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RISK ANALYSIS AND IDENTIFICATION OF CRITICAL CONTROL POINTS (CCP) IN PRODUCTION OF NATURAL INTESTINAL CASINGS

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Abstract
Implementation of the HACCP system in enterprises manufacturing natural intestinal casings is topical for ensuring high quality and confidence in safety of manufactured products. The paper examines hazardous factors in production of natural intestinal casings, analyzes risks with assessment of the probability of hazardous factor occurrence. To this end, a Pareto chart was constructed, unacceptable risks were determined, CCPs were revealed using the decision tree, critical control limits were established for each CCP and the requirements for their monitoring were specified. In addition, the paper gives risk analysis for the stage «salting» with expert assessment of the severity of consequences from realization of a certain hazardous factor and the probability of this realization for each risk. The risk of microbial growth due to addition of the insufficient amount of salt was classified as a biological factor with the severity of consequences 3 and the probability of realization 3. The risk of microbial growth due to violation of the temperature-humidity conditions and duration of holding on a site is also a biological factor with the severity of consequences 3 and the probability of realization 2. These stages are assigned to CCPs. Using the Pareto chart, the factors that had the highest effect on safety and quality of natural intestinal casings were grouped; with that, the percentage ratio of the revealed hazardous factors was established: biological/chemical/physical/allergens 65/20/15/0 for the whole technological process.

Introduction

Casings perform an important function in all types of sausage products; it is casings that give them a shape and also protect from an impact of an environment. Natural intestinal raw materials have been used for many centuries. Their protein composition is close to the meat composition and, therefore, they withstand the same technological regimes of processing as minced meat, obtain strength under the impact of smoke and hot air, and ensure stability of a finished meat product to microbial action [1].

It is worth noting that natural casings are exposed to the microbiological risk to a larger degree than, for example, polyamide casings as they are a favorable environment for the development of microorganisms. In this connection, the preference is increasingly given to artificial analogues [2].

At present, for production of different types and names of sausage products, manufacturers use beef, hog and sheep small intestine, beef bung, beef middle, beef fatend, hog bladder, hog middle, sheep bung [3].

Currently, the system used in the Russian Federation for the control of materials that are applied as packages for foods is harmonized with the international requirements and ensures their safety for population upon correct exploitation, adherence to the requirements of labeling and storage conditions. However, there is a problem of norming the safety indicators for natural casings due to the lack of a unified legislative document. As the regulative documentation for intestinal raw materials was absent for a long time, the Gorbatov Research Center for Food Systems developed in 2016 the interstate standards GOST 33791–2016 «Pig's casings and bladders. Specifications», GOST 33790–2016 «Bovine's casings and bladders. Specifications», GOST 34107–2017 «Sheep's and goat's casings. Specifications», which give classification of casings, their characteristics, requirements for materials and raw materials for production of intestinal casings, requirements for packaging and labeling, acceptance rules, methods for control and rules for transportation and storage [4].

The majority of manufacturers know that unsatisfactory quality of used casings and risks in the supply chain have an adverse effect on product quality characteristics, which as a result, negatively affect the economic component of any enterprise. Therefore, to ensure complete safety for an ultimate consumer, it is necessary to examine risks not only in the process of sausage production but also at the stages of preparation of casings to be used.

The process of risk management showed itself to be effective in many industrial branches. In the food industry, risk management was brought under regulation in 2013 with coming into force of the Technical Regulation TR CU 021/2011 «On food safety», according to which a manufacturer has to develop, implement and maintain procedures based on the HACCP principles in implementing processes of food production associated with safety requirements for such products [5].

In this connection, implementation of the HACCP system is also topical for enterprises that produce natural

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casings as it allows ensuring predicted high quality and confidence in safety of manufactured products, timely identifying causes of occurrence of non-conformity during the production process and predicting following steps to prevent them in the future.

Materials and methods

Taking into consideration importance of effective risk analysis, in 2018 the V.M. Gorbatov Federal Research Center for Food Systems of Russian Academy of Sciences carried out studies on safety and quality management for natural casings in the framework of model risk analysis. The objects of the research were hog small intestine as well as the system of management of hazardous factors in production of natural intestinal casings.

Within the framework of the conducted studies, at the first stage of work, the provisions of the HACCP system were implemented, including:

— the hazardous factors typical for production of natural intestinal casings were revealed and described successively for each stage of the technological process;
— risk analysis was carried out — the probability of occurrence and realization of hazardous factors in the production process, as well as severity of consequences of their realization for an ultimate consumer were assessed;
— a Pareto chart was built to reveal the main hazardous factors that affect product safety;
— cause and effect analysis of realization of the biological hazardous factor was carried out by the method of Ishikawa diagram building;
— unacceptable risks that affect safety and quality of finished products were determined;
— CCPs were revealed using the method of the decision tree; for each CCP, the critical control limits were established;
— requirements for CCP monitoring were established.

Analysis and identification of the unacceptable risk were carried out for each potential hazardous factor with consideration for the probability of its occurrence and severity of consequences. To this end, for each hazardous factor, an expert comparative assessment of severity of consequences from realization of this factor and the probability of this event was performed using designations (Figure 1).

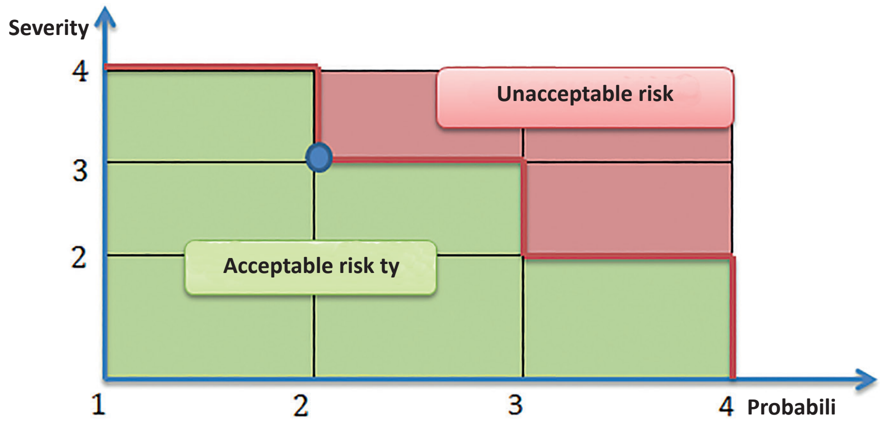
For CCP identification, the method of the decision tree, which is an undirected connected graph with no cycles, was used. The vertexes of this graph are tested hypotheses (assumptions) and «leaves» are possible decisions. Along the path from the root of the «tree» to «leaves», the sequential correction of a decision takes place. To simplify the procedure of building a decision tree and working with it in practice (including for implementation of the research data), only binary «trees» are used; with that, each of the questions linked with vertexes of the «tree» allows only two possible answers — YES and NO [6].

General requirements for the method of the decision tree are established by regulatory documents, in particular, GOST R 51705.1. During research, this method was used with considerations for peculiarities of the production process.

Results and discussion

All stages of the production process were successively analyzed according to the technological scheme presented in Figure 2 taking into account risks that were assigned to the category of unacceptable risks — the zone of the high and medium risk. With that, an effect of the following stages of the production process was taking into consideration regarding the probability of risk realization.

During the research, hazardous factors of manufacturing the natural intestinal casing (hog small intestine) were assessed. Table 1 presents analysis of risks for the stage «salting»; for each risk, an expert comparative assessment of severity of consequences was made with regard to real-



Severity of consequences	Score	Probability of realization
minor ailment that did not lead to serious disorders	1	unlikely (possible once a year)
temporal deterioration of health that did not lead to hospitalization	2	very seldom (once a month)
serious deterioration of health that required hospitalization	3	seldom (once a month)
serious deterioration of health that led to long-term disability or death	4	quite often (once a week)

Figure 1. Diagram of risk analysis

ization of this hazardous factor and the probability of this realization. Only those hazards were taken into account that were on the border and in the area of the unacceptable risk.

The HACCP system distinguishes four types of hazardous factors: biological (B) — microorganisms (including their toxins), viruses and parasites; chemical (C) — chemical substances of natural origin or incorporated into a product during technological processing, physical (Ph) — the presence in a finished product of materials that should not be there and allergens (A).

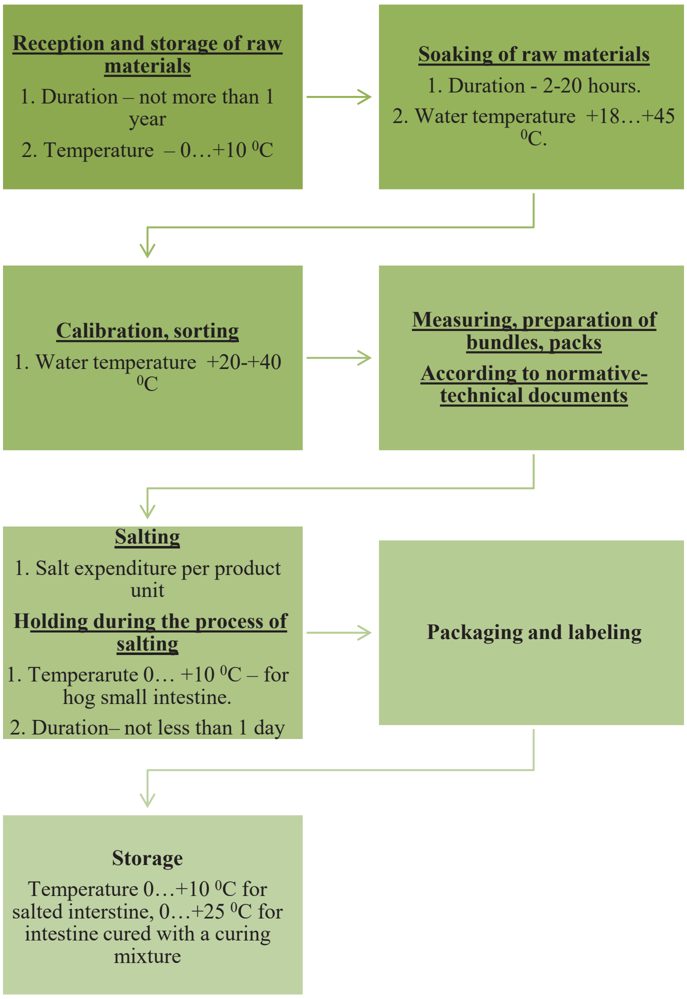


Figure 2. Block diagram for production of hog small intestine

Then, the Pareto chart was built (Figure 3), which made it possible to clearly reveal and assess the main hazardous factors that had the highest effects on safety and quality of natural intestinal casings.

The determinative advantage of the Pareto chart is the fact that it allows ungrouping factors into significant (occurring most frequently) and insignificant (occurring relatively seldom). The Pareto chart shows in the descending order a relative effect of each cause on the general problem.

As a result of classification of risks that affect safety and quality of finished products, it was found that the highest weight had the biological hazardous factor, namely the microbial growth due to violation of the temperature-humid conditions and duration of the presence on the site (26 %)

Table 1. Analysis of hazardous factors

A stage of production process	Description of a hazardous factor	Type of a hazardous factor	Name of a hazardous factor	Severity of consequences	Probability of realization	Potential CCP
Salting and holding of finished products during the process of salting	Microbial growth due to addition of the insufficient amount of salt	B	QMAFAnM, CFU/g coliforms. E.coli	3	3	Yes
	Microbial growth due to violation of temperature-humid conditions and duration of the presence on the site	B	QMAFAnM, CFU/g coliforms. E.coli Salmonella. Proteus. L.monocytogenes, molds, CFU/g, Yeasts, CFU/g	3	2	Yes
	Microbial contamination from personnel, containers, appliances	B	QMAFAnM, CFU/g coliforms	3	1	No
	Use of citric acid	C	Citric acid E330 is used in preservation of casings, it is not a food allergen according to Codex Alimentarius	2	1	No
	Contamination with residues of washing and disinfecting agents from containers	C	For production hygiene, washing agents and disinfectants with burning and irritating action are used to wash food equipment, containers, dressing tables, tools, floors and walls Upon insufficient rinsing of surfaces, the agents can enter raw materials, auxiliary materials and products	2	2	No
	Contamination with foreign bodies from personnel, containers, appliances	Ph	Foreign bodies, insects, rodents, dust, personal items of personnel	1	2	No
	Not detected	A		—	—	

as the used raw materials is unstable in storage as well as upon violation of technological processes and can be a source of human alimentary poisoning.

The conducted investigations allowed determining the ratio of hazardous factors for each chosen stage of natural casing production, which is presented in Figure 4.

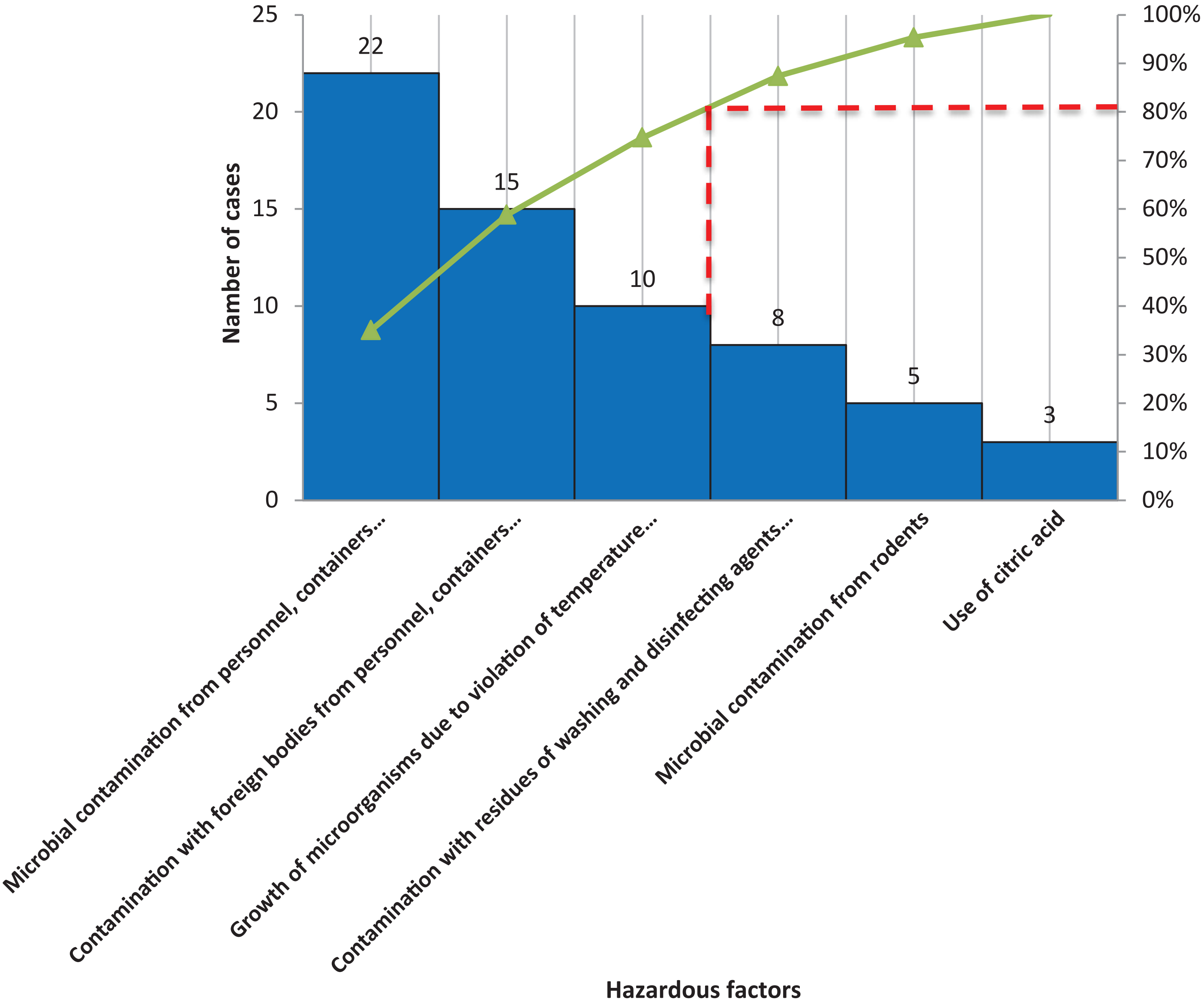


Figure 3. Pareto chart for manufacturing natural intestinal casings

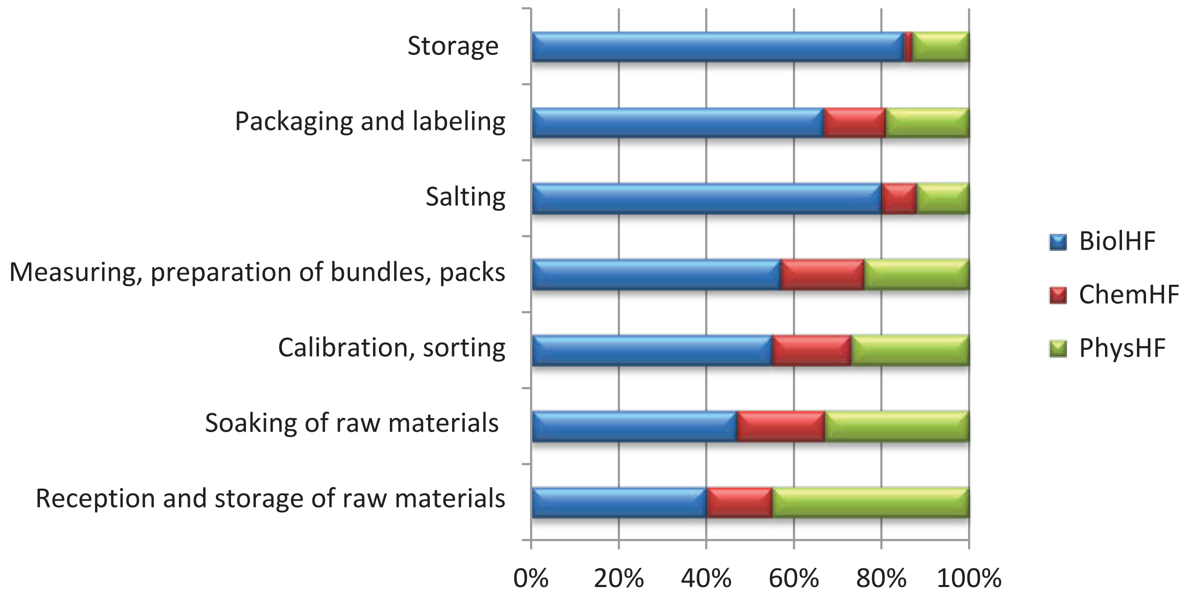


Figure 4. The ratio of the biological (BiolHF), chemical (ChemHF) and physical (PhysHZ) hazardous factors at different stages of manufacturing natural intestinal casings

It is evident that there is a reduction in the proportion of the physical hazardous process from 45 % at the stage of the incoming control to 13 % at the stage of finished product storage. A significant level at the stage of reception and sorting of intestine sets can be explained by the high risk of supply to an enterprise of contaminated raw materials, with package defects or foreign impurities, which suggests carelessness of suppliers and the necessity to revise the procedures of their assessment.

The proportion of the biological hazardous factors increases along the technological process and achieves maximum at the stages of salting and storage of the finished product, which can be explained by an increased risk of the growth of harmful microorganisms due to violation of storage conditions, shelf-life duration and package integrity.

A percentage of the chemical hazardous factors remains to be almost the same along the technological process and is on average 14 %.

It is worth noting that the physical factors in production of casings are the least hazardous as the finished intestinal casings are not the final food products but are used for the following production of meat products. When preparing casings for filling with sausage meat, foreign bodies that accidentally entered finished intestinal casings are removed and, therefore, the risk of their entry into a finished product consumed by humans is practically excluded. In addition, when adhering to the Good Hygiene Practice along with the use of hermetically closed containers, the probability of insect and rodent entry into a finished product is practically reduced to zero.

Using the obtained results, the percentage ratio of the revealed hazardous factors was established: biological/ chemical/ physical/ allergens 65/20/15/0 for the whole technological process.

Analysis of the literature sources [7,8] allows making a conclusion that in the process of organization of work on risk management, an important stage is also determination of the relation of the quality and safety indicator(s) with all possible causes that lead to non-conformity and identification of an effect of causes at all levels of the production process.

One of the effective tools of quality control is the method of the Ishikawa diagram, which helps to study not only the factors influencing the studied object, but also the cause and effect relationships of these factors [9].

The results of the performed cause and effect analysis of realization of the biological hazardous factor in production of the natural sausage casing (hog small intestine) by the method of the Ishikawa diagram are presented in Figure 5.

It was established in the process of Ishikawa diagram studying that personnel of an enterprise plays the largest role in the realization of the biological hazardous factor. Violation of the rules of personal hygiene and production sanitary leads to an increase in the probability of occurrence of this hazardous factor type in the finished product.

To minimize this risk, producers of natural casings should not only plan but also verify training of each employee contacting with a product regarding the rules of personal hygiene, washing and disinfection of equipment, apparatus and surfaces.

The most objective method to achieve this result is to organize a program of occupational training by training courses, instructions and so on. It is also necessary to develop and adhere to clear rules of behavior during disease of employees and visitors. The following cause in terms of impact is maintenance of the necessary production environment. In an enterprise manufacturing natural casings as well as in a food enterprise, it is necessary to pay attention to maintenance of the specified temperature-humid conditions, especially in the rooms for storage of raw materials and finished products, which violation leads to the growth of undesirable microorganisms.

An absence or insufficient use of the bactericidal lamps in the production process, which operation time should be strictly controlled and recorded by a responsible person in the corresponding registration document, also results in the risk of the growth of undesirable microflora [10].

When analyzing the causes of the realization of the chemical hazardous factor, it was found that the most significant are personnel and the technological parameters of equipment.

In analysis of hazardous factors, it is necessary to take into consideration the control procedures as arising problems can be prevented using permitted and non-toxic washing agents for disinfection of equipment, containers, appliances with corresponding supporting documents (certificates of conformity, instructions and so on) in all cases where it is possible. It is also necessary to remember about corresponding personnel training, control of disinfection procedures, control of equipment after cleaning.

A lubricant that is used for maintenance of equipment operation and is intended to be in contact with a product should have a class that envisages this use.

If we draw a parallel to the process of production of artificial packages for meat products (for example, trays for semi-prepared products), then in analysis of a chemical hazard, it is necessary to take into consideration that a technology of production contemplates addition of acetaldehyde, formaldehyde, ethyl acetate, lubricating materials, light stabilizers, antioxidants, solvents (hydrocarbons, alcohols, glycol ethers, ketones and esters) and other chemical compounds that can lead to a risk of chemical migration into a food product [11,12].

Therefore, in case of existence of this threat, for its prevention in production, it is necessary to introduce effective control measures, which can include timely equipment maintenance, adherence to the specified recipe, instruction of personnel and keeping corresponding documentation.

Dyes used for printing of packages should not contain hazardous substances, which can penetrate into the finished products that have a favorable wet environment.

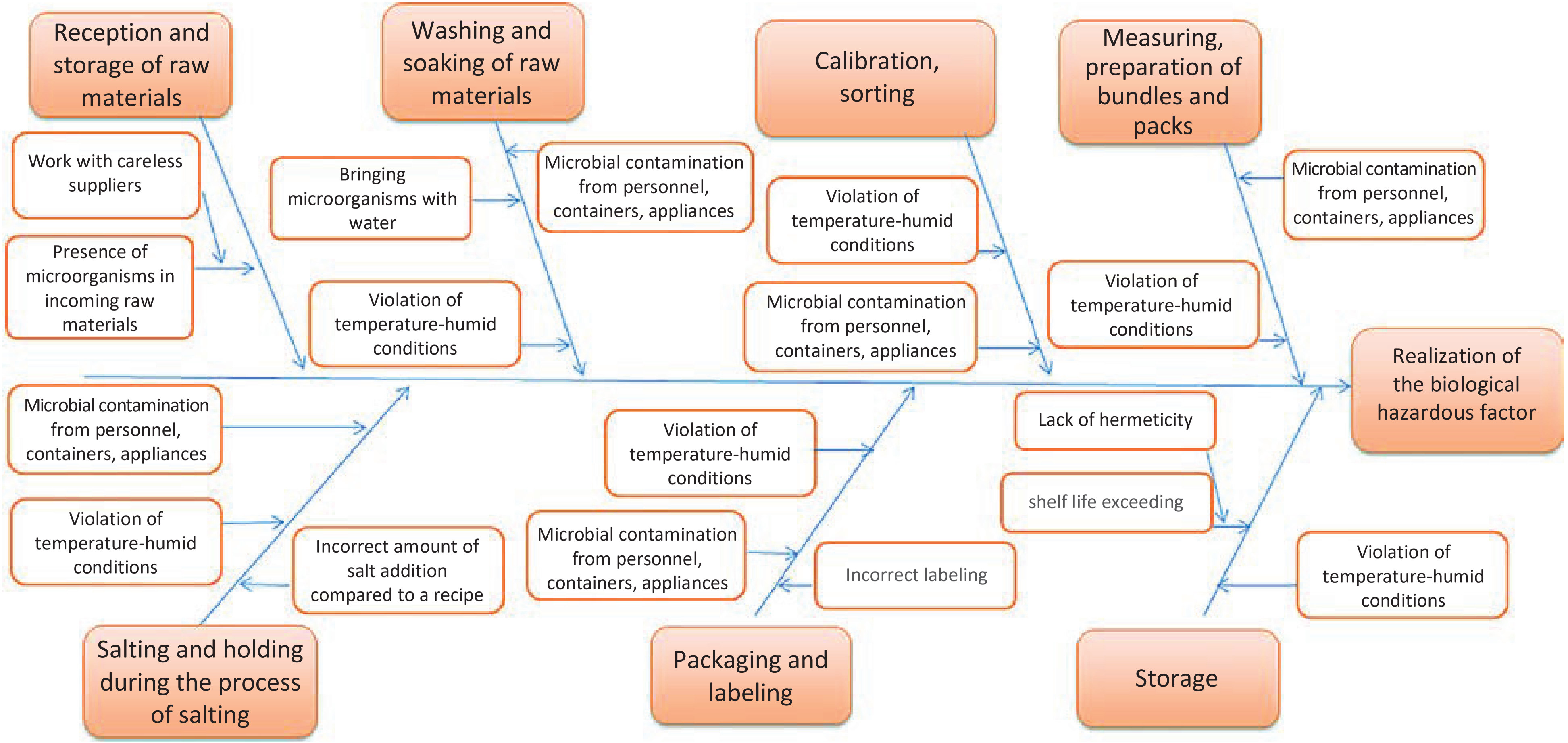


Figure 5. Cause and effect analysis of realization of the biological hazardous factors in production of natural casings

Correspondingly, if multi-layer films are used, all layers should be safe for a product and prevent surface contamination with hazardous substances.

When analyzing causes for realization of the physical hazardous factor, it was established that the physical hazard in the finished product can emerge from several sources such as inappropriate auxiliary facilities and equipment, production environment, employees upon violation of corresponding instructions, which eventually can lead to manufacture of unsafe meat products upon insufficient control by a supplier of casings and a manufacturer [10].

When studying a risk, it is also necessary to take into account a risk of incorrect package labeling, which is often underestimated by manufacturers as attention is largely paid to product safety at the stage of its production.

Meanwhile, inaccurate labeling is often a main cause of product recall as, not infrequently, producers forget to provide information, for example, about a presence of potential allergens in a product or use an incorrect font size. Manufacturers of labeled natural casings should carry out planned risk assessment and use control methods to prevent a risk of mixing labels or incorrectly labeled materials.

As a result of the performed analysis, preventive actions that are presented in Table 2 were developed.

Then, based on the revealed potentially hazardous factors, a critical control point (salting of finished intestinal casings) was identified using the decision tree (Table 3).

For revealed critical control points, the methods and frequency of hazardous factor control were developed, the controlling parameters were determined. The production monitoring and control actions are presented in Table 4.

To ensure safety of a product being at a stage identified as a critical control point, the critical limits of controlled indicators presented in Table 5 were established.

The final stage of the work was determination of corrective actions in case of departure of the process from the established critical limits (Table 6).

The questions of risk management in the food industry were studied by a sufficient number of foreign and national scientists. In Europe, the problems of safety and quality of food products began to be actively discussed already in the 1930th and this question is still topical today — in the age

Table 2. Preventive actions

Stages of production process	Description of hazardous factor	Type of hazardous factor	Preventive action
Salting and holding of finished products during the process of salting	Microbial growth due to addition of insufficient amount of salt	B	Control of salt amount according to the specified recipe Instruction of personnel
	Microbial growth due to violation of temperature-humid conditions and duration of the presence on the site	B	Control of temperature-humid conditions 3 times per shift Exclusion of holding of products before salting
	Microbial contamination from personnel, containers, appliances	B	1. Adherence to sanitary rules and norms by personnel
	Use of citric acid	C	1. Adherence to the established concentration according to a recipe 2. Control of accompanying documentation on citric acid during incoming control
	Contamination with residues of washing and disinfecting agents from containers	C	Control of container washing quality Control of the concentration of a washing agent Instruction of personnel
	Contamination with foreign bodies from personnel, containers, appliances	Ph	Visual examination. Observation of production sanitary Provision of personnel with work clothes adherence to personal hygiene rules by personnel
	Not detected	A	—

Table 3. Detection of critical control points

Stage or operation of production process	1. Is there control at this stage of the production process? YES/NO	1a. Whether control is necessary at this stage of the production process YES/NO	2. Whether this stage of the production process was developed specifically to eliminate or reduce a hazardous factor? YES/NO	3. Can a hazardous factor realize (emerge or increase) at this stage? YES/NO	4. Can the next step eliminate a revealed hazardous factor or reduce a possibility of its occurrence to the acceptable level? YES/NO	Critical Control point YES/NO	No. CCP
Salting and holding of the finished product during the process of salting							
Microbial growth due to addition of the insufficient amount of salt	YES	—	NO	YES	NO	YES	1
Microbial growth due to violation of the temperature-humid conditions and duration of the presence on the site	YES	—	NO	YES	NO	YES	1

Table 4. A list of critical control points

Critical control point	Number of CCP	Hazardous factor	Controlled parameter	Production monitoring		Control action
				frequency	Control method	
Salting and holding of the finished products during the process of salting	1	Microbial growth due to addition of the insufficient amount of salt	Compliance with the recipe: salt expenditure per a casing bundle	Once per shift	Instrumental/measuring salt expenditure	Daily calculation of salt expenditure by a technologist, recording of monitoring data in the»Journal of salt expenditure» control»
		Microbial growth due to violation of the temperature-humid conditions and duration of the presence on the site	Time from the moment of control until salting of the finished products	Upon accumulation of casing lots of the same name, size and category of quality	Instrumental/ time specifications	Control of duration of casing accumulation for salting at the site
			holding temperature for beef small intestine	Twice a day	Instrumental/ Measuring temperature and humidity using a portable thermometer and humidity meter	Monitoring recordings of a thermometer and humidity meter by a shop foreman; recording of monitoring data in a check list of control for temperature and humidity conditions

Table 5. The list of critical limits

No.	Operation	Number of CCP	Hazardous factor taken into account	Controlled parameters	Critical limits
1	Salting and holding of finished products during the process of salting	1	Biological: Microbial growth due to addition of the insufficient amount of salt	Salt expenditure per product unit	Not less: Hog small intestine — 0.55 kg/bundle
			Biological: Microbial growth due to violation of the temperature-humid conditions and duration of presence on the site	1. Duration of accumulation of hog small intestine before salting 2. temperature in the holding room 3. Humidity in the holding room 4. duration of holding	Not more than 3 hours 0…+10oC 60–90% Not less than 24 hours

Table 6. The list of the typical corrective actions

No.	Name and No. of CCP	Controlled parameter	Possible non-compliance	Corrective actions	Person responsible for corrective actions
1	Salting and holding of finished products during the process of salting CCP No. 1	Salt expenditure	Reduction of salt expenditure lower than the value established by a recipe	1. To identify production per shift of finished casings salted with reduced salt expenditure 2. To perform additional salting of casings in a package	shop manager packer
		Temperature (humidity) in the holding room for hog small intestine	Temperature lower than 0oC and higher than +10 °C. Humidity lower than 60% and higher than 95%.	1.To check verification of a thermometer and/or humidity meter 2. To check work of the refrigerator and ventilation system in the room	chief electrician
		Duration of holding during the process of salting	Duration of holding less than 24 hours (for hog small intestine) Duration of holding more than 3 days	1.To carry out visual examination, assess quality of salting and organoleptic indicators of casings. 2. When revealing non-compliance, register products with non-conformance in the journal of product registration and send to additional treatment (secondary processing, washing, additional salting and so on)	Technologist Chief technologist

of the struggle with zoonoses (salmonellosis, listeriosis), study of contaminants (mycotoxins, heavy metals), residuals of pesticides and accidental radioactive contamination.

In the opinion of G. Morgan, identification of risks for humans can often be difficult as in the case of antibiotic resistance. These problems arise due to the complex character of the technological chain of food production and can be revealed only in monitoring of each link of this chain from the perspective of hygiene, presence of contaminants and GMO, as well as other factors [13].

In France, there are several state agencies that are engaged in investigations and assessment regarding the questions of food safety. One of them is the French National Institute for Agricultural Research (INRA). The main activity of INRA is the study of the questions of microbiology and hygiene for optimization of the role of beneficial microorganisms and mitigation of the effect of hazardous microorganisms. With that, however, after analysis of its functions in the field of sanitary surveillance, prediction and expertise, INRA began to pay primary attention to the development of the risk analysis activities and provision of the process of decision making. The Institute also decided to increase by 40% its resources allocated for research of the problems of human nutrition and association between food and health in the nearest four years [14,15].

In 2013, Codex Alimentarius Commission called for division of the functions of risk assessment and their management to ensure independence and transparency of this highly professional type of scientific and technical support.

According to Khamidulina Kh.Kh., food safety assurance nowadays requires attention to all links of the production chain: from primary production operations (including veterinary and animal protection) and feedstuff production up to supply to the ultimate consumer. Food safety can be influenced by any element including environment, from which a corresponding product came [16].

It is also necessary to note an opinion of B. Pakbin who believes that in the risk management system of the food industry, the main risk factors (in addition to biological, chemical and physical) should also include price risk, reputation, brand damage and product recall as the economic risks are no less important for the processing industry [17].

Unfortunately, insufficient attention is paid to the question of risk management in production of natural casings. In our work, therefore, we carried out complex assessment of hazardous factors with detalization of causes for their occurrence. The results of the investigations were taken as a basis when creating a HACCP plan.

Conclusions

The research carried out in the Gorbatov Research Center for Food Systems showed that about 45% of non-compliance in enterprises that produce natural casings occur due to employees' inobservance and lack of knowledge of instructions or insufficient information from management. On this basis, it can be concluded that construction of an effective educational system and motivation of employees is a necessary stage for effective function of the risk management system.

In general, safety of natural casings is ensured by a complex of requirements for materials contacting with food, sanitary-hygienic indicators and physical impurities. It is necessary to note that these requirements apply to all package types regardless of the material used for its production (natural, metallic, polymer, cardboard, glass or from combined materials) [18].

At present, to confirm the above mentioned safety requirements, many large meat processing enterprises conduct audit of its suppliers, for whom the obligatory requirement for obtaining a status of the «approved supplier» is the certified HACCP-based food safety management system in an enterprise, which is one of the confirmations of real safety of used casings.

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