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FEATURES OF QUALITY MANAGEMENT OF NON-COMPLIANT PRODUCTS IN UKRAINE

ОСОБЛИВОСТІ УПРАВЛІННЯ ЯКІСТЮ НЕВІДПОВІДНОЇ ПРОДУКЦІЇ В УКРАЇНІ

Tkachenko Viktoriia
Sumy National Agrarian University
ORCID: https://orcid.org/0000-0002-2924-4012

Ткаченко Вікторія Вікторівна
кандидат економічних наук, доцент,
Сумський національний аграрний університет

The article establishes what is a non-compliant product; it's deals with procedures for managing non-compliant products in accordance to the requirements of DSTU ISO 22000; the requirements of DSTU ISO 9001:2015 and the regulatory framework of Ukraine for the management of non-compliant products are analyzed. Developed a single standard procedure for small and medium enterprises to implement and understand the sequence of actions in the implementation of this procedure. Improved the process of managing non-compliant products; the division of responsibilities for the implementation of the stages of the procedure was carried out; the block diagram of realization of procedure of management of non-conforming production is improved; requirements for registration of documentation are established and their forms are improved.

Keywords: quality management system, non-compliant (inappropriate) products, shortage, identification, current control, quality control of finished products.

У статті визначається поняття невідповідної продукції; аналізуються причини появи такої продукції на підприємстві, а також можливі наслідки такої невідповідності для життя і здоров'я людини. Метою роботи є виявлення недоліків та вдосконалення існуючого процесу управління невідповідною продукцією, а також обґрунтування необхідності використання системи НАССР для вдосконалення управління якістю і конкурентоспроможністю продукції харчових підприємств України та визначення перспектив її впровадження. Управління невідповідною продукцією – один із найважливіших процесів для кожної організації, від оперативності й правильності виконання якого залежить успішність роботи всього колективу. Невідповідна продукція повинна оперативно виявлятися та ізолюватися від продукції, що задовольняє встановленим вимогам. В процесі написання статті було застосовано метод системного аналізу (розгляд проблеми використання систем управління якістю як елементу системи управління організацією); факторний аналіз (для виявлення факторів, що впливають на процес впровадження системи якості на підприємстві та в управління); логічне узагальнення (для визначення сутності, критеріїв, принципів управління якістю); статистичні методи аналізу якості (для виявлення причин проблем в управлінні якістю, їх систематизації та узагальнення); експертні оцінки (для узагальнення результатів експертного опитування та визначення мотивації до впровадження систем управління якістю, підвищення продуктивності праці). Розглянута процедура управління невідповідною продукцією відповідно до вимог ДСТУ ISO 22000; аналізує вимоги ДСТУ ISO 9001:2015 та нормативну базу України щодо управління невідповідною продукцією. Для малих та середніх підприємств розроблено уніфіковану стандартну процедуру реалізації та визначення послідовності дій при реалізації цієї процедури. Покращений процес управління невідповідними продуктами; розподіл відповідальності сформувався в процесі виконання етапів процедури; вдосконалено структурну схему реалізації процедури управління невідповідною продукцією; встановлено вимоги до документації та вдосконалено їх форми.

Ключові слова: система управління якістю, невідповідна продукція, дефіцит, ідентифікація, поточний контроль, контроль якості готової продукції.

В статье определено, что является несоответствующей продукцией; проанализированы причины возникновения такой продукции на предприятии, а также возможные последствия такого несоответствия для жизни и здоровья человека. Рассмотрена процедура управления несоответствующей продукцией согласно с требованиями ДСТУ ISO 22000; анализируются требования ДСТУ ISO 9001:2015 и нормативная база Украины по управлению несоответствующей продукцией. Разработана единая стандартная процедура для малых и

средних предприятий по внедрению и определению последовательности действий при реализации данной процедуры. Улучшен процесс управления несоответствующими продуктами; сформировано разделение ответственности в процессе выполнения этапов процедуры; доработана структурная схема реализации процедуры управления несоответствующей продукцией; установлены требования к оформлению документации и усовершенствованы их формы.

Ключевые слова: система управления качеством, несоответствующая продукция, дефицит, идентификация, текущий контроль, контроль качества готовой продукции.

Formulation of the problem. According to the Law of Ukraine «On Basic Principles and Requirements for Food Safety and Quality», all food producers have three years to implement the HACCP safety management system (risk analysis and critical control point, which operates in Europe) [3].

Small capacity, which supplies products to the final consumer, with a staff of up to 10 people and an area of up to 400 square meters or those facilities that do not supply products and have a staff of up to 5 people, have deadlines for the development and implementation of the HACCP (Hazard Analysis and Critical Control Points) system until September 20, 2019.

Today, even very large companies with significant financial resources, technical capabilities and a high management culture may experience significant difficulties, and small and medium-sized enterprises may feel that the difficulties of HACCP are potentially insurmountable. The fact is that typical small and medium-sized enterprises usually have limited resources (staff, time, qualifications, experience, technical competence and finances). In the context of HACCP, the technical competence required to develop this system is of particular importance.

As we can see, the introduction of HACCP (and not another similar quality control system) was not envisaged before. As a result, this system has not been widely implemented in domestic enterprises.

There is another aspect that cannot be neglected: the lack of a mechanism to monitor the effectiveness of HACCP, as well as those responsible who are able to perform this management function at the right level. There was no clear delineation of responsibilities between official regulatory authorities and the manufacturer for violating food safety requirements.

This situation in the Ukrainian market has led to a situation where the HACCP system was used exclusively as part of standards based on the international food standard IFS, ISO 22000 and others [2]. Only those players who, in the course of searching for markets outside the domestic market, inevitably encountered the need to implement the system, switched to the system of analysis of dangerous factors and control at critical points.

The new system clearly states that the market operator is responsible for violating food safety legislation as part of its activities.

To ensure the safety of food raw materials and food products, all participants in the production chain, from the primary production of raw materials to the final consumer of the food product, must adhere to certain principles and rules established by relevant laws, regulations and guidelines, which are commonly called "Food law".

Analysis of recent research and publications. In the economic literature, attention to the introduction of quality systems in the activities of enterprises and organizations of various industries and spheres is paid by well-known domestic and foreign scientists, such as: Yu. Adler, A. Babansky, V. Gissin, V. Goncharov, I. Grishova, J. R. Evans, L. Kirichenko, P. Maidanevich, N. Merezhko, L. Naumova, A. Nikiforov, V. Ogvozdin, V. Pavlov, N. Salukhina, G. Locust, J. Harrington, M. Shapoval, O. Yazvinskaya and others.

In the works of these authors laid the scientific foundation of quality management of enterprises and organizations of the food industry. However, most of the work is devoted to ensuring compliance of quality management systems with international standards, which are universal and do not take into account the specifics of the food industry. The practical development and implementation of a quality management system in the food industry should take into account the specifics of production, and attention should be focused on the most problematic places in quality management.

The purpose of the article. Non-compliant product management is one of the most important processes for every organization, the efficiency and correctness of which depends on the success of the entire team. The success of the team is a well-organized work of the company's management, which developed and implemented the procedure. The purpose of the study is to substantiate the need to use the HACCP system to improve the management of quality and competitiveness of food companies

in Ukraine and determine the prospects for its implementation.

Presentation of the main results. Non-compliant products are considered to be raw materials, intermediates and/or finished products and auxiliary materials that do not meet the requirements and cannot be used in production.

ISO 9001 (paragraph 10.2 Non-compliant product management) stipulates that the organization must develop and approve a documented procedure for managing non-compliant products (services), i.e ensuring the identification and management of services that do not meet its requirements to prevent its unforeseen provision. The procedure should define the means of management, as well as the associated responsibilities and authorities for disposing of the inappropriate service [1, p. 19].

Management of non-compliant products in Ukraine is carried out in accordance with the requirements of DSTU ISO 9001:2015. This normative document covers the actions that the manufacturer of this product must take to prevent its unintended use or supply. As defined in DSTU ISO 9000:2015 "non-compliant products are products that do not meet the established requirements"; "Dangerous products are products that do not meet the established requirements for safety and can cause harm to the consumer" [1].

Potentially dangerous products are those that have been adversely affected or produced under non-conforming conditions.

Therefore, we propose to improve the procedure for managing non-compliant products by providing a complete description with an algorithm of actions.

In order to perform procedures that are based on the principles of the system of analysis of hazardous factors and control at critical points, market operators have:

1) provide the competent authority during the state control with evidence of compliance of their activities with the requirements of part four of this article, taking into account the scope and volume of production, as well as simplified requirements for small capacities and capacities with low risk to consumer health;

2) ensure that the documents describing the procedures developed in accordance with the requirements of this Article contain reliable information;

3) ensure the storage of documents and records on compliance with the principles of the system of analysis of hazardous factors and control at critical points for three months after the end date of sale of food on the label, unless otherwise provided by the recommendations of producer associations approved by the central executive body, which forms and ensures the implementation of state policy in the field of safety and certain indicators of food quality [4, p. 223].

Therefore, first of all, all the elements, requirements and provisions adopted in the food safety management system (further – HACCP) of the enterprise must be documented.

The documentation includes graphic, textual and electronic documents, which individually or in combination determine the technological process of manufacture, control of products, contain the necessary data on the organization of production, rights and responsibilities of employees, set technical requirements for products and materials.

Documents on the method of their implementation and the nature of use are divided into:

– control copy;

– working copy.

Management of HACCP documentation at the enterprise includes: development, approval, distribution, acquaintance of the personnel with requirements of the document, modification, review, updating, storage, archiving, removal of obsolete documents and their utilization.

HACCP documentation at the enterprise can be divided into the types listed in table 1.

The HACCP documents in the archive are subject to annual review. Based on the results

Table 1

Types of documentation HACCP

Types of documentation	Responsible for preservation / place of storage	
	Control	**Working**
a) a documented statement on food safety policy and objectives: – police in the field of food safety; – goals in the field of food safety.	Individual entrepreneur	Members of the HACCP group
b) documented procedures, instructions, prerequisites and protocols required by DSTU ISO 22000, including documents and protocols that the organization deems necessary to ensure the effective development, implementation and updating of HACCP	Head of the HACCP group	HACCP team members / places of use

of the review of the expired documents, they are subject to disposal.

Each procedure (as a document) describes a separate procedure to ensure compliance with the requirements of DSTU ISO 22000.

The procedure consists of the following sections:

– "Purpose and scope";
– "Links" (if necessary);
– "Terms, their definitions and accepted abbreviations" (if necessary);
– "Responsibility";
– "Description of the procedure";
– applications;
– change registration sheet.

We offer an improved procedure for managing non-compliant products.

The sequence of stages of management of such products, the division of responsibilities between the management and heads of divisions of the receiving enterprise participation in their implementation, source documents and data obtained in the process of performing the stages are important components for obtaining an effective result in the implementation of these stages [5, p. 37].

The algorithm for implementing the procedure for managing non-compliant products is shown in Figure 1.

Stage 1. Detection of non-compliant products and information

Detection of non-compliant products can occur during the initial control of raw materials, containers and packaging materials, as well as at any stage of the technological process. A person who has identified non-compliant products or has doubts about their compliance, in case of exceeding the critical limits at critical control points, loss of control in the operational program prerequisites or in the event of emergencies, addresses the head of the HACCP team.

In this case, further operations provided for products that are found to be non-compliant shall be suspended by the relevant order of the head of the HACCP group. Such products shall be identifiable in any way that detects their use in subsequent transportation, storage, non-compliance or shipment operations to the customer.

Product non-conformity criteria are considered (but not limited)

– non-compliance of the requirements of the specifications with the actual data on products, raw materials, containers and packaging materials;
– expiration of the shelf life of products;
– long-term violation of critical limits for critical control points.

Responsible: the person who found the discrepancy. Establishment of the fact of non-compliance is carried out by engineers – technologists and controllers on quality of finished products on control operations according to technological process, and also the representative of the management on quality on all complex of works carried out according to operations of a technological cycle.

Supervises: head of the HACCP group.

Data-in: non-compliance criteria (see above).

Data-out: documentation is carried out in the register of non-conforming products.

Stage 2. Analysis of discrepancies

The head of the HACCP group analyzes the information on non-compliance in order to identify its source (cause), and decides on further action with non-compliant products.

Responsible: head of the HACCP group.

Data-in: non-compliance, records in F. 7.10.3-01.

Data-out: identified source (cause). Records in F. 7.10.3-01.

Stage 3. Actions on non-compliant products

Step 3a. Proof of product safety

A batch of products produced in non-conformity conditions should be released as safe only if one of the following conditions is met:

a) evidence other than that provided by the monitoring system demonstrates that the management measures have been effective;

b) the evidence indicates that the aggregate impact of the management measures on the specific product is in line with the intended performance (i.e acceptable levels);

c) the results of random tests, analyzes and/or other verification actions demonstrate that the affected consignment satisfies a certain level of food hazards.

If the safety of the product has been proven, it is released as safe.

Table 2

Form of the log of registration of non-conforming production (F 7.10.3-01)

№	Name products	Description discrepancies, source	Date and time detection	Operations with non-conforming products	Decisions on non-conforming products	Signature responsible persons

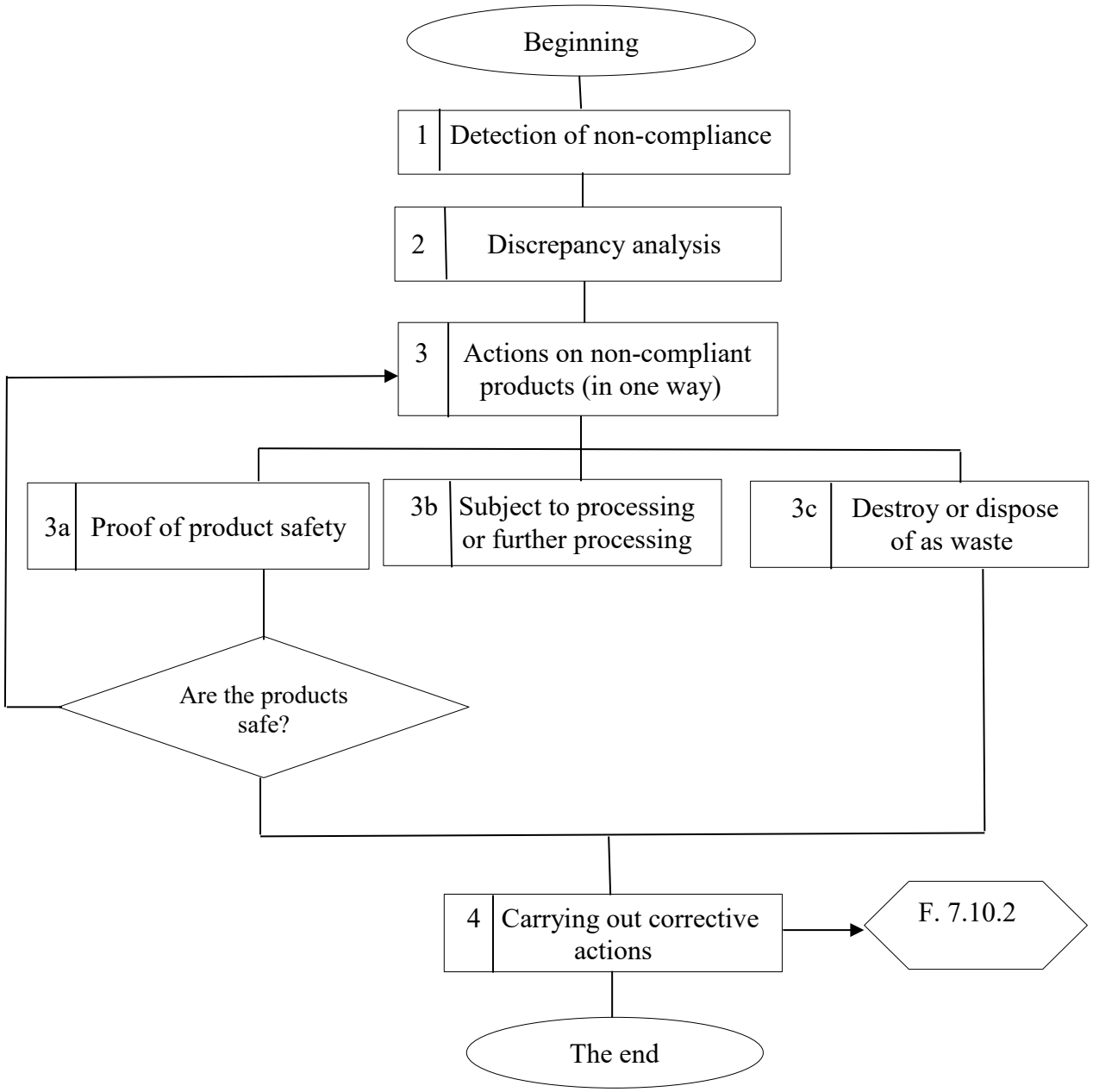

Figure 1. Algorithm for implementing the procedure for managing non-compliant products

If the safety of the product has not been proven, a different decision is made on further actions with non-compliant products (we return to stage 2 and make a new decision) (one of the remaining two) on further actions with non-compliant products.

The result of the action on non-conforming products is recorded by an entry in the journal on the form F. 7.10.3-01.

Responsible: head of the HACCP group.

Data-in: identified source (cause). Records in F. 7.10.3-01.

Data-out: identified source (cause). Records in F. 7.10.3-01.

Step 3b. Subject to processing or further processing

Where appropriate, non-compliant products may be processed or further processed within or outside the organization to ensure that the food hazard is eliminated or reduced to an acceptable level.

Responsible: head of the HACCP group.

Data-in: identified source (cause). Records in F. 7.10.3-01.

Data-out: identified source (cause). Records in F. 7.10.3-01.

Step 3c. Destroy or dispose of as waste

If it is not possible to prove the safety of the product, or to eliminate (reduce) the hazardous factor to the accepted level by processing or treatment, the hazardous product is destroyed or disposed of.

Table 3

Form of the journal of implementation of corrective actions F. 7.10.2-01.

№	Description of discrepancy	Reason inconsistencies	Description of corrective action	Responsible person	Date		Mark about implementation	Efficiency
					Acceptance	Implementation		

Responsible: head of the HACCP group.

Data-in: identified source (cause). Records in F. 7.10.3-01.

Data-out: identified source (cause). Records in F. 7.10.3-01.

Stage 4. Carrying out corrective actions.

Corrective actions are carried out according to the "Corrective actions" Procedure 7.10.2.

Successful adjustments or corrective actions are recorded by the head of the HACCP group in a journal in the form, F. 7.10.2-01.

Responsible: performer (group of performers) on Procedure 7.10.2

Supervises: head of the HACCP group.

Data-in: decision on F. 7.10.3-01.

Data-out: Entries in journals, F. 7.10.2-01 (Table 3).

The corrective action procedure establishes the selection and implementation of corrective actions at the enterprise in accordance with the requirements of DSTU ISO 22000.

Corrective action is an action taken to eliminate the cause of a discrepancy or other undesirable situation.

Corrective actions provided by the HACCP system should include the following elements:

1. Identification and elimination of causes of discrepancies;

2. Determining the location of non-compliant products;

3. Restoration of control over the technological process;

4. Registration of performed corrective actions;

5. Corrective actions should be developed for each critical control point.

The designated person(s) responsible for taking corrective action will implement measures to eliminate the non-compliance and its consequences (usually a non-compliant non-compliance). The natural person-entrepreneur analyzes the effectiveness of the implementation of actions for the purpose of adjustments and makes an entry in the journal in accordance with the relevant prerequisite program, depending on the type of non-compliance and implemented actions for the purpose of adjustments.

Evaluation of the effectiveness of adjustments and corrective actions is carried out once a year during the analysis of HACCP by management in accordance with the procedure of the analysis by management. The results of adjustments and corrective actions are reviewed by the internal and external auditors of the HACCP during inspections.

Conclusions. Based on the study, the following conclusions can be drawn: the article analyzes the requirements of DSTU ISO 9001:2015 and the regulatory framework of Ukraine for the management of non-compliant products; an improved procedure for managing non-compliant products is provided, which will help small and medium-sized enterprises to complete the implementation of the HACCP system; the procedure of realization of stages is described in detail; the division of responsibilities for the implementation of the procedures of the procedure; improved the block diagram of the implementation of the procedure for managing non-compliant products; requirements for registration of documentation are established; a template of a standard procedure for small and medium enterprises has been developed, which takes into account all the requirements of DSTU ISO 22000 and the requirements of the legislation of Ukraine.

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