# Submission on the Productivity Commission Draft Report on Regulation of Australian Agriculture

## This Submission is focussed on issues of regulation of GM crops

**About the Author:** a background synopsis is provided at the end of the submission to place the views of the author in the context of her expertise, experience and interests.

**Structure of this Submission:** This submission provides comments targeted at various aspects of the regulation of GM crops noted in the Productivity Commission Draft Report (herein called PC Report) and, particularly, provides additional information from a recent major US Report on regulation of GM crops.[1] It draws attention to disconnects within the current Australian R&D crop-development ecosystem that uses agbiotech tools and the long-standing failure of whole-of-government policies to address them. This has led to significant waste of taxpayer funds and, in the specific context the PC Report, is impeding innovation and increased agricultural productivity and competitiveness.

The key factors here are:

- The current Catch-22 for would-be Australian GM-crop developers or adopters flowing from existing government legislation for regulation of GM crops and its failure to keep up with developments of new agbiotech tools (called NBTs (new breeding techniques) in the PC Report). Consequences are the inability to take advantage of state-of-the-art national and international research and capture the benefits for increased productivity of Australian agriculture.

- The failure of the *Australian* government to provide education to the *Australian* public on the *current* status of developments (especially NBTs) and prospects for GM crops and the potential benefits for Australia, including fostering meaningful dialogue between the pro- and anti-GM communities. Public support is *necessary* to provide the political impetus for Parliamentary revision of legislation governing regulation of GM crops. The PC Report (and both initial and post-draft submissions) is replete with examples of continuing industry and community antagonism. Although acknowledging this well-known problem, the PC Report makes no suggestion - nor recommendations - on how to address it. The US Report provides specific recommendations; see point 1. next.

In the following, relevant issues are discussed in point form, with points 2. and 3. elaborating on the above dot points and point 1.

1. **The US Academies Press Report "Genetically Engineered Crops: Experiences and Prospects"** (Attachment 1)**.**[2] This Report was published online on 1 May 2016 after the submissions, hearings and deliberations underpinning the PC Report were complete. This is unfortunate as the US Report is an up-to-date thorough and

[1] "Genetically Engineered Crops: Experiences and Prospects", US National Academies Press, May 2016, 407 pp., http://www.nap.edu/23395

[2] see footnote 1.

scholarly reference for all of the GM-crop regulation issues dealt with in the PC Report and, most usefully, provides specific recommendations to address them. It is beyond the scope of this submission to provide a detailed summary of this tome. Comments here are confined to citing (with the author's bolding/underlining) the aims and methodology of the analysis, and its findings and recommendations of most relevance to the PC Report, i.e. regulation. Further reference to the US Academies' Report is made in subsequent points.

**From the Preface** (pp. ix-x)**;**

*"Our committee was given the task of examining the evidence regarding potential negative effects and benefits of currently commercialized genetically engineered (GE) crops and the potential benefits and negative effects of future GE crops."*

*"**Our committee embraced the Academies consensus-study process, which requires that 'efforts are made to solicit input from individuals who have been directly involved in, or who have special knowledge of, the problem under consideration' and that a study 'report should show that the committee has considered all credible views on the topics it addresses, whether or not those views agree with the committee's final positions**. Sources must not be used selectively to justify a preferred outcome.' We listened to presentations from 80 people who had diverse expertise, experience, and perspectives on GE crops to augment the diversity represented on the committee; …. We also received and read more than 700 comments and documents sent to us from individuals and organizations about specific risks and benefits that could be associated with GE crops and their accompanying technologies. Beyond those sources of information, our committee carefully examined literature – peer-reviewed and non-reviewed – relevant to benefits and risks associated with GE crops in the United States and elsewhere."*

*"**Although it is true that articles exist that summarize much of the literature on GE crops, we committed ourselves to taking a fresh look at the primary literature itself.** Our major goal in writing this report was to make available to the public, to researchers, and to policy-makers a comprehensive review of the evidence that has been used in the debates about GE crops and information on relevant studies that are rarely referred to in the debates. …."*

*"**We received impassioned requests to give the public a simple, general, authoritative answer about GE crops. Given the complexity of GE issues, we did not see that as appropriate. However, we hope that we have given the public and policy-makers abundant evidence and a framework to inform their decisions about individual agricultural products**."*

*"In 1999, Secretary of Agriculture Dan Glickman gave a speech about biotechnology in which he stated that **'with all that technology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust. Trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review – including complete and open public involvement.' Trust must be based on more than authority and appealing arguments for or against genetic engineering**."*

**From the Executive Summary** (pp. xvii-xviii)**:**

*"Since the 1980s, biologists have used genetic engineering of crop plants to express novel traits. For various reasons, only two traits – insect resistance and herbicide resistance – had been genetically engineered into a few crop species and were in widespread use in 2015. **Many claims of positive and negative effects of existing genetically engineered (GE) crops have been made. A main task of the Committee …. was to examine the evidence related to those claims. The committee was also asked to assess emerging genetic-engineering***

***technologies, how they might contribute to crop improvement, and what technical and regulatory challenges they may present****. The committee delved into the relevant literature, heard from 80 diverse speakers, and read more than 700 comments from members of the public to broaden its understanding of issues surrounding GE crops.* ***It concluded that sweeping statements about GE crops are problematic because issues related to them are multidimensional****."*

*"****There have been claims that GE crops have had adverse effects on human health. Many reviews have indicated that foods from GE crops are as safe as foods from non-GE crops, but the committee reexamined the original studies of this subject.*** *The design and analysis of many animal-feeding studies were not optimal, but the large number of experimental studies provided reasonable evidence that animals were not harmed by eating food derived from GE crops. Additionally,* ***long-term data on livestock health before and after the introduction of GE crops showed no adverse effects associated with GE crops. The committee also examined epidemiological data on incidence of cancers and other human-health problems over time and found no substantiated evidence that foods from GE crops were less safe than foods from non-GE crops****."*

*"****Molecular biology has advanced substantially since the introduction of GE crops two decades ago. Emerging technologies enable more precise and diverse changes in crop plants. Resistance traits aimed at a broader array of insect pests and diseases in more crops are likely. Research to increase potential yields and nutrient-use efficiencies is underway****, but it is too early to predict its success. The committee recommends a strategic public investment in emerging genetic-engineering technologies and other approaches to address food security and other challenges."*

*"****-Omics technologies enable an examination of a plant's DNA sequence, gene expression, and molecular composition. They require further refinements but are expected to improve efficiency of non-GE and GE crop development and could be used to analyze new crop varieties to test for unintended changes caused by genetic engineering or conventional breeding****."*

*"****National regulatory processes for GE crops vary greatly because they mirror the broader social, political, legal, and cultural differences among countries. Those differences are likely to continue and to cause trade problems****.* ***Emerging genetic technologies have blurred the distinction between genetic engineering and conventional plant breeding to the point where regulatory systems based on process are technically difficult to defend.*** *The committee recommends that new varieties – whether genetically engineered or conventionally bred – be subjected to safety testing if they have novel intended or unintended characteristics with potential hazards****. It proposes a tiered approach to regulation that is based in part on new -omics technologies that will be able to compare the molecular profiles of a new variety and a counterpart already in widespread use. In addition, GE crop governance should be transparent and participatory.****"*

## **From the Summary** (pp.1-16)**:**

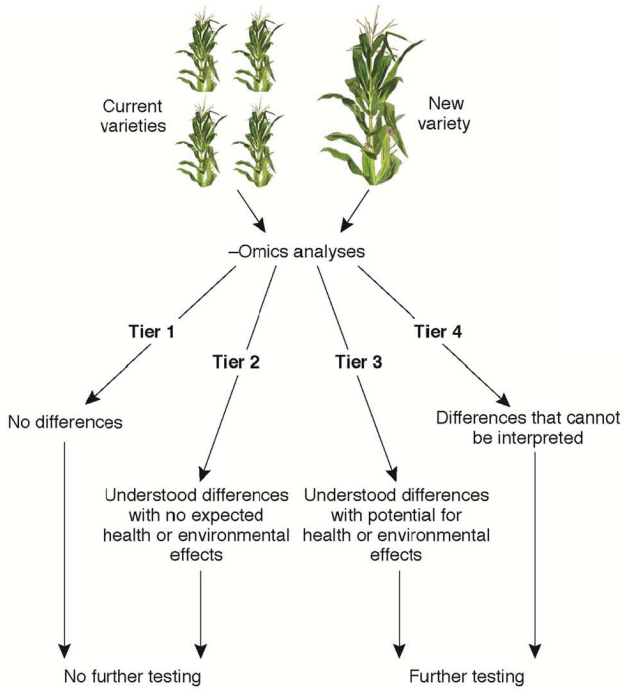
From p. 16 ***"Recommendations on Regulations:***

- ***In addition to issues of product safety, socioeconomic issues that go beyond product safety are technology-governance issues that should be addressed by policy-makers, the private sector, and the public in a way that considers competing interests of various stakeholders and inherent tradeoffs.***
- ***Regulating authorities should be particularly proactive in communicating information to the public about how emerging genetic-engineering technologies*** *(including genome editing and synthetic biology****) or their products might be regulated and about how new regulatory methodologies (such as the use of -omics technologies) might be used. They***

***should also be proactive in seeking input from the public on these issues.***

- *In deciding what information to exclude from public disclosure as confidential business information or on other legal grounds, regulating authorities should bear in mind the importance of transparency, access to information, and public participation and should ensure that exemptions are as narrow as possible.*
- *Regulatory agencies responsible for environmental risk should have the authority to impose continuing requirements and require environmental monitoring for unexpected effects after a GE crop has been approved for commercial release.*
- ***In determining whether a new plant variety should be subject to premarket government approval for safety, regulators should focus on the extent to which the novel characteristics of the plant variety (both intended and unintended) are likely to pose a risk to human health or the environment, the extent of uncertainty regarding the severity of potential harm, and the potential for exposure, regardless of the process by which the novel plant variety was bred.***

***The committee offers that final recommendation because the process-based approach has become less and less technically defensible*** *as the old approaches to genetic engineering become less novel and the emerging processes fail to fit old categories of genetic engineering. Moreover, because the emerging technologies have the potential to make both incremental changes that lack substantial risk and major changes that could be problematic,* ***the committee recommends that a tiered approach to regulation should be developed that uses trait novelty, potential hazard, and exposure as criteria****. -Omics technologies will be critical for such an approach. The committee is aware that those technologies are new and that not all developers of new varieties will have access to them; therefore, public investment will be needed."*




from p. 15 of the US Report: "***Figure S-3 Proposed tiered crop evaluation strategy using –omics technologies****. NOTE: A tiered set of paths can be taken, depending on the outcome of the various –omics technologies. In Tier 1, there are no differences between the variety under consideration and a set of conventionally bred varieties that represent the range of genetic and phenotypic diversity in the species. In Tier 2, differences that are well understood to have no expected adverse health effects are detected. In Tiers 3 and 4, differences that may have potential health or environmental effects are detected and thus require further safety testing".*

2. **The role of the OTGR in regulating GM crops.**[3] In Australia, the Gene Technology Act (2000) established a statutory officer (the Gene Technology Regulator) to make decisions under the Act, supported by an office of scientific, legal, policy, professional and administrative staff (the OTGR). The objective of the Act is to "*To protect the health and safety of people and to protect the environment by identifying risks posed or as a result of gene technology and by managing those risks. It does this by creating laws for certain dealings (or activities) with GMOs*."[4] However, as noted above in the US Academies' Report "*National regulatory processes for GE crops vary greatly because they mirror the broader social, political, legal, and cultural differences among countries"*. Historical differences could also be added to this list.[5]

   Although the PC Report summarizes comments from submissions and findings (pp. 227-231) related to the *efficiency* of OTGR procedures perceived by the, mostly, established agbiotech industry as well as contrary public opinions, and later deals with NBTs (pp. 241-242), it fails to draw the obvious conclusions (*cf.* US Academies' Report) and or make any recommendations. In general the coverage – and apparent quality of input from the submissions and OTGR (p. 242) – of NBTs is poor. Apart from the US Academies' Report, numerous freely available discussions – with vigorous debate – have been published in the last 2-3 years, both in the scientific literature and public media, on the regulatory challenges posed by developments in NBTs.

   In the author's view the structure of the GTR arising from its historical evolution,[6] and the now very wide responsibilities of the GTR under the Act, are no longer appropriate for *effective* current regulation of GM crops, or for the future (see point 3.). The author also questions whether the Ministry of Health is the appropriate overseer of the GTR, a placement with historical origins.[7]

3. **Impediments to development and uptake of GM crops in Australia.** As noted at the beginning of the submission, there is a Catch-22 for would-be Australian GM-crop developers or adopters from the current government legislation for regulation of GM crops and its failure to keep up with developments of new agbiotech tools (NBTs), and consequent problems for the GTR in interpretation of the law in particular cases and its administration by the OGTR. As just noted in point 2, the US Academies' Report summaries in point 1. provide more detail on these problems. In practice, these problems impede the ability to take advantage of state-of-the-art national and international research, especially using novel methods (including NBTs), novel traits with desirable properties, and a wider range of crops, due to cost, delays and risk of regulatory refusal by the OTGR. The net result is limitation on the ability to capture the potential benefits of GM crops for increased productivity of Australian agriculture.

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[3] This comment does not deal with competing/conflicting issues from state- and territory-based bodies on regulation of GM crops, as detailed in the PC Report.

[4] http://archive.industry.gov.au/Biotechnologyonline.gov.au/biotec/regulation.html

[5] 1975, Academy of Science Committee on Recombinant DNA molecules; 1981, replaced by the Recombinant DNA Monitoring Committee; 1987, taken over by the Genetic Manipulation Advisory Committee (GMAC); 2000, the Gene Technology Act.

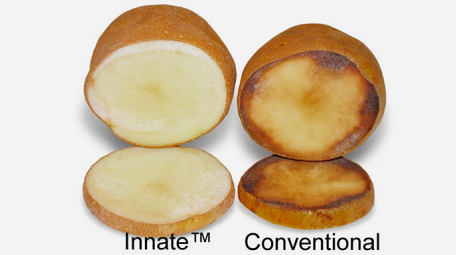
[6] ibid.

[7] ibid.

Of particular concern to the author, is the fate of the substantial Australian public-sector investment or co-investment (universities, CSIRO, RIRDCs, PPPs[8]) in basic, strategic and applied research on GM crop plants, including, as just noted, use of novel methods (including NBTs), novel traits with desirable properties, and a wider range of crops. Although this investment has benefits for Australia in capacity building of trained R&D staff, the difficulty of obtaining investment in Australia for progressing such research developed to POC (proof-of-concept) stage to commercialization is often terminal in a generally risk-averse agricultural ecosystem compounded by the regulatory hurdles.

Of further concern to the author is the disconnect between the above stark reality and exhortations from various government departments and initiatives (e.g. the Innovation Statement) to researcher-inventors and innovators in universities and other publicly-funded or co-funded institutions to collaborate with industry, not-for-profit or other bodies to translate their research findings for socio-economic and other public-good outcomes! There is a whole-of-government problem here of relevance to the PC Report.

Finally, as discussed in detail in the US Academies' Report and cited above ("*For various reasons, only two traits – insect resistance and herbicide resistance – had been genetically engineered into a few crop species and were in widespread use in 2015.")*, the full potential of GM crops has never been explored. So, the cost of the regulatory limitation on the ability to capture the potential benefits of GM crops for increased productivity of Australian agriculture is unknown. A hint of what is possible is provided by the recent example of the Innate™ potato[9] developed by the US company J.R. Simplot using an NBT (RNAi) to introduce within-species traits (i.e. potato only features). These traits include: reduced bruising and black spots; reduction of asparagine (known to produce a potential carcinogen, acrylamide, when potatoes are fried or baked at high temperature); resistance to late blight pathogens (the disease responsible for the Irish Potato Famine of 1845-1852); and enhanced cold storage capability. Afters successful approval by the USDA and FDA, the Innate™ potato is now in limited commercialization production and has been marketed successfully to consumers in the US.




[8] PPP; public private partnerships with Australian examples being partnerships between state-government entities (e.g. department of primary industry) and universities, usually with additional funding from industry bodies (e.g. RIRCDs) and industry.

[9] Richael, C. 2015. Innate™ Potatoes: An Introduction of Simplot Plant Sciences, a Division of the JR Simplot Company. Webinar presentation to the National Academy of Sciences' Committee on Genetically Engineered Crops: Past Experience and Future Prospects, April 21.

**Background of the Author:** Professor Jill Gready has held research positions at Oxford University, The University of Sydney, and The Australian National University for the last more than 20 years. She started her career after school as a work-study trainee in the then NSW Department of Agriculture. Her multidisciplinary research has combined computational, conceptual and experimental approaches to studies of proteins and genes directed towards providing solutions to biomedical and agbiotech problems. She is a Fellow of the Royal Australian Chemical Institute and is holder of its Adrien Albert Award and Masson Medal.

Her current scientific interests are focussed on re-engineering the plant enzyme Rubisco for improvement of productivity of crops. Progressing these interests requires a concurrent interest in policy for regulation of GM crops. She brings to these interests a long record of involvement in activities in social responsibility of science including a term as Honorary Director of the Centre for Human Aspects of Science at The University of Sydney and award of the Australian Future Justice Prize for 2013. Her views on how cutting-edge research and derived agbiotech tools may best be combined in development of improved crops that meet government and community expectations of socio-economic return, environmental sustainability and consumer acceptance, and assist in meeting the global challenge for food security are exemplified in a recent chapter (Attachment 2) "Best of the old and the new: a way forward for the food security dilemma?"[10]

To progress her interests she has recently founded a start-up company, TerreVerde Solutions P/L, to take to the field her ANU research on Rubisco developed over 20 years. TVS's commercial and social values are encapsulated in our goals for "A greener, better, healthier, more productive and fairer world by improvements to Nature's miracle, Rubisco, the engine of photosynthesis by plants."

[10] Attachment 2 and http://www.futureleaders.com.au/book_chapters/Love-of-Ideas/Jill-Gready.php