Australian Government
Department of Health
Office of the Gene Technology Regulator

Hon Matthew Swinbourn MLC
Chair
Standing Committee on Environment and Public Affairs

Via email: env@parliament.wa.gov.au

Dear Chair

RE: Inquiry into mechanisms for compensation for economic loss to farmers in Western Australia caused by contamination by genetically modified (GM) material

Thank you for your invitation of 21 December 2017 to provide a written submission to the Standing Committee on Environment and Public Affairs (Committee) on the inquiry into mechanisms for compensation for economic loss to farmers from contamination by GM material. I am pleased to provide the Committee with information on the role of the Commonwealth Gene Technology Regulator (Regulator) as it relates to the inquiry.

Regulatory role

In my capacity as the Regulator, I am charged with administering the national scheme for regulating gene technology. The object of the gene technology regulatory scheme, as set out in the *Gene Technology Act 2000* (Cth) (GT Act) and corresponding State and Territory laws, is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

National regulatory scheme

The national gene technology regulatory scheme is established under the Intergovernmental Gene Technology Agreement (IGA).[1] The scheme is comprised of Commonwealth, State and Territory gene technology laws. In addition to the Commonwealth GT Act, I am charged with administering the State and Territory Acts that are declared to be corresponding to the Commonwealth Act. This enables seamless regulation of gene technology across jurisdictions and ensures consistency of regulatory requirements and clarity for regulated stakeholders.

The regulatory scheme is transparent and consultative, particularly with key stakeholders such as the States and Territories. For instance, under the GT Act, the risk assessment for an environmental release of a GMO requires consultation with State and Territory Governments as well as a range of other stakeholders to the scheme.

The GT Act also requires that States and Territories be consulted on other issues relating to regulation of gene technology, including on the review of legislation and on appointments to the gene technology advisory committees. This is done via the Legislative and Governance

[1] Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

Forum on Gene Technology, comprising Ministerial membership from the Commonwealth and each State and Territory.

Role of States/Territories in trade and marketing considerations

In addition to the national nature of the scheme and State and Territory corresponding laws, the GT Act recognises a role for State and Territories in establishing laws for marketing purposes.

At the commencement of the scheme, separate to the consideration of protection of public health and safety and the environment, a number of States and Territories had expressed an interest in the potential impacts from the introduction of GMOs into agricultural production in their own State or Territory. This was addressed in the GT Act by allowing for the development of the *Gene Technology (Recognition of Designated Areas) Principle 2003* (the Policy Principle)[2] which recognises the right of States and Territories to establish laws which designate geographical areas for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops for marketing purposes.

Under the GT Act, I have no role in decisions relating to trade and marketing, and state laws established on the basis of the Policy Principle are not within my regulatory responsibilities. However licences issued for any environmental release of a GMO, include a reminder that dealings with GMOs in some areas may be prohibited as a result of the operation of State and Territory legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Previous reviews

The Committee may be aware that the subject of this inquiry was examined during the development of the GT Act and as part of the subsequent reviews of the legislation. For example, issues of liability, compensation and insurance to farmers from damage caused by GMOs, have been examined closely as part of the 2006 Review of the GT Act and the IGA. I am enclosing the relevant extract from the 2006 Statutory Review at Attachment A, for information.

I hope that this information will be of assistance. Should the Committee require any further information about the role of the Regulator, I would be happy to provide it.

Yours sincerely

R. Bhula

Dr Raj Bhula
Gene Technology Regulator
13 February 2018

[2] Available at https://www.legislation.gov.au/Details/F2007B00679

Strict liability for contamination

Many submissions to the Review from NGOs, consumer organisations and farming groups opposed to the introduction of GM crops called for the imposition on licence-holders of strict liability under common law for any damage caused by GMOs (note the Act currently provides for strict liability for offences and this is distinct from strict liability under the law of civil liability).

On the other hand, research, industry, and other farming groups argued that such a requirement was unnecessary because the common law provided effective remedies for persons incurring damage from GMOs. They argued that imposing strict liability on licensees would stop the development and marketing of GMO crops, because licensees would not be willing to accept liability for damages caused by GMO crops regardless of the circumstances in which the GMO crops were planted or cultivated.

In considering this issue the Review noted that the law of torts is a matter for State governments. Any codification of the law to impose strict liability would thus require amendments to State law rather than the Act.

The key reasons put forward for strict liability are discussed below.

1. The common law is deficient in not allowing recovery of damages for pure economic loss that farmers might suffer as a result of unintended presence of GMOs in their crops.

The Review noted that case law was developing to recognise pure economic loss, and that the *Perre v Apand*[1] case decided in the High Court in 1999 covered many of the issues that might be expected to arise concerning losses arising from unintended presence of GMOs in non-GM crops. The *Trade Practices Act 1974* and other consumer protection legislation would also afford redress to persons affected by purchasing seed supposed to be GM-free but containing GM material.

2. It would avoid the need for persons incurring damage from GMOs to initiate legal action.

However, while making licensees of GMOs strictly liable for any damage their GMOs might cause would obviate the need for plaintiffs to prove fault, the Review noted that plaintiffs would still need to demonstrate before a court the causal link between the GMO and the damage they had incurred as well as the extent of their loss in order to receive damages.

In considering the issue, the Review noted that there is no other product in Australia which has attracted a strict liability presumption under the common law. In the

1 [1999] 198 CLR 180

past, and also in overseas jurisdictions, courts have imposed a strict liability regime in relation to 'superhazardous goods'. Given that the object of the Act is to manage risks to protect health and safety of people and the environment, it is contradictory to categorise any GMO assessed by the Regulator and licensed for intentional release as a superhazardous good.

The Review also noted that applying strict liability to a licensee of a GMO intended for cropping could create a risk that farmers using the GMO would have less incentive to take care to avoid practices that could result in unintended presence in a neighbour's field. While this could be addressed by the licensee imposing strict conditions on the end-user, this would not be as efficient as exposing the end-user to direct liability for incautious use of the GMO. In some circumstances it would be inequitable to impose strict liability on a licensee. For example, if a person deliberately distributed GM seeds across his non-GM neighbour's paddock it would be unfair to require the licensee to bear any liability for the use of their product.

The Review noted that the European Union Directive 2004/35/EC8 on environmental liability specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives.

On balance, the Review concluded that a strict liability regime should not be introduced into the Act.

Compensation fund

A number of groups proposing a strict liability regime drew attention to the recent Danish law establishing a compensation fund for farmers adversely affected by the unintended presence of GMOs in their crops and suggested that a similar regime may be appropriate for Australia.

The Danish scheme is funded through a levy paid by growers of GMOs for areas planted. According to the EU decision authorising the scheme[2]:

> ***Conditions for receipt of compensation***
>
> 26) Payment of compensation is limited to cases, where GM-material is found in non-GM-crops of the same type as the GM-crops or a closely related type (GM-crops, which can cross into non-GM-crops) in the same cultivation season and within a specifically determined area (distance from GM-crops). With regard to the cultivation of ecological seed corn, the only condition relates to the cultivation season.

2 http://europa.eu.int/comm/secretariat_general/sgb/state_aids/agriculture-2004/n568-04.pdf

27) Compensation is only paid out for losses if the occurrence of GM-material in injured crops, as defined above, exceeds a threshold value of 0.9 per cent. This threshold value is the limit under which genetically modified foodstuff and feed stuff do not have to be marked for contents of genetically modified organisms, refer regulation (EF) Number 1829/2003.

28) The farmer must apply for compensation no later than 14 days after the occurrence of GM-material has been ascertained. Proof of the occurrence and amount of GM-material must be undertaken by officials or authorised persons.

29) Compensation is paid out, regardless of whether the farmer, from whose fields the GM-material has spread, can be identified.

30) Only those farmers who have suffered a loss in connection with primary production are entitled to compensation.

Amount of compensation

31) The amount of compensation is limited to the price difference between the market price of a crop, which has to be marked for contents of GM-material, and a crop, which does not demand such marking (that is contents of GM-material of under 0.9 percent). The Danish Plant Directorate sets the market price on the basis of monthly statistics from the Food Economics Institute (Fødevareøkonomisk Institut).

32) For organic cultivation, compensation may be granted for the time, which is spent on the replanting of acreage, until production again can be sold as organic. This time depends on the type of production and is set by the Danish Law of Ecology Number 118 of 3.3.1999. Compensation only covers the differences between the market price of the products and the price which would have been attainted had they been sold as organic products.

33) If the producer has entered into a contract about delivery of GM-free products to a certain price, the compensation is based on the difference between this price and the market price. Compensation is however only paid for the part of the product, in which the contents of GM-material is over 0.9 percent, regardless which limit for contents of GM- material, producer and buyer may have agreed upon.

34) Compensation from other sources is deducted from the compensation, which is paid out under the support measures in question.

The Government then seeks reimbursement for the cost of the compensation that has been paid from the farmer from whose fields the GM material emanated (if that person can be identified). If the farmer does not agree to make reimbursement the authorities may pursue the claim in court under standard civil law provisions, where fault must be proven.

The Review noted that the compensation is limited to the difference in market price between the crop that is sold as 'GM free' and a crop that is sold as co-mingled. As no premium has yet been identified for 'GM free' commodities[3], the amount of compensation is likely to be minimal.

The Review considered whether there would be any benefits for such a scheme in the Australian context. It concluded that the need for a compensation scheme rested on the presumption that the common law and consumer protection legislation would not prove adequate in dealing with losses covered under the Danish scheme.

Having considered these issues as well as the operation of the common law and consumer protection legislation in Australia, the Review concluded that a mandatory compensation scheme such as the Danish scheme should not be introduced.

Mandatory insurance for GMOs

A related issue to strict liability at common law was mandatory insurance. Sub section 62(3) of the Act provides that licence conditions for the release of GMOs into the environment may:

> ***include conditions requiring the licence holder to be adequately insured against any loss, damage, or injury that may be caused to human health, property or the environment by the licensed dealing.***

So far the Regulator has not imposed any conditions of this sort.

Many submissions to the Review from groups seeking the imposition of a strict liability regime under common law also called for mandatory insurance for licence holders to cover their obligations under such a regime. On the other hand, groups opposed to strict liability saw no need for mandatory insurance.

In considering this issue the Review noted that there are various mandatory schemes in Australia at present.

Some of these cover particular activities, such as driving a motor vehicle (to the extent of personal injury liability to other people) and employing staff (to the extent to which they are injured in the workplace). The policy rationale for these schemes is to afford protection to people against financial loss arising from personal injury.

3 Foster, M. 2003, *GM Canola: What are its Economics under Australian Conditions?*, Australian Grains Industry 2003, ABARE, Canberra.

Other schemes cover particular services, such as providing legal advice or building houses, to the extent to which there are deficiencies in the advice or the house. Some schemes are intended to protect consumers placing large sums of money in the hands of providers prior to completion of the service.

However, there are no products covered by statutory insurance requirements. Not even the manufacturers of products which can be seen as inherently dangerous, such as chemicals or explosives, are required to hold product liability insurance. The community instead relies on consumer protection legislation, product standards and industry codes of practice to ensure that products generally are fit for sale and to mitigate the risks of harm from potentially dangerous products. The Review sought comment from the Insurance Council of Australia (ICA) and noted that the ICA was not in favour of imposing mandatory insurance because of practical limitations.

On balance, the Review concluded that mandatory product insurance for GMOs should not be required. The Review considered that the Regulator should retain the existing power under the Act to impose such an insurance condition on a particular release if she considered it warranted by specific circumstances.

> ***Recommendation 4.1: The Review concluded that the object of the Act is being achieved and recommends that the principles of the regulatory framework stipulated in section 4 be maintained. (Some legislative amendments may be required to accommodate the remainder of the recommendations in this chapter).***

An efficient and effective system for the application of gene technologies

The Review identified a number of changes to the Act that would improve the efficiency and effectiveness of the gene technology regulatory system. These are discussed below.

Emergency approvals

The Regulator pointed out in her submission that she was unable to fast track an approval in an emergency. The Review noted that the Regulator had approved a genetically modified cholera vaccine for release into the environment in conjunction with the relevant approval from the TGA. It is conceivable in the future that genetically modified vaccines (either for human or veterinary use) may be required in an emergency. The current provisions in the Act would mean that such a vaccine (that may have already been approved overseas) could not be released into the environment in Australia without the standard 170 day approval process.