Food Science and Human Wellness 8 (2019) 106–114

Contents lists available at ScienceDirect

Food Science and Human Wellness

journal homepage: www.elsevier.com/locate/fshw

A review on *rules for examination of licensing criteria for producing foods for special medical purpose* in China

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ARTICLE INFO

Article history:
Received 19 April 2019
Accepted 27 May 2019
Available online 6 July 2019

Keywords:
Review
Foods for special medical purposes
Criteria of production
Examination of licensing

ABSTRACT

In this paper, the background, principles, and main contents of the rules for the examination of production licenses of foods for special medical purposes are introduced. The contents including general rules, production sites, equipment facilities, equipment layout, technological process, personnel management, management system and supplementary rules are interpreted item by item. This study has important value and historical significance for promoting the development of Chinese enterprises and industries of foods for special medical purposes.

1. Introduction

foods for special medical purposes (FSMP), originated in the United States, are the special foods for astronauts originally, and then widely used in hospital clinic as enteral nutrition preparations [1–5]. With the development of medicine and the demands of society, a series of standards and corresponding management policies associated with FSMP have been successively formulated in a large number of countries all over the world [6–20], and then FSMP have stepped on historical stage officially. In the 21 st century, more than 86% of global inpatients or elderly in rehabilitation centers and communities are being faced with the risk or problem of malnutrition. Therefore, nutritional diagnosis and treatment have become common medical practices in developed countries from Europe and the United States. Moreover, FSMP have already been brought into health care plan in many countries. In China, FSMP have been used for more than 40 years. Looking back at the policy development of FSMP in China, FSMP have been used in hospital as "pharmaceuticals" since 1970s. Subsequently, as the growth up of clinical nutrition and the development of parenteral and enteral nutrition, as well as the promulgation of standards for FSMP [21–27], ***rules for the Examination of licensing criteria for producing FSMP*** [29] was issued and implemented in January 2019, which marks a new historical development stage of FSMP industry in China.

In this study, the background, principles and main contents of ***rules for the Examination of licensing criteria for producing FSMP*** [29] are introduced. The contents including general principles, production sites, equipment facilities, equipment layout, technological process, personnel management, management system and supplementary regulations are compared with the contents of on-site verification in the ***General Principles for the Examination of Food Production Licenses*** [32] and interpreted item by item. This study has important value and historical significance for promoting the development of FSMP enterprises and industries in China.

2. Policy background

Article 35 of the ***Food Safety Law of the People's Republic of China*** [27] stipulates that production licenses should be granted for food production activities within the territory of the People's Republic of China. The Food Safety Supervision and

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Peer review under responsibility of KeAi Communications Co., Ltd.

Production and hosting by Elsevier

https://doi.org/10.1016/j.fshw.2019.05.005

Administration Department of the local government at or above county level should execute the examination and on-site verification of the relevant documents submitted by the applicant, such as production sites, equipment facilities, personnel management, management systems, equipment layout and technological process, as well as production and business sites (referred to production license examination) in accordance with the provisions of ***Administrative Permission Law of the People's Republic of China*** [28]. Article 8 of ***Measures for the Management of Food Production Licenses*** [30] stipulates that the State Food Safety Supervision and Administration Department should be responsible for formulating general rules for the examination of food production licenses and detailed rules for the examination of production licenses of various types of foods, which could be used to guide the food safety supervision departments at all levels in the implementation of the supervision of food production licenses. On January 29, 2019, the first ***Rules for the Examination of Licenses for producing FSMP*** [29] is issued by the State Administration of Market Supervision and Administration (SAMR) in China.

On December 21, 2010, the former Ministry of Health of the People's Republic of China (MOH) issued the first ***National Food Safety Standards of Infant Formula Products for Special Medical Purpose*** (GB 25596-2010) [21]. On December 26, 2013, the former National Health and Family Planning Commission (NHFPC) issued the ***National Food Safety Standards of General Rules of FSMP*** (GB 29922-2013) suitable for the population with the age of over one year old, and the ***National Food Safety Standards of Good Manufacturing Practice for FSMP*** (GB 29923-2013) [23] concerning the requirements of production and management of FSMP. Nowadays, China has basically established a standard system for FSMP. According to the provisions of the above national food safety standards, FSMP are the formulated foods specially processed and prepared to meet the special demands of nutrients or diets for persons with limited food intake, digestive and absorption disorders, metabolic disorders or specific diseases, including powders or liquid formula foods designed for infants (from the age of 10–12 months) with special medical conditions such as special disorders or diseases. Such products must be consumed alone or in combination with other foods under the guidance of a doctor or clinical dietitian [21–23].

Food Safety Law of the People's Republic of China [27] (***Food Safety Law***) newly revised in 2015 clarifies the concept of "special foods" for the first time from the legal level, and healthy foods, FMSP and infant formula foods are included the category of "special foods", with the requirement of strict supervision and management. Strict supervision and management measures for FSMP mainly include product registration, production and business licenses, good production management system establishment, and advertisements that should comply with the ***Advertisement Law of the People's Republic of China*** [31] and other laws and administrative regulations on drug advertising management.

In order to implement the requirements of the ***Food Safety Law*** [27], standardize the production license of FSMP, and avoid the situation without technical specifications in the examination of the production licenses for FSMP, the former China Food and Drug Administration (CFDA) has organized relevant technical institutions and experts to work out the first ***Rules for the Examination of licensing criteria for Producing FSMP*** in China [29], which is used as a normative technical document to guide local food safety supervision and administration departments to implement production licenses of FSMP, in accordance with its departmental regulations, ***Measures for the Management of Food Production Licenses*** [30], and supporting normative technical documents, ***General Principles for the Examination of Food Production Licenses*** [32].

3. Formulating principle

Measures for the Management of Food Production Licenses [30], ***General Principles for the Examination of Food Production Licenses*** and the rules for examining various kinds of food production licenses are the important technical guarantee for standardizing the implementation of food production licenses. The current ***Measures for the Management of Food Production Licenses*** and ***General Principles for the Examination of Food Production Licenses*** [30,32] are formulated by CFDA. ***General Principles for the Examination of Food Production Licenses*** is normative technical document to support ***Measures for the Management of Food Production Licenses*** (Regulations). ***Rules for Examination of Licensing Criteria for Producing FSMP***, which is compatible with ***Rules for Examination of Licensing Criteria for Producing FSMP*** is a normative technical document and specially used for the examination of the production license of FSMP [29,30,32]. On January 26, 2017, the Detailed ***Rules for Examination of Licensing Criteria for Producing FSMP (draft for comments)*** are published by former CFDA on its official website for soliciting the public opinions for the first time. The draft is divided into 14 chapters and 115 articles. It puts forward technical and normative requirements for many aspects, such as the basic requirements of food safety management, personnel, plant and workshop, equipment, raw materials (including food additives, packaging materials), production management, quality control and quality assurance, confirmation and verification, documents and records, information management, product traceability and recalling, product research and development [29].

In accordance with the requirements of the institutional reform of the State Council, the State Administration of Market Supervision and Administration (SAMR), established in April 2018, is responsible for the supervision and management of food safety. And then, ***Rules for Examination of Licensing Criteria for Producing FSMP (draft for comments)*** are drafted again. During the drafting process, a large number of enterprise survey, experts and industrial demonstration are carried out, and three formulation principles are emphasized in particular:

3.1. It should be consistent with the legal status of FSMP

The ***Food Safety Law*** offers the legal status of FSMP as "special foods", which belongs to the strict supervision and management category [27]. Therefore, in addition to satisfying the basic production licensing conditions of common foods, ***Rules for Examination of Licensing Criteria for Producing FSMP*** refers to ***Rules for Examination of Licensing Criteria for Producing Formula Milk for Infants and Young Children (2013 Edition)*** known as "the most stringent rules in history" for "special foods" [29,33], which provides sticker, more standardized, and more detailed production licensing conditions for FSMP, including on-site quality auditing of major suppliers, unique identification of raw materials before entering the factory, sampling inspection before use, microbial monitoring of production environment and disposal of positive results, food safety risk assessment of collinear products, and periodic verification of production conditions.

3.2. It should be mutually recognized with the technical requirements for the registration of FSMP products

The registration of FSMP products is stipulated in the ***Food Safety Law***. Obtaining the product registration certificate is a necessary precondition for domestic enterprises to apply for the production license for FSMP [27]. ***Provision of FSMP registration*** and the related technical specifications and documents stipulate that the applicant for the registration of FSMP should be a production enterprise with corresponding research and development capability, production capacity and inspection capability, equipped with food safety management personnel and food professionals and technicians to implement good production standards and food safety management system for FSMP [26]. These requirements overlap with production sites, equipment and facilities, equipment layout, technological process, personnel management and management system involved in the ***Rules for Examination of Licensing Criteria for Producing FSMP*** [29]. In order to avoid inconsistent technical requirements between product registration and production licenses, the ***Rules for Examination of Licensing Criteria for Producing FSMP*** quote or require applicants to comply with relevant technical requirements for product registration in several articles [29]. In addition, because the products with special medical uses must pass sampling inspection at the time of registration, the ***Rules for Examination of Licensing Criteria for Producing FSMP*** [29] stipulate that the qualified report of the trial-produced products should not be repeated during the on-site verification of the production license, thus exempting the necessary content of the on-site verification of the production license of common foods.

3.3. It has the same requirement as the ***National Food Safety Standards of General rule of FSMP*** *(GB 29923-2013)*

GB 29923-2013 is a national food safety standard, which is legally mandatory. Enterprises producing formula foods for special medical purposes should comply with the mandatory requirements of GB 29923-2013 associated with production site selection, factory environment, plant and workshop, internal structure and materials of buildings, facilities, equipment, hygiene management, raw materials and packaging materials, food safety control in production process, verification, inspection, storage and transportation of products, product traceability and recalling, training, management system and personnel, record and document management in the production process [24]. During the process of drafting and formulating the ***Rules for Examination of Licensing Criteria for Producing FSMP***, the compulsory requirements of GB 29923-2013 are classified and adjusted to the requirements of the production places, equipment facilities, personnel and management system, equipment layout, technological process required by the ***Food Safety Law*** [27], so as to ensure that the ***Rules for Examination of Licensing Criteria for Producing FSMP*** and the relevant requirements of GB 29923-2013 are same and consistent.

On November 7, 2018, the State Administration of Marketing Supervision and Administration (SAMR) released the ***Rules for Examination of Licensing Criteria for Producing FSMP (draft for comments)*** on its official website for the second time to solicit public opinions. Compared with the first draft, the second draft has made great changes in style, structure and contents, which is consistent with the requirements of Article 35 of the ***Food Safety Law*** [27] and the ***Measures for the Management of Food Production Licenses*** [30] and ***General Principles for the Examination of Food Production Licenses*** [32]. The second draft is divided into 8 chapters and 43 articles. Technical and normative requirements are put forward for the production and management of FSMP in terms of production sites, equipment facilities, equipment layout, technological process, personnel management and management system.

After soliciting public opinions, the State Administration of Marketing Supervision and Administration (SAMR) revised the ***Rules for Examination of Licensing Criteria for Producing FSMP (draft for comments)***. On January 29, 2019, SAMR issued its announcement No. 5 in 2019 on its official website that the ***Rules for Examination of Licensing Criteria for Producing FSMP*** are officially promulgated and implemented.

4. Main contents

The ***Rules for Examination of Licensing Criteria for Producing FSMP*** (***Examination Rules***) are formulated in accordance with the requirements of the ***Measures for the management of food production licenses*** and ***General Principles for the Examination of Food Production Licenses*** [29,30,32], and in combination with ***National Food Safety Standards of Good Manufacturing Practice for FSMP*** (GB 29923-2013***)***, which is divided into seven chapters, including general rules, production sites, equipment facilities, equipment layout, technological process, personnel management, management system and supplementary rules, with a total of 42 articles. In addition to the general rules and supplementary rules, the remaining five chapters correspond to the contents of the ***On-site Verification of the Score Record Table for the Production License of Food and Food Additives*** in the ***General Principles for the Examination of Food Production Licenses*** [32], thus laying a technical foundation for standardizing the examination of the production license of FSMP.

4.1. General provisions

Chapter I "***General Provisions***" mainly stipulates the scope of application of the "***Examination Rules***", the categories of application, the applicability of documents and standards cited, and prohibited packaging of FSMP.

4.1.1. The scope of application

In accordance with the contents of ***the Provision of foods for FSMP registration***, "***Examination Rules***" incorporate the definitions of FSMP in GB 25596-2010 and GB 29922-2013. The scope of FSMP application is described as "formula foods specially prepared to meet the special needs of persons with limited food intake, digestive and absorption disorders, metabolic disorders or specific diseases for nutrients or diets, including FSMP for infants with the age of 10–12 months and for children with the age of over 1 year old".

4.1.2. Categories of application

Article 11 of the ***Measures for the Management of Food Production Licenses*** [30] stipulates that the categories of foods for food production licenses include food processed products, edible oil, oil and its products, condiments, meat products, dairy products, beverages, instant foods, biscuits, canned products, frozen drinks, frozen foods, potatoes and puffed foods, candy products, tea and related products, wine, vegetables, fruit products, scrambled foods, nuts products, egg products, cocoa and roasted coffee products, sugar, aquatic products, starch and starch products, cakes, bean products, bee products, health foods, special medical use formula foods, infant formula foods, special dietary foods, other foods. FSMP is the 28th category of foods [30]. Article 28 of the ***Measures for the Management of Food Production Licenses*** [30] stipulates that the contents of a food production license include the categories of food licensed and the specific details of foods. In accordance with the ***Measures for the Management of Food Production Licenses***

Table 1
List of FSMPs categories under production licensing.

Food category	Category number	Category name	Variety detail	Remarks
Formulas for special medical purposes (FSMPs)	2801	Formulas for special medical purposes (FSMPs) (excluding formulas for special medical purposes intended for infants)	Nutritionally complete formulas Specific nutritionally complete formulas: including nutritionally complete formulas for diabetes, nutritionally complete formulas for respiratory diseases, nutritionally complete formulas for kidney disease, nutritionally complete formulas for tumor, nutritionally complete formulas for liver disease, nutritionally complete formulas for sarcopenia, nutritionally complete formulas for trauma, infection, surgery and other stress state, nutritionally complete formulas for inflammatory bowel disease, nutritionally complete formulas for food protein allergy, nutritionally complete formulas for intractable epilepsy, nutritionally complete formulas for gastrointestinal absorption disorder and pancreatitis, nutritionally complete formulas for fatty acid metabolic disturbance, and nutritionally complete formulas for obesity and fat reduction surgery, etc. Non-nutritionally complete formulas: including nutrient components, electrolyte formulas, thickening components, fluid formulas, and formulas for amino acid metabolism disorders, etc.	Product registration number
	2802	Formulas for special medical purposes intended for infants	Lactose-free formula Low lactose formula Partially hydrolyzed milk protein formula Extensively hydrolyzed milk protein formula Amino acid-based formula Premature/low-birth-weight infants formula Breast milk nutritional supplement Formula for amino acid metabolism disorder	Product registration number

[30] and the requirements of GB 25596-2010 and GB 29922-2013, the ***Examination Rules*** stipulate that the category number of production license for FSMP (excluding infant FSMP) is 2801, and the detailed list of food varieties includes three categories and 19 sub-categories; and the category number of production license for special medical use infant formula food is 2802.There are 8 kinds of foods in detail. Specific contents refer to Table 1 (Table 1 in this paper) of the ***Examination Rules***, "***Catalogue of Licensing Categories for the Production of FSMP***".

4.1.3. Partial packaging is prohibited

In order to standardize the production activity of special medical formula foods, unify production licensing conditions, reduce disorderly competition, and prevent food safety risks such as repackaging and selling of nearly expired or expired products, the ***Examination Rules*** explicitly prohibit the repackaging of FSMP, in accordance with the requirements of the ***Food Safety Law*** for strict supervision and management of special foods [27], and stipulate that production license should not be granted if the applicant only has the site (production site), process (technological process), equipment (facilities) for product packaging, and does not have complete production and processing conditions such as raw material processing, weighing and proportioning, processing and packaging (filling).

4.2. Production sites

Chapter II "***Production Sites***" stipulates the special technical requirements for the production sites of FSMP. Paragraph 1 (1) of Article 33 of the ***Food Safety Law*** stipulates that food producers should have places for the processing of foods and raw materials, packaging and storage of foods suitable for the variety and quantity of foods during production [27]. The production sites should be clean and tidy, and kept the prescribed distance from toxic, harmful places and other pollution sources. In accordance with the provisions of the law, the ***Examination Rules*** put forward corresponding technical requirements for production sites. It mainly includes:

4.2.1. Production workshops

According to the characteristics of the existing special medical formula food production, the production workshops stipulated in the ***Examination Rules*** usually include the workshops of raw materials and accessory pretreatments such as weighing and proportioning, heat treatment, sterilization, drying, mixing (premix) and packaging (filling) [29]. In order to conform to the technical requirements for registration of FSMP, the ***Examination Rules*** also stipulate that enterprises may adjust the types of production workshops according to the actual production process requirements for the approved and registered products [29]

4.2.2. Division of production areas

According to GB 29923-2013, production areas should be divided in accordance with the requirements of production technology and prevention of cross-contamination. Therefore, the production areas of FSMP should be divided into general operation zones, quasi-clean operation zones and clean operation zones. Effective physical isolation should be set up between working areas of different cleanliness levels and between wet and dry areas. Different from the general principle of dividing food production operation areas, the ***Examination Rules*** divides the raw material weighing and batching operation areas of liquid products into clean operation areas according to the provisions of

Table 2
Division of the production workshop and the work areas of FSMPs.

Serial number	Product type	Cleaning work area	Quasi-cleaning work area	Commonly work area
1	Liquid product	The workshop where the procedure coming into contact with the air environment is located (such as weighing, batching and filling, etc.); the area with special cleaning requirements (such as the temporary storage room for the cleaned and disinfected inner packaging materials).	Processing workshops for raw material pretreatment, heat treatment, sterilization, cleaning of inner packaging of raw materials, disinfection of packaging materials, and can (tin) unscrambling, etc.	Workshops for cleaning of outer packaging of raw materials, outer packaging, and milk collection (where the raw milk is used as raw materials) and warehouses for raw materials, packaging materials, and finished products, etc.
2	Solid (including powder) products	Workshops for storage, filling and inner packaging of bare semi-finished products to be packaged of solid (including powder) products; workshops for weighing, batching, feeding, pre-mixing and mixing, etc. of dry-mix process.	Processing workshops for raw material pretreatment, wet-mix process (such as weighing and batching, concentration and drying), cleaning of inner packaging of raw materials or tunnel sterilization, disinfection of packaging materials, and can (tin) unscrambling, etc.	Workshops for cleaning of outer packaging of raw materials, outer packaging, and milk collection (where the raw milk is used as raw materials) and warehouses for raw materials, packaging materials, and finished products, etc.

Table 3
Requirements for control of air cleanliness in cleaning work areas and quasi-cleaning work areas of solid product.

Items		Requirements		Test methods
Quasi-cleaning work area	Cleaning work area			
Dust count/m^3	≥0.5 μm	–	≤7,000,000	It shall be determined according to GB/T 16292, and the determination status is static.
≥5 μm	–	≤60,000		
Ventilation rate[a] (hourly)		–	10–15	–
Total bacterial count (CFU / dish)		≤30	≤15	It shall be determined according to the natural sedimentation method in GB/T 18204.1.

[a] Ventilation rate is applicable to the cleaning work area with a floor height of less than 4.0 m.

Table 4
Requirements for control of air cleanliness in cleaning work areas of liquid product.

Items		Requirements	Test methods
Cleaning work area			
Dust count/m^3	≥0.5 μm	≤3,500,000	It shall be determined according to GB/T 16292, and the determination status is static.
≥5 μm	≤20,000		
Ventilation rate[a] (hourly)		10–15	–
Total bacterial count (CFU / dish)		≤10	It shall be determined according to the natural sedimentation method in GB/T 18204.1.

[a] Ventilation rate is applicable to the cleaning work area with a floor height of less than 4.0 m.

Article 2.2 of GB 29923-2013, which improves the requirements of cleanliness control in relevant areas. Specific contents refer to Table 2 (Table 2 in this paper) of the Detailed Rules [29], "***Table for the Division of Workshops and Operation Areas for FSMP***". In addition, in order to conform to the actual production and meet the demands of different production processes, on the premise of ensuring food safety, the ***Examination Rules*** reduce the cleanliness requirements of the production area of sterilization process for liquid products after filling and sealing, and stipulate that the sterilization process for such liquid products after filling and sealing can be carried out in the general operation areas.

4.2.3. Control requirements for clean and quasi-clean operation areas

Clean operation areas and quasi-clean operation areas involved in the production process of FSMP are the key production areas to ensure food safety. Tables 1 and 2 (Tables 3 and 4 in this paper) of GB 29923-2013 (Tables 3 and 4 in the paper)indicate the control requirements for air cleanliness in clean operation areas and quasi-clean operation areas for producing solid and liquid products, including dust number, air exchange times, total bacterial counts, and so on. In order to meet the requirements of air cleanliness control, the ***Examination Rules*** [29] stipulate that an independent air purification system and an air conditioning facility with a filter should be installed in the clean operation areas to maintain a positive pressure (≧10 Pa). Ambient temperature and air humidity of clean operation areas for producing powdery products should be controlled. The temperature should not be higher than 25 °C, and the relative humidity should be less than 65%.

4.2.4. Other requirements

The structure, conditions and management of production workshops and warehouses should meet the corresponding requirements of the ***General Principles for the Examination of***

Food Production Licenses [32]. Appropriate measures of dust removal or collection should take in dust-producing workshops to prevent dust diffusion and avoid cross-contamination.

4.3. Equipment and facilities

Chapter III "***Equipment and Facilities***" specifies the equipment and facilities commonly required for the production of FSMP. Article 33, paragraph 1 (2) of the ***Food Safety Law*** [27] stipulates that food producers should have production equipment or facilities that are appropriate to the variety and quantity of foods during production, and suitable for disinfection, changing clothes, washing, lighting, ventilation, anti-corrosion, dust-proof, fly-proof, rat-proof, insect-proof, wastewater treatment, and garbage and waste storage. In accordance with the law and the ***General Principles for the Examination of Food Production Licenses*** [32], the ***Examination Rules*** put forward corresponding technical requirements for equipment and facilities. It mainly includes:

4.3.1. Equipment requirements

Different from infant formula milk powder, many kinds of products and production processes of FSMP are involved so that all of them can not be fully and comprehensively described in the ***Examination Rules***. In order to avoid dogma, rigidity, and divorce from production practice and restrict technological innovation, the ***Examination Rules*** put forward the principled requirements of equipment that enterprises should have production equipment suitable for the variety and quantity of products during production, and the performance and accuracy of equipment should meet the requirements of production and processing.

4.3.2. Facilities requirements

According to GB 29923-2013, the production facilities of FSMP include water supply and drainage, cleaning and disinfection, waste storage, personal hygiene, ventilation, lighting, temperature monitoring and control. Enterprises with self-inspection capacity should also have corresponding inspection equipment and reagents. In order to prevent cross-contamination in the production characteristics of FSMP in various production facilities, the ***Examination Rules*** specifically emphasize the technical requirements for personal hygiene facilities: a secondary dressing room should be provided at the entrance to the clean operation area, equipped with a blocking shoe cabinet, a storage cabinet of work clothes for clean operation area, and a disinfection facility. The air cleanliness of the room for the storage of working clothes in clean operation areas should meet the requirements of the clean operation areas. Working clothes in clean operation areas should be one-piece or one-time overalls with a hat (or hood), a mask and working shoes (or shoe covers). In addition, the ***Examination Rules*** also stipulate the basic purification process before entering the production area [29]. In order to adapt to the actual production situation of different enterprises, the ***Examination Rules*** do not set the personnel purification process as a unified mandatory requirement. For special cases, it is stipulated that other personnel purification processes can be adopted, but the purification effect should be verified to ensure the compliance with personnel purification requirements.

4.4. Equipment layout and technological process

Chapter IV "***Equipment Layout and Technological Process***" stipulates the equipment layout and production process requirements for the production of FSMP. Article 33, paragraph 1 (4), of the ***Food Safety Law*** [27] stipulates that food producers should have reasonable equipment layout and technological process to prevent cross-contamination between processed foods and directly imported foods, raw materials and final products, and to avoid the contact of the foods with toxic substances and impurities. In accordance with the law, the ***Examination Rules*** put forward corresponding technical requirements for equipment layout and technological process. It mainly includes:

4.4.1. Equipment layout

Production equipment should be arranged orderly and rationally according to the technological process so as to facilitate cleaning, disinfection and maintenance, and avoid cross-contamination.

4.4.2. Technological process

The technological process should be consistent with the technical requirements such as approved product formulation and production processes. Enterprises should formulate process documents such as batching, weighing, heat treatment, intermediate product storage, sterilization (commercial sterility), drying (powder products), cooling, mixing, and internal packaging (filling) in accordance with the technical requirements of approved and registered products and the requirements of GB 29923-2013 for specific processing of products.

4.5. Personnel management

Chapter V "***Personnel Management***" stipulates the personnel management requirements of special medical formula food production enterprises. Article 33, paragraph 1 (3), of the ***Food Safety Law*** [27] stipulates that food producers should have full-time or part-time food safety professional technicians and management personnel. According to the provisions of the law, the ***Examination Rules*** put forward corresponding technical requirements for personnel management. It mainly includes:

4.5.1. Food safety administration

FSMP manufacturers should establish independent food safety management agencies responsible for establishing, implementing and continuously improving the production quality management system in accordance with the requirements of GB 29923-2013.

4.5.2. Personnel qualification

The person in charge of the FSMP production enterprise is fully responsible for the food safety of the enterprise. The person in charge of the food safety management organization, the production management department, food safety management, and food safety technology should have the professional qualification of foods, medicine, nutrition or related special products, or have certain working experience and production management experience in food and drug production, and be on duty after training and examination. Inspectors and full-time personnel for research and development should also have corresponding professional, educational background and/or working experience. Production operators should master operation rules and skillfully operate production equipment and facilities. According to the requirement of the State Council to cancel the non-essential professional qualification and the current situation of recruitment and use of personnels in FSMP production enterprises in China, the ***Examination Rules*** have adopted the method of exchanging professional experience for professional and academic qualification, and appropriately relaxed the requirements for personnel qualification. It can not only examine the qualification of practitioners with professional and academic qualification, but also evaluate their occupational

capability from working experience, working years and practical working experience.

4.5.3. Personnel training and health management

The ***Examination Rules*** follow the requirements of the ***General Principles for the Examination of Food Production Licenses*** [32] concerning personnel training and the establishment of personnel health management system. In addition, the requirement of personnel training should be carried out in time when related laws, regulations and standards of food safety are updated.

4.6. Management system

Chapter 6 "**Management System**" stipulates the management system (except personnel health management system) that should be established by production enterprises of FSMP. Food safety management system is an important basis for enterprises to regulate production activities and ensure food safety. Article 33, paragraph 1 (3), of the ***Food Safety Law*** [27] stipulates that food producers should have rules and regulations to ensure food safety. In accordance with the provisions of the law, the ***Examination Rules*** specially refine and supplement the incoming inspection records, production process control, ex-factory inspection records, unsafe food recalling, food safety self-inspection, food safety accident disposal and other systems that enterprises should establish under the ***General Principles for the Examination of Food Production Licenses*** [32]. It mainly includes:

4.6.1. Control requirements of raw materials

The control requirements of raw materials are an integral part of the production process control system. In view of the requirements of raw material management for FSMP, the ***Examination Rules*** stipulate that enterprises should establish management systems for raw material supplier audit, procurement acceptance, storage, material control and production water control. In particular, the following requirements [29]:

(1) It should clearly stipulate that the quality management system of major nutrient suppliers such as protein, fat, carbohydrate, vitamins and minerals should be audited on site.
(2) The acceptance of qualified raw materials should be unique and correspond to the information of incoming inspection (or inspection) to ensure the effective traceability.
(3) For raw materials with long-time storage and potential changes in quality and safety status, the quality and safety status should be confirmed by regular or pre-use sampling.
(4) Water for production, equipment cleaning, ice making and steam preparation in direct contact with foods should meet the requirements of the ***Hygienic Standard for Drinking Water*** (GB 5749)[34]. The ***Examination Rules*** do not stipulate that purified water must be used in production.

4.6.2. Control requirements for key steps during production

According to the requirements of GB 29923-2013 for controlling biological, chemical and physical pollution in the production process, detailed regulations on process parameters (temperature, time) and workshop environmental conditions (air cleanliness, humidity), microbial monitoring plan, sanitary control of personnel and raw materials, weighing ingredients, product protection and packaging, collinear production, clearance, cleaning and disinfection, equipment management are stipulated in the ***Examination Rules*** [29]. In particular, the following requirements:

(1) The time from filling to sterilization of liquid products that need sterilization after filling should be controlled within the time limit required by the process regulations.
(2) Environmental monitoring plans for *Salmonella*, *Enterobacter sakazakii* and other *Enterobacteria* in the environment of clean working areas should be formulated for the production of powder formula foods with special medical use. When positive monitoring results are found, timely assessment and proper disposal should be made to ensure that released products meet the requirements of food safety standards.
(3) The weighing and batching process should ensure that the type and quantity of materials are consistent with the prescription registered in the product, and should be checked and recorded independently by others. For the automatic control of checking with computer information system, manual checking may not be used, but computer information system should be designed to prevent errors and checked regularly. This regulation is more applicable to advanced automation production lines, which is conducive to improving production efficiency and preventing and controlling human errors.
(4) Material balance control requirements should be established. When abnormal material balance is found, the reasons should be figured out and measures should be taken to prevent food safety risks.
(5) Packaging materials should not be reused under normal conditions, but should be reused under special circumstances (such as glass bottles, stainless steel containers, etc.) in accordance with the relevant requirements of the approved and registered products, and thoroughly cleaned and disinfected before use.
(6) When different varieties of products are produced on the same production line, they should be adequately analyzed for food safety risks. Effective cleaning measures should be formulated and validated to ensure that product switching does not affect the next batch of products, and should meet the corresponding requirements of the approved and registered products.

4.6.3. Inspection management system

Inspection management is also an important part of production process control. Enterprises should establish relevant management requirements for raw material inspection, semi-final product inspection and final product inspection. The ***Examination Rules*** highlight the following elements:

(1) It should be inspected the items that are required by national standards for batch inspection of milk-containing raw materials and items containing restricted ingredients (such as melamine).
(2) Enterprises may set up inspection and management systems to monitor the quality and safety of semi-final products according to the requirements of production process control.
(3) Enterprises should carry out batch-by-batch inspection of final products in accordance with the national food safety standards and technical requirements of the approved and registered products. For the production of infant FSMP, the final products should be self-inspected in batches and whole items before leaving from the factory. For the production of other FSMP, qualified third-party inspection institutions may be entrusted to carry out factory inspection of final products, and inspection equipment and facilities required for inspection items may not be equipped.

4.6.4. Other management systems

According to the regulations of GB 29923-2013, the ***Examination Rules*** specially refine and supplement other management systems of the enterprises required by the ***General Principles for the Examination of Food Production Licenses*** [32]. It mainly includes:

(1) Production verification scheme should be established. Installation, operation, performance, production process and quality control methods of the plant and equipment facilities are regularly or irregularly confirmed and verified.
(2) Pest control system should be established. The situation of pest control should be inspected regularly, and the sources of pests should be traced once found, so as to eliminate the hidden danger.
(3) Management system for detergents, disinfectants and other chemicals should be established. The disposition, use, storage and labeling of detergents and disinfectants should be controlled to prevent chemical pollution.
(4) Product retention system should be established. The products from each batch should be sampled and kept, and the quantity of samples should meet the re-inspection requirements.
(5) Document or record management system should be established to ensure the effective issuance, use and preservation of documents and records.
(6) Product traceability system should be established because there is no clear stipulation about the product batch number in the current food safety standard system. In order to ensure food safety and facilitate product traceability, the ***Examination Rules*** [29] stipulate that enterprises should determine the principle of product batching and the method of batch number preparation, rationally execute product batching, use product batch number or other methods for production identification, establish a record system for all links from raw material procurement, production processing, factory inspection before product selling, and ensure effective traceability of products according to the basic principle that the main responsibility of food safety is attributed to food production enterprises.

4.7. Supplementary provisions

Chapter VII "***Supplementary Provisions***" stipulates other requirements such as the use, interpretation and implementation time of the ***Examination Rules***. In accordance with the requirements of the State Council for "simplification and decentralization of government, combination of decentralization and regulation, and optimizing services", as for the issue of ***General Principles for the Examination of Food Production Licenses*** [32] requiring the verification of the qualified inspection reports of trial products, the ***Examination Rules*** adopt the concept of "one thing without two checks", approve the inspection qualified report at the time of product registration, and stipulate that the applicant should no longer be required to provide the test qualified report at the time of on-site verification of production license.

5. Conclusion

National Nutrition Plan in China (2017–2030) points out that nutrition is an important material basis for human life, growth, development and health, which is also correlated with the improvement of life quality of people from whole country and the development of economy and society. With the improvement of the living standard of the people in China, people have an urgent need for nutrition and health. FSMP plays a very important role in satisfying patients' nutritional support, improving patients' survival rate, alleviating the shortage of medical resources and saving national medical expenditure. In addition, the development of FSMP enterprises is important for the development of FSMP industry. Under this situation, the formulation of the rules for the examination of FSMP licenses is significant. Therefore, in this study, the background, principles and main contents of the ***Rules for Examination of Licensing Criteria for Producing FSMP*** are discussed, and the key points for the examination are elucidated from many aspects. Its content is of great significance to the development of traditional medicine food enterprises and even industries in China.

Acknowledgement

The authors acknowledge the support from "National Key R&D Program of China" (Project No. 2018YFC1603400).

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