

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 that it be passed with the amendments shown.

Introduction

The bill amends the Agricultural Compounds and Veterinary Medicines Act 1997 to include provisions to protect public health from the adverse effects of agricultural compounds, and to improve the workability of the “one stop shop” system for assessing and managing risks associated with agricultural compounds.

We have recommended a number of amendments to the bill after carefully considering the bill and the evidence. The amendments also address some of the issues raised by submitters.

Structure of the Agricultural Compounds and Veterinary Medicines Act

We note that the Legislation Advisory Committee has expressed concern that the functioning of the Act is insufficiently clear, and it considers that this bill perpetuates this problem. It also had concerns that the bill proposed to increase the powers of the Director-General (the chief executive of the Ministry of Agriculture and Forestry),

and that standards would not be subject to parliamentary or executive council scrutiny. We have recommended a number of changes to the bill to address these concerns.

Scheme of the Act

We recommend inserting new clause 5A to clarify the purpose of the Act. This proposed clause makes explicit the scheme of the Act, how the Act works, and its relationship to other Acts, and should therefore address any concerns regarding obscurity.

The clause clarifies that the Act achieves its purpose by providing that no agricultural compound may be used in New Zealand unless its use is authorised by or under the Act; by providing a mechanism for authorising agricultural compounds, setting the conditions of such authorisation, and by providing for the imposition of conditions on the use of these compounds to manage risks.

Standards

New section 28B in clause 21 provides for the Director-General to issue, amend, or revoke standards. The Legislation Advisory Committee expressed concern that these standards would not be subject to any form of parliamentary scrutiny. We agree, and recommend omitting new section 28B and including the power to issue standards in a redrafted clause 44(2). This would ensure that any standards would be issued as regulations, and would therefore be subject to scrutiny by the Regulations Review Committee.

Regulations

We recommend amending clause 44, to empower the use of regulations to set standards, to impose requirements relating to applications for the registration of trade name products, to impose requirements relating to the registration of trade name products and on exemption from registration requirements, to authorise the Director-General to issue specifications or other requirements regarding the way regulatory requirements are to be achieved, and to require the Minister to take into account consistency with international standards or practices when recommending the making of regulations.

We also recommend that the term “prescribe” be replaced with “authorise the use of” in new clause 44(2)(cd)(iii). The term “prescribing” has a specific meaning in the context of human or veterinary medicine, and only an appropriate professional may prescribe a medicine. The standards that apply to such activity in respect of

veterinary medicine are set by the Veterinary Council, whereas the bill as drafted seems to suggest that the Director-General would do so.

We recommend inserting new clause 44A to allow the Director-General to issue notices setting out the technical detail to give effect to compliance with the regulations.

Operating plans

We recommend substituting new clause 20 to delete all references to codes of practice, replacing them with provisions for the approval of operating plans. It sets out the circumstances in which such operating plans might be required and provides for their approval by the Director-General. Operating plans would relate only to a particular trade name product or recognised person.

The new clause provides for the continuance of any existing codes as operating plans until they are replaced by a new operating plan, or other relevant requirement or regulation under the Act, or on the expiry of three years from the commencement of the Act, whichever is earlier.

We recommend that new section 28A in clause 21 be deleted. This section provides for the maintenance of a register of codes of practice, and would be redundant given the changes proposed in clause 20.

As a consequence of this change, we recommend amending clause 4 to delete the definition of “code of practice” from the Act and to insert a definition of “operating plan”. We also recommend the redrafted clause 44 should substitute references to “an operating plan” for those to a code of practice in section 75(1)(a).

We also recommend inserting new clause 57 to ensure that the Agricultural Compounds and Veterinary Medicines Regulations 2001 are consistent with this change.

Cost recovery

Clause 50 inserts into the Act new sections 81 to 81L, setting out a cost recovery regime for situations where costs are not covered by an appropriation from Parliament.

We recommend an amendment to new section 81E(1) to delete the words “cost recovery under”. We believe that this wording may

have led to confusion on the part of submitters who believed that levies were being introduced to recover the costs of services provided under the Act.

Exemptions for finished-dose medicines

We heard concerns from some submitters that finished-dose veterinary medicines are subject to additional controls under the Hazardous Substances and New Organisms Act 1996, requiring approval by the Environmental Risk Management Authority before importation into New Zealand, in addition to registration under the Agricultural Compounds and Veterinary Medicines Act, whereas finished-dose human medicines are exempt. These submitters suggested that all finished-dose veterinary medicines should be exempt from the provisions of the Hazardous Substances and New Organisms Act.

We acknowledge that some finished-dose veterinary medicines are exactly the same as human medicines, the only difference being the intended recipient. The formulation of such products and the method of administration, to individual animals (usually cats and dogs), means there is no threat to human health or the environment. Products such as antibiotics that are administered in finished-dose form to individual animals also do not pose significant risks to humans or the environment. However, similar active ingredients formulated for administration in feed to food-producing animals could pose a threat to human health. Such veterinary medicines should undergo human health and environmental scrutiny and assessment for residues and resistance and the imposition of appropriate withholding periods. We are also aware that some veterinary medicines that are used on whole herds of animals, such as anti-parasite dips and drenches, pose significant risks to human health and the environment. These products should be assessed for public health and environmental risks, as provided for in the Hazardous Substances and New Organisms Act.

We do not believe, therefore, that a generic exemption for veterinary medicines from the provisions of the Hazardous Substances and New Organisms Act is appropriate.

Duplication of regulations

We do not share submitters' concern that the bill potentially duplicates regulatory requirements. We note that the Act already provides for safeguards against duplication of regulatory requirements; for

example, substances are exempt from registration requirements if the relevant risks are already adequately managed under other legislation. In addition, clause 15(5), new section 23(4), provides that the Director-General cannot impose conditions on the registration of a product if the relevant risks are already adequately managed by conditions or controls imposed by any other Act.

We are advised that the New Zealand Food Safety Authority has established a memorandum of understanding, supported by operational agreements, with the Environmental Risk Management Authority, Biosecurity New Zealand, and the Ministry of Agriculture and Forestry Quarantine Service to ensure integrated regulatory processes. We urge these agencies to work together cooperatively.

Compliance costs

Some submitters expressed concern that the bill will increase compliance costs. We disagree, and note that the Act provides a “one stop shop” to assess and manage the risks associated with agricultural compounds. This integration of these functions should minimise compliance costs.

The bill allows registrants to provide a single set of information pertaining to a product for risk assessment, which may be applied to the requirements of other Acts, thus reducing the need for multiple applications and resultant compliance costs.

We recognise that there may be a one-off cost as the industry becomes familiar with the changes to the Act. However, we believe that compliance costs can be reduced by the sharing of information within the sector.

Data protection

In New Zealand data protection is available for up to five years for the provisional registration of innovative new compounds, and a further five years from the date of application for full registration. Some submitters requested to have these provisions extended in time and coverage. However, we are unable to consider this further as it is outside the scope of this bill. We understand that a Government interdepartmental committee is examining the scope of data protection, and may provide guidance at a later date.

Research samples

We are aware that the Act requires the registration of “trade name products”. Although that term is defined in the Act as an agricultural compound identified and packaged under a trade name, the term “trade name” is not defined. This has resulted in uncertainty about the application of the Act for provisional registration of research samples, which are currently classed as “trade name product” even where these samples will never enter trade. We believe that the term “research samples” is not synonymous with “trade name product” and should not be treated as such.

However, we note that new section 8C in clause 10 allows the Director-General to approve an agricultural compound without registration in special circumstances. We are informed that research samples will be able to be considered under these special circumstances provisions. This seems an appropriate solution to the concerns raised by some submitters.

Minor amendments

We recommend a number of amendments to clarify the intention of the bill, to address omissions or drafting errors, or to make other improvements.

We recommend that clause 15 be amended to insert new subclause (1) and delete subclause (2). The amended subclause (1) would allow the Director-General to require an approved operating plan to be followed when registering a trade name product.

We recommend an amendment to clause 23 which inserts new section 33 to insert the words “or damages”, in order to clarify the intended coverage of the provision.

We recommend amending new sections 35D and 35E in clause 25 to omit the term “authorised person”, as clause 4(4) repeals the definition of “authorised person” in the Act. We recommend the term be replaced by “person authorised by the Director-General” in section 35D(1), and “persons authorised” in sections 35D(2) and 35E.

We recommend substituting a new clause 48 to omit from section 79 references to Acts which have been repealed. The new clause 48 will also retain the references to the Wine Act 2003 and the Health Act 1956 included in the original clause 48.

We recommend the deletion of clause 55, since the database in question contains only business information, and the Privacy Act 1993 applies to personal information only, not business information.

We recommend the insertion of clause 56 to revoke regulations which have expired.

Appendix

Committee process

The Agricultural Compounds and Veterinary Medicines Amendment Bill was referred to the committee on 6 December 2006. The closing date for submissions was 23 February 2007. We received and considered 6 submissions from interested groups and individuals. We heard 4 submissions.

We received advice from New Zealand Food Safety Authority.

Committee membership

Hon David Carter (Chairperson)

Dr Ashraf Choudhary (Deputy Chairperson)

Nathan Guy

Phil Heatley

Dave Hereora (until 20 February 2007)

Moana Mackey

Hon Mita Ririnui (from 21 February 2007)

Eric Roy

Hon Dover Samuels

Agricultural Compounds and
Veterinary Medicines Amendment

Key to symbols used in reprinted bill

As reported from a select committee

Struck out (unanimous)

Subject to this Act,

Text struck out unanimously

New (unanimous)

Subject to this Act,

Text inserted unanimously

(Subject to this Act,)

Words struck out unanimously

Subject to this Act,

Words inserted unanimously

Hon Annette King

Agricultural Compounds and Veterinary Medicines Amendment Bill

Government Bill

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Medicines Amendment**

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**Agricultural Compounds and Veterinary
Medicines Amendment**

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Agricultural Compounds and Veterinary Medicines Amendment Act **2006**.

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent. 5

3 Principal Act amended

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

Part 1

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Amendments to Parts 1 to 3 of principal Act

4 Interpretation

(1) Section 2(1) is amended by repealing the definition of **accredited person**.

(2) Section 2(1) is amended by inserting the following definition before the definition of **advertisement**: 15

“**ACVM officer** means a person for the time being appointed as an ACVM officer under **section 60**”.

(3) Section 2(1) is amended by repealing the definition of **agricultural compound** and substituting the following definition: 20

“**agricultural compound** means—

“(a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of— 25

“(i) managing or eradicating pests, including vertebrate pests; or

- “(ii) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
 - “(iii) fulfilling nutritional requirements; or
 - “(iv) the manipulation, capture, or immobilisation of animals; or 5
 - “(v) diagnosing the condition of animals; or
 - “(vi) preventing or treating conditions of animals; or
 - “(vii) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or 10
 - “(viii) marking animals; and
 - “(b) includes—
 - “(i) any veterinary medicine, substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce; and 15
 - “(ii) anything used or intended to be used as feed for animals; and
 - “(iii) any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2)”. 20
- (4) Section 2(1) is amended—
- (a) by repealing the definition of **authorised person**: 25
 - (b) by omitting from the definition of **authorised place** “inspector” and substituting “ACVM officer”:

New (unanimous)

- | | |
|---|--|
| (ba) by repealing the definition of code of practice : | |
|---|--|
- (c) by omitting from the definition of **Director-General** the words “of Agriculture”: 30
 - (d) by repealing the definition of **inspector**.
- (5) Section 2(1) is amended by inserting the following definition after the definition of **Minister**:
- “**Ministry** means the Ministry that, with the authority of the Prime Minister, has for the time being assumed responsibility for the administration of this Act”. 35

New (unanimous)

(5A) Section 2(1) is amended by inserting the following definition after the definition of **new organism**:

“**operating plan** means a plan approved under **section 28(2)**, and includes a code of practice deemed by **section 20(2)** of the Agricultural Compounds and Veterinary Medicines Amendment Act 2007 to be an operating plan approved under **section 28(2)**”.

5

(6) Section 2(1) is amended by inserting the following definitions after the definition of **primary produce**:

“**public health** means the health of all of—

10

“(a) the people of New Zealand; or

“(b) a community or section of such people

“**recognised person** means a person for the time being appointed as a recognised person under **section 62**”.

5 Purpose of Act

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Section 4(a) is amended by inserting the following subparagraph before subparagraph (i):

“(ai) risks to public health; and”.

New (unanimous)

5A New section 4A inserted

The following section is inserted after section 4:

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“4A Scheme of Act

“(1) This Act aims to achieve its purpose by providing that no agricultural compound may be used (including imported, manufactured, or sold) in New Zealand unless that use is authorised by or under this Act.

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“(2) The 2 main mechanisms for authorising use of an agricultural compound are—

“(a) an assessment of the compound, and its registration for use subject to specifically imposed conditions:

“(b) an exemption from the requirement to register the compound, so long as any specified conditions for exemption are met.

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New (unanimous)

- “(3) A range of conditions may be imposed to manage the risks associated with agricultural compounds. These conditions may relate to substances, products, systems, or people’s behaviour, and may be imposed—
- “(a) directly by the Director-General when an agricultural compound is registered or exempted from the requirement to be registered; or
 - “(b) generally, by regulations.
- “(4) The Director-General may also issue notices that set out the technical detail of how compliance with conditions imposed by regulations can be achieved.
- “(5) This Act, by its subject-matter, has a relationship with other Acts such as the Animal Products Act 1999, the Food Act 1981, the Wine Act 2003, the Animal Welfare Act 1999, the Biosecurity Act 1993, the Medicines Act 1981, and the Hazardous Substances and New Organisms Act 1986. Generally, the outcomes for which this Act regulates are those set under the other related Acts. For example:
- “(a) maximum residue limits for food products are set under the Food Act 1981; while
 - “(b) this Act assesses and controls agricultural compounds to ensure the Food Act residue limit is not breached.”

6 Imported agricultural compounds to be cleared for entry into New Zealand

Section 5 is amended by omitting “inspector” from paragraphs (a), (b), and (c) and substituting in each case “ACVM officer”.

7 Agricultural compound clearance

- (1) Section 6(1) is amended by omitting “section 7” and substituting “**sections 7 and 7A**”.
- (2) Section 6(2) is amended by omitting “inspector” and substituting “ACVM officer”.
- (3) Section 6(3)(a) is amended by repealing subparagraphs (iii) and (iv) and substituting the following paragraph:

“(iii) the goods are an agricultural compound and are exempt from registration as a trade name product under **section 8A**; and”.

8 Declaration

Section 7 is amended by omitting “statutory declaration declaring that” and substituting “a declaration in a manner determined by the Director-General to the effect that”. 5

9 New section 7A inserted

The following section is inserted after section 7:

“7A Uncleared or unauthorised goods 10

“(1) The powers provided for in this section apply in respect of goods that are in a transitional facility or biosecurity control area (within the meaning of the Biosecurity Act 1993) that have not been cleared in accordance with sections 5 and 6 of this Act. 15

“(2) An ACVM officer may seize any such goods that he or she has reasonable grounds to suspect—
“(a) do not comply with the requirements of this Act; or
“(b) constitute a risk to public health, agricultural security, trade in or market access for primary produce, the welfare of animals, or may breach domestic food residue standards. 20

“(3) The Director-General may, either generally or in any particular case, give any reasonable directions as to the disposal or treatment or destruction of, or any other dealing with, any goods seized under this section; and any person may dispose of, treat, destroy, or otherwise deal with the goods accordingly. 25

“(4) The Director-General may offer the importer or owner of any goods imported into New Zealand and seized under this section the option of exporting or returning the goods to their place of origin provided that the importer or owner undertakes the payment of any costs associated with the export or return of the goods. 30

“(5) The Director-General may hold goods seized under this section in his or her custody for such period as is necessary for the importer to obtain a clearance for entry into New Zealand 35

- in accordance with sections 5 and 6. In such a case the estimated costs and expenses of the custody and maintenance of the goods must be paid in advance to the Director-General.
- “(6) In exercising his or her powers under this section, the Director-General must, so far as is practicable while achieving the purposes of this Act, act in a manner that is consistent with avoiding or minimising loss to the importer or owner of the goods seized. 5
- “(7) All costs and expenses attendant upon the custody and disposal of goods seized under this section must be borne by the owner or other person in possession of the goods immediately before their seizure, and are recoverable from that person as a debt due to the Crown. 10
- “(8) If however satisfied that the person in possession of the seized goods was not aware that they did not comply with the requirements of this Act, the Director-General may, at his or her absolute discretion, waive or reduce the amount otherwise recoverable under **subsection (7)**.” 15
- 10 New sections 8 to 8C substituted** 20
Section 8 is repealed and the following sections are substituted:
- “8 Prohibition on sale, use, manufacture, or import of agricultural compound**
- “(1) No person may sell within New Zealand, or use, any agricultural compound unless that agricultural compound— 25
“(a) is a registered trade name product; or
“(b) is exempt from registration under **section 8A**; or
- “(2) No person may manufacture in New Zealand any agricultural compound unless that agricultural compound— 30
“(a) is a registered trade name product; or
“(b) is exempt from registration under **section 8A**; or
“(c) is manufactured for export only.
- “(3) No person may import any agricultural compound into New Zealand unless that agricultural compound— 35
“(a) is a registered trade name product; or
“(b) is exempt from registration under **section 8A**; or
“(c) is only to be exported, with or without further processing.

“8A Exemptions from requirement to register

- “(1) An agricultural compound is exempt from the requirement to be registered under this Part if—
- “(a) it is exempt from registration by regulations made under section 75; or 5
 - “(b) it is listed by the Director-General under **section 8B** as a substance generally recognised as safe for use as or in an agricultural compound; or
 - “(c) it is approved by the Director-General under **section 8C** on the basis of special circumstances. 10
- “(2) An exemption under this section is valid only if the compound or substance complies with any relevant conditions or requirements set by the regulations, or by the Director-General under **section 8B or section 8C**.

“8B Director-General may list as exempt substances generally recognised as safe 15

- “(1) The Director-General may from time to time determine that a substance is generally recognised as safe for use as or in an agricultural compound, and therefore need not be registered under this Part. 20
- “(2) The determination may be that the substance is safe for use either—
- “(a) without restriction; or
 - “(b) subject to conditions.
- “(3) The Director-General must maintain a list of such substances. The list must contain any applicable conditions for their sale or use. 25
- “(4) The Director-General must ensure that—
- “(a) the list is available to the public for inspection free of charge; and 30
 - “(b) copies can be taken on payment of a reasonable charge (if any).
- “(5) The Director-General must by notice in the *Gazette* notify the making of any addition or amendment to, or deletion from, the list, but the substances concerned need not be specified in the notice. 35

- “8C Director-General may approve agricultural compound as exempt in special circumstances**
- “(1) The Director-General may approve the importation, manufacture, sale, or use of an agricultural compound without registration if the Director-General considers that special circumstances make it appropriate to grant the approval. 5
- “(2) Sections 9 to 12, with any necessary or appropriate modifications, apply to applications for approval under this section.
- “(3) Sections 19 to 23 and section 25, with any necessary or appropriate modifications, apply to the Director-General’s consideration of an application for approval under this section, and the terms and conditions of any approval. 10
- “(4) In addition,—
- “(a) in considering an application for approval, the Director-General must have regard to whether the agricultural compound concerned fulfils a need that cannot be met by any compound currently available in New Zealand: 15
- “(b) in granting an approval, the Director-General may impose—
- “(i) a condition that the agricultural compound must not be used on or in products intended for human consumption, or in circumstances that may result in the compound being consumed directly or indirectly by humans: 20
- “(ii) a condition that the product cannot be imported, manufactured, sold, or used in circumstances other than those specified at the time of the approval. 25
- “(5) The Director-General may at any time, on giving such notice as is reasonable in the circumstances, revoke an approval given under this section, or amend the terms or conditions of an approval. 30
- “(6) A person who holds an approval may surrender the approval by notifying the Director-General in the form and manner specified by the Director-General. 35
- “(7) The provisions of this Act do not give the holder of an approval the sole right to import, manufacture, sell, or use the agricultural compound that is the subject of the approval.
- “(8) If a person acting under the delegated authority of the Director-General refuses to grant or revokes an approval under this 40

section, or amends the terms or conditions of an approval, the applicant for or holder of the approval may seek a review of that refusal, revocation, or amendment under **section 77A.**”

- 11 Application for registration** 5
Section 9(1)(b) is amended by omitting “by regulations made under section 75” and substituting “under **section 8A**”.
- 12 Waiver of notification**
Section 15(1) is amended by repealing paragraph (b) and substituting the following paragraph:
“(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 under section 21, when compared to the original evaluation under that section.” 10
- 13 Relevant risks and benefits** 15
(1) Section 19 is amended by repealing paragraph (a) and substituting the following paragraphs:
“(a) risks to public health:
“(ab) risks to trade and market access for primary produce arising from the use of the trade name product:” 20
- (2) Section 19(e) is amended by omitting “, including consideration of whether alternative means of achieving the stated purpose of the trade name product are available”.
- 14 Term of registration**
(1) Section 22(2)(b) is amended by inserting “or manufacture” after “sell”. 25
(2) Section 22 is amended by repealing subsection (3) and substituting the following subsection:
“(3) Where registration of a trade name product, other than a provisional registration under section 27, has ceased in accordance with a provision in **subsection (1)** of this section, the Director-General— 30
“(a) must remove the trade name product from the register under section 24; and

- “(b) must, by notice in the *Gazette*, give notice of the removal of the trade name product from the register; and
- “(c) may allow the sale and use of the trade name product (but not its manufacture) to continue for a period specified in the *Gazette* notice; and 5
- “(d) may require any person holding the trade name product—
- “(i) to surrender that product to the Director-General; or 10
- “(ii) to dispose of that product in the manner determined by the Director-General at the expense of the person holding the product.”

15 Conditions on trade name products

Struck out (unanimous)

- (1) Section 23(1)(f) is amended by inserting “distributing, storing, transporting,” after “selling,”. 15
- (2) Section 23(1) is amended by inserting the following paragraph after paragraph (f):
- “(fa) a condition requiring standards set by the Director-General under **section 28B** to be met for any relevant purpose:”. 20

New (unanimous)

- (1) Section 23(1) is amended by repealing paragraph (f) and substituting the following paragraph:
- “(f) a condition requiring an operating plan approved by the Director-General under **section 28** to be followed when importing, manufacturing, selling, distributing, storing, transporting, or using the trade name product:”. 25
- (3) Section 23(1) is amended by inserting the following paragraphs after paragraph (j):
- “(ja) a condition requiring that persons who import, manufacture, sell, or use a trade name product must do so under the authority of, and in compliance with any 30

- requirements of, a (*specified*) recognised person or any class or description of recognised persons:
- “(jb) a condition requiring that persons who (*prescribe*) authorise the use of a trade name product must do so in compliance with any requirements specified by the Director-General:” 5
- (4) Section 23(1) is amended by omitting “an inspector, or an authorised person” from paragraphs (k) and (l) and substituting in each case “or an ACVM officer”.
- (5) Section 23 is amended by adding the following subsections: 10
- “(4) The Director-General must not impose conditions under this section if he or she is satisfied that the relevant risks that the conditions would address are already adequately managed by conditions or controls imposed by or under any other Act.
- “(5) The specificity of the conditions listed in paragraphs (a) to (l) of subsection (1) does not limit the conditions that may be imposed under paragraph (m) of that subsection.” 15

New (unanimous)

- (6) Where any condition of registration imposed under section 23 of the principal Act before the commencement of this Act requires compliance with a code of practice, the condition is to be treated as requiring compliance with an applicable operating plan. 20

16 Register of agricultural compounds

- (1) Section 24(1) is amended by omitting “or section 27”.
- (2) Section 24 is amended by inserting the following subsection after subsection (1): 25
- “(1A) The register may be kept in such manner as the Director-General thinks fit.”
- (3) Section 24(2) is amended—

New (unanimous)

- (aa) by omitting “sections 73, 109, and 121” from paragraph (c) and substituting “section 73”: 30

- (a) by repealing paragraph (e):
- (b) by omitting “or section 27” from paragraph (f).
- (4) Section 24(2) is amended by inserting the following paragraph after paragraph (f):
- “(fa) the date and period of any suspension of registration under **section 30A**, and a brief indication of the reason for the suspension; and”.
- (5) Section 24(2) is amended by repealing paragraph (j) and substituting the following paragraph:
- “(j) the name and contact details of the persons who are or will be manufacturing the trade name product; and”.
- (6) Section 24(3) is repealed.
- (7) Section 24(4) is amended by inserting “or any class or description of agricultural compounds” after “agricultural compounds”.
- 17 Certificate of registration**
- (1) Section 25(1) is amended by omitting “(e),”.
- (2) Section 25 is amended by adding the following subsection:
- “(3) The Director-General must keep a copy of—
- “(a) each certificate of registration; and
- “(b) each application for registration.”
- 18 Application for provisional registration**
- Section 26(3) is amended by omitting “19(a)” and substituting “**19(a), (ab)**”.
- 19 Decision on application for provisional registration**
- Section 27(1) is amended by omitting “19(a)” and substituting “**19(a), (ab)**”.

Struck out (unanimous)

- 20 New section 28 substituted**
- Section 28 is repealed and the following section substituted:
- “(1) The Director-General may from time to time issue codes of practice for any matter in relation to which the Director-

Struck out (unanimous)

- General can issue standards under **section 28B**, and may amend or revoke any such code.
- “(2) The Director-General may also from time to time—
- “(a) approve codes of practice (**submitted codes**) submitted to him or her in relation to any such matter: 5
 - “(b) approve any amendment to a submitted code:
 - “(c) revoke his or her approval of a submitted code.
- “(3) Before issuing, amending, or revoking a code of practice, or approving a submitted code or a submitted code amendment or revoking his or her approval of a submitted code, the Director-General must consult with the organisations for the time being recognised by the Director-General as representing the interests of those persons who will or may be affected by the code of practice. 10
- “(4) A failure to comply with **subsection (3)** does not affect the validity of a code of practice issued, amended, or approved under this section, or the validity of a revocation of a code of practice or approval of a submitted code under this section. 15
- “(5) Any code of practice issued or approved by the Director-General under this section may apply to all agricultural compounds, any class or description of agricultural compounds, or any particular agricultural compound. 20
- “(6) The Director-General, when issuing, amending, or revoking a code of practice, or when approving a submitted code or submitted code amendment or revoking approval of a submitted code, must, if the code is one that requires compliance by virtue of a condition imposed under section 23(1)(f) or any requirement of regulations made under section 75,— 25
- “(a) notify the issue, amendment, or revocation of the code, or the approval of a submitted code or submitted code amendment or revocation of approval, in the *Gazette*; and 30
 - “(b) show in the notice the date of the relevant issue, approval, amendment, or revocation; and
 - “(c) specify in the notice the place or places at which copies of the code or the amendment are available for inspection or purchase. 35

Struck out (unanimous)

- “(7) The Director-General must ensure that copies of all codes of practice or amendments to such codes issued or approved under this section and requiring notification under **subsection (6)** are available for inspection at the place or places specified in the notice given under that subsection. 5
- “(8) Where a code or an amendment to a code that did not initially require notification under **subsection (6)** subsequently becomes a code that requires compliance by virtue of a condition imposed under section 23(1)(f) or any requirement of regulations made under section 75,— 10
- “(a) the Director-General must notify that fact in the *Gazette*; and
- “(b) the notification must specify the date of and explain the reason for the change, and must also specify the place or places at which copies of the code or the amendment are available for inspection or purchase. 15
- “(9) If a code is one that requires compliance by virtue of a condition imposed under section 23(1)(f) or any requirement of regulations made under section 75, the code does not have any force or effect under this Act until notified in the *Gazette*, and nor does any amendment, approval of amendment, revocation of code, or revocation of approval under this section have any force or effect until notified in the *Gazette*.” 20

New (unanimous)

- 20 New section 28 substituted**
- (1) Section 28 is repealed and the following section substituted: 25
- “28 Director-General may approve operating plans**
- “(1) This section applies where—
- “(a) an approved operating plan is required as a condition of—
- “(i) registration of a trade name product; or 30
- “(ii) exemption under **section 8A** from the requirement to be registered under section 21 or 27; or
- “(iii) recognition of a person under section 62 in relation to the performance of certain functions:

New (unanimous)

- “(b) an operating plan is submitted to the Director-General for approval.
- “(2) The Director-General may approve an operating plan submitted to him or her.
- “(3) The Director-General may, by notice in writing, amend or revoke any approval of an operating plan under **subsection (2)**, following consultation with the person whose operating plan it is.” 5
- (2) Any code of practice approved under section 28 of the principal Act before its repeal and replacement by **subsection (1)** of this section, being a code requiring compliance by virtue of a condition imposed under section 23(1)(f) or any requirement of regulations made under section 75, is deemed to be an operating plan approved under **section 28(2)** until the earlier of— 10
- (a) the expiry of 3 years from the commencement of this Act; or
- (b) the code’s replacement by an operating plan or other relevant requirement imposed by or under regulations made under the principal Act. 15 20

Struck out (unanimous)

- 21 New sections 28A and 28B inserted**
The following sections are inserted after section 28:
- “28A Register of codes of practice**
- “(1) The Director-General must keep and maintain a register of codes of practice that records— 25
- “(a) all codes issued or approved under section 28; and
- “(b) any amendment or revocation of the codes, and any approval of a submitted code amendment or revocation of approval of a submitted code under **section 28**.
- “(2) The purpose of the register is to enable members of the public to know what codes have been issued or approved, who proposed the codes, and generally what the codes cover. 30

Struck out (unanimous)

- “(3) The Director-General must ensure that—
- “(a) the register is available to the public for inspection free of charge; and
 - “(b) copies can be taken on payment of a reasonable charge (if any). 5
- “(4) The register may be kept in such manner as the Director-General thinks fit.
- “(5) The register must record, in respect of each code issued or approved,—
- “(a) the name and address of the code holder or preparer: 10
 - “(b) the date the code was approved:
 - “(c) the description of the matters the code covers:
 - “(d) the date and nature of any amendments to the code:
 - “(e) the date of any revocation of the code.
- “28B Standards 15**
- “(1) The Director-General may from time to time issue, amend, or revoke standards relevant to the registration of trade name products or exemptions from the requirement to register.
- “(2) Standards may cover the following matters;
- “(a) the information to be provided on applications for registration of trade name products or applications for approvals under **section 8C**: 20
 - “(b) conditions for exemption from the requirement to register:
 - “(c) standards relevant to consideration of applications for registration of trade name products and the conditions imposed on registration, including, without limitation, standards in relation to— 25
 - “(i) manufacturing processes and facilities:
 - “(ii) packing, storage, transport, and handling: 30
 - “(iii) prescribing, selling, or supplying agricultural compounds:
 - “(iv) the activities or behaviour of persons approved to carry out certain activities in relation to agricultural compounds: 35
 - “(v) identification and labelling:

Struck out (unanimous)

- “(vi) separating off portions of products into smaller quantities: 5
- “(vii) any other matter relevant to the management of products, activities, or behaviour to minimise the risks specified in section 4. 5
- “(3) In setting any standards under this section, the Director-General must have regard to the desirability of maintaining consistency between those standards and any relevant international standards, requirements, or recommended practices. 10
- “(4) Before issuing, amending, or revoking a standard, the Director-General must consult with the organisations for the time being recognised by the Director-General as representing the interests of those persons who will or may be affected by the standard. 10
- “(5) A failure to comply with **subsection (4)** does not affect the validity of a standard issued or amended under this section, or the validity of a revocation of a standard under this section. 15
- “(6) Any standard issued by the Director-General under this section may apply to all agricultural compounds, any class or description of agricultural compounds, or any particular agricultural compound. 20
- “(7) The Director-General, when issuing, amending, or revoking a standard, must— 25
- “(a) notify the issue, amendment, or revocation of the standard in the *Gazette*; and 25
- “(b) show in the notice the date of the issue, amendment, or revocation of the standard; and
- “(c) specify in the notice the place or places at which copies of the standard or the amendment are available for inspection or purchase. 30
- “(8) The Director-General must ensure that copies of all standards or amendments to standards issued under this section are available for inspection at the place or places specified in the notice given under **subsection (7)**.

Struck out (unanimous)

“(9) A standard does not have any force or effect under this Act until notified in the *Gazette*, and nor does any amendment or revocation of a standard under this section have any force or effect until notified in the *Gazette*.”

22 New section 30A inserted

5

The following section is inserted after section 30:

“30A Suspension of registration

- “(1) The Director-General may at any time suspend registration of a trade name product registered under section 21 or section 27 for a period of up to 3 months if the Director-General has reasonable grounds to believe that any condition imposed upon registration is not being complied with. 10
- “(2) The Director-General may impose conditions and requirements in respect of the implementation and operation of a suspension under this section. 15
- “(3) Where the Director-General proposes to suspend registration under this section, he or she must give written notice of that fact to the registrant, specifying—
- “(a) the reason for the suspension; and
 - “(b) the period of the suspension; and 20
 - “(c) the date on which or time at which it commences (which may not be earlier than the date or time of notification); and
 - “(d) any conditions or requirements in relation to the suspension. 25
- “(4) If the Director-General considers it necessary in the circumstances, and after having notified the registrant of the proposed extension and the reasons for it, and having given the registrant a reasonable opportunity to be heard, the period of suspension may be extended once for such further period not exceeding 3 months as the Director-General notifies to the registrant in writing before the expiry of the original suspension. 30
- “(5) The Director-General must notify any suspension of registration of a trade name product registered under section 21 in the *Gazette*. 35

- “(6) A suspension under this section does not affect any other actions that the Director-General or an ACVM officer may take under this Act.
- “(7) Where registration is suspended under this section, the Director-General may direct the registrant to take action appropriate to deal with any affected trade name product, and may exercise any of his or her other powers. 5
- “(8) If a person acting under the delegated authority of the Director-General suspends any registration under this section, the registrant may seek a review of the suspension under **section 77A**. 10
- “(9) 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, unless allowed to do so by a condition or requirement imposed under **subsection (2)**.” 15
- 23 New section 33 substituted**
- Section 33 is repealed and the following section substituted:
- “33 No compensation or damages following reassessment of trade name product or revocation or amendment of approval”** 20
- “(1) Where a registered trade name product is reassessed in accordance with section 29 or 30, no compensation (*is*) or damages are payable to any person for any loss whatsoever arising out of the reassessment. 25
- “(2) Where an approval is revoked or amended in accordance with **section 8C(5)**, no compensation (*is*) or damages are payable to any person for any loss whatsoever arising out of the revocation or amendment.”
- 24 Transfer and surrender of registration** 30
- (1) Section 34(1)(b) is amended by omitting “, by returning the certificate of registration to the Director-General”.
- (2) Section 34 is amended by inserting the following subsection after subsection (1):

- “(1A) A registrant who intends to transfer the registration to another person or to surrender the registration must notify the Director-General of that intention in the form and manner specified by the Director-General.”
- 25 New headings and sections 35A to 35G inserted** 5
The following headings and sections are inserted after section 35:
- “*Certificates of compliance for agricultural compounds*
- “35A Director-General may issue certificates of compliance**
- “(1) The Director-General, or a person authorised by the Director-General under **section 35E**, may issue a certificate of compliance in respect of any agricultural compound. 10
- “(2) Without limiting the matters to which a certificate of compliance may apply, a certificate of compliance is a general statement attesting, in respect of an agricultural compound,— 15
- “(a) that the agricultural compound complies with the requirements of this Act specified in the certificate of compliance:
- “(b) if appropriate, that the situation in New Zealand in relation to any matter concerning agricultural compounds is as stated in the certificate of compliance. 20
- “(3) A certificate of compliance is not a guarantee that the contents of all or any particular consignments of agricultural compounds to which it relates—
- “(a) necessarily meet the requirements of any person relying on the certificate of compliance; or 25
- “(b) are fit for use no matter what the status or description of the user or what has happened to the consignment or what has been its treatment since it left New Zealand; or
- “(c) are fit for use for a purpose other than that for which they were intended. 30
- “35B Form and content of certificate of compliance**
- “(1) A certificate of compliance may be in the form of a certificate or declaration or in such other form as the Director-General determines. 35
- “(2) A certificate of compliance may relate to—
- “(a) one or more consignments of agricultural compound; or
- “(b) one or more export destinations; or

- “(c) any combination of the above.
- “(3) A certificate of compliance may be communicated to its appropriate destination by writing, fax, electronic means, or any other form of communication that is accurate, clear, and verifiable. 5
- “35C Obtaining of certificate of compliance**
- “(1) A person who wishes to obtain a certificate of compliance in respect of any agricultural compound may apply in a manner approved by the Director-General, and must supply any information required by the Director-General and pay any relevant fee. 10
- “(2) The Director-General or person authorised under **section 35E** need not issue a certificate of compliance unless satisfied that the information obtained from the applicant justifies the giving of the certificate of compliance. 15
- “35D Certificate of compliance may be withdrawn, and reissued**
- “(1) A certificate of compliance may be withdrawn by the Director-General or other (*authorised*) person authorised by the Director-General if the Director-General or person is satisfied that— 20
- “(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. 25
- “(2) The Director-General or other (*authorised*) person authorised may, on application in a manner approved by the Director-General and on payment of the prescribed fee (if any), reissue a withdrawn certificate of compliance (with modifications, if appropriate) as a new certificate of compliance. 30
- “35E Persons authorised to issue certificates of compliance**
- The Director-General may designate 1 or more persons employed within the Ministry as (*authorised persons who may*) persons authorised to issue certificates of compliance for the purposes of this Act. 35

“35F 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 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. 5

“Recall of agricultural compound

“35G Recall of agricultural compound 10

- “(1) The Director-General may, by notice in writing, direct the recall of any agricultural compound for the purpose of rectification, disposal, or destruction if, in the opinion of the Director-General,—
- “(a) the compound does not comply with any requirements of this Act or of regulations made under this Act; and 15
 - “(b) the non-compliance could result in serious or significant risk to the matters referred to in section 4.
- “(2) A notice under this section (a **recall notice**) may require any person holding the agricultural compound to rectify the non-compliance under **subsection (1)**, or dispose of or destroy the compound in the manner determined by the Director-General at the expense of the person holding the compound. 20
- “(3) A recall notice may be directed to any 1 or more persons who own or have control over the agricultural compound in question. 25
- “(4) On receipt of a recall notice, the person on whom it is served must as soon as practicable—
- “(a) advise the Director-General of the details of the manner in which the notice is to be complied with; and 30
 - “(b) give written notice to the Director-General when the recall, and any specified requirement associated with the recall, has been completed.
- “(5) If a person who owns or has control of the agricultural compound fails or refuses to comply with a recall notice, the Director-General may— 35
- “(a) take any reasonable steps necessary to give effect to the recall notice (including entry by ACVM officers into premises under a warrant); and

“(b) recover the costs and expenses reasonably incurred under **paragraph (a)** as a debt due from that person.”

26 Section 37 repealed

(1) Section 37 is repealed.

(2) Despite **subsection (1)**, any delegations by the Director-General that were in existence immediately before the commencement of this Act are valid and continue in force until their expiry in their own terms, or until revoked by the Director-General. 5

27 Minister’s power to call in applications with significant effects 10

Section 39(1) is amended by inserting “(other than an application for an approval under **section 8C** or for a certificate of compliance under **section 35C**)” after “any application under this Act”.

28 Investigation by Board of Inquiry 15

Section 42(3) is amended by omitting “19(a)” and substituting “**19(a), (ab)**”.

Part 2
Amendments to Parts 4 to 8 and Schedules of principal Act 20

29 Appeal on question of law

Section 46(1) is amended by inserting the following paragraph after paragraph (a):

“(ab) party to an application for an approval under **section 8C**; or” 25

30 Offences

(1) Section 55(1) is amended by inserting the following paragraphs after paragraph (b):

“(ba) knowingly manufactures any agricultural compound in contravention of this Act; or 30

“(bb) knowingly imports any agricultural compound in contravention of this Act; or”.

(2) Section 55(1) is amended by inserting the following paragraphs after paragraph (d):

- “(da) knowingly contravenes any conditions of an approval given under **section 8B or section 8C**; or
- “(db) knowingly imports, manufactures, sells, or uses a product while that product’s registration is suspended under **section 30A**, unless allowed to do so by a condition or requirement imposed under **section 30A(2)**; or 5
- “(dc) knowingly contravenes or fails to comply with a condition or requirement imposed under **section 30A(2)**; or
- “(dd) knowingly fails to comply with a direction given under **section 30A(7)**; or 10
- “(de) knowingly contravenes the requirements of any recall notice issued under **section 35G**; or”.
- (3) Section 55(1) is amended by adding “; or”, and also by adding the following paragraphs:
- “(j) knowingly supplies false or misleading information to the Director-General or an ACVM officer under this Act; or 15
- “(k) knowingly supplies false or misleading information in support of an application under this Act; or
- “(l) knowingly withholds relevant information from an ACVM officer or person assisting an ACVM officer.” 20
- (4) Section 55 is amended by inserting the following subsection after subsection (1):
- “(1A) Every person commits an offence against this Act who, in contravention of an order made under **section 57A(2)**, or in contravention of such an order as varied under **section 57A(4)**, imports, manufactures, sells, or uses any trade name product or agricultural compound.” 25
- (5) Section 55(2) is amended—
- (a) by repealing paragraphs (a) and (b); 30
- (b) by omitting “inspector, authorised person, or accredited person” from paragraphs (c) and (d) and substituting in each case “ACVM officer or recognised person”.
- (6) Section 55(5) is amended by omitting “2 years” and substituting “4 years”. 35

31 Penalties

- (1) Section 56(1) is amended by repealing paragraph (a) and substituting the following paragraph:

- “(a) in the case of a natural person, to a term of imprisonment not exceeding 2 years or a fine not exceeding \$30,000, or both:”.
- (2) Section 56 is amended by inserting the following subsection after subsection (1): 5
- “(1A) Every person who commits an offence against **section 55(1A)** is liable on summary conviction to a term of imprisonment not exceeding 2 years or a fine not exceeding \$60,000, or both.”
- 32 New section 57 substituted** 10
- Section 57 is repealed and the following section substituted:
- “57 Revocation of registration or approval**
- “(1) When a registrant or an agent of a registrant is convicted of an offence against this Act, the Court may, instead of or in addition to a fine or imprisonment, revoke any registration held by that registrant of any trade name product. 15
- “(2) When a holder of an approval under **section 8C**, or any agent of such a holder, is convicted of an offence against this Act, the Court may, instead of or in addition to a fine or imprisonment, revoke the approval.”
- 33 New section 57A inserted** 20
- The following section is inserted after section 57:
- “57A Power to prohibit person from importing, manufacturing, selling, or using trade name product or agricultural compound**
- “(1) This section applies where— 25
- “(a) a person is convicted of an offence under section 55(1) and either—
- “(i) the person has been convicted of a previous offence against section 55(1); or 30
- “(ii) the Court is of the opinion that by reason of the serious nature of the offence the person’s activities relating to agricultural compounds should be restricted; or
- “(b) a person is convicted of breaching a restriction order issued under this section. 35
- “(2) The Court may, in addition to or substitution for any other penalty imposed on a person convicted of an offence to which

this section applies, issue an order prohibiting the person from importing, manufacturing, selling, or using any trade name product or agricultural compound.

- “(3) A person who is the subject of an order under **subsection (2)** may, at any time after the expiration of 12 months from the date of the order, apply to the Court for the cancellation of the order. 5
- “(4) At the hearing of the application the Court may, if it thinks fit, having regard to— 10
- “(a) the character of the applicant; and
 - “(b) the applicant’s conduct since the order was made; and
 - “(c) the nature of the offence of which the applicant was convicted; and
 - “(d) any other circumstances of the case,—
- order that, as from a date to be specified in the order, the prohibition be removed or the order be varied, or refuse the application. 15
- “(5) If the Court has, under **subsection (4)**, ordered that the order be varied or has refused the application, the person may not make a further application under **subsection (3)** within 12 months after the date of the order of variation or the refusal.” 20

34 Appointment of inspectors

- (1) Section 60 is amended—
- (a) by omitting from the section heading “**inspectors**” and substituting “**ACVM officers**”: 25
 - (b) by omitting from subsection (1) “inspectors” and substituting “agricultural compounds and veterinary medicines officers (**ACVM officers**)”:
 - (c) by omitting from subsection (2) “inspector” (twice) and “inspectors” and substituting, respectively, “ACVM officer” and “ACVM officers”: 30
 - (d) by omitting from subsection (3) “Inspectors” and substituting “ACVM officers”:
 - (e) by omitting from subsection (4) “inspectors” and “inspector” and substituting, respectively, “ACVM officers” and “ACVM officer”. 35
- (2) A person appointed under section 60 of the principal Act who, immediately before the commencement of this Act, held office as an inspector is deemed to have been appointed as an

ACVM officer under that section, and any such appointment or any authority evidencing such an appointment is valid as an appointment or authorisation to act as an ACVM officer until it expires or is suspended or revoked.

- 35 Section 61 repealed** 5
Section 61 is repealed.
- 36 Appointment of accredited persons**
Section 62 is amended—
- (a) by omitting from the section heading “**accredited**” and substituting “**recognised**”: 10
 - (b) by omitting from subsection (1) “accredit persons to carry out specified functions required under this Act” and substituting “recognise persons to carry out specified functions for the purposes of this Act”:
 - (c) by omitting from subsection (2) “accreditation” (twice) and substituting in each case “recognition”: 15
 - (d) by omitting from subsections (3), (4), and (5) “accredited” wherever it occurs and substituting in each case “recognised”:
 - (e) by omitting from subsection (6) “accreditation” and substituting “recognition”. 20
- (2) A person accredited to carry out any specified functions under section 62 of the principal Act before the commencement of this Act is deemed to have been recognised to carry out those specified functions under that section, and any such accreditation or any authority evidencing such an accreditation is valid as a recognition under section 62 of the principal Act until it expires or is suspended or revoked. 25
- 37 New section 63 substituted** 30
Section 63 is repealed and the following section substituted:
- “63 Protection of ACVM officers and recognised persons**
No action or proceedings may be brought against any ACVM officer or recognised person in respect of any actions taken by any such officer or person under this Act unless he or she has acted in bad faith or without reasonable cause.” 35

38 Powers of entry for inspection

(1) Section 64(1) is repealed and the following subsections are substituted:

“(1) Any ACVM officer may enter or go on, into, under, or over any place (including, to avoid doubt, any transitional facility or biosecurity control area within the meaning of the Biosecurity Act 1993) for the purpose of inspection to determine whether or not any person is complying with this Act. 5

“(1A) **Subsection (1)** does not apply to a place that is a dwellinghouse or a marae.” 10

(2) Section 64 is amended by omitting “inspector or authorised person” from subsections (2), (3), (3)(a), and (4) and substituting in each case “ACVM officer”.

39 New section 65 substituted

Section 65 is repealed and the following section substituted: 15

“65 ACVM officers may issue prohibition notices

“(1) Any ACVM officer who has reasonable grounds to believe that any person manufacturing, selling, importing or using any agricultural compound is acting in contravention of any provision of this Act, or any conditions on the registration of a trade name product or on an approval given under **section 8C** or any conditions determined under **section 8B(2)**, may give written notice to that person prohibiting the manufacture, sale, import, or use of that product or that agricultural compound by that person until such time as the contravention of the Act is rectified to the satisfaction of the ACVM officer. 20 25

“(2) A prohibition notice issued under **subsection (1)** must specify the contravention to which it relates, the action required to remedy the contravention, and the prohibition placed upon the manufacture, sale, import, or use of a trade name product or an agricultural compound. 30

“(3) A prohibition notice issued under **subsection (1)** may be issued subject to such conditions as the persons issuing it considers appropriate.”

- 40 Matters may be completed by different inspectors or authorised persons**
Section 67 is amended—
- (a) by omitting from the section heading “**inspectors or authorised persons**” and substituting “**ACVM officers**”: 5
 - (b) by omitting “inspector or authorised person” (twice) and substituting in each case “ACVM officer”.
- 41 Issue of search warrants**
- (1) Section 69(1)(a) is amended by inserting “or **section 55(1A)**” after “section 55(1)”. 10
 - (2) Section 69 is amended by omitting “inspector” from subsections (2) and (4) and substituting in each case “ACVM officer”.
- 42 Powers of entry with warrant** 15
- (1) Section 70(1) is amended—
 - (a) by omitting “inspector” (twice) and substituting in each case “ACVM officer”:
 - (b) by inserting in paragraph (c)(i) “or **section 55(1A)**” after “section 55(1)”: 20
 - (c) by inserting in paragraph (e) “manufactured or” after “agricultural compound”.
 - (2) Section 70(1)(f)(i) is repealed and the following subparagraph substituted:
 - “(i) is a risk to public health, agricultural security, 25
trade in or market access for primary produce, the
welfare of animals, or may breach domestic food
residue standards; and”.
 - (3) Section 70 is amended by omitting “inspector” wherever it occurs in subsections (1)(f)(ii), (2), (3), and (4) and substituting in each case “ACVM officer”. 30
- 43 Disposal of property seized**
- Section 71(1) is amended—
- (a) by inserting “under a search warrant issued under section 69” after “member of the Police”: 35
 - (b) by omitting “inspector” and substituting “ACVM officer under such a warrant”.

Struck out (unanimous)

44 Regulations

Section 75(1)(a) is amended—

- (a) by omitting “the prescribed conditions” and substituting “any prescribed conditions”:
- (b) by inserting “, or must meet any relevant standard set under **section 28B**” after “in accordance with section 28”.

New (unanimous)

44 Regulations

(1) Section 75(1)(a) is amended—

- (a) by omitting “the prescribed conditions” and substituting “any prescribed conditions”:
- (b) by omitting “a code of practice issued or” and substituting “an operating plan”.

(2) Section 75(1) is amended by inserting the following paragraphs after paragraph (c):

- “(ca) prescribing procedures, processes, and requirements relating to conditions imposed at the time of registration of trade name products under section 21 or 27:
- “(cb) prescribing procedures, processes, and requirements relating to conditions on those substances exempt from registration as an agricultural compound under **section 8B**:
- “(cc) prescribing procedures, processes, and requirements for applying for registration of a trade name product:
- “(cd) prescribing standards relevant to consideration of applications for registration of trade name products and the conditions imposed on registration, including, without limitation, standards in relation to—
 - “(i) manufacturing processes and facilities:
 - “(ii) packing, storage, transport, and handling:
 - “(iii) authorising the use of, selling, or supplying agricultural compounds:
 - “(iv) the activities or behaviour of persons recognised to carry out certain functions in relation to agricultural compounds:

New (unanimous)

- “(v) identification and labelling:
“(vi) separating off portions of products into smaller quantities:
“(vii) any other matter relevant to the management of products, activities, or behaviour to minimise the risks specified in section 4:”.
- (3) Section 75 is amended by inserting the following subsection after subsection (1):
- “(1A) Regulations made under this section—
“(a) may apply to all agricultural compounds or substances, any class or description of agricultural compounds or substances, or any particular agricultural compound or substance:
“(b) may authorise the Director-General to issue or impose any specifications or other detailed requirements that are necessary or desirable to amplify the manner in which the requirements of the regulations may or must be achieved.”
- (4) Section 75 is amended by inserting the following subsection after subsection (3):
- “(3A) When recommending the making of regulations under this section, the Minister must have regard to the desirability of maintaining consistency between those regulations and any relevant international standards, requirements, or recommended practices.”
- 44A New section 76A inserted**
The following section is inserted after section 75:
- “76A Director-General may set specifications and other detailed requirements**
- “(1) The Director-General may from time to time issue notices setting specifications and other detailed requirements that—
“(a) are specified or contemplated by or necessary to give effect to any regulation made under section 75; or
“(b) are necessary or desirable to amplify the manner in which the requirements of any such regulation may or must be achieved.

New (unanimous)

- “(2) Before issuing a notice under this section, the Director-General must do everything reasonably practicable to consult with the organisations for the time being recognised by the Director-General as representing the interests of persons who will or may be affected by the specifications or other detailed requirements contained in the notice. 5
- “(3) **Subsection (2)** does not apply where the Director-General considers it desirable in the public interest that the notice be issued urgently.
- “(4) A failure to comply with **subsection (2)** does not affect the validity of a notice issued under this section. 10
- “(5) Where a notice under this section affects only 1 person or a small number of persons, and the identity of those persons is known, the Director-General must—
- “(a) notify the persons individually in writing, whether personally by post or facsimile addressed to the person, or by electronic means acceptable to the person; and 15
- “(b) either—
- “(i) supply them with a copy of the specifications or other requirements; or 20
- “(ii) notify them where they may inspect a copy free of charge (which may include inspection by electronic means) or obtain a copy on payment of a reasonable charge.
- “(6) Where it is not possible or practicable to notify a matter in accordance with **subsection (5)**, the Director-General must— 25
- “(a) either publish the specifications or other requirements in the *Gazette*, or notify their making or existence in the *Gazette*; and
- “(b) where the Director-General considers it practicable, cause them to be brought to the attention of persons likely to be affected by them by notice or publication in any newspaper or trade journal, or by any other practicable means (including electronic means). 30
- “(7) If the specifications or other requirements are notified only, and not published, in the *Gazette*— 35

New (unanimous)

- “(a) the Director-General must make copies available for inspection free of charge, and for purchase at a reasonable cost, at the head office of the Ministry and at such other places as the Director-General determines; and
“(b) the *Gazette* notice must specify where a copy may be inspected or obtained.” 5

45 Warranties

Section 77 is amended by omitting “by regulations made under section 75” and substituting “under **section 8A**”.

46 New section 77A inserted 10

The following section is inserted after section 77:

“77A Right of review of registration decisions made under delegated authority

- “(1) This section applies to any decision made under any of sections **8C**, 21, 27, and **30A** by a person acting under the delegated authority of the Director-General. 15
- “(2) A person dissatisfied with any such decision may seek a review of the decision by the Director-General or by a person designated by the Director-General who was not involved in making the original decision. 20
- “(3) An application for a review must—
“(a) be in writing; and
“(b) state the grounds on which it is believed that the original decision was inappropriate; and
“(c) be provided to the Director-General within 20 working days after the original decision was notified to the applicant. 25
- “(4) The Director-General, or a person designated by the Director-General who was not involved in the original decision, must review the matter within 40 working days, or within such extended period not exceeding a further 20 working days as the Director-General or designated person may specify by notice in writing to the applicant. 30
- “(5) For the purposes of a review, the Director-General or designated person may require the applicant to supply information 35

additional to that contained in the application for review within a specified time. The time taken to supply any such information (or allowed for its supply, if the information is not in fact supplied) is not to be counted for the purposes of the time limits specified in **subsection (4)**.

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“(6) The decision sought to be reviewed remains valid unless and until altered by the Director-General or designated person.

“(7) The Director-General or designated person must, as soon as practicable, notify the applicant for review of his or her decision on the review in writing, giving reasons for the decision.

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“(8) A decision by the Director-General under this section is final, unless determined otherwise by a court of law of competent jurisdiction.”

47 Consultation before making of Orders in Council

Section 78(1) is amended by omitting “or section 81” and substituting “**section 81D, or section 81E**”.

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Struck out (unanimous)

48 Relationship to other Acts

Section 79 is amended by inserting “the Wine Act 2003, the Health Act 1956 (despite section 138 of that Act),” after “the Meat Act 1981,”.

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New (unanimous)

48 Relationship to other Acts

Section 79 is amended—

(a) by omitting “the Dairy Industry Act 1952,”;

(b) by omitting “the Meat Act 1981,”;

(c) by inserting “the Wine Act 2003, the Health Act 1956 (despite section 138 of that Act),” after “the Food Act 1981,”.

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49 Correction of errors

Section 80 is amended by omitting all the words after “for that purpose,” and substituting “may require the registrant or any holder of an approval to produce the certificate of registration

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or any other document held by the registrant or holder of the approval”.

50 New headings and cost recovery sections substituted

Sections 81 to 83 are repealed and the following headings and sections substituted:

5

“Cost recovery

“81 Principles of cost recovery

“(1) The Minister and the Director-General must take all reasonable steps to ensure that the direct and indirect costs of administering this Act that are not provided for by money appropriated by Parliament for the purpose are recovered under this section and **sections 81A to 83** (referred to in this section and those sections as the **cost recovery sections**), whether by way of fees, levies, or otherwise.

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“(2) In determining the most appropriate method of cost recovery under **section 81A**, and its level, in any particular case or class of cases of agricultural compound, business, person, or other matter, the Minister and Director-General must have regard, as far as is reasonably practicable, to the following criteria:

15

“(a) equity, in that funding for a particular function, power, or service, or a particular class of function, powers, or services, should generally, and to the extent practicable, be sourced from the users or beneficiaries of the relevant function, power, or service at a level commensurate with their use or benefit from the function, power, or service:

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“(b) efficiency, in that costs should generally be allocated and recovered in order to ensure that maximum benefits are delivered at minimum cost:

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“(c) justifiability, in that costs should be collected only to meet the reasonable costs (including indirect costs) for the provision or exercise of the relevant function, power, or service:

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“(d) transparency, in that costs should be identified and allocated as closely as practicable in relation to tangible service provision for the recovery period in which the service is provided.

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“(3) Costs should not be recovered under the cost recovery sections unless there has been appropriate consultation with

affected parties and relevant industry organisations in accordance with **section 78**, and the parties involved have been given sufficient time and information to make an informed contribution.

- “(4) Nothing in **subsection (3)** or **section 81C** or **section 78** requires consultation in relation to specific fees or charges, or the specific levels of fees or charges, so long as the fees or charges set are reasonably within the purview of any general consultation or any consultation carried out for the purposes of **section 78**, and a failure to comply with **subsection (3)** does not affect the validity of any regulations made for the purposes of these cost recovery sections. 5 10
- “(5) Nothing in this section requires a strict apportionment of the costs to be recovered for a particular function or service based on usage; and, without limiting the way in which fees or charges may be set, a fee or charge may be set at a level or in a way that— 15
- “(a) is determined by calculations that involve an averaging of costs or potential costs:
- “(b) takes into account costs or potential costs of services that are not directly to be provided to the person who pays the fee or charge but which are an indirect or potential cost arising from the delivery of the service in question to a class of persons or all persons who use the service. 20 25
- “81A Methods of cost recovery**
- The methods by which costs may be recovered under the cost recovery sections are as follows:
- “(a) fixed fees or charges:
- “(b) fees or charges based on a scale or formula or at a rate determined on an hourly or other unit basis: 30
- “(c) use of a formula or other method of calculation for fixing fees and charges:
- “(d) the recovery by way of fee or charge of actual and reasonable costs expended in, or associated with, the performance of a service or function: 35
- “(e) estimated fees or charges, or fees or charges based on estimated costs, paid before the provision of the service

- or function, followed by reconciliation and an appropriate further payment or refund after provision of the service or function:
- “(f) refundable or non-refundable deposits paid before provision of the service or performance of the function: 5
 - “(g) fees or charges imposed on users of services or third parties:
 - “(h) levies:
 - “(i) any combination of the above.
- “**81B Cost recovery to relate generally to financial year** 10
- “(1) Except as provided in **subsection (2)**, any regulations under the cost recovery sections that set a fee, charge, or levy that applies in any financial year—
- “(a) must have been made before the start of that financial year; but 15
 - “(b) except as the regulations may otherwise provide, apply in that year and all subsequent years until revoked or replaced.
- “(2) **Subsection (1)** does not prevent the alteration or setting during any financial year of a fee, charge, or levy payable in that year if either— 20
- “(a) the fee, charge, or levy is reduced, removed, or restated without substantive alteration; or
 - “(b) in the case of an increase or a new fee, charge, or levy,— 25
 - “(i) appropriate consultation in accordance with **section 78** has been carried out with persons or representatives of persons substantially affected by the alteration or setting; and
 - “(ii) the Minister is satisfied that those persons, or their representatives, agree or do not substantially disagree with the alteration or setting. 30
- “(3) **Subsection (1)** does not prevent the amendment of any regulation setting a fee, charge, or levy if any substantive alteration effected by the amendment is for the purpose of correcting an error. 35
- “(4) Recovery may be made in any financial year of any shortfall in cost recovery for any of the preceding 4 financial years, and allowance may be made for any over-recovery of costs in

those years (including any estimated shortfall or over-recovery for the immediately preceding financial year).

“81C Three-yearly review of cost recovery

- “**(1)** The Minister must cause to be reviewed, at least once in every 3-year period occurring since the original setting of, or latest change to, the levels and methods of cost recovery in relation to any class of agricultural compound, business, person, or other matter, the levels and methods of cost recovery in the relevant area that are likely to be appropriate for the following financial year or years. 5 10
- “**(2)** The Minister must ensure that appropriate consultation in accordance with **section 78** takes place in relation to any such review.
- “**(3)** A review may make provision for recovery in any relevant financial year of any shortfall in cost recovery for any of the preceding 4 financial years, or make allowance for any over-recovery of costs in those years (including any estimated shortfall or over-recovery for the immediately preceding financial year). 15
- “**(4)** **Subsection (1)** does not require all areas of cost recovery to be reviewed at the same time, nor does it impose any time limit on the making of regulations to implement the results of a review. 20

“81D Fees and charges to be prescribed by regulations

- “**(1)** Regulations may be made under this Act, on the recommendation of the Minister, prescribing fees and charges for the purposes of this Act. 25
- “**(2)** The fees and charges may be prescribed using any 1 or more of the methods specified in **section 81A**, or any combination of those methods. 30
- “**(3)** Different fees and charges, or different rates or types of fee or charge, may be prescribed in respect of different classes or descriptions of agricultural compound, persons or businesses, operations, or other matters, or any combination of them.
- “**(4)** Without limiting **subsection (3)**, the fees and charges prescribed may— 35
- “**(a)** differ depending on whether or not a special or urgent service is provided:

- “(b) include more than 1 level of fee or charge for the same service provided in different ways, or provided in or in respect of different places:
 - “(c) differ for otherwise similar services provided in different ways: 5
 - “(d) differ for otherwise similar services provided to different categories of person:
 - “(e) differ depending on the amount of service required or the components of the service required for the particular person or class of person. 10
- “(5) Where regulations prescribe a formula for determining a fee or charge, the formula may specify the value of 1 or more of its components as being an amount or amounts notified for these components by the Director-General by notice in the *Gazette*. 15
- “(6) The Minister may not recommend the making of regulations under this section unless satisfied that, to the extent appropriate in the circumstances, the requirements of **sections 81 and 81B** have been met.
- “81E Regulations may impose levies 20**
- “(1) Regulations may be made under this Act, on the recommendation of the Minister, prescribing levies for the purposes of (*cost recovery under*) this Act.
 - “(2) Different levies or rates of levy or bases on which an amount of levy is to be calculated or ascertained may be prescribed for different purposes, and different levies or rates of levy or bases for calculation may be set for different classes or descriptions of agricultural compound, persons or businesses, operations, or other matters, or any combination of them. 25
 - “(3) Without limiting the generality of **subsection (1)**, regulations imposing levies may— 30
 - “(a) specify when and how any levy is to be paid:
 - “(b) require that any levy, or estimated amount of levy, be paid in advance of performance of the services or functions to which it relates: 35
 - “(c) specify persons, other than persons primarily responsible for paying the levy, who are to be responsible for collecting a levy, and provide for retention of any part of the levy money collected as a fee for that service:

- “(d) require, or empower the Director-General to require, the provision of information and returns in relation to levies:
- “(e) require the keeping of separate trust accounts for levy money received or deducted by persons responsible for collecting levies, and prescribe matters in relation to those trust accounts: 5
- “(f) prescribe a method of arbitration or mediation in the case of disputes as to—
- “(i) whether or not any person is required to pay, or collect, the levy concerned; or 10
- “(ii) the amount of levy any person is required to pay or collect:
- “(g) provide for related matters, including procedures and remuneration for arbitrators or mediators. 15
- “(4) The Minister may not recommend the making of regulations under this section unless satisfied that, to the extent appropriate in the circumstances, the requirements of **sections 81 and 81B** have been met.
- “81F Trust accounts required to be kept by persons collecting levies 20**
- “(1) If regulations made under **section 81E** require the operation of a trust account for any levy money by the person responsible for collecting the levy,—
- “(a) any amount held in such an account that is due to be paid to the Director-General by the levy collector is to be treated as levy money held on trust for the Director-General; and 25
- “(b) any amount so held on trust is not available for the payment of any creditor (other than the Director-General) of the levy collector, and is not liable to be attached or taken in execution at the instance of any such creditor; and 30
- “(c) a person who ceases to be a person responsible for collecting a levy must continue to maintain the trust account until all the levy money payable to the Director-General in respect of the period during which the person was responsible for collecting the levy has been paid. 35

“(2) Nothing in **subsection (1)(c)** affects any obligation or liability under this Act of any other person who has become responsible for collecting the levy concerned.

“81G Other charges not requiring to be prescribed

“(1) Nothing in the cost recovery sections or in any other provision of this Act prevents the Director-General from requiring a reasonable charge to be paid for any of the services the Ministry provides in relation to the administration of this Act, or any actual and reasonable expenses incurred in providing the services, other than services in respect of which a fee or charge or levy is prescribed under these cost recovery sections. 5 10

“(2) Without limiting **subsection (1)**, and for the avoidance of doubt, the Director-General may—

“(a) operate a telephone information service for which each caller pays according to their usage or on some averaged basis: 15

“(b) charge persons for the cost of mailing, faxing, emailing, or couriering information to them:

“(c) charge for the cost of written material, unless that material is required by an Act or by regulations made under this Act to be provided free of charge: 20

“(d) charge for access to any website, or for information or services provided by any website, operated by the Ministry:

“(e) charge for access to any library or research services provided in relation to matters pertaining to agricultural compounds, or associated things: 25

“(f) charge any person for services provided in relation to a business importing, manufacturing, selling, or using agricultural compounds or otherwise under this Act. 30

“(3) All money received as a result of such charges received by the Ministry must be paid into the Departmental Bank Account.

“81H Exemptions, waivers, and refunds

“(1) Regulations made under this Act may provide for exemptions from, or waivers or refunds of, any fee, levy, or charge payable under this Act, in whole or in part, in any particular case or class of case. 35

- “(2) Any such regulations may authorise the Director-General to grant an exemption, waiver, or refund in any particular case or class of case.
- “**81I Fees, levies, and charges to constitute debt due to Director-General** 5
 Any fee, levy, or charge that has become payable is a debt due to the Director-General, and is recoverable as a debt by the Director-General in any court of competent jurisdiction. Until paid in full, it remains a debt due to the Crown.
- “**81J Penalties for failure to pay fee, levy, or charge** 10
- “(1) If a person has failed to pay to the Director-General by the due date any fee, levy, or charge payable under this (*subpart*) Act,—
- “(a) section 14 of the Ministries of Agriculture and Forestry (Restructuring) Act 1997 applies to increase the amount payable; and 15
- “(b) section 15 of that Act applies to allow the Director-General, in appropriate cases, to waive the payment of all or any of the amount of any such increase; and
- “(c) section 16 of that Act applies to allow the Director-General to withdraw, or refuse to provide the person in default with, any service of the kind to which the debt relates. 20
- “(2) For the purposes of **subsection (1)(c)** of this section and section 16 of the Ministries of Agriculture and Forestry (Restructuring) Act 1997, and without limiting the generality of that section 16, the references in those provisions to the withdrawal or refusal to provide any service are to be treated as also authorising the Director-General, in an appropriate case, to— 25
- “(a) withhold or suspend any registration or approval under this Act, or refuse to perform any function under this Act in relation to the person in default; 30
- “(b) withhold any certificate of compliance.
- “(3) Where any registration or approval is suspended under **subsection (2)(a)**, no person may import, manufacture, or sell a trade name product or agricultural compound under the authority of that registration or approval. 35

- “(4) Where the withholding, withdrawal, or suspension of any approval or registration under this section requires the Director-General to provide any further service, or perform any further function involved in the withholding, withdrawal, or suspension, the Director-General may recover any reasonable amount for the additional service, function, or costs as a debt due from the person in default. 5
- “**81K Obligation to pay fee, levy, or charge not suspended by dispute**
The obligation of a person to pay any fee, levy, or charge under this Act (including any penalty referred to in **section 81J**), and the right of the Director-General to receive and recover the fee, levy, charge, or penalty, are not suspended by any dispute between the person and the Director-General regarding the person’s liability to pay the fee, levy, or charge, or the amount of the fee, levy, or charge. 10 15
- “**81L Levy regulations to be confirmed**
- “(1) Where regulations imposing a levy have been made under the cost recovery sections on or after 1 January in any year and before 1 July in that year, and— 20
- “(a) have not been revoked with effect on or before 1 July in the next year; and
- “(b) have not ceased, and will not cease, to have effect on or before 1 July in the next year by virtue of the Regulations (Disallowance) Act 1989,— 25
- they are to be treated as having been revoked with the close of 30 June in that next year unless confirmed by an Act of Parliament passed on or before that day.
- “(2) Where any regulations imposing a levy have been made under the cost recovery sections after 30 June in any year and on or before 31 December in that year, and— 30
- “(a) have not been revoked with effect on or before 1 January in the year after the next year; and
- “(b) have not ceased, and will not cease, to have effect on or before 1 January in the year after the next year by virtue of the Regulations (Disallowance) Act 1989,— 35
- they are to be treated as having been revoked with the close of 31 December in the year after the year in which they were

made, unless confirmed by an Act of Parliament passed on or before that day.”

- 51 New heading inserted**
The heading “*Amendments, repeals, and revocations*” is inserted immediately before section 84. 5
- 52 Part 8 repealed**
Part 8 (sections 87 to 122) is repealed.
- 53 Schedule 1 amended**
Schedule 1 is amended by omitting “inspector” (4 times) and substituting in each case “ACVM officer”. 10
- 54 Schedule 5 repealed**
Schedule 5 is repealed.

Struck out (unanimous)

- 55 Privacy Act 1993 amended**
Part 1 of Schedule 2 of the Privacy Act 1993 is amended by inserting the following item in its appropriate alphabetical order: 15
- Agricultural Compounds and Veterinary
Medicines Act 1997 sections 24, **28A**

New (unanimous)

- 56 Regulations revoked**
The following regulations are revoked: 20
- (a) the Agricultural Compounds and Veterinary Medicines (Transitional Provisions) Regulations 2002 (SR 2002/136):
- (b) the Animal Remedies (Fees) Regulations 1997 (SR 1997/367): 25
- (c) the Pesticides Act Commencement Order 1981 (SR 1981/177):
- (d) the Pesticides Act Commencement Order 1983 (SR 1983/15):

New (unanimous)

| | | |
|-----------|--|----------|
| | (e) the Pesticides Amendment Act Commencement Order 1994 (SR 1994/308): | |
| | (f) the Pesticides (Fees) Regulations 1997 (SR 1997/368). | |
| 57 | Agricultural Compounds and Veterinary Medicines Regulations 2001 amended | 5 |
| (1) | Regulation 3 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 (the Regulations) is amended by inserting the following definition after the definition of animal material : | |
| | “ approved operating plan means an operating plan approved under section 28(2) of the Act; and includes a code of practice deemed by section 20(2) of the Agricultural Compounds and Veterinary Medicines Amendment Act 2007 to be an operating plan approved under section 28(2) of the Act”. | 10 |
| (2) | Regulation 3 of the Regulations is amended by revoking the definition of good manufacturing practice and substituting the following definition: | 15 |
| | “ good manufacturing practice means a practice that follows an approved operating plan”. | |
| (3) | Regulation 4 of the Regulations is amended— | 20 |
| | (a) by omitting “ codes of practice ” from the heading and substituting “ approved operating plans ”: | |
| | (b) by omitting “codes of practice” and substituting “approved operating plans”. | |
| (4) | Schedule 1 of the Regulations is amended— | 25 |
| | (a) by omitting “ codes of practice ” from the heading and substituting “ approved operating plans ”: | |
| | (b) by omitting “code of practice in force under section 28 of the Act” from item 1 and substituting “approved operating plan”. | 30 |
| (5) | Schedule 2 of the Regulations is amended— | |
| | (a) by omitting “code of practice in force under section 28 of the Act” from column 2, whenever occurring, and substituting “approved operating plan”: | |

New (unanimous)

- (b) by omitting “code of practice must be in force under section 28 of the Act” from column 2 and substituting “operating plan must have been approved”.

Legislative history

30 November 2006

Introduction (Bill 45-1)

6 December 2006

First reading and referral to Primary Production Committee
