



National Standard of the People's Republic of China

GB/T 27342-2009

Hazard Analysis and Critical Control Point (HACCP) System- Requirements for Dairy Processing Plant

危害分析与关键控制点 (HACCP) 体系

乳制品生产企业要求

- Released on 2009-02-17
- Implemented on 2009-06-01
- Issued by AQSIQ & Standardization Administration of China

Disclaimer: The English version is an unofficial translation of the original in Chinese for information and reference purposes only. In case of a discrepancy the Chinese original standard will prevail.

Contents

Foreword	2
Introduction.....	3
1. Scope	4
2. Normative references.....	4
3. Terms and Definitions	4
4. HACCP System for Dairy Processing Plant.....	5
5. Management responsibility	5
6. Pre-requisite programs.....	5
6.1 General principles	5
6.2 Human resources supporting plan	5
6.3 Good manufacturing practice (GMP).....	5
6.4 Sanitation Standard Operation Procedure (SSOP)	5
6.5 Safety and Sanitation supporting system of raw & auxiliary materials and packaging materials	6
6.6 Maintenance Program	6
6.7 Labeling, Tracing Plan and Dairy Product Recall	6
6.8 Emergency Response plan.....	7
7. Establishment and Implementation of HACCP Plan	7
7.1 General Principles	7
7.2 Preliminary Procedures	7
7.3 Hazard Analysis and Control Measure Establishment	7
7.4 Identification of the Critical Control Points (CCP) and Critical Limits (CL).....	8
7.5 CCPs monitoring.....	10
7.6 Corrective actions	10
7.7 Verification and Confirmation of HACCP System.....	10
7.8 Record Keeping	10

Foreword

This standard is proposed by and under the jurisdiction of Standardization Administration of China (SAC/TC261).

The main drafting units of this standard are as follows: Registration and Management Department of Certification and Accreditation Administration of the People's Republic of China, China Dairy Industry Association, China Certification & Accreditation Institute, National HACCP Application Study Center, Beijing Entry-Exit Inspection and Quarantine Bureau and Tianjin Entry-Exit Inspection and Quarantine Bureau, Beijing HSL Certification Service, China Quality Certification Center, China Quality Mark Certification Center and Beijing Zhongda Huayuan Certification Center.

Main drafters of this standard as follows: Shi Xiaowei, Song Kungang, Yang Zhigang, Zhang Shuyi, Liu Xiande, Liu Ke, Wang Maohua, Li Likai, Li Jingjin, Duan Qijia, Xi Liqun, Li Yuanchao, Ma Litian, Chen Encheng.

Introduction

The purchase, processing, storage, sales procedures of raw material (such as raw milk) may pose safety hazards to dairy products. The hazard analysis and critical control point (HACCP) system of dairy products is a preventive system for process control of dairy products production. The establishment, implementation and continuous improvement of the system will promote the control ability of dairy processing plant against food safety hazards.

This national standard adopts the principles of HACCP, in order to reduce the safety risks of dairy products and on the basis of considering the features of dairy product processing, it proposes the requirements for establishment, implementation, and improvement of HACCP system in dairy product processing procedures, which mainly include the requirements for sterilization and disinfection of materials, safety control of additives, ingredients and packaging, cold-chain control and so on, emphasize the requirements for transportation, storage, acceptance of raw materials such as raw and fresh milk, etc., and the requirements for acceptance and storage of auxiliary materials and packaging materials, and strengthen the monitoring requirements for production source and process.

This national standard includes the technical requirements and supplements for the application of GB/T 27341-2009 "Hazard Analysis and Critical Control Point (HACCP) System-General Requirements for Food Processing Plant" in dairy processing plant.

Hazard Analysis and Critical Control Point (HACCP) System Requirements for Dairy Processing Plant

1. Scope

This national standard specifies the requirements of the Hazard Analysis and Critical Control Point (HACCP) system for dairy processing plant, enabling the plant to provide safe dairy products in compliance with laws and regulations and meet the customers' requirements.

This national standard is applicable to the establishment, implementation and evaluation of the HACCP system for dairy processing plant, including the raw & auxiliary material purchase, processing, storage and transportation and so on.

2. Normative references

The normative references contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated reference documents, the latest version (including all its amendments) is applicable to this standard.

GB 2760 Standards for uses of food additives

GB/T 5410 Milk powder

GB 5749 Standards for drinking water quality

GB/T 6914 Standards for the qualifications of raw and fresh milk received from farms

GB 7718 General Standard for the labeling of prepackaged foods

GB 11674 Whey powder and whey protein powder

GB 12693 Good manufacturing practice for milk products

GB 13432 General Standard for the labeling of prepackaged foods for special dietary uses

GB 14880 Hygienic Standard for the use of nutritional fortification substances in foods

GB 19301 Raw milk

GB 19644 Milk powder

GB/T 27341-2009 Hazard analysis and critical control point (HACCP) system-General requirements for food processing plant

3. Terms and Definitions

The terms and definitions specified in GB/T 27341-2009, and the following ones apply to this national standard.

3.1 Dairy products

It refers to the product which is processed with raw and fresh cow (sheep or goat) milk as the main raw material, including the liquid milk (pasteurized milk, sterilized milk, yoghurt, formulated milk); the milk powders (whole milk powder, skimmed milk powder, sweetened whole milk powder and flavored milk powder, formula milk powder for infants and babies, and other formula milk powder); the condensed milk (unsweetened condensed whole milk, sweetened condensed whole milk, flavored/formulated condensed milk, formula condensed milk); the milk fats (cream, butter, anhydrous milkfat); the cheeses (natural cheese, processed cheese); and other dairy products (casein, lactose, whey powder, etc.).

3.2 Cleaning-in-place (CIP)

It refers to the fact that the power-off food processing machine and its pipeline interior go through the circulative washing treatment with assistance of water, detergent, disinfectant and related equipment.

Note: cleaning-in-place is also called as “on-site cleaning” or “on-spot cleaning”.

4. HACCP System for Dairy Processing Plant

Dairy processing plant should plan and develop the HACCP system, establish documentation, conduct, maintain, update and improve incessantly and ensure that its effectiveness meets Section 4.1 and 4.2 in GB/T 27341-2009.

5. Management responsibility

Dairy processing plant should conform to the requirements in Chapter 5 of GB/T 27341-2009.

6. Pre-requisite programs

6.1 General principles

Dairy processing plant should develop and implement proper pre-requisite programs according to the requirements in Chapter 6 of GB/T 27341-2009 and combining the concrete conditions of the plant.

6.2 Human resources supporting plan

The personnel engaged in the production, inspection and management of dairy products shall meet the requirements of GB 12693.

6.3 Good manufacturing practice (GMP)

Dairy processing plant shall formulate and implement the GMP applicable to the plant according to relevant laws and regulations and the requirements of GB 12693.

6.4 Sanitation Standard Operation Procedure (SSOP)

Dairy processing plant should develop and carry out the SSOP, which not only meets the requirements of Section 6.4 in GB/T 27341-2009 but applies to the plant itself. When appropriate, it shall include, but not be limited to the following:

- a) For recyclable warpage of dairy products, the corresponding sanitation operation procedures should be formulated and carried out; the monitoring requirements shall be specified, and then the warpage can be put into use through inspection. Re-use of non-returnable prepackaging containers must be banned;
- b) The plant should establish the CIP system program and verify its effectiveness, specify the requirements for temperature, time, flow rate, concentration of acid/ alkali liquor of each procedure, and carry it out as required. Shall monitor and test the cleaning effects and chemical residues of CIP effectively (e.g. conductivity meter, pH test paper or other monitoring and testmeasures);
- c) Should ensure there is no blind area or dead zone of cleaning and sterilization in process of cleaning and sterilizing the equipment and facilities;
- d) Should define the control flow of personnel, goods, water and air in the cleaning work areas such as semi-finished products storage, fermentation & inoculation, filling and inner packaging workshops, etc., in the production of dairy products;
- e) Should equip the freezing and refrigerating equipment or take the measures that can keep freezing and refrigerating conditions to confirm the temperature requirements of frozen and chilled dairy product;
- f) Develop appropriate procedures for inspection control, and shall perform sanitation inspection on packaging materials of dairy products, air, or the arms of personnel, production facilities and instruments;
- g) The facilities in contact with the dairy products and the water for cleaning the equipment should comply with

the provisions of GB 5749;

h) Should control the sanitation of surroundings, personnel, packaging machine and instruments during the process of packaging the milk powder.

6.5 Safety and Sanitation supporting system of raw & auxiliary materials and packaging materials

Dairy processing plant should meet the requirements in Section 6.5 of GB/T 27341-2009 adequately, to establish the safety and sanitation supporting system for raw materials such as raw and fresh milk, etc. and packaging materials. The system shall include, but not be limited to the following:

- a) The raw and fresh milk shall be from the dairy stock farm, dairy-breeding plot, and (or) raw and fresh milk purchasing stations with the license for raw and fresh milk purchasing. The vehicle for transporting raw and fresh milk should have the transport license. Shall have the interchange receipt of raw and fresh milk;
- b) In order to prevent the raw and fresh milk containing potential or unknown unsafe ingredients from entering the processing factory, the dairy processing plant should develop the accepting evaluation for the manufacturing enterprises, and perform the quality monitoring on raw and fresh milk in time;
- c) Develop the safe and sanitation supporting system for other raw & auxiliary materials and packaging materials, etc., the purchased product should come from the plants which comply with the provisions of laws and regulations, as well as the related quality safe standards.

6.6 Maintenance Program

Dairy processing plant should meet the requirements in Section 6.6 of GB/T 27341-2009. Developing the maintenance program shall include, but not be limited to the following:

- a) When the emergency maintenance is performed, the measures which can stop the other working production lines from being influenced and polluted;
- b) Should ensure the facilities are in good condition, including the facilities of disinfection, sterilization and monitoring, the automatic program control system, CIP system, burdening system, water supply facilities system, mono or combined type anti-mixing valve, the seal of important units or components, the important facilities for measurement and test, sterile filling and packaging system, supporting system for steam and compressed air, air purification system, refrigeration system, etc.;
- c) The equipment and facilities should conform to the temperature, pressure and other technological requirements required by production;
- d) Should inspect and maintain the production equipment and facilities in time, to prevent the metal and other foreign matter from the mixing into dairy product;
- e) Should reasonably mark the equipment, pipes and pipelines.

6.7 Labeling, Tracing Plan and Dairy Product Recall

Dairy processing plant shall meet the requirements in Section 6.7 of GB/T 27341-2009, and shall include, but not be limited to the following:

- a) The labeling of raw materials (e.g. raw and fresh milk), auxiliary materials, semi-finished products, and finished products should be clear and traceable. The labeling of finished products shall comply with the requirements of GB 7718, GB 13432 and other related standards, laws and regulations;
- b) The raw and fresh milk could be traced back to dairy stock farm, dairy-breeding plot, and (or) raw and fresh milk purchasing station. Dairy processing plant shall develop purchase records, and record the name of supplier, contact information, purchasing date, the quantity and other information faithfully;
- c) Dairy processing plant shall take the measures of bio-safety disposal and destruction to solve the recalled unsafe dairy products, and prevent them re-entering the market;

- d) The plant shall record the varieties, specifications, lot No., and quantity of the delivered products and the direction in which the products have gone;
- e) The plant should develop product recall procedures. When dairy processing plant finds that its dairy products do not meet the requirements of the national quality and safety standards of dairy products, those that may threaten human health and life safety and may possibly cause harms to the physical health or growth development of infants and babies, should stop production at once and report to the concerned competent department, and shall inform sellers and consumers, recall the substandard dairy products which have been delivered from the factory, and sold in the market, as well as record the recall situation.

6.8 Emergency Response plan

Dairy processing plant shall conform to the requirements in Section 6.8 of GB/T 27341-2009 and recognize and determine the potential safety accidents or emergencies of dairy products, carry out the emergency response plan, and make response when necessary to reduce the possible impacts of safety hazards. It shall include, but not be limited to the following:

- a) Sudden electricity or water cut-off, mechanical failures, natural disasters and so on;
- b) Others.

7. Establishment and Implementation of HACCP Plan

7.1 General Principles

Dairy processing plant shall conform to the requirements in Chapter 7 of GB/T 27341-2009, and combine the concrete conditions of the plant, to formulate and implement the suitable HACCP plan.

7.2 Preliminary Procedures

7.2.1 General Principles

Dairy processing plant shall conform to the requirements in Section 7.2 of GB/T 27341-2009, to complete the preliminary procedures.

7.2.2 Formation of the HACCP Team

The formation of the HACCP team should be in line with the requirements of professional coverage area of dairy processing plant, consisting of multi professional personnel, which includes: sanitary quality control personnel, research and development personnel, dairy productive technology technical personnel, equipment management personnel, purchasing, sales, storage and transport management personnel of raw and fresh milk and auxiliary materials etc. If necessary, the formation of the HACCP team could invite the personnel with professional knowledge of dairy stock raising and animal husbandry and veterinary to participate in.

7.2.3 Product Description

Dairy processing plant should perform the description of products according to the requirements of Section 7.2.2 in GB/T 27341-2009.

7.2.4 Identification of product's intended use

Dairy processing plant should identify the product's intended use according to the requirement of Section 7.2.3 in GB/T 27341-2009, the intended use of different groups of products should also be determined.

7.2.5 Formulation and verification of the flow chart

Dairy processing plant should formulate and verify the flow chart according to the requirements of Section 7.2.4 and 7.2.5 in GB/T 27341-2009.

7.3 Hazard Analysis and Control Measure Establishment

7.3.1 General Principles

Dairy processing plant shall conform to the requirements in Section 7.3 of GB/T 27341-2009, to perform the hazard analysis and establish control measures. Dairy processing plant also shall develop the defense plan of dairy products as control measures to deal with the major hazards caused by manmade harms or deliberate contamination.

7.3.2 Also, should consider the following information, when the hazard analysis is being performed.

- a) Adulteration of raw and fresh milk;
- b) Environmental pollutants (e.g. heavy metal, nitrate and nitrite and soon);
- c) Biotoxin (e.g. aflatoxin and so on);
- d) Suitable conditions for microbial multiplying;
- e) Antibiotic;
- f) Anaphylactogen
- g) Foreign matter.

7.3.3 Risk Evaluation of Dairy Product Safety

Dairy processing plant shall perform timely risk assessment according to the dairy product safety information issued by government departments.

7.4 Identification of the Critical Control Points (CCP) and Critical Limits (CL)

7.4.1 General Principles

Dairy processing plant shall identify the Critical Control Points (CCPs) and Critical Limits (CLs), according to the requirements of Section 7.4, 7.5 in GB / T 27341-2009.

7.4.2 The factors which should be considered when identifying the Critical Control Points (CCPs) and Critical Limits (CLs)

7.4.2.1 The following important production control procedures and factors could be considered, but not be limited to these, during the acceptance and storage of raw and fresh milk and other raw materials:

- a) The raw and fresh milk should be consistent with the quality and sanitation indexes and other requirements of GB/T 6914 and GB 19301 and should be protected from being polluted by toxic substance, harmful substance., That could be accepted after passing the inspection;
- b) The accepted raw and fresh milk should be processed to dairy products as soon as possible. when the raw milk need to be stored temporarily, it is necessary to refrigerate them at 0°C-4°C rapidly, put into milk storage tank for temporary storage, the temperature of storage should not be over 7°C, and the storage time should not exceed 24h;
- c) The acceptance of milk powder as raw material should meet the indicator requirements of GB/T 5410 and GB 19644, the acceptance of whey powder as raw material should comply with the indicator requirement of GB 11674. The temperature and humidity of storage should meet therequirements.
- d) The safety and sanitation indicators which are not covered by inspection department of the plant, such as, aflatoxin, pesticide residues and of veterinary drugs, heavy metal and so on should be submitted for test regularly by plant, and the test report shall be issued by inspection institutions with relevant qualifications.
- e) Plant should perform the regular certificate inspection on the vitamins, microelements and other use of nutritional supplement.

7.4.2.2 For the additives and ingredients, the following important production control procedures and factors should be considered, but not limited to;

- a) The variety and adding quantity of additive shall comply with the requirements of GB 2760 and GB 14880;
- b) According to the different varieties of dairy products, there shall be review procedures for its ingredient process,

to ensure that the variety, order, and quantity are correct;

c) During the processing of formula powder production, the degree of homogeneity of the mixed ingredients shall be confirmed periodically. When the formula, raw material, facility, technology and others are changed, they should be reconfirmed in a timely manner.

7.4.2.3 As to the sterilization and disinfection, it shall consider but without limitations to the following important production control procedures and factors:

a) When the heating sterilization technology is performed, shall develop evidence-based heating parameters according to the requirement of different varieties of products, and implement correctly, to ensure the security features of products. The sterilization temperature and holding time of pasteurized milk generally is 63°C-65°C, 30min or 72°C-85°C, 15s-20s; the sterilization temperature and holding time of the UHT milk (milk of ultra-high temperature short time sterilization) should be higher than 135°C for several seconds; the sterilization temperature and holding time of holding sterilized (second sterilizing) generally is no lower 110°C for more than 10min. There shall be the records of related sterilization and disinfection, if necessary there shall be automatic temperature record;

b) Before using of sterilization devices, or after the adjustment of the device or after modifying the technology, shall confirm the sterilized effects of products.

7.4.2.4 As to the fermented dairy products, it shall consider but without limitations to the following significant production control procedures and factors:

a) The purity and activity of fermenting agents;

b) The preparation of culture mediums.

7.4.2.5 As to the packaging (filling), it shall consider but without limitations to the following important production control procedures and factors:

a) The concentration of hydrogen peroxide and spraying volume of aseptic filling machine, and the working life of ultraviolet lamp;

b) Where applicable, shall perform the overlapping percent test to canned dairy product;

c) The packages of dairy products shall be sealed and unbroken.

7.4.2.6 As to the concentration and spray drying process in milk powder production in wet method, shall consider but without limitations to the following important production control procedures and factors:

a) The concentration of concentrated milk, and the temperature of concentrated milk;

b) The pressure of spray or the rotating speed of centrifugal disk;

c) The inlet air temperature and supply air rate of drying chamber, and the temperature of outlet air and exhaust air rate;

7.4.2.7 Regarding the storage and transport of frozen and refrigerated dairy products, it shall include, but without limitations to the following important production control procedures and factors:

a) The refrigerant temperature generally is 2°C-6°C;

b) The frozen temperature of butter and anhydrous butter products generally is lower than 15°C;

c) During transportation, the temperature inside the vehicle shall be maintained in the temperature range of production storage requirements.

7.4.2.8 Plant also shall consider other control procedures and factors which could affect the safety of dairy products, combined the technological conditions, product features, equipment facilities and personnel of the plant itself.

7.4.3 When the procedures and factors in Section 7.4.2 which are controlled according to the standard operating

procedure (SOP) control can be equal to the situation of CCP control, the evidence, parameters and documents for identifying SOP shall be retained.

7.5 CCPs monitoring

Dairy processing plant shall comply with the requirements in Section 7.6 of GB/T 27341-2009 to perform the CCPs monitoring.

7.6 Corrective actions

Dairy processing plant shall conform to the requirements in Section 7.7 of GB/T 27341-2009, to establish the corrective actions to deal with the deviation of critical limits.

7.7 Verification and Confirmation of HACCP System

Dairy processing plant shall conform to the requirements in Section 7.8 of GB/T 27341-2009, to perform the verification and confirmation of HACCP system. It shall include, but without limitations to the following:

- a) The low temperature inspection and storage inspection of dairy products;
- b) The packaging effects of sterile filling or packaging system;
- c) The test evidence proving that the addition of the additives and food nutritional fortification substances meets the requirements;
- d) Dairy processing plant shall carry out the test on the dairy products which are going to leave the factory according to the requirements of related laws and regulations or standards;
- e) The dairy products for special consumption uses (i.e. formula milk powder for infants and babies), shall conform the nutrition and other special elements regularly;

7.8 Record Keeping

Dairy processing plant shall maintain the HACCP plan and other related records according to the requirements in Section 7.9 of GB/T 27341-2009. The relevant inspection report should be kept for at least two years.