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Development And Implementation Of Management Systems - A State Priority In Providing Quality And Safety Of AIC Products.

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ABSTRACT

Based on the available data and the results of authors' own research, the benefit of using an integrated management system to ensure the quality and safety of food products produced at enterprises of the agro-industrial complex (AIC) is shown. Integrated product quality and safety management systems (IPQSMS) was developed and tested at Altayvitamin within the requirements of international and national standards of the ISO 9001, 22000 series adapted to them and GMP rules. The procedure of integrating the following sections was performed: organization of work on quality assurance; requirements for staff; premises and equipment; documentation; organization of production; quality control; self-inspection. Methods for assessing hazards through the establishment of critical control points and a program of mandatory measures were determined. Additional measures have been identified to reduce the probability of risks being realized. As applied to production, business processes have been identified: marketing and market research; development of new products and technologies; purchases of raw materials and feedstock; production; control and testing of finished products; management of nonconforming products; certification of finished products; marketing of finished products; document management; personnel management; maintenance and repair of equipment; maintenance of buildings and constructions; financial management; management of legal support; ensuring industrial safety; warehousing of raw materials and feedstock. Based on the analysis of the integration areas, the composition of the elements of the developed system was established, and its model was proposed representing the cyclic process used for continuous improvement within the framework of the concept of "Plan - Do - Check - Act". Certification was carried out as a logical completion of the process of development and implementation of the IPQSMS. The effectiveness of the system was proved by analyzing the data on the number of inconsistencies and recommendations. It is shown that in 2014 the number of identified inconsistencies by divisions decreased by 34% (from 12 to 8) compared to 2013. The received materials testify that the integrated system of quality and product safety management of Altayvitamin is in working order under controlled conditions and is characterized as effective.

Keywords: Integrated management system, food products, quality, safety, efficiency.

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INTRODUCTION

The issues of ensuring the quality and safety of agricultural raw materials and products of its processing are given priority at the state level: the regulatory framework is updated, based on the requirements of international and European standards; Laws of the Russian Federation and Decrees of the President and the Government are adopted and implemented.

This is due to the need to modernize the agro-industrial complex (AIC), expand the assortment of environmentally safe raw materials and healthy foods based on them. The latter is of particular importance in the correction of the diet and health of modern people, given the high level of food concentration and common deficiency of essential nutrients, the widespread distribution of nutritional diseases that cause significant harm to health, which ultimately leads to unreasonable social and economic losses [1].

One of the most effective and economically feasible ways to solve the problem under consideration is the development and implementation of quality and safety management systems at enterprises of the AIC within the requirements of international standards of the ISO 9001, 22000 series and GMP rules.

OBJECTS AND METHODS OF RESEARCH

We studied the organization of work of Altay vitamin in order to optimize it and ensure the stability of the quality and safety indicators of the products. In the work, methods of research of management systems within the requirements of international and domestic standards were used.

RESULTS AND DISCUSSION

A significant number of currently available standards and specifications allow management team to choose the most appropriate option: implement one system, or a set of systems that can represent an integrated management system (IMS). The main thing in this choice is the idea of the types of these management systems and the potential, additional opportunities, advantages that their implementation can bring.

Based on our findings and experience, Table 1 presents the benefits of implementing integrated management systems.

Table 1: Integrated management systems and their advantages

Management Systems	Advantages after implementation	Advantages in relation to others
ISO 9001	1. Improvement of the company's activities 2. Improving the quality of products 3. Minimization of production risks 4. Reducing the amount of defective goods and complaints 5. Enhancing the culture of production	Implementation of an integrated management system at an enterprise allows eliminating the following problems arising from the sequential or parallel independent implementation of several standards: 1. matching processes, documents, functions of units and jobs; 2. vagueness of interaction between systems: quality management, environment, safety and health; 3. complexity of the perception of the management system by the company's management, and, accordingly, low effect of planning, control and management; 4 time-consuming procedures for the implementation of standards in the
ISO 22000	1. Improvement of the company's activities in the field of ensuring the quality and safety of food products at all stages, from raw materials to the final product. 2. Reducing the amount of defective goods, complaints and return of the products through the use of preventive actions. 3. Determining clear responsibility for ensuring food safety 4. Savings of resources spent on quality assurance and safety management. 5. Getting the ability to integrate with other systems.	

GMP Standard	1. Improvement of the quality of products; 2. Guarantees of the safety and efficacy of medicines; 3. Further training of employees engaged in production; 4. Improvement of discipline in production; 5. Streamlined and coherent work of the whole team; 6. Increasing the responsibility of each link in the production chain; 7. Possibility of controlling production at each stage, traceability of the entire technological cycle; 8. Reducing the level of production risks.	company; 5 significant need for resources, labor intensity and during simultaneous implementation of groups of standards. 6 process of monitoring the effectiveness of the integrated management system in the enterprise. There are the following advantages, which are the result of the integration of the management system: 1. increasing the technological level of their development, implementation and operation; 2. creation of a unified coherent management structure; 3. minimizing the costs of developing, implementing, operating and certifying the systems; 4. combining a number of processes (planning, management review, documentation management, training, internal audit, etc.) 5. increased mobility and greater adaptation to changing conditions; 6. attractiveness for all parties.
OHSAS 18000	1. Possibility of managing risks arising in the production process 2. Control over hazardous production factors. 3. Reduction of losses from payment of sick leave certificates and fines related to occupational injuries and occupational diseases.	
ISO 14001	1. Optimization of the enterprise management system in the field of environment protection 2. Prevention of harmful effects on the environment. 3. Saving energy resources through effective implementation of environmental management. 4. Reducing the risks of environmental disasters. 5. Improvement of ecological situation in the region.	

At Altay vitamin, an integrated product quality and safety management systems (IPQSMS) was developed in accordance with the requirements of GOST ISO 9001-2011 (ISO 9001: 2008) "Quality management systems. Requirements ", GOST R 52249-2009 (GMP) "Rules for the production and quality control of medicinal products", GOST R ISO 22000-2007 (MC ISO 22000: 2005) "Food safety management systems. Requirements for organizations involved in the chain of food production."

"Quality management systems. Requirements." GOST ISO 9001 is an authentic one to the international standard ISO 9001 which is implemented as the most recognized and common guidelines on the organizational and methodological foundations for the creation of quality management systems (QMS) of organizations. For compliance with this standard, more than a million QMS of organizations have been developed and certified around the world. This is the main indicator that quality management systems that meet the requirements of this standard are highly effective means of improving the activities of the organization of any field and specifics.

Implementation of GMP principles is carried out in the case of production of specialized products, including dietary supplements, as well as medicines that must be guaranteed to meet their purpose and requirements, and not create a risk to consumers due to violation of safety, quality and efficiency requirements. This is achieved through the introduction of production and control rules in accordance with GOST R 52249-2009.

For the enterprise of the agro-industrial complex the problem of product safety is particularly significant. It is emphasized in the HACCP system. In the Russian Federation, this system is being implemented in accordance with the requirements of the national standard GOST R 51705.1-2001. The system defines critical control points where it is necessary to take into account potential risks. Based on the analytical work using the accumulated information, a project of activities is developed, the implementation of which minimizes the risk of obtaining unsafe products. The personnel responsible for the results of the activities are identified. Quality checks in accordance with the principles of HACCP are carried out throughout the entire process of manufacturing products, which determines an advantage and an important feature of the system [2].

The world's leading manufacturers of food products are building the activities of their enterprises using the international standards of the ISO 22000 series (the Russian national equivalent is GOST R ISO 22000-2007), which includes both HACCP principles and practical recommendations of the Codex Alimentarius Commission. GOST R ISO 22000 -2007 contains the requirements of GOST R 51705.1-2001, being a demanded higher standard, which combines the development and requirements of leading countries in the field of food safety [4-15, 19-20].

The analysis of GOST ISO 9001-2011, GOST R ISO 22000-2007 and GOST R 52249-2009 aimed at establishing the general requirements of these management systems and their integration into the requirements of an integrated product quality and safety management system. The following sections must be integrated: organization of work on quality assurance; requirements for staff; premises and equipment; documentation; organization of production; quality control; self-inspection.

GOST R ISO 22000-2007 contains clearly defined methods and techniques for ensuring safety, through assessing hazards, establishing critical control points, various programs of mandatory preliminary measures, etc. All these elements complement the system-wide requirements of ISO 9001. The study of the experience of the enterprises of the agro-industrial complex makes it possible to conclude that those industry organizations that plan to build and implement QMS according to the GOST ISO 9001-2011 standard will be forced to develop their own traceability system technological parameters that are monitored during the process, as well as rules for monitoring and evaluation of finished products. The system of food production management in accordance with GOST ISO 9001 includes the HACCP system; however, the company may not associate its development with the principles of HACCP. But a "working" production system for monitoring and measuring products and processes must necessarily provide for the identification and analysis of all identified and possible hazards. Documentation of critical control points at all stages of production and constant monitoring of established indicators, available corrective measures are mandatory conditions both within the requirements of GOST ISO 9001-2011 and the food safety management system.

In the IPQSMS of Altayvitamin, the following business processes were identified: marketing and market research; development of new products and technologies; purchases of raw materials and feedstock; production; control and testing of finished products; management of nonconforming products; certification of finished products; marketing of finished products; document management; personnel management; maintenance and repair of equipment; maintenance of buildings and constructions; financial management; management of legal support; ensuring industrial safety; warehousing of raw materials and feedstock.

General requirements and basic provisions of IPQSMS are defined in the Product Quality and Safety Guide. The organization and operation of processes (subprocesses) of the IPQSMS are documented in company standards for these processes (subprocesses). Company standards define specific methods of work and required quality characteristics, technical and regulatory documentation developed by Altayvitamin, as well as international, national and industry standards, normative and methodological documents of third-party organizations. The required quality characteristics can be indicated in the specifications for raw materials, auxiliary and packaging materials, specifications for the semi-finished product, finished products, operating sheets, tasks and other planning and administrative documents that perform the functions of the quality plan for specific works. Requirements for processes, criteria for their evaluation and acceptance of the results create a basis for effective management.

Processes in the general case are characterized by the following parameters:

- external connections - with which processes, organizations, units (suppliers, consumers) the process is connected; in what form (materials, products, equipment, services, software and methodologies) this connection is represented;
- content of the process (subprocess, operation);
- responsibility matrix;
- documentation for process management (enterprise standards and other regulatory documentation);
- executive documentation (including records on quality);
- main criteria for evaluating the process;

- resources.

The main responsibilities of process managers are:

- determination of the order and methods of working on the process by organizing the development and maintenance of RDs that apply to this type of activity;
- implementation of operational management and methodological guidance of the process by interpreting and explaining the requirements of existing RDs and instructions (tasks, orders) for actions not regulated (or unclearly regulated) by these documents;
- assessment of the process provision with resources and issuance of applications for required resources;
- control and analysis of the state of the process, implementation of its correction to the required criteria;
- development of proposals for improving the interaction of the process with other IPQSMS processes;
- definition, development of evaluation criteria for the process.

To ensure the stability of quality indicators, it is necessary to introduce a quality management system in accordance with GOST ISO 9001-20011 (ISO 9001: 2008)

We have proposed and tested a model of an integrated system of product quality and safety based on the concept of "Plan-Do-Check-Act" [16-18]. The model represents a cyclic process that the organization implements to achieve continuous improvement and can be applied to all elements of an integrated management system (Fig. 1).

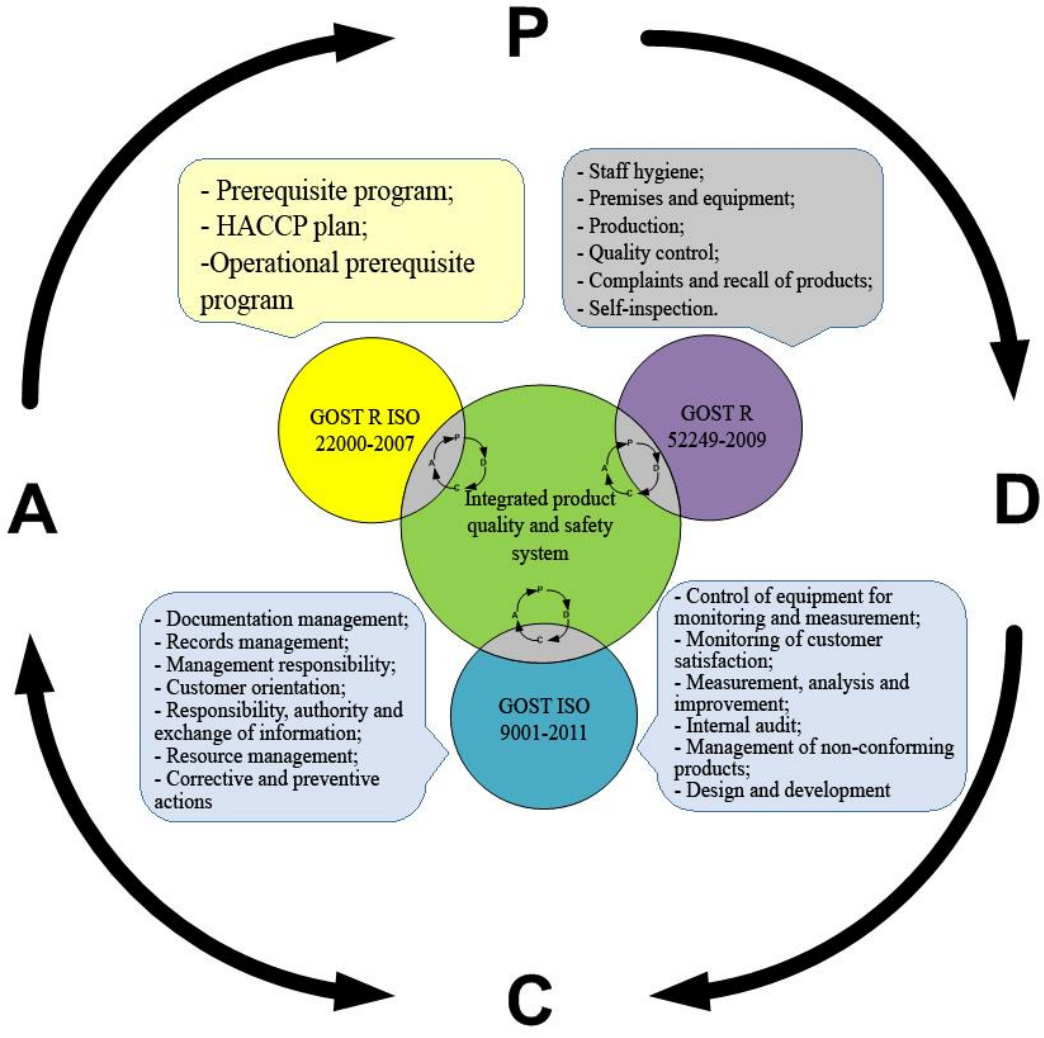

Figure 1: Model of the integrated product quality and safety system

Development of an integrated management system presupposes the establishment of its elements (composition) that encompasses the requirements of integrable standards. The composition of the elements of the developed management system is determined on the basis of the analysis of the integration areas. The available practical experience shows that IPQSMS contains 22 elements, 13 of which are GOST ISO 9001-2011, 3 elements - GOST R ISO 22000-2007, 6 elements - GOST R 52249.

Development of an integrated management system to ensure the stability of the quality and safety of agricultural products practically coincides with the schemes for implementing a separate management system. The following main stages can be distinguished:

1. General organization of work on the creation of IPQSMS (formation of a strategic decision on the establishment of IPQSMS: identification of the goals to be achieved, temporary and financial resources, potential benefits from the implementation of IPQSMS (strategic, marketing, economic, image). At this stage, it is recommended to begin the process of training the development team;
2. Designing IPQSMS. Configuration of the future integrated management system is determined, the development team and the detailed work plan are finally formed, the training process continues;
3. Documenting IPQSMS. To a large extent, the efficiency of the integrated system and its effectiveness depends on how this stage will be realized. System-wide and specific documents are developed, training of workers continues;
4. Implementing IPQSMS. It includes reconfiguring the enterprise to meet the requirements of the developed IPQSMS documentation, updating the documentation that is proven not viable during the IPQSMS trial operation. It is of fundamental importance to achieve a positive perception of the changes introduced by the created IPQSMS by all employees.

At this stage it is recommended to conduct internal audits to determine the degree of readiness of the developed and implemented integrated management system for certification audit;

5. IPQSMS certification. It is a logical conclusion of the process of development and implementation, despite the non-mandatory nature, along with the voluntary creation of all management systems. An important aspect of the final stage is the selection of the certification agency, which should be legitimate and valued by the consumers of the developed management systems. It is economically feasible to choose a certification agency that is able to certify all the management systems included in the IPQSMS. The successful outcome of this stage is the receipt of a set of certificates of compliance for management systems (each separately) within the established integrated management system of the enterprise.

As already mentioned above, in addition to the main activities of the company, specialized products are produced, including biologically active food additives (BAA) which are produced in the following forms: coated tablets; capsules (hard, soft gelatinous); pills, extracts, granulated drinks and jellies; syrups; oils from vegetable raw materials, etc.

The production widely uses natural raw materials - fruits of berry crops, various herbs and roots of food and medicinal plants.

The IPQSMS of Altayvitamin was developed to achieve constant satisfaction of customer requirements, increase the competitiveness of the enterprise, and ensure compliance with the requirements for the production of safe pharmaceutical and food products established by regulatory enactments. When designing the system, it is shown that IPQSMS applies to the activities of the units, services and officials of the enterprise which perform the management functions in this system, as well as the production activities associated with obtaining the finished product.

Product quality, cases of deviation from specifications and causes of claims are regularly analyzed. The withdrawal and management of products that do not comply with the requirements of the RD are carried out in accordance with the established procedure, prescribed in the relevant standards of the enterprise.

According to industrial regulations, critical points have been identified for the production of products, and a risk analysis has been carried out. The basic principles of quality assurance, GMP rules, quality control and a risk analysis system are interrelated and are of paramount importance in organizing the production of

specialized products.

In accordance with the developed requirements StP-OOK-41 "Procedure for conducting internal audit (self-inspection) at the enterprise" and according to the approved schedule, specially trained personnel conduct internal audits (self-inspection), followed by elimination of identified inconsistencies and remarks. Responsibility for organizing, conducting and summarizing the internal audit is assigned to the senior auditor - the Chief of the Production and Dispatching Office (PDO).

Food safety management system (GOST R ISO 22000 -2007). In order to increase the confidence in the safety of agricultural products manufacturing, the enterprise develops and implements a food safety management system that includes the following key points:

- information exchange;
- management system;
- prerequisite programs (PRP);
- HACCP principles.

PRP programs are created and maintained in working conditions, updated by the HACCP working group, and approved by the General Director.

The prerequisite program allows managing:

- the probability that the production environment will become a source of hazards threatening food safety;
- the biological, chemical and physical contamination, including cross-contamination between heterogeneous products;
- the level of danger threatening the safety of food products which is typical for the given products of the agro-industrial complex and the environment in which it is manufactured.

Verification of records on PRP and HACCP plans is carried out twice a year by the head of the HACCP working group.

The product safety management system is an analysis of the possible consequences of a violation of process flow patterns, and serves as a safety management tool.

To develop, implement and operate a food safety management system, implement and maintain HACCP plans, the organization has established a HACCP working group of qualified, most experienced specialists from different departments.

Specialists included in the HACCP working group undergo special training in risk analysis principles that are fundamental to their management.

On the basis of normative documentation, literary data, knowledge, and accumulated experience in attracting experts, an analysis of hazards has been carried out. Identification, assessment and management of hazards arising in the process of obtaining food products are given in StP-RG-HACCP-73 "HACCP Safety".

The conducted risk assessment made it possible to identify all the potential hazards associated with the production, storage and transportation of agricultural raw materials and finished products, determine their sources and the probability of occurrence. After identifying the risks, additional measures have been developed and introduced to reduce the probability of risk realization. Each risk is assessed in terms of the severity of its consequences: should this procedure be considered a CCP or it is part of the production program of mandatory preliminary activities. To determine the CCP, the "Decision Tree" proposed by the Codex Alimentarius Commission was used.

Critical limits are set for each critical control point - the maximum and minimum values which a biological, physical or chemical parameter should not exceed. This value is measured and monitored at the CCP with prevention, restriction or reduction to an acceptable level of probability of risk occurrence. For the

successful functioning of the HACCP system, CCP are monitored. Monitoring results are recorded for each CCP. Monitoring allows receiving a timely signal that the process is out of control. To restore the process to a controlled state, corrective actions have been developed for each CCP. To verify the effectiveness of the HACCP plan, verification procedures have been developed.

At the enterprise, works on deratization (rodent control) and disinfestations (insect control) are organized. Disinfestation and deratization of premises are carried out in accordance with the developed requirements of SOP-AKhO-Dz-Dr-05.

Waste Generation and Disposal Targets (WGDT) was developed and coordinated with ROSTEKHNADZOR. The resulting waste is disposed of by specialized enterprises, in accordance with the contracts. Disposal of microbiological laboratory waste is carried out in accordance with SOP-OKK.Mb-34 "Procedure for disinfection of pathogenic biological agents".

Accounting and control of production wastes is carried out in accordance with the procedure developed by StP-OOT-85 "Procedure for temporary placing, accounting, use and transportation of production and consumption waste". A detailed description of the process of hazard identification and risk management is described in StP-RG-HACCP-73 "Product Safety (HACCP)".

Analysis of the IPQSMS for the purpose of its continued usability, adequacy and effectiveness, as well as analysis of the activities of the divisions to ensure the required level of quality and safety of products and activities at the enterprise level are carried out twice a year by the Coordination Council, headed by the General Director. The results of the work of all the divisions included in the IPQSMS are analyzed, the relevance and effectiveness of the system are checked, and the system's consistency with the Policy and Objectives of the enterprise in the field of product quality and safety is examined. Decisions are made to clarify the Policy and Objectives, distribution of functions, resources, order of interaction and ways to improve the IPQSMS.

Based on the results of the coordinating council, a protocol of decisions is drawn up. Based on the protocol, in the divisions action plans for quality are developed. Analysis of the implementation of action plans is carried out on "Quality Days" in production divisions quarterly with the provision of protocols to the QAD. Collection of materials for analysis, structuring and generalization of data on the status of the IPQSMS is performed by the QAD. The procedure for IPQSMS analysis by top managers and heads of departments (processes) is defined by StP-OOK-59 "IPQSMS analysis by top management".

The initial data for the IPQSMS analysis are focused on assessing the effectiveness and efficiency of the system taking into account the opinions (positions, interests, needs) of consumers and other parties.

The main purpose of these results is the development of measures on their basis by top management to improve the IPQSMS and the processes it applies, make decisions on the quality and safety of products, improve its quality characteristics, according to the requirements of consumers, and provide the necessary resources.

To coordinate and analyze the work on the IPQSMS performance, the company has established a Quality Coordinating Council (QCC) that implements general methodological and organizational guidance in resolving fundamental issues related to quality problems. It initiates the implementation of measures aimed at preventing the yield of inappropriate products. It conducts analysis of the IPQSMS performance with proposals for improvement.

All production and quality control processes are documented. Responsibility for the functioning of the system of internal document circulation of the enterprise is assigned to the Chief of the QAD.

The organization of production is carried out in accordance with the documentation of the enterprise and the current regulatory documents.

The entire process of manufacturing and quality control is traced at the enterprise. For each item, a Dossier for a series (operating sheets of the process train, analytical sheets of raw materials used in this

process, quality control protocols, a passport for a series of finished products, a declaration of conformity, an authorization for the implementation) is developed and filled. Consumption and warehouse balances of raw materials, feedstock and finished products are recorded in racking cards, cards of warehouse accounting of the approved type.

Control of the initial and packaging materials, intermediate and finished products is carried out by the personnel of the QCD. The results are recorded in work sheets, analytical sheets, passports.

Identification and traceability of the movement of raw materials, auxiliary and packaging materials, and finished products is carried out according to the requirements of the developed documents:

- "Marking of raw materials, feedstock, semi-finished products, finished products, premises and equipment";
- "Procedure for accepting raw materials, auxiliary and packaging materials";
- "Principles of warehousing";
- "Procedure for sampling when conducting incoming raw materials inspection";
- "Procedure for sampling when conducting incoming inspection of incoming auxiliary and component materials and materials manufactured by Altayvitamin";
- "Procedure for submitting finished products for control by the QCD and its transfer to the warehouse of finished products";
- "Procedure for storage of goods";
- "Procedure for shipment of finished products to customers";
- "Procedure for sampling finished medicines";
- "Procedure for declaration and certification of finished products".

At the enterprise, identification and traceability of each series of raw materials, auxiliary and packaging materials, semi-finished products, finished products are conducted by using different types of containers, separate storage, individual numbering (coding), identification with information and status labels, filling of shelving cards and stock records with the status of goods and moving them to the divisions.

The movement of raw materials, feedstock and semi-products within divisions is recorded in logs and racking cards, indicating the name and number of the series of finished products for which this series of raw materials was used. Movement of goods between divisions is carried out by limit cards and requisition slips.

Incoming control of raw materials and feedstock is carried out according to the procedure developed by SOP-OKK-07 "Procedure for incoming control of raw materials".

Identification and traceability of products in the production process, movement within the boundaries of the enterprise are ensured by the personnel of the enterprise divisions by entries in logs and electronic carriers in the 1C system.

The transfer of products to the finished products warehouse is carried out in accordance with the procedure developed by StP-OOK-36 "Procedure for transferring finished products to the warehouse". Identification and traceability of the finished products in the process of storage and shipment are provided by storekeepers of warehouses according to the standards of the enterprise "Procedure for storage of goods" and "Procedure for shipment of finished products to customers."

The procedure for storage and verification of the integrity of inventory at the enterprise is set out in the developed document "Procedure for maintaining the conformity of products during warehousing and transportation". Depending on the specifics of the enterprise of the agro-industrial complex, the structure of the storage area includes: a warehouse of raw materials (storage room for substances, storage room for strong substances, room for raw materials with cool storage conditions, room for storing odorous raw materials, room for QCD sampling); alcohol storehouse; feedstock warehouse.

The process of storing raw materials and feedstock is described in detail in the developed standard "Procedure for storage of goods". Storage of raw materials in warehouses is carried out on pallets mounted on

shelves in 2-3 tiers in height, with observance of climatic parameters specified in RD.

It is prohibited to store raw materials and feedstock of different names, or different batches of the same product on the same pallet. To prevent cross-contamination and microbial contamination of goods, conditions of storage and distribution to production/consumers are monitored. Warehouse premises are daily subjected to wet cleaning with the use of authorized detergents according to SOP-OL-SZ-01 "Cleaning of warehouse premises". Quality control of cleaning of premises is assigned to the warehouse manager (storekeeper).

In the storage and other areas of the warehouse, measures are regularly taken to combat rodents, insects and other pests, in accordance with the requirements of SOP-AKhO-Dz-Dr-05 "Procedure for disinsection and deratization of premises."

Climate control is mandatory for storage of raw materials, feedstock and finished products. Records on monitoring of climatic parameters are kept daily in the "Climate Parameters Control Log".

Upon completion of acceptance of raw materials and sampling, the raw material is assigned the status "Quarantine", each packaging unit is identified by a white information label and a yellow status label. Packaging units from which sampling was made are additionally marked with a blue status label. When a positive QCD report is received, the raw material is assigned the status "QCD Approved", the yellow label is replaced with a green one.

Products which have passed all the stages of the process, the process engineer or the foreman submit to the control of the QCD in series. The results of the analyzes are drawn up in accordance with the "Handling procedure for the results of the control of finished products".

Finished products with a passport according to the invoice are transferred to the finished product warehouse of the LD, where they are stored until the receipt of the declaration/certificate of conformity and subsequent shipment to the consumer. Sampling of finished products for submission to certification bodies is controlled by the personnel of the Certification Department.

Loading and unloading are performed by loaders of the Logistics Department with maximum preservation of the quality level and consumer properties of the products in accordance with the instruction "Staff manual guide for the loader of the warehouse of finished products of the Logistics Department".

The performance evaluation of the IPQSMS developed at Altayvitamin was conducted for the period 2013-2014 based on data on process implementation and product conformity, and comparative data on the number of inconsistencies and recommendations (Table 2).

Work was carried out at the following divisions of the enterprise: Chief Power Supervisor Staff; Chief Mechanical Supervisor Staff; Occupational Safety and Health Department; Design Department; Central Plant Laboratory; Business Manager; Marketing Department; Sales Department; Logistics Department and Warehouse No. 902; Analytical Bureau; Procurement Department; Warehouse No. 901; Finished Pharma Product Shop; Shop for Processing Medicinal Raw Materials; Ointments and Solutions Shop; Printing House; Quality Control Department; Quality Assurance Department; Human Resources Department; Legal Department; Motor Transport Shop; Administrative-Economic Department [3].

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Table 2: Comparative data on the number of inconsistencies and recommendations

Division	The number of inconsistencies and recommendations			
	Inconsistencies		Recommendations	
	2013	2014	2013	2014
Chief Power Supervisor Staff (CPS)	-	1	-	1
Chief Mechanical Supervisor Staff (CMS)	3	1	-	2
Occupational Safety and Health Department (OSH)	2	-	-	1
Design Department (DD)	-	-	2	2
Central Plant Laboratory (CPL)	-	-	1	-
Business Manager	-	-	-	3
Marketing Department (MD)	1	-	-	-
Sales Department	-	-	-	1
Logistics Department, Warehouse No. 902 (LD)	-	-	-	2
Analytical Bureau	-	-	1	1
Procurement Department (PD)	1	1	1	-
Warehouse No. 901	-	-	1	-
Finished Pharma Product Shop (FPP)	-	-	1	-
Shop for Processing Medicinal Raw Materials (PMRM)	-	-	3	1
Ointments and Solutions Shop (OaS)	-	2	2	2
Printing House	1	-	1	1
Quality Control Department (QCD)	-	-	6	-
Quality Assurance Department (QAD)	-	-	2	-
Human Resources Department (HR)	1	-	-	-
Legal Department (LD)	1	1	1	1
Motor Transport Shop (MT)	1	-	-	-
Medical Centre	-	-	1	2
Administrative-Economic Department (AED)	1	2	-	-
TOTAL:	12	8	23	20

It is shown that in 2014 the number of identified inconsistencies by divisions decreased by 34% (from 12 to 8) compared to 2013. Thus, the assessment of evidence of ensuring the stability of quality and safety of products during the period under review allows us to conclude that the integrated system of quality and safety of the products of Altayvitamin is in working condition under controlled conditions and is characterized as effective.

Development and implementation of management systems is considered as the main factor that shapes quality characteristics of agricultural products and their competitiveness. It should be noted that management systems are dynamically developing and improving in connection with the constant updating of international, European and national standards.

REFERENCES

[1] Gerasimenko, N.F. Healthy nutrition and its role in ensuring the quality of life / N.F. Gerasimenko, V.M. Poznyakovskiy, N.G. Chelnakov // Technologies of food and processing industry of AIC – healthy food. - 2016. - No. 4 (12). - Pp.52-57.

[2] Quality management in food, processing industry, trade and public catering enterprises: textbook / I.V. Surkov, V.M. Kantere, E.O. Ermolaeva, V.M. Poznyakovsky. - 3rd ed., rev. and add. - Moscow: INFRA-M, 2014. - 336 p.

[3] Trikhina, V.V. Development and evaluation of the effectiveness of the integrated management system in the production of specialized products V.V. Trikhina, I.V. Surkov, K.Ya. Motovilov // Food industry. - 2017. - No. 2 (3). - Pp. 43-49.

[4] Akao, Y. (Ed.) (1990). Quality Function Deployment (QFD). Integrating Customer Requirements into Product Design (pp. 369). Portland, OR: Productivity Press.

[5] Akao, Y. (Ed.) (1990). Quality Function Deployment (QFD). *Integrating Customer Requirements into Product Design* (pp. 369). Portland, OR: Productivity Press.

[6] Cucu, T., Jacxsens L. & De Meulenaer B. (2013). Analysis To Support Allergen Risk Management: Which Way To Go? Journal of Agricultural and Food Chemistry, 61(24), 5624–5633.

[7] Cucu, T., Jacxsens, L., & De Meulenaer, B. (2013). Analysis To Support Allergen Risk Management: Which Way To Go? *Journal of Agricultural and Food Chemistry, 61*(24), 5624-5633.http://dx.doi.org/10.1021/jf303337z

[8] Kushchev, S. N. (2009). *Development of Methodology to Estimate Technological Risks while Producing Yoghurt Products* (pp. 206). Thesis of Candidate of Technical Sciences, Moscow State University of Applied Biotechnology, Moscow.

[9] Kushchev, S.N. (2009). Development of Methodology to Estimate Technological Risks while Producing Yoghurt Products (pp. 206). Thesis of Candidate of Technical Sciences, Moscow State University of Applied Biotechnology,Moscow.

[10] Mensah, L. D., & Julien, D. (2011). Implementation of food safety management systems in the UK. *Food Control, 22*(8), 1216-1225.

[11] Mensah, L.D. & Julien D. (2011). Implementation of food safety management systems in the UK. Food Control, 22(8), 1216–1225.

[12] Mizuno, Sh. & Akao Y. (ed.) (1994). QFD. The Customer-Driven Approach to Quality Planning and Deployment (pp. 365). Tokyo, Japan: Asian Productivity Organization.

[13] Mizuno, Sh., & Akao, Y. (ed.) (1994). QFD. The Customer-Driven Approach to Quality Planning and Deployment (pp. 365). Tokyo, Japan: Asian Productivity Organization.

[14] Sawe, C. T., Onyango, C. M., & Njage, P. M. K. (2013). Current food safety management systems in fresh produce exporting industry are associated with lower performance due to context riskiness: Case study. *Food Control, 40*(6), 335-343. http://dx.doi.org/10.1016/j.foodcont.2013.12.019

[15] Sawe, C.T., Onyango C.M. & Njage P.M.K. (2013). Current food safety management systems in fresh produce exporting industry are associated with lower performance due to context riskiness: Case study. Food Control, 40(6), 335–343.

[16] Surkov, I.V. Key processes management in development and implementation of management systems at food enterprises / I.V. Surkov, E.O. Ermolaeva, A.Y. Prosekov, G.A. Gorelikova, V.M. Poznyakovskiy // Life Science Journal. – 2014; 11(12). – P. 300–304.

[17] Surkov, I.V. Evaluation and preventing measures of technological risks of food production / I.V. Surkov, A.Y. Prosekov, E.O. Ermolaeva, G.A. Gorelikova, V.M. Poznyakovskiy // Modern Applied Science; Vol. 9, No. 4; 2015. – P. 45–52.

[18] Surkov, I.V. The development of integrated management system to ensure the quality stability food safety / I.V. Surkov, V.M. Kantare, K.Y. Motovilov, T.V. Renzyaeva // Food and Raw Materials. – 2015. – №1. – С. 111 – 119.

[19] Van Kleef, E., Houghton J.R. & Krystallis A. et al. (2007). Consumer evaluations of food risk management quality in Europe. Risk analysis:An official publication of the Society for Risk Analysis, 27(6), 1565–80

[20] Van Kleef, E., Houghton, J. R., & Krystallis, A., et al. (2007). Consumer evaluations of food risk management quality in Europe. *Risk analysis: An official publication of the Society for Risk Analysis*), 1565-80.