

2020

**LEGISLATIVE ASSEMBLY FOR THE
AUSTRALIAN CAPITAL TERRITORY**

**GENE TECHNOLOGY AMENDMENT REGULATION 2020 (No 1)
SL2020-38**

EXPLANATORY STATEMENT

**Presented by
Rachel Stephen-Smith MLA
Minister for Health**

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Amendment to the *Gene Technology Regulation 2004*

Overview

The nationally consistent legislative scheme for gene technology is comprised of the Commonwealth *Gene Technology Act 2000* (the Commonwealth Act) and the corresponding State or Territory legislation. The Commonwealth 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 Regulations 2001* (the Commonwealth Regulations) support the implementation of the Commonwealth Act. The Gene Technology Regulator (the Regulator) is a statutory office holder responsible for administering the Commonwealth Act.

In the Australian Capital Territory (ACT) the *Gene Technology Act 2003* (the Act) mirrors the Commonwealth Act, which is a national model of law.

The object of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

The *Gene Technology Regulation 2004* (the Principal Regulation) underpins the Act by providing technical details, such as the categorisation of different dealings with GMOs, as well as specifying administrative processes and procedures.

The Gene Technology Agreement 2001 (the Agreement) between the Commonwealth and state and territory governments, aims to support a nationally consistent regulatory system for gene technology. The Agreement acknowledges the need for a cooperative national legislative scheme, which collaborates with relevant, existing product regulators and is consistent with international obligations.

Purpose

The purpose of the Gene Technology Amendment Regulation 2020 (No 1) (the Regulation) 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 efficiency and effectiveness of the regulatory scheme; and
- assist users to better understand and comply with their legislative obligations.

The Regulation provides clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs and ensure gene technology is regulated in line with the risks posed.

The Regulation commences in two stages:

- 1) the Regulation, (other than schedule 1) commences on the day after its notification day.

2) Schedule 1 commences on 8 October 2020.

Outline of amendments

Clause [1] - Name of Regulation

This clause states the name of the Regulation.

Clause [2] - Commencement

This clause states that the Regulation commences in two stages on the day after its notification day and in accordance with the following:

- the Regulation, (other than schedule 1) commences on the day after its notification day.

The Regulator has supported staged commencement of the amendments to minimise disruptions to those undertaking GMO dealings that are affected by the amendments.

- Schedule 1 commences on 8 October 2020.

Commencement of this clause on the dates above follows the timetable outlined in the Commonwealth *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019* and ensures the ACT aligns with the Commonwealth Act.

Clause [3] - Legislation amended

This clause outlines that the Regulation amends the Principal Regulation.

Clause [4] - New section 4A

This clause inserts a new section 4A which, supported by a new Schedule 1B, describes organisms that are genetically modified organisms for the purposes of the definition of “genetically modified organism”.

Clause [5] - Section 5

This clause amends section 5 to avoid any doubt on the status of an organism in which multiple traits from gene technology are present, or that simultaneously meets clauses in Schedule 1 and new Schedule 1B.

This clause makes explicit that an organism meeting any of the items in Schedule 1 is not considered a GMO if it does not have other traits that occurred because of gene technology.

This clause 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.

Clause [6] - Section 9 (b)

This clause replaces the reference to the Australian Quarantine and Inspection Service (AQIS) as the agency no longer exists.

Clause [7] - Section 9 (f)

This clause updates section 9(f) to refer to the current name of the Therapeutic Goods Administration.

Clause [8] - Section 12 (1) (a)

Notifiable Low Risk Dealings (NLRDs) are activities with GMOs undertaken in containment (i.e. not released into the environment) that have been assessed as posing low risk to the health and safety of people and the environment. This clause amends section 12(1)(a) to make clearer the role of Schedule 3 Part 3 in determining what dealings are notifiable low risk dealings NLRDs and does not change the status of any dealings.

Clause [9] Section 13 (1) (b)

Parts 3.1 and 3.2 of Schedule 3 describe GMO dealings classified as NLRDs. Part 3.3 of Schedule 3 (dealings that are not NLRDs) qualifies the lists in Parts 3.1 and 3.2, so that a dealing of a kind described in Part 3.3 is not a NLRD even if it meets a description in Part 3.1 or Part 3.2. 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 3.1 or 3.2 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 3.3 of Schedule 3 (see also item [8] and clause [18]).

Clause [10] - Section 13 (1) (d)

Previous amendments to the Principal Regulation 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 clause [16] repeals the phase-in provisions. This clause replaces a reference to the provisions repealed by clause [16] with a uniform five-year time limit for stopping NLRDs.

Clause [11] - Section 13 (1) (e)

The existing section 13(1)(e) sets out requirements that must be met before a person can undertake a NLRD. This clause, with clause [13], amends existing provisions to better align the provisions with the requirements for institutional biosafety committee (IBC) records of assessments of NLRD proposals in section 13B, without changing the underlying requirements.

Clause [12]-[13] - Sections 13 (1) (f), 13 (1) (i) and note

Section 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 clauses, with clauses [14], [15], [34] and [28], clarify existing requirements.

Subsection 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. Item 12 amends existing provisions to better align the provisions with the

requirements for IBC records of assessment of NLRD proposals in section 13B, without changing the underlying requirements.

Clause [14]-[15] - Sections 13 (2) (b) and 13(3)

Section 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 clauses, with clauses [12]-[13], [34] and [28], 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 Regulation is allowed to require compliance with guidelines as in force from time to time (subsection 193(2) of the Act).

Clause [16] - Section 13A

Previous amendments to the Principal Regulation 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 clause repeals Section 13A which detailed the phased introduction.

Clause [17] - Section 13B (a) (i)

Clause [17] 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).

Clause [18] - Section 13B (a) (iii) and (iv)

Clause [18] replaces sections 13B (a) (iii) and (iv) with amended sections to make clearer that consideration of Schedule 3 Part 3.3 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 3.3 of Schedule 3.

Clause [19]- Section 13B (a) (vii)

Section 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. Clause [19] requires that IBCs have regard to the requirements of section 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 section 13(2) for the facilities in which NLRDs may be undertaken (including as amended by Item [15]).

Clause [20]- Section 13B (a) (x)

Section 13B (a) (x) requires IBCs to record who is proposing to undertake the dealing. Clause [20] 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.

Clause [21]- Section 13C (1) and (2)

This clause replaces section 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.

Clause [22]- Section 13C (3)

Section 13C (3) requires that a person given an IBC’s record of assessment of a NLRD proposal must retain it for eight years. Clause [22] specifies that this only applies to the NLRD proponent, not from any other person receiving a record of assessment from an IBC.

Clause [23]- Section 39

The Act requires the Regulator to maintain a public Record of GMO Dealings (the GMO Record), and section 39 details information to be included in the GMO Record for NLRDs and GM products. Clause [23] replaces section 39 with an amended version from which references to GM products have been removed, as these provisions do not have any effect.

This clause also updates the descriptions of particulars for NLRDs that must be included in the GMO Record, for consistency with terminology elsewhere in the Principal Regulation and Act. The information required is not changed.

Clause [24] - New Section 41

AS/NZS 2243.3:2010 is incorporated into the Principal Regulation (see dictionary, definition of AS/NZS 2243.3:2010). The Legislation Act, s 47 (5) provides that an incorporated document is taken to be a notifiable instrument. A notifiable instrument must be notified on the Legislation Register under the Legislation Act. However, the Legislation Act, s 47 (5) may be displaced by the authorising law (the Act) or the incorporating instrument (this Regulation) (see s 47 (7)). This clause provides that the Legislation Act, s 47 (5) is displaced here because the incorporated standards are subject to copyright and may be purchased over the internet.

Clause [25] - New part 10

This clause inserts a new part 10 to provide for the transition of dealings currently being conducted as exempt dealing or NLRDs, but which require a higher level of authorisation as a result of the amendments, or where the requirements for undertaking an NLRD change. A person conducting such a dealing has 12 months to either cease the dealing or to obtain suitable authorisation to undertake the dealing. This new part will expire 12 months after the commencement of the Regulation.

This clause 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 3.3 of Schedule 3, for NLRDs assessed prior to commencement of the requirement that IBCs record this information.

This clause also clarifies that for NLRDs assessed by an IBC on or after 1 July 2019 but before the commencement day, the NLRD reporting requirements under section 13C as amended by Schedule 1 apply.

Clause [26] - Schedule 1A, new item 11

This clause adds a new item 11 to Schedule 1A listing certain ribonucleic acid (RNA) interference techniques as techniques that are not gene technology. Schedule 1A supports section 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.

Clause [27] - New Schedule 1B

This clause inserts a new Schedule 1B to support new section 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 listed organisms as understood within the context of the current technology.

Clause [28] - Schedule 1, new item 4

This clause inserts a new item 4 to Schedule 1. New item 4 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, 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.

Clause [29] - Schedule 1, new items 8-12

This clause inserts new items 8-12 into Schedule 1.

- New item 8 of Schedule 1 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.

- New item 9 ensures that organisms inheriting traits described in items of Schedule 1 are not regulated as GMOs, if the requirements of section 5 (as amended by item [5]) are met.
- New item 10 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.
- New items 11-12: Clause [1.1] of the Regulation repeals Schedule 1 item 1, a descriptive item which the Explanatory Statement to the Commonwealth 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, clause [29] specifically lists the organisms in new items in Schedule 1. The organisms are *Agrobacterium radiobacter* strain K102+6 (sometimes known as NoGall) and *Pasteurella multocida* strain PMP1 (sometimes known as Vaxsafe PM).

Clause [30] - Schedule 2, part 2.1, item 4, column 2, subsections (2) (b) and (c)

This clause replaces the Greek letter mu (μ), as part of a recognised international symbol indicating “micrograms”, with the word “micrograms”. This provides a plain English explanation in the regulation.

Clause [31] - Schedule 2, part 2.1, item 4, column 2, paragraph (2) (e)

This clause 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 clause 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 clause 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.

Clause [32] - Schedule 2, part 2.1, item 5, column 2

This clause amends a cross-reference as a consequence of the substitution of table 2.2, items 1-6 [see clause [33]].

Clause [33] Schedule 2, part 2.2

This clause replaces part 2.2 of Schedule 2. The modifications on the table of hosts and vectors are as follows:

- clause 2.2 clarifies the meaning of references in the Principal Regulation 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 the Principal Regulation (see item [63]), 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 and as a plant tissue culture vector have been clarified to reflect the intent of the original provisions, that they are restricted to disarmed Ti and disarmed Ri plasmids.

Clause [34] - Schedule 3, section 3.1

This clause amends a cross reference as a consequence of the amendment of subsection 13(3) by clause [15].

Clause [35] - Schedule 3, section 3.1 (c)

This clause replaces section 3.1 (c) of Schedule 3 to clarify the status of dealings with 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 clause also amends a cross-reference as a consequence of the replacement of Part 2.2 of Schedule 2 (see clause [33]).

Clause [36] - Schedule 3, section 3.2

This clause amends a cross reference as a consequence of the amendment of section 13(3) by clause [15].

Clause [37] - Schedule 3, section 3.2 (d)

This clause amends a reference to host/vector systems for consistency with usage of the term elsewhere in the Principal Regulation.

Clause [38]-[40] - Schedule 3, sections 3.2(d) to (e) (i)

These clauses broaden the considerations required in sections 3.2(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.

Clause [41] - Schedule 3, section 3.2 (h)

This clause amends a cross-reference as a consequence of the replacement of part 2.2, item 1 of Schedule 3 (see item [25]).

Clause [42]-[50] - Schedule 3, sections 3.2 (i)-(m)

These clauses amend sections 3.2 (i)-(m) of Schedule 3 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.

Clause [51] Schedule 3, section 3.2A

This clause replaces section 3.2A of Schedule 3, to clarify the intention of the section as laid out in the Explanatory Statement to the *Gene Technology Amendment Regulations 2011 (No. 1)*, and to specify that the section does not apply to replication defective retroviral vectors given direct consideration in sections 3.2(l) and (m) of Schedule 3. Any other dealing classified as a NLRD under Part 3 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 section 13(2)(c) or section 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.

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.

Clause [52] - Schedule 3, part 3.3, heading, note 2

This clause replaces the second note to the heading of part 3.3 of Schedule 3 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.

Clause [53] - Schedule 3, section 3.3 (a) and (b)

This clause replaces the Greek letter mu (μ) as part of a recognised international symbol indicating “micrograms” with the word “micrograms”. This provides a plain English explanation in the regulation.

Clause [54]-[56] - Schedule 3, sections 3.3 (d)-(e) to (f)(ii), example

These clauses amend sections 3.3(d)-(e) of Schedule 3 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] also amends section 3.3(d) to clarify the status of dealings with the viral vector with no host.

Clause [57]-[58] - Schedule 3, sections 3.3 (q) to (s) and 3.3 (2) to (4)

Risk group 3 and 4 micro-organisms

These clauses insert new sections 3.3 (q)-(s) and 3.3 (2)-(4) to Schedule 3, to clarify the intention of clause 3.2A and paragraph 3.3 (p) of Schedule 3. New section 3.3(q) provides that dealings that would be NLRDs according to clause 3.2A 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 3.3(p) of Schedule 3 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 section 3.3(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 3.3(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 section 3.3(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 section 3.3(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 section 3.3(r). Where organisms contain some but not all components necessary for gene drive activity, these organisms do not meet new section 3.3(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 section 3.3(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.

Clause [59] - Dictionary, note 3

This clause adds a number of terms to the list of terms in the dictionary, note 3. The list contains terms used in the *Gene Technology Act 2003* that are also used in the *Gene*

Technology Regulation 2004. Terms used in the regulation have the same meaning as terms used in the Act (see the Legislation Act, s 148).

Clause [60]- Dictionary, note 3

Clause [60] removes “GM product” from the list of terms in the dictionary, note 3, as the Regulation repeals the term from the Principal Regulation. Note 3 to the Dictionary states that terms used in the Principal Regulation have the same meaning that they have in the Gene Technology Act 2003.

Clause [61]- Dictionary, note 3

Clause [61] removes “GM product” from the list of terms in the dictionary, note 3, as the Regulation repeals the term from the Principal Regulation. Note 3 to the Dictionary states that terms used in the Principal Regulation have the same meaning that they have in the Gene Technology Act 2003.

Clause [62] - Dictionary, new definition of characterised

This clause inserts a new definition of ‘characterised’

Clause [63]- Dictionary, new definitions

This clause inserts new definitions of ‘host’ and ‘host/vector system’.

Clause [64] - Dictionary, definition of toxin producing organism

This clause 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”.

Clause [65] - Dictionary, new definition of vector

This clause inserts a new definition of ‘vector’.

Clause [66] - Further amendments, mentions of part 2.2

This clause replaces references to Part 2.2 with table 2.2 as a consequence of the substitution of Part 2.2 of Schedule 2 with new table 2.2.

Schedule 1, item 1 - Delayed amendment - 8 October 2020

Schedule 1 item 1 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. Item [2.1] repeals Schedule 1 item 1.

The Explanatory Statement to the Commonwealth 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 clause [21]). 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.