

FSANZ - 2026-27 Cost Recovery Implementation Statement Submission



INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biologically-based pesticides) and agricultural biotechnology innovations. CropLife's membership includes both large and small, patent holding and generic, Australian and international companies. Accordingly, CropLife only advocates for policy positions that deliver benefits to the whole industry and the nation.

CropLife Australia is also a member of CropLife Asia and part of the CropLife International Federation of 91 national associations globally. Our focus, however, is specifically on the Australian agricultural sector, ensuring it remains internationally competitive through globally leading productivity and sustainability, achieved by accessing world-class technological innovations and products from the plant science sector.

The plant science industry contributes to the nation's agricultural productivity, environmental sustainability and food security through innovations in both plant breeding and pesticides that protect crops against pests, weeds, and disease. More than \$31 billion of the value of Australia's agricultural production is directly attributable to the responsible use of crop biotechnology and crop protection products (CPPs), while the plant science industry also employs thousands of people across the country.¹

OVERALL POSITION

The delivery of timely, efficient and predictable assessment of applications by Food Standards Australia and New Zealand (FSANZ) is essential to delivering the commercial certainty necessary to support an innovative food industry. It creates the confidence for businesses to invest in delivering new food products to the market that contribute to safe, affordable and healthy food choices for Australian

¹ Deloitte Access Economics, 'Economic Contribution of Crop Protection Products in Australia', (August 2023 Report) <https://www.croplife.org.au/resources/reports/economic-contribution-of-crop-protection-products-in-australia/>.

families. Towards this outcome, CropLife supports cost recovery where it is justifiable, appropriate and proportionate to recovering the efficient costs of a specific government activity.

In accordance with this position, CropLife welcomes the decision by FSANZ not to seek an increase to application fees as part of its 2026-27 Cost Recovery Implementation Statement (CRIS). This decision demonstrates the implementation of the principle within the Australian Government's Cost Recovery Policy that *'entities should aim to minimise cost recovery charges'*.²

Likewise, CropLife also supports the decision by FSANZ to consult with stakeholders on preferences regarding the fee structure, payment arrangements and other relevant matters. This feedback should be used to ensure future changes to FSANZ's operations and cost recovery arrangements delivers the statutory objective supporting *'an efficient and internationally competitive food industry ...'*³ Specifically, opportunities to reduce the fee-burden borne by industry through cost recovery should be investigated as part of this consultation.

GENERAL EXPERIENCE AND PRINCIPLES

1. What has been your experience with the current FSANZ cost recovery arrangements and fee structure?

The biotechnology products of the plant science industry are critical to maintaining and improving Australia's agricultural productivity to meet challenges around future food security while improving environmental sustainability. The Australia New Zealand Food Standards Code is the primary instrument regulating genetically modified (GM) food and food ingredients. It determines how members of the plant science industry bring agricultural biotechnology products to the Australian market.

CropLife has a strong history of engagement on FSANZ's cost recovery arrangements. Feedback provided by CropLife through these consultations has

² Department of Finance, 'Australian Government Cost Recovery Policy' (Department of Finance, 21 June 2023) <<https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmq-302/australian-government-cost-recovery-policy>>

³ *Food Standards Australia New Zealand Act (Cth)* s. 18(2)(c).

been influential in FSANZ's adoption of new operational models that have led to greater efficiency in the delivery of the regulatory services it provides.

The standout example of this is FSANZ's shared assessment process (SAP) with Health Canada, which reduces the cost and time of seeking regulatory approval for GM foods in both jurisdictions. The implementation of the efficiency gains provided by the SAP supports Australia's international competitiveness by enabling FSANZ to deliver regulatory outcomes without unnecessarily impeding investment in plant biotechnology.

2. What principles do you believe should guide the design of FSANZ's cost recovery arrangements (e.g., fairness, transparency, predictability, administrative simplicity)?

CropLife supports the general provisions outlined within the Australian Government Charging Framework, the Australian Government Cost Recovery Policy and the Department of Finance's Resource Management Guide 302 – Implementing the Charging Framework.

Specifically, with regard to any future consideration of FSANZ's cost recovery arrangements, CropLife supports the following principles:

- Cost recovery should only be used to recover the efficient cost of a specific recoverable activity.
- Costing of activities must be developed using transparent costing inputs and assumptions.
- Cost recovery should avoid cross-subsidisation between applications.
- Recognition that the policy objectives of food regulation support a range of policy objectives, including the export trade in Australian agricultural commodities and processed food. This should include a clear position on where an application for approval of a GM food has not been made in order to commercialise the trait in Australia, but rather as part of global stewardship efforts that support international trade. Such a position should delineate these applications as not creating an "Exclusive Capturable Commercial Benefit" and therefore not be subject to cost recovery.
- Any increases in fees must not negatively impact the investment necessary to promote an efficient and internationally competitive food

industry. Fees should be benchmarked against contestable service providers and comparable international regulators.

- Any increase in fees should be accompanied by a commensurate increase in productivity.
- Consultation on cost recovery arrangements should be predictable and scheduled.
- Impacted businesses should be provided with sufficient notice of increases in regulatory fees prior to implementation. Best practice would involve releasing CRIS documents at least twelve months prior to implementation.

FEE STRUCTURE PREFERENCES

3. Do you prefer a fee structure that is fixed (predictable) or variable (based on actual work performed)? Please explain your preference.

CropLife conditionally supports the maintenance of a variable fee system as the preferable method of cost recovery. Calculating the cost of application fees on the actual work done supports the efficient recovery of the cost of a specific activity and reduces the risk of cross-subsidisation between applicants.

However, CropLife seeks improvement across the following areas of operation and cost recovery to support industry confidence in the variable fee structure:

- Improved transparency on assessment assumptions and explanation of the time of assessment included within the workplan.
- Greater flexibility to pay in instalments, particularly for General Procedure Level 4 and 5. This includes lowering the initial instalment payment from 75 per cent to 50 per cent.
- Improved ability to reconcile and provide refunds during the assessment period, and not just at its completion. This will assist FSANZ to avoid overcharging and the related complications of large refunds and/or delays in refunds.

4. Are the current procedural levels (i.e. General 1-5, Major, High Level Health Claims) clear and appropriate for your needs?

It is the experience of the plant science industry that administrative assessment applications for assessment of GM foods are routinely categorised as General Procedure Level 5. To ensure the regulatory and fee burden is appropriate to the risk of each application, CropLife encourages FSANZ to investigate options that would enable lower risk GM applications to be systematically classified at a lower General Procedure level.

Towards this outcome, FSANZ should integrate the well understood concept of familiarity into its administrative assessment process. Such an approach would consider whether an application for the assessment of a GM food involves:

- A well-characterised crop species; and
- A trait that has been previously assessed by FSANZ and/or other comparable regulators; and
- No novel toxicological, allergenicity or compositional concerns.

Where this is the case, the scientific uncertainty is materially lower than for a first in class approval and it would be appropriate for FSANZ to apply a proportionate assessment pathway that reflects the reduced complexity and lower risk.

5. Would you support the introduction of new fee categories or changes to the existing categories? If so, what changes would you suggest?

CropLife is not opposed to the consideration of new fee categories or changes to categories, where the changes:

- Are well designed and enhance efficiency of assessment, remove cross subsidisation between categories of assessment and place downward pressure on industry-based cost recovery; and
- Are developed in consultation with impacted stakeholders to ensure proposed design does not have unintended consequences.
- Commence following appropriate transitional arrangements. Options for this include providing an appropriate period of notice to enable Australian divisions of global businesses to appropriately budget for changes; and

the option for an applicant to either grandfather existing applications or opt to transfer an application into any appropriate new category.

- Robust guidance is developed with industry to ensure applicants are provided with a predictable and efficient regulatory system.

Specifically, CropLife recommend FSANZ investigate the opportunity to create a new category of GM Food application where, on the basis of global GM food safety assessments, it is well known that no food safety risks exist. This would enable the application to be included within the Food Standards Code following administrative assessment with the fee only reflecting the flat rate amount prescribed in the regulations. Where administrative assessment does identify particular risks that are not well known, the classification of the assessment should be limited to those identified areas to ensure the assessment effort is commensurate with risk.

PAYMENT ARRANGEMENTS

Questions 6 and 7 are answered together

6. What are your views on the current arrangements for paying fees (e.g. upfront or in 2 instalments for higher-level applications)?

7. Would you prefer more flexible payment options (e.g. more instalments, staged payments, or other mechanisms)?

Payment arrangements should be designed to support the commercial considerations of applicants.

CropLife submissions to previous cost recovery consultations have raised the concern of high upfront payments due to over-estimation of work required. This has also led to situations in which companies have faced lengthy delays to receiving refunds. The introduction of payment by instalment in 2015 provided FSANZ with a tool to better manage the timing of costs incurred by applicants with FSANZ's assessment workflow.

Future amendments to FSANZ's cost recovery could better utilise payment by instalments through:

- Reducing the initial instalment cost for General Procedure Level 4 and 5 to 50 per cent.
- Increasing the number of instalments that can be agreed to between FSANZ and an applicant and aligning instalment payments to the completion of key work stages.

The latter of these suggestions would not only incentivise on-time performance but also create additional stage gates at which fee estimates could be reconciled against work performed. This reconciliation would enable any variance between the estimated and final cost to be managed more smoothly, through adjustments to subsequent instalments (including reducing them where appropriate).

8. Are there any barriers or challenges you have faced with the current payment process?

CropLife has no current views on this question.

TRANSPARENCY AND COMMUNICATION

9. Is the information provided about how fees are calculated and charged sufficient and clear?

CropLife reiterates the need for high levels of transparency for the costing assumptions used in the development of cost recovery implementation statements by FSANZ, and in the estimation of costs for individual assessments. This is consistent with the obligations under the Australian Government Cost Recovery Policy.⁴

CRIS transparency

CropLife supports improving the transparency of the assumptions and cost allocations that underpin FSANZ's calculation of cost recovery arrangements. This includes the assumptions that underpin the activity based costing model used in the calculation of costs to be recovered. Transparency should include which

⁴ Department of Finance, 'Australian Government Cost Recovery Policy' (Department of Finance, 21 June 2023) [26] – [29], <<https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmg-302/australian-government-cost-recovery-policy>>.

overheads have been apportioned to be cost recovered and how they are related to the specific assessment activity.⁵

In line with the Australian Government Cost Recovery Policy, consultation documents should clearly outline how costs that cannot be directly attributable to the assessment process have been excluded from the activity based cost model. This includes costs related to policy development, legislative drafting, developing general advisory material, provision of general advice to government and Parliament and compliance and enforcement.⁶

Other information CropLife believes should be make available to stakeholders during consultation on cost recovery include:

- Efforts to enhance operational efficiency to create efficiency dividends that place downwards pressure on cost recovery.
- Information about efforts to benchmark costs proposed for recovery against alternative means that would achieve policy outcomes, such as the contestable delivery of assessment and improved collaboration with other regulators.
- Sensitivity testing on whether proposed increases in cost recovery will negatively impact investment by the food industry in Australia and impede other policy objectives.

Fee Estimation

Historically, CropLife member companies have had situations in which initial fee estimations resulted in large upfront costs for GM food applications resulting in the accrual of substantial refunds at the completion of assessment. In addition to the disincentive created by the imposition of large fees, lengthy delays in receiving refund create unnecessary costs and increase the complexity of commercialising new GM food crops in the Australian market.

While the introduction of payment by instalment has improved the ability of FSANZ to manage these risks, improved guidance and time estimation tools will further

⁵ Department of Finance, 'Australian Government Cost Recovery Policy' (Department of Finance, 21 June 2023) see paragraphs [89], <<https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmg-302/australian-government-cost-recovery-policy>>

⁶ Ibid, Figure 12.

support FSANZ to deliver the statutory objective of supporting an efficient internationally competitive food industry.

10. What improvements could be made to the communication of fee arrangements and payment processes?

CropLife has no current views on this question

REFUNDS (WITHIN LEGISLATIVE CONSTRAINTS)

Questions 10 and 11 are answered together

11. Have you experienced the refund process? Was it timely and clear?

12. Are there improvements you would suggest to the way refunds are handled (noting that refunds must be paid if actual costs are less than the amount charged)?

As outlined in response to questions 6-7 and 9, CropLife members have reported concerns with the refund process. These concerns include:

- The overestimation of workdays required to complete the assessment meaning unnecessarily high upfront payments.
- Accounting difficulties created by delays in refunds that were returned in different financial years.
- Delays in refunds that resulted in additional real cost of application fees due to the cost of capital.

These issues impact the environment for commercialising GM crops for food use in Australia.

In these earlier responses, CropLife has provided suggestions that would further reduce the accumulation of a large refund. In addition to managing the quantum of refund, FSANZ should publish a service standard that establishes a requirement for refunds to be processed within a month of an assessment being finalised.

FUTURE ARRANGEMENTS AND INNOVATION

13. What ideas do you have for improving the cost recovery arrangements in the future?

CropLife proposes that the following issues are considered in any future consideration of the design of FSANZ's cost recovery arrangements.

- Improved transparency of FSANZ's activity based costing methodology that allows stakeholder to consider how costs have been estimated and apportioned to cost recovered assessment activities. The alignment of identified charges with the Australian Government's Cost Recovery Policy should be explicitly identified in published consultation documents; including in published cost recovery implementation statements.
- Commitment to regular independent business process and efficiency reviews. This will create an ongoing process that benchmarks FSANZ's delivery of its cost recovered regulatory services against alternative options that could be used to achieve policy outcomes. this would support FSANZ in meeting its requirement under the Australian Government's Cost Recovery Policy to enhance its operational efficiency.
- Ensure any increase in cost recovery is subject to a sensitivity analysis that examines the impact of proposed increases on the efficiency and international competitiveness of the Australian food industry.
- Continue to pursue initiatives known to deliver efficiency, such as the SAP with Health Canada. For example, SAP could be expanded to include other comparable regulators.
- Improve cost estimation tools used at the commencement of an application and enhanced use of instalments, project management, fund reconciliation and refund standards to reduce unnecessary regulatory costs associated with applications.
- A commitment to early engagement with stakeholders in the cost recovery process. This includes engagement prior to the development of a CRIS and the issuing of a draft CRIS for consultation at least twelve months prior to planned implementation.

14. How could FSANZ better support applicants through the fee and payment process?

CropLife has no current views on this question.

IMPACT AND EQUITY

15. How do the current fee arrangements impact your organisation or sector?

The Australian market for food innovation, such as GM crops, is comparably small. In recognition of this, it is important that cost recovery design recognises that fees can serve as a barrier to the commercialisation of these innovations. This impacts the investment intentions of both Australian and international developers alike, resulting in products not being brought to the Australian market or Australian innovations being commercialised offshore before in Australia.

As such, it is imperative that the design of cost recovery and magnitude of fees is set at levels that provides FSANZ with the resources that enable it, when operating efficiently, to deliver timely approval of applications.

16. Are there particular groups or types of applicants who are disproportionately affected by the current arrangements? How could this be addressed?

Exclusively Captured Commercial Benefit

Generally, CropLife members seek pre-market approvals for GM foods and food ingredients. This reflects global plant science industry stewardship commitments to secure approvals in all major trading markets to minimise the risk of low-level presence (LLP) incidents involving unapproved GM products. The decision to seek food approval in markets where cultivation approval (i.e. regulatory permission to grow the GM plant) is not also sought, imposes additional costs on CropLife members in the delivery of their commitment to best-practice stewardship.

Most applications for GM food approvals submitted to FSANZ by CropLife member companies do not confer financial gain (or a 'capturable economic benefit') directly on the Australian incorporated applicant. Any financial gain from these

applications is derived indirectly by the Australian government and agricultural exporters through the facilitation of trade and avoidance of any incidents involving the LLP of an unapproved genetically modified organism (GMO). Any LLP incident would generate significant compliance activity by FSANZ that would not be cost recoverable.

Raising costs beyond that which is appropriate and proportionate to recovering the efficient costs of the agency for this class of applications, may result in applicants choosing not to lodge submissions in Australia; increasing the possibility of an LLP incident occurring.

Therefore, there is a risk that higher fees may act as a deterrent to the trade in foods containing genetically modified commodities more broadly, which would conflict with the Australian Government's broader trade policy objectives. FSANZ is not well placed to assess the consistency of their proposed cost recovery arrangements with the Government's wider policy objectives in trade and agriculture. As such this may require input from other agencies including the Department of Foreign Affairs and Trade and the Department of Agriculture, Fisheries and Forestry (DAFF).

CropLife members have indicated that to date, they have not been given a choice by FSANZ as to whether their application is classed as ECCB or otherwise. CropLife suggests that FSANZ may have been incorrectly classifying some (but not all) applications from CropLife members as ECCB applications. This is because of the presumption that an application from a company creates an ECCB, when in fact the relevant provision of s146(6)(a) of the *Food Standards Australia New Zealand Act 1991* should not have applied.

CropLife **recommends** that as part of a review of its cost recovery arrangement, FSANZ make a policy determination guided by appropriate legal advice from the Office of the Australian Government Solicitor regarding the application of ECCB in instances where a benefit is not being derived by an Australian incorporated applicant.

OTHER COMMENTS

17. Do you have any other comments that you would like to make?

CropLife welcomes the initiative from FSANZ to undertake this broader consultation on its cost recovery arrangements. To ensure the benefits of this consultation support the future of Australia's food industry, it will be important that any insights gathered and their potential implications for the design of its cost recovery arrangements become subject to iterative stakeholder engagement. This will allow identified policy options to be tested and developed with industry to ensure FSANZ's regulatory stewardship contributes to Australia's ongoing productivity.