

Appendix 5-3-5

Registration conditions and key points of comparative inspection of overseas manufacturers of imported foods for special dietary use

Company registration nr :

Company name :

Company address:

Date :

Notes :

1. According to the "Regulations of the People's Republic of China on the Administration of Registration of Overseas Manufacturers of Imported Foods" (Order No. 248 of the General Administration of Customs), overseas manufacturers of special dietary foods that apply for registration in China shall have hygienic conditions that comply with Chinese laws, regulations and standards. This form is for overseas competent officials of imported special dietary food to conduct official inspections on special dietary food production enterprises according to the listed main conditions and basis, 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 officials and overseas special dietary food production enterprises should truthfully make compliance judgments based on the actual situation of the comparison inspection.

3. The submitted materials should be filled out in Chinese or English, with true and complete contents. The attachments should be numbered. The attachment numbers and contents should correspond exactly with the item numbers and contents in the column of "Filling Requirements and Certification Materials". At the same time, submit the list of attachments for certification materials.

Items	Conditions and basis	Filling requirements and supporting materials	Key points for review	Conformity determination	Remarks
1.Enterprise Overview					
1. 企业基本信息 Enterprise Overview	《中华人民共和国进口食品境外生产企业注册管理规定》(海关总署令第 248 号) "Regulations of the People's Republic of China on the Administration of Registration of Overseas Production Enterprises of Imported Food" (Order No. 248 of the General Administration of Customs)	填写 1.进口特殊膳食用食品境外生产企业基础信息表。 Fill in 1. Basic Information Form for Overseas Manufacturers of Imported Special Dietary Foods.	注册名称、地址、注册号等与官方主管机构提交的《申请书》中相关注册信息一致性。 The registered name, address, registration number, etc. are consistent with the relevant registration information in the Application Form submitted by the official competent authority.	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming <input type="checkbox"/> 不符合	
2 拟出口到中国产品信息 Product information to be exported to China	1. 《食品安全国家标准 婴儿配方食品》(GB 10765-2010);《食品安全国家标准 较大婴儿和幼儿配方食品》(GB10767-2010);《食品安全国家标准 特殊医学用途婴儿配方食品通则》(GB 25596-2010);《食品安全国家标准	1、产品名称 2、包装规格 3、包装类型 4、HS 编码/CIQ 编码 5、如已在我国食品安全监督管理部门注册请提供相关注册证	1、重点关注企业提供的注册产品是否符合相关标准中术语与定义; 2、特殊医学用途配方食品是否已经获得注	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming <input type="checkbox"/> 不符合	

	<p>准 辅 食 营 养 补 充 品 》(GB 22570-2014);《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013);《食品安全国家标准 运动营养食品通则》(GB 24154-2015);《食品安全国家标准 孕妇及乳母营养补充食品》(GB 31601-2015);</p> <p>2. 《中华人民共和国食品安全法》第八十条 特殊医学用途配方食品应当经国务院食品安全监督管理部门注册。</p> <p>第八十二条 保健食品、特殊医学用途配方食品、婴幼儿配方乳粉的注册人或者备案人应当对其提交材料的真实性负责。省级以上人民政府食品安全监督管理部门应当及时公布注册或者备案的保健食品、特殊医学用途配方食品、婴幼儿配方乳粉目录,并对注册或者备案中获知的企业商业秘密予以保密。保健食品、特殊医学用途配方食品、婴幼</p>	<p>书(特殊医学用途配方食品包括特殊医学用途配方食品和特殊医学用途婴儿配方食品)。</p> <p>1. Product name 2. Packaging specifications 3. Packaging type 4. HS code/CIQ code 5. If you have registered with the food safety supervision and administration department in China, please provide the relevant registration certificate (special medical use formula food includes special medical use formula food and special medical use infant formula food).</p>	<p>册证书,产品的产品名称包装规格、包装类型与注册证书所载明是否一致;</p> <p>1. Focus on whether the registered products provided by the enterprise meet the terms and definitions in the relevant standards; 2. Whether the formula food for special medical purpose has obtained the registration certificate, and whether the product name, packaging specification and packaging type of the product are consistent with those stated in the registration certificate;</p>		
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	<p>儿配方乳粉生产企业应当按照注册或者备案的产品配方、生产工艺等技术要求组织生产。</p> <p>1. "National Food Safety Standard for Infant Formula" (GB 10765-2010); "National Food Safety Standard for Older Infants and Young Children's Formula" (GB10767-2010); "National Food Safety Standard for Infant Formula for Special Medical Purposes" (GB 25596-2010); "National Food Safety Standard for Complementary Foods and Nutritional Supplements" (GB 22570-2014); "National Food Safety Standard General Rules for Formulas for Special Medical Purposes" (GB 29922-2013); "National Food Safety Standard for Sports Nutrition" General Principles of Food" (GB 24154-2015); "National Food Safety Standard Nutritional Supplements for Pregnant Women and Lactating Mothers" (GB 31601-2015);</p> <p>2. Article 80 of the "Food Safety Law of the People's Republic of China" The formula food for special medical purpose shall be registered with the food safety supervision and administration department of the State</p>				
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	<p>Council. Article 82 The registrant or filer of health food, formula food for special medical purpose, and infant formula milk powder shall be responsible for the authenticity of the materials submitted. The food safety supervision and administration department of the people's government at or above the provincial level shall publish the registered or filed catalogues of health food, formula food for special medical purpose, and infant formula milk powder in a timely manner, and keep confidential the business secrets of enterprises learned during the registration or filing. Manufacturers of health food, formula food for special medical purposes, and infant formula milk powder shall organize production in accordance with the registered or filed product formula, production process and other technical requirements.</p>				
2.原辅料和包装材料 Raw and packaging materials					
2.1 产品原料 Product raw materials	1. 《食品安全国家标准 婴儿配方食品》(GB 10765-2010) ;《食品安全国家标准 特殊医学用途婴儿配方食品通则》(GB 25596-2010)	1、按添加量从大到小的顺序提供产品配料 , 并注明比例 ; 2、如主要原料含有生乳、蔬菜 (含栽培食用菌)、肉及肉制品、	1、重点关注动物源性和植物源性食品原料的疫病疫情风险 , 如来自疫区 , 后续的生产工	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming <input type="checkbox"/> 不符合	

	<p>(不使用果糖、未经预糊化的淀粉；所使用的原料和食品添加剂不应含有谷蛋白。不使用辐照原料；不使用氢化植物油；)</p> <p>2 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013)(7.2.5 对大豆原料应确保脲酶活性为阴性。)</p> <p>3、《食品安全国家标准 辅食营养补充品》(GB 22570-2014) (3.2.1 食物基质应为可即食的食物原料，其质量应符合相应的标准和(或)相关规定。</p> <p>3.2.2 大豆类及其加工制品应经过高温等工艺处理以消除抗营养因子，如胰蛋白酶抑制物等。</p> <p>4. 《食品安全国家标准 孕妇及乳母营养补充食品》(GB 31601-2015)(3.2.1 优质蛋白质应来源于大豆、大豆制品、乳类、乳制品中的一种或一种以上，其含量占孕妇及乳母营养补充食品质量</p>	<p>蜂产品、水产品、燕窝的，需提供原料原产国；</p> <p>3、如使用大豆作为主要原料需注明是否为转基因大豆。</p> <p>1. Provide product ingredients in the order of adding amount from large to small, and indicate the proportion;</p> <p>2. If the main raw materials contain raw milk, vegetables (including cultivated edible fungi), meat and meat products, bee products, aquatic products, and bird's nest, the country of origin of the raw materials must be provided;</p> <p>3. If soybean is used as the main raw material, it must be indicated whether it is genetically modified.</p>	<p>艺是否可以去除风险；</p> <p>2、如使用大豆作为原料，应关注是否为转基因大豆，大豆类及其加工制品应经过高温等工艺处理以消除抗营养因子；</p> <p>3、孕妇和乳母营养补充食品中，优质蛋白质应来源于大豆、大豆制品、乳类、乳制品中的一种或一种以上，其含量占孕妇及乳母营养补充食品质量的18%-35%；</p> <p>4、婴幼儿食品不能使用氢化油脂，不使用经辐照处理过的原料。</p> <p>1. Focus on the epidemic risk of animal-derived and</p>		
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	<p>的 18%-35%。</p> <p>5. 孕妇及乳母营养补充食品所使用的原料应符合相应的标准和 (或) 有关规定。</p> <p>6. 大豆类及其加工制品应经过高温等工艺处理以消除抗营养因子 , 如胰蛋白酶抑制物等。</p> <p>7. 不应使用氢化油脂。</p> <p>8. 《食品安全国家标准 罐头食品生产卫生规范》(GB 8950-2016)(7.2 畜肉、禽、水产、果蔬等原料应按相关标准验收合格后方可投入使用。</p> <p>9. 《食品安全国家标准 饮料生产卫生规范》(GB 12695-2016)</p> <p>(菌种 使用菌种的产品,菌种必须符合国家有关标准或规定,菌种在投产使用前必须严格检验其特性,确保其活性,防止其他杂菌污染。发酵用菌种应根据菌种的特性在适宜温度下贮存,以保持</p>		<p>plant-derived food raw materials, such as from the epidemic area, whether the subsequent production process can remove the risk.</p> <p>2. If soybeans are used as raw materials, attention should be paid to whether they are genetically modified. Soybeans and their processed products should be treated with high temperature and other processes to eliminate anti-nutritional factors;</p> <p>3. In nutritional supplements for pregnant women and lactating mothers, high-quality protein should be derived from one or more sources like soybeans, soybean products, milk, and dairy products, and its content accounts for 18%-35% of the quality of nutritional supplements for pregnant</p>		
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	<p>菌种的活力。)</p> <p>1. "National Food Safety Standard - Infant Formula" (GB 10765-2010); "National Food Safety Standard - General Rules for Infant Formula for Special Medical Purposes" (GB 25596-2010) (raw materials and food additives used should not contain gluten, fructose, pregelatinized starch, irradiated raw materials and hydrogenated vegetable oils are not allowed)</p> <p>2."National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (7.2.5 For soybean raw materials, ensure that the urease activity is negative.)</p> <p>3. "National Food Safety Standard - Complementary Foods and Nutritional Supplements" (GB 22570-2014) (3.2.1 The quality of raw materials used to produce ready-to-eat food should meet the corresponding standards and/or relevant regulations.</p> <p>4. "National Food Safety Standard Nutritional Supplements for Pregnant Women and Lactating Mothers" (GB 31601-2015) (3.2.1 High-quality protein should be derived from</p>		<p>women and lactating mothers. ;</p> <p>4. In infant food cannot be used hydrogenated oils and fats, and irradiated raw materials</p>		
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	<p>one or more source like soybeans, soybean products, milk, and dairy products, and its content accounts for 18%-35% of the quality of nutritional supplements for pregnant women and lactating mothers.</p> <p>5.The raw materials used in the nutritional supplement food for pregnant women and lactating mothers shall comply with the corresponding standards and/or relevant regulations.</p> <p>6. Soybeans and their processed products should be treated at high temperature to eliminate anti-nutritional factors, such as trypsin inhibitors.</p> <p>7. Hydrogenated greases should not be used.</p> <p>8. "National Food Safety Standard - Hygienic Specifications for Canned Food Production" (GB 8950-2016) (7.2 Raw materials such as meat, poultry, aquatic products, fruits and vegetables should be accepted according to relevant standards before they can be used.</p> <p>9. "National Food Safety Standard Hygienic Specification for Beverage Production" (GB 12695-2016) (Bacterial strains For products using strains, the strains must meet the relevant national standards or regulations, and</p>				
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	the strains must be strictly tested for their characteristics before being put into production to ensure their activity and prevent contamination by other miscellaneous bacteria. The bacteria used for fermentation should be stored at suitable temperature according to the characteristics of the bacteria to maintain its vitality.)				
2.2 其他原料 (如使用食品添加剂 , 需要按照《食品安全国家标准 食品添加剂使用标准》 (GB 2760-2014) 种类	<p>1.《食品安全国家标准 特殊医学用途配方食品通则》 (GB 29922-2013) (7.3.8 对贮存期间质量容易发生变化的维生素和矿物质等营养强化剂应进行原料合格验证 , 必要时进行检验 , 以确保其符合原料规定的要求。</p> <p>2.食品添加剂和食品营养强化剂</p> <p>2.1 应依照食品安全国家标准规定的品种、范围、用量合理使用食品添加剂和食品营养强化剂。</p> <p>2.2 在使用时对食品添加剂和食品营养强化剂准确称量 , 并做好记录。)</p> <p>《食品安全国家标准 辅食营养补充品》</p>	<p>按照《食品安全国家标准 食品添加剂使用标准》 (GB 2760-2014) 种类提供所使用添加剂的名称。</p> <p>Provide the names of the additives used in accordance with the "National Food Safety Standard - Standard for the Use of Food Additives" (GB 2760-2014).</p>	<p>应依照食品安全国家标准规定的品种、范围、用量合理使用食品添加剂和食品营养强化剂。</p> <p>Food additives and food nutrition fortifiers should be used reasonably in accordance with the variety, scope and dosage specified in the national food safety standards.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p>	

<p>进 行 标 注) Other raw materials (such as the use of food additives, needs to be marked in accordance with the "National Food Safety Standard for the Use of Food Additives" (GB 2760-2014))</p>	<p>(GB 22570-2014) (食品添加剂的使用应符《食品安全国家 标准 食品添加剂使用标准 》(GB 2760-2014) 的规定。 营养强化剂的使用应符合《食品安全国家 标准 食品营养强化剂使用标准 》 (GB 14880-2012) 的规定。其中 , 乙二胺四乙酸铁钠的每日份添加量以 铁计不应超过2.8 mg。 食品添加剂和营养强化剂的质量规格 应符合相应的标准和有关规定。)</p> <p>1. "National Food Safety Standards General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (7.3.8 For nutritional fortifiers such as vitamins and minerals whose quality is likely to change during storage, raw material qualification verification shall be carried out, and inspection shall be carried out when necessary to ensure that they meet the requirements of raw material regulations. 2. Food additives and nutrition fortifiers</p>				
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	<p>2.1 Food additives and food nutrition fortifiers should be used rationally in accordance with the variety, scope and dosage specified in the national food safety standards.</p> <p>2.2 Accurately weigh food additives and food nutrition fortifiers when they are in use, and make records.) "National Food Safety Standard - Complementary Food Nutritional Supplements" (GB 22570-2014) (The use of food additives shall comply with the provisions of the "National Food Safety Standard - Standard for the Use of Food Additives" (GB 2760-2014). The use of nutritional fortifiers shall comply with the provisions of the "National Food Safety Standard - Standard for the Use of Food Nutrition Fortifiers" (GB 14880-2012). Among them, the daily dose of sodium ferric EDTA should not exceed 2.8 mg calculated as iron. The quality specifications of food additives and nutritional fortifiers shall comply with the corresponding standards and relevant regulations.)</p>				
2.3 各种原料执行的质量安	<p>《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013)(7.2.1 采购的食品原料应当查验供货者的许可</p>	<p>提供原料执行的质量安全标准，包括指标、限量、验收要求。 Provide quality and safety standards for raw material, including</p>	<p>对照相关国标，判别使用原料是否符合我国要求。</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> 符合</p> <p><input type="checkbox"/> Non-conforming</p>	

<p>全标准</p> <p>Quality and safety standards for various raw materials</p>	<p>证和产品合格证明文件；对无法提供合格证明文件食品原料，应当依照食品安全标准进行检验。)</p> <p>"National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013) (7.2.1 When purchase food raw materials supplier's license shall be checked so as the and product qualification certificate; For raw materials that cannot provide qualification certificates, they shall be inspected in accordance with food safety standards.)</p>	<p>indicators, limits, and acceptance requirements.</p>	<p>Check the relevant national standards to determine whether the raw materials used meet the requirements of China.</p>	<p><input type="checkbox"/>不符合</p>	
<p>2.4 原料供应方审核制度</p> <p>Raw material supplier audit system</p>	<p>GB 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013) (企业应建立供应商管理制度，规定供应商的选择、审核、评估程序。应对供应商采用的流程和安全措施进行评估，必要时进行定期现场评审或对流程进行监控。)</p> <p>"National Food Safety Standard General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (Enterprises should establish a supplier management system to stipulate</p>	<p>提供原料供应方的审核制度，包括供应商选择、审核、评估程序等，合格供应商表及 1 份主要原料供应商考核记录。</p> <p>Provide the audit system for raw material suppliers, including supplier selection, audit, evaluation procedures, etc., a list of qualified suppliers and 1 assessment record of major raw material suppliers.</p>	<p>重点审核是否满足原料执行的质量安全标准要求。</p> <p>Focus on reviewing whether the quality and safety standards for raw materials are met.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p>	

	procedures for supplier selection, review, and evaluation. The processes and security measures adopted by the supplier shall be assessed and, where necessary, periodic on-site reviews shall be conducted or processes shall be monitored.)				
2.5 产品内包装材料 Product inner packaging material	<p>1. 《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013) (7.4.1 采购食品包装材料、容器、洗涤剂、消毒剂等食品相关产品应当查验产品的合格证明文件 , 实行许可管理的食品相关产品还应查验供货者的许可证。食品包装材料等食品相关产品必须经过验收合格后方可使用。)</p> <p>2. 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013) (8.6 包装</p> <p>2.1 应符合《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013) 的相关规定。</p>	<p>详细描述产品的内包装材料的构成 , 列出内包装材料质量安全标准。</p> <p>Describe the composition of the inner packaging material of the product in detail, list the quality and safety standards of the inner packaging material.</p>	<p>重点关注企业是否提供了内包材安全证明信息 , 如企业声明等。</p> <p>Focus on whether the company has provided safety certification information for inner packaging materials, such as company declarations.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> 符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> 不符合</p>	

	<p>2.2 包装材料应清洁、无毒且符合国家相关规定。</p> <p>2.3 包装材料或包装用气体应无毒，并且在特定贮存和使用条件下不影响食品的安全和产品特性。</p> <p>2.4 可重复使用的包装材料如玻璃瓶、不锈钢容器等在使用前应彻底清洗，并进行必要的消毒。)</p> <p>3. 《食品安全国家标准 罐头食品生产卫生规范》(GB 8950-2016)(罐头食品所使用包装容器的材质、内涂料、接缝补涂料及密封胶应符合相关安全标准要求。)</p> <p>4. 《食品安全国家标准 饮料生产卫生规范》(GB 12695-2016)</p> <p>(包装容器、材料应符合相关标准或规定,并且在特定贮存和使用条件下不影响食品的安全和产品特性。食品接触的包装容器、材料用添加剂应符合</p>				
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	<p>GB9685及相关法规要求。)</p> <p>1. "National Food Safety Standard General Hygienic Specification for Food Production" (GB14881-2013) (7.4.1 When purchasing food packaging materials, containers, detergents, disinfectants and other food-related products, the product certification documents shall be checked so as those related to the supplier. Food-related products should also check the supplier's license. Food-related products such as food packaging materials must pass the inspection before they can be used.)</p> <p>2. "National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (8.6 Packaging</p> <p>2.1 It should comply with the relevant provisions of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013).</p> <p>2.2 Packaging materials should be clean, non-toxic and comply with relevant national regulations.</p> <p>2.3 Packaging materials or gases used for packaging purpose should be non-toxic and not affect food safety and product characteristics under specific storage and use conditions.</p>				
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	<p>2.4 Reusable packaging materials such as glass bottles and stainless steel containers should be thoroughly cleaned and disinfected as necessary before use.)</p> <p>3. "National Food Safety Standard Hygienic Specification for Canned Food Production" (GB 8950-2016) (The material, inner coating, seam repair coating and sealant of packaging containers used for canned food shall meet the requirements of relevant safety standards.)</p> <p>4. "National Food Safety Standard - Hygienic Specification for Beverage Production" (GB 12695-2016) (Packaging containers and materials shall comply with relevant standards or regulations, and shall not affect the safety and product characteristics of food under specific storage and use conditions. Food-contact packaging containers and materials shall comply with the requirements of GB9685 and relevant regulations.)</p>				
3.生产工艺信息 Production process information					
3.1 提供详细的生产工艺流	1. 《食品安全国家标准 粉状婴幼儿配方食品良好生产规范》(GB 23790-2010)(9.6 特定处理步骤)。	<p>提供详细流程图 ,流程图应包含工艺参数并进行工艺描述。</p> <p>Provide a detailed flow chart, which should include process description</p>	<p>1、关注企业的生产工艺是否符合产品定义 ;</p> <p>2、如属于婴幼儿配方</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> 符合</p> <p><input type="checkbox"/> Non-conforming</p>	

<p>程图，流程图应包含工艺参数并进行工艺描述。</p> <p>Provide a detailed production process flow chart, which should contain process parameters and describe the process.</p>	<p>2. 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013) (8.7.1 一般要求：特殊医学用途配方食品的生产工艺中各处理工序应分别符合相应的工艺特定处理步骤的要求，并应符合 8.7.2 ~ 8.7.9 的规定) 。</p> <p>1. "National Food Safety Standard - Good Manufacturing Practice for Powdered Infant Formula" (GB 23790-2010) (9.6 Specific processing steps).</p> <p>2. "National Food Safety Standard General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (8.7.1 General requirements: each food for special medical purposes processing steps should meet its specific the requirements and should comply with articles 8.7.2 ~ 8.7.9).</p>	<p>and parameters.</p>	<p>食品和特殊医学用途配方食品类别的，要重点关注其中属于特定处理步骤的加工工艺是否符合相关标准。</p> <p>1. Pay attention to whether the production process of the enterprise conforms to the product definition; 2. If it belongs to the categories of infant formula food and formula food for special medical purposes, it is necessary to pay attention to whether the processing technology belonging to the specific processing steps meets the relevant standards.</p>	<p><input type="checkbox"/>不符合</p>	
<p>3.2 提供覆盖整条生产线的清洗消毒</p>	<p>1. 《食品安全国家标准 粉状婴幼儿配方食品良好生产规范》(GB 23790-2010)(7.3 清洗和消毒)。</p> <p>2. 《食品安全国家标准 特殊医学用途</p>	<p>提供覆盖整条生产线的清洗消毒程序。</p> <p>Provide cleaning and disinfection procedures covering the entire production line</p>	<p>关注清洗消毒效果验证。</p> <p>Pay attention to the verification of cleaning and disinfection effects.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p>	

<p>程序。</p> <p>Provide cleaning and disinfection procedures for the entire production line.</p>	<p>配方食品通则》(GB 29922-2013)(6.3 清洁和消毒)。</p> <p>3. 《食品安全国家标准 食品生产通用卫生规范 》 (GB14881-2013) (8.2.1 清洁和消毒)。</p> <p>1. "National Food Safety Standard - Good Manufacturing Practice for Powdered Infant Formula" (GB 23790-2010) (7.3 Cleaning and Disinfection).</p> <p>2. "National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (6.3 Cleaning and Disinfection).</p> <p>3. "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013) (8.2.1 Cleaning and Disinfection).</p>				
<p>3.3. 提供主要设备清单及生产能力。</p> <p>Provide main equipment</p>	<p>1. 《食品安全国家标准 食品生产通用卫生规范 》 (GB14881-2013) (5.2 设备)。</p> <p>2. 《食品安全国家标准 罐头食品生产卫生规范》 (GB 8950-2016) (5.5 杀菌设备)。</p>	<p>1.提供关键工序设备的名称、型号、设计加工能力及图片。</p> <p>1. Provide name, model, design, processing capability and pictures of key process equipment</p>	<p>企业应具备与生产工艺相应的加工设备。</p> <p>Enterprises should have processing equipment corresponding to the production process.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p>	

list and production capacity.	<p>3. 《食品安全国家标准 饮料生产卫生规范》(GB 12695-2016)(5.3 设备)</p> <p>1. "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013) (5.2 Equipment).</p> <p>2. "National Food Safety Standard - Hygienic Specification for Canned Food Production" (GB 8950-2016) (5.5 Sterilization Equipment).</p> <p>3. "National Food Safety Standard Hygienic Specification for Beverage Production" (GB 12695-2016) (5.3 Equipment).</p>				
<p>3.4 提供危害分析工作单及 HACCP 计划表。</p> <p>Provide hazard analysis worksheet and HACCP plan sheet.</p>	<p>1. 《食品安全国家标准 危害分析与关键控制点(HACCP)体系 食品生产企业通用要求 》(GB/T 27341-2009)</p> <p>2. 《食品安全国家标准 食品生产通用卫生规范 》(GB14881-2013) (8.1.1 应通过危害分析方法明确生产过程中的食品安全关键环节，并设立食品安全关键环节的控制措施。在关键环节所在区域，应配备相关的文件以落实控制措施，如配料(投料) 表、岗位操作规程等。</p>	<p>1. 生产加工危害分析单和 HACCP 计划表。</p> <p>2.提供 CCP 点的监控记录，如有，请提供 CCP 关键限制发生偏离的相关措施及记录。</p> <p>1. Production and processing hazard analysis sheet and HACCP plan.</p> <p>2. Provide monitoring records of CCP points, if any, please provide relevant measures and records of deviations from CCP key restrictions.</p>	<p>1.重点关注 CCP 点的设置和关键限制以及纠偏和验证实施情况。</p> <p>2.HACCP 计划是否包括所有申请注册产品。</p> <p>1. Focus on the setting of CCP points and key constraints as well as correcting and verifying implementation.</p> <p>2. Whether the HACCP plan includes all products applied for registration.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p> <p><input type="checkbox"/>Not applicable</p> <p><input type="checkbox"/>不适用</p>	

	<p>鼓励采用危害分析与关键控制点体系 (HACCP) 对生产过程进行食品安全控制。)</p> <p>3. 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013) (8.7.7 粉状特殊医学用途食品干法工艺和干湿法复合工艺中干混合的关键因素控制)</p> <p>1. "National Food Safety Standard Hazard Analysis and Critical Control Points (HACCP) System General Requirements for Food Production Enterprises" (GB/T 27341-2009).</p> <p>2. "National Food Safety Standard General Hygienic Specifications for Food Production" (GB14881-2013) (8.1.1 The key links of food safety in the production process should be identified through hazard analysis methods, control measures for key links of food safety should be established. In the area where key links are located, relevant documents should be provided to implement control measures, such as ingredient (feeding) tables, post operation procedures, etc. The use of Hazard</p>				
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	<p>Analysis and Critical Control Points (HACCP) systems for food safety control of production processes is encouraged.)</p> <p>3. "National Food Safety Standard - General Principles of Formulas for Special Medical Purposes" (GB 29922-2013) (8.7.7 Control of key factors relevant to dry mixing in dry process and dry-wet composite process of powdered food for special medical purposes)</p>				
<p>3.5 如有热力杀菌工艺, 需提供热力杀菌有效性证明材料及具体的杀菌温度和时间要求</p> <p>If there is a thermal sterilization process, it</p>	<p>1. 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013)(C.6 产品的热处理)。</p> <p>2. 《食品安全国家标准 罐头食品生产卫生规范》(GB 8950-2016)(5.5.2 杀菌设备安装后应对其进行热分布测试, 确认热分布均匀后方可投入使用。在保证热量供给和传热介质通畅的前提下, 每三年至少进行一次热分布测试。如该设备结构、管道、阀门、程序等发生变化及必要时应重新进行热分布测试。)</p> <p>3. 《食品安全国家标准 饮料生产卫生规范》(GB 12695-2016)(8.2.7 杀菌</p>	<p>如有热力杀菌工艺, 需提供热力杀菌有效性证明材料及具体的杀菌温度和时间要求。</p> <p>If there is a thermal sterilization process, it is necessary to provide proof materials for the effectiveness of thermal sterilization and specific sterilization temperature and time requirements.</p>	<p>1、杀菌工序应有相应的杀菌参数(如温度、时间、压力等)的记录或图表, 并定时检查是否达到规定要求。</p> <p>The sterilization process should have records or charts of the corresponding sterilization parameters (such as temperature, time, pressure, etc.), and regularly check whether the specified requirements are met.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p> <p><input type="checkbox"/>Not applicable</p> <p><input type="checkbox"/>不适用</p>	

is necessary to provide proof materials for the effectiveness of thermal sterilization and specific sterilization temperature and time requirements	<p>工序应有相应的杀菌参数(如温度、时间、压力等)的记录或图表,并定时检查是否达到规定要求。)</p> <p>1. "National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (C.6 Heat Treatment of Products).</p> <p>2. "National Food Safety Standard Hygienic Specification for Canned Food Production" (GB 8950-2016) (5.5.2 After the sterilization equipment is installed, the heat distribution test should be carried out to confirm that the heat distribution is uniform before it can be put into use. After ensuring the heat supply and heat transfer on the premise is unobstructed, the heat distribution test shall be carried out at least once every three years. If the structure of the equipment, pipes, valves, procedures, etc. are changed or intervention is necessary, the heat distribution test shall be carried out again.)</p> <p>3. "National Food Safety Standard Beverage Production Hygiene Specification" (GB 12695-2016) (8.2.7 The sterilization process should have records or charts of the</p>				
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	corresponding sterilization parameters (such as temperature, time, pressure, etc.), and regularly check whether the requirements are met.)				
4.产品质量安全控制体系 Product Quality Safety Control System					
4.1 产品 在线控制 检查 Product online	1.《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013)(8 生产过程的食品安全控制); 2.《食品安全国家标准 特殊医学用途	1、应提交完整的产品在线检查计划, 应按照工序列明检查内容、参数、频次和验证频率; 2、粉状婴幼儿配方食品、特殊	1.在线控制措施, 是否对企业所分析的危害进行了有效监控; 2.重点关注在线检查	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming <input type="checkbox"/> 不符合	

control inspection	<p>配方食品通则》(GB 29922-2013) (8 生产过程的食品安全控制);</p> <p>均匀度 :</p> <p>3. 《食品安全国家标准 特殊医学用途 配方食品通则》(GB 29922-2013) (5.1.3.7 用于生产的计量器具和关键 仪表应定期进行校验。用于干混合的 设备应能保证产品混合均匀。</p> <p>8.7.7.3 与混合均匀性有关的关键工 艺参数 (如混合时间等) 应予以验证 ; 对 混合的均匀性应进行确认。)</p> <p>4 .《食品安全国家标准 粉状婴幼儿配 方食品良好生产规范》(GB 23790-2010) (9.6.5.3 与混合均匀性 有关的关键工艺参数 (如混合时间等) 应予以验证 ; 对混合的均匀性应进行 确认。)</p> <p>密封性 :</p> <p>5. 《食品安全国家标准 罐头食品生产</p>	<p>医学用途配方食品请提供均匀 度验证的相关资料 ;</p> <p>3、属于罐头类特膳食品的 , 需 提供终产品密封性的相关资料。</p> <p>1. A complete product online inspection plan should be submitted, and the inspection content, parameters, frequency and verification frequency should be specified in accordance with the process sequence;</p> <p>2. For powdered infant formula food and formula food for special medical purpose, please provide relevant information on uniformity verification;</p> <p>3. For canned special dietary products, relevant information on the sealing of the final product shall be provided.</p>	<p>设置点参数和频次与 HACCP 计划和工艺流程 的一致性 ;</p> <p>3.如有金检仪、温度计 等 , 要关注校准、维护 记录。</p> <p>4. 有均匀度要求的产 品 (粉状婴幼儿配方食 品、特殊医学用途配方 食品) 是否对混合的均 匀性进行过确认 ;</p> <p>5、属于罐头类的特膳 食品要对其终产品的 密封性进行检查 ;</p> <p>1. Online control measures, whether the hazards analyzed by the enterprise have been effectively monitored;</p> <p>2. Focus on the consistency of online inspection set point</p>		
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	<p>卫生规范》(GB 8950-2016)(8.4.3 密封性能的检查</p> <p>每班开机前,应检查封口设备的密封质量,合格后投入生产。</p> <p>生产过程中应按封口操作规程的要求,做好外观质量和密封性能的控制与检测,并做好记录。</p> <p>密封后的半成品应在2h内进行杀菌。)</p> <p>1. "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013) (8 Food Safety Control During Production);</p> <p>2. "National Food Safety Standards General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (8 Food safety control during production)</p> <p>Evenness:</p> <p>3. "National Food Safety Standard General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (5.1.3.7 Measuring instruments and key instruments used for production should be regularly calibrated. Equipment used for dry mixing</p>		<p>parameters and frequency with the HACCP plan and process flow;</p> <p>3. If there are gold detectors, thermometers, etc., pay attention to calibration and maintenance records.</p> <p>4. Whether the mixing uniformity of products with uniformity requirements (powdered formula for infants and young children, formula food for special medical purposes) has been confirmed;</p> <p>5. Special dietary products belonging to the canned category should be inspected for the airtightness of the final product;</p>		
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	<p>should be able to ensure product mixing evenly. 8.7.7.3 The key process parameters related to mixing uniformity (such as mixing time, etc.) should be verified; the mixing uniformity should be confirmed.)</p> <p>4. National Food Safety Standard Good Manufacturing Practice for Powdered Infant Formula (GB 23790-2010) (9.6.5.3 The key process parameters related to mixing uniformity (such as mixing time, etc.) should be verified and undergo verification.)</p> <p>Sealing</p> <p>5. "National Food Safety Standard - Hygienic Specification for Canned Food Production" (GB 8950-2016) (8.4.3 Inspection of sealing performance: before starting each shift, sealing equipment should be checked and put into production after passing the test. On sealing quality. During the production process, control and inspection about the sealing quality and external appearance should done according to the requirements of the sealing operation procedures, and records should be made. The sealed semi-finished product should be sterilized within 2 hours.)</p>				
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<p>4.2 终产品的检测及放行</p> <p>Final product testing and release</p>	<p>1.《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013)(9 检验)。</p> <p>2.《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013)(10.1 应符合《食品安全国家标准 食品生产通用卫生规范》(GB14881-2013)的相关规定。</p> <p>3.应逐批抽取代表性成品样品,按国家相关法规和标准的规定进行检验并保留样品。</p> <p>4. 应加强实验室质量管理,确保检验结果的准确性和真实性。</p> <p>5.《食品安全国家标准 饮料生产卫生规范》(GB 12695-2016)(9.2 灌装封盖(封口)后应对产品的外观、灌装量、容器状况、封盖(封口)严密性和可见物等进行检验。)</p> <p>1. "National Food Safety Standard - General Hygienic Specification for Food Production"</p>	<p>提供终产品放行的测试方案、检测标准及放行要求。</p> <p>Provide the testing plan, standards and release requirements for final product.</p>	<p>终产品检验报告应覆盖我国食品安全国家标准的限量要求。</p> <p>The final product inspection report should cover the limit requirements of Chinese' national food safety standards.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/>符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/>不符合</p>	
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	<p>(GB14881-2013) (9 inspection).</p> <p>2. "National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (article 10.1 It shall comply with the relevant provisions of "National Food Safety Standard - General Hygienic Practice for Food Production" (GB14881-2013).</p> <p>3. Representative samples of finished products should be taken batch by batch, inspected according to the relevant national regulations and standards, and the samples should be retained.</p> <p>4. Laboratory quality management should be strengthened to ensure the accuracy and authenticity of test results.</p> <p>5. "National Food Safety Standard Beverage Production Hygiene Specification" (GB 12695-2016) (9.2 After filling and capping (sealing),test should be carried out to check the appearance, filling amount, container condition, sealing/capping tightness)</p>				
4.3 霉菌、酵母、异物控制	1. 《食品安全国家标准 粉状婴幼儿配方食品良好生产规范》(GB 23790-2010)(附录A (规范性附录)	<p>提供霉菌、酵母、异物控制措施。</p> <p>Provides mold, yeast, foreign body control measures.</p>	1. 监控重点应涵盖微生物容易藏匿和滋生区域；	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming	

<p>措施</p> <p>Mold, yeast, foreign bodies control measures</p>	<p>粉状婴幼儿配方食品清洁作业区沙门氏菌、阪崎肠杆菌和其他肠杆菌的环境监控指南；</p> <p>2. 生产企业应采用有效的异物控制措施，预防和检查异物，如设置筛网、强磁铁、金属探测器等，对这些措施应实施过程监控或有效性验证。）</p> <p>3. 《食品安全国家标准 特殊医学用途配方食品通则》(GB 29922-2013)(附录B 粉状特殊医学用途配方食品清洁作业区沙门氏菌、阪崎肠杆菌和其他肠杆菌的环境监控指南；</p> <p>4. 生产企业应采用有效的异物控制措施，预防和检查异物，如设置筛网、强磁铁、金属探测器等，对这些措施应实施过程监控或有效性验证。）</p> <p>5. 《食品安全国家标准 食品生产通用卫生规范 》(GB14881-2013)(附录A食品加工过程的微生物监控程序指</p>		<p>2. 是否定期检查用于防止异物的相关设施的完整性。</p> <p>1. The focus of monitoring should cover areas where microorganisms are easy to hide and breed;</p> <p>2. Whether the integrity of the relevant facilities for preventing foreign objects is regularly checked.</p>	<p>□不符合</p>	
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	<p>南；</p> <p>6. 应建立防止异物污染的管理制度 ,分析可能的污染源和污染途径 ,并制定相应的控制计划和控制程序。</p> <p>1. "National Food Safety Standard for Good Manufacturing Practice for Powdered Infant and Young Children Formula" (GB 23790-2010) (Appendix A (normative) Salmonella, Enterobacter sakazakii and other Enterobacteriaceae in the cleaning work area of powdered infant formula environmental monitoring guidelines;</p> <p>2. Manufacturers should adopt effective foreign body control measures to prevent and check foreign bodies, such as setting screens, strong magnets, metal detectors, etc., and process monitoring or effectiveness verification should be implemented for these measures.)</p> <p>3. "National Food Safety Standard - General Rules for Formulas for Special Medical Purposes" (GB 29922-2013) (Appendix B Guidelines for Environmental Monitoring of Salmonella, Enterobacter sakazakii and other Enterobacteria in the Cleaning Operation Areas of Powdered Formulas for Special Medical</p>				
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	Purposes; 4. Manufacturers should adopt effective foreign body control measures to prevent and check foreign bodies, such as setting screens, strong magnets, metal detectors, etc., and process monitoring or effectiveness verification should be implemented for these measures.) 5. "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013) (Appendix A Guidelines for Microbiological Monitoring Procedures in Food Processing; 6. A management system to prevent foreign body contamination should be established, the possible sources and routes of contamination should be analyzed, and corresponding control plans and procedures should be formulated.				
5.声明 Statement					
5.1 企业声明 Declaration by Enterprise	1. 《中华人民共和国进口食品境外生产企业注册管理规定》(海关总署令第248号) 第八条、第九条。 1. Articles 8 and 9 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas		1. 应有法人签名和公司盖章。 1. Signature of legal person and company seal	<input type="checkbox"/> Conforming <input type="checkbox"/> 符合 <input type="checkbox"/> Non-conforming <input type="checkbox"/> 不符合	

	Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs)				
5.2 主管 当局确认 Confirmation by Competent Authority	<p>1. 《中华人民共和国进口食品境外生产企业注册管理规定》(海关总署令第248号) 第八条、第九条。</p> <p>1. Articles 8 and 9 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs)</p>		<p>1. 应有主管当局人员签名和主管当局盖章。</p> <p>1. Signature of principal and seal of competent authority</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> 符合</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> 不符合</p>	