EXPLANATORY STATEMENT

Select Legislative Instrument 2019 No. XX

Gene Technology Act 2000

Gene Technology Amendment (2019 Measures No. 1) Regulations 2019

The *Gene Technology Act 2000* (the Act) establishes the Australian Government's component of the nationally consistent scheme for regulating dealings with genetically modified organisms (GMOs) to protect the health and safety of people and the environment. The Gene Technology Regulator (the Regulator) is a statutory office holder responsible for administering the Act.

Subsection 193(1) of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Gene Technology Regulations 2001* (the Principal Regulations) support the implementation of the Act by providing technical details, such as the categorisation of different dealings with GMOs, as well as specifying administrative processes and procedures.

The purpose of the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019* (the Regulations) is to:

- ensure that certain 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 scheme; and
- assist users to better understand and comply with their legislative obligations.

Paragraph 27(g) of the Act provides that it is a function of the Regulator to advise the Ministerial Council (the Legislative and Governance Forum on Gene Technology) about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments. The Regulator recently completed a review of the Principal Regulations, with the aim of clarifying definitions and resolving technical issues to improve the effectiveness of the legislative framework.

Sections 140 and 141 of the Act provide for the Regulator to review the classification of dealings as notifiable low risk dealings (NLRDs) and exempt dealings, respectively. Subsection 140(2) of the Act provides that the basis of the Regulator's consideration of a NRLD must relate to the matters of which the Regulator must be satisfied under subsection 74(2) or the matters the Regulator must consider under subsection 74(3).

Subsection 74(2) provides that before the Governor-General makes regulations declaring a dealing with a GMO to be a NLRD, the Regulator must be satisfied that the dealing would not involve the intentional release of a GMO into the environment.

Subsection 74(3) provides that before the Governor-General makes regulations declaring a dealing with a GMO to be a NLRD, the Regulator must consider:

(a) whether the dealing with the GMO would involve any risk to the health and safety of people, or to the environment, taking into account:

(i) the properties of the GMO as a pathogen or pest; and
(ii) the toxicity of any proteins produced by the GMO; and

(b) if there is such a risk—whether one or more of the requirements prescribed in the regulations for the purposes of subsection 75(2) would be sufficient to manage that risk; and

(c) any other matter the Regulator considers appropriate.

The Legislative and Governance Forum on Gene Technology, comprising one relevant Minister from the Australian Government and each State and Territory government, has approved the Regulations, as is required under the intergovernmental Gene Technology Agreement 2001.

The Act specifies no other conditions which need to be satisfied before the power to make the Regulations may be exercised.

Details of the Regulations are set out in the Attachment.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence in three stages: measures relating to NLRD assessment and reporting on 1 July 2020, to align with financial year reporting periods; repeal of one provision on the day 18 months after registration on the Federal Register of Legislation, effectively providing a transitional period; and all other measures on the day six months after registration on the Federal Register of Legislation, providing time for jurisdictions to amend their gene technology legislation as necessary.

Consultation

The Regulator held two consultations as part of the review of the Principal Regulations, each time receiving submissions from members of the public, research organisations, individual researchers, companies, industry bodies, community groups, Australian Government agencies, States and Territories and others. These consultations were publicly notified on the Office of the Gene Technology Regulator (OGTR) website, and by notices in a national newspaper and the Australian Government Gazette. Invitations to comment were also sent to individuals and organisations registered on the OGTR News mailing list, organisations accredited under the Act, Institutional Biosafety Committees, relevant Australian Government agencies and States and Territories. The Regulator also sought the advice of the Gene Technology Technical Advisory Committee on various technical matters throughout the course of the review.

To inform the development of amendment proposals, the Regulator sought submissions in response to a discussion paper, from 17 October to 16 December 2016; 740 submissions were received. The issues raised by these submissions were taken into account in developing amendment proposals, which were the subject of consultation from 30 November 2017 to 21 February 2018. This consultation was undertaken pursuant to the requirements of section 142 of the Act in relation to reviewing NLRD and exempt dealing classifications. The 450 submissions received were taken into account in finalising the Regulations.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Gene Technology Amendment (2019 Measures No. 1) Regulations 2019

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The purpose of this Disallowable Instrument is to amend the *Gene Technology Regulations 2001* (the Principal Regulations) in order to improve their operation without changing the underlying policy intent of the gene technology regulatory scheme.

The Gene Technology Regulator, the statutory office holder responsible for administering the *Gene Technology Act 2000* and Principal Regulations, has reviewed the Principal Regulations with the aim of clarifying definitions and resolving technical issues. The purpose of the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019* is to give effect to the recommendations from the review, to:

- ensure that certain 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 scheme; and
- assist users to better understand and comply with their legislative obligations.

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Senator the Honourable Bridget McKenzie, Minister for Regional Services, Sport, Local Government and Decentralisation

ATTACHMENT

Details of the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019*.

Section 2 – Commencement

This section provides that the Regulations commence in accordance with the following:

- Sections 1 to 4 – the day after the Regulations are registered;
- Schedule 1 – the day after the end of the period of 6 months beginning on the day the Regulations are registered;
- Schedule 2 – on 1 July 2020; and
- Schedule 3 – the day after the end of the period of 18 months beginning on the day the Regulations are registered.

Section 3 – Authority

This section provides that the Regulations are made under the *Gene Technology Act 2000* (the Act).

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms. Schedules 1-3 specify amendments to the *Gene Technology Regulations 2001* (the Principal Regulations).

Schedule 1 – Amendments commencing 6 months after registration

Gene Technology Regulations 2001

Items [1]-[3] – regulation 3

These items amend the definitions of "characterised" and "non-vector system" in principal regulation 3, and insert a definition of "host/vector system", to support the use of these terms elsewhere in the Regulations.

Item [4] – regulation 3

This item replaces the Greek letter mu (μ), as part of a recognised international symbol indicating micrograms, with the word "micrograms", in the definition of "toxin-producing organism".

Item [5] – regulation 3

The note to regulation 3 draws attention to several words and expressions used in the Principal Regulations being given meanings by the Act. This item removes "GM product" from the list of examples provided, as the Regulations repeal the term from the Principal Regulations.

Item [6] – regulation 4

This item corrects a cross-reference to the Act.

Item [7] – organisms that are genetically modified organisms

This item inserts new regulation 4A which, supported by a new schedule, describes organisms that are genetically modified organisms (GMOs) for the purposes of the definition of "genetically modified organism" in subsection 10(1) of the Act. Item [25] of Schedule 1 inserts the new Schedule 1B to the Principal Regulations.

Item [8] – organisms that are not genetically modified organisms

This item amends principal regulation 5 to avoid any doubt about the status of an organism in which multiple traits from gene technology are present, or that simultaneously meets items in Schedule 1 and new Schedule 1B.

This item makes explicit that an organism meeting any of the items in Schedule 1 is not considered a GMO for the purposes of subsection 10(1) of the Act only if it does not have other traits that occurred because of gene technology. For example, if an organism described in one or more items of Schedule 1 was also modified by insertion of a transgene, or had inherited a transgene, that organism is considered a GMO.

This item also provides clarity about the status of any organism meeting items in both Schedule 1 and new Schedule 1B. Should an organism meet items in both schedules, that organism is considered a GMO for the purposes of subsection 10(1) of the Act.

Item [9] – paragraph 9(f)

This item amends paragraph 9(f) to refer to the current name of the Therapeutic Goods Administration.

Item [10] – notifiable low risk dealings (NLRDs)

Parts 1 and 2 of Schedule 3 describe GMO dealings classified as NLRDs. Part 3 of Schedule 3 (dealings that are not NLRDs) qualifies the lists in Parts 1 and 2, so that a dealing of a kind described in Part 3 is not a NLRD even if it meets a description in Part 1 or Part 2. This item amends paragraph 12(1)(a) to make clearer the role of Schedule 3 Part 3 in determining what dealings are NLRDs, and does not change the status of any dealings.

Item [11] – NLRD time limit

Previous amendments to the Principal Regulations introduced a time limit for stopping NLRDs, and provided for phased introduction of a time limit for existing NLRDs. The period of phased introduction is now complete, and item [19] of Schedule 1 repeals the phase-in provisions. This item replaces a reference to the provisions repealed by item [19] with a uniform five year time limit for stopping NLRDs.

Item [12] – persons who may undertake NLRDs

Subregulation 13(1) sets out the requirements that must be met before a person can undertake a NLRD, including that the person must be mentioned in the institutional biosafety committee's (the IBC's) record of assessment of the proposed NLRD. This item, with item [16] of Schedule 1, amends existing provisions to better align the provisions with the requirements for IBC records of assessments of NLRD proposals in regulation 13B, without changing the underlying requirements.

Items [13]-[15] – NLRD facilities

Regulation 13 sets out the requirements for the facilities in which NLRDs may be undertaken, and requirements for GMO transportation, storage and disposal outside those facilities (to the extent that those activities are part of a NLRD). These items, with items [17], [18], [34] and [36], clarify existing requirements.

Item [16] – persons who may undertake NLRDs

Subregulation 13(1) sets out the requirements that must be met before a person can undertake a NLRD, including that the person must be mentioned in the IBC's record of assessment of the proposed NLRD. This item, with item [12] of Schedule 1, amends existing provisions to better align the provisions with the requirements for IBC records of assessment of NLRD proposals in regulation 13B, without changing the underlying requirements.

Items [17]-[18] – NLRD facilities

Regulation 13 sets out the requirements for the facilities in which NLRDs may be undertaken, and requirements for GMO transportation, storage and disposal outside those facilities (to the extent that those activities are part of a NLRD). These items, with items [13]-[15], [34] and [36], clarify existing requirements.

In regard to GMO transportation, storage or disposal being allowed outside a permitted facility if it is conducted in accordance with the *Guidelines for the Transport, Storage and Disposal of GMOs*, the Regulations are allowed to require compliance with guidelines as in force from time to time (subsection 193(2) of the Act).

Item [19] – NLRD time limit

Previous amendments to the Principal Regulations introduced a time limit for stopping NLRDs, and provided for phased introduction of time limits to existing NLRDs. As the period of phased introduction is now complete, this item repeals provisions detailing the phased introduction.

Item [20] – subregulation 21(2)

This item removes an out-of-date website reference in the note to subregulation 21(2).

Items [21] and [22] – presiding member at committee meetings

Subregulation 26(1) and regulation 32 provide that the Chairpersons of the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee, respectively, or their nominee, must preside at meetings of each committee, and specify who the Chairperson may nominate. The provisions of the Act referred to in paragraphs 26(1)(b) and 32(c) have since been amended, and these items reinstate the original intention as clearly laid out in the Explanatory Statement to the Principal Regulations.

Item [23] – insert a new Part 8

This item provides for the transition of dealings currently being conducted as exempt dealings or NLRDs but which require a higher level of authorisation as a result of the Regulations, or where the requirements for undertaking a NLRD change (e.g. the required containment level increases). A person conducting such a dealing has one year to either cease the dealing or obtain a suitable authorisation to undertake the dealing.

Item [24] – techniques that are not gene technology

This item adds a new item to Schedule 1A to the Principal Regulations (techniques that are not gene technology), listing certain ribonucleic acid (RNA) interference techniques as techniques that are not gene technology. Schedule 1A supports principal regulation 4 for the purposes of the definition of "gene technology" in the Act. This provides clarity about the status of the described techniques, irrespective of whether the techniques otherwise meet the definition of "gene technology" in the Act.

This item provides that techniques involving applying RNA to an organism to temporarily induce RNA interference are not gene technology, provided that:

- the RNA cannot be translated into a polypeptide
- the organism's genome sequence cannot be altered as a result, and
- an infectious agent cannot be produced.

The RNAs could be introduced to the organism by any method including, but not limited to:

- uptake by the organism following external application to the organism (e.g. by spraying with or dipping in an RNA solution)

- injection into the organism, and
- methods leading to the organism consuming material which has had the RNA applied by another method (e.g. spraying a plant with RNA so that it would be consumed by insects feeding on plant material).

Introducing a variety of RNA molecules to an organism could potentially meet the requirements of this item, including, but not limited to: small interfering RNAs; artificial microRNAs; short or long double-stranded RNAs; and short hairpin RNAs. Provided that the requirements are satisfied, the RNA molecules could contain any RNA sequence, including, but not limited to, sequences with homology to sequences in the receiving organism, in a virus that may infect the receiving organism or in organisms that may consume the organism initially receiving the RNA molecule.

Regarding the requirement that the organism's genome sequence cannot be altered as a result of application of the RNA, changes to methylation of genomic deoxyribonucleic acid (DNA) are not considered an alteration of an organism's genome sequence.

Item [25] – organisms that are GMOs

This item inserts new Schedule 1B to support new regulation 4A, listing organisms that are GMOs for the purposes of the definition of "genetically modified organism" in the Act. This provides clarity about the status of the listed organisms as understood within the context of the current state of technology. Listing of organisms in Schedule 1B is not indicative of whether or not the organisms meet parts (a) and (b) of the definition of "genetically modified organism" in the Act, noting that listing in Schedule 1B may be for the avoidance of doubt. Listing of organisms in Schedule 1B is not indicative of whether or not the organisms might also meet items in Schedule 1 (organisms that are not GMOs). Should an organism meet items in both new Schedule 1B and Schedule 1, that organism is considered a GMO (see Schedule 1 item [8]).

This item lists as GMOs organisms modified by two techniques that use nucleic acid templates to direct genomic sequence changes, oligonucleotide-directed mutagenesis, and certain site-directed nuclease (SDN) techniques.

Oligonucleotide-directed mutagenesis involves directing genomic sequence changes by applying short pieces of nucleic acid (oligonucleotides) to an organism that closely, but not precisely, match genomic DNA sequences. The applied nucleic acid may be DNA, RNA or a combination of DNA and RNA bases, and may include synthetic or chemically modified bases. As a result of the activity of endogenous repair enzymes, the genomic sequence may be modified to match sequences present in the oligonucleotide.

SDNs are enzymes that are designed to act on specific target nucleotide sequences and make double- or single-strand DNA breaks. SDNs include, but are not limited to, clustered regularly interspaced short palindromic repeats (CRISPR)-CRISPR-associated protein 9, zinc finger nucleases and transcription activator-like effector nucleases. SDNs may be used to induce targeted breaks in the genomic DNA of an organism, and repair of the break may be directed by applying a nucleic acid

template that partially matches the genomic DNA sequence. As a result of the activity of endogenous repair enzymes, the genomic sequence may be modified to match sequences present in the template. The template may differ from the genomic sequence in any way, ranging from single nucleotide deletions, substitutions or additions to large sequence deletions or insertions. This item provides that, where an organism is modified by this process using an introduced nucleic acid template of any kind, the resulting organism is a GMO.

Items [26] and [27] – organisms that are not GMOs

These items add new items to Schedule 1 to the Principal Regulations, which supports regulation 4, listing organisms that are not GMOs for the purposes of the definition of "genetically modified organism" in the Act. This provides clarity about the status of these organisms, as understood within the context of the current state of technology. Listing organisms in Schedule 1 is not indicative of whether or not they meet parts (a) to (c) of the definition of "genetically modified organism" in the Act, noting that listing in Schedule 1 may be for the avoidance of doubt. Nevertheless, because of the effect of item [8] an organism that meets the description of paragraph (c) of the definition of "genetically modified organism" by listing in new Schedule 1B retains the status of GMO. Each item added to Schedule 1 by items [26] and [27] is described below.

Item 4

New item 4 of Schedule 1 to the Principal Regulations provides that organisms modified using SDNs are not GMOs, provided no nucleic acid template is added to guide homology-directed repair. The methodology applied to these organisms is sometimes known as SDN-1. Together with item 2 of new Schedule 1B (see Schedule 1 item [25]), item 4 of Schedule 1 provides clarity about the status of organisms modified using SDNs with and without the use of repair templates, respectively.

New item 4 applies where one or more SDNs has been used to induce genomic DNA breaks in an organism, provided that no nucleic acid template has been added to guide homology-directed repair. New item 4 relates only to organisms that do not have other traits as a result of gene technology. Specifically, this item does not apply to organisms expressing a SDN stably or transiently. It is noted that SDNs may be supplied to organisms in ways other than by stable or transient expression, for example injection of SDN proteins.

Item 8

New item 8 of Schedule 1 to the Principal Regulations provides, for the avoidance of doubt, that organisms derived from GMOs but which have not inherited traits that occurred because of gene technology are not GMOs, consistent with paragraph (b) of the definition of "genetically modified organism" in the Act. For example, if a genetically modified plant is hemizygous for an inserted sequence and produces progeny that do not inherit the inserted sequence or any other traits that occurred because of gene technology, those progeny are not GMOs. These organisms are sometimes known as null segregants.

In relation to organisms modified using SDN techniques, genomic sequence modifications as a result of these techniques are traits that occurred because of gene technology, and these organisms do not satisfy new item 8.

Item 9

Several items of Schedule 1 to the Principal Regulations describe organisms to which gene technology has been applied to produce a trait, but do not provide clarity about the status of organisms inheriting those traits. New item 9 ensures that organisms inheriting traits described in items of Schedule 1 are not regulated as GMOs, if the requirements of regulation 5 (as amended by item [8]) are met. For paragraph (a), an example is an organism inheriting traits from an organism that is not a GMO because it meets a description in one or more items in Schedule 1. This is providing the organism under consideration has no other traits from gene technology. For paragraph (b), an example is an organism inheriting a sequence modification that occurred through the SDN-1 technique described in new item 4, where the initial organism in which the SDN-1 modification occurred is a GMO because it also contains a SDN transgene, but that transgene has not been inherited by the organism under consideration.

Item 10

New item 10 of Schedule 1 to the Principal Regulations provides that organisms that have been modified by gene technology, but which no longer have the genetic modification or any traits that occurred because of gene technology, are not GMOs. An example of such an organism that is not a GMO is a cell supplied with an expression vector from which a protein is expressed, once the expression vector and any expressed protein have been degraded.

Items 11 and 12

Schedule 3 item [1] of the Regulations repeals Schedule 1 item 1 of the Principal Regulations, a descriptive item which the Explanatory Statement to the Principal Regulations indicates was intended to exclude mutagenised organisms from the scope of regulation as GMOs. To maintain the status of two organisms historically excluded from regulation as GMOs by Schedule 1 item 1 of the Principal Regulations, item [27] specifically lists the organisms in new items in Schedule 1. The organisms are *Agrobacterium radiobacter* strain K1026 (sometimes known as NoGall) and *Pasteurella multocida* strain PMP1 (sometimes known as Vaxsafe PM).

Items [28] and [29] – typographical errors

These items correct typographical errors in table item 4 of Part 1 of Schedule 2.

Item [30] – micrograms symbol

This item replaces the Greek letter mu (μ), as part of a recognised international symbol indicating “micrograms”, with the word “micrograms”.

Item [31] – exempt dealings involving viral sequences

This item expands the scope of dealings involving viral sequences that may be undertaken as exempt dealings, while maintaining the requirement that such dealings are not exempt dealings if they can result in the production of infectious agents. This item allows for cloning and propagation, in listed host/vector systems, of replication defective viral vectors or full-length viral genomes which are unable to be expressed in any unmodified host cell. In either case, if viral genes or other non-host factors necessary for replication and/or packaging into virions of viral nucleic acid are available during the dealings, this item does not apply.

Examples of dealings classified as exempt according to this item are dealings with a replication defective viral vector cloned into a plasmid and propagated in a bacterial host; and dealings with a modified or unmodified full-length viral genome cloned and propagated in a plasmid, provided the viral genome is unable to be transcribed from the plasmid in any potential host cell without additional factors being provided.

Item [32] – Part 1 of Schedule 2

This item amends a cross-reference to accommodate the substitution of Part 2 of Schedule 2 (see Schedule 1 item [33]).

Item [33] – host/vector systems for exempt dealings

This item replaces Part 2 of Schedule 2 to the Principal Regulations with an amended Part with an updated layout. Modifications to the table of hosts and vectors are as follows:

- New clause 2.1 clarifies the meaning of references in the Principal Regulations to hosts and vectors in this Part;
- A description of "host/vector system" has been added to support the new definition of "host/vector system" in Principal Regulation 3 (see Schedule 1 item [2]), and provides clarity that where a listed vector is itself a GMO (for example, some viral vectors), dealings with that vector without a host are exempt dealings, provided other requirements for exempt classification are met;
- Table items and vectors have been re-numbered to improve the clarity of references to table items;
- Two new hosts, which have been assessed to pose negligible risks to human health and safety or the environment, have been added: *Corynebacterium glutamicum* and *Zymomonas mobilis*; and
- The vectors permitted for exempt dealings involving certain *Agrobacterium* species as a host (table item 5) and as a plant tissue culture vector (table item 10) have been clarified to reflect the intent of the original provisions, that they are restricted to disarmed Ti and disarmed Ri plasmids.

Item [34] – clause 1.1 of Schedule 3

This item amends a cross-reference to accommodate the amendment of subregulation 13(3) by Schedule 1 item [18].

Item [35] – paragraph 1.1(c) of Schedule 3

This item replaces paragraph 1.1(c) of Schedule 3 to the Principal Regulations to clarify the status of dealings with the specified viral vectors with no host. It also broadens the relevant considerations to modifications other than insertion of donor nucleic acid, such as deletions, nucleotide substitutions, down-regulation of other genes or RNA interference, to enable more consistent consideration of the ability of modifications to cause harm. This item also amends a cross-reference to accommodate the replacement of Part 2 of Schedule 2 (see Schedule 1 item [33]).

Item [36] – clause 2.1 of Schedule 3

This item amends a cross-reference to accommodate the amendment of subregulation 13(3) by Schedule 1 item [18].

Item [37] – paragraph 2.1(d) of Schedule 3

This item amends a reference to host/vector systems for consistency with usage of the term elsewhere in the Regulations.

Items [38]-[40] – paragraphs 2.1(d) and (e) of Schedule 3

These items broaden the considerations required in paragraphs 2.1(d) and (e) of Schedule 3 to modifications other than insertion of donor nucleic acid, such as deletions, nucleotide substitutions, down-regulation of other genes or RNA interference, to enable more consistent consideration of the ability of modifications to cause harm.

Item [41]

This item amends a cross-reference to accommodate the replacement of Part 2 of Schedule 2 (see Schedule 1 item [33]).

Items [42]-[53] – paragraphs 2.1(i)-(m) of Schedule 3

These items amend paragraphs 2.1(i)-(m) of Schedule 3 to the Principal Regulations to clarify the status of dealings with a viral vector with no host, and amend paragraphs (k) and (m) to broaden the relevant considerations to modifications other than insertion of donor nucleic acid, such as deletions, nucleotide substitutions, down-regulation of other genes or RNA interference, to enable more consistent consideration of the ability of modifications to cause harm.

Item [54] – NLRDs with risk group 3 micro-organisms

This item replaces clause 2.2 of Schedule 3 to the Principal Regulations, to clarify the intention of the clause as laid out in the Explanatory Statement to the Gene Technology Amendment Regulations 2011 (No. 1), and to specify that the clause does not apply to replication defective retroviral vectors given direct consideration in paragraphs 2.1(l) and (m) of Schedule 3. Any other dealing classified as a NLRD under Part 2 of Schedule 3 involving a risk group 3 parent microorganism (where the

classification of the unmodified parent organism, according to the criteria of AS/NZS 2243.3:2010, is the relevant consideration) is required to 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 paragraph 13(2)(c) or subregulation 13(3). Noting that the risk grouping of the unmodified parent organism is the relevant consideration, it is not within the discretion of an IBC assessing a NLRD proposal to assess whether genetic modifications may reduce the risk grouping of the organism.

AS/NZS 2243.3:2010 is available from the distributor of all standards published by Standards Australia, SAI Global (by phoning 131 242; by mail to SAI Global Limited, Business Publishing, PO Box 5420, Sydney NSW 2001; or by visiting the website http://infostore.saiglobal.com).

Item [55] – note 2 to heading of Part 3 of Schedule 3

This item replaces the second note to the heading of Part 3 of Schedule 3 to the Principal Regulations with an amended note including new reference to the mechanisms under the Act, in addition to licensing, by which a person may be authorised to undertake a dealing that is not a NLRD.

Item [56] – clause 3.1 of Schedule 3

This item inserts subclause numbering in Clause 3.1 of Schedule 3 to the Principal Regulations, to accommodate the addition of a new subclause (see Schedule 1 item [62]).

Item [57] – micrograms symbol

This item replaces the Greek letter mu (μ), as part of a recognised international symbol indicating “micrograms”, with the word “micrograms”.

Items [58]-[61] – paragraphs 3.1(d)-(f) of Schedule 3

These items amend paragraphs 3.1(d)-(f) of Schedule 3 to the Principal Regulations to broaden the relevant considerations to modifications other than insertion of donor nucleic acid, such as deletions, nucleotide substitutions, down-regulation of other genes or RNA interference, to enable more consistent consideration of the ability of modifications to cause harm. Item [58] also amends paragraph 3.1(d) to clarify the status of dealings with the viral vector with no host.

Item [62] – risk group 3 and 4 micro-organisms and gene drive GMOs

Risk group 3 and 4 micro-organisms

This item inserts new paragraph (1)(q) and new sub-clause (2) to clause 3.1 of Schedule 3 to the Principal Regulations, to clarify the intention of clause 2.2 and paragraph 3.1 (p) of Schedule 3 to the Principal Regulations, as laid out in the Explanatory Statement to the Gene Technology Amendment Regulations 2011 (No. 1). New paragraph 3.1(1)(q) provides that dealings that would be NLRDs according to

clause 2.2 but are not undertaken in the facilities in which such a NLRD must be undertaken are not NLRDs, and require licensing under Part 5 of the Act.

Paragraph 3.1(p) of Schedule 3 to the Principal Regulations provides that a dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as risk group 4, is not a NLRD. New sub-clause 3.1(2) specifies that the classification of the unmodified parent organism is the relevant consideration. As a result, an IBC assessing whether a proposed NLRD meets paragraph 3.1(p) does not have discretion to assess whether genetic modifications may reduce the risk grouping of the organism.

Gene drive GMOs

Gene drives are genetic elements that are favoured for inheritance in sexually reproducing organisms. While most genomic sequences have a 50% chance of being inherited by offspring from sexually reproducing parents, a gene drive biases inheritance and causes a nucleotide sequence (or set of sequences) to be inherited at a higher rate. This item lists dealings with GMOs with engineered gene drives as dealings that are not NLRDs, with the result that a licence is necessary to undertake contained dealings with gene drive GMOs.

Dealings with organisms with genetic modifications that increase the likelihood that a nucleotide sequence is inherited by offspring of sexually reproducing parents, to any extent, are dealings that are not NLRDs under new paragraph 3.1(r) of Schedule 3. Dealings with viral vectors that are able to cause modifications in a host that create a functioning gene drive are treated the same as dealings with gene drive GMOs under new paragraph 3.1(s). These provisions do not alter the status of GMOs with traits providing a selective advantage or that improve reproductive fecundity, where those traits do not directly alter the rate at which particular sequences are inherited from parent to offspring.

Engineered gene drives require several components to cause biased inheritance, and only organisms containing all components necessary for gene drive activity meet paragraph 3.1(r). Where organisms contain some but not all components necessary for gene drive activity, these organisms do not meet new paragraph 3.1(r) of Schedule 3 because inheritance of sequences from these organisms is not biased.

Engineered gene drives may incorporate measures intended to limit the ability of the gene drive to persist across generations. Whether a gene drive GMO with such features meets new paragraph 3.1(r) depends upon whether biased inheritance is caused. For example, engineering gene drive components at unlinked genetic locations, such that each component is independently inherited, has been proposed as a mechanism to limit gene drive function through later generations of offspring (also known as a ‘split drive’). When all components of a split drive are present in one organism the gene drive is functional and biased inheritance occurs, and a licence is required for dealings with that organism.

Schedule 2 – Amendments commencing 1 July 2020

Gene Technology Regulations 2001

Item [1] – paragraph 13(1)(b)

Parts 1 and 2 of Schedule 3 to the Principal Regulations describe GMO dealings classified as NLRDs. Part 3 of Schedule 3 (dealings that are not NLRDs) qualifies the lists in Parts 1 and 2, so that a dealing of a kind described in Part 3 is not a NLRD even if it meets a description in Part 1 or Part 2. Paragraph 13(1)(b) requires that a person may undertake a NLRD only if an IBC has assessed the dealing to be a kind of dealing mentioned in Part 1 or 2 of Schedule 3. This item amends paragraph 13(1)(b) to further require that the dealing may be undertaken only if an IBC has also assessed that the dealing is not mentioned in Part 3 of Schedule 3 (see also Schedule 1 item [10] and Schedule 2 item [3]).

Items [2]-[5] – IBC records of assessment

Principal regulation 13B requires IBCs to make a record of their assessments of whether proposed dealings are NLRDs, with paragraph 13B(a) specifying information the record must include. Items [2]-[5] amends the information required as follows.

Item [2] clarifies that it is the person that submitted the NLRD proposal to the IBC, rather than the person proposing to undertake the dealing, that gives an identifying name to the dealing (noting that these may be the same person).

Item [3] replaces subparagraphs 13B(a)(iii) and (iv) with amended paragraphs to make clearer that consideration of Schedule 3 Part 3 is a necessary step in IBC assessment of whether a dealing is a NLRD, and requires this consideration be documented in the IBC's record of assessment. IBCs are required to record their assessment of whether or not the proposed dealing is mentioned in Part 3 of Schedule 3. This supports Schedule 2 item [1], which specifies that a person can only undertake a NLRD if it has been assessed to be a kind of dealing mentioned in Part 1 or Part 2 of Schedule 3 and not in Part 3 of Schedule 3. Item [3] only requires IBCs to record the kind of NLRD according to Part 1 or 2 of Schedule 3 if the dealing is not mentioned in Part 3 of Schedule 3.

Paragraph 13B(a)(vii) requires IBCs to record their assessment of the facilities suitable for the dealing, both in terms of physical containment level and facility type. Item [4] requires that IBCs have regard to the requirements of subregulation 13(2) when making this assessment. This ensures that the facilities IBCs may assess as suitable for the dealing are consistent with the requirements of subregulation 13(2) for the facilities in which NLRDs may be undertaken (including as amended by Schedule 1 item [17]).

Paragraph 13B(a)(x) requires IBCs to record who is proposing to undertake the dealing. Item [5] replaces a reference to "the name of the person or accredited organisation" with "the person or persons". The reference to accredited organisations has been removed because dealings can only be undertaken by legal persons, and accredited organisations may not be legal persons.

Item [6] – NLRD notifications to the Regulator

Item [6] replaces principal subregulations 13C(1) and (2) with amended requirements for NLRD proponents to notify the Regulator, which provide clarifications of the following:

- NLRD reporting to the Regulator is only required from the person or accredited organisation that requested the IBC assess the proposed NLRD, not from any other person receiving a record of assessment from an IBC.
- To align with standard accredited organisation reporting, reporting to the Regulator is required no later than 30 September in the financial year following the year of assessment, rather than within the year of assessment.
- Amending a reference to the "Record of GMO and GM Product Dealings" to the "Record of GMO Dealings", for consistency with previous amendments to the Act.
- Within the time limit for notification, providing additional flexibility for accredited organisations to provide notifications to the Regulator throughout the financial year and certify in their annual report that all NLRDs for the financial year have previously been notified.

Item [7] – subregulation 13C(3)

Principal subregulation 13C(3) requires that a person given an IBC's record of assessment of a NLRD proposal must retain it for eight years. Item [7] specifies that this only applies to the NLRD proponent, not from any other person receiving a record of assessment from an IBC.

Item [8] – regulation 39

The Act requires the Regulator maintain a public Record of GMO Dealings (the GMO Record), and regulation 39 details information to be included in the GMO Record for NLRDs and GM products. The Act was amended in 2015 to remove a requirement that the Regulator include GM product approvals by other agencies in the GMO Record. Item [8] replaces regulation 39 with an amended version from which references to GM products have been removed, as these provisions do not have any effect.

Item [8] also updates the descriptions of particulars for NLRDs that must be included in the GMO Record, for consistency with terminology elsewhere in the Principal Regulations and Act. The information required is not changed.

Item [9] – transitional provisions

This item provides for the continuation of NLRDs for which an IBC has not documented its assessment of whether the dealing is of a kind mentioned in Part 3 of Schedule 3, for NLRDs assessed prior to commencement of the requirement that IBCs record this information.

This item also clarifies that for NLRDs assessed by an IBC prior to the commencement of Schedule 2 of the Regulations, the NLRD reporting requirements under regulation 13C as amended by Schedule 2 apply.

Schedule 3 – Amendments commencing 18 months after registration

Gene Technology Regulations 2001

Item [1] – repeal of Schedule 1 item 1

Schedule 1 item 1 of the Principal Regulations is a descriptive item on the list of organisms that are not GMOs that, with changes in technology and use of scientific terminology, has become ambiguous, and has been interpreted in a variety of ways in respect to newly developed technologies. Schedule 3 item [1] of the Regulations repeals Schedule 1 item 1 of the Principal Regulations.

The Explanatory Statement to the Principal Regulations indicates Schedule 1 item 1 was intended to exclude mutagenised organisms from the scope of regulation as GMOs. Subsequent amendments have listed electromagnetic radiation mutagenesis, particle radiation mutagenesis and chemical mutagenesis techniques in Schedule 1A as techniques that are not gene technology, and the status of organisms modified by these techniques are not affected by repeal of Schedule 1 item 1. The two other organisms known to be historically excluded from regulation as GMOs by Schedule 1 item 1 are specifically listed in Schedule 1 to retain their status (see Schedule 1 item [27]). Public consultation seeking to establish whether any other organisms were considered to be excluded from regulation as GMOs under Schedule 1 item 1 did not identify any other organisms.

Commencement of this item is delayed until 18 months after registration to provide a suitable period in which authorisations can be sought for any other organisms which have been brought within the scope of GMO regulation as a result of this item.