

About the Crop Science Division of Bayer Australia Ltd.

Access to Australia's diverse agricultural sector, a large research base and proximity to Asian markets are key factors which underpin Bayer CropScience's investment in Australia.

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.

Investment in Australian partnerships

Investment in Australian production and research infrastructure underpins Bayer's agricultural business operations. Bayer operates two factories near Brisbane and Perth, ensuring year-round supply of some 400 products. The Brisbane factory is also now a major export centre supplying Asia and New Zealand and other global Bayer markets.

With innovation at the heart of Bayer CropScience, the company has taken a long-term view of investment in research and development. In 2014, Bayer opened a A\$14 million state-of-the-art Wheat and Oilseeds Breeding Centre at Longerenong College, near Horsham, Victoria – the first of its kind in Australia. The Centre is focusing on the development of new wheat and oilseeds varieties with higher yields and productivity improvements specifically for Australian agriculture. Bayer also recently opened an Animal Health Research Centre in New Zealand which has the proximity, experience and focus to provide tailored solutions for the Australian market.

These investments form the critical infrastructure for all facets of Bayer's agricultural business, including product manufacturing, crop protection, breeding, seed production and fundamental R&D.

1) current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development.

(i) New technologies

The recent technical review of the Gene Technology Regulations commenced by the Gene Technology Regulator canvassed four regulatory options to provide clarity in relation to new technologies. The technologies that were the focus of the technical review included oligo-directed mutagenesis (ODM) and site-directed nuclease techniques (SDN), which are defined in the Discussion Paper: Options for Regulating New Technologies of October 2016 (“Discussion Paper”, see Appendix 2). Current and foreseeable technological developments may be grouped into these general categories, however the way in which they are defined will need to be broader than that provided in the Discussion Paper for the Scheme to appropriately accommodate the continuum of technological developments. For example, the SDN definitions specify DNA cleavage by nucleases, which create double strand breaks, but applications have also been described that utilise nickases for single and double-stranded breaks,¹ and the use of deaminases for specific point mutations without the need for DNA cleavage or the use of a template to guide DNA repair.² Thus, technological developments are already blurring the “template” distinction between the “SDN-1” and “SDN-2” categories used in the technical review.

Submissions were made during the public consultation on the Discussion Paper by Bayer CropScience³ and CropLife Australia⁴ supporting Option 4, which in effect excludes the ODM, SDN-1 and SDN-2 categories from the scope of the regulatory Scheme, with the SDN-3 category regarded as comparable to regulated transgenics developed using established recombinant DNA technologies and regulated as such. Of the four options, this was considered to provide the most “future-proof” approach to enable the Scheme to accommodate current and future technological developments. It was also considered the option most consistent with the original scope and intent of the Scheme, and the central principle of regulation that is commensurate with risk. Option 4 is

¹ See: F. Ann Ran, Patrick D. Hsu, Chie-Yu Lin, Jonathan S. Gootenberg, Silvana Konermann, Alexandro Trevino, David A. Scott, Azusa Inoue, Shogo Matoba, Yi Zhang and Feng Zhang (2013) Double nicking by RNA-guided CRISPR Cas9 for enhanced genome editing specificity. *Cell* 154:1380–1389. doi:10.1016/j.cell.2013.08.021.

² See: Alexis C. Komor, Yongjoo B. Kim, Michael S. Packer, John A. Zuris and David R. Liu (2016) Programmable editing of a target base in genomic DNA without double-stranded DNA cleavage. *Nature* 533:420-424. doi:10.1038/nature17946.

³ Available at:

[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/\\$File/Bayer%20CropScience.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/$File/Bayer%20CropScience.pdf).

⁴ Available at:

[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/\\$File/CropLife%20Australia.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/$File/CropLife%20Australia.pdf).

also most consistent with the overarching objective of the present review of the Scheme of strengthening and improving it and ensuring its functionality into the future. Detailed scientific rationale in support of option 4 is provided in the Bayer CropScience and CropLife Australia submissions.

A perceived limitation of option 4, according to the Discussion Paper and some submissions made by others, is that it is product-focused, and its implementation is restricted by current policy settings. A central feature of the underlying policy is a process (“gene technology”) trigger for regulation as a “genetically modified organism”. While the policy setting was not in the scope of the technical review, it is in the scope of the review of the Scheme. However, we believe that option 4 can be implemented within the current policy setting with minor amendments to definitions in the *Gene Technology Act* and the lists of excluded gene technologies (Schedule 1A) and genetically modified organisms (Schedule 1) in the Gene Technology Regulations, provided that technology categories are defined broadly.

Box 1: Proposed amendment to the definition of “gene technology” in the *Gene Technology Act*
gene technology means any technique for the modification of genes or other genetic material, but does not include:

- (a) sexual reproduction;
- (b) homologous recombination;
- (c) techniques that do not result in the integration of one or more genes in a defined genetic construct into the genome;
- (d) any other technique specified in the regulations for the purposes of this paragraph.

The inserted text (underlined) gives effect to option 4 in that it excludes upfront from regulatory scope the technique categories of ODM, SDN-1 and SDN-2 when used in any organism. It also does not change the regulatory status of organisms that are currently, and have historically been, within regulatory scope as originally intended by the Scheme (namely, transgenic organisms). In addition, the newer SDN-3 category of techniques are captured within regulatory scope, as these involve the integration of a gene construct. The term “integration” is intended to include the mechanisms of “insertion”, as used in relation to transgenics developed using established recombinant DNA techniques, and “copying”, “addition” or “incorporation” of sequences with the use of SDN-3.

The proposed amendment to the definition of “gene technology” would capture the application termed “cisgenesis” used in plants within regulatory scope. While this application was not directly in the scope of the technical review, the submissions of Bayer CropScience and CropLife provided detailed scientific rationale for its use in plants to be excluded from regulatory scope. The exclusion of cisgenesis is considered to be consistent with regulation that is commensurate with risk as comparable outcomes can be achieved using conventional plant breeding methods that are not regulated, and we again propose here that it is excluded from regulatory scope. This can be achieved through amendment of Schedule 1A of the Gene Technology Regulations, as proposed in Box 2 below.

Box 2: Proposed amendment to the Schedule 1A in the Gene Technology Regulations

Schedule 1A Techniques that are not gene technology

Item Description of technique

- 1 Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
- 2 Electromagnetic radiation-induced mutagenesis.
- 3 Particle radiation-induced mutagenesis.
- 4 Chemical-induced mutagenesis.
- 5 Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
- 6 Protoplast fusion, including fusion of plant protoplasts.
- 7 Embryo rescue.
- 8 *In vitro* fertilisation.
- 9 Zygote implantation.
- 10 A natural process, if the process does not involve genetically modified material.

Examples

Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

- 11 Cisgenesis, when used in plants to transfer whole genes from the same or a cross-compatible species.

The inserted text (underlined) applies to cisgenesis used in plants only, which may be achieved using established recombinant DNA or SDN technologies, and this exclusion is intended to apply irrespective of the technology used.

- (ii) Null segregants

In the technical review the Gene Technology Regulator stated their intention to clarify that null (or negative) segregants are not GMOs and not subject to regulation. The Bayer CropScience and CropLife Australia submissions support this initiative, however proposals to change the *Gene Technology Act* to achieve this were not within the scope of the technical review. Here, we propose that this clarification can be achieved with minor amendment to the definition of “genetically modified organism” in the *Gene Technology Act* provided below in Box 3.

Box 3: Proposed amendment to the definition of “genetically modified organism” in the *Gene Technology Act*

genetically modified organism means:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism that has not inherited genes or other genetic material from an organism (the *initial organism*) that occurred in the initial organism because of gene technology;
- (f) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

This is intended to include null segregants derived from transgenic organisms (within regulatory scope), as well as organisms developed from techniques such as SDN-1 or SDN-2 where their development has involved an intermediate transgenic step.

(iii) Established technologies

The definition of “gene technology” in the *Gene Technology Act* includes “homologous recombination” as a technique that is excluded from regulatory scope. This is understood to refer to the conserved pathway of DNA repair in response to DNA strand breaks that occurs in all life forms. The function of homologous recombination is to maintain genomic integrity, but it also promotes the re-assortment of genetic material into new combinations and is important for

generating genetic diversity. Homologous recombination is one of the DNA repair mechanisms underlying the effectiveness of certain new technologies (e.g. SDN-2).

Homologous recombination is known to occur via horizontal gene transfer between microorganisms, particularly between species of bacteria, archaea, viruses, and also in fungi. In this process, DNA from a donor is integrated into the genome of a recipient cell, with regions of sequence identity (homology) in the two DNA molecules defining the exchange. Thus, this process can be utilized as a mechanism for the deliberate introduction of precise genetic modifications, and has been used for this purpose in bacteria since the 1970s. This approach should not be confused with new technologies (ODM, SDN) as it was well established at the time that the Scheme was developed. However, it should be recognised that the types of precise genetic modifications that can be achieved using homologous recombination are the same as that which can be achieved with new technologies (namely, deletions, edits, and additions). In addition, due to the challenging environments which microbes inhabit, genetic modifications, including those listed above, occur continuously and are inherent to their dynamic genetic blueprint.⁵ Thus, these types of outcomes may arise via DNA exchange occurring in the natural environment. They may also be induced by using long-established methods of bacterial strain improvement, such as radiation or chemical treatment.

Certain exchanges of genetic material, via processes that would include homologous recombination for introducing genetic modification, appear to be provided for in Schedule 1 of the Gene Technology Regulations. However, we do not do not consider that these provisions have been appropriately interpreted and applied, rather, an overly precautionous approach has been implemented. Such an approach is not consistent with the principles of the Scheme of risk-based, proportionate regulation, or scientific knowledge regarding exchanges of genetic material amongst micro-organisms. To address these concerns, we propose several amendments to Schedule 1 (items 1, 6 and 7) in Box 4 below. These amendments were not within the scope of the recent technical review.

⁵ McGee, DJ, Coker, C, Harro, JM, Mobley, HLT (2001) Bacterial genetic exchange. Encyclopaedia of Life Sciences. DOI: 10.1038/npg.els.0001416.

Box 4: Proposed amendments to Schedule 1 of the Gene Technology Regulations

Schedule 1 Organisms that are not genetically modified organisms

Item Description of organism

- 1 Two options:
 - (i) Deletion of this item; or
 - (ii) Amended text: A mutant organism in which the mutational event did not involve the introduction into the genome of genetic material that originates from another species, or for micro-organisms, genetic material that originates from another genus.
- 2 A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
- 3 Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
6. An organism whose genome has been modified by an exchange of DNA if:
 - (a) the donor species is also the host species, or for micro-organisms, the donor and host are from the same genus; and
 - (b) where a vector system is used, the vector DNA originated from the species, or for micro-organisms, the vector DNA originates from the same genus; and
 - (c) Where the organism is a micro-organism, such exchange can occur by a natural physiological process.
- 7 Deletion of this item.

The proposed amendments (underlined above) are explained below:

Item 1: Two options are proposed for this item. The first of these is that the item is deleted in its entirety. This is proposed because it is not clear what the item is applicable to. Rather, it appears to provide a catch-all to find any organism where genetic material has been introduced, even where it is introduced into the cell and not into the genome, to be a genetically modified organism. If applied this way, this constitutes an overly precautionary, non-scientific approach, particularly for micro-organisms. Also, in relation to new technologies, this item could apply to certain genome editing applications (e.g. SDN-1) but it has not been implemented to provide any clarity in this context. The Gene Technology Regulations are expected to be revised to provide regulatory clarity which should render this item unnecessary. Further, this item also appears to duplicate the exceptions from gene technology listed in Schedule 1A.

The second option proposed for item 1 amends the text rather than deletes it. This option is provided in case it may have relevance to applications that we are not familiar with, and that do not involve micro-organisms. The text is amended to clarify that the introduction of genetic material must be into the genome, and not merely the cell, and that where the organism is a micro-organism, the genetic material transferred by the host may originate from the same species (intra-specific) or genus (intra-generic) as the recipient. This is consistent with our text proposals for items 6 and 7, which reflect current scientific knowledge about exchanges of genetic material between such organisms in the natural environment. Such an approach is implemented under the *Toxic Substances Control Act* by the United States Environmental Protection Agency, where only “new” micro-organisms require regulatory assessment. “New” micro-organisms are defined as “inter-generic” (formed from organisms of different genera), and they are “new” on the basis of having a greater chance of exhibiting “new” traits or combinations of traits. Regulatory review of inter-generic organisms is considered to be warranted due to greater uncertainty as to their behaviour and potential effects on human health and the environment.⁶

Item 6: This item is not organism-specific, but one relevant application is the exchange of genetic material between micro-organisms. The amended text is intended to improve clarity, and for micro-organisms, expand the intra-specific scope to include intra-generic exchanges of genetic material. This item should apply regardless of the technology used to facilitate the exchange, including the use of homologous recombination for the deliberate introduction of precise genetic modifications in micro-organisms. The amendments specific to micro-organisms are consistent with scientific knowledge about the ubiquity and frequency of exchanges of genetic material in the natural environment. Therefore, it is appropriate, and consistent with the principles of the Scheme, to apply this item where intra-generic genetic modifications have been made. The text is also edited to remove the ambiguous and undefined term “heterologous DNA”.

Item 7: with the proposed changes to item 6 to include micro-organisms, this micro-organism specific item is no longer necessary.

⁶ Federal Register, 11 April 1997, Vol. 62 No. 70 p 17910-17958.

2) existing and potential mechanisms to facilitate an agile and effective Scheme which ensures continued protection of health and safety of people and the environment.

In addition to the amendments to the definitions in the Act for “gene technology” and “genetically modified organisms” proposed above to increase the flexibility of the Scheme, Bayer CropScience supports the Decision Tree, developed by CropLife Australia, intended to assist in improving the Regulatory Scheme such that it achieves a better balance between assessing the risks of the process applied in arriving at the product of biotechnology, and the risks associated with the product itself. The Decision Tree is described in the CropLife submission under Section 2.1.1 of that submission, “Improving risk based regulation”.

Bayer CropScience’s support for CropLife’s proposed Decision Tree stems from our understanding of the opportunity that exists for streamlining the Gene Technology Scheme such that products of biotechnology derived from well understood processes, and which result in products that have characteristics that are also well understood, need not undergo successive regulatory assessment at the highest level, which is duplicative and inefficient.

Removal of Regulatory Duplication between agencies for Crop Biotechnology

A recent comparison of the regulatory data requirements for assessment of GM products with incorporated pest and/or disease control by the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Office of the Gene Technology Regulatory (OGTR) and Food Standards Australia New Zealand (FSANZ) shows a high level of concordance. Bayer recommends acceptance by the APVMA of OGTR and FSANZ risk assessments to prevent duplication of assessment and the removal of APVMA regulatory responsibility for GM products already regulated by the OGTR and FSANZ . This would also be consistent with the Australian Government’s commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, business and community organisations *through duplication*.

Regulatory duplication is undesirable because it increases the cost burden for applicants, with no associated benefit. The history behind this regulatory duplication arose from a policy decision which was made in 1995, in the absence of other regulations, to treat biologically active pesticidal GM genes/proteins as agricultural chemicals, despite the fact that they did not fit logically into a scheme designed to regulate chemical pesticides. This policy decision permitted the APVMA to regulate GM insect-resistant cotton, prior to the establishment of the Office of Gene Technology

Regulator. However, upon the inception of the OGTR and the gene technology regulatory scheme, regulation of pesticides expressed *in planta* continued under the auspices of the APVMA in the absence of a decision by the Department of Agriculture and Water Resources in the intervening years to reverse the 1995 policy decision.

Under Section 6 of *The Agricultural and Veterinary Chemicals Code Act, 1994 (The Code)* there exists the opportunity for the APVMA to accept the risk assessments of the OGTR and FSANZ as part of their assessment. *The Code* also allows for certain products to be classified partially or completely exempt from APVMA regulation.

Acceptance by the APVMA of OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for GM products when the pest and/or disease control are incorporated *in planta* and captured under a corresponding legislation such as the GT Act, would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals and community organisations.

It has also been observed by the crop biotechnology industry that the APVMA have traditionally outsourced risk assessments for some modules to other government entities such as the Office of Chemical Safety (OCS; i.e. toxicology), and the Department of Environment (DoE; i.e. environmental risk) as a normal part of their regulatory assessment practice. This outsourcing of risk assessments to other government agencies has led to significant time delays in the evaluation of some applications at the APVMA, with issues having included, for example, disagreement between agency assessments (i.e. OGTR and Department of Environment), or at worst knock-back in the assessment of modules due to a lack of relevant expertise, for example knock-back in assessment of toxicology data packages by the Office of Chemical Safety. These knock-backs by agencies and disagreements have been the direct cause of the time delays in evaluation and approval due to i) the time needed to seek a suitable evaluation path for an assessment module in cases where expertise is lacking; and/or ii) the need to resolve the disagreement in evaluations conducted by different agencies when considering the how to forge a path to approval for a particular crop biotechnology product.

We recommend that the OGTR, FSANZ and APVMA work together to remove regulatory duplication where it exists and further the goal of a scheme that is completely streamlined and nationally consistent.

Low Level Presence

Comingling of grain cannot be completely avoided in agricultural production and transport, and new plant biotechnology products approved in the country of cultivation may be unintentionally present in small amounts in shipments to countries that have not yet approved them. This is known as “low level presence” (LLP): the unintentional, low level presence of an agricultural biotech product approved in one or more countries, but not yet approved in the importing country. Because the product has already undergone a full and rigorous safety assessment, found to be safe and has been authorised for cultivation and food use in the country of origin, the low level presence of that product does not present a food or feed safety issue for countries where approval is pending.

Australia currently does not have an established procedure for dealing with LLP in trade. Bayer supports the position of the Global Alliance for Ag Biotech Trade on LLP with respect to their recommendations associated with managing this issue in order to facilitate traded products of biotechnology, and in turn eliminating an important hurdle associated with bringing new products of biotechnology to market due to the impact of asynchronous approvals on trade (refer to the points under (a), (b) and (c) below for these recommendations). If commodity grain shipments are stopped when LLP is detected, economic consequences can be very significant. These include steep financial costs associated with detaining the shipment (demurrage), financing of goods, costs related to delays while waiting for results of grain analysis, and deterioration in grain quality as the shipment is diverted to other markets, repurposed or destroyed. Trade in a particular commodity can eventually cease if the risks of shipments being stopped are high, resulting in lost markets, disruption of grain supplies and ingredient pipelines , and commodity or food shortages in the importing country, which can impact food prices).⁷

To prevent trade disruptions to the products of biotechnology, and the potential impact that this may have on food supplies, it is proposed that Australia work towards an effective solution as part of the Gene Technology Scheme to minimize the risk to trade that stems from unresolved LLP situations. The current situation in Australia is such that a *de facto* zero tolerance policy exists for unapproved biotech products, in the absence of a clearly delineated mechanism under the Gene Technology Scheme for dealing with LLP. This means that within the Australian market it is illegal to sell or distribute a product known to contain a biotech product not approved for use in Australia.

⁷ “National policies to support biotech trade”, About GAABT and LLP, Global Alliance for Ag Biotech Trade (GAABT), http://www.gaabt.org/wp-content/uploads/2016/03/GAABT101_Public_Document_20_February_2015.pdf

Ideally, the adverse impact on trade of LLP situations may be avoided in Australia by striving for synchronized approvals with exporting countries. In the absence of synchronized approvals, Australia should recognize valid risk assessments that have been conducted by an exporting country in accordance with the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (the Codex Plant Guideline)⁸ as a basis for granting full approval to the event. The use of Codex Guidelines should encourage Australia to move away from current zero thresholds and establish practical low-level marketing thresholds for the purposes of supporting trade in biotech products (refer to (b) below)).

An example where the lack of a system in Australia for managing LLP could present a critical issue would be the case where Australian livestock producers may need to import feed in the event of an emergency drought situation. In such a case, feed importation may result in LLP detection under the current regulatory scenario, threatening trade in these important commodities at a crucial time.

Bayer proposes the following suggestions to overcome the negative scenario that currently exists with respect to LLP in Australia currently:

- (a) Given the potential impacts of LLP on global food commodity trade, some countries have implemented policies to promptly review regulatory applications for new biotech products entering global trade. It is suggested that in the absence of a regulatory approval in Australia for a biotech product approved overseas entering Australia, that reliance on regulatory safety assessments from another country could allow shipments with certain low level presence to proceed, temporarily or permanently. Reciprocal procedures in countries that import crop biotechnology products from Australia would also benefit innovation in these products in Australia by removing hurdles to their global trade. For example CSIRO's canola, genetically modified to enhance the omega-3 oil profile⁹, will require approval in major export markets to allow commercialisation and export from Australia. Because of "asynchronous" approval it is possible for LLP of this canola to be found in export shipments to destination countries before it has obtained the necessary import approval. A globally accepted LLP policy will ensure trade will not be disrupted.
- (b) Establishment of threshold levels for grain. Threshold levels are commonly used to allow a certain level of 'off-type' or non-standard grain to be present within commodity supplies without decreasing the value of the product or requiring additional handling costs

⁸ www.fao.org/input/download/standards/10021/CXG_045e.pdf

⁹ <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR155>

associated with grain channelling and quality management¹⁰. Developed based on practical global experience with unintentional comingling of conventional grain products, threshold levels could be applied to LLP of biotech products. Current legislative impediments, impose a “zero tolerance” for events which are not approved are unnecessary where there is no safety concern.

An example of a country which has recently developed a process to introduce a threshold level in line with GAABT proposal (b), is Colombia.

We recommend that the Gene Technology Act incorporate mechanisms to effectively deal with situations where LLP might arise, including the ability to set LLP thresholds or adopt the procedures recommended by Annex III of the Codex Alimentarius Commission’s Guideline for the Conduct of Food Safety Assessment of Foods Derived from DNA-Recombinant Plants, Annex III.¹¹

- (c) Continue Australia’s participation in the Global Low-Level Presence Initiative (GLI), and support the outcomes proposed by this international meeting that has broad stakeholder membership from governments, the grains industry and biotechnology developers. Also, Australia should Support initiatives from other organisations and countries who are actively seeking solutions to the issue of LLP, e.g. by adhering to the Codex Alimentarius Commission’s Guideline for the Conduct of Food Safety Assessment of Foods Derived from DNA-Recombinant Plants, Annex III¹²; supporting the Canada’s proposed domestic policy for management of LLP in imported foods.¹³

¹⁰ For examples of thresholds refer - http://www.graintrade.org.au/commodity_standards

¹¹ www.fao.org/input/download/standards/10021/CXG_045e.pdf

¹² www.fao.org/input/download/standards/10021/CXG_045e.pdf

¹³ <http://www.agr.gc.ca/eng/about-us/public-opinion-and-consultations/update-on-domestic-low-level-presence-policy-development/government-of-canada-proposed-domestic-policy-on-the-management-of-low-level-presence-of-genetically-modified-crops-in-imports-and-its-associated-implementation-framework/?id=1348076201400>

3) the appropriate legislative arrangements to meet the needs of the Scheme now and into the future, including the Gene Technology Agreement.

The Gene Technology Agreement

Recital B of the Gene Technology Agreement states that the Gene Technology Scheme should:

- a) provide an efficient and effective regulatory system for the application of gene technologies;
- b) operate in a seamless manner in conjunction with existing Commonwealth and State regulatory schemes relevant to genetically modified organisms and products derived from such organisms (for example, the schemes that regulate food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals);
- c) be nationally consistent, drawing on power conferred by the Commonwealth, State and Territory Parliaments;
- d) be based on a scientific assessment of risks undertaken by an independent regulator, whose decisions must be consistent with policy principles issued by a Council of Ministers concerning social, cultural, ethical and other non-scientific matters (which principles must not derogate from the health and safety of people or the environment);
- e) ensure that the regulatory burden is commensurate with the risks and consistent with achieving the objectives referred to in Recital A;
- f) be characterised by decision-making that is transparent, and that incorporates extensive stakeholder and community involvement;
- g) be able to be amended to respond to the development of gene technologies and their uses; and
- h) be consistent with Australia's relevant international treaty obligations.

- Arguably, the principles set out under Recital B of the Gene Technology Agreement are not being fulfilled on several fronts, and an efficient and effective regulatory system for the application of gene technology is not being achieved in Australia. Examples are provided throughout this submission demonstrating the need to address many issues, with further discussion on this point presented below under the Section entitled "National Regulatory System – Impact of State moratoria on GM crops". This was also identified in the findings of the 2006 and 2011 reviews of the Gene Technology Act 2000,¹⁴ with the 2011 review recommending that "All jurisdictions reconfirm their commitment to a national regulatory

¹⁴ <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review>

scheme for gene technology.” This recommendation remains unfulfilled, and has not materially altered since the 2011 review.

- In addition, operation of all Commonwealth regulatory schemes relevant to genetically modified organisms is currently duplicative – refer to Section entitled “Removal of Regulatory Duplication for Crop Biotechnology, under 2) above.”
- The operation of all Commonwealth regulatory schemes relevant to genetically modified organisms is also currently not uniform and nationally consistent
 - A principle of the national regulatory Scheme is regulation commensurate with risk, with a transparent risk assessment framework that is based on scientific evidence. The regulatory burden in Australia is not commensurate with the risks posed by the products of crops biotechnology while an additional regulatory burden is exacted by State regulatory systems that do not result in any additional protection to humans or the environment. This additional layer of regulatory oversight exists due to provisions in the Gene Technology Act 2000, Subdivision B, Section 21, 1 (aa), that permits State governments under the policy principle to effect State laws for the purposes of preserving the GM, or *non-GM*, status of crops for *marketing purposes*. It is under this provision of the Gene Technology Act 2000, that State moratoria originally took effect, and to this day, that legislation supports a number of the State regulatory systems discussed above. Further discussion on the policy principle, and how to eliminate its negative impact on innovation in crop biotechnology is discussed in the Section titled “Policy Principle and National Consistency of the Gene Technology Scheme”, below.
 - Discussion under the Terms of Reference 1 point 1, above points out several modifications to the definitions under the Act which will facilitate a much clearer, science-based path forward for the products of innovations in biotechnology. The current risk assessment framework of the OGTR national regulatory Scheme is science-based and transparent, (with notable exceptions discussed under Terms of Reference 1, above). However, the approach at the State level is non-uniform and displays none of the characteristics of good governance or regulations. In states where moratoria on GM crops are in effect, legislation for the most part impose blanket prohibition without a defined pathway for companies to apply to bring products to market. This is discussed further under the Section entitled “National Regulatory System – Impact of State moratoria on GM crops” below, along with proposals on how to amend the Act to achieve this under the Section entitled “Policy Principle and National Consistency of the Gene Technology Scheme”.

- To date, the Scheme has not been amended to respond to the development of new technologies and as a consequence it now lags several years behind the technology. The emergence of new technologies was recognised in the Terms of Reference of the 2011 review of the Act and was addressed in the All Governments response¹⁵ to the Recommendations associated with the 2011 Review, however the recommendations of this response has not yet been achieved. This is stifling innovation as access to resulting products is being prevented due to regulatory uncertainty. An amended Act that allows a more flexible process is required and proposals towards this are detailed in Section 1) (i) above.

National Regulatory Scheme – Impact of State moratoria on GM crops

The *Gene Technology Act 2000* (Cth) was intended to establish a nationally consistent system of regulating the products of biotechnology. Despite this, most states have implemented a second tier of legislation which has meant that Australia has no predictability and no nationally consistent scheme for bringing products of biotechnology to market. States systems are, for the most part, non-transparent, with no clearly defined process for gaining approvals, and are unpredictable. This has created uncertainty in the agricultural biotechnology industry in Australia, prevented clear paths to market for products and investment in research and development in Australia, and undermined the effective regulation of GM crops since the inception of the Scheme.

The lack of a clear path to market for products of crop biotechnology was demonstrated in 2003 when the Office of the Gene Technology Regulator approved Bayer's GM canola for commercial release and states immediately implemented moratoria on commercial cultivation of this crop that had no basis in risks to human or environmental safety. This subsequently led to an unnecessary long period of delay for introduction of GM canola into Australian cropping systems, which reduced profitability, choice and agronomic management options for Australian farmers. This situation also created uncertainty about the future of crop biotechnology in Australia, which remains today (and is exacerbated by the lack of uncertainty regarding new technologies). To this day, nearly 15 years after the OGTR first approved GM canola, it is still banned in two States , creating a disadvantage for farmers in those States and possibly contravening the provisions of

¹⁵ Australian Government and state and territory governments' response to the recommendations of the 2011 Review of the Gene Technology Act (2000)

([http://www.health.gov.au/internet/main/publishing.nsf/Content/0B75D2603FA5323BCA257BF0001C95BE/\\$File/Revised%20All%20Governments%20Response%20-%20Includes%20Queensland%20Position%20-%20November%202013%20\(D13-2046393\).pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/0B75D2603FA5323BCA257BF0001C95BE/$File/Revised%20All%20Governments%20Response%20-%20Includes%20Queensland%20Position%20-%20November%202013%20(D13-2046393).pdf)).

the Mutual Recognition Act 1992. This is also inconsistent with the intent of the Gene Technology Agreement, to which all States and Territories are signatories.

'Marketing concerns', which have subsequently been shown to have little foundation, and no business case for GM crop-free status has been established.^{16,17,18} State bans also cost growers and consumers, both in Australia and in key export markets. One analysis concluded that nationally, the bans on GM canola cultivation cost growers \$157 million per annum.¹⁹ A 2005 Australian Bureau of Agricultural Resource Economics (ABARE) report indicated that the economic loss to Australia's canola growers could amount to \$3 billion, in net present value terms, in the period to 2015, due to the state moratoria at the time on the commercial cultivation of GM canola.²⁰ These considerations are key, particularly where the OGTR has approved commercial release of the product.

In spite of the considerable hurdles that have been imposed by State-based moratoria on the commercialisation of products of crop biotechnology, there is abundant evidence that over the last 20 years these products have provided not only excellent tools for farmers to utilise in production, but also delivered positive environmental and economic benefits in agriculture for those who have been permitted to adopt the technology in Australia.²¹

Further to this, there has been an extensive Productivity Commission enquiry on the impact of regulation on agriculture in Australia. The results of this enquiry on the impact of regulations on Australian agriculture advises as a key finding that – “Some regulations lack a sound policy justification and should be removed. Examples include restrictions on the use of land held under pastoral lease arrangements, state bans on cultivating genetically modified crops, barriers to entry for foreign shipping providers, mandatory labelling of genetically modified foods, and the regulated marketing of rice in New South Wales and sugar in Queensland.”²²

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

¹⁹ Norton R.M., Roush, R.T., 2007, 'Canola and Australian Farming Systems 2003-2007'

²⁰ Apted S., McDonald D., Rodgers H., 2005, 'Transgenic Crops: Welfare implications for Australia. Australian Commodities, vol. 12, no. 3

²¹ Adoption and impact of GM crops in Australia, G. Brookes, 2016, https://www.croplife.org.au/wp-content/uploads/2016/05/CL_20-YearsGM_Lores.pdf

²² refer to the Productivity Commission Report on this enquiry at - <http://www.pc.gov.au/inquiries/completed/agriculture/report>

Previous reviews of the Gene Technology Act 2000 in 2006 and 2011, both of which canvassed a broad range of stakeholder opinion, have also expressed the need for a nationally consistent gene technology scheme:

“The Review noted that state moratoria on growing GM crops had undermined the nationally consistent framework, which the IGA (Intergovernmental Agreement) was intended to support. Some stakeholders expressed concern that the moratoria created regulatory uncertainty stopping further investment in GM food crops and impeding domestic farmers in competing internationally. Other groups supported the moratoria, arguing that the States should have the right to decide not to allow GM crops to be grown if growing them would threaten the market for non-GM crops. The Review concluded that the moratoria were having negative impacts, and recommended that all jurisdictions should commit to a nationally consistent scheme.” Refer- Final Report – Review of the Gene Technology Act 2000, 2011.²³

Despite inter-governmental efforts since 2006 to achieve these review recommendations on removing state moratoria to achieve a nationally consistent regulatory system, the moratoria remain in place. Recommendation 5 of the 2011 Review of the Gene Technology Act 2000, was one of several recommendations designed to increase the consistency of the Scheme. The recommendation supported that *“Those jurisdictions with GM moratoria that have not been reviewed in the last three years commit to reviewing them by the end of 2014.”* The intent of this recommendation was to create a mechanism by which moratoria could be repealed, or mechanisms be put in place to allow these moratoria to lapse so that the State-based legislation that supports the overall Scheme could come into “lock-step” with the Federal Gene Technology Act, and support a Scheme which is truly national (refer Recommendations 2, 3 and 4 of the same Review). Despite review of moratoria in jurisdictions which support them to date, very little change has taken effect since the 2011 Review of the Act.

Policy Principle and National Consistency of the Gene Technology Scheme

Bayer supports repeal of Section 21 (1) (aa) of the Gene Technology Act 2000, as currently it is the foundation for the State-based moratoria which are preventing a nationally consistent Gene Technology Scheme.

Section 21 (1) (aa) empowers State governments to enact moratoria based on the preservation of the identity of GM and non-GM crops for “marketing purposes”. This section of the Act states:

²³ <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review>

The Ministerial Council may issue policy principles in relation to the following recognising areas, if any, designated under State law, for the purpose of preserving the identity of one or both of the following

- (i) GM crops;
- (ii) Non-GM crops;

for marketing purposes.

Section 21(1)(aa) facilitated 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 in turn provided State and Territory governments with the power to create areas under State law that were, in effect, free from the cultivation of GM crop cultivation for the purpose of preserving the identity of non-GM crops for marketing purposes – State moratoria on growing GM crops.

This policy principle has been shown to be founded upon concerns that have not eventuated since the lifting of State-based moratoria in several States around the country, where it has been shown that grain-handling practices are capable of preserving the identity of both non-GM and GM crops without adversely impacting the marketing of these commodities. Identity preservation for marketing purposes does not require the provisions of this policy principle as currently framed.

The Gene Technology Scheme must deliver a system for regulation of gene technology that is consistent nationwide and that provides a single system that is predictable and incorporates regulatory best practice. It must dismantle the present two-tiered system that operates at a Federal and State level. Bayer can only reiterate that the impact of such moratoria is such that it leads to a complex regulatory Scheme that lacks transparency and this contributes further to a regulatory process for products of crop biotechnology that is stifling innovation as access to products associated with these technologies is being prevented due to regulatory uncertainty.

Bayer recommends that Section 21 (1) (aa) of the Gene Technology Act 2000 as it currently stands be amended and replaced with a policy principle that, while it allows State commercial interests to be taken into account, will also ensure that decisions made are nationally consistent and be evidence based; any such scheme allow for nationally uniform processes which are

predictable and incorporating regulatory best practices while including independent appeals processes.

Protection of regulatory data

A major disincentive to private investment in developing agricultural biotechnology tools is that regulatory data that is generated for assessment by the OGTR and Food Standards Australia New Zealand (FSANZ) is not protected in the same way as regulatory data that is submitted to the APVMA. Until recently, this has not been of huge consequence because the GM traits were protected by patents on the technology. However, the first patents on GM crops have started to expire.

Patent expiry will result in the possibility for companies that are not the originator of the GM traits to combine these traits with their own technologies. The regulatory costs of research, development and regulatory data generation for a new GM trait are large. A lack of data protection for the data generated to support approval of GM traits by OGTR and FSANZ means there is a real possibility that competitors will be able to utilise the approval of off-patent traits without having to bear the development and regulatory costs. Bayer firmly supports the industry position that the Government should consider introducing data protection provisions for regulatory data that is submitted to all regulators. Strong data protection provisions would prevent competitors from having the advantage of a “free-ride” on the investment made by the technology originating company. The free-ride scenario is considered poor economic policy because it discourages private investment by diminishing the competitive advantage available to the company that originally invests in bringing the technology to the market. This, in turn, reduces the research that is required to support the introduction of new innovative products that are necessary to meet new challenges in farming, and support competitiveness in the realm of agricultural biotechnology.

Bayer CropScience recommend that data submitted for regulatory purposes be protected for a minimum of ten years from unauthorised use from competitors, as exemplified by the data protection provisions of the APVMA. A new addition to the Act to incorporate data protection provisions is recommended.

4) funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme.

The current funding arrangements, whereby the OGTR is funded by the Federal government is appropriate. Many of the arguments against imposing a system where fees are charged have been put to the reviews conducted on cost recovery options since the inception of the OGTR. These arguments largely concern the hurdle to innovation of large regulatory application fees. Currently considerable regulatory fees apply for applications to FSANZ for food approval and where applicable, APVMA for insect resistance traits of biotech products. The addition of a fee structure to consideration of these products by the OGTR would negatively add to this existing regulatory fee burden.

The biotechnology industry, despite having commenced field research approximately 20 years ago in Australia, remains in its infancy as a commercial enterprise in Australia, and as a consequence cannot afford large regulatory fees. If fees were to be imposed this would have the effect of discouraging and decimating further research and investment in Australia, in particular with small and medium enterprises, with dire consequences for the future of the industry. It is important for government funding of the OGTR to continue as the industry matures, to support a broad range of products becoming commercially available.

Importantly, beyond the point where the biotechnology industry becomes commercially mature, the OGTR should continue to receive all of its required funding from the Federal government to reinforce its independence and to build and maintain public confidence in the Regulator and the neutrality of their decisions.

Bayer recommends maintaining the current funding arrangement for the OGTR whereby it is Federally funded by the government.