ISSN: 1220-3173; E-ISSN: 2457-7618

APPLICATION OF A SYSTEM BASED ON HACCP PRINCIPLES IN A PET NUTRITIONAL SUPPLEMENTS MANUFACTURING UNIT

APLICAREA UNUI SISTEM BAZAT PE PRINCIPIILE HACCP ÎNTR-O UNITATE PRODUCĂTOARE DE SUPLIMENTE NUTRITIVE PENTRU ANIMALE DE COMPANIE

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ABSTRACT | REZUMAT

The Hazard Analysis Critical Control Point (HACC P) system is an effective risk management tool used in various industries to control risks associated with production processes. Originally developed for the food industry, HACCP is now successfully applied in various fields. The main purpose of this study was the implementation and evaluation of the HACCP system for the production of complementary food and supplements for pets. The implementation of the HACCP system is a legislative requirement regarding complementary food for pets, according to European regulations. In this context, the HACCP system was specifically adapted to meet these requirements and to ensure the production of safe and high-quality products.

Keywords: HACCP, nutritional supplement, animal complementary food

Sistemul Hazard Analysis Critical Control Point (HA CCP) este un instrument eficient de gestionare a riscurilor, utilizat în diverse industrii pentru a controla riscurile associate cu procesele de producție. Inițial dezvoltat pentru industria alimentară, HACCP este acum aplicat cu success în diferite domenii. Scopul principal al acestui studiu a fost implementarea și evaluarea sistemului HACCP pentru producția de hrană complementară și suplimente pentru animale de companie. Implementarea sistemului HACCP este o cerință legislativă în ceea ce privește hrana complementară pentru animale de companie, conform reglementărilor europene. În acest context, sistemul HACCP a fost adaptat specific pentru a răspunde acestor cerințe și pentru a asigura producția unor produse sigure și de înaltă calitate.

Cuvinte cheie: HACCP, supliment nutritiv, hrană complementară animale

In the current context, where food safety and product quality are essential, the implementation of risk control and prevention systems becomes vital, not only for food intended for human consumption but also for pet food. HACCP (Hazard Analysis Critical Control Point) is an internationally recognised system that focuses on identifying, assessing, and controlling significant hazards to food safety (1).

Although HACCP was initially developed for the human food industry, its principles are equally applicable in the production of pet food, including complementary food and nutritional supplements.

These products play a crucial role in ensuring a balanced and healthy diet for pets, which is why their safety and quality must be guaranteed to the highest standards (4, 6).

Within the European Union's legislative framework, the term "nutritional supplement" for pets has been replaced by "complementary food" to eliminate confusion and standardise regulations (3). The ingredients in these products are referred to as feed additives and are strictly regulated to ensure their safety and efficacy. The shift to "complementary food" clarifies the role of these products in supplementing the main diet of pets, providing essential nutrients for their health and well-being (2).

Implementing a HACCP system in a complementary pet food factory not only helps prevent biological, chemical, and physical contamination but also contributes to the continuous improvement of production processes.

By identifying and controlling critical points in the production chain, HACCP allows manufacturers to minimise risks and ensure compliance with strict industry regulations (8).

The implementation of HACCP may face various challenges, such as limited resources and resistance to change. However, proper staff training and the use of advanced technologies can help overcome these difficulties (5). Numerous case studies demonstrate the success of HACCP implementation in the pharmaceutical and food sectors, highlighting risk reduction and product quality improvement (7).

This article aims to explore in detail the principles of HACCP and their applicability in the production of complementary food. It will address the importance and benefits of implementing this system, the challenges encountered, and solutions to overcome them.

Our objective is to provide a deep understanding of how HACCP can transform and improve the safety and quality of products intended for pets.

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MATERIALS AND METHODS

The present study was carried out in a pharmaceutical factory located in Oltenita, Romania, within the section for the manufacture of compressed products. This department, having the status of a drug factory, is authorised according to Good Manufacturing Practice (GMP) standards, thus ensuring compliance with the strictest safety and quality norms.

The factory has equipment for the manufacture of conditioned products in the form of tablets. This category includes equipment for homogenising the mixture, compression machine, deduster, metal detector, and blistering machine. Also, the factory is equipped with tables, transport containers (goods), and other auxiliary equipment necessary to support the entire production process.

To implement the HACCP system, the systematic and structured steps to identify, evaluate, and control significant food safety hazards were addressed:

1. Formation of the HACCP team
2. Product description and identification of intended use
3. Elaboration of the flow diagram
4. Checking the flow chart
5. Risk identification and analysis
6. Determination of critical control points (CCP)
7. Establishing critical limits for each CCP
8. Establishing monitoring procedures
9. Establishing corrective actions
10. Establishing verification procedures
11. Establishing a Record-Keeping and Documentation System
12. Staff Training and Education

RESULTS AND DISCUSSION

1. Formation of the HACCP team

The implementation of the HACCP system began with the formation of a multidisciplinary team, made up of specialists in quality assurance, production, and quality control. This team was charged with the task of developing, implementing, and monitoring the HACCP system. Following the initial assessment, the need for external training was identified. Team members were sent to training courses to obtain ISO 22000:2018 and ISO 19011:2018 certification.

2. Product description and identification of intended use

Each type of complementary food produced was described in detail, including all essential aspects. The ingredients used were presented, specifying the origin, quality, and characteristics of each component. Within the project, 10 products in tablet form were developed, each with specific uses and benefits. To ensure the stability of the active ingredients, the tablets were packaged in Alu-Alu and Alu-PVC blister packs (Fig. 1). Two types of tablets were selected for mixing: round tablets with two intersecting lines, allowing them to be divided into four equal quarters for easier administration, and oblong-shaped tablets with a central line.

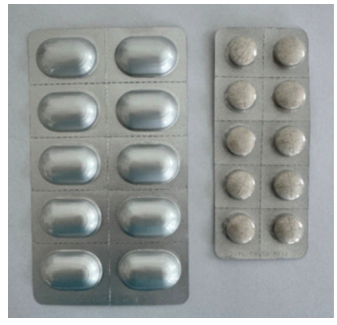

Fig. 1. Alu-Alu and Alu-PVC blister packs

The final use of the products was carefully analysed. Possible misuse scenarios were identified to prevent potential risks and to properly inform consumers. This included common scenarios of incorrect use, such as improper dosing, unsuitable storage conditions, or inappropriate food combinations. Additionally, clear instructions for use and storage were developed to guide users towards optimal and safe use of the products.

3. Elaboration of the flow diagram

The manufacturing process was detailed step by step, from the selection and weighing of the ingredients according to the recipe to the homogenisation of the mixture, the formation of the tablet and packaging, including the quality testing stage (Fig. 2).

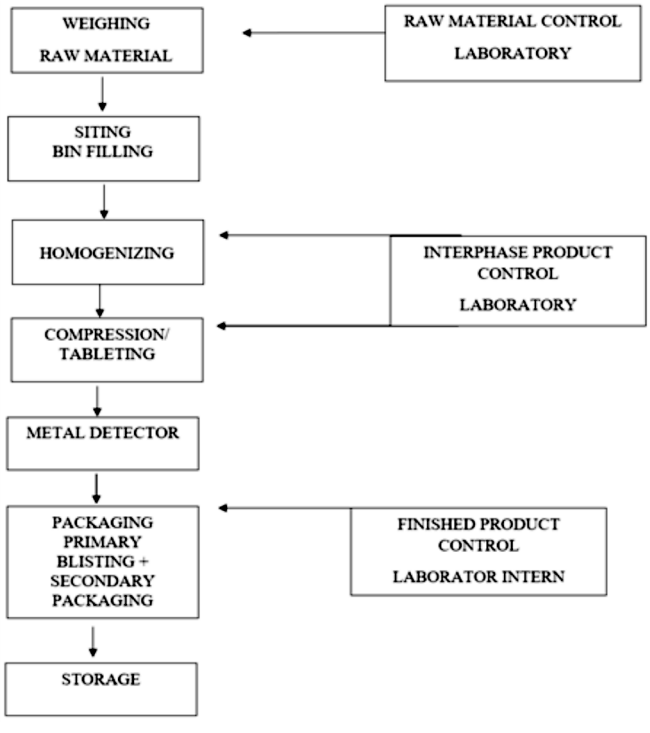

Fig. 2. Flow diagram presenting the steps in the manufacturing process of pet medicines and nutritional supplements

4. Checking the flow chart

The verification of the flow diagram was carried out through a detailed on-site inspection in the production department. Each stage of the manufacturing process described in the diagram was compared step by step with the actual activities performed in the department. This process included direct observation of operations and consultations with production staff to ensure the accuracy of the representation of the stages. Any discrepancies identified between the initial diagram and the actual process, such as omitted steps or inaccurate descriptions of procedures, were documented. Based on the observations, the flow diagram was updated to accurately reflect the real workflow. After implementing the changes, the diagram was re-verified to confirm that all corrections were properly made, thus ensuring an accurate and complete representation of the production process.

5. Risk identification and analysis

The HACCP team analysed hazards based on a decision tree (Fig. 3). Hazards are reviewed every six months or when a new hazard is identified that needs to be included in the HACCP plan. There are different types of hazards, such as chemical, biological, and physical hazards, which can occur at various stages of the production process.

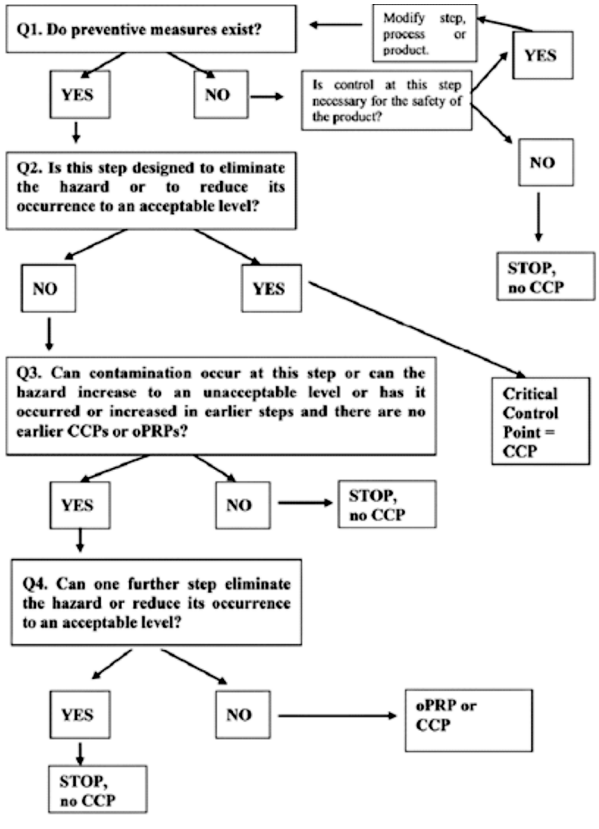

Fig. 3. Decision Tree for identifying critical control points (CCPs) (2022/C 355/01)

Chemical Hazards

These refer to the presence of chemical substances that could harm the health of animals. Examples of chemical hazards include:

- Unauthorised additives or preservatives: The use of chemicals that are either unapproved or in quantities exceeding legal limits.
- Cross-contamination with medications: This can occur if supplements are produced in a facility where products containing substances such as antibiotics or antiparasitics are processed.
- Improper dosing of active substances: Failing to follow the approved manufacturing recipe can lead to excessive amounts of active substances in the product mixture, increasing the risk of animal poisoning.

Physical Hazards

These include any foreign material or physical contaminants that could enter the final products and endanger the health of pets. Examples of physical hazards include:

- Metal fragments: These can originate from machinery, equipment, or raw materials.
- Glass shards: They may occur in the event of accidental breakage of equipment or packaging.
- Plastic or packaging fragments: These can come from packaging materials or equipment used in production.
- Raw material degradation: Improper storage of raw materials can lead to the breakdown of ingredients, particularly those of organic origin, that are used in the products.

Biological Hazards

These hazards are represented by pathogenic microorganisms that can cause illness in animals. Examples of biological hazards include:

- Pathogenic bacteria: Such as Salmonella, E. coli, and Listeria, which can contaminate raw materials or arise from poor hygiene during production.
- Moulds and mycotoxins: These can develop in raw materials, especially those containing high concentrations of polysaccharides or other plant-based products stored in humid and uncontrolled temperature conditions.
- Viruses: These can be transmitted through raw materials or by infected personnel.

6. Determination of critical control points (CCP)

The determination of Critical Control Points (CCPs) was carried out using a standardised decision tree, in accordance with HACCP principles. Each stage of the production process was evaluated to identify those points where preventive measures can be applied to prevent, eliminate, or reduce hazards to an acceptable level. In this analysis, potential biological, chemical, and physical hazards that could compromise the safety of the final product were taken into account. For each identified CCP, specific control measures were established to ensure that the hazards are properly managed. This determination of CCPs represents a crucial step in ensuring product safety, guaranteeing that critical processes are adequately monitored and controlled.

7. Establishing Critical Limits for Each CCP

Critical limits were established for each identified Critical Control Point (CCP) in the production process, in accordance with HACCP system requirements. These critical limits were defined as measurable values that must be met to ensure that the identified risks are effectively controlled. Critical limits were set for temperature, humidity, microbial load, and other factors relevant to product safety. Each critical limit was determined based on scientific data and best practice guidelines to maintain the production process under optimal safety conditions. In the event of exceeding these limits, corrective actions were put in place to address the situation and prevent product compromise.

8. Establishing Monitoring Procedures

Monitoring methods were developed using available equipment, such as real-time temperature and humidity sensors that automatically record data. The monitoring frequency was defined to be frequent enough to quickly detect any deviations from critical limits. Production personnel were made responsible for continuously checking these parameters, and the collected data was documented in a centralised system. Microbiological testing programs were implemented, including sanitation tests, testing of the water used in production, and testing of the final product. Physical and chemical analyses are performed for each batch of the final product to verify compliance with the characteristics described in the manufacturing dossier.

9. Establishing Corrective Actions

Corrective actions were defined to be applied immediately if monitoring indicates that a critical parameter, such as temperature, time, or humidity, is outside the established limits. These actions were developed to quickly restore control of the process and prevent affected products from reaching consumers. For example, if the storage temperature, set at a maximum of 25°C, is exceeded, the initial corrective action involved immediately checking the refrigeration or temperature control equipment to identify the cause of the problem (equipment failure, incorrect settings, etc.). At the same time, additional measurements were taken to assess the impact on the stored product. If the temperature increase was significant or persisted for an extended period, the affected batches were isolated and analysed to determine whether the integrity of the supplements had been compromised (e.g., by changes in chemical composition or microbiological activity). Depending on the analysis results, the product was either reintroduced into storage if deemed safe or completely withdrawn from production and destroyed to prevent the risk of accidental release for sale. These corrective actions were thoroughly documented, including the measures taken to correct the storage temperature and prevent the issue from recurring. The personnel responsible for monitoring the temperature were trained to respond promptly in such situations, minimising the impact on products while maintaining their safety and quality. Verification procedures were implemented to confirm the effectiveness of the HACCP system, including periodic checks, tests, and internal audits. Documentation and records required for all HACCP procedures and monitoring, including the results of verifications and corrective actions, were created and maintained.

10. Establishing Verification Procedures

Verification procedures included a series of actions such as periodic internal audits, laboratory tests, and visual inspections. The internal audit was conducted based on an annual program in which the HACCP team reviewed the HACCP system documentation and evaluated the accuracy of monitoring and the application of corrective actions.

11. Establishing a Record-Keeping and Documentation System

A detailed record-keeping and documentation system was established to efficiently monitor and manage all activities related to the HACCP system. Each document was assigned a unique code, along with a specific edition and revision, allowing for easy and reliable identification. For the manufactured product, a complete manufacturing dossier was created, containing all the necessary records to ensure the accuracy and traceability of the production process. These dossiers include detailed information on the raw materials used, production parameters, CCP monitoring, corrective actions applied, and verification procedures. This system ensures that every stage of production is properly recorded and can be traced in the event of an audit or a need to verify compliance.

12. Staff Training and Education

An annual training plan was developed to ensure the periodic updating of knowledge for production staff regarding the manufacturing process, followed by tests to verify the effectiveness of the training. Additionally, specialised personnel attended external HACCP certification training, which provided them with the necessary knowledge to properly implement the system.

CONCLUSIONS

The implementation of the HACCP system in the complementary pet food factory has demonstrated significant efficiency in ensuring product safety and quality.

The establishment and monitoring of critical control points (CCPs), as well as the rigorous application of verification and documentation procedures, allowed the effective management of risks associated with the production process. This research highlights that compliance with international standards such as HACCP and ISO 22000:2018 is critical to maintaining product compliance and safety, particularly in the pet food supplement industry.

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