

Comunicado CFDA 49/2013

(16/12/2013)

**Detailed Rules for Infant & Growing up Formula Milk
Powder Production Approval and Examination
(Version 2013)**

I. Application Scope

These Detailed Rules shall apply to the examination of the production conditions of an enterprise and the inspection on the products it is permitted to produce when it applies for the processing and production of infant formula milk powder (0-6 months, stage 1), follow on formula milk powder (6-12 months, stage 2) and growing up formula milk powder (12-36 months, stage 3) for infant & growing-ups (0-36 months) using cow milk or goat milk and their processed products (whey powder, whey protein powder, skim milk powder, whole milk powder, etc.) and vegetable oil as main ingredients, with appropriate amount of vitamins, minerals and other minor ingredients in accordance with the conditions specified by laws, regulations and standards.

There is 1 application unit for infant & growing up formula milk powder, and its category number is 0502. Infant & growing up formula milk powder (made through wet processing, dry processing or dry-wet processing) shall be given clear indication of in the product name of the production permit. The attached sheet of the production permit shall give clear indication of the

specific varieties of infant formula milk powder, follow on formula milk powder and growing up formula milk powder productions of which has been permitted.

No production permit shall be granted to an enterprise without complete production technological conditions which only has packing space, production processes and facilities. No production permit shall be granted to an enterprise which only produces infant & growing up formula milk base powder and does not produce finished products of infant & growing up formula milk powder. Where an enterprise is engaged in production through dry-wet processing, the dry mixing of base powder produced through wet processing and additive ingredients shall be completed within the same plant. As of the date on which these Detailed Rules are promulgated, application for production permit submitted by any newly established enterprise to produce infant & growing up formula milk powder through dry-wet processing using base powder in a place other than its plant shall not be accepted.

During a certain period of transition, if a plant producing base powder through wet processing and a plant producing infant & growing up formula milk powder through dry-wet processing using additive ingredients of the same group company are not located in the same region, they shall be subject to examination according to dry-wet processing technique.

For the purpose of these Rules, base powder refers to the semi-finished product of infant & growing up formula milk powder produced through wet processing using cow milk or goat milk and their processed products (whey

powder, whey protein powder, skim milk powder, whole milk powder, etc.) as main ingredients with some additive (or without) nutrient and other minor ingredients.

The documents and standards cited in these Detailed Rules shall become contents of these Detailed Rules through citation. The latest versions of all cited documents and standards (including all modification lists) shall be applicable to these Detailed Rules.

II. Examination on the Conditions for Production Permit

(i) Examination on the Management System

The establishment of food quality and safety management systems by enterprises shall be examined in accordance with the provisions of the *Food Safety Law of the People's Republic of China* and the regulations for its implementation, the *Regulations on the Supervision and Administration of the Quality and Safety of Dairy Products*, the *Circular of the General Office of the State Council on Further Strengthening the Work on the Quality and Safety of Dairy Products* (GBF [2010] NO. 42), the *Circular of the General Office of the State Council on Forwarding the Opinions of China Food and Drug Administration and Other Departments on Further Strengthening the Work on the Quality and Safety of Infant & Growing up Formula Milk Powder* (GBF [2013] NO. 57) and other relevant laws and regulations and the General Rules on the Examination for Food Production Permit. The main examination contents shall be as follows:

1. The Food Quality and Safety Management System

(1) An infant & growing up formula milk powder production enterprise shall strictly implement the Hazard Analysis and Critical Control Points (HACCP) system, the Good Manufacturing Practice (GMP) of infant & growing up formula powdered foods and other national standards, and shall establish and operate a quality management system in accordance with the requirements national standards. (2) An independent food quality and safety management organization shall be established, and full-time infant& growing up formula milk powder quality and safety management staffs shall be appointed to be responsible for the establishment, implementation and continued improvement of the food quality and safety management system. (3) The legal representative of the enterprise shall be the person responsible for the quality and safety of infant & growing up formula milk powder. A system of food quality and safety authorized person shall be established and implemented. The legal representative of the enterprise shall be responsible for food quality and safety or authorize food quality and safety management staff of the enterprise to be responsible for food quality and safety. The food quality and safety management staff shall, in the form of a document, be authorized to be responsible for the quality and safety of infant & growing up formula milk powder and the production and factory release of infant & growing up formula milk powder.

2. The Main Ingredient Management System

(1) Where the main ingredient is raw cow milk, the raw cow milk shall entirely come from the milk source base established and controlled by an

enterprise itself. In the future, raw cow milk shall gradually be produced in the farms wholly owned or controlled by the enterprise. In accordance with relevant State provisions, an examination and recording system shall be established for every batch of raw milk purchased. Each batch of raw milk shall be attached with an inspection report which indicates that it complies with the requirements of the *National Food Safety Standard-Raw Milk* (GB19301) on quality and safety. The certification and invoice examination system shall be strictly implemented and records shall be kept. The various quality and safety indicators of raw milk shall comply with the provisions of relevant national food safety standards. Where the main ingredients constitute whole milk powder or skim milk powder, the enterprise shall adopt strict control measures on the quality of the ingredients. A system of ingredient supplier examination system shall be established. The ingredient suppliers shall be relatively constant and shall receive regular examination and assessment. Inspection shall be conducted on every batch of whole milk powder and skim milk powder purchased to ensure that they meet the requirements of the *National Food Safety Standard-Milk Powder* (GB 19644) on quality and safety. (2) Inspection shall be conducted on every batch of whey powder and whey protein powder to ensure that they meet the provisions of relevant national food safety standards. Whey powder with ash content $\leq 1.5\%$ or whey protein powder with ash content $\leq 5.5\%$ shall be used to produce infant formula milk powder for infants of 0-6 months. (3) Edible vegetable oil shall comply with the provisions of relevant national standards,

and the varieties of edible vegetable oil used shall be specified. Hydrogenated oil and fat shall not be used. (4) Incoming examination shall be conducted on vitamins, microelements and other nutrition enhancers and food additives to ensure the quality and safety of products. (5) Packaging materials shall be clean, non-toxic and comply with relevant State provisions. The safety and product features of infant & growing up formula milk powder shall not be affected under specific storage and usage conditions. Packaging materials shall not be reused. (6) The quality of domestic water shall comply with sanitary standards for drinking water. (7) The ingredients and minor ingredients and packaging labels used to produce infant & growing up formula milk powder shall be put on records in accordance with provisions. (The main standards involved in the main ingredients and minor ingredients needed to produce infant & growing up formula milk powder and packaging are included in Annex 1)

3. The Ingredient and Minor Ingredient Purchase System

(1) The measures for examination of ingredient and minor ingredient suppliers, the provisions on the checking and acceptance of ingredients and minor ingredients, and the measures for the rejection, scrapping, and returning of unqualified ingredients and minor ingredients. (2) Quality and safety assessment shall be conducted when determining or changing suppliers of ingredients and minor ingredients, and the purchase may not be conducted until it is approved by the safety management organization. Quality agreements shall be signed with the suppliers of main ingredients and minor

ingredients purchased which shall specify the quality responsibilities of both parties. (3) Examination on the suppliers of ingredients and minor ingredients shall include at least the following: qualification documents of the suppliers, quality standards and inspection reports. Where on-site quality examination is conducted, the on-site quality examination report shall be also included. (4) On-site quality examination shall be conducted on the quality systems of the suppliers or producers of raw milk, whole (skim) milk powder, whey powder, whey protein powder, vegetable oil (fat powder), vitamins, microelements and other major ingredients and minor ingredients by the quality and safety management organization. (5) The purchase verification system shall include such contents as the handling suggestions on the verification, inspection, recording, reporting, acceptance or rejection of the ingredients and minor ingredients purchased and the approval procedures. (6) The purchase system shall ensure that the ingredients and minor ingredients comply with the provisions of relevant national standards, local standards and enterprise standards on food safety. Products made from animal protein other than milk or dairy products (except for food additives the use of which is allowed) or other non-food ingredients shall not be used as production ingredients. (7) Where imported ingredients and minor ingredients are used, examination shall be conducted on the qualification documents of the supplier or trader of the imported ingredients and minor ingredients, the quality standards of each batch of ingredients, factory inspection data and reports and relevant documentary evidence produced by entry-exit inspection and quarantine

departments. (8) The purchase system shall, according to relevant provisions, conduct inspection on melamine and other elements for each batch of milk ingredients purchased.

4. The Technical Standard, Technological Document and Record Management System

(1) The texts of the national standards currently in effect relating to production and the texts of effective enterprise standards that have been put on records. (2) Technical standards, technological documents, machine accounts, production processes, critical control points and other management provisions. (3) The effectiveness of technological requirements, technological records and lists of ingredients shall be subject to irregular inspections. During the production process, monitoring and inspection shall be conducted on the critical quality control points of various working procedures throughout the production process. (4) The machine accounts set up by an enterprise and the important records for the production process shall include: incoming acceptance records, incoming machine accounts, environmental and location cleaning records, cleaning and disinfection records of production facilities, warehouse keeping records, production and feeding records, control records of critical control points, delivery inspection records, records of reserved samples of product inspection, handling records of unqualified products, handling records of unqualified ingredients, product sales records, recall records of unqualified products, handling records of returned products, health examination records of practitioners, study and training records,

acceptance records of consumer complaints, risk collection records, food safety accident handling records, usage records of inspection equipment, production suspension and resumption records, and product release records. Relevant records shall be kept for three years.

5. The Product Formula Management System

(1) The product formulas of infant & growing up formula milk powder shall ensure the safety of infants & growing-ups, meet their nutritional requirements, and shall not use substances that are hazardous to infant & growing-ups' nutrition and health. (2) An enterprise shall organize experts in production, nutrition and medical science to conduct comprehensive argumentation on the safety and nutrition of the formulas of infant & growing up formula milk powder products. (3) Complete formula designing and argumentation documents and other materials shall be kept. (4) The Product formulas of infant & growing up formula milk powder shall be put on records in accordance with provisions.

6. The Process Management System

(1) A controlling system preventing microbial contamination, chemical contamination and physical contamination shall be established in accordance with the *National food safety standard-Good manufacturing practice for powdered formulae for infants and young children* (GB 23790). (2) The quality inspection organization of an enterprise shall, on a weekly basis, adopt the monitoring guidance and assessment measures specified in the *National food safety standard-Good manufacturing practice for powdered formulae*

for infants and young children (GB 23790) Appendix A to ensure that the salmonella, enterobacter sakazakii and other enterobacters in the clean operation area for the production of infant formula milk powder may be brought under effective control. (3) The staff members entering the clean operation area shall conduct regular or irregular surface microbiological examination. (4) The outfits of staff members in the clean operation area shall be conjoined or one-off outfits with caps, respirators and footwares. The outfits of staff members in quasi-clean operation areas and general operation areas shall be outfits meeting requirements with caps and footwares. The outfits and footwares to be used in designated areas cannot be worn outside of designated areas. Before disinfection and changing outfits, production staffs shall not engage in the processing and production of infant & growing up formula milk powder. (5) All facilities, tools and equipment must be regularly rinsed and or disinfected; the facilities, tools and equipment coming into contact with wet supplies shall be rinsed before and after being used, and the facilities, tools and equipment coming into contact with dry supplies shall be subject to dry cleaning before and after being used (or be rinsed when necessary). (6) Packaging materials shall be handed out by specially-assigned persons in accordance with operating specifications, and measures shall be taken to avoid confusion and mistakes so as to ensure the accuracy of the packaging materials to be used in production. Before packaging operation, examination shall be conducted on the markings of packaging materials to be put into use to avoid misuse of packaging materials. The examination shall be

recorded, and the contents of the record shall include the corresponding product names, quantities, operators and dates of the packaging materials. (7) When production is interrupted due to facility failure, power cut, the cutting off of water supply or other special reasons, the handling measures of the products produced shall ensure that products falling short of standards will be handled as unqualified products.

7. The Inspection Management System

(1) Management systems shall be established for the inspection of ingredient and minor ingredient examination, process inspection and finished product inspection. There shall be provisions deciding whether ingredients, minor ingredients, semi-finished products and finished products are unqualified together with relevant handling measures. (2) When leaving factory, each batch of infant & growing up formula milk powder shall be subject to self-inspection over all items. Where a product passes the delivery inspection, the inspection report shall be kept and inspection notes shall be taken; a product failing to pass inspection shall not leave factory; the inspection report shall be kept for three years. Reserved samples shall be kept for products, and the quantity of reserved samples shall meet the requirements on re-inspection and shall be kept until expiry of the guarantee period. (3) The infant & growing up formula milk powder passing the inspection shall be attached with labels indicating the certificate numbers which may be traced back to relevant delivery inspection reports. (4) An enterprise shall, at least once a year, verify its ability to conduct inspection over all items on infant &

growing up formula milk powder.

8. The Product Protection Management System

(1) The system shall effectively prevent infant & growing up formula milk powder from contaminations, damages or deterioration during production and processing. (2) The system shall ensure that the unqualified ingredients and minor ingredients purchased, the risk factors discovered during processing and the unsafe food discovered through delivery inspection may be brought under effective control; it may, based on the actual situation of the ingredients and minor ingredients purchased, conduct necessary examination on all the ingredients and minor ingredients used for possible adulterated substances. (3) The system shall voluntarily collect the food safety risk monitoring and assessment information released by the State and take effective measures to prevent risks.

9. The System for the Storage and Distribution of Supplies

(1) The warehouse areas shall have enough space to ensure the orderly storage of ingredients, minor ingredients, packaging materials, finished products and other types of supplies and products that are waiting for inspection, qualified, unqualified, returned, or recalled. (2) The warehouse areas shall be designed and constructed to ensure good storage conditions and shall be equipped with ventilation and lighting facilities. The warehouse areas shall be able to offer the storage conditions (e.g. temperature, humidity, dark storage) of supplies or products, meet the requirements for safe storage and examination and monitoring shall be conducted. (3) The reception,

distribution and dispatching areas shall be able to protect supplies and products from the weather conditions outside (e.g. rain and snow). (4) The layout of the reception areas and the facilities in such areas shall be able to ensure necessary cleaning of the outer packages of supplies before they enter the warehouse areas. (5) All the storage locations of supplies shall have distinct markings indicating different types of areas, and only authorized personnel shall be allowed to have access to such locations. (6) The supplies or products that are unqualified, returned or recalled shall be kept in isolation. (7) The distribution and use of each batch of supplies shall ensure its traceability and the balance of supplies. (8) The usage plan of supplies shall be formulated in light of the principles of first-in first-out and first-expire first-out. (9) Only qualified supplied may be distributed. (10) There shall be traceable and clear distribution records which shall include the names, codes, batch numbers and other information such as packaging numbers of relevant supplies. The relevant distribution records shall be signed by both the distributors and the receivers upon verification for confirmation.

10. The Personnel Management System

(1) Induction training and assessment measures for technicians and operating personnel. (2) Corresponding production, quality and inspection technicians with designated post responsibilities shall be assigned to important workshop sections. (3) Plans of training on the quality and safety, processing technologies, quality management, laws and regulations and vocational ethics concerning dairy products shall be regularly implemented.

(4) Safety protection measures shall be taken for production and processing staffs, and guarantee shall be provided to transfer production and processing staffs coming into direct contact with ingredients and products from production and processing posts when they suffer from diseases that impede food safety as provided for by laws and regulations. (5) Training plans shall be formulated for laboratory staffs which shall cover areas of professional knowledge, professional skills and knowledge concerning biological and chemical safety, protection and first aid.

11. The Information Management, Product Tracing and Recall System

(1) An electronic information recording system shall be established at least for the information concerning the following critical working procedures or critical points affecting the quality of infant & growing up formula milk powder products. The following records shall be kept for wet processing: information concerning checking and acceptance of ingredients and minor ingredients, burdening, homogeneity, sterilization, spray drying and packaging. The following records shall be kept for dry processing: information concerning checking and acceptance of ingredients and minor ingredients, sterilization, burdening, dry blending and packaging. In dry-wet processing, the information concerning the critical working procedures or critical points corresponding to wet processing and dry processing shall be recorded. (2) An enterprise shall establish an online product information inquiry system which shall provide tags, outer packing, quality standards, delivery inspection reports and other

information for the convenience of consumers' inquiry. (3) The product tracing system shall provide records of products from ingredient purchase to end products and product sales, and shall guarantee that all the records are effectively traceable. (4) A product recall system shall be established. The recall system of outgoing products shall include the relevant contents of the *National food safety standard-Good manufacturing practice for powdered formulae for infants and young children* (GB 23790), and shall include management provisions on the recall of electronic information systems. (5) Remedial measures, harmless treatment, destroying and other measures shall be taken for the products recalled under the supervision of relevant departments, and the recall and handling of food shall be reported to food and drug regulatory departments. (6) A mechanism concerning the handling consumers' complaints shall be established. Where a consumer puts forward an opinion or complaint, the relevant departments of the enterprise shall record it, find the reason and handle it properly.

12. Research and Development Capacities

(1) An infant & growing up formula milk powder production enterprise shall establish an independent research and development institution equipped with relevant full-time research and development staffs. (2) A research and development institution shall, at least, be able to accomplish the following tasks: the research and development of new infant & growing up formula milk powder products; tracking and assessment of the nutrition and safety of infant & growing up formula milk powder; determining the guarantee periods

of products; the research of risk factors existing in the production process and putting forward preventive measures. (3) A research and development institution shall have appropriate locations, equipment, facilities and guarantee in funds.

(ii) Site Examination

Following site examination shall be conducted in accordance with the requirements of the General Rules on the Examination for Food Production Permit and the *National food safety standard-Good manufacturing practice for powdered formulae for infants and young children* (GB 23790).

1. The selection and designing of workshops, interior structures and auxiliary production facilities shall comply with the provisions of relevant standards.

2. There shall be production workshops and auxiliary facilities appropriate for the enterprise's production capacity.

The production workshops adopting wet processing techniques generally include milk collection workshops, ingredient pretreatment workshops, processing workshops, semi-finished product storage and finished product packaging workshops. The production workshops adopting dry processing techniques generally include pretreatment workshops, mixing workshops and filling workshops. Auxiliary facilities include inspection rooms, warehouses of ingredients and minor ingredients, material warehouses and warehouses of finished products.

3. Production workshops and auxiliary facilities shall be orderly and

reasonably arranged in accordance with the need of production processes and sanitary requirements. Meanwhile, quarantine shall be conducted in accordance with the need of production processes and production operations and the requirements on cleanliness to prevent cross contamination.

4. A workshop shall be divided into clean operation areas, quasi-clean operation areas and general operation areas. Clean operation areas include powder outlet areas where wet processing is adopted and burdening and mixing areas, temporary storage spaces for packaging materials, storage spaces for semi-finished products, and filling and inner packaging workshops where dry processing is adopted. Quasi-clean operation areas include ingredient pretreatment workshops, other processing workshops and unpacking and tunnel sterilization areas where dry processing is adopted. General operation areas include milk collection workshops, warehouses of ingredients, warehouses of packaging materials, outer packaging workshops and warehouses of finished products.

5. An enterprise shall conduct regular air quality monitoring in the clean operation areas, and shall, on an annual basis, employ qualified third-party inspection agencies to conduct inspection and produce inspection reports on the cleanliness of the air. The interior partition walls and floors of clean operation areas shall be made from materials meeting production sanitation requirements; sterilization and disinfection or purification shall be conducted on the air, and positive pressures shall be maintained. The use of water shall be forbidden during production within clean operation areas of a

dry-processing workshop.

6. The floor of workshops shall be flat and easy to be cleansed, disinfected and kept clean.

7. Changing room shall be at the entrance of a workshop, next to the hand washing and disinfection room. A hand washing and disinfection room shall be equipped with enough amounts of non-manual hand washing facilities, disinfection facilities and sensor-controlled hand dryers. The entrance of a clean operation area shall have a second changing room together with disinfection facilities.

8. The toilets within production areas shall be equipped with hand washing and disinfection facilities, easily kept clean, and shall not be directly connected with production, packaging or storage areas.

(iii) Equipment Examination

Examination shall be conducted on the production capacity declared in the Application for Food Production Permit and the adaptedness of the quantity and parameters of the production equipment owned by the enterprise.

1. General Requirement on Production Equipment

(1) An infant & growing up formula milk powder production enterprise shall possess the production equipment appropriate for the production capacity declared in the Application for Food Production Permit. (2) The complete machine accounts, instructions and records of equipment shall be kept; the conditions of production and inspection equipment shall be marked

through formulating relevant procedures, and special persons shall be designed for management and complete records so as to ensure the accuracy of information concerning the condition and marking of instruments and equipment. Identity management shall be conducted on the operating conditions of production equipment, shared equipment, fixed pipeline facilities and metering and inspection equipment, clarify the definitions of various conditions and markings, and conduct regular examination and maintenance on the markings. (3) All the containers, tools and equipment coming into contact with the ingredients, process products and semi-finished products of infant & growing up formula milk powder products must be made from stainless steel or other non-toxic inert materials, and tools and containers made from bamboo or wood shall not be used. Equipment that are easily disassembled and cleaned shall be used in dry processing production so as to ensure there is no risk of interfusion by foreign matters and greasy dirt. (4) The containers containing wastes shall not be mixed up with those containing products and ingredients and shall be attached with striking markings. (5) The vulnerable equipment coming into direct contact with raw materials for production such as glass thermometers must be covered with safety shields. (6) Fluidized beds shall use clean low temperature air upon filtration and dehumidification treatment. The air blown into drying towers shall be filtered, and the filtration equipment shall be regularly examined and replaced to meet production requirements. The air discharged from drying towers shall receive dedusting treatment. (7) The equipment shall be well

maintained, and their performance and accuracy shall meet the requirements of production procedures. There shall be complete equipment maintenance plans and records. (8) Verification shall be conducted on equipment upon cleansing to ensure that their sanitation conditions comply with production requirements. (9) Air purification treatment in clean operation areas shall adopt a triple filtration process using primary, medium and high efficiency filters (sub-high efficiency air filters). (10) Both static and dynamic detection shall be conducted on the cleanliness of a clean operation area when the plant accepted, or when the installation of the processing equipment is over, or when the clean operation area is rebuilt due to other reasons (e.g. after a large-scale maintenance in the clean operation area). During daily operation, the detection and monitoring of the air cleanliness of the clean operation area shall be conducted according to the following table.

Controlling Table for Dynamic Standards in Clean Operation Area of
Infant & Growing up Formula Milk Powder Production

Item	Content	Detecting Method	Controlling Requirement	Monitoring Frequency
Maximum number of microorganisms	Airborne viable particles	GB/T 16293	≤ 200 cfu/m ³	1 time/week
	Colony forming units	GB/T 16294	≤ 100 cfu/4h (φ90mm)	1 time/week
	Surface microorganisms	Sampling with reference to GB 15982, counting based on GB 4789.2	≤ 50 cfu/vessel (φ55mm)	1 time/week

Pressure difference	Between clean operation area and non-clean operation area	Measuring with manometer	$\geq 10\text{Pa}$	Twice/shift
Ventilation rate	Verifying the ventilation rate through measuring wind speed	Measuring with anemoscope	≥ 12 times/h	When replacing with high efficient filters or 1 time/month
Temperature	-	Measuring with thermometer	16-25°C	Twice/shift
Relative humidity	-	Measuring with hygrometer	$\leq 65\%$	Twice/shift

Note: The ventilation rate is measured after the wind speed is converted. Calculation formula: $N=3600SV/A$, calculating with wind speed when monitoring. Among it, N=ventilation rate, times/h; S=ventilation area at air inlet, in m^2 ; A=cubage of workshop, in m^3 ; V=average wind speed measured at air inlet, in m/s.

2. Necessary Production Equipment and Requirements

(1) Necessary Production Equipment to Produce Infant & Growing up

Formula Milk Powder through Wet Processing

Equipment Name	Basic Condition	Minimum Parameter or Specific Requirement
1. Milk storage equipment	Ensure the low-temperature storage of raw milk needed by plant	With automatic constant temperature or heat preservation systems, total storage capacity shall not be lower than 30t. (This equipment is not necessary for techniques in which raw milk is not used as an ingredient)
2. Milk purifying equipment	Centrifugal milk purifying machine	Total disposal capacity shall not be lower than 5t/h, with spare parts. (This equipment is not necessary for techniques in which raw milk is not used as an ingredient)
3. Pasteurization equipment	-	Total disposal capacity shall not be lower than 5t/h. (This equipment is not necessary for techniques in which raw milk is not used as an ingredient)
4. Cleaning equipment	Full-automatic CIP cleaning equipment	Requirement: full automatic control, cover the production line prior to concentration, no dead angle.
5. Dispensing equipment	-	It shall be used together with electronic scale, flow meter or other measurement devices, high shear tank or vacuum mixing tank shall be used as dispensing equipment.
6. Homogenization equipment	Two-phase high pressure homogenizer	Total disposal capacity shall not be lower than 5t/h, with spare parts.
7. Refrigeration equipment	Ammonia or fluorine refrigeration unit or another equivalent equipment	Equipment the cooling capacity of which shall be above 54 kw under standard working condition.
8. Concentrator	Vacuum concentration evaporator	The evaporability shall not be lower than 2400kg/h, with automatic control in sterilizing temperature, able to conduct CIP cleansing.

Equipment Name	Basic Condition	Minimum Parameter or Specific Requirement
9. High-pressure pump	-	The processing capacity shall not be lower than 1000 kg/h, with spare parts.
10. Spray drying equipment	Vertical spray drying equipment	The evaporation capacity per tower shall be above 500 kg/h, equipped with fluidized beds for drying and cooling purposes.
11. Airtight conveying equipment	-	Airtight, dust-free and automatic continuous/batch conveying equipment meeting food-grade requirements.
12. Airtight temporary storage equipment	Food-grade materials; even and smooth feeding of supplies	Convenient for cleaning and maintenance, with manual or automatic sampling device.
13. Metal detection equipment	Online or finished product detection	Automatic control, able to detect metals with sphere diameters $\geq 2\text{mm}$.
14. Packaging equipment	Full-automatic packaging equipment	Full-automatic packaging machine with automatic mass measuring and calibration system.
15. Clean air-conditioning system	The area of clean operation workshops may meet production requirement.	The cleanliness of clean operation areas shall meet the dynamic standard control requirements for clean operation areas of infant & growing up formula milk powder production.

(2) Necessary Production Equipment to Produce Infant & Growing up

Formula Milk Powder through Dry Processing

Equipment Name	Basic Condition	Minimum Parameter or Specific Requirement
1. Tunnel sterilization equipment	Ultraviolet sterilization and other sterilization facilities	Tunnel sterilization equipment shall be continuous and airtight, and shall be switched into air and environment purifying mode upon sterilization.
2. Feeding equipment	Manual or automatic feeding	Auxiliary dedusting device, the dusts generated during feeding shall be kept away from the production environment.
3. Screening equipment	Online continuous screening	Food-grade stainless steel screen cloth, convenient for disassembly, cleaning and replacement.

Equipment Name	Basic Condition	Minimum Parameter or Specific Requirement
4. Airtight conveying equipment	-	Airtight, dust-free and automatic continuous/batch conveying equipment meeting food-grade requirements.
5. Measuring and dispensing equipment	Mass measurement	Autonomous or semi-autonomous weighing and measurement.
6. Premixing equipment	Mixing in batches or continuous mixing	The mixing process requires airtight, dust-free and automatic operation.
7. Mixing equipment	Mixing in batches or continuous mixing	The mixing process requires airtight, dust-free and automatic operation; it shall at least ensure the even mixing between two supplies the ratio of which is 1:1000, the processing capacity shall be 2000kg/h or above.
8. Airtight temporary storage equipment	Food-grade materials; even and smooth feeding of supplies	Convenient for cleaning and maintenance, with manual or automatic sampling device.
9. Metal detection equipment	Online or finished product detection	Automatic control, able to detect metals with sphere diameters $\geq 2\text{mm}$.
10. Packaging equipment	Full-automatic packaging equipment	Full-automatic packaging machine with automatic mass measuring and calibration system.
11. Clean air-conditioning system	The area of clean operation workshops may meet production requirement.	The cleanliness of clean operation areas shall meet the dynamic standard control requirements for clean operation areas of infant & growing up formula milk powder production.

(3) The production of infant & growing up formula milk powder through dry-wet processing shall be equipped with all the production equipment that shall be used through wet processing and the necessary production equipment for dry processing.

3. Necessary Inspection Equipment

The amount of inspection equipment shall be compatible with an enterprise's production capacity. The written report submitted by the enterprise concerning the compatibility between inspection equipment and production capacity shall be examined.

An enterprise shall possess all inspection equipment relevant to all inspection items suitable for infant & growing up formula milk powder prescribed by relevant food safety announcements released by State health and family planning administrative departments and national standards (including enterprise standards) on food safety. Where relevant national standards on food safety are amended or revised, an enterprise shall timely purchase corresponding inspection instruments and equipment. For the inspection methods involved in the *National food safety standard-Infant formula* (GB 10765) and the *National food safety standard-Older infants and young children formula* (GB 10767) please refer to Annex 2 and Annex 3.

An enterprise may use quick inspection equipment, but shall maintain the accuracy of the inspection result. The quick inspection methods and equipment used by an enterprise shall be regularly compared or verified against the inspection methods prescribed by national standards on food safety. When the inspection result turns out to be positive, it shall be confirmed using the inspection method prescribed by national standards on food safety.

(iv) Equipment Layout, Basic Technical Procedures, Critical

Control Points and site-clearing requirement

1. Equipment Layout

The layout of equipment shall meet technical and cleansing demands.

2. Basic technical Procedures

(1) Technical procedures of wet processing:

Whole milk powder, skim milk powder



Raw milk → Pure milk → Sterilization → Cold storage → Standard
burdening → Homogeneity → Sterilization → Concentration →
Spray drying → Secondary drying through fluidized bed → Packaging

(2) Technical procedures of dry processing:

Ingredients and minor ingredients → Feed preparation → Feeding →
Burdening (pre-mixing) → Feeding → Mixing → Packaging

(3) Technical procedures of dry-wet processing:

Technical procedures of dry-wet processing shall include all technical procedures of wet processing and relevant technical procedures of dry processing except for final product packaging.

An enterprise shall submit necessity and safety reports when adjusting the technical procedures and equipment of products.

Attention shall be paid to examine the production techniques and equipment that are forbidden to use or explicitly ordered by the State to eliminate.

3. Technical Requirements on Critical Control Points

(1) Procedural requirements on wet processing

① Transport and storage of raw milk. The temperature of raw milk shall drop to 0—4°C within two hours upon milking. Raw milk shall be transported with insulated milk tankers. The transport vehicles shall have complete certificates and records. The raw milk shall, upon arrival, be timely processed. If the raw milk cannot be timely disposed of, it shall be kept in refrigerated storage facilities, monitoring shall be conducted on the temperature and relevant indicators and records shall be kept.

② Mixing of product ingredients. The ingredients and minor ingredients required by relevant standards on infant & growing up formula milk powder shall be adopted. Upon verifying relevant information, the ingredients and minor ingredients shall be removed of their outer packages, undergo dedusting and purification treatment and then conveyed to the mixing workshop. The ingredients and minor ingredients shall be sufficiently dissolved with high shear tanks, vacuum mixing tanks or other mixing equipment. Food additives and food nutrition supplements shall be subject to management by specially-assigned staffs and shall be kept in specially designated areas. Strict verification shall be conducted on the names, purchase times and batch numbers of additives and nutrition supplements. The additives and nutrition supplements shall be accurately measured and kept on records. Compound vitamins and compound microelements shall be dissolved in different containers according to product requirements and added

according to requirement to avoid reactions.

③ Sterilization and concentration. The feeding temperature, vacuum degree, steam pressure and sterilization temperature shall be controlled within the scope of the parameters of the equipment and records shall be taken.

④ Spray drying and cooling. The working procedures of spray drying shall strictly control the use of vapor and water to reduce the reproduction of harmful microorganisms. Fluidized beds shall be adopted for the purpose of cooling, and operations such as manual screening and powder cooling with powder tanks that may leave semi-finished products exposed in clean operation areas shall not be adopted. The cooled products shall be stored in powder chambers and other airtight temporary storage devices.

⑤ Product packaging. The flows of people, goods and air shall be brought under strict control to prevent contamination. The products shall be packaged using automatic packaging machines. In order to avoid foreign matters from getting mixed in the products during the course of production due to equipment damage or equipment wear, metal detection shall be conducted before product packaging or online detection of metal foreign objects with X-ray detectors upon packaging. Removing equipment shall be equipped to ensure that packaged products do not contain metal or other foreign matters. Samples shall be taken from packaged products to undergo air tightness testing and full testing. Only products that have passed such testing may leave the factory.

(2) Procedural requirements on dry processing

① Ingredient preparation. The names, specifications, eligibility, and pollution-free outer package of ingredients and minor ingredients shall be confirmed. Independent buffer zones shall be established between ingredient areas and feeding areas which shall be equipped with relevant air shower and sterilization systems so as to ensure the degusting and sterilization of the outer packaging of supplies.

② Feeding. During the unpacking process, attention shall be paid to the electrostatic adherence of inner bags to fragments of outer bags, cords and ropes. Sanitary cleaning up shall be regularly conducted in unpacking and feeding areas, and checking shall be conducted on the inner bags of supplies to see if there are any breakages. When a breakage, agglomeration of supplies or another abnormal situation is found, the supplies shall be returned. Upon removal of the outer packaging, the supplies shall enter the clean operation area via the sterilization tunnel.

③ Burdening (Pre-mixing). The formulas of vitamins, microelements or other nutrients shall be subject to input and management by specially-assigned formula management staffs, and the formulas shall be reexamined by relevant staffs to ensure accurate of formula input. During the burdening process, the weight of supplies shall be consistent with the formula requirement. Upon weighing, tags shall be attached for the names, specifications and dates of supplies. Prior to pre-mixing, reexamination shall be conducted on the varieties and weights of supplies according to pre-mixing formulas so as to ensure accurate feeding. When the pre-mixing is over, tags

shall be attached to the names, specifications and dates of pre-mixed supplies. Relevant records shall be established for the entire burdening (pre-mixing) production, obtaining and using process so as to ensure the traceability of the production information of the products.

④ Feeding. Prior to feeding, efforts shall be made to guarantee that the environment and equipment in the feeding area comply with relevant site-clearing standards, communicate with purchasers of supplies on the varieties and amount of ingredients and check the tags, amount and feeding lists of the ingredients to be fed so as to ensure accurate feeding. Feeding operators shall regularly disinfect their hands and the environment and equipment in the feeding area to avoid supplies contamination. The supplies feeding and conveying system shall use vibrating screens to prevent foreign objects that might be blended in the supplies from entering the feeding system. The screened supplies shall be conveyed to relevant powder storage warehouses or mixing equipment.

⑤ Mixing. The mixing process shall realize whole process automatic control, and no manual intervention is needed if there are no abnormal situations. The mixing technique shall ensure the homogeneity of mixed supplies. Mixed semi-finished products shall not be exposed in the clean operation area and shall be stored in powder warehouses or other airtight temporary storage equipment.

⑥ Packaging. It's the same with the corresponding procedural requirement on wet processing.

(3) Procedural requirements on dry-wet processing

The procedures of dry-wet processing shall be consistent with the corresponding critical point requirements of wet processing and dry processing.

(4) Site-clearing

In order to prevent the cross contamination or confusion between different batches, different formulas and different varieties in infant & growing up formula milk powder production, site-clearing shall be conducted in each production process after production is completed and before variety or batch replacement. Site-clearing shall be recorded and the records shall include: work procedure, name, production batch, time of site-clearing, inspection items and results. The records shall be signed by responsible persons of site-clearing and reexaminers.

(v) Personnel Examination

1. Enterprise Responsible Persons, Quality and Safety Management Personnel, Production Management Personnel and Food Quality and Safety Authorized Persons

Enterprise responsible persons, quality and safety management personnel, production management personnel and food quality and safety authorized persons shall hold bachelor degrees or above in food and relevant majors, qualify through professional theory and hands-on training, grasp knowledge relevant to the quality and safety of infant & growing up formula milk powder, understand respective due responsibilities and obligations, and

have no records of violating the Food Safety Law of the People's Republic of China. Food quality and safety authorized persons shall mainly be responsible for product release, ensuring that the production and inspection of each batch of products released comply with relevant laws, regulations and food safety standards of the State. Prior to product release, food quality and safety authorized persons must produce product release examination records which shall be incorporated into batch records.

2. Production Technicians and Inspection Personnel

Production technicians shall hold college degrees or above in food and relevant majors, qualify through professional theory and hands-on training, and have at least three years of experience in infant & growing up formula milk powder production in dairy enterprises.

Inspection personnel of laboratories shall hold college degrees or above in food, chemistry or other relevant majors or have at least 10 years of experience in inspection, and shall hold vocational qualification certificates in food inspection. Responsible persons of laboratories shall hold bachelor degrees or above in food, chemistry or other relevant majors, and have least three years of experience in relevant technical posts. At least two persons with the ability to conduct independent inspection shall be assigned to each inspection item.

3. Production Operators

The number of production operators shall be suitable to an enterprise's scale and technical and equipment levels. Production operators shall have a

certain technical experience, grasp production and technical operation procedures, engage in production according to technical documents and be proficient in operating production equipment. The qualifications of production operators for special posts shall comply with relevant provisions.

4. Personnel Health Certificate

Field staffs of infant & growing up formula milk powder production may only engage in production upon receiving routine health examinations and obtaining health certificates issued by health and family planning departments.

III. Product Inspection for Production Permit

(i) Sampling and Sample Sealing

In accordance with the requirements of the General Rules on the Examination for Food Production Permit and these Detailed Rules, sampling shall be conducted in the finished product warehouse of an enterprise according to the following provisions, and the product shall be sealed.

For the application unit of infant & growing up formula milk powder submitted by an enterprise and the age group applicable for the product, permit inspection shall be conducted on one packing size of products randomly selected from among each type of products submitted by the enterprise (according to the standards on product application).

The sampling base shall not be less than 200 sales packages. The sampling amount of packages below 500g shall be 16 sales packages; the sampling amount of packages above 500g shall be 12 sales packages.

The samples selected shall be divided into two parts. For packages below 500g, 10 sales packages shall serve as inspection samples, and the rest 6 sales packages shall serve as backup samples; for packages above 500g, 8 sales packages shall serve as inspection samples, and the rest 4 sales packages shall serve as backup samples.

Upon confirmation of the samples, the sampler and the responsible person of the unit under sampling shall sign and stamp with seals on the sampling sheet, the samples shall be sealed on the spot and attached with paper strips for sealing. The paper strips for sealing shall have the signature of the sampler, the seal of the sampling unit and the date of sealing. The sampler shall notify the applicant the name and contact means of the inspection bodies that are eligible to assume the task of permit inspection for the product, and the applicant shall independently choose one from these inspection bodies. The applicant shall, within prescribe period of time, send the sealed samples to the selected inspection body.

(ii) Inspection Items

Inspection shall be conducted in accordance with the inspection items included in the contents of the *National food safety standard-Infant formula* (GB 10765), the *National food safety standard-Older infants and young children formula* (GB 10767), enterprise standards and relevant announcements of the State health and family planning administrative departments.

IV. Other Requirements

Infant & growing up formula milk powder production enterprises shall comply with the policies of the dairy industry.

Annexes: 1. Main Standards Involved in the Main Ingredients, Minor Ingredients and Packaging Materials Needed for Infant & Growing up Formula Milk Powder Production

2. *Inspection Items and Methods Prescribed in National food safety standard-Infant formula* (GB 10765)
3. *Inspection Items and Methods Prescribed in National food safety standard-Older infants and young children formula* (GB 10767)

Annex 1

Main Standards Involved in the Main Ingredients, Minor Ingredients and Packaging Materials Needed for Infant & Growing up Formula Milk Powder Production

S/N	National Standard	(Ingredients and Minor Ingredients) Standard Name
1	GB 19301	Raw milk
2	GB 19644	Milk powder
3	GB 11674	Whey powder and whey protein powder
4	GB 317	White granulated sugar
5	GB 14963	Honey
6	GB 1535	Soya bean oil
7	GB 1534	Peanut oil
8	GB 10464	Sunflowerseed oil
9	GB 19111-2003	Maize oil
10	GB 2716-2005	Hygienic standard for edible vegetable oil
11	GB 26687	General standard for food additive compound
12	GB 25542	Food additive glycine (amino acid)
13	GB 25543	Food additive L-alanine
14	GB 25550	Food additive L-Carnitine tartrate
15	GB 25558	Food additive tricalcium phosphate
16	GB 25559	Food additive monocalcium phosphate
17	GB 25595	Lactose
18	GB 9683	Hygienic standard for composite laminated food packaging bag
19	GB 9687	Hygienic standard for polyethylene products used as food containers and tablewares
20	GB 9688	Hygienic standard for polypropylene products used as food containers and tablewares
21	GB 9689	Hygienic standard for polystyrene products used as food containers and tablewares
22	GB/T 191	Packaging - Pictorial marking for handling of goods

S/N	National Standard	(Ingredients and Minor Ingredients) Standard Name
23	GB 13432	General standard for the labelling of prepackaged foods special dietary uses
24	GB 7718	General standard for the labeling of prepackaged foods
25	GB 2760	Using standard of food additives
26	GB 14880	Hygienic standard for the use of food nutrition supplements
27	GB 5749	Sanitary standard for drinking water

This table includes the main standards involved in the main ingredients, minor ingredients and packaging materials needed for infant & growing up formula milk powder production, which is for reference only.

Annex 2

Inspection Items and Methods Prescribed in National food safety standard-Infant formula (GB 10765)

S/N	Inspection Item	Inspection Item	Method and Standard
1	Sensory requirements	Color and lustre	According to relevant standards
2		Flavor, smell	According to relevant standards
3		Texture	According to relevant standards
4		Reconstitutability	According to relevant standards
5	Heat	Heat	According to relevant standards
6	Protein	Protein	GB 5009.5
8		Proportion of whey protein in protein	-
9	Fat	Fat	GB 5413.3
10		Linoleic acid	GB 5413.27
11		α -Linolenic acid (ALA)/(mg)	GB 5413.27
12		Ratio between Linoleic acid and α -Linolenic acid (ALA)	GB 5413.27
13		Ratio between total amount of lauric acid and myristic acid (tetradecanoic acid) and total fatty acid	GB 5413.27
14		Ratio between trans-fatty acid and total fatty acid	GB 5413.36
15		Ratio between erucic acid and total fatty acid	GB 5413.27
16	Carbohydrate	Carbohydrate	Implemented according to Table 2 of 4.3.2 of GB 10765
17		Proportion of lactose in carbohydrate	GB 5413.5
18	Vitamin indicators	Vitamin A	GB 5413.9
19		Vitamin D	GB 5413.9
20		Vitamin E	GB 5413.9
21		Vitamin K	GB 5413.10
22		Vitamin B ₁	GB 5413.11
23		Vitamin B ₂	GB 5413.12
24		Vitamin B ₆	GB 5413.13
25		Vitamin B ₁₂	GB 5413.14

S/N	Inspection Item	Inspection Item	Method and Standard
26		Niacin (nicotinamide)	GB 5413.15
27		Folic acid	GB 5413.16
28		Pantothenic acid	GB 5413.17
29		Vitamin C	GB 5413.18
30		Biotin	GB 5413.19
31	Mineral indicators	Sodium	GB 5413.21
32		Potassium	GB 5413.21
33		Copper	GB 5413.21
34		Magnesium	GB 5413.21
35		Iron	GB 5413.21
36		Zinc	GB 5413.21
37		Manganese	GB 5413.21
38		Calcium	GB 5413.21
39		Phosphorus	GB 5413.22
40		Ratio between calcium and phosphorus	GB5413.21、GB5413.22
41		Iodine	GB 5413.23
42		Chlorine	GB 5413.24
43		Selenium	GB 5009.93
44	Optional contents	Choline	GB/T 5413.20
45		Inositol	GB 5413.25
46		Taurine	GB 5413.26
47		L-Carnitine	-
48		Docosahexaenoic acid (DHA) (% total fatty acid)	GB 5413.27
49		Arachidonic acid (AA) (% total fatty acid)	GB 5413.27
50		Ratio between docosahexaenoic acid (DHA) and arachidonic acid (AA)	GB 5413.27
51		Ratio between eicosapentaenoic acid and docosahexaenoic acid (DHA)	GB 5413.27
52	Moisture contents	Moisture content	GB 5009.3
53	Ash contents	Milk-based powder product	GB 5009.4
54	Impurities	Milk-based powder product	GB 5413.30
55		Milk-based liquid product	GB 5413.30
56	Limits of pollutants	Lead	GB 5009.12
57		Nitrate (NaNO ₃)	GB 5009.33
58		Nitrite (NaNO ₂)	GB 5009.33

S/N	Inspection Item	Inspection Item	Method and Standard
59	Mycotoxin	Aflatoxin M ₁	GB 5413.37
60	Microbial limits	Total plate count	GB 4789.2
61		Coliform	GB 4789.3 plate count method
62		Staphylococcus aureus	GB 4789.10 plate count method
63		Enterobacter sakazakii	GB 4789.40 count method
64		Salmonella	GB 4789.4
65	Melamine	Melamine	GB 22388 No. 10 Announcement of Ministry of Health in 2011
66	Labels	Food labels	GB 7718, GB 13432

This table is a summary of the *Regulations on the Supervision and Administration of the Quality and Safety of Dairy Products* and the *National food safety standard- GB 10765*, which is for reference only.

Annex 3

Inspection Items and Methods Prescribed in National food safety standard-Older infants and young children formula (GB 10767)

S/N	Inspection Item	Inspection Item	Method and Standard
1	Sensory requirements	Color and lustre	According to relevant standards
2		Flavor, smell	According to relevant standards
3		Texture	According to relevant standards
4		Reconstitutability	According to relevant standards
5	Heat	Heat	According to relevant standards
6	Protein	Protein	GB 5009.5
7	Fat	Fat	GB5413.3
8		Linoleic acid	GB5413.27
9	Vitamin Indicators	Vitamin A	GB 5413.9
10		Vitamin D	GB 5413.9
11		Vitamin E	GB 5413.9
12		Vitamin K	GB 5413.10
13		Vitamin B ₁	GB 5413.11
14		Vitamin B ₂	GB 5413.12
15		Vitamin B ₆	GB 5413.13
16		Vitamin B ₁₂	GB 5413.14
17		Niacin (nicotinamide)	GB 5413.15
18		Folic acid	GB 5413.16
19		Pantothenic acid	GB 5413.17
20		Vitamin C	GB 5413.18
21		Biotin	GB 5413.19
22	Mineral indicators	Sodium	GB 5413.21
23		Potassium	GB 5413.21
24		Copper	GB 5413.21
25		Magnesium	GB 5413.21
26		Iron	GB 5413.21
27		Zinc	GB 5413.21

S/N	Inspection Item	Inspection Item	Method and Standard
28		Calcium	GB 5413.21
29		Phosphorus	GB 5413.22
30		Ratio between calcium and phosphorus	/
31		Iodine	GB 5413.23
32		Chlorine	GB 5413.24
33	Optional contents	Choline	GB/T 5413.20
34		Inositol	GB 5413.25
35		Taurine	GB 5413.26
36		L-Carnitine	
37		Docosahexaenoic acid (DHA) (% total fatty acid)	GB 5413.27
38		Arachidonic acid (AA) (% total fatty acid)	GB 5413.27
39		Selenium	GB 5009.93
40		Manganese	GB 5413.21
41	Moisture contents	Moisture content (only powder products)	GB 5009.3
42	Ash contents	Powder products/(%)	GB 5009.4
43	Impurities	Powder products (except for those added to Vegetable and fruit products)	GB 5413.30
44	Limits of pollutants	Lead	GB 5009.12
45		Nitrate (NaNO_3) (except for those added to Vegetable and fruit products)	GB 5009.33
46		Nitrite (NaNO_2)	GB 5009.33
47	Mycotoxin	Aflatoxin M_1	GB 5413.37
48	Microbial limits	Total plate count	GB 4789.2
49		Coliform	GB 4789.3 plate count method
50		Salmonella	GB 4789.4
51	Melamine	Melamine	GB 22388 No. 10 Announcement of Ministry of Health in 2011
52	Labels	Food labels	GB 7718 GB 13432

This table is a summary of the *Regulations on the Supervision and Administration of the Quality and Safety of Dairy Products* and the *National food safety standard- GB 10767*, which is for reference only.