Agricultural Compounds and Veterinary Medicines Amendment Bill

Government Bill

As reported from the Primary Production Committee

Commentary

Recommendation

The Primary Production Committee has examined the Agricultural Compounds and Veterinary Medicines Amendment Bill and recommends by majority that it be passed with the amendments shown.

Introduction

The bill seeks to amend the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). The bill as introduced would extend from 5 to 8 years the maximum period of protection for confidential information given in support of an application to register an innovative trade name product. It would also expand the scope of data protection to include confidential information given in support of applications to register non-innovative trade name products and uses.

The bill would amend the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) to ensure it remains aligned with the ACVM Act in protecting data relating to innovative products. It would also amend the Medicines Act 1991, to ensure that the definition of confidential information in that Act remains consistent with the ACVM Act.

This commentary covers the main amendments we recommend to the bill. It does not cover minor or technical amendments.

Innovative trade name products

For data provided with applications to register innovative trade name products, the bill as introduced would leave the base level of protection at 5 years after an application is decided, but would enable the period to be extended to a maximum of 8 years

through the registration of new uses for the product. We recommend amending clause 6, new section 74B, to extend the base level of data protection from 5 to 10 years. We note that increasing data protection to 10 years could reduce competition during the protection period. However, it should lead to greater competition in the medium and long term, as it would lead to more product registrations.

We do not recommend data protection in excess of 10 years. This period should be long enough for most registrants to recover the costs of generating the data.

New uses for innovative trade name products

The bill as introduced (clause 6, section 74B(7)) would allow one extra year of data protection for each new use that the innovative product is registered for, up to a maximum of 3 extra years. This aims to encourage registrants to register more new uses for innovative products.

We accept that new use applications may need even longer data protection. Therefore, we recommend amending clause 6, new section 74D, to allow new uses for trade name products to be protected for:

- the period remaining of the innovative product's original 10 year data protection period; or
- 5 years after the new use application is decided, whichever is longer.

This approach would encourage applicants to register new uses early in the protection period to maximise the length of time that data protection applies. It would also avoid discouraging applicants from registering new uses later in the protection period.

Non-innovative trade name products

We recommend amending clause 6, new section 74E, to allow data provided with applications to register non-innovative trade name products, including reformulations, to be protected for 5 years after the application is decided. The bill as introduced would allow 3 years' protection. We accept that 3 years may not be long enough for registrants to recover the costs of developing data. We consider that 5 years of data protection would both promote registrations and encourage competition. Any extension beyond 5 years might adversely affect competition for ACVM users.

New uses for non-innovative trade name products

The bill as introduced would provide 3 years' protection for data provided with applications to register new uses for non-innovative products. For the same reasons mentioned above, we recommend amending clause 6, new section 74FA, to allow data protection for new uses for non-innovative trade name products to be set at 5 years.

Definition of "new use" applications

The bill as introduced would allow for data provided with applications to register new uses for non-innovative products to be protected under the principal Act when the new use enables a product to be used on an additional animal or plant species. We consider that the definition of "new use" in the bill is too narrow.

Therefore, we recommend amending clause 6, new section 72(1), so applications could qualify for data protection if they seek to vary one or more conditions on an ACVM registration to permit change in the purpose for which an agricultural compound can be used, how or when the agricultural product is applied, or the withholding period for the product. We also recommend that the term used in the bill to describe these applications be amended to reflect this change.

Reassessments for data protection

On occasion, the Ministry for Primary Industries (MPI) may need to reassess a product (or group of products) that is or are already registered. This could occur, for example, if concerns are raised or new information becomes available that is different from the information available when a product is first registered.

There is no existing protection for data provided when products are being reassessed. This means that suppliers have little incentive to supply data as part of the reassessments process, which could lead to users needing to fund a reassessment in order to retain products in the New Zealand market. We consider it desirable to provide some protection and therefore recommend inserting clause 4A to amend section 29(3), and clause 4B to amend section 30. This would allow data supplied in support of reassessments under the principal Act to be protected for 5 years.

Confidentiality

We recommend amending new section 74A(1)(a) to clarify that confidential data may be disclosed to officials within MPI. The bill as introduced would require the Director-General to take reasonable steps to ensure he or she "does not disclose" confidential information. This could be interpreted as prohibiting the Director-General from disclosing confidential data to officials within MPI who need the data to process the application.

We also recommend amending new sections 55(3) and (4) of the HSNO Act to ensure that confidential data provided is protected even if it differs from the data provided under the principal Act or the Medicines Act. This would be consistent with the way that data protection under the HSNO Act currently operates.

Limit on data protection where no decision is made

The bill as introduced would limit the period of data protection where no decision is made on an application to 5 years for innovative applications and 3 years for other applications. We note that as applications will be approved, declined, or withdrawn well within these time limits, these provisions are unnecessary.

Therefore, we recommend removing proposed new subsections 74B(4), 74D(4), 74E(4), and 74F(4) which relate to time limits on data protection where no decision is made on an application.

Consequential amendments

We recommend various amendments in Schedule 1 to update cross-references in the principal Act and to delete redundant cross-references.

We also recommend some amendments in Schedule 2 relating to the HSNO Act to improve clarity and to ensure that any data protection existing at the time of enactment is maintained.

Transitional provisions

The bill as introduced does not contain any transitional provisions, instead relying on the default rules in the Interpretation Act 1999. This could create uncertainty regarding the effect of the bill. We recommend amending clause 4 (new section 2A and new Schedule 3) to insert new Schedule 1 in the principal Act. The new schedule would include transitional provisions to clarify that after the amendments came into force:

- the existing law would continue to apply in relation to existing applications and previously registered products
- new use applications made in respect of innovative products would be eligible for data protection.

Green Party of Aotearoa New Zealand minority view

This bill takes the frame that the industry's right to commercial sensitivity outweighs the rights of users and the community's right to know and understand what the compounds are that they are using, or are being used in their environment and food chain. Health statistics, supported by research, suggest considerable risk from agrichemicals. Aotearoa New Zealand needs fewer pesticides and more transparency. This bill promotes the opposite, and the Green Party cannot support it.

This bill intends encouraging more pesticides and other agricultural compounds through increased data protection. Increased data protection means less public transparency about product ingredients, and has been amended since the first reading to an even greater increase in data protection and now meets the data protection requirements of the Trans Pacific Partnership Agreement (TPPA).

"Industry stakeholders" who called for this bill say that they will not go to the expense and effort of registering new products, or register more uses for existing trade name products, if there is a risk their work will be undone by making the data available to competitors.

New pesticides had 5 years of data protection under the old Act and the bill, as introduced, intended an extension of the agrichemical companies' confidentiality or data protection on new compounds year by year from 5 years up to 8 years. Stakeholder submitters, including the New Zealand Law Society, called for a further extension of data protection that also met the TPPA's 10-year requirement.

The 5-year data protection period was portrayed as deterring companies from registering products, which would in turn, theoretically, cost users because of a lack of competition between compounds and brands. However, since 2008, ahead of this change,

1,100 new ACVM compounds were registered and just 239 cancelled or expired, and industry sectors such as in horticulture, could themselves apply for registration of a new use, if its value was considered high enough to them but not to the pesticide manufacturers.

The Ministry for Primary Industries (MPI) or the Environmental Protection Authority (EPA) could also instigate a reassessment themselves, that might allow wider use of a generic compound if such a public good was accepted. Compulsory compensation from other firms to the original registrant/data-holder for the cost of providing the data required for other firms, could have been an option rather than data being hidden.

In considering widening the use of existing products, a 2009 Covec report said, "The fact that most innovative agricultural compounds were eligible for a 20-year period of patent protection meant that a five year period of data protection did not appear to have a significant impact on the registration of new products."

And, "Companies' apparent reluctance to carry out the extra testing to add other uses to innovative compounds for the New Zealand context is therefore more likely to reflect the small size of the market, rather than lack of data protection."

We heard that the reformulation of products (non-innovative) may have apparent advantages; however, the Green Party believes increased data protection is more likely to lead to monopoly by the large corporates but with longer periods of secrecy about the contents of their products. Industry wants new uses and formulations to have data protection and for longer. The Green Party does not. Many additives (adjuvants—such as surfactants, penetrants, and stabilisers) are not currently identified, yet can be as toxic as the principal ingredient or act in a synergistic manner, further exacerbating risk.

Many companies are currently able to afford the cost of a new (innovative or non-innovative) application. New product registrations have averaged 180 per year for the past five years, and yet very few of the more than 3,000 different products registered for sale have been reassessed or removed.

MPI's Regulatory Impact Statement focused on the cost of products to industry and at no time considered the externalities of pesticides and other agricultural compounds, the cost to the environment, or to human and animal health. MPI will be leaving most of that responsibility to the EPA under the Hazardous Substances and New Organisms provisions, which also will not give the wider community the full list of ingredients of new formulations.

Currently MPI and the EPA appear to mostly rely on applicant-generated data, and focus on the principal ingredient, and appear to disregard independent peer-reviewed and published research. This suggests a lack of capacity for robust analysis of environmental and community health risks from product formulations being applied for, and is not the appropriate setting for an extension of data protection for an industry known for products causing significant community and environmental harms.

Appendix

Committee procedure

The Agricultural Compounds and Veterinary Medicines Amendment Bill was referred to the committee on 13 October 2015. The closing date for submissions was 29 January 2016. We received and considered nine submissions from interested groups and individuals. We heard five submissions.

We received advice from the Ministry for Primary Industries and the Ministry for the Environment.

Committee membership

Ian McKelvie (Chairperson)

Todd Barclay

Hon Chester Borrows

Steffan Browning

Barbara Kuriger

Hon Damien O'Connor

Richard Prosser

Stuart Smith

Rino Tirikatene

Key to symbols used in reprinted bill

As reported from a select committee

text inserted unanimously

~~text deleted unanimously~~

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)~~ (Transitional, savings, and related provisions)

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.~~

2A Transitional, savings, and related provisions

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

4A 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.

4B 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.

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,—

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 ~~applies~~ 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 ~~that~~ 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

~~**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~~ 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 ~~a variation application made in respect of~~ 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**:

(da) for confidential information supporting a non-innovative TNP application made under section 26, the period specified in **section 74F**:

(e) for confidential information supporting ~~a variation application made in respect of~~ an application to authorise a new use or method of use for a non-innovative trade name product, the period specified in **section 74FA**.

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~~ 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 ~~variation~~ application to authorise a new use or method of use.

(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.~~

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.

74FA 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

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~~ 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.

7 Section 81 amended (Principles of cost recovery)

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

Part 2
Consequential amendments and transitional provisions

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.

Transitional provisions

10 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

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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 "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 ~~approved~~ issued 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) an approval for that substance or organism has not been ~~approved~~ issued 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

s 9

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~~

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 **2015**)

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 (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 ~~that~~ 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—

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

(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**~~ **Part 6** of the Agricultural Compounds and Veterinary Medicines Act 1997 to protect ~~that~~ 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.~~

(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 10

Schedule 1
Transitional, savings, and related provisions

s 2A

Part 1
Provisions relating to Agricultural Compounds and Veterinary Medicines Amendment Act 2015

1 Interpretation

(1) In this Part,—

commencement means the commencement of the Agricultural Compounds and Veterinary Medicines Amendment Act **2015**

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 **2015** 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

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