



# Agricultural Compounds and Veterinary Medicines Amendment Act 2016

Public Act 2016 No 82  
Date of assent 7 November 2016  
Commencement see section 2

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**The Parliament of New Zealand enacts as follows:**

**1 Title**

This Act is the Agricultural Compounds and Veterinary Medicines Amendment Act 2016.

**2 Commencement**

This Act comes into force on the day after the date on which it receives the Royal assent.

**3 Principal Act**

This Act amends the Agricultural Compounds and Veterinary Medicines Act 1997 (the **principal Act**).

**Part 1****Substantive amendments to principal Act****4 New section 2A inserted (Transitional, savings, and related provisions)**

After section 2, insert:

**2A Transitional, savings, and related provisions**

The transitional, savings, and related provisions set out in Schedule 1 have effect according to their terms.

**5 Section 29 amended (Reassessment of trade name products)**

Replace section 29(3) with:

- (3) A decision under subsection (1) is deemed to be a new application for the trade name product, and—
- (a) sections 11, 12, and 17 to 25 apply to the application with any necessary modifications; and
  - (b) Part 6 applies to the application as if it were a non-innovative TNP application, and with any other necessary modifications.

**6 Section 30 amended (Reassessment of provisional registration)**

Replace section 30(3) with:

- (3) A decision under subsection (1) is deemed to be a new application for provisional registration for the trade name product, and—
- (a) sections 26 and 27 apply to the application with any necessary modifications; and
  - (b) Part 6 applies to the application as if it were a non-innovative TNP application, and with any other necessary modifications.

**7 Section 56 amended (Penalties)**

- (1) In section 56(3), replace “Subject to subsection (4), every” with “Every”.
- (2) Repeal section 56(4).

**8 Part 6 replaced**

Replace Part 6 with:

**Part 6**  
**Protection of confidential information about trade name products***Interpretation***72 Interpretation**

(1) In this Part, unless the context otherwise requires,—

**application to authorise a new use or method of use** means an application under section 9(2) to vary 1 or more conditions on a registered trade name product that relate to—

- (a) a purpose of use described in paragraph (a) or (b)(i) or (ii) of the definition of agricultural compound in section 2(1); or
- (b) 1 or more of the following:
  - (i) the rate at which the product must be applied;
  - (ii) when the product must or must not be applied;
  - (iii) how the product must be applied;
  - (iv) the withholding period for the product

**confidential information** has the meaning given to it in section 73

**innovative TNP application** means an application under section 9(1) or 26 to register or provisionally register a trade name product that includes an active ingredient to which the following apply:

- (a) the ingredient is referred to in the application as an active ingredient of the trade name product; and
- (b) at the time the Director-General receives the application, the ingredient has not previously been an active ingredient of—
  - (i) a trade name product registered under section 21; or
  - (ii) a pesticide that was registered under the Pesticides Act 1979; or
  - (iii) an animal remedy the manufacture or importation of which was licensed under the Animal Remedies Act 1967 (otherwise than by a provisional licence)

**innovative trade name product** means a trade name product registered on the granting of an innovative TNP application

**non-innovative TNP application** means an application under section 9(1) or 26 to register or provisionally register a trade name product (other than an innovative TNP application)

**non-innovative trade name product** means a trade name product registered on the granting of a non-innovative TNP application

**protected period** has the meaning given to it in section 74.

- (2) The grant of an experimental use permit for a pesticide under section 25 of the Pesticides Act 1979 does not constitute the registration of that pesticide for the purposes of paragraph (b)(ii) of the definition of innovative TNP application.

### 73 Meaning of confidential information

- (1) In this Part, **confidential information** means information received by the Director-General that—
- (a) is provided in support of an innovative TNP application, a non-innovative TNP application, or an application to authorise a new use or method of use; and
  - (b) is confidential information about the trade name product that is the subject of that application.
- (2) For the purposes of subsection (1)(b), confidential information includes—
- (a) trade secrets; and
  - (b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information.

### 74 Meaning of protected period

In this Part, **protected period** means,—

- (a) for confidential information supporting an innovative TNP application made under section 9(1), the period specified in section 74B;
- (b) for confidential information supporting an innovative TNP application made under section 26, the period specified in section 74C;
- (c) for confidential information supporting an application to authorise a new use or method of use for an innovative trade name product, the period specified in section 74D;
- (d) for confidential information supporting a non-innovative TNP application made under section 9(1), the period specified in section 74E;
- (e) for confidential information supporting a non-innovative TNP application made under section 26, the period specified in section 74F;
- (f) for confidential information supporting an application to authorise a new use or method of use for a non-innovative trade name product, the period specified in section 74G.

*Director-General must protect confidential information during protected period*

**74A Director-General must protect confidential information during protected period**

- (1) The Director-General must, during the protected period that applies to confidential information,—
  - (a) take reasonable steps to ensure that the confidential information is kept confidential to the Director-General; and
  - (b) not use the confidential information in determining whether to grant any other innovative TNP application, non-innovative TNP application, or application to authorise a new use or method of use.
- (2) This section is subject to section 74H.

*Protected periods for information about innovative trade name products*

**74B Innovative TNP application for full registration**

- (1) The protected period for confidential information supporting an innovative TNP application under section 9(1) starts when the Director-General receives the application.
- (2) The protected period ends on the date that is 10 years after the date on which the Director-General grants or refuses to grant the application.

**74C Innovative TNP application for provisional registration**

- (1) The protected period for confidential information supporting an innovative TNP application under section 26 starts when the Director-General receives the application.
- (2) The protected period ends on the date that is 5 years after the date on which the Director-General grants or refuses to grant the application, unless subsection (3) applies.
- (3) The protected period continues until the end of the protected period for confidential information supporting an innovative TNP application subsequently made under section 9(1) if—
  - (a) the application under section 9(1) is for the same trade name product; and
  - (b) the confidential information given in support of the application under section 26 is also given in support of the application under section 9(1); and
  - (c) the confidential information supporting the application under section 9(1) is received by the Director-General before the period specified in subsection (2) expires.

**74D Application to authorise new use or method of use**

- (1) The protected period for confidential information supporting an application to authorise a new use or method of use for an innovative trade name product starts when the Director-General receives the application.
- (2) The protected period ends on the later of—
  - (a) the end date of the protected period for confidential information supporting the innovative TNP application that resulted in the registration of the product; and
  - (b) the date that is 5 years after the date on which the Director-General grants or refuses to grant the application to authorise a new use or method of use.

*Protected periods for information about non-innovative trade name products***74E Non-innovative TNP application for full registration**

- (1) The protected period for confidential information supporting a non-innovative TNP application under section 9(1) starts when the Director-General receives the application.
- (2) The protected period ends on the date that is 5 years after the date on which the Director-General grants or refuses to grant the application.

**74F Non-innovative TNP application for provisional registration**

- (1) The protected period for confidential information supporting a non-innovative TNP application under section 26 starts when the Director-General receives the application.
- (2) The protected period ends on the date that is 5 years after the date on which the Director-General grants or refuses to grant the application, unless subsection (3) applies.
- (3) The protected period continues until the end of the protected period for confidential information supporting a non-innovative TNP application subsequently made under section 9(1) if—
  - (a) the application under section 9(1) is for the same trade name product; and
  - (b) the confidential information given in support of the application under section 26 is also given in support of the application under section 9(1); and
  - (c) the confidential information supporting the application under section 9(1) is received by the Director-General before the period specified in subsection (2) expires.

**74G Application to authorise new use or method of use**

- (1) The protected period for confidential information supporting an application to authorise a new use or method of use for a non-innovative trade name product starts when the Director-General receives the application.
- (2) The protected period ends on the date that is 5 years after the date on which the Director-General grants or refuses to grant the application.

*Director-General may disclose or use confidential information*

**74H Director-General may disclose or use confidential information**

- (1) In this section, **application** means an innovative TNP application, a non-innovative TNP application, or an application to authorise a new use or method of use.
- (2) Despite section 74A, the Director-General may, during a protected period, disclose or use confidential information in accordance with this section.
- (3) The Director-General may disclose the information, or use it in determining whether to grant an application other than the application to which the information relates or related, if—
  - (a) the applicant who made the application to which the information relates or related has consented in writing to the disclosure or use of the information; or
  - (b) the Director-General forms the opinion that the disclosure or use is necessary to protect the health or safety of members of the public.
- (4) The Director-General may disclose the confidential information to 1 or more of the following persons or organisations if the Director-General is of the opinion that they will take reasonable steps to ensure that they will not disclose the information to any other person:
  - (a) a government department or statutory body for the purposes of that government department or statutory body;
  - (b) an adviser for the purposes of obtaining advice about the agricultural compound to which the information relates;
  - (c) the World Health Organization;
  - (d) the Office International des Epizooties;
  - (e) the Food and Agriculture Organization;
  - (f) a regulatory agency of a country that is a party to the Agreement Establishing the World Trade Organization adopted at Marrakesh on 15 April 1994 (commonly known as a WTO country);
  - (g) a prescribed person or organisation or a person or an organisation within a prescribed class or prescribed classes of persons or organisations.

- (5) For the purposes of subsection (3)(a), a person other than the applicant may grant consent to the disclosure or use of the confidential information if—
- (a) the applicant has notified the Director-General in writing that the person may grant consent (and the applicant has not withdrawn that permission); or
  - (b) the applicant's rights in respect of the information have been transferred to the person and the applicant or the person has notified the Director-General in writing of the transfer.

**9 Section 81 amended (Principles of cost recovery)**

In section 81(1), replace “83” with “81L”.

**Part 2**

**Consequential amendments and transitional provisions**

*Consequential amendments*

**10 Consequential amendments to principal Act**

Amend the principal Act as set out in Schedule 1.

**11 Consequential amendments to other enactments**

Amend the enactments specified in Schedule 2 as set out in that schedule.

*Transitional provisions*

**12 New Schedule 1 inserted**

Insert the Schedule 1 set out in Schedule 3 of this Act as the first schedule to appear after the last section of the principal Act.

## Schedule 1

### Consequential amendments to principal Act

s 10

#### Section 4A

In section 4A(2)(a), after “and its registration”, insert “(as a trade name product)”.

In section 4A(3)(a), after “agricultural compound is registered”, insert “(as a trade name product)”.

#### Cross-heading above section 9

In the cross-heading above section 9, after “*agricultural compounds*”, insert “*as trade name products*”.

#### Section 11

In section 11(2), replace “sections 73, 109, and 121” with “section 74A”.

#### Section 13

In section 13(2), replace “sections 73, 109, or 121” with “section 74A”.

#### Section 14

In section 14(2)(f), replace “sections 73, 109, or 121” with “section 74A”.

#### Section 16

In section 16(2), replace “agricultural compound” with “trade name product contains an agricultural compound that”.

#### Section 20

In section 20(a), replace “section 73, section 109, or section 121” with “section 74A”.

#### Section 21

In section 21(1)(c), replace “decline the application” with “refuse to grant the application”.

In section 21(1)(d), after “in every other case,”, insert “grant the application and”.

In section 21(2), replace “decision to register a trade name product” with “decision to grant an application”.

Replace section 21(4) and (5) with:

(4) The Director-General must not grant an application without the consent of the Director-General of Health if the trade name product to which it relates is a prescription medicine within the meaning of section 3 of the Medicines Act 1981.

(5) The Director-General must not grant an application if—

**Section 21**—*continued*

- (a) the trade name product to which it relates contains an agricultural compound that is also a hazardous substance or new organism; and
- (b) an approval for that substance or organism has not been issued under the Hazardous Substances and New Organisms Act 1996.

**Section 24**

In the heading to section 24, replace “**agricultural compounds**” with “**trade name products**”.

In section 24(2)(c), replace “73” with “74A”.

**Section 26**

In section 26(1), delete “of an agricultural compound”.

**Section 27**

In section 27(2), after “The Director-General must”, insert “grant the application and”.

Replace section 27(7) with:

- (7) The Director-General must not grant an application if—
  - (a) the trade name product to which it relates contains an agricultural compound that is also a hazardous substance or new organism; and
  - (b) an approval for that substance or organism has not been issued under the Hazardous Substances and New Organisms Act 1996.

**Section 75**

In section 75(1)(i), replace “section 74(1)(c)” with “section 74H(4)(g)”.

## Schedule 2

### Consequential amendments to other enactments

s 11

#### Hazardous Substances and New Organisms Act 1996 (1996 No 30)

In section 2(1), insert, in their appropriate alphabetical order:

**innovative medicine application** has the meaning given to it in section 23A of the Medicines Act 1981

**innovative TNP application**—

- (a) has the meaning given to it in section 72(1) of the Agricultural Compounds and Veterinary Medicines Act 1997; and
- (b) includes an innovative agricultural compound application (as defined in section 72 of that Act as in force immediately before the commencement of the Agricultural Compounds and Veterinary Medicines Amendment Act 2016)

In section 25(6), replace “that is the subject of an innovative agricultural compound application” with “that is or has been the subject of an innovative TNP application”.

Replace section 25(7) and (8) with:

- (7) Subsection (6) ceases to apply in respect of a hazardous substance or new organism on the date that section 55(3) or (4) ceases to apply to the Authority.

Replace section 55(3) to (7) with:

- (3) Sections 23A to 23C of the Medicines Act 1981 apply (with the necessary modifications) to the Authority (as if it were the Minister of Health) in relation to confidential information received in respect of an application made under this Act if—
  - (a) the hazardous substance or new organism to which the application relates is or has been the subject of an innovative medicine application; and
  - (b) the confidential information is about that substance or organism; and
  - (c) the Minister of Health is, at the time the Authority wants to disclose or use the information, required under section 23B of the Medicines Act 1981 to protect information provided in, or in relation to, the innovative medicine application.
- (4) Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 applies (with the necessary modifications) to the Authority (as if it were the Director-General) in relation to confidential information received in respect of an application made under this Act if—
  - (a) the hazardous substance or new organism to which the application relates is or has been the subject of an innovative TNP application; and

**Hazardous Substances and New Organisms Act 1996 (1996 No 30)**—*continued*

- (b) the confidential information is about that substance or organism; and
  - (c) the Director-General is, at the time the Authority wants to disclose or use the information, required under Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 to protect information provided in support of the innovative TNP application.
- (5) Despite subsections (3) and (4),—
- (a) the Authority must make available a summary of the effects of a hazardous substance or new organism for the purposes of section 53(3)(c) if the Authority is required to publicly notify the application that relates to that substance or organism under section 53:
  - (b) the Authority may disclose confidential information to prescribed persons or organisations or persons or organisations within prescribed classes of persons or organisations.
- (6) For the purposes of subsection (5)(b), the Governor-General may, by Order in Council, make regulations prescribing persons, organisations, or classes of persons or organisations.
- (7) In this section, **confidential information** means information that includes either or both of the following:
- (a) trade secrets:
  - (b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information.

In section 141(1), replace “section 55(7)” with “section 55(6)”.

**Medicines Act 1981 (1981 No 118)**

In section 23A, replace the definition of **confidential information** with:

**confidential information** includes—

- (a) trade secrets; and
- (b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information

**Schedule 3**  
**New Schedule 1 inserted**

s 12

**Schedule 1**  
**Transitional, savings, and related provisions**

s 2A

**Part 1**  
**Provisions relating to Agricultural Compounds and Veterinary Medicines Amendment Act 2016**

**1 Interpretation**

(1) In this Part,—

**commencement** means the commencement of the Agricultural Compounds and Veterinary Medicines Amendment Act 2016

**innovative agricultural compound application** has the meaning given to it in section 72 as in force immediately before commencement.

(2) A term or expression used and not defined in this Part, but defined in section 72 as in force on commencement, has the meaning given to it in that section.

**2 Application of amendments**

(1) The amendments made by the Agricultural Compounds and Veterinary Medicines Amendment Act 2016 apply to the following applications or decisions only if they are made on or after commencement:

(a) an innovative TNP application:

(b) a non-innovative TNP application:

(c) an application to authorise a new use or method of use:

(d) a decision under section 29 or 30 to reassess a registered trade name product.

(2) Part 6 as in force immediately before commencement continues to apply to an innovative agricultural compound application made before commencement.

**3 Certain applications to authorise new uses or methods of use**

*Innovative trade name products*

(1) Subclause (2) applies to an application to authorise a new use or method of use made—

(a) on or after commencement; but

- (b) in respect of a trade name product registered on the granting of an innovative agricultural compound application made before commencement.
- (2) Part 6 as in force on commencement applies to the application as if it were made in respect of an innovative trade name product.
- Non-innovative trade name products*
- (3) Subclause (4) applies to an application to authorise a new use or method of use made—
- (a) on or after commencement; but
- (b) in respect of a trade name product registered on the granting of an application (other than an innovative agricultural compound application) made under section 9(1) before commencement.
- (4) Part 6 as in force on commencement applies to the application as if it were made in respect of a non-innovative trade name product.

### Legislative history

11 August 2015	Introduction (Bill 54–1)
13 October 2015	First reading and referral to Primary Production Committee
15 June 2016	Reported from Primary Production Committee (Bill 54–2)
20 September 2016	Second reading
12 October 2016	Committee of the whole House
2 November 2016	Third reading
7 November 2016	Royal assent

This Act is administered by the Ministry for Primary Industries.