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LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

GENE TECHNOLOGY AMENDMENT REGULATION 2011 (No 1)

SL2011-26

EXPLANATORY STATEMENT

Presented by the
Minister for Health
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Overview

Under the intergovernmental Gene Technology Agreement 2001 (IGA), all States and Territories have committed to ensuring a nationally consistent regulatory scheme for gene technology by maintaining corresponding legislation.

The Gene Technology Amendment Regulation 2011 (No 1) amends the Gene Technology Regulation 2004 (the regulation), a component of the national framework for the regulation of gene technology, to correspond with amendments made to the Commonwealth Gene Technology Regulations 2001 effected by the Commonwealth Gene Technology Amendment Regulations 2011 (No 1).

Background

Consistent with the roles and functions of the Gene Technology Regulator (the regulator) under the Commonwealth Act, the regulator undertook a review of the Commonwealth Principal Regulations. Sections 32 and 74 of the Commonwealth Act provide for the Principal Regulations to declare dealing with a genetically modified organism (GMO) to be an exempt dealing or a notifiable low risk dealing (NLRD), respectively. Sections 140 and 141 of the Commonwealth Act provide for the regulator to review the classification of dealings as NLRDs and exempt dealings, respectively. The regulator undertook consultation on the amendments pursuant to the requirements of section 142 of the Act.

Paragraph 27(g) of the Commonwealth Act provides that it is a function of the regulator to advise the Gene Technology Ministerial Council (GTMC) about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments. Under clause 40 of the intergovernmental Gene Technology Agreement 2001, amendment of legislation comprising the nationally consistent regulatory scheme requires approval from the GTMC. The GTMC agreed to the Commonwealth Regulations which were made on 2 June 2011 and commence on 1 September 2011.

The purpose of the amendments is to:

- ensure that dealings with GMOs continue to be classified appropriately according to current scientific understanding of risks which they may pose;
- improve the efficiency and effectiveness of the regulatory system; and
- assist users to better understand and comply with their legislative obligations.

This is achieved by:

- clarifying requirements for undertaking NLRDs, including introduction of a time limit;
- reclassifying certain dealings as exempt, NLRDs or as requiring licensing under the Act;
- and making some minor administrative changes.

Consultation
As part of the review process the regulator consulted widely. Initial consultation with the organisations accredited under the Commonwealth Act, Institutional Biosafety Committees (IBCs), State and Territory governments and Australian Government agencies identified a number of areas in the Commonwealth 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 Commonwealth Act. Comments were sought from 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*.

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NOTES ON CLAUSES

Clause 1 – Name of regulation – provides that the regulation is the *Gene Technology Amendment Regulation (No 1)*.

Clause 2 – Commencement – provides that the regulation commences on 1 September 2011. This is the date on which the Commonwealth *Gene Technology Regulation Amendment Regulations 2011 (No.1*) commence.

Clause 3 – Legislation amended – provides that the regulation amends the *Gene Technology Regulation 2004*.

Clause 4 – Section 6 (1) (e) - omits section 6 (1) (e) to remove reference to retroviral vectors able to transduce human cells. This paragraph is redundant following amendments introduced by the Commonwealth *Gene Technology Amendment Regulations 2007* which removed dealings involving retroviral vectors able to transduce human cells from the exempt category.

Clause 5 – Section 11A – **Time limit for deciding variation application** - substitutes the current section 11A and introduces 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 not to be counted in this period are:

- a Saturday, a Sunday or a public holiday as defined by the *Legislation Act* (see Clause 18);
- 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, this item corrects the implementation in the Commonwealth *Gene Technology Amendment Regulations 2007* of recommendation 5.9 of the *Statutory Review of the Gene Technology Act 2000 and The Gene Technology Agreement*, that there be a 90 working day

timeframe within which the regulator must assess applications to vary a licence. This item also provides that delays due to waiting for information from the applicant, which are beyond the control of the Regulator, do not count toward the statutory timeframe for decisions on licence variation applications.

Clause 6 – Section 12 (1) (a) – this amends references to the schedules to take into account amendments to schedule 3 introduced by this amendment regulation.

Clause 7 – Section 13 – substitutes the current section 13 to clarify the requirements, roles and responsibilities for people undertaking a notifiable low risk dealing (NLRD). Some requirements are unchanged from those in the current section, and other requirements are new or modified as described below.

Section 13 (1) amends the requirements of the current section 13 (1) 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 the amended section 13A, i.e. 5 years after the date of assessment for NLRD proposals assessed after commencement of the regulation;
- limit the people who may undertake the dealing to those mentioned in the Institutional Biosafety Committee (IBC) 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 amendments in clause 8 below.

These amendments clarify that only proposals which have been assessed by an IBC may be undertaken as NLRDs. IBC assessments 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 rest with the person undertaking the dealing. To ensure that this person clearly understands what constitutes the dealing assessed by an IBC to be a NLRD, that person must have access to a copy of the IBC's record of assessment. Responsibility to not compromise containment of the GMO, and to comply with the requirements of subsections (2) and (3) also lie with the person undertaking the dealing. If a person undertakes a NLRD in contravention of the requirements of the regulation, this may constitute an offence under the Act, section 37.

These amendments introduce a time limit on the authority to conduct a NLRD following the approval of a proposal by an IBC, operating in conjunction with section 13A. This ensures 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 Commonwealth

Principal Regulations. In addition, this amendment improves the effectiveness of oversight of NLRDs and improves transparency of the regulatory system clarifying which NLRDs included in the Record of GMO and GM Product Dealings may be ongoing at any particular time.

Section 13 (2) substitutes section 13 (2) to:

- clarify that for facilities to be appropriate for a NLRD it is necessary to meet the required physical containment level and be of an appropriate type (eg PC2 plant facilities are appropriate for the conduct of NLRDs involving GM plants);
- introduce a requirement that NLRDs listed in schedule 3, part 3.2 (kinds of dealings suitable for at least physical containment level 3) must be conducted in facilities certified to at least physical containment level 3 that are appropriate for the dealing. This includes all dealings involving GMOs for which the unmodified parent organism is classified as Risk Group 3 by AS/NZS 2243.3:2010. It is not intended to provide for IBCs to assess any change to risk group classification as a result of genetic modification, as such case-by-case assessment is considered beyond the scope of the NLRD category; and
- replace the provision in the regulation for dealings to be undertaken in another facility, in accordance with technical and procedural guidelines for undertaking the dealing, with a provision to allow NLRDs to be conducted in a facility agreed in writing by the Regulator.

This amendment clarifies the requirements for facilities in which NLRDs may be undertaken, and provides flexibility for the regulator to agree to dealings being undertaken in other facilities.

Section 13(3)

This amendment also replaces the provisions of paragraph 13 (2) (b) of the current regulation with a new subsection (3). Paragraph 13 (2) (b) of the regulation allows the transport of GMOs in accordance with guidelines issued by the regulator under section 27 (d) of the *Gene Technology Act 2003* (the Act), and subparagraph 13 (2) (a) (iii) of the regulation requires that dealings undertaken in another facility (including storage and disposal of GMOs) be undertaken in accordance with guidelines issued by the regulator under section 27 (d) of the Act. This item combines these requirements to a single subsection allowing the transportation, storage or disposal of a GMO outside a facility specified in subsection 13 (2), within the time limit for the NLRD. This item maintains the current requirement that these aspects of NLRDs be conducted in accordance with technical and procedural guidelines issued by the regulator under section 27 (d) of the Act for this purpose.

The amendment specifies that the applicable guidelines, the *Guidelines for the Transport, Storage and Disposal of GMOs*, are those in force on 1 September 2011. These guidelines, which are yet to be issued by the regulator, will be available from 1 September 2011 from the Office of the Gene Technology Regulator (OGTR) website. This item also allows that transport, storage or disposal may be undertaken in accordance with other requirements which the regulator agrees in writing are appropriate for the containment of GMOs.

Section 13 (4) requires that, in granting an agreement to dealings being undertaken in other facilities, the regulator must consider the capacity of the facility to contain the GMOs.

Clause 8 – Section 13A – substitutes the existing section 13A with three new sections which encompass and expand upon the requirements for NLRDs prescribed by the existing section 13A, and introduce new requirements. The amendments clarify the roles and responsibilities for persons or accredited organisations and IBCs regarding assessment and conduct of NLRDs, notification of NLRDs to the regulator and keeping of records.

Section 13A – Time limits for stopping notifiable low risk dealings

Section 13A prescribes the time limit within which a NLRD may be undertaken, operating through paragraph 13 (1) (d). This amendment provides for a phased introduction of NLRD time limits for those NLRDs assessed by IBCs prior to the commencement of the regulation, and a time limit of five years from the date of assessment for NLRDs assessed after commencement. If people wish to continue to conduct a NLRD beyond the time limit, they have to make a new written NLRD proposal to an IBC and obtain an assessment from the IBC that the dealing is a NLRD.

Section 13B – Requirements for institutional Biosafety committees about records of assessments or notifiable low risk dealing proposals

Section 13B details the requirements of IBC assessments of proposals for NLRDs. IBCs are required to make a record of assessment for NLRD proposals including information specified by the regulator, and give a copy of the record to the person or accredited organisation that submitted the proposal. The regulation requires that the record of assessment be made in a form approved by the regulator. Because the IBC record of assessment function primarily as a record used by NLRD proponents, it is intended that the regulator prescribes what information IBCs must include in their record of assessment, and allow IBCs the flexibility to determine the manner in which this information is recorded (eg in an electronic database, in a paper document of their design, or on a proforma made available by the regulator).

This removes the current requirement that a copy of the record of assessment be given to the project supervisor. In conjunction with section 13C, this clarifies that it is the person or accredited organisation making the NLRD proposal that is responsible for notifying the regulator and keeping records, and other actions flowing from an IBC assessment that the dealing is a NLRD. Paragraph 13B (b) requires that a person undertaking the dealing must have access to a copy of the record of assessment.

Those aspects of IBC assessment relevant to other parts of the regulation are specified in this section, for example information required for the Record of GMO and GM Product Dealings, and considerations related to requirements of section 13 (1) which limit who may undertake NLRDs and the facilities in which they may be undertaken. The regulator provides guidance on those matters which must be addressed by an IBC's assessment of NLRD proposals through the regulator's requirements for the record of assessment.

Section 13C – Information to be kept or given to the regulator by people or accredited organisations.

Section 13C details the requirements for people and organisations in relation to notification of NLRDs to the regulator, the keeping of records, and providing further information to the regulator on request.

Subsections (1) to (3) clarify that a person or accredited organisation given a copy of the IBC's record of assessment, i.e. the person who submitted the proposal to the IBC, is responsible for:

- notifying the regulator of the NLRD, in a form approved by the regulator, in an annual report for the financial year;
- keeping a copy of the IBC's record of assessment for a period of eight years after the date of assessment, i.e. for three years following the five year period in which the NLRD may be undertaken.

As a result of section 13B (requirements for IBC records of assessment), the scope of information IBCs must record for NLRD assessments is greater than that required by the regulator for the purpose of NLRD notifications. As a consequence, this item amends NLRD reporting requirements to specify that notification to the regulator must be in a form approved by the regulator, removing the requirement to provide a copy of the IBC's record of assessment. NLRD notifications to the regulator are required (through the form approved by the regulator) to contain information extracted from the IBC record of assessment, in order to ensure the records kept by NLRD proponents and the regulator are consistent. Information to be included in NLRD notifications to the regulator includes information required for the Record of GMO and GM Product Dealings, and information necessary for the regulator to uniquely identify the NLRD.

Subsections (4) and (5) require that, on written request from the regulator, the people or accredited organisation that proposed the NLRD or any other person involved with undertaking the dealing must give the regulator requested information regarding the conduct of a NLRD. This information must be provided by the end of the period specified in the written request from the regulator. The scope of information which may be requested by the regulator will be broadened to include information about how the NLRD is being undertaken.

This item removes a requirement that IBCs provide additional information to the regulator on request. This clarifies that IBCs are not responsible for keeping records or providing information to the regulator, these are responsibilities of the person or accredited organisation that proposed the NLRD.

Clause 9 – Section 39 (1) 9 (b) – allows insertion of a reference as a result of other amendments.

Clause 10 – Section 39 (1) (d) –amends paragraph 39 (1) (d) of the regulation to take into account previous amendments. Section 39 (1) prescribes information which must be contained in the Record of GMO and GM Product Dealings for NLRDs that are notified to the regulator. The section removes a requirement that NLRDs be notified to the regulator prior to dealings being conducted, allowing that NLRDs may be conducted following their assessment by an IBC to be a NLRD. This clause amends the information required for the Record of GMO and GM Product Dealings to remove the requirement for the date of notification of a NLRD, and to instead require the date of NLRD assessment by an IBC. This supports the implementation of the NLRD time limit and improves transparency of the regulatory system by clarifying which NLRDs included in the Record of GMO and GM Product Dealings may be ongoing at any particular time.

Clause 11 – New part 9 – ***Transitional Provisions***
Section 45 of this new part provides for the transition of dealings currently being conducted as exempt or notifiable low risk dealings (NLRDs) but which become licensable dealings under the regulation on 1 September 2011. A person conducting such a dealing has until 1 September 2012 to either cease the dealing or obtain a licence to undertake the dealing.

This part also provides for the transition of dealings currently being conducted as exempt dealings but which become NLRDs under the regulation. A person conducting such a dealing has until 1 September 2012 to either cease the dealing or have the dealing assessed by an Institutional Biosafety Committee (IBC) as a NLRD.

Section 46 of this new part provides that part expires on 1 September 2013.

Clause 12 – Schedule 1, item 7, subparagraph (b) (i) –amends the current subparagraph (b) (i) of schedule 1 item 7, to accommodate the inclusion of a definition of "AS/NZS 2243.3:2010" (see Clause 19 below).

Clause 13 – Schedule 2, part 2.1, new item 3A – This new item provides for dealings with animals whose somatic cells have been genetically modified *in vivo* to be classified as exempt dealings, where certain conditions are met. These dealings present the same risks as dealings with animals into which genetically modified somatic cells have been introduced (classified as exempt by schedule 2, part 2.1, item 3 of the regulation), provided that, in addition to conditions applying to item 3, the replication defective viral vector used in the modification is no longer present and no germline cells have been genetically modified.

For a person to be satisfied whether particular dealings are classified as exempt under this item, it is intended that they should document how the requirements of subitems (a) to (e) are met. Scientific data generated by the proponent or drawn from peer-reviewed published scientific literature could be used to establish that some 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 (subitem (b)). It could be established that no germ line cells have been genetically modified by reference to data from experiments using the same viral vector and inoculation methodology (subitem (c)). To establish that the animal is not infected with a virus that can recombine with the introduced GM nucleic acid (subitem (e)), proponents could document that the animal was sourced from a colony maintained so as to be free of relevant pathogens.

Clause 14 – Schedule 2, part 2.1, item 4 – substitutes a new item which clarifies and modifies the requirements relating to donor nucleic acid which must be met for a dealing involving a host/vector system mentioned in schedule 2, part 2.2 to be classified as an exempt dealing. Consideration of the potential for donor nucleic acid to increase the ability of a GMO to cause harm in item 4 are modified as follows:

- The volume of culture of GMOs per vessel which may be classified as an exempt dealing, for dealings involving host/vector systems listed in schedule 2, part 2.2 (host/vector systems for exempt dealings) increases from 10 litres to 25 litres. Experience indicates that dealings involving culture of these GMOs up to 25 litres with the large-scale reaction vessels now available are appropriately contained and therefore appropriate to be classified as exempt. Above this volume, such dealings remain classified as NLRDs.
- By 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.

- The requirement in the regulation that donor nucleic acid is characterised and 'not known to alter' features contributing to the ability of a pathogen to cause harm is replaced 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 clarifies that the requirements for classification as an exempt dealing are met in situations 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.

The wording of subparagraph (2) (e) (ii) is also amended. The amended wording is intended to improve the clarity of this subparagraph without changing its meaning.

This item removes the requirement in paragraph (2) (f) 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 of avipox vectors from schedule 2, part 2.2 (see clause 15), 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, and so these dealings are considered appropriate for the exempt classification.

Clause 15 – Schedule 2, part 2.2 - substitutes the current schedule 2, part 2.2, amending the list of approved host/vector systems for exempt dealings. Some paragraphs are unchanged. Other paragraphs are new or modified, as listed below:

- 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:
  - *Escherichia coli* Nissle 1917;
  - *Lactococcus lactis*;
  - *Streptococcus thermophilus*;
  - *Synechococcus* strains PCC 7942, PCC 7002 & WH 8102;
  - *Synechocystis* sp. strain PCC 6803;
  - *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 Principal Regulations. 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 schedule 2, part 2.2 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 schedule 2, part 2.2 (see clause 14 above).

Clause 16 – Schedule 2, part 2.3, definition of *non-vector system*, except note - amends the definition of *non-vector system* 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*.

Clause 17 – Schedule 3 - substitutes the current schedule 3 (Notifiable low risk dealings in relation to a GMO) to the regulation with an amended schedule 3, as detailed below.

Part 3.1 – Notifiable low risk dealings suitable for at least physical containment level 1

This item replaces the current schedule 3, part 3.1 with an amended list of NLRDs suitable for at least physical containment level 1. Amendments to each paragraph are as follows:

- The wording of part 3.1 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 sections 13 (2) or (3), for consistency with the wording of NLRD containment requirements in section 13 (2).
- Amendments to paragraph 3.1(a) includes 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 3.1 (b) is removed, consequential to the removal of a restriction on exempt dealings involving donor nucleic acid conferring oncogenic modifications (see clause 14 above).

- Paragraph 3.1 (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 schedule 2, part 2.2 (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.

Part 3.2 – Notifiable low risk dealings suitable for at least physical containment level 2 or 3

This item replaces the current schedule 3, part 3.2 with an amended list of NLRDs suitable for at least physical containment level 2 or 3. Some paragraphs are unchanged from those in the regulation. Other paragraphs are new or modified, as listed below:

- 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 3.2 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 sections 13 (2) or (3), for consistency with the wording of NLRD containment requirements in subsection 13(2).
- Current paragraphs 3.2 (aa) and (ab) are combined into paragraph 3.2 (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 1.1 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 3.2 (b) and (ba) are combined and simplified in paragraph 3.2 (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 regulator, in accordance with an amendment to subsection 13 (2). The classification of dealings involving GM plants does not change as a result of this amendment.
- Paragraphs 3.2 (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 3.2 (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 3.2 (d) and (g) are amended to clarify descriptions relating to the ability of a GMO to cause harm, as described for clause 14 above.
- Paragraph 3.2 (f) is amended, consequential to an amendment to increase the volume of culture of GMOs involving host/vector systems listed in schedule 2, part 2.2 (host/vector systems for exempt dealings) which may be classified as an exempt dealing, from 10 litres to 25 litres per vessel (see clause 14 above). 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 subsection 13 (2) for undertaking NLRDs.

- Paragraph 3.2 (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 schedule 2, part 2.2, 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 3.2 (j) and (k) are new paragraphs that classify as NLRDs particular dealings involving replication defective non-retroviral vectors able to transduce human cells. Paragraph 3.2 (j) classifies as NLRDs suitable for at least PC2 containment dealings involving the introduction of these vectors into a host mentioned in schedule 2, part 2.2, 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 3.2 (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 3.2 (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 3.2 (l) classifies as NLRDs dealings involving the introduction of these vectors into a host mentioned in schedule 2, part 2.2. Paragraph 3.2 (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 3.2A requires that any dealing classified as a NLRD under schedule 3, part 3.2 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 13 (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.

Part 3.3 – Dealings that are not notifiable low risk dealings

This item replaces the current schedule 3, part 3.3 with an amended list of dealings that are not NLRDs. Some paragraphs are unchanged from those in the regulation. Other paragraphs are new or modified, as listed below:

- Paragraphs 3.3 (d) and (e) replace the current paragraph 3.3 (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 3.3 (d) requires a licence for dealings involving the introduction of a replication defective viral vector into a host not mentioned in schedule 2, part 2.2, 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 3.2 (k) and (m) of schedule 3, part 3.2 (which specifically exclude these types of donor nucleic acid), and does not apply to dealings classified as NLRDs by paragraph 3.2 (i) (dealings involving replication defective viral vectors unable to transduce human cells where the donor nucleic acid is unable to restore replication competence).
- Paragraph 3.3 (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 schedule 3, part 3.2.
- Paragraph 3.3 (f) is similar to paragraph 3.3 (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, as described for clause 14 above.
- Paragraph 3.3 (g) is very similar to paragraph 3.3 (f), with a minor amendment to the wording of a cross-reference.
- Paragraph 3.3 (h) is very similar to paragraph 3.3 (g), with amended wording intended to clarify but not change the meaning of the paragraph.
- Paragraph 3.3 (i) is similar to paragraph 3.3 (h), with amended wording to clarify a reference to the capacity of a GMO to cause harm, as described for clause 14 above.
- Paragraph 3.3 (j) amends paragraph 3.3 (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 3.2. 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 3.3 (k) is relettered from current paragraph 3.3 (j) and remains unaltered.
- Paragraph 3.3 (l) is very similar to paragraph 3.3 (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 3.2.
- Paragraph 3.3 (m) is relettered from paragraph 3.3 (l) and remains unaltered.
- Paragraph 3.3 (n) is similar to paragraph 3.3 (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 regulation. 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 whom GM somatic cells have been introduced (including the GM somatic cells) is not subject to regulation under the Act.
- Paragraph 3.3 (o) is relettered from paragraph 3.3 (n) and remains unaltered.

- Paragraph 3.3 (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 18 – Dictionary, note 2 – adds 'public holiday' as one of the definitions or other provisions defined by the *Legislation Act* relevant to this regulation.

Clause 19 – Dictionary, new definition of *AS/NZS 2243.3:2010* –inserts a definition of Australian/New Zealand Standard (AS/NZS) 2243.3:2010 to support the use of the term elsewhere in the Regulation.

Clause 20 – Dictionary, new definitions – this inserts definitions of 'genetically modified laboratory guinea pig' and 'genetically modified laboratory rabbit' to support the use of the term elsewhere in the regulation. A definition of 'inspector' as a 'person appointed by the regulator under the Act, section 150 as an inspector' is also inserted.

Clause 21 – Dictionary, new definition of *oncogenic modification* – This item amends the definition of 'oncogenic modification' to increase clarity where this term is used. The amended definition provides examples of the types of genetic modifications which may contribute to tumour formation, thus making the modification fall within the amended definition of 'oncogenic modification'. The amended definition removes reference to 'vertebrate cells', instead allowing the situation in which a modification is oncogenic to be specified in conjunction with the use of this term elsewhere in the regulation.