Chapter 2

Consideration of the Bill

2.1 The committee received five submissions, all of which supported the amendments outlined in the Gene Technology Amendment Bill 2015 (the Bill). The submissions were from the Commonwealth Scientific and Industrial Research Organisation (CSIRO); the Gene Technology Regulator (the Regulator); the Australian Academy of Science; CropLife Australia (CropLife); and Food Standards Australia and New Zealand (FSANZ).

Submissions

CSIRO

2.2 The CSIRO declared its strong support for clear legislation in the oversight of gene technology regulation and advised that it did not have any specific comments to make regarding the Bill.[1]

Gene Technology Regulator

2.3 The Regulator noted that the amendments outlined in the Bill would implement minor and technical recommendations from the independent review of the Act, conducted in 2011 for the Legislative and Governance Forum on Gene Technology, which were agreed by the states and territories in 2013 (briefly discussed in Chapter 1). The Regulator expressed support for the provisions of the Bill, commenting that:

> I consider that the amendments would clarify and enhance the operation of the Act and support achieving its object "to protect human health and safety, and the environment, from risks posed by or as a result of gene technology, by managing those risks through regulating certain dealings with genetically modified organisms".[2]

2.4 The Regulator also noted that the amendments would not alter the policy settings of the regulatory scheme.[3]

Australian Academy of Science

2.5 The Australian Academy of Science described the amendments outlined in the Bill as 'conservative and justified' on the basis of the Regulator's accumulated experience of implementing Australia's system for the regulation of dealing with genetically modified organisms (GMOs). The Australian Academy of Science agreed that the amendments would improve the Act's operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme.[4]

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1 Commonwealth Scientific and Industrial Research Organisation, *Submission 1*, p. 1.

2 Gene Technology Regulator, *Submission 2*, p. 1.

3 Gene Technology Regulator, *Submission 2*, p. 1.

4 Australian Academy of Science, *Submission 3*, p. 3.

CropLife Australia

2.6 CropLife 'fully' supported the Bill, commenting that, 'the minor and technical amendments to the Act proposed by the Bill to make gene technology regulation in Australia more efficient, more effective and clearer.' However, CropLife also commented on the timeframes for the implementation of the recommendations following the 2011 review of the Act:

> …it is concerning that it has taken four years to implement what amounts to relatively minor administrative changes…the 2011 Review of the Act also recommended several more strategic and important changes to the national gene technology regulatory scheme and CropLife is hopeful the Department of Health is on track to deliver these significant improvements to the operation of the Act prior to the next review, which is anticipated in 2016.[5]

Food Standards Australia and New Zealand

2.7 Food Standards Australia and New Zealand (FSANZ) noted that the amendments outlined in the Bill were minor and technical in nature and supported 'the general intent of such amendments in simplifying and clarifying legislation.' In particular, FSANZ discussed and expressed its support for the amendments made in part 4 of the Bill, regarding the Record of GMO (and GM Products) Dealings:

> It has been a long standing practice of FSANZ to notify the OGTR [Office of the Gene Technology Regulator] of GM food product approvals so they may be entered into the GMO record. This practice is recognised in the MoU [Memorandum of Understanding] between FSANZ and the OGTR, however it has often been acknowledged that it represents a duplication of effort, and that information on approved GM food products can readily be obtained from FSANZ. Therefore, FSANZ supports the amendments removing this requirement.[6]

Changes to licence variation

Extension of licences beyond the scope of the original Risk Assessment Plan

2.8 Under subsection 71(2B) of the Act, the Regulator may only vary a licence if the risk assessment and risk management plan (RARMP) prepared for the original licence application covered the risks posed by the dealings proposed to be authorised by the varied licence. However, the amended subsection 71(2B) will allow licence variations to proceed, provided potential risks associated with the dealings are adequately addressed in an existing RARMP. The Explanatory Memorandum (EM) gave an example of how the amended subsection 71(2B) would function:

> In considering licence variation applications that utilise risk assessments contained in RARMPs for other licences, the Regulator would consider whether the two licences involve similar GMOs or similar dealings. For example, a limited and controlled plant DIR [Dealings involving Intentional Release] licence could potentially be varied to include dealings with a

5 CropLife, *Submission 4*, p. 1.

6 Food Standards Australia, *Submission 5*, p. 2.

> GMO of the same parent species carrying another gene or new methods of destroying GMOs, provided that these dealings had been assessed in the RARMP for another licence relating to the same parent species. For DNIRs [Dealings Not involving Intentional Release], licences could potentially be varied to include, for example, *in vivo* experiments with a GMO which is licenced for *in vitro* experiments, provided another RARMP considers *in vivo* dealings with the same GMO or with GMOs from the same parent organism with similar modifications.[7]

2.9 The Regulator supported the amendment, noting that it will 'improve the Regulator's ability to ensure licence conditions are appropriate to the circumstances, and increase flexibility for variations sought by the Regulator and licence-holders'. The Regulator asserted that it will also 'broaden the range of variations the Regulator may allow on application, while ensuring that the appropriate level of risk assessment continues to be undertaken for licence variations'. Furthermore, the Regulator assured the committee that the amendment will 'ensure continued transparency of the information underpinning variations sought by licence-holders to environmental release licences (DIR licences, e.g. GMO field trials and commercial releases).'[8]

2.10 The Australian Academy of Science described the change as 'justified' and noted its potential to reduce regulatory burden:

> Experience with the operation of the regulatory system has led to the accumulation of substantial information and practical experience with dealings with certain organisms and genetic modifications. Accordingly, the proposed changes to subsection 71(2B) to enable the Regulator to take into account the assessment of another licence application when considering an application to vary a licence in some circumstances are justified and represent an appropriate potential for reduction of the regulatory burden.[9]

2.11 CropLife also supported the proposed amendments 'to the extent that they represent the operational status quo', noting that the Act 'currently has no legislative provision that prevents the Regulator from using non-CCI [confidential commercial information] data submitted by Applicant A to support an application by Applicant B'. CropLife also commented that the amendments 'in no way extend licences beyond the scope of the original Risk Assessment and Risk Management Plan'.[10]

Removal of an unintended restriction on the Regulator

2.12 The EM noted that item 20 'will remove an unintended restriction on the Regulator's ability to initiate licence variations'. The amended 71(2B) will only apply to applications to vary a licence, not to variations initiated by the Regulator. Under the amended subsection, the Regulator will be able to initiate a variation whenever the Regulator becomes aware of any risks posed by licenced dealings which are not

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7 EM, pp 5–6.

8 Gene Technology Regulator, *Submission 2*, p. 4.

9 Australian Academy of Science, *Submission 3*, p. 2.

10 CropLife Australia, *Submission 4*, p. 1.

covered by the original RARMP or any other RARMP. This will allow the Regulator to manage these risks to protect the health and safety of the public and the environment.

2.13 The Regulator welcomed the removal of the unintended restriction, commenting that:

> This minor amendment would provide clarity and certainty by making explicit that the requirement for risks to have been considered in an existing RARMP relates only to variation applications from the licence holder, not variations initiated by the Regulator.[11]

2.14 The Australian Academy of Science also supported the amendment stating that, 'the removal of the unintended constraint on the Regulator's ability to initiative licence variations to enable newly identified risks to be managed is strongly supported'.[12]

Amendment regarding Notifiable Low Risk Dealings

2.15 Notifiable Low Risk Dealings (NLRDs) are a category of low-risk GMO dealings undertaken with standard conditions and containment, which may be conducted with notification to the Regulator, rather than under a licence from the Regulator. Subsection 74(3) of the Act outlines the considerations that the Regulator must take into account before regulations are made declaring a dealing with a GMO to be a NLRD.

2.16 The Bill amends the conditions that the Regulator must consider before regulations are made declaring a dealing with a GMO to be a NLRD. The amended conditions require the Regulator to consider any risks to the health and safety of people, or to the environment; and, if there is any risk, whether the NLRD requirements prescribed under subsection 75(2) would be sufficient to manage the risk.

2.17 The Regulator supported the amendment, stating that it will not change the classification of any GMO dealings or the process for making regulations declaring GMO dealings to be NLRDs. The Regulator outlined the impact of the changes:

> The proposed amendment would re-frame these considerations to:
>
> - emphasise identifying *any* risk, rather than determining whether the dealings involve *minimal* risk to human health and safety and the environment
> - explicitly invoke requirements for conduct of NLRDs prescribed in subsection 75(2), which includes the appropriate containment level, for determining whether any risk can be sufficiently managed
> - remove the undefined terms 'minimal risk' and 'minimal conditions'

11 Gene Technology Regulator, *Submission 2*, p. 4.

12 Australian Academy of Science, *Submission 3*, p. 2.

- make explicit that the Regulator may consider any other appropriate matter.[13]

2.18 Furthermore, the Regulator noted that the amendments provide definitive language, which 'aligns with current scientific understandings of risk assessment and risk management of GMOs', and which increases clarity and specificity about the matters the Regulator must consider.[14]

2.19 The Australian Academy of Science supported the amendment commenting that the changes enhance specificity:

> The proposed changes to subsection 74(3) provide enhanced specificity regarding matters that the Regulator should take into account regarding the declaration of a dealing with a GMO to be a low risk dealing, and creates an appropriate link to subsection 75(2) regarding the management of any identified risk.[15]

2.20 CropLife also supported the amendment noting that 'by definition NLRDs must not involve the intentional release of a GMO into the environment'.[16]

Removal of the requirement that a GMO be biologically contained

2.21 The amendment removes the requirement, under paragraph 74(3)(a) of the Act, that the Regulator consider whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention.

2.22 The Regulator asserted that the notion of whether a GMO is biologically contained does not significantly contribute to the Regulator's assessment of whether dealings are appropriate for the NLRD category. Furthermore, the Regulator noted that the Act currently only requires the Regulator to *consider* whether a GMO is biologically contained; it is not a requirement for dealings to be declared NLRD:[17]

> It should be noted that 'biological containment' is not a requirement in order for GMO dealings to be declared NLDRs, rather this is simply a consideration to be taken into account in assessing whether particular GMO dealings are appropriate for the NLRD category. Indeed, GMOs that are not biologically contained form a significant proportion of the dealings scheduled as NLRDs, and include dealings with a range of GM animals and GM products.[18]

2.23 The committee did not receive any submissions expressing concerns regarding the removal of the requirement that a GMO be biologically contained.

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13 Gene Technology Regulator, *Submission 2*, p. 5.

14 Gene Technology Regulator, *Submission 2*, p. 5.

15 Australian Academy of Science, *Submission 3*, p. 2.

16 CropLife Australia, *Submission 4*, p. 2.

17 Emphasis added.

18 Gene Technology Regulator, *Submission 2*, p. 5.

Committee view

2.24 The committee is confident that the amendments outlined in the Bill will enhance the Act without altering the underlying policy intent or overall legislative framework of the regulatory scheme, and without compromising the Act's object of protecting human health and safety, and the environment, from the risks posed by gene technology.

Recommendation 1

2.25 The committee recommends that the Bill be passed.

Senator Zed Seselja

Chair