Ministry for Primary Industries
Manatū Ahu Matua

Data Protection for Agricultural Compounds

Summary of Submissions

MPI Information Paper No: 2012/11

ISBN No: 978-0-478-40489-0 (online)
ISSN No: 2253-394X (online)

December 2012

New Zealand Government

Growing and Protecting New Zealand

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Introduction

In October 2011, the Ministry of Agriculture (now Ministry of Primary Industries – MPI) released a Discussion Paper on data protection for agricultural compounds[1]. This 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[2].

The proposals were:

- No change to the existing data protection provisions for innovative substances (remain at 5 years).
- No change to the existing data protection provisions for reassessments of existing registered agricultural compounds (no data protection).
- For new uses or reformulations of existing registered agricultural compounds, either:
  - No change (i.e. no data protection); or
  - Provide a period of data protection of 1, 2 or 3 years

Process

Submissions on the above Discussion Paper were analysed, and after consultation with other interested government agencies, final policy proposals were formulated and presented to Cabinet for approval.

Following Cabinet approval, the necessary legislative amendments to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and consequential amendments to the Hazardous Substances and New Organisms Act 1996, if any, will be drafted and follow due parliamentary process. It is anticipated that the amendments will come into force in late 2013.

[1] Data Protection for Agricultural Compounds - MAF Discussion Paper No: 2011/10

[2] - Proposed Amendments to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, MAF Discussion paper April 2002;
- Study of Data Protection for Agricultural Compounds and Veterinary Medicines – Covec Consultancy February 2009;
- Data Protection for Agricultural Compounds - NZFSA Public Discussion Paper No 07/09.

Submissions on 2011 Discussion Document

Twenty-nine submissions were received, from:

- 13 user groups (sector associations)
  - 8 horticulture/cropping
  - 3 animal products
  - 1 District Council
  - Federated Farmers
- 13 suppliers/manufacturers
  - Agcarm (industry association)
  - 4 veterinary medicine
  - 8 plant products (pest & weed control)
- 2 patent attorneys
- 1 research organisation

A majority of submitters (62%) favoured an increase in protection for innovative substances, from 5 years to 10 years. This view was held equally by both suppliers and users, who generally favoured 10 years protection for new uses and reassessments also (see Appendix 2).

A significant proportion of submitters (30%) did not comment on data protection for reassessments. Of those who did, 75% favoured introducing data protection, with most opting for 10 years.

Submissions were overwhelmingly (90%) in favour of introducing data protection for new uses and reformulations of existing registered compounds, with around half favouring a period of 10 years.

The key issues raised were

- the small size of the New Zealand market inhibiting returns on investment; and
- the need for the agricultural sector to have access to products available overseas, and products developed for New Zealand-specific problems.

MPI Comment – Role of data protection

New Zealand is a small market in world terms. This is reflected in the price and range of products in most, if not all, product markets, not just agricultural compounds, and is likely to be the main factor for companies in deciding whether to market a product here.

It is not government policy to provide marketing protection to individual companies to overcome this. It is a commercial decision for companies as to whether there is a viable market in New Zealand for their product(s).

Data protection is concerned with overcoming the “free rider” problem caused by the requirement to register. This includes competitors not having to incur some of the costs associated with registration of products and/or substances, and having the ability to shorten the time to bring competing products to market.

Data protection helps offset these costs by effectively establishing a period of market monopoly for the company whose data is protected. Other companies can generate their own data to support registration. However, in practice this does not generally occur, so that companies have time to recoup the costs of registration before competitors enter the market.

A recurring theme in submissions is that data protection is needed in order for companies to recover the costs of research and development for new products.[3] However, as stated in the Discussion Paper, that is not the role of data protection. It is not about protecting intellectual property, or recouping the costs of R & D per se.

Protecting the investment made by companies and individuals in researching and developing innovative products is the role of general business and consumer laws on theft, privacy of information, and trade secrets - patents and other legal mechanisms (such as the Official Information Act).

DATA PROTECTION FOR INNOVATIVE AGRICULTURAL COMPOUNDS

Proposal: no change to the existing protection period (5 years).

Analysis of Submissions

Eighteen submitters (62%) supported an increase in data protection:

- 17 favoured 10 years protection (8 suppliers, 8 user groups, 1 other);
- 1 favoured 8 years (user).

Five submitters favoured the status quo - 5 years (3 suppliers, 1 user, 1 other), while two supported data protection but did not explicitly state a favoured period.

Four submitters did not express an opinion.

Submitters' Comments:

- Five years is too short to allow for a return on investment in the small New Zealand market. The costs of development and registration are often not significantly less for small and medium sized markets.
- The cost to bring a new product to market is significant and five years does not give companies sufficient time to recoup costs of the IP proprietary data needed to support the registration.
- A 10-year data protection regime would be beneficial for New Zealand agriculture because it would encourage the introduction of modern, innovative, and potentially lower risk plant science and animal health technologies into New Zealand.
- If firms knew that they could gain another few years of data protection on the original product by finding a new use for it, they would undertake the research necessary to find a new use to take advantage of this window.
- Patent protection of 20 years for recouping and profiting from new active ingredient development should be adequate. Further controls that enhance the period of exclusivity will in itself have the effect of reducing the stimulus for further development of new active ingredients.
- An assessment is needed of the value to the industry of the new, innovative products that would enter the market if data protection were increased, compared to the cost of the resulting loss of generics. Chemical companies give the lack of data protection as the

[3] There appears to be some confusion about what constitutes an "innovative product" for the purposes of data protection. The ACVM Act defines "innovative" as products that are, or contain, active ingredients previously unregistered in New Zealand. Products developed using existing registered active ingredients are not "novel" or "innovative" in terms of data protection.

reason for their reluctance to register new, innovative chemicals, so if they were to be granted increased protection, it would be reasonable to expect them to specify the number and the expected registration date of new chemicals.

MPI Comment

For innovative products (new actives), New Zealand is not where international companies will be looking to recoup their R & D costs. The United States (US) and the European Union (EU) are the primary agricultural chemical markets.

Chemical innovators specifically target these markets because of their size. They factor the terms of the US and EU protection regimes into their business strategies to offset the costs of the development of a new chemical entity, other market entry outlays and a premium. It is through these mechanisms that they will recover almost all of these costs. In general, markets such as New Zealand are marginal and opportunistic, and are not factored into the principal business decisions.

Typically, transfer of innovation into New Zealand occurs significantly later than in the primary markets. As a consequence, most of the costs of innovation would have been recovered in the primary markets by the time the product enters the New Zealand market.

Innovative products are also 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.

The main cost to be recouped is for information that is specific to New Zealand circumstances, as New Zealand requires only a minor amount of additional data beyond that which is produced for the major US and EU markets. The marginal costs of entering the New Zealand market are significantly less than that for the primary markets.

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. However, officials accept that the addition to labels of uses for "minor" species or crops is a particular issue for New Zealand.

DATA PROTECTION FOR NEW USES AND REFORMULATIONS

Proposal: Either

a) No change (no data protection); or
b) Provide a period of data protection of 1, 2 or 3 years

Analysis of Submissions

Twenty-six submitters (90%) supported introducing data protection:

- 15 submissions favoured 10 years protection (6 suppliers, 7 users, 1 other)
- 1 favoured 8 years (user)
- 1 favoured between 5 and 10 years (supplier)
- 4 favoured 5 years (3 suppliers, 1 user)
- 2 favoured 3 - 5 years (1 supplier, 1 other)

- 2 favoured 3 years (1 user, 1 other)
- 1 favoured 2 – 3 years (user)

One submitter (supplier) favoured the status quo (no data protection), one did not explicitly state a favoured period, and one did not comment on the issue.

Submitters' Comments

The main theme from submitters was that lack of data protection is inhibiting the flow of new products onto the New Zealand market. Specific examples were supplied where lack of data protection has adversely affected decisions to register new uses.

"Minor" uses are a particular problem. 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 as they will be unable to recoup the costs.
- The limited number of products registered for use in minor species severely restricts treatment options and hinders good resistance-management practices.
- If minor uses are not registered, off-label use will be more likely to occur. This practice may mean higher than optimal animal welfare, environmental, and trade risks for New Zealand.
- Without data protection there is little incentive for companies to make the investment required for registration of new uses. Competitors simply get a free-ride off the initial registrant.
- 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.
- The cost of researching novel uses and reformulations of existing products is high and time consuming. Chemical companies are unlikely to see a return on their investment in registering new uses as they will face competition from existing generic products being used off label.
- New uses still require registration in a manner similar to innovative products, but the data collection costs may be reduced, so a shorter period of protection may be appropriate.
- The protection period for new uses should be shorter than new registrations i.e. 2-3 years. Registration costs for new use extensions would be considerably less than that for new products.

MPI Comment:

MPI accepts that the current lack of protection for data supplied in support of registration of new uses and reformulations of existing products may be deterring registrants from bringing products onto the New Zealand market, and inhibiting innovation based on existing chemistry to develop products for New Zealand- specific problems. If data protection were provided, the level of competition, in relation to products that are already approved and registered, is unlikely to be affected, as the rights or ability of existing product marketers to sell their products would be unaltered.

DATA PROTECTION FOR REASSESSMENTS

Proposal: no change to existing data protection provisions (no data protection).

Analysis of Submissions

Seventeen submitters (58%) provided specific comment on this issue.

Fifteen submitters (52%) supported introducing data protection, with 12 (five suppliers, six users, one other) favouring 10 years protection. Two submitters favoured the status quo (no data protection).

Ten submitters (34%) did not comment on this issue; two commented in general terms only and did not state a favoured period.

Most submitters who supported data protection for reassessment data did not comment on what form that protection should take.

Some submissions acknowledged that a system that removed existing registrants from the market would be inequitable. There was some support for a "taskforce" approach, whereby existing registrants form a group to share the cost of data provision, and that data is protected (cannot be cross-referenced without the approval of the data owner) for a specified period. Registrants who did not participate in the taskforce would be unable to maintain their marketing approval.

There was little comment on the costs of a US-style compulsory compensation approach, whereby the data owner is obliged to provide data to the regulator, but anyone else wishing to rely on that data to continue their product registration must offer to compensate the data owner.

Submitters' Comments

- Data protection is needed for reassessments to ensure that regulators have the best available data on which to made decisions so that valuable low cost, pest control options and alternative resistance management chemistry are not lost.
- EPA reassessments will most likely see the removal of some substances from the tool box available to growers, leaving growers and producers with an even more restricted range of plant protection products.
- If companies are reluctant to share new data that shows that some substances, if used appropriately, should be retained, perfectly safe and effective products may end up being pulled from the market.
- Lack of data protection reduces the quality of information available for the regulator to make an informed decision and leads to unnecessary controls being imposed, uses lost, or the potentially the drug being removed from the market.
- If the principle is to address the "free-rider" problem, any procedure that requires the provision of information should have a period of data protection available. The term could be shorter to reflect the reduced input required from the registrant.
- Cost-sharing between competing companies could be costly, cumbersome to implement and difficult to administer. Policy for reassessments should be considered on a case by case basis.
- Any option that would require an existing product to be withdrawn from the market is unacceptable, and cost-sharing is also problematic.

MPI comment:

Officials acknowledge that where costs are involved in providing data required for reassessments, data protection could address potential "free-rider" problems. However,

- data protection for the original registrant would have inequitable outcomes for other existing registrants and their customers, as it would effectively remove their products from the market; and
- the cost of setting up and enforcing a legislated compensatory system would be greater than the benefits.

The New Zealand agricultural compound market consists of large numbers of small and/or "generic" companies. This 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 than in the EU or US.

MPI has found, from interaction and communication with counterparts around the world, that compensation-type schemes are very costly and complex to administer and enforce. It is difficult for companies to reach agreement without recourse to enforced mediation or arbitration, with consequent (often lengthy) delays in the assessment process.

The international trend appears to be towards reducing the level of data protection for review data. For example, new EU Regulations on the marketing of plant protection products (effective June 2011) only give 30 months protection compared with the previous 10 years.

If an existing market is profitable for (all) the current registrants, it is likely to be in their interests to co-operate and share the costs of data provision. Such a voluntary "taskforce" approach would ensure that the market continues. If continued registration is important, stakeholders (suppliers and/or users) will assess whether it is worth investing in additional data, and if so make arrangements for its supply. For example:

- In the 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.

Most reassessments arise because authorities have become aware of new, publicly available, information about increases in risks from use of the product/substance in question. It is unlikely that "perfectly safe" products will be de-registered, although additional controls may be imposed.

Part of the reassessment process involves considering what alternatives may be available for the compound under review. In the majority of cases, alternative options with lower risk profiles are identified. However, in some cases these may not be currently registered for use on the crops under discussion. If this is because of lack of data protection, data protection for new uses should assist.

OTHER ISSUES RAISED IN SUBMISSIONS

Length of data protection period

- New Zealand's data protection regime should be in line with our major trading partners.

MPI Comment:
The nature of the New Zealand agricultural compound market 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. There is no inherent reason why our data protection regimes should be the same.

New Zealand's major trading partners (rank ordered as of June 2011) are Australia, People's Republic of China, United States, Japan, Republic of Korea, and the EU. Data protection varies considerably in these jurisdictions.

- Australia has eight years protection for innovative products, and lesser periods of protection for new uses (five years for agricultural chemicals, and three for veterinary medicines).
- China has six years data protection for the first registration of a new pesticide (new active ingredient).
- United States has ten years.
- Japan and Korea have 15 – 20 years.
- EU has ten years.

Start time for protection

- The term of data protection needs to be defined and predictable. Reduction in the effective term of protection can occur due to the time taken to achieve registration, so the actual data protection period will vary from product to product.
- The period of data protection should start from date registration is granted, not from when information is received by MPI.
- The period of data protection should apply regardless of how long it takes to achieve registration. The development period may take longer than the current 5 years allowed under provisional registration.

MPI Comment:

This is already the case. The definition of "protected period" in Part 6, Section 72 of the ACVM Act (the Act) means that:

1. For applications for full registration under section 9 of the Act, protection is provided from the time the information is supplied, until 5 years from the date that registration is granted or refused.
2. For applications for provisional registration under section 26 there is
   a) A five-year protection period from the time the information is supplied; and
   b) If application for full registration is made within that period, 5 years protection from the date that registration is granted or refused.

The term of "market exclusivity" (i.e. the period during which there will be no generic applications for identical products approved based on the original supporting data) conferred by data protection is always five years. It is not lessened by the length of the registration process.

Lack of data protection where new applicant differs from initial applicant for provisional registration

At present, the ACVM Act defines "innovative application" as one that refers to an active ingredient that has not, before the application is received by MPI, been referred to in any other application (except an application ***by the applicant*** for provisional registration under section 26.

This means that if a company, other than the original applicant, later finds another use for the active, different to that for which it was provisionally registered, no data protection is available. This is the case even if the original application did not proceed to full registration, i.e. the active was never registered for use in New Zealand.

This unnecessarily restricts the development of new products for the New Zealand market.

MPI Comment
MPI agrees and proposes to re-word the ACVM Act so that

a. "innovative application " means one that refers to an 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 the original applicant.

Appendix 1: List of submitters

User groups
Federated Farmers
Deer Industry Association
Horticulture NZ
Landcorp Farming Ltd
Pipfruit NZ
Marlborough District Council (Biosecurity Officer)
Nursery & Garden Industry Association
NZ Sports Turf Institute
NZ Winegrowers
NZ Veterinary Association
Poultry Industry Association
Tamarillo Growers Association
Vegetable Growers (group submission)–
NZ Asparagus Council, NZ Buttercup Squash Council, Potatoes New Zealand, Process Vegetable Product Group, Tomatoes New Zealand, Vegetables New Zealand.

Suppliers/manufacturers
Agcarm (industry association)
ARPPA (industry association)

Veterinary medicines
Agrihealth NZ Ltd
Ancare Scientific Ltd
Connovation NZ Ltd (VTAs – animal poisons)
Mr N Phillips (Lallemand Inc) (organic/biological animal nutrition products)

Plant products
Bayer NZ Ltd
Dow Agrosciences (NZ) Ltd
Etec Crop Solutions Ltd
Merial NZ Ltd
Nufarm NZ Ltd
Orion Crop Protection Ltd
Pfizer NZ Ltd
PGG Wrightson Ltd

Other:
Baldwins (patent attorneys)
NZ Institute of Patent Attorneys
Foundation for Arable Research

Appendix 2: Submitters preferred data protection periods

Submitter	Type*	Innovative	New uses & reformulations	Reassessments
		Years		
Agcarm	M	10	10	10
Nufarm Ltd	M	5	3 - 5	3
Etec Ltd	M	8 -10	5	No comment
Pfizer NZ Ltd	M	10	10	10
Mr N Phillips	M	No specified periods – general comments only		
Bayer NZ Ltd	M	10	10	10
Merial NZ Ltd	M	No comment	5	No comment
Dow Agrosciences Ltd	M	10	10 (minimum 5)	10
Agrihealth NZ Ltd	M	5	5	No comment
Ancare Scientific Ltd	M	10	5 – 10	No comment
Orion Crop Protection	M	5 (no change)	0 (No change)	0 (No change)
Connovation NZ Ltd	M	10	10	No comment
PGG Wrightson Ltd	M	10	10	10
ARPPA #	M	10	5 - 10	No comment
Federated Farmers	U	No comment	3	No comment
Deer Industry Assn	U	No comment	5	No comment
Vegetable growers	U	10	10	No comment
NZ Winegrowers	U	10	10 (minimum 5)	10 (minimum 5)
Pipfruit NZ	U	10	10	10
Horticulture NZ	U	10 (minimum 5)	10 (minimum 5)	10 (minimum 5)
Tamarillo Growers Assn	U	5 (no change)	2 - 3	0 (no change)
Nursery & Garden Industry Assn	U	10	10	10
NZ Sports Turf Institute	U	10	10	10
Poultry Industry Assn & Egg Producers Fedn	U	8	8	8
Landcorp Farming	U	Not clear – 10?	10	No comment
NZ Veterinary Assn	U	10	10	10
Marlborough District Council (Biosecurity)	U	10	No comment	No comment
Baldwins	O	5	4	2
NZ Institute of Patent Attorneys	O	No opinion on term	3	? (not clear)
Foundation for Arable Research	O	10	10 (or 7 +3)	10 (or 7 +3)

* M = Manufacturer/Supplier
  U = User
  O = Other

Late submission; not reflected in statistical analysis.