Regulation of foods from cell cultivation & precision fermentation: ANZ overview

September 2026

Updated September 2026 to reflect Food Standards Code amendments including Standards 1.5.2 & 1.5.4, Schedule 25A, and Standard 3.4.1

Cellular Agriculture Australia

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1. About this resource

This document creates a foundational knowledge base to support companies to understand and navigate the certification and regulatory requirements for food ingredients produced using precision fermentation and cell cultivation technologies.

Who should read this:

This resource is designed for companies looking to :

- manufacture for local sale, for export or, import cellular agriculture products for sale in Australia and New Zealand.
- produce cultivated foods (e.g. cultivated meat, seafood) or precision-fermented ingredients for human consumption.

Exclusions: This document is not relevant to companies producing ingredients for pet food applications.

What's inside:

- **The National Food Regulation Framework:** An overview of how food laws, policy development, and enforcement are shared between the Commonwealth, States, Territories, and local councils.
- **The Food Standards Code:** An explanation of the ANZ Food Standards Code structure, highlighting the most relevant Standards and Schedules.
- **Assessment Guidance**: An overview of the FSANZ pre-market evaluation approach for both technologies, labelling requirements, and key regulatory approval precedents
- **The Regulatory Approval Process:** A step-by-step breakdown of the Food Standards Australia New Zealand (FSANZ) application process, including procedural steps, fees, public consultation, and estimated assessment timelines.
- **Import, Export, and Agency Interfaces:** Guidance on cross-border regulations, Trans-Tasman mutual recognition with New Zealand, and the food-medicine interface.

Note: Throughout this overview, you will find '**Our Guidance**' sections containing actionable recommendations, recommended timelines, and strategic advice from Cellular Agriculture Australia to help prepare for the regulatory approval process.

How to use this resource

The resource could be used as a strategic roadmap to:

- **Build Foundational Knowledge:** Understand which specific pre-market safety assessments and regulatory permissions apply to your given product type before it can be legally sold.
- **Evaluate Strategic Alignment:** Determine if seeking regulatory approval in ANZ is the right commercial fit for your business goals.

- **Begin Early Planning:** Build baseline knowledge around FSANZ timelines, costs, and assessment steps to map out your initial launch strategy and plan commercial timelines accordingly.
- **Guide Early Stakeholder Engagement:** Inform timely outreach with FSANZ, DAFF, and state/territory enforcement agencies early in the development cycle to prevent costly procedural delays.
- **Benchmark International Requirements:** Compare ANZ regulatory requirements with those in other key jurisdictions to identify differences in evidence expectations and potential safety data gaps during product development.

Please Note: This document provides a foundational overview and does not constitute legal or bespoke regulatory advice. While it establishes the groundwork for your planning, companies may still need to engage a dedicated regulatory consultant to navigate product-specific technicalities and draft the formal submission

2. Glossary

Bioreactor: A device in which cell proliferation occurs under closed and controlled conditions.

Cell-cultured food: Also referred to as ***cell-cultivated*** or ***cultivated*** food, which is a food obtained by culturing cells isolated from livestock, poultry, game, seafood (including fish), or an egg or embryo of any of the former.

Cell-culturing food business: A cell-culturing food business produces food or food ingredients using cell cultivation.

Cell line: A collection of cells derived from a single source, prepared under specific culture conditions, with uniform composition, intended for use in production of a cell biomass.

Food Standards Code (commonly referred to as 'the Code'): A specific set of standards relating to the sale and advertising of foods, published as the ANZ Food Standards Code, and managed by FSANZ. Food Standards are adopted as regulations and enforced under state/territory food laws.

FSANZ: Food Standards Australia New Zealand.

Genetically modified food: A food that is, or is derived from, an organism that contains novel DNA; or contains an ingredient derived from such an organism.

Novel food: A non-traditional food that requires assessment of safety before it may be sold as food in Australia and New Zealand.

Policy: A system of guidelines prepared, in this case by governments, to guide decisions and achieve outcomes consistent with the intended purpose.

Precision fermentation: Precision fermentation harnesses microorganisms (e.g. yeast, bacteria, fungi) to produce specific ingredients that can be used in various food and agricultural products. The ingredients produced can include egg and dairy proteins as well as specific enzymes, flavours, colours, fats, and oils.

Precision-fermented ingredient: a food ingredient produced using precision fermentation technology.

Standards: Documents that set out specifications, procedures and guidelines to ensure products, services, and systems are safe and suitable.

3. The food-medicine interface

As a first step, companies should determine whether their product will be regulated as a food or as a therapeutic good, as this classification determines which regulatory pathway applies. The sections that follow focus on products that fall within the food regulatory system.

The **Therapeutic Goods Administration (TGA)** website includes information on considering whether products may be regulated as foods or therapeutic goods/medicines. The information is in the form of a guidance tool asking a series of questions about the product.

As a general rule, unless it contains ingredients that have been determined by TGA to be therapeutic goods, the presentation, form and usage instructions of a dietary supplement will determine how it is regulated. Products presented in a food-like manner (e.g. snack bars, beverages) and not carrying therapeutic claims will normally be regulated as foods. Products presented in a form consistent with medicines (e.g. tablets, capsules, powders) or carrying therapeutic-type claims are more likely to be classed as therapeutic goods.

All medicines supplied in Australia must be included in the Australian Register of Therapeutic Goods (ARTG) administered by the TGA. Regardless of whether a medicine is registered or listed in the ARTG, it must be manufactured in a licensed or approved facility in accordance with the principles of good manufacturing practice (GMP). GMP for the manufacture of formulated medicines listed on the ARTG must be certified by the TGA but this formal certification requirement does not extend to permissible ingredients used in medicines.

4. National food regulation framework

4.1 Implementation & enforcement of food law in Australia

Food law development and implementation is shared in Australia between the Commonwealth, States & Territories in accordance with constitutional responsibilities.

Under the Australian constitution, the responsibility for food is a State/Territory responsibility. Each jurisdiction maintains its own laws, regulations and agencies that oversee the primary production, manufacturing and sale of food within its own jurisdiction. They are also responsible for the enforcement of those laws within their own jurisdiction. Each jurisdiction has agreed to maintain food law(s) that contain and implement agreed common texts & principles and adopt food standards developed by **Food Standards Australia New Zealand (FSANZ)** or the Australian Pesticides and Veterinary Medicines Authority (APVMA) without amendment.

The states & territories also work with the **Office of the Gene Technology Regulator (OGTR)** in managing potential risks to the environment and human health and safety from GM organisms, some of which may have food uses.

Food moves between the different jurisdictions under a mutual recognition agreement, meaning that a food complying with the laws in the home state/territory jurisdiction of the manufacturer or distributor may be legally sold in any other Australian jurisdiction. In cases where a food is reported to be non-compliant, it is referred to the home jurisdiction (i.e. where the head office for the food business is based) for compliance and/or enforcement action.

The agencies responsible for managing inspections of food manufacturing facilities and regulating food for sale vary in each jurisdiction. Inspections of food manufacturing premises are conducted by local or state government agencies The regulation of food, particularly enforcement, is generally

the responsibility of relevant Departments of Health or Primary Industries - excepting Victoria where Safe Food Victoria reports to the Victorian Minister for Agriculture.

State enforcement:

Each Australian State & Territory is responsible for regulating the primary production, manufacturing, safety & suitability, and compliance with food standards of food produced within its jurisdiction. Each State addresses this in a way consistent with the jurisdiction's governance & administrative policies and agencies.

Your local State or Territory government is responsible for regulation of your food manufacturing processes and products. With the exception of specific types of primary products (e.g. meat, eggs, seafood and dairy), the first point of contact would normally be the relevant agency with overarching responsibility for food regulation. In all jurisdictions except NSW and NZ this will be within the Health Department.

State & Territory jurisdictions can be very helpful and need to be involved early in the conversation. They will not generally give a definitive answer to whether a food complies with the Code/food laws, as this is a matter for FSANZ given the broad requirement for pre-market assessment for foods produced through cellular agriculture. However, they can provide valuable guidance on local requirements and the practicalities of establishing food production facilities.

State & Territory Governments are also responsible for the regulation of primary production and food manufacturing facilities. In many cases, the jurisdiction regulations will require food businesses to implement risk-based, audited, HACCP management programs to ensure the safety & suitability of their products for human consumption. For cell-cultured food producers, this will need to beconsidered alongside the specific requirements of Standard 3.4.1.

Enforcement may also involve local government, with over 560 local councils are involved in monitoring and enforcement throughout Australia. The local councils normally report directly to the State Department or Agency responsible for food policy.

> *Our guidance: Early engagement with the relevant state or territory enforcement agency can help build familiarity with and understanding of the product and technology, develop support ahead of any future FSANZ application, and identify jurisdiction-specific implementation and compliance considerations relevant to eventual market entry.*

Imported foods:

The Commonwealth Government, through the Department of Agriculture, Fisheries and Forestry (DAFF), is responsible for biosecurity at Australia's external borders and for enforcing compliance with food standards at the border in relation to imported food. However, the Commonwealth Government is not responsible for the enforcement of food law domestically.

New Zealand:

Within the context of the Australia New Zealand (ANZ) Joint Food Standards Treaty and the Trans-Tasman Mutual Recognition Agreement, foods approved for sale by FSANZ can be sold in both Australia and New Zealand. Locally produced food products also move freely between Australia and New Zealand with compliance & enforcement responsibility defaulting back to the home jurisdiction (Australian States & Territories or New Zealand Government). However, it should be noted that New Zealand maintains its own controls on imports and exports to and from third countries and on domestic food production.

4.2 Food Policy - Food Ministers' Meeting

Food policy is cooperatively developed by a forum of ministers from the 10 Australian and New Zealand government jurisdictions, including: New Zealand, New South Wales, Victoria, Queensland, South Australia, Western Australia, Tasmania, Northern Territory, Australian Capital Territory, and the Australian Government.

The Australia and New Zealand Ministerial Forum on Food Regulation (known as the Food Ministers' Meeting) is chaired by the Australian Commonwealth Government. The Food Ministers' Meeting develops and publishes food policy guidelines that FSANZ must have regard to when considering amendments to the Code. Food Policy development is coordinated by the Australian Government Department of Health and Aged Care through the Food Regulation Secretariat.

The Food Ministers' Meeting is supported by the Food Regulation Standing Committee (FRSC), composed of senior members from government departments and agencies responsible for food regulation in each jurisdiction listed above. The jurisdictions also work together through the Implementation Subcommittee for Food Regulation (ISFR) to ensure food laws are implemented and enforced consistently where possible.

The Food Regulation System (summarised above) is detailed here. Funding and wider resourcing for the Commonwealth Health Department's agencies such as FSANZ and the Therapeutics Good Administration (TGA) is through Parliament's appropriation to the Health Department. Compared with international jurisdictions, funding per-capita annual investment in food standard-setting in Australia and New Zealand is low and therefore limits regulatory progress to best practice regulation.

4.3 Development & implementation of Food Standards

The development and implementation of food standards is the **responsibility of an independent statutory authority, FSANZ**, established under the Food Standards Australia New Zealand Act 1991 (FSANZ Act).

The role of FSANZ:

FSANZ develops and amends food standards published in the Australia New Zealand Food Standards Code (commonly referred to as 'the Code' by FSANZ and throughout this document) in accordance with specific objectives and procedures set out in detail in the FSANZ Act 1991. As outlined above, overarching food policy is set for FSANZ by the Food Ministers' Meeting.

The functions and responsibilities of FSANZ are listed in detail in the FSANZ Act 1991 and centre around developing standards & supporting guidelines and coordinating the states & territories linked to the Code. Whilst FSANZ may provide education & information, on request, to the public, this does not extend to providing legal advice on the application, interpretation or enforcement of the Code.

The current Strategic Plan for 2025–2028 of the Food Regulation System informs and prioritises FSANZ's work plan. The work of FSANZ is scoped within the FSANZ Corporate Plan 2026-27 and its 2030 Roadmap.

How Standards can be amended:

Standards in the Code may be amended as the result of:

- a proposal,

- initiated by FSANZ, or
- an application from any third party.

Amendments to the Code may be sought for a variety of reasons but the most common is to seek approval of a new food or ingredient (through third parties, such as food companies), or where FSANZ considers, or is asked (by the Food Ministers' Meeting), to consider amendments that may clarify requirements or introduce new standards.

The process of assessing a new food or ingredient will generally include at least one opportunity for public comment. There is provision for the protection of commercially confidential information during public consultation. If, after assessing a new food or ingredient, and considering issues raised through public consultation, FSANZ decides to prepare an amendment to the Code, it is provided to the FSANZ Board for approval. Once approved, it will then be recommended for consideration by the Food Ministers' Meeting, which may accept, reject or ask FSANZ to review its recommendation.

Importantly, once an amendment to the Code has been adopted by the Food Ministers' Meeting and published in the Commonwealth Gazette, enforcement becomes the responsibility of the individual state or local government jurisdictions. All states and territories have an offence provision in their legislation for failure to comply with a requirement of the Code. This results in gazetted food standards (once transition times are served) becoming legally enforceable by jurisdictions.

4.4 Food Export

The export of foods from Australia is administered by the Biosecurity and Trade Division at DAFF. The extent of involvement by DAFF in the export of food products will depend on the categorisation of foods (prescribed or non-prescribed goods) and/or the requirements of the importing country. Export of prescribed goods, such as animal or plant commodities (dairy, seafood, eggs, meat, plant products and live animals) is regulated by DAFF to ensure Australian agricultural products meet import requirements in other markets. Export of non-prescribed goods (the classification applied to Vow's cultivated quail products at the time of writing) is largely dependent on the requirements of the importing country, which may include certification or other controls.

> *Our guidance: You should liaise with DAFF if intending to export products in order to clarify how these products will be categorised in the importing country and what type of requirements may need to be met before products can be exported.*

5. Food Standards Australia New Zealand (FSANZ)

5.1 Structure of the Code

All food sold in Australia and New Zealand must comply with the Code. Although all food must comply with any relevant provisions in the Code and state/territory food legislation, not all foods require pre-market safety assessment before they may be lawfully sold according to the Code.

Foods that are 'used as a nutritive substance, processing aid or food additive', produced using gene technology, novel foods, cell-cultured foods, or are treated with irradiation require pre-market safety assessment and approval under the Code. Many common ingredients in foods (such as fruits, vegetables) are not subject to pre-market safety assessment in the Code as they are traditionally consumed foods with adequate dietary consumption data in Australia and New Zealand to support supply and sale without explicit permission in the Code.

The Code is broadly structured into four chapters and a series of schedules, including:

- **Chapter 1** contains standards that apply to all foods, including general requirements, offence provisions, labelling and pre-market assessment requirements for certain foods. This includes foods added for a nutritional purpose, enzyme processing aids, food additives, novel foods, cell-cultured foods and genetically modified foods.

- **Chapter 2** contains standards for defined foods, including definitional and compositional requirements (for example, dairy products, meat, eggs and fish) and special purpose foods such as Infant Formula Products.

- **Chapter 3** contains food safety standards that set out requirements for food safety practices associated with food handling and processing activities and food premises requirements. Of particular relevance to the cellular agriculture sector, Chapter 3 now includes Standard 3.4.1 which sets out specific food safety requirements for the processing of cell-cultured food. It is worth noting that Chapter 3 applies only in Australia.

- **Chapter 4** contains primary production standards for sectors including: poultry meat, seafood, meat, dairy products, eggs and egg products, seed sprouts, berries, leafy vegetables, melons, and wine production.

The **schedules** contain detailed listings including:

- permitted genetically modified food (Schedule 26),
- permitted novel foods (Schedule 25),
- permitted cell-cultured foods (Schedule 25A),
- permitted food additives (Schedule 15), allergen listings, microbiological limits and labelling requirements.

When referencing clauses and standards in the Code, the following nomenclature is commonly used. For example, Clause 3(a) of Standard 1.5.2 is written as section 1.5.2-3(a), and Clause 3(1) of Schedule 26 is written as section S26-3(1).

Standards relevant to the cellular agriculture sector:

Of particular interest to the cellular agriculture sector, in the context of obtaining approval to sell food products in Australia and New Zealand, are standards relating to:

- Cell-cultured foods (**Standard 1.5.4 and Schedule 25A**),
- Genetically modified food (**Standard 1.5.2 and Schedule 26**, which is relevant for precision fermentation products using GM organisms), and
- Novel foods (**Standard 1.5.1 and Schedule 25**, for other novel ingredients).

Section 1.1.1-10 of the Code provides that food for sale cannot be, or contain, cell-cultured foods, novel foods, or genetically modified food unless expressly permitted by the Code.

5.2 Guidance on the assessment of foods produced using cell cultivation and precision fermentation technology

On 25 November 2022, the Food Ministers' Meeting agreed that foods produced by cell-culturing (cultivation) processes or precision fermentation would require pre-market safety assessment. At that time, this occurred under Standard 1.5.1 (Novel foods) or Standard 1.5.2 (Genetically modified food), depending on the nature of the product.

Following the successful assessment of the first cell-cultivated food application (A1269 - cell-cultured quail from Vow), FSANZ established a dedicated regulatory framework in June 2025. This included the gazettal of Standard 1.5.4 (Cell-cultured foods), Schedule 25A (Permitted cell-cultured foods), and Standard 3.4.1 (Food safety requirements for processing of cell-cultured food). This dedicated framework reflects the unique characteristics of cell-cultured food production and provides clearer guidance for companies seeking to bring these products to market.

Cell-cultured foods

Foods produced using cell cultivation (commonly referred to as cultivated meat or cultivated seafood) are regulated under Standard 1.5.4. The Code defines a cell-cultured food as '*a food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former*.' At the time of writing, this definition does not reflect the current scope of cell-cultivated products in development. For example, it does not reflect the emergence of cultivated coffee or cocoa.

Cell-cultured foods require pre-market approval and must be listed in Schedule 25A before they can be sold. Any corresponding conditions listed in Schedule 25A must also be complied with. It is worth noting that cell-cultured foods cannot be added to foods standardised by Part 2.9 of the Code, which includes infant formula products, foods for infants, meal replacements, formulated supplementary sports foods, and foods for special medical purposes.

Labelling requirements

The Code also includes specific labelling requirements for cell-cultured foods. Foods containing cell-cultured ingredients must use the qualifying terms, 'cell-cultured' or 'cell-cultivated', in conjunction with the ingredient name in the statement of ingredients. Additionally, if a packaged food for retail sale is represented as being from the source animal (whether in words or images), the same ‘cell-cultured’ or ‘cell-cultivated’ statement must appear in the product name. These requirements ensure that consumers can clearly identify products containing cell-cultured ingredients.

Approval precedent

In June 2025, FSANZ approved the first cell-cultured food for sale in Australia and New Zealand: cell-cultured quail produced by Vow Foods (Application A1269). The product is derived from cell line 221523-Fib-Quail, which consists of embryonic fibroblast cells from Coturnix japonica (Japanese quail). It is worth noting that the approval is subject to conditions - the cell-cultured quail itself cannot be sold at retail as a standalone product but may be used as an ingredient in foods for retail sale. This approval represents a significant milestone and provides a useful precedent for other companies considering applications for cell-cultured products.

Precision fermentation

Foods produced using precision fermentation, where microorganisms are genetically modified to produce specific proteins or other ingredients, will generally require pre-market approval under Standard 1.5.2 (Genetically modified food). Food additives and processing aids (such as recombinant enzymes) are approved under Standards 1.3.1 and 1.3.3 respectively.

If the product meets the definition of genetically modified food, pre-market approval will be required, meaning an application to FSANZ and subsequent listing in Schedule 26. The Code defines 'genetically modified food' as a food that is, or is derived from, an organism that contains novel DNA; or a food that contains an ingredient or other component that is, or is derived from, such an

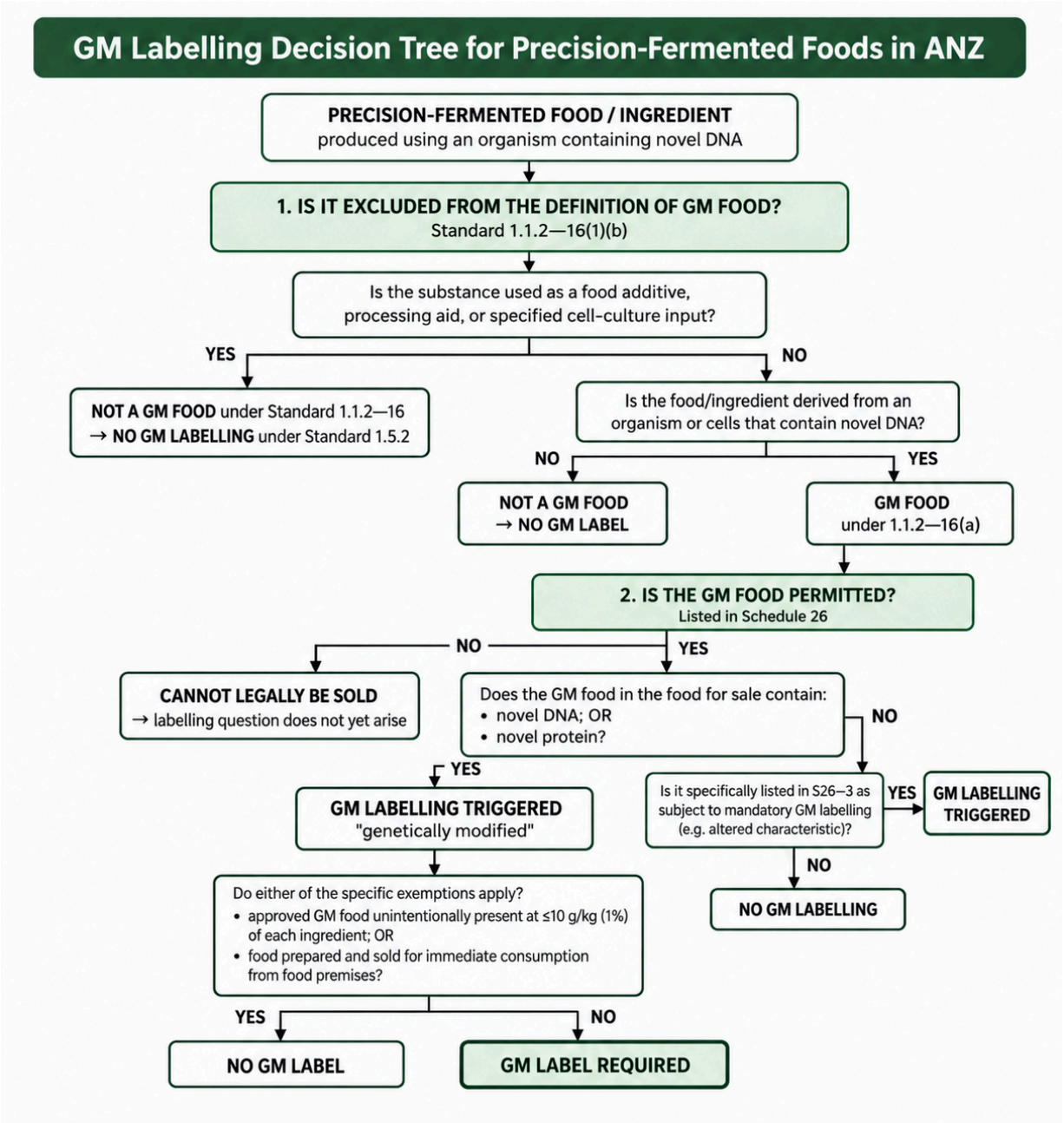
organism. It is important to note that this definition does not include food derived from an animal or other organism which has been fed genetically modified food, unless the animal or other organism itself is genetically modified.

Labelling requirements

Whether a precision-fermented ingredient requires GM labelling depends on what is present in the final food. Under the current Code, the presence of **novel DNA or novel protein** triggers a requirement to label the food as "genetically modified", with a few exceptions.

FSANZ's assessment of Eden Brew's beta-casein protein preparation (BCPP1) helps clarify how this applies to PF ingredients. For **PF-derived proteins**, the recombinant target protein itself is considered a novel protein because it is encoded by novel DNA. This means GM labelling is required even where the GM production organism and residual host-strain DNA or proteins have been removed from the final ingredient. Residual novel DNA or protein from the production strain can also independently trigger the requirement.

By contrast, **PF-derived non-protein ingredients**, such as carbohydrates including human milk oligosaccharides (HMOs), may not require GM labelling where no novel DNA or novel protein remains in the final ingredient. PF-derived processing aids (e.g. chymosin), which have no technological function in the final food, are exempted from GM labelling requirements.



5.3 Food Safety Requirements for Cell-Cultured Food Production

Standard 3.4.1 establishes specific food safety requirements for businesses involved in the production of cell-cultured foods. It is worth noting that this standard applies in Australia only. The standard addresses requirements for both cell line suppliers and cell-culturing food businesses.

Cell line suppliers

For cell line suppliers, the standard requires that cell lines be free of bacteria, fungi, prions, and viruses. The species of cells comprising a cell line must be identified and recorded, and cell lines must be sourced from a donor animal that is free of disease. A traceability system must also be in place that identifies and tracks cells from collection from a donor animal through to supply of a cell line, identifies the donor animal, and identifies to whom a cell line was supplied.

Cell culturing food businesses

For cell culturing food businesses, the standard requires compliance with Standard 3.2.1 (Food safety programs) with additional specific requirements. The food safety program must detail the indicators of a loss of process control in a bioreactor, as well as food handling activities related to cell sourcing, selection and banking; cell proliferation including serial sub-culturing in flasks; seeding and proliferation of cells in a bioreactor; cell differentiation; and cell extraction. The program must also detail how the business will identify when cell proliferation is non-conforming, and how the business will undertake calibration, cleaning and sterilisation of all relevant equipment.

Additionally, any substance used in cell proliferation, cell differentiation, cell extraction, handling of cell biomass, or storage of cell biomass must not make the cell-cultured food unsafe or unsuitable.

Our guidance: Companies planning to establish cell-cultured food production facilities in Australia should engage with state and territory regulators early to understand how these requirements will be implemented and enforced in their jurisdiction.

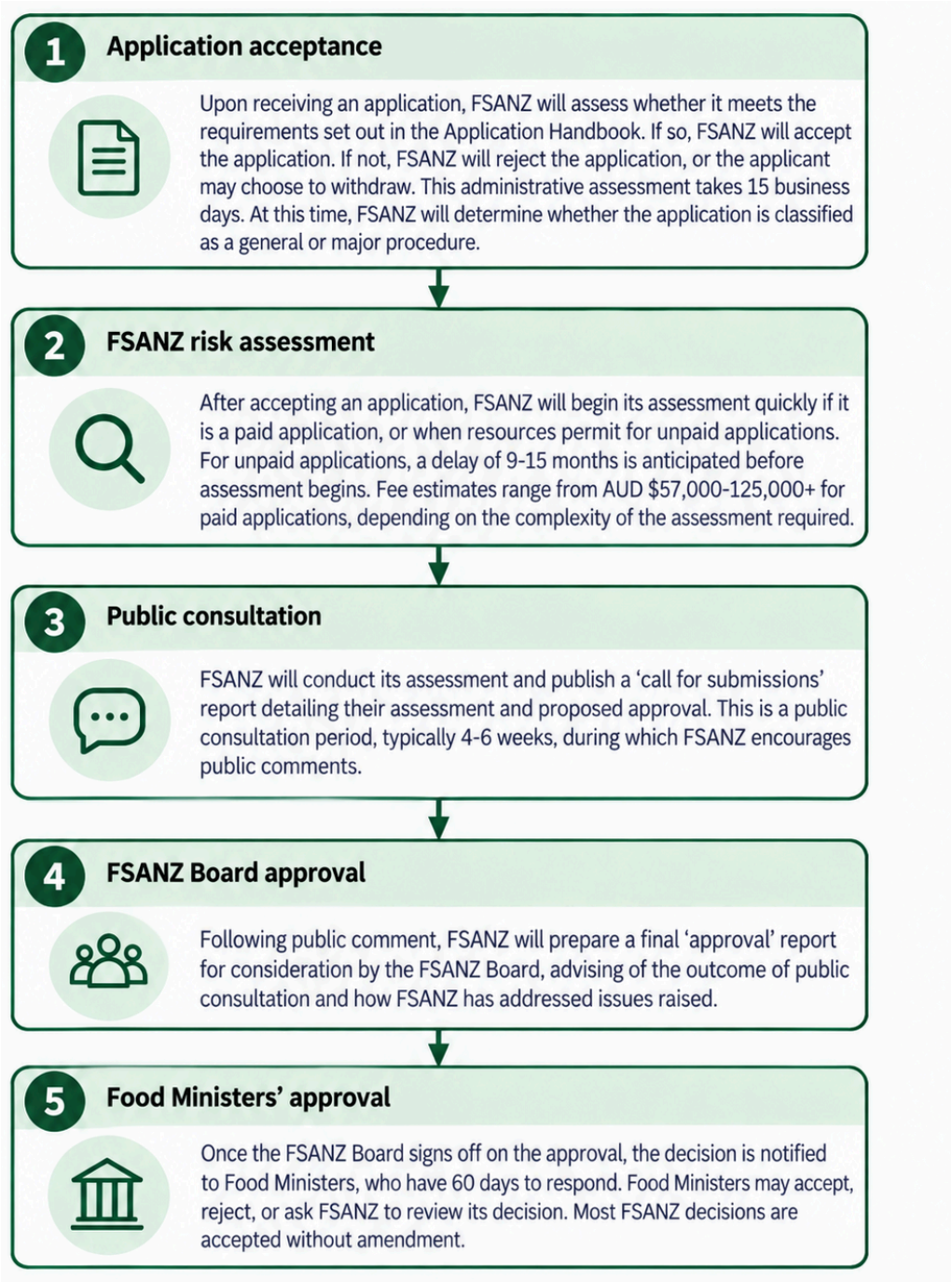
6. Regulatory approval for the sale of foods produced using cell cultivation and precision fermentation technology

To obtain approval to sell cultivated meat and precision-fermented ingredients, companies will need to submit an application to FSANZ, requesting permission in the Code to sell these products. Applications must contain sufficient data to enable FSANZ to assess the safety of these foods. Applications are subject to requirements set out in FSANZ's Application Handbook.

Our guidance: Producers should engage FSANZ at least 2 years before the intended launch of their product to allow adequate time for approval to be granted. Early engagement with FSANZ is strongly encouraged and can help ensure that applications contain all required information, reducing the likelihood of delays.

6.1 Application process

See below for a high-level overview of the FSANZ application process:



6.2 Timeframes

From acceptance of the application to FSANZ Board agreement, the timeline is estimated to be 9 months for a general procedure (one round of public consultation) or 12 months for a major procedure (two rounds of public consultation). Food Ministers have an additional 60 days to respond. If Ministers agree, the Code will be amended approximately two weeks following the decision.

Therefore, the total timeline for a general procedure application is approximately 12 months and for a major procedure, 15 months. It is important to note that additional time may be required if FSANZ needs additional information from the applicant. These 'stop clocks' pause the assessment until

information is received, and can add significantly to the overall timeline if applications are incomplete.

6.3 Key considerations when preparing an application

1. Consult early

It is strongly recommended that you consult with FSANZ early. FSANZ encourages early consultation before submitting an application. Early discussions will provide guidance on what FSANZ expects to see and how it intends to conduct its assessment. This can save significant time and resources in the application process.

2. Submit a draft application

You should consider submitting a draft application for comment. FSANZ will provide written comments on draft applications, including detailed feedback on areas that may require additional information or data. This is a valuable opportunity to identify gaps before formal submission.

3. Understand transparency requirements

It is important to understand the transparency requirements. FSANZ's assessment process is transparent, with most documents made publicly available. You can request that certain information be treated as commercial in confidence if public release would be commercially damaging, though FSANZ will assess such requests carefully.

4. Consider exclusive permission

You may wish to consider exclusive permission. You can request exclusive permission for your brand of food or ingredient for a period of time (generally 15 months). You must pay the assessment fee to obtain exclusive permission, but you will also skip the waiting queue for assessment. This can be particularly valuable for companies seeking a competitive advantage.

5. Ensure data quality

You should ensure data quality. The Handbook includes requirements on the quality of data provided in applications. Section 3.1.1.E includes information on data requirements including expectations for literature searches, safety studies, analytical surveys, and epidemiological or intervention studies. Applications with high-quality, comprehensive data are more likely to proceed smoothly through assessment.

6. Leverage overseas approvals

Finally, you can leverage overseas approvals. Where applicants have sought approvals in other jurisdictions (particularly EFSA or FDA), these dossiers will provide valuable supporting information. While FSANZ does not automatically adopt overseas approvals, they will take them into consideration as part of their assessment.