CropLife AUSTRALIA

*Representing **the best** of the plant science industry*

CropLife submission to Phase 2 of the Review of the National Gene Technology Regulatory Scheme

15 December 2017

1 THEME ONE: TECHNICAL ISSUES

1. What technological advances can be foreseen that might pose regulatory challenges for the Scheme?

Technological advancement is a constant, and not a recent phenomenon in biotechnology as emphasised in this review of the National Gene Technology Scheme 2017 ("review" and "Scheme" hereinafter). While the current Scheme is efficient, effective, robust, and most importantly, science-based, it only provides certainty for certain long-established gene technologies and needs modernisation. Technologies that have existed for at least a decade but are still labelled as "new" challenge the Scheme today, because the Scheme is not sufficiently reactive to technological change.

To be "future-proof", the Scheme needs to retain broad definitions, in combination with lists of exclusions that include certain technologies and/or organisms that do not pose new risks when compared to those technologies and/or organisms already excluded. Establishment of mechanisms for the regular review and revision of these exclusion lists is key: technologies/organisms to be excluded can be identified based on scientific evidence and the body of accumulated knowledge and experience with biotechnology, and where that is not available today it should be considered as it develops.

Similarly, there may be established technologies and/or organisms that are presently regulated but should be excluded. Such an approach promotes the underlying principles of the Scheme of efficient and effective regulation, regulation that is proportionate to risk and regulation that is focussed on the protection of the health and safety of people and of the environment.

The CropLife Australia ("CropLife" hereafter) submission for Phase One of this review includes a Decision Tree to illustrate what a future Scheme with improved risk-based regulation could look like. This approach seeks to tailor the degree of regulatory oversight to identification and management of risks posed by an end-product and is discussed further under other questions in this submission (*see Theme Two*). We encourage the Review Secretariat and the Expert Advisory Panel to contact us to further discuss the practicality and implementation of this proposal.

This question invites technological advances that can be "foreseen". While reform that remains applicable long-term may be an ambition of this review, to be effective it needs to be limited to a scope that is realistic and foreseeable, and it would not be appropriate to attempt to regulate concepts that are today merely speculation. The focus of this review should, therefore, be on providing regulatory certainly in the short-medium term, but to also provide the mechanisms that enable the Scheme to be reactive in the longer-term. For example, the recent report of the National Academy of Sciences, "*Preparing for Future Products of Biotechnology*"[1] considered technological advances and products likely to emerge over the next 5-10 years and new risks presented by these compared to that already existing. Practical recommendations in this report included implementing the necessary mechanisms for regulators to continuously "scan the

[1] National Academies of Sciences, Engineering, and Medicine (2017) Preparing for the future products of biotechnology. Washington, DC. National Academies Press.

horizon" for new processes and products that could present novel risks, and to ensure their approaches to risk assessment remain robust and effective.

2. What are the potential impacts of the capability to make small edits in the DNA of an organism using no foreign DNA?

Genetically modified (GM) crops derived from established techniques of genetic modification have been commercially cultivated since 1996 without unexpected effects on ecosystems or a single documented adverse effect on human or animal health. As predicted by scientists early on, these GM crops have posed no unique or incremental risks different from those posed by crop varieties produced through conventional breeding techniques, including mutagenesis.

The CropLife submission for the technical review of the Gene Technology Regulations provides detailed scientific rationale in support of Option 4: *exclude certain new technologies from regulation on the basis of the outcomes they produce*. In effect, this option excludes organisms developed using genome editing methods that make small edits and do not involve the insertion of foreign DNA from the scope of regulatory oversight, including site directed nucleases (SDN-1, SDN-2) and oligo directed mutagenesis (ODM). This exclusion is justified based on comparison of the DNA sequence changes obtained using these methods, and the resulting risks, with that arising from spontaneous mutation or developed using conventional breeding techniques. The CropLife submission for Phase One of this review then makes specific recommendations for minor changes to the Gene Technology Act (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A) to give effect to Option 4.

3. Under what circumstances might it be practical, efficient or appropriate to regulate gene editing under the GT Act when, from an enforcement perspective, it may not be possible to distinguish the products of gene editing from the products of conventional methods?

If it is not possible to distinguish the products of genome editing methods from the products of conventional breeding, or even spontaneous mutations, then regulation of such products cannot be practical, efficient or appropriate.

The ability to develop a detection method for an organism developed using genome editing depends on the type of DNA sequence change(s). For example, where this involves an insertion of "foreign" DNA, standard PCR-based detection methods can be developed in the same way they are for current transgenic organisms, provided that the insert is of sufficient size to design PCR primers. Where the DNA sequence change is a point mutation (e.g. SDN-1) or an edit to an endogenous gene (e.g. SDN-2), the ability to develop a detection method depends on the ability to identify suitable sequences in the flanking regions for PCR primer design.

Sequencing is another option for determining the presence of small sequence changes. However, at present there is insufficient information to make any general statements on whether PCR or sequencing-based methods can be developed for such DNA sequence changes, or if they will be effective for detecting the modification in commerce, e.g. a single grain versus a bulk shipment.

An important consideration regarding detection of organisms developed using genome editing is the likelihood of false positives due to the possibility of the same DNA sequence changes arising via other means, e.g. in plants due to spontaneous mutations, or mutations induced by conventional breeding methods. Thus, it is not possible to conclusively determine the mechanism by which the changes in DNA sequence arose. Regulation of such organisms would not be based on protecting the health and safety of people and the environment, it would be contrary to efficient and effective regulation that is proportionate to risk, and it would also constitute an indefensible process-based application of the precautionary approach.

4. Do these (emerging) applications of gene technologies present unique issues for consideration? If so, how might these issues be addressed by the Scheme?

The Consultation Paper for this review refers to synthetic biology, human germline therapy and gene drives in relation to this question. CropLife **does not agree** with the definition of synthetic biology provided by the Consultation Paper, and is of the view that this is simply a new umbrella term analogous to biotechnology (or "gene technology" as used in the Scheme). This term encompasses accumulated and constantly advancing knowledge and understanding in biological engineering, and is used in the scientific literature to represent a heterogeneous mix of activities spanning "new" and established (and re-labelled) biotechnological methods.

The key question here is whether risks presented by the resulting organisms can be assessed according to the current Scheme. Experienced regulators engaged in work programs on synthetic biology under the Convention on Biological Diversity, and on risk assessment under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, have yet to identify an example of an organism developed using "synthetic biology" that could not be assessed according to existing case-by-case approaches to risk assessment. A case-by-case approach is a fundamental principle of risk assessment, and this is the approach employed in the Risk Analysis Framework used by the OGTR.

Gene drives, which are also often labelled as "synthetic biology", are "genetically modified organisms" (GMOs) that are within the scope of the current Scheme, and are not excluded from the scope of regulatory oversight by the recommendations of CropLife. The current case-by-case approach to risk assessment of the OGTR is sufficiently flexible to assess these types of GMOs.

5. What are the potential implications of the release of a GMO targeting an invasive species in Australia?

As noted in response to question 4 (Theme One), the key question is whether risks presented by the resulting organisms can be assessed according to the current Scheme. GMOs developed for managing an invasive species should be subject to the existing Risk Analysis Framework (RAF) employed for dealings involving intentional release (DIR) into the environment by the OGTR. The Risk Assessment and Risk Management Plan (RARMP), as is currently developed on a case-by-case basis by the OGTR for the release of GMOs into the environment, remains the most appropriate mechanism for determining the scope of regulation for these types of GMOs. This remains applicable where the GMO contains a gene drive.

6. What are the technical issues to consider in the scenario of a GMO used to target an introduced plant, vertebrate or invertebrate pest?

As noted in response to question 5 (Theme One), the existing RARMP and DIR licensing processes of the OGTR are appropriate for identifying and managing risks to human health and the environment posed by GMOs used to target invasive species. The current Scheme includes specific risk assessment requirements for organisms to be used in biological control, and these are examined on a case-by-case basis depending on the GMO and its intended use.

There should not be a presumption that where an organism is "new" it presents unprecedented challenges. There is a large body of relevant risk assessment experience and guidance to support adaptation of risk assessment methodologies (if required) on a case-by-case basis, e.g.: the foundational materials of the OECD[2] and the National Academy of Sciences[3], materials developed by experienced regulatory agencies[4], risk assessments shared by regulatory agencies in the Biosafety Clearing House of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[5], standards developed by the International Plant Protection Convention[6], biology consensus documents[7], and the scientific literature.

For organisms containing gene drives, many potential applications have been proposed, however, the only application with proof-of-concept to date is the control of mosquito populations to prevent disease transmission. The World Health Organization Special Programme for Research and Training in Tropical Diseases published the "Guidance Framework for Testing of Genetically Modified Mosquitoes" in 2014, and this document is currently being revised to include mosquitoes containing gene drives.

2 OECD (1986) Recombinant-DNA safety considerations. Organization for Economic Cooperation and Development, Paris.

3 National Academy of Sciences (1987) Introduction of recombinant DNA-engineered organisms into the environment: key issues. National Academy Press, Washington DC.

4 E.g. United States Environmental Protection Agency (1998) Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F.

5 http://bch.cbd.int/database/riskassessments/.

6 Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms. International Standard for Phytosanitary Measures 3 (ISPM 3). Adopted 2005.

7 E.g. OGTR http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1; and OECD http://www.oecd.org/science/biotrack/safetyassessmentoftransgenicorganismsoecdconsensusdocuments.htm.

2 THEME TWO: REGULATORY ISSUES

1. What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies?

The current Scheme is a hybrid of process and product based regulation. The trigger for regulation is process: an organism is regulated as a GMO where it has been modified by gene technology, unless the gene technology or organism is excluded by the Gene Technology Regulations. The Scheme is "hybrid" insofar as certain products (organisms) are excluded from regulatory oversight based on knowledge of risks posed to the health and safety of people and to the environment and a history of safe use. The risk assessment is also largely based on the characteristics of the organism.

Given the diversity of the regulated community covered by the Scheme, it is unlikely that a solely process-based or product-based system will be the most appropriate solution for all. For example, a process-based approach may be more appropriate for the research community, as indicated by some members of that community (based on submissions for Phase One of this review), but for developers with well characterised products for release into the environment, a greater emphasis on regulation that is product-based is generally favoured.

As noted for previous questions, the CropLife submission for the technical review of the Gene Technology Regulations recommended the adoption of Option 4: *exclude certain new technologies from regulation on the basis of the outcomes they produce*. This option has been interpreted as a product-based approach and therefore an outcome beyond the scope of the technical review due to the underlying process-based policy setting. CropLife, however, made specific proposals in its submission for Phase One of this review that amounted to minor changes to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A) to give effect to Option 4.

These recommendations retain the broad definitions of the Scheme and the process-trigger, and add certain exclusions that are both process-based (SDN-1, SDN-2, ODM, cisgenesis used in plants) and product-based (null segregants) from the scope of regulatory oversight. CropLife therefor recommends that the Scheme should combine elements of both a process and product-based system.

There is a perception that solely product-based systems are better suited to technological advancement than process-based systems, and the Consultation Paper mentions the product-based approach of Canada's regulatory scheme. This system is based on "novelty" of the plant trait, with other related regulations for "novel foods" and "novel feeds". In practice, the scope of this system is broad: it includes plants developed using conventional breeding methods and imposes a regulatory burden on plant breeders that is absent in process-based systems. The scope of this system has also included plants developed using "new" genome editing

techniques, e.g. herbicide tolerant canola developed using ODM[8], which was excluded from regulatory scope elsewhere. Thus, for proportionate risk-based regulation, process-based systems also need to include mechanisms to allow for exclusions of organisms (products) developed using certain technologies.

Regardless of the regulatory trigger, both process and product-based systems need to be defined by appropriate protection goals, be based on appropriate definitions, and contain mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation. Exclusion lists should be updated at regular intervals as technology advances and knowledge is gained about technologies and/or organisms. It is also important that the Scheme retains its underlying principles of efficient and effective regulation that is proportionate to risk.

As noted previously, the CropLife submission for Phase One of this review included a Decision Tree to illustrate what a future Scheme that improves risk-based regulation could look like. This retains a process-based regulatory trigger and it incorporates process-based and product-based exclusions according to the risks posed by the resulting organism (product). We encourage the Review Secretariat and the Expert Advisory Panel to contact us to further discuss the practicality and implementation of this proposal.

2. What factors need to be taken into account in the design of a product-based or a hybrid process/product regulatory scheme?

As noted in response to question 1 (Theme Two), CropLife recommends that the Scheme should be risk-based, and combine elements of both a process and product-based system. The Scheme needs to be defined by appropriate protection goals, be based on appropriate definitions, and contain mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation. The current Scheme allows for technical reviews of the Gene Technology Regulations, which would allow for additions to the exclusion lists in Schedules 1 and 1A, however, this has not been utilised to provide regulatory clarity for “new” technologies.

Exclusion lists should be reviewed and updated at more regular intervals, e.g. every two years, as technology advances and knowledge is gained about technologies and/or organisms. This requires, as recommended by the National Academy of Sciences[9], regulatory agencies to have the capacity and expertise to continuously “scan the horizon” and evaluate emerging processes and organisms, and to keep up to date with the corpus of scientific knowledge on existing processes and organisms. The Scheme needs to keep pace with technological and knowledge advances in order to be consistent with its underlying principles of efficient and effective regulation that is proportionate to risk.

As referred to previously, the CropLife Australia submission for Phase One of this review included a Decision Tree to illustrate a Scheme that combines elements of process- and product-based regulation to improve risk-based regulation.

[8] http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669.

[9] National Academies of Sciences, Engineering, and Medicine (2017) Preparing for the future products of biotechnology. Washington, DC. National Academies Press.

3. Are there any 'fixes' the scheme needs right now to remain effective?

As noted in response to questions 1 and 2 (Theme Two), the Scheme needs to be defined by appropriate protection goals, be based on appropriate definitions, and contain mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation. CropLife Australia considers the existing protection goal of the Scheme – the health and safety of people and of the environment – to remain appropriate.

In its submission for Phase One of this review, CropLife made specific recommendations for amendments to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A). These amendments aimed to give effect to Option 4 proposed in the technical review of the Gene Technology Regulations, while retaining broad definitions and the process-trigger, and adding certain process-based exclusions (SDN-1, SDN-2, ODM, cisgenesis used in plants), as well as product-based exclusions (null segregants) from the scope of regulatory oversight.

These "fixes" are aimed at improving the effectiveness of the Scheme by providing regulatory clarity for "new" technologies that is risk-based and proportionate. Similarly, the Decision Tree proposed by CropLife in Phase One of this review provides several streamlining "fixes" for both established and "new" technologies that could be incorporated now. To remain effective in the longer term, technical reviews of the Gene Technology Regulations need to be undertaken at more regular intervals, such as every two years, so that the Scheme keeps pace with emerging technologies and the corpus of scientific knowledge for these as well as existing/established technologies.

The "fixes" proposed promote the implementation of outstanding recommendations from the 2011 Review of the National Gene Technology Regulatory Scheme, which have been agreed to by the Commonwealth, States and Territories. Recommendation 9 is relevant to Theme Two of this review:

> *"The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined."*

The commentary associated with this recommendation noted that all governments considered the need for legislation to keep up with, and allow for expeditious responses to technological advances, including the sufficiency of definitions and the process for legislative amendment to promote regulatory clarity.

4. How would you streamline the existing scheme?

This question is addressed in our responses to questions 1, 2 and 3 (Theme Two). These provide several recommendations and refer to detailed rationale provided in the CropLife submissions for the technical review of the Gene Technology Regulations and Phase One of this review. The submission for Phase One of this review includes a Decision Tree with a streamlined risk assessment (SRA) process. The responses provided in this submission are designed to be read in conjunction with CropLife's two earlier submissions.

5. What efficiencies could be gained through adjusting the interface between the Scheme and other regulators?

The CropLife submission for Phase One of this review sets out in detail its concerns regarding duplication of regulation between the OGTR, FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for products regulated as GMOs, and the regulatory burden, time delays and costs this imposes with no associated benefit. To improve this situation, CropLife recommends that the APVMA accepts the risk assessments of the OGTR and FSANZ, or that APVMA regulatory responsibility for GM products with incorporated pest and/or disease control is removed. This regulatory responsibility is an outdated remnant of the pre-OGTR system and these changes would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, business and community organisations.

6. What support exists for a regulatory framework providing for tiered risk?

Please refer to our responses provided in this submission for questions 1, 2 and 3 (Theme Two). These include reference to the Decision Tree provided by CropLife in its submission for Phase One of this review, which is consistent with a tiered approach to risk-based regulation. We encourage the Review Secretariat and the Expert Advisory Panel to contact us to further discuss the practicality and implementation of this proposal.

7. What examples exist of licence applications to the Regulator that could be 'fast-tracked', under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered?

CropLife's submission to Phase One of this review includes a Decision Tree with a Streamlined Risk Assessment (SRA) process for regulated technologies and/or organisms for release into the environment under a licence. This process would not apply where the technology and/or organism is excluded from regulatory scope.

The SRA applies when the following criteria are met:

a) The genetically modified organism (GMO) is well characterised (i.e. an OGTR Ecology and Biology document already exists); OR

b) The genetic modification results in the same or a substantially similar protein and/or substance to one previously approved in Australia; OR

c) The GMO has been approved for cultivation in another country with a 'recognised' biosafety regulatory system.

If one or more of those criteria are met, the SRA process features:

a) Reduced data package requirements, with a focus on environmental risk assessment; AND

b) Mandatory consultation only with the states, the Gene Technology Technical Advisory Committee and the Federal Environment Minister; AND

c) A reduced assessment timeframe commensurate with acknowledgement of lower risk (90 days for a Limited and Controlled Release licence and 120 days for a Commercial Release licence).

This SRA process aims to apply different levels of risk assessment commensurate with risk and incorporates accumulated scientific knowledge since the early assessments of similar products, and the familiarity and history of safe use of certain traits and crops. While it was developed for crops for which most knowledge and experience exists for GMOs to be released into the environment, it could also be adapted for other organisms. Existing examples the SRA process could apply to include varieties of insect resistant and herbicide tolerant GM cotton that have been cultivated in Australia for a significant period of time.

8. Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders?

A streamlined approach, as described for question 7 (Theme Two) that incorporates different levels of risk assessment is aimed at reducing unwarranted regulatory burden for the regulated community. This is promoted by reduced timelines for regulatory approval and reduced time and cost requirements for regulatory data generation.

9. How could efficiency gains to the Regulator be quantified?

A streamlined approach, as described for question 7 (Theme Two) that incorporates different levels of risk assessment improves the efficiency of the Regulator and the use of OGTR resources, as time is not wasted repeating unnecessary risk assessments. For example, the reduction of assessment timeframes could result in numerous 'saved days' work by OGTR regulatory scientists.

10. What justification is there to regulate animals, plants or microbes differently?

The Scheme already regulates different organisms and applications differently. While the process-trigger does not discriminate, the requirements for contained dealings and licence risk assessments do vary, and licence conditions are imposed on a case-by-case basis. For example, Contained Dealings involving knockout mice require a PC1-level facility, whereas GM plants and some GM animals require a PC2-level facility, and gene technology work involving pathogenic micro-organisms may require a PC3 or PC4 level facility. For licences, there are different application forms (i.e. risk assessment requirements) for microorganisms, vaccines, vertebrate and invertebrate animals, aquatic organisms, and for particular intended uses such as biological control, remediation and animal feed.

As described for question 7 (Theme Two) CropLife's submission to Phase One of this review includes a Decision Tree with a Streamlined Risk Assessment (SRA) process for regulated technologies and/or organisms for release into the environment under a licence. While this was developed for crops based on scientific knowledge and experience, it could be adapted for other organisms where this is also justified based on scientific knowledge and experience.

As noted several times in this submission, the CropLife submission for the technical review of the Gene Technology Regulations provides detailed scientific rationale in support of excluding certain "new" technologies from the scope of the Scheme. These proposals include broad exclusions (not organism-specific) and exclusions applicable to plants, and these are justified based on current understanding of the technologies and the accumulated body of scientific knowledge and expertise for biotechnology in plants.

11. In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc)?

This question is addressed in our response to question 10 (Theme Two).

12. How might the Scheme accommodate the DIY-biology movement?

The Scheme should apply equally to all users of gene technology, regardless of whether they are associated with a university, a research institution, a private sector company, or they are an individual. Risks to human health and safety and to the environment do not change based on the person or organisation undertaking the work.

As for other entities, regulation of the DIY community should include certification of facilities, notifications of notifiable low risk dealings, and licences for dealings involving/not involving releases into the environment. This is only a "new issue" for the Scheme in the sense that such users may require greater support from the OGTR to identify regulated activities and assist them with compliance.

13. What measures might be warranted to identify potential long-term or 'downstream' effects of gene technologies on humans and the environment?

The existing risk analysis framework used by the OGTR is scientifically robust and there is no credible evidence for adverse effects on humans or the environment resulting from dealings with GMOs anywhere in the world since they were first commercially cultivated in the mid-1990s. Studies that claim to report adverse effects are routinely discredited by regulatory agencies around the world[10], including FSANZ[11]. Calls for "long-term" studies or studies into "unknown unknowns" have no basis in sound science, and are used only to arouse fear and suspicion in the public.

14. What opportunities are there for principles-based regulation in the Gene Technology Scheme? What advantages could be gained from doing this? What drawbacks are there from such an approach to regulation?

CropLife cautiously supports the exploration of a principles-based approach to gene technology regulation where it could lead to a more outcomes-based approach to regulation. CropLife recognises the key advantage of principles-based regulation is its facilitation of regulatory flexibility through the statement of general principles that can be applied to new and changing gene technologies.

Principles-based regulation would allow a greater degree of future-proofing and enable the Scheme to respond to new gene technologies as they arise without having to create new rules each time. This approach would overcome the comparative rigidity of rules-based regulation.

10 E.g. European Food Safety Authority (EFSA): https://www.efsa.europa.eu/en/press/news/121128.

11 http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman%27s-study.aspx; http://www.foodstandards.gov.au/consumer/gmfood/safety/documents/Table%20of%20Studies%20on%20GM%20foods_15July2011%20FINAL.pdf.

Regulatory clarity and certainty is of the greatest importance to CropLife members and there are genuine concerns about the potential ambiguity of principles-based regulations. Prescriptive rules can provide greater clarity, as it is easier for a regulated entity to determine what rules it must comply with and the minimum standards of compliance expected.

Principle-based regulation may not provide the required level of certainty, or may create an unpredictable regulatory regime in which regulators can act retrospectively.

CropLife would be willing to explore a hybrid approach between rules-based and principles-based regulation with the Review Secretariat as this could provide the regulated community with the benefits of both systems. We would, however, need to see a specific set of proposals to comment on before committing any support to a revised approach.

To give an existing example of 'principles-based' regulation in the Scheme, the OGTR's Monitoring and Compliance section already work on an outcome basis. For example, while a licence may require the holder to have "control" of a trial site, or to "prevent volunteers from flowering", it does not say how the holder must do these things, but rather describes the desired outcome. To date, this has worked as it has negated the need for the OGTR to develop the compliance system as a one-size-fits-all, which could never cover the gambit of GMOs, and puts the implementation squarely with the licence holder and what they are able to do.

15. Are there any non-science aspects that would enhance the object of regulation, that do not place unnecessary burdens on the regulated community? How might these be considered?

The gene technology regulatory scheme should remain firmly focussed on science and risk-based regulation. Non-science aspects, such as trade and marketing, consumer choice and socio-economic considerations that are referred to in the Consultation Paper are not consistent with the underpinning principles of the Scheme, do not contribute to regulatory clarity and may in fact contribute to arbitrary decision-making, and they increase regulatory burden.

16. What are the potential impacts on market access for exporters of animal or plant derived food products?

CropLife believes in access to the benefits of crop biotechnology. Asynchronous authorisation, combined with importing countries maintaining a 'zero tolerance' for unapproved crop biotechnology products, has the potential to result in major trade disruptions.

The potential for trade disruption could be significantly reduced if all countries provided authorisation simultaneously, or if there was international government consensus eliminating zero tolerance policies.

Codex has developed and approved an international food safety standard for the low-level presence (LLP) of recombinant-DNA plant material in food. Such an international standard helps to address the problem of asynchronous approvals. Another pragmatic approach is to minimise the number of asynchronous approvals in key markets. This can be addressed by product developers commercialising their new crop biotechnology products in Australia only after meeting applicable regulatory requirements from the key countries most likely to import those seeds or products.

To help ensure the continued adoption of crop biotechnology globally, and to continue to have products of crop biotechnology bring value to the marketplace, CropLife supports actions that facilitate trade and minimise disruptions. Product developers should, prior to commercialisation in Australia, meet applicable regulatory requirements in key countries identified in a market and trade assessment that have functioning regulatory systems and are likely to import the new crop biotechnology product.

3 THEME THREE: GOVERNANCE ISSUES

1. What will reassure the Australian public and regulated communities of the integrity of the Scheme?

Reviews of the Scheme in 2006 and again in 2011 reaffirmed the policy and regulatory integrity of the Scheme, and confirmed the policy objectives were still appropriate. To reassure the regulated community, the Scheme must keep pace with technology and provide for proportionate regulation of risk. This requires retaining the underlying principles of effective and efficient regulation with a focus on science-based risk assessment.

The process must also be clear, transparent, and consistently applied. Keeping pace requires mechanisms allowing for regular and focussed reviews. The present review process is seeking input on broad issues such as trade and consumer choice. While these may be aimed at reassuring the public, they cannot be reconciled with a transparent, consistently applied and credible science-based Scheme. In relation to reassuring the public, please see our responses provided for questions in Theme Four.

2. What mechanisms could address the challenges that making changes in the Scheme might entail:

Domestically – across a federated government system experiencing different political agendas and community sentiments?

Internationally – relating to other agreements, trade agreements, and harmonised regulatory approaches?

CropLife supports the nationally consistent approach to regulation provided by the intergovernmental Gene Technology Agreement, and supports continued efforts to ensure that there is clarity in the regulatory environment. CropLife is concerned about both potential and actual politicisation of the Scheme, particularly at state level. For example, through the implementation of GM moratoria. Better communication between state and federal agencies and with stakeholder groups will reduce politicisation of the regulatory process.

CropLife supports international regulatory harmonisation to prevent global regulatory inconsistences (such as incidents of LLP; refer to question 16, Theme 2) and to encourage access to new technologies from overseas.

3. What principles should guide the level at which a decision is made within the Scheme?

The Scheme should retain its goals of protecting the health and safety of people and protecting the environment, and the underlying principles listed in the Consultation Paper: transparency, independence of the Regulator, focus on science-based risk assessment, national consistency, effective and efficient regulation that is proportionate to risk, and reactive to technological change. The principles also recognise that there is a range of perspectives. There are perspectives that are ideologically opposed to gene technology irrespective of the integrity of the Scheme and these need to be balanced against the other principles so that the Scheme remains fit for purpose and does not present unjustifiable barriers to R&D or commercialisation

in Australia. 4. Does reviewing the Scheme every five years best address the needs of the Scheme? Is there a preferable option?

This cannot be determined due to a lack of implementation of agreed Recommendations from previous reviews. Therefore, as stated previously in this submission, CropLife recommends that these are implemented as a matter of priority. We also recommend more regular technical reviews of the Gene Technology Regulations, such as every two years, so that the exclusion lists and scope of regulatory oversight keep pace with technological developments and knowledge gained about technologies and/or organisms.

5. Is the existing role of the Forum the most suitable way of providing oversight and guidance for the Scheme?

To date, the Forum has not proven to be an efficient and effective mechanism for oversight and guidance of the Scheme. As stated in question 4 (Theme Three), there has not been implementation of recommendations from previous reviews of the Scheme, and the Scheme lacks the necessary agility to keep pace with the technologies it regulates.

6. What criteria should be used to determine what legislative amendments are minor and could be progressed without going to the Forum?

Amendments that allow for lowering of the level of regulatory oversight (or risk class) for a given gene technology or class of GMO, e.g. via implementation of the Decision Tree proposed by CropLife in its submission for Phase One of this review, or exclude them from regulatory scope, e.g. via exclusions in the Gene Technology Regulations, could be considered by the Forum. All other amendments can be progressed directly through federal and state parliamentary processes.

7. What evidence is there to support economic and trade advantages of GM moratoria – or indeed, the absence of GM moratoria?

Nearly 15 years after GM moratoria were first introduced in Australian states, there remains zero evidence to support any trade or marketing advantages of being “GM free”. In contrast, there is ample evidence and data to support the agronomic, environmental and economic benefits that GM crops have provided Australian farmers in the states where they can be grown. This information has been provided by CropLife previously in the Phase One submission and is provided here again.

Evidence to support the absence of moratoria include 2005 and 2008 reports of the then Australian Bureau of Agricultural Resource Economics (ABARE). The 2005 report stated that Australia’s canola growers were suffering an economic loss because of the state moratoria on the commercial cultivation of GM canola, and concluded that if the moratoria were to continue, it could result in a loss of $3 billion, in net present value terms, in the period to 2015[12]. The 2008 report indicated that the estimated economic benefit to Western Australia from adopting GM canola from 2008-09 for the following ten years would be $180 million in 2006-07 dollars.

12 Apted S., McDonald D., Rodgers H., 2005, *‘Transgenic Crops: Welfare implications for Australia’* Australian Commodities, vol. 12, no. 3

Over the same period, the benefit to New South Wales' farmers (excluding those in the Murray Catchment Area) was estimated to be $273 million and South Australian farmers would receive a benefit of $115 million. Similarly, an academic study estimated that the GM canola moratoria in Australia cost farmers nearly $500 million in lost revenue.[13]

Several Australian states still have legislative bans on GM technology, maintaining vague 'market considerations' legislation, even in states where GM canola is now commercially produced. New South Wales, Victoria and Western Australia now allow the commercial production of GM canola, after at least a five-year delay following approval by the Scheme. It is not clear if such a delay will be repeated in those states if future GM crops are introduced in Australia. CropLife notes that the New South Wales Government announced on 1 June 2011 that it would be extending its *Gene Technology (GM Crops Moratorium) Act* until 2021, 25 years after GM cotton was first commercially grown in that state.

South Australia introduced the *Genetically Modified Crops Management Act 2004* (SA) to ensure that the cultivation of GM crops was regulated in that state. On 8 February 2008, against the advice of its own scientific advisory committee, the South Australian Government decided to extend its moratorium on growing GM canola in South Australia beyond the end of April 2008 when the regulations were due to expire. Recently, without any consultation or review, the South Australian Parliament passed a Bill extending the moratorium to 2025. This is despite the *Adelaide Advertiser* reporting in 2015 that the South Australian Agriculture Minister, the Hon Leon Bignell MP, had admitted that the South Australian State Government did not have solid economic data to support its decision to maintain the South Australian GM moratorium[14]. The South Australian Government has even gone beyond marketing concerns and banned the transport through their state of sealed bags containing GM seed.

Independent market analysis by Mecardo in 2016 and 2017 showed there is little evidence to determine that South Australia has achieved a premium for its non-GM canola crop due to the moratorium on GM technology. Comparing the difference between non-GM canola in Adelaide (SA) and Kwinana (WA) demonstrated a clear premium for non-GM in Kwinana throughout the entire season. There is even evidence of GM canola in Kwinana achieving a premium over Adelaide non-GM.[15]

In January 2014, the Tasmanian Government also extended its moratorium on GM crops in direct contradiction to two consultants' reports commissioned by the Government on the issue of market benefit from GM-free status[16,17]. With both reports concluding there was little to no indication of a price premium generated by a GM free status, the decision was clearly political and not based on actual scientific and economic evidence[18]. The Government's own

13 Smyth, SJ (2017) *Genetically Modified Crops, Regulatory Delays, and International Trade*. Food and Energy Security 6:78-86.

14 Adelaide Advertiser, 24 July 2015.

15 Whitelaw A (2016) 'Is the GM ban in South Australia providing a premium?'. Mercado Expert Market Analysis: 25 July 2016; and Whitelaw A (2017) 'Controversial canola'. Mercado Expert Analysis: May 25 2017.

16 FreshLogic 2013, An attitudinal assessment of key domestic market gatekeepers to gauge perception of and attitudes towards Tasmania, GM crops and food grown in areas that allow the cultivation of GM food and non-food crops, Hawthorn VIC.

17 Macquarie Franklin 2012, Market Advantage of Tasmania's GMO-free Status, Devonport TAS.

18 http://dpipwe.tas.gov.au/Documents/Final%20Report_v.final_16-12-13.pdf

commissioned report states that over the past decade, Tasmania's agricultural sector has suffered a $40 million net farm-gate loss due to this moratorium[19].

The Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture in November 2016 recommended that "the New South Wales, South Australian, Tasmanian and ACT Governments should remove their moratoria on GM crops. All states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs by 2018".[20] The state moratoria on GM crops were also identified in the March 2015 Harper *Competition Policy Review* as a significant example of a regulatory restriction on competition[21].

The situation in Australian states is a prime example of how important decisions that affect the competitive future of an entire sector, with far-reaching implications for the environment, innovation in agriculture and the state economy, should not be made on political and ideological grounds, but rather on data and facts. Agriculture suffers from chronic underinvestment, both in the development of new crop varieties and in the technologies used to develop them[22]. The Australian Government should recognise that evidence to date has demonstrated that GM crops do not pose any risks to human health and the environment that cannot be identified and managed by the Scheme, and consequently the state and territory moratoria on these crops is anti-competitive, hinders investment in R&D, stifles innovation in agriculture, and is in no way commensurate with risk or the underlying principles of the Scheme.

The ability of states to circumvent the Scheme is facilitated by section 21(1)(aa) of the *Gene Technology Act 2000,* which allowed the making of the Gene Technology (Recognition of Designated Areas) Principle 2003 by the then Gene Technology Ministerial Council on 31 July 2003.

The making of this policy principle gave the states and territories the power to recognise areas (if any) designated under a state law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes. Western Australia, South Australia, Tasmania, Victoria, New South Wales and the Australian Capital Territory immediately used this policy principle to legislate for moratoria on the commercial cultivation of GMOs.

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for the purpose of preserving the identity of GM and non-GM crops, and it removes farmer choice. **CropLife strongly recommends** the repeal of s21(1)(aa) in the Commonwealth *Gene Technology Act 2000*, the repeal of the corresponding Section in State and Territory Acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

19 Macquarie Franklin, Op. Cit.

20 Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.

21 Harper I, Anderson P, McCluskey S and O'Bryan M 2015, The Australian Government Competition Policy Review, pp116.

22 Smyth SJ, Falck-Zepeda J, Ludlow K (2016) The Costs of Regulatory Delays for Genetically Modified Crops. Journal of International Law and Trade Policy 17:173-195.

8. How could regulated stakeholders access the benefits of a national scheme, whilst ensuring jurisdictions are able to effectively trade in the international context?

Those jurisdictions in which GM and non-GM crops coexist all effectively trade in key international markets, there is absolutely no evidence of lack of market entry of a non-GM crop that is grown in the same jurisdiction as a GM crop.

Since the adoption of GM canola in Australia, the industry has not lost any markets for non-GM canola, and no shipments of grain have been rejected due to the unintended presence of GM canola in non-GM canola loads. The GM-sensitive European Union market continues to be a major destination for Australia's non-GM canola.

9. What other mechanisms could be utilised in order to realise the outcomes currently achieved through moratoria?

Mechanisms allowing for bans of gene technology or GMOs on the grounds of ideology or vague 'market considerations' are inconsistent with a national Scheme that is supposed to be focussed on protecting the health and safety of people and protecting the environment with underlying principles of effective and efficient regulation that is proportionate to risk. Such mechanisms should not be considered by this review. Decisions to regulate GM crops at the state level completely undermine the national Scheme and the ability of the Legislative and Governance Forum on Gene Technology (LGFGT) to make policy principles should be repealed.

10. Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians?

As stated repeatedly throughout this submission, the Scheme has not effectively kept pace with technological developments since the establishment of the Scheme to provide for proportionate regulation of risk. It is difficult to determine whether existing mechanisms are insufficient, or they have just not been used effectively. Either way, the impacts on agriculture are discussed in question 7 (Theme Three) and include reduced investment in R&D, stifling of innovation, and consequently, lacking commercialisation of innovative products for Australian agriculture.

The environmental benefits of adopting GM crops are well-established. For example the CropLife International publication database currently contains 354 publications identifying benefits resulting from changes in agricultural practices including improvements in soil moisture and biodiversity (beneficial insects and earthworms), reduced chemical inputs, reduced fossil fuel inputs and carbon dioxide emissions, more efficient water usage, and yield improvements (see http://biotechbenefits.croplife.org/impact_areas/environmental-benefits/).

These benefits are not harnessed for Australians if mechanisms exist in the Scheme that allow for state moratoria on grounds that are inconsistent with its principles. Further, these benefits will not be harnessed for Australians in the future if the Scheme does not provide timely regulatory clarity for new technologies that are needed in agriculture.

11. Should other policy principles be developed that are tailored to horizon technology management?

The term "horizon technology" is not defined in the Consultation Paper so it is not clear what is meant by this term. As stated previously, however, for the Scheme to be effective its scope needs to be limited to one that is realistic and foreseeable, and not attempt to regulate concepts that are today merely speculation. As recommended by CropLife, the Scheme needs the appropriate mechanisms to allow for regular technical reviews of the Gene Technology Regulations, such as every two years, and amendment of the lists of gene technology and GMO exclusions so that the Scheme keeps pace with emerging technologies and advances in scientific knowledge.

12. What other factors could be considered in the regulatory decision?

As stated previously, CropLife supports the protection goals of the Scheme and its underlying principles. It is therefore appropriate for regulatory decision-making to be focussed on managing risks posed by gene technology to human health and safety and to the environment. CropLife disagrees with assertions that the 'precautionary approach' should be the predominant consideration or an underlying principle, and considers that the Scheme currently takes an overly precautious approach that is inconsistent with the underlying principle of proportionate regulation.

For example, certain GM crops remain regulated despite 20 years of commercialisation and no credible evidence for adverse effects on the health and safety of people or on the environment, and "new" technologies are currently regulated despite having the same outcomes (and risk) as conventional breeding[23].

In considering the factors to be considered when making regulatory decisions, it should be remembered that Australia has relevant international obligations. For example, any decision not allowing the cultivation of a GM crop must be compliant with World Trade Organization agreements [24] requiring decisions to be based on appropriate and defensible scientific justifications.

13. What data sets are required to assist the regulator to consider benefits in addition to the risks?

CropLife **strongly opposes** a 'benefit' consideration as part of the Scheme. The Scheme should remain focussed on identifying and managing risks posed by gene technology to human health and safety, and to the environment. While benefits have been demonstrated for gene technologies, and investment in their development would not be made unless they provided some benefit, there are no established methodologies for ex-ante assessments of benefits, they rely on assumptions, and they provide weak and speculative data with limited application in decision-making.

[23] See the CropLife submission for the Technical Review of the Gene Technology Regulations for detailed scientific rationale demonstrating this point: https://www.croplife.org.au/wp-content/uploads/2017/06/CropLife-Sub_OGTR-Discussion-Paper-161216.pdf

[24] E.g. Agreement on the Application of Sanitary and Phytosanitary Measures.

14. What aspects of gene technology would benefit from greater policy position clarity?

One aspect of gene technology that could benefit from clarity in policy position is low level presence (LLP). CropLife's views and recommendations concerning LLP are provided in detail in our Phase One submission for this review. CropLife supports:

- Global adoption of science-based risk assessment approaches to LLP policy to avoid unnecessary economic costs (caused by, for example, recall of grain shipments due to co-mingling of GM grains that may be unapproved in the destination jurisdiction) and improve consumer confidence in our food supply chain and regulatory framework.
- LLP policies that are proportionate to risk to provide continued food, human health and environmental safety for consumers, farmers, processors and grain handlers.
- The Australian Government's continued active participation in coordinated discussions related to LLP and global trade efforts, including the Global LLP Initiative.

Australia's current legislation imposes 'zero tolerance' to LLP, which is unsustainable. The Australian Government needs to develop specific policies to recognise its trading partners' systems for risk assessment and management, particularly in relation to import of GM-derived plant materials (grain or seed). Enhanced communication, data sharing and recognition of regulatory equivalence between and among global regulators could minimise the differences in approach and timing of approval, and reduce the time required to conduct risk assessments and make management decisions in countries where LLP situations may occur.

CropLife encourages the Departments of Agriculture and Water Resources, Health, Foreign Affairs and Trade, together with the regulatory agencies FSANZ and the OGTR to coordinate and articulate a comprehensive and systematic LLP assessment and management process to reduce the trade impacts of instances where LLP may occur.

15. What other mechanisms would provide suitable policy clarity that would enhance the Scheme and support compliance?

CropLife has made recommendations regarding regular review of the Gene Technology Regulations (see Theme One) and a streamlined process for risk-based regulation (see Theme One and the CropLife submission for Phase One of this review) to enhance the effectiveness of the Scheme. If these changes to the Scheme are adopted, the Regulator should proactively communicate the need and justification for these, consistent with the underlying principles of transparency and the need to remain effective as technology evolves.

16. What are the pressure points at the boundaries between regulatory schemes that are caused by regulatory gaps or overlaps? and

17. How can existing coordination functions be utilised more effectively to support the Scheme to be agile and facilitate transitions across regulatory framework boundaries? What other activities would enhance this?

CropLife's concerns and recommendations regarding regulatory duplication for gene technology/GMOs are detailed in our submission for Phase One of this review. Our concerns are focussed on crops, and the need for multiple regulatory approvals depending on the product – the OGTR, FSANZ and the APVMA. The need to interact with multiple regulatory agencies

and frameworks is not a new situation – it has not arisen with developments such as synthetic biology as referred to in the Consultation Paper – with duplication already unnecessarily increasing the regulatory burden, uncertainty and cost for applicants. CropLife recommends that this regulatory duplication be addressed as a matter of urgency. One way to do this is for the APVMA to accept OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for GM products with incorporated pest and/or disease control.

18. What amendments to the funding model would support an agile Scheme that will cope with increased future activity? and

19. How could some aspects of the Scheme be funded through other mechanisms that will support innovation and competition in gene technology, whilst retaining public confidence in the Scheme?

As detailed in our submission for Phase One of this review, CropLife supports regulatory cost recovery where it is justifiable, appropriate and proportionate to undertaking core business, and not used to subsidise a regulator's non-cost recovered budget shortfalls.

Australia is already one of the most expensive markets in the world to bring a regulated GM crop product to market. The plant biotechnology industry is already subject to regulatory cost recovery via FSANZ, and by the APVMA (if there is an agricultural chemical registration required). As we have outlined in our submission for Phase One of this review, there is significant regulatory duplication for certain gene technology products between the OGTR and the APVMA. To avoid 'double charging' this overlap would need to be removed. If the OGTR were to also adopt cost-recovery mechanisms, a similar regulatory overlap between OGTR and FSANZ would need to be very closely examined to ensure double charging of applicants did not occur.

The cost of establishing, managing and signing-off on large scale, multi-year, multi-jurisdiction field trials to generate data for the OGTR is a significant cost already borne by the applicant. The cost of managing an Institutional Biosafety Committee is also already a significant cost borne by the applicant. The regulated gene technology sector in Australia remains a fledgling industry, with a very limited number of companies in the commercial agricultural biotechnology market. A user pays model would only increase inefficiencies as the bulk of the gene technology research carried out is within government funded research and teaching institutions, so would only result in a cost shifting exercise.

Other cost recovery schemes entitle the applicant, once successful, to access the market. Due to ongoing state moratoria (discussed previously) on commercial GM products, this is not the case for products approved by the OGTR, where a successful application can still be denied commercialisation by state governments. It is important to note that imposing such costs on registrants of the system simply imposes additional costs on end users and (for agricultural applications) on the farm gate.

4 THEME FOUR: SOCIAL AND ETHICAL ISSUES

1. How do we help the community to best understand the benefits and risks of a complex, science-based technology?

The 2017 Productivity Commission Final Report on the Regulation of Australian Agriculture notes that governments have a role in providing information about the benefits and risks of GM technology. This is analogous to the role of government in providing information about vaccinations to counter misleading safety claims, which can harm public health. Misinformation about GM technology could result in the community forgoing the benefits of GM foods. Governments are uniquely placed to provide information about GM technologies.

The Commission notes that some agencies already provide information to the public about GM technologies. For example, both FSANZ and the OGTR provide clear and accessible information about their risk assessment processes on their websites. In addition, risk communication is a key part of the OGTR's risk analysis framework, and FSANZ publishes its responses to studies that claim to show that GM foods have adverse effects, or that have been interpreted by others as being evidence of adverse effects.

There is, however, scope for governments and regulatory agencies to provide more information and to clarify misinformation about GM technologies. The recent[25] (and previous) studies on public attitudes to gene technology commissioned by the OGTR clearly indicate this. For example, according to the 2017 report, the public has a high level of trust in the OGTR, however, there is a lack of awareness of who they are. Thus, while information may be available on regulator websites in an effort to be transparent, the public do not know where to find it. The report provides a wealth of information that may be used to help the community better understand the risks and benefits of gene technology, such as the type of information that the public wants to receive from the OGTR, and this needs to be used. There is also a large body of published literature demonstrating the benefits of gene technology accumulated over the past twenty years that regulators can use. For example, CropLife International has compiled an extensive database (publicly accessible: http://biotechbenefits.croplife.org/) of publications demonstrating agronomic, environmental, and socio-economic benefits.

Further, CropLife believes there is the opportunity for the Government to re-launch the agency *Biotechnology Australia*, that existed within the Department of Industry from 1999 to ~2010. There is also the opportunity for a revised and refreshed National Biotechnology Strategy to build on the Strategy first outlined in 2000 and map the way forward for biotechnology policy in Australia.

[25] Craig Cormick and Rob Mercer (2017) Community attitudes to gene technology. Office of the Gene Technology Regulator.

2. Where does the community have confidence in the gene technology regulatory scheme? How can this be maintained?

As stated in question 1 (Theme Four), the 2017 (and previous) surveys on public attitudes regarding gene technology commissioned by the OGTR provide a wealth of information that if used could improve public confidence in the Scheme. It is clear in the report that the public trust and want to hear from regulators, and regulators need to improve public awareness of who they are and what they do. The report also shows that many respondents do not know about the Scheme but believe biotechnology can improve their way of life, and they are open to it provided it is adequately regulated or proven safe. This is information that regulators can more proactively provide to improve confidence in the Scheme.

3. Where is there a lack of community confidence in the gene technology regulatory scheme? Why might this be, and how can confidence be built?

As stated in our responses to questions 1 and 2 (Theme Four), there is a lack of public awareness of the Scheme and regulators, and this is detailed in the 2017 (and previous) surveys on public attitudes regarding gene technology commissioned by the OGTR. An additional problem is the prevalence and easy accessibility of misinformation on gene technology. CropLife believes that regulators have a role in more proactively, and more visibly, countering this misinformation to defend their risk assessments. FSANZ does this in response to studies that claim to demonstrate adverse effects of GM foods, and the OGTR could also publish reviews of studies claiming adverse effects relevant to the environmental risk assessment.

4. What does the public need to know?

This question is addressed in our responses to questions 1, 2 and 3 (Theme Four). The public needs to know that the Scheme exists, who the regulators are, that the Scheme regulates risks to human health and to the environment, and that the Scheme is sufficiently rigorous and complied with. The 2017 public attitudes document sets out the information that the public would like to receive from regulators.

5. Who is best placed to provide that information?

This question is addressed in our responses to questions 1, 2 and 3 (Theme Four): governments and regulators.

6. What does the public need in order to accept the increasing availability and range of use of gene technologies?

This question is addressed in our responses to questions 1, 2, 3 and 4 (Theme Four). The Consultation Paper refers to balancing consumer choice within the scope of the Scheme, however, this cannot be reconciled with the Scheme's goal of protecting human health and the environment on the principles of science-based risk regulation.

7. What does the public need in order to determine whether to provide social licence for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector?

This question is addressed in our responses to questions 1, 2, 3, 4, 5 and 6 (Theme Four).

8. What are the ethical considerations for enabling access to medical treatments?

CropLife recommends the Review Secretariat seek advice from the National Health and Medical Research Council who are the Australian experts in this area.

9. How do we ensure that information is available to the community on the value of GM and what it can do? Who is responsible for providing this, and why?

This question is addressed in our responses to questions 1, 2, 3 and 5 (Theme Four).

10. Is the Scheme putting up barriers to research and development and commercialisation of agricultural applications?

Yes, the uncertainty regarding pathways to market and the associated costs has limited industry investment in the development of technologies, and of new agricultural products for Australia. For example, while commercial cultivation of GM crops has been approved by the Scheme (via DIR licences), the Scheme has also allowed for state moratoria on commercial cultivation of GM crops, and repealing the ability of the states to impose these moratoria must be a priority of this review. In addition, the delay in providing regulatory clarity for "new" technologies such as genome editing has prevented technology investment and development, and this must also be a priority of this review.

Additional commentary on Compensation Funds

Considering the recent announcement by the Parliament of Western Australia of an Inquiry into mechanisms for compensation for economic loss to farmers in Western Australia caused by contamination by genetically modified material, CropLife believes it is important for this review to reconfirm the reasons a compensation scheme was rejected in the 2005-06 Statutory Review of the *Gene Technology Act 2000*. As outlined in CropLife's submission to Phase 1 of the review, in 2006, the Independent Panel concluded that:

> *"the need for a compensation scheme rested on the presumption that the common law and consumer protection legislation would not prove adequate for dealing with losses…"*
>
> *"Having considered these issues as well as the operation of the common law and consumer protection legislation in Australia, the Review concluded that a mandatory compensation scheme such as the Danish scheme should not be introduced."*[26]

[26] Statutory Review of the Gene Technology Act and the Gene Technology Agreement (2006), Commonwealth of Australia, p39.

CropLife supports the 2006 findings of the Independent Panel and recommends the 2017 Reviewers reconfirm the findings of the 2006 review that the common law and consumer protection legislation continue to provide adequate protection. There have been no incidences or situations since the Independent Panel's last assessment of this matter that would justify a change in this position.

Given that there is a national cooperative regulatory scheme for gene technology, no jurisdiction should be able to introduce arrangements to address the compensation issue unilaterally. Any proposals regarding compensation would need to be considered by the LGFGT.