Attachment 4-3-2

Registration conditions and comparative inspection points for overseas manufacturers of imported infant formula milk products

1. Registration number:
2. Company Name:
3. company address:
4. Form filling date:
* Instructions for filling out the form:
* 1. According to the "Regulations on the Administration of Registration of Overseas Manufacturers of Imported Foods" (According to Order No. 248 of the General Administration of Customs), the sanitary conditions of overseas infant formula milk manufacturers that apply for registration in China shall comply with the relevant laws, regulations and standards of China. It complies with the requirements of the Protocol on Inspection and Quarantine of Dairy Products Exported to China. This form is for the overseas authorities in charge of imported infant formula to conduct official inspections on infant formula production enterprises based on the listed main conditions and bases, and check the main points of review; Fill in and submit supporting materials, and self-examination can also be carried out according to the review points, which is used for self-assessment before the enterprise applies for registration.
* 2. Overseas competent authorities and overseas infant formula milk production enterprises should truthfully make compliance judgments based on the actual situation of the comparison inspection.
* 3. The submitted materials should be filled in in Chinese or English, the content is true and complete, the attachments should be numbered, and the number and content of the attachments should accurately correspond to the item number and content in the column of "Filling Requirements and Certification Materials". At the same time, submit the list of attachments of the certification materials.

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| project | Conditions and basis | Fill in the requirements and supporting materials | Review points | Compliance determination | Remark |
| **A. Basic information** |
| 1. Basic information of the enterprise | Articles 8 and 9 of the Regulations on the Administration of Registration of Overseas Production Enterprises of Imported Food (Order No. 248 of the General Administration of Customs) . | 1. Fill out the "Application for Registration of Overseas Manufacturers of Imported Infant Formula (Formula Milk Powder and Formula Liquid Milk)". | 1. The registered name, address, registration number, etc. are consistent with the relevant registration information in the "Official Declaration of Conformity for Registration of Imported Dairy Products" and "Format of List of Overseas Dairy Enterprises Applying for Registration" submitted by the official competent authority. | □Compliant□ does not meet |  |
| 2. Workshop layout | 1. 5.1, 9.6.5.1, 9.6.6.1 of "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010).2. "National Food Safety Standard Dairy Good Manufacturing Practice" (GB12693-2010) 5.1. | 2. Provided workshop floor plan. The figure shows the flow of people, the direction of logistics, the functions of different processing areas, and the range of areas with different degrees of cleanliness. | 1. The layout of the workshop should be able to clearly identify the division of areas with different degrees of cleanliness.2. Reasonable layout of human flow and logistics to prevent cross-contamination.3. Infant preparation enterprises adopting wet process and dry-wet mixing process should effectively isolate dry area and wet area. | □Compliant□ does not meet |  |
| 3. To export Chinese products | 1. "Detailed Rules for Examination of the Production License of Infant Formula Milk Powder" (2013 edition) requires subsections, infant formula milk powder (0-6 months old, paragraph 1), older infant formula milk powder (6-12 months old, 2 segment) and infant formula milk powder (12-36 months old, segment 3). | 3. Fill in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula (Formula Milk Powder and Formula Liquid Milk)". | 1. Whether the segmentation of the products to be exported to China is consistent with the segmentation requirements of my country. | □Compliant□ does not meet |  |
| 4. The actual production volume of finished infant formula milk products in the last two years (tons/year). |  | 4. Fill in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)". |  | □Compliant□ does not meet□Not applicable |  |
| **B. Production Information** |
| 1. Production process | 1. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010 ) 3, 9.6. | 1 Provide a process flow diagram.1.1 If it is produced by wet process, the submitted materials should also include:a) Verification report of heat treatment (heat sterilization and other processes).1.2 If it is produced by dry process, the provided materials should also include:a) Guarantee measures for product mixing degree.b) The latest mixing degree verification report for infant formula milk products exported to China.1.3 If it is produced by dry-wet mixing process, the content provided shall also include the following:a) Verification report of heat treatment (heat sterilization and other processes);b) safeguard measures for product mixing degree;c) The latest mixing degree verification report for infant formula milk products exported to China.* 1.4 Provide relevant materials proving the scientificity and rationality of product formulations exported to China, including :
* a ) Provide formula development process for products exported to China .
* b ) Provide description materials for formula characteristics and research and development objectives of products exported to China , to prove the use of raw materials and additives in the formula of products exported to China, and the setting of nutrient composition indicators, with reference to the daily nutrient intake of infants and young children recommended by international organizations and China's national food safety standards quantity. Provide proof of scientificity and rationality of the formula ( detailed list of all relevant standards or scientific experimental conclusions based on, scientific experiments indicate the exact source and experimental time, provide corresponding test certificates, testing certificates, etc.) ;
* c ) Provide a written statement stating that the nutritional ingredients of the product formula exported to China are reasonably matched, which can promote the growth and development of infants and young children , and can meet the requirements of relevant Chinese regulations and standards .
 | 1. The process flow chart should describe all processing steps completely and clearly.2. Heat treatment (heat sterilization and other processes) effectiveness.3. The scientific nature of the safeguard measures for product mixing degree. | □Compliant□ does not meet |  |
| 2. Production capacity and equipment | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 6.1.1.1.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 6.1.3.2. | 2. Fill in the relevant content in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)". | 1. Enterprises should have processing equipment compatible with the production process.2. Whether the production capacity of the main equipment matches the production capacity declared by the enterprise. | □Compliant□ does not meet |  |
| 3. Hygiene quality management system | 1. General Requirements for Hazard Analysis and Critical Control Points (HACCP) System Food Production Enterprises (GB/T 27341-20 09 ). | 3. Fill in the relevant content in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)", and provide the corresponding attachments. | 1. The HACCP plan shall analyze and effectively control biological, physical and chemical hazards.2. The production process should be reasonable to avoid cross-contamination.3. The setting of CCP points should be scientific and feasible, and the corrective and verification measures should be appropriate.4. Whether the HACCP plan includes all products applied for registration. | □Compliant□ does not meet |  |
| 4. Isolation and cleaning (or cleaning) measures between different products | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 7.3.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 9.6.6.5. | 4. Fill in the relevant contents in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)". The provided isolation and cleaning (or cleaning) measures should include the isolation and cleaning (or cleaning) method, frequency, and effectiveness verification measures. | 1. The cleaning (or cleaning) measures are comprehensive and the effect can be verified. | □Compliant□ does not meet |  |
| 5. Environmental monitoring plan and air cleanliness testing plan for cleaning work areas | 1. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 5.1.8 and Appendix A.2. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 9.1.3. | 5. The provided environmental monitoring plan and air cleanliness test plan in the cleaning work area shall include test items, determination standards, test frequency, test methods, sampling point settings, corrective measures for positive results and the last two test reports. | 1. The focus of monitoring should cover areas where microorganisms are easy to hide and breed.2. Sampling point setting. In the event of major maintenance, construction activities, or deteriorating sanitary conditions, add necessary sampling points to the monitoring plan.3. Whether to adjust the frequency of environmental monitoring plan implementation based on test results and the severity of pollution risks.4. Corrective measures for positive results.5. Whether to monitor the air cleanliness in the clean area. High cleaning operation area≤30cfu/dish; Quasi-cleaning operation area≤50cfu/dish. | □Compliant□ does not meet |  |
| 6. Cleaning and disinfection | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 7.3.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 7.3.3 | 6. Fill in the relevant content in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)", and the cleaning and disinfection procedures provided should cover the entire production line. | 1. Whether the heated surfaces of pipes and equipment are pickled or otherwise removed to remove denatured proteins and salts.2. Cleaning agent residual verification (detect conductivity, pH value, etc.).3. Verification of cleaning effect (detection of microorganisms, sensory inspection, etc.). | □Compliant□ does not meet□Not applicable |  |
| 7. Chemical Management | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 9.2. | 7. List the names of chemicals such as disinfectants and cleaning agents used by the enterprise for the production area. | 1. Whether disinfectants and cleaning agents can be applied to food contact surfaces. | □Compliant□ does not meet□Not applicable |  |
| 8. Water/ice/steam supply | 1. 5.3.1 and 5.3.2 of "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010).2. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 5.3.1, 5.3.2. | 8.1 Fill in the relevant content in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)", and provide the corresponding attachments.8.2 The water supply and drainage diagrams provided shall reflect the flow direction of water.8.3 The provided monitoring plan for production water and ice/steam (if applicable) in direct contact with food shall include the items, methods, frequency of bacteriological inspections and the latest two test reports. | 1. The water supply and drainage diagrams should be complete and clear.2. The production water monitoring plan should cover all water outlets in the factory.3. Whether the testing items and methods meet the requirements of "National Food Safety Standard for Drinking Water" (GB5749-2006 ) . | □Compliant□ does not meet□Not applicable |  |
| **C. Raw material information** |
| 1. Raw milk | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 8.2.2. Article 5 of " Regulations on the Administration of Registration of Overseas Production Enterprises of Imported Food " ( Order No. 248 of the General Administration of Customs ) .3. "National Food Safety Standard Raw Milk" (GB 19301-2010). | 1 If raw milk raw materials are used, fill in the relevant contents of C.1 (1) in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)" . | 1. Raw milk complies with the "National Food Safety Standard Raw Milk" (GB 19301-2010).2. The milk source comes from the epidemic-free area. | □Compliant□ does not meet□Not applicable |  |
| 2. Dairy products <whole milk (powder), skim milk (powder), whey (powder), etc.> | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 8.2.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 8.2.3. Infant formula does not use fructose, unpregelatinized starch. "National Food Safety Standard - Infant Formula" (GB10765-2010) "General Principles of National Food Safety Standard for Infant Formula for Special Medical Purposes" (GB25596-2010).The raw materials and food additives used should not contain gluten, and no irradiated raw materials are used. "National Food Safety Standard - Infant Formula" (GB10765-2010), "National Food Safety Standard - Older Infant and Young Child Formula " (GB10767-2010).Do not use hydrogenated vegetable oil "National Food Safety Standard - Infant Formula" (GB10765), "National Food Safety Standard - Older Infant and Young Child Formula" (GB10767-2010) | 2 If raw milk raw materials are used, fill in the relevant contents of C.1(2) in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)" . | 1. A complete list of dairy raw materials that the enterprise should submit.2. The raw materials of dairy products used shall meet the national food safety standards of China.3. The main raw materials of dairy-based products (including base powder, whey powder, whey protein powder, skim milk/powder, whole milk/powder) should come from approved and registered overseas enterprises. | □Compliant□ does not meet□Not applicable |  |
| 3. Raw material supplier audit system | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 8.2.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 8.2. | 3. Provide the audit procedures of raw material suppliers and the list of qualified suppliers of main raw materials.The attachments provided should list the attachment name and number in this column. | 1. Enterprises should establish supplier audit procedures and stipulate procedures for supplier selection, audit and evaluation. | * □Compliant
* □ does not meet
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| **D. Product traceability and recall** |
| 1. Product traceability | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 12. | 1 Fill in D.1 of the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)"If there is a logo, mark or number printed on the product package for traceability, please explain the meaning of the logo, logo or number for traceability, the printing position on the package, and how consumers use the logo, logo or number. | 1. The enterprise should clearly describe the representative meaning of the product identification, logo or number used for traceability. | □Compliant□ does not meet |  |
| 2. Product recall | 1. 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 12.
 | 2 Fill in D.2 in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)" . |  | □Compliant□ does not meet |  |
| **E. Product inspection** |
| 1. Finished product factory testing laboratory | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 10.2. "National Food Safety Standard Powdered Infant Formula Food Good Manufacturing Practice" (GB23790-2010) 10. | 1 Fill in E.1 in the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)" and provide the corresponding attachments. | 1. Laboratory testing capabilities can cover the "National Food Safety Standard for Infant Formula" (GB10765-2010) andThe corresponding test indicators in "National Food Safety Standard for Older Infants and Young Children Formula Food" (GB 10767-2010). | □Compliant□ does not meet |  |
| 2. Disposal procedures for unqualified raw materials, semi-finished products and finished products | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 8.2.3. | 2. Provide the disposal procedures for raw materials, semi-finished products and finished products. |  | □Compliant□ does not meet |  |
| **F. Enterprise location and factory environment** |
| 1. Enterprise address and surrounding environment | 1 "National Food Safety Standard General Hygienic Specification for Food Production" (GB14881-201 3 ). | 1 Provide pictures of the plant location and surrounding environment (eg, satellite location map). | 1. Whether there are pollution sources around the buildings and facilities around the company.2. The layout of the company's factory area meets the needs of production and processing. | □Compliant□ does not meet |  |
| 2. Pest control map | 2. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010) 7.5. | 2 Provide pest control charts. | 1. The layout of pest and rodent control points is reasonable, which can effectively prevent and control pests and rodents. | □Compliant□ does not meet |  |
| **G. Statement** |
| 1. Corporate Statement | 1. Articles 6 and 7 of "Regulations on the Administration of Registration of Overseas Production Enterprises of Imported Food". | 1. The enterprise makes a statement in Part G of the "Application for Registration of Overseas Manufacturers of Imported Infant Formula Milk Products (Formula Milk Powder and Formula Liquid Milk)" . | 1. It should be signed by the legal person and stamped by the company. | □Compliant□ does not meet |  |
| 2. Official statement | 1. Articles 6 and 7 of "Regulations on the Administration of Registration of Overseas Production Enterprises of Imported Food". | 2. The overseas competent authority makes a statement in Part H of the "Application for Registration of Overseas Manufacturers of Imported Infant Formula (Formula Milk Powder and Formula Liquid Milk)" . | * 1. It should be signed by the competent authority and stamped by the competent authority.
* 2. The review report of the competent authority of the country (region) where the relevant enterprise has been audited and inspected.
 | □Compliant□ does not meet |  |