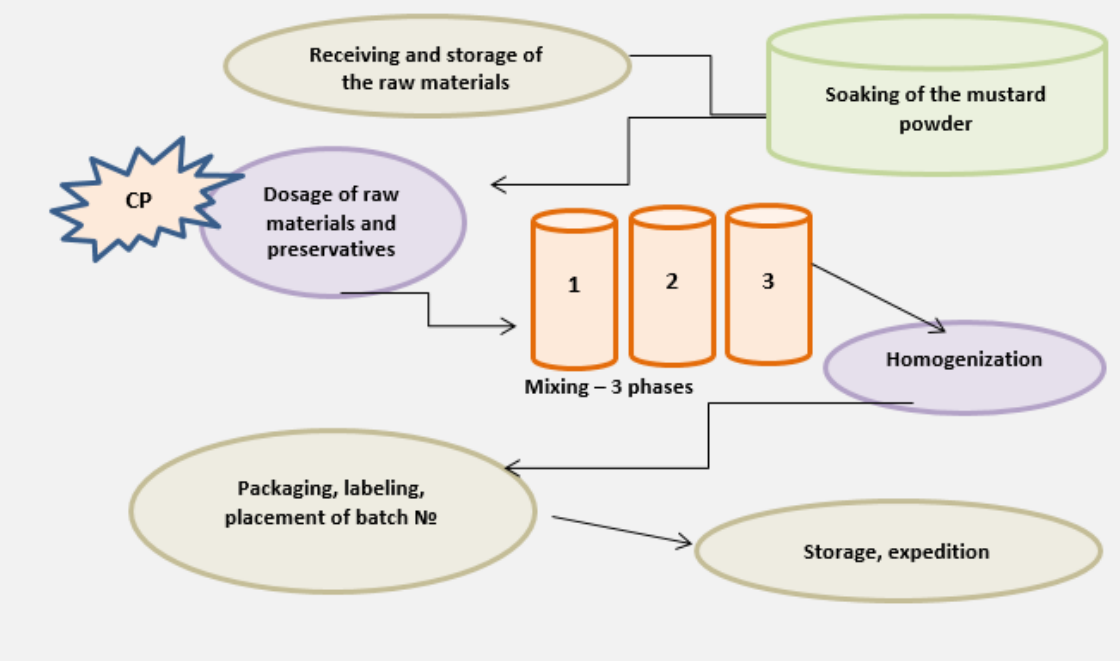

Figure 7 - Technological process of the production of mustard

The technology of Chili, Mexican and Barbecue sauces and Ketchup sauces, which are essentially tomato products, is heat-treated - high one-stage pasteurization (Figure 8). This also determines the differences in the requirements to the microbiological safety criteria, which are compiled similarly to lyutenitsa and tomato products with preservatives.

Errors in their wording must be corrected in accordance with the above considerations and suggestions:

- the total number of mesophilic micro-organisms to be: not more than 8000 cfu / g;

- to include indicator "Enterobacteriaceae" - <10 cfu / g;

- molds and yeast to be normalized to <10 cfu / g;

- to replace the criterion "Sulfite-reducing clostridia" with "anaerobic microorganisms - not allowed" by the method of BDS 6916-87.

There are other inconsistencies in the Technology Records that could be corrected as follows:

- Depending on the period of development of the TD, it is appropriate to update some of their texts in accordance with the changes in the EU Regulations, national by-laws and methodological standards.

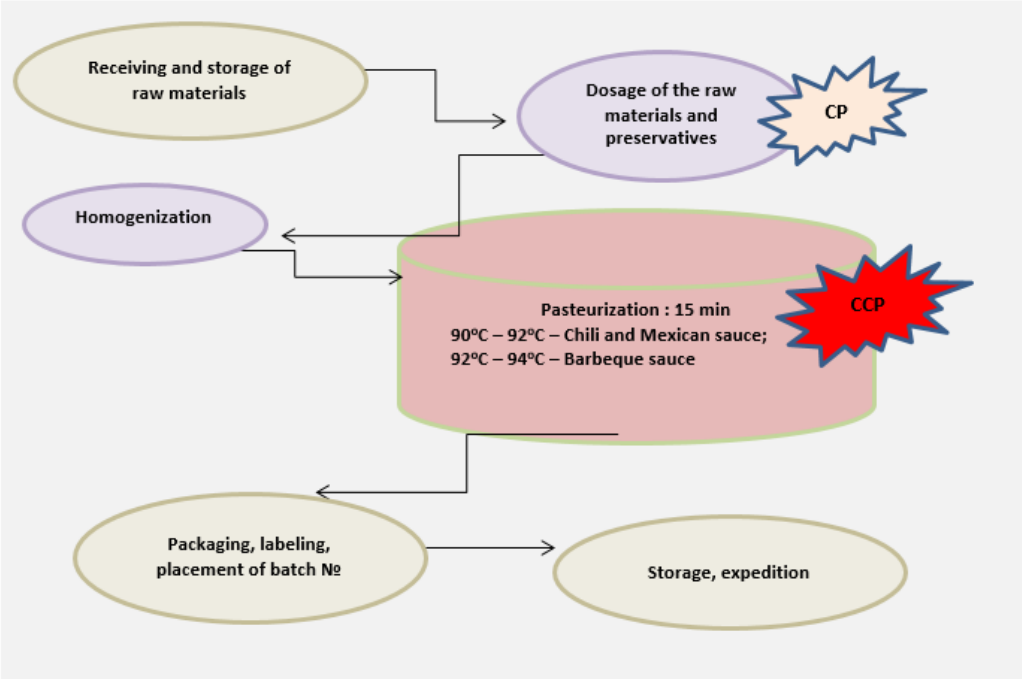

Figure 8 - Technological scheme for the production of Chili, Mexican, Barbecue sauces and Ketchup

- It is inadmissible to entrust the selection of methods for analysis of health and hygiene indicators to accredited laboratories. They must be specified in the text of the TD, as this guarantees the interests of the manufacturer.

Under the HACCP System: The hazards of the raw materials used in the production of sauces and identified by the HACCP team, in addition to the physical, chemical and biological contaminants described above, include another factor - allergens, and most of all mustard flour and egg yolk. Mycotoxins are vaguely mentioned, but without specifying which of the raw materials it is and whether there are preventive measures to prevent them.

In sauces without heat treatment, only critical points (CP) are determined - when dosing technological additives. There the critical limits are set in the recipe. In the pasteurized sauces the place of CCP is the thermal impact - the pasteurization regime, and the critical limits are within the temperatures and exposures established in the TD. The parameters of the respective monitoring are also given, supplemented by monitoring of the water and the working environment.

Storage has a limited potential to increase hazards, and heat treatment in some of the range eliminates microbial contaminants. In sauces produced without heat treatment, the risk of secondary contamination with microorganisms is neglected by the HACCP team, not indicated in the relevant work card, but in practice through the

microbiological criteria set out in the TD, it is under control. Only in these assortments is the absence of salmonella and staphylococci normalized. The limitations imposed by the specific composition of emulsion products on the ability of microorganisms to grow and reproduce justify such an approach.

Verification, in addition to routine inspections, internal and external audits, control of measuring instruments and other mandatory steps, also includes observations of finished products, carried out according to an annual plan and necessarily including the most key safety criteria - microbiological.

The analysis of the Internal Control System in the production of sauces gives grounds for the following more important considerations:

The sauces produced at the site, as a rule, do not carry risk of acute foodborne diseases of microbial origin. This is due to the nature of the assortments, the applied effective decontamination technologies, the systematic maintenance of the hygienic condition of the working environment, the appropriate internal control policy. It is important that the composition of the sauces does not allow intensive development of microorganisms. The leading dangers in this case are allergens, which should be subject to an exact announcement on the labels of the respective assortments.

The HACCP system defines adequate control (LC) and critical control points (CC), critical limits and well-documented monitoring of safety factors.

Some elements of health and hygiene significance in which deficiencies have been identified may be corrected:

• In the Technological documentation it is necessary for most sauces to correct and reduce the salt content, which is above reasonable limits and puts similar products in the group of unhealthy foods;

• To correct the microbiological criteria and requirements with indicators, corresponding to the applied technologies (see above), and to be controlled through the verification procedures;

• There is a need to improve the presentation of nutrition information, especially with regard to allergens, in full compliance with EU Regulation № 1169/2011.

CHAPTER 7

HACCP PLAN FOR THE PRODUCTION OF JAMS WITH WHOLE FRUITS, JAMS WITH CRUSHED FRUIT, MARMALADE AND TOPING

The products are diverse – jams with whole fruit, jams with fruit pieces, marmalades and toppings, intended for direct consumption or as additives to confectionery, pastries, desserts. The main raw materials used in the products are frozen fruits - whole or pureed (strawberries, raspberries, apricots, peaches, berries, oranges and orange peels, cherries, sour cherries, pineapple, mango, kiwi, figs, roses). Apple and rosehip flour, sugar and glucose-fructose syrup, cocoa are also used. The technological additives are pectin, modified starch, citric acid, guar gum and xanthan, flavorings; the colorant caramel, preservative - potassium sorbate.

The pre-requisite GHP and GMP Programs are used. For all products a general Technological documentation has been compiled, containing health-hygienic and

quality indicators and norms, separated separately for 4 groups of products - marmalades, toppings, jam with whole fruit and jams with pieces of fruit.

The health-hygienic and quality criteria and norms in the Technological documentation are objective, correctly composed and well reflecting the differences in the assortments in each of the groups of products. This applies in particular to physico-chemical and microbiological indicators and requirements that give rise to a low risk assessment. The most important criteria for microbial safety are presented in Table 15:

Table 15 -Physico-chemical and microbiological parameters in jam with whole fruits, jam with fruit pieces, marmalades and toppings

Product	Quality and safety criteria				
	Total sugar,%	pH	Mesophilic aerobes cfu/g	Mesophilic anaerobes cfu/g	Mold and yeast cfu/g
Jam with whole fruits	40 - 60	2,8 – 3,4	< 100	Are not allowed	< 10
Jam with fruit pieces	40 - 65	2,8 – 3,6	< 100	Are not allowed	< 10
Marmalades	55 - 65	2,8 – 3,5	< 100	Are not allowed	< 10
Toppings	55 - 65	3,5 - 5,0	< 100	Are not allowed	< 10

Schematically, the main technological processes of the production of jams with whole fruit, jams with fruit pieces, marmalades and toppings are presented in Figure 9. The figure shows the technology of production of assortments with preservatives. The assortments without preservatives are marmalades and jam with over 65% sugar content and jam with whole fruit. The only food additives in these ranges are pectin and citric acid.

According to the HACCP System: Products from this group of canned fruits do not carry a risk of acute foodborne diseases with microbial etiology. They do not represent an environment conducive to the development of pathogenic microorganisms. The hazards identified in the HACCP plan for this production are similar to those described above for vegetable products (see Chapter 5), but supplemented by the many different food additives, possible carriers of mycotoxins and physical contaminants.

However, the only, and yet very important, criterion underestimated in the hazard analysis is the potential risk of mycotoxins in the raw materials. This is especially true of the absence of patulin in frozen fruits and fruit purees and of ochratoxin in fruit flours, pectins and cocoa. These mycotoxins should be eliminated at the beginning of production. A company document requiring a certificate for the quality of raw materials, including the absence of mycotoxins, must be included in the relevant prerequisite program. In such circumstances, it is not necessary to include mycotoxins in the Technology Documentation as a criterion for evaluation of the finished product. Specific forms should be developed in the GMP, requiring, among other chemical and biological contaminants, certificates for the absence of

mycotoxins. Such a requirement for suppliers would eliminate this type of hazards and guarantee the safety of the finished product.

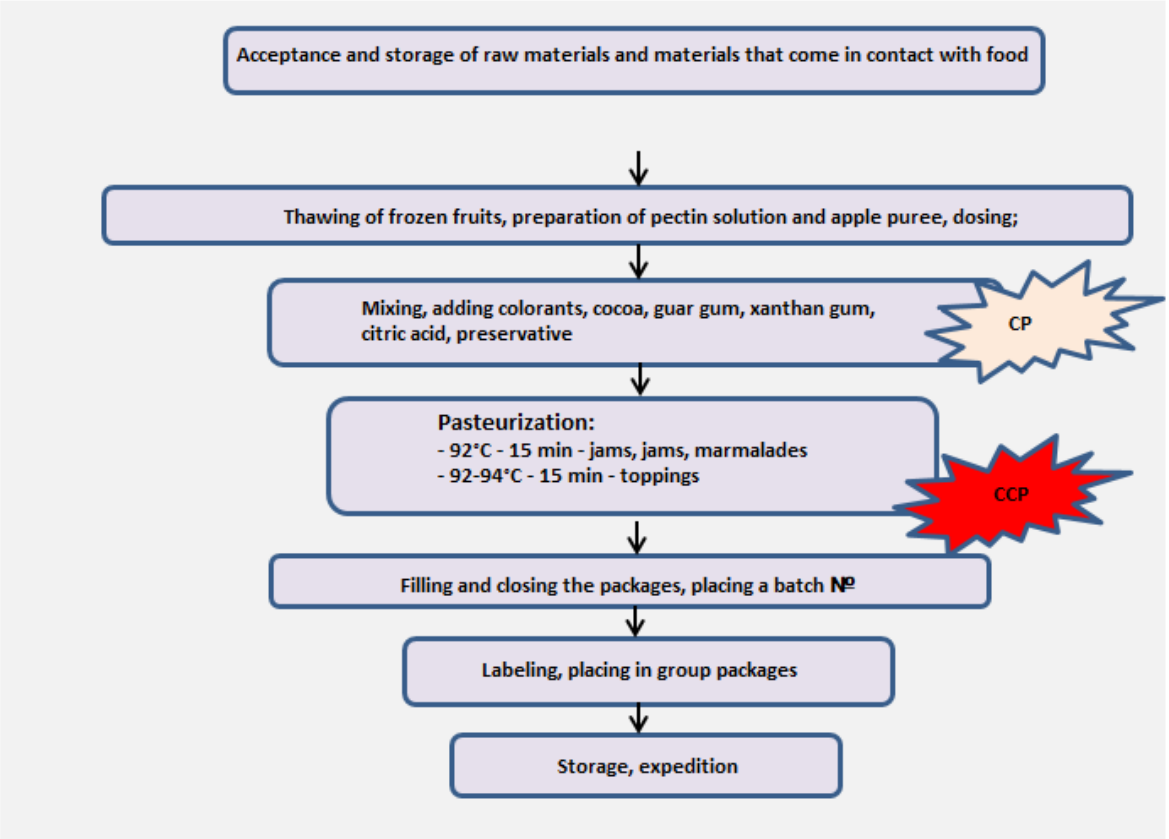

Figure 9 - Technological scheme for production of jams with whole fruits, marmalades, jams with fruit pieces and toppings with preservatives

The dangers in the storage of raw materials and additives and in the technological processing of jams with whole fruits, jams with fruit pieces, marmalades and toppings are similar to those described for canned vegetables. In the finished product, the greatest importance is given to osmotolerant microorganisms, such as molds and yeasts. In assortments with a sugar concentration above 60%, the dangers of this nature are not particularly important. In assortments with a sugar content below 60%, the development of microscopic fungi is eliminated by applying preservatives. There are justifiably formulated CP in the application of preservatives and CCP in the stages of heat treatment, which successfully destroy biological hazards - bacteria and molds. The monitoring in CP and CCP is adequate, supplemented by another monitoring program - the microbiological condition of the working environment.

All necessary steps are included in the verification of the HACCP plan. Monitoring of finished products, including physico-chemical and microbiological indicators, is also used, albeit to a lesser extent.

In conclusion: The HACCP team has carefully assessed the physical, chemical and biological hazards in jams with whole fruits, jams with fruit pieces, marmalades and toppings and has adequately identified CP and CCP, with one exception - the risk of mycotoxins, which may be carriers of raw materials. An appropriate corrective

action in this case is to require appropriate certificates for the absence of mycotoxins during the incoming control.

CHAPTER 8

HACCP IN THE PRODUCTION OF GERMINATED SEEDS AND PRODUCTS FROM THEM

Sprouted seeds are not a traditional Bulgarian food. Sprouts - bamboo, soybeans and others, are exotic, known from Asian cuisinea - China, Indochina, India. But globalization has also changed eating habits, and today sprouts are becoming more prominent in Europe and North America, including in our country. They are considered healthy foods and are recommended mainly in raw but also in processed form - sandwiches, salads, as part of various diets - vegetarianism, veganism, raw diets, but are also sought after by a wider range of lovers of unique foods. They are proclaimed as "living food" and as a means of preventing and even treating various diseases or slowing down the aging process. It is claimed that they control the balance in the microbiome, affect the immune system, are useful in gastritis, colitis, biliary-liver and other gastrointestinal pathologies, that they contain antioxidants. Vitamins, macro- and microelements, bioflavonoids, fibers affect the metabolic processes, relieve the effects of stress, normalize excretory functions, improve the functional status of the body. There are many examples of different types of sprouted seeds, in any case we can refer them to "useful" foods. Naturally, these merits should be supported by objective analyzes of the chemical composition and convincing medical evidence. The production of germinated seeds is becoming more industrial in character, even in our country. The market offers sprouts from the seeds of wheat, oats, rye, peas, lentils, chickpeas, sunflowers, buckwheat, einkorn, milk thistle, radishes, alfalfa, sesame, mustard, beans, rice, soybeans, bamboo and others.

In terms of nutritional characteristics, they can be attributed to the group of fruits and vegetables, but they are based on some cereals and seeds of various plants. The main chemical hazards that pose a health risk to cereals are pesticide residues and mycotoxins - aflatoxins, ochratoxins, zearalenone, etc., in respect of which European regulations have set strict hygiene standards. These hazards can be eliminated by using clean and tested batches in the production.

The nature of the processes, however, in sprouted seeds creates another type of potential hazards - those of a biological nature. They come from the main raw material naturally contaminated with bacteria - grain and seeds, and these are primarily soil microorganisms. Among them there are many opportunistic species and, theoretically, although rarely, even pathogenic causes of intestinal infectious diseases. Contamination occurs in the field, but also during storage - from soil contaminated with human and animal excreta, from transport, from dust, weathering, storage pests - rodents, birds, mites, insects. There are also secondary influences such as the purity of the water and the work facilities, as well as the personal hygiene culture of the operators.

The technological scheme of production together with CCP can be presented as follows (Figure 10):

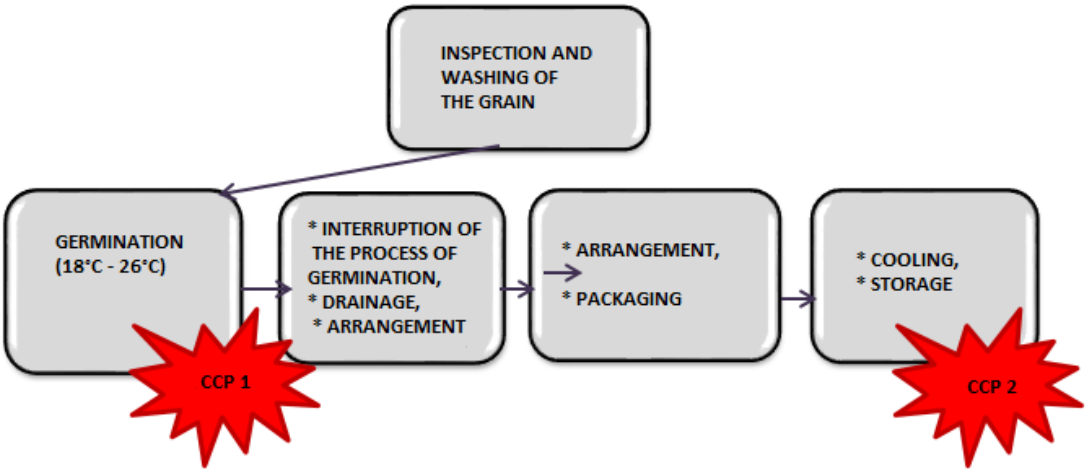

Figure 10 - Technological scheme of production of sprouted seeds

During the germination process, the microflora of the seeds multiplies in parallel. Secondary contamination can occur from water and work equipment. After the interruption of germination, the processes of draining, arranging, putting in salads, sandwiches and other products are of great importance. The personal hygiene culture of the staff, the cleanliness of the work containers and equipment, the process of cooling and refrigerated storage can also be a factor for the secondary contamination of the sprouts.

As can be seen from Figure 10, there is no technological step in the process to perform decontamination by microorganisms. The reproduction of unwanted microflora is precisely during the germination of seeds. Germination technology does not contain a limiting factor of the microflora. The leading process - germination, takes place in a humid environment for a long period of time - several days, at a moderate temperature within +16°C - +28°C. The temperature in the process of germination is favorable, especially for bacteria with a psychrotrophic character, and the time for germination is enough for the generation of many microbial populations. Under these growing conditions, a variety of bacteria, including pathogenic and conditionally pathogenic, multiply and can form toxins at the same time. At the end of the vegetation, the amounts of microorganisms can be quite sizable. The consumer receives this dose of bacteria and microscopic fungi, which has developed unhindered during germination.

Probable contaminants are genera and species such as Salmonella spp., Listeria monocytogenes, Yersinia enterocolitica, Staphylococcus aureus, Bacillus cereus, pathogenic and non-pathogenic Escherichia coli and many others. The risk of Shiga-toxin-carrying E. coli verotoxigenic serotypes (STEC) is particularly relevant today. There is information in the scientific literature on the registration of morbidity after consumption of contaminated sprouted seeds.

In studies of a severe epidemic situation in Germany in 2011 by E. coli 0104, a carrier of Shiga-toxin, provoking fatal kidney damage and high mortality, raw sprouts were one of the foods in which the finding of this microorganism was common and cited by the European Commission and EFSA as a very likely factor in the outbreak of the E. coli explosion (STEC). This situation provokes the purposeful assessment of

the risk to public health from pathogenic bacteria - contaminants of seeds and sprouts for direct human consumption. In their opinions on the problem, the authoritative European organizations state that "due to the high humidity and the favorable temperature during the germination process, bacterial pathogens can multiply on the dried seeds, resulting in a risk to public health". An impressive list of foodborne outbreaks associated with the consumption of sprouted seeds was compiled by the US Department of Health and Human Services (Centers of Disease Control and Prevention) from 1973 to 2016. The most common cause is various serotypes Salmonella spp., But there are many other species - Bacillus cereus; Escherichia coli 0157, 0104: H4, 0121, 026; Listeria monocytogenes. Among the types of sprouts the first place is occupied by those of alfalfa, followed by clover, legumes, less often mango, onion, radish, iceberg lettuce, watercress, soybeans, mustard. Many authors and organizations, including the European Commission, EFSA and Codex Alimentarius, have called for serious measures and a strategy to prevent bacterial foodborne diseases from sprouted seeds. Regulations EC № 2073/2005 and № 1441/2007 regulate the absence of Salmonella spp. in sprouts, and later 4 more EC Regulations №№ 208/2013, 209/2013, 210/2013 and 211/2013 set special requirements for the hygiene of sprouts and seeds intended for their production. Special requirement of EC Regulation № 209 / 2013 e "Shiga-toxin producing E. coli (STEC) - O157, O26, O111, O103, O145 and O104: H4 - absence in 25 g in 5 batch samples" (Table 16):

Table 16 - Current microbiological requirements in the EU for sprouts

Food Category	Microorganisms/their toxins and metabolites	Sampling plan		Boundaries		Reference analytical methods	Stage at which the criterion is applied
		n	*c*	*m*	*M*		
EC Regulation № 2073/2005 (1441/2007) (Annex 1, Chapter 1. Food safety criteria)							
1.18. Sprouted seeds (ready to eat)	***Salmonella* spp.**	**5**	**0**	**Absence in 25 g**		**ISO 6579-1**	**Products placed on the market within their shelf life**
EC Regulation № 209/2013 (Annex 1, Chapter 1. Food safety criteria)							
1.29. Sprouts	**Shiga-toxin producing E. coli (STEC) 0157, 026, 0111, 0103, 0145, 0104-H4**	**5**	**0**	**Absence in 25 g**		**CEN/ISO TS 13136**	**Products placed on the market within their shelf life**

What is missing in the current European normative documents are the microbiological criteria for hygiene of the processes or the indicator microorganisms, which would serve for current control and / or verification of the internal HACCP system in the critical points of the germinated seed production. The dynamics of development of indicator microorganisms in the process of germination can serve as an indicator of the level of hygiene of sprout production and the potential risk of intestinal pathogens. Suitable indicator tests would be Enterobacteriaceae, Coliforms or Escherichia coli.

To minimize the epidemic risk of consumption of sprouted seeds, Codex Alimentarius and later EFSA have formulated hygiene requirements for their production as follows:

– The access of domestic animals to the terrains where the seeds are grown is excluded;

– Fertilization and application of pesticides are under control;

– During the harvest, measures are taken to limit the soil contamination of the seeds and their mechanical damage;

– The seeds for the production of sprouts are to be stored, appropriately labeled, separately from any other type of cereal production, under conditions of optimal humidity and without being steamed;

– The seeds for production of sprouts are stored under strictly observed conditions for prevention of birds, rodents and other types of storage pests;

– Preliminary examination of batches for pathogenic microorganisms and prevention of infected batches for sprouting production is appropriate;

The Codex Alimentarius document CAC / RCP 53-2003 also provides methodological recommendations, according to which prevention begins with the hygiene and appropriate treatment of seeds used for the production of sprouts for human consumption. Measures to protect the grain and control its microbiological condition become key to minimizing the risk of food poisoning, infections and intoxications. They read: “Sprouts are produced in compliance with the General Principles of Food Hygiene and a number of specific additional requirements that minimize the risk of secondary and cross-contamination during the processes. The measures include:

– Primary washing of seeds with clean drinking water;

– Treatment of seeds with antimicrobials before placing them for germination;

– Good rinsing to remove traces of antimicrobials;

– Soaking the seeds, washing with clean drinking water;

– Germination - is carried out in well-disinfected facilities, exclusively in an aquatic environment with clean drinking water;

– Putting the finished sprouts in properly washed and disinfected containers;

– Final rinsing of the sprouts, fast cooling to prevent additional microbial growth;

– Cooling temperature - not higher than + 5^{o}C;

– Taking measures to prevent cross-contamination of the finished product."

In Bulgaria there is a production of sprouts, which are available on the market both in natural form and in the form of salads and as an ingredient in sandwiches. We will look at the main hygiene problems of one of the companies producing sprouted seeds. The critical analysis of the Internal Control System of the enterprise gave grounds for the following findings:

The company produces sprouts from seeds of cereals, legumes, oilseeds and vegetables, as well as vegetarian salads and sandwiches with sprouts. It has more than 10 years of experience and well-developed GMP programs and GHP Applications.

One of the serious critical remarks is related to the incoming control of the main raw material - the grain. In addition to the data for external inspection of the batch and declarations for GMOs, certificates for content / absence of pesticides, nitrates and mycotoxins should be included in the contract forms with suppliers and in the registration form filled in upon acceptance of the seeds. The most adequate and effective measure would be the preliminary analysis of the batches for the content of pathogenic microorganisms - Salmonella spp., Listeria spp., Shiga-toxin producing Escherichia coli and others. But these are expensive procedures, which is why such measures would be unrealistic in our conditions.

The main requirements to the production and the technology of its production are contained in the Technological documentation. They are 3 pieces as follows:

- sprouts from seeds of cereals, legumes, oilseeds and vegetables;
- sandwiches with sprouts - 100% vegetarian;
- salads with sprouts.

The technological documentation is developed methodologically correctly, in sufficient detail and correctly, completely in the style of the requirements of Ordinance № 1 of the Ministry of Health and the Ministry of Agriculture and the EU Regulations №№ 208 - 211/2013. The most important in this case is TD for natural sprouts. The raw materials used are wheat seeds, rye, sunflower, alfalfa, lentils, soybeans, peas, broccoli, turnips, onions, einkorn, buckwheat, quinoa.

The quality and health requirements for the sprouts describe in detail the organoleptic qualities, norms for the absence of foreign impurities, for ash content, for the toxic elements lead and cadmium, for the mycotoxins zearalenone and deoxyvalenol.

The microbiological criteria are in accordance with EC Regulations №№ 2073/2005 and 209/2013: absence in 25 g of Salmonella spp. and Shiga-toxin producing Escherichia coli (STEC) O157, O26, O111, O103, O145 and O104: H4. "No visible mold" added. No indicator microorganisms are regulated - the model of the European Regulations is followed, which do not refer to criteria for hygiene of the processes in this type of raw food.

The important section for the production technology gives a description of the technical equipment and tools and the main technological stages - inspection of the grain, washing the grain with clean drinking water, vegetation of the seeds to the desired degree of germination. Washing the grain is a very important preventive measure. In the relevant section of the GMP, however, this point is developed very briefly, without details - how long the process lasts, whether the washing drinking water is flowing, at what temperatures the manipulation is performed, whether there is a control mechanism to complete the process. The last stage - vegetation, is a confidential company property. Information about it can be found in the first part of the prerequisites - in the description of the technological process. The germination temperature is from 18^{o}C to 28^{o}C, and the duration - from 2 to 14 days. These conditions are realized, under which there is undoubtedly a parallel development of microorganisms and which is the main danger in this specific production. Here the application of any measures cannot eliminate the growth of the grain microflora.

The prerequisites prepared in this way are a good basis for the development of the HACCP system itself.

According to the HACCP system: The hazard analysis is made, logically following the stages and procedures in the production. The first part identifies physical hazards as foreign impurities with a low level of severity and probability and chemical hazards as toxic elements and mycotoxins with low and medium risk, with the main preventive role given to incoming control. Biological hazards also carry a low and medium degree of risk - foreign seeds, soil and intestinal microorganisms, storage pests and their excretions. Their importance increases in the stage of grain germination - soil bacteria, molds, pathogenic and opportunistic bacteria - Salmonella spp., Listeria spp., Clostridia, E. coli - STEC, VTEC, EPEC and others imported with the raw material, from the staff or from storage pests. It is stated that there is realistic danger of reproduction. Control and preventive measures have been identified - all those discussed above and recommended by Codex Alimentarius and other authoritative sources. CCP 1 is also rightly placed here (Figure 10).

In the subsequent stages, in which not only the sprouts but also the derived sandwiches and salads are important, there is also the possibility of their secondary contamination by the working environment, tools and personnel. But more serious is the importance of the refrigeration circuit and the potential danger of breaking it. Psychrotrophs are also referred to here, which would be important both at low temperature and in deviations from the cooling temperature - from 0 to +6ºC. In the stage of refrigerated storage of the finished products CCP 2 is completely objectively placed.

The monitoring covers in good faith not only the values and parameters in the critical control points, but also in the preliminary stages of storage of raw materials. The developed corrective actions are also adequate. The inspection (verification), in addition to technical and calibration measures, includes additional work with staff, training and personal hygiene, but also periodic sampling and analysis of the microbiological condition - as in the normalized in TD pathogens (Salmonella spp. And Shiga-toxin producing Escherichia coli) and presumptive Escherichia coli, which are not only beta-glucuronidase coliforms, but also enteropathogenic and enterotoxigenic strains. It is obvious that in this case the business operators have used competent consulting assistance for the prevention of unwanted microbiological processes during germination. These verification procedures also apply to derivative sandwiches and salads, in which another, third CCP is added - the shaping of products where secondary contamination by staff is very likely. There the measures are clear - high hygiene of the working environment and precise observance of personal hygiene by the operators. The human factor in this case is very important.

The stated findings give grounds for the following more important conclusions:

– The business operator has developed the Internal Control System and the HACCP plan, strictly adhering to the requirements of the Codex Alimentarius, the EU Regulations and Ordinance № 1 of the Ministry of Health and the Ministry of Agriculture and Food. Both the prerequisite programs and the Technological documentation are presented in detail and consistently and represent a good basis for the development of the HACCP system.

– Even in the Program for incoming control of the main raw material - seeds, it is necessary to supplement it with requirements for certificates for content / absence of pesticides, fertilizers and mycotoxins. The most effective preventive measure would be to require certificates for the absence of pathogenic microorganisms, but these are expensive procedures and such a practice would be unrealistic in our conditions.

– It is necessary in the GMP to develop in much more detail and demanding the section for washing the main raw material - seeds, with clean drinking water.

– The HACCP system is developed correctly, the hazards are formulated correctly, the defined CCP are adequate to the nature of the processes. The verification procedures also include checks of the microbiological condition of the finished products not only for the content of pathogenic, but also indicator microorganisms - presumptive Escherichia coli.

– For sandwiches and salads with sprouts, a third critical control point is required - CCP3 in manual operations for shaping the products.

– This interesting segment of the production of original food for our table - sprouted seeds, should be in the field of view not only of nutritionists but also of food safety specialists, respectively control authorities in order to limit the specific risk in a timely manner and to keep the consumer safe and secure.

CHAPTER 9

HACCP IN AN ENTERPRISE FOR THE PRODUCTION OF MINCED MEAT, MEAT PREPARED FOR COOKING AND CUTS OF RED AND WHITE MEAT

The plant is essentially a slaughterhouse combined with a well-organized slaughterhouse, ie. it concerns 'primary production' as defined in Regulation № 853/2004. It processes raw meat - pork, chicken and large ruminants. The end products are raw minced meat, raw "prepared for cooking" and raw "cuts". "Cuts" means pieces of meat from different anatomical parts of the carcass intended for retail sale in the raw state on the market, in catering establishments or in meat processing establishments. “Prepared for cooking" are understood as various culinary semi-finished products from raw minced meat mass with additives and spices, shaped without casing and in casing such as kebabs, meatballs, sausages, sujuks, karnache sausages and other traditional for our country pork, beef and poultry products. Both types of products are intended for storage in a refrigerated or frozen state. The hygiene requirements for this type of animal product are subject to Regulation (EC) No 853/2004 and there is no regulatory vacuum in this respect. In the prerequisite part of the Internal Control and Safety System, the company has developed programs of mixed type for GMP and GHP.

The pre-requisites data for the enterprise are compiled competently, do not repeat the standard texts of Regulation EU №853/2004, but are specific with regard to the specific conditions of production. Thus, GMP with GHP are a good basis for the development of the HACCP system.

We will examine in detail the pre-requisite Technological documentation for the initial finished products of the enterprise, leaving aside the one from the slaughter segment, which concerns carcasses and pork by-products.

The technological documentation for the finished products are 5:

- TD-01/2018 "Pork cuts";
- TD-02/2018 "Cuts of meat of large ruminants";
- TD-03/2018 "Minced meat and minced meat preparations";
- TD-04/2018 "Poultry cuts";
- TD-05/2018 "Bones for broth".

The documentation, which sets out the requirements for cuts of pork, poultry and large ruminant meat, emphasizes the anatomotopographic areas with precise and detailed descriptions of the anatomical boundaries and especially of the organoleptic qualities of the final products. These are raw meat products that are consumed exclusively after proper heat treatment. They also regulate the microbiological requirements for safety and hygiene of processes set out in EC Regulations №№ 2073/2005 and 1441/2007. The storage conditions for both chilled and frozen products are in harmony with the requirements of Regulation № 853/2004.

The situation is different in TD 03/2018, where minced meat and minced meat preparations are exhibited - the traditional for our country kebabs, meatballs, sausages, sujuks and other raw meat delicacies offered in raw form. A positive fact is that the enrichment with vegetable protein - soy granulate or soy isolate, is practiced only in the range of minced meat, but not in traditional delicacies. Only edible natural collagen casings are used for the sausage assortments. It is also positive that machine separated meat (MSM) is not used in minced meat products. The sequence of operations in the production of minced meat preparations is presented in Figure 11.

But in the developed technological documentation for this extensive group of meat preparations there are obvious gaps, which relate mainly to the nutritional qualities of the products.

The technological documentation TD 3/2018, presenting the minced meat preparations, is compiled in form and content in accordance with the requirements of Ordinance №1 / 2016 of the Ministry of Health, but it lacks some main subsections. A table with quality indicators and requirements has been developed only for minced pork, for other types of minced meat - beef, pork and beef and chicken, as well as for the variants with added soy protein, such tables are not presented. There are also no tables with quality requirements for the assortment of sausages, including those of "Grandpa", "Banska", for "Master’s Sujuks". In this situation, it would be difficult to carry out differentiated controls. The exhibition includes the idea that detailed "technological maps" with the recipes have been developed for these assortments, but the latter are not part of the representative documentation of the company.

Annex VI to Regulation (EC) No 1169/2011 lays down special requirements for minced meat as regards the quality of the raw meat used. These are restrictions on the fat content and the content of low-quality connective tissue proteins, expressed as the percentage of collagen in the meat protein (as hydroxyproline content multiplied by a factor of 8) [207].

The fat content of minced pork is limited to 20% (up to 30% in the EC Regulation № 1169). This is a good quality indicator. But for the other types of minced meat there are no data and regulations. In the preparations, the total fat content of the kebabs is from 13 to 17% and this is a good certificate of quality. But in the other assortments (meatballs, sausages) the total fat content is "not less than 17%". The absence of an upper limit raises many questions about the consistency in the qualities of the company's delicacy meat products.

As far as the collagen content is concerned, this fundamental quality criterion is not provided at all in the company's production - neither in minced pork nor in other traditional preparations. Its absence makes it impossible to control the nutritional value of the products, which should have a stable content of quality meat protein, respectively. low in connective tissue proteins. According to the above Regulation, the criterion varies from ≤12% to ≤18% depending on the type of minced meat.

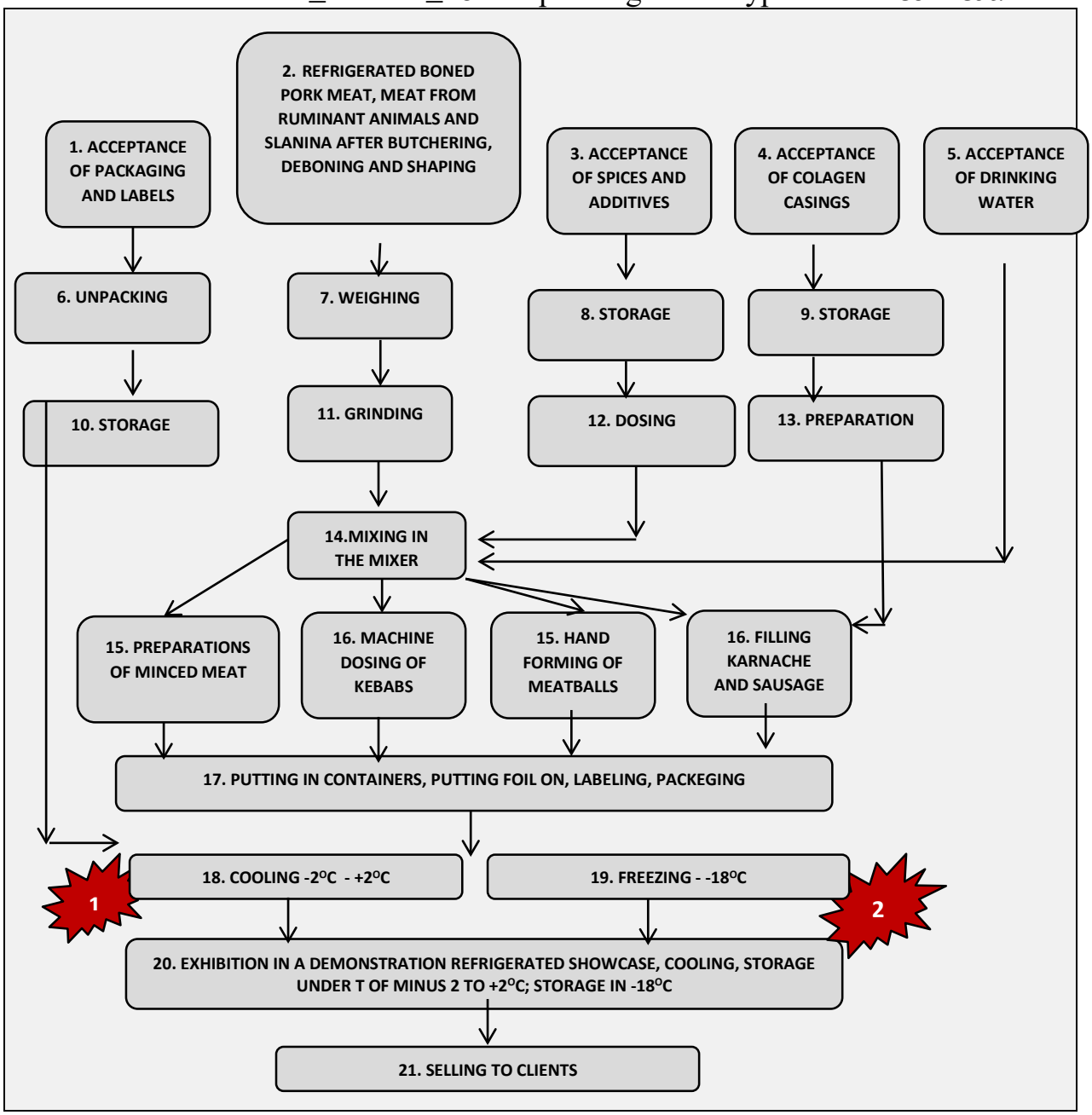

Figure 11 - Technological scheme of production of minced meat products.

The minced meat has a very high content of table salt - 2.0%, which will undoubtedly affect the sodium content in dishes prepared with such minced meat. The products contain, in addition to common salt and spices, potassium nitrate, vitamin C and other "EU" additives, and a mixture of additives authorized for use in the production of minced meat and minced meat preparations in accordance with the requirements of Ordinance № 4 of the Ministry of Health of 03.02.2015. However, there are no specifics. This means that it is possible to add additional colorants, preservatives, regulators of taste and acidity, water-retaining compounds and others in the manufactured products. They are not cited anywhere in the documentation, and there is no information at all about the applied concentrations. Their presence is obvious, judging by the established rather long shelf life of the refrigerated assortments - up to 6 days at 0ºC to + 6ºC. Specialists in the meat industry justify the use of mixtures of the above improvers with the fact that they are permitted by Regulation EC № 1333/2008 and the above-cited Ordinance № 4 of the Ministry of Health. But nowhere in the technological documentation is there accurate data on the applied concentrations and as a final result - the concentration of sodium in the finished products. This is a relevant and painful topic in our modern meat industry, related to the high content of "hidden" sodium, due to the fact that the above additives are most often sodium salts of phosphoric, acetic, ascorbic and other acids.

Another problem in Technological documentation № 3/2018 is the microbiological standardization of minced meat. It does not fully comply with the requirements of Regulations EC №№ 2073/2005 and 1441/2007. The total number of aerobic mesophilic microorganisms is not standardized - a serious indicator of the hygiene of technological processes, which is required by the above Regulations. This is a direct sensitive measure of hygiene at the end of the whole minced meat production process (n = 5; c = 2; m = 5 x 105 cfu / g; M = 106 cfu / g).

Under the HACCP system: In essence, the company has developed two HACCP - plans - for cuts of red and white meat and minced meat and minced meat prepared for cooking in compliance with the classical rules for establishing the internal control system.

The HACCP plan for the production of cuts of whole meat has a scope from the moment of weighing, packing, labeling and packaging to the moment of transport and dispatch of the finished products. It includes cooling and storage at positive refrigeration temperatures (from 0ºC to + 6ºC) and respectively freezing and storage at minus refrigeration temperatures (at minus 18ºC). The only hazards are biological - "psychrophilic microorganisms in violation of the specified temperature and time", and they are recorded from the beginning to the end of the range. The critical limits are the above-quoted cooling / freezing / storage temperatures, and the critical points are 4 - CCP 1 - during cooling, CCP 2 - during storage of chilled cuts, CCP 3 - during freezing, CCP 4 - during storage of frozen cuts. The verification is unclear - it includes verification of the technological operation under GMP, and a monitoring program. A true verification of the quality of the cut meat, including microbiological criteria, should be included here. The greatest probative value would be the study of the main danger identified by the authors of the HACCP plan - psychrophilic

microorganisms, which according to the team, and in essence, represent an authentic danger of a biological nature and should be a reliable indicator of the correctness of the processes: butchering, cooling, freezing and storage.

The scope of the HACCP plan for minced meat preparations starts with the intake of chilled boned pork, meat from large ruminant animals and chicken from the cutting plant. The intake of packaging, labels, spices, additives, soy protein, natural casings, salt, drinking water is also taken into account. Identifying hazards is simple. Some physical hazards are defined as insignificant during the intake – uncharacteristic, metal objects, pieces of polyethylene foil, and in the water - residual amounts of chemical elements above the permissible norms, coliforms and enterococci. Throughout the further food chain, the dangers are exclusively of a biological nature - the presence and reproduction of pathogenic and opportunistic microorganisms, and it is not specified which microbiological criteria are involved. When taking the spices, the danger of mold and yeast is rightly indicated. Additional contamination and contamination with biological agents from machines, equipment and workers are noted in the stages of manipulation - weighing, grinding, mixing, dosing, filling in the casings, etc. The nature of the biological agents is not specified. In the stages of cooling, freezing and storage of prepared minced meat and meat prepared for cooking, the main biological hazard is formulated as "multiplication of psychrophilic microorganisms" in the absence of certain process temperatures. The control measures are temperature control, checklist entries and batch control on a first-come, first-served basis. Control of the psychrophilic microflora of the products is not provided.

Physical and chemical hazards are not referred. Control of the additives used individually or in the form of mixtures, which is a serious risk of overdose of unhealthy chemical treatment of meat products, including salt concentrations, is not planned. The result of the hazard analysis is the establishment of two critical control points - the cooling and freezing of finished products and the corresponding storage. In this production, the only factors that can limit the risk of multiplication of psychrophilic microorganisms are the corresponding low temperatures inside - up to + 4^{o}C for chilled and up to -18^{o}C - for frozen minced meat products and these are in fact the critical limits.

The performance check, etc. Verification in this case consists not only of control measurements of temperatures in depth of the finished product, but also in microbiological tests according to the monitoring program. However, the criteria have not been defined. Probably the tests are performed according to the criteria set out in the TD. However, they are not enough. The total number of aerobic microorganisms, and more precisely the total number of psychrophiles, needs to be included in the HACCP plan. In the meats prepared for cooking, in which there are many technological additives and spices, it is appropriate to trace both molds and yeasts. It is then that we will have a complete picture of the effectiveness of the implemented GMP measures and the implementation of the HACCP plan.

The present analyzes give grounds for the following more important conclusions and recommendations:

– The prerequisite programs for good production and hygiene practice are developed systematically, consistently and thoroughly and are a good basis for the development of the internal system for control of hygiene and product safety;

– The technological documentation is detailed, systematically developed and provides a basis for the construction of the HACCP plan, but some of them need a much more detailed presentation, which covers all options and ranges. This refers to TD 03/2018 for minced meat and minced meat products, which must be supplemented as follows:

✓ To develop tables with the quality requirements for minced beef, veal and pork and poultry meat and for minced meat with added soy protein;

✓ To specify the amount of soy protein used in some of the assortment of minced meat;

✓ To adjust the upper limits of the fat content of some of the assortments of minced meat;

✓ To comply with the requirement of Regulation EC № 1169 to limit connective tissue proteins in minced meat (by including the percentage of collagen in the TD);

✓ Enter accurate data on the types and concentrations of technological additives used in minced meat products.

– For the improvement of the HACCP plans the important final stage is of special importance - the verification of the HACCP procedures and of the whole system. It should coincide with the examination of precisely those elements which constitute the main hazards in the food chain, namely biological contaminants. And biological contaminants are not only those indicated in TD (Salmonella and Escherichia coli), but also criteria such as the total number of mesophilic and psychrotrophic aerobic bacteria, molds and yeasts, why not Enterobacteriaceae - all these are integral indicators of the hygiene of production processes.

CHAPTER 10

SOME HIGHLIGHTS ON CHARACTERISTICS, DECISIONS AND GAPS IN THE COMPILATION AND FUNCTIONING OF HACCP SYSTEMS IN THE FOOD INDUSTRY ENTERPRISES.

The ultimate goal of any internal control system, the main component of which is the HACCP plan and its daily and hourly operation, is to ensure the production of foods of high biological value, free of hazardous agents - physical contaminants, chemical toxic substances, biological contaminants. The system provides order, stability and automation of internal control. That leads to relative independence from failures and human errors in the production process. However, enterprise teams do not always have sufficient competence to design the system to ensure a healthy product and prevention of all possible hazards. The authentic cases we have developed in the previous chapters confirm these judgments.

The documentation provided to us was not in all cases fully informative, most likely due to the confidential information contained in it concerning the exact recipes of various products - confectionery, meat delicacies, ready meals and others, representing company property and secrets. Sterilization formulas for cans with different types of packaging and especially volume, which are crucial for biosafety, are also not provided. Such information in the actual control of proceedings may be required by the official authorities in order to provide more information necessary for the final risk assessment.

Not all companies engaged in the food business have a sufficient number and quality of staff. This is a challenge in the first stage - the composition of the HACCP teams. Often the appointment of the team is made formally, its members are not placed high in the hierarchy of the company, respectively do not have more authority to organize and manage the processes. It is very common for the work of compiling the HACCP to be outsourced, often in the "gray" economy. This leads to a formal, insufficiently related to the real problems of production and incompetent development of the HACCP system.

We pay attention to some characteristic advantages and disadvantages of the construction of HACCP plans based on the current facts of the study.

The preparatory phase before the development of the HACCP plan requires serious work on the development of prerequisite programs, which usually include the rules of good industrial hygiene practices (GMP & GHP). The format of these documents is given in the basic EU Regulations №№ 852/2004 and 853/2004 and in the standards EN ISO 22 002-1-4. From the qualification of the business operators, resp. HACCP teams, the adequate, specific for the given production statement depends on the rules. In our country, companies are also assisted in this regard by the branch associations of food producers, providing their members with competently developed rules, specified for the respective industry. Therefore, the real prerequisite GMP & GHP programs in the companies' systems are developed relatively adequately.

The next steps of the prerequisites are the description of the product, as well as the scheme of the technological processes. These are required by the Codex Alimentarius and the EU Regulations. But in Bulgaria according to the national regulations there is a very positive achievement - the mandatory development of technological documentation, legitimized by Ordinance № 1/2016 of the Ministry of Health and the Ministry of Agriculture. This fulfills some of the very important prerequisite stages - the description of the product, the criteria for its safety and technology. With this the Bulgarian legislation upgrades the requirements of Codex Alimentarius and EU Regulations №№ 852/2004 and 853/2004. Along with the description and technology of the food, TD contains a classification of the produced food, indicates the raw materials, determines the quality indicators and requirements, the methods for their control, the conditions and terms of storage of the product, the labeling. The technological documentation performs the role of real company standards and is developed for all food produced, including the cases considered in the present study. However, not all of them meet the requirements for quality and

safety. We have presented the critical remarks and suggestions for corrections for each food group considered.

Health professionals are called upon in the first place to require the business operator the main condition - the provision of food, the composition of which guarantees that it is healthy and suitable for the health of the population. It is more complicated in the production of special purpose foods, baby foods, food supplements and other non-standard cases. The requirements for them are specific and are not the subject of this statement.

As a rule, most often the problem with the composition and quality of food in compiling the HACCP plan is ignored. Thus, foods with a low content of complete proteins, products with complete proteins displaced from collagen or vegetable proteins, with a high content of fat, of added table salt, of chemical additives containing excessive amounts of sodium and / or phosphates, of nitrates, of hydrogenated fats at risk of trans-isomers, oxidized fats and acroleins, preservatives, colorants, added sugars and sweeteners and other adverse factors are produced. This, of course, has to do with the price of food. But in this case - in the development of HACCP internal control systems, these adverse factors do not fall within the scope of HACCP teams, are not treated as "hazards", are not subject to systematic monitoring and control. Examples from the present study are - added salt, sugars and chemical additives in confectionery, in those of minced meat, in pasteurized egg products, in ready meals and others.

The first stage of any HACCP system is hazard identification. And the first stage of any food chain is the selection of raw materials. It is at this stage that negligible hazards such as chemical contaminants, toxic elements, mycotoxins, pesticide residues, pathogenic microorganisms, etc. may enter the product, against which production technologies are unable to eliminate or reduce to negligible levels. At this point in time, however, critical control points are not marked during the incoming control. The selection of suppliers and the procedures for incoming control is relied on. However, it is weak. With rare exceptions, the documentation at the entrance does not contain specific requirements for certificates for the absence of certain contaminants characteristic of the production - chemical, biological. Perhaps only formal evidence of the absence of GMOs make an exception, but we know that they are only declarative, without evidence based on direct analytical data.

Hazard identification is the most vulnerable point in the actual design and operation of HACCP systems. This is where the qualification of the teams is not enough for a real risk assessment. The most accurate identification can only be made by a person with a high medical culture. This means knowing the nature of the disease processes that would cause a chemical or biological hazard, knowledge of etiological agents, their spread in the biosphere, epidemiology, clinical picture, diagnosis, prevention. In practice, some dangers are underestimated, while others, more insignificant, are favored. The elimination of the marked hazards in the course of the technological process is not monitored, despite the fact that the team adheres to the "decision tree". The latter is at the heart of the CCP's identification. But the most significant system error is that in the verification, ie. checking the effectiveness of technology, hazards are not monitored and checked. We will give some examples:

1. Pasteurized egg products - hazards identified as significant in production:

– Biological: multiplication of psychrophilic microorganisms and molds in the egg mass in defects of the refrigeration chain during storage and transport; survival of psychrophilic microorganisms and molds in disorders of pasteurization regimes. The two CCPs are related to them - during pasteurization and during storage of the pasteurized egg mass. The primary contamination with pathogenic salmonella and listeria, and the secondary contamination with enterobacteria, enterococci, molds are recognized as hazards, but not significant ones;

– Chemical: residues of detergents and disinfectants;

– Natural: shell remnants in the pasteurized egg mass;

The verification plan lacks criteria related to the measurement of the quantities of psychrotrophic microorganisms and molds. There is no CCP and verification related to physical and chemical hazards.

2. Sterilized canned vegetables - hazards identified as significant in production:

– Biological: "Contamination with pathogenic microorganisms (E. coli)"; "Survival of spores of pathogenic bacteria - E. coli, St. aureus, enterococci, coliforms during storage" (cited microorganisms do not form spores at all). The main CCP is connected to the microorganisms - during sterilization;

– Physical: depressurization; broken glass packaging;

– Chemical: not determined.

The real biological dangers here are the spore-forming aerobic and especially anaerobic microorganisms of the family Bacillaceae. Aerobic mesophilic and thermophilic bacteria in case of insufficient sterilization can cause serious spoilage of cans. Anaerobes - too, among them is the cause of the most serious food intoxication - botulism. Thus, the microorganisms cited above have nothing to do with the risk of biological hazards in canned food. There is a clear example of incompetence in the development of the HACCP system.

There is no CCP and verification in the HACCP plan related to physical and chemical hazards. Correct verification requires the definition of standard criteria for industrial sterility, which are by no means the no spore-forming E. coli, St. aureus, enterococci, coliforms but the high risk for all canning productions spore-forming aerobic and anaerobic mesophilic and thermophilic microorganisms.

3. Confectionery from sponge cake dough. The most serious dangers of moist sponge cake confectionery are:

– Biological: pathogenic bacteria and mold spores, secondary and cross-contamination;

– Physical: metal, plastic, hair;

– Chemical: detergents and disinfectants.

The authors of the system do not specify which pathogenic bacteria are relevant for the current production. There is no CCP and verification related to chemical hazards in the HACCP plan. CCP 1 is based on the real risk of physical contamination of the flour. CCP 2 is placed during the firing of the countertops. But after baking, the process continues with manual operations, which are the most likely place for intestinal bacteria, staphylococci and other current microorganisms. This means that CCP 2 is not in place. The real dangers of secondary contamination with

microorganisms have not been taken into account in the manual processes of confectionery shaping. After this stage, there is no technological process that limits the hazards of a biological nature. This is where the CCP should be placed.

Verification procedures include microbiological tests for control in CCP 3, determined during the refrigerated storage of the produce. Why? By what microbiological criteria will we judge the efficiency of the processes - quantitative or only qualitative; pathogenic or indicator? Obviously, the team is not able to make concrete and clear decisions in this case.

The other cases we are considering also place CCP in those segments of the technological chain in which biological, mainly microbiological hazards prevail. And these are - the main processes associated with heat treatment or refrigerated storage of food products. Very often biological hazards are formulated incorrectly, without taking into account the exact taxonomic names of microorganisms and groups of microorganisms, their pathogenicity or their importance as indicators of hygiene conditions. A common mistake of business operators is the introduction of complex and inadequate verification procedures that have nothing to do with the effectiveness of technology in eliminating the main dangers. They do not allow for a real test of the effectiveness. Its real proof is clear - periodic microbiological control of finished products on indicators of real importance for product safety. Instead, unnecessary and inadequate activities are performed such as:

- "storage conditions are monitored";
- "examination of the knowledge and skills of workers ... ";
- "inspection of premises and records";
- "medical examination to certify health records";
- "washes by machine contact surfaces";
- "temperature control in depth of the finished product".

In fact, there is a mixture of monitoring and verification. In part, the avoidance of control on microbiological indicators directly related to the identified hazards is due to the fact that verification microbiological tests should be performed in accredited laboratories, and this has certain cost requirements. The companies with their own production laboratories are in the most favorable position. Thus, it is possible to trace the dynamics of microbiological processes in real production conditions along the food chain.

It is easier for all enterprises to conduct the actual internal control - the monitoring of indicators in critical control points. This can be automatic or manual, visual monitoring of the parameters and the implementation of their registration and records. In case of deviations from the critical limits, established during the development of the HACCP plan, corrective actions are taken. These are the most understandable elements of HACCP systems by business operators.

As in all business areas, so in HACCP systems in the food industry, the documentation of actions and data are of great importance for the correct implementation of HACCP plans. Here we can make critical remarks on almost all the cases we are considering. There is a very serious complication and multiplication of the records made. These are protocols, lists, checklists, worksheets, forms, procedures and other forms. They are usually not arranged in a logical order in

common registers with the respective record keepers. This often leads to chaos, extremely disrupts teams and operators, prevents the prompt reading of monitoring data and immediate responses to deviations from critical production limits. Such documentation does not guarantee the traceability of the processes. It does not stimulate the periodic analysis of the results of the activities and their possible optimization. Not to mention the time wasted on records from more operators according to the established hierarchy in companies.

Documentation is crucial in performing corrective actions and in making important management decisions to optimize the production and control of the HACCP plan. It must be adequately composed, accurate, easy to complete, without duplicate records, have marked responsibilities, be kept in strict order and available to the team, company management and control bodies.

The highlighted accents, systemic omissions and recurring errors are most closely related to the level of qualification of the HACCP teams operating in each company in the food industry and, in part, in public catering. These are specialists with different educational qualifications, largely insufficient to adequately address the problems of nutritional, biological value of foods and their safety for the public health. This is where the need for highly professional supervision of the Internal Control Systems is assigned to the specialists of the health system - the doctors specializing in "Nutrition and Dietetics" and the inspectors for protection and control of public health. Their training and professional intervention in the organization and functioning of HACCP systems are absolutely necessary both as a preliminary stage in the preparation and as an ongoing assessment, auditing and other forms of control, namely in avoiding mistakes or correcting production and hygiene practices, when necessary. On the other hand, medical professionals should not deal with Internal Control Systems for engineering and technological problems of production (eg. water supply, sewerage, ventilation, equipment, etc., for which they have no competence) - these are tasks for other members of HACCP teams. This is what obliges the separation of the specific tasks of the medical specialists for the overall assessment of the HACCP systems. In the spirit of the requirements of the Codex alimentarius, they should undertake the assessment of the nutritional, biological value of food and its compliance with European and national safety criteria and standards. This is crucial for the algorithm of the medical specialist's activity in audits and evaluations. This algorithm should focus its attention and activities on the following aspects:

– The quality of GMP and the Technological documentation and their compliance with the health requirements for nutritional, biological value and food safety;

– Adequate identification of the real hazards that could arise in each proceeding;

– Correct assessment of the location of the safety-critical stages in the production and the respective points of internal control (CCP);

– Adequate actions for verification of the effectiveness of the HACCP system through evidence of the qualities and safety of the finished product.

CONCLUSIONS

1. The functioning of the HACCP systems in the enterprises of the food industry ensures order, stability and automation of the internal control. They lead to relative independence from failures and human errors in the processes of ensuring the production of healthy food and preventing the risk of possible dangers to the health of the consumer.

2. The criteria for nutritional information, ie. the indicators for the nutritional value of the foods are not within the scope of the internal Control System, resp. of HACCP planning. This applies to the content and quality of protein, fat, carbohydrates, vitamins, or the content of table salt (sodium), dietary fiber, probiotic bacteria and more. They are treated as quality indicators and not as safety criteria and are beyond the scope of internal control.

3. The technological documentation is a fundamental prerequisite document, which unites the requirements of the HACCP systems to give a description of the product, to put in the criteria for its safety and to mark the critical processes of each production in order to determine them in the system of daily, hourly control. With the obligatory development and implementation of the TD, the Bulgarian national legislation upgrades and concretizes the European norms and standards in the field of food quality and safety.

4. HACCP plans are developed almost exclusively on the basis of biological hazards. An obvious fact is the poor knowledge of the authentic biological hazards concerning foods of different origin and composition. The hazards in this case are formulated with general terms such as "pathogenic bacteria", "psychrotrophic pathogens", "bacteria and molds", "spore-forming microorganisms" and other general terms, without specifying the group, genus or species of the microorganisms and this prevents of the implementation of consistent control and traceability of unwanted biological contaminants in the course of the technological chain.

5. No actual verification of the efficiency of production processes against the relevant biological hazards is applied. Their elimination or reduction to negligible quantities in the course of the technological process determines the critical control points and is usually reduced to monitoring the temperatures of heat treatment or refrigeration storage, which have a lethal effect, resp. limit the reproduction of the microflora to undesirable amounts.

6. Systematically in productions where, after heat treatment, there are processes related to cross-contamination possibilities, critical control points are placed at the point of application of high temperature, and subsequent operations carrying authentic risk are ignored, not recognized as critical points. The measures in them are not subject to monitoring (eg confectionery production).

7. In the practice of food business operators, critical control points related to the risk assessment of physical or chemical hazards are very rarely identified.

8. The chemical hazards for most food products come with the raw materials. These can be toxic elements, pesticide residues, antibiotics and sulfonamides, hormones, nitrates and nitrites, mycotoxins, persistent organic contaminants, etc., which do not reduce their levels in food processing technology. There is an underestimation of the importance of incoming control as a barrier against primary

contamination of production. The HACCP plans systematically lack critical points related to the incoming control, resp. with this type of hazards.

9. The development and operation of HACCP systems require very high qualification of the working teams in the food industry for competent hazard identification and risk assessment. The practice shows insufficient knowledge of this specific matter, lack of certain medical knowledge and convinces of the need to attract to the teams trained in the field of risk assessment specialists for adequate formulation of hazards, identification of critical control points and their place in the food chain.

10. In many cases, the development of prerequisite programs, including technical documentation, and HACCP plans is outsourced, the selection of which is not always appropriate. The branch associations of producers have a positive role, which provide their members with correctly developed prerequisite programs for good manufacturing and good hygiene practice and thus support the preventive segments of the internal control systems.

11. The most vulnerable place of the HACCP systems is the verification of the effectiveness of the preventive measures taken in the course of the food chain in the enterprise. Systematic negative practice is the entry of verification actions that are not related to the effectiveness of the applied technologies for elimination or reduction of risk.

12. A frequently observed error in the Internal Control System is the inadmissible mixing of the monitoring activities with those of the verification.

13. A serious omission is the ignorance of the European and national normative documents concerning food safety. It leads to errors in the formulation of food safety criteria in the technological documentation, or in their mechanical application in the identification of hazards and the determination of critical points and critical limits.

14. In the development of the Internal Control Systems, a common practice is the complication and unnecessary duplication of the HACCP documentation, as well as the absence of systematized registers of the forms. This creates difficulties in the daily practice of the operators and does not contribute to an objective periodic review during the monitoring. The identification of adequate corrective actions is delayed, it is difficult to trace the processes at each stage of the production process, and hence the quality and safety of the products.

CONTRIBUTIONS

Contributions of theoretical significance

1. For the first time in a scientific format an in-depth analytical review of the Systems for internal control of enterprises in the food industry in Bulgaria with a critical assessment of the developed and operating HACCP-plans was performed. It gives an idea of the functioning of the Internal Control Systems in our country and substantiated conclusions about their effectiveness in providing quality and safe for the health of the consumer food.

2. Systemic gaps in the development and operation of HACCP systems have been identified. In pre-requisite programs, the leading documents - the Technological documentation, do not always objectively reflect the characteristics of the products

and often do not contain correctly formulated requirements for the composition and food safety. Disadvantages in the HACCP plans are the inaccurate determination of the location of the critical control points, the incorrect identification of the real hazards and the approaches to their control.

3. The role of incoming control of raw materials is underestimated as a critical point. The choice of suppliers and their control are not enough - it is necessary to require certificates of compliance with established standards of hazards such as toxic elements, mycotoxins, pesticide residues, pathogenic microorganisms and others that production technologies can not eliminate completely or bring to negligible quantities.

4. In the functioning of the HACCP plans in various types of proceedings, a systematic inadequate use of principle 6 - verification of the effectiveness of the Systems, also called "verification", has been established. As a rule, the verification criteria and procedures do not answer the basic question: is the elimination of the dangers to the health of the consumer or their reduction to negligible quantities done effectively? The planning and implementation of the verification of the Systems is a fundamental principle in the responsibilities of the medical specialist.

5. The place of the medical specialist in the development and functioning of the Internal Control Systems in the food establishments and the respective HACCP plans is emphasized. Its qualification is necessary in order to competently determine the critical points, limits and norms in terms of the purpose of these systems for the prevention of diseases and injuries caused by foods of low biological and nutritional value and carriers of hazards to human health.

6. An original algorithm of the analysis of the HACCP Systems, performed by medical specialists, for assessment of the adequacy of the determined CCP and of the effectiveness of the monitoring has been developed:

• In the analysis of the prerequisite programs the emphasis should be on the quality of the Technological documentation and their compliance with the health requirements for nutritional, biological value and with the European and national criteria and safety norms;

• The HACCP systems should be subject to analysis and assessment of the localization of CCP in terms of the processes of elimination of hazards, adequate identification of the real hazards to the health of the consumer and verification - they are crucial for the medical effectiveness of internal control systems;

Contributions of scientific and applied significance:

1. As a result of the critical evaluations of the Systems for each type of food produced, specific proposals have been made for optimization of hygiene requirements and norms for achieving high biological, nutritional value and safety, as well as for verification of their effectiveness, as follows:

1.1.For the pasteurized egg products: radical processing of the Technological documentation with standardization of the content of protein, table salt, sugars; announcement of preservatives; serious clarifications of the real biological hazards, clearing of unnecessary and insignificant indicators; authentic verification criteria for process safety and hygiene; systematization of HACCP documentation.

1.2.For the sterilized canned vegetables: updating the records in the TD for the microbiological criteria for industrial sterility; correction of the identified biological hazards and their replacement with real indicators; introduction of control points in HACCP in addition to the set CCP; introduction of two verification procedures - in the preparation of raw materials and in the finished product.

1.3.For the catering confectionery and culinary desserts: correction of the thermal regimes, new criteria and norms for physico-chemical characteristics, microbiological safety and shelf life in TD; change of the location of CCP from the point of heat treatment to the point of manual operations with the risk of secondary contamination of the production; algorithm for checking the microbiological condition of the working environment; revision of verification procedures.

1.4.For the catering soups, dishes and grilled meat products: corrections in the TD of the thermal regimes of storage and heating, inclusion of appropriate physico-chemical and pathogenic and indicator microbiological criteria, limitation of the table salt; supplementing HACCP with CCP in the section for storage of hot culinary products; supplementing the verification program with appropriate organoleptic and microbiological safety criteria at a certain periodicity of the examinations.

1.5.For the pasteurized canned vegetables (lyutenitsa, tomato products): corrections in TD with reduction of table salt content, incoming control of vegetable raw materials for the mycotoxin patulin, regulation of appropriate microbiological criteria; in the HACCP plan, the verification program should be supplemented by periodic inspections of the microbiological safety of the products.

1.6.For the production of sauces: to adjust the microbiological criteria and norms and the content of table salt in the TD; through verification to control the achievement of the required microbiological purity, to improve the presentation of nutritional information regarding the allergens contained in the sauces.

1.7.For the the production of canned fruit – jams with whole fruits, marmalades, jams with fruit pieces, toppings: to provide incoming control of raw materials for mycotoxin patulin.

1.8.For the production of germinated seeds and their products: the program for incoming control of raw materials to be supplemented with requirements for certificates for content of pesticide residues, fertilizers and mycotoxins; if possible to control the absence of pathogenic microorganisms; verification procedures to include control of indicator micro-organisms; for sprout products - sandwiches and salads, to include a third CCP in manual operations with a risk of secondary contamination.

1.9.For the production of cuts and preparations of red and white meat: TD for the products of minced meat to be supplemented with quality requirements, to specify the quantities of soy protein, to adjust the upper limits of the fat content, to introduce an indicator of the content of connective tissue proteins; to indicate the types and concentrations of the used technological additives containing hidden sodium; to optimize the criteria for verification of the HACCP plan.

2. The algorithm of inspections by medical specialists can be used by control authorities and specialists in the inspection of prerequisite programs, technological documentation and the implementation of the principles of HACCP in the realistic conditions of production of various foods.

The results of the performed critical analysis are provided to the manufacturers together with the specific proposals for improvement of the prerequisite programs, respectively TD, and adjustments of the HACCP systems.