BAYER CROPSCIENCE

SUBMISSION FOR THE REVIEW OF THE NATIONAL GENE TECHNOLOGY SCHEME 2017

PHASE TWO CONSULTATION

INTRODUCTION

Bayer CropScience, a division of Bayer AG which recorded annual consolidated sales of € 46.7 billion in 2016, is one of the world's leading innovative crop science companies in the areas of seeds and traits, crop protection and non-agricultural pest control. The company has a global presence in over 120 countries and has operated in Australia for nearly 90 years. Bayer's Crop Science division in Australia has a long history of leading innovation in sustainable agriculture and a strong focus on sales and research and development (R&D) in Australia.

Bayer CropScience welcomes the opportunity to provide input into Phase Two of the review of the national gene technology scheme ("review" and "Scheme" hereinafter). This submission should be consulted in conjunction with Bayer's previous submissions for Phase One of this review, and for the technical review of the Gene Technology Regulations ("technical review" hereinafter). Bayer also supports submissions made by CropLife Australia for this review, both Phases One and Two, and for the technical review.

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. While the Scheme commenced in 2001, its evolution began in the mid-1970s following the emergence of "recombinant DNA" technologies. It has since provided efficient, effective, robust, and most importantly, science-based regulation of any resulting genetically modified organisms (GMOs). However, today the Scheme only provides certainty for some long-established gene technologies that result in well-known outcomes and needs modernisation. Technologies that have emerged since its inception, but have already existed for at least a decade, are still labelled as "new", e.g. site directed nucleases (SDN-1, SDN-2, SDN-3) and oligo directed mutagenesis (ODM) which were the subject of the technical review. These "new" technologies challenge the Scheme today because it is not sufficiently reactive to technological change.

To be "future-proof", the Scheme needs to retain broad protection goals and definitions, but its regulatory scope should be tempered by up-to-date lists of exclusions that include certain technologies and/or organisms that do not pose new risks relative to that already existing or that can arise using other unregulated technologies. Mechanisms for the regular review and revision of these exclusion lists are 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. Such an approach also promotes stakeholder confidence in the Scheme.

In conjunction with exclusion mechanisms, the regulatory scope of the Scheme should also be streamlined for certain new and established gene technologies and/or well-characterised GMOs. For example, the CropLife Australia submission for Phase One of this review includes a Decision Tree to illustrate improved risk-based regulation consistent with a tiered approach. This approach seeks to tailor the level of regulatory oversight to the risks posed by an end-product, and is discussed further under other questions in this submission (see Theme Two).

The scope of this question is technological advances that can be "foreseen". While reform that remains applicable long term may be an aspiration of this review, to be effective the scope needs to be realistic and foreseeable, and it would not be appropriate to attempt to regulate technology concepts that are today merely speculation. For example, many potential applications of gene drives have been proposed, however after several years of research proof-of-concept studies are limited and significant knowledge and technical challenges remain[1]. 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"[2] 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 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?

Concerns raised about the human health and safety and environmental impacts of "new" technologies are the same as those raised in regard to genetic modification since the 1970s. Genetically modified (GM) crops developed using established techniques have been commercially cultivated since 1996 without credible evidence for adverse environmental effects, or a single substantiated adverse effect on human or animal health. Regulatory agencies, international organisations (e.g. World Health Organisation[3]) and scientific organisations throughout the world

[1] Australian Academy of Science (2017) Synthetic Gene Drives in Australia: Implications of Emerging Technologies. Discussion Paper.
[2] National Academies of Sciences, Engineering, and Medicine (2017) Preparing for the Future Products of Biotechnology. Washington, DC. National Academies Press.
[3] See: http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/.

that have reviewed the available research have declared GM crops and food derived from them to be safe. The available evidence was recently reviewed by the National Academy of Sciences, who could not find conclusive evidence of cause-and-effect relationships between GM crops and environmental problems, or substantiated evidence that foods derived from GM crops were less safe than foods from non-GM crops[4]. Further, a recent meta-analysis of the available evidence for herbicide tolerant and insect resistant crops revealed significant agronomic and environmental benefits[5]. Thus, as predicted by scientists based on the available scientific evidence, GM crops have posed no unique or incremental risks different from those posed by crop varieties produced through conventional breeding methods.

The Bayer submission for the technical review provides detailed scientific rationale in support of Option 4 that was proposed in the Discussion Paper:

"E*xclude certain new technologies from regulation on the basis of the outcomes they produce*."

In effect, Option 4 excludes organisms developed using genome editing methods that make small edits from the scope of regulatory oversight, including SDN-1, SDN-2 and ODM. This exclusion is justified based on comparison of the DNA sequence changes obtained using these methods, and the potential risks, with that arising from spontaneous mutation or developed using conventional breeding methods, e.g. cross breeding, hybridisation, induced mutagenesis. The Bayer submission for Phase One of this review then provides 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) to give effect to Option 4.

In crops, genome editing may be used in various applications with outcomes ranging from transgenic (e.g. SDN-3 to insert a gene from outside of the crop's germplasm pool) to targeted mutagenesis (e.g. SDN-1, SDN-2, ODM). Either way, the environmental impacts of such crops will be comparable to that developed with earlier breeding tools – conventional or GM. We have not identified an application of a "new" technique that presents a fundamental change from existing GM or non-GM crops, and for both extensive evidence exists regarding their environmental impacts.

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 methods, then regulation of such products cannot be practical, efficient or proportionate as it would not be addressing new or increased risks for human health or the environment.

The ability to distinguish a product for the purpose of regulatory compliance requires some form of detection method. The ability to develop a DNA-based detection method for an organism developed using genome editing depends on the type of DNA sequence change(s). For example, where this involves stable insertion of DNA sequence, PCR-based detection methods can be developed in the

[4] National Academies of Sciences, Engineering, and Medicine (2017) Genetically Engineered Crops: Experiences and Prospects. Washington, DC. National Academies Press.
[5] Klümper W, Qain M (2014) A Meta-Analysis of the Impacts of Genetically Modified Crops. *PLOS One* 9: e111629.

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 an alternative option to PCR for identifying sequence changes. However, at present there is insufficient information to make any general statements on whether PCR or sequencing-based methods can be successfully developed or practically implemented for such DNA changes, or if they will be effective for detecting and identifying the modification in commerce, e.g. a single grain versus a bulk shipment.

A very important consideration and limitation regarding the 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 may not be possible to conclusively determine the mechanism by which the changes in DNA sequence arose.

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. Bayer 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 (RAF) used by the OGTR.

Gene drives, which are also often labelled as "synthetic biology", are GMOs that are within the scope of the current Scheme. There may be some misconception that gene drives are developed using technologies that may be excluded from the scope of regulatory oversight because they are primarily developed using the genome editing technique known as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR). However, gene drives and are not currently excluded from the scope of regulatory oversight, and they are not excluded by the recommendations of Bayer or CropLife Australia for updating the Scheme, or by the proposed amendments to the Gene Technology Regulations resulting from the technical review. 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 question 4 above, the key consideration is whether risks presented by the resulting organisms can be assessed according to the current Scheme. GMOs developed for managing an invasive species are within the scope of the existing risk assessment process of the OGTR, and are therefore subject to the RAF applicable to dealings involving intentional release (DIR) into the environment. 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 the case for GMOs containing 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 question 5 above, the existing RAF, RARMP and DIR licencing 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 or its intended use is perceived to be "new" it presents unprecedented challenges for risk assessment and risk management. There is a large body of relevant experience and guidance to support adaptation (if required) of risk assessment methodologies and risk management on a case-by-case basis, e.g.: the foundational materials of the OECD[6] and the National Academy of Sciences[7], materials developed by experienced regulatory agencies[8], risk assessments shared by regulatory agencies in the Biosafety Clearing House of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[9], standards developed by the International Plant Protection Convention[10], biology consensus documents[11], and the scientific literature.

For organisms containing gene drives, many potential applications have been proposed however proof-of-concept studies are limited and significant knowledge and technical challenges remain[12]. The most advanced application is the control of mosquito populations to prevent disease transmission. The use of gene technology to control mosquitoes is not new, and the World Health

[6] OECD (1986) Recombinant-DNA Safety Considerations. Organization for Economic Cooperation and Development, Paris.
[7] National Academy of Sciences (1987) Introduction of Recombinant DNA-engineered Organisms into the Environment: Key Issues. National Academy Press, Washington DC.
[8] E.g. United States Environmental Protection Agency (1998) Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F.
[9] See: http://bch.cbd.int/database/riskassessments/.
[10] E.g. 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.
[11] E.g. see OGTR: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1; and OECD: http://www.oecd.org/science/biotrack/safetyassessmentoftransgenicorganismsoecdconsensusdocuments.htm.
[12] Australian Academy of Science (2017) Synthetic Gene Drives in Australia: Implications of Emerging Technologies. Discussion Paper.

Organisation Special Programme for Research and Training in Tropical Diseases published the "Guidance Framework for Testing of Genetically Modified Mosquitoes" in 2014. In response to gene drive developments for mosquitoes, the framework in this document is currently being revised.

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 can be described as 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 of products for release into the environment, a greater emphasis on regulation that is product-based is more suitable.

As noted previously, the Bayer submission for the technical review 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 of the Scheme. However, the Bayer submission for Phase One of this review made specific proposals that amounted to minor amendments to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (exclusion lists in Schedules 1 and 1A) to give effect to Option 4. The recommended amendments retain broad definitions 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. Therefore, Bayer recommends that the Scheme should combine elements of both a process and product-based system.

There is a perception that 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. Under this scheme, the regulation of plants is triggered by trait "novelty" irrespective of the method used to develop it, with other related regulations for "novel foods" and "novel feeds". In practise, the scope of this system is broad: it may cover novel traits developed using conventional breeding methods and therefore imposes a disproportionate regulatory burden on plant breeders that is absent in process-based systems. The scope of this system also extends to plants with novel traits developed using "new" genome editing techniques,

e.g. herbicide tolerant canola developed using ODM was approved in 2014[13]. In contrast, this product was excluded from regulatory scope by the United States Department of Agriculture, which is also a product-based system. These two systems regulate specific, but different, defined product risks. For a broad product-based system like Canada's, as for process-based systems, proportionate risk-based regulation requires additional mechanisms that allow for exclusions of certain organisms (products).

Thus, regardless of the regulatory trigger, a regulatory 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. It is also important that the Australian Scheme retains its underlying principles of efficient and effective regulation that is proportionate to risk. The exclusions provided for in the Gene Technology Regulations are a mechanism by which the Regulator can improve regulatory efficiency, effectiveness and proportionality. As long as these are reviewed and updated regularly on the basis of scientific understanding and experience, the process trigger could remain appropriate for the Scheme.

As noted previously, the CropLife Australia submission for Phase One of this review included a Decision Tree to illustrate improved risk based regulation that is consistent with a tiered approach. 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).

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

As stated above in question 1, Bayer recommends that the Scheme should maintain its emphasis on risk, and combine elements of both a process and product-based system. The Scheme also 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.

The exclusion lists in the Gene Technology Regulations 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. The time taken to amend the Gene Technology Regulations also needs to be faster, e.g. less than one year. This requires, as recommended by the National Academy of Sciences[14], 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. Importantly, any amendments to the exclusion lists must be clearly written; as pointed out in the Bayer submission for Phase One of this review, existing exclusions that appear to apply to "mutants" and certain exchanges of DNA sequence, e.g. between micro-organisms, may be interpreted differently and/or inconsistently.

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

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

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, and for stakeholder confidence in the Scheme. 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.

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

As stated in questions 1 and 2 above, the Scheme needs to be defined by appropriate protection goals, be based on appropriate definitions, and provide mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation. Bayer considers the existing protection goal of the Scheme – the health and safety of people and of the environment – to remain appropriate. Also, in its submission for Phase One of this review, Bayer 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 Discussion Paper for the technical review, 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.

The Bayer submission for Phase One also recommended amendments to the exclusion lists of the Gene Technology Regulations to clarify regulatory oversight regarding the use of established technologies in micro-organisms. These technologies, e.g. DNA sequence exchanges via homologous recombination, can have similar outcomes as "new" genome editing technologies, but they have been since the 1970s and should not be confused with them. These technologies also have similar outcomes to exchanges of genetic material that occur in nature, and to conventional methods used for microbial strain improvement, e.g. induced mutagenesis. Currently, it is unclear how exclusions in the Gene Technology Regulations apply to organisms developed using these methods, with advice from the OGTR taking a precautionary approach that is out of step with current scientific knowledge.

Also, the Decision Tree proposed by CropLife Australia in Phase One of this review provides several streamlining "fixes" for both established and "new" technologies that could be incorporated now. While this Decision Tree was developed for use with crops, it could be adapted for micro-organisms, or any other organism.

These "fixes" recommended by Bayer are aimed at improving the effectiveness and responsiveness of the Scheme by providing regulatory clarity for both "new" and established technologies that is risk-based and proportionate, and these could be incorporated now. These "fixes" also 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. To remain effective and responsive 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 time taken to amend the Gene Technology Regulations also needs to be faster, e.g. less than one year.

4. How would you streamline the existing scheme?

This question is addressed in our responses to questions 1, 2 and 3 above. These provide several recommendations, and refer to detailed rationale provided in the Bayer submissions for the technical review and Phase One of this review. In addition, the CropLife Australia submission for Phase One of this review includes a Decision Tree with a "Streamlined Risk Assessment" (SRA) process. The responses provided in this submission should be read in conjunction with the earlier submissions of Bayer and CropLife.

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

The Bayer submission for Phase One of this review sets out in detail its concerns regarding duplication between the OGTR, FSANZ and the APVMA for plant and animal products regulated as GMOs, and the regulatory burden, time delays, and costs this imposes with no associated benefit. To improve this situation, Bayer recommends that the APVMA accept 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 a 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 above for questions 1, 2 and 3 (Theme Two). These include reference to the Decision Tree provided by CropLife Australia in its submission for Phase One of this review which is consistent with a tiered approach to risk-based regulation.

The Decision Tree is designed to operate in conjunction with CropLife's recommendations regarding Option 4, which excludes SDN-1, SDN-2, ODM and cisgenesis when used in plants from being gene technology, and null segregants from being GMOs. Detailed scientific rationale for these recommendations are provided in the Bayer and CropLife Australia submissions for the technical review. If all of those recommendations are ultimately not adopted via this review or the technical review (which has proposed exclusion of SDN-1 and null segregants), the technologies should fall within the scope of the "Regulatory Notification" (RN) process in the Decision Tree proposed by CropLife. The RN process applies to crops where the following criteria are met:

a) The genetic changes are indistinguishable from that resulting from spontaneous mutation or the use of conventional breeding methods. This would include genetic changes resulting from SDN-1, SDN-2 and ODM.

b) The genetic modification is the result of cisgenesis or intragenesis.

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?

As described previously, CropLife Australia's submission to Phase One of this Review includes a Decision Tree with RN and SRA processes (questions 4 and 6 above) providing for risk tiering. The SRA process applies to regulated technologies and/or organisms intended to be released into the environment under a licence (DIR). The SRA applies when the following criteria are met:

a) The GMO is well characterised (e.g. an OGTR Ecology and Biology document exists);

OR

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

OR

c) The GMO has been approved for cultivation in another country with a "recognised" biosafety regulatory system (e.g. one that follows the OECD or Codex Risk Assessment Guidelines).

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 would not apply where the technology and/or organism is excluded from regulatory scope by the Gene Technology Regulations, or where the RN process should apply. As noted above in question 6, the RN process may apply to technologies/organisms not expressly excluded by the Gene Technology Regulations.

This SRA process aims to tailor risk assessment and incorporate accumulated scientific knowledge since the early assessments of similar products, and the familiarity and history of safe use of certain traits and crops. Existing examples the SRA process could apply to include insect resistant and herbicide tolerant GM cotton that has been cultivated on a commercial scale in Australia for a long period of time.

While the SRA and RN processes were 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.

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

A streamlined and tiered approach, such as the Decision Tree proposed by CropLife Australia that tailors risk assessment, aims to incorporate current scientific understanding and accumulated experience to reduce 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 and tiered approach, such as the Decision Tree proposed by CropLife Australia that tailors risk assessment, also improves the efficiency of the Regulator and the use of OGTR resources, as time is not wasted on repeating unnecessary or lengthy risk assessments that may be required as a result of Scheme's process trigger.

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

And

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

The Scheme already regulates different organisms and applications differently, and it should be remembered that other regulatory Schemes are applicable to the products of some of these applications. While the Scheme's 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 plants, microorganisms, vertebrate and invertebrate animals, and aquatic organisms, and for particular intended uses such as biological control, vaccines, remediation and animal feed. These different approaches are necessary for the identification and management of the different risks posed by the different organisms and their intended uses, and it is not necessary to change the broad definition of GMO.

As described above for question 7 (Theme Two) CropLife Australia's submission to Phase One of this Review includes a Decision Tree with RN and SRA processes. While this was developed for crops based on current scientific knowledge and experience, it could be adapted for other organisms where this is also justified based on scientific knowledge and experience.

Also as noted several times in this submission, the Bayer submissions for the technical review and Phase One of this review provides detailed scientific rationale in support of amendments that exclude certain "new" and established technologies from the scope of the Scheme. These proposals include broad exclusions (not organism-specific), exclusions applicable to plants, and exclusions applicable to micro-organisms, and these are justified based on current understanding of the technologies and the accumulated body of scientific knowledge and expertise in biotechnology for these organisms.

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 current requirements of the Scheme related to risk assessment and risk management are adequate for identifying potential long term effects on humans and the environment. Regulatory decisions are made based on the best available scientific evidence, and for commercial releases under licence in Australia, the evidence for lack of risks to human health and the environment has been unambiguous. We note that there is no credible evidence for adverse effects on humans or the environment resulting from dealings with GM crops anywhere in the world since they were first commercially cultivated in the mid-1990s (see also question 2, Theme One). Studies that claim to report adverse effects have been examined and discounted by regulatory agencies around the world[15], including FSANZ[16]. Criticisms of such studies generally concern weaknesses in the methodology used. In contrast, wherever possible, regulatory data generated for risk assessment is based on established scientific principles and international best practice, e.g. the guidelines of Codex, the World Health Organisation and the Food and Agriculture Organisation of the United Nations. These studies are also aimed at addressing questions about the organism that are relevant to risk assessment. Where novel hazards are not identified, there is no scientific justification for long-term studies or speculative studies searching for "unknown unknowns".

[15] E.g. European Food Safety Authority (EFSA): https://www.efsa.europa.eu/en/press/news/121128.
[16] See: http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman%27s-study.aspx; http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx.

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?

Bayer 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. Bayer's understanding is that principles-based regulation could allow for more outcomes-based regulation and flexibility, e.g. general principles could be applied to new gene technologies. However, it is also important for developers to have regulatory clarity and certainty, and for the public to have confidence in the Scheme, and some measure of rules-based regulation may be required. We would need to see a specific set of proposals to comment on before committing any support to a revised approach.

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 Scheme should retain its focus on science and risk-based regulation. Non-science aspects, such as trade, 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, they 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?

Experience has shown that trade disruptions can result where a GM-derived product does not have the required regulatory approvals in an importing country, irrespective of the crop/product being approved in the country of cultivation and export. Asynchronous regulatory approvals, combined with importing countries maintaining a 'zero tolerance' for unapproved crop biotechnology products, present trade barriers. This problem is exacerbated if low levels of the unapproved product are detected in a shipment of otherwise non-GM or approved GM product, referred to as low level presence (LLP).

Bayer is a member of the industry initiative "Excellence Through Stewardship" and is committed to launching GM crops in cultivation countries when approvals have been obtained in key trading partners that have functional regulatory systems. This is effectively a "global registration", which is an extremely expensive undertaking with unpredictable timelines to market, and it presents a substantial hurdle for small enterprises and public research institutions. To improve this situation, Bayer encourages the participation of the OGTR in international fora to foster best practice and harmonisation in relation to LLP and regulatory standards.

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 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 integrity of the scheme and the credibility of the Regulator will be immeasurably preserved by a Scheme that is nationally consistent and robustly science-based, and including the principles of good governance, including clarity, predictability, transparency, and consistency in application.

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, 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?

Bayer supports the nationally consistent approach to regulation provided by the intergovernmental Gene Technology Agreement, and supports continued efforts to ensure regulatory clarity. Bayer does not support politicisation of the Scheme, particularly at State level, e.g. through the implementation of GM crop moratoria.

In the previous reviews of the Scheme, the implementation of a nationally consistent system has been a key recommendation, and it is also an underlying principle of the Scheme. However, this has not been realised with States continuing to impose moratoria, despite the lack of evidence to support them. Bayer recommends that the policy principle, as it currently stands, should be deleted or substantially amended, e.g. opt out provisions for States should only be on the basis of clear evidence of adverse impacts on human health or the environment. This issue is addressed in more detail in question 7 below.

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

Bayer supports international regulatory harmonisation to prevent global regulatory inconsistences (such as incidents of LLP; see question 16, Theme Two) and to encourage access to new technologies. Australia's regulatory system is influential and precedent setting, particularly in the Asia-Pacific region. It is in Australia's interest that other countries also adopt regulatory systems based on sound science, and the OGTR should participate in international standards setting fora and capacity building activities internationally when opportunities arise.

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 latter should also include the ability to appropriately adjust regulation (e.g. a tiered approach) to incorporate scientific knowledge and experience. In addition to these, regulation should not be influenced by political and other non-science based criteria.

The underlying principles of the Scheme also recognise that there are a range of perspectives. There are perspectives that are ideologically opposed to gene technology irrespective of the integrity of the Scheme and the corpus of scientific evidence. These perspectives 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, Bayer 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 scientific knowledge and experience. The time taken to amend the Gene Technology Regulations also needs to be faster, e.g. less than one year.

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 four above, 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 to the Scheme that allow for lowering of the level of regulatory oversight, e.g. risk tiering, 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?

Moratoria based on political and ideological grounds are not consistent with the protection goals and underlying principles of the Scheme, and therefore this question is not relevant to the review of the Scheme.

However, it should be noted that nearly 15 years after GM moratoria were first introduced in Australian States, there remains zero evidence to support any trade or marketing advantages provided by them. 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 in detail in the submissions of Bayer and CropLife for Phase One of this review.

The situation in Australian States has had a detrimental impact on the competitive future of an entire sector, with far-reaching implications for the environment, investment in R&D, innovation in agriculture, and State economies. 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. Bayer recommends that Section 21(1)(aa) of the *Gene Technology Act 2000*, by which the Forum can make policy principles that enable States to circumvent and undermine the Scheme, should be repealed.

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

Considerations of economics and trade are not consistent with the protection goals and underlying principles of the Scheme, and therefore this question is not relevant to the review of the Scheme.

However, it should be noted that those jurisdictions in which GM and non-GM crops coexist, all effectively trade in key international markets, and there is no evidence for lack of market entry of a non-GM crop that is grown in the same jurisdiction as a GM crop. As an example, 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.

Furthermore, since the adoption of GM crops, farmers all over the world and in Australia have grown and marketed GM and non-GM crops (including organic) without impacting on each other's production system, i.e. coexistence of different production systems is a reality.

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 that include transparent, science-based, 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 Forum to make policy principles should be repealed.

The ability of States to introduce moratoria on unsubstantiated grounds has prevented a clear and predictable pathway to market for developers of GM crops in Australia. This has had a detrimental impact on agriculture, which suffers from chronic underinvestment, both in the development of new crop varieties and in the technologies used to develop them[17]. If moratoria or mechanisms that achieve similar outcomes are supported by the Scheme, it is rendered unfit for purpose.

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, there is no clear path to market in Australia for crops developed using "new" technologies, and is reflected in reduced investment in R&D and agricultural innovation.

As also stated previously in this submission, there is also no clear path to market for GM crops in Australia due to mechanisms in the Scheme allowing for State moratoria, and for the Scheme to be effective, the ability of the Forum to make policy principles should be repealed. This situation has had a detrimental impact on Australian agriculture, with reduced investment in R&D and limited commercialisation of innovative products. The environmental benefits of adopting GM crops have been demonstrated since the establishment of the Scheme, for example the CropLife International publication database[18] currently contains 354 publications identifying benefits resulting from changes in agricultural practices that include 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. The lost opportunities due to regulatory delays preventing adoption of GM crops have also been estimated[19].

These benefits of gene technology GM crops are not harnessed for Australians as long as mechanisms exist in the Scheme that allow for State moratoria on grounds that are inconsistent with its principles, and mechanisms are not introduced to allow for timely exclusions and risk-tiering of regulation consistent with scientific knowledge and experience. 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. These issues prevent a clear path to market and impose undue regulatory burden on developers that discourages investment.

[17] 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.
[18] See: http://biotechbenefits.croplife.org/impact_areas/environmental-benefits/.
[19] Zilberman D, Kaplan S, Wesseler J (2015) The Loss From Underutilising GM Technologies. *AgBioForum* 18:312-319.

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

As recommended by the NAS report (see question 1, Theme One), regulators need the capacity and necessary mechanisms to continuously "scan the horizon" for new processes and products that could present novel risks, and to ensure their approaches to risk assessment remain robust and effective. However, for the Scheme to be effective, its regulatory scope needs to be limited to one that is realistic and foreseeable, and it should not attempt to regulate technology concepts that are today merely speculation. As recommended by Bayer throughout this submission, 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 scientific knowledge and experience. The time taken to amend the Gene Technology Regulations also needs to be faster, e.g. less than one year.

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

As stated previously, Bayer 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. Bayer 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 potential risk as conventional breeding methods.

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 Organisation agreements[20] 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?

Bayer does not support the consideration of "benefits" as part of the Scheme's risk assessment or decision-making process. 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; rather, these rely on assumptions, and they provide weak and speculative data with limited application.

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

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

An aspect of gene technology that could benefit from clarity in policy position is low level presence (LLP). The submissions of Bayer and CropLife Australia for Phase One of this review provide detailed views and recommendations concerning LLP. These include:

- 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 among global regulators could minimise the differences in approach and timing of approvals, and reduce the time required to conduct risk assessments and make management decisions in countries where LLP situations may occur.

Bayer 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?

Bayer has made recommendations regarding regular review of the Gene Technology Regulations (see Theme One) and streamlined processes for risk-based regulation (see Theme One and the CropLife Australia 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. This would promote more confidence in the Scheme, for the regulated community and the public.

The Scheme would also be enhanced by national consistency. Currently, decisions made by the Regulator in accordance with the Scheme are in effect vetoed by decisions of States to impose moratoria on unsubstantiated grounds. This has prevented a clear path to market and commercialisation of GM crops in Australia, and stifled investment in agricultural innovation. This situation needs to be rectified by removing the mechanisms that give States the ability to impose moratoria on unsubstantiated grounds that are not relevant to the protection goals of the Scheme.

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?

Bayer's concerns and recommendations concerning 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. Bayer 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, Bayer 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 Australian Pesticides and Veterinary Medicines Authority (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.

It should be noted that significant costs are already borne by applicants. For example, the management of Institutional Biosafety Committees, and establishing, managing and signing-off on large-scale, multi-year, multi-jurisdiction field trials to generate data for the OGTR's risk assessment. The regulated gene technology sector in Australia remains a fledgling industry, with a limited number of companies in the commercial agricultural biotechnology market, and most research is carried out is within Government funded research and teaching institutions.

Another very important consideration is that other cost recovery schemes entitle the applicant, once successful (approved), to access the market. This is not the case with an OGTR approval, as ongoing State moratoria prevent GM crop commercialisation.

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 RAF, and FSANZ publishes responses to studies that claim to demonstrate adverse effects from GM crop-derived foods[21].

However, there is scope for governments and regulatory agencies to provide more information and to clarify misinformation about GM technologies. The recent[22] (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 the OGTR needs to be resourced to make use of this information. 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[23] of publications demonstrating agronomic, environmental, and socio-economic benefits. Estimations of lost opportunities due to prevented adoption of GM crops have also been reported[24].

Further, Bayer 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.

[21] See: http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx.
[22] Craig Cormick and Rob Mercer (2017) Community Attitudes to Gene Technology. Office of the Gene Technology Regulator.
[23] See: http://biotechbenefits.croplife.org/.
[24] Zilberman D, Kaplan S, Wesseler J (2015) The Loss From Underutilising GM Technologies. *AgBioForum* 18:312-319.

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

As stated in question 1 above, 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, provided they are appropriately resourced to do so.

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 above, there is lacking 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. Bayer believes that regulators have a role in more proactively, and more visibly, countering this misinformation to defend their risk assessments, and they need to be resourced to do so. 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 above: 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 additional 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 above: governments and regulators. The 2017 survey of public attitudes also indicated a high level of awareness and trust in the CSIRO, indicating that the public are receptive to information from the scientific community also.

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 above. 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 above. It is also important that the public understands the protection goals and underlying principles of the Scheme, and that regulators are resourced to carry out their functions.

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

Bayer recommends the Review Secretariat seek advice from the NHMRC 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 the questions above.

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

Yes, as stated throughout this submission, the uncertainty regarding pathways to market and the associated costs has limited industry investment in the development of gene technologies, and of new agricultural products for Australia. For example, while commercial cultivation of GM crops has been approved by the Scheme (via OGTR DIR licences), the Scheme has also allowed for State moratoria on commercial cultivation of GM crops, and repealing the mechanisms that provide the States with the ability to impose moratoria on unsubstantiated grounds that are not relevant to the protection goals of the Scheme 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. Bayer makes several recommendations throughout this review to address this.