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. We recommend all amendments unanimously.

Introduction

The Agricultural Compounds and Veterinary Medicines (ACVM) Amendment Bill would amend the Agricultural Compounds and Veterinary Medicines Act 1997.

The bill would implement policy changes arising from the Ministry for Regulation's regulatory review of agricultural and horticultural products.[1] The ministry made sixteen recommendations as a result of the review, which aim to improve the proportionality, efficiency, transparency, and certainty of approval pathways for agricultural and horticultural products. The bill would give effect to the recommendations that relate to the ACVM Act.

The bill is intended to improve approval pathways for agricultural compounds and veterinary medicines and reduce unnecessary costs, complexity, and delays for applicants seeking approval of agricultural compounds and veterinary medicines.

The bill would help to modernise the regulatory framework for agricultural compounds and veterinary medicines. It would do so by:

- empowering the Director-General to:

[1] You can read about the review on the Ministry for Regulation's website.

  - approve and vary specifications relating to manufacturing and other matters
  - grant exemptions from registration requirement for low-risk agricultural compounds
- enabling statutory timeframes to be set by regulation rather than the Act itself
- enabling recognition of overseas regulators
- modernising public notification requirements
- introducing a modern consent regime for research and information-gathering
- improving how prescription medicines are considered
- updating variation and suspension provisions
- establishing a scheme for Good Manufacturing Practice standards and certificates of compliance
- strengthening the independent data assessor framework.

Legislative scrutiny

As part of our consideration of the bill, we have examined its consistency with principles of legislative quality. We wish to bring the House's attention to an issue related to clause 10, which was also brought to our attention by the Regulations Review Committee. We discuss this in more detail later in this commentary.

Proposed amendments

This commentary covers the main amendments we recommend to the bill as introduced. We do not discuss minor or technical amendments.

Publication of exemptions granted

Clause 10 of the bill would insert new section 8AA, which would give the Director-General a discretionary power to exempt agricultural compounds from the registration requirement.

The Regulations Review Committee wrote to us about its concerns that the bill would not require the Director-General to publish reasons for exemption decisions. We agree that the Director-General should be required to publish the reasons for granting an exemption, including why the exemption is considered appropriate. Those reasons should be published alongside the exemption notice.

We therefore recommend amending new section 8AA to insert new subsection (7A). New subsection (7A) would require the Director-General to publish the reasons for granting an exemption, or a link to a document setting out those reasons, on the Ministry for Primary Industries' website with the exemption.

We also recommend a consequential amendment to clause 8 of proposed new Part 2 of Schedule 1. The transitional provisions in the bill would allow exemptions currently set out in regulations to be transferred to be exemptions granted under section

8AA without having to comply with the preconditions in that section. We consider that transfers should also occur without having to comply with new section 8AA(7A). Our suggested amendment would exempt transferred exemptions from the publication requirement in new section 8AA(7A).

Method of public notification

Clause 75 of the bill as introduced proposes new section 82, which sets out how public notification requirements would be met. The Director-General could determine the most appropriate method, or methods, of notification in the circumstances. This could include by notice in the Gazette, by publication in newspapers or on the internet, or in any other way that the Director-General is reasonably satisfied with.

Some submitters were concerned that greater flexibility in notification methods could reduce the visibility of regulatory decisions and limit opportunities for interested parties to participate in decision-making processes.

We support the policy intent of modernising public notification requirements and giving the Director-General flexibility to use notification methods that are appropriate in particular circumstances. However, we consider that a minimum level of consistency and accessibility should be maintained.

We consider that publication in both the Gazette and on the Ministry for Primary Industries' website should be mandatory. These channels would provide a clear and reliable means of accessing regulatory information. The Director-General should also be able to use other notification methods where this would help ensure that a matter is sufficiently brought to the attention of the public.

We therefore recommend amending new section 82, to:

- state that any matter required to be publicly notified under the Act must be notified by notice in the Gazette and by publication on the Ministry for Primary Industries' website (new subsection (1))
- insert new subsection (1A) to allow a matter to also be publicly notified "in any other way that the matter is sufficiently notified to members of the public". This would retain the ability for the Director-General to use additional notification methods where satisfied that those methods would help ensure the matter is sufficiently notified to members of the public
- make a consequential amendment to subsection (2) as a consequence of new subsection (1A).

Evaluation of risks and benefits

Section 20 of the ACVM Act sets out the matters that the Director-General must have regard to when evaluating the risks and benefits of a trade name product as part of considering an application to register a trade name product. Clause 20 would insert an additional requirement, through new paragraph (aa). Paragraph (aa) would require the Director-General to have regard to any assessment of a recognised overseas regulator

that is held by the Director-General and has been carried out by the regulator for the purpose of determining whether to register an agricultural compound.

Some submitters were concerned that the existing requirement in the Act for the Director-General to "have regard to" certain matters may not provide sufficient assurance that those matters would be considered when evaluating the risks and benefits of approving an application.

We note that the bill would not change the requirement for the Director-General to evaluate the risks and benefits of an agricultural compound in a New Zealand context. Clause 20 would require the Director-General to consider assessments produced by recognised overseas regulators, but those assessments would not replace New Zealand's regulatory decision-making framework.

However, we consider that the requirement could be strengthened. We recommend amending clause 20 to replace the words "have regard to" in section 20 with "take into account" (clause 20(1)). We consider that this would impose a stronger obligation on the Director-General to address the matters listed in section 20 when evaluating risks and benefits of an application. It would make clear that recognised overseas assessments must be addressed as part of the evaluation, while preserving the Director-General's responsibility to assess risks and benefits in New Zealand's circumstances.

We also recommend a consequential amendment to clause 2(2). This amendment would allow for clause 20(1) to come into force on a date set by Order in Council, rather than on the day after Royal assent.

Recognition of overseas regulators

New section 20A, proposed through clause 21, would empower the Director-General to declare a person to be a recognised overseas regulator for the purposes of new section 20(aa). New sections 20A(1) to (3) would set out the criteria that would need to be satisfied before a declaration could be made. New section 20A(4) would allow the Director-General to withdraw recognition if they are satisfied that the recognised overseas regulator no longer meets those criteria.

Some submitters sought greater clarity about how recognised overseas regulators would be monitored over time. We agree that recognition should be subject to ongoing review. We consider that periodic reviews, and public notification of those reviews, would help ensure that recognition remains appropriate over time, and would support confidence in the regulatory framework.

We also consider that new section 20A(4) should be strengthened. In the bill as introduced, section 20A(4) would give the Director-General discretion to withdraw recognition if a recognised overseas regulator no longer satisfies the statutory criteria. We consider that withdrawal should be mandatory in those circumstances.

We therefore recommend amending new section 20A by:

- inserting new subsection (3A), which would require the Director-General to review declarations recognising overseas regulators at least once every 10 years
- requiring reviews to be publicly notified. (Subsections (5) and (6))
- requiring the Director-General to withdraw recognition, in whole or in part, if satisfied that one or more of the criteria for recognition in new section 20A(3) are no longer met. (Change to subsection (4).)

Right of review of decisions

Clause 42 would insert new sections 35FD and 35FE. Both relate to certifying compliance with manufacturing practice standards. New section 35FD would enable applications for, and the issuing of, certificates of compliance with manufacturing practice standards. New section 35FE would enable the Director-General to withdraw a certificate of compliance, and reissue it on application.

The New Zealand Law Society noted that the bill would not provide a right of review for some decisions made under these provisions. This would include decisions to decline an application for a certificate of compliance, withdraw a certificate, or refuse to reissue a withdrawn certificate.

We agree that decisions of this nature should be subject to review. A certificate of compliance could have significant implications for a person's ability to conduct regulated activities. We consider it appropriate that affected persons have access to the internal review process in section 77A of the ACVM Act. We consider that providing review rights would promote fairness and consistency with other significant regulatory decisions made under the Act.

We recommend amending section 77A of the Act so that decisions under new sections 35FD and 35FE are subject to review. In particular, we consider that decisions to decline an application for a certificate of compliance, withdraw a certificate, or refuse to reissue a certificate should be reviewable.

We proposed amendments to allow a person dissatisfied with any of the decisions noted above to seek a review by the Director-General, or by a person who was not involved in the original decision. To give effect to this, we recommend amending section 77A(1) (amended by clause 71) to insert new paragraphs (ed) to (ef).

Other matters considered

As part of our consideration of this bill, we also discussed the following matters. While we do not recommend any drafting changes as a result, we consider it worth noting these matters.

Hazardous Substances and New Organisms Amendment Bill

We considered this bill alongside the Hazardous Substances and New Organisms Amendment Bill (HSNO), which was referred to our committee for consideration

with a similar timeframe. We wish to clarify the differences between these two bills, and how they would interact in practice.

Both of these bills responded to the Ministry for Regulation's regulatory review of agricultural and horticultural products, giving effect to the recommendations relevant to each Act.

The HSNO Act governs the approval of hazardous substances and new organisms. The Environmental Protection Authority is the primary regulator under that Act, responsible for assessing and deciding on applications to introduce hazardous substances or new organisms into New Zealand. The HSNO Bill aims to improve access to agricultural and horticultural products for farmers, growers, and businesses. It also aims to strengthen the overall operation of the regulatory systems for hazardous substances and new organisms.

The ACVM Act regulates the importation, manufacture, sale, and use of agricultural compounds and veterinary medicines to ensure they are fit for purpose and manages their risks to public health, trade in primary produce, animal welfare, and agricultural security. It also ensures agricultural compound residues are compliant with domestic residue standards and that sufficient consumer information is provided about them. The ACVM Bill, as discussed previously in this commentary, is intended to improve approval pathways in the Act for agricultural compounds (including veterinary medicines).

Agricultural compounds and veterinary medicines may contain hazardous substances or new organisms, and as such might require approvals under both the HSNO Act and the ACVM Act.

Relationship between the ACVM Act and the HSNO Act

Any hazardous substance or new organism that is also an agricultural compound must first be approved under the HSNO Act. While product applications through the ACVM Act could be considered at the same as an approval application under the HSNO Act, they would ultimately require an approval under the HSNO Act before becoming registered under the ACVM Act. Neither bill would change the relationship between the two Acts.

Recognition of overseas regulators

The bill aims to strengthen and increase the use of trusted overseas assessments. Many submitters expressed concern about relying on assessments from overseas regulators. They argued that this could weaken New Zealand's specific assessment of agricultural compounds, and that it could overlook risks specific to a New Zealand context.

We wish to clarify that the bill would not change any processes around the consideration of risks and benefits, and would not permit automatic acceptance of overseas assessments. As per our proposed amendment, the bill would require that the Director-General must "take into account" assessments from recognised overseas

regulators. It would not remove the requirement to evaluate the risks and benefits of manufacturing or using a product in New Zealand.

Genetically modified organisms

We heard from several submitters who raised concerns that modernising approval pathways under the ACVM Act could increase the likelihood of genetically modified organisms (GMOs), including gene edited agricultural compounds, entering New Zealand. They suggested that the bill should explicitly confirm that it does not alter this particular framework, and that any agricultural compound involving genetic modification must continue to comply with the Hazardous Substances and New Organisms Act 1996 (HSNO).

Submitters also told us that allowing approvals based on recognised overseas regulators could lead to approvals for product that are inconsistent with New Zealand's GMO regulatory settings.

We note that the bill does not amend the HSNO Act, or alter New Zealand's regulatory settings, in relation to GMOs. Any GMO products would still be subject to approval under the HSNO Act. Additionally, any use of overseas regulators would still have to meet New Zealand's legislative requirements. As the approval of GMO based agricultural compound products is already restricted through the ACVM Act and other legislation, we consider that no further changes are necessary.

Appendix

Committee process

The Agricultural Compounds and Veterinary Medicines Amendment Bill was referred to this committee on 14 May 2026. (The calendar date was 15 May 2026.) The House instructed us to report the bill back no later than 17 September 2026. We invited the Minister for Food Safety to provide an oral submission on the bill. He did so on 25 June 2026.

We called for submissions on the bill with a closing date of 15 June 2026. We received and considered submissions from 1,148 interested groups and individuals. We heard oral evidence from 16 submitters. We wish to acknowledge the efforts of all submitters and thank them for their engagement.

Advice on the bill was provided by the Ministry for Primary Industries. The Office of the Clerk provided advice on the bill's legislative quality. The Parliamentary Counsel Office assisted with legal drafting. The Regulations Review Committee reported to us on the powers contained in clause 10.

Committee membership

Miles Anderson (Chairperson)

Steve Abel

Rachel Boyack

Mark Cameron

Dana Kirkpatrick

Hon Jo Luxton

Suze Redmayne

Related resources

The documents we received as advice and evidence are available on the Parliament website.

Key to symbols used in reprinted bill

As reported from a select committee

text inserted unanimously

~~text deleted unanimously~~

Hon Andrew Hoggard

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 **2026**.

2 Commencement

(1) This Act comes into force on a date set by Order in Council.

(2) However, **sections 4(2), 6, 7, 9** (to the extent that it inserts a subpart heading and a cross-heading), **10** (to the extent that it inserts a cross-heading), **14(1), 17(1), 18, 20(2), 21, 24(6) and (7), 24A(2) and (4), 28(1) and (3), 33(1), (2), and (5), 34, 41 to 43, 50(2), 51(2), 68, and 73 to 77** come into force on the day after Royal assent.

(3) Any part of this Act that has not come into force 2 years after Royal assent comes into force then.

(4) An Order in Council made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

3 Principal Act

This Act amends the Agricultural Compounds and Veterinary Medicines Act 1997.

Part 1
Main amendments

4 Section 2 amended (Interpretation)

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

approved form means a form that is approved by the Director-General

approved information means information of a kind that is approved by the Director-General

(2) In section 2(1), repeal the definition of **operating plan**.

(3) In section 2(1), definition of **registered**, delete "or section 27".

5 Section 4A amended (Scheme of Act)

(1) In section 4A(2), replace "2" with "3".

(2) After section 4A(2)(a), insert:

(aa) an assessment of the compound, and consent for its use in research or for obtaining further information to decide whether it should be registered as a trade name product, subject to specifically imposed conditions:

(3) In section 4A(3)(a), after "product)", insert ", approved,".

6 Part 2 heading amended

In the Part 2 heading, replace "**and sale**" with "**sale, and use**".

7 Cross-heading above section 5 replaced

Replace the cross-heading above section 5 with:

Subpart 1—Specific controls relating to importation

8 Section 6 amended (Agricultural compound clearance)

(1) In section 6(3)(a)(ii), delete "or its provisional registration under section 27".

(2) After section 6(3)(a)(ii), insert:

(iia) the goods are an agricultural compound, are the subject of a consent under **section 35AAD**, and comply with the conditions imposed on that consent; or

(3) In section 6(3)(a)(iii), after "section", insert "**8AA** or".

9 Section 8 replaced (Prohibition on sale, use, manufacture, or import of agricultural compound)

Replace section 8 with:

Subpart 2—Main controls on importation, manufacture, sale, or use of agricultural compounds

General restrictions

8 Restrictions on importation, manufacture, sale, or use of agricultural compounds

(1) A person may import an agricultural compound into New Zealand only if—

(a) the agricultural compound—

(i) is a registered trade name product; or

(ii) is exempt from registration under **section 8AA** or 8A; or

(iii) is only to be exported, with or without further processing; or

(b) the person holds a consent under **section 35AAD** that allows the agricultural compound to be imported into New Zealand.

(2) A person may manufacture an agricultural compound in New Zealand only if—

(a) the agricultural compound—

(i) is a registered trade name product; or

(ii) is exempt from registration under **section 8AA** or 8A; or

(iii) is manufactured for export only; or

(b) the person holds a consent under **section 35AAD** that allows the manufacture of the agricultural compound.

(3) A person may sell an agricultural compound within New Zealand only if—

(a) the agricultural compound—

(i) is a registered trade name product; or

(ii) is exempt from registration under **section 8AA** or 8A; or

(b) the person holds a consent under **section 35AAD** that allows the sale of the agricultural compound.

(4) A person may use an agricultural compound only if—

(a) the agricultural compound—

(i) is a registered trade name product; or

(ii) is exempt from registration under **section 8AA** or 8A; or

(b) the person holds a consent under **section 35AAD** that allows the use; or

(c) the agricultural compound has been sold to the person by the holder of a consent under **section 35AAD** that allows the sale to and use by—

(i) the person; or

(ii) a class of persons to which the person belongs.

10 New sections 8AA and 8AAB and cross-heading inserted

After section 8, insert:

Exemptions from registration

8AA Exemption from requirement to register for agricultural compound or class

Power to exempt and conditions of exemption

(1) The Director-General may exempt any agricultural compound or any class of agricultural compounds from the requirement to be registered under this subpart.

(2) An exemption granted under this section is subject to—

(a) any conditions that are prescribed by the regulations and that apply—

(i) generally; or

(ii) in the case of an exempted agricultural compound, to a class of agricultural compounds to which the exempted compound belongs; or

(iii) in the case of an exempted class of agricultural compounds, to a class of agricultural compounds to which the exempted class belongs; and

(b) any conditions specified in the exemption that are not inconsistent with any conditions referred to in **paragraph (a)**.

(3) Despite **subsection (2)**,—

(a) an exemption granted under this section may disapply or modify any conditions that are prescribed by the regulations (but only to the extent that the regulations allow those conditions to be disapplied or modified); and

(b) in that case, the exemption is not subject to the disapplied conditions (if any) and is subject to the modified conditions (if any).

Preconditions to granting exemption

(4) The Director-General may grant an exemption under this section only if satisfied that—

(a) the exemption is not inconsistent with the purpose of this Act as set out in section 4; and

(b) at least 1 of the following applies:

(i) the likely cost of assessing and registering the agricultural compound, or agricultural compounds of the relevant class, under this subpart outweighs the likely risks from the use of that agricultural compound, or those agricultural compounds, without registration; or

(ii) the likely risks of the substance concerned, or substances of the relevant class concerned, being used as an agricultural compound or agricultural compounds are already adequately managed by restrictions that apply under another Act to that substance or those substances (*see* **subsection (9)**).

(5) The Director-General may grant an exemption under this section only if—

(a) the Director-General has done everything reasonably practicable to consult the organisations that the Director-General considers represent the persons who will or may be affected by the exemption; and

(b) those persons have had an opportunity to comment; and

(c) the Director-General has considered those comments.

(6) **Subsection (5)** does not apply if the Director-General considers it desirable in the public interest that the exemption be granted urgently.

(7) A failure to comply with **subsection (5)** does not affect the validity of any exemption granted under this section.

Reasons to be provided

(7A) The Director-General's reasons for granting an exemption (or a link to a document that sets out those reasons) must be published together with the exemption.

Exemption is secondary legislation

(8) An exemption granted under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Definition

(9) In this section, **substance** includes a mixture of substances or a biological compound.

8AAB Requirements relating to records, returns, and information

(1) A person who belongs to a class of persons that is prescribed by the regulations must, in accordance with the regulations, keep records on agricultural compounds that are exempt from registration under **section 8AA**.

(2) A person who belongs to a class of persons that is prescribed by the regulations must, in accordance with the regulations, report returns or information to the

Director-General on agricultural compounds that are exempt from registration under **section 8AA**.

11 Section 8A amended (Exemptions from requirement to register)

(1) In the heading to section 8A, replace "**Exemptions**" with "**Other exemptions**".

(2) In section 8A(1), replace "Part" with "subpart".

(3) Repeal section 8A(1)(a).

(4) Replace section 8A(2) with:

(2) An exemption under this section is subject to any applicable conditions imposed under section 8B or 8C (as the case may be).

12 Section 8B amended (Director-General may list as exempt substances generally recognised as safe)

In section 8B(1), replace "Part" with "subpart".

13 Section 8C amended (Director-General may approve agricultural compound as exempt in special circumstances)

(1) In section 8C(3), replace "to 23 and section 25" with ", 20, 21, 22, 23, and 25".

(2) After section 8C(3), insert:

(3A) If a condition is to be imposed on the approval of the agricultural compound under section 23(1)(d), **(Ia), or (Ib)** (as applied by subsection (3)), **section 23A(1)** applies, with any necessary or appropriate modifications.

(3B) **Section 23A(2) to (4)** applies in relation to the variation of specifications that are approved by the Director-General under **section 23A(1)** (as applied by **subsection (3A)**).

(3) In section 8C(8), replace "77A" with "**85**".

14 Section 9 amended (Application for registration)

(1) In the heading to section 9, after "**registration**", insert "**or variation of conditions**".

(2) In section 9(1)(b) and (3), replace "as an agricultural compound under section 8A" with "under **section 8AA** or 8A".

15 Section 10 replaced (Form of application)

Replace section 10 with:

10 Approved form and information for application

(1) An application to register a trade name product, or to vary the conditions of a registered trade name product, must be in the approved form and contain, or be accompanied by, the approved information.

(2) Without limiting the approved information that the applicant may be required to supply, the applicant may be required to supply information obtained from a person belonging to a particular class, including, for example, from—

(a) a recognised agency or a recognised person; or

(b) a person who meets specified criteria (including, for example, particular qualifications or skills).

16 Section 12 amended (Director-General to withhold information)

(1) Replace the heading to section 12 with "**Public notification under section 14: information involving trade secrets, etc, to be withheld**".

(2) Repeal section 12(2) to (4).

17 Section 14 amended (Notification of application)

(1) Replace section 14(1) with:

(1) On receiving an application, the Director-General must arrange for the application to be publicly notified (*see* **section 82**).

(2) Replace section 14(2)(e) with:

(e) the closing date by which submissions must be received by the Director-General that is determined in accordance with the regulations; and

18 Section 15 amended (Waiver of notification)

(1) Replace section 15(1)(b) with:

(b) the application is made under section 9(2) and the proposed variation of conditions does not affect the evaluation of the risks relevant to the trade name product when compared with the original evaluation under section 21.

(2) In section 15(2), replace "a trade name product" with "the trade name product that is the subject of the application".

(3) In section 15(3)(a), after "product", insert "that is the subject of the application".

(4) After section 15(3), insert:

(4) The Director-General may waive the requirement to publicly notify an application under section 14 if, in the Director-General's opinion,—

(a) an emergency has arisen that involves risks to public health, risks to trade in primary produce, risks to animal welfare, or risks to agricultural security; and

(b) the trade name product that is the subject of the application is likely to be required for use in that emergency.

19 Section 16 replaced (Time limits and waivers)

Replace section 16 with:

16 Time limits relating to applications

Date for deciding application

(1) The Director-General must decide the application within any period determined in accordance with the regulations.

Date by which decision publicly notified

(2) The Director-General must publicly notify the Director-General's decision on the application by no later than any date determined in accordance with the regulations (*see also* **section 82**).

Guidance note

See **section 35AAO** in relation to the variation of time limits under this subpart.

20 Section 20 amended (Evaluation of risks and benefits)

(1) In section 20, replace "have regard to" with "take into account".

(2) After section 20(a), insert:

(aa) any assessment of a recognised overseas regulator that—

(i) is held by the Director-General; and

(ii) has been carried out by that regulator for the purpose of determining whether to register, or grant a licence or similar authorisation relating to, an agricultural compound that has the same formulation as the trade name product concerned under a legislative scheme that is comparable to the scheme for registration set out in this subpart; and

21 New section 20A inserted (Recognition of overseas regulators for purposes of section 20(aa))

After section 20, insert:

20A Recognition of overseas regulators for purposes of section 20(aa)

(1) The Director-General may declare that a person in another jurisdiction is a recognised overseas regulator for the purposes of **section 20(aa)**.

(2) The declaration may apply in relation to all agricultural compounds or a class of agricultural compounds.

(3) The Director-General may make a declaration in relation to the person only if the Director-General is satisfied that the following criteria are met:

(a) the person operates in a way that is comparable to the Director-General in regulating agricultural compounds or the class of agricultural compounds concerned:

(b) the person operates under a legislative scheme for regulating agricultural compounds or the class of agricultural compounds that is comparable to the scheme provided for by this subpart:

(c) the person is willing and able to provide assessments of a kind referred to in **section 20(aa)** to the Director-General:

(d) any criteria prescribed by the regulations.

(3A) The Director-General must review the declaration at intervals not exceeding 10 years.

(4) The Director-General ~~may~~ must declare that the recognition of a person under this section is withdrawn (in whole or in part) if satisfied that 1 or more of the criteria set out in **subsection (3)** are no longer met.

(5) Before making a declaration or completing a review under this section, the Director-General must—

(a) publicly notify the Director-General's proposal to make the declaration or the review (*see* **section 82**); and

(b) consult any person that the Director-General considers appropriate; and

(c) have regard to any written submissions received by the Director-General, and the results of consultation, on or before the date specified under **subsection (6)(d)**.

(6) The notice that is published under **subsection (5)(a)** must—

(a) state that the Director-General proposes to make, or is reviewing, the declaration; and

(b) state the effect of the proposed or existing declaration; and

(c) invite written submissions in relation to the proposed or existing declaration; and

(d) specify the closing date by which written submissions must be received by the Director-General (being a date that allows for a reasonable period within which submissions must be received).

(7) A declaration under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

22 Section 21 amended (Decision on application)

(1) In the heading to section 21, after "**application**", insert "**to register trade name product**".

(2) In section 21(1), replace "The Director-General must consider any application made under section 9 and" with "In considering an application made under section 9(1), the Director-General".

(3) In section 21(2) and (5), after "application", insert "made under section 9(1)".

(4) Replace section 21(4) with:

(4) The Director-General may grant an application made under section 9(1) to register a trade name product that is a prescription medicine (within the meaning of section 3 of the Medicines Act 1981) only if—

(a) the Director-General obtains the consent to grant the application from the Director-General of Health; or

(b) the prescription medicine is, or belongs to a class that is, prescribed by the regulations.

23 New section 21A inserted (Decision on application to vary conditions: section 9(2))

After section 21, insert:

21A Decision on application to vary conditions: section 9(2)

(1) The Director-General must decide an application made under section 9(2) in accordance with the regulations.

(2) Subject to the provisions of Part 6, the Director-General must give the decision in writing, with reasons, to the applicant and to every person who made a submission.

(3) The Director-General may grant an application made under section 9(2) relating to a trade name product that is a prescription medicine (within the meaning of section 3 of the Medicines Act 1981) only if—

(a) the Director-General obtains the consent to grant the application from the Director-General of Health; or

(b) the prescription medicine is, or belongs to a class that is, prescribed by the regulations.

(4) The Director-General must not grant an application made under section 9(2) 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.

24 Section 22 amended (Term of registration)

(1) In the heading to section 22, replace "**Term**" with "**Duration**".

~~(2) In section 22(1)(a), delete "or section 27(3)".~~

(2) In section 22(1)(a), replace ", 22B(2), or 27(3)" with "or 22B(2)".

(3) In section 22(1)(b), delete "27(6) or".

(4) In section 22(1)(c), delete "or section 30,".

(5) In section 22(3), delete ", other than a provisional registration under section 27,".

(6) Replace section 22(3)(b) with:

(b) must publicly notify the removal of the trade name product from the register (*see* **section 82**); and

(7) In section 22(3)(c), replace "*Gazette* notice" with "public notice required to be given under **paragraph (b)**".

(8) Repeal section 22(4).

24A Section 22A amended (Renewal of registration)

(1) In section 22A(1)(b), replace "the conditions and approvals granted as part of the registration" with "any condition imposed under section 23 that specifies requirements with which the trade name product must comply".

(2) In section 22A(2)(b)(ii), after "21(2)", insert ", 22B(2),".

(3) In section 22A(2)(b)(ii), replace ", 22B(2), or 27(3)" with "or 22B(2)".

(4) In section 22A(4), replace "and 13 to 21" with ", 13 to 20, and 21".

24B Section 22B amended (Decision on application for renewal)

(1) Before section 22B(1), insert:

(1AAA) The Director-General must decide an application made under section 22A within any period determined in accordance with the regulations.

Guidance note

See **section 35AAO** in relation to the variation of time limits under this subpart.

(2) In section 22B(1), replace "an application made under section 22A" with "the application".

(3) In section 22B(1)(b), replace "the conditions and approvals granted as part of the registration" with "any condition imposed under section 23 that specifies requirements with which the trade name product must comply".

25 Section 23 amended (Conditions on trade name products)

(1) In section 23(1)(d), after "requirements", insert "(including, for example, a condition requiring the labelling or advertising of the product to be in accordance with specifications approved by the Director-General under **section 23A**)".

(2) In section 23(1)(f), replace "section 28" with "**section 83**".

(3) After section 23(1)(l), insert:

(la) a condition requiring the product to be manufactured in accordance with specifications approved by the Director-General under **section 23A**:

(lb) a condition requiring characteristics of the product (including, for example, its formulation, purity, shelf life, packaging, and use) to conform to the specifications approved by the Director-General under **section 23A**:

26 New section 23A inserted (Approval and variation of specifications)

After section 23, insert:

23A Approval and variation of specifications

(1) The Director-General may approve specifications for the purposes of any condition to be imposed on the registration of a trade name product under section 23(1)(d), **(Ia), or (Ib)**.

(2) A person may apply to the Director-General to vary any of those specifications.

(3) The application must be in the approved form and contain, or be accompanied by, the approved information.

(4) Without limiting the approved information that the applicant may be required to supply, the applicant may be required to supply information obtained from a person belonging to a particular class, including, for example, from—

(a) a recognised agency or a recognised person; or

(b) a person who meets specified criteria (including, for example, particular qualifications or skills).

(5) The Director-General must decide the application in accordance with the regulations.

27 Section 24 amended (Register of trade name products)

Repeal section 24(4).

28 Section 25 amended (Certificate of registration)

(1) Before section 25(1), insert:

Issue of certificate

(2) In section 25(1), delete "or section 27".

(3) Before section 25(3), insert:

Certificate and application to be kept

29 Sections 26 and 27 repealed

Repeal sections 26 and 27.

30 Section 28 amended, renumbered as section 83, and repositioned (Director-General may approve operating plans)

(1) After section 28(1)(a)(i), insert:

(ia) a consent under **section 35AAD**; or

(2) Replace section 28(1)(a)(ii) with:

(ii) exemption under **section 8AA** or 8A from the requirement to be registered under section 21; or

(3) Renumber section 28 as **section 83** and reposition it after **section 82** (as inserted by **section 74** of this Act).

31 Section 29 amended (Reassessment of trade name products)

(1) In section 29(3)(a), replace "and 17 to 25" with "17 to 20, 21, 22, 23, 24, 25, and **35AAP**".

(2) After section 29(3)(a), insert:

(aa) if a condition is to be imposed on the registration of the trade name product under section 23(1)(d), **(Ia), or (Ib)** (as applied by paragraph (a)), **section 23A(1)** applies; and

(3) In section 29(3)(b), replace "non-innovative TNP application" with "non-innovative application made under section 9(1)".

(4) After section 29(3), insert:

(4) The Director-General may, if the Director-General thinks fit, prohibit or restrict the importation, manufacture, sale, or use of the trade name product or group of trade name products until a decision is made under section 21 (as applied by subsection (3)(a)).

(5) The Director-General must publicly notify the prohibition or restriction (if any) (*see* **section 82**).

(6) In this section, **new information**, in relation to a registered trade name product or group of registered trade name products, includes, but is not limited to,—

(a) information not previously considered by the Director-General during an assessment of the registered trade name product or group; and

(b) information indicating that conditions placed on the trade name product or group in accordance with section 23 do not adequately manage the risks associated with that trade name product or group.

32 Section 30 repealed (Reassessment of provisional registration)

Repeal section 30.

33 Section 30A amended (Suspension of registration)

(1) Replace section 30A(1) with:

(1) The Director-General may suspend the registration of a registered trade name product, for a period of up to 3 months, if the Director-General has reasonable grounds to believe that—

(a) a condition imposed on the registered trade name product is not being complied with; or

(b) the registered trade name product poses a risk to public health, trade in primary produce, animal welfare, or agricultural security.

(2) Replace section 30A(3) and (4) with:

(3) The effect of a suspension of registration under this section is that no person may import, manufacture, sell, or use the relevant trade name product during

the period of suspension, except as authorised by the Director-General and subject to any condition or requirement imposed under subsection (2).

(4) If satisfied that it is necessary in the circumstances, the Director-General may extend the period of suspension once for a further period not exceeding 3 months that the Director-General notifies to the registrant in writing before the original suspension expires.

(3) Replace section 30A(5) with:

(5) The Director-General must publicly notify any suspension or extension of a suspension under this section (*see* **section 82**).

(4) Replace section 30A(8) with:

(8) If a person acting under the delegated authority of the Director-General suspends or extends the suspension of any registration under this section, the registrant may seek a review of the suspension or extension (as the case may be) under **section 85**.

(5) Repeal section 30A(9).

34 New section 30B inserted (Provisions to be complied with before suspension or extension)

After section 30A, insert:

30B Provisions to be complied with before suspension or extension

(1) Before suspending or extending the suspension of a registration under section 30A, the Director-General must—

(a) notify the registrant in writing of the proposed suspension or extension and the reasons for it and, in the case of a proposed suspension,—

(i) the date on which or the time at which it is proposed to commence (being no earlier than the date or time of notification); and

(ii) any conditions or requirements proposed to be imposed in relation to the suspension; and

(b) give the registrant a reasonable opportunity to be heard.

(2) The Director-General is not required to give the registrant an opportunity to be heard before suspending or extending the suspension of a registration if—

(a) the Director-General is satisfied that the suspension or extension is required to respond to an emergency involving a risk to public health, trade in primary produce, animal welfare, or agricultural security; and

(b) the written notice states that it is required to respond to an emergency of that kind.

(3) However, the registrant must be given a reasonable opportunity to be heard as soon as practicable after the suspension or extension commences.

35 Sections 31 and 32 repealed

Repeal sections 31 and 32.

36 Section 32A amended (Cancellation of registration)

(1) In section 32A(6), replace "77A" with "**85**".

(2) Replace section 32A(7)(b) with:

(b) any application for review must be provided to the Director-General under **section 85(3)** within 20 working days after the date on which the trade name product's removal from the register is first publicly notified (*see* **section 82**).

37 Section 33 amended, renumbered as section 84, and repositioned (No compensation or damages for loss arising from certain changes)

(1) Repeal section 33(b).

(2) In section 33(c), delete "or 30".

(3) After section 33(e), insert:

(ea) the reassessment of a consent under **section 35AAH**; or

(eb) the suspension of a consent under **section 35AAI**; or

(ec) the cancellation of a consent under **section 35AAK**; or

(4) Replace section 33(f) with:

(f) the revocation under section 57 of any of the following:

(i) an approval of an agricultural compound under section 8C:

(ii) the registration of a trade name product:

(iii) a consent under **section 35AAD** in respect of an agricultural compound; or

(5) Renumber section 33 as **section 84** and reposition it after **section 83** (as renumbered and repositioned by **section 29** of this Act).

38 Section 34 amended (Transfer and surrender of registration)

(1) Replace section 34(1) with:

(1) The registration of a trade name product—

(a) may be transferred by the registrant to any other person; or

(b) may be surrendered by a registrant.

(2) In section 34(2), replace "subsection (1)(a)" with "this section".

39 Section 35 amended (Rights of registrant)

Repeal section 35(2).

40 New sections 35AA to 35AAP and cross-headings inserted

After section 35, insert:

Consent to import, etc and use agricultural compounds for research and other purposes

35AA Application

Making of application

(1) A person may apply to the Director-General for consent—

(a) to import, manufacture, or sell an agricultural compound to enable it to be used—

(i) for the purpose of obtaining further information on it to decide whether it should be registered as a trade name product under section 21; or

(ii) in research for a purpose other than the registration of the compound as a trade name product under section 21; and

(b) to use the agricultural compound for the purpose of obtaining that further information or in that research.

(2) An application may not be made under this section in relation to any agricultural compound that is—

(a) a substance, mixture of substances, or biological compound prohibited from use as an agricultural compound, or prohibited from use as an ingredient in an agricultural compound, in accordance with the regulations; or

(b) exempt under **section 8AA** or 8A.

Approved form and information for application

(3) The application must be in the approved form and contain, or be accompanied by, the approved information.

(4) Without limiting the approved information that the applicant may be required to supply, the applicant may be required to supply information obtained from a person belonging to a particular class, including, for example, from—

(a) a recognised agency or a recognised person; or

(b) a person who meets specified criteria (including, for example, particular qualifications or skills).

Additional information to assess application

(5) If, in the opinion of the Director-General, information additional to that provided under **subsection (3)** is required to assess the application, the Director-General may—

(a) request the applicant to provide any additional information that the Director-General specifies in writing; and

(b) with the permission of the applicant, request that any other person supply any additional information that the Director-General specifies in writing.

(6) For the purpose of verifying any information supplied to the Director-General under any of **subsections (3) to (5)**, the Director-General may request any person to provide additional information (other than information protected by section 74A) that the Director-General specifies in writing.

35AAB Notification of application

(1) On receiving an application under **section 35AA**, the Director-General must notify the Environmental Protection Authority established by section 7 of the Environmental Protection Authority Act 2011.

(2) The notice must include information on the nature and proposed use of the agricultural compound.

(3) The Director-General must supply further information to any person notified under this section, if requested by that person, unless that information is protected in accordance with section 74A.

(4) The Director-General may waive the requirement to notify an application under this section if there is a registered trade name product with the same active ingredients as, and an equivalent formulation to, the agricultural compound that is the subject of the application.

35AAC Period within which application to be decided

The Director-General must decide the application within any period determined in accordance with the regulations.

Guidance note

See **section 35AAO** in relation to the variation of time limits under this Act.

35AAD Decision on application

(1) In considering an application made under **section 35AA**, the Director-General must identify the risks likely to arise from the proposed use of the agricultural compound concerned if the Director-General grants the consent.

(2) The Director-General must grant the application if the Director-General is satisfied that the risks likely to arise from the proposed use of the agricultural compound can be adequately managed by imposing conditions on the consent that ensure that—

(a) neither of the following is sold, released, or used in any way for purposes other than those for which the consent is granted:

(i) the agricultural compound:

(ii) any animal, plant, or primary produce to which the compound has been applied or that has been exposed to it; and

(b) the agricultural compound and any animal, plant, or primary produce referred to in **paragraph (a)** is disposed of in a way that minimises the risks.

(3) However, the Director-General must not grant the application if—

(a) the agricultural compound 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.

(4) In granting a consent under this section, the Director-General may impose any conditions on the consent that the Director-General is satisfied are necessary—

(a) to achieve the purposes of the consent; and

(b) to manage any risks likely to arise from the proposed use of the agricultural compound.

(5) In this section, **risks**, in relation to an agricultural compound, means any of the following:

(a) risks to public health:

(b) risks to trade and market access for primary produce arising from the use of the agricultural compound:

(c) risks to agricultural security:

(d) risks to the welfare of animals that result from treatment with or exposure to the agricultural compound:

(e) risks to domestic food residue standards.

35AAE Duration of consent

(1) A consent is in force for the period starting on the date on which consent is given and ending on the date specified in the consent.

(2) That period—

(a) must be a period that the Director-General is satisfied is sufficient only to achieve the purposes of the consent; and

(b) may be extended by the Director-General, and the date specified in the consent amended accordingly, if the Director-General is satisfied that an extension is necessary to achieve the purposes of the consent.

(3) Despite **subsection (1)**, a consent ceases to be in force—

(a) at the close of the day on which it is reassessed in accordance with **section 35AAH** and declined; or

(b) when it is cancelled under **section 35AAK**; or

(c) when it is surrendered under **section 35AAL**; or

(d) when it is revoked under section 57.

(4) As soon as practicable after a consent ceases to be in force under this section, the agricultural compound to which it applied must be disposed of in accordance with any applicable conditions imposed on the consent.

(5) For that purpose only, the consent is to be treated as continuing in force.

35AAF Conditions relating to approved specifications

(1) The conditions that may be imposed on a consent include those that require any 1 or more of the following matters to be in accordance with specifications approved by the Director-General under **section 35AAG**:

(a) labelling or advertising of the agricultural compound:

(b) manufacturing of the agricultural compound:

(c) how, the location at which, or how much of the agricultural compound is used:

(d) characteristics of the agricultural compound (including, for example, its formulation, purity, shelf life, packaging, and use).

(2) This section does not limit **section 35AAD(4)**.

35AAG Approval and variation of specifications

(1) The Director-General may approve specifications for the purposes of any condition of a kind referred to in **section 35AAF** that is to be imposed on a consent.

(2) The person to whom the consent is granted may apply to the Director-General to vary any of those specifications.

(3) The application must be in the approved form and contain, or be accompanied by, the approved information.

(4) Without limiting the approved information that the applicant may be required to supply, the applicant may be required to supply information obtained from a person belonging to a particular class, including, for example, from—

(a) a recognised agency or a recognised person; or

(b) a person who meets specified criteria (including, for example, particular qualifications or skills).

(5) The Director-General must decide the application in accordance with the regulations.

35AAH Reassessment of consent

(1) The Director-General may, after consultation with the person to whom a consent has been granted (the **consent holder**), decide to reassess the agricultural compound to which a consent applies if, in the opinion of the Director-General, significant new information on the agricultural compound has become available.

(2) The Director-General's decision to reassess the agricultural compound must be notified to the consent holder.

(3) The Director-General's decision to reassess the agricultural compound is to be treated as a new application for a consent in respect of the agricultural compound, and **sections 35AA to 35AAE** apply with any necessary modifications.

(4) Part 6 applies to the application—

(a) as if it were a non-innovative application made under **section 35AA**; and

(b) with any necessary modifications.

(5) The Director-General may, if the Director-General thinks fit,—

(a) prohibit or restrict the importation, manufacture, sale, or use of the agricultural compound until a decision is made under **section 35AAD** (as applied by **subsection (3)**); and

(b) publicly notify the prohibition or restriction.

(6) In this section,—

agricultural compound, in relation to a consent, includes a group of agricultural compounds to which 1 or more consents apply and that have the same active ingredients and similar formulations

new information, in relation to an agricultural compound, includes, for example,—

(a) information not previously considered by the Director-General during an assessment of the agricultural compound; and

(b) information indicating that conditions imposed on the consent do not adequately manage the risks arising from the use of the agricultural compound

risks, in relation to an agricultural compound, has the same meaning as in **section 35AAD**.

35AAI Suspension of consent

(1) The Director-General may suspend a consent in respect of an agricultural compound, for a period of up to 3 months, if the Director-General has reasonable grounds to believe that—

(a) a condition imposed on the consent is not being complied with; or

(b) the agricultural compound poses a risk to public health, trade in primary produce, animal welfare, or agricultural security.

(2) The Director-General may impose conditions and requirements in relation to the implementation and operation of a suspension under this section.

(3) The effect of a suspension of consent under this section is that no person may import, manufacture, sell, or use the agricultural compound during the period

of suspension, except as authorised by the Director-General and subject to any condition or requirement imposed under **subsection (2)**.

(4) If satisfied that it is necessary in the circumstances, the Director-General may extend the period of suspension once for a further period not exceeding 3 months that the Director-General notifies to the consent holder in writing before the original suspension expires.

(5) A suspension under this section does not affect any other actions that the Director-General or an ACVM officer may take under this Act.

(6) If a consent is suspended under this section, the Director-General—

(a) may direct the consent holder to take action appropriate to deal with any affected agricultural compound; and

(b) may exercise any other powers conferred on the Director-General under this Act.

(7) If a person acting under the delegated authority of the Director-General suspends or extends the suspension of any consent under this section, the consent holder may seek a review of the suspension or extension (as the case may be) under **section 85**.

35AAJ Provisions to be complied with before suspension or extension of suspension

(1) Before suspending or extending the suspension of a consent under **section 35AAI**, the Director-General must—

(a) notify the consent holder in writing of the proposed suspension or extension and the reasons for it and, in the case of a proposed suspension,—

(i) the date on which or the time at which it is proposed to commence (being no earlier than the date or time of notification); and

(ii) any conditions or requirements proposed to be imposed in relation to the suspension; and

(b) give the consent holder a reasonable opportunity to be heard.

(2) The Director-General is not required to give the consent holder an opportunity to be heard before suspending or extending the suspension of a consent if the Director-General is satisfied that, and the written notice states that, the suspension or extension is required to respond to an emergency involving a risk to public health, trade in primary produce, animal welfare, or agricultural security.

(3) However, the consent holder must be given a reasonable opportunity to be heard as soon as practicable after the suspension or extension commences.

35AAK Cancellation of consent

(1) The Director-General may cancel a consent in respect of an agricultural compound if satisfied that the risks arising from the use of the agricultural compound are not being adequately managed.

(2) In this section, **risks**, in relation to an agricultural compound, has the same meaning as in **section 35AAD**.

35AAL Surrender of consent

A consent in respect of an agricultural compound may be surrendered by the person to whom the consent is granted.

Exemption, registration, or consent: other

35AAM No implied warranty

An exemption of any agricultural compound from registration under **section 8AA** or 8A, the registration of any trade name product under section 21, or a consent under **section 35AAD** in respect of any agricultural compound does not imply a warranty by the Crown or the Director-General that the agricultural compound or trade name product—

(a) is reasonably fit for the purpose for which it is sold; or

(b) complies with any labelling or other consumer information relating to that compound or product.

35AAN Waivers and directions relating to supply of information

The Director-General may, on the application of a person,—

(a) waive a requirement as to the information that the person must supply under this subpart; or

(b) give a direction as to the terms on which the person must supply information under this subpart.

35AAO Variation of time limits

(1) The Director-General may, on the application of a person, vary a time limit imposed under this subpart.

(2) The Minister may vary any time limit imposed under this subpart whether or not an application has been made under this section in relation to the time limit or that time limit has expired.

(3) In any case, the Minister must be satisfied that the matter to which the time limit applies will be carried out as promptly as is reasonable in the circumstances.

(4) The Director-General or the Minister may vary the closing date by which submissions made in response to public notification under section 14 or **20A** must be received only if satisfied that the specified persons—

(a) have consented to the variation; or

(b) have not consented to, but would not be unduly prejudiced by, the variation.

(5) The **specified persons** are,—

(a) in any case, any persons who the Director-General or the Minister, as the case may be,—

(i) is aware have made a submission in response to the public notification; or

(ii) is satisfied are likely to make a submission in response to the public notification; or

(b) in the case of the variation of a closing date under section 14,—

(i) the applicant for the application under section 9 that is required to be publicly notified under section 14; or

(ii) the registrant in the case of a decision under section 29 that is required to be publicly notified under section 14.

35AAP Requests under Official Information Act 1982 involving trade secrets, etc

(1) This section applies if—

(a) the Director-General receives a request under the Official Information Act 1982 to release any information held by the Director-General in respect of an application under this subpart (other than information to which Part 6 applies); and

(b) the information to which the request relates,—

(i) in the Director-General's opinion, may be able to be withheld under section 9(2)(b) of the Official Information Act 1982; or

(ii) has been classified as commercially sensitive by the person who gave the information to the Director-General (the **information-giver**).

(2) The Director-General must make all reasonable efforts to, as soon as practicable, notify the information-giver that the Director-General has received a request to release the information.

(3) Within 10 working days after a person receives a notice under this section, the person must respond to the Director-General by—

(a) stating whether the person believes that the information should be withheld under section 9(2)(b) of the Official Information Act 1982; and

(b) giving reasons for that belief.

(4) The Director-General may, in accordance with the Official Information Act 1982, release the information or withhold the information if—

(a) the Director-General has complied with **subsection (2)**; and

(b) the time limit applying under **subsection (3)** to the person receiving a notice has expired.

41 Cross-heading above section 35A replaced

Replace the cross-heading above section 35A with:

Subpart 3—Certifying compliance of agricultural compounds with Act

42 New subpart 4 of Part 2 inserted

After section 35F, insert:

Subpart 4—Manufacturing practice standards

Specification and application of manufacturing practice standards

35FA Specification of standards

(1) The Director-General may, by notice, specify standards (**manufacturing practice standards**) that apply to manufacturing agricultural compounds in New Zealand.

(2) The manufacturing practice standards may relate to 1 or more of the following:

(a) the standards to be maintained, and the plant and equipment to be used, at premises used for manufacturing agricultural compounds:

(b) procedures for quality assurance and quality control to be applied in manufacturing agricultural compounds:

(c) the people engaged in manufacturing agricultural compounds, including (for example) the qualifications, training, and experience required of those people:

(d) the manufacturing practices to be applied in manufacturing agricultural compounds:

(e) procedures relating to complaints about, and the tracing and recall of, agricultural compounds:

(f) records to be kept in connection with the manufacture of, sale of, complaints about, and tracing and recall of, agricultural compounds and the periods for which those records are to be kept:

(g) audits, and other checks, of compliance with the manufacturing practice standards that relate to 1 or more of the matters set out in the other paragraphs of this subsection:

(h) other matters relating to—

(i) the prevention and management of the risks referred to in section 4(a); or

(ii) the quality and efficacy of agricultural compounds that are manufactured in New Zealand.

(3) A manufacturing practice standard may apply to—

(a) all agricultural compounds; or

(b) a class of agricultural compounds; or

(c) particular agricultural compounds.

(4) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

35FB Certain manufacturers required to comply with manufacturing practice standards

A manufacturer of an agricultural compound must comply with the manufacturing practice standards, and ensure that the people engaged in manufacturing the agricultural compound for the manufacturer comply with those standards, to the extent required by a condition of—

(a) registration of the agricultural compound as a trade name product; or

(b) a consent under **section 35AAD** in respect of the agricultural compound; or

(c) an exemption from the requirement to register the agricultural compound.

Certifying compliance with manufacturing practice standards

35FC Meaning of certificate of compliance: sections 35FD to 35FF

For the purposes of **sections 35FD to 35FF**, a **certificate of compliance** is a certificate attesting that the manufacturer of specified agricultural compounds, or a specified class of agricultural compounds,—

(a) has complied with any manufacturing practice standards specified in the certificate; and

(b) has ensured that the people engaged in manufacturing the agricultural compounds, or compounds of the specified class, for the manufacturer have complied with any manufacturing practice standards specified in the certificate.

35FD Application and issue of certificate of compliance

General

(1) The Director-General may issue a certificate of compliance on—

(a) an application made in the approved form and containing, or accompanied by, the approved information; and

(b) payment of the fee prescribed by the regulations.

Additional information to assess application

(2) If, in the opinion of the Director-General, information additional to the relevant information is required to assess the application, the Director-General may—

(a) request the applicant to provide any additional information that the Director-General specifies in writing; and

(b) with the permission of the applicant, request any other person to supply any additional information that the Director-General specifies in writing.

(3) The **relevant information** is—

(a) the approved information that is required to be contained in, or to accompany, the application; and

(b) the results of any audit or other checks (*see* **section 35FA(2)(g)**).

Matters to be taken into account

(4) In deciding whether to issue a certificate of compliance, the Director-General may take into account any matters that the Director-General considers relevant, including the results of any audit or other checks.

Other

(5) A certificate of compliance may be issued in respect of the manufacture of an agricultural compound, or an agricultural compound of a specified class, whether or not the manufacturer is required to comply with the specified manufacturing practice standards as referred to in **section 35FB**.

Guidance note

For example, the agricultural compounds may not be required by **section 8** to be registered, approved, or exempted as referred to in **section 35FB** and may be manufactured for export only (*see* **section 8(2)(a)(iii)**).

(6) A certificate of compliance must be in the approved form.

(7) A certificate of compliance may be communicated to its appropriate destination by writing, electronic means, or any other form of communication that is accurate, clear, and verifiable.

35FE Withdrawal and reissue of certificate of compliance

(1) A certificate of compliance may be withdrawn by the Director-General if the Director-General is satisfied that—

(a) the certificate was incorrectly or inappropriately given; or

(b) events or circumstances occurring since the certificate was issued mean that it no longer holds true or is misleading.

(2) The Director-General may reissue a withdrawn certificate of compliance as a new certificate of compliance (with modifications, if appropriate) on—

(a) an application made in the approved form and containing, or accompanied by, the approved information; and

(b) payment of the fee prescribed by the regulations.

(3) **Section 35FD(2)** applies in relation to the decision of the Director-General about whether to reissue a certificate of compliance.

35FF No Crown liability

The Crown, the Director-General, and employees of the Ministry are not liable, by reason of the issue, refusal or failure to issue, or withdrawal of a certificate of compliance in respect of the manufacture of any agricultural compound, for any loss arising through the refusal or failure of the relevant authority of an overseas market to admit an agricultural compound intended to be exported to that market.

43 Cross-heading above section 35G replaced

Replace the cross-heading above section 35G with:

Subpart 5—Recall of agricultural compounds

44 Section 39 amended (Minister's power to call in applications with significant effects)

In section 39(1), replace "this Act (other than an application for approval under section 8C or for a certificate of compliance under section 35C)" with "section 9 or **35AA**".

45 Section 42 amended (Investigation by Board of Inquiry)

(1) In section 42(1)(a), after "14", insert "(including if the application is made under **section 35AA**)".

(2) In section 42(1)(b), after "11", insert "or **35AA(5) or (6)** (as applicable)".

(3) Replace section 42(1)(c) and (d) with:

(c) must investigate an application made under section 9(1) having regard to all relevant matters, including matters under sections 19, 20, and 21 and the Minister's reasons for giving the direction under section 39; and

(d) must investigate an application made under section 9(2) having regard to all relevant matters, including matters under **section 21A** and the Minister's reasons for giving the direction under section 39; and

(e) must investigate an application made under **section 35AA** having regard to all relevant matters, including matters under **section 35AAD** and the Minister's reasons for giving the direction under section 39.

(4) Replace section 42(2) and (3) with:

(2) Sections 17 to 20, 21, 22, and 23 apply with all necessary modifications to an inquiry into an application made under section 9(1) as if the conduct of the inquiry were the consideration of that application.

(3) Sections 17 to 20 and **21A** apply with all necessary modifications to an inquiry into an application made under section 9(2) as if the conduct of the inquiry were the consideration of that application.

(4) **Section 35AAD** applies with all necessary modifications to an inquiry into an application made under **section 35AA** as if the conduct of the inquiry were the consideration of that application.

46 Section 44 amended (Minister to decide application and notify decision)

In section 44(3), replace "section 27" with "**35AAD**".

47 Section 44K amended (Proposal to refuse application to recognise agency, person, or class of persons)

In section 44K(3)(b), replace "77A" with "**85**".

48 Section 44L amended (Proposal to exclude members, or categories of members, from recognition of class)

In section 44L(3)(b), replace "77A" with "**85**".

49 Section 44M amended (Director-General may impose or vary conditions of recognition)

In section 44M(4), replace "77A" with "**85**".

50 Section 44ZA amended (Method of suspension of recognition)

(1) In section 44ZA(2)(d), replace "77A" with "**85**".

(2) Replace section 44ZA(3) with:

(3) The Director-General may publicly notify any suspension of recognition (*see* **section 82**).

51 Section 44ZE amended (Method of withdrawal of recognition)

(1) In section 44ZE(2)(d), replace "77A" with "**85**".

(2) Replace section 44ZE(3) with:

(3) The Director-General may publicly notify any withdrawal of recognition (*see* **section 82**).

52 Section 46 amended (Appeal on question of law)

(1) In section 46(1)(a), replace "sections 9 and 26" with "section 9".

(2) After section 46(1)(a), insert:

(aa) party to an application for a consent under **section 35AA**; or

53 Section 55 amended (Offences)

(1) In section 55(1)(c), delete "or section 27".

(2) In section 55(1)(d), replace "by regulations made under section 75" with "under **section 8AA**".

(3) After section 55(1)(d), insert:

(daa) knowingly contravenes any conditions of a consent granted under **section 35AAD**; or

(4) After section 55(1)(dd), insert:

(dda) knowingly imports, manufactures, sells, or uses a product while that product's registration is suspended under **section 35AAI**, unless allowed to do so by a condition or requirement imposed under **section 35AAI(2)**; or

(ddb) knowingly contravenes or fails to comply with a condition or requirement imposed under **section 35AAI(2)**; or

(ddc) knowingly fails to comply with a direction given under **section 35AAI(6)**; or

(5) Replace section 55(1)(f) with:

(f) knowingly makes a false representation that any agricultural compound—

(i) is registered as a trade name product in accordance with section 21; or

(ii) is the subject of a consent under **section 35AAD**; or

(iii) is exempt from registration under **section 8AA**; or

54 Section 57 amended (Revocation of registration or approval)

(1) In the heading to section 57, replace "**or approval**" with "**, approval, or consent**".

(2) In section 57(2), after "8C", insert "or a consent under **section 35AAD**".

(3) In section 57(2), after "the approval", insert "or consent".

55 Part 6 heading amended

In the Part 6 heading, replace "**about trade name products**" with "**supporting certain applications**".

56 Section 72 amended (Interpretation)

(1) In section 72(1), insert in their appropriate alphabetical order:

innovative application means a TNP application, or a **section 35AA** application, relating to a trade name product or an agricultural compound to which the following apply:

(a) the ingredient is referred to in the application as an active ingredient of the trade name product or agricultural compound; and

(b) at the time when 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 before its repeal by the Hazardous Substances and New Organisms Act 1996; or

(iii) an animal remedy the manufacture or importation of which was licensed (otherwise than by a provisional licence) under the Animal Remedies Act 1967 before its repeal by this Act

non-innovative application means a **section 35AA** application, or a TNP application, that is not an innovative application

section 35AA application means an application under **section 35AA** for a consent relating to an agricultural compound

TNP application means an application under section 9(1) to register a trade name product

(2) In section 72(1), repeal the definitions of **innovative TNP application** and **non-innovative TNP application**.

(3) In section 72(1), definitions of **innovative trade name product** and **non-innovative trade name product**, delete "TNP".

(4) In section 72(2), delete "TNP".

57 Section 73 amended (Meaning of confidential information)

(1) In section 73(1)(a), delete "TNP" in each place.

(2) In section 73(1)(b), after "trade name product", insert "or agricultural compound".

58 Section 74 amended (Meaning of protected period)

(1) In section 74(a) and (d), delete "TNP".

(2) In section 74(b), replace "innovative TNP application made under section 26" with "innovative application made under **section 35AA**".

(3) In section 74(e), replace "non-innovative TNP application made under section 26" with "non-innovative application made under **section 35AA**".

59 Section 74A amended (Director-General must protect confidential information during protected period)

In section 74A(1)(b), delete "TNP" in each place.

60 Cross-heading above section 74B amended

In the cross-heading above section 74B, after "*products*", insert "*or agricultural compounds*".

61 Section 74B amended (Innovative TNP application for full registration)

(1) Replace the heading to section 74B with "**Innovative application for registration**".

(2) In section 74B(1), delete "TNP".

62 Section 74C amended (Innovative TNP application for provisional registration)

(1) Replace the heading to section 74C with "**Innovative application for consent under section 35AA**".

(2) In section 74C(1), replace "innovative TNP application under section 26" with "innovative application under **section 35AA**".

(3) In section 74C(3), delete "TNP".

(4) In section 74C(3)(a), replace "for the same trade name product" with "for registration of the same agricultural compound as a trade name product".

(5) In section 74C(3)(b), replace "section 26" with "**section 35AA**".

63 Section 74D amended (Application to authorise new use or method of use)

In section 74D(2)(a), delete "TNP".

64 Cross-heading above section 74E amended

In the cross-heading above section 74E, after "*products*", insert "*or agricultural compounds*".

65 Section 74E amended (Non-innovative TNP application for full registration)

(1) Replace the heading to section 74E with "**Non-innovative application for registration**".

(2) In section 74E(1), delete "TNP".

66 Section 74F amended (Non-innovative TNP application for provisional registration)

(1) Replace the heading to section 74F with "**Non-innovative application for consent under section 35AA**".

(2) In section 74F(1), replace "non-innovative TNP application under section 26" with "non-innovative application under **section 35AA**".

(3) In section 74F(3), delete "TNP".

(4) In section 74F(3)(a), replace "for the same trade name product" with "for registration as a trade name product of the same agricultural compound".

(5) In section 74F(3)(b), replace "section 26" with "**section 35AA**".

67 Section 74H amended (Director-General may disclose or use confidential information)

In section 74H(1), delete "TNP" in each place.

68 New subpart 1 heading in Part 7 inserted

After the Part 7 heading, insert:

Subpart 1—Regulations and other secondary legislation

69 Section 75 amended (Regulations)

(1) Repeal section 75(1)(a) and (c).

(2) Replace section 75(1)(ca) with:

(ca) prescribing procedures, processes, and requirements relating to conditions imposed at the time of—

(i) registration of trade name products under section 21; or

(ii) granting consents under **section 35AAD** in respect of agricultural compounds:

(3) In section 75(1)(cb), delete "as an agricultural compound".

(4) Replace section 75(1)(cc) with:

(cc) prescribing procedures, processes, and requirements for applying for—

(i) registration of a trade name product under section 21; or

(ii) variation of the conditions on a registered trade name product; or

(iii) consent under **section 35AAD** in respect of an agricultural compound:

(5) In section 75(1)(he)(i), after "registration", insert ", consent,".

70 Sections 76 and 77 repealed

Repeal sections 76 and 77.

71 Section 77A amended, renumbered as section 85, and repositioned (Right of review of decisions made under delegated authority)

(1) In section 77A(1)(b), after "21", insert "or **21A**".

(2) Repeal section 77A(1)(c).

(3) After section 77A(1)(e), insert:

(ea) a decision made under **section 35AAD**:

(eb) a decision to suspend a consent under **section 35AAI**:

(ec) a decision to cancel a consent under **section 35AAK**:

(ed) a decision to refuse an application for a certificate of compliance under **section 35FD**:

(ee) a decision to withdraw a certificate of compliance under **section 35FE**:

(ef) a decision to refuse an application for the reissue of a certificate of compliance under **section 35FE**:

(4) Renumber section 77A as **section 85** and reposition it after **section 84** (as renumbered and repositioned by **section 36** of this Act).

72 Sections 79 and 80 renumbered as sections 86 and 87 and repositioned

Renumber sections 79 and 80 as **sections 86 and 87**, respectively, and reposition them after **section 85** (as renumbered and repositioned by **section 70** of this Act).

73 Cross-heading above section 81 replaced

Replace the cross-heading above section 81 with:

Subpart 2—Cost recovery

74 Section 81J amended (Penalties for failure to pay fee, levy, or charge)

In section 81J(2)(b), after "certificate of compliance", insert "issued under **subpart 3 or 4 of Part 2**".

75 New subpart 3 of Part 7 inserted

After section 81K, insert:

Subpart 3—Other

82 Method of public notification

~~(1) If any matter is required to be publicly notified under this Act, it must be notified in 1 or more of the following ways:~~

~~(a) by notice in the *Gazette*:~~

~~(b) by publication in all major metropolitan daily newspapers on at least 2 occasions:~~

~~(c) by publication, either temporarily or permanently, on the Ministry's Internet site:~~

~~(d) in any other way that the Director-General is reasonably satisfied will ensure that the matter is sufficiently notified to members of the public.~~

(1) If any matter is required to be publicly notified under this Act, it must be notified—

(a) by notice in the *Gazette*; and

(b) by publication on the Ministry's Internet site.

(1A) The matter may also be publicly notified in any other way that the Director-General is reasonably satisfied will ensure that the matter is sufficiently notified to members of the public (including, for example, by publication in all major metropolitan daily newspapers on at least 2 occasions).

(2) In deciding which methods of notification under **subsection (1A)** are most appropriate in any particular case, the Director-General must consider—

(a) the nature and significance of the matter required to be publicly notified; and

(b) the desirability of ensuring that the matter is brought to the attention of people likely to have an interest in the matter.

76 Sections 85 and 86 and cross-heading repealed

Repeal sections 85 and 86 and the cross-heading above section 85.

Part 2
Other amendments

77 Schedule 1 amended

In Schedule 1,—

(a) insert the Part set out in **Schedule 1** of this Act as the last Part; and

(b) make all necessary consequential amendments.

78 Consequential amendments related to Part 1

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

Schedule 1
New Part 2 inserted into Schedule 1

s 77

Part 2
Provisions relating to Agricultural Compounds and Veterinary Medicines Amendment Act 2026

Interpretation

4 Interpretation

(1) In this Part,—

2011 regulations means the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011

amendment Act means the Agricultural Compounds and Veterinary Medicines Amendment Act **2026**.

(2) In this Part,—

(a) a reference to a **new** provision is a reference to the provision as inserted or replaced by the amendment Act; and

(b) a reference to an **old** provision is a reference to the provision as in force immediately before it was repealed or replaced by the amendment Act.

Exemptions

5 Expiry of clauses 6 and 8

Clauses 6 and 8 expire on the earlier of the following dates:

(a) 30 June 2029:

(b) the date on which regulations 5 and 6 of the 2011 regulations are revoked by regulations made under section 75.

6 Exemptions in regulations continued

(1) Regulations 5 and 6 of the 2011 regulations—

(a) continue in force until the expiry of this clause; and

(b) are revoked when this clause expires.

(2) However, any of regulations 5 and 6 and Schedule 2 of the 2011 regulations may be amended or revoked (by regulations made under section 75) at any time before they would otherwise be revoked by this clause.

(3) An agricultural compound that, immediately before old section 8A(1)(a) is repealed by the amendment Act, is exempt from registration under the 2011 regulations is to be treated as exempt from registration under new **section**

8AA (subject to any conditions and requirements applying under the 2011 regulations).

(4) **Subclause (3)** does not apply to an agricultural compound that ceases to be exempt from registration under the 2011 regulations.

(5) Until the expiry of this clause, old section 24(4) continues to apply in relation to an agricultural compound that is to be treated as exempt from registration under **subclause (3)**.

7 Certain conditions in 2011 regulations continued

(1) On and from the commencement of new **section 8AA**, the conditions set out in regulations 7 to 13 of the 2011 regulations, as in force immediately before that commencement, are to be treated as being prescribed for the purposes of new **section 8AA(2)(a)**.

(2) However, nothing prevents any of those regulations from being amended or revoked at any time on or after that commencement.

8 Preconditions ~~to granting exemption~~ and requirement to publish reasons switched off

(1) The Director-General may grant an exemption under new **section 8AA** that—

(a) applies to any agricultural compound or class of agricultural compounds that is exempt from registration under that section because of **clause 6**; and

(b) specifies conditions that have the same effect as, or a similar effect to, all or any of the conditions and requirements applying to the compound or class of compounds under the 2011 regulations.

(2) The Director-General is not required to comply with the preconditions set out in new **section 8AA(4) and (5)** before granting an exemption under **subclause (1)**.

(2A) The requirement in **section 8AA(7A)** does not apply in relation to an exemption granted under **subclause (1)**.

(3) **~~Subclause (2)~~** ~~ceases~~ **Subclauses (2) and (2A)** cease to apply in relation to an agricultural compound or a class of agricultural compounds when an exemption under **subclause (1)** that applies to the agricultural compound or class of agricultural compounds commences.

(4) If an agricultural compound or a class of agricultural compounds ceases to be the subject of an exemption granted by the Director-General under **subclause (1)**, the authority conferred by **~~subclause (2)~~ subclauses (2) and (2A)** is not revived.

Registrations other than provisional registrations

9 Existing applications for registration

(1) This clause applies to an application for registration of a trade name product under section 21 that is made, but is not finally decided, before new **section 16** commences.

(2) Each of the following is to be done in accordance with this Act as in force immediately before new **section 16** commences:

(a) the giving of any waiver relating to the notification of the application:

(b) the giving of any waiver or extension of, or any direction concerning, the time or time period by or within which any action relating to the application must be carried out:

(c) the giving of any waiver or any direction concerning—

(i) information that must be supplied in connection with the application; or

(ii) the terms on which that information must be supplied.

(3) The application is to be notified (if required) and decided, and the decision is to be notified, in accordance with this Act as in force immediately before new **section 16** commences.

(4) However, if the Director-General proposes to grant the application and register the trade name product on or after the specified commencement,—

(a) the Director-General may approve specifications under new **section 23A(1)** for the purposes of a condition to be imposed under any of section 23(1)(d) (as amended by the amendment Act) and new **section 23(1)(la) and (lb)** on the registration; and

(b) the Director-General may register the trade name product with the condition.

(5) This clause does not limit **clause 14** (applications for registration that are called in by the Minister).

(6) In this clause, **specified commencement** means the commencement of each of the following:

(a) new **section 23A(1)**:

(b) the amendment of section 23(1)(d) by the amendment Act:

(c) new **section 23(1)(la) and (lb)**.

10 Application for variation of conditions

(1) This clause applies to an application for the variation of 1 or more of the conditions on a registered trade name product that is made, but is not finally decided, before new **section 16** and new **section 21A** commence.

(2) Each of the following matters is to be done in accordance with this Act as in force immediately before new **section 16** commences:

(a) the giving of any waiver relating to the notification of the application:

(b) the giving of any waiver or extension of, or any direction concerning, the time or time period by or within which any action relating to the application must be carried out:

(c) the giving of any waiver or any direction concerning—

(i) information that must be supplied in connection with the application; or

(ii) the terms on which that information must be supplied.

(3) The application is to be notified (if required) and decided, and the decision is to be notified, in accordance with this Act as in force immediately before new **section 16** commences.

(4) New **section 21A** does not apply in relation to the application.

(5) This clause does not limit **clause 14** (applications for registration that are called in by the Minister).

(6) In this clause, **registered trade name product** means a trade name product that is registered under section 21.

11 Approved product and manufacturing specifications

(1) This clause applies to any condition—

(a) that is imposed, in accordance with section 23 or 44, on a trade name product's registration before the specified commencement; and

(b) that requires the labelling or manufacturing of the product or any other matter relating to the product to comply with the product and manufacturing specifications approved as part of the product's registration.

(2) The condition is to be treated as being imposed under whichever of the conditions referred to in section 23(1)(d) (as amended by the amendment Act) and new **section 23(1)(la) or (lb)** most closely corresponds to the condition.

(3) For that purpose, a reference in the condition to the product and manufacturing specifications approved as part of the product's registration is to be treated as a reference to specifications approved by the Director-General under new **section 23A**.

(4) New **section 23A** applies in relation to the variation of those specifications.

(5) In this clause, **specified commencement** has the same meaning as in **clause 9**.

12 Reassessment of trade name products

(1) This clause applies to a decision under section 29(1) that—

(a) is deemed under section 29(3) to be a new application for registration of a trade name product; and

(b) is made, but is not finally decided, before the commencement of the amendments made to section 29(3) by the amendment Act.

(2) Section 29(3), as in force before that commencement, continues to apply in relation to the deemed application.

(3) However, if the Director-General proposes to grant the application and register the trade name product on or after the specified commencement, the Director-General may—

(a) approve specifications under new **section 23A(1)** for the purposes of a condition to be imposed under any of section 23(1)(d) (as amended by the amendment Act) and new **section 23(1)(la) and (lb)** on the registration; and

(b) register the trade name product with the condition.

(4) In this clause, **specified commencement** has the same meaning as in **clause 9**.

13 Extension of suspension of registration

Requirement for public notification

(1) New **section 30A(5)** does not apply in relation to the extension, before that new provision commences, of a suspension of a trade name product (even if the extended suspension is in force when that new provision commences).

Provisions to be complied with before extension

(2) New **section 30B** applies in relation to any extension, on or after that new section commences, of a suspension of a trade name product (even if the original suspension is in force before that new section commences).

14 Applications for registration that are called in by Minister

(1) This clause applies to an application for registration of a trade name product under section 21 that—

(a) is made, but is not finally decided, before section 42 is amended by the amendment Act; and

(b) is the subject of a direction under section 39 made before or after the commencement of those amendments.

(2) This Act, as in force immediately before section 42 is amended by the amendment Act, continues to apply in relation to the application.

(3) However, if the Minister proposes to grant the application and register the trade name product on or after the specified commencement,—

(a) the Director-General may approve specifications under new **section 23A(1)** for the purposes of a condition to be imposed under any of sec-

tion 23(1)(d) (as amended by the amendment Act) and new **section 23(1)(la) and (lb)** on the registration; and

(b) the Minister may register the trade name product with the condition.

(4) This clause does not affect the treatment of a decision under section 44 as a decision by the Director-General (*see* section 44(3)).

(5) In this clause, **specified commencement** has the same meaning as in **clause 9**.

15 Application for variation of conditions

(1) This clause applies to an application for the variation of 1 or more of the conditions on a registered trade name product that—

(a) is made, but is not finally decided, before section 42 is amended by the amendment Act; and

(b) is the subject of a direction under section 39 before or after the commencement of those amendments.

(2) This Act, as in force immediately before section 42 is amended by the amendment Act, continues to apply in relation to the application.

(3) In this clause, **registered trade name product** means a trade name product that is registered under section 21.

Provisional registrations

16 Application for provisional registration

(1) An application for registration of a trade name product under old section 27 that is made, but is not finally decided, before the repeal of that section is to be decided under this Act as in force immediately before that repeal.

(2) If the application is granted, this Act, as in force immediately before the repeal of old section 27, applies in relation to—

(a) the trade name product; and

(b) the trade name product's provisional registration.

17 Saving of provisional registrations and old law

This Act, as in force immediately before the repeal of old section 27, continues to apply in relation to—

(a) a trade name product that is provisionally registered immediately before that repeal; and

(b) the trade name product's provisional registration.

18 Director-General may approve operating plans

(1) This clause applies if an approved operating plan is required as a condition of the registration of a trade name product that is referred to in **clause 16(2) or 17**.

(2) The Director-General may—

(a) approve the operating plan (whether it is submitted before or after the commencement of the amendments made to section 28 by the amendment Act); or

(b) amend or revoke any approval of an operating plan (following consultation with the person whose operating plan it is) that is approved under—

(i) **paragraph (a)**; or

(ii) old section 28(2).

Protection of confidential information, etc

19 Requests under Official Information Act 1982 involving trade secrets, etc

(1) A reference in new **section 35AAP(1)(a)** to an application under **subpart 2 of Part 2** includes a reference to a relevant application that is made before new **section 35AAP** commences.

(2) In this section, **relevant application** means—

(a) an application for an exemption under section 8C; or

(b) an application for registration of a trade name product under section 21; or

(c) an application for registration of a trade name product under old section 27; or

(d) a decision under section 29(1) that is deemed under section 29(3) to be a new application for a trade name product.

20 Confidential information supporting old section 26 applications: unamended Part 6 continues to protect

(1) This clause applies to any information received by the Director-General that—

(a) is provided in support of an innovative TNP application or a non-innovative TNP application made under old section 26; and

(b) is confidential information (within the meaning of section 73(2)) about the trade name product that is the subject of that application.

(2) Part 6, as in force immediately before it is amended by the amendment Act, continues to apply in relation to any information to which this clause applies.

(3) In this clause, **innovative TNP application** and **non-innovative TNP application** have the same meanings as in section 72(1) (as in force immediately before it is amended by the amendment Act).

21 Restricted use of certain confidential information in deciding section 35AA application

(1) This clause applies to any information received by the Director-General that is—

(a) provided in support of—

(i) an innovative TNP application or a non-innovative TNP application made under old section 26; or

(ii) a deemed application to which **clause 12** applies; and

(b) is confidential information (within the meaning of section 73(2)) about the trade name product that is the subject of that application or deemed application.

(2) During the protected period that applies to the information, the Director-General must not use that information in determining whether to grant an innovative application, or a non-innovative application, that is a **section 35AA** application.

(3) **Subclause (2)**—

(a) does not limit section 74A (as in force before its amendment by the amendment Act), as applied by **clause 12(2) or 20(2)**; and

(b) is subject to section 74H (as amended by the amendment Act).

(4) In this clause,—

innovative application and **non-innovative application** have the same meanings as in section 72(1) (as amended by the amendment Act)

innovative TNP application and **non-innovative TNP application** have the same meanings as in section 72(1) (as in force immediately before it is amended by the amendment Act)

protected period has the same meaning as in section 74 (as in force immediately before it is amended by the amendment Act)

section 35AA application has the same meaning as in section 72(1) (as amended by the amendment Act).

Schedule 2
Consequential amendments related to Part 1

s 78

Animal Welfare Act 1999 (1999 No 142)

After section 181(a), insert:

(aa) any agricultural compound that is the subject of a consent for that use under **section 35AAD** of the Agricultural Compounds and Veterinary Medicines Act 1997 and is used—

(i) in accordance with the conditions imposed on the consent; and

(ii) by the holder of the consent or, if the consent allows the sale to and use by a person or a class of persons, the person or a person belonging to that class (as the case may be); or

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

In section 2(1), repeal the definitions of **innovative medicine application** and **innovative TNP application**.

Replace section 25(6) with:

(6) A person may do a thing specified in subsection (1)(a) or (b) in relation to any hazardous substance or new organism that is or has been the subject of any of the following kinds of application only if the person has applied for and been granted an approval under this Act to do the thing:

(a) an innovative medicine application (as defined in section 23A of the Medicines Act 1981):

(b) an innovative application (as defined in section 72(1) of the Agricultural Compounds and Veterinary Medicines Act 1997):

(c) an innovative TNP application (as defined in section 72(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 as in force immediately before the repeal of that definition by the Agricultural Compounds and Veterinary Medicines Amendment Act **2026**):

(d) an innovative agricultural compound application (as defined in section 72 of the Agricultural Compounds and Veterinary Medicines Act 1997 as in force immediately before 7 November 2016).

In section 55(3)(a), after "innovative medicine application", insert "as defined in section 23A of the Medicines Act 1981".

Replace section 55(4)(a) with:

(a) 1 or more of the following apply:

(i) the hazardous substance or new organism to which the application under this Act (the **HSNO application**) relates is or has been the subject of an innovative application (as defined in section 72(1) of

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

the Agricultural Compounds and Veterinary Medicines Act 1997 (the **ACVM Act**)); or

(ii) the hazardous substance or new organism to which the HSNO application relates has been the subject of an innovative TNP application (as defined in section 72(1) of the ACVM Act as in force immediately before the repeal of that definition by the Agricultural Compounds and Veterinary Medicines Amendment Act **2026**); or

(iii) the hazardous substance or new organism to which the HSNO application relates has been the subject of an innovative agricultural compound application (as defined in section 72 of the ACVM Act as in force immediately before 7 November 2016); and

Legislative history

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