



6 EQUIVALENCY STATEMENT ON LAW & REGULATION

Please provide supporting documents to prove equivalency to Chinese dairy related GMP (see attached form).

The authoritative versions of Australia's legislation and standards are on the Australian Government ComLaw website at <http://www.comlaw.gov.au>

The *Export Control (Milk and Milk Products) Orders 2005* and the standards under Chapter 3 and 4 of the *Australia New Zealand Food Standards Code* contain the mandated legislative requirements for Good Manufacturing Practice (GMP) for dairy products. Specific references in the *Export Control (Milk and Milk Products) Orders 2005* and the following standards under the *Australia New Zealand Food Standards Code* (referred to as the *Food Code*) are included in the table in the document.

These standards in the *Food Code* apply to all dairy products manufactured or sold in Australia. The latest versions of these legislative standards are available at:

- *Standard 3.2.1 Food Safety Programs* – <http://www.comlaw.gov.au/Details/F2011C00551>
- *Standard 3.2.2 Food Safety Practices and General Requirements* – <http://www.comlaw.gov.au/Details/F2012C00767>
- *Standard 3.2.3 Food Premises and Equipment* – <http://www.comlaw.gov.au/Details/F2012C00774>
- *Standard 4.2.4 Primary Production and Processing Standard for Dairy Products* – <http://www.comlaw.gov.au/Details/F2012C00458>

The *Export Control Act 1982* and *Export Control (Prescribed Goods) Orders 2005* provide the legislative basis for the *Export Control (Milk and Milk Products) Orders 2005*.

The *Export Control Act 1982* applies to all exports of prescribed foods exported from Australia. This legislation provides powers to the Department of Agriculture provide an inspection service, issue certificates to meet specific importing country authority requirements and prohibit the export of goods, unless prescribed conditions are met. The latest version of this legislation is available at <http://www.comlaw.gov.au/Details/C2013C00265>

The *Export Control (Prescribed Goods) Orders 2005* provide administrative details for all *commodities* under Department of Agriculture control (so called prescribed goods). The requirements in this legislation include mandatory export registration, issuance of export permits prior to leaving Australia, and the requirement for export certificates to be issued in line with importing country requirements. The latest version of this legislation is available at <http://www.comlaw.gov.au/Details/F2005C00433>

The *Export Control (Milk and Milk Products) Orders 2005* applies to all prescribed milk and milk products exported from Australia. The latest version of this legislation is available at <http://www.comlaw.gov.au/Details/F2007C00778>

The Standards in the *Food Code* are legislative instruments under the *Legislative Instruments Act 2003* which is available at <http://www.comlaw.gov.au/Details/C2013C00347>



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In addition, to the Chapter 3 and Chapter 4 standards of the *Food Code* that relate to GMP, there are specific Chapter 1 general food standards and Chapter 2 product standards that relate to dairy products, infant formula and foods for infants.

The latest versions of these legislative standards which apply to all food manufactured or sold in Australia are available at:

- *Standard 1.1.1 Preliminary Provisions - Application, Interpretation and General Prohibitions* – <http://www.comlaw.gov.au/Details/F2013C00618>
- *Standard 1.1.2 Supplementary Definitions for Foods* – <http://www.comlaw.gov.au/Details/F2011C00530>
- *Standard 1.1A Transitional Standard for Health Claims* – <http://www.comlaw.gov.au/Details/F2013C00095>
- *Standard 1.2.1. Requirements* – <http://www.comlaw.gov.au/Details/F2013C00617>
- *Standard 1.2.2 Food Identification Requirements* – <http://www.comlaw.gov.au/Details/F2009C00836>
- *Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations* – <http://www.comlaw.gov.au/Details/F2011C00610>
- *Standard 1.2.4 Labelling of Ingredients* – <http://www.comlaw.gov.au/Details/F2013C00983>
- *Standard 1.2.5 Date Marking of Packaged Food* – <http://www.comlaw.gov.au/Details/F2012C00762>
- *Standard 1.2.6 Directions for Use and Storage* – <http://www.comlaw.gov.au/Details/F2011C00535>
- *Standard 1.2.7 Nutrition, Health and Related Claims* – <http://www.comlaw.gov.au/Details/F2008B00607>
- *Standard 1.2.8 Nutrition Information Requirements* – <http://www.comlaw.gov.au/Details/F2013C00098>
- *Standard 1.2.9 Legibility Requirements* – <http://www.comlaw.gov.au/Details/F2011C00563>
- *Standard 1.2.10 Characterising Ingredients and Components of Food* – <http://www.comlaw.gov.au/Details/F2011C00538>
- *Standard 1.2.11 Country of Origin Requirements* – <http://www.comlaw.gov.au/Details/F2013L00051>
- *Standard 1.3.1 Food Additives* – <http://www.comlaw.gov.au/Details/F2013C00984>
- *Standard 1.3.2 Vitamins and Minerals* – <http://www.comlaw.gov.au/Details/F2013C00099>
- *Standard 1.3.3 Processing Aids* – <http://www.comlaw.gov.au/Details/F2014C00038>
- *Standard 1.3.4 Identity and Purity* – <http://www.comlaw.gov.au/Details/F2013C00137>



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- *Standard 1.4.1 Contaminants and Natural Toxicants – <http://www.comlaw.gov.au/Details/F2013C00140>*
- *Standard 1.4.2 Maximum Residue Limits – <http://www.comlaw.gov.au/Details/F2014C00081>*
- *Standard 1.4.3 Articles and Materials in Contact with Food – <http://www.comlaw.gov.au/Details/F2008B00620>*
- *Standard 1.6.1 Microbiological Limits for Food – <http://www.comlaw.gov.au/Details/F2012C00862>*
- *Standard 1.6.2 Processing Requirements – <http://www.comlaw.gov.au/Details/F2013C00028>*
- *Standard 2.5.1 Milk – <http://www.comlaw.gov.au/Details/F2012C00772>*
- *Standard 2.5.2 Cream – <http://www.comlaw.gov.au/Details/F2011C00621>*
- *Standard 2.5.3 Fermented Milk Products – <http://www.comlaw.gov.au/Details/F2011C00622>*
- *Standard 2.5.4 Cheese – <http://www.comlaw.gov.au/Details/F2013C00144>*
- *Standard 2.5.5 Butter – <http://www.comlaw.gov.au/Details/F2011C00616>*
- *Standard 2.5.6 Ice Cream – <http://www.comlaw.gov.au/Details/F2011C00583>*
- *Standard 2.5.7 Dried Milks, Evaporated Milks and Condensed Milks – <http://www.comlaw.gov.au/Details/F2011C00584>*
- *Standard 2.9.1 Infant Formula Products – <http://www.comlaw.gov.au/Details/F2013C00621>*
- *Standard 2.9.2 Foods for Infants – <http://www.comlaw.gov.au/Details/F2013C00622>*
- *Standard 2.9.3 Formulated Meal Replacements and Formulated Supplementary Foods – <http://www.comlaw.gov.au/Details/F2013C00623>*
- *Standard 2.9.4 Formulated Supplementary Sports Foods – <http://www.comlaw.gov.au/Details/F2013C00104>*
- *Standard 2.9.5 Food for Special Medical Purposes – <http://www.comlaw.gov.au/Details/F2013C00147>*



CHINESE OPERATIONAL STANDARD 中国生产规范标准		NATIONAL LEGISLATION/ STANDARD 本国法规/标准
Good Manufacturing Practice of Dairy Products (GB12693-2010)		
Scope	1	
Location and factory environment	4	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Schedule 1, Part 1, Part 10, Plans and specifications.
Factory buildings and workshops	5	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 1, Registration; and – Schedule 3, Division IV, Section 20, Water supply; and – Part 10, Schedule 3, Division IV, Section 19, Ventilation; and – Part 10, Schedule 3, Division IV, Section 18, Lighting; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 2, Design and construction of food premises; and – Division 2, Section 4, Water supply; and – Division 2, Section 7, Ventilation; and – Division 2, Section 8, Lighting. • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Dairy primary production requirements.
Facilities	5.3	
Air facilities	5.3.5	
Lighting facilities	5.3.6	
Factory buildings shall have sufficient natural lighting or artificial lighting, coefficient of lighting in workshops shall not below standard IV. Mixed intensity of illumination of work faces in quality control areas shall not below 540lx, work faces in processing areas not below 220lx, other areas not below 110lx, light sensitive testing areas are excluded. Light source shall not change the colour of food products.	5.3.6.1	
Equipment	6	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 1, Part 1, Plans and specifications; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 4, Section 12, Fixtures, fittings and equipment: and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 4, Specific requirements.
Health management	7	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 4, Division II, Hygiene controls for processing; and – Part 10, Schedule 4, Division III, Personal hygiene and health requirements; and • Standard 3.2.2 Food Safety Practices and General Requirements:
Requirements of staff health and hygiene	7.4	



		<ul style="list-style-type: none"> – Division 4, Section 14, Health of food handlers; and – Division 4, Section 14, Hygiene of food handlers.
Requirements of raw materials and packing materials	8	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 4, Part 1, General requirements; and – Part 10, Schedule 5, Part 1, Sourcing; and – Part 10, Schedule 4, Part 1, Section 10, Measures to prevent contamination. – Part 10, Schedule 5, Part 2, Temperature controls; • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 3, Section 6, Food storage; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 3, Dairy collection and transport; and – Division 3, Time and temperature controls; and – Division 4, Dairy processing.
Procurement and acceptance requirements of raw materials and packing materials	8.2	
Transportation and storage requirements of raw materials and packing materials	8.3	
Transportation and storage of raw milk	8.3.2	
Raw milk, within two hours after milking, shall be lowered to temperature of 0°C~4°C. It shall be transported with insulated milk tankers. Transportation vehicles shall have sound proves and records.	8.3.2.2	
Food safety control in production processes	9	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005 <ul style="list-style-type: none"> – Part 10, Schedule 5, Division III, Pasteurisation and other treatments; and – Part 10, Schedule 5, Part 3, Preserving milk; and – Division 3, Section 7, Food processing; and – Part 10, Schedule 3, Division IV, Section 19, Ventilation. • Standard 3.2.1 Food Safety Programs: <ul style="list-style-type: none"> – Division 2, Section 3, General food safety program requirements; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 3, Section 6, Food storage; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products <ul style="list-style-type: none"> – Division 4, Dairy processing.
Microbial contamination control	9.1	
Air cleanliness of work areas	9.1.3	
Total count of colony of air for clean work areas shall be controlled below 30CFU/ⅢⅢ in accordance with determination of natural sedimentation method of GB/T 18204.1.	9.1.3.2	
Inspection	10	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 6, Part 1, Method of sampling and examination.
Storage and transportation of products	11	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 5, Part 2, Section 7, Storage, handling, loading and transport; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 3, Dairy collection and transport.
Traceability and re-call of products	12	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 1, Division I, Section 3, Objectives of these



		<p>Orders; and</p> <ul style="list-style-type: none"> – Part 10, Schedule 8, Part 2, Supply and preparation; <ul style="list-style-type: none"> • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 4, Section 12, Food recall; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 5, Tracing; and – Division 4, Section 14, Product tracing.
Training	13	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 3, Division III, Management Practices; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 6, Skills and knowledge.
Management agencies and personnel	14	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 3, Division III, Section 3, Management practices, organisational structure, resources and competence; and – Part 3, Division III, Section 7, Internal audit and management review; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 6, Skills and knowledge.
Management of records and documents	15	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 2, Division III, Section 7, Internal audit and management review; and – Part 10, Schedule 2, Division III, Section 10, Requirement to retain documents; and – Part 10, Schedule 8, Part 1, General requirements; and • Standard 3.2.1 Food Safety Programs: <ul style="list-style-type: none"> – Division 2, Section 5, Content of food safety programs.
Requirements of the application of computer system	Appendix A	This is not specified in Australian legislation.



CHINESE OPERATIONAL STANDARD 中国生产规范标准		NATIONAL LEGISLATION/ STANDARD 本国法规/标准
Good Manufacturing Practice of Powdered Infant and Young Children Formula Food (GB 23790-2010)		
Scope	1	
Location and factory environment	4	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 1, Part 1, Plans and specifications; and – Part 10, Schedule 3, Division I, Section 4 Immediate surrounds.
Factory buildings and workshops	5	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 1, Registration; and – Part 10, Schedule 3, Division I, Section 2 Construction of premises; and – Part 10, Schedule 3, Division I, Premises, equipment and vehicles; and – Part 10, Schedule 3, Division II, Cleaning and sanitising facilities; and – Part 10, Schedule 3, Division IV, Essential services; and – Part 10, Schedule 3, Division IV, Section 20, Water supply; and – Part 10, Schedule 3, Part 1, Division III, Section 14, Amenities; and • Standard 3.2.3 Food Premises and Equipment: <ul style="list-style-type: none"> – Division 2, Design and construction of food premises; and – Division 2, Section 4, Water supply; and – Division 4, Section 12, General requirements; and – Division 4, Section 14, Hand washing facilities; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 4, Specific requirements.
Design and layout	5.1	
Factory buildings and workshops shall be reasonably designed, constructed and planned with relevant facilities and equipment in conjunction with production, to prevent disoperation of breeding and contamination of microorganisms, in particularly to prevent contamination of Salmonella and <i>Enterobacter sakazakii</i> (Cronobacter genera), at the same time to avoid or reduce the presence or reproduction of these bacteria in hiding places. The design shall consider below factors to prevent breeding of microorganisms.	5.1.2	
The design shall isolate and separate wet areas and dry areas, shall effectively control contamination caused by staff, equipment and materials flow, and shall prevent Salmonella and <i>Enterobacter sakazakii</i> entering into cleaning work area.	5.1.2.1	
Cleanliness levels of work areas shall be determined in accordance with requirements of production technology, health and quality. In principle, they shall be divided as general work areas, quasi cleaning work areas and cleaning work areas. Cleaning work areas shall be equipped with independent air purification system with filter devices and shall maintain positive pressure.	5.1.5	
Facilities	5.3	



Personal hygiene facilities	5.3.4	
Equipment	6	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 1, Part 1, Plans and specifications; and • Standard 3.2.3 Food Premises and Equipment: <ul style="list-style-type: none"> – Division 4, Section 12, Fixtures, fittings and equipment; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 4, Specific requirements.
Health Management	7	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 4, Division II, Hygiene controls for processing; and – Part 10, Schedule 4, Division III, Personal hygiene and health requirements; and – Part 10, Schedule 4, Operational hygiene; and – Part 10, Schedule 4, Division II, Part 3.1 Requirement to clean and maintain; and – Part 10, Schedule 4, Division III, Personal hygiene and health requirements; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 5, Section 20, Cleaning and Sanitising of specific equipment; and – Division 4, Section 14, Health of food handlers; and – Division 4, Section 15, Hygiene of food handlers.
Requirements of staff health and hygiene	7.4	
Staff in cleaning work areas shall wear work clothes (or disposable work clothes) in accordance with hygiene requirements for the work areas and shall be provided with hats, masks and work shoes. Staff in quasi cleaning or general work areas shall wear work cloths in accordance with hygiene requirements for corresponding work areas and shall be provided with hats and work shoes. Work clothes and work shoes for cleaning and quasi cleaning work areas shall not be worn beyond designated areas.	7.4.2	
Requirements of raw materials and packing materials	8	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 4, Part 1, General requirements; and – Part 10, Schedule 5, Part 1, Sourcing; and – Part 10, Schedule 4, Part 1, Section 10, Measures to prevent contamination; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 4, Dairy Processing.
Procurement and acceptance of raw materials and packing materials	8.2	
For ingredients directly adding into dry mix process, producers shall take measures to ensure microbial indicators of the ingredients meet requirements of product standard, for soybean ingredients, the urease activity is negative. Processes and safety measures adopted by suppliers shall be assessed and regular onsite audit or processes monitoring shall be conducted when necessary.	8.2.2	
Food safety control in production processes	9	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 5, Division III, Pasteurisation and



Specific processing steps	9.6	<p>other treatments; and</p> <ul style="list-style-type: none"> • Standard 3.2.1 Food Safety Programs: <ul style="list-style-type: none"> – Division 2, Section 3, General food safety program requirements; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 3, Section 6, Food Storage; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 4, Dairy Processing.
Heat treatment (wet production process and wet and dry bounding process)	9.6.1	
Dry mix	9.6.5	
Bare powder process in contact with open air environment (such as premix and packing, mixing and feeding) shall be carried out in cleaning work areas. The temperature and relative humidity of the cleaning work areas shall correspond with production processes of powdered infant and young children formula food. The temperature shall not be higher than 25° C and relative humidity shall be lower than 65% when there are no special requirements.	9.6.5.1	
Inspection	10	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 9, Division V, Sampling and analysis; and • Standard 3.2.2 Food Safety Practices and General Requirements: <ul style="list-style-type: none"> – Division 3, Section 12, Food recall.
Storage and transportation of products	11	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 5, Part 2, Section 7 Storage, handling, loading and transport.
Traceability and re-call of products	12	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 1, Division I, Section 3, Objectives of these Orders; and – Part 10, Schedule 8, Part 2, Supply and preparation; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 5, Tracing; and – Division 4, Section 14, Product tracing
Training	13	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 3, Division III, Management Practices; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 6, Skills and knowledge.
Management agencies and personnel	14	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 3, Division III, Section 3, Management practices, organisational structure, resources and competence; and – Part 3, Division III, Section 7, Internal audit and management review; and • Standard 4.2.4 Primary Production and Processing Standard for Dairy Products: <ul style="list-style-type: none"> – Division 2, Section 6, Skills and knowledge.
Management of records and documents	15	<ul style="list-style-type: none"> • Export Control (Milk and Milk Products) Orders 2005: <ul style="list-style-type: none"> – Part 10, Schedule 2, Division III, Section 7, Internal



		<p>audit and management review; and</p> <ul style="list-style-type: none">– Part 10, Schedule 2, Division III, Section 10, Requirement to retain documents; and– Part 10, Schedule 8, Part 1, General requirements; and <ul style="list-style-type: none">• Standard 3.2.1 Food Safety Programs:<ul style="list-style-type: none">– Division 2, Section 5, Content of food safety programs.
Effective monitoring and assessment of food safety control measures	16	<ul style="list-style-type: none">• Export Control (Milk and Milk Products) Orders 2005:<ul style="list-style-type: none">– Part 10, Schedule 4, Operational hygiene.