

**Abstract****Tsv. Vitkova,****R. Enikova,****M. Stoynovska,***Department of Hygiene, Medical Ecology, Occupational Diseases and Disaster Medicine, Medical University-Pleven, Pleven, Bulgaria***MEDICAL EVALUATION OF HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS EFFECTIVENESS IN THE PRODUCTION OF HIGH-RISK FOODS**

The current European legislation assigned the responsibility for food safety to the food producers and traders. The introduction and functioning of HACCP systems strives to achieve serious medical goals – consumer's health protection, minimizing the risk for foodborne toxico-infections, infections and intoxications, for chemical contamination and additives, as well as for other specific hazards. The approach is entirely preventive. The current experience has revealed numerous omissions and discrepancies in HACCP elaboration and functioning referring to the real extent of the hazard. This paper presents results from a critical analysis of the performance of HACCP systems in the production of confectionery, ready-to-serve foods, pasteurized egg products, sterilized canned foods, etc., highlighting the major defects in hazard analysis, adequacy of the critical points, correction activities, and verification procedures. Suggestions are provided concerning the optimization of the relationships between the producers and the control authorities aiming to eliminate the established system discrepancies.

Keywords: HACCP, microorganisms in foods, microbiological criteria, pasteurized egg products, confectionery products, vegetable canned foods, ready-to-serve dishes.

Corresponding author: mstoynovska@gmail.com**Резюме****Ц. Віткова,****Р. Енікова,****М. Стойновська,***Кафедра гігієни, медичної екології, професійних захворювань та медицини катастроф, медичний університет м. Плевен, Болгарія***МЕДИЧНА ОЦІНКА ЕФЕКТИВНОСТІ СИСТЕМИ АНАЛІЗУ РИЗИКІВ І КРИТИЧНИХ КОНТРОЛЬНИХ ТОЧОК У ВИРОБНИЦТВІ ПРОДУКТІВ З ВИСОКОЮ СТУПЕНЕМ РИЗИКУ**

Відповідно до чинного європейського законодавства, відповідальність за безпеку харчових продуктів несуть виробники і продавці продуктів харчування. Впровадження та функціонування системи НАССР націлено на досягнення серйозних медичних цілей: захисту здоров'я споживачів, мінімізації ризику зараження харчовими токсигенами, інфекцій і інтоксикацій, пов'язаних з харчовими продуктами, як щодо хімічного забруднення і добавок, так і для інших специфічних факторів ризику. Цей підхід є повністю превентивним.

Сучасний досвід показав численні упущення і розбіжності в розробці і функціонуванні НАССР з урахуванням реального ступеня небезпеки. У даній роботі представлені результати критичного аналізу ефективності системи НАССР у виробництві кондитерських, кулінарних виробів, пастеризованих продуктів переробки яєць, стерилізованих консервів і т. д., які вказують на основні недоліки в аналізі ризиків, відповідність критичних точок, коригувальні дії та процедури перевірки. Запропоновано рекомендації щодо оптиміза-

ції взаємин між виробниками і органами контролю, спрямовані на усунення встановлених системних невідповідностей.

Ключові слова: HACCP, мікроорганізми в харчових продуктах, мікробіологічні критерії, пастеризовані продукти переробки яєць, кондитерські вироби, овочеві консерви, кулінарні страви.

Резюме

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МЕДИЦИНСКАЯ ОЦЕНКА ЭФФЕКТИВНОСТИ СИСТЕМЫ АНАЛИЗА РИСКОВ И КРИТИЧЕСКИХ КОНТРОЛЬНЫХ ТОЧЕК В ПРОИЗВОДСТВЕ ПРОДУКТОВ С ВЫСОКОЙ СТЕПЕНЬЮ РИСКА

В соответствии с действующим европейским законодательством ответственность за безопасность пищевых продуктов возлагается на производителей и продавцов продуктов питания. Внедрение и функционирование систем HACCP направлено на достижение серьезных медицинских целей: защиты здоровья потребителей, минимизации риска заражения пищевыми токсигенами, инфекций и интоксикаций, связанных с пищевыми продуктами, как в отношении химического загрязнения и добавок, так и для других специфических факторов риска. Этот подход является полностью превентивным.

Нынешний опыт показал многочисленные упущения и расхождения в разработке и функционировании HACCP с учетом реальной степени опасности. В данной работе представлены результаты критического анализа эффективности системы HACCP в производстве кондитерских, кулинарных изделий, пастеризованных продуктов переработки яиц, стерилизованных консервов и т. д., которые указывают на основные недостатки в анализе рисков, соответствие критических точек, корректирующие действия и процедуры проверки. Предложены рекомендации относительно оптимизации взаимоотношений между производителями и органами контроля, направленные на устранение установленных системных несоответствий.

Ключевые слова: HACCP, микроорганизмы в пищевых продуктах, микробиологические критерии, пастеризованные продукты переработки яиц, кондитерские изделия, овощные консервы, кулинарные блюда.

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Introduction

The introduction of HACCP systems in the practice of all food production enterprises, in catering establishments and even in hyper- and supermarkets pursues major medical goals: restriction of foodborne toxicoinfections rate, minimization of the population risk for chronic exposure to chemical contaminants, additives, mycotoxins and other health hazards with direct or remote effects [4, 8, 9]. At the same time the development, implementation and maintenance of this systematic preventive-medical activity and the associated responsibilities are totally assigned to food business operators. In spite of the expectations, no visible restriction of this morbidity rate has been observed in the European countries compared to

previous periods when the measures for implementation of HACCP systems everywhere in food chains have not been active.

In accordance with those findings the MAIN TASK of this study was to perform and present a critical analysis of the functioning of HACCP systems in the manufacturing of foods providing risk for specific physical, chemical and biological hazards for the public health.

MATERIAL AND METHODS

The critical analysis was performed by direct observations over enterprises producing four food groups and by evaluation of their authentic documents associated with production hygiene, in-plant control systems and HACCP-plans. The items



covered were foods providing potential risk – confectionery products, ready-to-serve warm dishes, sterilized preserves and pasteurized egg semi-ready products – a number of various industries differing because of the specificity of the input materials, technologies, composition, duration, purpose and use of the products. Their HACCP systems, though, is based on similar basic principles.

The analyses of each production covered:

- Prerequisite programs;
- Descriptions of the products;
- Production design and technology;
- Technological documents (TD) for the ready products;
- HACCP teams organization;
- Full scope and documentation of the developed HACCP and their implementation in the production process.

The analyses emphasized the hazards identified by the teams, the adequacy of the suggested critical and critical control points (CP and CCP), the systematic monitoring and its results, the verification of the system elements [4].

RESULTS AND DISCUSSION

1. Confectionery products

The analysis covered confectionery products with high water content, such as pastry, cakes, rolls etc., on paste basis garnished with glazes, couverture, chocolate and with milk, cream and butter creams. Those products are stored in refrigerating conditions and have limited shelf-life – from 5 to 8 days. This type of patisserie provides confirmed risk for bacterial foodborne diseases, mainly salmonella and staphylococcal food poisoning.

The main input materials are flour, sugar, eggs, milk, milk butter, vegetable natural and hydrogenated fats and oils, etc. as well as food additives – preservatives, emulsifiers, stabilizers, glazing agents,

synthetic colorants, flavors, permitted by the European legislation.

The production technology is traditional for confectionery. The paste bases are baked at temperatures of 170 °C to 300 °C, followed by the preparation of the creams, glazes, pastry fillings. The creams are cold, prepared from powder semi-ready products. The patisserie products are finalized by manual garnishing and decorating operations with fillings, creams, glazes, couverture, etc. This is the decisive moment for the main biological hazards to penetrate into the product – secondary contamination with microorganisms, including pathogenic ones – at presence of intestinal, droplet and dermal infections, transmitted by the staff, the workplace environment and equipment. The manual operations determine the extent of risk for disease accidents or production decay [3, 7].

Figure 1 presents the scope of HACCP in the food chain of production of mellow confectionery and the observed defects. They are found mainly in unconformity of the identified CCP and the risk extent. CCP 1 and CCP 3 are established correctly – in the first case it is the place to prevent physical hazards and in the second – the prevention of reproduction of unwanted flora in the ready product. The place, though, of CCP 2 is not in the thermal processing of the bases but in that part of the chain where the manual operations are deployed – garnishing and decoration of the products and cold preparation of creams. The possible secondary contamination with unwanted microorganisms is realized at those two stages of the chain. After the manual operations there is practically no factor that could eliminate or reduce the available microflora to safe levels. As a result of this analysis we suggest that CCP 2 would belong with the manual operations, and the baking itself to be only a CT.

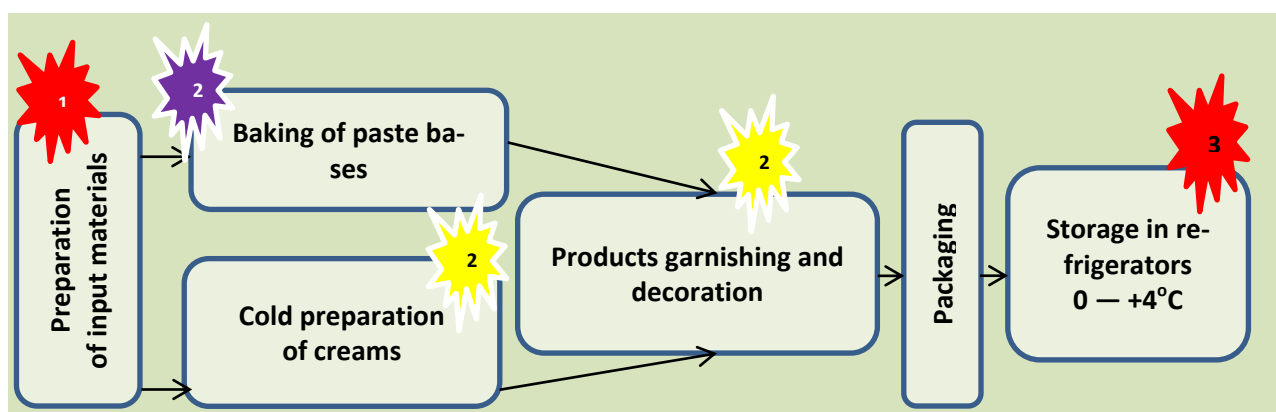


Figure 1 – Scope of HACCP in the food chain of mellow confectionery production and the observed defects

The difficulty with the proposed CCP 2 belongs with the determination of the critical limits. There are no factors here that could be measured. There is observation and control of the personal hygiene rules and workplace environment rules at particularly high level, especially:

- Operators with signs of diseases – gastrointestinal discomfort or disorders, inflammation processes in the respiratory tract or on the skin should not be admitted to the workplace;
- High level hygiene of working clothes;
- Regular microbiological control of hands, working clothes, workplace environment, equipment;
- Periodical control for presence of intestinal

infections and pathogenic staphylococci in the upper respiratory tract and skin of the staff;

- High, controlled level of washing and disinfection of the premises, workplace surfaces and equipment.

Another defect of the developed HACCP system is the absence of reliable verification procedures. Because of the leading importance of the biological hazards the verification should be performed using microbiological tests of the ready product as well as of the workplace environment and of the staff. Because of the incomplete and imperfect criteria for evaluation of biohazards in the elaborated HACCP-plan, we propose the following verification schemes that could also be used as a basis for hygienic limits in the technological documentations (Table 1 and Table 2).

Table 1 – For ready confectionery products in CCP 3:

Criteria	Limits				Periodicity
	<i>n</i>	<i>c</i>	<i>m</i>	<i>M</i>	
<i>Coliforms, CFU/g</i>	5	2	10	100	Monthly
<i>Coagulase-positive staphylococci, CFU/g</i>	5	2	10	100	Each trimester
<i>Salmonella spp.</i>	5	0	Not present in 25 g		Once per 6 months

Table 2 – Samples collected from workplace environment, equipment and operators engaged in garnishing and decoration of the products, in direct contact with the products at CCP 2:

Sample type	Microbiological criteria	Limits	Periodic
Working surfaces and equipment	<i>Coliforms</i>	Not admitted	Monthly
Staff hands	<i>Coliforms</i>	Not admitted	Once per 2 months
	Coagulase-positive staphylococci	Not admitted	
Working clothes	<i>Coliforms</i>	Not admitted	Once per 2 months
Upper respiratory tract (nose, throat)	Coagulase-positive staphylococci	Not admitted	Once per 6 months

2. Ready-to-serve dishes

Ready-to-serve dishes are a specific product type that is the most frequent cause for bacterial foodborne diseases, mainly through catering establishments [3, 6, 7].

Within this group the following cooked dishes were analyzed: cooked dishes with meat (one- and multi-component), soups (meat, fish or offal, and vegetable) and culinary products, grilled or baked in a convection oven – a very rich list of foods offered for direct consumptions warm or cooled and warmed before offering in catering establishments. The recipes are complex, mainly traditional Bulgarian, of whole and cut poultry, pork and veal,

with vegetables, pulses, eggs, dairy products, butter and sunflower oil, flour, spices. This envisages a very diverse and numerous microflora of the input materials and serious technological processing for its elimination and reduction to acceptable limits. The key moment in the technologies is the thermal processing. It is realized by boiling, baking, processing in convection ovens and, in all cases, it requires reaching of full culinary readiness and of temperatures within the dishes of over 75 °C and in practice – much higher, close to the boiling point at sufficient processing duration.

The major hazards are biological in this group too – residual microflora after the processing and



secondary occurring unwanted microflora. The residual microflora is scarce, presented by spore forms of *Bacillaceae*, most often *C. perfringens*, *B. cereus*, *B. subtilis*, *spp. mesentericus*. The risk with grilled products is greater – there the temperature often does not penetrate deeply enough in-depth of the portions and it is possible that non-spore forming bacteria would also survive there – *Salmonella*, *Listeria*, *E.coli* and others as a result of primary contamination of the major input materials.

The general risk is presented not only by the quick decay of the dishes when staying in the warm kitchen, but also by potential toxicoinfections and intoxications. The dishing, portioning and string to the time of consumption operations cause inevitable secondary contamination and very quick reproduction of residual spores as well as of secondary introduced microorganisms.

Figure 2 presents the chart of HACCP scope and outlined CCP for the three types of ready-to-serve dishes (cooked dishes, soups and baked dishes).

There are two omissions in the technical documents and in HACCP as well. The first one is that the temperature at which the dishes are stored warm before the consumption is not set. It should be not lower than 65 °C. Lower temperatures, such as 30 °C -45 °C, would play the role of a thermostat for mes-

ophilic and thermophilic microorganisms, place to reproduce and accumulate high infectious doses. It is exactly that moment that is the real cause for most toxicoinfection or intoxication outbreaks through the fault of catering establishments. An additional CCP 4 should be deployed here. Another omission is the lack of adequate microbiological requirements to the ready-to-serve-production. Various criteria are set for the three groups of dishes, all of them minimal, not accounting the real hazards. That is why we recommend the following microbiological criteria for safety and hygiene of the processes, basis for verification schemes as well (Table 3).

In this way the ready-to-serve dishes will conform to the requirements of the amended Regulation (EU) № 2073/2005 and their control will be established on a sound basis considering the real biohazards.

3. Sterilized canned foods

Sterilized canned foods are foods for which the elaboration of a HACCP system is not a difficult methodological problem because of the clear vision for the major CCP – the sterilization itself, when the dominating biohazard – anaerobic, spore-forming bacteria, respectively botulism risk - is eliminated [2]. The discussed production produces sterilized multicomponent vegetable cans – Figure 3.

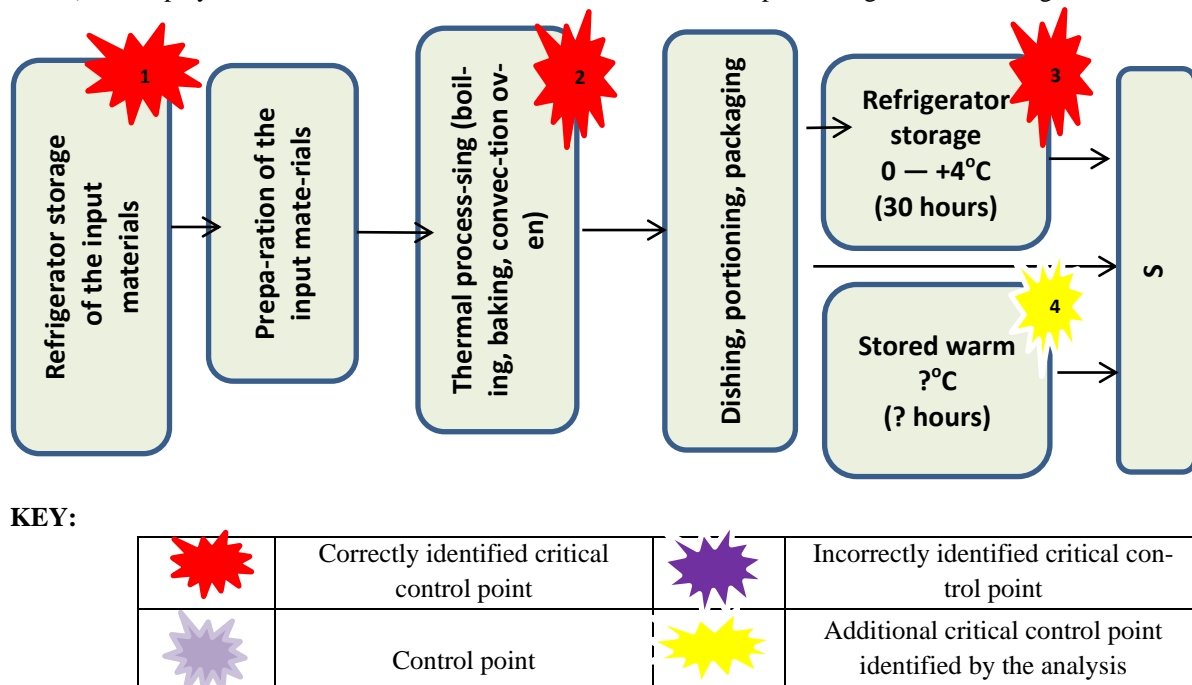


Figure 2 – Chart of HACCP scope and outlined CCP for the three types of ready-to-serve dishes



Table 3 – Ready-to-serve dishes (soups, cooked dishes, baked products) at CCP 3:

Criteria	Limits				Periodicity
	<i>n</i>	<i>c</i>	<i>m</i>	<i>M</i>	
<i>Escherichia coli</i> , CFU/g	5	2	10	100	Monthly
<i>Bacillus cereus</i> , CFU/g	5	2	10	100	Once per 3 months
<i>Sulfite reducing clostridia</i> , CFU/g	5	2	10	100	Once per 6 months
<i>Listeria monocytogenes</i>	5	0	Not present in 25 g		Once per 6 months
<i>Salmonella spp.</i>	5	0	Not present in 25 g		Once per 6 months

The HACCP team has correctly identified the hazards and respective CP and CCP using the standard questions of the “decision tree”. Depending on the leading hazards – biological and physical (fragments of glass jars) the team has identified three CP and one CCP.

The monitoring of the sterilization process is a complex issue. The natural daily, of each lot and of

each device (autoclave, rotomat) control is the registration of the three components – temperature, exposure, pressure. An indirect evaluation off the effect could be given by a test of the lot after storage but it is not enough. The real assessment is given by the microbiological control of industrial sterility which, naturally cannot be performed for each lot.

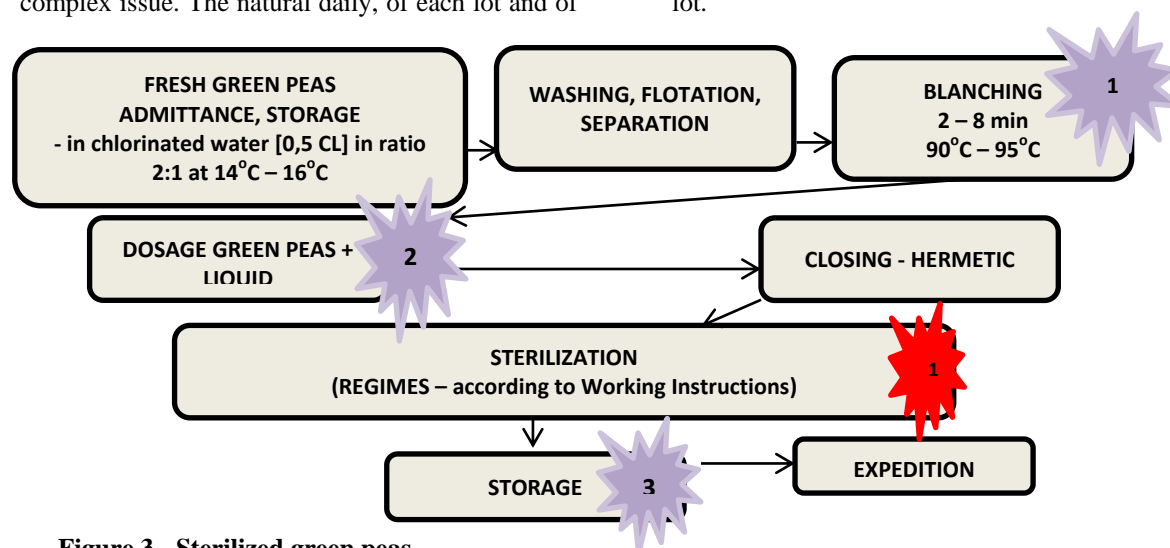


Figure 3 - Sterilized green peas

Here comes the place of verification of HACCP procedures where the answers about their effectiveness at CP or CCP are provided by the periodical microbiological analyses. We would like to propose to include verification procedures in the HACCP system for sterilized vegetables and ready-to-serve vegetable dishes representing periodical tests of the following microbiological criteria (Table 4, Table 5).

4. Pasteurized egg products

Pasteurized egg products – egg mélange, egg yolk and egg white are concentrated semi-ready products for confectionery, bakery and catering and could carry serious biohazards – salmonella, listeria and other causes of zoonoses [1, 5]. Their thermal processing is the main factor for microbial decontamination of the raw egg mass, but it is within the limits of low pasteurization - between 57 °C

and 67 °C at flow rate of 1500 to 3000 l/h. Thus the denaturation of egg whites is prevented and they preserve their nutritional and biological value, though there is still the non-negligible epidemical risk to be considered. That is why the adequacy of the HACCP plan in this industry is of particular importance. Figure 4 presents the major stages of the technological chain and the envisaged CCP for this industry.

Though pasteurization is quite effective towards pathogenic *Enterobacteriaceae* and other non-spore forming bacteria, it cannot decontaminate raw egg mass completely and the residual microflora can further reproduce and compromise the production at low refrigeration temperatures. Psychrotrophic microorganisms, moulds and yeasts are leaders in those processes.

Table 4 – Verification of HACCP for sterilized vegetable canned foods at CP 1 (preparation of the input materials/blanching)

Criteria	Periodicity
<i>Total count of mesophilic aerobic and facultative anaerobic microorganisms, CFU/g</i>	Once per 6 months
<i>Spores of mesophilic aerobic and facultative anaerobic microorganisms, CFU/g</i>	Once per 6 months
<i>Thermophilic microorganisms – vegetative and spore forms</i>	Once per 6 months
<i>Enterobacteriaceae, CFU/g</i>	Once per 6 months
<i>Yeasts and moulds, CFU/g</i>	Once per 6 months

Table 5 – Verification of HACCP for sterilized canned vegetables at CCP 1 (sterilization)

Criteria	Periodicity
<i>Mesophilic aerobic and facultative anaerobic microorganisms – non spore forming and vegetative forms of spore forming ones</i>	Monthly
<i>Spores of mesophilic aerobic and facultative anaerobic microorganisms</i>	Monthly
<i>Mesophilic anaerobic microorganisms</i>	Monthly
<i>Thermophilic microorganisms – vegetative and spore forms</i>	Once per three months
<i>Moulds and yeasts, CFU/g</i>	Monthly

From this point of view the analysis of the HACCP plan shows correct design of CCP in the food chain, but unconvincing verification of the monitoring at pasteurization and storage. In this relation we would propose the following scheme of verification tests adequate to the character of the risk with pasteurized egg products (Table 6).

In all four productions the HACCP systems do not identify chemical hazards emerging within the

range of the technological chains. They can be carried by the input materials and their elimination is realized by the input control.

The results of the performed critical analyses are presented to the business operators together with the proposals for revision and optimization of HACCP plans and verification procedures and tests.

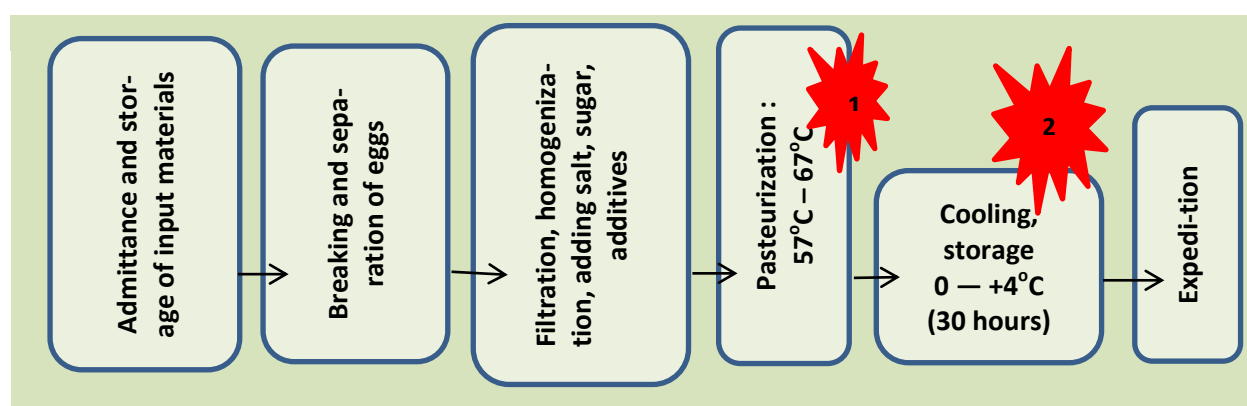
**Figure 4 – The major stages of the technological chain and the envisaged CCP for this industry**

Table 6 – Verification tests in HACCP for pasteurized egg products at CCP 2

Microbiological criteria	In-plant limits	Periodicity
1. <i>Total count of mesophilic aerobic and facultative anaerobic microorganisms</i>	< 50 000 cfu/g	Once per three months
2. <i>Enterobacteriaceae</i>	< 10 cfu/g	Once per three months
3. <i>Moulds and yeasts</i>	< 10 cfu/g	Once per three months
4. <i>Salmonella spp.</i>	N = 5; c = 0; m – absence in 25,0 g of the product	Once per three months

Conclusions

1. The analyzed types of production of foods at high risk as carriers of pathogenic microorganisms, respectively of infectious foodborne diseases have elaborated and implemented HACCP plans in conformity with the requirements of the EU Regulations;

2. Biohazards due to primary or secondary contamination with microorganisms, disease agents or causes for unwanted changes of the quality, nutritional and biological value of the foods during the storage process are leading;

3. A common defect is the business operators' underestimation and unawareness of the nature of biohazards, incorrect and improper identification of CCP and CP, as well as inadequate system for verification of the effectiveness of the procedures.

4. Strict medical assessment of the hazards and mandatory consultation with medical specialists are necessary at elaboration and implementation of HACCP plans for foods carrying high risk of bacterial foodborne diseases.

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