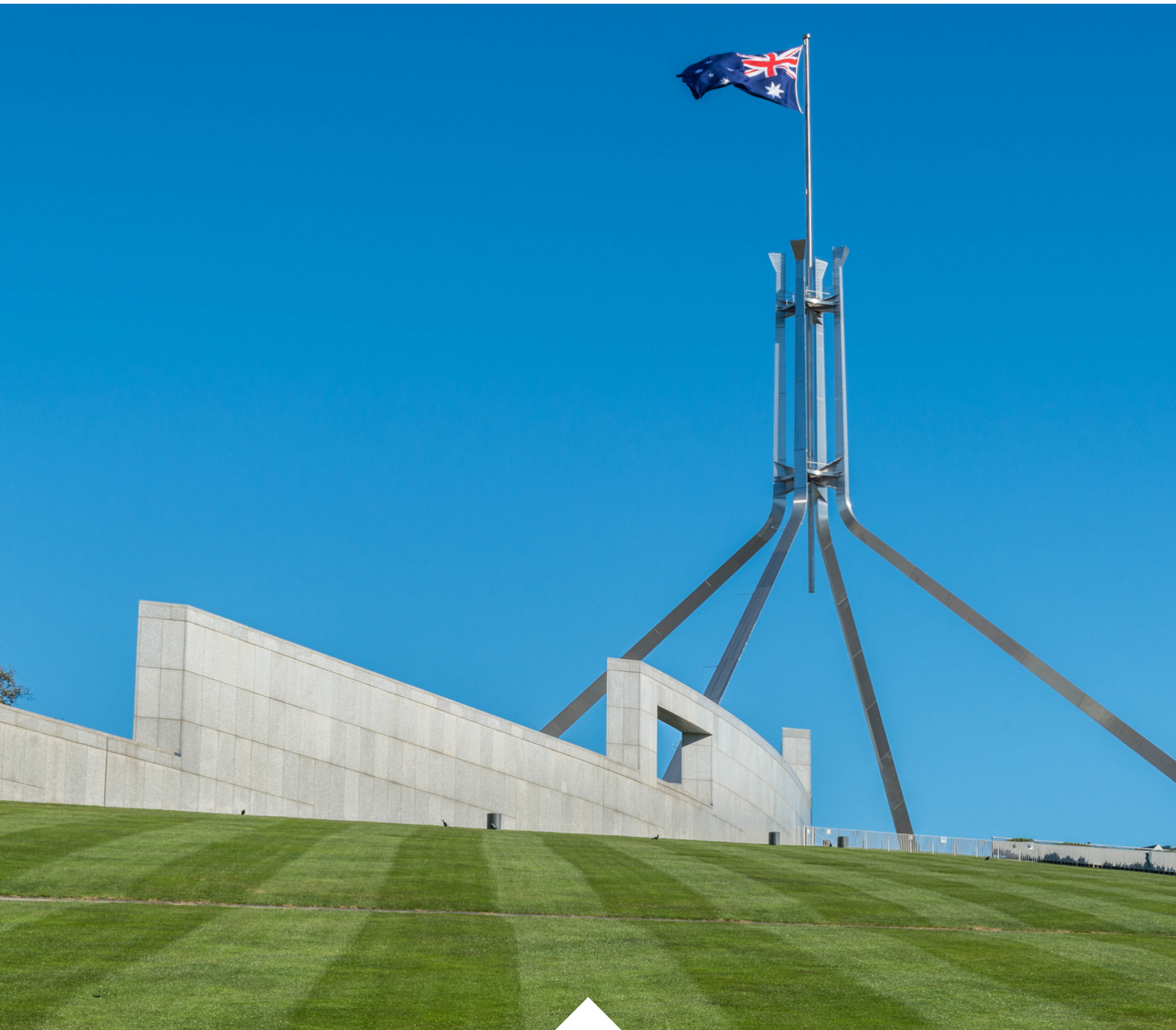


# Pre-budget submission

2023-24



## 1. INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biologically based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, Australian and international companies and accordingly, CropLife advocates for policy positions that deliver whole of industry and national benefit. Our focus is, however, specifically on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability. Both of which are achieved through access to world-class technological innovation and products of the plant science sector.

The plant science industry contributes to the nation's agricultural productivity, environmental sustainability and food security through innovation in plant breeding and pesticides that protect crops against pests, weeds and diseases. The plant science industry is worth more than \$20 billion annually to the Australian economy and directly employs thousands of people across the country.<sup>1</sup> CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

CropLife and its members have a long-standing record and commitment to the stewardship of their products with a whole-of-lifecycle approach. This approach ensures human health and safety, and the responsible and sustainable management of the environment and trade issues associated with agricultural chemical and crop biotechnology use in Australia. Our member companies contribute millions of dollars each year to stewardship activities that ensure the safe and effective use of their products.

CropLife ensures the responsible use of these products through its mandatory code of conduct and a suite of world-leading industry stewardship initiatives and programs, StewardshipFirst. We have set a benchmark for industry stewardship through waste management and recycling programs for our industry's products with **drumMUSTER**<sup>®</sup> and ChemClear<sup>®</sup>, administered by CropLife's wholly-owned stewardship and safety organisation, Agsafe. These programs provide a pathway for disposing of and recycling farm chemical waste, including those classified as dangerous goods, and containers.

CropLife welcomes the opportunity to submit to the 2023-24 Pre-Budget process. CropLife's submission highlights opportunities for the Federal Government to responsibly invest in Australian agriculture, an industry key to economic growth in Australia.

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<sup>1</sup> [https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products\\_web.pdf](https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf)

**CropLife Australia submits the following recommendations to the 2023-24 Federal Budget:**

1. Extend patent protection provisions for innovative agvet chemicals to compensate for mandatory regulatory time under review, to align with pharmaceutical provisions under s70 of the *Patents Act 1990*
2. Improve the efficiency and effectiveness of the Australian Pesticides and Veterinary Medicines Authority (APVMA)
  - a. Commit to permanent Commonwealth funding of the APVMA Governance Board
  - b. Update the outdated APVMA fee and levy model with a reduced cost recovery regime that is fit for purpose in today's dynamic environment and keeps downward pressure on costs, encourages and supports improved efficiencies, and incentivises innovation being brought into the Australian market
  - c. Fund the public benefit functions of the APVMA to reinforce both the independence of the Regulator and not unfairly impose costs onto the farming sector, noting that other regulators in Australia, and similar regulatory agencies in comparable countries, are provided with such funding
  - d. Fund the establishment of an Agvet Chemical & Technology Innovation Centre of Excellence
3. Strengthen the regulatory environment by removing identified barriers to innovation and growth of the agricultural sector
  - a. Improve access to crop protection for minor uses and specialty crops through ongoing funding of the Agricultural Collaborative Forum initiative
  - b. Impose acceptable timelines for review of applications by the Therapeutic Goods Administration for scheduling of chemicals
  - c. Introduce national legislation for GM crops based on scientific evidential analysis, and remove remaining state-based moratoria
  - d. Introduce voluntary labelling requirements for approved GM crops
  - e. Implement the recommendations from the Department of Health's Third Review of the National Gene Technology Scheme
4. Fund communications campaigns to counter the disruptive misinformation regarding agricultural biotechnology as well as chemical and biological crop protection products
5. Fund all national Regulators in such a way that they can maintain international relationships
6. Provide seed funding to launch new and expand existing successful industry funded stewardship and recycling initiatives like an industry-led, not-for-profit initiative to collect and recycle plastic agricultural input bags

2. **EXTEND PATENT PROTECTION PROVISIONS FOR INNOVATIVE AGVET CHEMICALS TO COMPENSATE FOR MANDATORY REGULATORY TIME UNDER REVIEW, TO ALIGN WITH PHARMACEUTICAL PROVISIONS UNDER S70 OF THE PATENTS ACT 1990**

Before any agricultural chemical product or crop biotechnology innovation is brought to market, it is subject to mandatory regulatory assessment and approval. This is akin with the pharmaceutical industry. Where these industries differ, however, is that agricultural chemical and crop biotechnology product developers do not have access to the same patent term extension as pharmaceutical companies. This means competitive generic manufacturers can spring-board their own products as soon as the patent term expires.

The 2010–2012 Raising the Bar reforms of Australia’s IP arrangements amended the Patents Act 1990 to introduce an exemption from patent infringement for activities undertaken for the purpose of obtaining information required for regulatory approval of non-pharmaceutical products. This practice, commonly called ‘spring-boarding’, permits generic manufacturers to obtain regulatory approval during the term of the patent so they can compete with the patentee as soon as the term expires.

In recognition of both the importance and impact of the regulatory approval process and the need for a return on the substantial investments of money and time expended on the generation of new pharmaceuticals, many countries have introduced a system of patent term extensions in relation to patents that protects regulated pharmaceutical products. In Australia, s70 of the Patents Act 1990 provides for patent term extensions for pharmaceutical products of up to five years in appropriate circumstances.

While CropLife is composed of both patent holding and generic companies and advocates for an accessible and competitive generic market, reform to the patent system is needed to equitably deal with product spring-boarding. Mechanisms, such as patent extensions, need to be put into place to recognise the loss of patent protection value that occurs when agricultural chemical or crop biotechnology products are undergoing mandatory regulatory assessment and the serious disincentive this creates to bring new innovation to the Australian market, hence disadvantaging the Australia farming sector and our international competitiveness.

While spring-boarding new products may have some benefits (e.g. it can reduce the market cost of products) companies commercialising in the innovation space must be treated equitably with their generic competitors. Amendments should be made to Australia's IP arrangements to compensate patent owners for the real loss of the value of their patents as a result of the inability to get a commercial return during the assessment period imposed by the mandatory registration process. It is for this reason that when the reforms to formally enable 'spring boarding' were introduced it was recognised that such a patent extension system should be introduced to ensure a competitive and balanced IP regulatory system was maintained for regulated agricultural chemical products.

### 3. IMPROVE THE EFFICIENCY AND EFFECTIVENESS OF THE AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

CropLife notes the final report by the independent panel conducting the review of Australia's agricultural and veterinary chemical regulation framework released in July 2021.

The report's 58 recommendations were intended to deliver significant benefits to a broad range of industry and agvet chemicals users, especially farmers, across Australia. The Panel estimated that around \$160 million in savings in regulatory costs would be delivered to industry over 10 years as a result of the proposed reforms.

However, while many of the Panel's overarching analyses of the current regulatory framework support long-held views by industry to improve the agvet system, many of the individual recommendations will not achieve the outcomes desired by both the Panel, industry and governments. Significant feedback from industry stakeholders, state and territory governments and the Australian Pesticides and Veterinary Medicines Authority (APVMA) was provided during this process. It seems largely to have been ignored.

While CropLife – and other key stakeholders – do not support the majority of the suggestions included in the report, we remain committed to constructively participating in the process to fine tune what will become the next generation regulatory system. As such, CropLife has drafted an alternative set of recommendations to address the same concerns raised by the Panel.

This package of precise, targeted, industry-supported reforms is strongly aligned with government priorities and will result in increased access to new and safe pesticides for farmers, while protecting the independence and integrity of Australia's world-leading regulatory system. These recommendations deliver targeted, implementable improvements that utilise existing structures, procedures and, most importantly, the expertise already housed at the APVMA.

The Government must ensure sufficient funding to implement the appropriate recommendations to modernise the agricultural chemical regulatory system, deliver genuine efficiency gains and ensure Australia maintains a world-class scientifically and technically competent Regulator.

#### **Commit to permanent Commonwealth funding of the APVMA Governance Board**

A Governance Board for the APVMA was legislated in December 2021. This additional layer of bureaucracy comes at a high a cost without addressing the core inefficiencies in the APVMA's operations.

In passing the legislation, the former Federal Government committed to funding only the establishment and first two years of operations of the APVMA Governance Board. From 2024 the farming sector and supporting industries is expected to foot the bill.

This Regulator is already fully funded through industry fees and levies. If the Federal Government does not commit to fully funding the ongoing operations of the APVMA board it will be the only governance board of a federal regulator that is not government funded.

**Replace the outdated APVMA fee and levy model with a reduced cost recovery regime that is fit for purpose in today's dynamic environment and keeps downward pressure on costs, encourages and supports improved efficiencies, and incentivises innovation being brought into the Australian market**

The current APVMA cost recovery arrangement is based on a fee and levy model initially designed in 1984. The Regulator needs a modernised cost recovery regime that is fit for purpose in today's dynamic changing environment.

ABC models can be adopted successfully when the majority of costs for service are variable and not fixed or semi-fixed in nature. This is not the case with the APVMA. For example, almost all employees (contributing over 70 per cent to the cost base) are permanent and on-going.

Accordingly, the APVMA's ability to downsize if volumes fall or skills needs change dramatically and then upsize quickly if volumes rise, is not possible.

In all likelihood, given the resourcing model and current lack of strategic planning for workforce needs, the APVMA will continue to generate deficits despite the increased fees and levies presented to industry.

The current regulatory framework for agricultural chemicals discourages innovators from investing in delivering valuable new products and use patterns for Australian farmers. The relatively small market for agricultural chemicals compared with, for example, the United States and European Union, can create significant commercial constraints on industry.

While CropLife acknowledges that the cost of product registration is similar in Australia to that of international jurisdictions on a dollar-for-dollar basis, this economy of size means that registering each product use pattern equates to a considerably increased cost to industry. A funding structure that promotes innovation, supports agility for industry to respond quickly to external events (such as impacts associated with a global pandemic) and reduces financial and timeliness inhibitors to enter the Australian market, is urgently required.

**Fund the public benefit functions of the APVMA to demonstrate both the independence of the Regulator and not unfairly impose costs onto the farming sector, noting that other regulators are provided with such funding**

Prohibitive cost recovery arrangements from government regulators reduces Australia's agricultural competitiveness. The costs of the APVMA is almost entirely met through application fees and levies recovered from applicants and registrants of agricultural chemicals and veterinary products. This has led to some public criticism that agricultural chemical manufacturers have "captured" the APVMA, leading to perceptions that the decisions of the APVMA are not independent.

While a cost recovered regulatory environment poses no scope for undue influence from the industry it regulates, CropLife recognises that the perception of independence by the Australian public – and therefore confidence in the APVMA – would be considerably increased under a public funding arrangement. A public funding arrangement would align the APVMA with other regulators, including the Office of the Gene Technology Regulator, which is entirely funded via government appropriation, receiving more than \$8 million each year to conduct its regulatory responsibilities.

Adequate funding for public benefit activities should be provided in accordance with the Federal Government's own cost recovery guidelines. Comprehensive public funding for the APVMA would address and neutralise the ongoing criticisms from activist organisations who claim the APVMA is not independent of industry as a result of its funding structure. Comprehensive public funding would significantly reduce barriers to market entry for smaller registrants and facilitate the deployment of new products by small and medium businesses tailored for lesser grown crops and smaller industries.

Comparable regulators internationally receive a significant level of public funding.

#### *The APVMA Governance Board*

As above, the Governance Board was sold as delivering a public good in the oversight of the APVMA. While the first two years of establishment and operation of the board have been funded by the Commonwealth, this funding expires in 2024 and the Minister has indicated that future funding will revert to recovered levy funds. This will leave the APVMA as the only Australian regulator with a board which is not publicly funded. This is also unique amongst comparable global agvet regulators – the EU, Canada, the USA and New Zealand.

#### *The APVMA Chief Scientist*

At a bare minimum, the role of Chief Scientist should be publicly funded.

#### *Website and publications*

The APVMA website and other corporate publications are for both government and non-government audiences. The website is largely a platform for the communication of information to both industry and the general public.

#### *Consultative committees, presentations and seminars*

The agvet industry is not the only recipient of services relating to consultative committees, presentations and seminars provided by the APVMA. Each has an element of providing information to the public and/or other government sectors involved in Federal Government policy.

#### *Risk mitigation oversight activities for the public good*

The APVMA's monitoring, compliance and enforcement activities are critical to supporting and maintaining the integrity of the regulatory system. This does require the APVMA to take a broad approach to monitoring and compliance. The APVMA must not only focus on product registrants and approval holders, but manufacturers and importers that deliberately seek to avoid Australia's regulatory system.

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Publicly funding monitoring, compliance and enforcement activities of pesticides will offer significant benefits to governments, industry and the community. It will:

- Ensure the magnitude and scope of compliance and enforcement activities can be effectively matched to the size of the problem. It will not be restrained by the APVMA's limited budget;
- Demonstrate that registrants and approval holders have not captured the Regulator and increase public perception of an independent compliance function; and
- Facilitate greater voluntary stewardship initiatives by industry to support government compliance functions.

#### Reconsideration program

The reconsideration program is a public benefit function.

Following initial registration, the ongoing human, animal health and/or environmental safety of an agricultural or veterinary chemical product is constantly monitored. As part of the regulatory process, all new scientific information regarding an agricultural or veterinary chemical product is considered in a timely manner.

This system provides a highly responsive regulatory review system, whereby a formal review or 'reconsideration' that focusses on new scientific information, rather than a purely administrative process, can be initiated at any time.

If any new, relevant scientific information that contradicts the current information or shows a product or constituent may not meet the safety, trade or efficacy criteria, the registrant is required by law to provide it to the APVMA. Legislative amendments implemented in 2014 were intended to ensure that reconsiderations are conducted in a transparent, predictable and efficient process.

#### Corporate governance

The annual report is not only an information tool for external stakeholders, but a key government reporting tool required under legislation. The annual report is used by the Department of Agriculture, Water and Environment and the Department of Finance in the preparation of consolidated reports.

Other corporate publications are also used for a variety of purposes, by government and non-government stakeholders.

#### Government regulator productivity dividends

CropLife recommends the APVMA should be subject to the same productivity dividends as other government agencies, with dividends either reinvested into core operations of the agency or providing fee relief to registrants. A more equitable split between cost recovered and government funding should encourage the APVMA and the Department of Agriculture to seek out and implement genuine efficiency and productivity reforms.

The Federal Government's Cost Recovery Guidelines must provide clarity on what can and cannot be cost recovered, and what agency expenses can be included for calculating cost recovery fees and levies. The current CRGs are not sufficiently clear on this matter.

Similarly, there remains a lack of clarity around when levies can be used in addition to fees under a cost recovery model. Equally important is a justification of the efficiency of a levy system, particularly with regard to ensuring agency operations are not being inappropriately subsidised by larger levy payers.

**Fund the establishment of an Agvet Chemical & Technology Innovation Centre of Excellence at the University of New England in Armidale**

CropLife and the University of New England (UNE) propose the establishment of an agricultural and veterinary chemical and associated technology innovation Centre of Excellence (CoE), to be housed in support of the APVMA at Armidale. The proposed CoE responds to the urgent need for high-level, dynamic public policy to ensure effective regulatory pathways allow farmers to access the latest agricultural chemistry and robust risk-based evaluation to deliver the best productive, profitable and sustainable farming outcomes.

The CoE brings together farmers, scientists and industry experts from across Australia and globally, through the establishment of a Chair of Regulatory Sciences and supporting secretariat located at UNE. The new position will explore the synergies between the APVMA and the University in regional Australia, with significant agricultural credentials that will build capacity in the regulatory sciences for agvet chemical science and regulation. It will additionally be the central point of coordination with CSIRO in matters of agvet chemical regulation and risk-based evaluation and future farming practices, as well fostering improved best-practices for Great Barrier Reef management through coordination with James Cook University in Brisbane.

This would also deliver the previous commitments of the Federal Government to support the relocation of the APVMA to Armidale and build, utilise and grow the UNEs capacity in this important public policy and regulatory field. Such a structure would also be ideal for attracting and securing project specific funding from the private sector, from both Australia and internationally.

Building capacity for improved regulatory support in regional Australia delivers the on final phase in the relocation of the APVMA to Armidale: an ongoing commitment to ensuring the best outcomes for both Australian farmers, consumers and the environment. The APVMA is a world-leading, internationally renowned regulatory agency. The support provided by this Centre of Excellence will help ensure this remains so, as the APVMA transitions into a true next-generation regulatory agency.

#### **4. STRENGTHEN THE REGULATORY ENVIRONMENT BY REMOVING IDENTIFIED BARRIERS TO INNOVATION AND GROWTH OF THE AGRICULTURAL SECTOR**

##### **Improve access to crop protection for minor uses and specialty crops through ongoing funding of the Agricultural Collaborative Forum initiative**

Manufacturers of agricultural chemicals rarely make applications for minor and specialty use (including emergency use). Applications for minor and specialty use are predominately made by farming sector groups or individual farmers seeking permission to use an existing crop protection product for an off-label use.

In the 2014 Federal Budget, where very few project proposals received funding, the Federal Government committed an initial \$8 million over four years towards helping farmers gain improved access to safe and effective agricultural chemicals. Further funding of \$4 million over two years was announced in the 2018 Federal Budget towards correcting the market failure caused by a mandatory regulatory system, by better enabling the inclusion of minor uses and specialty crops on agvet labels. This has most recently been renewed as a \$9 million commitment for 2022-2026.

These investments, leveraged by additional funding from CropLife, its members and research and development corporations, have begun to deliver significant value to the Australian agricultural sector through the approval of label uses for minor crops and specialty uses. In 2017:

- 360 unique crop/pest issues were identified by grower industry bodies
- 160 of these had no identified solution, for which 51 new potential solutions were identified by registrants
- An additional 64 new solutions were identified by registrants adding to existing options proposed by industry

The economic gains achieved so far could be exponentially more. Structural change and further funding are required to alleviate the existing economic and regulatory market failure, deliver more sustainable pest management practices and increase the Australian GDP.

Similar programs in the United States have demonstrated that every dollar invested in the minor use program generates a net return to the economy of US\$500. The minor use and specialty crops program in the US, known as IR-4 or Interregional Research Project number 4, began over 50 years ago and receives government funding of approximately US\$14 million a year. The success of the IR-4 Project, with additional U.S. Department of Agriculture funding, is proven and can be measured in its development of data to support nearly 20,000 food use and ornamental horticulture label approvals.

IR-4 is managed by Rutgers, the state university of New Jersey. Part of its success is due to the program leveraging a network of university researchers. With appropriate funding from government, the University of New England could accomplish similar feats in Australia.

In Australia, grant applications totaling well over the \$8 million allocated were received. This shows significant demand and need for an additional and ongoing funding commitment. This important initiative has delivered significant value to the Australian agricultural sector through the approval of label uses for minor uses and specialty crops. It is noted that a 2020 ABARES report estimated an average return of \$117 per government dollar or \$17 million per project over 20 years through this initiative, which must provide considerable support for such an initiative to continue and to be improved and expanded upon.

The grants program will continue to assist rural Research and Development Corporations in generating data required to support applications to the APVMA to gain, maintain or broaden access to priority minor uses of agvet chemicals and must continue to be funded.

### **Impose acceptable timelines for review of applications by the Therapeutic Goods Administration for scheduling of chemicals**

The Department of Health, via the Therapeutic Goods Administration (TGA), is responsible for scheduling medicines and chemicals, which controls how they are made available to the public.

Medicines and chemicals are classified into schedules according to the level of regulatory control over the availability of that medicine or chemical required to protect public health and safety.

In 2017, the Department of Health initiated a review of the Scheduling Policy Framework (SPF). The review was completed in early 2018, with the updated SPF and accompanying Scheduling Handbook published on 18 January 2018. Resulting from the review, the SPF now allows for applications for scheduling of chemicals to be submitted directly to the TGA, in a manner similar to the one previously only available for pharmaceuticals.

Although it is now legislated, the TGA is not supportive of receiving scheduling applications for agricultural chemicals directly from manufacturers, citing a lack of available resources to complete application assessments and implement the new legislation. As such, agricultural chemical scheduling applications must still be made directly to the APVMA for assessment and evaluation prior to being referred to the Department of Health for scheduling.

The unpredictability associated with poison scheduling has long been a significant concern of the plant science and Australian farming sectors. It leads to unnecessary delays to the introduction of new and innovative crop protection products to the Australian market.

Considering scheduling of chemicals is a public benefit, CropLife recommends the costs associated with resourcing the Department of Health to implement the 2018 legislative amendments and carry out their legislative requirement be funded by the Federal Government.

Enabling applicants to submit scheduling applications directly to the TGA will provide the registrant with more control of when submissions are made for scheduling and therefore reduce the risk of missing key deadlines during the product registration process. Implementation of this legislation would, in principle, remove unnecessary discrimination of agricultural chemicals compared to their pharmaceutical chemical counterparts.

### **Introduce national legislation for GM crops based on scientific evidential analysis, and remove remaining state-based moratoria**

Regulating GM crops at a state level undermines the National Regulatory Scheme for Gene Technology. As recommended in the Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture, remaining state and territory (Tasmania and the Australian Capital Territory) governments should remove their moratoria on GM crops. All states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs.

The circumvention of the national scheme is facilitated by section 21(1)(aa) of the Gene Technology Act 2000, which states:

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) allowed the then Gene Technology Ministerial Council to introduce the Gene Technology (Recognition of Designated Areas) Principle 2003. In doing so, states and territories have the power to disallow the cultivation of GM crops for marketing purposes.

The principle was used by Western Australia, South Australia, Tasmania, Victoria, New South Wales and the Australian Capital Territory to legislate for moratoria on the commercial cultivation of GMOs, leading to what was identified in the March 2015 Harper Competition Policy Review as a significant example of a regulatory restriction on competition.

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for preserving the identity of GM and non-GM crops and it removes farmer choice, with Australian farmers missing out on billions in additional farm income.

Since their introduction, moratoriums remain only for the ACT, Tasmania and Kangaroo Island (SA).

CropLife recommends the repeal of s21(1)(aa) in the Commonwealth Gene Technology Act 2000, the repeal of the corresponding section in state and territory acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

### **Introduce of unnecessary voluntary labelling requirements for approved GM crops**

CropLife supports Food Standards Australia New Zealand's (FSANZ) rigorous and transparent process for assessing the safety of GM foods, based on internationally established scientific principles and guidelines.

Every legitimate scientific and regulatory body that has examined the evidence has arrived at the conclusion that approved GM crops and the foods derived from them are as safe as their conventional counterparts.<sup>2</sup> This includes the World Health Organization; the Australian Academy of Science; the European Commission; and the American National Academy of Sciences.<sup>3</sup>

CropLife does not support the mandatory labelling of GM foods and food ingredients in Australia where it bears no relevance to the health or safety of the food or ingredients. Mandatory labelling for non-health and safety reasons can imply a regulatory concern where none exists and only serves to reinforce misconceptions in the community.<sup>4</sup>

<sup>2</sup> International Service for the Acquisition of Agri-biotech Applications, 'Pocket K No. 3: Are Food Derived from GM Crops Safe?' <<https://www.isaaa.org/resources/publications/pocketk/3/default.asp#:~:text=All assessed GM foods are, gene has been successfully introduced.>>

<sup>3</sup> World Health Organization and the UNFAO, *Safety Aspects of Genetically Modified Foods of Plant Origin*, 2000 <<https://apps.who.int/iris/rest/bitstreams/63075/retrieve>>; Australian Academy of Science, *Genetic Modification: Questions and Answers*, 2019 <<https://www.science.org.au/files/userfiles/learning/documents/genetic-modification.pdf>>; European Commission, *Study on the Status of Genomic Techniques under Union Law and in Light of the Court of Justice Ruling in Case C-528/16*, 2021 <[https://ec.europa.eu/food/system/files/2021-04/gmo\\_mod-bio\\_ngt\\_eu-study.pdf](https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf)>; The National Academies of Sciences Engineering and Medicine, *Genetically Engineered Crops: Experiences and Prospects - New Report*, 2016 <<https://www.nationalacademies.org/news/2016/05/genetically-engineered-crops-experiences-and-prospects-new-report>>.

<sup>4</sup> Bárbara Juliana Pinheiro Borges and others, 'Genetically Modified Labeling Policies: Moving Forward or Backward?', *Frontiers in Bioengineering and Biotechnology*, 6 (2018) <<https://doi.org/10.3389/fbioe.2018.00181>>.

A food label has finite space and can only contain a certain amount of information. Unnecessary mandatory requirements reduce the ability of food manufacturers to provide product information that might be more important to consumer purchasing decisions. All information on labels comes at a cost. Consumers should not be required to pay for mandatory information where there is no risk to human health or safety.

CropLife supports voluntary labelling of foods and food ingredients where that information is not misleading or deceptive. Voluntary labelling recognises a balance between the provision of consumer information with the cost and other practicalities of providing it. Food manufacturers will voluntarily provide production information according to consumer demand. For example, 'organic', 'low-fat', 'low-salt' and 'free-range' are all marketing terms widely and voluntarily used by food manufacturers in response to customer preference.

A voluntary labelling system for approved GM foods and food ingredients would allow flexibility for manufacturers regarding what information is of interest to consumers. For example: if a manufacturer chose not to provide certain voluntary marketing information to consumers and producing food at a lower cost without losing market share, then competitors would quickly emulate this approach. Alternatively, if a large proportion of consumers preferentially purchased products containing certain voluntary information, manufacturers would react to this promptly.

CropLife recommends amending Food Standard 1.5.2 of the Australia New Zealand Food Standard Code to remove the requirement for mandatory labelling of approved GM foods and food ingredients.

### **Implement the recommendations from the Department of Health's Third Review of the National Gene Technology Scheme**

In October 2018, the Legislative and Governance Forum on Gene Technology met to endorse the Third Review of the National Gene Technology Scheme and its 27 recommendations. Forum Ministers said these recommendations will enhance and strengthen the Scheme, crucial to ensuring it addresses future developments and challenges across health, medicine, agriculture, plants and animals.

A Forum Action Plan has been produced to progress these recommendations; however, they are taking far too long to be implemented.

The implementation is more than two years behind schedule and a new Review should soon begin as they are scheduled to happen every five years. The delay in implementing changes that are welcomed by the entire regulated community, and seen as a bare minimum to ensure the Scheme remains fit for purpose, is unacceptable. This lack of action from the

Department of Health on the matter has led to an unnecessary regulatory burden and a damaging lack of clarity for both private and public sector researchers and product innovators. As it stands, the Scheme is inconsistent with several decades of accumulated scientific evidence.

**Deliver a National Gene Technology Scheme that is flexible, streamlined and risk-based, and a regulatory process that is future-proof**

The Gene Technology Ministers Meeting was held on July 2021 for the consideration of the Decision RIS on *Modernising and future proofing the National Gene Technology Scheme* (Scheme) CropLife welcomes the decision to recommend 'Option B: risk tiering model' to improve the authorisation pathway for dealing with genetically modified organisms.

CropLife's feedback, which was primarily addressing GM definitions, notifiable dealings and authorisation pathways, were addressed. Also captured are CropLife's statements regarding enhancements to Option B, including those associated with:

- Recognition of safe use and previous risk assessments
- Streamlining of applications between regulators
- Provision of a specific regulatory pathway for clinical trials involving GMOs.

To therefore ensure the delivery of a Scheme that is more flexible, streamlined and risk proportionate, and a regulatory process that is future-proof, it is crucial that the Commonwealth Department of Health drafts legislation that delivers a fully enhanced and comprehensive Option B, i.e., one that will genuinely modernise the system and deliver on the sector's intentions. Achieving a fully enhanced and comprehensive Option B will also support the continued advancement and prosperity of the agricultural and medical research sectors.

Should the comprehensive industry feedback acknowledged in the Decision RIS not be fully captured in subsequent draft legislation, then the new Scheme will not be genuinely future proofed and as such, all efforts to date would be undermined. The Department of Health has responsibility to deliver a genuinely modern system that delivers on the sector's intentions for the benefit of both agricultural and medical biotechnology innovations.

CropLife Australia urges the Department of Health to implement the recommendations from the Third Review of the National Gene Technology Scheme as a matter of critical importance. The future of innovation in Australian agriculture depends on it.



## **5. FUND COMMUNICATIONS CAMPAIGNS TO COUNTER THE DISRUPTIVE MISINFORMATION REGARDING AGRICULTURAL BIOTECHNOLOGY AS WELL AS CHEMICAL AND BIOLOGICAL CROP PROTECTION PRODUCTS**

Misinformation about agricultural biotechnology and crop protection products is extensive. Akin to governments providing information about vaccinations to counter misleading safety claims, governments have a role to play in providing facts about the benefits and risks of agricultural innovations, including crop protection products, genetically modified crops and food derived from GM crops.

Without government intervention, the Australian community could forgo the benefits to productivity, food safety and nutrition provided by crop protection products and GM crops.

While the APVMA, FSANZ and the Office of the Gene Technology Regulator provide information about the roles of crop protection products and GM technologies in producing plentiful safe, nutritious food and publish clear and accessible information about their risk assessment processes, there is scope for more accessible information and elimination of misinformation.

CropLife recommends the Federal Government re-launch the agency Biotechnology Australia that existed within the then Department of Industry from 1999 to ~2010. In doing so, a revised National Biotechnology Strategy can be developed to map the way forward for biotechnology policy in Australia. This strategy has not been revised since 2000.

**6. FUND ALL NATIONAL REGULATORS IN SUCH A WAY THAT THEY CAN MAINTAIN INTERNATIONAL RELATIONSHIPS**

CropLife recommends the Federal Government ensure funding of Australian regulatory agencies is sufficient to allow regulators/representatives to adequately represent Australia at the international level. Such representation plays a critical role in the regulatory community, allowing in-depth discussions with world leaders in technology development, risk analysis, regulation, policy and communication.

The work done by FSANZ and Health Canada on shared risk assessments is a good example of the importance of developing and maintaining international relations. This work, now entering its final test phase was made possible thanks to meetings such as the International Society for Biosafety Research (ISBR) symposiums. With meetings now held mostly in person only, current budget restrictions on travel make it almost impossible for our regulators to attend such events.

## **7. PROVIDE SEED FUNDING TO LAUNCH NEW AND EXPAND EXISTING SUCCESSFUL INDUSTRY FUNDED STEWARDSHIP AND RECYCLING INITIATIVES LIKE AN INDUSTRY-LED, NOT-FOR-PROFIT INITIATIVE TO COLLECT AND RECYCLE PLASTIC AGRICULTURAL INPUT BAGS**

CropLife and its members are committed to the stewardship of their products throughout their lifecycle, ensuring human health and safety, and the responsible and sustainable management of the environment and trade issues associated with agricultural chemical use in Australia.

This is why CropLife established our StewardshipFirst program, which is a comprehensive suite of whole-of-lifecycle stewardship and best-practice initiatives and programs for the responsible use of the plant science industry's products. This commitment is long standing and preceded and regulatory requirements with **drumMUSTER**<sup>®</sup> and ChemClear<sup>®</sup> established in 1998 and 2000, respectively. Although **drumMUSTER**<sup>®</sup> and ChemClear<sup>®</sup> are now funded by an industry levy, the programs were initially established with significant upfront investment by CropLife and our member companies.

### **bagMUSTER**<sup>®</sup>

The plant science industry recognises that packaging for their products, which include pesticides and seeds, negatively contribute to agriculture's plastic waste challenge. In acknowledging the issue and demonstrating thought-leadership through industry-led product stewardship, CropLife and the Australia Seed Federation (ASF) have formed a strategic partnership to develop and deliver bagMUSTER<sup>®</sup>, Australia's first not-for-profit, whole-of-industry collection and recycling program for agricultural plastic bags. bagMUSTER<sup>®</sup> further extends and demonstrates the plant science industry's commitment to product stewardship.

Industry has invested over \$250,000 into the conceptualisation, scoping and development of bagMUSTER<sup>®</sup> and the initiative is now at a stage where government support will be critical for the successful delivery of the initial pilot phase. Government support will allow bagMUSTER<sup>®</sup> to collect all bags, not just bags of CropLife and ASF member products. Following the pilot phase, bagMUSTER<sup>®</sup> will be fully funded by industry to collect all agricultural input bags.

### **ChemClear**<sup>®</sup>

ChemClear<sup>®</sup> supports the removal of obsolete chemicals off farms and out of regional Australia, allowing farmers to safely dispose of these unwanted products. This is particularly pertinent during events such as floods and bushfires.

ChemClear® has a successful history in partnering with state governments to conduct collections to safely capture, remove and dispose of unwanted or unknown pesticides from properties or surrounding public lands following natural disasters. These partnerships have diverted thousands of litres of pesticides from landfill, waterways and inadequate storage, which has minimised the risk of pollution events both on-farm and in native environments.

Chemicals collected by ChemClear® are categorised into two groups: Group 1 chemicals are part of the **drumMUSTER**® program and are collected for free. Group 2 chemicals comprise those that are no longer registered for use, unknown, unlabeled, expired, mixed or are from non-**drumMUSTER**® participating manufactures. In a recent example of government co-support for industry stewardship, farmers and primary producers in Queensland received funding to support up to a 50 per cent reduction in the removal of Group 2 chemicals. The safe management of these chemicals as part of the ChemClear® program means the risk of these chemicals entering the environment is minimised.

The bagMUSTER®, **drumMUSTER**® and ChemClear® programs are undertaken voluntarily by industry and would benefit significantly from government funding as part of the Recycling and Waste Reduction Act 2020.

### **SprayRIGHT – Best-practice product application**

In line with CropLife’s approach to whole-of-lifecycle product stewardship, resources have also been developed to support farmers, spray contractors and environmental land managers implement best-practice methods when using CropLife member company products.

Spray drift is the most common cause of off-target chemical movement. Spray drift causes economic and productivity losses as well as potential damage to the surrounding natural environment. CropLife already produces two freely available best-practice guides to mitigate the risk of spray drift, MyAgCHEMUSE and SprayBEST. Extending the StewardshipFirst suite of resources, CropLife proposes the development of a free to use smart phone record keeping app, SprayRIGHT, to assist pesticide users maintain spray records in compliance with the *Pesticide Act 1999* and *Pesticides Regulation 2017*. There is a need to improve levels of compliance with record-keeping requirements among pesticide users and SprayRIGHT provides an opportunity for the Federal Government to partner with industry to develop a solution to a community-wide problem.

### **Overview of StewardshipFirst at CropLife**

The StewardshipFirst initiative supplements CropLife’s mandatory code of conduct for members and includes:

- i. best-practice application resources (SprayBest and MyAgCHEMUSE)
- ii. resistance management strategies for herbicides, insecticides, fungicides,

- iii. the Pollinator Protection Initiative, involving BeeConnected® and the Seed Treatment Stewardship Strategy
- iv. Agsafe, CropLife's wholly owned stewardship and safety organisation, who deliver **drumMUSTER**® and ChemClear® as well as a training for best-practice storage, handling and transport of pesticides.

CropLife members recognise they have an ongoing responsibility to ensure the sustainability and longevity of their products. For this reason, CropLife and our members support and adhere to the International Code of Conduct on Pesticide Management of the Food and Agriculture Organization and the World Health Organization of the United Nations. This Code specifies obligations about the stewardship of agricultural chemicals throughout their lifecycle, from innovation, discovery and development, through to ultimate responsible disposal of packaging waste. This is in addition to CropLife Australia members abiding by the CropLife Australia code of conduct.

Additionally, many CropLife members engage in significant supplementary stewardship of their products, which ensures the products sold by a company are being used responsibly in accordance with all the conditions and precautions necessary for that product and to ensure the longevity of products.

Collectively, these controls help maintain the sustainability of Australian agriculture by responsibly and efficiently managing farm inputs. The **drumMUSTER**® and ChemClear® industry stewardship programs also address environmental and health and safety concerns by disposing of, and recycling farm chemical waste. To date, these programs have collected and disposed of more than 40 million chemical containers and over 790,000 litres of obsolete or unwanted chemical nationally. As a result, more than 40,000 tonnes of metal and plastic have been diverted from landfill and recycled into re-usable products and 98 per cent of the collected chemical subsequently used as an alternative fuel source.

The 2017-18 Australian Plastics Recycling Survey reported that just seven per cent of agricultural plastics are being recycled. While this figure is concerningly low, the **drumMUSTER**® program accounts for almost one-third of all agricultural plastics being recycled in Australia<sup>5</sup>.

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<sup>5</sup> <https://www.environment.gov.au/protection/waste-resource-recovery/publications/australian-plastics-recycling-survey-report-2017-18>

## 8. CONCLUSION

Australian agriculture and its associated industries generate over \$155 billion each year and underpin 12.1 per cent of Australia's GDP. The plant science industry is an integral input driving this performance. A 2018 Deloitte Access Economics report<sup>6</sup> estimates \$20.6 billion of Australian agricultural output (or 73 per cent of the total value) is attributable to the use of crop protection products. The same report found the plant science sector contributes 9,225 in full time equivalent employees. This consists of 1,725 directly in the manufacturing sector and 7,500 in the sectors that supply inputs to the industry.

The world's population is predicted to increase to 9.7 billion by 2050, requiring an increase in global food production of 70 per cent and to do so in the face of climate change. Providing enough food in the context of production constraints, volatile consumption patterns and a changing climate will be an unprecedented scientific, economic and public policy challenge. The situation provides an opportunity for Australian farmers and agricultural input industries to both assist in the global food security effort and to profit from increased demand for their products. By adopting innovative farming practices, such as the sustainable and efficient use of biological and chemical crop protection products and genetically modified (GM) crops, the Australian farming sector will be able to produce more sustainably and with greater productivity. These innovative farming practices must be promoted through education to the next generation of potential farmers.

Tackling the challenges presented by sustainably increasing food production to meet growing global demand will require science-based policies that support all production systems, including existing and future production tools and technologies. Sustainable production systems will include the conventional systems reliant on the timely, responsible and considered application of crop protection products in ways that maximise yield and manage pests, weeds and diseases. Crop protection products (including fungicides, herbicides and insecticides) are relied upon to increase global food production by between 30 and 50 per cent<sup>8</sup>. Supporting industries and their workforces to develop and introduce new crop protection products that are better targeted to Australian pests, climates and crops will help Australia play its part in addressing global food security.

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<sup>6</sup> [https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products\\_web.pdf](https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf)

The responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, inappropriate and ineffective regulation. Farmers need these products because of the benefits they provide to their businesses and consumers need these products to ensure they have access to safe, affordable and nutritious food. While it is important for governments to provide for appropriate and rigorous regulation of pesticides and biotechnologies, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes.

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among target pests, diminishing the efficacy of chemical options. The economic impact of weeds alone is estimated to be in excess of \$4.8 billion each year, or \$13 million per day<sup>7</sup>. A more recent study by researchers at the CSIRO and Flinders University demonstrated that invasive plants are the costliest pests in Australia, costing \$200 billion since 1960.<sup>8</sup> There is a need for a paradigm shift in thinking from regulating the science (as it has been proven safe) to facilitating the growth of the Australian economy by driving the plant science industry and workforce (both in the public and private domain) to its full potential.

GM crops, an application of modern biotechnology, are just another step along the same path of technological innovation that led to Australian agricultural inventions such as the combine harvester and 'Federation' wheat varieties. Over 1 billion acres of GM crops have been cultivated since 1996 and over 1 trillion meals containing GM food ingredients have been consumed globally. GM crops are the most tested and regulated food product in history. There are no substantiated scientific reports of any food safety issues related to the consumption of genetically modified crops, nor any unexpected effects on ecosystems.

Current GM crops and those in development are a necessary and important tool in meeting the global food and nutrition security challenge. Since being first commercially cultivated in 1996, GM crops have contributed to global food security, sustainability and helped farmers to adapt to and mitigate climate change<sup>9</sup>.

If the Australian economy is to take full advantage of the innovations from the plant science industry, CropLife's recommendations must be seriously considered.

<sup>7</sup> <https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf>

<sup>8</sup> Corey J A Bradshaw and others, 'Detailed Assessment of the Reported Economic Costs of Invasive Species in Australia', *NeoBiota*, 67 (29AD), 511–50 <<https://doi.org/10.3897/neobiota.67.58834>>.

<sup>9</sup> Brookes G and Barfoot P (2018) 'GM crops: global socio-economic and environmental impacts 1996-2016'. PG Economics, Dorchester, UK.