Bioactive processing options
FINAL REPORT

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1.0 EXECUTIVE SUMMARY

Australian Country Choice (ACC) and AMPC commissioned this project to examine if bioactive products can increase returns for items that are currently rendered. Extracting bioactive components from these raw materials will allow greater value adding to materials destined for rendering. Bioactives are molecules that provide extra health benefits beyond normal nutrition.

The drivers for the global bioactive market are an increased concern for foods with functional ingredients to maintain health, to proactively ward off disease, aid treatment of chronic diseases and a general move from synthetic remedies to those derived from natural products. According to 360iResearch (2020) the pandemic has caused 75% of consumers to desire healthier options causing a 25% spike in immunity supplements during 2020. As the standard of living in developing countries is rising, higher amounts of disposable income are being used to purchase dietary supplements and functional foods and beverages. This same awareness also sees the need for improved pet health, increased performance of livestock, and improved flavourings to foods as well as packaging that maintains the integrity of the product, minimises oxidation and spoilage and has its own bacterial control.

Some of the challenges are the approval and different approval processes across geographic areas, regulation and the complex extraction requirements of some specific substances. The increased production capacity in the Asia-Pacific market may also affect prices as supply and demand are better understood. Fortunately, Australia is highly regarded with respect to our food safety standards and disease-free status, and this creates a distinct competitive advantage if processing costs can be refined.

The high-level feasibility scoping conducted in this report has surmised that blood derived bioactives and hydrolysed collagen present significant potential opportunity to ACC in value adding blood and bone products. Both scenarios have a level of trialability and scalability. Whilst greenfield sites will come with slower time to market outcomes, there are potential partners for blood products and bone products. It is recommended that ACC proceed with an in-depth feasibility study into these areas to determine detailed capital and operational costs as well as potential partnership opportunities to access specialised skills and expertise.

2.0 INTRODUCTION

Numerous studies demonstrate that bioactive compounds have properties such as anti-inflammatory, antioxidant, anticoagulant, and anticarcinogenic. For meat processors these compounds can be derived from current non-meat components such as blood, bones, lungs and rumen digesta that are currently rendered for low value profit products such as bone meal and fertilizer. It represents an opportunity to value-add and achieve better utilisation and return for a carcass. The scope of this project was to specifically look at the bioactive potential for blood and bone.

The supply chain covering blood and bone value add products is a very different supply chain to the traditional meat supply chain. This 'Preliminary Feasibility Review' will document some of the alternative supply chains.

3.0 PROJECT OBJECTIVES

The project outcome will be the preliminary feasibility review that will outline the cost benefit of a range of potential bioactive products that could be collected with initial processing and storage by Australian Country Choice.

The review will be focused on potential cost benefits based on published research papers and information related to commercially available services.

4.0 METHODOLOGY

Market research reports were purchased, and desktop research was conducted to determine the market opportunities and to understand the value available in the bioactive market for ACC.

As this was a high-level feasibility review, an analysis of market status and drivers, high level value chain analysis, and scoping of risks, opportunities and constraints, was conducted.

There are numerous constraints that need to be understood, and potential solutions that needed to be identified, related to blood and bone value add processing options for Australian Country Choice.

These constraints include:

1. Available research papers and information from commercial service providers.
2. Alternative use cost of Blood and Bone base material compared to current usage (e.g. rendering to tallow and meal).
3. Current work practices and operational system in use at Australian Country Choice related to potential Blood and Bone Value Add.
4. Available markets and their value for Blood and Bone Value Add products potentially available from Australian Country Choice.
5. Capital cost and operational costs for Blood and Bone Value Add collection, initial processing, storage, and transport.
6. Blood and Bone Value Add may have very specific traceability and commercial information requirements that need to be understood and determined if feasible within Australian Country Choice.

There is limited available information on current operational equivalent systems in Australia. This will mean review of overseas operations, which are often difficult to replicate in Australia due to different labour, regulatory and commercial environments.

5.0 PROJECT OUTCOMES AND DISCUSSION

5.1 Bioactives market overview

The global bioactive ingredients market is forecasted to grow to value of USD$49.71 billion by 2025 at a CAGR of 8.04% (360iResearch, 2020).

The global bioactive market is comprised of several application categories. The application categories as analysed in this report are as follows:

- Alcoholic Beverages
- Animal Nutrition
- Dietary Supplements
- Functional Food & Beverages
- Personal Care (i.e. Cosmetics)
- Pharmaceuticals (i.e. Medical)

Forecasts, such as shown in Figure 1 and Table 1, show substantial growth across all categories.

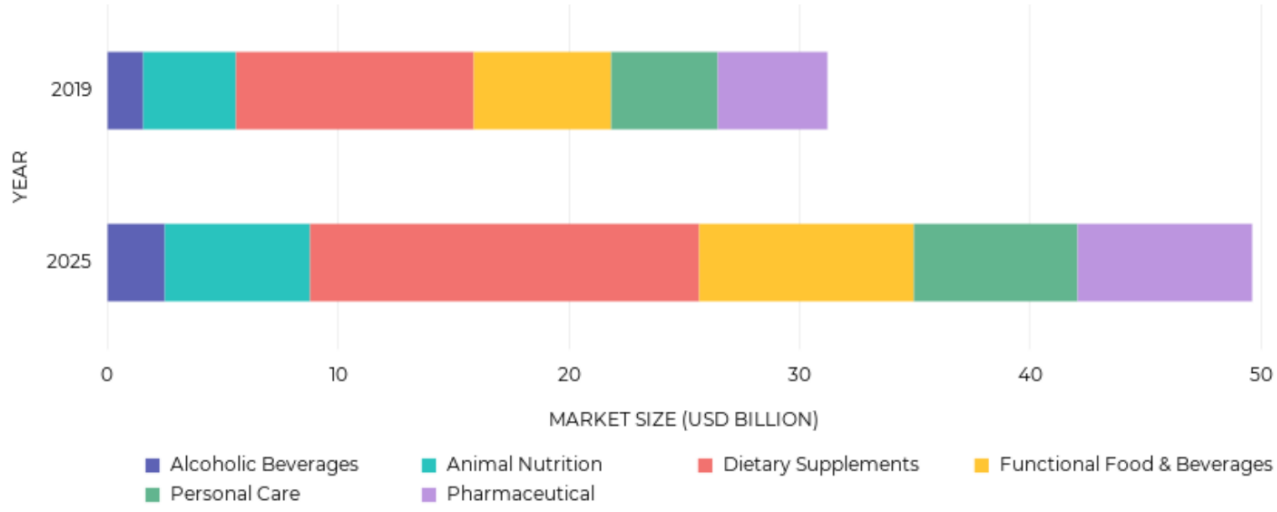


Figure 1. Global bioactive ingredients market size by application, 2019 vs 2025 (USD billion). Source: (360iResearch, 2020)

Table 1. Global bioactive ingredients market size by application, 2019 vs 2025 (USD billion). Source: (360iResearch, 2020)

	Global Market Size (2020)- $USD bn	Global Market Size (2025)- $USD bn	CAGR % (2020-25)
Alcoholic Beverages	1.7	2.49	7.9%
Animal Nutrition	4.29	6.32	8.1%

Dietary Supplements	11.19	16.85	8.5%
Functional food & beverages	6.33	9.35	8.1%
Personal Care	4.89	7.11	7.8%
Pharmaceuticals	5.08	7.56	8.3%

As with many commodities, it is the Asia-Pacific market that presents as the highest growth region (see Figure 2). This is due to a rapidly growing population with higher levels of disposable income.

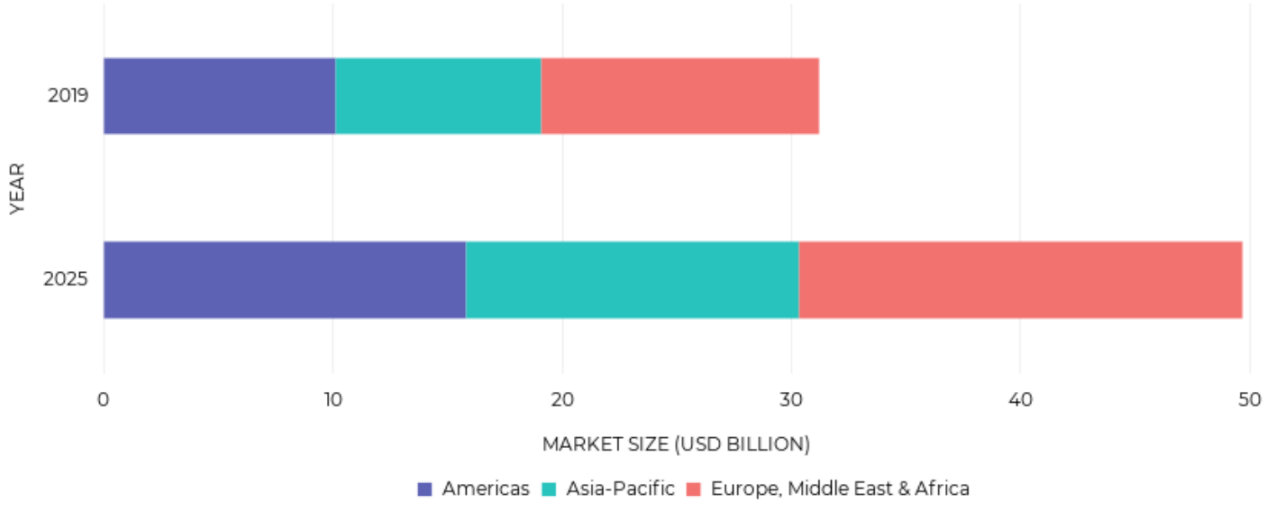


Figure 2. Global bioactive ingredients market size by geography, 2019vs 2025 (USD billion). Source: (360iResearch, 2020)

Growth overall is being driven by increased health concerns as populations age, social media trends highlight healthy habits and COVID-19 raises awareness of value of health (360iResearch, 2020). This has driven a rise in demand for naturally derived bioactive ingredients across the human functional food and beverage and dietary additives categories. Animal nutrition is also seeing rapidly reducing margins in all species, and with an increased focus on sustainability, bioactives are being used to boost performance of livestock, reduce emissions and enable to use of by-product feeding.

From an Australian perspective, the CSIRO (Wynn, 2020) estimate that ten percent of food and agribusiness sector revenue by 2030 could come from healthy and sustainable lifestyle products worth 25 billion dollars (see Figure 3).

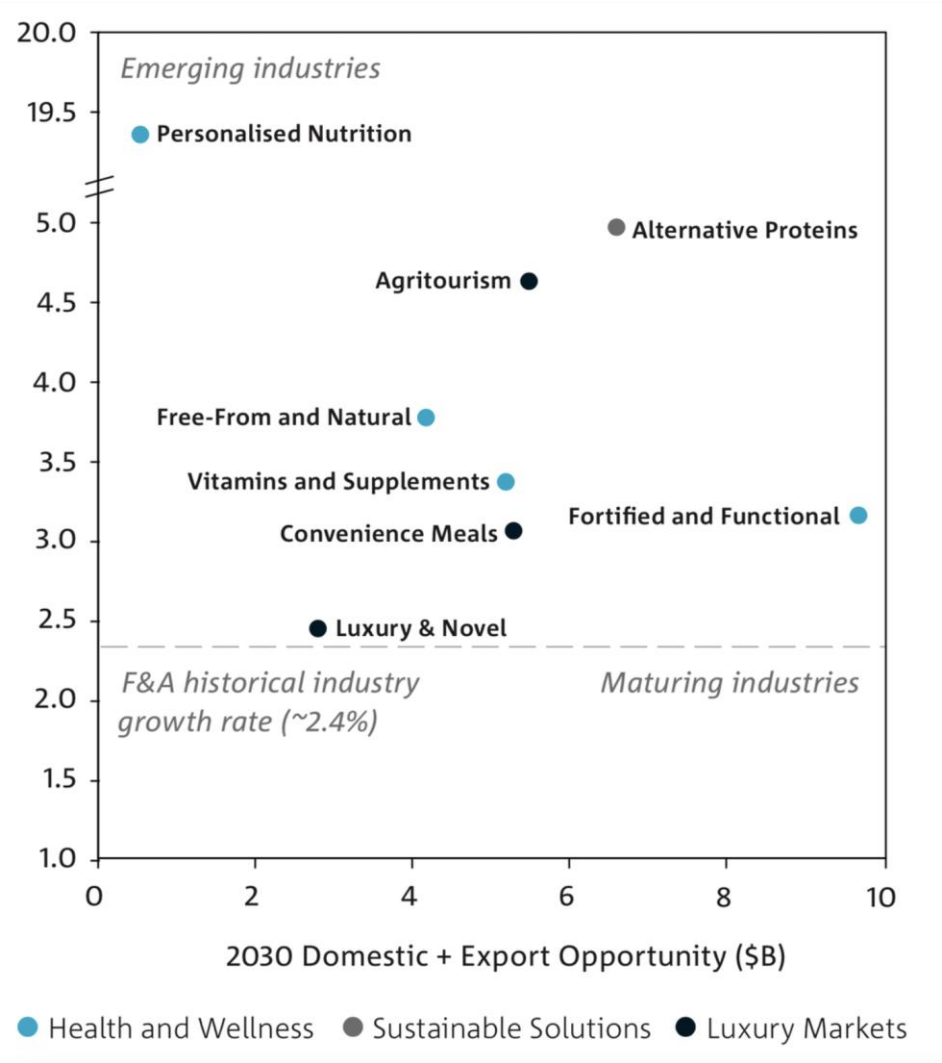


Figure 3. 2030 domestic and export opportunity in agriculture. Source: (Wynn, 2020)

CSIRO see opportunities in fortified and functional products as consumers increasingly look for more healthful foods (see Figure 4). Additionally, CSIRO see a market for sustainable biodegradable packaging that could be achieved through bioactive peptides. The environmental savings with sustainable packaging could be in the region of 1.7 billion dollars (Wynn, 2020).

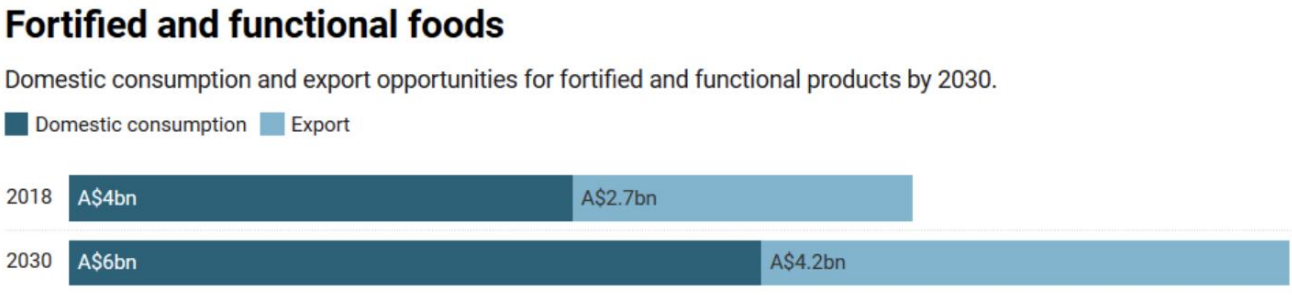


Figure 4. Fortified and functional foods. Source: (Wynn, 2020)

5.2 Bioactive ingredients

There are hundreds of bioactive compounds however this report categorises and address the bioactive ingredients as follows:

- Carotenoids and antioxidants
- Fibre
- Minerals
- Peptides and proteins
- Photochemical and plant extracts
- Prebiotics and amino acids
- Vitamins
    - Vitamin A
    - Vitamin B
    - Vitamin C

Whilst there are multiple bioactive ingredient categories, it is peptides and proteins that hold the largest market proportion (see Figure 5). It is however vitamins followed by peptides and amino acids that are expected to experience the highest rate of growth.

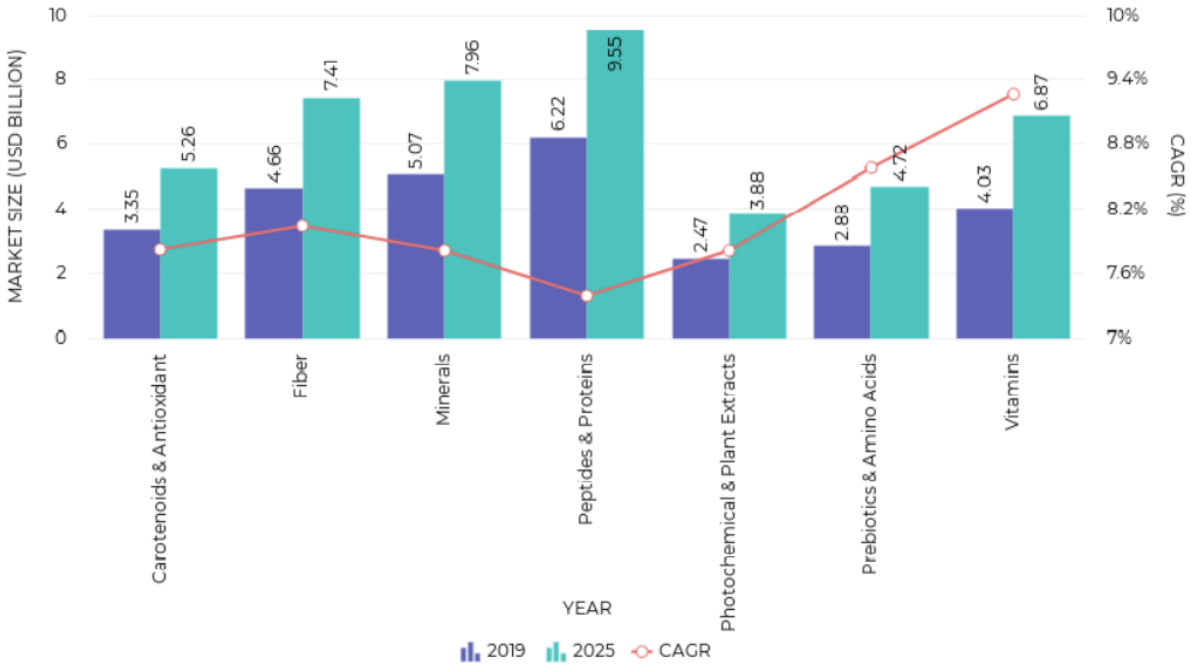


Figure 5. Global bioactive ingredients market size by ingredient, 2019 vs 2025 (USD billion). Source: (360iResearch, 2020)

Carotenoids and antioxidants

These are strong cancer-fighting ingredients that are also essential to vision and growth and development. The primary ingredients are; alpha-carotene, beta-carotene, and beta-cryptoxanthin, lutein, and zeaxanthin lycopene.

Fibre

It is a complex component obtained from various sources. It is an increasingly important ingredient as diets are becoming more processed and people look to supplement their diets with fibre. Fibre however is most commonly sourced from plant sources making bovine unviable.

Peptides and proteins

Ingredients include; collagen, keratine, casein and silk. Peptides are often used in cosmetic products for its film forming properties suited for hair care and skin care. Vegetables are also a source of peptides with soy, wheat, pea and rice common raw materials.

Phytochemicals and plant extracts

Many are recognised for their bioactive properties in traditional herbal medicine. For example, salicylates (asprin) is found in willow bark and is used as an anti-inflammatory, quinine from cinchona bark I used to treat malaria. As the name suggests there are derived from plant sources and therefore are an unviable option for ACC.

Vitamins

Thiamin and riboflavin are bioactive ingredients in Vitamin B and support energy, metabolism, heart and cognitive health. Bioactive vitamin C includes compounds such as sodium ascorbate and ascorbic acid and act as immune boosters among other things. Vitamin A has bioactive compounds such as propionate and mandelic acid and they help to boost collagen synthesis. These are common dietary supplements and cosmetic products. Most vitamin A sources are plant based however fish and liver are also suitable sources.

5.3 Raw materials

The Raw Material Matrix below (Table 2) is based on the consideration that ACC is focused on rapidly delivering low-cost validation that an opportunity exists in the bioactives market. Successful execution of this approach will build confidence that investment in bioactive production at a greater scale will deliver substantial ROI & maintain commercial viability in the long-term.

Other considerations for ACC include:

- Availability of the raw material used to obtain bioactive material
- The process required to extract the bioactive content from the raw material
- What the raw material-specific bioactive product is typically used for

It was determined by ACC that bone and blood products would be the focus for this project.

Table 2. Raw material matrix

Evaluated Raw Materials	*Core Applications (Relevant market segments)**	*Volume per head*	*Processing Difficulty / Complexity*
Blood	All but alcoholic beverages	18kg	Low
Skin / Hide	All but alcoholic beverages	31.8kg	Moderate
Bones	All but alcoholic beverages	72.8kg	Moderate

Tripe / Stomach	All but alcoholic beverages	3.8kg	Moderate
Trachea	Pharmaceutical	2.71kg	High
Plasma fractionations (further processing beyond blood)	Pharmaceutical	11.34kg	High

5.4 Blood products

The objective is to take waste stream material with low value and add value to improve maximum value from waste by-products. Blood products are well suited to the ACC raw material profile and provide significant opportunities. Glenn (2015) suggests that if health benefits could be demonstrated from bioactives then their price could be estimated at AUD $7000-8000/tonne. However there needs to be a proven substantive claims and traceability protocols established.

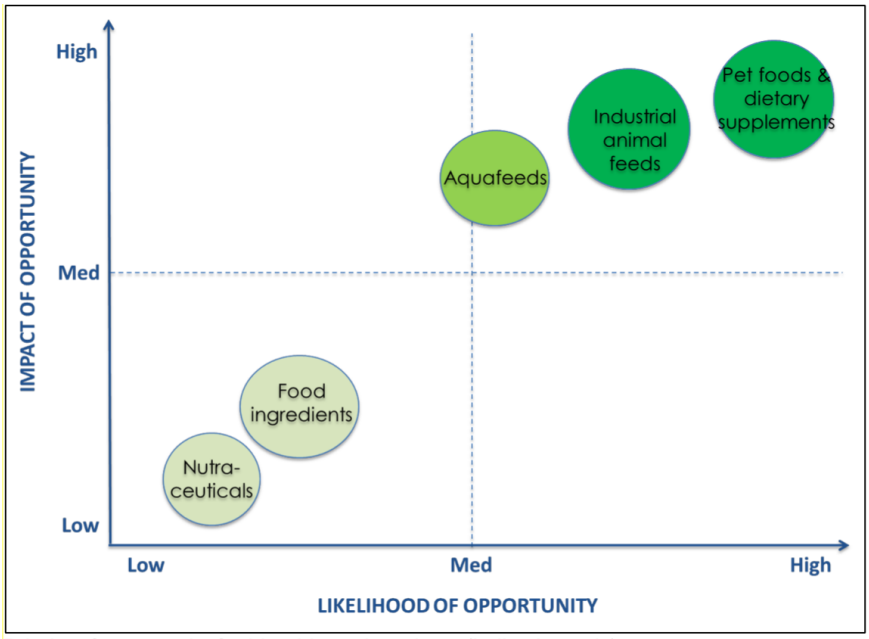


Figure 6. Priority of opportunity for blood-based products. Source: (Glenn, 2015)

Blood collection

Previous research into Australian meat processors capability to collect blood for the production of blood-derived products identified several methods for collection. [9] That report listed manual processes where collection is done through either a bucket or with a hollow-bladed knife. Either process requires collection tanks very close to the slaughter room and would require either reconstruction or a fit for purpose construction, such as a blood collection tunnel. [12]

Choice of blood collection method should be driven by the products that are needed to be produced. As Lynch et. al. (2017) brings up, the use of open-draining systems (such as a bucket or floor drain)

means a high likelihood of contamination. [7] Blood collected this way cannot be used for food, pharmaceutical or cosmetic use in a global market, as it runs the risk of mixing with material that may contain BSE and is therefore a break in regulatory compliance. It would have to be sold or processed into a lower value product, such as fertilizer.

5.5 Bovine derived bioactive compounds for consideration

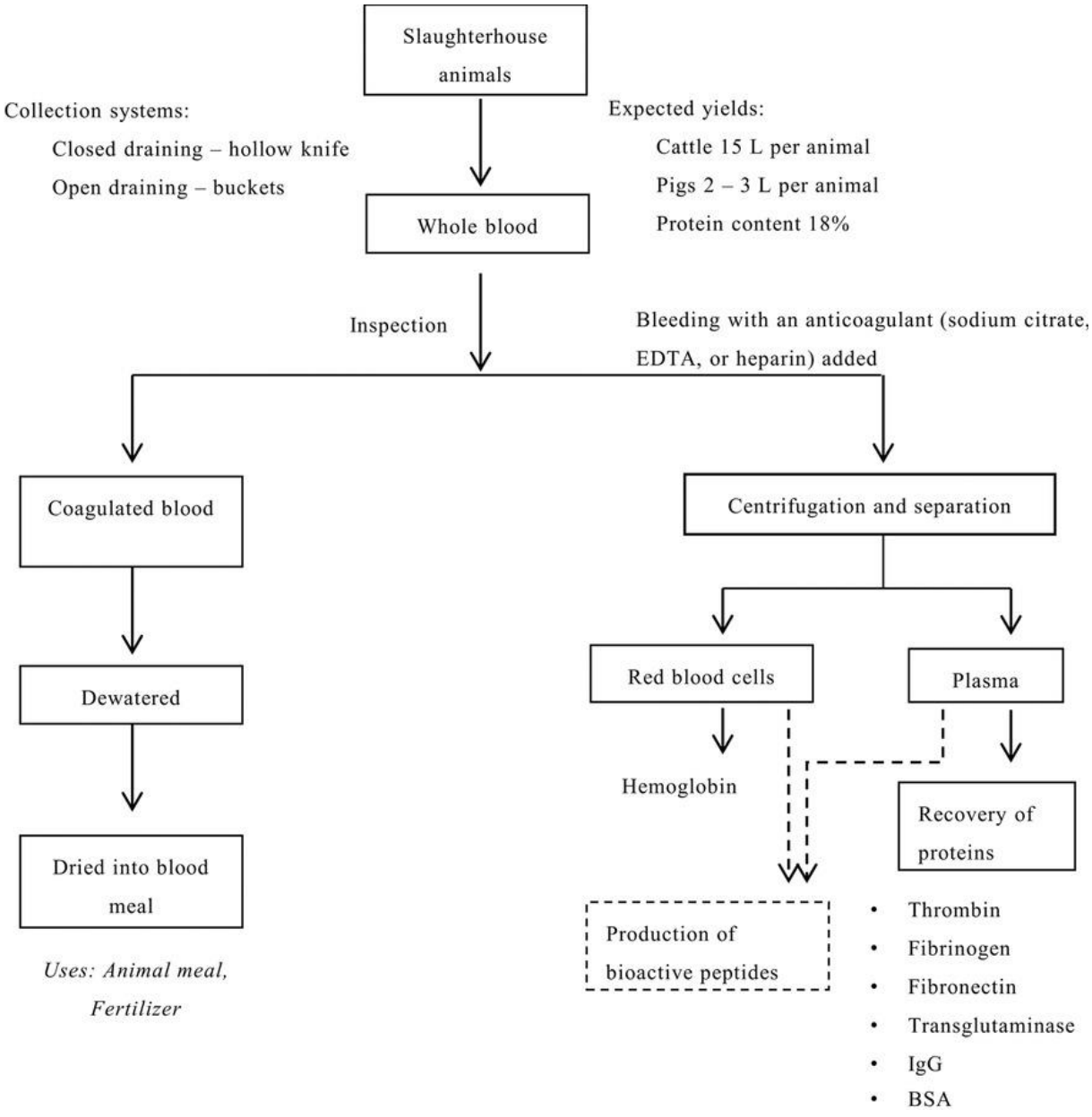


Figure 7. Animal blood collection and separation into usable fractions. Source: (Bah et al., 2013)

As seen in Figure 7, there are several compounds that can be harvested from bovine blood. This flexibility allows for adaption to market, supply and resourcing conditions.

Bovine Serum Albumin

Serum albumin is the most abundant blood plasma protein. Serum albumin is only found in the blood of animals, and whilst foetal blood albumin (FBS) is more valuable than adult blood albumin (BSA)

due to higher concentrations of growth promoting factors and nutrients, BSA is easier to extract and is more abundant.

Bioactive compound	Tissue source & weight per head	Abundance (per/kg of tissue)
Serum albumin	Plasma – 11.34kg/head	Typical concentration >50g/L

BSA is added to foods to act as a binding agent but there is growing demand for its use in nutraceuticals to boost protein content and act as an immune enhancer. One such product example is NutraGammax from Proliant. This is a bioactive protein isolate used in sports nutrition products and protein supplements. The benefits of using BSA is that is can cater for lactose intolerance as a replacement for milk proteins, casein and gamma-lactoglobin. There is limited use for BSA in cosmetics, but it is commonly used in research as a chemical reagent, cell culture media and other such uses in chemistry and molecular research and diagnostics. BSA is preferred due to its stability, low reactivity, and low cost. Australia has the competitive advantage with BSA due to being BSE and FMD free.

Company	Amount	Price	Source	Reference
Sigma	500g	$1830.00	Bovine	https://www.sigmaaldrich.com/catalog/product/sial/a9056?lang=en&region=AU
Bioma	1000g	$2079.00	Bovine	https://gentaur.com/2066972053/albumin-bovine-serum-bsa-fraction-v-heat/bioma?p=8012612048

Methods of extraction and purification of BSA from blood includes heat shock, chromatography and other types of fractionation methods. [3][8] Fractionation refers to a broad range of methods that separate material based on differences in the materials physical properties. Most fractionation methods used to extract albumin from blood follow some form of the Cohn method, which uses the solubility of albumin in an ethyl alcohol solution to separate it from the other material. Some Serum Albumin extraction methods are reported to combine the Cohn method with a liquid chromatography method afterwards. [8] Liquid chromatography is a particular method of fractionation that, in this context, passes plasma through a container filled with tiny, silica-made balls. [27] These balls will be coated, or have incorporated into them, a specific molecule that will easily bind to your material of choice, such as albumin.

Heat shock relies on the relative stability of albumin through changes in heat. This can allow for safe extraction of albumin, as you raise it to temperatures, up to 60˚C, it pasteurizes the plasma and kills pathogens. Some methods add heat shock into their processes solely because it is anti-pathogenic. [8]

Fibrinogen

Fibrinogen is the inactive precursor to fibrin which is the principle protein involved in the clotting of blood. Fibrinogen is applied to meat where thrombin transforms fibrinogen to fibrin which in turn binds with collagen in the meat, acting to bind meat pieces in re-constituted meat products. It is also used in medical applications as a tissue sealant to stop excessive bleeding in surgery or injuries.

Bioactive compound	Tissue source & weight per head	Abundance (per/kg of tissue)
Fibrinogen	Plasma – 11.34kg/head	Typical concentration ~1g/L

Typical fibrinogen manufacturing involves precipitation. Blood is separated into plasma and cells. The plasma is frozen then melted and centrifuged to separate out the fibrinogen.

Company	Amount	Price	Source	Reference
Innova research	25mg	$259	Bovine	https://www.innov-research.com/products/bovine-fibrinogen-purified
Sigma	25g	$3040	Bovine	https://www.sigmaaldrich.com/catalog/product/sigma/f8630?lang=en&region=AU

Thrombin and Prothrombin

Prothrombin is the inactive precursor of thrombin. Thrombin is a coagulation protein. Prothrombin is more stable than thrombin in storage and transport. Thrombin is used to stop minor bleeding in surgery and to release growth factors in wound sites to accelerate the healing of bones and tissues. It is also used in medical and research diagnostics.

Bioactive compound	Tissue source & weight per head	Abundance (per/kg of tissue)
Prothrombin	Plasma – 11.34kg/head	100mg/mL
Thrombin	Plasma – 11.34kg/head	100mg/mL

Blood fractionation and precipitation occurs before prothrombin is extracted by dilute calcium bicarbonate. Prothrombin is then activated by sodium citrate and prothrombinase to yield thrombin. Thrombin is then purified by ion exchange chromatography.

Gamma-Globulin

Gamma-globulins are a class of proteins found in blood as well as other bodily fluids. There are five classes of immunoglobulins: IgA, IgD, IgE, IgG, and IgM. These compounds are utilised by the immune systems to identify and neutralise foreign bodies.

Bioactive compound	Tissue source & weight per head	Abundance (per/kg of tissue)
Gamma-Globulin	Plasma – 11.34kg/head	Up to 75g/L

Bovine sourced gamma-globulins are used in research and diagnostics as a stabiliser, marker and standard protein. Bovine sourced gamma-globulins are also used in livestock colostrum supplements to prevent bacterial and viral infections. This reduces scours and reduces mortality rates in young animals, as well as potentially boosting weaning weights.
IgG is also used in sports supplements such as protein powders, and the use of serum derived IgG provides an alternative for lactose intolerant people.

Company	Amount	Price	Source	Reference
Merk	10g	$273.00	Bovine	https://www.sigmaaldrich.com/catalog/product/sigma/g7516?lang=en&region=AU

Gamma-globulins can be extract from bovine serum through polyphosphate precipitation and chromatography. This enables gamma-globulins to be extracted as further stages from the BSA process.

Haemoglobin

The iron containing, oxygen transporting protein in red blood cells. This protein is abundant and is a by-product of BSA production as red blood cells are separated from plasma.

5.6 Biotech companies operating in bovine blood bioactives

Research has found two biotechnology companies in Australia who produce bovine blood products:

- Bovogen Biologicals – East Keilor VIC https://bovogen.com/
- Moregate Biotech – Bulimba QLD https://www.moregatebiotech.com/

Bovogen was acquired in 2016 by ANZCO Foods of New Zealand and has been manufacturing BSA since 2003. Bovogen specialises in animal serums and plasmas of high quality and full traceability. Products include: FBS, BSA, immunoglobulin, fibrinogen, fetuin, as well as haemoglobin and placenta powders.

Moregate is located within close proximity to AC and boasts disease free raw materials from Australia and New Zealand. Like Bovogen, Moregate special FBS and BSA products.

Both of these companies could be potential manufacturing partners and it is likely that Moregate is already sourcing ACC product at times.

Production costs

An MLA and AMPC factsheet published in 2001 details expected processes and costs for producing albumin from bovine blood. This factsheet can be found in Appendix 1: MLA and AMPC factsheet on albumin production.

Taking figures used in this factsheet applying inflation and checking with industry representative with similar operations, the following has been estimated. Two areas of production are required: production of plasma (separating blood) and production of albumin. It is estimated that the plasma production capital costs could be approximately $18,000 to $22,000 per square metre. These costs include the buildings and fittings, blood collection equipment blood separation equipment and laboratory. The second stage is the albumin production capital costs at between $7500 and $9000 per square metre. This second stage requires specialty processing equipment plus the building. Specialist equipment could include rotary drum vacuum filter, flow through filters, and ultrafiltration. These costs are estimates alone and it is unknown how much engineering and process improvement have impacted capital and operating costs. This 2001 report estimate a yield of 4.78L of albumin from 8L blood however it is highly possible that this process is more efficient 19 years on.

Note this does not include capability cots as this process would require oversight of at least one biotechnologist and additional laboratory staff. Depending on the scale there could be a reduction in rendering processes with product being diverted and hence staff from this area could be upskilled for bioactive production. There would be additional costs for the likes of further processing and marketing.

5.7 Bone products

The benefits of collagen are well understood however unlike previous reports of this nature, this project analyses the potential for collagen from bone products. Whilst gelatine is used in items such as food and beverages, hydrolysed collagen is most commonly used in nutraceuticals and supplements, but also in livestock feeds. Research shows benefits in taking hydrolysed collagen to treat osteoporosis and there is data showing anti-ageing properties for skin.

Hydrolysed collagen can be extracted from numerous raw materials including tracheas and hides, however this project examined bones in particular.

Market research has projected the value of collagen hydrolysate market to be worth USD$1 billion by 2026 with a CAGR of 7%, with health supplements driving the majority of this growth (Global Insights, 2020).

Company	Amount	Price	Source	Reference
Bulk Nutrients	3kg	$139	Bovine	https://www.bulknutrients.com.au/products/hcp/
Collagenx	4.5kg	$275	Bovine	https://www.ebay.com.au/itm/Collagen-Powder-Pure-Hydrolysed-GrassFed-4-5k-Bulk-100-Australian-owned-Trusted-/313103254929
The Source Bulk Foods	100g	$15.50	Bovine	https://thesourcebulkfoods.com.au/shop/health/collagen-powder/

Hydrolysis Process

Given ACC's familiarity with rendering, the following is provided as an insight to bioactive peptide processes and to assess ACC's capacity.

Hydrolysis is a process of breaking animal tissue and bone into proteins. It can be performed either with an alkaline or enzymatic mixture in a pressure vessel, heated and circulated. The processes involved in transforming by-products to bioactives generally involve hydrolysis where liquid molecules such as water rupture chemical bonds.

Different Hydrolysis Methods

Acid and Alkaline Hydrolysis

Acid hydrolysis in undertaken with hydrochloric or a sulphuric acid whilst alkaline hydrolysis uses sodium hydroxide or potassium hydroxide.

Enzymatic Hydrolysis

Enzymes from animal, vegetable or microbes are used in the reaction. Whilst the reactions are effective and easier to control, they are higher cost due to batching loads and cost of the enzyme. Time, temperature and pH are critical. Examples of enzymes are papain (papaya), bromelain (pineapple), thermolysin (bacteria), Alcalase (bacteria), Flavourzyme (fungal), pepsin(stomach), trypsin (pancreas).

Sub-Critical Hydrolysis
This process uses high pressure and water as a solvent at temperatures of 100 (0.10 MPa)-374 degrees Celsius (22MPa). The water is a liquid at temperatures above boiling point.

Ultrasound
Uses cavitation, rapid changes of pressure. It is a faster method resulting in a small molecular weight.

Microbial Fermentation
As the name implies microbes are used to ferment the by-products.

Protein Hydrolysate Purification
Once the hydrolysis process has concluded purification is conducted to extract the peptides. The process involves ultrafiltration and separation of the different compounds using fractionalism (separating out components)

Concentration
The final step is to freeze or spray dry.

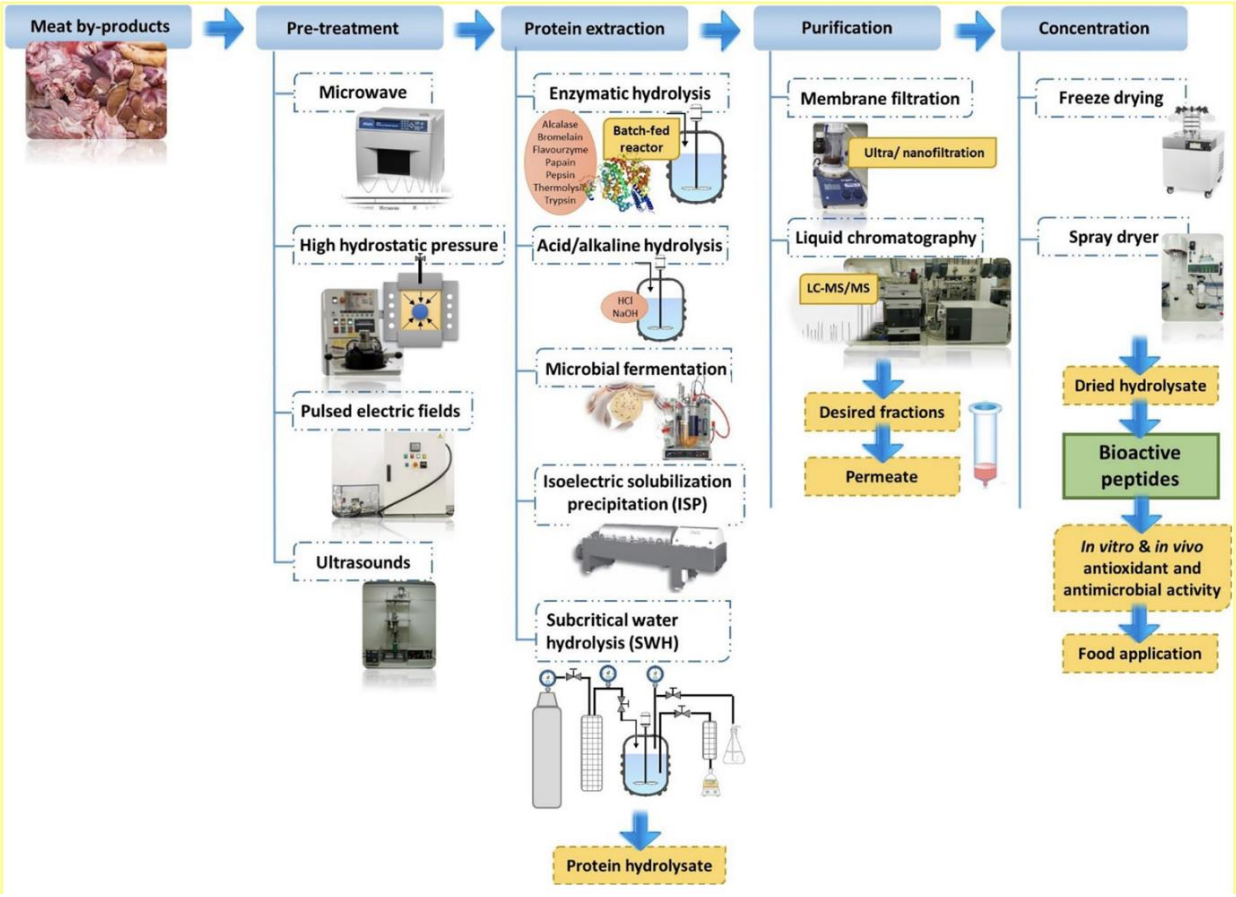


Figure 8. Extraction process of bioactive peptides from meat by-products. Source: (Borrain et al., 2019)

Hydrolysed Collagen
Hydrolysed Collagen can be extracted from bone through repeated rounds of chemical and enzymatic hydrolysis. [4][6] Both processes can take anywhere from 2-14 days to complete the

hydrolysis, requiring multiple rounds to complete. A thesis analysing these methods has attempted to grind bones into a powder prior to hydrolysis, in an effort to reduce time and increase yield. [1] This process does restrict market, as it can only be used for hydrolysed collagen. Other collagen products require either the molecular structure or other chemical makeup to be maintained throughout extraction and purification. Hydrolysed collagen does not have this requirement, so harsher processes that compromise on the accuracy required from other products can be used instead.

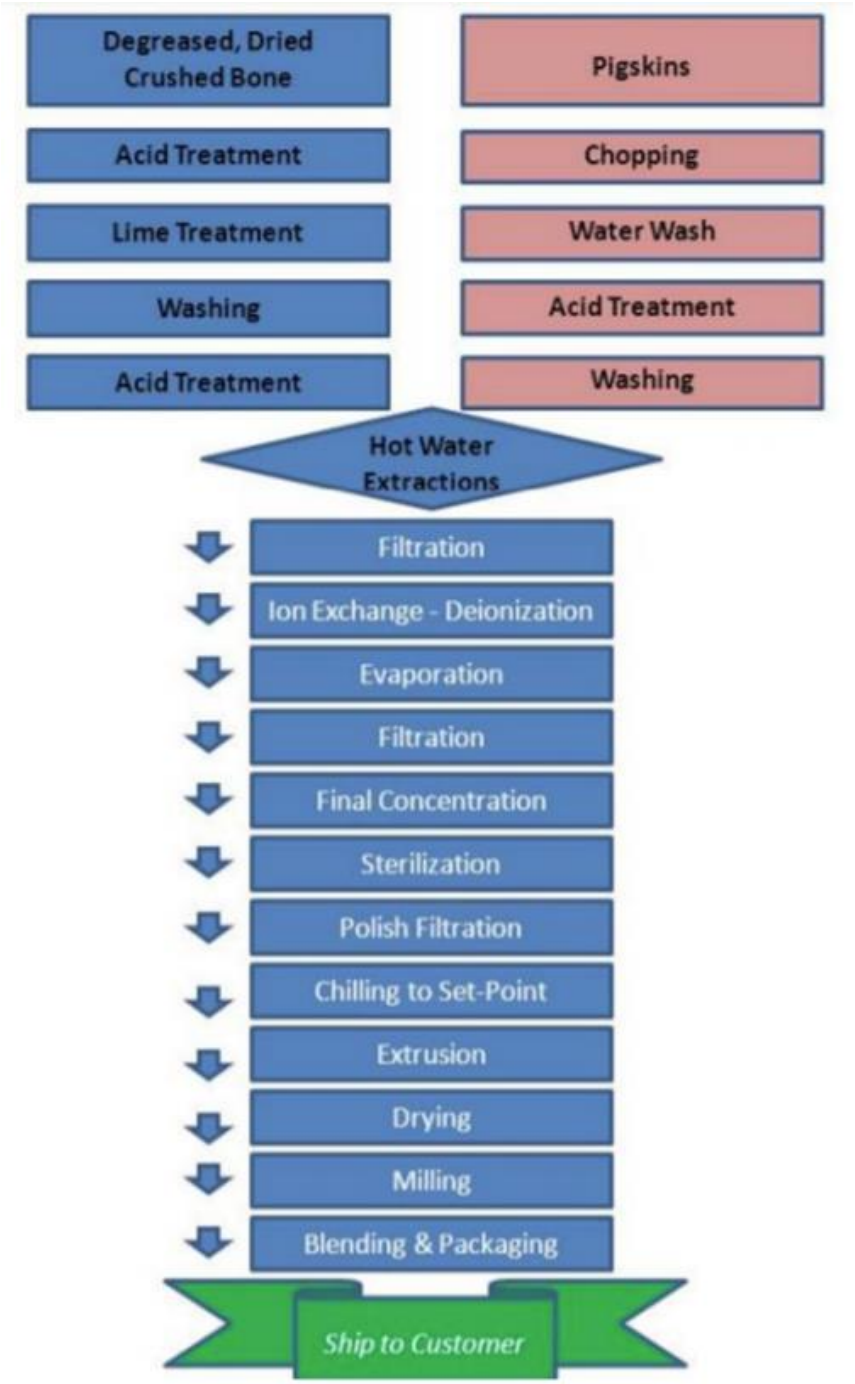


Figure 9. Gelatine Processing Plan from the Gelatine Manufacturers Institute of America (GMIA) from the Gelatine Handbook. This process is used by all members incorporated in GMIA 2019, Gelita North America, Nitta Gelatine NA, Inc., Rousselot, Inc. and Weishardt International NA - TERGEL Inc. Source: (Gelatine Manufacturers Institute America, 2019)

The diagram from Figure 9 shows that the base process flow enables the interchange of raw material in the hydrolysis process. Whilst this diagram demonstrates pig skin, bovine hides could be substituted. There is no substantial literature on the detail for each process rather this is commercially sensitive information.

Trialability and scalability

Undertaking a change in processing can be intimidating and possesses risks. One way to lessen concerns is by examining existing operations similar to ACC.

In 2011 the Meat and Livestock Australia investigated whether bioactive peptides could be extracted from Meat and Bone Meal. Two plants were selected Throsby in the ACT which rendered at a high temperature and Rockdale in Sydney. Both methods yielded Collagen Type I alpha 1. The resulted favoured low temperature processing yielding Calmodulin (5 peptides) AHNAK (desmoyokin) and 300 unmatched peptides. The higher temperature rendering at Throsby produced lower numbers of peptides, lower energy, slightly higher ash and lipid and lower levels of each amino acid.

This could be an entry point for ACC to trial bioactives:

- Without interrupting existing MBM operations,
- Protein and moisture percentages won't be affected by the removal of primary ingredients e.g. blood
- Animal feed grade could be produced as the process is refined and over time human grade be produced at a potentially higher margin

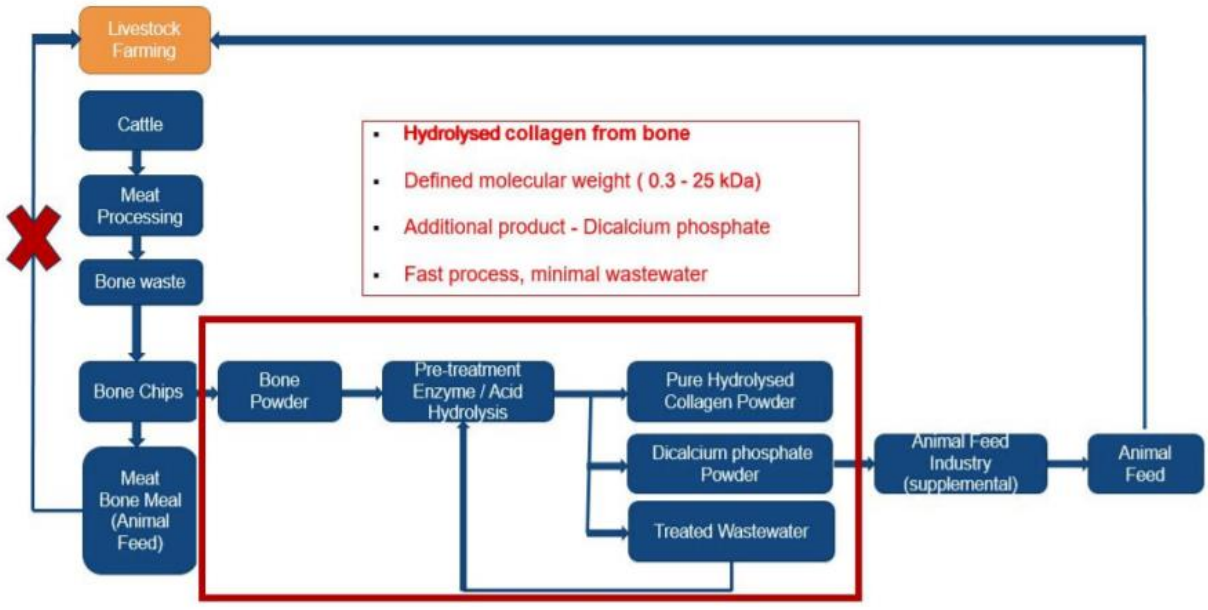


Figure 10. Diagram demonstrating that hydrolysed collagen can be developed as an accessory from the current MBM process to enable value adding of product. Source: (Angela, 2020)

ACC could develop this capability internally or alternatively partner with a collagen specialist company in order to reduce time to market and access the whole values chain.

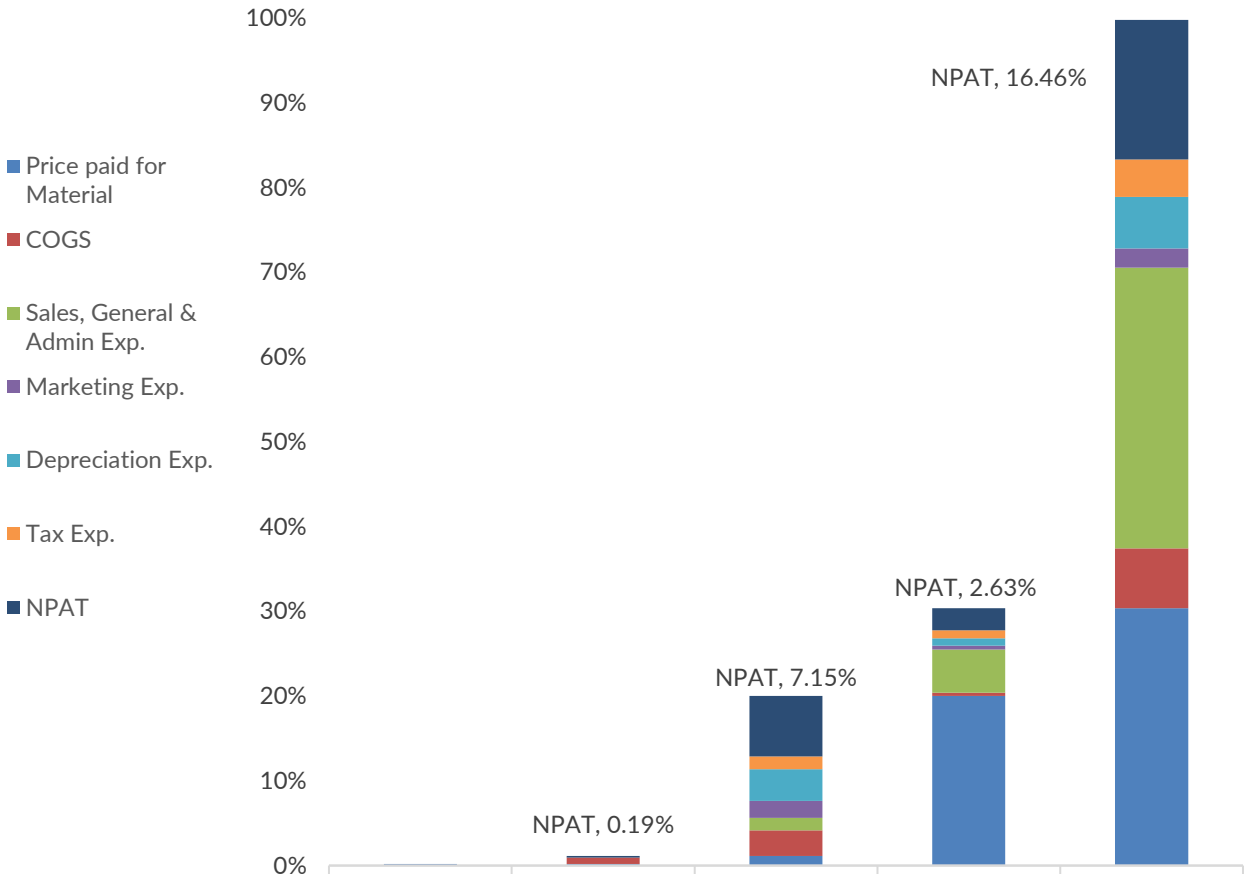
Potential partners domestically include:

- Gelita, based in Beaudesert QLD
    - Producing gelatin and collagen peptides, as well as other by-products, they deal in a hide-to-retail production line
    - Products range from food and nutraceuticals to pet and livestock feeds, fertilizer and technical applications.
    - One of the most likely partners for collagen production given company profile and proximity to ACC
    - https://www.gelita.com/en
- Maverick Biosciences, based in Dubbo NSW
    - They produce collagen from a wide range of bovine and other animal sources as well as numerous bioactive compounds
    - Medical grade production line with international market
    - Another quite likely partner for ACC due to production range
    - http://maverickbio.com/

5.8 Bioactive value chain

An MLA report from 2006 (MLA, 2006) examined bioactive supply chains and found that all have a producer and processor and a retailer and depending on the product there can be two or three additional processing steps in between. The next steps from processor is a value adder however it is viable that this role may be fulfilled by the processor. The value adder receives raw material and produces a bulk ingredient. The next step in the value chain is the manufacturer who generally buys the raw ingredient from the value adder and converts it into a finished product. This step involves stages such as purification, formulation, and encapsulation. Whilst this stage is shown separately, it is viable that the manufacturer will also do value adding as well. Some manufacturers will sell on to distributers for retail sale, however this is increasingly less common and therefore has not been examined and has instead been included in the manufacture stage.

Figure 11 examines the relative cost breakdown of each step of the value chain. The major cost components examined are as followed: cost of raw material, additional costs of good sold (COGS), sales, general, and administrative (SG&A) costs, marketing depreciation, tax and profit after tax. The selling price at each step of the supply chain becomes the cost of raw material at the next step. The value chain breakdown was developed based off work by MLA (2006) that uses CSIRO and published financial reports. This results in an approximate value however it is accurate to a level suitable for a high-level feasibility review such as this.



	Producer	Processor	Value Adder	Manufacturer	Retailer
NPAT		0.19%	7.15%	2.63%	16.46%
Tax Exp.			1.50%	0.94%	4.42%
Depreciation Exp.			3.76%	0.84%	6.11%
Marketing Exp.			1.98%	0.47%	2.26%
Sales, General & Admin Exp.			1.50%	5.08%	33.11%
COGS		0.75%	3.01%	0.38%	7.06%
Price paid for Material	0.19%	0.19%	1.13%	20.03%	30.37%

Figure 11. Cost breakdown for typical pharmaceutical/nutraceutical bioactives value chain

An analysis was done in terms of market segment (USD), typical price per kilogram of the retail product. The range of retail product size, the suitability of bovine bioactives and the ease of market penetration.

These segments have been validated (at a high level) as suitable & not suitable for ACC.

Table 3. Market breakdown of bioactive applications

	Market Size- 2020	***RRP- $/kg range***	***Avg. Product size (i.e. 500g)***	***Bovine* Suitability***	***Competition (Ease of Entry)***	***Overall Current Opportunity***
Alcoholic beverages	$1.70 bn US	$25+	Medium (1g-100g)	Low	Competitive	Not suitable
Animal Nutrition	$4.29 bn US	$25+	Large (100g+)	High	Reasonable	Suitable
Dietary Supplements	$11.19 bn US	$100+	Large (100g+)	High	Reasonable	Suitable
Functional Food & Drink	$6.33 bn US	$50+	Large (100g+)	High	Reasonable	Suitable
Personal Care	$4.89 bn US	$1k+	Medium (1g-100g)	Moderate-High	Competitive	Not suitable
Pharmaceuticals	$5.08 bn US	$100k+	Small (<0.1g)	Moderate-High	Exclusive	Not suitable

From the market matrix above it is apparent that the best segments would be animal nutrition, dietary supplements and functional foods and drink. The above was determined based on the consideration that ACC is focused on rapidly delivering low-cost validation that an opportunity exists in the bioactives market. Successful execution of this approach will build confidence that investment in bioactive production at a greater scale will deliver substantial ROI & maintain commercial viability in the long-term.

Despite the promising market reports, the ability to find consumer products actively advocating bioactives is quite limited in the market and is quite segmented as to the source of the bioactives i.e. shellfish, plant and bovine. Some products often labelled, “Made from Australian and Imported Ingredients” do not disclose the provenance of the product.

Personal supplements are starting to emerge that actively identify the source of their collagen hydrolysate.

Table 4. Retail prices and sources of collagen products

Product	Source Material	Consumer price AUD Price per 100g
Gelpro Advanced Marine Collagen	Wild caught deep sea fish	$29.98
Japanese BCAAs 4:1:1 Unflavoured - 200grams	Amino Acid -All plant based no animal content	$21.48
Peptide Collagen Hydrolysate Sachets 20 x 15g sachets	Unstated	$13.32
Richgrow Blood and Bone Fertilizer (which could have been processed to extract Collagen Hydrolysate)	Meat and Bone Meal	$0.18

Personal supplements are increasing with demand for collagen hydrolysate. Prices for these products current retail for between $8-13 AUD per 100 grams. In comparison blood and bone fertilizer which could have been processed to yield collagen hydrolysate only achieve a value of $0.18 per 100 grams at retail outlets. The processing plant's share of the blood and bone component may be low at 40%. On the assumption that this material could have been processed for food grade supplements at even a low yield of 10% the cost at the processing plant would be minimal. It therefore represents a potential large value-adding proposition.

Sales channels

There is an increased number of companies and retail operations that are moving to online ecommerce channels. This speaks to the generation that purchase nutraceutical and supplement options as it allows them to rapidly compare prices and product offerings. This has only been amplified with the effects of COVID-19 and has driven older generations to embrace ecommerce platforms. Therefore, it is essential that ACC utilise online sales if they are producing a value added or retail product and/or ensure their partners have this presence.

Challenges facing the bioactive sector

The most significant challenge facing the industry apart from product processing patents, is the unmonitored advertising and misleading labelling of products. Governments and regulatory bodies around the world are providing guidelines to broadcast direct-to-consumer advertising.

There is also increased numbers of plant and laboratory derived bioactives as alternatives to traditionally animal based products. These products are often cheaper to produce and speak to new trends in plant-based products.

5.9 Key market players

The bioactives market is increasingly moving away from a monopolistic environment to a more diversified completion environment with new smaller competitors moving in to harness the rapid growth trends. Entry barriers are relatively high with slow time to market, high costs of production

and a small but growing marketplace. Premium quality and product-based differentiation allows successful operation. Key domestic players are listed above in the appropriate sections.

5.10 Operational considerations

There are numerous operational considerations that need to be detailed related to blood and bone value add processing options.

Work flow considerations

Workplace considerations include the changing of existing work practices for blood and bone products and the alterative use for blood and bone value add processing. This may require a high level of raw material segregation based on livestock vendors and other classifications related to market claims. This action has been mostly unmonitored, and benefits can be overstated. The use of social media 'influencers' has allowed unsubstantiated claims to be used to make product sales which can be potentially dangerous. There is potential opportunity for Australian manufacturers to provide increased traceability and assurance of product origins and claims, in order to provide a premium product to the discerning consumer.

QA considerations

QA work practices related to blood and bone value add production are yet to be determined. There is likely to be a considerable level of testing and analysis reporting required to meet market requirements.

Customer and regulatory compliance considerations

The process of taking base biological material and producing valuable bulk pharmaceutical grade materials out of them will likely require considerable and complex customer and regulatory compliance approvals. Some of these compliance outcomes might take several years to obtain. This is because the history for production data and history of production material analysis results can from part of the compliance approvals. In other words, the pharmaceutical manufacturing facility needs to have produced enough product over a long enough period to demonstrate compliance to the requirements to obtain necessary approvals.

Consideration will need to be given on how to commercially manage the process of customer and regulatory compliance approvals that could potentially take a long time to obtain. This might mean that product may need to be sold to a lower value market until the necessary approvals are obtain.

It must be acknowledged that the regulatory requirements for some bioactive ingredients vary between countries therefore it is recommended that one base raw product is developed initially to obtain required licenses and sign offs before commencing with further development.

6.0 CONCLUSIONS/RECOMMENDATIONS

Both blood and bone derived bioactives present significant opportunities for ACC. Substantial growth is forecast cross bioactive categories and given the abundant source of raw material, ACC should continue to investigate the role bioactives can play in their business.

Blood derived bioactives is a potentially feasible option for ACC as there are numerous points in the production process to harness bioactives for sale. Blood bioactives does present constraints such as the need for significant workflow interruptions and costs to harness blood on the slaughter floor in order to utilise for food and human grade products. Blood is however scalable and there is the potential for ACC to partner with biotech companies to establish supply and to access specialised skill sets.

Bone derived bioactives require capital costs to develop the processing facility as well as specialised skills. Hydrolysed collagen does however enable additional raw materials such as hides to be utilised thereby permitting higher throughputs and a greater flexibility in material composition. Like blood derived bioactives, bone derived bioactives have animal feed channels that could be harnessed to reduce the regulatory burden of human grade product and enable faster access to market. Hydrolysed collagen is processed in such a way that some collagen types cannot by salvaged, however by-products of the process can be sold and there is enough market variation for hydrolysed collagen that risk is reduced to a low enough extent to harness current rendering capacity and skill sets.

It is recommended that ACC and AMPC proceed with detailed feasibility studies on a spectrum of blood bioactives and hydrolysed collagen through discussions with various product and equipment manufacturers. It is important that regulatory aspects be included in their scoping as this will likely influence feasibility outcomes depending on destination market. Likewise, partnership opportunities could be scoped to allow ACC access to the appropriate skills and to reduce start-up capital costs by leveraging existing operations nearby.

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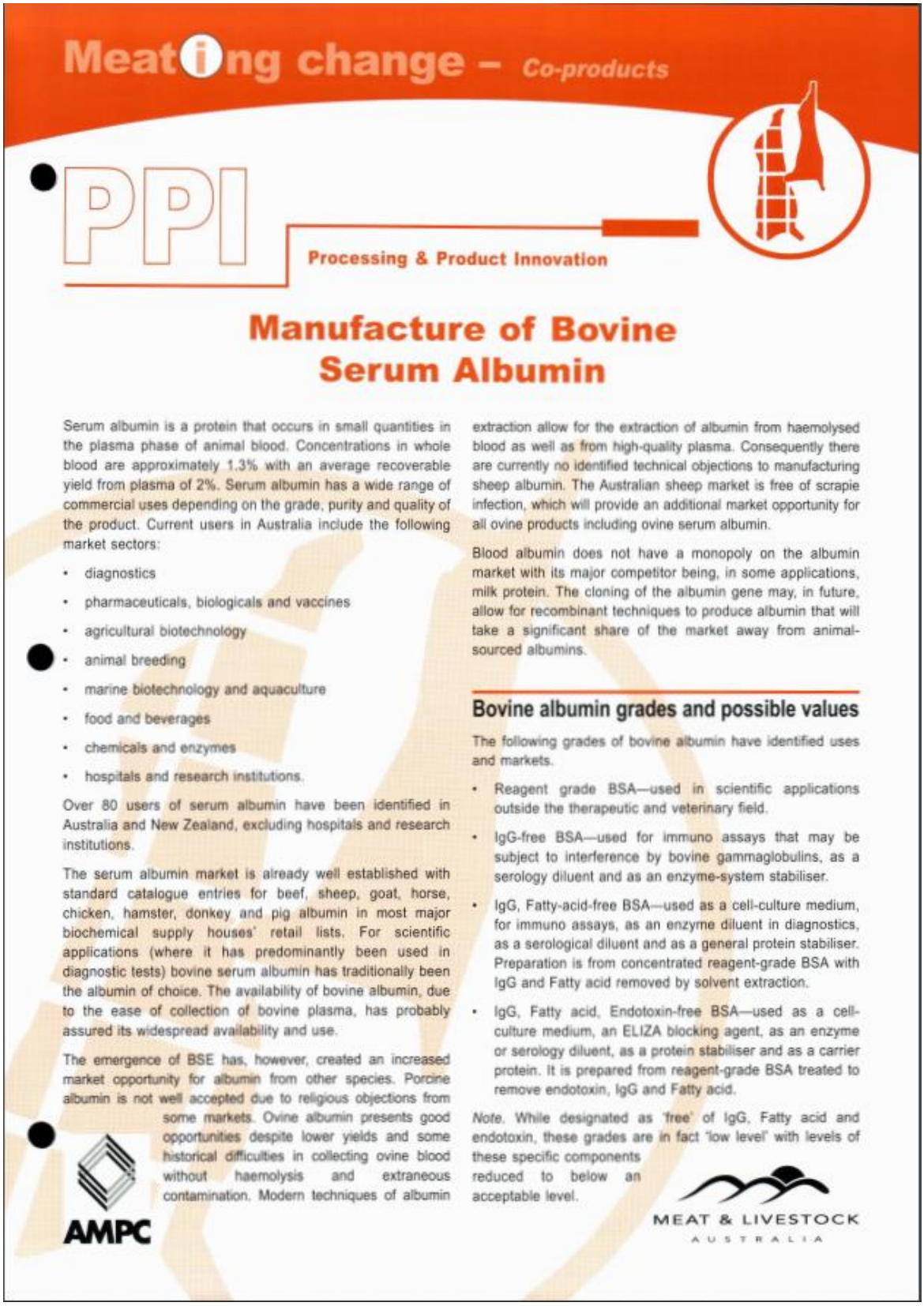
8.0 APPENDICES

Appendix 1: MLA and AMPC factsheet on albumin production



Meating change – Co-products

PPI

Processing & Product Innovation

Manufacture of Bovine Serum Albumin

Serum albumin is a protein that occurs in small quantities in the plasma phase of animal blood. Concentrations in whole blood are approximately 1.3% with an average recoverable yield from plasma of 2%. Serum albumin has a wide range of commercial uses depending on the grade, purity and quality of the product. Current users in Australia include the following market sectors:

- diagnostics
- pharmaceuticals, biologicals and vaccines
- agricultural biotechnology
- animal breeding
- marine biotechnology and aquaculture
- food and beverages
- chemicals and enzymes
- hospitals and research institutions.

Over 80 users of serum albumin have been identified in Australia and New Zealand, excluding hospitals and research institutions.

The serum albumin market is already well established with standard catalogue entries for beef, sheep, goat, horse, chicken, hamster, donkey and pig albumin in most major biochemical supply houses' retail lists. For scientific applications (where it has predominantly been used in diagnostic tests) bovine serum albumin has traditionally been the albumin of choice. The availability of bovine albumin, due to the ease of collection of bovine plasma, has probably assured its widespread availability and use.

The emergence of BSE has, however, created an increased market opportunity for albumin from other species. Porcine albumin is not well accepted due to religious objections from some markets. Ovine albumin presents good opportunities despite lower yields and some historical difficulties in collecting ovine blood without haemolysis and extraneous contamination. Modern techniques of albumin extraction allow for the extraction of albumin from haemolysed blood as well as from high-quality plasma. Consequently there are currently no identified technical objections to manufacturing sheep albumin. The Australian sheep market is free of scrapie infection, which will provide an additional market opportunity for all ovine products including ovine serum albumin.

Blood albumin does not have a monopoly on the albumin market with its major competitor being, in some applications, milk protein. The cloning of the albumin gene may, in future, allow for recombinant techniques to produce albumin that will take a significant share of the market away from animal-sourced albumins.

Bovine albumin grades and possible values

The following grades of bovine albumin have identified uses and markets.

- Reagent grade BSA—used in scientific applications outside the therapeutic and veterinary field.
- IgG-free BSA—used for immuno assays that may be subject to interference by bovine gammaglobulins, as a serology diluent and as an enzyme-system stabiliser.
- IgG, Fatty-acid-free BSA—used as a cell-culture medium, for immuno assays, as an enzyme diluent in diagnostics, as a serological diluent and as a general protein stabiliser. Preparation is from concentrated reagent-grade BSA with IgG and Fatty acid removed by solvent extraction.
- IgG, Fatty acid, Endotoxin-free BSA—used as a cell-culture medium, an ELIZA blocking agent, as an enzyme or serology diluent, as a protein stabiliser and as a carrier protein. It is prepared from reagent-grade BSA treated to remove endotoxin, IgG and Fatty acid.

Note. While designated as 'free' of IgG, Fatty acid and endotoxin, these grades are in fact 'low level' with levels of these specific components reduced to below an acceptable level.

AMPC

MEAT & LIVESTOCK AUSTRALIA

The costs to produce, and prices received for, these products depend on the level of purity, extent of further processing required and yields obtained. Indicative prices for the different grades range from $4,000 to $50,000 per kilogram.

Production of albumin

Albumin can be recovered by a number of different techniques including ion-exchange chromatography, salt fractionation, selective denaturation and pH titration. Large-scale production requires:

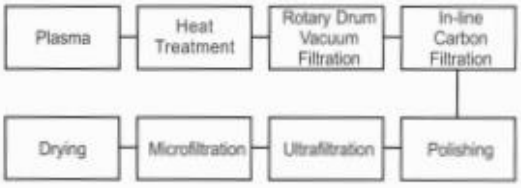
- simple methodology;
- readily available plant and equipment;
- a good source of raw material;
- qualified staff.

Selective denaturation techniques are the most likely application for Australian meat industry partners. They are the most attractive option because they are:

- simple, minimum-step methods that provide a good yield of product (20 kg per tonne of plasma);
- capable of producing product with protein purity that is generally high (>98%);
- suitable for recovery of albumin from bovine, ovine and porcine plasma;
- techniques requiring 'off-the-shelf' filtration equipment, drawing on the same equipment suppliers as the food industry and, in particular, the wine industry.

The process flow is outlined in Figure 1.

Figure 1. Selective denaturation of plasma to extract albumin



The food and wine industries commonly use the type of equipment required for vacuum filtering and ultrafiltration. Proprietary activated carbon filters and micro-filters, which are used in the brewing industry, are ideal for polishing the albumin solution.

Drying of the product is generally by freeze drying although spray drying may also be used. Services are available in Australia for contract freeze drying and spray drying; however dependence on contract drying services may create a weak link in the production process as the highest standards are required to produce sterile product. Commercial freeze driers are manufactured in Australia (eg Oriel manufacturing) so that a suitable drier could be included at the processing site.

Estimated capital costs (1995 estimates + 2% CPI), not including drying equipment, for a batch process handling 3,000 – 5,000 litres of plasma per triple shift have been determined as follows.

200 sq metre building & fittings	$433,000
Rotary drum vacuum filter	$86,000
Flow-through filters	$13,000
Ultrafiltration	$65,000
Plumbing, tanks, services, CIP	$49,000
Total	**$646,000**

As the selective-denaturation technique for albumin recovery includes a heat-treatment step, it is logical to site the process at the plasma collection point to eliminate the need to chill the plasma for transportation to the processing site. As it may be difficult to match multi-shift albumin production to a single blood-collection shift, it may be impossible to totally eliminate plasma chilling. Costs for chilling and reheating plasma can be minimised with careful planning and equipment sizing.

The preliminary costing above has been prepared on a batch process. The process can, however, operate on a continuous basis which would be expected to realise some economies related to reduced processing time and reduced energy consumption.

Plasma production should be established at a level to achieve economy of scale. This would enable the provision of plasma to the process at a competitive price. This may be achieved with a plant dedicated to high-volume production of plasma for the edible-food market. As identified in the MLA Co-products brochure *'Potential uses of blood products'* many food producers in Australia are currently reluctant to use plasma products in food because of the perceived reaction of consumers to blood products and the ambiguous labelling situation throughout the food industry.

The raw material for the albumin process need not be the best quality plasma—based on the level of haemoglobin present. This process can tolerate plasma with high amounts of haemoglobin; however, the plasma needs to be screened for virus content as well as the final product. This can be done by the Department of Primary Industries Animal Research Institute in Brisbane.

This process is a higher technology process than those normally encountered on an abattoir site. Consequently it will need to be under the supervision of a person having knowledge of the required processes and standards to be achieved. It would be expected that the person would hold a science degree, or equivalent, and preferably have experience in the processing of fine chemicals or pharmaceutical products.

Plasma costs

This process is reliant on a stable and economic supply of plasma. Estimated costs have been prepared for the construction and fitting of a facility for the collection of edible blood and its separation to plasma and cell fraction at an abattoir in Australia. Costs are estimated for an abattoir with slaughter capacity of 525 head of cattle on a single shift and 825 head over two shifts and are given in Table 1.

Table 1. Estimated costs for facility to produce plasma on an abattoir site (1996 figures + 2% pa CPI)

Item	Budget cost
Building construction/alterations	$102,000
Blood collection equipment	$127,000
Blood separation equipment	$105,000
Laboratory	$11,000
Miscellaneous	$30,000
Total	$375,000

The profitability of the plant is dependent on the blood throughput. Preliminary cost analysis has indicated that, for a range of throughputs, the cost of production, break-even selling price for plasma, and payback period for the plant is likely to be as given in Table 2. These estimates are based on recovery of 8 litres of blood per head of cattle.

Table 2. Estimated returns for blood separation to plasma and cell fraction. (1996 figures)

Slaughter per day	No. of shifts	Production cost per kg plasma	Break-even plasma sell price per litre	Payback period
525	1	$0.94	$1.40	15 months
750	2	$0.93	$1.25	10 months
825	2	$0.89	$1.20	9 months

It is essential that all costs and prices be confirmed as part of a cost/benefit analysis prior to considering investment in new technology.

It is important, when considering an investment in this technology, to recognise that the serum albumin is only a small part of the plasma raw material and that other plasma components can be co-produced with the serum albumin. Any cost/benefit analysis should consider the cost and return from any co-products produced.

Further reading

This information is a summary of information from the following project funded by the Meat Research Corporation.

Project UGR.002: Value Added Proteins and Enzyme Recovery from the Meat Industry

Further detail is available from the final project report for this project and the project paper 'Estimates of the Cost of Manufacture of Bovine Serum Albumin'—both of which are available from Meat and Livestock Australia.

Related information is given in these MLA Co-products brochures.

- Potential Uses of Blood Products
- Edible Collection of Blood
- Separation and Stabilisation of Useable Blood Components
- Recovery of specific proteins and enzymes from blood: Part 1 – Aprotinin, transglutaminase, fibronectin and related proteins
- Recovery of specific proteins and enzymes from blood: Part 2 – Growth factors

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