

# Departmental Disclosure Statement

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Agricultural Compounds and Veterinary Medicines Amendment Bill
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The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry for Primary Industries.

The Ministry for Primary Industries certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation.

14/07/2015

**Contents**

Contents..... 2

Part One: General Policy Statement ..... 3

Part Two: Background Material and Policy Information ..... 5

Part Three: Testing of Legislative Content..... 7

Part Four: Significant Legislative Features ..... 9

Appendix One: Further Information Relating to Part Two ..... 11

## Part One: General Policy Statement

### General Policy Statement

The Agricultural Compounds and Veterinary Medicines Act 1997 (**the Act**) currently protects confidential information given in support of an application to register an innovative trade name product. The Act currently protects the information for 5 years after an application is decided. Under certain conditions, this Bill extends the period of protection from 5 to 8 years. The Bill also expands the scope of data protection coverage to include confidential information provided in support of applications to register non-innovative trade name products and uses.

The policy objective of the changes in the Bill is to encourage businesses that own trade name products to register new trade name products and to register more uses for existing trade name products.

The changes are being made to support primary sector productivity and international competitiveness. The changes represent a balance between the objectives of:

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

#### Innovative trade name products

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

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

#### Non-innovative trade name product

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

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

#### New uses

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

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

### **Consequential amendments**

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

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

## Part Two: Background Material and Policy Information

### Published reviews or evaluations

<b>2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?</b>	<b>YES</b>
<p>Data Protection for Agricultural Compounds and Veterinary Medicines, Covec Ltd, 2009  <a href="http://www.foodsafety.govt.nz/elibrary/industry/data-protection-agricultural-discussion-document/covec-data-protection-report.pdf">http://www.foodsafety.govt.nz/elibrary/industry/data-protection-agricultural-discussion-document/covec-data-protection-report.pdf</a></p> <p>Data Protection for Agricultural Compounds – Discussion paper and Summary of Submissions, Ministry for Primary Industries, 2010/11  <a href="http://www.foodsafety.govt.nz/elibrary/industry/consultation-data-protection/">http://www.foodsafety.govt.nz/elibrary/industry/consultation-data-protection/</a></p>	

### Relevant international treaties

<b>2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?</b>	<b>NO</b>
<p><i>The Bill is consistent with New Zealand's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).</i></p>	
<b>2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty?</b>	
<p><i>Parliament considered the TRIPS agreement at the time it was ratified.</i></p>	

### Regulatory impact analysis

<b>2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?</b>	<b>YES</b>
<p><a href="http://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/">www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/</a></p>	
<b>2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?</b>	<b>NO</b>
<p><i>The Bill did not meet the threshold for RIA Team evaluation.</i></p>	
<b>2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?</b>	<b>NO</b>

## Extent of impact analysis available

<b>2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?</b>	<b>NO</b>

<b>2.5. For the policy to be given effect by this Bill, is there analysis available on:</b>	
<b>(a) the size of the potential costs and benefits?</b>	<b>NO</b>
<b>(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?</b>	<b>NO</b>
<i>Regulatory Impact Analysis was performed at a high level and identified costs and benefits at a qualitative level. Some analysis was done in Covec Ltd report examining the status quo.</i>	

<b>2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:</b>	
<b>(a) the level of effective compliance or non-compliance with applicable obligations or standards?</b>	<b>No</b>
<b>(b) the nature and level of regulator effort put into encouraging or securing compliance?</b>	<b>No</b>

## Part Three: Testing of Legislative Content

### Consistency with New Zealand's international obligations

**3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?**

*MPI's assessment is that the policy is consistent with New Zealand's international obligations.*

### Consistency with the government's Treaty of Waitangi obligations

**3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?**

*MPI has assessed the proposals against the principles of the Te Tiriti o Waitangi and consulted Te Puni Kokiri.*

*MPI's assessment is that the policy does not appear to be inconsistent with the principles of Te Tiriti o Waitangi.*

### Consistency with the New Zealand Bill of Rights Act 1990

**3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?**

**NO**

*MPI has consulted with the Ministry of Justice Bill of Rights Team.*

*No advice has been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990.*

### Offences, penalties and court jurisdictions

**3.4. Does this Bill create, amend, or remove:**

**(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?**

**NO**

**(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?**

**NO**

### Privacy issues

**3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?**

**NO**

<b>3.5.1. Was the Privacy Commissioner consulted about these provisions?</b>	<b>YES</b>
<i>MPI consulted with the Privacy Commissioner. No concerns were raised.</i>	

## External consultation

<b>3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?</b>	<b>YES</b>
<p><i>MPI has engaged extensively with industry representative groups and individual organisations on the data protection issue.</i></p> <p><i>In October 2011, the Ministry of Agriculture and Forestry (now Ministry for Primary Industries – MPI) released a Discussion Paper on data protection for agricultural compounds<sup>1</sup>. The paper outlined policy proposals for protection of information supplied to regulatory authorities in support of registrations of innovative agricultural compounds, new uses and reformulations of existing registered compounds, and reassessments of existing registered products. The proposals were based on previous public consultations, and an independent study of the effects of the current data protection regime.</i></p> <p><i>29 submissions were received from thirteen industry representatives, thirteen agricultural compound and veterinary medicine suppliers, two patent attorneys and one research organisation.</i></p> <ul style="list-style-type: none"> <li><i>Major ‘brand name’ agricultural compound suppliers and horticultural sectors, particularly those affected by pests, sought broader data protection and longer protection periods to encourage registration of new products and uses.</i></li> <li><i>Generic agricultural compound suppliers and Federated Farmers sought narrow data protection and short protection periods to support competition and low costs.</i></li> </ul>	

## Other testing of proposals

<b>3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill’s provisions are workable and complete?</b>	<b>YES</b>
<p><i>MPI has done scenario analysis across the Bill and considered the risks.</i></p> <p><i>MPI also hosted a workshop on a near-final draft Bill with interested parties from the Agricultural Compounds and Veterinary Medicines Advisory Council and other government agencies. Feedback has been incorporated in the Bill, where appropriate.</i></p>	

<sup>1</sup> Ministry for Primary Industries (2011), *Data Protection for Agricultural Compounds*, MAF Discussion Paper No: 2011/10



## Part Four: Significant Legislative Features

### Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	NO

### Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	NO

### Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	NO

### Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	NO
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	NO

### Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	NO

### Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	NO

### Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	NO
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4.8. Does this Bill create or amend any other powers to make delegated legislation?	NO

**Any other unusual provisions or features**

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	NO

## Appendix One: Further Information Relating to Part Two

### Extent of impact analysis available – question 2.5(a)

The costs and benefits of extending data protection was assessed using information gained from several rounds of public consultation and an independent study of the effects of the current regime on the New Zealand agricultural compounds market.

The regulatory impact statement summarising MPI's analysis is available at the following link:

<http://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/>

Covec Economic Consultants 2009 report on *Data Protection for Agricultural Compounds and Veterinary Medicines* is available at the following link:

<http://www.foodsafety.govt.nz/elibrary/industry/data-protection-agricultural-discussion-document/covec-data-protection-report.pdf>