INSTITUTIONAL BIOSAFETY COMMITTEE
LA TROBE UNIVERSITY

La Trobe Institutional Biosafety Committee Submission

Background

La Trobe University has a fine history as an excellent university with an enduring social conscience. As part of our 'Future Ready' strategy, our plan is to grow and develop La Trobe's traditional leadership in areas of research, scholarship and learning that matter to the Australian community. Having taken a detailed investigation of our capabilities and strengths, we have identified five Research Focus Areas (RFAs) and seven Disciplinary Research Programs (DRPs). La Trobe University's RFAs are:

- Securing food, water and the environment
- Sport exercise and rehabilitation
- Understanding disease
- Building healthy communities
- Transforming human societies.

La Trobe University conducts research using gene technology and potentially harmful biological material in a safe, secure, ethical and environmentally responsible framework. This framework helps us meet the needs of national legislative schemes and the Australian community.

At La Trobe University, all activities involving hazardous biological materials and genetically modified organisms (GMOs) or gene technologies must be assessed and approved by the LTIBC. LTIBC must apply a set of principles as outlined in the Australian Standard for Microbiological Safety in Laboratories AS/NZS 2243.3:2010, the *Gene Technology Act 2000* (the *'Act'*) and *Gene Technology Regulations 2001* and any amendments that govern biosafety, biosecurity, the classification of dealings with GMOs, the containment of hazardous biological materials and dealings with GMOs and the conduct of people whose work involves hazardous biological materials, recombinant DNA or gene technology. Activities involving hazardous biological materials, GMOs or gene technologies must not commence prior to the receipt of written approval by the LTIBC. The LTIBC assesses activities to ensure that any real or potential hazards concerning biological materials and dealings with GMOs are identified and managed appropriately, research environments conform to internal and OGTR certification rules and informs the OGTR of relevant dealings with GMOs at La Trobe University.

The LTIBC welcomes this opportunity to respond and comment on the *Review National Gene Technology Scheme (the Scheme), including gene technology legislation, the Gene Technology Agreement and its interface with other regulatory schemes.*

LTIBC Response to the Terms of Reference

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

In October 2016, the Regulator called for submissions and comments related to a discussion paper "*Options for Regulating New Technologies*" in supporting a technical review of the Gene Technology Regulations 2001. The primary aim of this review was to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs and ensure that new technologies are regulated in a manner commensurate with the risks they pose.

The LTIBC considered the options set out in the discussion paper and provided a submission to this review in support of Option 4 that proposed to exclude organisms from regulation as GMOs if the genetic changes they carry are similar or indistinguishable from the outcomes/products of other mutagenesis processes (e.g. chemical and radiation mutagenesis methods and natural mutations). It was the view of the LTIBC that Option 4 provides clarity to the scope of the Gene Technology Regulations in relation to the outcomes/products of new technologies in a manner that is consistent with the original scope and intent of the regulatory scheme (i.e. exclusion from regulation of techniques with a history of safe use).

Like many of the IBCs associated with higher education institutions, the scope of the LTIBC has broadened significantly to provide governance, advice and support to stakeholders across all biosafety and biosecurity activities. That is both GMOs and organisms considered a risk to human health and safety or to the environment. As such, it would be logistically easier for IBCs to have new technologies regulated as GMOs because they would be captured through existing policies and processes. However, simplicity and the status quo is not a driver of innovation and in this case, not consistent with a science / risk based regulatory system. Supporting Option 4 is consistent with the principal consideration that organisms created using gene technologies should be regulated in a manner that is commensurate with the biosafety risks they pose to human health and safety and to the environment and not on what might be logistically simple in providing governance and oversight.

In the LTIBC submission, information was provided that supports Option 4. Since the outcomes from the technical review are yet to be released, this information is also provided in this submission.

In consideration of current developments and techniques, the LTIBC recommends the following:

a) That the Scheme continue to be based on scientific evidence and best practice with products of gene technology regulated in a manner commensurate with the risks they pose

b) That Item 1 of the Gene Technology Regulations be clarified or removed and that Schedule 1 be revised to provide the framework whereby the regulation of new technologies is commensurate to the risks. That is, only applicable when applied to pests or disease-causing outcomes and not for products that have a history of safe use or are similar to, or indistinguishable from those that could have been produced through other technologies (e.g. chemical mutagenesis)

c) Mechanisms be included in the Scheme to allow for greater flexibility and adaptation to future developments. This may include, for example, provisions in the Act that empower advisory bodies such as IBCs, GTTAC and GTCCC to take a greater role in administering the scheme and / or initiate more regular reviews of the regulations

d) Definitions within the Act and the Regulations to be reviewed and aligned to and be consistent with other regulatory agencies (e.g. FSANZ).

Supporting Information–Options for Regulating New Technologies (Option 4)

The mutagenesis techniques based on cellular DNA repair (SDN-1, SDN-2 and ODM techniques) included in Option 4 have been used in several research and product development applications for the targeted mutagenesis of endogenous genes to induce the loss of gene function, modulate activity or alter function. At La Trobe University, the techniques are a valuable tool for the study of important areas with direct community impact across all RFAs.

Option 4 enables the same regulatory treatment of products developed with new technologies and those that can similarly be obtained with various "conventional" tools – such as use of the allelic variation within an organism, spontaneous mutations, or traditional chemical or radiation induced mutagenesis. The application of DNA repair mechanisms, such as mutagenesis, have a long safe history of use in the development of useful agricultural traits particularly in plants including, for example, herbicide tolerance, changed nutritional composition, and resistance to biotic (e.g. disease) and abiotic stresses[1].

The scientific literature consistently report that new breeding technologies such as SDN-1, SDN-2 and ODM, present no greater risk to human health safety and the environment than those posed by conventional mutagenesis techniques (Supplement 1). Further, the weight of evidence supports a key benefit of new technologies namely their precision and the enhanced predictability of off-target effects compared to conventional random mutagenesis techniques. As such, and with due consideration of the Pro's and Con's presented within the OGTR discussion paper, the LTIBC recommended and support Option 4.

Option 1 was not supported as it would provide no clarity for the LTIBC in dealing with such technologies going forward and poses a risk that uncertainty will lead to inconsistency in application of the Regulations (i.e. across institutions) and will be difficult for IBCs to monitor, provide appropriate advice and governance in a scientifically robust manner.

Options 2 and 3 are also not supported since they would impose unnecessary regulation on techniques that are functionally equivalent to other mutagenesis techniques. This is an undesirable outcome for academia, industry, the public, and government and does not align with the principles outlined in The Australian Government Guide to Regulation[2].

The LTIBC would like to note that it received commentary from and considered the views of two LTU stakeholders that favoured Options 2 or 3 and not Option 4. The stakeholders did not fully accept the argument that the new technologies are unlikely to pose risks and therefore this should not mean they are exempt from being regulated, particularly in non-plant systems. Further, the stakeholders highlighted concern over the use of successive rounds of new technologies that could lead to substantial change (i.e. as discussed in the Discussion Paper). Although not backed by scientific evidence, these views emphasise the importance of

[1] The FAO/IAEA Mutant Variety Database (https://mvd.iaea.org)
[2] Australian Government Guide to The Regulation (www.cuttingredtape.gov.au)

engagement by the Regulator with all stakeholders and the need for leadership in addressing public uncertainty around perceived biosafety risk.

The LTIBC recognised the challenges of broadly applying Option 4 to all organisms, for example, pests or disease-causing organisms where exclusions may not be commensurate with the level of risk posed by these techniques. The LTIBC believes there is sufficient scope within the current regulatory framework to develop or amend existing Schedules to provide guidance for IBCs and researchers in applying regulation to such applications. For example, regulation could easily be applied to applications whereby the outcome/product is immunomodulatory, a pathogenic determinant, oncogenic or increases the likelihood of establishment and persistence in the environment or the host/parent organism is from Risk Group 2, 3 or 4.

The LTIBC is of the view is that products developed through technologies such as SDN-1, SDN-2 and ODM should not be differentially regulated if the products are like or indistinguishable from those that could have been produced through established conventional mutagenesis techniques. The literature provided in Supplement 1 provide peer reviewed scientific support to this notion. Further, any application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation. It is the view of the committee that the current Regulations do not.

The LTIBC is of the view that any additional regulatory impost should be based on the risks inherent to the outcome/end-product, not the process used to develop that outcome/product. The scientific literature demonstrates that technologies such as SDN-1, SDN-2 and ODM offer potentially lower risk to human health safety and the environment than traditional mutagenesis techniques that have a long history of safe use.

The LTIBC advocate that if the adoption of either Options 2 or 3 are considered then the information and data requirements for undertaking a biosafety risk assessment should be commensurate with the lower level of risk that has been demonstrated with the use of these technologies.

Item 1 of Schedule 1A states: "*Mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).*"

This item is incongruent with other definitions within the *'Act',* such as:

> ***gene technology:*** any technique for the modification of genes or other genetic material
>
> ***genetically modified organism***: an organism that has been modified by gene technology

There is a need to provide more definitions around mutagenesis as well as providing consistency in the definitions with other government agencies (e.g. FSANZ).

The LTIBC sought guidance from the OGTR with respect to governance over dealings with modified genes where no 'foreign DNA' was introduced (i.e. interpretation of Item 1 with respect to new techniques).

Based on OGTR advice, dealings with old and new technologies that modify genes and genetic material (other than those listed in Schedule 1A) have been considered as genetically modified organisms and regulated in accordance with the *'Act'.*

Given the current uncertainty, the LTIBC has taken a precautionary and conservative approach to new technologies and advises researchers to seek IBC assessment and approval for applications that will utilise any new technologies. This has been met with some resistance from several

researchers citing the lack of regulatory consistency with other mutational techniques. However, the use of new technologies is typically part of much broader research programs that require assessment and approval under the current regulatory framework. As such, the current "in lab" burden is minor, but it is expected that as the costs associated with the technologies reduce and opportunities for products to have a commercial value increase so too will the regulatory burden.

Examples of how the LTIBC currently provides governance to new technologies is provided below. The recommended classification of dealings is dependent on the type of Site Directed Nuclease application used. For example:

- the propagation of plasmids with the non-specific CRISPR-associated endonuclease (CAS9) gene and the targeted guide RNA (gRNA) is considered an Exempt Dealing with a Host/Vector system Bacteria/non-conjugative plasmid
- the introduction of the CRISPR/Cas9 system for Non-Homologous End Joining (NHEJ) and homology directed repair (HDR), (and for HDR, the template 'donor' or guide DNA), in cell culture is considered an Exempt Dealing with a Host/Vector system, Tissue culture/non-conjugative plasmid or Tissue culture/none (non-vector systems). Tissue culture can, for example, be *C. elegans* cells, cell lines or early non-human mammalian embryos cultured *in vitro*
- if, for example, a modified animal embryo is implanted into an animal or a culture or tissue is used to regenerate into a whole plant then the dealing is deemed capable of generating a whole animal or plant and NLRD classifications are considered (other than for *C. elegans* which remains Exempt). For example, NLRD PC1 1.1 (a) for edited mice, NLRD PC2 2.1 (b) for edited plants and NLRD PC2 2.1 (a) for other edited animals.
- All edited dealings that utilise a lentivirus system are classified as NLRD PC2 2.1 (l).

The LTIBC provides oversight for several programs that utilise RNA interference. Principally it is used as a tool for the targeted down regulation of gene expression in a research and development context. This process is highly conserved in plants, insects, fungi, nematodes, and animals.

Current activities are undertaken under containment conditions as assessed on a case by case basis. This may not be commensurate to the risk to human health and safety or to the environment. RNA interference has been used to develop several commercial products that are consumed by humans and animals. Over 130 food and feed approvals exist in 16 countries for biotech crops using siRNA[3]. In Australia, the bi-national government agency, Food Standards Australia New Zealand (FSANZ), which evaluates food safety requirements from biotech foods stated, "*There is no scientific basis for suggesting that small dsRNA present in some GM foods have different properties or pose a greater risk than those already naturally abundant in conventional foods*"[4]. FSANZ has assessed and approved for human consumption several products that use RNA interference[5].

Based on the large number of international assessments and approvals there appears to be a global regulatory consensus that consumption by humans and animals of RNA including RNA transcripts, such as dsRNA and siRNA, is safe. Therefore, the level of containment and oversight ascribed to RNA interference should be re-examined.

[3] ISAAA 2015–Brief 51: 20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015

[4] FSANZ 2013–Response to Heinemann et al on the regulation of GM crops and foods developed using gene silencing

[5] http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx

2. Existing and potential mechanisms to facilitate an agile and effective Scheme, which will ensure continued protection of health and safety of people and the environment.

The LTIBC recommends additional amendments to the Act and Regulations to facilitate an agile and effective Scheme that maintains the core tenet of the Act, the protection of health and safety of people and the environment.

Greater utilisation of advisory bodies

As discussed above, mechanisms are required in the Scheme to allow for greater flexibility and adaptation to current and future technological developments. This may include, for example, provisions in the Act that empower advisory bodies such as IBCs, GTTAC and GTCCC to initiate more regular regulation review. The mechanisms would require an ability for the Gene Technology Regulator to implement review recommendations without the need for policy review and additional amendments to the Gene Technology Act.

IBCs are an important resource that provide governance and oversight to stakeholders across Australia. The expertise that reside in IBCs should be acknowledged with committees empowered to take a greater role in the monitoring and evaluation of dealings under the Act (e.g. facility certification, lower risk licenced dealings).

IBCs could be provided greater powers in the management of containment facility certification. The OGTR relies heavily on IBCs to provide information and confirmation that physical containment facilities meet the guidelines and requirements of certification. However, the timeframes for new certifications (i.e. 90 working days) are not reasonable and often lead to unnecessary time delays that have direct costs to organisations. To circumvent this, many institutions are submitting partial applications to start the clock to ensure that the certification process does not prevent teaching or research activity. Also, organisations consult extensively with the OGTR during the review period in order to seek expeditious certification. This puts OGTR personnel in awkward situations and under unnecessary pressure.

Similarly, the current methodology for managing certified facility suspension and reinstatement is largely an administrative process relying on OGTR personnel guided by advice from IBCs. This is an unnecessary burden on the OGTR and can lead to significant delays to research programs and business continuity at the institutional level. This issue is further compounded by the promotion (encouraged by OGTR) of larger and fewer certification areas. As such, under the current conditions, when minor works are required in a containment facility the entire certification area must be suspended and research ceased until written confirmation from the OGTR that area certification can be reinstated. The OGTR relies on confirmation from the IBC that the area meets the conditions of certification.

The LTIBC advocates greater responsibility for IBCs to manage the suspension and reinstatement of physical containment certification. This would free resources within OGTR allowing for an expeditious new certification and re-certification process.

Clear delineation of OGTR responsibilities and consistency amongst regulatory agencies

The gene technology scheme was designed to fill the gaps between regulatory schemes for human food, human therapeutics, veterinary medicines, agricultural chemicals and industrial

chemicals. The scheme focuses on live and viable GMOs and managing any risks they pose as a result of gene technology. However, the delineation between the different regulatory schemes is often not clear for stakeholders, particularly in the development of a GM product that may be regulated by more than one agency. For example, a GM pharmaceutical may be assessed by the OGTR several times during the research and development phase through to the assessment and issue of a commercial licence. However, a pharmaceutical product is also regulated through the Therapeutics Goods Administration (TGA). The TGA regulates therapeutic goods through: pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts. As such, there is the potential for a duplication of regulatory oversight that is further compounded by differences in requirements and expectations. For example, it would be a requirement from both agencies to report adverse events associated with the pharmaceutical product. However, the timeframes for reporting and the information required by OGTR and the TGA are different.

The LTIBC recommends that there be greater clarity on the roles and responsibilities of regulatory agencies with respect to GM products and alignment of requirements such as reporting.

Review assessment timeframes for certain licenced dealings

The LTIBC supports the views of the Australian Academy of Technology and Engineering (ATSE) and the Australian Academy of Science (AAS) in the need to review the application requirements and assessment timeframes for certain licenced dealings. It is the view of the LTIBC and its stakeholders that where it has been established and/or demonstrated that proposed licenced dealings are low risk, that the requirements and timeframes for assessment could be substantially reduced. Under some circumstances, IBCs could play a greater role conducting evaluation and assessment for certain licenced dealings and provide the Regulator with a set of recommendations. The Regulator could undertake a review of the assessment and, if satisfied, issue a licence with appropriate conditions.

Review the risk classifications of certain dealings

The LTIBC have consulted with its stakeholders and on their behalf, recommend:

A. That zebrafish (*Danio rerio*) be considered similarly to laboratory animals listed in Schedule 3 Part 1.1(a) for which a PC1 level of containment is considered sufficient, unless the nature of the donor DNA warrants a higher level of containment (e.g. Donor DNA is a pathogenic determinant, oncogenic or immunomodulatory). Our reasons for requesting this include:

    i. Unlike mice, rats or rabbits, zebrafish have not become, and do not appear able to become, feral in the Australian environment and are not able to cross-breed with Australian native species.

    ii. Zebrafish gametes or embryos cannot survive for lengthy periods under sub-optimal environmental conditions and therefore there is a negligible risk that any genetically modified zebrafish will escape into the Australian environment[6]

[6] Spence R, Gerlach G, Lawrence C, Smith C. The behaviour and ecology of the zebrafish, *Danio rerio*. Biological Reviews. 2008;83:13–34.

iii. Appropriate containment conditions for aquatic organisms that are infected with, or which may contain, hazardous or infectious microorganisms, will be detailed in the revised AS2243.3 Aquatic Organisms Section.

iv. Changes to the current restrictions on GMO work with zebrafish that are commensurate to the risks to human health and safety and to the environment could mean that the aquaria that house them may not be subject to expensive over-designed containment facilities and conditions in order to deal with them.

B. That *Drosophila melanogaster* (the vinegar fly) be considered similarly to laboratory animals listed in Schedule 3 Part 1.1(a) for which a PC1 level of containment is considered sufficient, unless the nature of the donor DNA warrants a higher level of containment (e.g. Donor DNA is a pathogenic determinant, oncogenic or immunomodulatory). Our reasons for requesting this include:

i. The PC2 containment levels in Australia are out of step with other modern countries conducting research with GM flies (e.g. US, UK, Europe), where work is conducted at a PC1 level, unless the nature of the genetic modifications has an inherent higher risk and warrants PC2.

In the United States, almost all transgenic Drosophila research is considered at Biosafety Level 1, the least restrictive containment level under the NIH Guidelines (http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html). However, when the nature of the Genetic Modifications constitutes a real risk to human health and safety, then a higher level of containment is required. For example, flies expressing prion sequences or gene drive constructs.

ii. *Drosophila melanogaster* is an experimental species that has been used for genetic research since 1909. There is a very low level of inherent risk to the environment and human health with this species because:

- It is already an established species in Australia, and is found throughout the world.
- It is not a disease carrying vector like mosquitoes, Tsetse fly, etc.
- It does not bite or sting
- It is not a crop pest.
- Although *D. melanogaster* is often called a fruit fly it is not a true fruit-fly such as the family Tephritidae. Therefore, it does not affect any agricultural crop. It should also be distinguished from the spotted winged Drosophila species *Drosophila suzukii* that is a fruit pest species.

iii. Laboratory-kept Drosophila are disadvantaged and do not survive or persist outside of controlled laboratory conditions. In the literature, studies have shown that when wild Drosophila are brought into a laboratory setting and cultured under standard laboratory conditions they rapidly adapt to a 'laboratory life' and lose inherent advantages such as tolerances to abiotic stress or lose the traits required to survive and successfully reproduce in the wild[7] [8].

[7] Hoffmann, A. A., R. Hallas, C. Sinclair, and L. Partridge. 2001. 'Rapid loss of stress resistance in Drosophila melanogaster under adaptation to laboratory culture', Evolution, 55: 436-8.
[8] Sgro, C. M., and L. Partridge. 2001. 'Laboratory adaptation of life history in Drosophila', Am Nat, 158: 657-8.

C. That an Exemption classification for low risk GM mice and GM rats be established. Mice or rats with modifications that do not confer an advantage to the animal or do not secrete any infectious agents should could be re-classified as an "Exempt Dealing" to be conducted with in a Physical Containment Level 1 facility. An exemption classification would be commensurate with the low risk nature of these organisms and significantly reduce the regulatory burden on researchers and Accredited Organisations. The oversight provided by Institutional Biosafety Committees is more than sufficient to manage the low level of biosafety risk.

Techniques that should not be classified as genetic modification-based on negligible risk

The LTIBC recommends that the following techniques, when applied to plants, should not be classified as genetic modification:

A. The generation and use of null-segregants. There is no scientific basis for organisms that are derived from GMOs that no longer contain a functional DNA insert that was integrated into the genome to be regulated under the *'Act'*. Null segregants are no longer a transgenic event due to loss of the transgene by segregation following conventional breeding with a sexually compatible plant that did not contain the transgenic event. These organisms do not contain any elements of the transgenic event and therefore cannot be identified as being a GMO, or derived from one, using molecular detection tools. Null segregants are therefore indistinguishable from that obtained through conventional breeding methods and should not be regulated.

B. Cisgenics. Cisgenic plants are characterised by using donor DNA cassettes (i.e. protein coding genes and non-coding regulatory sequences) that originate from the species being modified or a sexually compatible species (i.e. from the wider sexually compatible gene pool for the species). The resulting plants could, in principle, be developed using conventional breeding techniques.

   This is consistent with the conclusion reached by the GMO Panel of the European Food Safety Authority that cisgenic and conventionally bred plants share similar hazard profiles[9]. The types of changes that may occur in the genome due to cellular DNA repair mechanisms during conventional breeding are also expected to occur at the integration site in cisgenic plants, but only at that locus[10].

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

In concert with other regulatory agencies the Scheme is pivotal in ensuring the health and safety of people and the environment as well as meeting the expectations of the public in terms of responsible governance and oversight of gene technology. However, there are several challenges such as national inconsistency in application of the Scheme and recent technology advances that warrant a structural review of the process based legislative framework.

[9] European Food Safety Authority Panel on Genetically Modified Organisms (2012) Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis, EFSA Journal 10: 2561.
[10] European Food Safety Authority Panel on Genetically Modified Organisms (2012) Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis, EFSA Journal 10: 2561.

Regulation Impact Statement

The current legislative framework is activated by the process of gene technology. The LTIBC recommends that the Department of Health, in accordance with the principles outlined in The Australian Government Guide to Regulation[11], seek practical solutions that balances risk with the need for regulatory systems that support a strong, more productive and diverse economy where innovation and investment are captured. The Department of Health should, therefore, undertake and make available a Regulation Impact Statement on the Scheme considering if the framework still provides an applicable mechanism that is consistent with current and future advances in technology and that it ensures the health of people and the environment without imposing unnecessary regulatory burden to teaching, research and development, and commercialisation.

National consistency of the Scheme

The intention of the Scheme was to provide Australia with a nationally consistent approach to the protection of the health of people and the environment as a result of gene technology. The Scheme is underpinned by an Inter- Government Agreement between the federal and the state and territory governments. To date, national consistency is lacking, whereby state and territory governments may impose restrictions and/or ban products that have been evaluated and approved by the OGTR. This creates confusion and concern among international collaborators and investors where no clear domestic pathway to market is apparent. This inconsistency has prevented the commercialisation of many potential products developed by public sector organisations where only companies with substantial capital can afford to navigate the regulatory barriers to market. The LTIBC recommends that the Gene Technology Ministerial Council re-confirm their commitment to a nationally consistent scheme for gene technology.

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

In accordance with the obligations of an Accredited Organisation, La Trobe University invests significant resources to the administration of the Scheme. This includes provision of an Institutional Biosafety Committee (LTIBC) that provides guidance, advice and support to teaching and research personnel who are undertaking gene technology dealings. The committee is supported by full time biosafety expertise through the Ethics and Integrity team within the Research Office. The LTIBC, facilitated through the Research Office, undertakes assessments of new projects and annual inspections of all physical containment facilities across its campuses to ensure they remain compliant with the Guidelines for Certification. Additional external expertise is also engaged to support the construction and/or refurbishment of containment facilities. Given the substantial annual financial commitment that La Trobe University already makes towards ongoing compliance with the Scheme, it is strongly against any implementation of a cost recovery model that would significantly increase direct costs to the University.

The University has observed that the current resourcing of the Office of the Gene Technology Regulator does not appear to be adequate to meeting the needs of stakeholders. In particular,

[11] Australian Government Guide to The Regulation (www.cuttingredtape.gov.au)

resourcing of the administration of facility certification and the monitoring and compliance teams does not appear to have increased commensurate with the growth in the number and diversity of physical containment facilities and licenced dealings across Australia. La Trobe University advocates improvements that result in operational savings and increased efficiency and effectiveness of the Scheme. This could include, for example, increasing responsibilities of IBCs.

Supplement 1 – New Breeding Technology Literature Reviewed

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