Ministry for Primary Industries
Manatū Ahu Matua

Regulatory Impact Statement

Data Protection for Agricultural Compounds

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Growing and Protecting New Zealand

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Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

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Regulatory Impact Statement – Data Protection for Agricultural Compounds

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry for Primary Industries (MPI).

It provides an analysis of options for possible changes to the data protection regime for agricultural compounds provided under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

The analysis is based on a cost benefit study of the effects of the current regime on New Zealand market for agricultural compounds and extensive stakeholder consultation.

A precise determination of the net economic impact of any changes is not possible because:

- much of the relevant information regarding the impact of the data protection rules is confidential, commercially sensitive information that is held by suppliers and is not publicly available;
- the competitive conditions in the large number of different product markets vary considerably and change over time.

Without detailed, firm-specific information and analysis, it is not possible to

- verify the extent to which it is actually the current rules that are the cause of a particular product or new use not being registered; or
- evaluate the extent to which the development of new products using existing chemistry is being inhibited.

A particularly strong case is required before options that involve introducing or extending data protection are considered. This is because they have the potential to impair market competition, since data protection (in the absence of patent protection) effectively provides a period of market exclusivity (monopoly) for the registrant.

Barbara Whittington

Senior Policy Analyst

Food Policy

12th September 2012

1 Summary

MPI has reviewed the data protection regime for agricultural compounds provided by the ACVM Act 1997. The review was undertaken in response to ongoing concerns expressed by industry stakeholders that the current regime is inadequate and deters the development and registration of products needed by the New Zealand market, in particular the New Zealand agricultural sector.

Options for data protection have been reviewed in respect of three areas:

1. Innovative agricultural compounds – compounds that are, or contain, an active chemical ingredient not previously registered in New Zealand. The current regime provides five years protection for confidential information provided in support of registration applications.
2. New uses and reformulations of non-innovative compounds – compounds that are or contain active chemical ingredients that have been previously registered in New Zealand. A new use may involve approval to use an existing product on a different species or crop than that for which it is currently registered; reformulations may involve combining two or more existing compounds, or changing the form of an existing compound, for example from a powder to a spray. There is currently no data protection available in such cases.
3. Reassessments of existing approved compounds – reassessments are usually of older chemicals, and usually, but not exclusively, initiated by the regulator (MPI or EPA), for example where they have become aware of a change in the risks associated with use of the chemical. There is currently no protection provided for data supplied to the regulator for the purposes of a reassessment.

The costs and benefits of extending data protection in these areas have been 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.

MPI has concluded that:

- There is no compelling reason to increase the basic length of the data protection term for innovative compounds, principally due to the interface with the patent system.

  However, the ability to extend the length of the data protection period for the original product if extra uses are added may provide an incentive to add “minor” uses to labels, which is a particular issue for New Zealand.

- The benefits of providing a period of data protection for new uses and reformulations of existing non-innovative compounds outweigh the potential costs, compared with the status quo (no data protection).

- The costs of providing data protection for reassessments in the form of either market exclusivity or compulsory compensation would outweigh the benefits.

2 Background

Agricultural compounds are substances used in the management of plants and animals - pesticides, herbicides, vertebrate toxic agents such as rat poison, and veterinary medicines.

Agricultural compounds have to be registered before they can be manufactured, sold or used. The regulatory approval process requires applicants to supply supporting information regarding product features, such as safety, efficacy and the likelihood of residues remaining after use.

The requirement to supply supporting information to the registration authority gives rise to a potential negative externality for the data producer. In the absence of a registration requirement, companies would be able to keep the information secret (through, for example, trade secrets legislation). However, under the regulatory approval process, the regulator has to take into account the information already held on that product when considering whether another application for a similar ("copy cat" or generic) product should be approved. Competitors could thus "free ride" on the supporting data. Provided that the original product was not protected by a patent, the competitor would be able to enter the market without incurring the same costs as the initial applicant. There would be other benefits such as a reduced time to bring their product to the market, because of the shorter time taken to gain regulatory approval. Thus the registration of new products may be discouraged.

"Data protection" is a regulatory mechanism provided to offset this negative externality. It prevents information provided in support of an application for registration of an agricultural compound from disclosure, or use by the registration authority to assess other applications.

The New Zealand agricultural compounds sector

Agricultural compounds are used by a range of different groups. The main purchaser of agricultural chemicals is the agricultural sector, but they are also used for a variety of other land uses, such as forestry, domestic gardens and public land, including conservation areas, parks, sports fields, school grounds. Similarly, veterinary medicines are heavily used for the treatment of companion animals as well as in the commercial livestock industry.

Around 300 companies have approximately 3,000 different products registered for sale in New Zealand under the ACVM Act. The breakdown of these products into agricultural chemicals and veterinary medicines is roughly 35:65. The number of new registrations varies from year to year, but has averaged around 180 per year for the past 5 years (to 2011).

The number of products in any given market varies considerably, and individual product markets range greatly in size; turnover in some markets may be worth only tens of thousands of dollars per year, whereas other markets have sales in excess of several million dollars. However, the majority are at the smaller end of the market; a large proportion of products have annual sales of less than $50,000, and only around 30 to 40 are estimated to have sales in excess of $1 million p.a.

The total value of the New Zealand market is estimated at just over $500 million per year - $250 million for the crop protection market and $270 million for the animal health market.

3 Status Quo and Problem Definition

New Zealand's current regulatory regime in respect of data protection for agricultural compounds was implemented in 1995 to meet obligations under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Article 39.3 of that Agreement requires signatories to provide some form of data protection for agricultural chemicals that involve new chemical entities; it does not set a minimum period of protection. New Zealand's regime provides five years data protection for applications to register "innovative" agricultural compounds (i.e. those containing an active chemical ingredient that has not previously been registered in New Zealand). The data protection provisions are compliant with TRIPs obligations under Article 39.3.

Some industry stakeholders, both suppliers and users, have over several years contended that the current data protection regime is inadequate, and inhibits the supply of products to the New Zealand market, with consequent negative effects for the agricultural sector.

In particular, because the provisions of the ACVM Act only relate to the application for the registration of "innovative" agricultural compounds and veterinary medicines[1]:

a) innovation based on existing chemistry, and extension of the registration of existing products to cover use on other species and/or crops, is inhibited; and

b) lack of protection for data supplied to support continued marketing approval of existing registered products (reassessments) means that information may not be made available to the regulator, and New Zealand agriculture could potentially be adversely affected if products do not survive the reassessment process due to unavailability of data.

An officials' working group, established in 2008 to review the data protection regime, commissioned an independent study of the effects of New Zealand's current data protection rules on the market for agricultural compounds[2] ("the Covec Study"). Its findings have informed the analysis of the problems and of the regulatory options.

[1] An innovative compound is defined in the ACVM Act as a compound that is, or contains, an active chemical ingredient not previously registered in New Zealand.

[2] Study of Data Protection for Agricultural Compounds and Veterinary Medicines, Covec Consultancy, February 2009

4 Objectives

The objectives are to establish data protection rules that will provide a balance between

- encouraging competition in the agricultural compounds market, resulting in more products and/or lower prices; and
- not discouraging the registration of products needed by the New Zealand agricultural sector for pest and disease management, and to enhance agricultural productivity.

In theory, data protection periods should be set at a level that provides an innovator with just sufficient time in which to recoup the costs of generating the information required by the regulatory authority, through sales of products. However, different products will have different pay-back periods, so any fixed period of protection will over-compensate in some cases and under-compensate in others. To the extent that protection over-compensates the data owner, there will be a loss of consumer welfare.

In practice, the level tends to be arbitrary. The TRIPS Agreement requires WTO members to provide some level of data protection for innovative compounds, but the period of protection varies across jurisdictions - some countries (including New Zealand) have 5 years, Australia has 8, the EU and USA have 10, Japan has 15.

5 Regulatory Impact Analysis

Options for data protection have been reviewed in respect of three areas:

1. Innovative agricultural compounds – compounds that are, or contain, an active chemical ingredient not previously registered in New Zealand.
2. New uses and reformulations of non-innovative compounds – compounds that are or contain active chemical ingredients that have been previously registered in New Zealand. A new use may involve approval to use an existing product on a different species or crop than that for which it is currently registered; reformulations may involve combining two or more existing compounds, or changing the form of an existing compound, for example from a powder to a spray.
3. Reassessments of existing approved compounds – reassessments are usually of older chemicals, and usually, but not exclusively, initiated by the regulator (MPI or EPA), for example where they have become aware of a change in the risks associated with use of the chemical.

5.1 INNOVATIVE COMPOUNDS

Option 1: Status quo (five years data protection)

Option 2: Basic length of protection remains at 5 years, but extension of protection available when additional uses are added.

Option 3: Increase the data protection period.

5.1.1 Summary of Regulatory Impacts

Option	**Objectives**		**Impacts**		**Net economic impact**
	Competition	**Incentive to register products**	**Costs/Risks**	**Benefits**	
Option 1 Status quo (5 years protection)	Meet	Meet	Products available overseas not registered in NZ	Early entry into market of generics, with consequent beneficial effects of competition	Positive
Option 2 Extension of protection for additional uses.	Meet, but to lesser extent than option 1	Meet - increased compared to Option 1	Benefits of competition from generics delayed	Increased incentives for companies to add NZ-specific uses to existing products.	Positive
Option 3 Increase data protection period.	Fail	Meet	**Government** Potential reduction in competition in agricultural compounds markets in New Zealand, with consequent effects on economic growth and development. **Suppliers (Generics)** Loss of business due to delayed registration and production of products. **Consumers/Users** • Reduced choice due to delayed registration & production of generic products. • Higher prices due to lack of competition. • Greater length of time before NZ-specific innovation based on existing technology or products can be undertaken by other than initial registrant.	**Government** Potential increase in competitiveness of agricultural sector through quicker access to latest products, with consequent effects on economic growth and development. **Suppliers (Initial Registrant)** Increased ability to recoup costs of registering new products in New Zealand. **Consumers/Users** Potentially quicker access to innovative products	Negative

5.1.2 Covec Study comment/conclusion

- No significant issues with respect to the current length of the data protection period for innovative new products were identified. No evidence was provided that the current five-year period is inhibiting the flow of products onto the New Zealand market. The fact that most innovative agricultural compounds were eligible for a 20 year period of patent protection meant that a five year period of data protection did not appear to have a significant impact on the registration of new products.
- A longer period of protection could mean a longer time before generic products could enter the market, thus reducing competition and keeping prices higher, with negative effects for users.

5.1.3 MPI comment/conclusion

Innovative products are typically eligible for patent protection of 20 years. Even allowing for the fact that products may come onto the market with less than this amount of patent protection left, if multinational companies are reluctant to release a product onto the New Zealand market at around the same time as it is introduced into other markets, it is more to do with their assessment of the value of the market. Data protection is unlikely to make a significant difference to this decision.

Competition from generic products has been shown to be effective in reducing the price of innovative products following their entry into market upon expiry of patent or data protection.

There is no compelling reason to increase the basic length of the data protection term. However, the addition of "minor" uses to labels is a particular issue for New Zealand. Many, if not most, New Zealand horticultural crops and commercially farmed animals (deer, goats, even sheep) are minor commercial crops or species internationally, so products are not registered for use on them overseas. New uses added to registered innovative products under data (or patent) protection would benefit from that protection, as there would be no competing products in the market. Companies' apparent reluctance to carry out the extra testing to add other uses to innovative compounds for the New Zealand context is therefore more likely to reflect the small size of the market, rather than lack of data protection.

But to the extent that firms value a longer period of market exclusivity for their products, the ability to extend the length of the data protection period for the original product if extra uses are added may provide an incentive for this to occur.

5.2 NEW USES AND REFORMULATIONS

Option 1: Status quo (no protection)

Option 2: Introduce a period of protection for data supplied in support of registration of new uses and significant reformulations of existing registered (non-innovative) products.

Providing data protection for new uses for existing (non-innovative) products would mean that only the initial applicant could make a claim on the product label (and thus in advertising and promotion) that the product can be used for the "new" purpose. Existing "copy cat" products could be used for the new purpose, but would not be able to state this on their label.

While other generic products could be used for the new use, benefits would accrue to the new-use applicant that might influence a decision to invest. These benefits arise from:

- Market incentives - for off-label use of generics, the default residue limits would be lower, and withholding periods higher, than for the registered products.
- Trade considerations - there is an increasing trend for purchasers both internationally and domestically to require suppliers to show that they have only used approved products, in accordance with label directions. For example the Eurepgap programme in the EU and, within New Zealand, Regional Council air quality plans require that spraying must be carried out as per label.

Reformulations of products can involve existing products being reformulated so as to be sold in a different format, for example a wettable powder instead of a concentrated liquid. This may involve active ingredients being combined with a new additive and can allow products to be stored and/or used in different ways. For instance, an animal remedy may be reformulated so that it can be applied as a pour-on instead of as an oral treatment.

Providing data protection for such reformulations would mean that other existing registrants would not be able to produce/sell the product in its re-formulated state.

5.2.1 Summary of Regulatory Impact

Option	Objectives		Impacts		Net economic impact
	Competition	**Incentives to register products**	**Costs/Risks**	**Benefits**	
Option 1. Status quo	Meet	Fail	**Government** - **Suppliers (Initial Registrant)** Reduced profitability of registering or developing new uses in New Zealand through competitors' lower costs and reduced time to enter market. **Suppliers (Generics)** - **Consumers/Users** • Reduced range of products for minor and/or specific uses, with resultant productivity losses, if companies are inhibited from registering products for the New Zealand market. • Potential loss of international trade from inability to comply with purchasers' requirements to show that only approved products have been used.	**Government** - **Suppliers (Initial Registrant)** - **Suppliers (Generics)** Increased sales/ market share **Consumers/Users** Increased choice due to quicker registration & production of generic products. Lower prices due to competition	Negative
Option 2: Introduce a period of data protection	Meet	Meet	**Government** - **Suppliers (Initial Registrant)** - **Suppliers (Generics)** Reduced sales/ market share **Consumers/Users** -	**Government** - **Suppliers (Initial Registrant)** Increased profitability of registering or developing new uses in New Zealand **Suppliers (Generics)** - **Consumers/Users** Increase range of products for minor and/or specific uses	Positive

5.2.2 Covec Study conclusions:

- Anecdotal evidence suggests that the current rules are likely to have resulted in fewer new products using existing chemistry and fewer existing products being registered for new uses. This is because of the reduced ability of suppliers to recover development and regulatory costs and make sufficient returns from new products or new uses.
- Although this effect applies throughout the industry, the market segments that appear to be most affected are smaller-scale agricultural industries, including a range of horticultural crops and some arable crops (e.g. vegetable seed crops). These are smaller markets which are likely to generate smaller expected returns for agricultural compound suppliers. Consequently, data generation costs are likely to constitute a larger proportion of the total expected gross returns in these markets.
- As well as deterring the registration of specific products that are available overseas and, perhaps more likely, deterring the registration of new uses for existing products, the data protection rules also create a more general disincentive to undertake product development activity using existing chemistry. The development costs for reformulations can be significant.
- It is not possible to determine with certainty whether the net impact of these rules is positive or negative across the entire sector, or for New Zealand as a whole.
- However, if data protection were provided for new uses, it would be unlikely to allow suppliers to raise prices for any products that are already on the market. This is because a product registered for a new use would already be subject to competition in the market/s for which it is currently registered, and thus competitively priced. The benefit of data protection for new-use applicants is that it would provide them with the opportunity to obtain a high market share in the new use market, as their product could be marketed directly for the new use. This would better allow them to recoup development and registration costs without having to raise prices.
- Regarding reformulations, a supplier selling a reformulated product may be able to charge a price premium during a period of data protection, if its new formulation were sufficiently superior to existing products.

5.2.3 Submissions

Several examples of the adverse effects of the current lack of data protection for new uses/reformulations were given in submissions:

- Contorta pine is a serious environmental weed that because of its prolific seeding requires the same area to be cleared every three years – currently by hand-cutting. It is well known that 2,4-D does a very good control job at a low cost. However, to date no company with the capability of providing the data for registration has added this use to a label, due to an absence of data protection.

- A New Zealand company developed a product for controlling whitefly in glasshouse tomatoes. The formulation contained an active ingredient first registered over 10 years ago for control of fleas on cats and dogs. The previous animal health registration prevented any data protection being granted to the efficacy and residue

information that the company generated to obtain the registration for its new product. After less than eight months of registration, a generic competitor was approved.

- Western flower thrip is an insect pest that affects glasshouse crops. A product that is currently on the market could potentially be used to deal with this pest, but is not registered for this use. If this product were to be registered for use on this pest, the registrant expects that returns could increase by around $20,000 per year. However, the cost of providing data for registration would be around $50,000 to $60,000. There is a generic competitor already in the market for this product. Consequently, the absence of data protection may influence the decision to register this product for use on this pest as it is likely to curtail the registrant's ability to recover registration costs.
- Application for registration is currently on hold for:
    - an existing product as a plant growth regulator on avocados (a new use) due to cost ($200,000 for development of efficacy and residues data, and at least two years work). Market size only 4,000 ha. With a generic product on the market, the registrant could not recover these costs.
    - A new use for of an existing product for psyllid control in tamarillos. Small market size, generic products on market. Too expensive to do the residue and efficacy work with no data protection.
    - Approval for use of an existing product at a higher label rate for psyllid control in tomatoes (new pest claim). Cost of doing residue work too high with no data protection.

5.2.4 MPI comment/conclusion

MPI considers that the evidence from the Covec study and information supplied in submissions shows that a lack of protection for data supplied in support of registration of new uses and reformulations of existing products is deterring some registrants from these activities - in particular, adding crops/species to existing uses for registered products, and inhibiting innovation based on existing chemistry to develop products for New Zealand-specific problems. This imposes costs on users.

Any negative effects of the current rules are most likely to be felt in niche markets, which are where growth and innovation are more likely to happen, compared with major markets/new discoveries.

There is likely to be little effect on prices from providing a period of data protection, because of existing competition in current registered-use markets. That is, registrants would have little, if any, ability to increase prices, as they have to continue to compete with other suppliers in existing markets for the product. The advantage to the initial registrant comes from having an exclusive label claim for the new use. The rights or ability of other existing product marketers to sell their products would be unaltered. In respect of reformulations, any price effect would be market-driven, as users would still be able to purchase the alternative, existing product.

MPI considers that the benefits of option 2 outweigh the potential costs, compared with the status quo (option 1).

5.3 REASSESSMENTS

Option 1: Status quo (no data protection).

Option 2: Provide a flat period of data protection.

Option 3: Compulsory compensation. This requires other firms in the market to compensate the original registrant/data-holder for the cost of providing the data required.

5.3.1 Summary of regulatory impact

	Objectives		**Impacts**		**Net economic impact**
	Compet-ition	**Incentive to register products**	**Costs/Risks**	**Benefits**	
Option 1 Status quo (no protection)	Meet	?	***Government*** Decisions may be based on incomplete data. ***Users*** Loss of access to products that do not survive the reassessment process due to non-provision of data	No effect on competition. Creates incentives for voluntary arrangements. Reassessment process is not unduly delayed.	Undetermined
Option 2 Fixed period of data protection.	Fail	Meet	***Government*** Negative effect on relationship with generic industry: • anticompetitive • potential for litigation. ***Industry (Generics)*** Loss of business ***Users*** Reduced choice with exit of generics from market; potential for increased prices.	***Government*** Fuller access to data on which to base decisions. ***Industry (initial registrant)*** - Increased sales due to removal of competition. - Ability to recoup cost of providing additional data required. ***Users*** Continued access to products that would not otherwise survive the reassessment process.	Negative
Option 3 Compulsory compensation	Meet?	?	Cost of negotiating and implementing cost-sharing arrangements. Delays in reassessment process while negotiations are carried out ***Users*** Potential for increased prices, due to above costs for industry.	***Industry (initial registrant)*** Ability to recoup cost of providing additional data required. ***Users*** Continued access to products that would not otherwise survive the reassessment process.	Negative

5.3.2 Covec comments

The Covec study concluded that:

- If data protection were provided in relation to reassessments this could lead to a reduction in competitive pressure in existing product markets. In this case, this sole recipient of data protection may be able to exploit any market power from the temporary 'monopoly' this protection may provide. Conversely, a positive impact of providing data protection could be that more firms are willing to provide data requested by regulators. Whether the potential benefits of this change would be outweighed by potential adverse impacts cannot be ascertained without knowing precisely what compounds would be reassessed and what data the regulator would require in the course of each reassessment.
- Whether the net impact of introducing data protection for reassessments would be positive is uncertain, although there may be policy approaches (e.g. cost sharing) that could address any anti-competitive impacts that may arise from such a change. (The Covec study did not assess such an approach).

5.3.3 MPI comment

Option 1

The status quo preserves competition in the marketplace.

There are incentives for voluntary arrangements under the current system. If continued registration is profitable for (all) the current registrants, and/or important for others (users), stakeholders will assess whether it is worth investing in additional data, and if so make arrangements for its supply. For example:

- In the 2007 reassessment of 1080, the New Zealand Government and the Animal Health Board paid for the production of data, as the major users/beneficiaries of the substance, and because of the wider national economic benefit to the environment.
- A submission noted a recent reassessment of a compound important for growers, where the two registrants of the active ingredient in New Zealand were both generic companies that did not have data to support the reassessment. The industry body therefore became the lead contributor, including organising an independent review of the toxicology aspect for the risk assessment.

Option 2

Under this option, other firms in the market would in effect have their marketing approval withdrawn, as they would not be able to show the regulator that their product complied with requirements, unless they generated the same data themselves. This would impinge on existing rights of generic suppliers, and result in monetary losses from loss of business and prior investment in marketing and distribution. It would also confer a monopoly on the original product for the period of protection, with consequent potential price effects.

The nature of the New Zealand agricultural compound market (large numbers of small and/or "generic" companies) means that the impact of data protection legislation is different than in the EU and US, where markets are dominated by larger companies and the proportion of generic companies is low. Removing generics from the New Zealand market would have a much greater impact on competition and prices.

MPI considers that the costs of providing data protection in the form of market exclusivity would outweigh the benefits.

Option 3

This option would address most of the anti-competitive impacts that may arise from data protection for reassessment data, as there would be no market exclusivity conferred.

However, evidence from other jurisdictions (United States, Australia) is that such arrangements are complex, difficult to administer and enforce, and thus costly for both industry and regulators. Major factors include how to determine and authenticate costs (the incentive for data holder/provider is to inflate costs), and access to information (for example, market share) to ensure fair allocation of costs between firms. It is difficult for companies to reach agreement without recourse to enforced mediation or arbitration, with consequent (often lengthy) delays in the assessment process.

MPI considers that the cost of implementing compulsory cost-sharing arrangements would outweigh the benefits.

5.3.4 MPI Conclusion

Where costs are involved in providing data required for reassessments, data protection could address potential "free-rider" problems.

However, reassessments are carried out on a case-by case basis, and it is not possible to determine the scale and scope of any data requests, and thus the costs of data provision, in advance.

- Most reassessed chemicals are old and have a body of data available on them. While there are restrictions on the ability to use overseas reassessments as the basis for a New Zealand reassessment[3], there is usually sufficient publicly available information on the effects of the substances in question to reach the same conclusions.

Increasing user demand for newer, "softer" (environmentally-friendly) chemicals has as much, if not more, influence on the market for older chemicals and companies' willingness to stay in that market, than government reassessments.

MPI considers that current processes and arrangements for obtaining data for reassessments are adequate for most situations. The lack of data protection is not unduly inhibiting regulatory activity in this area.

[3] OECD Monograph Guidance requires that such studies can only be used if the original owner has given permission, or if the registration authority has a mandatory compensation scheme in place.

6 Consultation

Data protection for agricultural compounds has been the subject of several rounds of consultation:

- 2006 – the issue was raised during consultation on wider amendments to the ACVM Act. Following analysis of submissions, an officials' working group[4] was set up to assess the concerns raised. It was decided to commission an independent study of the effects of New Zealand's current data protection rules, to see if there were any quantifiable, verifiable information that could be used to inform policy decisions on possible changes to the rules, and to assess the net benefits to New Zealand of any such changes. This study was carried out during 2008 by Covec Consultancy, and involved input from, and discussion with, manufacturers/suppliers and user groups[5].
- 2009 – the Study Report and accompanying Discussion Paper canvassing views on possible options for changes to data protection rules were released[6]. Eleven submissions were received - nine from manufacturers/suppliers, one from a user group, and one from a research institute.

  The issue of data protection was also discussed at a number of meetings of the Agricultural Compounds and Veterinary Medicines Advisory Council during this period.
- 2011 - Initial policy proposals were formulated, but a lack of submissions from user groups prompted a further round of consultation, with a Discussion Paper released in October 2011[7].

Twenty-nine submissions were received in the latest consultation, from 13 user groups, 13 manufacturers/suppliers, two patent attorneys and one research institute.

The key concerns raised by submitters were:

Innovative products

- The small size of the New Zealand market inhibiting returns on investment.
- The need for the agricultural sector to have access to products available overseas.

New/minor uses and reformulations of existing (non-innovative) products

- Need for the agricultural sector to have access to products developed for New Zealand-specific problems.
- Many, if not most, New Zealand horticultural crops and commercially farmed animals (deer, goats) are minor commercial crops or species internationally, so products are not registered for use on them overseas.
- Because of the small size of the New Zealand market, without data protection international companies are unlikely to be interested in carrying out the trials and field tests required to add New Zealand-specific uses to their product labels and thus allow their use (registration) in New Zealand, as they will be unable to recoup the costs.

[4] The former New Zealand Food Safety Authority, Environmental Risk Management Authority, and Ministry of Economic Development; now Ministry for Primary Industries, Environmental Protection Authority, and Ministry of Business, Innovation and Employment)

[5] Study of Data Protection for Agricultural Compounds and Veterinary Medicines, Covec Consultancy, February 2009

[6] Data Protection for Agricultural Compounds - NZFSA Public Discussion Paper No 07/09, July 2009

[7] Data Protection for Agricultural Compounds - MPI Discussion Paper No: 2011/10

- Small market size is a particular issue for minor crops/species, since the cost of obtaining data on residues does not vary significantly regardless of market size.
- Off-label use: If minor uses are not registered, “off-label” use (i.e. using products in a use for which they are not registered) will be more likely to occur. This practice may mean higher than optimal animal welfare, environmental, and trade risks.

Reassessments

- If products do not survive the reassessment process due to lack of data, the range of plant and/or animal management products available to growers and producers will be restricted, resulting in fewer options.

Other issues

Other issues raised were:

- The start of period of data protection (variations in time taken to process application results in variable periods of protection).
- The lack of data protection where new applicant differs from initial applicant for provisional registration.

MPI has noted these concerns. In the first instance, the issue seems to stem from a misunderstanding of the legislation; the term of data protection is always 5 years, it is not lessened by the length of the registration process. This will be communicated to stakeholders.

With respect to the second issue, MPI agrees that the current definition appears unduly restrictive in this respect and proposes to re-word the ACVM Act to address this.

7 Conclusions and Recommendations

MPI's conclusions and preferred options in respect of the three areas reviewed and the issue raised in submissions are:

7.1 INNOVATIVE AGRICULTURAL COMPOUNDS

Notwithstanding some stakeholder support for increasing data protection, there is no compelling reason to increase the basic length of the data protection term, principally due to the interface with the patent system.

However, the addition of "minor" uses to labels is a particular issue for New Zealand, and there is some evidence, albeit largely anecdotal, that the current data protection regime does not provide incentives for this to occur. To the extent that firms value a longer period of market exclusivity for their products, the ability to extend the length of the data protection period for the original product if extra uses are added should provide such an incentive.

MPI's preferred option is to leave the basic term of protection for innovative agricultural compounds at five years, but provide for an extension of the period of data protection, by one year for each additional use added to the original approved compound within three years of its initial registration, to a maximum of three years additional protection.

7.2 NEW USES AND REFORMULATIONS

It is assessed that the benefits of providing a period of data protection outweigh the potential costs, compared with the status quo (no data protection).

MPI's preferred option is to provide a period of three years protection for data supplied in support of applications to register new uses or significant reformulations of existing registered (non-innovative) compounds.

The period of protection recommended takes into account that the costs of an application to vary an existing approval will be less than for a new innovative compound registration, so that the appropriate period of protection should be shorter.

7.3 REASSESSMENTS

MPI considers that the costs of providing data protection in the form of either market exclusivity or compulsory compensation would outweigh the benefits. Current processes and arrangements for obtaining data for reassessments are adequate for most situations. The lack of data protection is not unduly inhibiting regulatory activity in this area.

MPI's preferred option is to maintain the status quo (no data protection).

7.4 DEFINITION OF INNOVATIVE AGRICULTURAL COMPOUND APPLICATION

MPI considers that the current definition is unduly restrictive. It is proposed to amend the definition so that:

a. such an application is one that refers to an ingredient active that has not previously been granted full registration in New Zealand at the time of the application; and

b. where there has been a previous application for provisional registration, an application for full registration is not restricted to that original applicant.

8 Implementation

The proposals will be given effect by amending Part 6 of the ACVM Act 1997. Section 72 Interpretation will need to have definitions of "new use" and "reformulation" added, and the definition of "protected period" will need to be amended to cover the extension available when uses are added to existing registered innovative compounds, and the three year period for new uses and reformulations of non-innovative products. The amendments would be relatively minor - it is estimated that they would involve 1 to 5 clauses of low to medium complexity.

The ACVM Group within MPI will implement the new provisions. MPI will develop guidance material on the changes in discussion with affected parties, including other interested government agencies.

There will be additional administrative costs including

- one-off implementation costs
    - updating of forms, information requirements and guidance documents for both internal and external stakeholders;
    - communications for applicants on the new rules via publications and/or workshops;
    - updating the database to allow for capture of, and reporting on, data protection information
- ongoing operational costs
    - an increased number of applications that will require screening to determine whether they are eligible for data protection, or where trying to "piggy back" off another product, whether they can do so (whether there is data protection for the referenced product);
    - monitoring of data protection periods and associated products for both internal and external use.
    - managing the interface with the HSNO Act.

All ACVM registrations are cost recovered, so no additional government funding will be required. Fees may need to be reviewed to take account of increased costs.

Effects on existing regulation

Agricultural compounds that are also hazardous substances must also be approved under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). Data protection under that Act is provided by cross-referencing the relevant provisions in the ACVM Act.

It is not intended to alter this arrangement - data protection under the HSNO Act will remain applicable to innovative substances only. Depending on the final drafting of amendments to Part 6 of the ACVM Act, minor consequential amendments to the HSNO Act may be required, to ensure that the correct section of the ACVM Act is cross-referenced appropriately.

9 Monitoring, Evaluation and Review

MPI has not set a time in which to review the new provisions. Their effectiveness will be considered as part of MPI's ongoing assessment of its administration of the ACVM Act.