

Translating food-grade red meat coproducts into evidence-supported bioactives

Project code
2026-1048

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1.0 Abstract

Australia's red-meat industry generates large, recurring biological coproduct streams from traceable livestock and highly controlled processing systems. Most are sold into established commodity and ingredient markets. The opportunity is to selectively develop suitable fractions for higher-value human-health applications while preserving existing coproduct value.

AMPC Project 2026-1048 tested the downstream development pathway. A preparation derived from bovine adipose tissue collected through a commercial processing environment was progressed into an ethics-approved, TGA-notified first-in-human study. Eleven adults aged 50 to 80 years completed 42 days of daily administration and follow-up. No serious adverse events were reported. Exploratory functional and biological assessments informed further development and support no efficacy claim.

The project also tested an integrated early-development model combining material preparation, regulatory and ethics navigation, human safety assessment, functional and biological measurement, and development learning. It demonstrated that a processor-derived biological preparation can be progressed into human research while identifying where product definition, regulation, measurement and execution require stronger early alignment.

A key industry lesson is that higher-value development starts at the processor. Collection conditions, traceability and material specification can determine which downstream pathways remain available. The next opportunity is to strengthen processor supply capability, deepen regulatory understanding, continue adipose and plasma development, and progressively advance the strongest product opportunities toward market entry through staged investment and evidence-led decisions.

2.0 Executive summary

Population ageing is increasing demand for products that support health, function and independence later in life, creating sustained market pull for evidence-supported ingredients and products associated with healthy longevity. Australia enters this opportunity from a strong starting position. Its red-meat industry is underpinned by a predominantly pasture-based production system, national animal identification and traceability, animal-health surveillance, carcase inspection, established food-safety systems and highly developed processor quality and export controls. Built for meat production and market access, these systems also provide much of the provenance, traceability and source assurance that higher-value biological materials may require.

Much of this biological material is currently directed into established commodity and ingredient markets. The opportunity is not to displace those markets, but to build additional value above them by selectively recovering and qualifying higher-value fractions where market demand, technical feasibility, evidence and regulation support doing so.

AMPC Project 2025-1073 began testing that proposition at processor level. It demonstrated recovery of higher-value biological fractions from red-meat coproduct streams under commercial conditions and showed that value could potentially be added while preserving residual coproduct value. For blood and plasma, it identified suitable collection as the binding constraint: some source-material conditions, once lost, cannot be recreated downstream.

AMPC Project 2026-1048 extended that work into human evaluation. The project progressed CX-50, a freeze-dried preparation derived from bovine adipose tissue, from a commercial processing environment into an ethics-approved, TGA-notified first-in-human study. Eleven adults aged 50 to 80 years completed 42 days of daily administration and follow-up. No serious adverse events were reported.

The project was designed to do more than establish an initial human safety and feasibility record. It tested whether several activities that are often handled separately—material preparation, regulatory and ethics navigation, repeated human administration, functional and biological measurement, endpoint-feasibility testing and downstream development learning—could be combined within one early-stage development programme. RE-ENVIGOR was the clinical study through which that broader model was tested.

The project demonstrated that this integrated approach is feasible, but it also exposed the complexity of applying it within existing food, therapeutic-goods and clinical-research systems. Some assessment systems worked as intended and others did not, which identified the methods to carry forward and those to redesign before a larger controlled study.

A major lesson was that the pathway from food-derived biological material to evidence-supported product development cannot be treated as a simple linear progression. The intended use, product category, claim, evidence requirements, manufacturing system and source-material specification are closely connected. The food–therapeutic-goods interface therefore needs deeper and earlier consideration.

For processors, the opportunity does not require ownership of the full downstream development chain. Higher-value participation can begin with reliable supply of defined, traceable biological material to an agreed specification. The producer and processor are therefore not simply sources of raw material; they are the upstream custodians of provenance, identity and handling conditions on which downstream product quality may depend.

The project also supports treating coproduct streams as biological resource platforms rather than optimising them too early around a single finished product. Adipose remains an active development opportunity, while plasma should continue as a high-priority parallel stream because of its broader fractionation and product potential.

This project builds on a sustained AMPC and MLA program of higher-value coproduct development. Earlier work mapped bioactive and blood-derived opportunities, progressed selected materials through value-chain and processor studies, and supported the development of collagen and nutraceutical ingredients (MLA 2009a; Occum Enterprises 2012; Greenleaf Enterprises & Management for Technology 2021a; Coleby 2024; Dobbrick and Hendra 2024). Recent AMPC and MLA work continues this direction, while growing interest in health, wellness and healthy longevity is strengthening the market case for evidence-supported products derived from red-meat coproducts (AMPC 2025c; Food and Nutrition Australia 2025; MLA 2025a; Longevity.Technology 2026).

The recommended next phase is therefore to progressively build practical processor supply capability, deepen regulatory and evidence understanding, and continue product development across adipose and plasma. The aim is to support better industry investment decisions and progressively advance at least one well-defined product proposition toward market entry. Investment should remain staged, with each step used to continue, narrow, redirect or stop as uncertainty is reduced. Together, Projects 2025-1073 and 2026-1048 provide the foundation for a repeatable industry development model: preserve the value of existing coproduct streams, qualify selected biological materials, understand the regulatory and evidence pathway early, use specialist capability to progress downstream development, and invest progressively. The value lies in combining Australia's strong producer and processor foundation with reliable supply, product definition, evidence, regulatory positioning and disciplined downstream development.

3.0 Introduction

3.1 Industry opportunity and Australian advantage

Population ageing is increasing demand for products that support health, function and independence later in life. Healthy longevity has become an important consumer, scientific and product-development theme, creating sustained market pull for ingredients and products supported by credible evidence. In Australia, consumer participation in the broader health-products market is already substantial: in 2023, 33.6 per cent of Australians aged two years and over reported taking a dietary supplement in the previous day, up from 28.5 per cent in 2011–12 (ABS 2025).

MLA's 2025 review of Australian red meat's role in health and wellness identified ageing populations and changing consumer expectations as important drivers of future demand. It identified immune health, weight management, and cognitive health in older adults, including healthy longevity, as priority areas for innovation, and described the nutritional and bioactive content of red meat as a platform for future product development (Food and Nutrition Australia 2025). MLA's Strategic Plan 2030 also identifies growing health and wellness demand for products derived from red-meat coproducts, including collagen and nutraceutical ingredients (MLA 2025a).

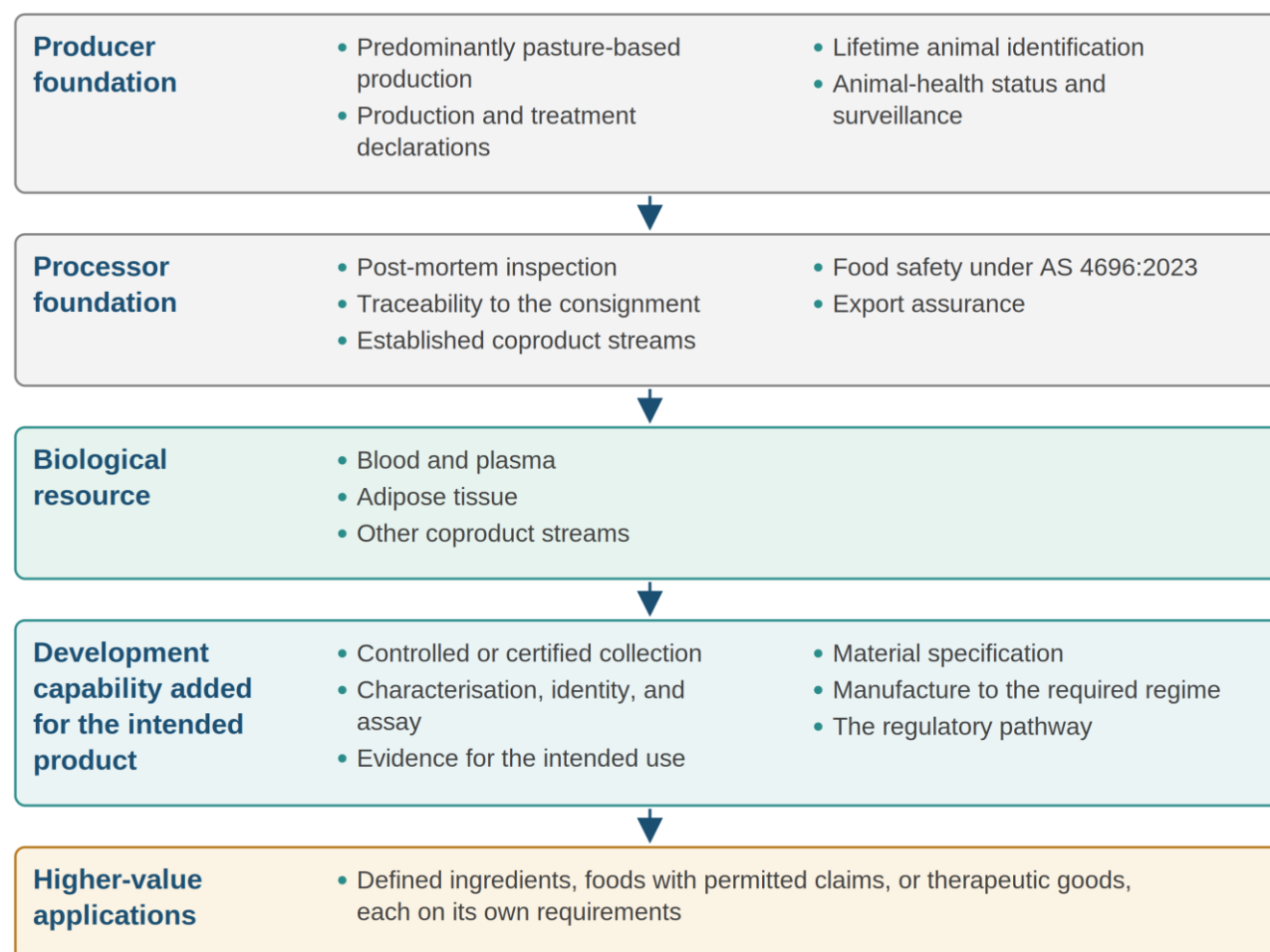
International activity provides a further timing signal. The 2026 *Longevity Biotech Report* records \$18.4 billion invested in longevity biotechnology during 2025, almost four times the previous year, with a further \$12.1 billion reported in 2026 to date (Longevity.Technology 2026). These figures are industry market intelligence rather than an independent market forecast, but they provide contemporary evidence that investment and product-development activity focused on maintaining health and function later in life is increasing.

Australia enters this opportunity from a strong upstream position. Its red-meat industry is underpinned by a predominantly pasture-based production system and an established framework of animal identification, traceability, animal-health surveillance, carcase inspection, food-safety controls, processor quality systems and export assurance. Much of the source information that may ultimately be required for higher-value biological materials is already captured somewhere in the livestock and processing system. Cattle carry lifetime identification through the National Livestock Identification System; consignments carry production and treatment information through the Livestock Production Assurance framework (Integrity Systems Company 2026); carcasses undergo post-mortem inspection; processors operate under AS 4696:2023 (Standards Australia 2023); and export establishments operate within additional assurance systems (Export Control (Meat and Meat Products) Rules 2021). Australia's negligible bovine spongiform encephalopathy risk status (WOAH 2026) also provides an important animal-origin assurance where downstream applications require it.

These systems were built primarily to support meat production, food safety and market access. They do not, by themselves, create a higher-value ingredient or establish superior biological activity. Their importance is more fundamental: they provide a strong provenance, traceability and quality foundation from which more demanding biological-material specifications can be built (Figure 3.1).

Australian processors therefore do not begin with an unknown biological resource. They begin with large, recurring streams of blood, plasma, adipose tissue and other coproducts generated from identified and inspected animals within highly developed production and processing systems. Much of this material is currently directed into established commodity and ingredient markets.

The opportunity is not to displace those markets unnecessarily. It is to determine where selected biological fractions can be recovered and developed into higher-value products while preserving the value of the underlying coproduct stream.

Figure 3.1 Australia's upstream advantage and the higher-value opportunity

Existing production and processing systems provide the upstream foundation; additional controls are required according to the intended downstream product. Sources: Integrity Systems Company 2026; Standards Australia 2023; WOA 2026.

3.2 From coproduct to higher-value biological resource

The Australian red meat industry has been building capability in higher-value coproducts for more than two decades. MLA's *Bioactives Compendium* and associated coproduct program mapped biological materials, technologies and markets and was accompanied by industry adoption work covering blood products, chondroitin sulphate, powdered meat and other opportunities (MLA 2009a; MLA 2009b). The work then became more specific. MLA's *High Value Added Bioactives* program identified five priority opportunities—bovine serum albumin, immunoglobulins, (pro-)thrombin, haemoglobin and chondroitin sulphate—and subsequent work modelled the value chains needed to recover and commercialise them (Occum Enterprises 2012).

The program continued into practical product development. AMPC's 2021 *Bio-active Processing Options* project examined the recovery of bioactive components at a commercial red-meat plant and concluded that blood-derived bioactives could provide a significant value-add opportunity for processors (Greenleaf Enterprises & Management for Technology 2021). MLA projects have since progressed organ and gland materials into freeze-dried nutraceutical ingredients, including work with Kilcoy Global Foods to establish collection, preparation and supply-chain requirements (Coleby 2023; MLA 2024). Other work has developed collagen and other coproduct-derived ingredients toward commercial markets.

That direction remains current. AMPC's 2025–26 operating program includes harvesting extracellular vesicles from blood as a new value stream, while MLA's recent health-and-wellness work identifies the

bioactive content of Australian red meat as a platform for future product innovation. AMPC Project 2025-1073 extended this work under commercial processor conditions by demonstrating EV recovery from abattoir plasma, and Project 2026-1048 moves the pathway further by examining how a defined coproduct preparation can progress into human evidence and toward market..

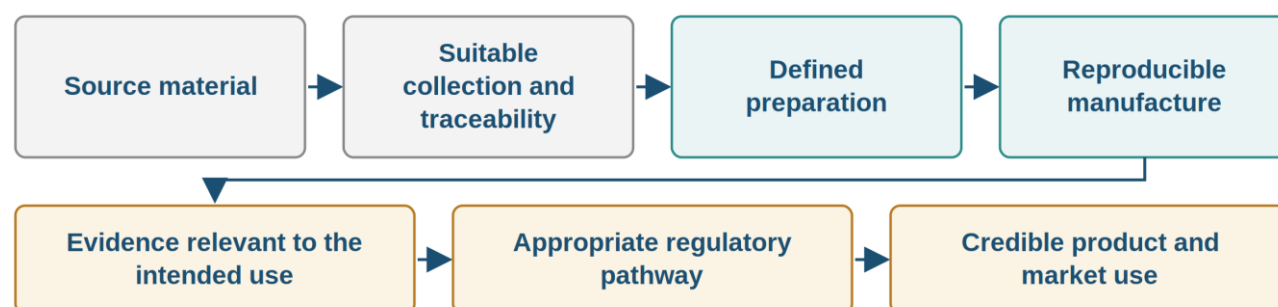
One of the most important findings of that work was that the quality and regulatory status of a biological coproduct can be determined much earlier than the downstream processing step. For blood and plasma, Project 2025-1073 identified suitable collection as the binding constraint. The participating plants were not configured to collect blood through a dedicated edible-grade system at the stick, and the project concluded that, for blood and plasma, quality is built in at collection and primary separation rather than recovered afterwards. This has become a central development priority.

If Australian processors are to preserve access to higher-value human-use pathways, selected coproduct streams need to be collected under conditions appropriate to their intended downstream use. For some products that may mean edible-grade collection; for others it may mean another suitably controlled or certified pathway appropriate to the regulatory category being pursued. The objective is not to impose the highest possible standard on every coproduct stream. It is to understand which collection, traceability and certification conditions are required for the credible downstream options and preserve them where the commercial opportunity justifies doing so.

Higher-value coproduct development therefore starts at the point of recovery, not at the point of fractionation.

The work is to connect the producer and processor systems already in place to the recovered coproduct lot and, ultimately, to the specification of the downstream material. This changes the development question. The issue is no longer simply whether an interesting biological fraction can be recovered. It becomes whether the entire chain can be established (Figure 3.2).

Figure 3.2 From source material to credible product and market use

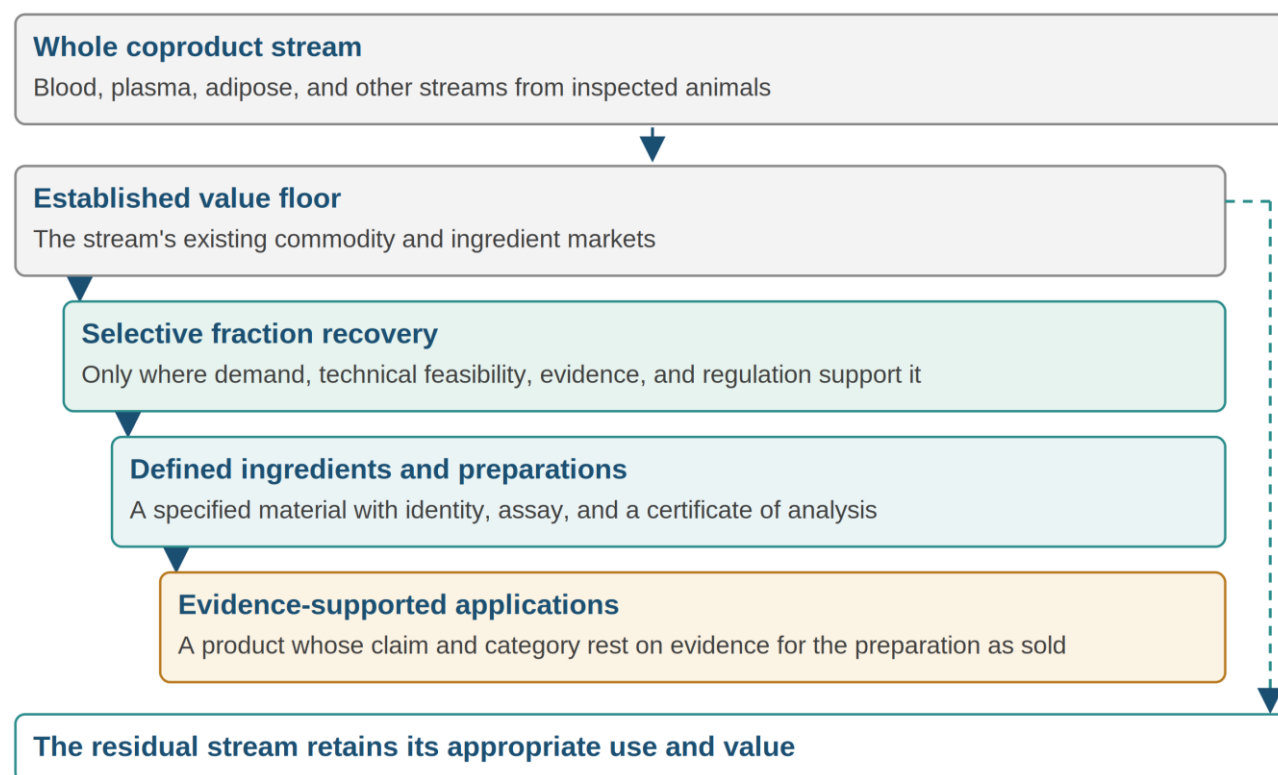
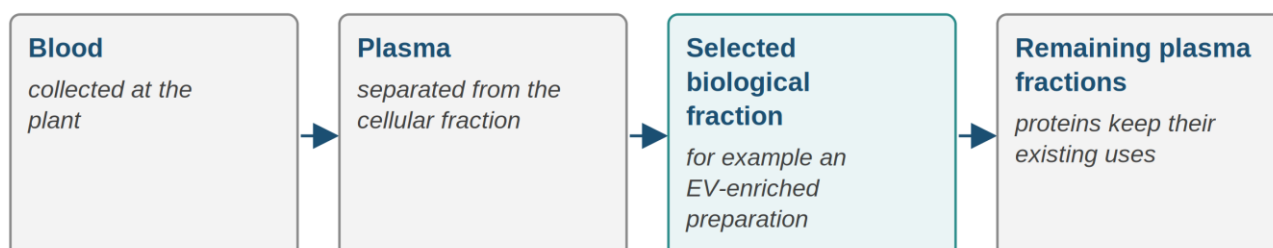


Higher-value development starts at the point of recovery and depends on every link in the chain.

The underlying coproduct can retain value throughout that process. Project 2025-1073 showed this in plasma, where EV recovery did not deplete the residual plasma proteins. This supports a value-cascade approach in which higher-value fractions are selectively recovered while existing downstream uses are retained where practical (Figure 3.3).

This also suggests a broader industry opportunity. Blood, plasma, adipose and other coproduct streams can be considered potential biological resource platforms rather than being optimised prematurely around a single product. A qualified stream may support multiple downstream preparations, provided the material, process and evidence remain appropriate to each use.

Figure 3.3 The coproduct value cascade

**Illustration: blood**

Higher-value recovery sits above the existing value floor rather than necessarily replacing it. Conceptual; no volumes, prices, or values are implied.

For processors, participation does not therefore require becoming a finished-product or biotechnology company. Significant value may begin with the ability to supply a defined, traceable material under suitable collection conditions and to an agreed specification. Specialist downstream capability can then connect that material to manufacturing, analytical, regulatory, clinical and commercial development.

3.3 Evidence, claims and the evidence-value hierarchy

The Research Agreement describes the project as operationalising a Tier 2 to Tier 3 evidence progression. These tiers are strategic descriptions of product development rather than regulatory categories. A material does not become a medicine simply by accumulating evidence.

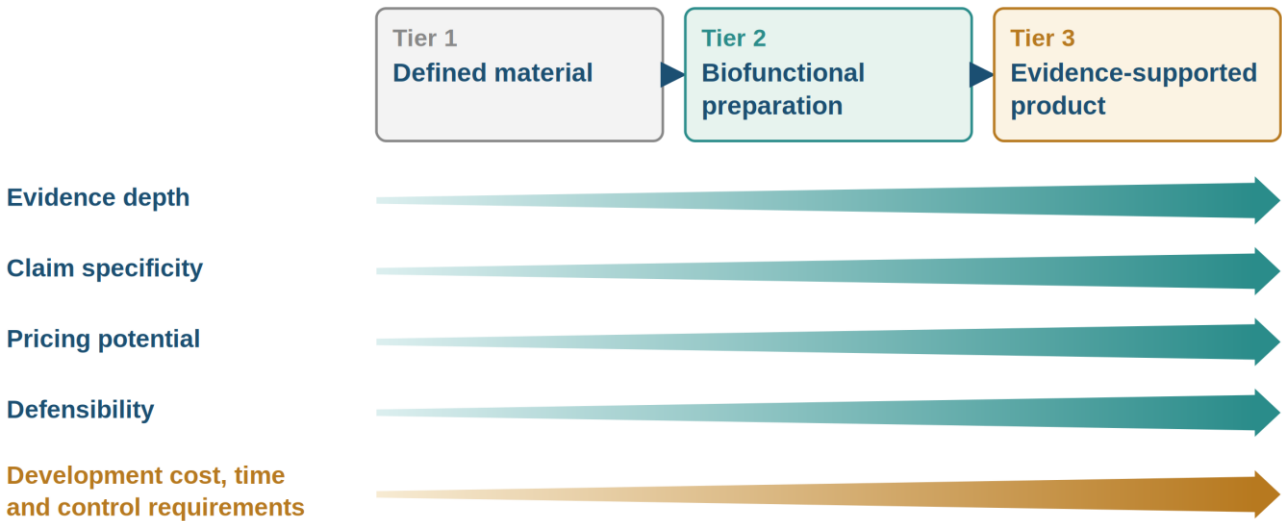
At Tier 1, the customer is buying a dependable material for an established nutritional, technical or processing use. Tier 2 adds evidence of biological activity and the case for a more specific application. Tier 3 adds human evidence and product conditions sufficient to support a defined benefit or claim under the applicable regulatory framework (Table 3.1 and Figure 3.4).

Table 3.1 The three-tier development, evidence and value model

Element	Tier 1 — Defined material	Tier 2 — Biofunctional preparation	Tier 3 — Evidence-supported product
Development state	Dependable nutritional, technical or processing material	Defined preparation with credible biological activity	Human evidence supports a defined benefit or lawful claim
What has been established	Source, specification, repeatability, and safety and quality appropriate to the use	Characterisation, reproducible process, analytical evidence, and biological rationale	Human evidence, product definition, dose, regulatory pathway, and claim support
What it can support	Ingredient supply, processing use, baseline product integration	Higher-value ingredient development, targeted formulation, technical partnerships and further product development	Evidence-backed ingredient proposition or finished product positioned for a defined use or benefit
What can be said	Primarily composition, provenance, quality and technical-function statements within the applicable category	Stronger technical and scientific positioning, but claims remain limited by the evidence and regulatory route	More specific lawful benefit or therapeutic positioning, where supported by the evidence and permitted by the selected regulatory pathway
Typical market position	Commodity or conventional ingredient	Differentiated ingredient or development-stage bioactive	Claim-bearing or evidence-supported product proposition
Typical customer	Ingredient buyer, processor, food or feed manufacturer	Specialist ingredient buyer, formulator, R&D-led brand, development partner	Brand owner, regulated-product developer, premium health-product market or other defined end-use customer
Pricing potential	Primarily market- and specification-driven	Greater premium potential through differentiation and technical value	Greatest premium potential where evidence supports a valued benefit and the customer recognises that differentiation
Defensibility	Mainly supply reliability, provenance, specification and processor capability	Process know-how, analytical identity, preparation definition, biological rationale and partner relationships	Defined evidence base, product identity, route alignment, claim position, know-how and any applicable statutory or IP protection
Substitutability	Relatively high where comparable material is readily available	Reduced where the preparation and process are differentiated	Lowest where evidence is tightly linked to a defined preparation, dose, process and market proposition
Development burden	Lowest	Moderate	Highest
Commercial role	Establishes the value floor	Creates differentiated ingredient and development value	Creates the strongest opportunity for premium value capture and defensibility

The tiers describe states of development, evidence and commercial readiness. They are not regulatory categories. A material does not become a medicine by reaching Tier 3. The applicable legal category still depends on the preparation, intended use, presentation and claims.

Figure 3.4 What rises from Tier 1 to Tier 3



Each step adds evidence, claim specificity, pricing potential and defensibility, and each costs more in development, time and control.

Project 2025-1073 primarily advanced the processor and biological-recovery platform through Tier 1 and Tier 2 questions. Project 2026-1048 tested the next translational step by taking a defined preparation into human evaluation and generating the evidence and pathway learning required for progression toward Tier 3.

Higher-value coproduct markets in human health ultimately depend on evidence relevant to a defined product and intended use. Where a health claim is sought, the evidence must support the claim permitted by the applicable regulatory pathway. Composition and laboratory activity may justify development, but they do not by themselves establish that a human benefit exists or that a particular claim can lawfully be made.

Experience in established natural-origin ingredient categories shows what successful progression tends to require. Differentiated ingredients generally combine a defined preparation, source and compositional specifications, reproducible manufacture, a practical dose, analytical or potency methods, evidence appropriate to the intended benefit and a claim no broader than that evidence. Plant sterols and collagen are contrasting examples: plant sterols show how composition, dose, evidence and regulatory permission can be connected (Schedule 4; European Commission 2009), while collagen illustrates both the ability of a red-meat-derived ingredient to reach market (Dobbrick and Hendra 2024) and the importance of ensuring that the evidence actually supports the proposed claim (EFSA 2011).

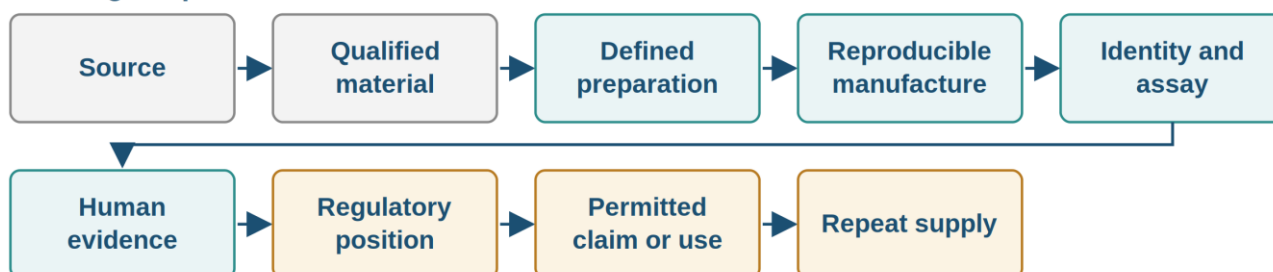
The commercial lesson is equally important. Regulatory status and evidence can support retailer and practitioner acceptance, advertising and export dossiers, but they do not create demand by themselves. A product must still address a recognised need in a form, dose and price acceptable to the intended customer. For higher-value biological materials, the process contributes to the product value. Source, collection conditions, traceability, processing, stabilisation, analytical characterisation, batch comparability and storage may all affect whether later material remains sufficiently similar to the preparation on which evidence was generated. Evidence therefore attaches to a defined preparation and cannot automatically be transferred to every material derived from the same tissue or coproduct stream.

This is also why intended use and regulatory pathway cannot be left until the end of development. Product category, proposed claim, evidence requirements and manufacturing obligations can reach upstream into how the source material is collected and controlled. Some conditions can be added later; others cannot be repaired economically once they have been lost (Figure 3.5). The development task is therefore to

preserve credible downstream options early, while avoiding unnecessary controls or capital expenditure before the likely product and market pathway are sufficiently understood.

Figure 3.5 From source material to a claimable product

Building the product, from the source forward



Designing the product, from the intended claim backward



Each step sets the requirement for the next: the claim fixes the evidence, the evidence the endpoint, and so on back to what has to be true of the material when it is collected.

The reverse logic is why regulatory and commercial decisions reach upstream to the processor.

3.4 Selection of the adipose-derived preparation

AMPC Project 2025-1073 concentrated primarily on blood and plasma. For Project 2026-1048, Exomed selected an adipose-derived preparation, CX-50, for human evaluation. That decision reflected the development circumstances at the time rather than a conclusion that adipose was inherently safer, biologically superior or commercially preferable to plasma. The plants participating in Project 2025-1073 were not configured for edible-grade blood collection at the stick, whereas adipose tissue was already recovered downstream of post-mortem inspection within the edible workflow. Adipose therefore provided a practical way to test the next translational question: whether a processor-derived biological preparation could be taken from a commercial processing environment into human research, and what that progression would require. Plasma remains a separate and high-priority development stream. Findings from an adipose-derived preparation cannot be assumed to establish the safety, quality or performance of a plasma-derived preparation. Each material requires its own material definition, manufacturing assessment, regulatory pathway and evidence base.

What can be carried across is the development logic: suitable recovery and traceability at the processor, a defined material before human study, early understanding of the intended market and regulatory pathway, and evidence designed for the destination in which it will ultimately be used.

3.5 The translational gap

The technical recovery work completed before Project 2026-1048 established that higher-value fractions could be produced. The remaining question was whether one of those processor-derived preparations

could be progressed into human evaluation and generate information useful for its next stage of development.

The proposal's duplication assessment found no earlier AMPC or MLA project that had taken a red-meat-derived, food-grade bioactive into an ethics-approved human study notified to the Therapeutic Goods Administration (TGA). Project 2026-1048 was designed to address that specific translational gap.

This gap matters because the move from promising biological material to an evidence-supported product requires more than another recovery experiment. It requires material preparation, regulatory and ethics navigation, human safety assessment, reliable clinical measurement and an understanding of how the evidence generated will be used in subsequent development.

The central question was therefore not simply whether CX-50 could be administered to people. It was whether a processor-derived preparation could be moved through that wider development system in a form that produced useful learning for what should happen next.

3.6 Project rationale: testing an integrated early-development model

Project 2026-1048 was funded to progress a selected red-meat coproduct preparation into human evaluation and document the requirements encountered. Its significance was broader than conducting a first-in-human safety study. Early product-development programmes often address material preparation, regulatory pathway, safety, endpoint feasibility and biological or functional exploration as separate activities. The project tested whether several of these questions could be addressed within one early-stage programme while maintaining clear boundaries around what each result could establish. Its first-in-human study, RE-ENVIGOR, was the clinical component of that integrated development model. The study therefore brought together preparation of processor-derived material for human research, regulatory and ethics navigation, repeated human administration, initial safety and tolerability assessment, functional and biological measurement, endpoint-feasibility testing and downstream development learning. RE-ENVIGOR was a first-in-human, open-label, single-arm safety and feasibility study. The absence of a comparison group meant that changes observed during the study could not be attributed to the preparation. The exploratory functional and biological assessments were therefore included to inform future development rather than establish efficacy.

This made it possible for the first human exposure to address several development questions at the same time: whether the preparation could be administered as planned, whether the proposed measurements could be obtained reliably, whether any observations justified deeper investigation, and what would need to change before a controlled study. The project therefore tested both the preparation and the development system around it. This integrated approach is particularly relevant to coproduct development because the pathway crosses systems that are usually managed separately: livestock production, food processing, biological-material characterisation, manufacturing, food and therapeutic-goods regulation, human-research governance, clinical delivery and commercial product development. The project also demonstrated that this interface can create substantial friction if product definition, regulatory assumptions and operating responsibilities are not aligned early. That experience is part of the value generated by the programme and informs the development model set out later in this report.

3.7 Intended use of this report

The primary audience for this report is AMPC and Australian red-meat processors considering higher-value coproduct opportunities. It is also relevant to producers, ingredient manufacturers, research organisations, clinical providers, regulatory specialists and commercial partners whose activities may form part of a downstream development pathway.

The report does not propose that producers or processors should carry the entire development chain. Their role may be concentrated upstream, where source quality, provenance, traceability, collection conditions and repeatable supply are established. These attributes may determine whether downstream product options remain available and whether evidence generated later remains relevant to commercial supply. Specialist downstream capability can then connect processor-supplied material to characterisation, manufacture, regulatory strategy, human evidence and product development. The broader industry objective is therefore not confined to CX-50. It is to develop a repeatable capability for assessing selected coproduct streams, preserving suitable human-use pathways where justified, qualifying materials for higher-value development and progressively investing as technical, regulatory, evidentiary and commercial uncertainty is reduced.

The immediate project tested the far end of that value chain by taking one adipose-derived preparation into human research. The sections that follow describe how that work was conducted, what it produced, what worked, what did not, and what the experience means for the next stage of adipose, plasma and wider coproduct development.

4.0 Project objectives

The project objectives, as set out in the Research Agreement Schedule for AMPC Project 2026-1048 (AMPC 2025), are reproduced below without alteration. The objectives of this project are to:

1. Generate Australia's first regulator-aligned human-safety dataset for food-derived plasma and adipose fractions containing regenerative biofunctional extracellular vesicles (EVs), confirming tolerability and establishing data integrity under Good Clinical Practice (GCP) and ISO 14155 standards.
2. Validate the translational pathway developed in AMPC Project 2025-1073 by converting processor-level feasibility into human evidence suitable for FSANZ and TGA alignment, thereby operationalising the Tier 2 → Tier 3 evidence progression within the red-meat coproduct stream.
3. Establish standardised quality and documentation frameworks for EV-enriched food fractions—including characterisation, batch traceability, and analytical reproducibility—to ensure compliance with AS 4696:2023, HACCP, and regulatory-admissible study documentation.
4. Collect early functional data mapped to regulator-recognised surrogate endpoints (e.g., lipid metabolism, immune biomarkers, or validated functional measures) to substantiate future claim-level dossier design under FSANZ and TGA Section 26AE pathways.
5. Define a replicable commercial and regulatory model for advancing red-meat coproducts into evidence-supported markets, establishing the sector's first template for scientifically validated, globally defensible Evidenced Biofoods™.

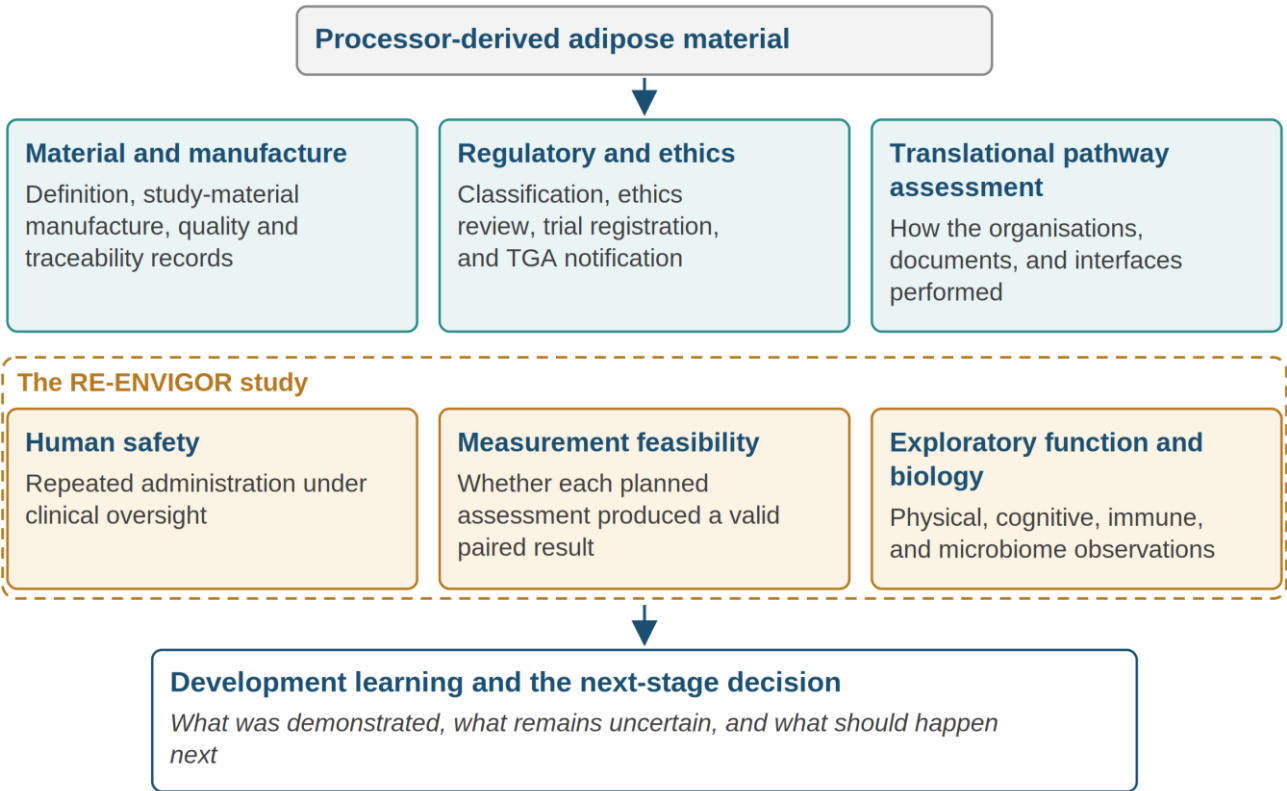
5.0 Methodology

5.1 Overall project design and development approach

AMPC Project 2026-1048 combined material preparation, regulatory and ethics development, first-in-human clinical evaluation, exploratory functional and biological assessment, and review of the development pathway used to connect those activities. The project was designed around a defined processor-derived preparation rather than around the clinical study in isolation. The sequence began with selection and preparation of the source material, continued through product definition, manufacture, regulatory and ethics preparation, and culminated in the RE-ENVIGOR human study and analysis of the resulting safety, feasibility and exploratory data. The central methodological objective was to reduce several early-development uncertainties within one programme. The project therefore addressed four connected questions (Figure 5.1):

1. whether a red-meat coproduct preparation could be defined, manufactured and documented appropriately for human research;
2. whether it could be progressed through the required regulatory, ethics and clinical-governance steps;
3. whether initial human safety and tolerability could be assessed alongside candidate physical, cognitive, immune and biological measurements; and
4. whether the resulting experience could identify which methods, endpoints and development requirements should be carried into a subsequent controlled programme.

Figure 5.1 Project 2026-1048 integrated development architecture



RE-ENVIGOR was one part of a wider project. Safety, feasibility, and exploratory evidence were kept separate throughout.

This integrated approach was deliberate. A conventional first-in-human study could have been limited principally to safety observations. RE-ENVIGOR instead combined safety and tolerability assessment with measurement-feasibility and exploratory functional and biological assessments so that the first human exposure could also inform the design and direction of subsequent development.

The approach was not intended to establish efficacy. The functional and biological assessments were exploratory and were used to test the assessment system, generate observations relevant to downstream development and determine which questions justified more rigorous investigation.

This approach also reflected Exomed's wider healthy-ageing development programme. Physical, cognitive and immune function had already been identified as areas of interest, and Exomed retained these domains because of their relevance to downstream planning. The methodology therefore distinguished three different forms of evidence throughout the project:

- **Safety evidence:** concerning observations associated with administration of CX-50;
- **Feasibility evidence:** concerning whether the planned clinical and analytical assessments could be completed reliably in the intended population and setting; and
- **Exploratory evidence:** concerning biological or functional observations that might justify focused investigation in a later controlled study.

These categories were kept separate when interpreting the project results.

5.2 Study material and manufacture

The preparation selected for human evaluation was CX-50, a freeze-dried preparation derived from bovine adipose tissue. Adipose tissue was collected at a commercial red-meat processing establishment from carcasses that had passed post-mortem inspection and was handled within the establishment's existing edible-product workflow. The material was segregated, traceably handled and stored under controlled conditions before processing.

Adipose was selected in part because it already sat within the edible workflow and therefore did not present the same upstream collection constraint encountered with blood in AMPC Project 2025-1073. The participating blood-processing sites examined in that earlier programme were not configured for edible-grade blood collection at the stick. The adipose stream therefore provided a more suitable starting material for testing the downstream development pathway.

The study material was produced using scaled batch handling, concentration and freeze-drying methods under AS 4696:2023 and the establishment's Hazard Analysis and Critical Control Point programme (Standards Australia 2023). No chemical modification, genetic manipulation or biological derivatisation was applied.

Quality-assurance activities described in the project records included extracellular-vesicle concentration and size-distribution characterisation, microbiological testing, endotoxin testing, stability assessment under controlled storage and documentation under Good Documentation Practice. A reserve batch was retained.

The methodological purpose of this stage was not only to produce sufficient material for RE-ENVIGOR. It was also to preserve a documented connection between source material, processing conditions, the preparation administered to participants and the evidence subsequently generated from that preparation.

5.3 Regulatory and ethical preparation

RE-ENVIGOR was progressed through the Therapeutic Goods Administration Clinical Trial Notification (CTN) scheme alongside Human Research Ethics Committee (HREC) approval (TGA 2024a). The clinical and regulatory documentation package included the study protocol, Investigator's Brochure, participant information and consent documentation, product information, safety information, data-management arrangements, insurance, ethics documentation, trial registration and CTN documentation. The approved protocol was EXO-CT-2501, *A Phase I, unblinded, single-arm study to investigate the safety and feasibility of orally ingested exosomes in healthy volunteers 50 to 80 years of age (RE-ENVIGOR)*. The project records identify Version 1.2 dated 13 February 2026 as the approved study version.

The study material was supplied under the regulatory arrangements applicable to initial experimental use in human volunteers. It was manufactured under the processing establishment's food-safety system and the first-in-human manufacturing exemption relied upon for this study (TGA 2021; TGA 2024g). It was not described in this report as commercial therapeutic-goods manufacture. The purpose of the regulatory methodology was to document the route actually used for CX-50 rather than assume that the same classification or manufacturing pathway would automatically apply to another coproduct or later commercial product. The broader implications of classification, subsequent manufacture and market entry are addressed in Section 7.

5.4 RE-ENVIGOR study design and rationale

RE-ENVIGOR was a first-in-human, open-label, single-arm safety and feasibility study. The protocol permitted enrolment of up to 20 adults aged 50 to 80 years. Participants received one oral dose of CX-50 each day for 42 days. The first dose was supervised at the clinical site and subsequent doses were self-administered at home from supplied study material. Measurements were obtained before administration and repeated after completion of the 42-day intervention period. The study design deliberately combined three related functions.

5.4.1 Safety and tolerability

The first function was to establish an initial record of human administration under clinical oversight. Safety monitoring included clinical observations, vital signs, laboratory assessments and adverse-event monitoring.

5.4.2 Measurement feasibility

The second function was to test whether the candidate outcome measures could be delivered successfully in the intended population and clinical setting. Feasibility was assessed separately from participant attendance or study completion. A participant attending a visit did not necessarily mean that a planned test was completed successfully or that a valid result was produced. For each assessment, the project therefore distinguished:

- attendance;
- attempted assessment;
- completion;
- availability of a valid result; and
- availability of a valid paired baseline and follow-up measurement.

This was important because one objective of the study was to identify problems with the measurement system before those measures were used in a larger controlled study.

5.4.3 Exploratory functional and biological assessment

The third function was to obtain early observations across several possible downstream areas of human benefit. The exploratory programme covered:

- physical function;
- cognitive function;
- immune responsiveness;
- immune-cell characteristics; and
- gut microbial composition.

The purpose was not to demonstrate efficacy across these domains. Rather, the assessments were intended to determine whether the measures were workable, whether potentially informative patterns could be observed and which domains justified deeper investigation. This reflected the wider development objective of identifying product propositions capable of ultimately demonstrating benefits relevant to human function, rather than relying only on changes in laboratory markers.

5.5 Participants and clinical procedures

NovaTrials operated the clinical site in Newcastle under arrangements coordinated by the Hunter Medical Research Institute (HMRI). Screening addressed informed consent, general health status, relevant medications and other eligibility criteria affecting participant safety or interpretation of the planned assessments. The clinical schedule included:

- screening and eligibility assessment;
- baseline clinical, functional and biological measurements;
- supervised first administration of CX-50;
- home administration for the remainder of the 42-day period;
- re-supply visits incorporating adherence, medication and adverse-event review; and
- follow-up assessment one to five days after completion of administration.

Participant adherence was assessed from study diaries together with dispensing and returned-product records. Participant retention, adherence and assessment completeness were treated as different measures. Completion of the study therefore did not automatically establish complete adherence, and attendance at an assessment did not automatically establish that a valid measurement had been generated.

For functional assessments, procedural consistency between baseline and follow-up was important. The protocol specified relevant test methods, participant preparation, equipment or assessment conditions and recording procedures. Participants were instructed to avoid strenuous exercise for 24 hours before assessment visits. Any assessment changes, substitutions, incomplete measurements or failures were recorded and considered part of the feasibility outcome.

5.6 Safety, functional and biological assessments

5.6.1 Safety monitoring

The safety programme included clinical observations, vital signs, haematology, blood biochemistry, urinalysis and adverse-event recording. Investigators assessed adverse events for severity, seriousness, relationship to the study preparation and expectedness. Severity grading used the Common Terminology Criteria for Adverse Events, version 5.0 (NCI 2017). Abnormal clinical or laboratory findings were subject to investigator review in accordance with the approved protocol and applicable safety-reporting requirements (NHMRC 2016).

5.6.2 Physical function

Physical function was assessed using tests intended to provide information on mobility and lower-body performance. The assessment programme included a six-minute walk test and lower-body strength testing. The protocol also specified a graded exercise test for cardiopulmonary capacity. These assessments were included because physical function represents a potential downstream outcome of interest in healthy-ageing development and because the project needed to determine whether the procedures could be delivered consistently in the intended population.

5.6.3 Cognitive function

Cognitive performance was assessed using NIH Toolbox cognitive subtests. The purpose was to obtain standardised measures across selected cognitive domains and to determine whether the assessment platform could be implemented successfully within the clinical programme. The study was not powered to establish a treatment effect on cognition.

5.6.4 Immune responsiveness and immune-cell characteristics

The immune programme combined measurement of circulating immune-cell characteristics with functional laboratory challenge. Blood immune cells collected before and after the intervention were exposed to defined laboratory stimuli and their responses measured. This provided information beyond routine cell counts by examining how collected cells behaved under controlled challenge conditions. The assay did not measure absorption of CX-50 and could not attribute an observed change to a particular component of the preparation.

5.6.5 Gut microbiome

Faecal samples were collected for microbial DNA sequencing and analysis of microbial composition and diversity. The microbiome component was exploratory. Its inclusion allowed the project to assess whether sample collection and metagenomic analysis could be incorporated into this form of early human study and whether the resulting information warranted further investigation.

5.7 Data management and statistical analysis

Study data were captured in HMRI's REDCap system under coded participant identifiers and analysed by HMRI biostatisticians (HMRI 2026). The statistical approach was descriptive. Baseline and follow-up measures were summarised, and within-participant change was assessed where valid paired observations were available. Confidence intervals were reported where provided by the statistical analysis. No formal efficacy hypothesis was tested and no confirmatory statistical inference was planned. The interpretation framework explicitly considered:

- the small sample size;

- the single-arm design;
- absence of a concurrent comparator;
- multiple exploratory measures;
- incomplete or substituted assessments; and
- measurement completeness.

Observed changes were therefore treated as exploratory observations rather than evidence that CX-50 caused a particular effect. The statistical and exploratory analyses were used to inform later endpoint selection, measurement design and development decisions.

5.8 Assessment of the translational pathway

The project also examined the pathway used to move CX-50 from processor-derived material into human research. This assessment drew on the project proposal, milestone reports, manufacturing and quality records, regulatory and ethics documentation, the clinical protocol, project correspondence, study-delivery records, statistical outputs and subsequent project review. The analysis followed the preparation through processor recovery, material definition, manufacture, regulatory and ethics preparation, clinical commissioning, human administration, and analysis and interpretation.

At each stage, the project identified:

- the organisation responsible;
- the material or information required to proceed;
- the documents generated;
- dependencies on earlier stages;
- issues encountered; and
- requirements carried forward into subsequent development.

The project records were then used to distinguish three classes of requirement:

1. requirements specific to CX-50 and RE-ENVIGOR;
2. requirements created by the regulatory and clinical pathway selected for this study; and
3. requirements likely to recur in future red-meat coproduct development programmes.

Particular attention was given to interfaces between organisations because no single participant controlled the full pathway. The processor controlled source material and the initial production environment. Exomed coordinated the material definition, downstream development, study sponsorship and regulatory interfaces. HMRI coordinated clinical delivery, data management and statistical analysis. NovaTrials undertook participant-facing clinical activities. Specialist laboratories and advisers contributed analytical and scientific capability. This allowed the project to assess how those capabilities could be coordinated without requiring a processor to internalise every downstream function. The methodology did not assume that the same operating structure should be applied to every future programme. Its purpose was to document the sequence actually used, identify which activities could be reused or adapted and determine where future programmes would require product-specific assessment.

5.9 Development-learning framework

The final methodological step was to treat RE-ENVIGOR as an early development decision point rather than as an isolated clinical event. The project therefore assessed the study outputs against three questions:

1. **What was demonstrated?**
For example, whether a procedure was successfully completed or usable paired measurements were generated.
2. **What remained uncertain?**
For example, whether an observed change represented a treatment effect or whether an assessment method was sufficiently reliable for confirmatory research.
3. **What should happen next?**
Whether a measurement should be retained, redesigned, replaced or tested under controlled conditions.

This framework was particularly important for the exploratory functional and biological assessments. A measure did not have to show an apparent positive change to be useful. A successful measurement could support its use in a later study, while a failed or incomplete assessment could identify a design weakness before larger investment. The methodological value of RE-ENVIGOR therefore came from using a single early human programme to generate safety information while simultaneously testing the clinical measurement system and informing the narrowing of subsequent product and evidence development. This distinction forms the basis for the interpretation of the results in Section 7.

6.0 Results

6.1 Study completion and principal findings

AMPC Project 2026-1048 progressed a defined red-meat coproduct preparation from a commercial processing environment into first-in-human evaluation and completed the planned 42-day clinical programme. The principal experimental deliverable was RE-ENVIGOR, the first-in-human safety and feasibility study of CX-50. Eleven adults aged 50 to 80 years were enrolled. All 11 remained in the study through the 42-day administration period and attended follow-up. No serious adverse events were reported.

The project also demonstrated the feasibility of the broader development model tested around the study. Within one programme, CX-50 was defined and manufactured as study material, progressed through ethics and the Australian clinical-trial framework, administered repeatedly to participants, monitored for safety, and assessed using candidate physical, cognitive, immune and microbiome measures. The study therefore generated three distinct sets of results:

1. an initial human safety and tolerability record for CX-50 under the conditions studied;
2. evidence about which candidate functional and biological assessments could be implemented successfully in the intended population; and
3. a completed development pathway connecting processor-derived material with regulated human research.

These results are separate from evidence of efficacy. RE-ENVIGOR was small, open-label and single-arm, and no formal efficacy hypothesis was tested. The exploratory measurements were used to inform subsequent development rather than to establish that CX-50 caused a functional or biological benefit.

6.2 RE-ENVIGOR study completion and participant disposition

RE-ENVIGOR was conducted as a first-in-human, open-label, single-arm safety and feasibility study with exploratory functional and biological assessments. The approved protocol permitted enrolment of up to 20 adults aged 50 to 80 years. Eleven participants were enrolled (Table 6.1). Each participant received one oral dose of CX-50 each day for 42 days. The first administration was supervised at the clinical site, with subsequent doses self-administered at home from supplied study material. All 11 participants completed the administration period and attended follow-up.

Table 6.1 RE-ENVIGOR study completion

Element	Result
Study	RE-ENVIGOR, protocol EXO-CT-2501
Design	First-in-human, open-label, single-arm safety and feasibility study with exploratory functional and biological assessments
Population	Adults aged 50 to 80 years
Maximum permitted enrolment	20
Participants enrolled	11
Administration period	42 days
Administration	One oral dose of CX-50 daily; first dose supervised, subsequent doses self-administered at home
Participant retention	11 of 11 completed the administration period and attended follow-up
Adherence	Assessed separately using participant diaries and study-material dispensing and return records
Clinical delivery	NovaTrials, Newcastle, coordinated by HMRI
Data management	REDCap
Statistical analysis	HMRI

Source: HMRI study records.

Retention, adherence and measurement completeness were deliberately treated as different results. Completion of the 42-day study period established that the participants remained in the study through the planned exposure and follow-up period. It did not by itself establish that every scheduled dose was taken. Likewise, attendance at an assessment did not necessarily mean that a valid measurement was produced. This distinction became important when assessing the feasibility of the functional and biological programme.

6.3 Safety and tolerability results

The safety programme included clinical observations, vital signs, laboratory testing and adverse-event recording. No serious adverse events were reported. Safety observations and laboratory results were reviewed by the study investigators. The safety result should be interpreted within the boundaries of the study. RE-ENVIGOR involved 11 participants, a 42-day administration period and the eligibility criteria specified in the approved protocol. The study therefore provides an initial safety and tolerability record for CX-50 under those conditions. It does not establish safety across larger populations, different doses, different preparations or longer periods of use.

6.4 Functional and biological assessment feasibility

One of the principal development questions was whether the candidate outcome measures could actually be delivered and produce usable information within an early human study. The assessment programme included physical function, cognitive function, immune responsiveness, immune-cell characteristics and gut microbial composition. The results were mixed, which provided useful information for subsequent

study design. Some measures produced valid paired observations at baseline and follow-up. Others were substituted, incomplete or not obtained (Table 6.2).

Table 6.2 Functional and biological assessment programme

Domain	Planned or delivered assessment	Result	Development disposition
Physical function	Six-minute walk test	Valid paired baseline and follow-up measurements obtained	Retain and refine
Physical function	Graded exercise test for cardiopulmonary capacity	Not obtained; six-minute walk testing was used as the available functional measure	Redesign or replace
Physical function	Lower-body strength	Paired knee-extensor measurements obtained; the protocol-specified one-repetition-maximum method was not used	Review the method
Cognitive function	NIH Toolbox cognitive assessments	Four of five required subtests obtained at both visits	Retain; repair data capture
Cognitive function	Intended cognitive composite	Could not be calculated because one required subtest was not captured at either visit owing to an application error	Repair the software and scoring chain
Immune responsiveness	Ex vivo challenge of blood immune cells collected before and after administration	Paired assessment completed; one observation without a valid follow-up result was excluded from revised analysis	Retain and refine
Immune-cell characteristics	Blood-cell measurement and immune-cell profiling	Obtained	Evaluate utility
Inflammatory status	Laboratory index specified in the protocol	Obtained	Evaluate utility
Gut microbiome	Faecal collection, microbial DNA sequencing and profiling	Samples collected and successfully sequenced; paired analysis completed within the exploratory dataset	Evaluate utility

Source: HMRI statistical analysis (HMRI 2026).

The development disposition records what each measure means for the next study. It is not a pass or fail judgement of the science or of CX-50.

These findings are important because they answer a different question from whether CX-50 was efficacious. They show which parts of the proposed endpoint architecture were workable in this population and clinical setting. The six-minute walk assessment, immune work and microbiome programme demonstrated that several relatively different forms of measurement could be incorporated into the same early human study. The unsuccessful assessments were also informative. Failure to obtain the graded exercise test, loss of a required cognitive component through an application error and absence of the planned inflammatory measure identified weaknesses that would need to be resolved before those endpoints were relied upon in a larger controlled study.

The feasibility result was therefore not that every planned assessment succeeded. It was that the early study was able to identify, before larger investment, which parts of the measurement system were operationally robust and which were not.

6.5 Exploratory functional and biological information

The study generated exploratory observations across physical, cognitive, immune and microbiome domains. These analyses were descriptive. Measurements were compared between baseline and follow-up in participants with valid paired observations. No formal hypothesis of efficacy was tested, and the study had no concurrent control group. The exploratory programme therefore had a different evidentiary purpose from the safety programme. Its role was to provide an early view of:

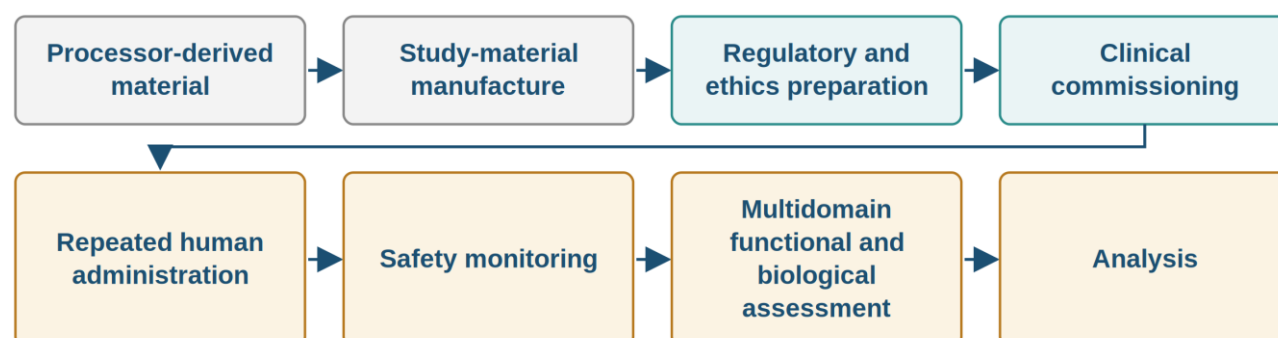
- whether potentially relevant biological and functional responses could be measured;
- whether the selected measures produced information suitable for further analysis;
- whether particular domains justified deeper investigation; and
- what would need to change before those domains were assessed in a controlled efficacy study.

The project records show that the exploratory programme covered physical performance, cognitive function, functional immune responsiveness, immune-cell characteristics and gut microbial composition. These measures were selected to inform subsequent study design and downstream development rather than to support a claim from RE-ENVIGOR itself. This report does not infer treatment effect from changes observed between baseline and follow-up. That boundary is important. RE-ENVIGOR generated observations capable of informing the next study; it did not establish efficacy, clinical benefit or claim substantiation.

6.6 What the integrated study design demonstrated

Viewed as an early-development programme rather than only as a clinical safety exercise, RE-ENVIGOR demonstrated that several development questions could be addressed within the same first-human programme. The project successfully connected every step from processor-derived material to analysis (Figure 6.1).

Figure 6.1 The development sequence connected within one first-in-human programme



Material, pathway and human-study steps were completed in sequence within RE-ENVIGOR.

That sequence was completed without first requiring separate clinical programmes for safety, endpoint feasibility and exploratory functional assessment. This is a substantive result of Project 2026-1048. The study demonstrated that an early human programme could be used not only to generate a safety record, but also to test the measurement architecture required for later development and obtain early information across several possible downstream areas of value. The result was not that every element worked perfectly. Rather, the project demonstrated that the integrated approach was feasible while simultaneously exposing the areas requiring further control.

The study showed that:

- participants could be recruited and retained through the planned 42-day programme;
- a processor-derived adipose preparation could be administered repeatedly within an approved human study;
- safety monitoring could be incorporated alongside functional and biological assessment;
- several candidate outcome systems generated usable paired observations;
- complex sample-based assessments, including functional immune work and microbiome analysis, could be incorporated into the programme; and
- shortcomings in endpoint delivery could be identified before progression to a more expensive controlled trial.

This is the principal methodological result underlying the replicable development model considered later in this report. The results do not establish that every future coproduct should use the same protocol, endpoint set or regulatory pathway. They establish that the underlying development functions can be integrated into a single early-stage programme where the material, study objectives and regulatory pathway make that appropriate.

6.7 Regulatory and ethics pathway completed

The project also completed the regulatory and ethics sequence required to progress CX-50 into RE-ENVIGOR. Study documentation was submitted to the Human Research Ethics Committee in November 2025. During the first review cycle, the document set was considered as describing a therapeutic investigational product and additional product-specific safety information was requested. The product definition and supporting documentation were subsequently revised into a consistent set. Bellberry Limited granted ethics approval on 17 February 2026. The study was registered before recruitment and notification was lodged with the TGA before investigational supply (Table 6.3).

Table 6.3 Regulatory and ethics pathway as completed

Step	Timing	Result
Study and product documentation	2025	Protocol, Investigator’s Brochure, participant documentation, safety information, insurance and data arrangements prepared
Ethics submission	November 2025	Submitted through the clinical partner
Ethics review and document revision	November 2025–February 2026	Product definition and supporting documents revised during review
Ethics approval	17 February 2026	Bellberry Limited, reference 2025-11-1989
Trial registration	Before recruitment	ACTRN12625001345471p
TGA Clinical Trial Notification	Before first investigational supply	Notification completed
Study material	Before first administration	CX-50 manufactured and released for the study under the arrangements described in Section 5

Source: ethics approval and trial registry.

The important result for this section is the completed sequence. The wider implications of classification, the distinction between investigational and commercial supply, and the regulatory lessons for future coproduct programmes are considered in Section 7.

6.8 Delivery against the original project plan

The clinical design was refined during development as the product definition, regulatory pathway, ethics requirements and practical study constraints became clearer. The original project plan contemplated a randomised, double-blind, placebo-controlled study, but the final protocol was appropriately narrowed to a first-in-human, open-label, single-arm safety and feasibility study with exploratory assessments. This allowed the project to focus on the key first-stage questions of human administration, safety, measurement feasibility and development learning. The refined design was reported to AMPC through project reporting.

Study documents were submitted in November 2025, ethics approval was granted on 17 February 2026, final participant follow-up was completed in April 2026, and HMRI supplied the biostatistics report in May 2026 (HMRI 2026).

Figure 6.2 Regulatory, ethics and study events through to the biostatistics report



Schematic; the spacing of events is not to scale. Sources: HMRI study records; HMRI 2026.

Table 6.4 Planned and actual project delivery

Milestone	Original plan	Delivered
Activation, ethics, notification and study material	December 2025	Ethics approval 17 February 2026; Milestone Report 1 submitted April 2026
Clinical initiation and conduct	January 2026	Recruitment commenced February 2026; final follow-up April 2026
Analysis	March 2026	HMRI statistical analysis supplied May 2026; supplementary analyses undertaken
Final reporting	April 2026	AMPC project update May 2026; final report completed subsequently

Source: Research Agreement (AMPC 2025) and HMRI records.

6.9 Development knowledge generated

The project produced more than a clinical dataset. It established a documented development sequence connecting source material, study preparation, regulatory and ethics work, human administration, functional measurement, biological analysis and subsequent development review. It also generated practical information about how specialist capabilities can be assembled across the development pathway. The processor supplied source material within the edible workflow. Exomed coordinated preparation development, study sponsorship and the regulatory interface. HMRI coordinated clinical delivery, data management and statistical analysis. NovaTrials operated the participant-facing site, while specialist laboratories and advisers contributed analytical and scientific capability.

The practical result was a demonstrated model in which the required capabilities could be brought together around a red-meat coproduct without requiring the processor to develop every downstream function internally. The project also reinforced the importance of keeping four questions distinct during early-stage human evaluation: whether participants completed the study; whether the preparation was tolerated under the conditions studied; whether planned measurements produced valid results; and whether the study design was capable of establishing a treatment effect.

RE-ENVIGOR generated useful information across the first three questions. As a first-in-human, open-label, single-arm safety and feasibility study, it was not designed to establish a treatment effect conclusively. This distinction is important to the interpretation of the results and to the design of subsequent controlled studies.

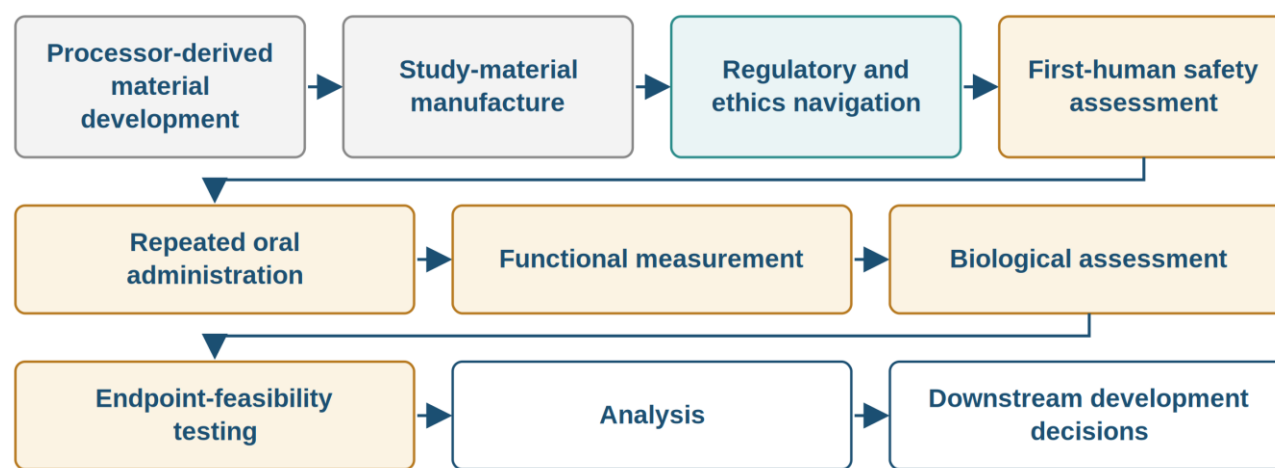
The significance of Project 2026-1048 therefore extends beyond the administration of CX-50 to eleven participants. It demonstrated that a processor-derived preparation could be progressed through an integrated first-in-human development programme, generated initial safety information, tested a multidomain clinical measurement system, identified practical refinements for subsequent development, and established a workable pathway connecting Australian red-meat coproduct recovery with human evidence. The implications for product development, regulatory strategy, processor participation and the design of future controlled studies are considered in Section 7.

7.0 Discussion

7.1 The central finding: an integrated early-development model

The principal contribution of AMPC Project 2026-1048 was not simply that a first-in-human study was completed. The project tested whether several activities that are commonly approached as separate stages of product development could be combined within one early human programme. RE-ENVIGOR brought them together in one sequence, from processor-derived material development to downstream development decisions (Figure 7.1).

Figure 7.1 The development activities RE-ENVIGOR brought together



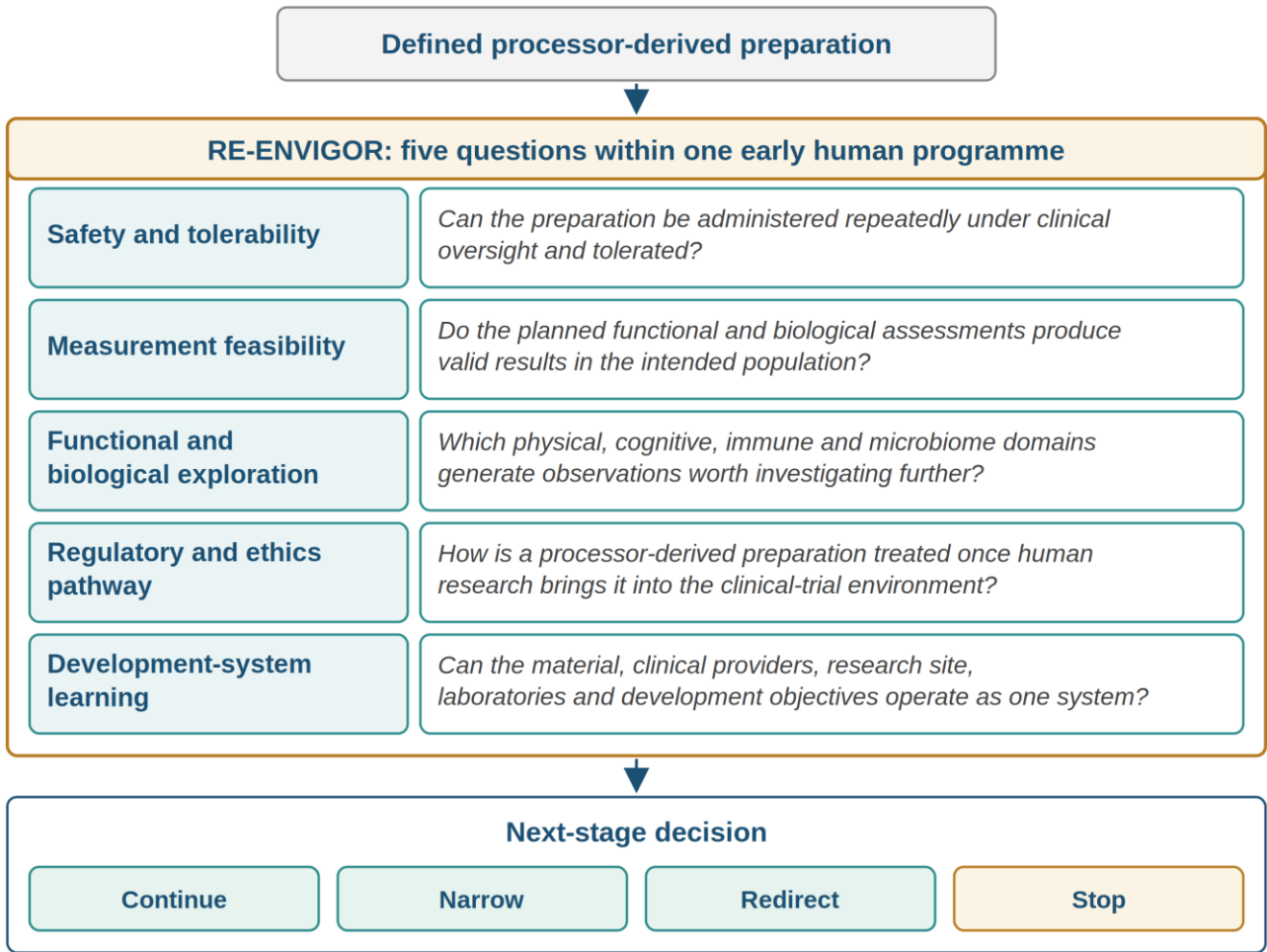
Activities commonly approached as separate stages of product development were combined within one early human programme.

The study therefore tested both CX-50 as an investigational preparation and the development model surrounding it. This distinction is central to interpretation of the project. A conventional first-in-human programme might concentrate principally on whether a preparation can be administered safely and tolerated under controlled conditions. RE-ENVIGOR deliberately sought additional development value from the same human exposure. It asked whether candidate measures of physical, cognitive and immune function could be incorporated into an early safety programme; whether biological and microbiome assessments could be collected alongside those measures; whether the measurement systems themselves worked in the intended population; and whether the resulting information could improve the choice and design of the next development stage. The project therefore attempted to reduce several different kinds of uncertainty in parallel rather than resolving them entirely through separate sequential programmes. This was consistent with the original project objectives, which included generation of a first human-safety dataset, validation of the translational pathway, collection of early functional information and development of a replicable commercial and regulatory model.

The result supports the feasibility of that integrated approach. Eleven participants completed the 42-day administration period and follow-up. Initial safety information was generated. Several physical, immune and microbiome assessments produced usable paired information. Other assessments exposed weaknesses in endpoint execution that would need to be corrected before a larger controlled study. The regulatory and ethics pathway was completed, and a working sequence connecting processor-derived material with human research was documented. The model should not be interpreted as a fixed clinical protocol for future coproducts. Its transferable value is the development logic: Use an appropriately designed early human programme to generate initial safety information while also testing the measurement system, exploring relevant areas of potential human benefit, identifying operational weaknesses and informing the next product-development decision.

That is a substantially broader output than a safety dataset alone. The project can be represented as five questions being addressed within one early human programme (Figure 7.2).

Figure 7.2 The RE-ENVIGOR integrated early-development model



The five questions were investigated together, with different evidentiary strength across each domain; their roles were kept separate.

The importance of the model is not that all five questions were answered conclusively. It is that the study demonstrated that they can be investigated together, provided their evidentiary roles remain clearly separated.

7.2 What the integrated model allowed the project to learn

The integrated design produced information at several levels. The first was safety. RE-ENVIGOR established an initial record of repeated human administration of CX-50 under clinical oversight. No serious adverse events were reported during the study. That finding is limited to the preparation, population, dose and duration studied and should not be generalised beyond those conditions.

The second was measurement feasibility. The project did not assume that attendance at a study visit meant an endpoint had been successfully measured. It distinguished participant retention, adherence, test completion and availability of a valid result. This distinction proved important. The six-minute walk assessment generated paired measurements. Immune-cell challenge work was completed, immune-cell profiling was undertaken and microbiome samples were collected and sequenced. In contrast, the graded exercise test was not obtained, the protocol-specified cognitive composite could not be calculated because one required subtest was not captured, and a planned inflammatory measure was not obtained.

These were not merely administrative observations. They directly inform what should and should not be carried into the next clinical programme. The third level was functional and biological exploration. RE-ENVIGOR examined physical performance, cognition, immune responsiveness, immune-cell characteristics and gut microbial composition. These measurements were intended to identify questions suitable for further investigation and to inform subsequent controlled research. The fourth was regulatory learning.

The project established how a food-derived processor material was treated once the proposed study, functional endpoints and representations brought the preparation into the therapeutic-goods clinical-trial environment. The fifth was development-system learning. The project showed what happens when the material, sponsor, regulatory framework, clinical provider, research site, analytical laboratories and downstream product-development objectives all have to operate as one system. That final category of knowledge became more important than initially anticipated.

7.3 Why functional assessment mattered

The functional component of RE-ENVIGOR was not an incidental addition to a safety trial. It reflected the intended downstream value proposition. Exomed's longer-term objective was not simply to identify a red-meat-derived preparation that changed a laboratory marker. The stronger opportunity was to develop preparations capable of ultimately demonstrating benefits that matter to people and can be measured through human function. Physical, cognitive and immune function therefore represented potential domains of downstream human value. These domains were retained in the early study because they increased its value for downstream planning. The scientific purpose at this stage was not to prove efficacy. RE-ENVIGOR was too small and uncontrolled to establish that CX-50 caused a change in any of those domains. The value was in creating an early map. By examining several domains, the programme could ask: Which outcomes can actually be collected? Which measurement systems are robust? Which domains appear sufficiently informative to warrant deeper investigation? Which approaches should be abandoned or redesigned? Where should the next substantial clinical investment be concentrated? This is particularly important where the final product proposition has not yet been fixed. Committing immediately to one narrow application can lock the programme into a weak endpoint or an unattractive regulatory pathway before enough human information exists to justify that choice. The RE-ENVIGOR approach instead supported broad exploration followed by disciplined narrowing. That principle should carry forward. Future early-stage studies should not attempt to measure everything. They should deliberately include enough high-value exploratory information to identify the stronger development options and then progressively reduce the programme to the endpoints required for the selected product proposition.

7.4 What did not work was also an important result

RE-ENVIGOR demonstrated that a successful clinical programme cannot be assessed only by participant recruitment and completion. All participants completed the intervention and follow-up, but several planned measurements were incomplete, substituted or unavailable. That is an important finding. A future controlled study is an expensive place to discover that a clinical test cannot be delivered consistently, that software has not been configured correctly, that a scoring pipeline cannot produce the intended composite, or that a planned laboratory measure has not been completed. The early study therefore reduced measurement and execution risk as well as safety uncertainty. The lesson is that functional outcomes must be treated with the same procedural discipline as analytical laboratory measurements. A valid functional endpoint depends on more than the name of the test.

It depends on:

- the protocol;
- the equipment;
- the testing environment;
- participant preparation;
- assessor training;
- software configuration;
- data capture;
- scoring;
- export; and
- verification that the entire chain works before recruitment.

The same applies to specialist laboratory assays and externally delivered analyses. For future programmes, endpoint systems should therefore be commissioned end to end before participants are enrolled. A failed endpoint in an early feasibility programme can be useful learning. A failed endpoint in a pivotal or expensive controlled programme can materially damage the value of the study.

7.5 The project encountered substantial structural friction

One of the strongest findings from Project 2026-1048 was that the proposed development model did not fit neatly into the established paradigms of the organisations required to deliver it. This should not be interpreted simply as resistance by individual organisations. The deeper issue was structural. The project crossed boundaries between:

- food production;
- food-derived biological materials;
- clinical research;
- therapeutic-goods regulation;
- functional health outcomes;
- clinical-trial operations; and
- commercial product development.

The systems used by clinical and regulatory organisations are largely constructed around established categories. RE-ENVIGOR deliberately challenged some of those boundaries. CX-50 originated from an edible red-meat processing stream. The study nevertheless investigated physiological and functional outcomes and ultimately proceeded under the TGA Clinical Trial Notification framework as an unapproved therapeutic good.

The project record shows that this distinction became material during protocol and ethics development. The ethics committee read the documentation as describing a therapeutic investigational product and

requested product-specific safety evidence. The product definition and supporting documents then had to be revised into one consistent framework before approval was granted.

The project initially approached the concept using language around a continuum from food through clinical evidence toward therapeutic or claim-bearing products. The Australian legal system does not operate as a single continuous “food as medicine” category. Food and therapeutic goods are separate statutory systems, and the preparation must be described and assessed within the legal framework that actually applies. The project therefore required substantial translation between the development concept and the systems through which it had to pass. Once assumptions became embedded in protocol language, product descriptions, ethics documentation, data systems and provider workflows, correcting them became increasingly difficult. This is one of the major practical lessons from the project: Course correction becomes progressively more expensive once an incorrect or incomplete assumption has propagated through the development system.

Future programmes should resolve the key assumptions before the documentation and operational systems are built around them.

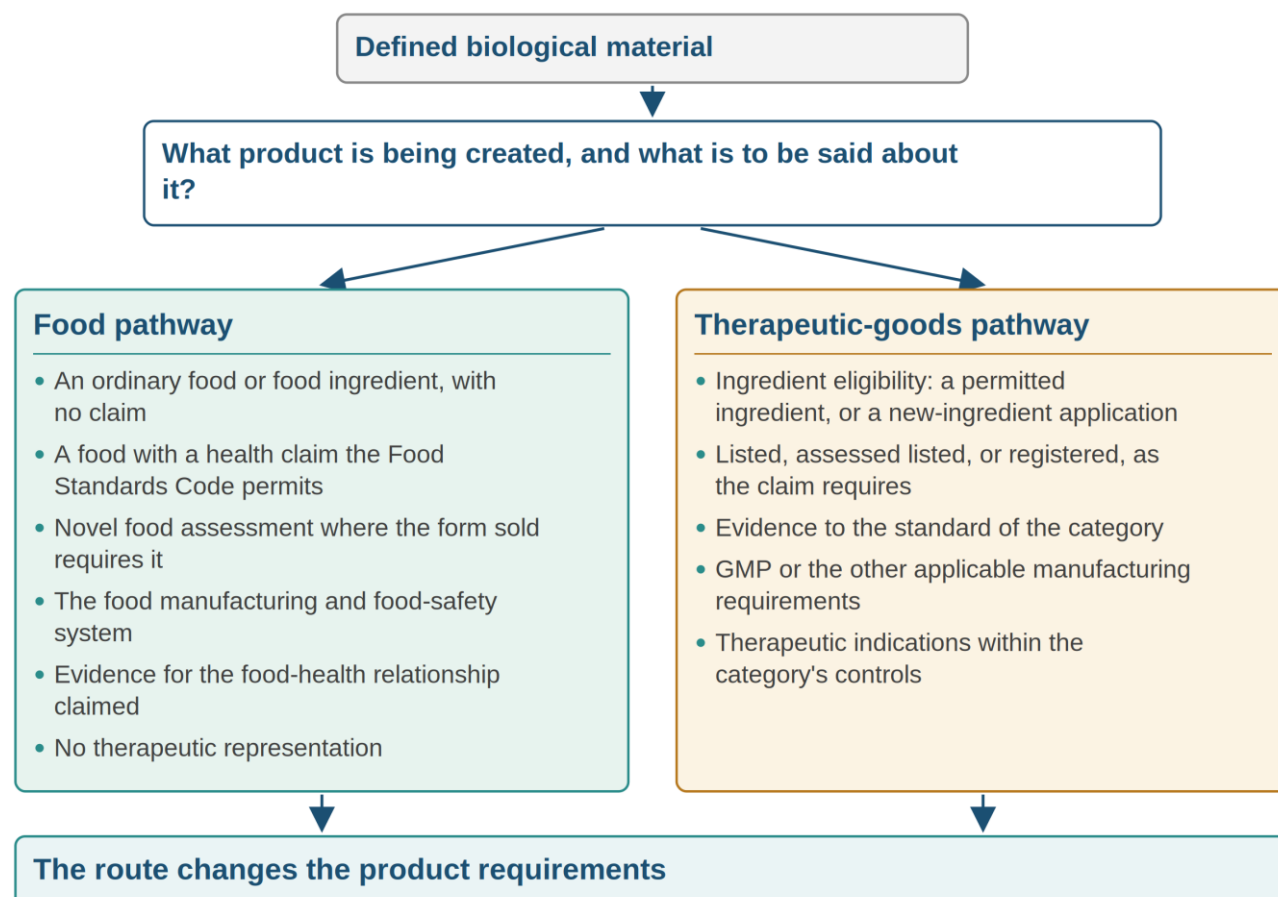
7.6 The FSANZ–TGA interface as a development capability

The project exposed the importance of the area between the food system, for which Food Standards Australia New Zealand (FSANZ) develops the standards, and the therapeutic-goods system, which the TGA administers. For red-meat-derived bioactives, this is not a marginal issue. It is likely to be one of the principal determinants of product architecture, evidence strategy and commercial opportunity. A material may originate in the edible food chain yet enter the therapeutic-goods framework depending on its presentation, intended use and representations. A food product can also carry certain health claims within the Food Standards Code without becoming a medicine. The difficult development question is therefore not “Is this material a food or a medicine?” It is “What product are we ultimately trying to create, what are we proposing to say about it, what evidence will be required to support that proposition, and which legal system permits that outcome?”

That question must be answered early. The pathway affects the claim, and through it the evidence, the endpoint, the preparation, the manufacture and the source-material specification, in that order.

The direction runs upstream as well as downstream (Figure 3.5). Figure 7.3 shows the fork.

Figure 7.3 The regulatory and evidence fork



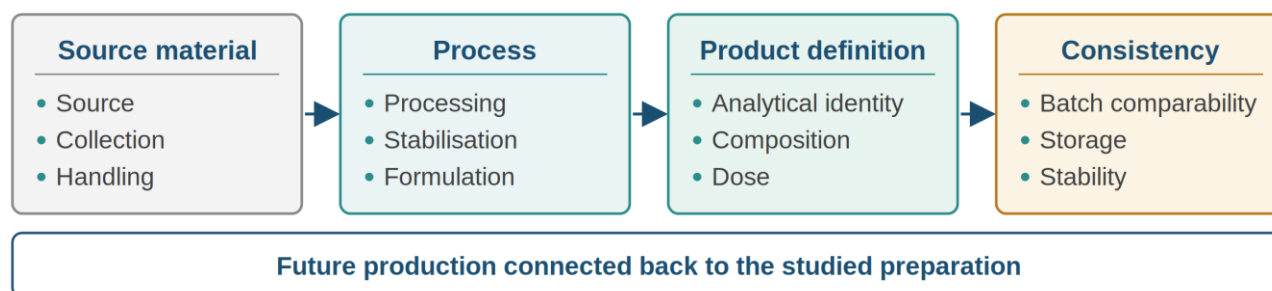
The route changes the product requirements; neither route is preferable in every case. Appendix 1 sets out the classification test (Figure A1.1) and the pathways (Figure A1.3). Sources: Food Standards Code Standards 1.2.7 and 1.5.1; Therapeutic Goods Act 1989 section 3(1); TGA 2022a; TGA 2025b.

The important message is not that one route is preferable in every case. The route changes the product. A food with a health claim and a listed medicine differ in allowable claims, evidence, manufacturing regime, channels and protection of the evidence investment (Appendix 1, Table A1.1). The development task is to choose the route deliberately rather than discover it through an ethics review after the study architecture has already been built. Future Exomed and industry work should therefore invest substantially more effort in understanding the FSANZ–TGA interface, including areas where interpretation is uncertain. That work should involve specialists who understand both systems and, where appropriate, direct engagement with the relevant regulator before material commitments are made. Appendix 1 sets out the two systems, the classification test and the pathways to market in more detail, as a standalone regulatory reference.

7.7 The process contributes to product value

The project reinforces one of the most important conclusions of the wider coproduct-development programme: for higher-value biological materials, the process contributes to the product value.

Human evidence does not attach to “bovine adipose” in the abstract. It attaches to the preparation actually administered. The value of that evidence depends on the ability to connect future production back to the studied material through relevant attributes, which fall into four groups (Figure 7.4).

Figure 7.4 Attributes that connect future production to the studied material

Human evidence attaches to the preparation actually administered; these attributes carry that connection into future production.

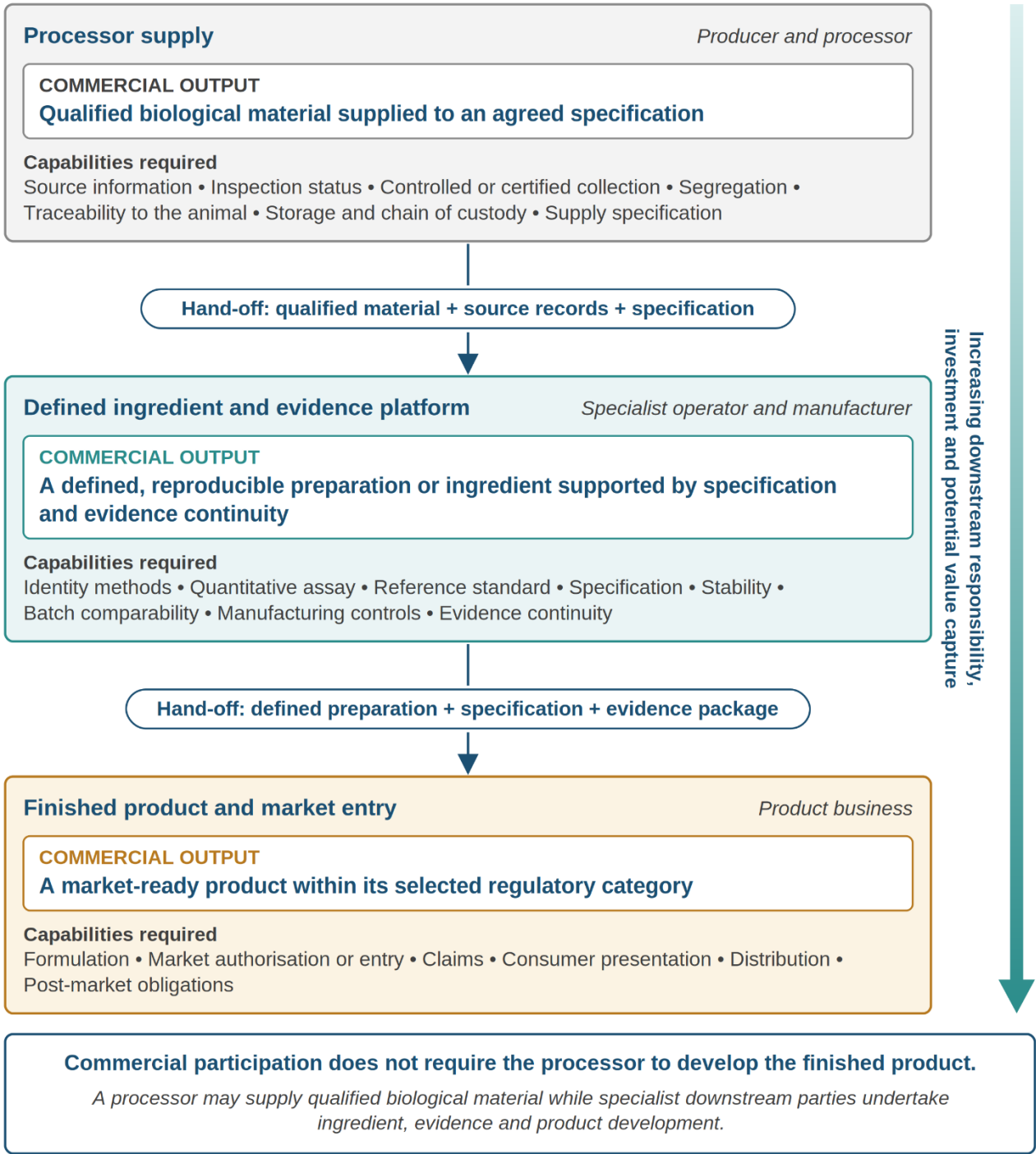
This creates a direct connection between processor practice and downstream evidence. Collection is therefore one of the first product-defining operations. The conditions under which a stream is collected, segregated, traced and, where required, certified can decide which downstream pathways remain available, and some of those conditions cannot be recreated by later processing. A processor may supply two materials that appear physically similar, while only one carries the documented history and specification needed to support the intended product pathway. Likewise, changing the preparation substantially after human evidence has been generated can weaken the applicability of that evidence. The next stage of development therefore needs to establish the relationship between the CX-50 study material and commercially representative future production. The objective is not necessarily to reproduce every historical process parameter. It is to identify which material and process attributes are critical to identity, quality and the biological proposition and then control those attributes sufficiently for the evidence to remain relevant.

This is the point at which source-material specification, analytical methods and clinical evidence become part of the same commercial system.

7.8 How far does a processor need to go?

A processor does not need to become a biotechnology company, clinical-research organisation or finished-product company in order to participate in higher-value biological markets. The development chain can be separated into different depths of participation (Figure 7.5).

Figure 7.5 Three depths of industry participation



Participation depth describes how far downstream a business goes; it is distinct from the three tiers of Table 3.1, which describe how developed and evidence-supported a preparation is. Controlled or certified collection preserves options; it does not by itself decide the classification of the final product (Appendix 1, A1.4).

Each depth depends on the one beneath it, and each hand-off defines the commercial interface with the next party. This is strategically important for AMPC and processors because it separates participation in the opportunity from ownership of every stage of the value chain. A processor may decide that its strongest position is supplying a highly controlled raw material. Another may invest further downstream. The model allows both.

7.9 The specialist operator is the missing integration function

Once the development chain is separated into those stages, a second question arises: Who holds the whole system together?

The processor controls source material and collection. A specialist manufacturer may control downstream processing. Analytical laboratories perform characterisation. Clinical organisations conduct human studies. Regulatory specialists interpret legal requirements. Product businesses handle formulation, market entry and distribution. No single participant necessarily owns the continuity across those interfaces. That is the specialist operator's role. In this architecture, the processor supplies the defined material and holds source and collection records; producers contribute animal-level source information; the specialist intermediary maintains the specification, reference material, methods and evidence; and the downstream product business carries formulation, market entry, distribution and the continuing obligations of the selected category. Exomed's intended role sits within that integration layer. The specialist operator should therefore not be understood principally as a regulatory consultant. Its function is broader: it spans material, manufacture, evidence, regulation, product and market.

It needs enough knowledge of each interface to ensure that decisions in one part of the chain do not unintentionally destroy value in another. Project 2026-1048 showed that this integration function also needs a stronger operational component than originally appreciated. It is not enough to design the pathway and commission specialists. The operator must maintain sufficient visibility during delivery to know whether the intended pathway is actually being executed.

7.10 Specialist outsourcing does not remove sponsor responsibility

RE-ENVIGOR relied substantially on specialist clinical providers. HMRI's contracted scope included clinical-trial operations, ethics management, trial registration and CTN support, site management, data management, source-data verification, biostatistics and project-management activities. NovaTrials undertook participant-facing site activities. Using specialists was necessary and appropriate. However, the project demonstrated an important limitation of highly outsourced delivery. In a highly outsourced model the sponsor remains accountable for the development programme, while much of the detailed execution occurs inside the provider and site systems. This becomes particularly important where a study is novel and the sponsor is testing not merely a conventional protocol but a new development model. Where a procedure is missed, a system is configured incorrectly, information is delayed or an endpoint does not operate as expected, the issue may not surface early enough to be corrected. The result can be a completed study with less usable information than the protocol was intended to generate. This experience does not support bringing every specialist function in-house. It supports stronger sponsor-side programme control.

Future studies should therefore establish, contractually and operationally, a dedicated sponsor-side project-management role with sufficient access to observe critical activities, review study execution in near real time and escalate problems before they become irreversible. For Exomed, this should include an on-the-ground presence at critical stages of future studies. The role is not to interfere with investigator independence or replace clinical-site responsibilities. Its purpose is to maintain transparency across the development system.

7.11 Stakeholder alignment must be demonstrated, not assumed

Another important project lesson is that contractual participation does not necessarily mean conceptual alignment.

A provider may understand its individual work package while holding a different interpretation of:

- the product;
- the regulatory pathway;
- the study purpose;
- the role of individual endpoints; or
- the intended downstream use of the evidence.

In a conventional development programme, those differences may be limited by familiar precedents. In a programme spanning food-derived biological material, therapeutic-goods research, functional health outcomes and several specialist scientific domains, small differences in interpretation can propagate through the entire project. Future programmes should therefore include a formal alignment stage before mobilisation. The test should be simple: Can all major parties explain the project in the same way?

Before protocol finalisation and site activation, the sponsor, clinical provider, site, relevant laboratories and regulatory advisers should share a common understanding of:

- what the preparation is;
- what it is not;
- why the study is being conducted;
- what each endpoint is intended to establish;
- what each endpoint cannot establish;
- which regulatory pathway is being used;
- why that pathway applies;
- how the study relates to the intended downstream product; and
- which decisions will be made from the results.

This should be evidenced through project commissioning rather than assumed from document circulation. The study protocol remains the controlling clinical document. But the protocol alone does not guarantee that every organisation understands the strategic development model within which that protocol sits.

7.12 Human execution is a material development risk

Project 2026-1048 also reinforced a basic but important point. Not all important development failures are scientific. Some arise from execution. A missed measurement, incorrect application configuration, delayed communication, unclear responsibility, incomplete record or slow escalation can reduce the value of a study as effectively as a flawed scientific assumption. This is particularly important in a small exploratory programme. With only 11 participants, each missed or invalid measurement represents a material proportion of the potential information available. Future programmes therefore need stronger controls around the ordinary mechanics of delivery.

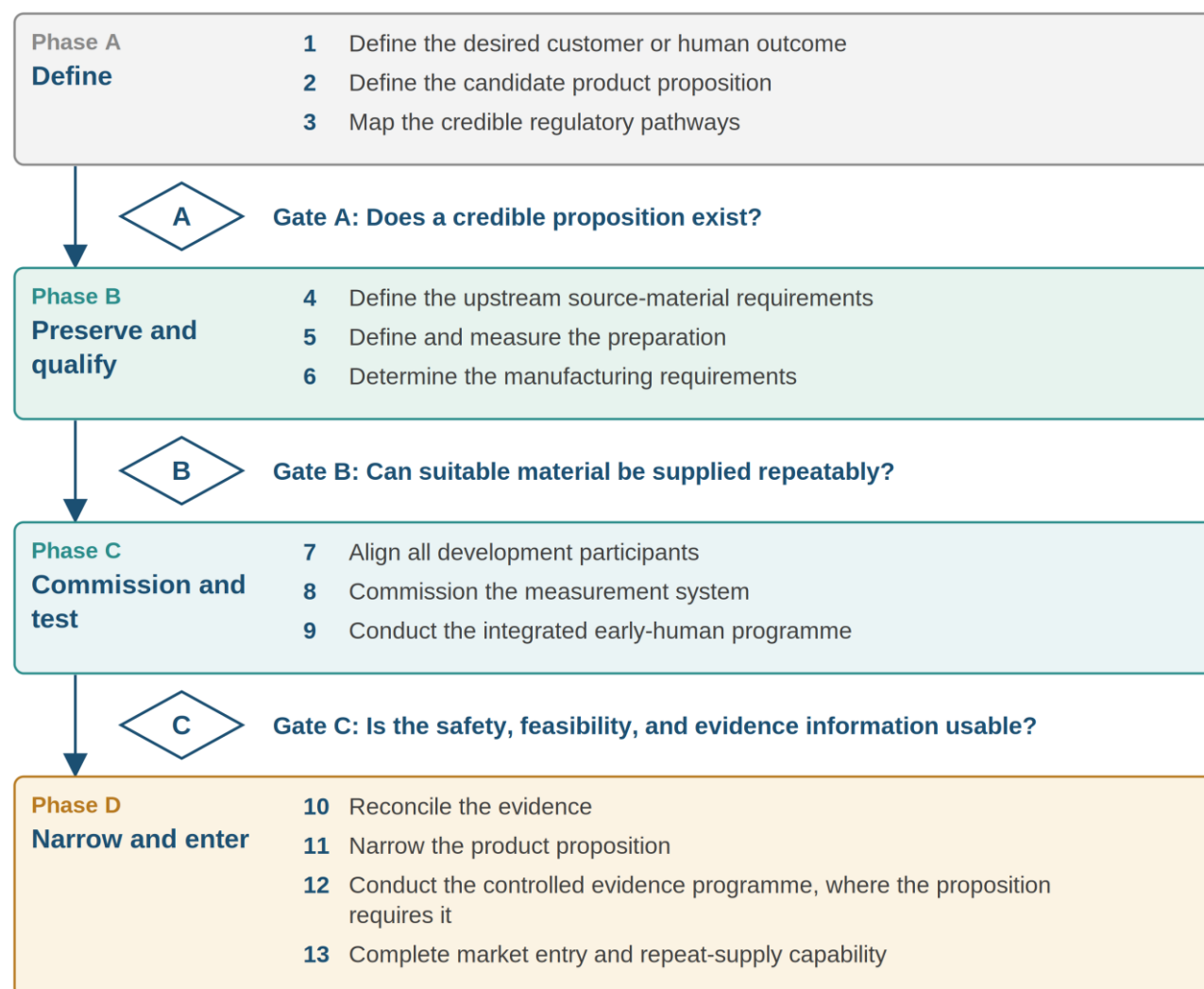
These should include:

- endpoint dry runs before recruitment;
- verification of electronic systems from data entry through final scoring;
- vendor-readiness checks;
- clear responsibility for every planned measurement;
- defined escalation timeframes;
- immediate reporting of missed or substituted procedures;
- contemporaneous sponsor visibility; and
- documented corrective action while correction remains possible.

The objective is not excessive bureaucracy. It is the opposite. The purpose is to detect problems early enough that they remain small.

7.13 A staged development sequence with decision gates

The development sequence in Figure 7.6 draws together the classification, evidence and manufacturing dependencies set out in this report with what RE-ENVIGOR taught about execution. It is arranged in four phases, each ending with a decision gate that is a decision point rather than an automatic commitment to the next stage.

Figure 7.6 A staged development sequence with decision gates

At each gate the options are to continue, narrow, redirect, partner, or stop. Each gate is a decision point, not an automatic commitment to the next stage.

Appendix 1 places the legal dependencies within these phases (Figure A1.5).

The important addition from Project 2026-1048 is that stakeholder alignment, endpoint commissioning and sponsor visibility must become explicit gates in the sequence. They cannot remain assumed operational details. Coproduct programmes lose value when classification is not written down, evidence is generated before the category is selected, public representations outrun the evidence, or an essential condition ceases to be true without clear ownership (Appendix 1, A1.8). RE-ENVIGOR adds another category: A technically sound development plan can lose value when the people and systems responsible for execution are not sufficiently aligned or visible to permit timely correction.

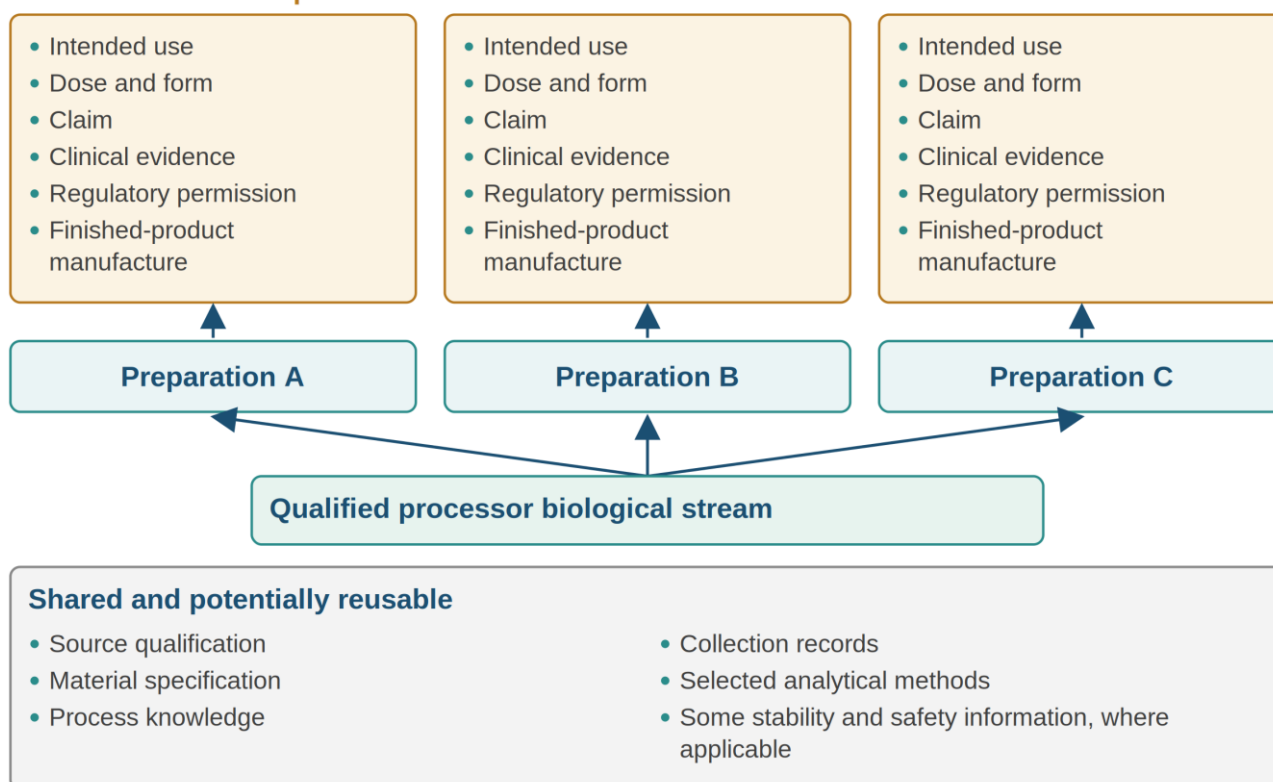
7.14 From a single product to a biological resource platform

The wider opportunity extends beyond CX-50. AMPC Project 2025-1073 established a staged value model for blood in which EV recovery could coexist with continued use of the residual plasma and later protein fractionation. Project 2026-1048 adds the evidence-development layer to that model. The strategic question is therefore not simply “Which single EV product should the industry make?” It is “How can the industry build upstream material and development capabilities that support multiple downstream products over time?”

This changes the optimisation problem. If a processor builds a collection system solely around one finished product, the value of the capability may disappear if that product fails. If instead the processor establishes a qualified, traceable biological stream, and the specialist operator establishes reusable analytical, manufacturing and evidence infrastructure, the platform can potentially support several products. Source qualification, collection records, analytical methods, process knowledge and some safety and stability information may be reusable where the material and evidence remain applicable, although product-level claims and approvals still need to be established for each application. That is an important distinction. Reuse should never be assumed merely because two products share the same animal source. But a well-designed platform can avoid rebuilding every capability from zero (Figure 7.7). This is why higher-value coproduct development should be viewed as the development of biological resource platforms, not only individual products.

Figure 7.7 Biological resource platform and value reuse

Established for each product



Shared source and infrastructure may reduce repeated development work, but evidence and regulatory status do not automatically transfer between materially different preparations or products.

7.15 The value cascade remains the correct commercial architecture

This platform concept also supports the broader value-cascade model established in AMPC Project 2025-1073. The objective is not to divert an entire coproduct stream into one premium application. Existing commodity and ingredient markets provide the economic base. Selected fractions can then be directed into progressively higher-value applications where evidence, technical feasibility, regulatory pathway and customer demand justify doing so. The approach preserves the existing value of the stream while advancing a smaller number of candidate bioactives through progressively greater development. That is the commercially important architecture. For blood, plasma proteins and other fractions can remain valuable irrespective of whether an EV product is ultimately successful. For adipose, future work should similarly determine what residual value remains after recovery of selected biological fractions and how the entire material stream is best utilised. The value of a higher-order fraction should therefore be assessed

as an addition to the stream rather than automatically as a replacement for lower-order uses. This reduces dependence on a single product-development outcome.

In the terms of the three-tier model (Table 3.1), one qualified stream can carry several preparations at different tiers at the same time: a defined material supplied at Tier 1, a characterised fraction in development at Tier 2, and a preparation advancing toward Tier 3 through human evidence. Each progresses at the speed its evidence and market justify, and the Tier 1 and Tier 2 value of the stream does not depend on any one preparation reaching Tier 3.

7.16 Implications for producers and processors

The project also clarifies where producers and processors create value within this system. Higher-value biological development depends on information and controls that often originate before the specialist manufacturer ever receives the material.

Relevant attributes can include:

- animal identification;
- source;
- health status;
- declarations;
- inspection history;
- collection conditions;
- segregation;
- storage; and
- traceability.

Some of this information already exists within Australian production and processing systems. The commercial opportunity is to connect it deliberately to the recovered biological lot where the downstream specification requires it. This is analogous to an approach the red-meat industry already understands. Meat Standards Australia links a consumer-valued outcome—eating quality—to production, processing and handling conditions that influence whether the outcome can be delivered consistently (MLA 2026). A higher-value biological coproduct requires the same basic discipline: define the desired downstream outcome, identify what material and process conditions influence it, measure what matters, and preserve that connection through the supply chain.

The valued outcome is different. The supply-chain logic is not.

7.17 Limitations and evidentiary boundaries

The project's wider development significance should not obscure the limitations of the clinical evidence itself. RE-ENVIGOR was a small, open-label, single-arm first-in-human study involving 11 participants. **There was no concurrent control group, no blinding and no efficacy-powered sample-size calculation. Within-participant changes cannot therefore be attributed to CX-50.** The exploratory programme also included multiple outcomes and experienced incomplete or substituted assessments. The project does not establish:

- clinical efficacy;
- a substantiated health or therapeutic claim;
- a final commercial indication;
- safety beyond the population, dose, duration and preparation studied; or
- automatic applicability of the CX-50 evidence to future preparations.

These limitations define what needs to happen next. They do not remove the value of the development model. The project was designed to reduce uncertainty and prepare the programme for a stronger subsequent study, not to complete the entire evidence pathway in one small trial.

7.18 Overall interpretation

Project 2026-1048 should therefore be understood as a successful but demanding test of a new development approach. The project sought to bring together activities that are often separated: food-derived material development, regulatory positioning, first-human safety, functional assessment, biological exploration, endpoint feasibility and downstream product learning.

RE-ENVIGOR demonstrated that these functions can be combined within one early-stage human programme. It also exposed why doing so is difficult. The existing development environment is organised around established regulatory categories, institutional processes, contractual boundaries and specialist disciplines. A programme that crosses those boundaries requires substantial integration. The project encountered significant friction in achieving that integration. Product definition had to be reconciled with regulatory interpretation. Documentation had to be corrected once inconsistent assumptions became visible. Some endpoint systems did not deliver the information intended. Communication across provider interfaces slowed the correction of some issues. The project confirmed that outsourced specialist delivery needs strong sponsor-side programme control and direct visibility into critical execution, and Exomed is building both into its next programme. Those findings are not peripheral to the project. They are among its most important outputs. The next development programme should therefore retain the core RE-ENVIGOR concept while substantially improving its execution.

The improved model is:

1. define the human and commercial outcome first;
2. understand the FSANZ–TGA pathway before the study architecture is fixed;
3. preserve the necessary source-material conditions upstream;
4. define and characterise the preparation;
5. align every stakeholder to the same product and evidence model;
6. commission all critical endpoints before recruitment;
7. maintain direct sponsor visibility throughout delivery;
8. combine safety, feasibility and targeted exploratory learning where scientifically appropriate; and
9. use the resulting evidence to narrow the next investment decision.

The project therefore provides more than a result for CX-50. It provides the first practical version of a repeatable development system through which selected Australian red-meat coproducts can be moved from processor-derived biological material toward evidence-supported, higher-value human-health products. The model is not finished. Project 2026-1048 showed that it is worth building.

8.0 Conclusions

AMPC Project 2026-1048 progressed a selected red-meat coproduct preparation from a commercial processing environment into first-in-human evaluation and documented the development pathway required to do so. CX-50, a freeze-dried preparation derived from bovine adipose tissue, was progressed through study-material manufacture, ethics approval, TGA notification and clinical delivery. Eleven adults aged 50 to 80 years completed 42 days of daily administration and follow-up. The study generated an initial human safety and feasibility dataset, with no serious adverse events reported.

The broader value of the project was the development model tested through RE-ENVIGOR. Rather than conducting safety, endpoint feasibility, functional exploration and regulatory learning as entirely separate activities, the study combined them within one early-stage human programme. This demonstrated that a processor-derived biological preparation can be used to investigate several development questions in parallel, provided the different evidentiary purposes remain clearly separated. Delivery against the Research Agreement objectives is summarised below:

- **Objective 1 — first regulator-aligned human safety dataset:** A first-in-human safety and feasibility dataset was generated for CX-50 under the conditions studied.
- **Objective 2 — validated translational pathway:** The project completed and documented the sequence from processor-derived material through manufacture, regulatory and ethics preparation, human administration and analysis.
- **Objective 3 — quality and documentation frameworks:** Traceability, quality and study-material documentation were established for the preparation used in RE-ENVIGOR.
- **Objective 4 — early functional data:** Physical, cognitive, immune and microbiome assessments generated both exploratory observations and important information about which measurement systems were suitable for further development.
- **Objective 5 — replicable commercial and regulatory model:** The project established a reusable development architecture linking processor supply, specialist manufacture and analysis, regulatory and ethics preparation, clinical delivery and downstream development decisions.

The project also exposed important limitations in the current development environment. A food-derived material moving toward health-related human evidence does not sit naturally within one continuous “food as medicine” pathway. The project encountered substantial friction at the interface between food, therapeutic-goods and clinical-research systems, particularly where assumptions about product definition, classification and evidence had already become embedded in documentation and operating processes.

RE-ENVIGOR also showed that successful participant completion does not guarantee complete development learning. Several assessment systems worked as intended, while others did not. This demonstrated the importance of endpoint feasibility, stakeholder alignment and operational execution as development outcomes in their own right.

The project therefore established more than a pathway for CX-50. It provided a practical first model for taking a red-meat-derived biological material into an integrated early-human development programme and

using that programme to reduce uncertainty before committing to a larger controlled study or final product pathway.

For industry, the opportunity remains broader than a single product. Producers and processors can participate by collecting, preserving and supplying defined, traceable biological materials under conditions suited to the intended downstream use, while specialist operators connect those materials to manufacturing, analytical, regulatory, clinical and commercial capability.

AMPC Project 2025-1073 established the technical recovery and value-cascade opportunity. Project 2026-1048 extended that work into human evidence. Together, they provide the foundation for treating selected red-meat coproduct streams as biological resource platforms capable of supporting multiple higher-value development pathways.

In the terms of the three-tier model, Project 2026-1048 operationalised the Tier 2 to Tier 3 transition for a processor-derived preparation: it took a defined preparation into human evaluation and generated the evidence and pathway learning that progression toward Tier 3 requires.

9.0 Recommendations

The recommendations arising from Project 2026-1048 are intended to provide a practical basis for further industry development of higher-value red-meat coproducts. The next phase should focus on building capability without prematurely fixing the final product, regulatory pathway or commercial model. The objective is to progressively reduce uncertainty, preserve credible downstream options and support better investment decisions by processors and industry partners. Six priorities emerge.

9.1 Establish qualified processor supply capability

Further work should demonstrate that **selected processor sites can consistently supply defined, traceable biological material suitable for downstream development**. The central priority is to establish repeatable processor capability to recover selected materials under collection, traceability and certification conditions suited to credible downstream human-use pathways. The emphasis should be on understanding what level of collection, handling, documentation and quality control is required to support higher-value uses without imposing unnecessary burden on processors. This work should provide a practical foundation for subsequent product development while allowing different processors to participate according to their capability and commercial interest.

9.2 Deepen FSANZ–TGA regulatory capability

The regulatory environment for food-derived biological products is complex and can materially influence product design, evidence requirements and market-entry options. Future work should continue to build a much deeper understanding of the interface between food, therapeutic-goods and human-research pathways so that regulatory implications are considered early in development rather than resolved after major commitments have been made. The aim is to become materially better at determining which route permits the desired product and claim, and what that decision requires upstream. The purpose should be to improve decision quality and preserve flexibility, not to predetermine a single regulatory route.

9.3 Progress adipose product development

Adipose should remain an active development priority. The next stage should build on the material, clinical and regulatory learning generated through RE-ENVIGOR and progressively refine the most credible product opportunities. The aim should be to move from broad opportunity assessment toward at least one increasingly well-defined product proposition, while retaining alternative pathways until sufficient evidence exists to justify narrowing. The work should build on what was learned from CX-50 without treating it as the only adipose proposition.

9.4 Continue plasma development as a high-priority parallel stream

Plasma should continue to be developed in parallel. **Previous work indicates that plasma represents a broader biological resource with several potential higher-value applications**. Further development should therefore continue to examine how the stream can support multiple product opportunities rather than being optimised around a single fraction too early.

For plasma, collection comes first. Project 2025-1073 identified blood collection through a suitably controlled or certified system as the binding constraint, and that requirement should be resolved at the sites that would supply the stream before major downstream investment. Adipose and plasma should be treated as complementary development streams rather than sequential projects.

9.5 Strengthen integrated development execution

Future programmes should build on the integrated model tested through RE-ENVIGOR while improving the areas that created friction. This includes stronger early alignment between the material, intended use, regulatory approach, evidence strategy and specialist providers, together with endpoint commissioning before recruitment, sponsor visibility and operational controls during execution. The objective is to retain the efficiency and learning value of an integrated model while reducing avoidable rework and loss of information.

9.6 Build reusable industry capability

Where possible, future work should create capabilities that can be reused across more than one product or coproduct stream. This may include processor supply arrangements, material specifications, analytical capability, regulatory knowledge, manufacturing experience and development methods. The long-term benefit to industry is therefore not limited to the first successful product. It is the progressive development of a repeatable capability for identifying, qualifying and advancing higher-value biological opportunities from red-meat coproducts. The commercial objective remains to advance at least one real product proposition far enough that the platform is tested against actual market-entry requirements.

9.7 Overall direction

The recommended next phase should therefore balance three objectives:

- Establish practical processor supply capability
- Deepen the regulatory and development knowledge required to navigate the market successfully
- Continue advancing both adipose and plasma opportunities toward credible product development and market entry

The programme should remain flexible enough to respond to new evidence, customer requirements and regulatory interpretation as the work progresses.

10 Project outputs

10.1 Outputs

The project produced the outputs summarised in Table 10.1. Their findings, interpretation and implications for industry are presented in Sections 5 to 9.

Table 10.1 Project outputs

Output	Status
Study material	Delivered. The adipose-derived preparation used in RE-ENVIGOR, with study-material quality, traceability and supporting documentation.
Regulatory documentation set	Delivered. Study protocol, Investigator's Brochure, participant information and consent documentation, ethics approval, trial registration and Clinical Trial Notification.
Human evaluation	Delivered. RE-ENVIGOR completed; eleven participants completed the 42-day administration period and follow-up.
Data analysis	Delivered. HMRI biostatistics report (HMRI 2026) and supplementary analyses.
AMPC project reporting	Delivered. Milestone Reports 1 and 2, the project update of 29 May 2026, and this final report.

All project deliverables have been met.

10.2 Acknowledgements

The project was funded by AMPC and the Commonwealth Government through AMPC's matching funding arrangements. Exomed Pty Ltd was the research provider and Exomed Australia Pty Ltd was the study sponsor. The Hunter Medical Research Institute coordinated clinical delivery, data management and statistical analysis, and NovaTrials operated the clinical site in Newcastle. The participating processing establishment supplied the adipose material within its existing edible-product workflow and supported preparation of the study material. Specialist scientific and analytical providers contributed to the study programme. The project acknowledges the participants in the RE-ENVIGOR study and the industry and research partners who contributed to its delivery.

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12 Appendices

12.1 Appendix 1

Food or medicine: how a coproduct preparation is classified, what each pathway requires, and the order of the work

A1.1 Purpose, limits, and reading order

This appendix provides an orientation framework for Australian regulatory pathway analysis of red-meat-derived preparations. It does not classify a particular future product. Classification depends on the preparation, presentation, intended use, representations and instruments in force at the relevant time.

This appendix is for processors, ingredient manufacturers, and product developers who have a coproduct stream and want to know what can lawfully be done with it. It assumes no regulatory background. It explains how Australian law decides whether a preparation is a food or a medicine, what each pathway to market requires, how far a business has to go to take part, and the order in which the work is done. It supports Sections 7.6 to 7.8 and rests on the primary instruments and the regulators' published guidance listed in Section 11, as at September 2026.

It is organised by the questions a reader asks, in the order they arise:

- Which system applies to the preparation, and who decides? (A1.2 and A1.3)
- What happens when a stream is transformed, and where can each product go? (A1.4)
- What are the pathways to market, and what does each one permit a business to say? (A1.5)
- How far does a business go to take part? (A1.6)
- What does a human study involve? (A1.7)
- Which legal dependencies fix the order of the work? (A1.8)
- What do the terms mean? (A1.9 and Table A1.3)

Regulators decide how a provision applies to a particular material, process, and presentation, and instruments are amended, so the instrument in force is confirmed before any step is relied on. This appendix is not legal advice, and it does not classify any product. Deeper regulatory work of this kind is recommended for the next stage (Section 9.2).

The findings below are those of this project and of AMPC and MLA coproduct work before it, and every figure in this appendix expands one of them.

- For a product taken by mouth, the two categories exclude each other: a therapeutic good is not a food (Food Standards Australia New Zealand Act 1991, section 5(2)). Which it is depends on how it is presented; the composition alone does not decide it.
- The food status of the tissue does not necessarily carry over to a fraction or extract made from it. Each preparation is classified on its own form.
- The TGA does not classify a preparation in advance, and FSANZ does not approve individual food products. The business makes the classification itself, and that assessment is examined later, by an ethics committee, in a compliance review, or in enforcement.

- Statements about a product are regulated in both systems. A statement that a preparation influences a body process is a representation for therapeutic use whether or not a disease is named. It makes the goods a therapeutic good unless they are a food in the form presented and the statement is a health claim Standard 1.2.7 permits. Advertising a therapeutic good that is not on the register is an offence.
- The claim selects the category, and the category sets the evidence, the manufacturing standard, and the sequence of the work.

A1.2 The two systems

Under Australian law a product taken by mouth is ordinarily regulated either as a food or as a therapeutic good, and it cannot be both: the Food Standards Australia New Zealand Act 1991 defines food so as to exclude a therapeutic good (section 5(2)). Other categories and exclusions exist, and the instruments in force decide a particular case. The two systems are run by different bodies under different legislation. They differ on what a business most needs to know: whether anything has to happen before sale, what may be said about the product, what evidence is required, and how the product must be made (TGA 2025b). Table A1.1 sets them side by side.

Food Standards Australia New Zealand (FSANZ) develops the Australia New Zealand Food Standards Code, and the state and territory food authorities enforce it. An ordinary food needs no approval before sale; the food business is responsible for compliance and is checked after the food is on the market. A food may carry nutrition content claims and health claims within Standard 1.2.7, and no food claim may refer to the prevention, diagnosis, cure, or alleviation of a disease, disorder, or condition. A food sold in a form that has no history of consumption in Australia or New Zealand may be a novel food, which cannot be sold until a permission is added to the Code (Standard 1.5.1; Schedule 25; FSANZ 2024a).

The Therapeutic Goods Administration (TGA) administers the Therapeutic Goods Act 1989. Except where an exemption or an access pathway such as a clinical trial scheme applies, a medicine is entered in the Australian Register of Therapeutic Goods (ARTG) before it is supplied, at one of three levels that carry increasing claims and increasing scrutiny: listed, assessed listed, and registered. A medicine is manufactured under a licence or accepted overseas Good Manufacturing Practice (GMP) evidence unless an exemption applies, and advertising is regulated by the Therapeutic Goods Advertising Code (Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021). Advertising a therapeutic good that is not entered in the register is an offence, and the definition of advertising is not limited to consumer media. Communications to investors, partners, and conference audiences can fall within it, and only advertising directed exclusively to health professionals and the other classes in section 42AA is exempt (Therapeutic Goods Act 1989, sections 3(1), 42AA, and 42DL; TGA 2026e).

Table A1.1 The food system and the therapeutic goods system compared

Element	Food	Therapeutic good (medicine)
Legislation	Food Standards Australia New Zealand Act 1991; Australia New Zealand Food Standards Code; state and territory food acts	Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990; the Permissible Ingredients, Permissible Indications, and Manufacturing Principles determinations
Who sets the rules	FSANZ develops the Code; food ministers set policy	The Commonwealth Parliament and the Minister; the TGA administers the Act
Who checks compliance	State and territory food authorities, after the food is on sale	The TGA: before entry to the register for assessed listed and registered medicines, and after listing for listed medicines
Pre-market step	None for an ordinary food. A Code variation for a novel food or for a new high level health claim relationship	Entry in the Australian Register of Therapeutic Goods by listing, assessed listing, or registration
Claims permitted	Nutrition content claims; general level health claims on a Schedule 4 relationship or a self-substantiated and notified relationship; high level health claims on a relationship in Schedule 4, existing or added by Code variation. No reference to preventing, diagnosing, curing, or alleviating a disease, disorder, or condition	Listed: permitted indications. Assessed listed: an intermediate indication assessed by the TGA. Registered: any indication the evaluated evidence supports, including treatment of a serious disease
Evidence	For the food as sold, at an amount a normal diet supplies, on the food–health relationship claimed	Held by the sponsor for each indication and checked after listing, or submitted for assessment before listing or registration
Manufacturing	State food licence and food safety programme; for meat, AS 4696:2023 and HACCP	Manufacturing licence or accepted overseas GMP evidence for the active ingredient and the finished product; an animal-origin (TSE) file for bovine material
Protection of the evidence investment	Exclusive use of a new novel food or nutritive substance permission, limited to the applicant's brand and to 15 months	Five-year data protection for an assessed listed medicine; two years of exclusive use for a new listed-medicine ingredient
A human study of an unapproved product	Ethics review under the National Statement; no TGA clinical trial scheme where the material is not a therapeutic good as presented	Ethics committee review and a Clinical Trial Notification or a Clinical Trial Approval

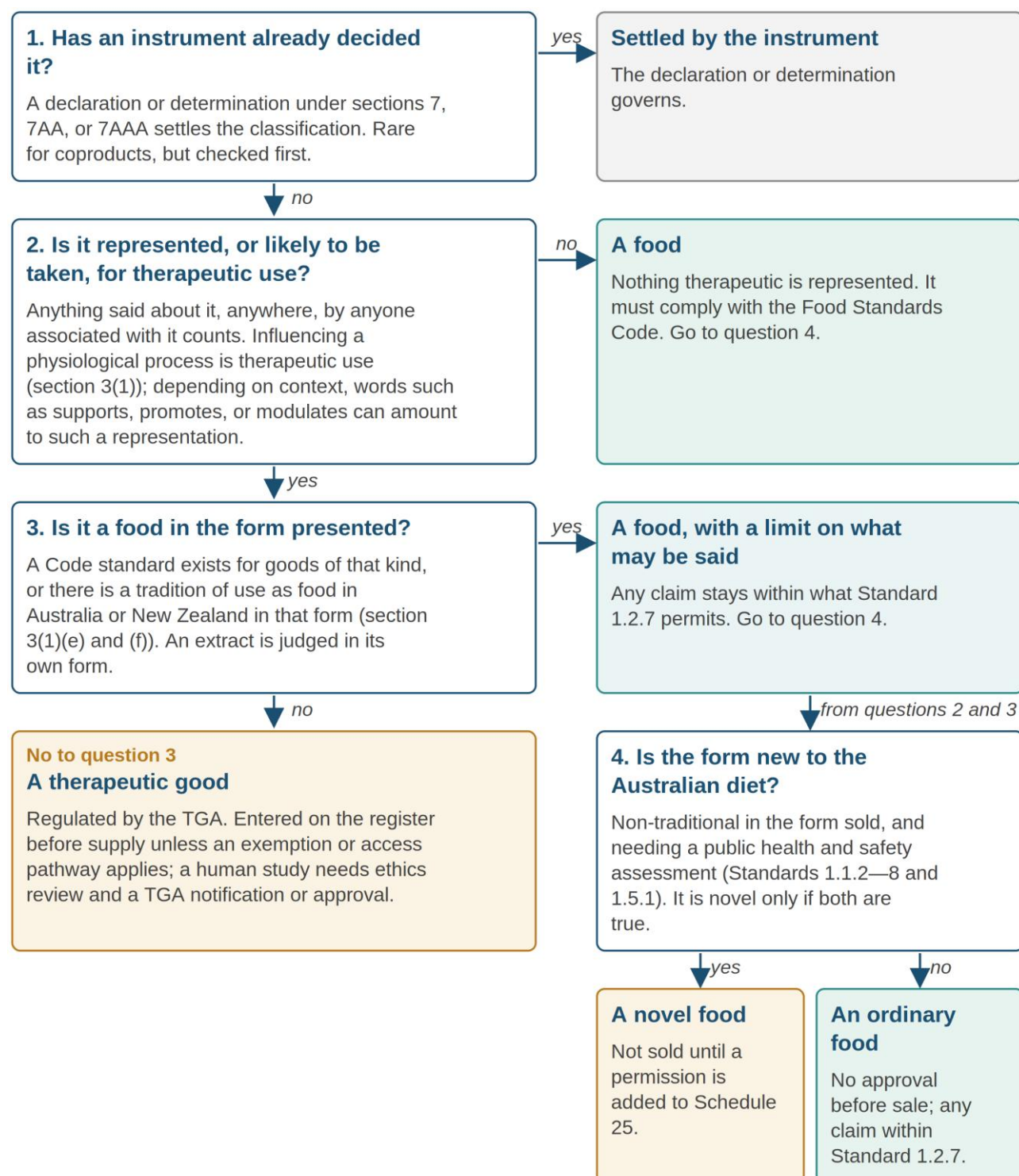
Sources: *Food Standards Australia New Zealand Act 1991*, sections 5 and 13; *Food Standards Code Standards 1.2.7 and 1.5.1 and Schedules 4, 6, and 25*; *Therapeutic Goods Act 1989*; *TGA 2021*; *TGA 2024b*; *TGA 2024c*; *TGA 2024d*; *TGA 2024e*; *TGA 2024g*; *TGA 2025b*; *TGA 2026b*; *FSANZ 2025*.

A1.3 Deciding which system applies

The test is in the Therapeutic Goods Act 1989 (section 3(1)) and applies in a fixed order. Figure A1.1 states it as four questions. They ask whether an instrument has already decided the classification, and whether the goods are represented, or likely to be taken, to be for therapeutic use. They then ask whether the goods are a food in the form presented, and, for a food, whether the form sold is novel. The answers depend on the preparation in the form presented, on everything said about it, and on the instruments in force. The sponsor makes the assessment itself, and the TGA does not classify a product in advance (TGA 2022a).

The TGA recognises the overlap between foods carrying health claims and medicines, which it calls the food–medicine interface, and publishes a guidance tool for the classification (TGA 2022a; TGA 2025b).

Figure A1.1 Food or therapeutic good: the four questions in the order they apply



Source: Therapeutic Goods Act 1989 section 3(1) and sections 7, 7AA, 7AAA, 32A, and 41BD; Therapeutic Goods (Declared Goods) Order 2019; Therapeutic Goods (Biologicals—Specified Things) Instrument 2021; Food Standards Code Standards 1.1.2 and 1.5.1. Simplified for orientation; the instruments govern.

Two drums of the same powder from the same batch can be two different goods in law. One is labelled as a protein ingredient and is a food. The other is described as relieving joint pain, is represented for therapeutic use, which includes influencing a physiological process, and is a therapeutic good. Nothing about the powder changed (Therapeutic Goods Act 1989, section 3(1), definitions of therapeutic goods

and therapeutic use; TGA 2022a). The representation can be made in any medium by anyone associated with the goods, and it need not name a disease. Depending on context, wording such as supports, modulates, promotes, or enhances can amount to a therapeutic representation; the full presentation and the food-claim provisions are assessed together.

For a coproduct preparation the questions turn on the preparation as it will be sold or studied, and two questions decide most cases. First, an extract is judged in its own form. The food status of the source tissue does not necessarily carry over to a fraction, concentrate, or enriched extract recovered from it, because a Code standard covers goods of a particular kind and the consumption history attaches to the form presented (Standard 1.1.2—8; Standard 2.2.1). Second, the same substance can lawfully be sold as a food or as a medicine according to its presentation and claims. Gelatin and hydrolysed collagen are food ingredients with a tradition of use and are also permissible active ingredients for listed medicines (Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026). Table A1.2 sets out what decides the classification and what does not.

Table A1.2 What decides the classification and what does not

Decides the classification	Does not decide it
What is represented about the goods, in any medium, by anyone associated with them (section 3(1), paragraph (a))	That the material is edible
Whether the goods are in a class whose principal use is therapeutic, or are for use as an ingredient in therapeutic goods (section 3(1), paragraphs (a) and (b))	That nothing therapeutic has been said on the label
Whether a Food Standards Code standard exists for goods of that kind (section 3(1), paragraph (e))	That it is manufactured under food-safety controls
Whether there is a tradition of use as food in Australia or New Zealand in the form presented (section 3(1), paragraph (f))	That the source tissue is a familiar food
Whether a declaration or determination has settled it (sections 7, 7AA, and 7AAA)	That the sponsor intends it to be a food

Sources: *Therapeutic Goods Act 1989*, section 3(1) and sections 7, 7AA, and 7AAA; TGA 2022a; TGA 2025b.

The classification is recorded with the product definition it was made on, the reasons, the instruments checked, and the date, and it is repeated whenever the process, form, concentration, use, population, or description changes. A new brochure or label is a new representation and is assessed in the same way. At an ethics review the whole document set is read for the representation made, which is how this project’s classification was examined (Section 6.7).

A1.4 Material transformation and the pathways from a stream

The same stream supports several kinds of preparation, and they do not share a regulatory position. A broad preparation such as dried plasma protein or a whole-tissue powder is the kind most likely to have a history of use, or to fall within an existing Code standard. A selected fraction such as an albumin-rich or immunoglobulin-rich fraction establishes its own history, because Standard 1.1.2—8 treats a substance derived from a food, with no history of consumption other than as a component of that food, as non-traditional. An enriched preparation such as an EV-containing extract may be non-traditional in the form sold and requires assessment of that form against the applicable food and therapeutic-goods tests. Where its presentation and representations bring it within the statutory definition, it is a therapeutic good. A health claim that Standard 1.2.7 permits does not by itself make a food a medicine. Figure A1.2 sets out where each kind of preparation can go.

Two points about transformation follow for a processor. Edible source tissue does not by itself make a fraction or an enriched preparation made from it an edible or authorised product; each preparation is assessed on the form that results. Controlled or certified collection preserves the options that depend on the source, such as the traceability a specification requires or the source records an animal-origin file draws on, and it does not by itself determine the classification of the final product. That follows from the preparation, its presentation, and what is said about it.

Each column shows the same pattern. The broad preparation reaches the food and feed pathways without a permission more often, because it is the kind most likely to have a consumption history in the form sold. For a fraction or an enriched preparation the food pathways remain available on the same two questions as everything else: whether the form is non-traditional and whether it requires a public health and safety assessment. Enrichment changes composition, exposure, and the relevance of the parent food's history, which are inputs to that test and often decisive ones, and the test is still answered for the form sold. Where the answer is novel, a Schedule 25 permission is the way in (Standard 1.5.1); where it is not, the food pathways are open on the same terms as for any other food. Where the position is unclear, FSANZ's Advisory Committee on Novel Foods gives a view on request, which is not legally binding (FSANZ 2026a; FSANZ 2026b).

Biologicals and export sit outside the figure. A biological is engaged only by a preparation that comprises or contains live animal cells, tissues, or organs (Therapeutic Goods Act 1989, section 32A; Therapeutic Goods (Biologicals—Specified Things) Instrument 2021). A cell-free preparation is a medicine or a food on its own presentation, and the absence of live cells is shown by a defined release method. Export is a separate question worked beside each candidate, and an overseas permission creates no Australian permission and no Australian consumption history.

Figure A1.2 From a stream to a product: where each kind of preparation can go

	Broad preparation <i>dried plasma protein, rendered fat, a whole-tissue powder</i>	Selected fraction <i>an albumin- or immunoglobulin-rich fraction, a hydrolysate, a refined lipid</i>	Enriched preparation <i>an EV-containing extract, a purified fraction</i>
Food ingredient, no claim	Open Where the form sold has a history of use	Conditional History of use shown for the fraction; the tissue's history does not count	Conditional After a novel food permission, presented without a therapeutic representation
Food with a health claim	Conditional Claim on a Schedule 4 relationship, or self-substantiated	Conditional After the novelty question, then the claim requirements	Conditional After the permission, a claim Standard 1.2.7 permits
Novel food (permission first)	Conditional Only if the form is non-traditional and needs a safety assessment	Conditional Likely non-traditional; novel if a safety assessment is required	Conditional Novel unless equivalence to an eaten comparator is shown
Listed medicine (permitted ingredient)	Conditional Only if an ingredient entry already exists	Conditional Only if an ingredient entry already exists	Conditional Only if an entry exists; identity anchor first
New ingredient, then listed medicine	Conditional New-ingredient application first	Conditional New-ingredient application; identity and assay first	Conditional Identity, assay, stability, safety, and TSE clearance
Non-ruminant feed ingredient	Open Four APVMA exclusion conditions met	Conditional Whether the fraction qualifies as an ingredient is open	Conditional Species evidence needed for any claim

□ Open: reachable on the plant's existing status once the condition in the cell is met

□ Conditional: reachable, and the cell names the step that has to be taken first

Each cell states what the pathway turns on for that preparation; it describes the test, and the answer for a particular product is a separate assessment. Every food cell assumes the goods are not therapeutic goods as presented (Figure A1.1, question 2), and every medicine cell assumes the reverse. Sources: Therapeutic Goods Act 1989 section 3(1); Food Standards Code Standards 1.1.2—8, 1.2.7, 1.5.1, and 2.2.1; Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026; APVMA 2025.

A1.5 The pathways to market and the claims each permits

Figure A1.3 sets the pathways a red meat coproduct preparation is likely to enter side by side, as alternatives, from the pathway with no pre-market step to the pathway assessed in full by the TGA before

sale. For each it states what a business may say, what the pathway takes, and when compliance is checked.

Figure A1.3 Pathways to market for a coproduct preparation and the claims each permits

Animal feed	Food	Therapeutic goods
Non-ruminant feed ingredient May say No claim, or a claim on published evidence in the species Before sale The four APVMA exclusion conditions met; never for ruminants	Food ingredient, no claim May say Nutrition content and provenance statements Before sale Nothing, if the form sold is not a novel food	Listed medicine May say A permitted indication, on evidence the sponsor holds Before sale Listing on the register; a permitted ingredient; GMP
	Food with a general level health claim May say A health effect not referring to a serious disease, on a Schedule 4 relationship or a self-substantiated one Before sale Notification to FSANZ where self-substantiated	Assessed listed medicine May say An intermediate indication assessed by the TGA Before sale TGA assessment of the evidence before listing
	Food with a high level health claim May say A serious disease or a biomarker, on a Schedule 4 relationship, existing or added by Code variation Before sale A Code variation where no relationship is listed	New ingredient, then listed medicine May say As for a listed medicine once the ingredient is admitted Before sale TGA admission of the ingredient, then listing
		Registered medicine May say Any indication the evaluated evidence supports, including a serious disease Before sale Full TGA evaluation of quality, safety, and efficacy

The categories are alternatives, each entered on its own requirements; a food with a health claim and a medicine are not stages on the way to each other. Biologicals, medical devices, cosmetics, and export sit outside the figure. Sources: Food Standards Code Standards 1.2.7 and 1.5.1 and Schedules 4, 6, and 25; Therapeutic Goods Act 1989; Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026; Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025; TGA 2024e; APVMA 2025.

Two pathways, a food ingredient without a claim and a non-ruminant feed ingredient, have no pre-market step and can be supplied earlier, while a claim-carrying product is developed. That holds provided the form sold is not a novel food and, for feed, the four APVMA exclusion conditions are met. A listed medicine on an ingredient already in the Permissible Ingredients Determination is entered on the register without pre-market assessment, and the evidence for each indication as worded is complete at listing, because it is checked afterwards in compliance review (TGA 2022b; TGA 2026b; TGA 2026c). A new ingredient carries the longest sequence, because the ingredient is defined, measured, and shown to be

stable before its application is lodged, and only then can a product be listed on it (TGA 2023a; TGA 2024c).

The food pathway and the medicine pathway differ in kind. An ordinary-food pathway may involve fewer pre-market steps but permits a narrower class of claims. Therapeutic-goods pathways can impose additional evidence and manufacturing requirements while also providing different statutory mechanisms for claims and for the protection of some evidence investments. The protection is five years of data protection for an assessed listed medicine and two years of exclusive use for a new listed-medicine ingredient, against a brand-limited 15 months for a new novel food permission (TGA 2024e; TGA 2024c; FSANZ 2025). Table A1.1 compares the two systems on these and the other fields.

A1.6 How far a business goes

A processor can take part without developing a finished product. Figure 7.5 (Section 7.8) sets out three depths of participation: processor supply, a defined ingredient and evidence platform, and finished product and market entry. Each depends on the one beneath it, and a business can stop at any of them and supply the next party.

Every pathway in Figure A1.3, and every human study, starts with processor supply: a defined material, collected at grade, traceable to the animal, from an inspected establishment, supplied to a written specification. Whether a stream can be collected at grade is a plant-infrastructure fact, established by examining the plant; hygiene performance does not show it. It was the binding constraint for the blood stream in AMPC Project 2025-1073. Identity and assay, from the defined ingredient and evidence platform, are required by every claim-carrying category and are retained whichever category is chosen. It carries one consequence that is easy to miss. Goods for use as an ingredient in the manufacture of therapeutic goods are themselves therapeutic goods (Therapeutic Goods Act 1989, section 3(1)), so an ingredient manufacturer supplying a medicine sponsor inherits that sponsor's manufacturing regime and specification, whatever its own claims.

A1.7 A human study under each system

A human study of a food-derived preparation raises two independent questions, decided by two different bodies. Whether an unapproved therapeutic good is being supplied is decided by the classification test in A1.3, on what the study documents represent. Which of the National Statement's risk categories the research falls in, negligible, low, or more than low risk, is assessed through the institution's review process, on the risk to participants. Figure A1.4 sets out the review pathway for each combination.

Figure A1.4 Oversight of a human study of a food-derived preparation

Columns: classification of what is supplied (Figure A1.1)

	No therapeutic good supplied	Unapproved therapeutic good supplied
Negligible risk <i>No foreseeable risk of harm or discomfort; any foreseeable risk is no more than inconvenience</i>	The institution may exempt the research from ethics review under its own policy	HREC review whatever the risk category: a trial under the notification or approval scheme is not eligible for exemption or a low-risk review process, and the committee monitors each site
Low risk <i>The only foreseeable risk is one of discomfort</i>	Reviewed through the institution's low-risk review process, or by an HREC	
More than low risk <i>The risk, even if unlikely, is more serious than discomfort</i>	Reviewed by an HREC; no TGA clinical trial scheme	HREC review plus a clinical trial notification or approval

Rows: the National Statement's risk categories, assessed through the institution's review process

Sources: National Statement on Ethical Conduct in Human Research 2007 (updated 2023), chapters 2.1 and 5.1, the edition in force from 1 January 2024 to 22 June 2026 under which this study was approved and conducted (NHMRC 2023); the National Statement 2025, in effect from 23 June 2026, governs later submissions (NHMRC 2025); Australian clinical trial handbook (TGA 2024g); Therapeutic Goods Regulations 1990, regulation 12AD.

Every configuration falls within the National Statement. Research at more than low risk, and any study supplying an unapproved therapeutic good, is reviewed by a Human Research Ethics Committee; for other research, low-risk research may be reviewed through the institution's low-risk review process, and negligible-risk research may be exempted from review by the institution. Where the study documents make no therapeutic representation and the material is not otherwise a therapeutic good, no TGA clinical trial scheme applies, and the evidence may support a food claim where it meets the requirements of Standard 1.2.7. Where an unapproved therapeutic good is supplied, the study runs under one of two TGA schemes. Under the Clinical Trial Notification scheme the sponsor notifies the TGA, which does not evaluate the study, and the ethics committee assesses the science and the safety. Under the Clinical Trial Approval scheme the TGA evaluates the data, and the ethics committee reviews after the TGA's approval or in parallel with it; both approvals are needed before the study starts (TGA 2024g; TGA 2024h). This project used the notification scheme (Sections 5.3 and 6.7). Material for a first-in-human study may be manufactured under an exemption from the manufacturing licence requirement. The exemption applies to the initial experimental studies in human volunteers. Whether a later study remains within it is confirmed against the TGA's guidance before that study begins, and where it does not, the material is manufactured under a licence, accepted overseas GMP evidence, or another applicable exemption (TGA 2021; TGA 2024g). A trial is a development step. Permission to conduct a study establishes nothing about commercial supply, and trial supply creates no consumption history.

A1.8 The order of the work

Figure 7.6 (Section 7.13) sets out the practical development sequence in four phases with decision gates. Figure A1.5 places the legal dependencies within those phases, with the question at each point and the condition that stops the work. The intended claim and the customer are determined and the material is described; the category that permits the claim is selected; the preparation is measured, and the evidence

and the manufacturing are designed to that category; and the regulator is engaged with the required application.

Figure A1.5 The legal dependencies within the development sequence of Figure 7.6

Phase A Steps 1 to 3	Classify and record Classify with the product definition, and repeat on every change to process, form, dose, use, or description. Claim before category The category is chosen for the claim, so the proposition precedes the category. Category before evidence The endpoint follows the category. A disease endpoint gives a result a food claim cannot carry; a high level food claim needs a Schedule 4 relationship, existing or added by Code variation.
Phase B Steps 4 to 6	Collection at grade Collection conditions lost at the plant cannot necessarily be recreated downstream; certified collection preserves options and does not decide the classification. Measurement before evidence A study that cannot state the amount consumed cannot meet the food-side evidence standard. Manufacturing before a later study Whether a later study stays within the first-in-human exemption is confirmed against the TGA's guidance before it begins.
Phase C Steps 7 to 9	The study documents They are read for the representation they make, which decides whether an unapproved therapeutic good is supplied (Figure A1.4).
Phase D Steps 10 to 13	Statements and conditions What is said publicly stays within the evidence and the regulatory status, and every condition that must stay true has an owner.

Classification is a statement about a described material, made when the proposition is first described and repeated whenever the description changes. Sources: Therapeutic Goods Act 1989 section 3(1); Food Standards Code Standard 1.2.7 and Schedules 4 and 6; TGA 2021; TGA 2024g.

The following dependencies fix the order. A study that cannot state the amount of the defined substance consumed cannot be reported to the food-side evidence standard, so measurement precedes the evidence plan. The category is chosen for the claim, so the proposition precedes the category. The endpoint follows the category, because an endpoint framed as treatment or prevention produces a result a food claim cannot carry, and a high level food claim depends on a relationship in Schedule 4, existing or added by Code variation, so the category precedes the evidence plan. The first-in-human manufacturing exemption applies to the initial experimental studies in human volunteers, and whether a later study remains within it is confirmed against the TGA's guidance before that study begins, so the manufacturing basis precedes it. Classification is a statement about a described material, made when the proposition is first described and repeated whenever the description changes, and it is kept current through the sequence.

Coproduct programmes lose the value of work already done in the following ways, in the order they occur. The classification was never written down. Evidence was generated before the category was chosen. What was said publicly went beyond what the evidence and the regulatory status supported. A condition that had to remain true, such as a licence, a release test, or an ethics approval that continues only while reports are filed, stopped being true and nobody owned it. Each arises from meeting the wrong requirement, or the right one in the wrong order. This project met the first at ethics review and resolved it by revising the document set around one product definition (Section 6.7).

A1.9 Glossary

Table A1.3 Terms used in this report

Term	Meaning in this report
Therapeutic good	Goods represented, or likely to be taken, to be for therapeutic use, or in a class whose principal use is therapeutic, or for use as an ingredient in therapeutic goods, unless a food or otherwise excluded (Therapeutic Goods Act 1989, section 3(1))
Therapeutic use	Use in preventing, diagnosing, curing, or alleviating a disease, or in influencing, inhibiting, or modifying a physiological process (Therapeutic Goods Act 1989, section 3(1))
Representation	Anything said or implied about goods, in any medium, by anyone associated with them; it decides the classification
Food	Goods for which a Food Standards Code standard exists, or with a tradition of use as food in Australia or New Zealand in the form presented, and not a therapeutic good (Food Standards Australia New Zealand Act 1991, section 5)
Non-traditional food	A food, or a substance derived from a food, with no history of significant human consumption in Australia or New Zealand in the form presented (Standard 1.1.2—8)
Novel food	A non-traditional food that requires an assessment of public health and safety before sale; it cannot be sold until permitted in Schedule 25 (Standards 1.1.2—8 and 1.5.1)
Health claim	A statement of a relationship between a food and a health effect; general level (no reference to a serious disease) or high level (refers to a serious disease or a biomarker of one) (Standard 1.2.7)
Schedule 4, Schedule 6	Schedule 4 lists the pre-approved food–health relationships; Schedule 6 sets the systematic review process by which a business substantiates its own general level claim
ARTG	The Australian Register of Therapeutic Goods; a medicine is entered before supply unless an exemption or access pathway applies
Listed medicine (AUST L)	A lower-risk medicine using ingredients from the Permissible Ingredients Determination and indications from the Permissible Indications Determination; entered without pre-market assessment, with the evidence checked afterwards
Assessed listed medicine (AUST L(A))	A listed medicine carrying an intermediate indication assessed by the TGA before listing
Registered medicine (AUST R)	A medicine evaluated in full for quality, safety, and efficacy before registration
Permissible ingredient	A substance in the Permissible Ingredients Determination that may be used in a listed medicine, subject to any conditions on its entry
Permissible indication	A claim in the Permissible Indications Determination that a listed medicine may carry
Sponsor	The person or company responsible for a therapeutic good, including for a clinical trial

Term	Meaning in this report
CTN, CTA	The Clinical Trial Notification scheme (the TGA is notified and does not evaluate) and the Clinical Trial Approval scheme (the TGA evaluates the data), under which an unapproved therapeutic good is supplied in a study (TGA 2024g)
HREC	A Human Research Ethics Committee, constituted under the National Statement
National Statement	The National Statement on Ethical Conduct in Human Research, which governs ethics review (NHMRC 2023; NHMRC 2025)
First-in-human exemption	The exemption from the manufacturing licence requirement for goods prepared for the initial experimental studies in human volunteers. Whether a later study remains within it is confirmed against the TGA's guidance before that study begins (Therapeutic Goods Regulations 1990, Schedule 7; TGA 2024g)
GMP	Good Manufacturing Practice under the Manufacturing Principles; required for medicines, including the active ingredient, unless an exemption applies (Therapeutic Goods (Manufacturing Principles) Determination 2020; PIC/S 2023)
Animal-origin (TSE) file	The record of source, establishment, inspection, animal age, and traceability that a medicine containing bovine material holds (TGA 2023b; TGA 2024f)
AS 4696, HACCP	The Australian Standard for the hygienic production and transportation of meat for human consumption, and the hazard-based food safety program a processing establishment operates under its state licence (Standards Australia 2023)
APVMA exclusion	The four conditions on ingredients, manufacturing, labelling, and claims under which an animal nutrition product is excluded from veterinary registration; never available for bovine material fed to ruminants (APVMA 2025)
Nutraceutical, functional food, food as medicine	Market descriptions with no corresponding category in Australian law; the product is a food, with or without a health claim, or a medicine
EV preparation	A preparation enriched for extracellular vesicles; used in this report in preference to narrower terms until identity is established

A1.10 Sources

All of the instruments are published. Legislation is on the Federal Register of Legislation ([legislation.gov.au](https://www.legislation.gov.au)). Food standards and the novel foods record of views are at [foodstandards.gov.au](https://www.foodstandards.gov.au). Therapeutic goods guidance, the Australian Register of Therapeutic Goods, and published compliance outcomes are at [tga.gov.au](https://www.tga.gov.au). Animal feed exclusions are at [apvma.gov.au](https://www.apvma.gov.au), and export registration at [agriculture.gov.au](https://www.agriculture.gov.au).