Queensland

Gene Technology Amendment Regulation (No. 1) 2011

Explanatory Notes for SL 2011 No. 232

made under the

Gene Technology Act 2001

General outline

Short title

Gene Technology Amendment Regulation (No. 1) 2011.

Authorising law

Sections 5 and 193 of the *Gene Technology Act 2001* enable the Queensland government to meet the obligation under the Gene Technology Agreement 2001 (as amended in 2008) to participate in the national scheme which regulates dealings in Genetically Modified Organisms. National consistency is achieved through the regulation-making power which allows Queensland, like other participating jurisdictions, to replicate amendments made from time to time to the Commonwealth legislation known as the Principal Act and the Principal Regulations.

Policy objectives and the reasons for them

The Queensland *Gene Technology Act 2001* (GTAQ) provides the legislative basis for the Queensland Government to participate in the national scheme which aims to ensure the protection of the health and safety of people and the environment through the regulation of dealings

with Genetically Modified Organisms (GMOs). Subsection 193(1) of the GTAQ authorises the Governor-General to make regulations under the Act.

The Queensland Gene Technology Regulation 2002 (GTRQ) supports the implementation of the national scheme in Queensland by duplicating those parts of the Principal Regulations which provide the detailed regulatory framework to categorise and regulate all GMO dealings. The regulatory approach of the scheme is to prohibit specific GMO dealings unless a dealing is exempt, is the subject of an emergency dealing determination, is a notifiable low risk dealing, is included on the GMO Register or is licensed by the Regulator. The mechanism underpinning enforcement of this regime in Queensland is the offence provision in GTAQ section 37 (Offence relating to notifiable low risk dealings of the Act).

The Gene Technology Regulator (the Regulator) is a statutory role created by the GTAC with responsibility for administering the Act. The Regulator is required to periodically review the operation of the national scheme and may seek approval from the Gene Technology Ministerial Council (GTMC) to amend the GTRCs in order to:

- ensure that GMO dealings are classified to accurately reflect risk assessment based on current scientific understanding;
- improve the effectiveness of the regulatory system; and
- where necessary improve the level of assistance available to users to comply with the legislation.

Section 140 of the GTAC permits the Regulator to consider whether proposed or existing GMO dealings should be exempt or classified as Notifiable Low Risk Dealings (NLRDs). However, the Regulator must take into account the matters set out in GTAC sections 74(2) and (3) which require the Regulator to be satisfied that the dealing would not involve the intentional release of a GMO into the environment and to consider whether for the dealing the GMO:

- is biologically contained so that it is not able to survive or reproduce without human intervention;
- involves minimal risk to the health and safety of people and to the environment, considering the pathogenic or pest properties of the GMO and the toxicity of any proteins produced by the GMO; and
- needs prescribed conditions for the management of risk.

The policy objectives of the amendments to the Principal Regulations made on 1 September 2011, and which will be replicated in the GTRQ, are to:

- clarify certain requirements for undertaking NLRDs;
- introduce a time limit for some dealings;
- reclassify dealings as either exempt, as NLRDs or those which must be licensed; and
- to make some minor administrative changes.

Achievement of policy objectives

The policy objectives will be achieved through clarifying requirements for undertaking NLRDs, introducing a time limit for all NLRDs and reclassifying certain GMO dealings as either exempt, as NLRDs or as falling within the category of dealings which require a license.

Some minor administrative changes will also be made.

Consistency with policy objectives of authorising law

The amendments are consistent with the policy objectives of the national scheme, as applied in Queensland by the GTAQ, which are to protect the health and safety of people and the environment through regulating dealings with GMOs.

The Regulation is consistent with the intent of GTAQ section 74 (Notifiable low risk dealings) and of Section 75 (Regulation of notifiable low risk dealings) which authorise the making of a regulation to declare GMO dealings to be notifiable low risk dealings only after the Regulator is satisfied of the matters listed in the section. Section 75 allows a regulation to be made for different classes of NLRDs a well as for differing requirements for persons and situations such as:

(a) the class of person who may undertake NLRDs;

(b) notifying the regulator of NLRDs;

(c) supervision by institutional biosafety committees of

NLRDs; and

(d) the containment level of facilities in which NLRDs are undertaken.

Section 193 (1) of the GTAQ) provides that the Governor in Council may make regulations under the Act including a regulation to require a person to comply with a code of practice or guideline issued under the Act.

Inconsistency with policy objectives of other legislation

The subordinate legislation is not inconsistent with any policy objectives of any other legislation.

Alternative ways of achieving policy objectives

There are no feasible alternative means of delivering the policy objectives as this regulation is part of a co-operative national legislative scheme based on the *Gene Technology Agreement 2001* to which the Commonwealth government and the governments of all other Australian jurisdictions are signatories.

The Queensland government is legally bound by clause 39 of the GTA to use its best endeavours to ensure that the legislation forming part of the scheme (including all subordinate instruments) will remain nationally consistent. That means that the Queensland government must make legislation to adopt any amendments made by the Commonwealth government to the Principal Act or Principal Regulations.

Benefits and costs of implementation

The benefits of the legislation are associated with supporting the national scheme purpose which is to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and to manage those risks through regulating certain dealings with GMOs.

The GTA also provides for a bilateral agreement on a fee-for-service basis for the administration and regulation of the scheme. The Commonwealth reimburses the parties for certain expenses whilst other expenses are borne by the parties.

The amendments will not significantly impact on the costs associated with Queensland's role in administering and regulating the scheme.

Consistency with fundamental legislative principles

The amendment Regulation raises no issues in regard to fundamental legislative principles.

Consultation

As part of the review process the Regulator consulted widely. Initial consultation with the organisations accredited under the Act, Institutional Biosafety Committees, State and Territory governments and Australian Government agencies identified a number of areas in the Principal Regulations that could be improved. Based on this input and issues identified through operational experience with the Principal Regulations, proposals for amendment were presented to the GTMC which gave approval to draft the amendments. The Gene Technology Technical Advisory Committee (GTTAC) was consulted on whether the proposed changes to the classification of dealings were commensurate with risks.

A second round of consultation on the draft amendments to the Regulations was conducted according to the requirements of section 142 of the GTAC. Comments were sought from the GTTAC, accredited organisations, Institutional Biosafety Committees, State and Territory governments, Australian Government agencies and individuals and organisations that have registered on the Office of the Gene Technology (OGTR) mailing list. Public notification and an invitation for written submissions were undertaken through advertising in The Australian newspaper, on the OGTR website and in the Government Notices Gazette.

Notes on Provisions

Short title

Clause 1 provides that the title of this Regulation is the *Gene Technology Amendment Regulation (No. 1) 2011*.

Regulation amended

Clause 2 explains that the Regulation amends the *Gene Technology Regulation 2002*.

Clause 3 amends section 6 by deleting paragraph 6(1)(e) to remove the reference to retroviral vectors able to transduce human cells. This paragraph is redundant following amendments introduced by the *Gene Technology Amendment Regulation (No. 1) 2007* which removed dealings involving retroviral vectors able to transduce human cells from the exempt category.

Clause 4 replaces section 11A (Time limit for deciding variation application) with a new section to introduce limitations on the days counted for the period during which the Gene Technology Regulator (the Regulator) must vary, or refuse to vary, a licence after the receipt of an application for a variation of the licence. Days which cannot to be counted in this period are:

- a Saturday, a Sunday or a public holiday in the Australian Capital Territory;
- a day on which the Regulator cannot proceed with the decision-making process, or a related function, because the Regulator is waiting for information that the applicant has been asked, in writing, to give.

In part, new section 11A ensures that recommendation 5.9 of the *Statutory Review of the Gene Technology Act 2000 and The Gene Technology Agreement* is more accurately implemented by excluding weekends and public holidays from the 90 day period during which the Regulator must make a decision about varying a licence. Further, that 90 day time period will now be adjusted by deducting any delays caused by waiting for information from the applicant, which are beyond the control of the Regulator. In other words, the 90 day period will be extended by the number of days which can be attributed to waiting for an applicant to supply information.

Clause 5 replaces sections 13 and 13A with revised sections and inserts new sections 13B and 13C.

Replacement section 13 clarifies requirements, roles and responsibilities for persons undertaking NLRDs. Some requirements are unchanged from those in the current regulation, and other requirements are new or modified as described below.

Subsection 13(1) amends the current requirements to:

- require that NLRD proposals to be assessed by an IBC must be submitted in writing;

- limit the dealings which may be undertaken to those described in the IBC's record of assessment of the proposal;
- limit the time within which a NLRD may be undertaken to that specified by section 13A, being 5 years after the date of assessment for NLRD proposals assessed either before commencement of the Regulation and for dealings assessed before the commencement a specific end date is supplied;
- limit persons who may undertake the dealing to those mentioned in the IBC's record of assessment as having the appropriate training and experience to undertake the dealing, noting that this can include classes of persons;
- limit the facilities in which the dealing may be undertaken to those mentioned in the IBC's record of assessment as being appropriate for the dealing, noting that this can include classes of facilities;
- require that a person undertaking the dealing must be able to give a copy of the IBC record of assessment to an inspector, on request;
- require that the person undertaking the dealing does not compromise containment of a GMO involved in the dealing;
- require that a person may only undertake a NLRD in accordance with subsections (2) and (3); and
- remove references to the project supervisor, consistent with new sections 13A, 13B and 13C.

These amendments support the central legislative principle that only proposals which have been assessed by an IBC may be undertaken as NLRDs. IBC assessments must include consideration of the scope of the dealing, the persons (or classes of persons) with appropriate training and experience to undertake the dealing, and the facilities (or classes of facilities) appropriate for undertaking the dealing. The responsibility for ensuring NLRDs are conducted in this way rests with the person undertaking the dealing.

The person undertaking a dealing is responsible for not compromising containment of the GMO and for complying with the requirements of subsections 13(2) and (3). Any failure to meet these requirements may result in a breach of the offence provision in section 37 of the Act.

Section 13(1) time limit amendments operate in conjunction with section 13A to ensure that dealings are periodically reassessed, taking into account any changes in the scope of the dealings a proponent wishes to undertake and any later amendments to the Principal Regulations. In addition, these amendments improve the effectiveness of the transparency and regulatory oversight of NLRD dealings by ensuring the accuracy of the Record of GMO and GM Product Dealings.

Section 13(2) amends the current requirements by specifying the facilities in which NLRDs may be undertaken and by allowing the Regulator flexibility to certify facilities by:

- clearly stating that NLRD facilities must meet the required physical containment level and be of an appropriate type, for example, PC2 plant facilities are appropriate for the conduct of NLRDs involving GM plants;
- introducing a requirement that NLRDs listed in Schedule 3 Part 2(Notifiable low risk dealings suitable for physical containment level 2) must be conducted in a facility certified to at least physical containment level 2 that is appropriate for the dealing. For dealings involving GMOs for which the unmodified parent organism is classified as Risk Group 3 by AS/NZS 2243.3:2010 the facility must be certified to at least physical containment level 3 which is appropriate for the dealing; and
- allowing the Regulator to approve in writing a facility in which an NLRD may be undertaken.

Section 13(3) focuses on NLRD dealings which involve the transportation, storage or disposal of a GMO and limits these actions to the day before the day specified in section 13A as the day on or before which the dealing must stop being undertaken.

If actions are to be undertaken outside a facility they must comply with any guidelines or written requirements issued by the Regulator under paragraph 27(d) of the GTAQ.

Replacement section 13A applies a time limit for the operation of both existing and prospective NLRDs by providing for a phased introduction of either a 5 year time limit for those assessed after 1 September 2011 or a specific time limit for those dealings assessed before that date. A person seeking an extension of the time limit must apply in writing to an IBC for a new assessment that the dealing is a NLRD.

New sections13B and 13C expand on the NLRD information requirements for IBCs and for persons and accredited organisations by:

- clarifying the rules for IBCs which assess NLRDs;
- describing the information which must be given by an IBC to the proposer of a NLRD;
- setting out the information which must be given to the Regulator by persons or accredited organisations which have been given a copy of an IBC record of assessment which finds that a proposal is an NLRD;
- applying time limits for giving information to the Regulator;
- requiring that records be kept for a specified period of time; and
- allowing the Regulator to serve a notice requesting information about a NLRD be provided by a date specified in the notice.

New section 13B sets out the mandatory content for records of NLRD assessments made by an IBC. An IBC must supply a copy of the assessment to the person or accredited organisation which submitted the proposal in a form approved by the Regulator and which contains the prescribed information. Note that an IBC will no longer be required to supply a copy of the record of assessment to the project supervisor as it is the applicant who is now responsible for keeping and supplying a record of assessment to the Regulator. An IBC is required to give the record of assessment to the entity proposing the NLRD so that there is a full understanding of all of the matters relevant to that NLRD.

New section13C specifies which information must be kept by persons or accredited organisations about a dealing which has been assessed as a NLRD, the form for that record and when the record must be supplied to the Regulator. The record must be given to the Regulator in the financial year during which the IBC made an assessment and the person or accredited organisation must keep a copy of that record for 8 years. The Regulator may also request by notice information about how a NRLD is being undertaken.

The amendments shift the responsibility for keeping records or giving information to the Regulator from an IBC to the person or organisation which proposed the NLRD.

Clause 6 amends paragraph (d) of section 39(1) to take into account previous amendments by requiring records of GMO and GM Product

Dealings to include the date of an IBC NLRD assessment instead of the date of notification for that NLRD.

Clause 7 inserts a transitional provision section 42 located in new *Part 9 Transitional provision for Gene Technology Amendment Regulation (No. 1) 2011*.

New section 42(Transitional provision for particular dealings) provides for the transition of dealings which were classified as exempt or NLRDs but which become licensable dealings after the commencement of the Regulation.

A person or accredited organisation conducting a licensable NLRD has until 1 September 2012 to either cease the dealing or to obtain a licence to undertake the dealing. Where the dealing is currently exempt but is likely to become a licensable NLRD if assessed as such by an IBC the option is to either cease the dealing or to have it assessed by an IBC as an NRLD before 1 September 2012.

Clause 8 amends schedule 1 item 7(b)(i) to make it consistent with the reference to "AS/NZS 2243.3:2010" which is now defined in schedule 5.

Clause 9 amends schedule 2 (Dealings exempt from licensing) in Part 1 by inserting new item 3A.

New item 3A reclassifies dealings with animals whose somatic cells have been genetically modified *in vivo* as being exempt dealings if certain conditions are met. It is considered that these dealings present the same risks as item 3 dealings with animals into which genetically modified somatic cells have been introduced. So in addition to the conditions applied by item 3 the item 3A dealings will only be exempt if the replication defective viral vector used in the modification is no longer present and no germline cells have been genetically modified.

In order for a person to be satisfied whether particular dealings are classified as exempt under new item 3A, it is intended that they should document how the requirements of sub items 3A(a) - (e) are met. Scientific data generated by the proponent or drawn from peer-reviewed published scientific literature could be used to establish that some of the requirements are met. For example, knowledge of the half-life of the viral vector could be used to establish that the replication defective viral vector is no longer in the animal (sub item 3A(b)). To establish that no germ line cells have been genetically modified reference could be made to experiments using the same viral vector and inoculation methodology (sub item 3A(c)). To

establish that the animal is not infected with a virus that can recombine with the introduced GM nucleic acid (sub item 3A(e)), proponents could document that the animal was sourced from a colony maintained so as to be free of relevant pathogens.

Clause 9 also amends Schedule 2, Part 1in sub item 4(1) by increasing from 10 litres to 25 litres the volume of culture of GMOs per vessel which may be classified as exempt dealings involving host/vector systems listed in Schedule 2, Part 2 (host/vector systems for exempt dealings). Experience now indicates that due to the availability of large-scale reaction vessels culture of these GMOs up to 25 litres are appropriately contained and can safely be classified as exempt. Above this volume such dealings remain classified as NLRDs.

Clause 9 further amends schedule 2, part 1 by replacing sub item 4(2) to clarify and modify requirements relating to donor nucleic acid which must be met for a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 to be classified as an exempt. The potential for donor nucleic acid to increase the risk of harm by a GMO is dealt with in sub item 4(2)(a) as follows:

- Specifying that donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in *otherwise healthy* human beings, animals, plants or fungi, the scope of this item is broadened to include consideration of donor nucleic acid from those organisms which may cause disease only in unusual situations, for example in immunocompromised hosts.

- Replacing the characterisation of donor nucleic acid as 'not known to alter features contributing to the ability of a pathogen to cause harm' with a requirement that 'the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm'. This amendment exempts dealings where donor nucleic acid is characterised and known to reduce the ability of a pathogen to cause harm. Additionally, describing this requirement in terms of outcomes (i.e. the capacity to cause harm, illustrated by examples) ensures this requirement is applicable to an appropriately broad range of characteristics which may contribute to the ability of an organism to cause harm.

Sub item 4(2)(e) is amended solely to improve the wording whilst sub item 4(2)(f) has been deleted to remove the requirement that donor nucleic acid

must not confer an oncogenic modification. This amendment is consistent with the need to protect the health and safety of laboratory workers because, with the removal by this regulation of avipox vectors from Part 2 of Schedule 2, none of the host/vector systems permitted for use in exempt dealings is able to transduce human cells. Without the potential for GMOs to transduce human cells the theoretical risk of laboratory workers developing cancer, following inadvertent exposure to a GMO carrying an oncogenic modification, is extremely low with the result that these dealings are considered appropriate for the exempt classification.

Clause 10 replaces schedule 2, part 2 (Host/vector systems for exempt dealings) with a new part 2 to amend the list of approved host/vector systems for exempt dealings. Although some provisions are unchanged others have been modified:

- New hosts are added to the list of approved host/vector systems for exempt dealings. A host/vector system is a system facilitating introduction of a foreign gene or nucleic acid sequence into the host organism. The hosts which are added have been assessed to pose negligible risks to human health and safety or the environment, and to offer a high level of biological containment. The new hosts are:

o *Escherichia coli* Nissle 1917;

o *Lactococcus lactis*;

o *Streptococcus thermophilus*;

o *Synechococcus* strains PCC 7942, PCC 7002 & WH 8102;

o *Synechocystis* sp. strain PCC 6803;

o *Yarrowia lipolytica*.

- An error in the spelling of the host *Pseudoalteromonas tunicata* is corrected.

- The descriptions of tissue culture hosts is expanded to clarify the dealings with animal or human and plant tissue cultures which may be classified as exempt dealings. This amendment is not intended to change the scope of dealings which may be classified as exempt by the GTRQ. In addition to listing types of cultures, the descriptions specify appropriate limits for exempt dealings. Animal tissue cultures are restricted to those which cannot spontaneously generate a whole animal. Plant tissue cultures are

restricted to those which are not intended, and do not without human intervention, reproduce vegetatively or sexually. Tissue culture dealings not meeting these requirements are not considered appropriate for classification as exempt dealings, e.g. dealings involving whole GM plants or animal embryos sufficiently developed to be able to survive to form a whole animal without human intervention. Dealings in which it was intended to produce a whole GM plant or animal is not appropriate for classification as exempt. These restrictions reflect the requirement under paragraph 6(d) that exempt dealings involve no intentional release of a GMO into the environment, by the inclusion of only those hosts offering a high level of biological containment. The descriptions are intended to be applicable to a broad range of host species with different developmental and physiological characteristics.

- Avipox vectors (attenuated vaccine strains) are removed from the list of approved vectors for animal tissue culture hosts. These vectors are the only vectors listed in Part 2 of Schedule 2 of the Regulation able to transduce human cells. Their removal allows for the removal of a restriction on the use of donor nucleic acid conferring oncogenic modifications in exempt dealings involving host/vector systems listed in Part 2 of Schedule 2.

Clause 11 substitutes Schedule 3 (Notifiable low risk dealings in relation to a GMO) with an amended Schedule 3 as follows:

The list in Part 1 (Notifiable low risk dealings suitable for at least physical containment level 1) is amended:

- The wording in section 1.1 is amended to require that dealings must be undertaken in facilities certified to at least physical containment level 1 and that are appropriate for the dealing, unless allowed otherwise under subsections 13(2) or (3), for consistency with the wording of NLRD containment requirements in subsection 13(2).

- Amendments to paragraph 1.1(a) include dealings involving GM laboratory rabbits and laboratory guinea pigs in this category of NLRDs, unless an advantage is conferred on the animal by the genetic modification, or the animal is capable of secreting or producing an infectious agent. Physical containment level 1 is appropriate to the risk posed by such GMOs.

- Paragraph 1.1(b) is removed, consequential to the removal of a restriction on exempt dealings involving donor nucleic acid conferring oncogenic modifications.
- Paragraph 1.1(c) is amended to restrict the dealings which may be conducted as NLRDs in physical containment level 1 facilities to those involving non-retroviral vectors able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (animal or human tissue culture hosts for exempt dealings). The amended paragraph only encompasses dealings with vectors derived from *Human Adenovirus* or *Adeno associated virus* involving donor nucleic acid which cannot restore replication competence and does not confer an oncogenic modification or encode an immunomodulatory protein. Dealings involving other replication defective non-retroviral vectors able to transduce human cells, or other donor nucleic acid, which were formerly encompassed by this paragraph are classified as NLRDs suitable for physical containment level 2.

The list in Part 2 (Notifiable low risk dealings suitable for at least physical containment level 2 or 3) is amended. Although some provisions are unchanged others are either new or have been modified:

- The title of this Part is amended to refer to facilities certified to at least physical containment level 2 or 3 and that are appropriate for the dealing, for consistency with the NLRD containment requirements of section 13(2).
- The wording of section 2.1 is amended to require that dealings must be undertaken in facilities certified to at least physical containment level 2 and that are appropriate for the dealing, unless allowed otherwise under subsections 13(2) or (3), for consistency with the wording of NLRD containment requirements in subsection 13(2).
- Current paragraphs 2.1(aa) and (ab) are combined into paragraph 2.1(aa), which does not alter the classification of the dealings described in these paragraphs. Additional changes to paragraph 2.1(aa) are consequential to the amendment to Schedule 1, Part 1 paragraph 2.1(a) allowing some NLRDs involving GM laboratory rabbits and laboratory guinea pigs in physical containment level 1.

- The requirements for NLRDs involving GM plants described in the current paragraphs 2.1(b) and (ba) are combined and simplified in paragraph 2.1(b). References to specific containment measures for reproductive material are removed because they are redundant with conditions imposed upon PC2 plant facilities certified by the Regulator. Dealings with GM plants must be undertaken in these facilities or other facilities approved by the Gene Technology Regulator, in accordance with an amendment to section13(2). The classification of dealings involving GM plants does not change as a result of this amendment.

- Paragraphs 2.1(c) and (d) are amended to specify that dealings described are those where neither the host nor vector has been implicated in, or has a history of causing, disease in *otherwise healthy* human beings, animals, plants or fungi. The reference in paragraph 2.1(e) to donor nucleic acid characteristics is similarly amended. These amendments allow for the classification as NLRDs of dealings involving hosts or vectors or donor nucleic acid sources which may cause disease only in extreme situations, for example in immunocompromised hosts.

- Paragraphs 2.1(d) and (g) are amended to clarify descriptions relating to the ability of a GMO to cause harm.

- Paragraph 2.1(f) is amended, consequential to an amendment to increase the volume of culture of GMOs involving host/vector systems listed in Schedule 2, Part 2 (host/vector systems for exempt dealings) which may be classified as an exempt dealing, from 10 litres to 25 litres per vessel. There is no change to the classification of dealings involving GMO cultures of more than 25 litres. The requirement that dealings be carried out in at least physical containment level 2 are removed because it is redundant with the requirements of section 13(2) for undertaking NLRDs.

- Paragraph 2.1(i) is a new paragraph that classifies as NLRDs all dealings involving the introduction of a replication defective viral vector unable to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid is unable to restore replication competence to the vector. This recognises that these dealings pose negligible risks to human health and safety, in particular to laboratory workers, because these vectors cannot efficiently enter human cells.

- Paragraphs 2.1(j) and (k) are new paragraphs that classify particular dealings involving replication defective non-retroviral vectors able to transduce human cells as NLRDs. Paragraph 2.1(j) classifies as NLRDs suitable for at least PC2 containment dealings involving the introduction of these vectors into a host mentioned in Part 2 of Schedule 2, except where the dealing is classified as a NLRD suitable for PC1 containment according to paragraph 1.1(c) (particular dealings with vectors derived from *Human adenovirus* or *Adeno associated virus*). Paragraph 2.1(k) classifies as NLRDs dealings involving the introduction of these vectors into any other host, including animals, provided that the donor nucleic acid does not present specific risks (ie confers an oncogenic modification, or encodes an immunomodulatory protein).

- Paragraphs 2.1(l) and (m) are new paragraphs that classify as NLRDs particular dealings involving replication defective retroviral vectors (including lentiviral vectors) able to transduce human cells. These dealings are limited to dealings involving these viral vectors with specific safety features which reduce the likelihood of adverse outcomes for laboratory workers inadvertently exposed to the vectors. These safety features primarily reduce the potential for replication competence to be regained. Paragraph 2.1(l) classifies as NLRDs dealings involving the introduction of these vectors into a host mentioned in Part 2 of Schedule 2.paragraph 2.1(m) classifies as NLRDs dealings involving the introduction of these vectors into any other host, including animals, provided that the donor nucleic acid does not present specific risks (ie confers an oncogenic modification, or encodes an immunomodulatory protein).

- Section 2.2 requires that any dealing classified as a NLRD under Part 2 of Schedule 3 involving a Risk Group 3 microorganism (according to the criteria of AS/NZS 2243.3:2010) must be undertaken in facilities that are certified to at least physical containment level 3 and that are appropriate for the dealing, unless allowed otherwise under sections(2) or (3). Risk group 3 microorganisms pose high risk to individuals, and AS/NZS 2243.3:2010 indicates that work with these microorganisms should be carried out in PC3 facilities to manage risks to human health and safety. This paragraph encompasses all dealings involving GMOs for which the unmodified parent organism is

classified as Risk Group 3, and does not provide for IBCs to assess any change to risk group classification as a result of genetic modifications. Such case-by-case assessment is considered beyond the scope of the NLRD category.

The list in Part 3 (Dealings that are not notifiable low risk dealings) is amended. Although some provisions are unchanged others are either new or have been modified:

- Paragraphs 3.1(d) and (e) replace the current paragraph 3.1(d). The amended wording is intended to improve clarity and specificity with respect to dealings involving viral vectors where the donor nucleic acid may pose increased risks to human health and safety and the environment, and which therefore require licensing.
- Paragraph 3.1(d) requires a licence for dealings involving the introduction of a replication defective viral vector into a host not mentioned in Part 2 of Schedule 2, including animals, where the donor nucleic acid presents specific risks (i.e. confers an oncogenic modification, or encodes an immunomodulatory protein). This paragraph complements NLRDs described by paragraphs 2.1(k) and (m) of Schedule 3 Part 2 (which specifically exclude these types of donor nucleic acid), and does not apply to dealings classified as NLRDs by paragraph 2.1(i) (dealings involving replication defective viral vectors unable to transduce human cells where the donor nucleic acid is unable to restore replication competence).
- Paragraph 2.1(e) requires a licence for dealings involving replication competent viral vectors, where the donor nucleic acid presents specific risks (i.e. confers an oncogenic modification, or encodes an immunomodulatory protein). This requirement does not apply to dealings involving viral vectors mentioned in Part 2 of Schedule 3.
- Paragraph 2.1(f) is similar to paragraph 2.1(e), with amended wording to clarify references to the donor nucleic acid increasing the capacity of a GMO to cause harm and the ability of a host or vector microorganism to cause disease.
- Paragraph 2.1(g) is very similar to paragraph 2.1(f), with a minor amendment to the wording of a cross-reference.

- Paragraph 2.1(h) is very similar to paragraph 2.1(g), with amended wording intended to clarify but not change the meaning of the paragraph.
- Paragraph 2.1(i) is similar to paragraph 2.1(h), with amended wording to clarify a reference to the capacity of a GMO to cause harm.
- Paragraph 2.1(j) amends paragraph 2.1(i), broadening its scope to require a licence for particular dealings involving any retroviral vector, in addition to lentiviral vectors, which are replication defective and able to transduce human cells. This requirement does not apply to dealings involving replication defective retroviral vectors carrying particular safety features, which are classified as NLRDs according to paragraphs 2.1(l) and (m) of Schedule 3 Part 2. This recognises that, in the absence of these safety features, retroviral vectors have the potential to regain replication competence, which presents a risk to the people involved in the dealing.
- Paragraph 2.1(k) is re numbered and replaces 2.1(j) which is unaltered.
- Paragraph 2.1(l) is very similar to paragraph 2.1(k), and increases the minimum volume of GMO culture for which dealings must be licensed from 10 to 25 litres, other than those dealings classified as NLRDs according to paragraph 2.1(f) of Schedule 3 Part 2.
- Paragraph 2.1(m) is re numbered from paragraph 2.1(l) and is unaltered.
- Paragraph 2.1(n) is similar to paragraph 2.1(m), amended to exclude particular dealings involving the introduction of a GMO into a human being for somatic cell gene therapy from the requirement for licensing. This exclusion is limited to situations involving the introduction of human GM somatic cells that are incapable of secreting any infectious agents into a human being. *Ex vivo* dealings involving GM human cells prior to introduction into the patient continues to be regulated according to their classification in Schedules 2 and 3 of the GTRQ. The definition of a GMO in section 10 of the Act specifically excludes people who have undergone somatic cell gene therapy from being considered GMOs in the regulatory scheme, so a patient into

which GM somatic cells have been introduced (including the GM somatic cells) is not subject to regulation under the Act.

- Paragraph 2.1(o) is re numbered from paragraph 2.1(n) and is unaltered.
- Paragraph 2.1(p) requires a licence for a dealing involving a genetically modified microorganism derived from an unmodified parent organisms which is classified as Risk Group 4 according to the criteria of AS/NZS 2243.3:2010. Risk group 4 microorganisms pose high risk to individuals and the community, and AS/NZS 2243.3:2010 indicates that work with these microorganisms should be carried out in PC4 facilities to manage risks to human health and safety. Licensing of dealings with these microorganisms ensures that appropriate containment requirements can be imposed upon such dealings. This paragraph encompasses all dealings involving GMOs for which the unmodified parent organism is classified as Risk Group 4, and does not provide for IBCs to assess any change to risk group classification as a result of genetic modifications. Such case-by-case assessment is beyond the scope of the NLRD category.

Clause 12 amends Schedule 5 (Definitions) to define words and phrases including the updated reference for *AS/NZS 2243.3:2010* and new definitions for *genetically modified laboratory guinea pig* and *genetically modified laboratory rabbit*.

The definition of *oncogenic modification* is amended to improve the clarity of sections which use this term. The amended definition provides examples of the types of genetic modifications which may contribute to tumour formation so that they fall within the definition The amended definition removes reference to 'vertebrate cells' to allow an oncogenic modification to be specified in conjunction with the use of this term elsewhere in the Regulation.

The definition for *non-vector system is amended* to include situations where a vector was used to genetically modify a host but the vector is no longer present in, or is present and unable to be remobilised from, the host. In such a situation, any risk associated with the potential for the donor nucleic acid to be transferred to a new host cell is the same as that for situations in which a GMO was generated without the use of a nucleic acid-based vector. If no free vector is present, the risks posed by the

dealing relate solely to the characteristics of the host and the donor nucleic acid, features which form the basis of classification of dealings involving non-vector systems in Schedules 2 and 3.

It is intended that the properties of the GMO and vector are the primary consideration in determining whether a system meets the amended definition of *non-vector system*. Vectors which could be remobilised only through human intervention (e.g. by using experimental procedures to retrieve vector sequences) are not considered to have an innate ability to be remobilised, and meet the amended definition of *non-vector system*.

ENDNOTES

1 Laid before the Legislative Assembly on . . .

2 The administering agency is the Department of Employment, Economic Development and Innovation.