MEAT & LIVESTOCK AUSTRALIA

WHITE PAPER

Accessing the China nutraceuticals market

A guide for Australian bovine collagen producers

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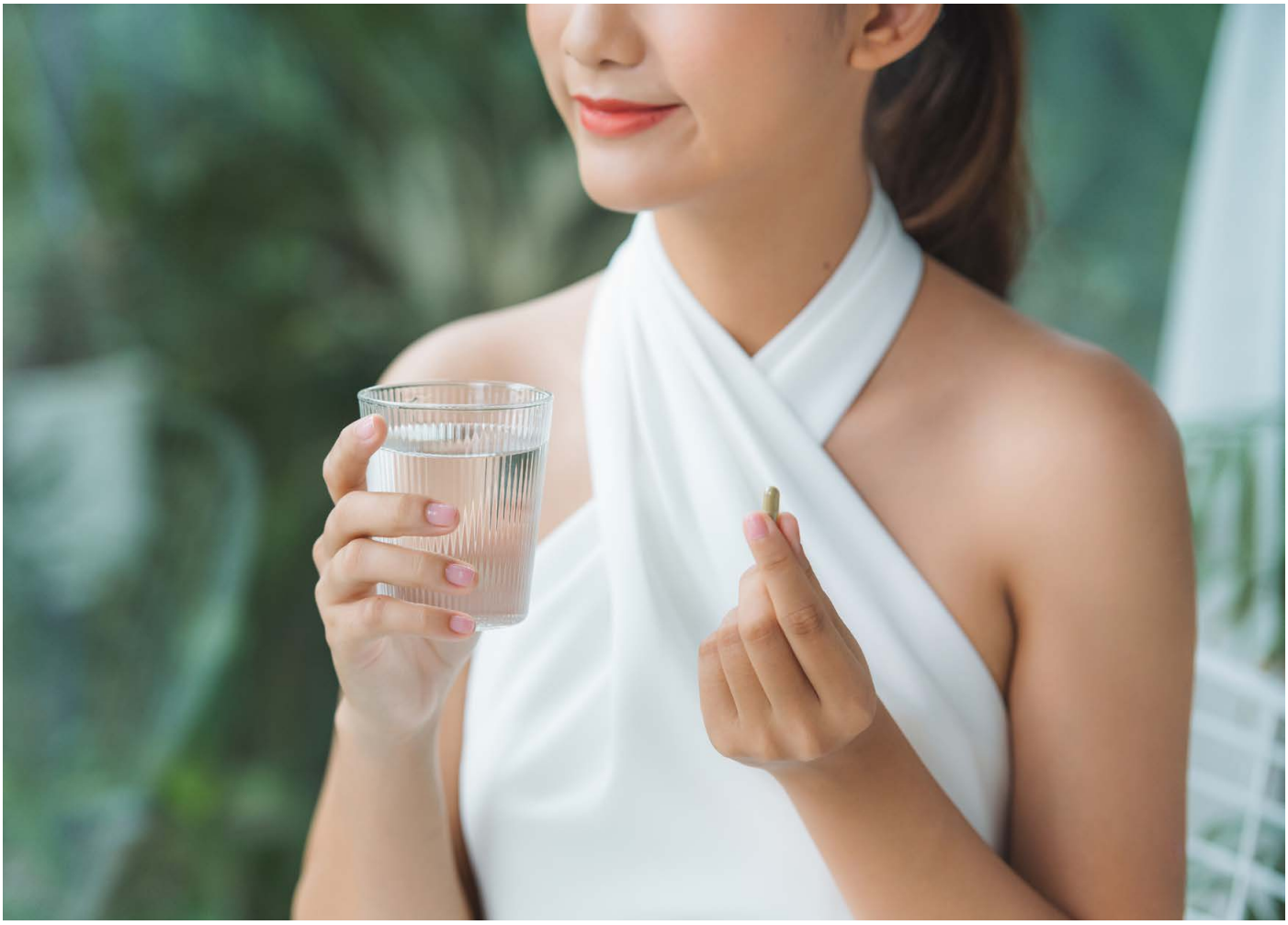

Table of contents

1. Executive summary **4**

2. Objectives **5**

3. Market overview – bovine collagen in China **6**

3.1 Key market segments for bovine collagen 6

4. China market entry – step-by-step summary of key focus areas **7**

5. China regulatory requirements for imported bovine collagen **8**

5.1 GACC registration of the overseas manufacturer 8

5.2 BSE risk assessment and source country eligibility 8

5.3 Meeting the China National Food Standard 8

5.4 Product packaging and labelling 9

5.5 Practical guidance for Australian exporters 10

5.6 HS Codes 10

5.7 Regulatory summary and checklist for Australian exporters 11

5.8 Health foods ("Blue Hat") – regulatory pathway 11

6. Route-to-market options for Australian bovine collagen producers **13**

6.1 Route-to-market selection matrix 15

6.2 Route-to-market models – important considerations 16

7. Major potential customers in China for bovine collagen **17**

7.1 Nutraceutical manufacturers 17

7.2 Collagen manufacturers and distributors 18

7.3 Major potential customer groups in Australia for bovine collagen 19

7.4 China-based agents/distributors for foreign food and nutraceutical ingredients 20

8. Selling to contract manufacturers and brands – what customers look for **21**

9. Assessing the market opportunity – attending trade shows in China **22**

10. Entering the China market – some lessons from the frontline **23**

11. Resources **24**

12. Sources **25**

Attachment A **26**

GB 31645—2018 – National Food Safety Standard 27

Annex A Determination of the proportion of collagen peptides with relative molecular mass <10,000 29

Attachment B **30**

Checklist for appointing a China-based agent or distributor in the food ingredients industry 30

1. Executive summary

Australian producers seeking to export bovine collagen into China's rapidly growing nutraceuticals sector face a complex but navigable landscape. This guide summarises market demand, export processes and regulatory obligations to help companies make informed decisions and avoid costly missteps. China's collagen peptides market is expanding steadily thanks to rising health consciousness, an ageing population and growing sports participation. Collagen applications span four major segments: food and beverage, nutraceutical supplements, pharmaceutical and biomedical uses, and personal care and cosmetics. Demand drivers include consumers' focus on joint and muscle health, beauty and anti-ageing benefits, and the convenience of functional foods and ready-to-drink beverages.

While potential opportunities exist, Australian producers need to be aware that China's import controls and technical standards are stringent. The General Administration of Customs of the People's Republic of China (GACC) oversees facility registration, declaration procedures and labelling requirements under Decree 248 and Decree 249. Products must comply with GB 31645-2018 for bovine collagen peptides, meet strict microbiological and heavy-metal limits and provide certificates of analysis and BSE/TSE safety statements.

The guide outlines a step-by-step pathway, from defining product specifications and assessing market demand through customs classification, regulatory pathway selection, documentation and import clearance. It summarises route-to-market options and highlights possible Chinese manufacturing and distribution customers. Practical tips for doing business in China and a list of references and resources conclude the guide. By following these recommendations, Australian exporters can better navigate China's regulatory environment and capitalise on the country's appetite for high-quality bovine collagen ingredients.

2. Objectives

The goal of this guide is to serve as a resource for Australian companies looking to explore opportunities for the export of bovine collagen as a raw ingredient (not as a finished, packaged product for retail consumer sale) to the China market.

The China collagen peptides market is witnessing robust growth, fueled by increasing consumer demand for natural and functional ingredients. Key market players are investing in research and development to introduce innovative collagen peptide products tailored to Chinese consumer preferences. With a burgeoning health and wellness sector and a rapidly expanding middle class, the market is poised for continued expansion in the foreseeable future.

While the market offers significant potential opportunities, Australian exporters need to be aware that China's regulatory system for food safety, imported ingredients and finished products in the food, beverages, nutraceuticals and pharmaceutical industries have significantly strengthened in recent years. In January 2022, Decree 248 and Decree 249 came into effect, creating new challenges for companies wishing to enter the Chinese market, especially for so called high-risk category products like meat and meat-derived products and ingredients.

Notably, the General Administration of Customs of the People's Republic of China (GACC) plans to amend Decree 248, highlighting the importance of staying updated with the latest regulations, which can be particularly challenging for foreign companies.

These guidelines will cover aspects of the export process, including protocols and company approvals, requirements for exporters, an overview of the main laws and regulations relating to meat-derived ingredient imports as well as the primary routes to market.

The focus of these guidelines is primarily for bovine collagen as an ingredient for the nutraceuticals industry. Nutraceuticals are food-derived products that offer health benefits beyond basic nutrition. They are essentially a combination of "nutrition" and "pharmaceutical", providing both nutritional value and therapeutic effects. These products can range from functional foods and dietary supplements to medical foods used to promote overall wellbeing and support various healthy bodily functions.

3. Market overview – bovine collagen in China

The Chinese market for bovine collagen is expanding steadily, supported by rising health consciousness, an ageing population, growing sports participation and the affordability of bovine raw materials. Bovine collagen continues to dominate collagen applications in food and beverages, nutraceuticals, pharmaceuticals and cosmetics, but the landscape is evolving as synthetic biotechnology introduces recombinant alternatives.

China's overall nutraceuticals market was valued at approximately US$45.5 billion in 2023 and is projected to reach US$58.2 billion by 2027. Collagen supplements occupy a growing share of this market with the collagen-supplement industry in China forecast to expand at about 5.4% per year through 2034. This growth is driven by greater health awareness, an ageing population and increased participation in sports and fitness, which is boosting demand for collagen-infused drinks and functional foods.

China is expected to become the fastest-growing region in the world for collagen, spurred by strong demand for bovine and marine collagen in supplements, joint-health products and foods.

3.1 Key market segments for bovine collagen

Food and beverage

- Functional foods and beverages are the fastest-growing applications. The food and beverage segment holds a significant share of the China collagen market due to its multi-functionality; collagen is added to protein bars, snacks, smoothies and protein drinks to aid muscle repair and maintenance. Collagen also provides structural support to ligaments and tendons and may reduce exercise-related injuries.
- Drivers:
  - growing participation in sports and fitness
  - popularity of high-protein snacks
  - convenience of collagen-infused ready-to-drink beverages
  - COVID-19 pandemic – increased consumer focus on immunity and wellness, encouraging adoption of collagen-enriched foods.

Nutraceuticals (dietary supplements)

- Collagen supplements are part of the broader health-supplements market. Nutraceutical collagen products include powders, capsules, gummies and liquids. Athletes and sports enthusiasts consume collagen peptides for joint health and muscle recovery, while the aging population uses supplements for skin elasticity and bone health.
- Animal-based collagen remains dominant because bovine collagen is cheaper and has high extraction yields. Emerging recombinant collagen products (e.g. those launched by L'Oréal and Chinese biotech firms) illustrate a nascent but growing segment.

Pharmaceuticals and biomedical applications

- Pharmaceuticals are one of the largest applications for bovine collagen. Bovine collagen is used as a bone void filler, wound-healing scaffold and ingredient in nutraceutical products for arthritis, bone disease and skin disease. Its compatibility with human tissue and ability to be sterilised also make it suitable for implants.
- In China, active collagen derived from bovine tendons is produced by companies such as Carel Bio, which supplies high-purity collagen for medical dressings. The Chinese pharmaceutical sector has also embraced recombinant humanised collagen for injectable fillers and wound dressings. However, demand for bovine collagen persists because it is cost-effective and readily available.

Personal care and cosmetics

- Personal care and cosmetics constitute the largest end-user segment in China's collagen market. Chinese consumers associate collagen with anti-aging benefits; products include topical creams, serums and ingestible beauty supplements. L'Oréal's launch of collagen creams containing recombinant collagen indicates international brands' confidence in this market. Domestic brands also incorporate both bovine and recombinant collagens in anti-aging products.
- Drivers:
  - high beauty consciousness
  - popularity of K-beauty trends
  - celebrity endorsements and social-media influence
  - aging population
  - rising disposable incomes.
- A number of private market research companies sell detailed reports on the China collagen market which may be of interest to potential exporters to the market:
  - Mark Wide Research – markwideresearch.com/china-collagen-peptides-market/
  - MRA – marketreportanalytics.com
  - Verified Market Research – verifiedmarketresearch.com/product/china-collagen-market

4. China market entry – step-by-step summary of key focus areas

Step	Description
1. Define product and capacity	Finalise specifications (mesh size, average MW/Da), form (powder/granule), pack size, quality certifications (HACCP, ISO, FSSC), annual volumes, and target pricing. Align with collagen peptide specs meeting Chinese GB standards.
2. Assess the market	Analyse China's bovine collagen peptides demand. Map competitors, pricing, and identify key application segments. Gather customer technical needs and validate whether the business case is viable.
3. Customs classification and taxes	Confirm HS code. Likely HS code: 35040090. Duty rate under MFN: 6.5%. Check eligibility for zero duty under ChAFTA.
4. Regulatory pathway	Determine if your facility requires GACC registration under Decree 248 (CIFER). Ensure importer record filing is completed. Confirm whether specific CNCA product listing applies for collagen peptides.
5. Standards and quality	Applicable China GB standard: GB 31645-2018. Set specification limits for microbiological indicators, heavy metals, nitrogen content, ash, and moisture. Arrange accredited lab tests and Certificates of Analysis (COA).
6. Close compliance gaps	If tests do not meet GB standard limits or customer specifications, adjust manufacturing processes or raw material sourcing, then retest.
7. Build import documentation pack	Prepare: COA, DAFF health certificate, Certificate of Origin (ChAFTA format if applicable), BSE/TSE statement, commercial invoice, packing list, sales contract, and bill of lading/ air waybill.
8. Select route-to-market	Direct sale to Chinese manufacturer, Distributor/Importer-of-Record, Direct import via your own Trading WFOE, Bonded warehouse + Vendor Managed Inventory (VMI).
9. Target customers and materials	Identify OEM/ODM nutraceutical manufacturers, ingredient distributors, and leading brands. Localise datasheets/specifications into Chinese with applications guidance.
10. Technical engagement and trials	Provide samples, technical support, complete vendor approval, run pilot trials, and agree on MOQs, forecasts, payment terms, and a quality agreement.
11. Pre-shipment readiness	Perform batch testing against GB standard, prepare Chinese packaging and labelling, confirm port-specific CIQ requirements.
12. Import and clearance	Arrange CIQ inspection /quarantine, customs declaration, apply ChAFTA preference if eligible, pay duties and VAT, release goods and deliver to customer or bonded stock.
13. Launch and scale	Position local stock or VMI for key accounts, conduct QA audits, monitor GB standard updates and Decree amendments, protect IP and Chinese brand name, co-develop marketing with customers.
14. Continuous improvement	Pursue cost reductions, develop new SKUs (mesh size/MW variations), improve service levels. Expand customer base and consider finished goods OEM for branded customers.

5. China regulatory requirements for imported bovine collagen

Food, beverage and nutraceuticals

Before considering exporting to China, it is critical that Australian companies assess their products against the technical requirements for the import and sale of bovine collagen peptides to the China market.

Powdered bovine collagen hydrolysate for human consumption falls under:

- 'Food products of animal origin' (even when highly processed like peptides), thus requiring animal-origin controls. It is not exempt just because it is not traditional meat as collagen is still derived from bovine hides/bones and China treats this cautiously due to BSE (mad cow disease) risk.

Australian exporters of powdered bovine collagen hydrolysate (collagen peptides) to China must have the product manufactured in a facility that is approved and registered with Chinese authorities, specifically under the GACC (General Administration of Customs of China).

Key requirements

5.1 GACC registration of the overseas manufacturer

Under **Decree 248**, effective from January 1, 2022:

- All overseas food manufacturers exporting edible products of animal origin (including bovine collagen peptides) must register with GACC.
- Registration must be done through the competent authority of the exporting country. In Australia's case, this is DAFF (Department of Agriculture, Fisheries and Forestry).
- Australian manufacturers/processors/cold stores shipping food to China must be registered in GACC's China Import Food Enterprise Registration (CIFER) system system (Decree 248). DAFF provides detailed guidelines on this process at agriculture.gov.au/biosecurity-trade/export/export-registration-with-china/cifer
- The Australian manufacturing facility will be issued a unique GACC registration number, which must appear on:
  - the inner and outer packaging
  - the export health certificate
  - all labelling and customs declarations.

5.2 BSE risk assessment and source country eligibility

China prohibits imports of collagen from BSE high-risk countries.

- **Australia is classified as BSE negligible risk**, which permits bovine-sourced collagen imports. Still, exporters must declare the source materials (e.g. hides vs bones) and must prove that no prohibited materials (e.g. spinal cord, brain) are used.

5.3 Meeting the China National Food Standard

Products must meet the **China National Food Standard GB 31645-2018** (食品安全国家标准 胶原蛋白肽) – National Food Safety Standard Collagen Peptides.

A copy of the standard in English (unofficial translation) is shown at Attachment A. English language translations are also available online from various China regulatory consulting agencies. (e.g. Chemlinked – chemlinked.com)

The key technical requirements from the China's National Food Safety Standard GB 31645-2018 (Collagen Peptides) for hydrolysed collagen used in foods and supplements are as follows:

GB 31645-2018 National Food Safety Standard – Collagen Peptides

This standard is mandatory in China; imported products must comply. For full details, refer to the official Chinese text of GB 31645-2018.

1. Scope

This standard applies to edible collagen peptides (hydrolysed collagen) produced from animal connective tissues (e.g. skin, bones, tendons) through processes such as hydrolysis, extraction, and purification, intended for use in foods and dietary supplements.

2. Technical requirements

2.1 Raw material requirements

- Source materials must come from edible parts of healthy animals, complying with relevant veterinary quarantine regulations.
- No genetically modified (GMO) or prohibited tissues (e.g. diseased animals) may be used.

2.2 Processing requirements

- Production must follow Good Manufacturing Practices (GMP).
- Hydrolysis methods – enzymatic, acid, or alkaline hydrolysis (residual solvents must meet safety limits).
- No toxic or harmful additives permitted during processing.

2.3 Sensory requirements

- Appearance – light yellow or white powder/granules.
- Odour and taste – characteristic collagen peptide smell, no off-flavours.

2.4 Physicochemical indicators

Parameter	Requirement
Protein (dry basis)	≥ 90%
Ash (dry basis)	≤ 5.0%
Moisture	≤ 7.0%
Peptide content (MW < 10,000 Da)	≥ 90%
Hydroxyproline	≥ 3.0%
Lead (Pb)	≤ 0.5mg/kg
Arsenic (As)	≤ 0.3mg/kg
Mercury (Hg)	≤ 0.1mg/kg
Cadmium (Cd)	≤ 0.1mg/kg

2.5 Microbiological limits

Micro-organism	Limit
Total plate count (CFU/g)	≤ 10,000
Coliforms (MPN/100g)	≤ 40
Staphylococcus aureus	Not detected/25g
Salmonella	Not detected/25g
Molds & yeasts (CFU/g)	≤ 50

2.6 Food additives

- Only additives approved under GB 2760 may be used, within specified limits.

2.7 Labeling requirements

- Must be labeled as “Collagen Peptides” or “Hydrolyzed Collagen”.
- Indicate source animal (e.g., bovine, porcine, marine).
- If used in supplements, comply with GB 13432 labeling rules.

3. Testing methods

- Protein: GB 5009.5
- Heavy metals: GB 5009.12–5009.17
- Microbiological tests: GB 4789.2–4789.15

4. Storage and transport

- Store in dry, cool conditions, protected from contamination.

Important: If products do not meet these technical standards, producers will need to undertake processing changes to ensure all technical requirements of the standard are met or exceeded.

Cosmetic or pharmaceutical use

Imported bovine collagen hydrolysate (collagen peptides) intended for cosmetic or pharmaceutical use in China are subject to different regulatory pathways than food ingredients and registration is required depending on the product type and intended use.

While these guidelines focus primarily on the food, beverage and nutraceuticals category, a summary of cosmetics and pharmaceuticals use is as follows:

Cosmetics

Regulated by: National Medical Products Administration (NMPA)

If used as a cosmetic raw material (e.g. in creams, masks, serums), hydrolysed collagen must comply with the following:

- Registration or filing depending on risk category (e.g. preservatives = high risk).
  Hydrolysed collagen is considered an existing raw material, but safety documentation is still required:
  - source of raw material (e.g., bovine, porcine, marine)
  - BSE/TSE risk control certification
  - manufacturing process and quality standards
  - toxicological safety data.
- A Chinese Responsible Person (CRP) is required to submit filings through the Cosmetic Ingredients Registration Platform.

Pharmaceuticals

Regulated by: NMPA (National Medical Products Administration)

When used as an API or excipient in pharmaceuticals:

- Requires registration under the NMPA Drug Master File (DMF) system.
  Full technical dossier is required, including:
  - GMP compliance
  - quality specifications and testing methods
  - BSE/TSE-free certification
  - safety and preclinical data (depending on use).
- Additional requirements apply for injectables or TCM products.

5.4 Product packaging and labelling

Chinese regulatory requirements for packaging and labelling powdered bovine collagen hydrolysate (collagen peptides) shipped in bulk as an ingredient for food or nutraceutical manufacturing are noted below.

Relevant regulatory framework

Chinese laws and standards governing food imports consist of the Food Safety Law, General Administration of Customs (GACC) decrees and national standards. Key instruments that may affect bulk collagen peptide shipments are summarised below.

- Food Safety Law and Implementing Rules: prohibits the use of packaging materials that may contaminate food and require packaging to prevent contamination and spoilage.
- GACC Decree 248 – Registration of Overseas Manufacturers: requires all overseas manufacturers of imported food to register with GACC. Edible collagen and gelatin are classified under “other food”; Australian producers must hold a Chinese registration number for export. (See details shown in Section 5.1 above)

- GACC Decree 249 – Administrative Measures on Import Food Safety: requires imported food to be packaged in food-grade materials that prevent contamination, damage, soaking or penetration and prohibits labels such as “not for human consumption”. Labels and logos must comply with Chinese laws.
- GB 7718-2011/GB 7718-2025 – General Principles for the Labelling of Pre-Packaged Foods: applies to consumer-facing labels. GB 7718-2025 (effective 16 March 2027) adds requirements for dual date marking, descending ingredient order, allergen declarations, digital labelling and stricter design. These rules apply once the collagen peptide powder is repacked into retail packages.
- GB 28050-2011 – Nutrition Labelling of Pre-Packaged Foods: requires a “4 plus 1” nutrition facts table (energy, protein, fat, carbohydrate and sodium) on retail packages; not applicable to bulk ingredients.
- AQSIQ/GACC Notice 27 (2012): requires importers of pre-packaged foods to file Chinese labels, the original label and translation, nutrition test reports and business licences with customs for the first import.

Application to bulk collagen peptides

Collagen peptides shipped in bulk for further manufacturing are treated as raw food ingredients rather than pre-packaged retail foods. Therefore, consumer labelling rules under GB 7718 are generally not triggered until the product is repackaged for sale. Key considerations for bulk shipments include:

- **Packaging** – bulk powders must be placed in new, food-grade packaging such as lined bags or drums. Packaging must be sealed, clean and capable of preventing contamination, damage, soaking or penetration. Decree 249 expressly forbids statements like “not for human consumption” and requires packaging to comply with China’s food-contact material standards.
- **Outer-package labelling** – a full consumer label is not required on bulk sacks. However, each bag or drum should bear a basic label (or be accompanied by a document) indicating the product name (e.g. “Hydrolysed bovine collagen”), net weight, batch/lot number, production date, shelf life or retest date, storage conditions, country of origin (Australia), manufacturer/exporter name and address, and the GACC registration number. Information may be in English, but a Chinese translation should be provided in the shipping documents.
- **Documentation** – importers must obtain a quarantine import permit and provide a health certificate, invoice, packing list and bill of lading. Because the product is not for direct consumption, nutrition tests and Chinese consumer labels are generally not required until the ingredient is packaged for retail sale.
- **Facility registration** – the Australian manufacturer must complete GACC registration under Decree 248 and include the issued registration number on shipping documentation.
- **Repackaging and retail sale** – if the collagen powder is later repacked into retail packages, the Chinese entity responsible for repacking must ensure the finished product label complies with GB 7718 (and GB 28050) and, from 2027, GB 7718-2025. This means adding a Chinese label with ingredient list, net content, production and expiry dates, storage conditions, nutrition table, manufacturer/importer details, origin and other mandated items.
- **Health-food claims** – if marketed as a health food, the final product must also meet the requirements for health foods (special foods), including the “blue-hat” logo and approved functional claims. These requirements apply at the finished-product stage, not to bulk raw material.

5.5 Practical guidance for Australian exporters

To facilitate smooth customs clearance and compliance, Australian collagen-peptide exporters should take the following steps:

- **Register early** – ensure the manufacturing facility is registered with GACC and that the registration number is included on export documentation.
- **Use compliant packaging** – choose food-contact compliant packaging materials that protect against contamination and damage.
- **Provide Chinese translations** – include a Chinese translation of key information (product name, origin, manufacturer) in the shipping documents to assist customs.
- **Coordinate with the importer** – work with Chinese importers to obtain necessary permits and plan for consumer labelling if the product will be repacked for retail sale.
- **Avoid labelling errors** – pay attention to format and terminology; incorrect punctuation, additive names or missing local contact information have previously led to customs rejections.

5.6 HS Codes

China HS Codes for bovine collagen imports

Primary relevant codes:

- 3504.00.9000 – “Other protein substances and their derivatives, not elsewhere specified or included.” This category broadly covers bovine collagen, gelatin-like proteins, and peptones. China uses this as its 10-digit customs classification for bovine-derived collagen ingredients.
- 35040099 – A subcategory under HS 3504 used in international trade data, often applicable to irregular forms of collagen. Used interchangeably in some declarations.

Related codes (alternative/medicinal applications):

- 2106.90.99 – Used for “other food preparations not elsewhere specified”, sometimes applied to collagen supplements or finished collagen-containing food products rather than raw ingredient form.
- 2932.99.9099 – Hydrolysed collagen may occasionally appear under this chemical classification if marketed for specific food-chemical, pharmaceutical or functional uses. Not typical for bulk food ingredient shipments.

For Australian companies exporting raw or hydrolysed bovine collagen peptides to Chinese food or nutraceutical manufacturers:

- Use 10-digit HS code beginning with 3504.00.9000, which aligns with China’s customs classification for other protein substances and derivatives of animal origin, including collagen.
- Declare under 35040099 if required within export documentation, especially where detailed sub-category reporting is needed.

Customs declaration tips

- Check with your Chinese importer or customs broker to ensure use of the specific 10-digit code format required by China's customs system.
- Refer to product specifications (e.g. hydroxyproline content, peptide profile) to align with the appropriate subheading under HS.
- If collagen is sold as a finished food supplement or beverage, check whether 21069099 (food preparations) may apply instead –even though bulk ingredient shipments typically fall under 3504.
- Always confirm with your Chinese regulatory or customs partner to ensure alignment with the exact 10-digit classification used at import.

5.7 Regulatory summary and checklist for Australian exporters

Australia origin – risk and registry context

- Australia is officially recognised as having negligible BSE risk by WOAH (supportive context for bovine-origin materials).
- China exporter setup – Australian manufacturers/ processors/cold stores shipping food to China must be registered in GACC's CIFER system (Decree 248).
- China partners – the Chinese importer and the overseas exporter/agent must complete record-filing with GACC (Decree 249).

Classification and standards (food-grade ingredient)

- HS Code (indicative): 3504.90.00 (Other protein substances and derivatives; peptones and derivatives). Final HS coding is determined by China Customs at import.
- National standard: GB 31645-2018 (National Food Safety Standard – Collagen Peptide) applies to food-grade collagen peptides (sensory, technical specs, limits).
- Labeling baseline for prepackaged food ingredients: GB 7718 (General Labeling) and GB 28050 (Nutrition Labeling). Plan for migration to the newly issued 2025 revisions within the official transition period.

Import documentation pack (typical)

- GACC Decree 248 registration certificate/number (CIFER) for the Australian site(s); printed on inner and outer packaging as required.
- GACC Decree 249 filings for the Chinese importer and the overseas exporter/agent; copies of filing screenshots/records.
- Product specification and COA aligned to GB 31645-2018; contaminants and microbiological results per lot/batch.
- Commercial docs: contract, invoice, packing list, BL/AWB; shipment marks including manufacturer name, address, lot, production date, shelf life.
- Any port-requested quarantine declarations/testing notices for bovine-origin materials (confirm prior to shipment).

Quality, supply chain and testing notes

- Specifications – align peptide content, molecular weight distribution, ash, moisture, contaminants, and microbiological criteria to GB 31645-2018 and the registration dossier.
- Change control – lock supplier and process parameters referenced in the SAMR dossier; material or label changes may trigger supplements or re-approvals.
- Testing – plan China in-country testing (stability and mandatory items) early; retain retains/samples and lot traceability records for Decree 249 audits.
- Storage and transport – maintain conditions stated on label/ spec; document cold/dry chain where applicable.

Practical checklist

- Confirm HS code with your broker based on formula and presentation; align tax and VAT assumptions.
- Verify Australian facilities are active in CIFER (Decree 248); ensure your GACC number is printed on packs.
- Ensure importer/exporter GACC filings are current (Decree 249).
- Prepare GB 31645-2018 compliant COAs and specifications for each lot.
- Pre-alert port Customs on any bovine-origin documentation they expect; monitor any temporary disease-control measures.
- Maintain full traceability and post-market records per Decree 249.

Important note:

This is a practical summary only. Requirements vary by product formula, origin, and port; authorities may update rules without notice.

Final HS coding, quarantine items, and regulatory pathway decisions rest with Chinese authorities at the time of import.

5.8 Health foods ("Blue Hat") – regulatory pathway

Health-food classification: Collagen peptides are not included in China's Health Food Raw Materials Catalogue; they are treated as ordinary food ingredients. Finished supplements containing collagen must undergo health-food registration or filing with the State Administration for Market Regulation (SAMR) if they make functional claims (e.g., "improve skin moisture" or "joint health"). Registration can be costly and time-consuming.

Without registration, the product can only be sold as an ordinary food and cannot carry health claims.

- Pathway: Imported collagen health foods (with claims) require full SAMR registration – called a "Blue Hat" registration, as collagen peptides are outside the vitamins/ minerals filing catalogue (called the listing and filing or "Orange Hat" system).
- Preconditions: Evidence that the product has been legally sold for more than one year in Australia (certificate of sale/ marketing plus supporting proof).

- Dossier: Product formula and rationale, raw material quality specs, safety evaluation (toxicology where applicable), stability, manufacturing QMS, testing reports from Chinese-qualified labs, labels and claims (Chinese).
- Claims: Only permitted health food functions, claims must be supported by evidence. No disease treatment claims, comply with China's Advertising Law.
- Registration holder: For imported products, registration is with SAMR; a China responsible entity and after-sales contact details are required on labeling.
- Timelines for registration: Typical 18–36 months from project kickoff depending on testing scope, dossier quality, and review cycles.

6. Route-to-market options for Australian bovine collagen producers

The information below provides a structured overview of the main route-to-market (RTM) models for foreign companies selling raw ingredients (e.g. collagen peptides, dairy powders, botanical extracts) to Chinese manufacturers in the food, beverage, nutraceutical, pharmaceutical, or personal care sectors. This covers both operational structure and regulatory considerations.

> It is critically important that Australian producers realistically assess their experience and capabilities for international export and business transactions with overseas companies as part of assessing the best route-to-market model. For Australian producers with little or no experience, dealing with an Australian-based wholesaler or agent/distributor is likely to be a much lower risk option.

1. Direct export (general trade model)

Description

You sell directly from your overseas facility to a Chinese manufacturer (e.g. nutraceutical OEM/ODM, food processor). The manufacturer acts as the importer of record.

Process flow

1. **GACC registration** – your manufacturing site must be approved and registered with China's General Administration of Customs (GACC) under Decree 248 for animal-origin or other regulated ingredients.
2. **Chinese importer** – buyer must hold a valid import licence for food/raw materials.
3. **Customs clearance** – importer declares goods using correct HS code, pays duties/VAT, and provides required documents (health certificate, COA, packing list, invoice, contract, origin certificate).
4. **Delivery** – goods move directly to manufacturer's facility for production.

Advantages:

- full control over branding, pricing, and product positioning
- direct relationship with end manufacturer
- higher margins (no intermediary markup).

Considerations:

- requires in-house or contracted China regulatory expertise
- you bear responsibility for after-sales quality and compliance support
- potential payment/credit risk with Chinese buyers
- only recommended for producers with considerable experience and capabilities undertaking overseas business in complex regulatory markets such as China.

2. Indirect export via Chinese import agent or distributor

Description

You sell to a **Chinese-based** partner who acts as either:

- **Agent** – facilitates import, arranges regulatory paperwork, sells on your behalf for a commission.
- **Distributor** – buys goods from you, imports into China, and resells to multiple manufacturers.

Process flow

1. Select a reputable agent/distributor with market coverage in your target sector.
2. Sign a distribution/agency agreement (with performance clauses, territory exclusivity, IP protection).
3. Partner handles import licences, customs clearance, and regulatory filings.
4. Distributor sells in China, manages logistics, and collects payment from manufacturers.

Advantages:

- faster market entry; leverages partner's network
- distributor takes on import risk and working capital
- reduces need for your own in-country team.

Considerations:

- lower margins due to partner's markup
- less direct visibility of end customers
- risk of dependency on one partner.

Benefits – local partners understand regulatory requirements, maintain relationships with manufacturers and handle logistics, warehousing and currency settlements. They can help new entrants overcome cultural and language barriers.

Pricing – pricing is usually quoted as ex-works, FOB or CIF denominated in agreed currency between supplier and agent/distributor.

Challenges – dependence on intermediaries reduces margins and control. Selecting trustworthy partners is critical; exclusive contracts should include performance milestones and protection of intellectual property.

3. Trading wholly foreign-owned enterprise (Trading WFOE)

Description

You establish your own wholly owned Chinese legal entity (WFOE) with a trading licence to import and sell ingredients domestically.

Process flow

1. Register WFOE in China with approved business scope covering import/distribution of your product type.
2. WFOE acts as importer of record, directly buying from your overseas factory.
3. Sell directly to manufacturers or via sub-distributors.
4. Handle after-sales technical and regulatory support in-house.

Advantages:

- maximum control over pricing, branding, and relationships
- ability to invoice in RMB and receive local payments
- builds long-term local presence and trust.

Considerations:

- high setup and compliance cost (registration, tax filing, HR, office)
- requires GACC registration and Chinese staff for regulatory, sales, and logistics
- ONLY suitable for companies with high-volume, long-term plans as the establishment of a WFOE is complex and time-consuming.

4. Bonded warehouse and vendor managed inventory (VMI)

Description

Goods are shipped in bulk to a bonded logistics zone in China (or Free Trade Zone warehouse) and held in stock until local manufacturers place orders.

Process flow

1. Ship goods under bond into China's bonded warehouse (no duties/VAT yet).
2. When Chinese customer orders, goods are cleared through customs for that batch.
3. Shortens delivery lead time for local buyers (one to three days vs weeks).

Advantages:

- fast delivery to customers
- customs duties/VAT are paid only when goods are sold (cash flow advantage)
- ability to serve multiple buyers from one bonded stock.

Considerations:

- requires bonded warehouse partner or WFOE
- still need GACC-registered manufacturing site for imports
- inventory holding costs.

5. Cross-border E-commerce (CBEC) – limited relevance for raw ingredients

Description

This is primarily for finished retail products sold directly to Chinese consumers via CBEC platforms (Tmall Global, JD Worldwide). While not widely used for bulk raw ingredients, it could apply in rare cases (e.g., small trial shipments to small Chinese processors).

Regulatory requirements common to all routes

- GACC registration – manufacturing site must be registered (Decree 248 for animal-origin or certain high-risk products).
- HS Code classification – Must use correct 10-digit China Customs code for duties/VAT.
- GB Standards Compliance – must meet relevant China National Standards (GB) for product category (e.g. GB 31645-2018 for collagen peptides).
- Import documentation pack – includes COA, origin certificate (ChAFTA if applicable), invoice, packing list, bill of lading, health certificate, BSE/TSE statement.
- Labeling – bulk ingredients require basic outer package label in English/Chinese with product name, net weight, batch number, date, origin, manufacturer, GACC number.

6.1 Route-to-market selection matrix

Model	Speed to market	Control	Cost	Risk	Suitable for
Direct export	Medium	High	Low	Medium	Experienced exporters with regulatory capacity
Agent/distributor	High	Low	Low	Low/medium	New entrants, low China market knowledge
Trading WFOE	Low	High	High	High	Long-term market commitment, high volume
Bonded warehouse/VMI	Medium	Medium	Medium	Medium	Products needing fast delivery, multiple buyers

Direct export

Overseas manufacturer
↓
Chinese manufacturer (importer)
↓
End production

Pros: high control, direct relationships, higher margins

Cons: regulatory complexity, after-sales responsibility, credit risk

Best for: experienced exporters with regulatory capacity

Agent/distributor

Overseas manufacturer
↓
Chinese agent/distributor
↓
Chinese manufacturers

Pros: fast entry, local market expertise, reduced admin burden

Cons: lower margins, less visibility, partner dependancy

Best for: new entrants, limited China market knowledge

Trading WFOE

Overseas manufacturer
↓
Own trading WFOE in China
↓
Chinese manufacturers

Pros: max control, invoice in RMB, build local presence

Cons: high setup cost, requires staff and compliance, longer setup

Best for: high volume, long-term commitment

Bonded warehouse/VMI

Overseas manufacturer
↓
Bonded warehouse in China
↓
Chinese manufacturers

Pros: fast delivery, pay duties/VAT on sale, serve multiple buyers

Cons: inventory costs, still need GACC registration, warehouse partner needed

Best for: fast delivery needs, multi-buyer supply

For completeness of this guide, a summary is also included below for the route-to-market for finished goods (branded products). China offers two distinct channels for foreign food products:

General trade import – as noted above this is the traditional route where bulk goods are imported into China by you or a local distributor. Products must be fully compliant with Chinese regulations including GACC registration, Chinese labeling, and conformity with all local food safety standards. This model supports B2B distribution and is ideal for brands targeting large-scale retail or supermarket presence.

Cross-border E-commerce (CBEC) – CBEC allows foreign brands to sell directly to Chinese consumers via approved online platforms with simplified rules. Products on the official CBEC positive list can be sold without full regulatory registration or physical Chinese labels – only an online "e-label" in Chinese is required. CBEC offers tax incentives: no import duties under certain order limits, and a reduced VAT (typically 9.1%). Goods benefit from faster customs clearance through e-commerce pilot zones.

There are two CBEC Logistics Models:

- Bonded warehouse model – products are bulk-shipped to a bonded facility in China and cleared individually when a customer places an order. This enables fast delivery (one to three days) and is used in most CBEC operations.
- Direct shipping model – orders are shipped from your home country directly to Chinese consumers. It saves on warehousing costs but involves longer delivery times (one to two weeks), making it better for low-volume or test runs.

6.2 Route-to-market models – important considerations

Your route-to-market (RTM) model is one of the most important decisions to deliver success or failure in a new market

- Put in the time to understand the nuances of the market and the model that will deliver sustainable long-term success – it may be different to what you originally thought.
- Seek the assistance of organisations such as Austrade, state government trade and industry agencies and their in-market China teams, your banking partners, chambers of commerce and other organisations with China experience to obtain insights, case studies (good and bad) of the different RTM models.
- DO NOT rush into it – unwinding partnerships is expensive, risk-laden and usually brand and business destructive.
- Review deeply and be brutally honest about your experience, capabilities and bandwidth to manage different types of RTM models.
- Consider a phased 'test and learn' and 'try before you buy' approach to market entry models.
- Put in the time, effort and commitment to really understand potential partners and their 'fit' with you, your team and company.
- Smaller, passionate, engaged partners are often a better fit than the big end of town where your company is just one of many in their portfolio.
- A checklist for appointing a China-based agent or distributor in the food ingredients industry which provides useful areas to review and consider is shown at Attachment B.

7. Major potential customers in China for bovine collagen

7.1 Nutraceutical manufacturers

These companies represent the leading contract manufacturers in China's nutraceutical industry. Major players such as TCI and Sirio operate global CDMO platforms with multiple facilities across China and overseas, enabling end to end product development. Domestic specialists like Handian Nutrition, Jiabeikang and Shandong Health Biotech provide one stop OEM/ODM services covering formulation, production, packaging and logistics with GMP compliant facilities and low minimum order quantities. Niche gummy manufacturers (Hebei Huanwei, Dalian Dante) focus on trendy formats while companies like Daran Bio supply multiple dosage forms for smaller brands.

Company	Website	Key capabilities and highlights
TCI Co. Ltd.	tci-bio.com	Global CDMO+ provider offering end-to-end product lifecycle solutions. Provides research, development and manufacturing for health, nutrition, and beauty products, ensuring innovation and quality.
Sirio Pharma Co. Ltd.	siriopharma.com	Global leader with seven automated facilities across China, USA and Europe. Provides large-scale contract manufacturing of capsules, soft gels, gummies and functional drinks.
Handian Nutrition Co. Ltd.	hdnutra.com	30-year veteran with one-stop services from R&D to packaging. Offers effervescent tablets, chewable tablets, powders, gummies and capsules with large daily production capacities.
Richvit Nutraceutical	richvit.com	Provides full-service solutions including raw material control, formulation, manufacturing, private labeling, packaging and logistics for various dosage forms.
Medipro Pharmaceuticals Co. Ltd.	medipro.com.cn	Global nutraceutical OEM/ODM offering product development, manufacturing, customised packaging, and logistics for high-quality supplements.
Shandong Health Biotech Group	sdhealthbio.com	Offers private-label solutions across gummies, capsules, powders, tablets, soft gels, and liquids. Features NSF-GMP certified facilities, low MOQs and fast lead times.
Jiabei Health Technology (JiaBeiKang)	jbksupplements.com	GMP-certified facility producing gummies, soft gels, capsules, tablets, powders and functional drinks. Emphasises full service from formulation to logistics with global compliance.
Hebei Huanwei Biotech Co. Ltd.	huanweibio.com	Specialises in specialty nutraceutical gummies such as ACV, elderberry, probiotics and omega-3. Offers organic/vegan formulations and holds Halal and ISO certifications.
Dalian Dante Biotechnology Co. Ltd.	dentbio.com (Chinese language only)	Operates an 18,000m^2 GMP-grade plant with FDA, FSSC 22000, Halal and Kosher certifications. Known for sugar-free gum and expanding into functional candies like xylitol gummies.
Daran Biotech Ltd.	daranbio.com	One-stop contract manufacturer for soft gels, capsules, tablets and gummies. Offers customised product development and private-label packaging solutions for dietary supplements.

7.2 Collagen manufacturers and distributors

The companies listed below are key players in China's bovine collagen market. They range from local specialists such as Jiangxi Hanfei, Jiangxi Cosen and Gelken – which operate large hydrolysed collagen production lines – to international subsidiaries like Rousselot and Gelita, which have established Chinese manufacturing facilities. These manufacturers not only supply collagen to domestic food, cosmetic and nutraceutical companies but also export globally, reflecting China's growing role as a hub for bovine collagen production.

Top bovine collagen manufacturers and distributors in China

The following table lists major Chinese companies that manufacture or distribute bovine collagen (hydrolysed collagen from cattle). Details and evidence supporting their role in the market are provided below the table.

Company	Website	Key capabilities and highlights
Jiangxi Hanfei Biotechnology Co. Ltd. (ZXCHEM)	zxchem.com	Leading hydrolysed collagen manufacturer focusing on bovine and fish sources; fully automated processes with capacity about 15,000t and global supply.
Jiangxi Cosen Biology Co. Ltd.	knowde.com/stores/jiangxi-cosen-biology	Manufactures hydrolysed collagen peptides (bovine and fish) using GMP-standard production lines.
Gelken Gelatin Co. Ltd.	gelkengelatin.com/bovine-collagen/	Produces bovine collagen from hides, strict quality management, offers one-stop purchase and exports worldwide.
Yasin Gelatin Co. Ltd.	yasingelatin.com	33-year veteran gelatin and collagen producer with a strong reputation and global customer base.
SEMNL Group	semnlgroup.com	Premium bovine collagen supplier using bio-enzymatic hydrolysis to produce hydrolysed collagen from bovine bone or hide.
HSF Biotech (Co. Ltd.)	hsfbiotech.com/vegenutri-nutrition-ingredients/bovine-hydrolysed-collagen.html	Produces hydrolysed bovine collagen powder refined from fresh bovine skin; product contains about 92% protein and holds ISO 9001, ISO 22000, Kosher and Halal certifications.
Foodmate Co. Ltd.	foodmategelatin.com	National leader with over 10 years of gelatin and collagen-peptide production, offers fish and bovine collagen peptides, certified HALAL, FSSC 22000, FDA and ISO 9001.
Foodchem International Corporation	foodchem.cn/	Professional collagen-peptide supplier and manufacturer, exporting collagen peptides from China for nearly a decade.
Rousselot (Wenzhou) Gelatin Co. Ltd.	rousselot.com	Chinese facility of global leader Rousselot, supplies gelatin and collagen peptides manufactured with state-of-the-art operations.
Gelita China	gelita.com/en/shanghai	Liaoyuan plant (est. 2005) spans 140 000m^2 and produces high-quality gelatin and collagen peptides for food, health and technical sectors.
Shanghai Nitta Gelatin Co. Ltd.	nitta-gelatin.co.jp/en/index.html	Listed among Nitta Gelatin's Chinese affiliates, producing and selling gelatin and collagen peptides.

7.3 Major potential customer groups in Australia for bovine collagen

Australian producers should also consider Australian-based manufacturers with extensive exposure to brands selling finished goods into the China market. This provides a much lower risk model to access the scale and growth of the China market without direct engagement with the market.

Major Australian contract manufacturers active in the China nutraceutical space include, but are not limited to, the following manufacturers:

Company	Website	Key capabilities and highlights
Vitex Pharmaceuticals	vitex.com.au	One of Australia's largest contract manufacturers producing vitamins, supplements, sports nutrition, and functional foods. Tablets, capsules, powders, liquids, and packaging.
Lipa Pharmaceuticals	lipa.com.au	A leading GMP-certified manufacturer specialising in nutraceuticals, pharmaceuticals, and cosmetics. Softgels, tablets, capsules, and custom formulations.
Nutraceuticals International	nutra.com.au	Formulation, manufacturing, and packaging of vitamins and supplements.
PharmaCare Laboratories	pharmacare.com.au	Major private-label and contract manufacturer. Has own brands – Natures Care, Bioglan etc
Australian NaturalCare	australiannaturalcare.com.au	Contract manufacturing for vitamins, probiotics, and health supplements.
GMP Pharmaceuticals	gmppharma.com	Produces supplements for private-label and third-party brands. Extensive production for Chinese/Australian brands selling in China.
Key Pharmaceuticals	keypharm.com.au	Specialises in tablets, capsules, and liquid supplements.
BJP Laboratories	bjplaboratories.com.au/	A specialised manufacturer of softgel capsules, including nutraceuticals, vitamins, and fish oils.
Homart Pharmaceuticals	homart.com.au	Well-established Australian-owned manufacturer specialising in nutraceuticals, skincare, and herbal extracts.

7.4 China-based agents/distributors for foreign food and nutraceutical ingredients

Details are provided below of key China-based companies experienced in acting as agents or distributors for foreign food and nutraceutical ingredient suppliers.

Company	Website	Core capabilities	Coverage in China
IMCD China	imcdgroup.com/worldwide/china-MCMUN3K5VZ35GZHFEDGMNUIYLLVU	Global specialty ingredients distributor with strong presence in food and nutrition.	National China network; strong in specialty food and nutraceuticals.
Azelis China	azelis.com/en/regions-and-locations/asia-pacific/china	Global distributor with food and nutrition division, offers technical support and formulation expertise.	Covers key Tier 1 and Tier 2 cities, network in multiple application segments.
DKSH performance materials (China)	dksh.com/cn-en/home/performance-materials	Distributor with food and beverage business unit, provides market entry, regulatory, and logistics support.	China-wide operations, backed by global DKSH network.
Brenntag China/ Zhongbai Xingye	brenntag.com/en-cn/	Global leader in chemicals and ingredients distribution, JV with Zhongbai Xingye for nutrition market expansion.	Strong in dairy, nutrition, and functional ingredients, wide customer base in China.
Caldic China (formerly Connell, now Connell Caldic)	caldic.com/en-cn/	Distributor of life-science and specialty ingredients.	Nationwide China reach, expertise in food, beverage, and nutraceutical applications.
Barentz China	barentz.com/en/china/	Human nutrition and supplements distributor.	Covers China's main regions, strong in dietary supplements.
Univar Solutions China	univarsolutions.com/contact-us	Global distributor with dedicated food and nutrition segment, technical and supply chain services.	Shanghai HQ with regional coverage across China.
Jebsen & Jessen Ingredients (China)	ingredients.jjsea.com/	Distributor of life-science ingredients, offers product sourcing, marketing, and technical services.	Operations in major industrial clusters across China.
Stern Ingredients (Suzhou) Co., Ltd.	en.sterningredients.com.cn/	China arm of Stern-Wywiol Gruppe, distributes functional systems, enzymes, vitamins, and nutritional blends.	Manufacturing and distribution hub in Suzhou, covers national clients.
Nagase (China)/ Nagase Food Ingredients	nagase.com/company/global-network/greater-china	Trading and distribution group, supplies food and nutrition ingredients including through Prinova brand.	Presence in multiple Chinese cities, access to regional and global sourcing network.

8. Selling to contract manufacturers and brands – what customers look for

Australian bovine collagen producers need to be aware that the market is highly competitive and contract manufacturers and brands, whether in Australia, China or other markets expect raw ingredient suppliers to provide more than just keen pricing.

Contract manufacturers and brands increasingly look for suppliers to provide some, or all, of the following:

- ingredient range
- full traceability of supply chain from source to processed extract for sale
- history and longevity for the supplier company and experience in the category
- record of quality and no issues
- IP, patents and research and development
- branding of extracts with clinical trials – ability to present an evidence package to customers that the brand can then use easily
- willingness to undertake joint studies/clinical trials with brands to develop an evidence package for exclusive use by the brand
- patented ingredients
- sustainable raw material growing practices and evidence to support sustainability claims
- extensive marketing collateral, training programs, education and information to support the brand
- support for end-customer engagement for the brand, retailer ‘toolkits’ – videos, white papers, infographics, e-Books etc
- guidance on testing methods and labs where testing can be undertaken
- delivery technologies to increase absorption or efficacy.

9. Assessing the market opportunity – attending trade shows in China

To gain a first-hand insight into the China market, meet potential customers and assess how their products compare with other international and domestic companies, Australian producers may wish to consider either visiting, or participating with a show presence, at the following industry focused trade shows in China.

Q4 2025

- **HOTELEX Shenzhen 2025**

  Dates: December 16–18, 2025

  Location: Shenzhen

  Focus: coffee and tea, beverages, food and catering ingredients, light meals – ideal for ingredient sourcing in preparation venues and quick-service formats.

2026

- **Food Ingredients China (FIC 2026)**

  Dates: March 17–19, 2026

  Location: National Exhibition and Convention Center (NECC), Shanghai

  Focus: Asia's largest platform for food additives, processing aids, functional ingredients, machinery, and technical services.

- **Hi & Fi Asia-China 2026**

  Dates: June 15–17, 2026

  Location: NECC, Shanghai

  Focus: food, beverage, and health ingredients – including natural extracts, nutraceuticals, and processing innovations.

10. Entering the China market – some lessons from the frontline

> **"If you would know the road ahead, ask someone who has travelled it"**
>
> **– Chinese proverb**

In considering expanding into new markets, particularly complex markets like China, Australian producers can learn from the experience of other successful companies.

- Deeply assess (and then re-assess) why you are expanding offshore and ensure you've fully exploited ALL domestic opportunities.
- Be conscious and wary of your/company ego – new market expansion can cloud jugdement.
- Be brutally realistic about capabilities to execute in complex markets a long way from headquarters – it's not just you, it's the total company, your suppliers and partners.
- Sometimes the best decision is not to do it!
- ROI and profit are what matters – time to profitability will always be longer than forecasted.
- Big markets don't necessarily equal big profits. Don't underestimate the contribution of smaller and easier markets, e.g. Singapore, Hong Kong.
- In-market resources are critical to success – you always need to 'own' your brand. Consider embedding your own resource within your partners' team.
- Always listen to gut instinct when assessing markets, partners, customers and opportunities – if something doesn't feel right, don't do it.
- It will be 10x harder than you think – there is no easy new market entry.

Doing business with China – ten tips

1. Halve your expectations, double your time and budget.
2. Never ever assume anything – research, check, monitor.
3. Always do the right thing right – NEVER engage in unlawful business practices.
4. If it seems too good to be true – it almost certainly is.
5. Expect the unexpected – be prepared to rapidly adopt and adapt.
6. Partnerships – be conscious of different expectations or objectives.
7. China demands a total company approach to operate at the right pace.
8. Chinese language, business and cultural capability (or access to it) is critical.
9. Persistence, tenacity, resilience, flexibility, and passion are required everyday.
10. China's a market ...it's not The Magic Pudding!

11. Resources

There are a wide range of excellent resources and services available to Australian companies seeking to expand into overseas markets, including to China. A number of these relevant to the Australian bovine collagen industry are shown below.

Australian Trade Commission (Austrade) – Go Global Toolkit:

State Government trade and investment agencies:

State/Territory	Agency name(s)	Website
New South Wales	Investment NSW	investment.nsw.gov.au
Victoria	Global Victoria	invest.vic.gov.au
Queensland	Trade and Investment Queensland (TIQ)	tiq.qld.gov.au
South Australia	Invest South Australia	invest.sa.gov.au
Western Australia	Invest and Trade Western Australia	investandtrade.wa.gov.au
Tasmania	Invest Tasmania/Trade Tasmania	trade.tasmanian.com.au
Northern Territory	Department of Trade, Business and Asian Relations (NT Government)	dtbar.nt.gov.au/trade-investment

For detailed advice on **China regulations** relating to the food, beverage and nutraceuticals category, the following agencies have significant experience with Australian companies:

- ChemLinked – chemlinked.com/
- RegAsk – regask.com/
- Knudsen & CRC – knudsencrc.com/
- CIRS-Reach – cirs-reach.com/

Business organisations:

- Australia China Business Council (ACBC) – acbc.com.au/
- Australian Chamber of Commerce in China – austcham.org/
- Export Council of Australia – export.org.au/
- Complementary Medicines Australia – cmaustralia.org.au/
- China Chamber of Commerce in Australia – cccaau.org/en/

12. Sources

This guide was prepared using a diverse range of source materials combined with the author's extensive in-market experience in China. Key sources are noted below.

- Exporting Meat Products to China 2025 – EU SME Centre
- Standardization Administration of China – SAC
- National Food Safety Standard Database (China National Center for Food Safety Risk Assessment)
- China National Medical Products Administration (NMPA)
- General Administration of Customs of China (GACC)
- Department of Agriculture, Fisheries and Forestry (DAFF)
- ChemLinked
- Meat and Livestock Australia (MLA)
- Dezan Shera & Associates
- Complementary Medicines Australia (CMA)
- U.S. Commercial Service
- U.S.-China Health Products Association

Attachment A

GB 31645—2018 – National Food Safety Standard

English (unofficial translation)

Annex A Determination of the proportion of collagen peptides with relative molecular mass <10,000

GB 31645—2018 – National Food Safety Standard

(Unofficial Translation)

National Standard of the People's Republic of China

Collagen peptide

Released on: 21-16-2018

Implementation date: 21-12-2018

Issued by: National Health Commission of the PRC and State Administration for Market Regulation

1 Scope

This Standard applies to collagen peptide products used for food processing.

2 Terms and definitions

2.1 Collagen peptide

A product produced from fresh animal tissues rich in collagen (including skins, bones, tendons, scales, etc.) by extraction, hydrolysis and refining, with a relative molecular mass less than 10,000.

3 Technical requirements

3.1 Raw material requirements

3.1.1 Permitted raw materials

a. Fresh skins, bones, tendons and scales of cattle, pigs, sheep and fish that have been inspected and found qualified, provided by slaughterhouses, meat processing plants, canning plants and markets
b. Edge skins with hair trimmed before the leather-making process or inner hides trimmed before dehairing
c. Clean bone granules processed by bone granule processing plants and naturally air-dried bone materials
d. Edible aquatic animal scales, edible echinoderms and jellyfish.

3.1.2 Prohibited raw materials

a. Any waste after tanning in leather factories
b. Skins, bones, tendons and scales of cattle, pigs, sheep or fish without valid inspection and quarantine certificates
c. Skins, bones, tendons and scales that have been treated with harmful substances or degreased using organic solvents such as benzene.

3.2 Sensory requirements

Sensory requirements shall comply with the provisions of Table 1.

Table 1 – Sensory requirements

Item	Requirement	Test method
Colour	White or pale yellow	
Taste and odour	The product shall have its inherent taste and odour, with no off-flavours.	Take 2g of sample and place it in a clean beaker. Use 200mL warm boiled water to prepare a 1% solution. Observe the colour and presence or absence of sediment under natural light. Smell the odour, rinse the mouth with warm boiled water and taste.
Appearance	Powder or granules, free of agglomeration, with no foreign matter visible to normal eyesight.	

3.3 Physico-chemical indicators

Physico-chemical indicators shall comply with the provisions of Table 2.

Table 2 – Physico-chemical indicators

Item	Index	Test method
Proportion of collagen peptides with relative molecular mass < 10,000 (%)	≥ 90.0	Annex A
Hydroxyproline (on dry basis) (g/100g)	≥ 3.0	GB/T 9695.23
Total nitrogen (on dry basis) (g/100g)	≥ 15.0	GB 5009.5
Ash (g/100g)	≤ 7.0	GB 5009.4
Moisture (g/100g)	≤ 7.0	GB 5009.3 Method 1

3.4 Contaminant limits

Contaminant limits shall comply with the provisions of Table 3.

Table 3 – Contaminant limits

Item	Limit (mg/kg)	Test method
Lead (as Pb)	1.0	GB 5009.12
Cadmium (as Cd)	0.1	GB 5009.15
Total arsenic (as As)	1.0	GB 5009.11
Chromium (as Cr)	2.0	GB 5009.123
Total mercury (as Hg)	0.1	GB 5009.17

3.5 Microbiological limits

Microbiological limits shall comply with the provisions of Table 4.

Table 4 – Microbiological limits

Item	n	c	m	M	Test method
Total bacterial count (CFU/g)	5	2	10^4	10^5	GB 4789.2
Coliforms (CFU/g)	5	2	10	10^2	GB 4789.3

Note – Samples shall be collected and handled in accordance with GB 4789.1.

3.6 Food industry processing aids

The use of food industry processing aids shall comply with GB 2760.

Annex A Determination of the proportion of collagen peptides with relative molecular mass <10,000

(High-performance size exclusion chromatography)

A.1 Method summary

This method uses high-performance size exclusion chromatography. A porous packing is used as the stationary phase, and the sample components are separated based on differences in molecular volume. Detection is performed at a UV wavelength of 220nm. The chromatograms and data of the standards and samples are processed using specialised software for determining molecular weight distribution (GPC software). According to the calibration curve for relative molecular mass, the relative molecular mass and distribution range of collagen peptides are calculated.

A.2 Reagents

A.2.1 **Acetonitrile**: chromatographic grade.

A.2.2 **Trichloroacetic acid**: analytical grade.

A.2.3 **Water**: Grade 1 water as specified in GB/T 6682.

A.2.4 **Standard substances for preparing the calibration curve of relative molecular mass**:

a. Cytochrome C (MW 12384);
b. Aprotinin (MW 6512);
c. Bacitracin (MW 1423);
d. Glycine–glycine–tyrosine–arginine (MW 451);
e. Glycine–glycine–glycine (MW 189).

A.3 Instruments and equipment

A.3.1 High-performance liquid chromatograph equipped with a UV detector and a chromatographic workstation containing GPC data processing software.

A.3.2 Vacuum filtration degassing device for the mobile phase.

A.3.3 Ultrasonic oscillator.

A.3.4 Analytical balance with a sensitivity of 0.0001g.

A.4 Chromatographic conditions and system suitability test

A.4.1 **Column**: TSKgel G2000 SWXL 300mm × 7.8mm (GEL LOT 502R) or other similar gel columns with comparable performance suitable for determining the molecular weight distribution of peptides.

A.4.2 **Mobile phase**: acetonitrile : water : trichloroacetic acid in a volume ratio of 40 : 60 : 0.05.

A.4.3 **Detection wavelength**: 220nm.

A.4.4 **Flow rate**: 0.5mL/min.

A.4.5 **Column temperature**: 30°C.

A.4.6 **Injection volume**: 10µL.

A.4.7 To ensure that the chromatographic system meets the test requirements, under the above chromatographic conditions, the column efficiency (theoretical plates, *N*) of the gel column calculated using the tripeptide standard (glycine–glycine–glycine) peak shall not be less than 5,000, and the distribution coefficient *(K*d) of the protein peptide shall be between 0 and 1.

A.5 Preparation of the relative molecular mass calibration curve

Use the mobile phase to prepare peptide standard solutions with concentrations of about 1.0g/L for the above different relative molecular masses. Filter through 0.2µm to 0.5µm polytetrafluoroethylene or nylon membranes and inject separately to obtain chromatograms of the series of standards. Plot the logarithm of the relative molecular mass (lg MW) versus the retention time or perform linear regression to obtain the relative molecular mass calibration curve and its equation.

A.6 Sample preparation

Weigh about 125.0mg of sample on weighing paper and transfer it to a 25mL volumetric flask. Make up to volume with the mobile phase. Ultrasonically shake for 10 min to fully dissolve and mix. Filter through a 0.2µm to 0.5µm PTFE or nylon membrane; the filtrate is used for determination.

A.7 Calculation of relative molecular mass

Inject the sample solution prepared in A.6 under the chromatographic conditions specified in A.4. Use GPC data processing software and the calibration curve equation for relative molecular mass to process the chromatogram and data of the sample. This provides the relative molecular mass and distribution range of collagen peptides in the sample. Use the peak area normalisation method to calculate the sum of the relative percentages of collagen peptides with relative molecular mass less than 10,000.

Attachment B

Checklist for appointing a China-based agent or distributor in the food ingredients industry

1. Strategic and market assessment

- ☐ Define objectives – sales targets, brand positioning, and market share goals in China.
- ☐ Clarify route-to-market model – exclusive distributor, non-exclusive distributor, multi-agent network, or hybrid (direct + agent).
- ☐ Market demand review – confirm end-user industries (e.g. bakery, beverage, nutraceutical) and growth trends.
- ☐ Competitor mapping – identify current importers and competing ingredient suppliers.

2. Regulatory and compliance checks

- ☐ Import regulations – confirm if your ingredient requires China NMPA, GACC, or SAMR registrations.
- ☐ Food safety standards – check GB standards for your ingredient category.
- ☐ Import licensing – ensure distributor holds valid food business licences and import permits.
- ☐ Customs & CIQ – confirm experience with Customs declaration and CIQ processes.

3. Distributor/agent due diligence

- ☐ Business licence – verify legal entity status in China.
- ☐ Financial health – review credit reports, annual filings, or bank references.
- ☐ Experience – confirm track record with imported food ingredients.
- ☐ Reputation check – industry references, online reviews, litigation records.
- ☐ Sales coverage – assess regional network (Tier 1–3 cities, sector focus).
- ☐ Import capability – bonded warehouse, cold chain (if needed), distribution channels.

4. Commercial terms

- ☐ Territory – clearly define geographic or industry scope.
- ☐ Exclusivity – decide if exclusive or non-exclusive appointment.
- ☐ Performance targets – set sales volumes, timelines, and review milestones.
- ☐ Pricing policy – define ex-works/FOB/CIF pricing, currency, payment terms.
- ☐ Marketing support – agree on promotional budgets, trade show participation, sampling programs.

5. Contractual protections

- ☐ Written agreement – bilingual (English + Simplified Chinese) with clear governing law and dispute resolution.
- ☐ Termination clauses – define notice periods, performance failure terms, post-termination obligations.
- ☐ IP protection – trademark registration in China before product launch.
- ☐ Confidentiality – protect product formulations, customer lists, pricing.
- ☐ Compliance obligations – ensure adherence to China's Anti-Unfair Competition Law, Advertising Law, and anti-bribery rules.

6. Onboarding and relationship management

- ☐ Training – product knowledge, applications, compliance requirements.
- ☐ Joint planning – co-develop sales and marketing plan for first 12 months.
- ☐ Regular reporting – monthly/quarterly sales data and market feedback.
- ☐ Site visits – annual audits of facilities and key customers.
- ☐ Cultural engagement – invest in building trust and long-term partnership.

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