Agricultural Compounds and Veterinary Medicines Amendment Bill

Government Bill

Explanatory note

General policy statement

The Agricultural Compounds and Veterinary Medicines Act 1997 (the **ACVM Act**) protects confidential information given in support of an application to register an innovative trade name product. The ACVM Act currently protects the information for 5 years after an application is decided. Under certain conditions, this Bill extends the period of protection from 5 to 8 years. The Bill also expands the scope of data protection coverage to include confidential information provided in support of applications to register non-innovative trade name products and uses. The policy objective of the changes in the Bill is to encourage businesses that own trade name products to register new trade name products and to register more uses for existing trade name products. The changes are being made to support primary sector productivity and international competitiveness. The changes represent a balance between the objectives of—

- encouraging competition in the innovative and generic agricultural compounds markets so that New Zealand businesses can access reasonably priced products; and
- encouraging registration of innovative products, and new uses of registered products, needed by the New Zealand agriculture sector, particularly smaller industries, to be competitive internationally.

Innovative trade name products

The ACVM Act currently confers 5 years' protection for confidential information provided in support of applications to register innovative trade name products. An innovative trade name product is one that contains an active ingredient that has not previously been referred to in any other application.

The Bill would extend protection by 1 year for each new use that is subsequently added to the registration (up to a maximum of 8 years).

Non-innovative trade name products

The ACVM Act does not currently protect confidential information provided in support of applications to register non-innovative trade name products or new uses for non-innovative trade name products. The Bill would introduce data protection for both those categories by conferring—

- 3 years' protection for confidential information provided in support of applications to register non-innovative trade name products, including reformulations; and
- 3 years' protection for confidential information provided in support of applications to register new uses of non-innovative trade name products.

New uses

Applications to vary conditions on the registration of a trade name product may be made under section 9(2) of the ACVM Act.

This Bill confers data protection on confidential information provided in support of a variation application only if the granting of the application authorises the product to be used on a new species.

Consequential amendments

Data protection under the Hazardous Substances and New Organisms Act 1996 (the **HSNO Act**) is provided by cross-referencing the relevant parts of the ACVM Act.

The Bill makes minor consequential amendments to the HSNO Act to maintain generally consistent data protection arrangements under the ACVM Act and the HSNO Act. It also makes a minor consequential amendment to the Medicines Act 1981.

Departmental disclosure statement

The Ministry for Primary Industries is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2015&no=54.

Regulatory impact statement

The Ministry for Primary Industries produced a regulatory impact statement on 12 September 2012 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- http://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/
- http://www.treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 provides that the Bill comes into force on the day after the date on which it receives the Royal assent.

Clause 3 provides that the Bill amends the Agricultural Compounds and Veterinary Medicines Act 1997 (the **principal Act**).

Part 1
Substantive amendments to principal Act

Clause 4 inserts *new section 2A*, which clarifies the status of examples.

Clause 5 repeals section 56(4) of the principal Act (and makes a consequential amendment to section 56(3)). Section 56(4) is redundant because it relates to provisions of the principal Act that have been repealed.

Clause 6 replaces Part 6 of the principal Act, which provides for the protection of confidential information provided in support of innovative agricultural compound applications. *New Part 6* also protects that information, although it uses the term innovative TNP application to refer to applications to register innovative trade name products (in place of the term innovative agricultural compound application). In addition, *new Part 6* provides for the protection of—

- confidential information provided in support of applications to register non-innovative trade name products (**non-innovative TNP applications**); and
- confidential information provided in support of applications to vary conditions imposed on the registration of trade name products (**variation applications**).

The provisions contained in *new Part 6* are as follows:

- *new sections 72 to 74* define the terms used in *new Part 6*:
- *new section 74A* provides that, during a protected period, the Director-General of the Ministry for Primary Industries must take steps to prevent protected confidential information from being disclosed and that he or she must not use the information when deciding other innovative TNP applications, non-innovative TNP applications, or variation applications:
- *new section 74B* sets out the protected period for confidential information supporting an innovative TNP application. The basic period, which lasts for 5 years after an application is decided, may be extended by 1 year for each new use authorised as a result of 1 or more successful variation applications. The period may be extended in this way up to a maximum of 8 years:

- *new section 74C* sets out the protected period for confidential information supporting an innovative TNP application for provisional registration:
- *new section 74D* sets out the protected period for confidential information supporting a variation application relating to an innovative trade name product. If conditions set out in *new section 74D* are met, the period has the same end date as applies under *new section 74B* to the information that supported the application to register the product:
- *new section 74E* sets out the protected period for confidential information supporting a non-innovative TNP application for full or provisional registration:
- *new section 74F* sets out the protected period for confidential information supporting a variation application relating to a non-innovative trade name product:
- *new section 74G* re-enacts (with minor changes in form and terminology) the current section 74 of the principal Act, which provides for the use and disclosure, in specified circumstances, of otherwise protected confidential information.

Clause 7 updates a cross-reference in section 81 of the principal Act.

Part 2
Consequential amendments

Clause 8 and *Schedule 1* provide for consequential amendments to the principal Act.

Clause 9 and *Schedule 2* provide for consequential amendments to the Hazardous Substances and New Organisms Act 1996 (the **HSNO Act**) and the Medicines Act 1981. The amendments to the HSNO Act amend provisions that apply the information protection requirements under the principal Act and the Medicines Act 1981 to the Environmental Protection Authority. The amendment to the Medicines Act 1981 aligns the definition of confidential information in that Act with the definition of that term in *new section 73* of the principal Act.

Hon Jo Goodhew

Agricultural Compounds and Veterinary Medicines Amendment Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Agricultural Compounds and Veterinary Medicines Amendment Act **2015**.

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 (Status of examples)

After section 2, insert:

2A Status of examples

(1) An example used in this Act is only illustrative of the provisions to which it relates. It does not limit those provisions.

(2) If an example and a provision to which it relates are inconsistent, the provision prevails.

5 Section 56 amended (Penalties)

(1) In section 56(3), replace "Subject to subsection (4), every" with "Every".

(2) Repeal section 56(4).

6 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,—

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 applies:

(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 that was licensed under the Animal Remedies Act 1967 (other than by a provisional licence)

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

new use has the meaning given to it in **section 74B(6)**

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**

variation application means an application under section 9(2) to vary 1 or more conditions imposed on a registered trade name product.

(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 a variation application; 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 a variation application made in respect of an innovative trade name product, the period specified in **section 74D**:

(d) for confidential information supporting a non-innovative TNP application, the period specified in **section 74E**:

(e) for confidential information supporting a variation application made in respect of a non-innovative trade name product, the period specified in **section 74F**.

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 he or she does not disclose the confidential information; and

(b) not use the confidential information in determining whether to grant any other innovative TNP application, non-innovative TNP application, or variation application.

(2) This section is subject to **section 74G**.

Protected periods for information about innovative trade name products

74B Innovative TNP application for full registration

(1) This section applies to confidential information supporting an innovative TNP application made under section 9(1).

Basic protected period

(2) The protected period starts on the date on which the Director-General receives the application.

(3) 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 if that decision is made within 5 years after the date on which the Director-General receives the application.

(4) The protected period ends on the date that is 5 years after the date on which the Director-General receives the application if a decision to grant or refuse to grant the application has not been made by that time.

Extended protected period

(5) The end date that applies under **subsection (3)** is extended by a period of 1 year for each new use authorised by the granting of a variation application that—

(a) is made in respect of the relevant innovative trade name product; and

(b) is received within 3 years after the date on which the Director-General granted the application to register the product (the **original application**).

(6) A **new use** is authorised if the conditions on the registration of a product are varied so as to authorise the product's—

(a) use on a species of plant or animal on which the product could not be used under the conditions as they were before the variation was granted:

(b) labelling for use on a species of plant or animal on which the product could not be labelled for use under the conditions as they were before the variation was granted.

(7) The end date of the protected period may be extended under **subsection (5)** to no more than 8 years after the date on which the Director-General granted the original application.

Example

The Director-General grants an innovative TNP application (the **original application**) within 5 years of receiving it. The Director-General registers the innovative trade name product subject to the condition that it be labelled for use only on species A.

Within 3 years of granting the original application, the Director-General receives an application to vary the condition so that the product may also be labelled for use on species B and C (the **variation application**). The Director-General grants the variation application.

When the Director-General grants the variation application, the end date of the protected period for the confidential information supporting the original application is extended from 5 years to 7 years after the date on which the Director-General granted the original application.

74C Innovative TNP application for provisional registration

(1) This section applies to confidential information supporting an innovative TNP application made under section 26.

(2) The protected period starts on the date on which the Director-General receives the application.

(3) The protected period ends on the date that is 5 years after the date on which the Director-General receives the application.

74D Variation application

(1) This section applies to confidential information supporting any variation application made in respect of an innovative trade name product, unless the Director-General receives the variation application more than 3 years after the date on which the innovative trade name product was registered.

(2) The protected period starts on the date on which the Director-General receives the variation application.

(3) The protected period ends on the same date as the protected period for the confidential information that supported the original application (as determined under **section 74B**, taking into account any extension of the protected period under **section 74B(5)**) if—

(a) the variation is granted within 3 years after the date on which the Director-General receives the variation application; and

(b) the granting of the application results in a new use being authorised.

(4) The protected period ends on the date that is 3 years after the date on which the Director-General receives the variation application if a decision to grant or refuse to grant the application has not been made by that time.

(5) In any other circumstances, the protected period ends on the date on which the Director-General grants or refuses to grant the variation application.

(6) To avoid doubt, there is no protected period for confidential information that supports a variation application made more than 3 years after the date on which the Director-General registered the innovative trade name product to which the variation application relates.

Protected periods for information about non-innovative trade name products

74E Non-innovative TNP application for full or provisional registration

(1) This section applies to confidential information supporting a non-innovative TNP application made under section 9(1) or 26.

(2) The protected period starts on the date on which the Director-General receives the application.

(3) The protected period ends on the date that is 3 years after the date on which the Director-General grants or refuses to grant the non-innovative TNP application if that decision is made within 3 years after the date on which the Director-General receives the application.

(4) The protected period ends on the date that is 3 years after the date on which the Director-General receives the application if a decision to grant or refuse to grant the application has not been made by that time.

74F Variation application

(1) This section applies to confidential information supporting any variation application made in respect of a non-innovative trade name product.

(2) The protected period starts on the date on which the Director-General receives the variation application.

(3) The protected period ends on the date that is 3 years after the date on which the Director-General grants the variation application if—

(a) the variation is granted within 3 years after the date on which the Director-General receives that application; and

(b) the granting of the application results in a new use being authorised.

(4) The protected period ends on the date that is 3 years after the date on which the Director-General receives the variation application if a decision to grant or refuse to grant the application has not been made by that time.

(5) In any other circumstances, the protected period ends on the date on which the Director-General grants or refuses to grant the variation application.

Director-General may disclose or use confidential information

74G Director-General may disclose or use confidential information

(1) In this section, **application** means an innovative TNP application, a non-innovative TNP application, or a variation application, as the case may be.

(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.

7 Section 81 amended (Principles of cost recovery)

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

Part 2
Consequential amendments

8 Consequential amendments to principal Act

Amend the principal Act as set out in **Schedule 1**.

9 Consequential amendments to other enactments

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

Schedule 1
Consequential amendments to principal Act

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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 "73" with "**74A**".

Section 13

In section 13(2), replace "73" with "**74A**".

Section 14

In section 14(2)(f), replace "73" with "**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 "73" with "**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) that substance or organism has not been approved under the Hazardous Substances and New Organisms Act 1996.

Section 22

In section 22(1)(c), replace "and declined" with "and the Director-General refuses to grant the application".

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) that substance or organism has not been approved under the Hazardous Substances and New Organisms Act 1996.

Section 75

In section 75(1)(i), replace "section 74(1)(c)" with "**section 74G(4)(g)**".

Schedule 2
Consequential amendments to other enactments

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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** has the meaning given to it in **section 72(1)** of the Agricultural Compounds and Veterinary Medicines Act 1997

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), as the case may be, 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 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 that information.
>
> (4) **Part 6** of the Agricultural Compounds and Veterinary Medicines Act 1997 applies (with the necessary modifications) to the Authority 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
>
> (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 **section 74A** of the Agricultural Compounds and Veterinary Medicines Act 1997 to protect that information.
>
> (5) Despite **subsections (3) and (4)**,—

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

(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

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