CropLife Australia

February 2026

Proposed Amendments to the Gene Technology Regulations 2001 Submission

1 SUMMARY

This submission addresses the proposed Amendments to the Gene Technology Regulations with a focus on the overall regulatory architecture, coherence and long-term operability of the National Gene Technology Scheme ('the Scheme'). While CropLife supports the objective of modernising and streamlining the Scheme toward a risk-proportionate framework, the following issues are highlighted:

- **Prolonged reform and regulatory finality:** After more than eight years of review activity and multiple consultations, continued deferral of substantive policy decisions to future instruments risks undermining confidence that the reform will deliver a stable and predictable regulatory endpoint needed for investment into Australian innovation.
- **Undefined regulatory triggers:** Continued reliance on undefined or discretionary concepts—particularly 'novelty', designation and regulatory familiarity—creates uncertainty across consultation triggers, licensing pathways and assessment thresholds, increasing the risk of inconsistent interpretation and regulatory creep. Measurable, technology-neutral triggers should be adopted that provide certainty across licensing and assessment pathways.
- **Codify clear exclusions for genome editing outcomes:** Explicitly exclude organisms that do not contain novel DNA and that could arise through conventional breeding, ensuring low-risk outcomes are not subject to unnecessary regulatory capture.
- **Harmonise regulatory triggers with the Food Standards Code:** The absence of alignment with established Australian frameworks, most notably the Food Standards Code definition of 'novel DNA', represents a missed opportunity to promote regulatory harmony and reduce duplication across Commonwealth schemes.
- **Genome editing policy gaps:** Despite its prominence in the Third Review, genome editing has not been addressed through a coherent, explicit policy framework. Indirect regulatory treatment via the GMO Register, designated dealings and novelty concepts risk capturing low-risk organisms without a clear risk-based rationale.
- **Complexity of regulatory pathways:** The proliferation of notifiable, non-notifiable, licensed and permit-based pathways, combined with containment-based descriptors, risks increasing complexity for routine, low-risk activities such as germplasm importation for breeding, without commensurate regulatory benefit.
- **Retained discretion and scope expansion:** Broad discretion to reconsider risks already assessed by other specialist regulators undermines predictability and risks

duplicative assessment, inconsistent expectations and gradual expansion of regulatory scope over time.

Taken together, these issues point to the need for greater precision, codification and coherence in the design of the Regulations. CropLife's responses seek to identify practical opportunities to strengthen regulatory clarity, improve alignment with the intent of the Third Review, and support a Gene Technology Scheme that is transparent, administrable and fit for purpose over the long term.

INTRODUCTION

The responses set out below are provided in recognition that many of the most consequential issues raised by the proposed Gene Technology Amendment Regulations Consultation Paper (the Consultation) are structural and cross-cutting in nature. As such, they cannot be adequately addressed by responding to individual consultation questions in isolation. While the Consultation poses 11 discrete questions, several foundational matters cut across multiple questions and, in some cases, are not squarely captured by the questions as framed.

CropLife members have a longstanding and demonstrable commitment to the safe, responsible and transparent development and use of biotechnology. This includes robust stewardship systems that operate across research, development, commercialisation and post-market phases. That commitment underpins CropLife's engagement with the Scheme and informs the positions set out below, which are directed toward ensuring that regulatory settings support both effective risk management and the practical delivery of stewardship in the field.

There remains an expectation among proponents that the amended Scheme will deliver a stable, predictable and enduring regulatory framework. However, after more than eight years of review, multiple rounds of consultation, and successive implementation phases, CropLife considers that the prolonged and fragmented nature of the reform process has itself become a substantive regulatory issue.

In the absence of certainty, the regulatory ambiguity present in Australia, especially in comparison to other key trade competitors, has constrained commercial investment in gene technology. This has adversely impacted investment decisions, particularly for long-lead research, breeding and commercialisation programs that require confidence in regulatory settings over multiple years. Continued deferral of key policy decisions to future instruments, rules or guidance exacerbates this effect, undermining confidence that regulatory reform will reach a clear endpoint even after the passage of amending

legislation. The perpetuation of this uncertainty creates knock-on impacts for productivity, innovation uptake and Australia's agricultural competitiveness.

CropLife emphasises that trade and market access considerations are a core and unavoidable requirement for businesses operating in agricultural biotechnology. Decisions relating to research investment, breeding strategy and commercial deployment are inherently global in nature and cannot be made in isolation from international markets.

At the same time, CropLife recognises that trade considerations do not fall within the statutory remit of the *Gene Technology Act 2000*. As such, any issues herein are therefore raised not as regulatory objectives, but to illustrate the practical and foreseeable consequences of regulatory uncertainty for investment, innovation and the competitiveness of Australian agriculture.

CropLife members operate within well-established product launch stewardship frameworks that govern the responsible development, introduction, and lifecycle management of biotechnology-derived products. These frameworks include participation in:

- Excellence Through Stewardship (ETS),[1] a globally recognised stewardship certification program.
- the Plant Breeding Innovation Management Program,[2] a global management platform for plant products created through advanced breeding techniques, such as genome editing in agriculture.
- Stewardship First,[3] CropLife Australia's industry-led initiative promoting best-practice product management and compliance.

Stewardship obligations extend beyond satisfaction of statutory approval requirements. They incorporate risk management practices, product performance monitoring, identity preservation systems, coexistence measures, and supply chain controls designed to ensure that biotechnology products are introduced consistently with regulatory determinations and market expectations. In this respect, stewardship frameworks function as a critical complement to formal regulatory oversight.

[1] Global Stewardship Group, Excellence Through Stewardship Program Overview (Website, accessed February 2026)) https://www.gsg.ag/ets.

[2] Global Stewardship Group, Plant Breeding Innovation Management Program (Website, accessed February 2026)) https://www.gsg.ag/pbimp.

[3] CropLife Australia, Stewardship First Initiative (Website, accessed February 2026) https://stewardshipfirst.com.au.

The effectiveness of stewardship systems is intrinsically linked to regulatory clarity and predictability. Clear classification triggers, stable regulatory pathways, and transparent data expectations enable stewardship measures to be appropriately calibrated to product characteristics and risk profiles. Conversely, regulatory ambiguity or evolving interpretive approaches may introduce stewardship burdens that are disproportionate to the risks posed by the organism or trait.

Recognition of the interaction between regulatory assessment and stewardship systems would strengthen the Scheme's practical operability. A risk-proportionate and predictable regulatory framework supports not only efficient regulatory decision-making but also the recognition of stewardship controls that underpin safe and responsible product launch.

A recurring theme across CropLife's responses to the questions posed in the consultation paper is the absence of sufficiently clear and operational definitions to support risk-proportionate regulation in practice. Concepts such as 'novelty', 'designation' and regulatory familiarity play a critical role in determining consultation triggers, licensing pathways and assessment thresholds. Where these concepts remain undefined or are applied indirectly through discretionary mechanisms, their use creates uncertainty that has implications well beyond any single regulatory pathway. These issues are therefore addressed across several questions, even where they are not explicitly called out in the Consultation.

Similarly, the regulatory treatment of gene-edited organisms represents a core policy challenge that intersects with multiple aspects of the proposed framework, including exemptions, non-notifiable and notifiable dealings, licensing scope, the use of the GMO Register, and the exercise of regulatory discretion. While gene editing was identified as a key emerging technology in the Third Review, the absence of a coherent and explicit policy framework for its treatment during implementation has created uncertainty that cannot be resolved solely through pathway-specific questions.

CropLife also notes that the increasing reliance on discretion raises broader concerns about regulatory creep, duplication and predictability. These issues relate not only to specific provisions, but to the overall architecture of the Scheme and its interaction with other specialist regulators.

A recurring justification for retaining broad regulatory capture is the possibility of unknown risks. However, it is important to distinguish between hypothetical uncertainty and scientifically plausible risk. For many gene-edited organisms, particularly those containing genetic changes indistinguishable from conventional breeding outcomes, there is no credible evidence of novel hazard pathways arising solely from the technique used. In these

circumstances, the concept of residual risk should not be invoked in a manner that results in automatic regulatory escalation.

Where a genome-edited organism contains genetic changes equivalent to those arising through conventional breeding or natural mutation, there is no scientifically plausible basis to presume the existence of residual risk solely by virtue of the technique used. In these circumstances, regulatory escalation should require identification of a credible novel hazard pathway.

International regulatory practice increasingly recognises that risk should be assessed in relation to the characteristics of the organism and the nature of the genetic change, rather than the breeding method employed. Where an outcome is comparable to variations routinely generated through conventional breeding or natural processes, regulatory treatment should reflect the absence of additional risk. Applying regulatory controls that are not risk-commensurate undermines both scientific credibility and the efficiency objectives of the Scheme.

A risk-proportionate approach does not imply the absence of oversight. Rather, it ensures that regulatory scrutiny is directed toward organisms exhibiting genuinely novel risk profiles. Maintaining this distinction is critical to preserving regulator resources, supporting innovation, and avoiding the creation of de facto barriers for technologies that do not introduce new risk.

Accordingly, the responses below are framed to address both the specific questions posed and the broader regulatory design issues that underpin them. Where relevant, CropLife has sought to highlight interactions between provisions and identify areas where further clarity or codification would materially improve outcomes. Additionally, this submission suggests approaches that would better align the Regulations with the intent of the Third Review, established regulatory practice in Australia, and comparable international frameworks.

These comments are provided in a constructive spirit, with the objective of supporting the development of a gene technology regulatory framework that is risk-proportionate, transparent and administrable in practice, while providing the regulatory certainty necessary to support long-term investment, innovation and market access.

Regulatory clarity, proportionality, and finality are not merely administrative preferences; they are enabling conditions for agricultural productivity, innovation uptake, and investment certainty.

CONSULTATION QUESTIONS

Question 1 – Do you have any comments or concerns with regards to the proposed changes to the structure of the Regulations generally?

Recommendation: Embed key policy settings and existing exemptions, harmonised with other regulatory frameworks, directly in the Regulations to provide regulatory finality and protect existing low-risk activities.

CropLife supports the objective of modernising and streamlining the Scheme towards a risk-proportionate regulatory system. However, we are now over eight and a half years, nine public consultations, and numerous missed deadlines, into this process.[4] Despite this, significant details, to be included in subordinate legislation, relating to risk-tiering triggers remains to be articulated. This means that the flexibility afforded by these instruments has become a two-edged sword. After almost nine years, there remains no clear commitment that the amended framework will not expand regulatory obligations for product types that are currently regulated under streamlined or exempt pathways.

Therefore, while initially positive, CropLife is concerned that the proposed structure of the Regulations defers too many substantive policy decisions to future instruments, creating ongoing uncertainty and undermining regulatory finality even after extensive consultation. Codifying existing exemptions into legislation would have aided in providing assurances after all this time.

In response to specific questions on the operation of the GMO Register, CropLife was provided with additional operational information not reflected in the consultation materials. The absence of such detail from formal documentation limits the ability of participants to provide fully informed feedback, therefore impeding the ability of the Department to test the regulatory proposals they have developed. This underscores the need for greater transparency regarding proposed regulatory mechanics.

[4] Commonwealth of Australia, 'National Gene Technology Scheme reviews and consultations' (Website, Accessed February 2026) <https://www.genetechnology.gov.au/reviews-and-consultations>

Question 2 – Do you consider that any other terms are unclear and require definition?

Recommendation: Harmonise the Gene Technology Scheme with the Food Standards Code by incorporating a clear, objective definition of 'novel', drawing directly on the recently approved definition of 'novel DNA'.

CropLife Australia raised several concerns in its submission to the draft Bill consultation regarding the absence or ambiguous nature of key definitions.[5] The Consultation has done little to alleviate these concerns.

In particular, the continued absence of a clear and operational definition of 'novel' remains a significant issue. While the Consultation proposes a formulation for 'novel dealing', this does not resolve the underlying ambiguity where the concept of novelty itself is undefined. As a result, application of the term is left to discretionary interpretation, with direct consequences for consultation triggers, licensing pathways and assessment timeframes. This issue is compounded by the protracted regulatory review, particularly as the concept of 'novel', either expressly such as in Canada,[6] or by way of precisely articulated regulatory triggers, such as in Brazil,[7] is now used in the regulation of new breeding techniques.

In addition to international developments, the Australian and New Zealand Food Standards Code has adopted a clear and objective definition of 'novel DNA'. That definition provides certainty to regulators and proponents alike by focusing on the origin and nature of inserted genetic material, rather than relying on subjective assessments of novelty. This definition is also closely aligned with the Canadian 'foreign DNA' definition.[8]

For clarity, novel DNA is now defined in the Food Standards Code as DNA that:

> *(a) a person has inserted into the genome of an organism, cell or cells; and*
> *(b) is:*
> > *(i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or*
> > *(ii) from a species that has previously been crossed or hybridised with the species of the organism, cell or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or*

[5] CropLife Australia, Response to the Proposed amendments to the Gene Technology Act 2000, (Response, November 2024) <https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/consultation/view_respondent?uuId=871681515>

[6] Food and Drug Regulations, CRC, c 870, div 28.

[7] Comissão Técnica Nacional de Biossegurança (CTNBio), Resolução Normativa No 16/2018 (Brazil).

[8] Health Canada, Guidelines for the Safety Assessment of Novel Foods (Webpage, accessed February 2026) https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-2006.html.

(iii) not from an existing species [9]

This definition was approved, submitted to the Food Ministers' Meeting, and subsequently incorporated into the Food Standards Code.[10] While FSANZ is a separate regulatory body, it should be acknowledged there is significant overlap in ministerial membership across food and gene technology portfolios.

In CropLife's view, the absence of comparable definitional alignment represents a missed opportunity to promote regulatory harmony across Commonwealth frameworks. Given the extensive scientific analysis and public consultation already undertaken by FSANZ across Australia and New Zealand, duplicating this discussion within the Scheme risks unnecessary divergence, regulatory inefficiency and ongoing uncertainty for both regulators and proponents.

CropLife therefore considers that adopting a clear, objective and outcome-based definition of 'novel' within the Gene Technology Regulations, in a way that aligns closely with the approach already embedded in the Food Standards Code, would materially improve regulatory certainty and reduce discretionary interpretation. This would support a more proportionate and harmonised regulatory framework. Moreover, such an approach is noted in the Final Report of the Third Review:

> ***Recommendation 4:*** *The Review recommends updating, where required, the existing definitions in the Gene Technology Act 2000 (Cth), to clarify the scope of regulation in light of ongoing technical advances. Any changes to definitions should take into account concurrent work, including relevant domestic reviews and ongoing work internationally.* [11]

CropLife acknowledges the position articulated by the Gene Technology Regulator during the Consultation information session that the intention of novel is to reduce the regulatory burden on thoroughly examined dealings.[12] However, this does not preclude defining 'novel' if this is indeed the case. An alternative approach, which ensures alignment with the growing regulatory consensus, is to replace 'novel' as a regulatory trigger with the concept of 'familiarity'. CropLife considers that the term 'novel' should not be used when describing regulatory familiarity, as it conflates two separate concepts: novelty (a characteristic of

[9] Australia New Zealand Food Standards Code (Cth), Standard 1.1.2 – Definitions, s 1.1.2–17.

[10] Food Standards Australia New Zealand, Proposal P1055 – Definitions for gene technology and new breeding techniques (Website, 2 September 2025), 'https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques'.

[11] Department of Health (Cth), Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) [Recommendation 4 p9].

[12] Department of Health, Disability and Ageing, 'National Gene Technology Scheme – Proposed amendments to the Gene Technology Regulations – Information Session' (Webinar, 06 February 2026).

genetic composition) and familiarity (a reflection of prior risk assessment and regulatory experience).

Such a definition would reflect regulatory experience and history of safe use, to achieve the streamlining of objectives without importing unintended regulatory meanings associated with novelty. We propose that 'unfamiliar dealing', covered by sections 49(1)(b)(i) or (ii) of the draft Bill, should be defined as:

> a GMO derived from a parent organism that is unfamiliar; or
> a GMO that displays an unfamiliar trait or traits that occurs because of gene technology.

Familiarity should be determined, on a case-by-case basis, having regard to objective evidence, including:

- Prior OGTR Risk Assessments and Risk Management Plans (RARMPs) relevant to the organism, trait, or comparable genetic modification.
- Established knowledge of the host organism and introduced genetic material.
- The existence of an OGTR biology document relevant to the organism or trait.

We disagree that there is a substantive reason why the FSANZ 'novel DNA' could not be introduced into the Scheme.

Question 3 - Are you satisfied with the proposal of certain risks being excluded from the requirement of ministerial and Regulator consideration if they are already considered under another scheme?

Recommendation: Constrain discretion so that risks already assessed under other Commonwealth schemes are not re-opened under the National Gene Technology Scheme except in clearly defined circumstances.

CropLife Australia supports the policy intent of reducing regulatory overlap by excluding risks that are already assessed and managed under other Commonwealth regulatory schemes. A clear allocation of risk assessment responsibilities between regulators is essential to achieving a proportionate, efficient and predictable regulatory framework.

However, CropLife has concerns that the proposed operation of section 15A of the draft Bill and corresponding amendments to the Regulations do not provide sufficient certainty that duplication will, in practice, be avoided. While the provisions are framed as excluding certain risks from consideration where they are addressed under another scheme, this

exclusion is qualified by language indicating that it is not intended to preclude the Regulator or Minister from considering those risks where they consider it necessary or appropriate.[13]

This qualification effectively preserves broad discretion for the Regulator and Minister to reconsider risks that are otherwise allocated to specialist regulators. As drafted, it is unclear in what circumstances such discretion would be exercised, what evidentiary threshold would apply, or how proponents can have confidence that risks already assessed under other statutory frameworks will not be re-opened during gene technology assessments.

The retention of such unconstrained discretion creates a material risk of regulatory creep over time, including the gradual expansion of matters considered by the Regulator beyond those contemplated by the primary risk allocation framework. This may result in inconsistent data requirements, extended assessment timeframes and variable expectations between applications, undermining predictability for proponents and increasing compliance burden without a corresponding risk-based justification.

In particular, the proposed framework appears to permit reconsideration of matters such as food safety risks already assessed by FSANZ, human therapeutic risks assessed by the Therapeutic Goods Administration (TGA), or chemical use risks assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA). This is difficult to reconcile with the stated objective of minimising regulatory overlap and duplication, and risks duplicating extensive assessments undertaken by specialist regulators with established expertise.

CropLife considers that greater clarity and constraint are required to ensure that exclusions of risk domains are effective in practice, rather than merely indicative. Without clear limits, the proposed approach risks undermining confidence in the stability, proportionality and predictability of the Scheme.

Although this may sit outside the immediate scope of the Regulations, detailed guidance on data requirements for each licence type would greatly assist applicants. This is particularly important for products involving pesticidal substances or traits expressed in plants (including plant-incorporated protectants), where regulatory triggers and evidentiary expectations may span multiple frameworks. Ideally, harmonised guidance developed jointly with the APVMA, FSANZ, TGA and Biosecurity Australia would improve predictability by clearly articulating regulatory pathways and associated data requirements across current and emerging gene technologies.

[13] Department of Health and Aged Care (Cth), Consultation Paper: Proposed Amendments to the Gene Technology Regulations 2001 (Consultation Paper, January 2026) p 11.

Question 4 – Do you consider concept of designated dealing clear?

CropLife considers that the clarity and utility of the concept of 'designated dealing' is dependent on resolving underlying definitional and structural issues within the Scheme. As currently framed, designation relies on concepts such as novelty and regulatory classification that are themselves undefined or discretionary, creating uncertainty as to when and why a dealing would be designated.

In practice, the designated dealing concept appears to function as a gatekeeper mechanism that determines regulatory pathway, escalation and oversight. However, the Consultation does not clearly articulate the criteria, thresholds or decision points that would trigger designation, nor how proponents can assess designation risk upfront. This creates the potential for circular reasoning, where a dealing is treated as novel because it is designated, rather than being designated on the basis of clearly defined characteristics.

Our concerns have been articulated in greater detail elsewhere, but these concerns are particularly acute for genome-edited organisms, where the absence of objective triggers may result in inconsistent or unintended classification outcomes. This includes the escalation of low-risk dealings into licensing or permit pathways without a clear risk-based rationale. Greater precision in upstream definitions, along with clearer criteria for designation, would materially improve predictability, transparency and the practical operation of the designated dealing framework.

Question 5 – Do you have any concerns with the proposed consultation process for RARMPs?

CropLife recognises the importance of consultation in the development of Risk Assessment and Risk Management Plans. However, the effectiveness of consultation is closely linked to the clarity and stability of the underlying regulatory framework. Prolonged reform and repeated consultation on overlapping issues risk contributing to stakeholder fatigue and diminishing the value of engagement. Clearer regulatory architecture and earlier resolution of foundational policy questions would support more focused and meaningful participation in RARMP consultation processes.

Question 6 – Do you have any concerns with revised timeframes?

Recommendation: The proposed 12-month delay in the commencement of reforms following the promulgation of an amendment should be removed to avoid prolonged regulatory uncertainty for proponents. If it is to be retained it must be clearly justified.

CropLife has ongoing concerns regarding the proposed timeframes, particularly the 12-month commencement delay following passage of amending legislation. In the context of an extended reform process and the agreed five-year review cycle,[14] such a delay represents a significant period of regulatory uncertainty for proponents planning research, breeding and commercialisation activities.

One of the substantive reasons other stakeholders have provided in support of the 12-month delay has been a lack of certainty over how the new scheme would operate following the introduction of risk tiering reforms. This uncertainty was at least in part a result of the Department's failure to adequately describe its intentions to transitioning current exemptions gazetted in the regulations into the new system. The ongoing delays in modernising and streamlining the scheme now extend more than eight and a half years since the review commenced. As such it is incumbent upon the Department to ensure that the scheme commences as soon as practicable following legislative amendment to meet any semblance of regulatory stewardship.

If a delay between promulgation and commencement is required, greater clarity on the rationale, scope and practical impact of the commencement delay should be provided. This should include assurances that proponents will not face extended periods of regulatory limbo or duplicative transitional requirements.

Question 7 – Do you have any concerns around the proposed range of dealings that will be required to be licenced?

Recommendation: Limit licensing to dealings that introduce genuinely new risk pathways and avoid indirect capture of low-risk genome-edited organisms.

CropLife is concerned that the proposed range of dealings requiring a licence may expand unintentionally due to undefined regulatory triggers and the indirect treatment of genome-edited organisms. In particular, reliance on concepts such as novelty and the proposed use of the GMO Register may result in the capture of organisms that do not present new or increased risk pathways.

The Scheme is set to maintain largely process-based triggers for regulation due to the Third Review's Recommendation 8.[15] However, the process classification that employs site-

[14] Gene Technology Agreement (Intergovernmental Agreement between the Commonwealth of Australia and the States and Territories, signed 3 July 2001) ('Gene Technology Agreement') cl 44.

[15] Department of Health (Cth), Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) [Recommendation 8, p10].

directed nuclease (SDN) terminology, as used in the Scheme, is a technical classification and not ideal for regulatory differentiation, especially in a risk-tiered system.[16] SDN-1, SDN-2 and SDN-3 do not necessarily correlate with the risk profile or characteristics of the final organism.[17]

In contrast, regulatory reform internationally has increasingly shifted toward outcome-based approaches that focus on the properties and safety of the resulting organism rather than the technique used.

Genome editing was identified as a key emerging technology throughout the Third Review and featured prominently in the Final Report.[18] However, despite this emphasis, the regulation of organisms developed using genome editing has not been substantively addressed through a dedicated and coherent policy framework during implementation.

The Department previously indicated separate consultation would be undertaken in relation to genome editing.[19] If truly needed, any such consultation should have been undertaken in the initial stages of implementation. The value of a separate consultation on genome editing is also diminished if core legislative and regulatory architecture is finalised in advance of that discussion, particularly when a comprehensive discussion of the science and policy has been undertaken by FSANZ. In the interests of productivity and efficiency, we would suggest incorporation of FSANZ materials, taking a particular note of the robust literature reviews and consultation responses. [20]

CropLife is also concerned that the Consultation does not adequately recognise the scale and operational realities of modern plant breeding. Since the Third Review commenced, genome editing has shifted from a relatively discrete tool used to introduce individual traits into elite germplasm, to a routine and widely deployed technique used to rapidly generate, stack and refine traits across breeding populations.

In contemporary breeding programs, genome editing may be applied iteratively and at scale, including across hundreds or thousands of lines during early-stage selection and trait consolidation. Many of these edits do not result in novel outcomes. Moreover, they are

[16] Osman Mewett et al, 'Reevaluating the Site Directed Nuclease Classification as a Regulatory Trigger for Genome Edited Plant Products' (Nature Biotechnology, In Press).

[17] Ibid.

[18] See, eg, Department of Health (Cth), Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) pp 23-25.

[19] Department of Health and Aged Care (Cth), Consultation Paper: Gene Technology Amendment Bill 2024 (Consultation Paper, September 2024), p69.

[20] Food Standards Australia New Zealand, Approval Report – Proposal P1055:Definitions for gene technology and new breeding techniques (Report, 18 June 2025).

often indistinguishable from those achievable through conventional breeding at the molecular level. Regulatory frameworks that assume genome editing is applied sparingly, or that require individualised regulatory consideration of each edited line, do not reflect current practice and risk imposing disproportionate and un-administrable regulatory burdens.

The proposal to address genome-edited organisms indirectly, through mechanisms such as the GMO Register and undefined concepts of novelty, risks capturing previously unregulated organisms without a clear policy rationale. The Consultation proposes gene edited organisms "with cisgenic modifications, **deletions** and introduction of naturally occurring transfer DNA (T-DNA) sequences from Agrobacterium spp" will be regulated via the GMO register.

CropLife proposes a decision logic for regulatory capture and exemption for genome-edited organisms that is aligned with the recommendations of the Third Review and consistent with previous revisions to the National Gene Technology Scheme. In a previous revision of the regulations, it was noted that:

> [B]*ecause the changes brought about through SDN-1, including off-target effects, are no different to natural mutations, they do not give rise to any different risks to natural mutations. At the commencement of the gene technology regulatory scheme, the list of 'organisms that are not GMOs' in Schedule 1 of the GT Regulations was intended to exclude techniques on the basis that they "give rise to organisms that can occur in nature and as such do not pose a particular biosafety risk to the environment or human health and safety."* [21]

The impact statement also noted:

> *organisms modified using SDN-1 and RNA-delivered RNAi do not warrant regulation for several reasons:*
>
> - *they pose equivalent risks to organisms with natural mutations, and so regulating these organisms would not be commensurate with the risks they pose and*
> - *reliably detecting organisms that might be indistinguishable from naturally occurring mutants or the products of techniques that are not gene technology presents a great challenge for enforcing compliance with the scheme.* [22]

These extracts highlight the logic underpinning the exclusion of SDN-1 organisms from regulation or licensing under the Scheme. It also aligns closely with the logic used by FSANZ in the development and application of the 'novel DNA' definition. However, this logic,

[21] Office of the Gene Technology Regulator, Risk Analysis and Management in the Gene Technology Regulatory Scheme: Decision RIS (ConsultationRIS, Australian Government, July 2021) p9.

[22] Ibid p12.

formally employed by the OGTR, does not appear to be consistently applied in the proposed implementation of the recommendations from the Third Review.

In practical terms, the rationale for excluding SDN-1 outcomes is not merely administrative convenience, it reflects the absence of a credible additional risk pathway. Where a genetic change is equivalent to variation that can arise through natural processes or conventional breeding, the relevant question is not the technique used, but whether the end product exhibits any novel hazard profile. In these circumstances, further regulatory escalation is not risk-commensurate and diverts oversight away from organisms that present genuinely novel risks.

Recommendation: Amend Schedule 1 to exempt organisms that do not contain 'novel DNA', as defined in the Australia New Zealand Food Standards Code.

To align the National Gene Technology Scheme with the recommendations of the Review, CropLife proposes a risk-proportionate science-based pathway for genome-editing (Figure 1). Consistent with the current Scheme architecture, the pathway first turns on whether gene technology was used during development. Organisms are then assessed against the exclusions and exemptions contained within Schedule 1 (organism-level exemptions) and Schedule 2 (dealing-level exemptions). The incorporation of a novel DNA test introduces a product-focused criterion intended to differentiate organisms based on the nature of the genetic outcome rather than the developmental process alone.

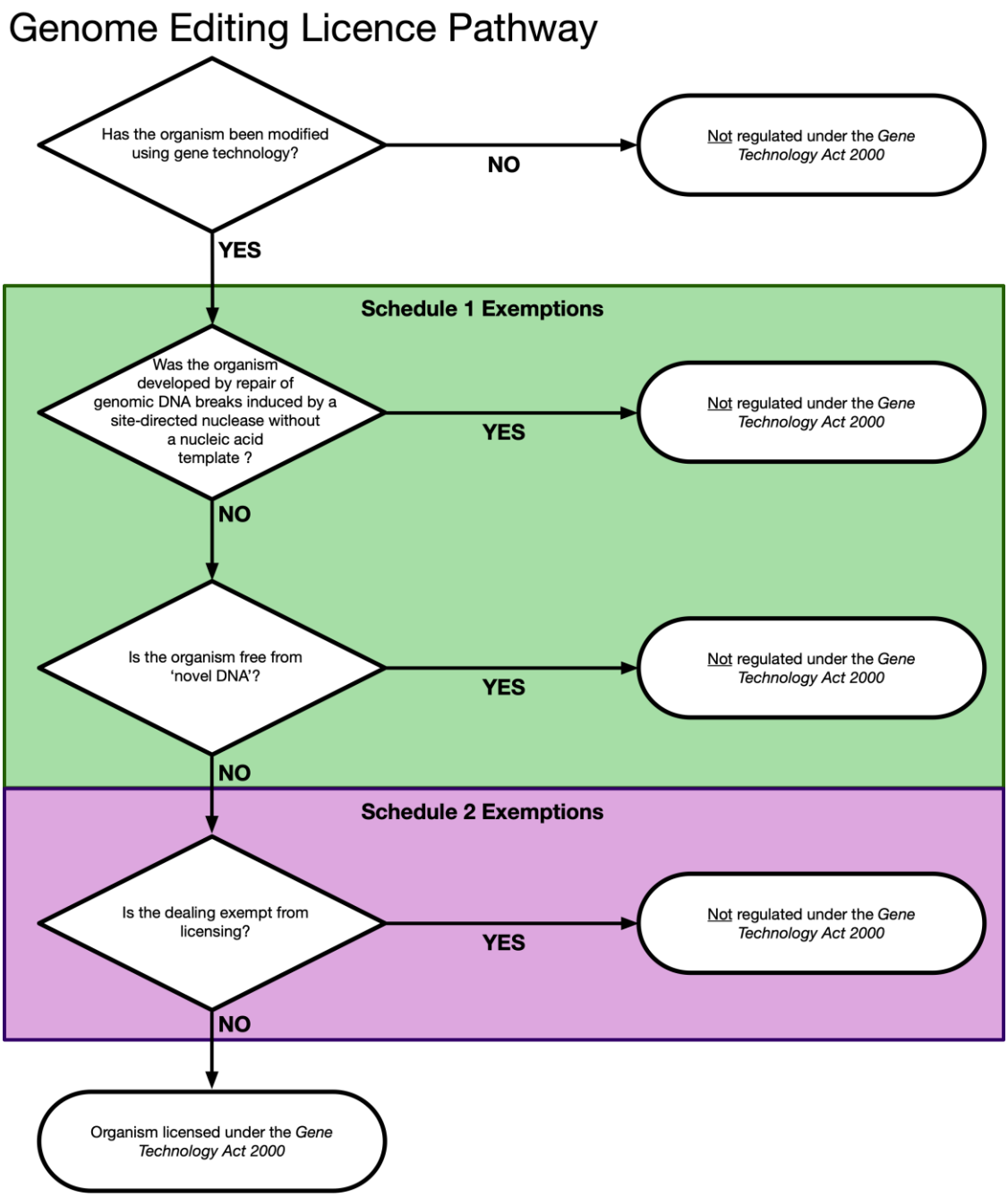

Figure 1 – Proposed Genome Editing Licence Exemption Pathway. Indicative decision pathway for determining the regulatory status of genome-edited organisms. The diagram shows the sequential assessment of (1) modification using gene technology, (2) eligibility for Schedule 1 exemptions, (3) whether the organism contains "novel DNA", and (4) whether the dealing is exempt under Schedule 2. The figure highlights the layered structure of organism-level and dealing-level exemptions within the Gene Technology Act 2000 and associated Regulations.

Question 8 – Do you have any concerns with dealings that are proposed to be authorised by a GMO permit?

Recommendation: Use the GMO Register for downstream management of established GMOs, not as a mechanism to classify genome-edited organisms.

CropLife notes that the GMO permit framework and the GMO Register were designed to support reduced and more predictable oversight for GMOs with established regulatory familiarity. We are concerned that the proposed approach may use these mechanisms as a gateway to regulate gene-edited organisms that have not been demonstrated to warrant classification as GMOs. This risks expanding the regulatory scope and reclassifying organisms previously outside the Scheme. A clearer distinction between classification decisions and downstream regulatory management would better reflect the intent of the Third Review.

The GMO Register serves a specific and important function within the Scheme. It was designed to support reduced and more predictable regulatory oversight, on a case-by-case basis, for GMOs whose risk profiles are well characterised and for which regulatory familiarity has been established. [23]

Its role is therefore cumulative and evidentiary in nature, reflecting prior regulatory assessment and familiarity, rather than serving as a classificatory mechanism for determining whether emerging technologies or organisms should fall within the Scheme in the first instance. In this context, the proposal to utilise the GMO Register as the primary regulatory mechanism for genome-edited organisms raises significant concerns. Genome editing does not represent a class of organisms that has progressed through the Scheme and accrued regulatory familiarity. Rather, it represents a set of techniques that, in many cases, produce organisms that are indistinguishable from those arising through conventional breeding or existing exempt processes.

The proposed approach risks conflating two distinct policy objectives: improving the use of the GMO Register, as suggested by Recommendation 11 of the Third Review [24], and determining the appropriate regulatory treatment of genome-edited organisms. Using the Register to address genome editing appears to be a procedural response to Recommendation 11, rather than a considered implementation of its intent.

[23] Gene Technology Act 2000 (Cth) pt 6 div 3.

[24] Department of Health (Cth), Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) [Recommendation 11, p10].

Moreover, listing genome-edited organisms on the GMO Register risks reclassifying organisms that have previously been outside the Scheme as GMOs, even where no novel genetic material has been introduced and no new risk pathway is created. Although CropLife has received verbal assurances that existing exemptions will remain,[25] their codification is needed to provide regulatory certainty. For example, it was noted that an SDN-1 deletion would remain exempt, as per existing provisions,[26] but deletions, that are otherwise identical, that result from non-SDN-1 genome editing would be regulated via the GMO Register.[27] In addition to the ambiguous nature of any such implementation, it is difficult to understand how such an implementation would be risk proportionate. This would represent an expansion of regulatory scope, rather than the risk-proportionate reduction of regulatory burden articulated by the Third Review as stated in:

> ***Recommendation 20:*** *The Review recommends that the Scheme ensures regulation remains commensurate with the level of risk posed by a dealing (see Recommendations 9 and 10) so that no unnecessary regulatory burdens are imposed.* [28]

A more coherent approach would be to address genome-edited organisms explicitly through clear definitions and exclusions within the Act and Regulations, with the GMO Register reserved for its intended purpose of managing GMOs that have demonstrated a history of safe use and regulatory familiarity over time.

Question 9 – Do you have concerns in relation to the proposed notifiable dealings classes?

Recommendation: Clarify eligibility and transition rules so notifiable dealings provide a simple, reliable pathway for routine low-risk activities.

CropLife considers that notifiable dealings classes present an opportunity to support risk-proportionate regulation, particularly for low-risk activities and organisms. However, the consultation does not clearly address how various existing activities may be treated within these classes. Greater clarity on eligibility and thresholds would help ensure that notifiable dealings operate as an effective and predictable pathway, rather than defaulting to more burdensome regulatory mechanisms.

[25] Department of Health, Disability and Ageing, 'National Gene Technology Scheme: Proposed amendments to the Gene Technology Regulations – Information Session' (Webinar, 06 February 2026).

[26] Gene Technology Regulations 2001 (Cth) sch 1B.

[27] Department of Health, Disability and Ageing, 'National Gene Technology Scheme: Proposed amendments to the Gene Technology Regulations – Information Session' (Webinar, 06 February 2026).

[28] Department of Health (Cth), Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) [Recommendation 20, p 11].

In particular, the importation of genetically modified germplasm, and, in future, gene-edited germplasm, for use in local breeding programs, are typically managed through well-understood pathways, including DNIR licences. This provides clarity, predictability and proportionate oversight for contained, low-risk breeding activities.

The Consultation proposes a greater number of regulatory pathways, including revised notifiable and non-notifiable classes, designated dealings, GMO permits and expanded use of the GMO Register. While intended to provide flexibility, the proliferation of pathways risks increasing complexity for proponents in determining the appropriate regulatory route, particularly where activities sit at the interface between categories.

CropLife is concerned that in scenarios such as the import of germplasm for breeding, the proposed framework may be more complex to navigate than the current system, without delivering a commensurate improvement in risk management outcomes. Greater clarity on how proponents should determine the appropriate pathway and how transitions between pathways will be managed would be essential to avoid uncertainty and inadvertent non-compliance.

Question 10 – Do you have concerns in relation to the proposed non-notifiable dealings classes?

Recommendation: Consistent with the draft Bill consultation and the Third Review, non-notifiable dealings (NNDs) should not be limited to contained dealings.

CropLife notes that clarity around non-notifiable dealings will be critical for breeding programs that rely on the import and use of germplasm. Where multiple pathways are available, uncertainty as to whether an activity falls within a non-notifiable, notifiable or licensed category risks undermining the usability of the framework for routine, low-risk activities.

CropLife is concerned that the proposed framework does not clearly preserve existing non-notifiable treatment for certain gene-edited organisms, particularly those developed using SDN-1 techniques that are not currently considered GMOs in Australia. Indirect regulatory capture through undefined concepts or register-based mechanisms risks undermining established regulatory positions and creating uncertainty for proponents. Explicit clarification within the Regulations would improve certainty and alignment with current practice.

Of greater concern is the unnecessary limitation of the NND framework in contradiction to the Third Gene Technology Review and past draft Bill consultation. Currently, the Gene Technology Regulations provide that Schedule 2 exempt dealings do 'not involve an

intentional release of the GMO into the environment'.[29] However, this is not a requirement of the Gene Technology Act 2000.[30] Consistent with the Third Review, risk, rather than containment, should remain the primary determinant of whether a dealing is appropriately exempt, with containment being one factor relevant to risk assessment rather than a defining criterion.

It was previously stated that 'there will be no requirement in the GT Act that all non-notifiable dealings are contained; however, it is intended that most classes of non-notifiable dealing specified in the GT Regulations will be contained dealings'.[31] This is not consistent with the statement that NND1-4 would only cover contained GMO dealings.[32] This shift in intention creates uncertainty for proponents in distinguishing between exempt, notifiable and licensed dealings and does not reflect the stated intentions of the Third Review.

Question 11 – Do you consider the language 'not involving intentional release into the environment' appropriate for NNDs?

Recommendation: In reference to NNDs, retain or adapt the language employed in Schedule 2 of the Gene Technology Regulations 2001—'exempt dealings'—rather than defining exemptions by reference to non-release.

CropLife Australia has concerns that the use of the phrase 'not involving intentional release into the environment' as a defining descriptor for non-notifiable dealings (NNDs) risks creating confusion within the regulatory framework.

Under the Scheme currently, 'dealings not involving intentional release' (DNIRs) are a distinct class of licensed GMO dealings where activities do not meet the criteria for exempt dealings or notifiable low risk dealings. The DNIR concept is therefore closely associated with licensed activities conducted under a GMO licence and is conceptually distinct from exemption-based pathways.

CropLife is concerned that reusing language closely associated with DNIR licensing for a pathway intended to replace Schedule 2 exemptions risks blurring the distinction between exempt, notifiable and licensed dealings. This is particularly problematic where activities

[29] Gene Technology Regulations 2001 (Cth) s 6(1)(d).

[30] (Cth) s 32.

[31] Department of Health and Aged Care (Cth), Consultation Paper: Gene Technology Amendment Bill 2024 (Consultation Paper, September 2024) p 23.

[32] Department of Health and Aged Care (Cth), Consultation Paper: Proposed Amendments to the Gene Technology Regulations 2001 (Consultation Paper, January 2026) p 20.

are undertaken in containment but involve genetically modified or genome-edited material that does not warrant licensing based on risk.

Clear and stable pathway differentiation is essential to avoid inadvertent over-regulation, conservative pathway selection and inconsistent interpretation over time. In CropLife's view, retaining established exemption terminology, or adopting alternative language that clearly distinguishes NNDs from DNIR licensing, that avoids unnecessary containment-based limitations, would better support clarity, usability and regulatory predictability, and more closely reflect the intent of the Third Review.